TC1600 Restriction Training for Examiners

August 2004

Two Be or Not To Be:
or Divide and Conquer:
or A Case Divided Cannot Stand:

Principles in Restriction Practice
TC 1600

TC 1600 Restriction Team

- ✓ Anthony Caputa-TCPS
- ✓ Deborah Reynolds-TCPS
- ✓ Brian Stanton - QAS
- ✓ Sreeni Padmanabhan - Workgroup 1610
- ✓ Christopher Low - Workgroup 1610
- ✓ Joseph McKane - Workgroup 1620
- ✓ Cecilia Tsang – Workgroup 1620
- ✓ Amy Nelson - Workgroup 1630
- ✓ Jim Housel - Workgroup 1640
- ✓ Bruce Campell-Workgroup 1650
- ✓ Julie Burke-SPrE

Topics for Today

- ✓ Basic Restriction Requirements
- ✓ Linking Claims
- ✓ Alternative Language and Restriction Practice
- ✓ Rejoinder Opportunities - In re Ochiai and others

Basic Restriction Requirements

- ✓ Restriction is a discretionary tool to limit the examination to one of a plurality of claimed inventions under 35 USC 121
- ✓ Restriction is between inventions not claims. The claims merely define the inventions.

Basic Restriction Requirements

- ✓ There are two criteria for a proper requirement for restriction between patentably distinct inventions:
  - The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
  - There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

Basic Restriction Requirements

✓ Independent Inventions
- Not disclosed as capable of use together
- Not disclosed as connected in design, operation or effect
- MPEP 806.04, 808.01; Form Paragraph 8.20.02
- Facts relied on to establish independence may also support the reason(s) for insisting upon restriction (burden) (MPEP 808.01)

Basic Restriction Requirements

✓ Related Invention Relationships
1. Subcombinations useable together (MPEP 806.05(d); Form Paragraph 8.16)
2. Combination/Subcombination (MPEP 806.05(a)-(c); Form Paragraph 8.15)
3. Process and Apparatus for its Practice (MPEP806.05(e); Form Paragraph 8.17)
4. Product and Process of Making (MPEP 806.05(f); Form paragraph 8.18)
5. Apparatus and Product Made (MPEP 806.05(g); Form paragraph 8.19)

Basic Restriction Requirements

✓ Related Invention Relationships
6. Product and Process of Using (MPEP 806.05(h); Form paragraph 8.20)
7. Intermediate/Final Product (MPEP 806.04(b); Form paragraph 8.14)
8. Special case: Product, Process of Making and Process of Using (MPEP806.05(i); Form Paragraph 8.20.01)

Basic Restriction Requirements

✓ Criteria for Burden (MPEP 808.02; Form paragraph 8.21.01-8.21.03)
1. Separate classification
2. Separate status in the art
3. Divergent field of search

Linking Claims - What are they?

✓ Definition: One or more claims inseparable from claims to two or more otherwise properly divisible inventions. MPEP 809.

✓ Effect: When found allowable, linking claims prevent maintaining a restriction requirement between inventions that are otherwise divisible.

Linking Claims – Types (MPEP 809.02 and 809.03)

✓ Genus claims linking species claims (809.02 and 809.03)

✓ Claim to the necessary process of making a product linking proper process and product claims (product and process of making are not patentably distinct) (MPEP 809.03)

✓ Claim to "means" for practicing a process linking proper apparatus and process claims (MPEP 809.03)

✓ Claim to the product linking a process of making and a process of using (MPEP 809.03)

Linking Claims - Caution

- ✓ If a generic or linking claim is subsequently allowed, the restriction requirement MUST be withdrawn, even where claims to non-elected linked inventions have been canceled. The indication of withdrawal must also be clearly stated on the record.
- ✓ When a restriction requirement is withdrawn, 35 USC 121 no longer shields claims from double patenting considerations
- ✓ Double patenting situations may arise where the restriction requirement was made subject to the nonallowance of generic or other linking claims which are then subsequently allowed and the restriction is then withdrawn.

Linking Claims - Office Action

- ✓ Form Paragraph 8.12:
- ✓ Claim **[1]** link(s) inventions **[2]** and **[3]**. The restriction requirement **[4]** the linked inventions is **subject to** the nonallowance of the linking claim(s), claim **[5]**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Linking Claims - Office Action

- ✓ ¶ 8.01 Election of Species:
- ✓ This application contains claims directed to the following patentably distinct species of the claimed invention: [1].
  Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, [2] generic.
  Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
  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 include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
  Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

species to be obvious variants or clearly admit on the record that this is the case. In either instance, 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.

Linking Claim - Product

- ✓ Claim 1. A composition for reducing HIV viral load in an HIV infected patient, comprising an agent inhibiting viral replication and a pharmaceutically acceptable carrier.
- ✓ Claim 2. The composition of claim 1, wherein the agent is a polypeptide having the amino acid sequence of SEQ ID NO:2.
- ✓ Claim 3. The composition of claim 1, wherein the agent is a polynucleotide having the sequence of SEQ ID NO:5.
- ✓ Claim 4. The composition of claim 1, wherein the agent is 3,3'-methoxysilyl-3,3'-organophosphate.

Linking Claim - Method

- ✓ Claim 1. A method for treating a neurodegenerative disorder comprising administering a peptide conjugate to a patient.
- ✓ Claim 2. The method of claim 1, wherein the neurodegenerative disorder is Alzheimer's disease.
- ✓ Claim 3. The method of claim 1, wherein the neurodegenerative disorder is multiple sclerosis.
- ✓ Claim 4. The method of claim 1, wherein the neurodegenerative disorder is encephalitis.

Linking Claims - Notes

- ✓ Applicant is entitled to retain claims directed to non-elected inventions
- ✓ If a linking claim is allowed, examination must extend to the linked non-elected inventions
- ✓ At that time, the restriction requirement is withdrawn and the linked inventions are rejoined together

Linking Claims - Helpful Hints

- ✓ When writing a restriction involving linking claims per MPEP 809.03, the linking claims should not appear in the list of claims for any particular invention group. The linking claim itself appears only in form paragraph 8.12.
- ✓ When writing a restriction involving genus-species linking claims per MPEP 809.02, there are no groupings and the linking claim(s) appears as the generic claims in form paragraph 8.01.
- ✓ If claims to non-elected inventions are canceled, but a linking claim is allowed, the Office must notify Applicant and provide an opportunity to reinstate the canceled claims.

Markush practice

- ✓ Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Markush Practice

- ✓ Markush Language – Ex. "selected from the group consisting of…" or "any of A, B, or C".
- ✓ Apply *In re Harnisch* test for "unity of invention"
  - Compounds have a common utility
  - Compounds as a whole have a substantial structural similarity

Markush practice

- ✓ Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. See MPEP 803.02.

Markush Practice – Example

- ✓ Unity exists under *Harnisch* test

  Claim 1: A method of treating diabetes comprising administering compound X and further administering a compound selected from the group consisting of A, B and C.

  Disclosure: A, B and C have similar function and have a common structure.

Markush practice-MPEP 803

- ✓ If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.
- ✓ Should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush type claim will be extended.

In re Ochiai Rejoinder

- ✓ MPEP 821.04, See also the Clarification Memo of March 2004
- ✓ Proper restriction between product and process claims
- ✓ Applies only where product claims are elected
- ✓ Requires allowable product claim
- ✓ Applies only to process claims that depend from or include all the limitations of the allowable product claim

In re Ochiai Rejoinder

- ✓ If application discloses both product and process(es) of making and/or using, but claims the product only and a product claim is allowed, process claims may be entered prior to final rejection
- ✓ After final rejection is governed by 37 CFR 1.116
- ✓ After allowance practice is governed by 37 CFR 1.312

In re Ochiai Rejoinder

- ✓ Rejoinder by the Office is *sua sponte*
- ✓ Less than all pending process claims may be rejoined where less than all process claims include all the limitations of the allowable product.
- ✓ Obviousness double-patenting may be applied where product and process claims are voluntarily filed in separate applications

Other Rejoinder Situations

- ✓ MPEP 806.05(c)
- ✓ Combination/subcombination inventions when an evidence claim is found to be non-allowable

Helpful Hints

- ✓ Use the correct rule-
  - For applications filed under 35 USC 111, use 35 USC 121
  - For applications filed under 35 USC 371, use 35 USC 372 and 35 USC 121
    - When a continuation or divisional is filed under 35 USC 111 based on a 371, use 35 USC 121
- ✓ If the inventions, now being restricted, were searched and examined together in either the current application or a parent, it will be difficult to justify the assertion of burden

Helpful Hints

- ✓ Provide detailed explanation of why each group is restrictable from each other group
  - Include facts and/or reasoning to support the conclusion
  - Also include the reasoning as to why there is an undue burden
- ✓ All claims must be accounted for
  - Either in a group, or in a linking claim paragraph
- ✓ In the ensuing Office Actions on the merits do not reject claims solely because they encompass non-elected subject matter
- ✓ Send petitions to the deciding official before you complete an office action

The End

1610/1620 Example 1 - Claim Set

CLAIMS:
What Is Claimed Is:

1. A formulation comprising at least one hydrolyzed whole egg, at least one emollient substance and at least one humectant substance.

2. The formulation of Claim l wherein said humectant substance is selected from a group consisting of glycerin, butylene glycol, propylene glycol, pentylene glycol, and mixtures thereof.

3. The formulation of Claim 1 wherein said emollient substance is selected from a group consisting of Prunus Amygdalus Dulis (Sweet Almond) Oil, Squalene, Prunis Armeniaca (Apricot) Kernel Oil, Carthamus Tinetorius (Safflower) Oil, Helianthus Annuus (Sunflower) Seed Oil, synthetic oils and extracts thereof and mixtures thereof.

4. The formulation of Claim 1 wherein said formulation is a cosmetic formulation.

5. The formulation of Claim 1 wherein said formulation is a cosmopharmaceutical formulation.

6. The formulation of Claim 1 wherein said formulation is a pharmaceutical formulation.

7. A cellulite formulation comprising at least one hydrolyzed whole egg, at least one emollient substance, at least one humectant substance and at least one aromatherapeutical substance.

8. The formulation of Claim 7 wherein said humectant substance is selected from a group consisting of glycerin, butylene glycol, propylene glycol, pentylene glycol, and mixtures thereof.

9. The formulation of Claim 7 wherein said emollient substance is selected from a group consisting of Prunus Amygdalus Dulis (Sweet Almond) Oil, Squalene, Prunus Armeniaca (Apricot) Kernel Oil, Carthamus Tinetorius (Safflower) Oil, Helianthus Annuus (Sunflower) Seed Oil, synthetic oils and extracts thereof and mixtures thereof.

10. The formulation of Claim 7 wherein said aromatherapeutical substance is selected from a group consisting of Lavendula Angustifolia (Lavender) oil, Geranium Maculatum Oil, Citrus Grandis (Grapefruit) oil, Juniperus Communis Oil, Pimenta Acris (Bay) Oil, Lavendula Hybrida, Geranium Robertianum, Geranium Thunbergil, Citrus Aurantium Dulsis (Orange) Oil, Citrus Nobilis (Mandarin Orange) Oil, Citrus Limonum (Lemon) Oil and extracts thereof and mixtures thereof.

11. A skin care formulation comprising at least one hydrolyzed whole egg, at least one emollient substance, at least one humectant substance and at least one skin nourishing/wound healing substance.

12. The formulation of Claim 11 wherein said humectant substance is selected from a group consisting of glycerin, butylene glycol, propylene glycol, pentylene glycol and mixtures thereof.

13. The formulation of Claim 11 wherein said emollient substance is selected from a group consisting of Prunus Amygdalus Dulis (Sweet Almond) Oil, Squalene, Prunis Armeniaca (Apricot) Kernel Oil, Carthamus Tinetorius (Safflower) Oil, Helianthus Annuus (Sunflower) Seed Oil, synthetic oils and extracts thereof and mixtures thereof.

14. The formulation of Claim 11 wherein said skin nourishing/wound healing substance is selected from a group consisting of aloe barbadensis leaf juice, white willow bark, and extracts thereof and mixtures thereof.

15. The formulation of Claim 11 further comprising an acne drug and said formulation functions as an acne formulation.

16. The formulation of Claim 15 wherein said active drug is salicylic acid.

17. A muscle soothing formulation comprising at least one hydrolyzed whole egg, at least one emollient substance, at least one humectant substance and a muscle soothing substance.

18. The formulation of Claim 17 wherein said humectant substance is selected from a group consisting of glycerin, butylene glycol, propylene glycol, pentylene glycol and mixtures thereof.

19. The formulation of Claim 17 wherein said emollient substance is selected from a group consisting of Prunus Amygdalus Dulis (Sweet Almond) Oi1, Squalene, Prunus Armeniaca (Apricot) Kernel Oil, Carthamus Tinetorius (Safflower) Oil, Helianthus Annuus (Sunflower) Seed Oil, synthetic oils and extracts thereof and mixtures thereof.

20. The formulation of Claim 17 wherein said muscle soothing substance comprises a blend of Menthol, Methyl Salicylate, Eucalyptus Globulus Oil, Camphor, and Mentha Piperita (Peppermint) Oil.

21. A method for making a formulation, said method comprising:

shearing a mixture of water, triethanolamine, glycerin and methyl paraben and heating said mixture to a temperature from about 70 degrees Celsius to about 80 degrees Celsius;

adding sweet almond oil, stearic acid, glyceryl stearate, and propylparaben to said mixture and shearing and heating the entire mixture to a temperature from about 90 degrees Celsius to about 100 degrees Celsius;

adding a hydrolyzed egg to the oil phase of the entire mixture while stopping the heating process and adding the oil phase to the water phase to form an emulsion; and

upon formation of the emulsion, cooling the entire formulation.

22. The method of Claim 21 further comprising adding additional substances to said formulation during said cooling process.

23. The method of Claim 21 wherein said method is a process for making a cosmetic formulation.

24. The method of Claim 21 wherein said method is a process for making a cosmopharmaceutical formulation.

25. The method of Claim 21 wherein said method is a process for making a pharmaceutical formulation.

26. A method for making a skin care formulation, said method comprising:

shearing a mixture of water, triethanolamine, trisodium EDTA, glycerin and methyl paraben and heating said mixture to a temperature from about 70 degrees Celsius to about 80 degrees Celsius;

adding cetearyl alcohol, sweet almond oil, cetyl alcohol, stearic acid, glyceryl stearate, sorbitan stearate, tocopherol, retinyl palmitate, tetrahexyldecyl ascorbate and propylparaben to said mixture and shearing and heating the entire mixture to a temperature from about 90 degrees Celsius to about 100 degrees Celsius;

adding a hydrolyzed egg to the oil phase of the entire mixture while stopping the heating process and adding the oil phase to the water phase to form an emulsion;

upon formation of the emulsion cooling the entire formulation; and

adding glycerin, salicylic acid and phenoxyethyanol and shearing the entire formulation.

27. The method of Claim 26 wherein said method is a process for making a skin care formulation used for acne skin care.

28. A method for making a muscle soothing formulation, said method comprising:

shearing a mixture of water, triethanolamine, glycerin, trisodium EDTA, and methyl paraben and heating said mixture to a temperature from about 70 degrees Celsius to about 80 degrees Celsius;

adding sweet almond oil, cetearyl alcohol, stearic acid, glyceryl stearate, cetyl lactate, tocopherol, retiryl palmitate, tetrahexyldecyl ascorbate and propylparaben to said mixture and shearing and heating the entire mixture to a temperature from about 90 degrees Celsius to about 100 degrees Celsius;

adding a hydrolyzed egg to the oil phase of the entire mixture while stopping the heating process and adding the oil phase to the water phase to form an emulsion;

upon formation of the emulsion, cooling the entire formulation; and

adding cyclomethicone, menthol, methyl salicylate, eucalyptus globules oil,

camphor, peppermint oil, phenoxyethanol and chlorophyll and shearing the entire formulation.

29. A method for making a cellulite formulation, said method comprising:

shearing a mixture of water, triethanolamine, glycerin, propylene glycol and methyl paraben and heating said mixture to a temperature from about 70 degrees Celsius to about 80 degrees Celsius;

adding sweet almond oil, cetyl lactate, stearic acid, paraffin, sorbitan stearate, glyceryl stearate, cyclomethicone and dimethicone copolyol, and propylparaben to said mixture and shearing and heating the entire mixture to a temperature from about 90 degrees Celsius to about 100 degrees Celsius;

adding a hydrolyzed egg to the oil phase of the entire mixture while stopping the heating process and adding the oil phase to the water phase to form an emulsion;

upon formation of the emulsion, cooling the entire formulation; and

adding grapefruit oil, lavender oil, geranium maculatum oil, juniperus communis oil, cumen extract, sambucus nigra extract, caraway extract, sage extract, parsley extract, primula veris extract and phenoxyethanol and shearing the entire formulation.

1610/1620 Example 1- Restriction Requirement

Disclaimer: The purpose of the following restriction example is to demonstrate how the groupings, patentable distinction and search burden may be set forth for a representative claim set. The emphasis of this example is to (1) clearly show how the claim set is divided into groups so that there is no overlap or loss of scope of the claimed inventions among the groups and (2) provide reasoning and analysis of various groups of inventions which result in conclusions that inventions may be patentably distinct and may result in undue search burden. The groupings, analysis and conclusions of a restriction requirement may vary from case to case, depending upon the fact patterns presented by individual applications. The example is set forth without a specification and is demonstrative in nature only.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a formulation comprising a hydrolyzed whole egg, an emollient, a humectant, and optionally an aromatherapeutical substance, acne medication, etc, classified in class 514, subclass various.

II. Claims 21-29, drawn to a process of making a formulation comprising hydrolyzed whole egg, classified in class 424, subclass 401.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

formulations can be made by the mere mixing of the ingredients, in addition to the methods described in group II which require shearing, heating, and emulsification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as exemplified by the different classes and subclasses. Further, a search for the invention of the 2 groups would not be coextensive because a search indicating the process is novel or unobvious would not extend to a holding that the product itself is novel or unobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

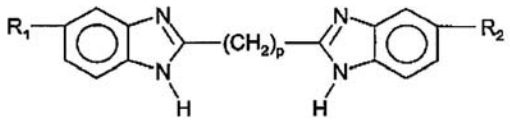
of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

1610/1620 Example 2 - Claim Set

1. A method of treating Parkinson's Disease in a mammalian subject in need of such treatment, said method comprising administering to said subject a compound according to formula I:



(I)

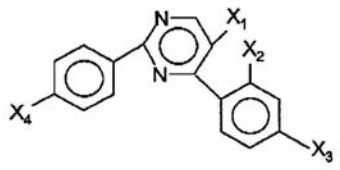
or a pharmaceutically acceptable salt thereof, wherein:

p is an integer ranging from 1 to 8;

R_1 and R_2 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, diaminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen;

and wherein said compound is administered in an amount sufficient to treat Parkinson's Disease.

2. A method of treating Parkinson's Disease in a mammalian subject in need of such treatment, said method comprising administering to said subject a compound according to formula III:



(III)

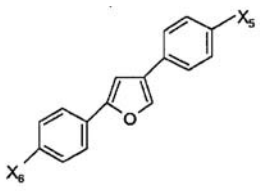
or a pharmaceutically acceptable salt thereof, wherein:

X_1 and X_2 are independently selected from H, loweralkyl, or loweralkoxy;

X_3 and X_4 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen;

and wherein said compound is administered in an amount sufficient to treat Parkinson's Disease .

3. A method of treating Parkinson's Disease in a mammalian subject in need of such treatment, said method comprising administering to said subject a compound according to formula IV:



(IV)

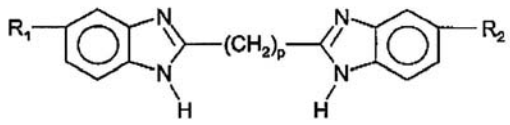
or a pharmaceutically acceptable salt, wherein:

X_5 and X_6 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen;

and wherein said compound is administered in an amount sufficient to treat Parkinson's Disease .

4. The method according to any of claims 1-3, wherein the mammalian subject is a human.

5. A compound according to formula I:



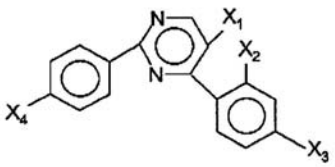
(I)

or a pharmaceutically acceptable salt thereof, wherein:

p is an integer ranging from 1 to 8;

R_1 and R_2 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, diaminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen.

6. A compound according to formula III:



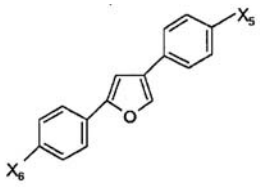
(III)

or a pharmaceutically acceptable salt thereof, wherein:

X_1 and X_2 are independently selected from H, loweralkyl, or loweralkoxy;

X_3 and X_4 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen.

7. A compound according to formula IV:

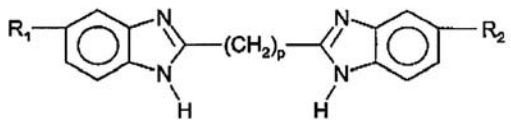


(IV)

or a pharmaceutically acceptable salt thereof, wherein:

X_5 and X_6 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen.

8. A pharmaceutical formulation comprising a compound according to formula I:



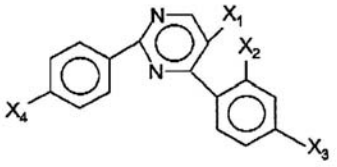
(I)

or a pharmaceutically acceptable salt thereof, wherein:

p is an integer ranging from 1 to 8;

R_1 and R_2 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, diaminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, or halogen; and a pharmaceutically acceptable carrier.

9. A pharmaceutical formulation comprising a compound according to formula III:



(III)

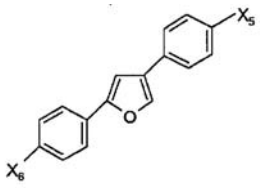
or the pharmaceutically acceptable salt thereof, wherein:

X_1 and X_2 are independently selected from H, loweralkyl, or loweralkoxy;

X_3 and X_4 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl,

or halogen; and a pharmaceutically acceptable carrier.

10. A pharmaceutical formulation comprising a compound according to formula IV:



(IV)

or a pharmaceutically acceptable salt thereof, wherein:

X_5 and X_6 are independently selected and each represented by loweralkyl, loweralkoxy, alkoxyalkyl, hydroxyalkyl, aminoalkyl, alkylamino, alkylaminoalkyl, cycloalkyl, aryl, alkylaryl, halogen; and a pharmaceutically acceptable carrier.

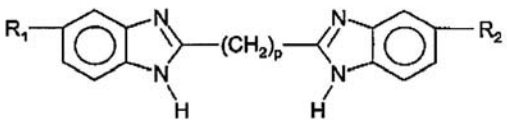
1610/1620 Example 2- Restriction Requirement

Disclaimer: The purpose of the following restriction example is to demonstrate how the groupings, patentable distinction and search burden may be set forth for a representative claim set. The emphasis of this example is to (1) clearly show how the claim set is divided into groups so that there is no overlap or loss of scope of the claimed inventions among the groups and (2) provide reasoning and analysis of various groups of inventions which result in conclusions that inventions may be patentably distinct and may result in undue search burden. The groupings, analysis and conclusions of a restriction requirement may vary from case to case, depending upon the fact patterns presented by individual applications. The example is set forth without a specification and is demonstrative in nature only.

Election/Restriction

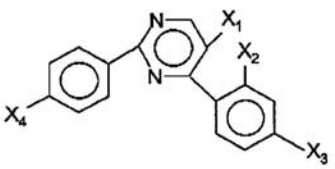
For the reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein a Group is a patentably distinct invention:

I. Claims 1 and 4 (as it depends from claim 1), drawn to methods of treating Parkinson's Disease in a mammal subject by administering a compound of the formula (I) , classified in class 514 subclass 394.



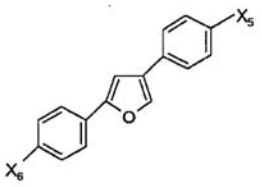
(I)

II. Claims 2 and 4 (as it depends from claim 2), drawn to methods of treating Parkinson's Disease in a mammal subject by administering a compound of the formula (III), classified in class 514 subclasses 256 and 269.



(III)

III. Claims 3 and 4 (as it depends from claim 3), drawn to methods of treating Parkinson's Disease in a mammal subject by administering a compound of the formula (IV), classified in class 514 subclasses 461 and 471.



(IV)

IV. Claims 5 and 8 drawn to products of the formula (I), classified in class 548 subclass 305.7 and class 514 subclass 394.

V. Claims 6 and 9 drawn to products of the formula (III), classified in class 544 subclasses 242, 298, 334 and 335 and class 514 subclasses 256 and 269.

VI. Claims 7 and 10 drawn to products of the formula (IV), classified in class 549 subclass 491, 497, 502, and 505; and class 514 subclasses 461 and 471.

Rationale Establishing Patentable Distinctiveness Between The Groups

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure. Further, given the rebuttable presumption that chemical compounds that are not similar in structure are not presumed to function similarly, the claimed compounds are expected to have different chemical properties, modes of action, different effects, and reactive conditions

(MPEP 806.04, MPEP 808.01). Additionally, considering the level of skill in the art, it does not appear that the compounds in one group would have been obvious over the compounds in another Group.

The above groups represent inventions which are independent and distinct, each from the other because of the following reasons:

Inventions IV-VI and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different method. For instance, the specification at page X line Y states that the claimed compounds can be used to treat Alzheimer's Disease or shingles. Note that each of these diseases has distinct etiologies from Parkinson's Disease.

Inventions IV-VI are independent and distinct products which differ materially in structure and composition. These compounds are chemically recognized to differ in structure and function, and the recognized chemical diversity can be seen by the various classification of these compounds, such as in various subclasses of class 549, class 548 and class 546. These compounds are independent and distinct from one another due to their diverse chemical structure, their expected different chemical properties, modes of action, different effects and reactive conditions.

Inventions I-III are independent and distinct methods which differ materially in the products administered. These methods require compounds which are chemically recognized as having diverse chemical structures as discussed above.

In addition, because of the different classification of each Group based upon the distinct chemical compounds, a serious burden is imposed on the examiner to perform a complete search of the defined areas in both the patent and non-patent literature. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to _____ on _____ to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[Note: If a telephonic election is made to the product, and the product is found to be allowable prior to first action, the Office will, at that time, *sua sponte* rejoin the corresponding method claims that recite products of the same scope. Therefore, the first Office Action will include examination of any rejoined method claims. However, if the applicant elects the product of formula (I) by phone and then the examiner determines that such product is unpatentable over the prior art that this evidence further strengthens the examiner's reasons for restriction if applicant traverses the requirement.**]**

1630/1640/1650 Example 1 - Claim Set

1. An isolated nucleic acid molecule selected from the group consisting of:
    a) a nucleic acid molecule comprising a nucleotide sequence which is at least 70% identical to the nucleotide sequence of SEQ ID NO:1;
    b) a nucleic acid molecule comprising a fragment of at least 30 nucleotides of the nucleotide sequence of SEQ ID N0:1;
    c) a nucleic acid molecule which encodes a polypeptide comprising an amino acid sequence which is at least 80% identical to the amino acid sequence of SEQ ID N0:2; and
    d) a nucleic acid molecule which hybridizes under stringent conditions to a nucleic acid molecule comprising SEQ ID NO:1.

2. The isolated nucleic acid molecule of claim 1, which is selected from the group consisting of:
    a) a nucleic acid comprising the nucleotide sequence of SEQ ID NO:1; and,
    b) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2.

3. The nucleic acid molecule of claim 1 further comprising vector nucleic acid sequences.

4. The nucleic acid molecule of claim 1 further comprising nucleic acid sequences encoding a heterologous polypeptide.

5. An isolated host cell which contains the nucleic acid molecule of claim 3.

6. The isolated host cell of claim 5 which is a mammalian host cell.

7. An isolated polypeptide which is at least 70% identical to SEQ ID NO: 2.
8. The polypeptide of claim 7 further comprising heterologous amino acid sequences.
9. An isolated antibody which specifically binds to amino acid residues 110-118 of SEQ ID NO: 2.
10. The antibody of claim 9, which is a monoclonal antibody.
11. The antibody of claim 9, comprising an immunologically active portion selected from the group consisting of:
    a) an scFV fragment; and
    b) an Fab fragment.
12. The antibody of claim 9 selected from the group consisting of:
    a) a humanized antibody;
    b) a human antibody;
    c) a nonhuman antibody; and,
    d) a single chain antibody.
13. A method of diagnosing an autoimmune disease in a patient, which method comprises contacting a fluid sample from the patient with the isolated antibody which specifically binds to the polypeptide of claim 1, quantitating binding thereof to a polypeptide in said sample, and comparing the quantity of binding in the sample to binding with normal subjects, wherein the autoimmune disease is present where the quantity of binding in the sample is less than the quantity in normal subjects.
14. A kit comprising an isolated antibody of claim 9 and instructions for use.
15. A method for diagnosing an autoimmune disease in a patient, which method comprises the steps of contacting a fluid sample from a patient with a nucleic acid probe comprising comprising at least 30 nucleotides of SEQ ID No 1 or its complement; and comparing the quantity of binding of the primer or probe in the sample to binding with normal subjects.

16. The method of claim 15, wherein the sample comprises mRNA molecules and is contacted with a nucleic acid probe.

17. A method for treating an autoimmune disease in a patient in need thereof comprising administering a polypeptide comprising SEQ ID No 2 to said patient.

1630/1640/1650 Example 1 Restriction Requirement

Disclaimer: The purpose of the following restriction example is to demonstrate how the groupings, patentable distinction and search burden may be set forth for a representative claim set. The emphasis of this example is to (1) clearly show how the claim set is divided into groups so that there is no overlap or loss of scope of the claimed inventions among the groups and (2) provide reasoning and analysis of various groups of inventions which result in conclusions that inventions may be patentably distinct and may result in undue search burden. The groupings, analysis and conclusions of a restriction requirement may vary from case to case, depending upon the fact patterns presented by individual applications. The example is set forth without a specification and is demonstrative in nature only.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 drawn to polynucleotides, vectors, and host cells classified in class 435, subclass 69.1.

II. Claims 7 and 8, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 9-12, and 14, drawn to an antibody and a kit comprising said antibody, classified in class 530, subclass 387.1.

IV. Claim 13, drawn to a method of diagnosing an autoimmune disease in a patient using an antibody, classified in class 435, subclass 7.1.

V. Claims 15 and 16, drawn to a method of diagnosing an autoimmune disease using a nucleic acid molecule, classified in class 435, subclass 6.

VI. Claim 17, drawn to a method of treating an autoimmune disease using a polypeptide, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-III are patentably distinct products.

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I does not necessarily encode a polypeptide of group II. For example, as disclosed in the specification, SEQ ID NO: 2 is 250 amino acids in length, whereas the nucleic acid molecule of claim 1(b) requires only 30 nucleotides (which would encode at most a polypeptide of 10 amino acids in length). Similarly, the nucleic acid molecule of claim 1(d) is complementary to the coding sequence, and therefore would not encode the polypeptide of group II. Furthermore, the information provided by the polynucleotide of group I can be used to make a materially different polypeptide than that of group II. For example, a nucleic acid which hybridizes to SEQ ID NO: 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 2. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious

search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive**.** In addition, the polypeptide claims include polypeptides having 70% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1(b) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group II and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2

light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group II is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group III is defined in terms of its binding specificity to a small structure within SEQ ID NO: 2. Thus immunization with the polypeptides of group II would result in the production of antibodies outside the scope of group III (i.e., antibodies that bind to regions other than residues 110-118 of SEQ ID NO: 2). Furthermore, an antibody of group III would not specifically bind all of the polypeptides of group II because the polypeptides of group II are not required to include residues 110-118 of SEQ ID No 2 to which the antibody binds. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group II and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. Similarly,

an amino acid sequence search for residues for 110-118 is required to determine the novelty and nonobvious of the antibodies of group III, however such a search is not required or sufficient to identify all of the polypeptides of group II. In addition, the technical literature search for the polypeptide of group II and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group III would impose a serious search burden since a search of the polynucleotide of group I is would not be used to determine the patentability of an antibody of group III, and vice-versa.

Inventions IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of diagnosing an autoimmune disease using an antibody (group IV), the method of diagnosing an autoimmune disease using a polynucleotide (group V), and the method of treating an autoimmune disease using a polypeptide' (group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of the autoimmune disease differ significantly for each of the materials. For diagnosis using the polynucleotide, hybridization may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. For treatment of an autoimmune disease using the polypeptide, the polypeptide is administered to a patient having autoimmune disease using any mode of administration. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV, V and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV, V and VI together.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group I can be used to make recombinant proteins as opposed to its use in diagnosing an autoimmune disease.

Searching the inventions of Groups I and V together would impose serious search burden. The inventions of Groups I and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of diagnosing autoimmune disease using a polynucleotide are not coextensive. Group I encompasses molecules which are claimed in terms of hybridization and percent identity in regard to reference sequence SEQ ID NO 1, which are not required for the search of Group V. In contrast, the search for group V would require a text search for the method of diagnosing autoimmune diseases in addition to an oligonucleotide search of 30-mer fragments of SEQ ID No 1 or complements of the 30-mer fragments. Prior art which teaches a polynucleotide that is 70% identical to SEQ ID No 1 would not necessarily be applicable to the method of using the 30-mer fragments of SEQ ID No 1. Moreover, even if the polynucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

Inventions I and either IV or VI are unrelated because the product of group I is not used or otherwise involved in the process of group IV or VI.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to catalyze an enzymatic reaction as opposed to its use in a method of treating an autoimmune disease.

Searching the inventions of Groups II and VI together would impose serious search burden. The inventions of Groups II and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treating autoimmune disease using a polypeptide are not coextensive. Group II encompasses molecules which are claimed in terms of 70% identical to SEQ ID No 2, which are not required for the search of Group VI. In contrast, the search for group VI would require a text search for the method of treating autoimmune diseases in addition to a search for SEQ ID No 2. Prior art which teaches a polypeptide which is 70% identical to SEQ ID No 2 would not necessarily be applicable to the method of using the polypeptide comprising SEQ ID No 2. Moreover, even if the polypeptide product were known, the method of treatment which uses the product may be novel and unobvious in view of the preamble or active steps.

Inventions II and V are unrelated because the product of group II is not used or otherwise involved in the process of group V.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used to immunize an animal to produce an antibody, as opposed to being used as a control which is present in the sample taken from normal subjects and used for comparison to patient samples in the diagnosis of an autoimmune disease. Further, the polypeptide present in the sample, is not encompassed within group II because as claimed, the polypeptide has been isolated.

Inventions III and V or VI are unrelated because the product of group III is not used or otherwise involved in the processes of groups V or VI.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to treat an autoimmune disease, as opposed to being used to diagnose an autoimmune disease.

Searching the inventions of Groups III and IV together would impose serious search burden. The inventions of Groups III and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the method of diagnosing autoimmune disease using an antibody are not coextensive. Group III encompasses molecules which are claimed in terms of binding to residues 110-118 of SEQ ID No 2, which are not required for the search of Group IV. In contrast, the search for group IV would require a text search for the method of diagnosing autoimmune diseases in addition to an oligo search of SEQ ID No 2. Prior art which teaches an antibody that binds to a protein which

is 70% identical to SEQ ID No 2 would not necessarily be applicable to the method of using the antibody which binds to residues 110-118 of SEQ ID No 2. Moreover, even if the antibody product were known, the method of diagnosis which uses the product may be novel and unobvious in view of the preamble or active steps.

The inventions of Groups I, II, III, IV, V and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I, II, III, IV, V or VI together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).