

Friday Seminar Series

July 16, 2010

Restriction Requirements

Restriction Practice

- A patent application is generally assumed to include claims directed to a single invention.
- The application will typically disclose and/or claim different aspects of the invention:
 - a machine, a method for making the machine, a method for using the machine, and a system wherein the machine is used as one component in a larger system;
 - a product, a method for making the product, and a method for using the product.

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.

Restriction Requirement

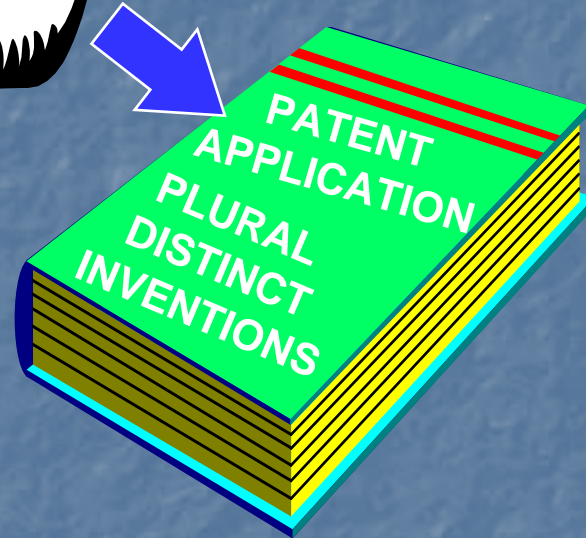
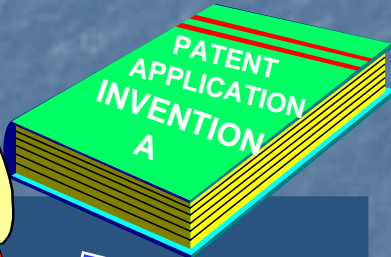
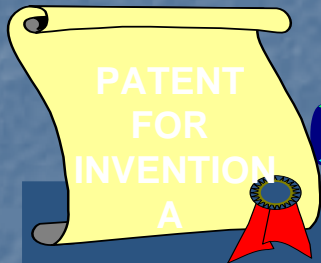
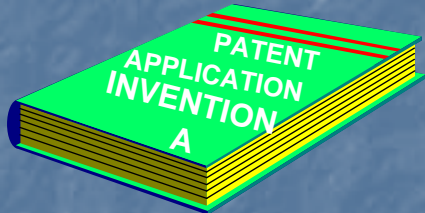
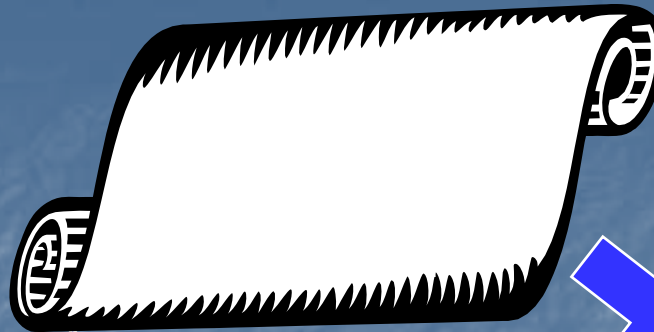
- Examiner may assert that more than one invention is being claimed in a patent application.
- Examiner will identify the different inventions represented by the different claims and indicate that only a subset of the inventions will be examined.

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,…”

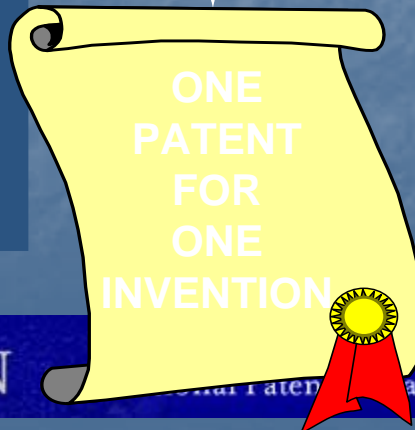
- 35 U.S.C. § 121 - Divisional Applications

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. . .



DOUBLE PATENTING:

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



RESTRICTION
35 U.S.C. 121

Rationale

- The rationale supporting the Patent Office's ability to limit the number of inventions that will be examined in a single application originates from the **fee structure** funding the PTO operations.
- Restriction requirement assists the PTO in ensuring generation of sufficient fees to support the cost of examining a patent application.
- Examination of application by one Examiner.

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. . .
- Restriction is discretionary, not mandatory.

35 U.S.C. § 121 - Divisional Applications

A patent issuing on an application with respect to which a **requirement for restriction** under this section has been made, or on an application filed as a result of such a requirement, **shall not be used as a reference** either in the Patent and Trademark Office or in the courts **against a divisional application** or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

37 CFR § 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 or otherwise include all the limitations of the generic claim.

37 CFR § 1.142 - Requirement for restriction.

- (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an **Office action** will require the applicant in the reply to that action to **elect an invention** to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made **before any action on the merits**; however, it may be made **at any time** before final action.
- (b) Claims to the invention or inventions **not elected**, if not canceled, are nevertheless **withdrawn** from further consideration by the examiner by the election, subject however to **reinstatement** in the event the requirement for restriction is withdrawn or overruled.

37 CFR § 1.143 - Reconsideration of requirement.

- If the applicant **disagrees** with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefore.
- In requesting reconsideration the applicant must indicate a **provisional election** of one invention for prosecution, which invention shall be the one elected in the event the requirement becomes **final**. The requirement for restriction will be reconsidered on such a request.
- If the requirement is repeated and made final, the examiner will at the same time act on the claims to the invention elected.

37 CFR § 1.144 - Petition from requirement for restriction.

- After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may **petition the Director** to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested.

37 CFR § 1.145 - Subsequent presentation of claims for different invention.

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

37 CFR § 1.146 - Election of species.

- In the first action on an application containing a **generic claim** to a generic invention (genus) and claims to more than one patentably distinct **species** embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.
- However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application.

37 CFR § 1.141 - Different inventions in one national application

- (a) Two or more **independent and distinct inventions** may not be claimed in one national application . . .
- MPEP 802.01 Meaning of “Independent” and “Distinct”
 - “Independent”, of course, means not dependent, or unrelated.
 - The term “independent” means there is no disclosed relationship between the two or more subjects claimed; they are unconnected in design, operation and effect.

- MPEP 802.01 Meaning of “Independent” and “Distinct”
 - Two or more inventions are related (i.e., not independent) if they are disclosed as **connected** in at least one of design (e.g. structure or method of manufacture), operation (e.g., function or method of use), or effect.
 - Related inventions are **distinct** if the inventions **as claimed** are not connected in at least one of design, operation, or effect and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art).

Correlation Between Independent Inventions and Distinct Inventions

Independent Inventions

Unrelated in design, operation, and effect

The natural consequence of the lack of any relationship is that **each invention is patentable over the other.**

Distinct Inventions

Related in at least one of design, operation, or effect, and

Not connected in at least one of design, operation, or effect, and

At least one invention is patentable over the other.

- **35 U.S.C. § 121** – If two or more independent and distinct inventions are claimed in one application . . .
- **37 CFR § 1.141** - Two or more independent and distinct inventions may not be claimed in one national application . . .
- The Patent Office takes the position that restriction may be required if the inventions are independent or distinct.
- MPEP 803 - Restriction - When Proper
Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent or distinct.
- MPEP 802.02 - Definition of Restriction
Restriction is the practice of requiring an applicant to elect a single claimed invention for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application.

803 Restriction - When Proper

- Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to **support separate patents** and they are either **independent or distinct**.
- If the search and examination of all the claims in an application can be made without serious **burden**, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions.

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.

808.02 Establishing Burden

- (A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search.
- (B) **A separate status in the art when they are classifiable together:** Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors.
- (C) **A different field of search:** Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims.
- The *prima facie* showing may be rebutted by the applicant.

Burden – cont.

Serious burden may be established based on a different field of search if it is necessary to search for one of the inventions in a manner not likely to result in finding art pertinent to the other invention(s), e.g.,

- searching different classes/subclasses
- searching different electronic resources
- employing different search queries

A serious burden may be shown when the inventions are classified together if the examiner can explain how the searches differ.

806 - Determination of Distinctness or Independence of Claimed Inventions

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

- (A) Where inventions are independent (i.e., no disclosed relation there between), restriction to one thereof is ordinarily proper.
- (B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper.
- (C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.

806.06 Independent Inventions

- Inventions as claimed are independent if there is **no disclosed relationship** between the inventions, that is, they are **unconnected in design, operation, and effect**. If it can be shown that two or more inventions are independent, and if there would be a serious burden on the examiner if restriction is not required, applicant should be required to restrict the claims presented to one of such independent inventions. For example:
 - (A) Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions and different effects are independent. An article of apparel and a locomotive bearing would be an example. A process of painting a house and a process of boring a well would be a second example.
 - (B) Where the two inventions are process and apparatus, and the apparatus cannot be used to practice the process or any part thereof, they are independent. A specific process of molding is independent from a molding apparatus that cannot be used to practice the specific process.

Independent Inventions

Independent inventions have **no disclosed relationship**, i.e., they are unrelated.

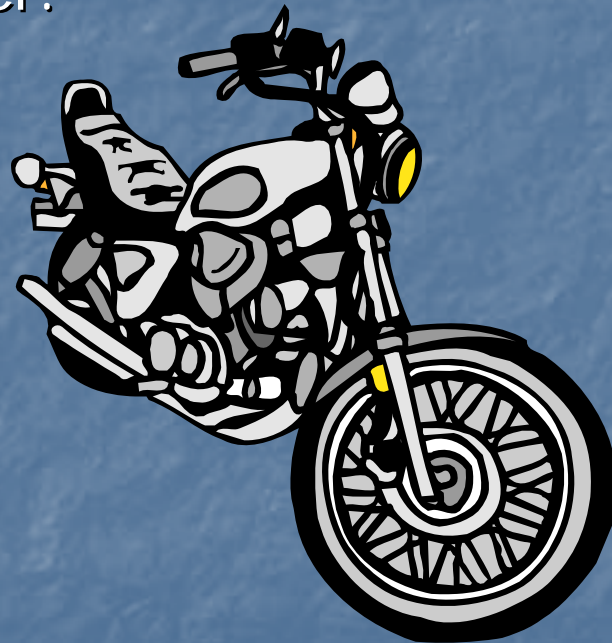
In other words, the inventions as disclosed are **not connected** in any of:

- a. DESIGN
- b. OPERATION *and*
- c. EFFECT

MPEP 802.01 (subsection I)

Independent

- Unconnected in design, operation and effect; not disclosed as useable together.



Related

Related inventions have a disclosed relationship, i.e.,
are **connected in at least one of:**

- a. DESIGN (structure or method of manufacturing)
- b. OPERATION (function or method of use) *or*
- c. EFFECT

MPEP 802.01(subsection II)

Related but Distinct Inventions

Related inventions are **distinct** if the claimed inventions are **not connected in at least one of:**

- a. DESIGN
- b. OPERATION *or*
- c. EFFECT

AND at least one invention is patentable over the other.

MPEP 802.01 (subsection II)

Related – but are they distinct?

Could be distinct if disclosed as related inventions that are “unconnected in one of design, operation or effect.” Electric cash register and a mechanical register that have same effect but differ in design.



Establishing Distinctness Between Related Inventions

- **806.05 Related Inventions**

Where two or more related inventions are claimed, the principal question to be determined in connection with a requirement to restrict is whether or not the inventions as claimed are distinct. If they are distinct, restriction may be proper. If they are not distinct, restriction is never proper.

Establishing Distinctness Between Related Inventions - Different Statutory Category

Process of using an apparatus & apparatus for its practice – See MPEP 806.05(e)

Process of making a product & product made by the process – See MPEP 806.05(f)

Apparatus for making a product & product made by the apparatus – See MPEP 806.05(g)

Product & process of using the product – See MPEP 806.05(h)

Establishing Distinctness Between Related Inventions - Same Statutory Category

Combination – Subcombination – See MPEP 806.05(c)

Subcombinations Usable Together – See MPEP 806.05(d)

Related products or related processes (including intermediate/final product) – See MPEP 806.05(j)

■ 806.05(c) Distinctness Between Combination and Subcombination

To support a requirement for restriction between combination and subcombination inventions, both two-way distinctness and reasons for insisting on restriction are necessary, i.e., there would be a serious search burden if restriction were not required as evidenced by separate classification, status, or field of search.

The inventions are distinct if it can be shown that a 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 can be shown to have utility either by itself or in another materially different combination.

■ 806.05(d) Subcombinations Usable Together

Two or more claimed subcombinations, disclosed as usable together in a single combination, and which can be shown to be separately usable, are usually restrictable when the subcombinations do not overlap in scope and are not obvious variants.

Each subcombination is distinct from the combination as claimed if:

(A) the combination does not require the particulars of the subcombination as claimed for patentability (e.g., to show novelty and unobviousness), and

(B) the subcombination can be shown to have utility either by itself or in another materially different combination.

■ 806.05(e) Process and Apparatus for Its Practice

Process and apparatus for its practice can be shown to be distinct inventions, if either or both of the following can be shown:

(A) that the process *as claimed* can be practiced by another materially different apparatus or by hand; or

(B) that the apparatus *as claimed* can be used to practice another materially different process.

■ 806.05(f) Process of Making and Product Made

A process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown:

(A) that the process *as claimed* is not an obvious process of making the product and the process *as claimed* can be used to make another materially different product; or

(B) that the product *as claimed* can be made by another materially different process.

■ 806.05(g) Apparatus and Product Made

An apparatus and a product made by the apparatus can be shown to be distinct inventions if either or both of the following can be shown:

(A) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus as claimed can be used to make another materially different product; or

(B) that the product as claimed can be made by another materially different apparatus.

■ 806.05(h) Product and Process of Using

A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown:

(A) the process of using as claimed can be practiced with another materially different product; or

(B) the product as claimed can be used in a materially different process.

- 806.05(i) Product, Process of Making, and Process of Using

37 CFR 1.141 Different inventions in one national application.

(b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.

Where an application contains claims to a product, claims to a process specially adapted for making the product, and claims to a process of using the product, applicant may be required to elect either (A) the product and process of making it; or (B) the process of using. If the examiner can not make a showing of distinctness between the process of using and the product (MPEP § 806.05(h)), restriction cannot be required.

■ 806.05(j) Related Products; Related Processes

For related product inventions, or related process inventions, the inventions are distinct if

(A) the inventions *as claimed* do not overlap in scope, i.e., are mutually exclusive;

(B) the inventions *as claimed* are not obvious variants; and

(C) the inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

■ 810 Action on the Merits

In general, in an application when only a nonfinal written requirement to restrict is made, no action on the merits is given. A **1-month** (not less than 30 days) shortened statutory period will be set for reply when a written restriction requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a).

■ 811 Time for Making Requirement

37 CFR 1.142(a), second sentence, indicates that a restriction requirement “will normally be made before any action upon the merits; however, it may be made at any time before final action.” This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops.

Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required.

■ 812.01 Telephone Restriction Practice

If an examiner determines that a requirement for restriction should be made in an application, the examiner should formulate a draft of such restriction requirement including an indication of those claims considered to be linking or generic. Thereupon, the examiner should telephone the attorney or agent of record and request an oral election, with or without traverse, after the attorney or agent has had time to consider the restriction requirement. However, no telephone communication need be made where the requirement for restriction is complex, the application is being prosecuted by the applicant *pro se*, or the examiner knows from past experience that an election will not be made by telephone. The examiner should arrange for a second telephone call within a reasonable time, generally within 3 working days. If the attorney or agent objects to making an oral election, or fails to respond, a restriction letter will be mailed, and this letter should contain reference to the unsuccessful telephone call. When an oral election is made, the examiner will then proceed to incorporate into the Office action a formal restriction requirement including the date of the election, the attorney's or agent's name, and a complete record of the telephone interview, followed by a complete action on the elected invention as claimed, including linking or generic claims if present.

- **814 Indicate Exactly How Application Is To Be Restricted**

The examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121.

- **815 Make Requirement Complete**

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

■ 818 Election and Reply

- **Election** is the designation of the **particular one** of two or more disclosed inventions that will be prosecuted in the application.
- A reply should be made to **each point** raised by the examiner's action, and may include a traverse or compliance.
- A **traverse** of a requirement to restrict is a statement of the **reasons** upon which the applicant relies for his or her conclusion that the requirement is in error.

■ 818.01 Election Fixed by Action on Claims

Election becomes fixed when the claims in an application have received an action on their merits by the Office.

■ 818.02 Election Other Than Express

Election may be made in other ways than expressly in reply to a requirement as set forth in MPEP § 818.02(a) and § 818.02(c).

■ 818.02(a) By Originally Presented Claims

Where claims to another invention are properly added and entered in the application **before an action** is given, they are treated as original claims for purposes of restriction only.

The claims originally presented and **acted upon** by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination (**RCE**) which has been filed for the application.

818.03 Express Election and Traverse

37 CFR 1.143 - Reconsideration of requirement.

- If the applicant disagrees with the requirement for restriction, he may **request reconsideration and withdrawal or modification of the requirement**, giving the reasons therefore. In requesting reconsideration the applicant must indicate a **provisional election** of one invention for prosecution, which invention shall be the one elected in the event the requirement becomes final. The requirement for restriction will be reconsidered on such a request. If the requirement is repeated and made final, the examiner will at the same time act on the claims to the invention elected.
- Election in reply to a requirement may be made either with or without an accompanying **traverse** of the requirement.
- **Applicant must make his or her own election**; the examiner will not make the election for the applicant.

818.03(a) Reply Must Be Complete

- As shown by the first sentence of 37 CFR 1.143, the traverse to a requirement **must be complete** as required by 37 CFR 1.111(b) which reads in part: "In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which **distinctly and specifically points out the supposed errors** in the examiner's action and must **reply to every ground** of objection and rejection in the prior Office action. . . . The applicant's or patent owner's reply must appear throughout to be a *bona fide* attempt to advance the application or the reexamination proceeding to final action. . . ."
- Under this rule, the applicant is required to specifically point out the reasons on which he or she bases his or her conclusions that a requirement to restrict is in error. A mere broad allegation that the requirement is in error does not comply with the requirement of 37 CFR § 1.111. Thus the required provisional election becomes an **election without traverse**.

818.03(b) Must Elect, Even When Requirement Is Traversed

As noted in the second sentence of 37 CFR 1.143, a provisional election must be made even though the requirement is traversed.

818.03(c) Must Traverse To Preserve Right of Petition

37 CFR 1.144 Petition from requirement for restriction.

- After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may **petition the Director** to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested.
- If applicant does not distinctly and specifically point out supposed errors in the restriction requirement, the election should be treated as an election without traverse.

819 Office Generally Does Not Permit Shift

- The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant **cannot, as a matter of right**, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). When claims are presented which the examiner holds are drawn to an invention other than the one elected, he or she should treat the claims as outlined in MPEP § 821.03.

821 Treatment of Claims Held To Be Drawn to Nonelected Inventions

- Claims held to be drawn to nonelected inventions, including claims drawn to nonelected species or inventions that may be eligible for rejoinder, are treated as indicated in MPEP § 821.01 through § 821.04. All claims that the examiner holds as not being directed to the elected subject matter are **withdrawn** from further consideration by the examiner.

- **821.01 After Election With Traverse**

Where the initial requirement is traversed, it should be **reconsidered**. If, upon reconsideration, the examiner is still of the opinion that restriction is proper, it should be repeated and **made final** in the next Office action. In doing so, the examiner should reply to the reasons or arguments advanced by applicant in the traverse.

If the examiner, upon reconsideration, is of the opinion that the requirement for restriction is improper **in whole or in part**, he or she should clearly state in the next Office action that the requirement for restriction is withdrawn in whole or in part, specify which groups have been rejoined, and give an action on the merits of all the claims directed to the elected invention and any invention rejoined with the elected invention.

- **821.02 After Election Without Traverse**

Where the initial requirement is not traversed, if adhered to, appropriate action should be given on the elected claims.

- **821.03 Claims for Different Invention Added After an Office Action**

Claims added by amendment following action by the examiner, to an invention other than previously claimed, should be treated as indicated by 37 CFR 1.145.

- **37 CFR 1.145 Subsequent presentation of claims for different invention.**

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

Election by Original Presentation

821.04 Rejoinder

- The propriety of a restriction requirement should be **reconsidered** when all the claims directed to the elected invention are in **condition for allowance**, and the nonelected invention(s) **should be considered** for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

PCT Unity of Invention

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

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

Resources and Guidance Available at

International Search and Examination Guidelines
(ISPE Guidelines)

See, Chapter 10, pp 75-103

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

MPEP, Chapter 1800, section 1850

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**.

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

"a priori" and "a posteriori"

Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration.

ISPE Paragraph 10.03

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.

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.

However, 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 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.

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.

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.

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.

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.

Unity of Invention

- Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. There should be a broad, **practical consideration** of the degree of interdependence of the alternatives presented, in relation to the state of the art. . . rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the **applicant**.

ISPE Paragraph 10.04

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

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)

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.

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

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

Intermediate/Final Products (cont.)

(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.

Examples Concerning Unity of Invention

The application of the principles of unity of invention is illustrated by the following examples for guidance in particular cases.

- *Claims in Different Categories*
- *Claims in the Same Category*
- *Markush Practice*
- *Intermediate/Final Product*
- *Biotechnological Inventions*

ISPE Paragraph 10.21-10.59

PCT vs. U.S. Restriction

- Easier to have different categories of claims permitted in single application.

PCT vs. U.S. Restriction

- Product and process specially adapted to make the product.
- “specially adapted” does not imply that the product cannot be made by a different process, or that a similar process could not also be used to make other products.

PCT vs. U.S. Restriction

- Process and an apparatus or means specially adapted to carry out the process.
- “specially designed” does not require that the apparatus or means could be carried out using an alternative apparatus or means.

PCT vs. U.S. Restriction

- Intermediate and Final Products can be grouped together where they have same “essential structural element” or chemical structures are “closely interrelated” or if not structure then if evidence are “technically interrelated”.
- Flexibility in grouping claim to intermediate and final products if satisfy above test.
- U.S., if intermediates also exhibit other effects or activities then may form a basis for restriction.

PCT vs. U.S. Restriction

- Markush - Unity when alternatives of similar in nature: common property or activity and shared structural element or recognized class of compounds.
- U.S. - Restriction within Markush group often based on variations of single functional group even when most significant structural element of compounds is identical.
- U.S. - Election of species practice, greater degree of flexibility to make restriction within Markush grouping.

PCT vs. U.S. Restriction

- “a priori” and “a posteriori”
- Unity of invention must be continually examined throughout prosecution and issues of unity and arise at any time.

DEPARTMENT OF COMMERCE

**United States Patent and Trademark
Office**

[Docket No.: PTO–P–2010–0030]

**Request for Comments on Proposed
Changes to Restriction Practice in
Patent Applications**

AGENCY: United States Patent and
Trademark Office, Commerce.

ACTION: Request for comments.

Request for Comments on Proposed Changes to Restriction Practice in Patent Applications

- 1. What should be included in an Office action that sets forth a restriction requirement?
- 2. What practice changes would result in more effective ways to seek higher level review of restriction requirements?
- 3. How could the Office clarify requirements for restriction between related product inventions or related process inventions where the relationship is not specifically provided for in MPEP Chapter 800?
- 4. How could the Office modify Markush practice?
- 5. How could the Office improve rejoinder practice?
- 6. What other areas of restriction practice can the Office improve and how?