Chapter 800 Restriction in Applications Filed Under 35 U.S.C. 111; Double Patenting

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801 Introduction [R-07.2015]

This chapter is limited to a discussion of the subjects of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International **Preliminary** Examining Authority, and applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in MPEP Chapter 1800.

See MPEP § 823 for a summary of the guidance set forth in this chapter with regard to other substantive and procedural matters that generally apply to national stage applications submitted under 35 U.S.C. 371.

The general principles set forth in this chapter apply to design applications, except as identified in MPEP § 1504.05 and § 1504.06. The general principles set forth in this chapter apply to reissue applications, however see MPEP § 803.05 and § 1450 for a discussion of the prerequisites to making a restriction requirement in reissue applications. With regard to reexamination proceedings, restriction is not permitted. Basic principles of double patenting apply to reexamination proceedings, as explained in this chapter and in MPEP Chapters 2200 and 2600 (see especially MPEP § 2258).

802 Basis for Restriction Practice in Statute and Rules [R-07.2015]

The basis for restriction practice is found in the following statute and rules:

35 U.S.C. 121 Divisional applications.

[Editor Note: Applicable to any patent application filed on or after September 16, 2012. See <u>pre-AIA 35 U.S.C. 121</u> for the law otherwise applicable.]

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. If the other invention is

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made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. 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. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

pre-AIA 35 U.S.C. 121 Divisional applications.

[Editor Note: Not applicable to any patent application filed on or after September 16, 2012. See 35 U.S.C. 121 for the law otherwise applicable.]

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. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. 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. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

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 (§ 1.75) or otherwise include all the limitations of the generic claim.
- (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.

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.

The pertinent Patent Cooperation Treaty (PCT) Articles and Rules are cited and discussed in MPEP Chapter 1800. Sections 1850, 1875, and 1893.03(d) should be consulted for discussions on unity of invention:

- (A) before the International Searching Authority;
- (B) before the International Preliminary Examining Authority; and
 - (C) in the National Stage under <u>35 U.S.C. 371</u>.

802.01 Meaning of "Independent" and "Distinct" [R-08.2012]

35 U.S.C. 121 quoted in the preceding section states that the Director may require restriction if two or more "independent and distinct" inventions are claimed in one application. In 37 CFR 1.141, the statement is made that two or more "independent and distinct inventions" may not be claimed in one application.

This raises the question of the inventions as between which the Director may require restriction. This, in turn, depends on the construction of the expression "independent and distinct" inventions.

"Independent", of course, means not dependent, or unrelated. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the codification of the patent laws indicate that 35 U.S.C. 121: "enacts as law existing practice with respect to

division, at the same time introducing a number of changes."

The report on the hearings does not mention as a change that is introduced, the inventions between which the Director may properly require division.

The term "independent" as already pointed out, means not dependent, or unrelated. A large number of inventions between which, prior to the 1952 Act, division had been proper, are dependent inventions, such as, for example, combination and a subcombination thereof; as process and apparatus used in the practice of the process; as composition and the process in which the composition is used; as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Director never to approve division between dependent inventions, the word "independent" would clearly have been used alone. If the Director has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions, e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term "distinct" with the term "independent", indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, "distinct" inventions, even though dependent.

I. INDEPENDENT

The term "independent" (i.e., unrelated) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. For example, a process and an apparatus incapable of being used in practicing the process are independent inventions. See also MPEP § 806.06 and § 808.01.

II. RELATED BUT 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. Examples of related inventions include combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc. In this definition the term related is used as an alternative for dependent in referring to inventions other than independent inventions.

Related inventions are distinct if the inventions *as claimed* are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art). See MPEP § 806.05(c) (combination and subcombination) and § 806.05(j) (related products or related processes) for examples of when a two-way test is required for distinctness.

It is further noted that the terms "independent" and "distinct" are used in decisions with varying meanings. All decisions should be read carefully to determine the meaning intended.

802.02 Definition of Restriction [R-08.2012]

Restriction is the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application.

803 Restriction — When Proper [R-07.2022]

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 (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j)).

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.

I. CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 § 806.05(j)); and
- (B) There would be a serious search and/or examination burden on the examiner if restriction is not required (see MPEP § 803.02, § 808, and § 808.02).

II. GUIDELINES

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.

Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.

If there is an express admission that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required. *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

For purposes of the initial requirement, a serious search burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. Similarly, a serious examination burden, for example, may be prima facie shown by appropriate explanation of non-prior art issues under 35 U.S.C. 101, pre-AIA 35 U.S.C. 112, first paragraph, and/or 35 U.S.C. 112(a) relevant to one invention that are not relevant to the other invention. A prima facie showing of serious search and/or examination burden may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush claims is concerned, the criteria is set forth

in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP § 806.04 - § 806.04(i) and § 808.01(a).

803.01 Review by Examiner with at Least Partial Signatory Authority [R-07.2015]

Since requirements for restriction under 35 U.S.C. 121 are discretionary with the Director, it becomes very important that the practice under this section be carefully administered. Notwithstanding the fact that this section of the statute apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENT BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. See MPEP § 804.01. Therefore, to guard against this possibility, only an examiner with permanent full signatory authority or temporary full signatory authority may sign final Office actions containing a final requirement for restriction. An examiner with permanent partial signatory authority or temporary partial signatory authority may sign non-final Office actions containing a final requirement for restriction.

803.02 Election of Species Requirements – Markush Claims [R-07.2022]

I. MARKUSH CLAIMS

A "Markush" claim recites a list of alternatively useable members. *In re Harnisch*, 631 F.2d 716, 719-20, 206 USPQ 300, 303 (CCPA 1980); *Ex parte Markush*, 1925 Dec. Comm'r Pat. 126, 127 (1924). The listing of specified alternatives within a Markush claim is referred to as a Markush group or a Markush grouping. *Abbott Labs v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 1280-81, 67 USPQ2d 1191, 1196 (Fed. Cir. 2003)(citing to several sources that describe Markush groups).

When examining a Markush claim, the examiner may generally choose to require a provisional election of species from among patentably indistinct species or patentably indistinct groups of species. See subsection III, below. The applicant's election serves as a starting point for the search and examination of the claim.

See MPEP § 2117 for a general discussion of Markush claims, guidance and examples regarding the determination of whether a Markush grouping is proper, and rejections on the basis that a claim contains an improper Markush grouping. A rejection based on an improper Markush grouping should be made in an Office action on the merits. In certain circumstances, both a provisional election of species requirement and an improper Markush grouping rejection may apply to the same claim.

See MPEP § 2111.03, subsection II, and MPEP § 2173.05(h) for a discussion of Markush claims and compliance with the definiteness requirement of 35 U.S.C. 112(b).

II. PROPER MARKUSH GROUPING

Pursuant to the Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications ("Supplementary Guidelines"), 76 Fed. Reg. 7162 (February 9, 2011), a Markush grouping is proper if: (1) the members of the Markush group share a "single structural similarity," and (2) the members share a common use. Id. (citing In re Harnisch, 631 F.2d 716, 721-22, 206 USPQ 300, 305 (CCPA 1980)).

Where a Markush grouping describes part of a combination or process, the members following "selected from the group consisting of" (or a similar introductory phrase) must be substitutable, one for the other, with the expectation that the same intended result would be achieved. Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1357, 119 USPQ2d 1773, 1779 (Fed. Cir. 2016)("It is generally understood that ... the members of the Markush group ... are alternatively usable for the purposes of the invention")(citations omitted). Where a Markush grouping describes part of a chemical compound, regardless of whether the claim is limited to a compound per se or the compound is recited as part of a combination or process, the members following

"selected from the group consisting of" (or similar introductory phrase) need not share a community of properties themselves; the propriety of the grouping is determined by a consideration of the compound as a whole. See *Harnisch*, 631 F.2d at 722, 206 USPQ at 305 ("in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components").

See MPEP § 2117 for guidance and examples regarding the determination of whether a Markush grouping is proper.

In accordance with the principles of compact prosecution, if the examiner determines that one or more claims appear to include an improper Markush grouping (see MPEP § 2117), the examiner should require the applicant to elect a species. Note that if a written provisional election of species requirement must be made separate from the first Office action on the merits, it should not include a rejection on the basis of an improper Markush grouping. Any appropriate improper Markush grouping rejection should be made in an Office action on the merits.

III. ELECTION OF SPECIES PRACTICE FOR MARKUSH CLAIMS

A. Overview

Markush claims recite a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush claim may include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing a Markush claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species (or grouping of patentably indistinct species) prior to examination on the merits, with one exception. If the members of a proper 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 may be directed to independent and distinct inventions. In such a case, the examiner will not require provisional election of a single species. See MPEP § 808.02

An election of species requirement is a type of restriction requirement. An examiner should set forth a requirement for election of a single disclosed species (or a grouping of patentably indistinct species) in a Markush claim using form paragraph 8.01 when claims limited to species are present or using form paragraph 8.02 when no species claims are present. See MPEP \struct 808.01(a) and \struct 809.02(a). If a Markush claim depends from or otherwise requires all the limitations of another generic or linking claim, see MPEP \struct 809.

Following election, the Markush claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. Note that where a claim reads on multiple species, only one species needs to be taught or suggested by the prior art in order for the claim to be anticipated or rendered obvious. See, e.g., *Fresenius USA*, *Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1298, 92 USPQ2d 1163, 1171 (Fed. Cir. 2009)(the entire element is disclosed by the prior art if one alternative in the Markush group is in the prior art).

If the Markush claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. As an example, in the case of an application with a Markush claim drawn to the compound X-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, XA, XB, XC, XD, or XE. The Markush claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species.

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush claim and claims to the elected species will be rejected, and claims to the nonelected species will be held withdrawn from further consideration.

If the examiner determines that the elected species is allowable over the prior art, the examination of the Markush claim will be extended. If prior art is then found that anticipates or renders obvious the Markush claim with respect to a *nonelected species*, the Markush claim shall be rejected; claims to the nonelected species would still be held withdrawn from further consideration. The prior art search will not be extended unnecessarily to cover all nonelected species, and need not be extended beyond a proper Markush grouping. See subsection III.C.2, below, for additional guidance.

Should applicant, in response to a rejection of a Markush claim, overcome the rejection by amending the Markush claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush claim will be examined again. The examination will be extended to the extent necessary to determine patentability of the Markush claim. In the event prior art is found during this examination that anticipates or renders obvious the amended Markush claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in <u>37 CFR 1.97(c)</u> with the fee set forth in <u>37 CFR</u> 1.17(p). See MPEP § 706.07(a). Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry if they do not comply with the requirements of 37 CFR 1.116. See MPEP § 714.13.

B. Provisional Election of Species

If a claim that includes a Markush grouping reads on two or more patentably distinct inventions, a provisional election of species requirement may be made at the examiner's discretion. When making such a requirement, the examiner will require the applicant to elect a species or group of patentably indistinct species for initial search and examination. The examiner should not require provisional election between species that are not patentably distinct, or

when the Markush group is proper and there would be no serious burden if the species were searched and examined together. The examiner should not invite the applicant to elect any group of species that would clearly be rejectable either as an improper Markush grouping or under 35 U.S.C. 112(a) if presented in a separate claim.

In accordance with current practice, when an examiner chooses to require a provisional election of species, in most cases the examiner should call the applicant to request a telephonic election. See MPEP \sigma 812.01. If the applicant elects by telephone, form paragraph 8.23 should be used in the next Office action on the merits. The examiner should note whether the election was made with or without traverse. If a rejection on the basis of an improper Markush grouping is to be made, it should be done in the first Office action on the merits with the written provisional election of species requirement.

If a written provisional election of species requirement is made prior to the first Office action on the merits, it should not include a rejection on the basis of an improper Markush grouping. Any appropriate improper Markush grouping rejection should be made in an Office action on the merits. If during prosecution a new claim is added that includes an improper Markush grouping, or an existing claim is amended to include an improper Markush grouping, the examiner may require provisional election of species at that time, in the same action as any appropriate rejections. Include form paragraph 8.23.01 if the applicant declined to elect by telephone.

C. Initial Examination of Elected Species

1. Rejection of Claims to Elected Species

Examination on the merits begins after the applicant's election. If the elected species or group of patentably indistinct species is anticipated by or obvious over the prior art, an appropriate art-based rejection of any claim that reads on the elected species or group of patentably indistinct species should be made. Non-prior art rejections that apply to the elected species or group of patentably indistinct species should also be made. If the election

was made with traverse, it should be treated in accordance with MPEP § 821.01.

If the Markush grouping was improper, a rejection on the basis of there being an improper Markush grouping should be made as described in MPEP § 2117. The examiner should use form paragraph 8.40 to make the improper Markush grouping rejection and to advise the applicant of the species that do not belong to a proper Markush grouping that includes the elected species. The form paragraph also serves to advise the applicant that a rejection on the basis of there being an improper Markush grouping is an appealable rather than a petitionable matter.

Example 1.

A claim is drawn to a proper Markush grouping of species A, B, or C. The three species are patentably distinct, and the examiner requires a provisional election. Species A is elected. The examiner rejects species A over prior art, and indicates that species B and C have not been searched and examined. Use form paragraph 8.01 or 8.02 as appropriate to set forth the election requirement.

Example 2.

A claim is drawn to a Markush grouping of species A, B, C, D, or E. The five species are patentably distinct, and the examiner requires a provisional election. The grouping of species A, B, or C is a proper Markush grouping. However, the grouping of species A, B, C, D, or E is not a proper Markush grouping. Species A is elected. The examiner rejects species A over prior art, and indicates that species B, C, D, and E have not been searched and examined. Use form paragraph 8.01 or 8.02 as appropriate to set forth the election requirement. The examiner should also reject the claim on the basis of there being an improper Markush grouping using form paragraph 8.40. The improper Markush grouping rejection should indicate that species D and E do not belong to the proper Markush grouping of species A, B, or C.

2. Elected Species in Proper Markush Grouping Allowable over the Prior Art

If the elected species or group of patentably indistinct species is not anticipated by or obvious over the prior art, the examiner should extend the search and examination to a non-elected species or group of species that falls within the scope of a proper Markush grouping that includes the elected species. The search and examination should be continued until either (1) prior art is found that anticipates or renders obvious a species that falls within the scope of a proper Markush grouping that includes the elected species, or (2) it is determined

that no prior art rejection of any species that falls within the scope of a proper Markush grouping that includes the elected species can be made. The examiner need not extend the search beyond a proper Markush grouping. In other words, the examiner need not extend the search to any additional species that do not share a single structural similarity and a common use with the elected species (i.e., do not belong to the same recognized physical or chemical class or to the same art-recognized class and/or do not have a common use and/or do not share a substantial structural feature of a chemical compound and a use that flows from the substantial structural feature). The examiner should continue examination of the Markush claim to determine whether it meets all other requirements of patentability (e.g., 35 <u>U.S.C. 101</u> and <u>112</u>, nonstatutory double patenting, and proper Markush grouping).

In the interest of compact prosecution, the examiner should ensure that the record is clear as to which species have been searched and have been found allowable over the prior art. The examiner should indicate that the provisional election of species requirement has been modified if additional species beyond the elected species have been searched and determined to be allowable over the prior art. The examiner should indicate that the provisional election of species requirement has been withdrawn if the full scope of the Markush grouping has been searched and been determined to be allowable over the prior art. Note that the examiner can only make or maintain any restriction requirement if there would be serious search and/or examination burden. Clarity of the record with regard to the provisional election of species requirement is critical to proper application of 35 U.S.C. 121 in later divisional applications.

If a Markush grouping as set forth in a claim is proper and election of species has been required, the examiner must continue to search the species of the claim unless the claim has been found to be unpatentable over prior art. An examiner may not (such as by way of an Ex parte Quayle action or a Notice of Non-Responsive Amendment) seek to require an applicant to limit the scope of a claim that is directed to a proper Markush group to a subset of species that falls within the scope of the claim in the absence of a rejection of the claim for not complying

with the requirements for patentability (e.g., <u>35</u> <u>U.S.C. 101</u>, <u>102</u>, <u>103</u>, and <u>112</u>, and nonstatutory double patenting).

D. Final Rejection; Finality of Election Requirement

An Office action may be made final if the requirements of MPEP §§ 706.07 - 706.07(b) are met. If a claim in a first application recites a proper Markush grouping that encompasses patentably distinct inventions, an examiner who has required a provisional election of species need not continue to search the claim if the claim is rejected over prior art in a proper final rejection. That is, in this circumstance, the applicant's election loses its provisional status and is given full effect under 35 U.S.C. 121. Furthermore, if an applicant files a second application that is a divisional application claiming benefit under 35 U.S.C. 120 of the first application, the 35 U.S.C. 121 shield may be applicable. So long as the consonance requirement is met, a claim in the divisional application to a previously non-elected and unexamined embodiment may not be rejected on the ground of non-statutory double patenting over an embodiment examined in the first application. An amendment canceling the rejected species received after final under 37 CFR 1.116 may typically be denied entry on the basis that it would require further consideration and/or search. If the applicant's provisional election was made with traverse and the requirement has been made final, the applicant may file a petition for review under 37 CFR 1.144. See MPEP §§ 818.01(c) and 818.01(d).

Note that no Markush claim can be allowed until any improper Markush grouping rejection has been overcome or withdrawn (see MPEP \ \ 2117, subsection III), and all other conditions of patentability have been satisfied.

803.03 Transitional Applications [R-08.2012]

PRACTICE RE TRANSITIONAL APPLICATION

37 CFR 1.129 Transitional procedures for limited examination after final rejection and restriction practice.

(b)(1) In an application, other than for reissue or a design patent, that has been pending for at least three years as of June 8, 1995; taking into account any reference made in the

application to any earlier filed application under 35 U.S.C. 120, 121 and 365(c), no requirement for restriction or for the filing of divisional applications shall be made or maintained in the application after June 8, 1995, except where:

- (i) The requirement was first made in the application or any earlier filed application under <u>35 U.S.C. 120</u>, <u>121</u>, and <u>365(c)</u> prior to April 8, 1995;
- (ii) The examiner has not made a requirement for restriction in the present or parent application prior to April 8, 1995, due to actions by the applicant; or
- (iii) The required fee for examination of each additional invention was not paid.
- (2) If the application contains more than one independent and distinct invention and a requirement for restriction or for the filing of divisional applications cannot be made or maintained pursuant to this paragraph, applicant will be so notified and given a time period to:
- (i) Elect the invention or inventions to be searched and examined, if no election has been made prior to the notice, and pay the fee set forth in 1.17(s) for each independent and distinct invention claimed in the application in excess of one which applicant elects;
- (ii) Confirm an election made prior to the notice and pay the fee set forth in § 1.17(s) for each independent and distinct invention claimed in the application in addition to the one invention which applicant previously elected; or
- (iii) File a petition under this section traversing the requirement. If the required petition is filed in a timely manner, the original time period for electing and paying the fee set forth in § 1.17(s) will be deferred and any decision on the petition affirming or modifying the requirement will set a new time period to elect the invention or inventions to be searched and examined and to pay the fee set forth in § 1.17(s) for each independent and distinct invention claimed in the application in excess of one which applicant elects.
- (3) The additional inventions for which the required fee has not been paid will be withdrawn from consideration under § 1.142(b). An applicant who desires examination of an invention so withdrawn from consideration can file a divisional application under 35 U.S.C. 121.
- (c) The provisions of this section shall not be applicable to any application filed after June 8, 1995.
- "Restriction" under <u>37 CFR 1.129(b)</u> applies to both restriction requirements under <u>37 CFR 1.142</u> and election of species requirements under <u>37 CFR 1.146</u>.
- 37 CFR 1.129(b)(1) provides for examination of more than one independent and distinct invention in certain applications pending for 3 years or longer as of June 8, 1995, taking into account any reference to any earlier application under 35 U.S.C. 120, 121, or 365(c). Applicant will not be permitted to have

- such additional invention(s) examined in an application if:
- (A) the requirement was made in the application or in an earlier application relied on under <u>35 U.S.C.</u> <u>120</u>, <u>121</u>, or <u>365(c)</u> prior to April 8, 1995;
- (B) no restriction requirement was made with respect to the invention(s) in the application or earlier application prior to April 8, 1995, due to actions by the applicant; or
- (C) the required fee for examination of each additional invention was not paid.

Only if one of these exceptions applies is a normal restriction requirement appropriate and telephone restriction practice may be used.

Examples of what constitute "actions by the applicant" in 37 CFR 1.129(b)(1) are:

- (A) applicant abandoned the application and continued to refile the application such that no Office action could be issued in the application,
- (B) applicant requested suspension of prosecution under <u>37 CFR 1.103(a)</u> such that no Office action could be issued in the application,
- (C) applicant disclosed a plurality of independent and distinct inventions in the present or parent application, but delayed presenting claims to more than one of the disclosed independent and distinct inventions in the present or parent application such that no restriction requirement could be made prior to April 8, 1995, and
- (D) applicant combined several applications, each of which claimed a different independent and distinct invention, into one large "continuing" application, but delayed filing the continuing application first claiming more than one independent and distinct invention such that no restriction requirement could be made prior to April 8, 1995.

In examples (A) and (B), the fact that the present or parent application claiming independent and distinct inventions was on an examiner's docket for at least 3 months prior to abandonment or suspension, or in examples (C) and (D), the fact that the amendment claiming independent and distinct inventions was first filed, or the continuing application first claiming the additional independent and distinct inventions

was on an examiner's docket, at least 3 months prior to April 8, 1995, is *prima facie* evidence that applicant's actions did not prevent the Office from making a requirement for restriction with respect to those independent and distinct inventions prior to April 8, 1995. Furthermore, an extension of time under 37 CFR 1.136(a) does not constitute such "actions by the applicant" under 37 CFR 1.129(b)(1).

NOTE: If an examiner believes an application falls under the exception that no restriction could be made prior to April 8, 1995, due to applicant's action, the application must be brought to the attention of the Technology Center (TC) Special Program Examiner for review.

Under 37 CFR 1.129(b)(2), if the application contains claims to more than one independent and distinct invention, and no requirement for restriction or for the filing of divisional applications can be made or maintained, applicant will be notified and given a time period to:

- (A) elect the invention or inventions to be searched and examined, if no election has been made prior to the notice, and pay the fee set forth in 37 CFR 1.17(s) for each independent and distinct invention claimed in the application in excess of one which applicant elects,
- (B) in situations where an election was made in reply to a requirement for restriction that cannot be maintained, confirm the election made prior to the notice and pay the fee set forth in 37 CFR 1.17(s) for each independent and distinct invention claimed in the application in addition to the one invention which applicant previously elected, or
- (C) file a petition under 37 CFR 1.129(b)(2) traversing the requirement without regard to whether the requirement has been made final. No petition fee is required.

37 CFR 1.129(b)(2) also provides that if the petition is filed in a timely manner, the original time period for electing and paying the fee set forth in 37 CFR 1.17(s) will be deferred and any decision on the petition affirming or modifying the requirement will set a new time period to elect the invention or inventions to be searched and examined and to pay the fee set forth in 37 CFR 1.17(s) for each

independent and distinct invention claimed in the application in excess of one which applicant elects.

Under 37 CFR 1.129(b)(3), each additional invention for which the required fee set forth in 37 CFR 1.17(s) has not been paid will be withdrawn from consideration under 37 CFR 1.142(b). An applicant who desires examination of an invention so withdrawn from consideration can file a divisional application under 35 U.S.C. 121.

37 CFR 1.129(c) clarifies that the provisions of 37 CFR 1.129(a) and (b) are not applicable to any application filed after June 8, 1995. However, any application filed on June 8, 1995, would be subject to a 20-year patent term.

Form paragraph 8.41 may be used to notify applicant that the application is a transitional application and is entitled to consideration of additional inventions upon payment of the required fee.

¶ 8.41 Transitional Restriction or Election of Species Requirement – pre-GATT Filing

This application is subject to the transitional restriction provisions of Public Law 103-465, which became effective on June 8, 1995, because:

- 1. the application was filed on or before June 8, 1995, and has an effective U.S. filing date of June 8, 1992, or earlier;
- 2. a requirement for restriction was not made in the present or a parent application prior to April 8, 1995; and
- 3. the examiner was not prevented from making a requirement for restriction in the present or a parent application prior to April 8, 1995, due to actions by the applicant.

The transitional restriction provisions permit applicant to have more than one independent and distinct invention examined in the same application by paying a fee for each invention in excess of one.

Final rules concerning the transition restriction provisions were published in the *Federal Register* at 60 FR 20195 (April 25, 1995) and in the *Official Gazette* at 1174 OG 15 (May 2, 1995). The final rules at <u>37 CFR 1.17(s)</u> include the fee amount required to be paid for each additional invention as set forth in the following requirement for restriction. See the current fee schedule for the proper amount of the fee.

Applicant must either: (1) elect the invention or inventions to be searched and examined and pay the fee set forth in <u>37 CFR 1.17(s)</u> for each independent and distinct invention in excess of one which applicant elects; or (2) file a petition under <u>37 CFR 1.129(b)</u> traversing the requirement.

Examiner Note:

1. This form paragraph should be used in all restriction or election of species requirements made in applications subject to the transition restriction provisions set forth in 37 CFR 1.129(b). The procedure is NOT applicable to any design or reissue application.

803.03(a) Transitional Application — Linking Claim Allowable [R-08.2012]

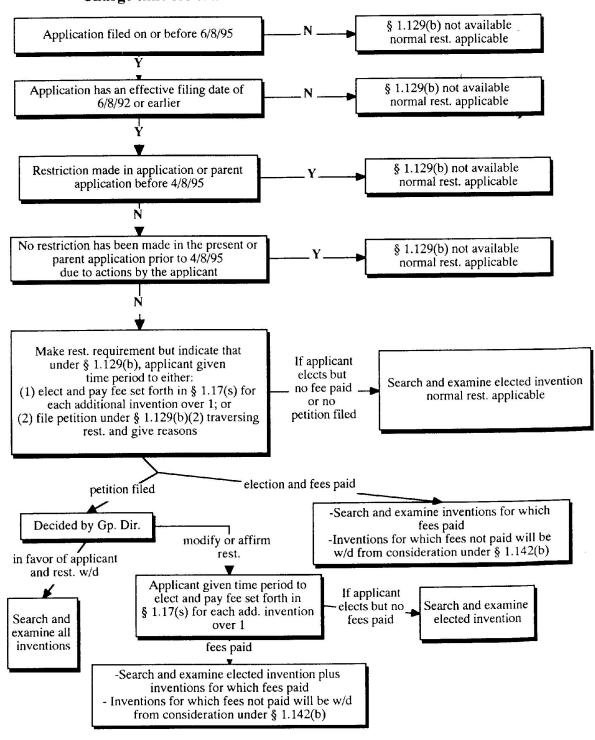
Whenever divided inventions in a transitional application are rejoined because a linking claim is allowable (MPEP § 809, § 821.04, and § 821.04(a)) and applicant paid the fee set forth in 37 CFR 1.17(s) for the additional invention, applicant should be notified that he or she may request a refund of the fee paid for that additional invention.

803.03(b) Transitional Application — Generic Claim Allowable [R-08.2012]

Whenever claims drawn to an additional species in a transitional application for which applicant paid the fee set forth in 37 CFR 1.17(s) are no longer withdrawn from consideration because they are fully embraced by an allowable generic claim, applicant should be notified that he or she may request a refund of the fee paid for that additional species.

The determination of when claims to a nonelected species would no longer be withdrawn from consideration should be made as indicated in MPEP § 806.04(d), § 821.04, and § 821.04(a).

Transitional Restriction Provision - 37 CFR 1.129(b) Starting June 8,1995 No Telephone restriction Charge time for examination of additional inventions to 112055



803.04 Nucleotide Sequences [R-07.2015]

Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode different proteins are structurally distinct

chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of <u>35 U.S.C.</u> <u>121</u>. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to <u>35 U.S.C.</u> <u>121</u> and <u>37 CFR 1.141</u> *et seq.*

In 1996, the Commissioner of Patents and Trademarks decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 OG 68 (November 19, 1996).

In 2007, the Commissioner for Patents rescinded the waiver. See Examination of Patent Applications Containing Nucleotide Sequences, 1316 OG 123 (March 27, 2007). All pending applications are subject to the 2007 OG notice. Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits for multiple nucleotide sequences in the absence of extenuating circumstances. For national applications filed under 35 U.S.C. 111(a), polynucleotide inventions will be considered for restriction, rejoinder, and examination practice in accordance with the standards set forth in MPEP Chapter 800. Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden in the same manner as claims to any other type of molecule.

See MPEP § 1850 for treatment of claims containing independent and distinct nucleotide sequences in international applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. 371.

803.05 Reissue Application Practice [R-07.2022]

37 CFR 1.176 Examination of reissue.

(b) Restriction between subject matter of the original patent claims and previously unclaimed subject matter may be required (restriction involving only subject matter of the original patent claims will not be required). If restriction is required, the subject matter of the original patent claims will be held to be constructively elected unless a disclaimer of all the patent claims is filed in the reissue application, which disclaimer cannot be withdrawn by applicant.

Restriction practice relating to reissue applications is governed by 37 CFR 1.176(b) which specifies that restriction may only be required between the invention(s) of the original patent claims and previously unclaimed invention(s) set forth in new claims added in the reissue application. The claims of the original patent must not be restricted as being directed to two or more independent and distinct inventions and must be examined together. Where restriction is required by the examiner, the invention(s) set forth by the original patent claims and any newly added claims that are directed to the same invention(s) will be held as constructively elected. Any new claim that is directed to an invention that is independent and distinct from the invention(s) of the original patent claims will be withdrawn from consideration. See MPEP § 1450 for a detailed explanation of this practice. Note that applicant may initiate a division of the claims by filing more than one reissue application in accordance with 37 CFR 1.177. See MPEP § 1451 for a detailed explanation of this practice.

Where a restriction (including an election of species) requirement was made in an application and applicant permitted the elected invention to issue as a patent without filing a divisional application on the non-elected invention(s) or on non-claimed subject matter distinct from the elected invention, the non-elected invention(s) and non-claimed, distinct subject matter cannot be recovered by filing a reissue application. Once an applicant acquiesces to a restriction (including an election of species) requirement, any invention distinct from that elected and prosecuted to allowance—whether originally claimed or not—can only be pursued in a timely-filed divisional application. A reissue applicant's failure to timely file a divisional application is not considered to be error causing a patent granted on the elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Accordingly, this is not correctable by reissue of the original patent under 35 U.S.C. 251. In re Watkinson, 900 F.2d 230, 14 USPQ2d 1407 (Fed. Cir. 1990); In re Weiler, 790

F.2d 1576, 229 USPQ 673 (Fed. Cir. 1986). See MPEP § 1412.01.

804 Definition of Double Patenting [R-07.2022]

35 U.S.C. 101 Inventions Patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 121 Divisional Applications.

[Editor Note: Applicable to any patent application filed on or after September 16, 2012. See <u>pre-AIA 35 U.S.C. 121</u> for the law otherwise applicable.]

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. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. 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. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

pre-AIA 35 U.S.C. 121 Divisional Applications.

[Editor Note: **Not applicable** to any patent application filed on or after September 16, 2012. See <u>35 U.S.C. 121</u> for the law otherwise applicable.]

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. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. 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. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent

shall not be questioned for failure of the Director to require the application to be restricted to one invention.

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

In re Zickendraht, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). Double patenting results when the right to exclude granted in one patent is unjustly extended by the grant of another patent or patents. *In re Van Ornum,* 686 F.2d 937, 943-44, 214 USPQ 761, 766-67 (CCPA 1982).

Some commonality of inventorship or (deemed) ownership must exist between two or more patents or applications before consideration can be given to the issue of double patenting. For example, the patents or applications may have the same inventive entity. The patents or applications may also have at least one common (joint) inventor, which covers the situations where at least one patent or application names a sole inventor and the other patent(s) or application(s) names joint inventors and where all the patents or applications name joint inventors. For example, if one application names inventor A and the second application names joint inventors A and B, then the applications have one common (joint) inventor. As another example, if one application names joint inventors A and B and a second application names joint inventors A, B, and C, then the applications have two common joint inventors, and thus, have at least one common joint inventor. See 35 U.S.C. 100(f) for definition of "inventor" and 35 U.S.C. 100(g) for definition of "joint inventor". Alternatively, the patents or applications may have a common applicant, and/or be commonly

assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or in pre-AIA 35 U.S.C. 103(c)(2) and (3). To determine if subject matter excepted as prior art under 35 U.S.C. 102(b)(2)(C) or disqualified as prior art under pre-AIA 35 U.S.C. 103(c) may be considered for double patenting issues, see MPEP § 804.03.

There are generally two types of double patenting rejections. One is the "same invention" type double patenting rejection based on 35 U.S.C. 101 which states in the singular that an inventor "may obtain a patent." The second is the "nonstatutory-type" double patenting rejection based on a judicially created doctrine grounded in public policy and which is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. Since the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis.

The doctrine of nonstatutory double patenting also seeks to prevent the possibility of multiple suits against an accused infringer by different assignees of patents claiming patentably indistinct variations of the same invention. In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982) (citing Chisum, Patents, § 9.04(2)(b) (1981)). A terminal disclaimer, submitted in compliance with 37 CFR 1.321(c) or (d) to overcome a double patenting rejection, includes a provision that the patent or any patent issuing from the application is only enforceable for and during such period that it is owned by the same party (or parties) that owns the other patents or applications, identified in the terminal disclaimer, that claim obvious variations of one invention. Van Ornum, 686 F.2d at 944-45, 214 USPQ at 767 (citing Chisum, Patents, § 9.04(2)(b) (1981)).

Nonstatutory double patenting includes rejections based on anticipation, a one-way determination of "obviousness," or a two-way determination of "obviousness." It is important to note that the "obviousness" analysis for "obviousness-type" double-patenting is "similar to, but not necessarily

the same as, that undertaken under 35 U.S.C. 103." *In re Braat*, 937 F.2d 589, 592-93, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991) (citing *In re Longi*, 759 F.2d 887, 892 n.4, 225 USPQ 645, 648 n.4 (Fed. Cir. 1985)); *Geneva Pharmaceuticals*, 349 F.3d 1373, 1378 n.1, 68 USPQ2d 1865, 1869 n.1 (Fed. Cir. 2003). In addition, nonstatutory double patenting also includes rejections based on the equitable principle against permitting an unjustified timewise extension of patent rights. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); see also subsection II.B.6, below.

The charts below are an overview of the treatment of applications having conflicting claims (e.g., where a claim in an application is not patentably distinct from a claim in a patent or another application). Note that although double patenting and unpatentability over prior art are two separate issues (for example, a double patenting reference that contains conflicting claims need not qualify as prior art), the charts speak to both issues when the reference is a patent or application for completeness. Specifically, the charts cover when two applications have claims to the same invention (Charts I-A) or to patentably indistinct inventions (Charts I-B) and when an application and a patent have claims to the same invention (Charts II-A) or to patentably indistinct inventions (Charts II-B). The charts also include first to invent (FTI) versions (i.e., Charts I-A_FTI, I-B_FTI, II-A_FTI, and II-B_FTI) for use when examining an application that is subject to 35 U.S.C. 102 and 103 in effect on March 15, 2013 (e.g., pre-AIA 35 U.S.C. 102 and 103) and America Invents Act (AIA) versions (i.e., Charts I-A_AIA, I-B_AIA, II-A_AIA, II-B_AIA) for use when examining an application that is subject to 35 U.S.C. 102 and 103 in effect on March 16, 2013 (AIA 35 U.S.C. 102 and 103). Therefore, in certain situations, examiners may have to use the FTI versions of the charts for an earlier-filed application that is subject to pre-AIA 35 U.S.C. 102 and 103 and the AIA versions of the charts for the later-filed application that is subject to AIA 35 U.S.C. 102 and 103 or vice versa. The charts show possible rejections based upon an earlier-filed application or patent that may be applicable if the record supports such rejections. For example, examiners should determine if an earlier-filed application or patent is prior art under pre-AIA 35 U.S.C. 102(e) or 35 U.S.C. 102(a)(2)

before making an anticipation or obviousness rejection based upon the earlier-filed application or patent.

The AIA versions of the charts provide that a (provisional) rejection under 35 U.S.C. 102(a)(2) should not be applied if the earlier-filed application or patent is not prior art in view of 35 U.S.C. 102(b)(2)(A) or (B). The evidence necessary to show that the disclosure is by the inventor or a joint inventor or another who obtained the subject matter disclosed from the inventor or a joint inventor, and is therefore not prior art in view of 35 U.S.C. 102(b)(2)(A), requires a case-by-case analysis, which depends on whether it is apparent from the disclosure itself or the patent application specification that the disclosure is an inventor-originated disclosure. In the situation where a previous public disclosure by the inventor or a joint inventor (or which originated with the inventor or a joint inventor) was not within the grace period but was effective to establish that an intervening disclosure was not 35 U.S.C. 102(a)(2) prior art in view of the exception of 35 U.S.C. 102(b)(2)(B), the previous inventor-originated public disclosure would qualify as prior art under 35 U.S.C. 102(a)(1) and no exception provision could possibly apply. See MPEP §§ 717 et seq. and 2155 et seq. for more information

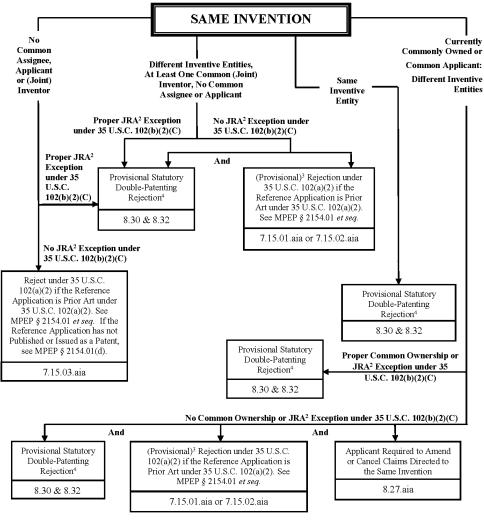
about the prior art exceptions under 35 U.S.C. 102(b)(2).

The AIA versions of the charts do not address the transition cases in which pre-AIA 35 U.S.C. 102(g) applies to applications subject to AIA 35 U.S.C. 102 and 103. See MPEP § 2159.03 to determine if an application is a transition application. Examiners should consult with a Technology Center Practice Specialist if an application is a transition application and the examiner finds potential pre-AIA 35 U.S.C. 102(g) issues.

Finally, the AIA versions of the charts also do not address rejections under 35 U.S.C. 101 and 115 for improper naming of inventor. Although the AIA eliminated pre-AIA 35 U.S.C. 102(f), the patent laws still require the naming of the actual inventor or joint inventors of the claimed subject matter. See 35 U.S.C. 115(a). In the rare situation where there is evidence on the record that the application does not name the correct inventorship, examiners should consult MPEP § 2157 to determine if a rejection under 35 U.S.C. 101 and 115 should be made.

See <u>MPEP § 2258</u> for information pertaining to double patenting rejections in reexamination proceedings.

CHART I-A_AIA: WHEN EXAMINING AN AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN TWO APPLICATIONS



¹An AIA application is subject to 35 U.S.C. 102 as in effect on or after March 16, 2013. See MPEP § 2159 et seq. Certain AIA applications may also be subject to pre-AIA 35 U.S.C. 102(g). Consult with a Technology Center Practice Specialist if there are potential pre-AIA 35 U.S.C. 102(g) issue(s).

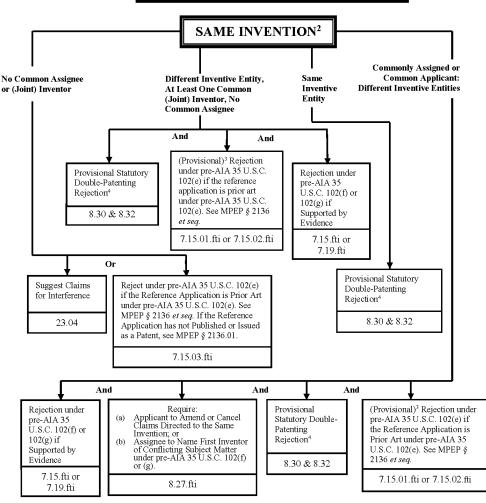
² Joint Research Agreement as defined in AIA 35 U.S.C. 102(c).

³ Where the application being applied as a reference has NOT been published, the rejection should be provisional.

⁴ For determining whether to make or maintain a provisional statutory double patenting rejection, see MPEP § 804, subsection I.B.2.

Subsection ID: The chart does not include rejection(s) under 35 U.S.C. 101 and 115 for incorrect inventorship. See MPEP § 2157 for more information on rejections under 35 U.S.C. 101 and 115.

CHART I-A_FTI: WHEN EXAMINING A PRE-AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN TWO APPLICATIONS



 $^{^1}$ A pre-AIA application is subject to 35 U.S.C. 102 as in effect on March 15, 2013. See MPEP § 2159 *et seq.* for more information on the applicability of pre-AIA 35 U.S.C. 102.

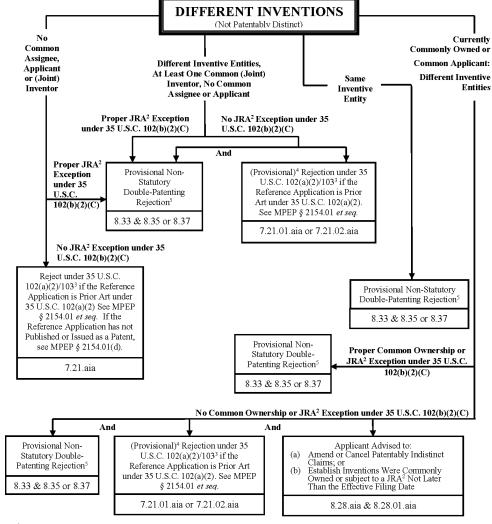
² The common ownership and joint research agreement (JRA) disqualifications, as defined in pre-AIA 35 U.S.C. 103(c), are not applicable where claims are to the same invention because the exclusions only apply to rejections under pre-AIA 35 U.S.C. 103(a) based on prior art under pre-AIA 35 U.S.C. 102(e), (f), or (g).

U.S.C. 103(a) based on prior art under pre-AIA 35 U.S.C. 102(e), (f), or (g).

³ Where the application being applied as a reference has NOT been published, the rejection under pre-AIA 35 U.S.C. 102(e) should be provisional.

 $^{^4}$ For determining whether to make or maintain a provisional statutory double patenting rejection, see MPEP \S 804, subsection I.B.2

CHART I-B_AIA: WHEN EXAMINING AN AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN TWO APPLICATIONS



¹ An AIA application is subject to 35 U.S.C. 102 as in effect on or after March 16, 2013. See MPEP § 2159 *et seq.* Certain AIA applications may also be subject to pre-AIA 35 U.S.C. 102(g). Consult with a Technology Center Practice Specialist if there are potential pre-AIA 35 U.S.C. 102(g) issue(s).

² Joint Research Agreement as defined in AIA 35 U.S.C. 102(c).

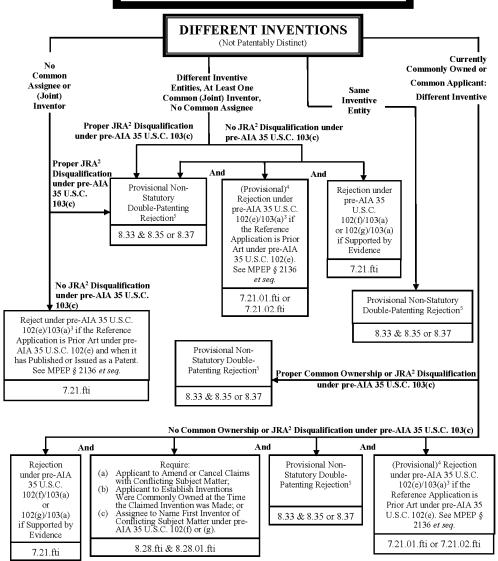
³ Where the reference is available as anticipatory prior art, a (provisional)⁴ rejection should be made under 35 U.S.C. 102(a)(2).

⁴ Where the application being applied as a reference has NOT been published, the rejection should be provisional.

⁵ For determining whether to make or maintain a provisional nonstatutory double patenting rejection, see MPEP § 804, I.B.1. or MPEP § 1490, VI.D.

The chart does not include rejection(s) under 35 U.S.C. 101 and 115 for incorrect inventorship. See MPEP § 2157 for more information on rejections under 35 U.S.C. 101 and 115.

CHART I_B_FTI: WHEN EXAMINING A PRE-AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN <u>TWO APPLICATIONS</u>



¹ Pre-AIA applications are subject to 35 U.S.C. 102 as in effect on March 15, 2013. See MPEP § 2159 et seq. for more information on the applicability of pre-AIA 35 U.S.C. 102.

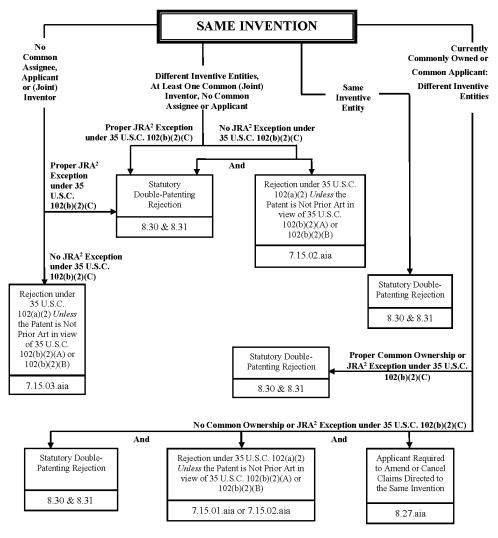
² Joint Research Agreement as defined in pre-AIA 35 U.S.C. 103(c).

³ Where the reference is available as anticipatory prior art, a (provisional)⁴ rejection should additionally be made under pre-AIA 35 U.S.C. 102(e) and the common ownership and JRA exclusions, as defined in pre-AIA 35 U.S.C. 103(c), are not applicable.

⁴ Where the application being applied as a reference has NOT been published, the rejection should be provisional.

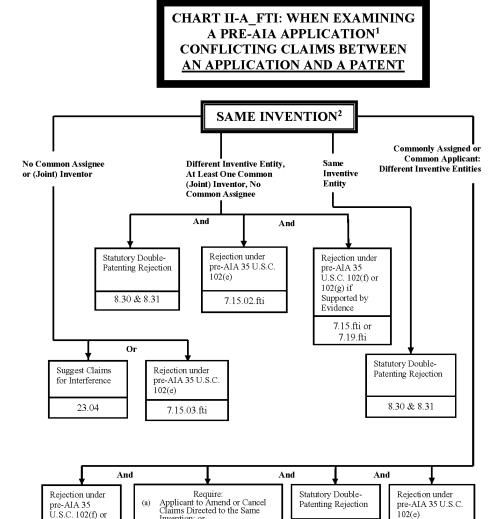
⁵ For determining whether to make or maintain a provisional nonstatutory double patenting rejection, see MPEP § 804, I.B.1. or MPEP § 1490, VI.D.

CHART II-A AIA: WHEN EXAMINING AN AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN AN APPLICATION AND A PATENT



¹ An AIA application is an application subject to 35 U.S.C. 102 as in effect on or after March 16, 2013. See MPEP § 2159 *et* seq. for more information on the applicability of AIA 35 U.S.C. 102. Certain AIA applications may also be subject to pre-AIA 35 U.S.C. 102(g). Consult with a Technology Center Practice Specialist if there are potential pre-AIA 35 U.S.C. 102(g)

² Joint Research Agreement as defined in AIA 35 U.S.C. 102(c).
The chart does not include rejection(s) under 35 U.S.C. 101 and 115 for incorrect inventorship. See MPEP § 2157 for more information on rejections under 35 U.S.C. 101 and 115.



8.30 & 8.31

7.15.02.fti

Invention; or
Assignee to Name First Inventor
of Conflicting Subject Matter
under pre-AIA 35 U.S.C. 102(f)

8.27.fti

102(g) if

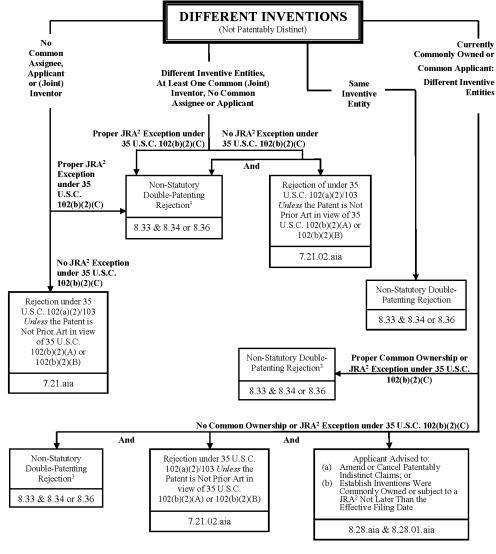
Supported by Evidence 7.15.fti or

7.19.fti

 $^{^1}$ Pre-AIA applications are subject to 35 U.S.C. 102 as in effect on March 15, 2013. See MPEP \S 2159 $\it et\, seq.$ for more information on the applicability of pre-AIA 35 U.S.C. 102.

² The common ownership and joint research agreement (JRA) exclusions, as defined in pre-AIA 35 U.S.C. 103(c), are not applicable where claims are to the same invention because the exclusions only apply to rejections under pre-AIA 35 U.S.C. 103(a) based on prior art under pre-AIA 35 U.S.C. 102(e), (f), or (g).

CHART II-B AIA: WHEN EXAMINING AN AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN AN APPLICATION AND A PATENT

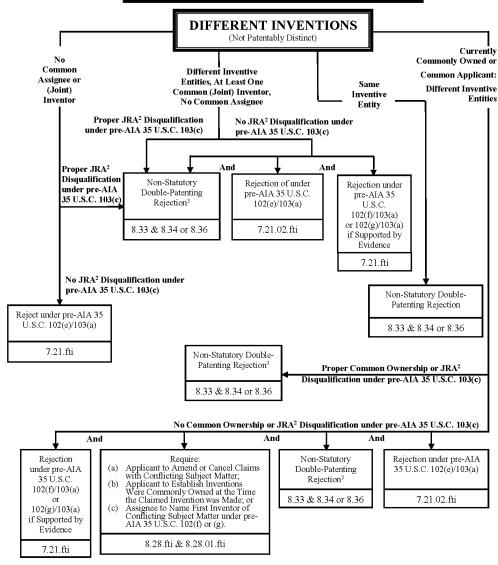


¹ AIA applications are subject to 35 U.S.C. 102 as in effect on or after March 16, 2013. See MPEP § 2159 *et seq.* for more information on the applicability of AIA 35 U.S.C. 102. Certain AIA applications may also be subject to pre-AIA 35 U.S.C. 102(g). Consult with a Technology Center Practice Specialist if there are potential pre-AIA 35 U.S.C. 102(g) issue(s).

Joint Research Agreement as defined in AIA 35 U.S.C. 102(c).

³ Where the reference is available as anticipatory prior art, a rejection should be made under AIA 35 U.S.C. 102(a)(2). The chart does not include rejection(s) under 35 U.S.C. 101 and 115 for incorrect inventorship. See MPEP § 2157 for more information on rejections under 35 U.S.C. 101 and 115.

CHART II-B_FTI: WHEN EXAMINING A PRE-AIA APPLICATION¹ CONFLICTING CLAIMS BETWEEN AN APPLICATION AND A PATENT



¹ Pre-AIA applications are subject to 35 U.S.C. 102 as in effect on March 15, 2013. See MPEP § 2159 et seq. for more information on the applicability of pre-AIA 35 U.S.C. 102.

² Joint Research Agreement as defined in pre-AIA 35 U.S.C. 103(c).

³ Where the reference is available as anticipatory prior art, a rejection should additionally be made under pre-AIA 35 U.S.C. 102(e) and the common ownership and JRA exclusions, as defined in pre-AIA 35 U.S.C. 103(c), are not applicable.

I. INSTANCES WHERE DOUBLE PATENTING ISSUE CAN BE RAISED

A double patenting issue may arise between two or more pending applications, or between one or more pending applications and a patent. A double patenting issue may likewise arise in a reexamination proceeding between the patent claims being reexamined and the claims of one or more applications and/or patents. Double patenting does not relate to international applications which have not yet entered the national stage in the United States.

A. Between Issued Patent and One or More Applications

Double patenting may exist between an issued patent and an application which share the same inventive entity, at least one common (joint) inventor, a common applicant, and/or common owner/assignee. See In re Hubbell, 709 F.3d 1140, 1146-47, 106 USPQ2d 1032, 1037-38 (Fed. Cir. 2013) (in the context of an application and a patent that had two common joint inventors, but different inventive entities and no common owners or assignees, the court held that complete identity of ownership or inventive entities is not a prerequisite to a nonstatutory double patenting rejection). Double patenting may also exist where the inventions claimed in a patent and an application were made as a result of activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3). Since the inventor/applicant/patent owner has already secured the issuance of a first patent, the examiner must determine whether the grant of a second patent would give rise to an unjustified extension of the rights granted in the first patent.

B. Between Copending Applications—Provisional Rejections

An examiner may become aware of two or more copending applications which share the same inventive entity, at least one common (joint) inventor, a common applicant, and/or a common owner/assignee, or that claim an invention resulting from activities undertaken within the scope of a joint

research agreement as defined in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a provisional rejection on the ground of double patenting. In re Mott, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); In re Wetterau, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). An application that was published under 35 U.S.C. 122(b) without redactions can be utilized as a double patenting reference without violating the confidential status required by 35 U.S.C. 122. An unpublished application, or an application that has been published as redacted, can be utilized as a double patenting reference without violating the confidential status required by 35 U.S.C. 122 when it has at least one common (joint) inventor, applicant, assignee, or owner, or is deemed commonly owned (35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2)) with the application under examination. See MPEP §§ 2136.01 and 2154.01(d) for information on provisional rejections based on prior art. The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

A provisional double patenting rejection should be made and maintained by the examiner until the rejection has been obviated or is no longer applicable except as noted below.

1. Provisional Nonstatutory Double Patenting Rejections

A complete response to a nonstatutory double patenting (NSDP) rejection is either a reply by applicant showing that the claims subject to the rejection are patentably distinct from the reference claims, or the filing of a terminal disclaimer in accordance with 37 CFR 1.321 in the pending application(s) with a reply to the Office action (see MPEP § 1490 for a discussion of terminal disclaimers). Such a response is required even when the nonstatutory double patenting rejection is provisional.

As filing a terminal disclaimer, or filing a showing that the claims subject to the rejection are patentably distinct from the reference application's claims, is necessary for further consideration of the rejection of the claims, such a filing should not be held in abeyance. Only compliance with objections or requirements as to form not necessary for further consideration of the claims may be held in abeyance until allowable subject matter is indicated. Replies with an omission should be treated as provided in MPEP § 714.03. Therefore, an application must not be allowed unless the required compliant terminal disclaimer(s) is/are filed and/or the withdrawal of the nonstatutory double patenting rejection(s) is made of record by the examiner. See MPEP § 804.02, subsection VI, for filing terminal disclaimers required to overcome nonstatutory double patenting rejections in applications filed on or after June 8, 1995.

If two (or more) pending applications are filed, in each of which a rejection of one claimed invention over the other on the ground of provisional nonstatutory double patenting (NSDP) is proper, the provisional NSDP rejection will be made in each application. Where there are three applications containing claims that conflict such that a provisional NSDP rejection is made in each application based upon the other two, and it is necessary to file terminal disclaimers to overcome the rejections, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to require common ownership or enforcement for all three applications. A terminal disclaimer may be required in each of the three applications in certain situations. See subsections (a)-(c) below. See also MPEP § 1490, subsection VI.D.

(a) Patent Term Filing Date for Original Utility or Plant Applications

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. For utility and plant patents issuing on applications filed on or after June 8, 1995, 35 U.S.C. 154(a)(2) provides that the patent term ends on the date that is twenty years from the date

on which the application for the patent was filed in the United States, or if the application contains a specific reference to one or more earlier-filed application(s) under <u>35 U.S.C. 120</u>, <u>121</u>, <u>365(c)</u>, or 386(c), twenty years from the filing date of the earliest such application. For a patent that issues on an international (PCT) application that entered the national stage under 35 U.S.C. 371, the date that the application was filed in the United States is the international filing date; see MPEP § 2701, subsection II. Thus, where there are two or more original applications (applications which are not reissue applications - see MPEP § 201.02) with conflicting (i.e., patentably indistinct) claims, it may be necessary to determine the respective date from which the twenty year term is measured in view of 35 U.S.C. 154(a)(2) (hereinafter referred to as the "patent term filing date") for each of the applications which could potentially issue as patents.

The patent term filing date of an original utility or plant application filed on or after June 8, 1995 is the earliest of:

- (1) The actual filing date of the application; or
- (2) The filing date of the earliest application for which the application claims the benefit of an earlier filing date under 35 U.S.C. 120, 121, 365(c), or 386(c). See 37 CFR 1.78. See also MPEP § 211.

For example, if an original (non-reissue; see MPEP § 201.02) patent application has no specific reference to any earlier-filed application under 35 U.S.C. 120, 121, 365(c), or 386(c), then the patent term filing date is the date that the application was actually filed. However, if an original patent application does include one or more specific references to an earlier-filed application under 35 U.S.C. 120, 121, 365(c), or 386(c), then the patent term filing date is the filing date of the earliest reference application for which the benefit is properly claimed. See MPEP § 2701. For an application to properly claim the benefit of an earlier-filed application, it must meet the requirements of <u>37 CFR 1.78</u> (e.g., having a (joint) inventor in common, copendency, timeliness, and a proper reference). See 37 CFR 1.78 and MPEP § 211.01 et seq. It does not require a determination that the earlier-filed application discloses the invention in a manner provided by 35 U.S.C. 112(a). In other words, the issue of entitlement of a claimed

invention to the benefit of the filing date of an earlier-filed application does not affect the expiration date of a patent containing the claims, and therefore need not be considered when determining the patent term filing date for the purpose of a double patenting analysis.

The patent term filing date of a reissue application for purposes of nonstatutory double patenting analysis is the patent term filing date of the original application that resulted in the patent for which reissue is sought.

Benefit claims under 35 U.S.C. 119(e) and foreign priority claims under 35 U.S.C. 119(a)-(d) or (f), 365(a) or (b), or 386(a) or (b) are not taken into account when determining the term of an issued patent (see 35 U.S.C. 154(a)(2) and (a)(3)), and therefore, are not taken into account in determining the patent term filing date of an application.

(b) Provisional nonstatutory double patenting rejection is the only rejection remaining in a utility or plant application

Subsections (i)-(iv) below discuss examination procedures when two or more utility or plant patent applications, filed on or after June 8, 1995, contain provisional nonstatutory double patenting rejections over each of the other application(s). The explanations refer to pairs of applications, but also apply when more than two applications are involved.

(i) Application under examination has the earlier patent term filing date

If a provisional nonstatutory double patenting rejection is the only rejection remaining in an application having the earlier patent term filing date, the examiner should withdraw the rejection in the application having the earlier patent term filing date and permit that application to issue as a patent, thereby converting the provisional nonstatutory double patenting rejection in the other application into a nonstatutory double patenting rejection upon issuance of the patent.

(ii) Application under examination has the same patent term filing date

If both the application under examination and the reference application have the same patent term filing date, the provisional nonstatutory double patenting rejection made in each application should be maintained until it is overcome. Provisional nonstatutory double patenting rejections are subject to the requirements of 37 CFR 1.111(b). Thus, applicant can overcome a provisional nonstatutory double patenting rejection by filing a reply that either shows that the claims subject to the rejection are patentably distinct from the claims of the reference application, or includes a compliant terminal disclaimer under 37 CFR 1.321 that obviates the rejection. If the reply is sufficient, the examiner will withdraw the nonstatutory double patenting rejection in the application in which it was submitted.

(iii) Application under examination has the later patent term filing date

If a provisional nonstatutory double patenting rejection is the only rejection remaining in an application, and that application has the later patent term filing date, the rejection should be maintained until applicant overcomes the rejection. Replies to overcome the rejection are discussed in subsection (ii) above.

(iv) After Board decision not reaching provisional double patenting rejection

If a decision by the Patent Trial and Appeal Board does not include an opinion on a provisional nonstatutory double patenting rejection, and includes a reversal of all other grounds as to a claim rejected based on provisional nonstatutory double patenting, and the applicant has not filed a proper terminal disclaimer, the examiner must act upon the provisional nonstatutory double patenting rejection. The examiner must first determine if any reference application used in the provisional nonstatutory double patenting rejection has issued as a patent. If the reference application has issued, the provisional rejection should be re-issued as a nonprovisional rejection and a terminal disclaimer should be required, for example, by using form paragraphs 8.33-8.39 as appropriate. See MPEP § 804,

subsection II.B. The rejection may be made final, if otherwise appropriate. If the reference application has been abandoned or where the reference application has not matured to a patent and the provisional double patenting rejection is the only remaining rejection in the application, the examiner should withdraw the provisional rejection. See MPEP \text{\text{\text{\text{\text{\text{8}}}}}

(c) Design Applications and Utility or Plant Applications Filed Prior to June 8, 1995

For design applications, patent term is measured from the issue date, and therefore, the determination of the patent term filing date is not necessary. If a provisional double patenting rejection (statutory or nonstatutory) is the only rejection remaining in the earlier filed of the two conflicting design applications, the examiner should withdraw that rejection and permit that application to issue as a patent. The examiner should maintain the provisional double patenting rejection in the later filed application and that rejection will be converted into a double patenting rejection when the allowed application issues as a patent unless the rejection has already been obviated. If both conflicting applications were filed on the same date, the provisional double patenting rejection made in each application should be maintained until it is overcome. See also MPEP § 804.03, subsection IV, to resolve issues in applications that name different inventors and claim indistinct inventions.

For double patenting analysis involving a utility or plant application filed prior to June 8, 1995, examiners should consult with their TQAS or SPE to determine if any of the provisional nonstatutory double patenting rejections should be withdrawn or not made. Likewise, for double patenting analysis for a utility or plant application and a reference design application or vice versa, examiners should consult with their TQAS or SPE to determine if any of the provisional nonstatutory double patenting rejections should be withdrawn or not made.

2. Provisional Statutory Double Patenting Rejections (35 U.S.C. 101)

A terminal disclaimer cannot be filed to obviate a statutory double patenting rejection. A statutory

double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. A complete response to a statutory double patenting rejection is either a reply by applicant showing that the claims subject to the rejection are not the same as the reference claims, an amendment in response to the statutory double patenting rejection, or cancelation of the conflicting claims. Such a response is required even when the statutory double patenting rejection is provisional.

When two or more utility or plant patent applications, filed on or after June 8, 1995, each contain a provisional statutory double patenting rejection, and that is the only rejection remaining in the application having the earliest patent term filing date, the examiner should withdraw the rejection in the application having the earliest patent term filing date and permit that application to issue as a patent, thereby converting the provisional statutory double patenting rejection in the other application(s) into a statutory double patenting rejection when the application with the earliest patent term filing date issues as a patent.

If a provisional statutory double patenting rejection is the only rejection remaining in an application, and that application has a patent term filing date that is later than, or the same as, the patent term filing date of at least one of the reference application(s), the rejection should be maintained until applicant overcomes the rejection. In accordance with 37 CFR 1.111(b), applicant's reply must present arguments pointing out the specific distinctions believed to render the claims, including any amended or newly presented claims, patentable over any applied references.

For design applications and utility or plant applications filed prior to June 8, 1995, see subsection I.B.1(c) above for guidance on maintaining or withdrawing provisional statutory double patenting rejections.

C. Between One or More Applications and a Published Application - Provisional Rejections

Double patenting may exist where a published patent application and an application share the same

inventive entity, at least one common (joint) inventor, a common applicant, and/or a common owner/assignee. Double patenting may also exist where a published application and an application claim inventions resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3). If the published application has not yet issued as a patent, the examiner is permitted to make a provisional rejection on the ground of double patenting when the published application has not been abandoned and claims pending therein conflict with claims of the application being examined. See the discussion regarding provisional double patenting rejections in subsection B. above.

D. Between a Patent and a Reissue Application or Patent under Reexamination

When a potential nonstatutory double patenting situation arises between two related patents (as in a reissue or reexamination), it is necessary to determine whether the patents are subject to the same patent term statutory law. Section 532(a)(1) of the Uruguay Round Agreements Act (URAA) (Pub. L. No. 103-465, 108 Stat. 4809, 4983 (1994)) amended 35 U.S.C. 154 to provide that the term of a plant or utility patent issuing from an original application filed on or after June 8, 1995, i.e., a post-URAA patent, begins on the date the patent issues and ends on the date that is twenty years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under <u>35 U.S.C. 120</u>, <u>121</u>, or <u>365(c)</u>, twenty years from the filing date of the earliest of such application(s) (excluding any terminal disclaimers or any patent term adjustment or extension). The Patent Law Treaties Implementation Act of 2012, Public Law 112-211, which implemented the provisions of the Hague Agreement, amended <u>35 U.S.C. 154(a)(2)</u> to delete "section 120, 121, or 365(c)" and to insert "section 120, 121, 365(c), or 386(c)" and <u>35 U.S.C. 154(a)(3)</u> to delete "section 119, 365(a), or 365(b)" and to insert "section 119, 365(a), 365(b), 386(a), or 386(b)." See MPEP § 2701.

A plant or utility patent that was in force on June 8, 1995, or that issued on an application that was filed

before June 8, 1995, i.e., a pre-URAA patent, has a term that is the greater of twenty years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121, or 365(c), twenty years from the filing date of the earliest of such application(s) or seventeen years from the patent grant. Filing for reissue on or after June 8, 1995 of a patent issued on an original application filed prior to June 8, 1995 does not change the patent term of the patent or the reissued patent. See MPEP §§ 1405 and 2701 for more information.

"[T]he proper reference point for an obviousness-type double patenting inquiry is the expiration date of the patent in question." *Novartis Pharms. v. Breckenridge Pharm.*, 909 F.3d 1355, 1362-63, 128 USPQ2d 1745, 1747 (Fed. Cir. 2018) (citing *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215, 110 USPQ2d 1551, 1558 (Fed. Cir. 2014)).

Where both the patent under examination (via a reexamination proceeding or a reissue application) and the reference patent are post-URAA, "an earlier-expiring patent can qualify obviousness-type double patenting reference for a later-expiring patent." Gilead Sciences, Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1217, 110 USPQ2d 1551, 1558 (Fed. Cir. 2014). See also Novartis Pharms. v. Breckenridge Pharm., 909 F.3d 1355, 1360, 128 USPQ2d 1745, 1747 (Fed. Cir. 2018) (Gilead "holds that a later-filed but earlier-expiring patent can serve as a double-patenting reference for an earlier-filed but later-expiring patent in the post-URAA context."). However, where at least one of the patent under examination (via a reexamination proceeding or a reissue application) or the reference patent is pre-URAA, the patent with the earlier issuance date is available as a reference against a patent with a later issuance date "because, under the law pre-URAA, the expiration date of the patent was inextricably intertwined with the issuance date." Id. at 1362, 128 USPQ2d at 1749. Based on the particular facts in Novartis, the court held that the post-URAA patent that expired prior to the pre-URAA patent is not a proper nonstatutory double patenting reference for the pre-URAA patent. Id. at 1367, 128 USPQ2d at 1752 ("To find that

obviousness-type double patenting applies here because a post-URAA patent expires earlier would abrogate Novartis's right to enjoy one full patent term on its invention."). An examiner should consult with the TC Quality Assurance Specialist if an otherwise proper nonstatutory double patenting rejection is not being made based on *Novartis*.

See MPEP § 804.05 for information regarding the impact of patent term extension on a double patenting analysis.

E. Reexamination Proceedings

A double patenting issue may raise a substantial new question of patentability of a claim of a patent, and thus can be addressed in a reexamination proceeding. *In re Lonardo*, 119 F.3d 960, 966, 43 USPQ2d 1262, 1266 (Fed. Cir. 1997) (In giving the Director authority under 35 U.S.C. 303(a) to determine the presence of a substantial new question of patentability, "Congress intended that the phrases 'patents and publications' and 'other patents or publications' in section 303(a) not be limited to *prior art* patents or printed publications.") (emphasis added). Accordingly, if the same issue of double patenting was not addressed during original prosecution, it may be considered during reexamination.

Double patenting may exist where a reference patent or application and the patent under reexamination share the same inventive entity, at least one common (joint) inventor, a common applicant, and/or a common owner/assignee. Where the patent under reexamination was granted on or after December 10, 2004, double patenting may also exist where the inventions claimed in the reference reexamination proceeding resulted from activities undertaken within the scope of a joint research agreement pursuant to 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3), as applicable, and if evidence of the joint research agreement has been made of record in the patent being reexamined or in the reexamination proceeding. A double patenting rejection may NOT be made on this basis if the patent under reexamination issued before December 10, 2004. See MPEP § 804.03.

The prior art exception under 35 U.S.C. 102(b)(2)(C)or disqualification under pre-AIA 35 U.S.C. 103(c) generally cannot be used to overcome a double rejection, whether patenting statutory nonstatutory. However, since a secondary reference used to support an obviousness analysis for a nonstatutory double patenting rejection must be prior art, a reference excepted under 35 U.S.C. 102(b)(2)(C) cannot be used as a secondary reference in a nonstatutory double patenting rejection. See MPEP §§ 717.02 et seg. and 2154.02(c) for more information on 35 U.S.C. 102(b)(2)(C) and MPEP § 2146 for more information on pre-AIA 35 U.S.C. 103(c). See MPEP § 2258 for more information on making double patenting rejections in reexamination proceedings. Subsection II, below, describes situations wherein a double patenting rejection would be appropriate. In particular, see paragraph II.B. for the analysis required to determine the propriety of a nonstatutory double patenting rejection.

II. REQUIREMENTS OF A DOUBLE PATENTING REJECTION (INCLUDING PROVISIONAL REJECTIONS)

When a double patenting rejection is appropriate, it must be based either on statutory grounds or nonstatutory grounds. The ground of rejection employed depends upon the relationship of the inventions being claimed. Generally, a double patenting rejection is not permitted where the claimed subject matter is presented in a divisional application as a result of a restriction requirement made in a parent application under 35 U.S.C. 121.

Where the claims of an application are the same as those of a first patent, they are barred under 35 U.S.C. 101 - the statutory basis for a double patenting rejection. A rejection based on double patenting of the "same invention" finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

Where the claims of an application are not the "same" as those of a first patent, but the grant of a patent with the claims in the application would unjustly extend the rights granted by the first patent, a double patenting rejection under nonstatutory grounds is proper.

In determining whether a proper basis exists to enter a double patenting rejection, the examiner must determine the following:

- (A) Whether a statutory basis exists;
- (B) Whether a nonstatutory basis exists; and
- (C) Whether a nonstatutory double patenting rejection is prohibited by the third sentence of 35 U.S.C. 121 (see MPEP § 804.01; if such a prohibition applies, a nonstatutory double patenting rejection cannot be made).

Each determination must be made on the basis of all the facts in the application before the examiner. The charts in MPEP § 804 illustrate the methodology of making such a determination.

Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. In re Kaplan, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); In re Sarett, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964). However, the presence of domination does not preclude a double patenting rejection. See, e.g., In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); see also AbbVie Inc. v. Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 112 USPQ2d 1001 (Fed. Cir. 2014).

A. Statutory Double Patenting — <u>35 U.S.C. 101</u>

In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? 35 U.S.C. 101 prevents two patents from issuing on

the same invention. "Same invention" means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. In re Vogel, 422 F.2d 438, 164 USPO 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine." On the other hand, claims may be differently worded and still define the same invention. Thus, a claim reciting a widget having a length of "36 inches" defines the same invention as a claim reciting the same widget having a length of "3 feet."

If it is determined that the same invention is being claimed twice, <u>35 U.S.C. 101</u> precludes the grant of the second patent regardless of the presence or absence of a terminal disclaimer. *Id.*

Form paragraphs 8.30 and 8.31 (between an issued patent and one or more applications) or 8.32 (provisional rejections) may be used to make statutory double patenting rejections.

\P 8.30 35 U.S.C. 101, Statutory Basis for Double Patenting "Heading" Only

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are

directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Examiner Note:

The above form paragraph must be used as a heading for all subsequent double patenting rejections of the statutory (same invention) type using either of form paragraphs 8.31 or 8.32.

¶ 8.31 Rejection, 35 U.S.C. 101, Double Patenting

Claim [1] is/are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim [2] of prior U.S. Patent No. [3]. This is a statutory double patenting rejection.

Examiner Note:

- This form paragraph must be preceded by form paragraph 8.30 and is used only for double patenting rejections of the same invention claimed in an earlier patent; that is, the "scope" of the inventions claimed is identical.
- If the claims directed to the same invention are in another copending application, do not use this form paragraph. A provisional double patenting rejection should be made using form paragraph 8.32.
- 3. Do not use this form paragraph for nonstatutory-type double patenting rejections. If nonstatutory type, use appropriate form paragraphs 8.33 to 8.39.
- This form paragraph may be used where the patent and the application under examination:
- name the same inventive entity, or
- name different inventive entities but are commonly assigned, or
- c. are not commonly assigned but name at least one common (joint) inventor, or
- are filed by a common applicant (35 U.S.C. 118), or
- claim patentably indistinct inventions made as a result of activities undertaken within the scope of a joint research agreement under pre-AIA 35 U.S.C. 103(c) for applications examined under pre-AIA (first to invent) law, or
- claim patentably indistinct inventions and the claimed invention and the patent were commonly owned under 35 U.S.C. 102(b)(2)(C) or deemed to be commonly owned under 35 U.S.C. 102(c) not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention, for applications examined under the first inventor to file (FITF) provisions of the AIA.
- 5. In bracket 3, insert the number of the patent.
- For applications being examined under pre-AIA (first to invent) law: If the patent is to a different inventive entity and is commonly assigned with the application, form paragraph 8.27.fti should additionally be used to require the assignee to name the first inventor.
- If evidence is of record to indicate that the patent is prior art under either pre-AIA 35 U.S.C. 102(f) or (g), a rejection

- should also be made using form paragraphs 7.15.fti and/or 7.19.fti, if applicable, in addition to this double patenting rejection.
- For applications being examined under pre-AIA (first to invent) law: If the patent is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, a rejection should additionally be made using form paragraph 7.15.02.fti.
- For applications being examined under the first inventor to file (FITF) provisions of the AIA: If the patent is to a different inventive entity and is commonly assigned with the application, form paragraph 8.27.aia should additionally be used to request that the applicant take action to amend or cancel claims such that the application no longer contains claims directed to the same invention. A rejection under 35 U.S.C. 102(a)(2) should also be made if appropriate.

¶ 8.32 Provisional Rejection, 35 U.S.C. 101, Double **Patenting**

Claim [1] provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim [2] of copending Application No. [3] (reference application). This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Examiner Note:

- This form paragraph must be preceded by form paragraph 8.30 and is used only for double patenting rejections of the same invention claimed in another copending application; that is, the scope of the claimed inventions is identical.
- 2. If the claims directed to the same invention are in an issued patent, do not use this paragraph. See form paragraph 8.31.
- Do not use this paragraph for nonstatutory-type double patenting rejections. See form paragraphs 8.33 to 8.39.
- This form paragraph may be used where the reference application and the application under examination:
- name the same inventive entity, or
- name different inventive entities but are commonly b. assigned, or
- are not commonly assigned but name at least one common (joint) inventor (unless disclosure of the reference application would violate the duty of the USPTO to keep the reference application confidential under 35 U.S.C. 122 e.g., the applicant or assignee of record has specifically requested that the inventor not be permitted to access the record in the manner provided in MPEP § 106), or
- are filed by a common applicant (35 U.S.C. 118), or
- claim patentably indistinct inventions made as a result of activities undertaken within the scope of a joint research agreement under pre-AIA 35 U.S.C. 103(c), for applications examined under pre-AIA (first to invent) law, or
- claim patentably indistinct inventions and the claimed invention and the reference application were commonly owned under 35 U.S.C. 102(b)(2)(C) or deemed to be commonly owned under 35 U.S.C. 102(c) not later than the effective filing date

under 35 U.S.C. 100(i) of the claimed invention, for applications examined under the first inventor to file (FITF) provisions of the AIA.

- 5. Form paragraph 8.28.fti or 8.28.aia, as appropriate, should also be used.
- 6. In bracket 3, insert the number of the reference application.
- 7. A provisional double patenting rejection should also be made in the reference application.
- 8. For applications being examined under pre-AIA (first to invent) law: If the reference application is by a different inventive entity and is commonly assigned, form paragraph 8.27.fti should additionally be used to require the assignee to name the first inventor.
- 9. If evidence is also of record to show that either application is prior art unto the other under <u>pre-AIA 35 U.S.C. 102(f)</u> or (g), a rejection should also be made in the reference application using form paragraphs 7.15.fti and/or 7.19.fti, if applicable, in <u>addition</u> to this provisional double patenting rejection.
- 10. For applications being examined under pre-AIA (first to invent) law: If the reference application is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, a provisional pre-AIA 35 U.S.C. 102(e) rejection should additionally be made using form paragraph 7.15.01.fti. If the reference application has been published, use form paragraph 7.15.02.fti instead.
- 11. For applications being examined under first inventor to file (FITF) provisions of the AIA: If the reference application is to a different inventive entity and is commonly assigned with the instant application, form paragraph 8.27.aia should additionally be used to request that the applicant take action to amend or cancel claims such that the applications no longer contain claims directed to the same invention. A rejection under 35 U.S.C. 102(a)(2) should also be made if appropriate.

If the "same invention" is not being claimed twice, an analysis must be made to determine whether a nonstatutory basis for double patenting exists.

B. Nonstatutory Double Patenting

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A double patenting rejection also serves public policy interests by preventing the possibility of multiple suits against an accused infringer by different assignees of patents claiming patentably indistinct variations of the same invention. *In re Van Ornum*, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982).

A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPO2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is: Is any invention claimed in the application anticipated by, or an obvious variation of, an invention claimed in the patent? If the answer is yes, then a nonstatutory double patenting rejection may be appropriate. To decide the question above, the examiner should first construe the claim(s) in the application under examination and the claim(s) in the reference application or patent to determine what are the differences. Then the examiner should determine whether those differences render the claims patentably distinct using an anticipation analysis and/or an obviousness analysis. See *Pfizer, Inc. v.* Teva Pharms. USA, Inc., 518 F.3d 1353, 1363, 86 USPQ2d 1001, 1008 (Fed. Cir. 2008).

Nonstatutory double patenting also requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001); *Ex parte Davis,* 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

1. Construing the Claim Using the Reference Patent or Application Disclosure

When considering whether the invention defined in a claim of an application would have been anticipated by or is an obvious variation of the invention defined in the claim of a patent or copending application, no part of the reference patent or application may be used as if it were prior art. General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1281, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992) ("Our precedent makes clear that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims"). This does not mean that one is precluded from all use of the reference patent or application disclosure to understand the meaning of the reference claims.

The specification can be used as a dictionary to learn the meaning of a term in the claim. Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999) ("[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning."); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."). "The Patent and Trademark Office ('PTO') determines the scope of the claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art." Phillips v. AWH Corp., 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) (en banc) (quoting In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364, 70 USPQ2d 1827, 1830 (Fed. Cir. 2004); see also MPEP § 2111.01. Further, those portions of the specification which provide support for the reference claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the reference patent or application (as distinguished from an obvious

variation of the subject matter disclosed in the reference patent or application). In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent or application which provides support for the claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined." In AbbVie Inc. v. Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 112 USPQ2d 1001 (Fed. Cir. 2014), the court explained that it is also proper to look at the disclosed utility in the reference disclosure to determine the overall question of obviousness in a nonstatutory double patenting context. See Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 95 USPQ2d 1797 (Fed. Cir. 2010); Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008); Geneva Pharmaceuticals Inc. GlaxoSmithKline PLC, 349 F3d 1373, 1385-86, 68 USPQ2d 1865, 1875 (Fed. Cir. 2003).

To avoid improperly treating what is disclosed in a reference patent or copending application as if it were prior art in the context of a nonstatutory double patenting analysis, the examiner must first properly construe the scope of the reference claims. The portion of the specification of the reference that describes subject matter that falls within the scope of a reference claim may be relied upon to properly construe the scope of that claim. In particular, when ascertaining the scope of the reference's claim(s) to a compound, the examiner should consider the reference's specification, including all of the compound's uses that are disclosed. See Sun Pharm. Indus., 611 F.3d at 1386-88, 95 USPQ2d at 1801-02. If claims to the compound's use and the compound were subject to a restriction requirement, and the compound was elected, a nonstatutory double

patenting rejection may not be appropriate in a divisional application claiming the restricted compound's use. See MPEP § 804.01. However, subject matter disclosed in the reference patent or application that does not fall within the scope of a reference claim cannot be used to support a nonstatutory double patenting rejection as this would effectively be treating the reference patent or application as prior art.

Properly construing the reference claims does not complete the nonstatutory double patenting analysis. It merely provides a determination as to how the earlier issued claim should be understood in making a nonstatutory double patenting rejection. To do a full analysis to determine whether a nonstatutory double patenting rejection should be made, one must go through the "anticipation analysis" and "obviousness analysis" noted below, and consider the "nonstatutory double patenting rejection based on equitable principles" discussed in subsection II.B.6 below.

In construing the claims of the reference patent or application, a determination is made as to whether a portion of the specification, including the drawings and claims, is directed to subject matter that is within the scope of a reference claim. For example, assume that the claim in a reference patent is directed to a genus of compounds, and the application being examined is directed to a species within the reference patent genus. If the reference patent discloses several species within the scope of the reference genus claim, that portion of the disclosure should be analyzed to properly construe the reference patent claim and determine whether it anticipates or renders obvious the claim in the application being examined. Because that portion of the disclosure of the reference patent is an embodiment of the reference patent claim, it may be helpful in determining the full scope and obvious variations of the reference patent claim. As an alternative example, assume that the claim in the reference patent is directed to a genus of compounds, and the application being examined is directed to a method of making compounds within the genus. Further assume that the reference patent discloses a nearly identical method of making compounds within the genus. Here, the disclosed method of making the compounds in the reference patent does not fall

within the scope of the genus of compounds claimed in the reference. Thus, the reference disclosure directed to the method of making the compounds cannot be used to construe the claim to the genus of compounds in the context of a nonstatutory double patenting analysis. This would effectively result in treating the reference as prior art. Nevertheless, there may be cases in which permitting claims to a method of making a compound could essentially result in an unjustified timewise extension of the period of exclusivity for the compound itself. In such cases, the "Nonstatutory Double Patenting Rejection Based on Equitable Principles" discussed in paragraph II.B.6 below should be considered. Cf. Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC, 349 F3d 1373, 1385-86, 68 USPQ2d 1865, 1875 (Fed. Cir. 2003) (rejecting claims to methods of use over claims to compound based on unjustified timewise extension rationale).

The result in In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968) is consistent with the analysis set forth above. In Schneller, the examined claims were directed to a clip comprising ABCY and a clip comprising ABCXY; the reference patent claimed a clip comprising ABCX and disclosed an embodiment of a clip having ABCXY. The ABCXY clip disclosed in the reference patent falls within the scope of the reference patent claim to a clip "comprising ABCX." Thus the disclosed embodiment of ABCXY may be relied upon to properly construe the scope of the reference claim and determine the propriety of a nonstatutory double patenting rejection against the examined claim. However, nonstatutory double patenting rejections based on Schneller will be rare. The Technology Center (TC) Director must approve any nonstatutory double patenting rejections based on Schneller. If an examiner determines that a double patenting rejection based on *Schneller* is appropriate, the examiner should first consult with the examiner's supervisory patent examiner (SPE). If the SPE agrees with the examiner then approval of the TC Director must be obtained before such a nonstatutory double patenting rejection can be made. See subsection II.B.6 below for a more detailed discussion.

Each nonstatutory double patenting situation must be decided on its own facts.

2. Anticipation Analysis

A nonstatutory double patenting rejection is appropriate where a claim in an application under examination claims subject matter that is different, but not patentably distinct, from the subject matter claimed in a prior patent or a copending application. The claim under examination is not patentably distinct from the reference claim(s) if the claim under examination is anticipated by the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015-16 (Fed. Cir. 1993). This type of nonstatutory double patenting situation arises when the claim being examined is, for example, generic to a species or sub-genus claimed in a conflicting patent or application, i.e., the entire scope of the reference claim falls within the scope of the examined claim. In such a situation, a later patent to a genus would, necessarily, extend the right to exclude granted by an earlier patent directed to a species or sub-genus. In this type of nonstatutory double patenting situation, obviousness analysis is not required for the nonstatutory double patenting rejection. The nonstatutory double patenting rejection in this case should explain the fact that the species or sub-genus claimed in the conflicting patent or application anticipates the claimed genus in the application being examined and, therefore, a patent to the genus would improperly extend the right to exclude granted by a patent to the species or sub-genus should the genus issue as a patent after the species or sub-genus.

The analysis required is different in situations where the claim in the application being examined (1) is directed to a species or sub-genus covered by a generic claim in a potentially conflicting patent or application, or (2) overlaps in scope with a claim in a potentially conflicting claim or claims of the patent or application but the potentially conflicting claims cannot be said to anticipate the examined claims. Both of these situations require an obviousness analysis unless one of ordinary skill in the art would, on reading the potentially conflicting patent or application, at once envisage the invention claimed in the examined application. See AbbVie Inc. v. Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 112 USPQ2d 1001 (Fed. Cir. 2014). For example, in the genus-species situation, the examiner typically should explain why it would have been obvious to select the claimed species or sub-genus given the genus claimed in the potentially conflicting patent or application. See MPEP § 2131.02 and MPEP § 2144.08 for discussions of genus-species situations with respect to anticipation obviousness, respectively. Note that the genus-species and overlapping subject matter scenarios discussed in this paragraph may result in nonstatutory double-patenting rejections based on the principle against unjustified timewise extension of patent rights, discussed below in paragraph II.B.6.

3. Obviousness Analysis

A nonstatutory double patenting rejection, if not based on an anticipation rationale or an "unjustified timewise extension" rationale, is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent disclosure principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Even though the specification of the applied patent or copending application is not prior art, it may still be used to interpret the applied claims. See paragraph II.B.1, above. The analysis employed with regard to nonstatutory double patenting is "similar to, but not necessarily the same as that undertaken under 35 USC § 103." In re Braat, 937 F.2d 589, 592-93, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991) (citing In re Longi, 759 F.2d 887, 892 n.4, 225 USPQ 645, 648 n.4 (Fed. Cir. 1985)); see also Geneva Pharmaceuticals, 349 F.3d at 1378 n.1, 68 USPQ2d at 1869 n.1 (Fed. Cir. 2003); In re Basell Poliolefine, 547 F.3d 1371, 1379, 89 USPQ2d 1030, 1036 (Fed. Cir. 2008).

In view of the similarities, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 should be considered when making a nonstatutory double patenting analysis based on "obviousness." See MPEP § 2141 for guidelines for determining obviousness. These factual inquiries are summarized as follows:

(A) Determine the scope and content of a patent claim relative to a claim in the application at issue;

- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

Any nonstatutory double patenting rejection made under the obviousness analysis should make clear:

- (A) The differences between the inventions defined by the conflicting claims a claim in the patent compared to a claim in the application; and
- (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent.

Any secondary reference used to support an obviousness analysis for a nonstatutory double patenting rejection must be prior art under 35 U.S.C. 102 or pre-AIA 35 U.S.C. 102. See MPEP § 2120 et seq. for more information on determining if a reference is prior art and MPEP § 2141, subsection II.A, for determining the scope and content of the prior art.

4. One-Way Test for Distinctness

If the patent term filing date of an application under examination is the same or later than that of a reference application or patent, only a one-way determination of distinctness is needed in resolving the issue of double patenting, i.e., whether the invention claimed in the application would have been anticipated by, or an obvious variation of, the invention claimed in the reference application or patent. See, e.g., In re Berg, 140 F.3d 1428, 1435, 46 USPQ2d 1226, 1231-32 (Fed. Cir. 1998). The court in Berg applied a one-way test where an applicant filed two separate applications even though all claims could have been filed in a single application, because the applicant's action could have resulted in an improper timewise extension of rights if one patent expired later than the other. If a claimed invention in the application would have been obvious over a claimed invention in the patent, there would be an unjustified timewise extension of

the patent and a nonstatutory double patenting rejection is proper. According to the *Berg* court, improperly extending the patent term "is precisely the result that the doctrine of obviousness-type double patenting was created to prevent." *Id.* See also MPEP § 804, subsection II.B above.

Similarly, even if the application under examination has the earlier patent term filing date, only a one-way determination of distinctness is needed to support a double patenting rejection in the absence of a finding: (A) that "the PTO is solely responsible for any delays" in prosecution of that application (In re Hubbell, 709 F.3d 1140, 1150, 106 USPQ2d 1032, 1039 (Fed. Cir. 2013)); and (B) that the applicant could not have filed the conflicting claims in a single (i.e., the earlier-filed) application (In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986)). In Kaplan, a generic invention (use of solvents) was invented by Kaplan, and a species thereof (i.e., use of a specific combination of solvents) was invented by Kaplan and Walker. Multiple applications were necessary to claim both the broad and narrow inventions because at the time the applications were filed, 35 U.S.C. 116 did not expressly authorize filing a patent application in the name of joint inventors who did not make a contribution to the invention defined in each claim in the patent. Compare In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998), wherein the genus and species claims could have been filed in the same application.

Form paragraph 8.33 and the appropriate one of form paragraphs 8.34 - 8.37 may be used to make nonstatutory double patenting rejections based on anticipation or obviousness analyses. See subsection II.B.6, below, and form paragraphs 8.38 and 8.39 if the basis for the nonstatutory double patenting rejection is equitable principles.

\P 8.33 Basis for Nonstatutory Double Patenting, "Heading" Only

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over,

the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 et seq. for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself **is not a complete reply** to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

Examiner Note:

This form paragraph is to be used as a <u>heading</u> before a nonstatutory double patenting rejection using any of form paragraphs 8.34 - 8.39. Although nonstatutory double patenting is sometimes called obviousness-type double patenting ("ODP"), an obviousness analysis is required only if the examined application claim(s) is not anticipated by the reference claim(s).

¶ 8.34 Rejection, Nonstatutory Double Patenting - No Secondary Reference(s)

Claim [1] rejected on the ground of nonstatutory double patenting as being unpatentable over claim [2] of U.S. Patent No. [3]. Although the claims at issue are not identical, they are not patentably distinct from each other because [4].

Examiner Note:

- 1. Form paragraph 8.33 must precede any one of form paragraphs 8.34 to 8.39 and must be used only ONCE in an Office action.
- 2. This form paragraph is used for nonstatutory double patenting rejections based upon a patent.
- 3. If the nonstatutory double patenting rejection is based upon another application, do not use this form paragraph. A provisional double patenting rejection should be made using form paragraph 8.33 and either form paragraph 8.35 or 8.37.
- 4. This form paragraph may be used where the patent and the application under examination:
- a. name the same inventive entity, or
- name different inventive entities but are commonly assigned, or
- c. are not commonly assigned but name at least one common (joint) inventor, or
- d. are filed by a common applicant (35 U.S.C. 118), or
- e. claim patentably indistinct inventions made as a result of activities undertaken within the scope of a joint research agreement under pre-AIA 35 U.S.C. 103, for applications examined under pre-AIA (first to invent) law, or
- f. claim patentably indistinct inventions and the claimed invention and the patent were commonly owned under 35 U.S.C. 102(b)(2)(C) or deemed to be commonly owned under 35 U.S.C. 102(c) not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention, for applications examined under the first inventor to file (FITF) provisions of the AIA.
- 5. In bracket 3, insert the number of the patent.
- 6. In bracket 4, provide appropriate explanation for anticipation or rationale for obviousness of the claims being rejected over the claims of the cited patent.
- 7. A rejection should additionally be made under <u>pre-AIA 35 U.S.C. 103(a)</u> using form paragraph 7.21.fti if:
- a. evidence indicates that the patent is prior art under <u>pre-AIA 35 U.S.C. 102(f)</u> or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the patent has not been disqualified as prior art in a <u>pre-AIA</u> 35 U.S.C. 103(a) rejection pursuant to <u>pre-AIA</u> 35 U.S.C. 103(c).
- 8. For applications being examined under pre-AIA (first to invent) law: If the patent is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, a rejection under pre-AIA 35 U.S.C. 102(e)/103(a) may be made using form paragraph 7.21.02.fti. Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the patent is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.
- 9. For applications being examined under the first inventor to file (FITF) provisions of the AIA: A rejection under 35 U.S.C. 102(a)(2) or 35 U.S.C. 103 should also be made if appropriate.

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\P 8.35 Provisional Rejection, Nonstatutory Double Patenting - No Secondary Reference(s)

Claim [1] provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim [2] of copending Application No. [3] (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because [4].

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Examiner Note:

- 1. Form paragraph 8.33 must precede any one of form paragraphs 8.34 to 8.39 and must be used only ONCE in an Office action.
- 2. This form paragraph should be used when the patentably indistinct claims are in another copending <u>application</u>.
- 3. If the patentably indistinct claims are in a <u>patent</u>, do not use this form paragraph. Use form paragraphs 8.33 and 8.34.
- 4. This form paragraph may be used where the reference application and the application under examination:
- a. name the same inventive entity, or
- name different inventive entities but are commonly assigned, or
- c. are not commonly assigned but name at least one common (joint) inventor (unless disclosure of the reference application would violate the duty of the USPTO to keep the reference application confidential under 35 U.S.C. 122 e.g., the applicant or assignee of record has specifically requested that the inventor not be permitted to access the record in the manner provided in MPEP § 106), or
- d. are filed by a common applicant (35 U.S.C. 118), or
- e. claim patentably indistinct inventions made as a result of activities undertaken within the scope of a joint research agreement under pre-AIA 35 U.S.C. 103(c), for applications examined under pre-AIA (first to invent) law, or
- f. claim patentably indistinct inventions and the claimed invention and the reference application were commonly owned under 35 U.S.C. 102(b)(2)(C) or deemed to be commonly owned under 35 U.S.C. 102(c) not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention, for applications examined under the first inventor to file (FITF) provisions of the AIA.
- 5. If the reference application is currently commonly assigned but the file does not establish that the patentably indistinct inventions were commonly owned at the time the later invention was made, form paragraph 8.28.fti may be used in addition to this form paragraph to resolve any issues relating to priority under pre-AIA 35 U.S.C. 102(f) and/or (g).
- 6. In bracket 3, insert the number of the reference application.
- 7. A provisional nonstatutory double patenting rejection should also be made in the reference application.

- 8. A rejection should additionally be made under <u>pre-AIA 35 U.S.C. 103(a)</u> using form paragraph 7.21.fti if:
- a. evidence indicates that the reference application is prior art under pre-AIA 35 U.S.C. 102(f) or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the reference application has not been disqualified as prior art in a <u>pre-AIA 35 U.S.C. 103(a)</u> rejection pursuant to <u>pre-AIA 35 U.S.C. 103(c)</u>.
- 9. For applications being examined under pre-AIA (first to invent) law: If the reference application is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, use form paragraph 7.21.01.fit to additionally make a provisional rejection under pre-AIA 35 U.S.C. 102(e)/103(a). Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the reference application is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.
- 10. See MPEP § 1490 for guidance regarding terminal disclaimers and withdrawal of nonstatutory double patenting rejections when these are the only rejections remaining. Note especially that priority or benefit claims under 35 U.S.C. 119(a) and (e) are not taken into account in determining which is the earlier-filed application for double patenting purposes.
- 11. For applications being examined under the first inventor to file (FITF) provisions of the AIA: A rejection under 35 U.S.C. 102(a)(2) or 35 U.S.C. 103 should also be made if appropriate.
- 12. In bracket 4, provide appropriate explanation for anticipation or rationale for obviousness of the claims being rejected over the claims of the cited application.

\P 8.36 Rejection, Nonstatutory Double Patenting - With Secondary Reference(s)

Claim [1] rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim [2] of U.S. Patent No. [3] in view of [4]. [5]

- 1. Form paragraph 8.33 must precede any one of form paragraphs 8.34 to 8.39 and must be used only ONCE in an Office action.
- 2. This form paragraph is used for nonstatutory double patenting rejections where the primary reference is a <u>patent</u> that includes claims patentably indistinct from those in the application under examination.
- 3. If the nonstatutory double patenting rejection is based on another <u>application</u>, do not use this form paragraph. A provisional nonstatutory double patenting rejection should be made using form paragraphs 8.33 and either 8.35 or 8.37.
- 4. This form paragraph may be used where the patentably indistinct invention is claimed in a patent where the patent and the application under examination:
- a. name the same inventive entity, or
- b. name different inventive entities but are commonly assigned, or

- are not commonly assigned but have at least one common (joint) inventor, or
- d. are filed by a common applicant (35 U.S.C. 118), or
- claim patentably indistinct inventions made as a result of activities undertaken within the scope of a joint research agreement under <u>pre-AIA 35 U.S.C. 103(c)</u>, for applications examined under <u>pre-AIA</u> (first to invent) law, or
- f. claim patentably indistinct inventions and the claimed invention and the patent were commonly owned under 35 U.S.C. 102(b)(2)(C) or deemed to be commonly owned under 35 U.S.C. 102(c) not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention, for applications examined under the first inventor to file (FITF) provisions of the AIA.
- 5. In bracket 3, insert the number of the primary reference patent.
- 6. In bracket 4, insert the secondary reference, which must be prior art under <u>35 U.S.C. 102</u> or <u>pre-AIA 35 U.S.C. 102</u>, as applicable.
- 7. In bracket 5, insert an explanation of the obviousness analysis.
- 8. A rejection should additionally be made under <u>pre-AIA 35</u> <u>U.S.C. 103(a)</u> using form paragraph 7.21.fti if:
- a. evidence indicates that the primary reference patent is prior art under pre-AIA 35 U.S.C. 102(f) or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the primary reference patent has not been disqualified as prior art in a <u>pre-AIA 35 U.S.C. 103(a)</u> rejection pursuant to <u>pre-AIA 35 U.S.C. 103(c)</u>.
- 9. For applications being examined under pre-AIA (first to invent) law: If the primary reference patent is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, a rejection under pre-AIA 35 U.S.C. 102(e)/103(a) may be made using form paragraph 7.21.02.fti. Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the patent is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.
- 10. For applications being examined under first inventor to file (FITF) provisions of the AIA: A rejection under 35 U.S.C. 102(a)(2) or 35 U.S.C. 103 should also be made if appropriate.

¶ 8.37 Provisional Rejection, Nonstatutory Double Patenting - With Secondary Reference(s)

Claim [1] provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim [2] of copending Application No. [3] in view of [4]. [5]

This is a <u>provisional</u> nonstatutory double patenting rejection.

Examiner Note:

1. Form paragraph 8.33 must precede any one of form paragraphs 8.34 to 8.39 and must be used only ONCE in an Office action.

- 2. This form paragraph is used for nonstatutory double patenting rejections requiring an obviousness analysis where the primary reference is a copending <u>application</u>.
- 3. If the patentably indistinct claims are in a <u>patent</u>, do not use this form paragraph, use form paragraph 8.36.
- 4. This form paragraph may be used where the patentably indistinct claims are in a copending application where the copending application and the application under examination:
- a. name the same inventive entity, or
- b. name different inventive entities but are commonly assigned, or
- c. are not commonly assigned but name at least one common (joint) inventor (unless disclosure of the reference application would violate the duty of the USPTO to keep the reference application confidential under 35 U.S.C. 122 e.g., the applicant or assignee of record has specifically requested that the inventor not be permitted to access the record in the manner provided in MPEP § 106), or
- d. are filed by a common applicant (35 U.S.C. 118), or
- e. claim patentably indistinct inventions made as a result of activities undertaken within the scope of a joint research agreement under <u>pre-AIA 35 U.S.C. 103(c)</u>, for applications examined under pre-AIA (first to invent) law, or
- f. claim patentably indistinct inventions and the claimed invention and the primary reference application were commonly owned under 35 U.S.C. 102(b)(2)(C) or deemed to be commonly owned under 35 U.S.C. 102(c) not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention, for applications examined under the first inventor to file (FITF) provisions of the AIA.
- 5. If the application under examination and primary reference application are currently commonly assigned but the application under examination does not establish that the patentably indistinct inventions were commonly owned at the time the later invention was made, form paragraph 8.28.fti may be used in addition to this form paragraph to also resolve any issues relating to priority under pre-AIA 35 U.S.C. 102(f) and/or (g).
- 6. For applications being examined under first inventor to file (FITF) provisions of the AIA: If the primary reference application is to a different inventive entity and is commonly assigned with the application under examination, form paragraph 8.28.aia should additionally be used if there is no evidence of common ownership not later than the effective filing date of the invention claimed in the examined application. A rejection under 35 U.S.C. 102(a)(2) or 35 U.S.C. 103 should also be made if appropriate.
- 7. In bracket 3, insert the number of the primary reference application.
- 8. In bracket 4, insert the secondary reference, which must be prior art under <u>35 U.S.C. 102</u> or <u>pre-AIA 35 U.S.C. 102</u>, as applicable.
- 9. In bracket 5, insert an explanation of the obviousness analysis.

- 10. A provisional nonstatutory double patenting rejection should also be made in the primary reference application.
- 11. A rejection should additionally be made under <u>pre-AIA</u> 35 U.S.C. 103(a) using form paragraph 7.21.fti if:
- a. evidence indicates that the primary reference application is prior art under <u>pre-AIA 35 U.S.C. 102(f)</u> or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the primary reference application has not been disqualified as prior art in a <u>pre-AIA 35 U.S.C. 103(a)</u> rejection pursuant to <u>pre-AIA 35 U.S.C. 103(c)</u>.
- 12. For applications being examined under pre-AIA (first to invent) law: If the reference application is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, use form paragraph 7.21.01.fti to additionally make a rejection under pre-AIA 35 U.S.C. 102(e)/103(a). Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the primary reference application is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.
- 13. See MPEP § 1490 for guidance regarding terminal disclaimers and withdrawal of nonstatutory double patenting rejections when these are the only rejections remaining. Note especially that priority or benefit claims under 35 U.S.C. 119(a) and (e) are not taken into account in determining which is the earlier-filed application for double patenting purposes.

5. Two-Way Test for Distinctness

If a reference patent has a later patent term filing date than the application under examination, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application and the Office is solely responsible for any delays. *In re* Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998) ("The two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application In Berg's case, the two applications could have been filed as one, so it is irrelevant to our disposition who actually controlled the respective rates of prosecution." 140 F.3d at 1435, 46 USPQ2d at 1232); In re Hubbell, 709 F.3d 1140, 106 USPQ2d 1032 (Fed. Cir. 2013) ("[P]rosecution choices resulted in the foreseeable consequence that the 685 patent issued before the application claims on appeal. Given these circumstances, and because it is undisputed that the PTO was not solely

responsible for the delay, Hubbell is not entitled to a two-way obviousness analysis." 709 F.3d at 1150, 106 USPQ2d at 1039.); see also In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993) (in a situation where delayed issuance equated to later expiration, applicant's voluntary decision to obtain early issuance of claims directed to a species and to pursue prosecution of previously rejected genus claims in a continuation is a considered election to postpone by the applicant and not administrative delay). Unless the record clearly administrative delay caused solely by the Office and that applicant could not have avoided filing separate applications, the examiner may use the one-way distinctness determination and shift the burden to applicant to show why a two-way distinctness determination is required.

When making a two-way distinctness determination, where appropriate, it is necessary to apply the obviousness analysis twice, first analyzing the obviousness of the application claims in view of the patent claims, and then analyzing the obviousness of the patent claims in view of the application claims. Where a two-way distinctness determination is required, a nonstatutory double patenting rejection based on obviousness is appropriate only where each analysis leads to a conclusion that the claimed invention is an obvious variation of the invention claimed in the other application/patent. If either analysis does not lead to a conclusion of obviousness, no double patenting rejection of the obviousness-type is made, but this does not necessarily preclude a nonstatutory double patenting rejection based on equitable principles. Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

Although a delay in the processing of applications before the Office that causes patents to issue in an order different from the order in which the applications were filed is a factor to be considered in determining whether a one-way or two-way distinctness determination is necessary to support a double patenting rejection, it may be very difficult to assess whether the administrative process is solely responsible for a delay in the issuance of a patent. On the one hand, it is applicant who presents claims for examination and pays the issue fee. On the other hand, the resolution of legitimate differences of

opinion in an appeal process or the time spent in an interference proceeding can significantly delay the issuance of a patent. Nevertheless, the reasons for the delay in issuing a patent have been considered in assessing the propriety of a double patenting rejection. Thus, in Pierce v. Allen B. DuMont Laboratories, Inc., 297 F.2d 323, 131 USPQ 340 (3d. Cir. 1961), the court found that administrative delay may justify the extension of patent rights beyond 17 years but "a considered election to postpone acquisition of the broader [patent after the issuance of the later filed application] should not be tolerated." In Pierce, the patentee elected to participate in an interference proceeding [after all claims in the application had been determined to be patentable] whereby the issuance of the broader patent was delayed by more than 7 years after the issuance of the narrower patent. The court determined that the second issued patent was invalid on the ground of double patenting. Similarly, in In re Emert, 124 F.3d 1458, 44 USPQ2d 1149 (Fed. Cir. 1997), the court found that the one-way test is appropriate where applicants, rather than the Office, had significant control over the rate of prosecution of the application at issue. In support of its finding that the applicants were responsible for delaying prosecution of the application during the critical period, the court noted that the applicants had requested and received numerous time extensions in various filings. More importantly, the court noted, after initially receiving an obviousness rejection of all claims, applicants had waited the maximum period to reply (6 months), then abandoned the application in favor of a substantially identical continuation application, then received another obviousness rejection of all claims, again waited the maximum period to reply, and then again abandoned the application in favor of a second continuation application substantially identical to the original filing. On the other hand, in General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 23 USPQ2d 1839 (Fed. Cir. 1992), the court did not hold the patentee accountable for a delay in issuing the first-filed application until after the second-filed application issued as a patent, even where the patentee had intentionally refiled the first-filed application as a continuation-in-part after receiving a Notice of Allowance indicating that all claims presented were patentable. Where, through no fault of the applicant, the claims in a later-filed application

issue first, a nonstatutory double patenting rejection is improper, in the absence of a two-way distinctness determination, because the applicant does not have complete control over the rate of progress of a patent application through the Office. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991). While acknowledging that allowance of the claims in the earlier-filed application would result in the timewise extension of an invention claimed in the patent, the court in *Braat* was of the view that the extension was justified under the circumstances, indicating that a nonstatutory double patenting rejection would be proper only if the claimed inventions were obvious over each other — a two-way distinctness determination.

See, however, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998), wherein the claims at issue could have been filed in the same application. The *Berg* court explained, "Braat was an unusual case; moreover, its factual situation is not likely to be repeated since the 1984 Act [amending 35 U.S.C. 116, and permitting joint inventorship even though not all inventors contributed to each claim] went into effect." 140 F.3d at 1433-34, 46 USPQ2d at 1230.

Form paragraph 8.33 and the appropriate one of form paragraphs 8.34-8.37 may be used to make nonstatutory double patenting rejections based on anticipation or obviousness analyses. See MPEP § 804, paragraph II.B.4, above. See paragraph II.B.6, below, and form paragraphs 8.38 and 8.39 if the basis for the nonstatutory double patenting rejection is equitable principles.

6. Nonstatutory Double Patenting Rejection Based on Equitable Principles

In some circumstances a nonstatutory double patenting rejection is applicable based on equitable principles. Occasionally the fundamental reason for nonstatutory double patenting – to prevent unjustified timewise extension of patent rights – is itself enforceable no matter how the extension is brought about. Examples of this occurred in *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385-86, 68 USPQ2d 1865, 1875 (Fed. Cir. 2003).

In *In re Schneller*, 397 F.2d 350, 158 USPQ 210, 216 (CCPA 1968), the court affirmed a double patenting rejection after summing up the situation as follows:

[I]n appellant's own terms: The combination ABC was old. He made two improvements on it, (1) adding X and (2) adding Y, the result still being a unitary clip of enhanced utility. While his invention can be practiced in the forms ABCX or ABCY, the greatest advantage and best mode of practicing the invention as disclosed is obtained by using both inventions in the combination ABCXY. His first application disclosed ABCXY and other matters. He obtained a patent claiming [a clip comprising] BCX and ABCX, ... so claiming these combinations as to cover them no matter what other feature is incorporated in them, thus covering effectively ABCXY. He now, many years later, seeks more claims directed to and ABCXY. Thus, protection he ABCY already had would be extended, albeit in somewhat different form, for several years beyond the expiration of his patent, were we to reverse.

397 F.2d at 355-56, 158 USPQ at 216 (emphasis in original).

The court recognized that "there is no double patenting in the sense of claiming the same invention because ABCX and ABCY are, in the technical patent law sense, different inventions. The rule against 'double patenting,' however, is not so circumscribed. The fundamental reason for the rule is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about. To . . . prevail here, appellant has the burden of establishing that the invention claimed in his patent is 'independent and distinct' from the invention of the appealed claims.... [A]ppellant has clearly not established the independent and distinct character of the inventions of the appealed claims." 397 F.2d at 354-55, 158 USPQ at 214-15 (emphasis in original). The court observed:

The controlling fact is that patent protection for the clips, fully disclosed in and covered by the claims of the patent, would be extended by allowance of the appealed claims. Under the circumstance of the instant case, wherein we find no valid excuse or mitigating circumstances making it either reasonable or equitable to make an exception, and wherein there is no terminal disclaimer, the rule against "double patenting" must be applied.

397 F.2d at 355, 158 USPQ at 215.

The decision in In re Schneller did not establish a rule of general application and thus is limited to the particular set of facts set forth in that decision. The court in Schneller cautioned "against the tendency to freeze into rules of general application what, at best, are statements applicable to particular fact situations." Schneller, 397 F.2d at 355, 158 USPQ at 215. Nonstatutory double patenting rejections based on Schneller will be rare. The Technology Center (TC) Director must approve any nonstatutory double patenting rejections based on Schneller. If an examiner determines that a double patenting rejection based on Schneller is appropriate, the examiner should first consult with the examiner's supervisory patent examiner (SPE). If the SPE agrees with the examiner then approval of the TC Director must be obtained before such a nonstatutory double patenting rejection can be made.

A fact situation similar to that in *Schneller* was presented to a Federal Circuit panel in In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986). Kaplan had been issued a patent on a process of making chemicals in the presence of an organic solvent. Among the organic solvents disclosed and claimed as being useful were tetraglyme and sulfolane. One unclaimed example in the patent was specifically directed to a mixture of these two solvents. The claims in the application to Kaplan and Walker, the application before the Office, were directed to essentially the same chemical process, but requiring the use of the solvent mixture of tetraglyme and sulfolane. In reversing the double patenting rejection, the court stated that the mere fact that the broad process claim of the patent requiring an organic solvent reads on or "dominates" the narrower claim directed to basically the same

process using a specific solvent mixture does not, *per se*, justify a double patenting rejection. The court also pointed out that the double patenting rejection improperly "used the disclosure of the appellants' joint invention [solvent mixture] in the Kaplan patent specification as though it were prior art." *Kaplan*, 789 F.2d at 1577, 229 USPQ at 681.

A significant factor in the *Kaplan* case was that the

broad invention was invented by Kaplan, and the narrow invention (i.e., using a specific combination of solvents) was invented by Kaplan and Walker. Since these applications (as the applications in Braat) were filed before the Patent Law Amendments Act of 1984 (Public Law 98-622, November 8, 1984) amending 35 U.S.C. 116 to expressly authorize filing a patent application in the names of joint inventors who did not necessarily make a contribution to the invention defined in each claim in the patent, it was necessary to file multiple applications to claim both the broad and narrow inventions. Accordingly, there was a valid reason, driven by statute, why the claims to the specific solvent mixture were not presented for examination in the Kaplan patent application.

More recently, in Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1385-86, 68 USPQ2d 1865, 1875 (Fed. Cir. 2003), the court applied nonstatutory double patenting to invalidate a claim without analyzing anticipation or obviousness. In this case, the earlier patent claimed a compound and the written description disclosed a single utility of that compound as administration to a human in amounts effective for inhibiting B-lactamase. The later patent claimed nothing more than the earlier patent's disclosed utility as a method of using the compound. Thus, the court found that the claims of the later patent and the claims of the earlier patent were not patentably distinct. The Geneva court relied on equitable principles, not an obviousness-type analysis, in reaching its conclusion. Id. at 1386, 68 USPQ2d at 1875 (quoting In re Byck, 48 F.2d 665, 666 (CCPA 1931)).

Each double patenting situation must be decided on its own facts.

Form paragraph 8.38 (between an issued patent and one or more applications) or 8.39 (provisional

rejection) may be used to make this type of nonstatutory double patenting rejection.

¶ 8.38 Double Patenting - Nonstatutory (Based Solely on Improper Timewise Extension of Patent Rights) With a Patent

Claim [1] rejected on the ground of nonstatutory double patenting over claim [2] of U.S. Patent No. [3] since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: [4]

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

- 1. Form paragraph 8.33 must precede any one of form paragraphs 8.34 to 8.39 and must be used only ONCE in an Office action.
- 2. This form paragraph should only be used where approval from the TC Director to make a nonstatutory double patenting rejection based on *In re Schneller* has been obtained.
- 3. Use this form paragraph only when the subject matter of the claim(s) is fully disclosed in, and covered by at least one claim of, an issued U.S. Patent which is commonly owned or where there is at least one common (joint) inventor or a common applicant (35 U.S.C. 118).
- 4. In bracket 3, insert the number of the patent.
- 5. In bracket 4, insert a description of the subject matter being claimed which is covered in the patent.
- 6. A rejection should additionally be made under <u>pre-AIA 35 U.S.C. 103(a)</u> using form paragraph 7.21.fti if:
- a. evidence indicates that the patent is also prior art under pre-AIA 35 U.S.C. 102(f) or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the patent has not been disqualified as prior art in a <u>pre-AIA 35 U.S.C. 103(a)</u> rejection pursuant to <u>pre-AIA 35 U.S.C. 103(c)</u>.
- 7. For applications being examined under pre-AIA (first to invent) law: If the patent is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, a rejection under pre-AIA 35 U.S.C. 102(e)/103(a) may be made using form paragraph 7.21.02.fti. Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the patent is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.

8. For applications being examined under first inventor to file (FITF) provisions of the AIA: A rejection under 35 U.S.C. 102(a)(2) or 35 U.S.C. 103 should also be made if appropriate.

¶ 8.39 Double Patenting - Nonstatutory (Based Solely on Improper Timewise Extension of Patent Rights) With Another Application

Claim [1] provisionally rejected on the ground of nonstatutory double patenting over claim [2] of copending Application No. [3]. This is a provisional double patenting rejection because the patentably indistinct claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: [4]

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Examiner Note:

- 1. Form paragraph 8.33 must precede any one of form paragraphs 8.34 to 8.39 and must be used only ONCE in an Office action.
- 2. This form paragraph should only be used where approval from the TC Director to make a nonstatutory double patenting rejection based on *In re Schneller* has been obtained.
- 3. Use this form paragraph only when the subject matter of the claim(s) is fully disclosed in, and covered by at least one claim of, another copending application (reference application) which is commonly owned, or where there is at least one common (joint) inventor or a common applicant (35 U.S.C. 118).
- 4. In bracket 3, insert the number of the reference application.
- 5. In bracket 4, insert a description of the subject matter being claimed which is covered in the reference application.
- 6. If the reference application is currently commonly assigned but the prosecution file of the application under examination does not establish that the patentably indistinct inventions were commonly owned at the time the later invention was made, form paragraph 8.28.fti may be used in addition to this form paragraph to resolve any issues relating to priority under pre-AIA 35 U.S.C. 102(f) and/or (g).
- 7. For applications being examined under first inventor to file (FITF) provisions of the AIA: If the reference application is to a different inventive entity and is commonly assigned with the application under examination, form paragraph 8.28.aia should additionally be used if there is no evidence of common ownership not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention. A rejection under 35 U.S.C. 102(a)(2) or 35 U.S.C. 103 should also be made if appropriate.
- 8. A provisional double patenting rejection should also be made in the reference application.

- 9. A rejection should additionally be made under <u>pre-AIA 35</u> <u>U.S.C. 103(a)</u> using form paragraph 7.21.fti if:
- a. evidence indicates that the reference application is prior art under <u>pre-AIA 35 U.S.C. 102(f)</u> or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the reference application has not been disqualified as prior art in a <u>pre-AIA 35 U.S.C. 103(a)</u> rejection pursuant to <u>pre-AIA 35 U.S.C. 103(c)</u>.
- 10. For applications being examined under pre-AIA (first to invent) law: If the reference application is prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention, use form paragraph 7.21.01.fti to additionally make a rejection under pre-AIA 35 U.S.C. 102(e)/103(a) in the application with the later effective U.S. filing date. Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the reference application is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.
- 11. See MPEP § 1490 for guidance regarding terminal disclaimers and withdrawal of nonstatutory double patenting rejections when these are the only rejections remaining. Note especially that priority or benefit claims under 35 U.S.C. 119(a) and (e) are not taken into account in determining which is the earlier-filed application for double patenting purposes.

7. Design/Plant — Utility Situations

Double patenting issues may be raised where an applicant has filed both a utility patent application (35 U.S.C. 111) and either an application for a plant patent (35 U.S.C. 161) or an application for a design patent (35 U.S.C. 171). In general, the same double patenting principles and criteria that are applied in utility-utility situations are applied to utility-plant or utility-design situations. Double patenting rejections in utility-plant situations may be made in appropriate circumstances.

Although double patenting is rare in the context of utility versus design patents, a double patenting rejection of a pending design or utility application can be made on the basis of a previously issued utility or design patent, respectively. *Carman Indus. Inc. v. Wahl*, 724 F.2d 932, 220 USPQ 481 (Fed. Cir. 1983). The rejection is based on the public policy preventing the extension of the term of a patent. Double patenting may be found in a design-utility situation irrespective of whether the claims in the reference patent/application and the claims in the application under examination are directed to the same invention, or whether they are directed to inventions which are obvious variations

of one another. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

In *Carman Indus.*, the court held that no double patenting existed between a design and utility patent since the claims in the utility patent, drawn to the interior construction of a flow promoter, were not directed to the same invention or an obvious variation of the invention claimed in a design patent directed to the visible external surface configuration of a storage bin flow promoter. The majority opinion in this decision appears to indicate that a two-way distinctness determination is necessary in design-utility cases. 724 F.2d at 940-41, 220 USPQ at 487-88.

In Thorington, the court affirmed a double patenting rejection of claims for a fluorescent light bulb in a utility patent application in view of a previously issued design patent for the same bulb. In another case, a double patenting rejection of utility claims for a finger ring was affirmed in view of an earlier issued design patent, where the drawing in both the design patent and the utility application illustrated the same article. In re Phelan, 205 F.2d 183, 98 USPQ 156 (CCPA 1953). A double patenting rejection of a design claim for a flashlight cap and hanger ring was affirmed over an earlier issued utility patent. In re Barber, 81 F.2d 231, 28 USPQ 187 (CCPA 1936). A double patenting rejection of claims in a utility patent application directed to a balloon tire construction was affirmed over an earlier issued design patent. In re Hargraves, 53 F.2d 900, 11 USPQ 240 (CCPA 1931).

III. CONTRAST BETWEEN DOUBLE PATENTING REJECTION AND REJECTIONS BASED ON PRIOR ART

Rejections over a patent or another copending application based on double patenting or under 35 U.S.C. 102 or 103 are similar in the sense that both require comparison of the claimed subject matter with at least part of the content of another patent or application, and both may require that an anticipation or obviousness analysis be made. However, there are significant differences between a rejection based on double patenting and one based on prior art under 35 U.S.C. 102 or 103. "[O]bvious-type double patenting and [pre-AIA] §102(e)/§103 rejections

may be analogous in the sense that an obviousness analysis is performed in both cases, but they are not analogous in terms of what is analyzed." *In re Bartfeld*, 925 F.2d 1450, 1453, 17 USPQ2d 1885, 1888 (Fed. Cir. 1991).

One significant difference is that a double patenting rejection must rely on a comparison with the claims in an issued patent or pending application, whereas an anticipation or obviousness rejection based on the same patent or application under 35 U.S.C. 102 or 103 relies on a comparison with what is disclosed (whether or not claimed) in the same issued patent or pending application. In a 35 U.S.C. 102 or 103 rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. *In re Heck*, 699 F.2d 1331, 216 USPQ 1038 (Fed. Cir. 1983).

A second significant difference is that a terminal disclaimer cannot be used to obviate a rejection based on prior art under 35 U.S.C. 102 or 103 prior art, even though it may overcome a nonstatutory double patenting rejection. *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991). The purpose of a terminal disclaimer is to obviate a nonstatutory double patenting rejection by removing the potential harm to the public by issuing a second patent, and not to remove a patent as prior art. See, for example, *Agrizap*, *Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344, 86 USPQ2d 1110, 1115 (Fed. Cir. 2008).

IV. DOUBLE PATENTING REJECTIONS AND PRIOR ART DISQUALIFICATION UNDER PRE-AIA 35 U.S.C. 103(c)

For pre-AIA applications filed on or after November 29, 1999 and for pre-AIA applications pending on or after December 10, 2004, a commonly assigned/owned patent or application may be disqualified as pre-AIA 35 U.S.C. 102(e) prior art in a pre-AIA 35 U.S.C. 103(a) rejection. See pre-AIA 35 U.S.C. 103(c)(1). For pre-AIA applications pending on or after December 10, 2004, a patent or application may be disqualified as pre-AIA 35 U.S.C. 102(e) prior art in a pre-AIA 35 U.S.C. 103(a) rejection if evidence of a joint research agreement pursuant to pre-AIA 35 U.S.C. 103(c)(2)

and (3) is made of record in the application (or patent) being examined (or reexamined), and the conflicting claims resulted from a joint research agreement that was in effect on or before the date the later claimed invention was made. See MPEP § 2146 et seq. for more information. The prior art disqualification under pre-AIA 35 U.S.C. 103(c) may also be applicable in post-grant Office proceedings if the application, which matured into the patent under reexamination or review, meets the above-mentioned conditions.

An examiner should make both a pre-AIA 35 U.S.C. 102(e)/103(a) rejection and a double patenting rejection over the same reference when the facts support both rejections. See the charts in MPEP § 804 for an overview of possible rejections based on prior art as well as double patenting. Note that even if an earlier patent or application to another is disqualified as prior art in a pre-AIA 35 U.S.C. 103(a) rejection based on common ownership or a joint research agreement as discussed above, that patent or application may still form the basis of a double patenting rejection and is still available as prior art under pre-AIA 35 U.S.C. 102(e) to form the basis of an anticipation rejection. See MPEP § 804.03, subsection IV. If the examiner makes only one of these rejections when each is separately applicable, and if the next Office action includes the previously omitted rejection, then the next Office action cannot be made final. A prior art reference that anticipates or renders claimed subject matter obvious under pre-AIA 35 U.S.C. 102(e)/103(a) does not support a double patenting rejection where that subject matter is not claimed in the reference patent or application. For pre-AIA applications pending on or after December 10, 2004, rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection. See MPEP § 2146.01 for information regarding when prior art is disqualified under pre-AIA 35 U.S.C. 103(c) based on common ownership or as a result of activities undertaken within the scope of a joint research agreement.

As an alternative to invoking the prior art disqualification under <u>pre-AIA 35 U.S.C. 103(c)(1)</u>, the assignee could have taken some preemptive measures to avoid having a commonly

assigned/owned copending application become prior art under pre-AIA 35 U.S.C. 102(e). The applications could have been filed on the same day, or copending applications could have been merged into a single continuation-in-part application and the parent applications abandoned. If these steps are undesirable or the first patent has issued, the prior art effect of the first patent may be avoided by a showing under 37 CFR 1.132 that any unclaimed invention disclosed in the first patent was derived from the inventor of the application before the examiner in which the pre-AIA 35 U.S.C. 102(e)/103(a) rejection was made. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). See also MPEP § 716.10. It may also be possible for applicant to respond to a <u>pre-AIA 35</u> U.S.C. 102(e)/103(a) rejection by showing, under 37 CFR 1.131(a), that the date of invention of the claimed subject matter was prior to the pre-AIA 35 U.S.C. 102(e) date of the reference patent which has been relied upon for its unclaimed disclosure. See MPEP § 715. See also 37 CFR 1.131(c) and MPEP § 718 for affidavits or declarations to disqualify a commonly owned patent as prior art under pre-AIA 35 U.S.C. 103(c).

V. DOUBLE PATENTING REJECTIONS AND PRIOR ART EXCEPTION UNDER 35 U.S.C. 102(b)(2)(C) and 102(c)

For AIA applications, subject matter in a commonly assigned/owned patent or application may be excepted as prior art under 35 U.S.C. 102(a)(2). See 35 U.S.C. 102(b)(2)(C). Also, if the requirements of 35 U.S.C. 102(c) are met, common ownership can be established by a joint research agreement. This prior art exception also applies in post-grant Office proceedings of patents if the patent under reexamination or review is subject to AIA 35 U.S.C. 102 and 103. See, e.g., MPEP § 2258, subsection I, for more information about which prior art regime applies in an ex parte reexamination. See also MPEP § 717.02 et seq. for more information on the prior art exception for commonly owned or joint research agreement subject matter.

An examiner should make both a prior art rejection under either 35 U.S.C. 102(a)(2) or 103 and a double patenting rejection over the same reference when the facts support both rejections. See the charts in MPEP § 804 for an overview of possible rejections

based on prior art as well as double patenting. If the prior art exception under 35 U.S.C. 102(b)(2)(C) is properly invoked, the excepted subject matter disclosed in the commonly owned or joint research agreement reference is not available as prior art under 35 U.S.C. 102(a)(2) for an anticipation and/or obviousness rejection, and also may not be used as a secondary reference in a nonstatutory double patenting rejection. However, the claims of a reference excepted under 35 U.S.C. 102(b)(2)(C) may still be the basis for a double patenting rejection, whether statutory or nonstatutory. See MPEP § 804.03, subsection IV. A prior art reference that anticipates or renders claimed subject matter obvious under <u>35 U.S.C.</u> <u>102(a)(2)</u> or <u>103</u> does not support a double patenting rejection where that subject matter is not claimed in the reference patent or application. Rejections under 35 U.S.C. 102(a)(2) or 103 should not be made or maintained if the reference is not prior art because of the exception under 35 U.S.C. 102(b)(2)(C). See MPEP § 717.02 et seq. for information regarding when prior art meets the exception under <u>35 U.S.C. 102(b)(2)(C)</u> and <u>102(c)</u> based on common ownership or a joint research agreement.

VI. DOUBLE PATENTING REJECTIONS ONCE A JOINT RESEARCH AGREEMENT IS ESTABLISHED

Under both pre-AIA and AIA law, examiners cannot rely on the joint research agreement provisions to apply a nonstatutory double patenting rejection until applicant establishes the existence of a joint research agreement in accordance with 37 CFR 1.104(c)(4)(ii) or (c)(5)(ii). Therefore, it is not appropriate for an examiner to assume that the pre-AIA common ownership disqualification or the AIA common ownership exception applies merely on the basis of assignment information. If in reply to an Office action applying a prior art rejection, applicant establishes that the relied upon reference is not prior art under the joint research agreement provision of 35 U.S.C. 102(c), or disqualifies it as prior art under pre-AIA 35 U.S.C. 103(c), and a subsequent nonstatutory double patenting rejection based upon conflicting claims in the same reference is applied, the next Office action may be made final even if applicant did not amend the claims (provided the examiner introduces no other new ground of rejection that was not necessitated by either amendment or an information disclosure statement filed during the time period set forth in <u>37 CFR 1.97(c)</u> with the fee set forth in <u>37 CFR 1.17(p)</u>). The Office action is properly made final because the new nonstatutory double patenting rejection was necessitated by the applicant's amendment of the application.

804.01 Prohibition of Nonstatutory Double Patenting Rejections Under 35 U.S.C. 121 [R-07.2022]

35 U.S.C. 121 authorizes the Director to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application in which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application in a nonstatutory double patenting rejection, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. The U.S. Court of Appeals for the Federal Circuit has concluded that the protection of 35 U.S.C. 121 does not extend to all types of continuing applications, stating that "the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications." Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353, 1362, 86 USPQ2d 1001, 1007-1008 (Fed. Cir. 2008). Note that a patentee cannot retroactively recover the safe harbor protection of 35 U.S.C. 121 against nonstatutory double patenting by amending a patent that issued from a continuation-in-part application to only subject matter in the parent application and redesignating the CIP as a divisional of the parent application. See In re Janssen Biotech, Inc., 880 F.3d 1315, 1322, 125 USPQ2d 1525, 1529-30 (Fed. Cir. 2018)("[A] patent owner cannot retroactively bring its challenged patent within the scope of the safe-harbor provision by amendment in a reexamination proceeding."); G.D. Searle LLC v.

Lupin Pharm., Inc., 790 F.3d 1349, 1355, 115 USPQ2d 1326, 1330 (Fed. Cir. 2015)("Simply deleting that new matter from the reissue patent does not retroactively alter the nature of the [] application.").

This apparent nullification of nonstatutory double patenting as a ground of rejection or invalidity in divisional applications imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and where acquiescence to the restriction requirement might result in the issuance of several patents for the same invention. "[I]f an examiner issues a restriction requirement between patentably indistinct claims, two patents may issue and prolong patent protection beyond the statutory term on obvious variants of the same invention. This prolongation would occur because § 121 would immunize the restricted application against nonstatutory double patenting rejections." Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1379, 68 USPQ2d 1865, 1869 (Fed. Cir. 2003). "[W]hen the existence of multiple patents is due to the administrative requirements imposed by the Patent and Trademark Office, 35 U.S.C. Section 121 provides that the inventor shall not be prejudiced by having complied with those requirements. Thus when two or more patents result from a PTO restriction requirement, whereby aspects of the original application must be divided into separate applications, Section 121 insulates the ensuing patents from the charge of double patenting." Applied Materials Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1568, 40 USPO2d 1481, 1484 (Fed. Cir. 1996) (citing Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 354, 228 USPQ 837, 840 (Fed. Cir. 1986)).

The prohibition against holdings of nonstatutory double patenting applies to requirements for restriction between independent or distinct inventions, such as the related subject matter treated in MPEP § 806.04 through § 806.05(j), namely, between a combination and a subcombination thereof, between subcombinations disclosed as usable together, between a process and an apparatus for its practice, between a process and a product made by such process and between an apparatus and

a product made by such apparatus, etc., so long as the claims in each application are filed as a result of such requirement.

The following are situations where the prohibition against nonstatutory double patenting rejections under <u>35 U.S.C. 121</u> does not apply:

- (A) The applicant voluntarily files two or more applications without a restriction requirement by the examiner. In order to obtain the benefit of 35 U.S.C. 121, claims must be formally entered, restricted in, and removed from an earlier application before they are filed in a divisional application. Geneva Pharms. Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1379, 68 USPQ2d 1865, 1870 (Fed. Cir. 2003) (For claims that were not in the original application and are first formally entered in a later divisional application, 35 U.S.C. 121 "does not suggest that the original application merely needs to provide some support for claims that are first entered formally in the later divisional application." *Id.*); In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).
- (B) The claims of the application under examination and claims of the other application/patent are not consonant with the restriction requirement made by the examiner, since the claims have been changed in material respects from the claims at the time the requirement was made. For example, the divisional application filed includes additional claims not consonant in scope with the original claims subject to restriction in the parent. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991); Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990). In order for consonance to exist, the line of demarcation between the independent and distinct inventions identified by the examiner in the requirement for restriction must be maintained. 916 F.2d at 688, 16 USPQ2d at 1440.
- (C) The restriction requirement was withdrawn because the requirement was written in a manner which made it clear to applicant that the requirement was made subject to the nonallowance of generic or other linking claims and such generic or linking claims are subsequently allowed.
- (D) The requirement for restriction (holding of lack of unity of invention) was only made in an

international application by the International Searching Authority or the International Preliminary Examining Authority. However, the prohibition against nonstatutory double patenting rejections does apply to requirements for restriction (lack of unity of invention holdings) made in national stage applications submitted under 35 U.S.C. 371.

- (E) The requirement for restriction was withdrawn, in its entirety or in pertinent part, by the examiner before the patent issues. With the withdrawal of the restriction requirement, the non-elected claims that are no longer withdrawn from consideration become subject to examination. "The restriction requirement disappears; it is as though it had not been made. With the disappearance of the restriction requirement, the need for a divisional application and the need for the [double patenting] prohibition also disappear." In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 132 (CCPA 1971). Note that a restriction requirement in an earlier-filed application does not carry over to claims of a continuation application in which the examiner does not reinstate or refer to the restriction requirement in the parent application. Reliance on a patent issued from such a continuation application to reject claims in a later-filed divisional application is not prohibited under <u>35 U.S.C. 121</u>. *Bristol-Myers* Squibb Co. v. Pharmachemie BV, 361 F.3d 1343, 1348, 70 USPQ2d 1097, 1100 (Fed. Cir. 2004).
- (F) The claims of the second application are drawn to the "same invention" as the first application or patent. Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 228 USPQ 837 (Fed. Cir. 1986). A statutory double patenting rejection under 35 U.S.C. 101 should be made, thus it is not necessary to determine whether the 35 U.S.C. 121 prohibition against making double patenting rejections is applicable. "Same invention" means identical subject matter. See, e.g., Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). The <u>35 U.S.C. 121</u> prohibition against certain nonstatutory double patenting rejections does not apply to statutory double patenting rejections under 35 U.S.C. 101 of claims to the "same invention."
- (G) Where a requirement for restriction between a product, a process of making the product, and a process of using the product was made subject to the non-allowance of the product and the product is

- subsequently allowed. In this situation if any process claims are rejoined, the restriction requirement between the elected product and any rejoined process should be withdrawn in accordance with <u>37 CFR</u> 1.141(b) and MPEP § 821.04.
- (H) The second application is a continuation-in-part (CIP) application that includes claims restricted from the original application. A CIP, by definition, is an application filed during the lifetime of an earlier application by at least one common (joint) inventor that repeats some substantial portion or all of the earlier application and adds matter not disclosed in the earlier application, i.e., the application in which the restriction requirement was originally made. 35 U.S.C. 121 refers specifically and only to divisional and original applications, and does not afford protection to CIP applications. Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353, 1362, 86 USPQ2d 1001, 1007-08 (Fed. Cir. 2008). See also In re Janssen Biotech, Inc., 880 F.3d 1315, 1322,125 USPQ2d 1525, 1529-30 (Fed. Cir. 2018) and G.D. Searle LLC v. Lupin Pharm., Inc., 790 F.3d 1349, 1355, 115 USPQ2d 1326, 1330 (Fed. Cir. 2015).
- 35 U.S.C. 121 does not prevent a double patenting rejection when the identical invention is claimed in the divisional application and the application/patent in which a restriction requirement was made. While identical claims should not arise if appropriate care is exercised in defining the independent and distinct inventions in a restriction requirement, if they do, the Office will make the statutory (35 U.S.C. 101) double patenting rejection because the patentee is entitled only to a single patent for an invention. As expressed in *Studiengesellschaft Kohle*, 784 F.2d at 361, 228 USPQ at 844, (J. Newman, concurring), "35 U.S.C. 121 of course does not provide that multiple patents may be granted on the identical invention."

804.02 Avoiding a Double Patenting Rejection [R-07.2022]

I. STATUTORY

A rejection based on the statutory type of double patenting can be avoided by amending the conflicting claims so that they are not coextensive in scope. Where the conflicting claims are in one or more pending applications and a patent, a rejection based on statutory type double patenting can also be avoided by canceling the conflicting claims in all the pending applications. Where the conflicting claims are in two or more pending applications, a provisional rejection based on statutory type double patenting can also be avoided by canceling the conflicting claims in all but one of the pending applications. A terminal disclaimer is not effective in overcoming a statutory double patenting rejection.

The use of a 37 CFR 1.131(a) affidavit in overcoming a statutory double patenting rejection is inappropriate. *In re Dunn*, 349 F.2d 433, 146 USPQ 479 (CCPA 1965). *Knell v. Muller*, 174 USPQ 460 (Comm'r. Pat. 1971) (citing the CCPA decisions in *In re Ward*, 236 F.2d 428, 111 USPQ 101 (CCPA 1956); *In re Teague*, 254 F.2d 145, 117 USPQ 284 (CCPA 1958); and *In re Hidy*, 303 F.2d 954, 133 USPQ 650 (CCPA 1962)).

II. NONSTATUTORY

A rejection based on a nonstatutory type of double patenting can be avoided by filing a terminal disclaimer in the application or proceeding in which the rejection is made. In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Knohl, 386 F.2d 476, 155 USPQ 586 (CCPA 1967); and In re Griswold, 365 F.2d 834, 150 USPQ 804 (CCPA 1966). The use of a terminal disclaimer in overcoming a nonstatutory double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public. In re Jentoft, 392 F.2d 633, 157 USPQ 363 (CCPA 1968); In re Eckel, 393 F.2d 848, 157 USPQ 415 (CCPA 1968); In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Note that a terminal disclaimer filed after the expiration of the reference patent is not effective to obviate a nonstatutory double patenting rejection. Boehringer Ingelheim Int'l v. Barr See Laboratories, 592 F.3d 1340, 93 USPQ2d 1417 (Fed. Cir. 2010). See also MPEP § 1490, subsection VI.A. A disclaimer filed in a reference patent that has an earlier expiration date and that disclaims the patentably indistinct claim(s) would have no impact on whether a nonstatutory double patenting rejection is proper in a patent that has, or an application for a patent that would have, a later expiration date. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 n.5, 58 USPQ2d 1869, 1878 n.5 (Fed. Cir. 2001)("A patent owner cannot avoid double patenting by disclaiming the earlier patent.").

The use of a 37 CFR 1.131(a) affidavit in overcoming a double patenting rejection is inappropriate because the claim or claims in the application are being rejected over a patent which claims the rejected invention. In re Dunn, 349 F.2d 433, 146 USPQ 479 (CCPA 1965). 37 CFR 1.131(a) is inapplicable if the claims of the application and the patent are "directed to substantially the same invention." It is also inapplicable if there is a lack of "patentable distinctness" between the claimed subject matter. Knell v. Muller, 174 USPQ 460 (Comm'r. Pat. 1971) (citing the court decisions in In re Ward, 236 F.2d 428, 111 USPO 101 (CCPA 1956); In re Teague, 254 F.2d 145, 117 USPQ 284 (CCPA 1958); and In re Hidy, 303 F.2d 954, 133 USPQ 65 (CCPA 1962)).

A patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term of a patent. 35 U.S.C. 253. The statute does not provide for a terminal disclaimer of only a specified claim or claims. The terminal disclaimer must operate with respect to all claims in the patent.

The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). In *Quad Environmental Technologies*, the court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

A terminal disclaimer filed to obviate a nonstatutory double patenting rejection is effective only with respect to the application identified in the disclaimer, unless by its terms it extends to continuing applications. If an appropriate provisional nonstatutory double patenting rejection is made in

each of two or more pending applications, the examiner should follow the practice set forth in MPEP § 804, subsection I.B.1. and subsection VI. below.

35 U.S.C. 101 prevents two patents from issuing on the same invention. "Same invention" means identical subject matter. See, e.g., Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Ockert, 245 F.2d 467, 114 USPO 330 (CCPA 1957). Claims that differ from each other (aside from minor differences in language, punctuation, etc.), whether or not the difference would have been obvious, are not considered to be drawn to the same invention for double patenting purposes under 35 U.S.C. 101. In cases where the difference in claims would have been obvious, terminal disclaimers are effective to overcome nonstatutory double patenting rejections. Such terminal disclaimers must include a provision that the patent shall be unenforceable if it ceases to be commonly owned or enforced with the other application or patent. Note 37 CFR 1.321(c) and (d). 37 CFR 1.321(d) sets forth the requirements for a terminal disclaimer where the claimed invention resulted from activities undertaken within the scope of a joint research agreement. It should be emphasized that a terminal disclaimer cannot be used to overcome a prior art rejection under 35 U.S.C. 102 or 103.

A nonstatutory double patenting rejection may also be avoided if consonance between the originally restricted inventions is maintained in a divisional application. "Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement." Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1381, 68 USPO2d 1865, 1871 (Fed. Cir. 2003). "Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained ... Where that line is crossed the prohibition of the third sentence of Section 121 does not apply." Symbol Techs, Inc. v. Opticon, Inc., 935 F.2d 1569, 1579, 19 USPQ2d 1241, 1249 (Fed. Cir. 1991) (quoting Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1440 (Fed. Cir. 1990)). "However,

even if such consonance is lost, double patenting does not follow if the requirements of Section 121 are met or if the claims are in fact patentably distinct ... The purpose of Section 121 is to accommodate administrative convenience and to protect the patentee from technical flaws based on this unappealable examination practice." Applied Materials Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1568, 40 USPQ2d 1481, 1484 (Fed. Cir. 1996).

III. TERMINAL DISCLAIMER REQUIRED DESPITE REQUEST TO ISSUE ON COMMON ISSUE DATE

Applicants are cautioned that reliance upon a common issue date cannot effectively substitute for the filing of one or more terminal disclaimers in order to overcome a proper nonstatutory double patenting rejection, particularly since a common issue date alone does not avoid the potential problems of dual ownership by a common assignee, or by parties to a joint research agreement, of patents to patentably indistinct inventions. In any event, the Office cannot ensure that two or more applications will have a common issue date.

IV. DISCLAIMING MULTIPLE DOUBLE PATENTING REFERENCES

If multiple conflicting patents and/or pending applications are applied in nonstatutory double patenting rejections made in a single application, then prior to issuance of that application, it is necessary to disclaim the terminal part of any patent granted on the application which would extend beyond the expiration date of each one of the conflicting patents and/or applications. A terminal disclaimer fee is required for each terminal disclaimer filed. To avoid paying multiple terminal disclaimer fees, a single terminal disclaimer based on common ownership may be filed, for example, in which the term disclaimed is based on all the conflicting, commonly owned nonstatutory double patenting references. Similarly, a single terminal disclaimer based on a joint research agreement may be filed, in which the term disclaimed is based on all the conflicting nonstatutory double patenting references.

Each one of the commonly owned conflicting nonstatutory double patenting references must be included in the terminal disclaimer to avoid the problem of dual ownership of patents to patentably indistinct inventions in the event that the patent issuing from the application being examined ceases to be commonly owned with any one of the double patenting references that have issued or may issue as a patent. Note that 37 CFR 1.321(c)(3) requires that a terminal disclaimer for commonly owned conflicting claims "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting."

Filing a terminal disclaimer including each one of the conflicting nonstatutory double patenting references is also necessary to avoid the problem of separate enforcement of patents to patentably indistinct inventions by parties to a joint research agreement. 37 CFR 1.321(d) sets forth the requirements for a terminal disclaimer where the claimed invention resulted from activities undertaken within the scope of a joint research agreement.

V. REQUIREMENTS OF A TERMINAL DISCLAIMER

A terminal disclaimer is a statement filed by an owner (in whole or in part) of a patent or a patent to be granted that is used to disclaim or dedicate a portion of the entire term of all the claims of a patent. The requirements for a terminal disclaimer are set forth in 37 CFR 1.321. Sample forms of a terminal disclaimer, and guidance as to the filing and treatment of a terminal disclaimer, are provided in MPEP § 1490.

VI. TERMINAL DISCLAIMERS REQUIRED TO OVERCOME NONSTATUTORY DOUBLE PATENTING REJECTIONS IN APPLICATIONS FILED ON OR AFTER JUNE 8, 1995

Public Law 103-465 (1994) amended <u>35 U.S.C.</u> <u>154(a)(2)</u> to provide that any patent issuing on a utility or plant application filed on or after June 8, 1995 will expire 20 years from its actual filing date,

or, if the application claims the benefit of an earlier filed application under 35 U.S.C. 120, 121, or 365(c), 20 years from the earliest filing date for which a benefit under 35 U.S.C. 120, 121, or 365(c) is claimed. The Patent Law Treaties Implementation Act of 2012, Public Law 112-211, which implemented the provisions of the Hague Agreement, amended 35 U.S.C. 154(a)(2) to delete "section 120, 121, or 365(c)" and to insert "section 120, 121, 365(c), or 386(c)" and 35 U.S.C. 154(a)(3) to delete "section 119, 365(a), or 365(b)" and to insert "section 119, 365(a), 365(b), 386(a), or 386(b)." Therefore, any patent issuing on a continuing utility or plant application filed on or after June 8, 1995 will expire 20 years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, 365(c), or 386(c), subject to the provisions of 35 U.S.C. 154(b) and 156 (providing for certain patent term adjustments and extensions). Thus, situations will often arise in which two copending applications subject to a provisional double patenting rejection will have the same patent term filing date, and thus, potentially will have the same patent term. Note that a benefit claim under <u>35 U.S.C. 120, 121, 365(c)</u>, or 386(c) that meets the requirements of 37 CFR 1.78 determines the twenty year patent term for utility and plant applications filed on or after June 8, 1995. For patent term, it is not relevant if any claimed invention in the patent actually has 35 U.S.C. 112(a)) support in an earlier application and is therefore entitled to benefit of the earlier filing date for the purpose of avoiding prior art. See MPEP § 804, subsection I.B.1(a).

There are at least two reasons for insisting upon a terminal disclaimer to overcome a nonstatutory double patenting rejection in an application subject to a 20-year term under <u>35 U.S.C. 154(a)(2)</u>. First, 35 U.S.C. 154(b) includes provisions for patent term adjustment based upon prosecution delays during the application process. Thus, <u>35 U.S.C. 154</u> does not ensure that any patent issuing on a continuing utility or plant application filed on or after June 8, 1995 will necessarily expire 20 years from the earliest filing date for which a benefit is claimed under <u>35 U.S.C. 120, 121, 365(c)</u>, or <u>386(c)</u>. However, 35 U.S.C. 154(b)(2)(B) states that no patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the

disclaimer. As the presence of a terminal disclaimer affects whether the patent is granted an adjustment, it is necessary that the terminal disclaimer be filed in the application in order to accurately determine whether the patent is entitled to a term adjustment. Second, 37 CFR 1.321(c)(3) requires that a terminal disclaimer filed to obviate a nonstatutory double patenting rejection based on commonly owned conflicting claims include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection. 37 CFR 1.321(d) sets forth the requirements for a terminal disclaimer where the claimed invention resulted from activities undertaken within the scope of a joint research agreement and limits enforcement of the patent only to that period when the patent and the reference application or patent are not separately enforced. These requirements serve to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention. See, e.g., In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982). Not insisting upon a terminal disclaimer to overcome a nonstatutory double patenting rejection in an application subject to a 20-year term under 35 U.S.C. 154(a)(2) would result in the potential for the problem that 37 CFR 1.321(c)(3) was promulgated to avoid. Further, as a terminal disclaimer is only effective in the application in which it is filed, it is necessary to require that the terminal disclaimer be filed in each application and/or patent that is subject to the common ownership requirement in order to provide complete notice to the public of this obligation.

Accordingly, a terminal disclaimer under <u>37 CFR 1.321</u> is required in an application to overcome a nonstatutory double patenting rejection, even if the application was filed on or after June 8, 1995 and even if the application claims the benefit under <u>35 U.S.C. 120, 121, 365(c)</u>, or <u>386(c)</u> of the filing date of the patent or application which forms the basis for the rejection. Examiners should respond to arguments that a terminal disclaimer under <u>37 CFR 1.321</u> should not be required in a continuing application filed on or after June 8, 1995 to overcome a nonstatutory double patenting rejection due to the change to <u>35 U.S.C. 154</u> by citing to this

section of the MPEP. See Terminal Disclaimers Required to Overcome Judicially-Created Double Patenting Rejections in Utility and Plant Applications Filed on or After June 8, 1995,1202 OG 112 (September 30, 1997). See also AbbVie Inc. v. Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 112 USPQ2d 1001 (Fed. Cir. 2014).

If a terminal disclaimer is filed in an application in which the claims are then canceled or otherwise shown to be patentably distinct from the reference claims, the terminal disclaimer may be withdrawn before issuance of the patent by filing a petition under 37 CFR 1.182 requesting withdrawal of the recorded terminal disclaimer. A terminal disclaimer may not be withdrawn after issuance of the patent. See MPEP § 1490, subsection VIII, for a complete discussion of withdrawal of a terminal disclaimer.

804.03 Commonly Owned Inventions of Different Inventive Entities; Non-Commonly Owned Inventions Subject to a Joint Research Agreement [R-07.2022]

35 U.S.C. 102 Conditions for patentability; novelty.

[Editor Note: Applicable to any patent application subject to the first inventor to file provisions of the AIA (see 35 U.S.C. 100 (note)). See pre AIA 35 U.S.C. 102 for the law otherwise applicable.]

- (b) Exceptions.-
- (2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—

(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

- (c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—
- (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

- (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

Pre-AIA 35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.

[Editor Note: Not applicable to any patent application subject to the first inventor to file provisions of the AIA (see 35 U.S.C. 100 (note)). See 35 U.S.C. 103 for the law otherwise applicable.]

- (c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.
- (2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if —
- (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
- (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
- (3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

37 CFR 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(g) Applications or patents under reexamination naming different inventors and containing patentably indistinct claims. If an application or a patent under reexamination and at least one other application naming different inventors are owned by the same person and contain patentably indistinct claims, and there is no statement of record indicating that the claimed inventions were commonly owned or subject to an obligation of assignment to the same person on the effective filing date (as defined in § 1.109), or on the date of the invention, as applicable, of the later claimed invention, the Office may require the applicant or assignee to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person on such date, and if not, indicate which named inventor is the prior inventor, as applicable. Even if the

claimed inventions were commonly owned, or subject to an obligation of assignment to the same person on the effective filing date (as defined in § 1.109), or on the date of the invention, as applicable, of the later claimed invention, the patentably indistinct claims may be rejected under the doctrine of double patenting in view of such commonly owned or assigned applications or patents under reexamination.

37 CFR 1.131 Affidavit or declaration of prior invention or to disqualify commonly owned patent or published application as prior art.

- (c) When any claim of an application or a patent under reexamination is rejected under 35 U.S.C. 103 as in effect on March 15, 2013, on a U.S. patent or U.S. patent application publication which is not prior art under 35 U.S.C. 102(b) as in effect on March 15, 2013, and the inventions defined by the claims in the application or patent under reexamination and by the claims in the patent or published application are not identical but are not patentably distinct, and the inventions are owned by the same party, the applicant or owner of the patent under reexamination may disqualify the patent or patent application publication as prior art. The patent or patent application publication can be disqualified as prior art by submission of:
- (1) A terminal disclaimer in accordance with § 1.321(c); and
- (2) An oath or declaration stating that the application or patent under reexamination and patent or published application are currently owned by the same party, and that the inventor named in the application or patent under reexamination is the prior inventor under 35 U.S.C. 104 as in effect on March 15, 2013.

The guidance provided in this section pertains only to a double patenting analysis when the subject matter in the reference is excepted as prior art under 35 U.S.C. 102(b)(2)(C) or the reference is disqualified as prior art under pre-AIA 35 U.S.C. 103(c). The guidance as to the application of the prior art exception in 35 U.S.C. 102(b)(2)(C) or the prior art disqualification in pre-AIA 35 U.S.C. 103(c) in this section as well as MPEP §§ 717.02 et seq., 2146.02, and 2154.02(c) is not determinative as to whether there is a common applicant, assignee, or owner in a double patenting analysis. Specifically, the "same person" requirement in 35 U.S.C. 102(b)(2)(C) and pre-AIA 35 U.S.C. 103(c) that "the subject matter disclosed and the claimed invention" be "owned by the same person or subject to an obligation of assignment to the same person" strictly requires that each owner be the same. For purposes of whether there is a common applicant in a double patenting analysis, the examiner will need to determine the ownership at the time of examination.

This analysis is different from the analysis required by 35 U.S.C. 102(b)(2)(C), which requires determining ownership not later than the effective filing date of the claimed invention, and pre-AIA 35 U.S.C. 103(c), which requires determining ownership at the time the claimed invention was made.

I. DOUBLE PATENTING

Claims in commonly owned applications of different inventive entities may be rejected on the ground of double patenting. This is in accordance with existing case law and prevents an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter. See *In re Zickendraht*, 319 F.2d 225, 138 USPQ 22 (CCPA 1963) (the doctrine is well established that claims in different applications need be more than merely different in form or content and that patentable distinction must exist to entitle applicants to a second patent); see also *In re Christensen*, 330 F.2d 652, 141 USPQ 295 (CCPA 1964).

Claims may also be rejected on the grounds of nonstatutory double patenting in certain non-commonly owned applications that claim inventions resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2). This prevents the parties to the joint research agreement from obtaining two or more patents with different expiration dates covering nearly identical subject matter.

Nonstatutory double patenting rejections can be overcome in certain circumstances by disclaiming, pursuant to the provisions of 37 CFR 1.321(c), the terminal portion of the term of the later patent and including in the disclaimer a provision that the patent shall be enforceable only for and during the period the patent is commonly owned with the application or patent which formed the basis for the rejection, thereby eliminating the problem of extending patent life. Nonstatutory double patenting rejections can also be overcome in cases subject to a joint research agreement, under certain circumstances, by disclaiming the terminal portion of the term of the later patent and including in the disclaimer the provisions of 37 CFR 1.321(d).

See MPEP § 717.02 et seq. for information pertaining to establishment of common ownership and the existence of a joint research agreement pursuant to 35 U.S.C. 102(c), as well as examination practice relating to 35 U.S.C. 102(b)(2)(C). See MPEP § 2146 et seq. for information pertaining to establishment of common ownership and the existence of a joint research agreement pursuant to pre-AIA 35 U.S.C. 103(c), as well as examination practice relating to pre-AIA 35 U.S.C. 103(c).

II. IDENTIFYING COMMONLY OWNED AND NON-COMMONLY OWNED INVENTIONS SUBJECT TO A JOINT RESEARCH AGREEMENT

A. Common Ownership by the Same Person(s) or Organization(s)

Applications or patents are "commonly owned" pursuant to 35 U.S.C. 102(b)(2)(C) if they were wholly or entirely owned by the same person(s), or organization(s)/business entity(ies) not later than the effective filing date of the claimed invention. Applications or patents are "commonly owned" pursuant to pre-AIA 35 U.S.C. 103(c)(1) if they were wholly or entirely owned by the same person(s), or organization(s)/business entity(ies) at the time the claimed invention was made. If the person(s) or organization(s) owned less than 100 percent of the subject matter which would otherwise be prior art to the claimed invention, or less than 100 percent of the claimed invention, then common ownership would not exist. Common ownership requires that the person(s) or organization(s)/business entity(ies) own 100 percent of the subject matter and 100 percent of the claimed invention. See MPEP § 717.02(a), subsection I, and MPEP § 2146.02 for a detailed definition of common ownership. 35 U.S.C. 102(b)(2)(C) provides that disclosures shall not be prior art under 35 U.S.C. 102(a)(2) if the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person. If the prior art exception under 35 U.S.C. 102(b)(2)(C) is properly invoked, the excepted subject matter disclosed in the commonly owned or joint research agreement reference is not available as prior art under 35 U.S.C. 102(a)(2) for both

anticipation and obviousness rejections and also may not be used as a secondary teaching in a nonstatutory double patenting rejection. See MPEP § 717.02(a) for more information on invoking this prior art exception and MPEP § 717.02(b) for more information on evaluating when the exception applies and is properly invoked.

Under <u>pre-AIA 35 U.S.C. 103(c)(1)</u>, two inventions of different inventive entities come within the common ownership provisions when:

- (A) the later invention is not anticipated by the earlier invention under 35 U.S.C. 102;
- (B) the earlier invention qualifies as prior art for purposes of obviousness under 35 U.S.C. 103 against the later invention only under subsections (f) or (g) of 35 U.S.C. 102, or under 35 U.S.C. 102(e) for applications pending on or after December 10, 2004, for reexamination proceedings in which the patent under reexamination was granted on or after December 10, 2004, and for reexamination proceedings in which the patent under reexamination was filed on or after November 29, 1999; and
- (C) the inventions were, at the time the later invention was made, owned by the same person or subject to an obligation of assignment to the same person.

B. Non-Commonly Owned Inventions Subject to a Joint Research Agreement

The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) (Public Law 108-453; 118 Stat. 3596 (2004)), which amended pre-AIA 35 U.S.C. 103(c), was enacted on December 10, 2004. The CREATE Act permits an applicant or patentee, who is a party to a joint research agreement, to disqualify prior art that is applied in a rejection under pre-AIA 35 U.S.C. 103(a) and that is otherwise available as prior art only under pre-AIA 35 U.S.C. 102(e), (f) or (g). Congress recognized that this amendment to pre-AIA 35 U.S.C. 103(c) would result in situations in which there would be double patenting between patents or applications not owned by the same party. See H.R. Rep. No. 108-425, at 5-6 (2003).

Pursuant to the CREATE Act, non-commonly owned applications or patents that are subject to a joint

research agreement may be treated as if they are "commonly owned," i.e., owned or subject to assignment by the same person, for the purposes of determining obviousness if certain conditions are met. See <u>pre-AIA 35 U.S.C. 103(c)(2)</u>. The term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention. See <u>pre-AIA 35 U.S.C. 103(c)(3)</u>. See also <u>MPEP § 2146.02</u>.

Two inventions come within the provisions of pre-AIA 35 U.S.C. 103(c)(2), for pre-AIA applications pending on or after December 10, 2004, and for reexamination proceedings in which the patent under reexamination issued after December 10, 2004 and is subject to pre-AIA law, when:

- (A) the later invention is not anticipated by the earlier invention under <u>35 U.S.C. 102</u>;
- (B) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made:
- (C) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (D) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

The joint research agreement provisions of <u>35 U.S.C.</u> <u>102(c)</u> generally track those of the Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act). See <u>MPEP § 2146.01</u>. The major differences between <u>35 U.S.C. 102(c)</u> and the CREATE Act are the following:

- A. <u>35 U.S.C. 102(c)</u> is keyed to the effective filing date of the claimed invention, while the CREATE Act (<u>pre-AIA 35 U.S.C. 103(c)</u>) focuses on the date that the claimed invention was made; and
- B. The 2004 CREATE Act provisions (pre-AIA 35 U.S.C. 103(c)) only apply to obviousness rejections and not to anticipation and double patenting rejections. This follows from the fact that the CREATE Act merely provides that a reference may not be applied to support obviousness rejections

under <u>pre-AIA 35 U.S.C. 103(a)</u>, while the prior art exceptions of <u>35 U.S.C. 102(b)</u> establish that a reference is not prior art for any purpose.

C. Timing of Double Patenting Rejections

The examiner should make both a double patenting rejection based on common ownership and a rejection based on prior art when the facts support both rejections. Until applicant has established that a reference is excepted as prior art under the joint research agreement defined in 35 U.S.C. 102(c) or disqualified as prior art under the joint research agreement defined in pre-AIA 35 U.S.C. 103(c)(2) and (3), the examiner should NOT apply a double patenting rejection based on a joint research agreement. See MPEP §§ 706.07(a), 717.02(c), and 804, subsection VI, for information regarding when an Office action that includes a new subsequent double patenting rejection based upon a reference subject to a joint research agreement defined in 35 U.S.C. 102(c) and pre-AIA 35 U.S.C. 103(c)(2) and (3) may be made final.

III. DETERMINING INVENTION PRIORITY

A determination of priority is not required when two inventions are commonly owned as set forth in 35 U.S.C. 102(b)(2)(C) or pre-AIA 35 U.S.C. 103(c)(1).

Pursuant to 37 CFR 1.78(g), where an application or a patent under reexamination and at least one other application by different inventive entities are owned by the same party and contain conflicting claims, the examiner may require the assignee to state whether the claimed inventions come within the provisions of 35 U.S.C. 102(b)(2)(C) (i.e., indicate whether common ownership or an obligation of assignment to the same person existed on or before the effective filing date) or pre-AIA 35 U.S.C. 103(c) (i.e., indicate whether common ownership or an obligation of assignment to the same person existed at the time the later invention was made). For example, if the assignee states that the provisions of pre-AIA 35 U.S.C. 103(c) do not apply to the conflicting claimed inventions, the assignee is required to indicate which named inventor is the prior inventor. Form paragraphs 8.27.aia, 8.27.fti, 8.28.aia, 8.28.fti, 8.28.01.aia and 8.28.01.fti may be used to require the applicant to identify the prior inventor under 37 CFR 1.78(g) or to take certain

actions. In order to avoid abandonment, the assignee must comply with the requirements under 37 CFR 1.78(g) unless the conflicting claims are eliminated in all but one application. If, however, the two inventions come within the provisions of 35 U.S.C. 102(b)(2)(C) or pre-AIA 35 U.S.C. 103(c), it is not necessary to determine priority of invention since the earlier invention cannot be used as prior art against the later invention and since double patenting rejections can be used to ensure that the patent terms expire together. Accordingly, a response to a requirement under 37 CFR 1.78(g) which states that the inventions of different inventive entities come within the provisions of 35 U.S.C. 102(b)(2)(C) or pre-AIA 35 U.S.C. 103(c) is complete.

Before making a requirement to identify the prior inventor in an application subject to pre-AIA 35 U.S.C. 102(f) or (g), and threatening to hold the application abandoned if the statement is not made by the assignee, the examiner must make sure that claims in the application under examination or patent under reexamination and the claims in the other application(s) are conflicting as defined in MPEP § 804. See *In re Rekers*, 203 USPQ 1034 (Comm'r Pat. 1979).

In some situations the prosecution file histories may reflect which invention is the prior invention, e.g., by reciting that one invention is an improvement of the other invention. See *Margolis v. Banner*, 599 F.2d 435, 202 USPQ 365 (CCPA 1979) (Court refused to uphold a holding of abandonment for failure to name the prior inventor since the record showed what was invented by the different inventive entities and who was the prior inventor.).

An application in which a requirement to name the prior inventor has been made will not be held abandoned where a timely response indicates that the other application is abandoned or will be permitted to become abandoned and will not be filed as a continuing application. Such a response will be considered sufficient since it renders the requirement to identify the prior inventor moot because the existence of conflicting claims is eliminated. Also, any conflict between two or more pending applications can be avoided by abandoning the applications and filing a continuation-in-part

application merging the conflicting inventions into a single application.

IV. REJECTIONS UNDER 35 U.S.C. 102 AND 103 AND DOUBLE PATENTING

If it is determined that the provisions of 35 U.S.C. 102(b)(2)(C) or pre-AIA 35 U.S.C. 103(c) do NOT apply to a reference disclosure, the examiner should make (A) any appropriate double patenting rejection(s), and (B) the appropriate prior art rejection(s) under 35 U.S.C. 102 and/or 35 U.S.C. 103 in the application being examined. See the charts in MPEP § 804. Rejections under 35 U.S.C. 102 or 35 U.S.C. 103 cannot be obviated solely by filing a terminal disclaimer.

If the prior art exception under 35 U.S.C. 102(b)(2)(C) is properly invoked, the excepted subject matter disclosed in the commonly owned or joint research agreement reference is not available as prior art under 35 U.S.C. 102(a)(2) for an anticipation and/or obviousness rejection, and also may not be used as a secondary reference in a nonstatutory double patenting rejection. However, the claims of a reference excepted under 35 U.S.C. 102(b)(2)(C) may still be the basis for a double patenting rejection, whether statutory or nonstatutory.

If the prior art disqualification under pre-AIA 35 U.S.C. 103(c) is properly invoked, the excepted subject matter disclosed in the commonly owned or joint research agreement reference is not available as prior art under pre-AIA 35 U.S.C. 103(a) for an obviousness rejection. The prior art disqualification under pre-AIA 35 U.S.C. 103(c) does not apply to subject matter that qualifies as anticipatory prior art under pre-AIA 35 U.S.C. 102 and also cannot be used to overcome a double patenting rejection, whether statutory or nonstatutory.

Form paragraphs 8.27.aia, 8.27.fti, 8.28.aia, 8.28.fti, 8.28.01.aia, and 8.28.01.fti may be used to require the applicant to resolve issues that may arise in applications that have different inventors but a common assignee and claim the same or patentably indistinct inventions.

¶ 8.27.aia Different Inventors, Common Assignee, Same Invention, Examined under First Inventor To File (FITF) Provisions of the AIA

Claim [1] directed to the same invention as that of claim [2] of commonly assigned [3]. Under 35 U.S.C. 101, more than one patent may not be issued on the same invention.

The USPTO may not institute a derivation proceeding in the absence of a timely filed petition. The U.S. Patent and Trademark Office normally will not institute a derivation proceeding between applications or a patent and an application having common ownership (see <u>37 CFR 42.411</u>). The applicant should amend or cancel claims such that the reference and the instant application no longer contain claims directed to the same invention.

Examiner Note:

- 1. Form paragraph 7.03.aia must be included in any Office action that contains this paragraph.
- 2. In bracket 3, insert the U.S. patent number or the copending application number.
- 3. The claims listed in brackets 1 and 2 must be for the same invention. If one invention would have been obvious in view of the other, do not use this form paragraph; see form paragraph 8.28.aia.
- 4. A provisional or actual statutory double patenting rejection should also be made using form paragraph 8.31 or 8.32.
- 5. If the commonly assigned application or patent is prior art under 35 U.S.C. 102(a)(2), a rejection may also be made using form paragraph 7.15.01.aia or 7.15.02.aia.

¶ 8.27.fti Different Inventors, Common Assignee, Same Invention, Examined Under Pre-AIA (First to Invent) Provisions

Claim [1] directed to the same invention as that of claim [2] of commonly assigned [3]. The issue of priority under <u>pre-AIA 35 U.S.C. 102(g)</u> and possibly <u>pre-AIA 35 U.S.C. 102(f)</u> of this single invention must be resolved.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application having common ownership (see MPEP Chapter 2300). Either the applicant must amend or cancel claims such that the reference and the instant application no longer contain claims directed to the same invention, or the assignee must state which entity is the prior inventor of the commonly claimed subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under pre-AIA 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Examiner Note:

1. Form paragraph 7.03.fti must be included in any Office action that contains this paragraph.

- 2. In bracket 3, insert the U.S. patent number or the copending application number.
- 3. The claims listed in brackets 1 and 2 must be for the same invention. If one invention would have been obvious in view of the other, do not use this form paragraph; see form paragraph 8.28.fti.
- 4. A provisional or actual statutory double patenting rejection should also be made using form paragraph 8.31 or 8.32.
- 5. If the commonly assigned application or patent is prior art under <u>pre-AIA 35 U.S.C. 102(e)</u>, a rejection may also be made using form paragraph 7.15.01.fti or 7.15.02.fti.
- ¶ 8.28.aia Different Inventors, Common Assignee, Inventions Not Patentably Distinct, No Evidence of Common Ownership Not Later Than the Effective Filing Date of the Claimed Invention, Examined Under First Inventor to File (FITF) Provisions of the AIA

Claim [1] directed to an invention not patentably distinct from claim [2] of commonly assigned [3]. Specifically, [4].

Examiner Note:

- 1. This form paragraph should be used when the application being examined is commonly assigned with an application or patent that includes claims patentably indistinct from those in the present application, but it has not been established that they were commonly owned or deemed to have been commonly owned not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention. See 35 U.S.C. 102(b)(2)(C) and 35 U.S.C. 102(c).
- 2. A rejection under 35 U.S.C. 102(a)(2)/103 using form paragraph 7.21.aia, 7.21.01.aia or 7.21.02.aia also should be made, as appropriate.
- 3. In bracket 3, insert the number of the patent or application that includes claims patentably indistinct from those in the present application.
- 4. A nonstatutory double patenting rejection should also be included in the action using one of form paragraphs 8.34 to 8.37.
- 5. In bracket 4, explain why the claims in the present application and the reference patent or application are patentably indistinct.
- 6. Form paragraph 8.28.01.aia MUST follow this paragraph.
- ¶ 8.28.fti Different Inventors, Common Assignee, Inventions Not Patentably Distinct, No Evidence of Common Ownership at Time of Invention, Examined Under Pre-AIA (First To Invent) Provisions

Claim [1] directed to an invention not patentably distinct from claim [2] of commonly assigned [3]. Specifically, [4].

Examiner Note:

1. This form paragraph should be used when the application being examined is commonly assigned with an application or patent that includes claims patentably indistinct from those in the present application, but there is no indication that they were commonly assigned at the time the invention was made.

- 2. A rejection under pre-AIA 35 U.S.C. 102(e)/103(a) using form paragraph 7.21.fti, 7.21.01.fti or 7.21.02.fti also should be made, as appropriate. Rejections under pre-AIA 35 U.S.C. 102(e)/103(a) should not be made or maintained if the patent is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection.
- 3. In bracket 3, insert the number of the reference patent or application.
- 4. A nonstatutory double patenting rejection should also be included in the action using one of form paragraphs 8.34 to 8.37.
- In bracket 4, explain why the claims in the present application and the reference patent or application are patentably indistinct.
- 6. Form paragraph 8.28.01.fti MUST follow this paragraph.

¶ 8.28.01.aia Advisory Information Relating to Form Paragraph 8.28.aia

The U.S. Patent and Trademark Office may not institute a derivation proceeding in the absence of a timely filed petition. The USPTO normally will not institute a derivation proceeding between applications or a patent and an application having common ownership (see 37 CFR 42.411). Commonly assigned [1], discussed above, may form the basis for a rejection of the noted claims under 35 U.S.C. 102 or 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(a)(2) and the patentably indistinct inventions were not commonly owned or deemed to be commonly owned not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention.

In order for the examiner to resolve this issue the applicant or patent owner can provide a statement under 35 U.S.C. 102(b)(2)(C) and 37 CFR 1.104(c)(4)(i) to the effect that the subject matter and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person. Alternatively, the applicant or patent owner can provide a statement under 35 U.S.C. 102(c) and 37 CFR 1.104(c)(4)(ii) to the effect that the subject matter was developed and the claimed invention was made by or on behalf of one or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention, and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; the application must also be amended to disclose the names of the parties to the joint research agreement.

A showing that the inventions were commonly owned or deemed to be commonly owned not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention will preclude a rejection under 35 U.S.C. 102 or 103 based upon the commonly assigned case. Alternatively, applicant may take action to amend or cancel claims such that the applications, or the patent and the application, no longer contain claims directed to patentably indistinct inventions.

Examiner Note:

This form paragraph should follow form paragraph 8.28.aia and should only be used ONCE in an Office action.

\P 8.28.01.fti Advisory Information Relating to Form Paragraph 8.28.fti

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned [1], discussed above, may form the basis for a rejection of the noted claims under pre-AIA 35 U.S.C. 102 or 103(a) if the commonly assigned case qualifies as prior art under pre-AIA 35 U.S.C. 102(e), (f) or (g) and the patentably indistinct inventions were not commonly owned at the time the claimed invention in this application was made. In order for the examiner to resolve this issue the assignee can, under pre-AIA 35 U.S.C. 103(c) and 37 CFR 1.78(g), either show that the patentably indistinct inventions were commonly owned at the time the claimed invention in this application was made, or name the prior inventor of the subject matter at issue.

A showing that the inventions were commonly owned at the time the claimed invention in this application was made will preclude a rejection under pre-AIA 35 U.S.C. 103(a) based upon the commonly assigned application that qualifies as a reference under pre-AIA 35 U.S.C. 102(e), (f) or (g). Alternatively, applicant may take action to amend or cancel claims such that the applications, or the patent and the application, no longer contain claims directed to patentably indistinct inventions.

Examiner Note:

This form paragraph should follow form paragraph 8.28.fti and should only be used ONCE in an Office action.

¶ 7.15.aia Rejection, 35 U.S.C. 102(a)(1)/102(a)(2)

Claim(s) [1] is/are rejected under <u>35 U.S.C. 102</u> [2] as being [3] by [4].

Examiner Note:

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. In bracket 1, insert the claim numbers which are under rejection.
- 3. In bracket 2, insert either "(a)(1)" or "(a)(2)" or both. If paragraph (a)(2) of 35 U.S.C. 102 is applicable, use form paragraph 7.15.01.aia, 7.15.02.aia or 7.15.03.aia where applicable.
- 4. In bracket 3, insert either --clearly anticipated-- or --anticipated-- with an explanation at the end of the paragraph.
- 5. In bracket 4, insert the prior art relied upon.
- 6. This rejection must be preceded <u>either</u> by form paragraph 7.07.aia and form paragraphs 7.08.aia, and 7.12.aia as appropriate, <u>or</u> by form paragraph 7.103.
- 7. For applications claiming priority to, or the benefit of, an application filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.

¶ 7.15.fti Rejection, Pre-AIA 35 U.S.C. 102(a), (b) Patent or Publication, and (g)

Claim(s) [1] is/are rejected under pre-AIA 35 U.S.C. 102 [2] as being [3] by [4].

Examiner Note:

- 1. In bracket 2, insert the appropriate paragraph letter or letters of pre-AIA 35 U.S.C. 102 in parentheses. If paragraph (e) of pre-AIA 35 U.S.C. 102 is applicable, use form paragraph 7.15.01.fti, 7.15.02.fti or 7.15.03.fti.
- 2. In bracket 3, insert either --clearly anticipated-- or --anticipated-- with an explanation at the end of the paragraph.
- 3. In bracket 4, insert the prior art relied upon.
- 4. This rejection must be preceded either by form paragraph 7.07.fti and form paragraphs 7.08.fti, 7.09.fti, and 7.14.fti as appropriate, or by form paragraph 7.103.
- 5. If pre-AIA 35 U.S.C. 102(e) is also being applied, this form paragraph must be followed by either form paragraph 7.15.01.fti, 7.15.02.fti or 7.15.03.fti.
- 6. For applications with an actual filing date on or after March 16, 2013, that claim priority to, or the benefit of, an application filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.

¶ 7.19.fti Rejection, pre-AIA 35 U.S.C. 102(f), Applicant Not the Inventor

Claim [1] is/are rejected under pre-AIA 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. [2]

Examiner Note:

- 1. This paragraph must be preceded either by paragraphs 7.07.fti and 7.13.fti or by paragraph 7.103.
- 2. In bracket 2, insert an explanation of the supporting evidence establishing that applicant was not the inventor. See MPEP § 2137.

¶ 7.21.aia Rejection, 35 U.S.C. 103

Claim [1] is/are rejected under <u>35 U.S.C. 103</u> as being unpatentable over [2].

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. This form paragraph must be preceded by either form paragraph 7.20.aia or form paragraph 7.103.
- 3. An explanation of the rejection must follow this form paragraph. See MPEP § 2144.
- 4. If this rejection is a provisional <u>35 U.S.C. 103</u> rejection based upon a copending application that would constitute prior art under <u>35 U.S.C. 102(a)(2)</u> if patented or published, use form paragraph 7.21.01.aia instead of this paragraph.

- 5. In bracket 1, insert the claim numbers which are under rejection.
- 6. In bracket 2, insert the prior art relied upon.
- 7. For applications claiming priority to, or the benefit of, an application filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.

¶ 7.21.fti Rejection, Pre-AIA 35 U.S.C. 103(a)

Claim [1] is/are rejected under <u>pre-AIA 35 U.S.C. 103(a)</u> as being unpatentable over [2].

Examiner Note:

- 1. This paragraph must be preceded by either form paragraph 7.20.fti or form paragraph 7.103.
- 2. An explanation of the rejection must follow this form paragraph. See MPEP § 2144.
- If the rejection relies upon prior art under pre-AIA 35 <u>U.S.C. 102(e)</u>, use pre-AIA 35 U.S.C. 102(e) as amended by the American Inventors Protection Act to determine the reference's prior art date, unless the reference is a U.S. patent issued directly, or indirectly, from an international application which has an international filing date prior to November 29, 2000. In other words, use pre-AIPA 35 U.S.C. 102(e) only if the reference is a U.S. patent issued directly or indirectly from either a national stage of an international application (application under 35 U.S.C. 371) which has an international filing date prior to November 29, 2000 or a continuing application claiming benefit under 35 U.S.C. 120, 121 or 365(c) to an international application having an international filing date prior to November 29, 2000. See the Examiner Notes for form paragraphs 7.12.fti and 7.12.01.fti to assist in the determination of the reference's 35 U.S.C. 102(e) date.
- 4. If the applicability of this rejection (e.g., the availability of the prior art as a reference under pre-AIA 35 U.S.C. 102(a) or pre-AIA 35 U.S.C. 102(b)) prevents the reference from being disqualified under pre-AIA 35 U.S.C. 103(c), form paragraph 7.20.01.fti must follow this form paragraph.
- 5. If this rejection is a provisional <u>pre-AIA 35 U.S.C. 103(a)</u> rejection based upon a copending application that would comprise prior art under <u>pre-AIA 35 U.S.C. 102(e)</u> if patented or published, use form paragraph 7.21.01.fti instead of this paragraph.
- In bracket 1, insert the claim numbers which are under rejection.
- 7. In bracket 2, insert the prior art relied upon.

Further, if a copending application has an effectively filed date under 35 U.S.C. 102(d) that is earlier than the effective filing date of claims under examination, the examiner should consider making a provisional rejection based on the copending application, under 35 U.S.C. 102(a)(2), using form paragraph 7.15.01.aia or under 35 U.S.C. 103 using form paragraph 7.21.01.aia. Similarly for pre-AIA applications, rejections should be considered under

pre-AIA 35 U.S.C. 102(e) or 102(e)/103(a), using form paragraph 7.15.01.fti or 7.21.01.fti. Rejections under 35 U.S.C. 102 or 103 cannot be obviated solely by the filing of a terminal disclaimer.

¶ 7.15.01.aia Provisional Rejection, 35 U.S.C. 102(a)(2) - Common Assignee, Common Applicant, or At Least One Common (Joint) Inventor

Claim(s) [1] is/are provisionally rejected under 35 U.S.C. 102(a)(2) as being anticipated by copending Application No. [2] which has a common [3] with the instant application.

The copending application would constitute prior art under 35 U.S.C. 102(a)(2) if published under 35 U.S.C. 122(b) or patented under 35 U.S.C. 151. This provisional rejection under 35 U.S.C. 102(a)(2) is based upon a presumption of future publication or patenting of the copending application. [4].

This provisional rejection under 35 U.S.C. 102(a)(2) might be overcome by: (1) a showing under 37 CFR 1.130(a) that the subject matter disclosed in the copending application was obtained directly or indirectly from the inventor or a joint inventor of this application and is thus not prior art in accordance with 35 U.S.C. 102(b)(2)(A); (2) a showing under 37 CFR 1.130(b) of a prior public disclosure under 35 U.S.C. 102(b)(2)(B); or (3) a statement pursuant to 35 U.S.C. 102(b)(2)(C) establishing that, not later than the effective filing date of the claimed invention, the subject matter disclosed in the copending application and the claimed invention were either owned by the same person or subject to an obligation of assignment to the same person or subject to a joint research agreement.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. This form paragraph is used to provisionally reject over a copending application that discloses the claimed invention and would constitute prior art under 35 U.S.C. 102(a)(2) if published under 35 U.S.C. 122 or patented. The copending application must have either a common assignee, common applicant (35 U.S.C. 118) or at least one common (joint) inventor.
- 3. <u>35 U.S.C. 102(a)(2)</u> may be applied if the reference names another inventor (i.e., a different inventive entity) and is one of the following:
- a. a U.S. patent granted under 35 U.S.C. 151 that has an effectively filed date earlier than the application;
- b. a U.S. Patent Application Publication published under 35 U.S.C. 122(b) that has an effectively filed date earlier than the effective filing date of the claimed invention; or

- c. a WIPO publication of an international application (PCT) or international design application that designates the United States where the WIPO publication has an effectively filed date earlier than the effective filing date of the claimed invention. If any of the three types of prior art documents under 35 U.S.C. 102(a)(2) issued or was published before the effective filing date of the claimed invention under examination, then the prior art document is also applicable under 35 U.S.C. 102(a)(1).
- 4. If the claims would have been obvious over the invention disclosed in the other copending application, use form paragraph 7.21.01.aia.
- 5. In bracket 1, insert claim number(s) under rejection.
- 6. In bracket 2, insert the application number.
- 7. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 8. In bracket 4, provide an appropriate explanation of the examiner's position on anticipation.
- 9. Under 35 U.S.C. 101, two patents are not permitted to issue on identical subject matter. Any claims in the instant application directed to the same invention claimed in the reference should be provisionally rejected using form paragraphs 8.30 and 8.32. Additionally, the applicant should be required to amend or cancel claims such that the applied reference and the instant application no longer contain claims directed to the same invention using form paragraph 8.27.aia.
- 10. Any claims in the instant application that are directed to subject matter that is not patentably distinct from an invention claimed in the reference should be rejected (or provisionally rejected if the reference has not yet issued as a patent) on the grounds of nonstatutory double patenting using form paragraph 8.33 and at least one of form paragraphs 8.34 8.39.
- 11. For applications claiming priority to, or the benefit of, an application filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.

¶ 7.15.01.fti Provisional Rejection, Pre-AIA 35 U.S.C. 102(e) - Common Assignee, Common Applicant, or At Least One Common (Joint) Inventor

Claim(s) [1] is/are provisionally rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by copending Application No. [2] which has a common [3] with the instant application.

The copending application would constitute prior art under pre-AIA 35 U.S.C. 102(e) if published under 35 U.S.C. 122(b) or patented. This provisional rejection under pre-AIA 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application. [4].

This provisional rejection under pre-AIA 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131(a).

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

- 1. This form paragraph is used to provisionally reject over a copending application that discloses the claimed invention and would constitute prior art under pre-AIA 35 U.S.C. 102(e) if published under 35 U.S.C. 122 or patented. The copending application must have either a common assignee, a common applicant (35 U.S.C. 118), or at least one common (joint) inventor.
- 2. Use pre-AIA 35 U.S.C. 102(e) as amended by the American Inventors Protection Act (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 (form paragraph 7.12.fti) to determine the copending application's prior art date, unless the copending application is based directly, or indirectly, from an international application which has an international filing date prior to November 29, 2000. If the copending application is either a national stage of an international application (application under 35 U.S.C. 371) which has an international filing date prior to November 29, 2000, or a continuing application claiming benefit under 35 <u>U.S.C. 120, 121, 365(c)</u>, or <u>386(c)</u> to an international application having an international filing date prior to November 29, 2000, use pre-AIPA 35 U.S.C. 102(e) (form paragraph 7.12.01.fti). See the Examiner Notes for form paragraphs 7.12.fti and 7.12.01.fti to assist in the determination of the reference's 35 U.S.C. 102(e) date.
- 3. If the claims would have been obvious over the invention disclosed in the other copending application, use form paragraph 7.21.01.fti.
- 4. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 5. In bracket 4, an appropriate explanation may be provided in support of the examiner's position on anticipation, if necessary.
- 6. Under 35 U.S.C. 101, two patents are not permitted to issue on identical subject matter. Any claims in the instant application directed to the same invention claimed in the reference should be provisionally rejected using form paragraphs 8.30 and 8.32. Additionally, the applicant should be required to amend or cancel claims such that the applied reference and the instant application no longer contain claims directed to the same invention using form paragraph 8.27.fti.
- 7. Any claims in the instant application that are directed to subject matter that is not patentably distinct from an invention claimed in the reference should be rejected (or provisionally rejected if the reference has not yet issued as a patent) on the grounds of nonstatutory double patenting using form paragraph 8.33 and at least one of form paragraphs 8.34 8.39.
- 8. If evidence is additionally of record to show that either invention is prior art to the other under <u>pre-AIA 35 U.S.C. 102(f)</u> or (g), a rejection using form paragraphs 7.13.fti and/or 7.14.fti should also be made.
- 9. For applications with an actual filing date on or after March 16, 2013 that claim priority to, or the benefit of, an application

filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.

¶ 7.15.02.aia Rejection, 35 U.S.C. 102(a)(2), Common Assignee, Applicant, or Joint Inventor(s)

Claim(s) [1] is/are rejected under <u>35 U.S.C. 102(a)(2)</u> as being [2] by [3].

The applied reference has a common [4] with the instant application. Based upon the earlier effectively filed date of the reference, it constitutes prior art under 35 U.S.C. 102(a)(2). This rejection under 35 U.S.C. 102(a)(2) might be overcome by: (1) a showing under 37 CFR 1.130(a) that the subject matter disclosed in the reference was obtained directly or indirectly from the inventor or a joint inventor of this application and is thus not prior art in accordance with 35 U.S.C. 102(b)(2)(A); (2) a showing under <u>37 CFR 1.130(b)</u> of a prior public disclosure under 35 U.S.C. 102(b)(2)(B) if the same invention is not being claimed; or (3) a statement pursuant to 35 U.S.C. 102(b)(2)(C) establishing that, not later than the effective filing date of the claimed invention, the subject matter disclosed in the reference and the claimed invention were either owned by the same person or subject to an obligation of assignment to the same person or subject to a joint research agreement.

Examiner Note:

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. This form paragraph is used to reject claims as anticipated over a U.S. patent, U.S. patent application publication, or WIPO publication with an earlier prior art date under 35 U.S.C. 102(a)(2). These references must have either a common assignee, a common applicant (35 U.S.C. 118), or at least one common (joint) inventor.
- 3. <u>35 U.S.C. 102(a)(2)</u> may be applied if the reference names another inventor (i.e., a different inventive entity) and is one of the following:
- a. a U.S. patent granted under <u>35 U.S.C. 151</u> that has an effectively filed date earlier than the effective filing date of the claimed invention;
- b. a U.S. Patent Application Publication published under 35 U.S.C. 122(b) that has an effectively filed date earlier than the effective filing date of the claimed invention; or
- c. a WIPO publication of an international application (PCT) or international design application that designates the United States where the WIPO publication has an effectively filed date earlier than the effective filing date of the claimed invention. If any of the three types of prior art documents under 35 U.S.C. 102(a)(2) was published before the effective filing date of the claimed invention under examination, then the prior art
- 4. In bracket 1, insert the claim numbers which are under rejection.

document is also applicable under 35 U.S.C. 102(a)(1).

- 5. In bracket 2, insert either --clearly anticipated-- or --anticipated-- with an explanation at the end of the paragraph.
- 6. In bracket 3, insert the prior art relied upon.
- 7. In bracket 4, insert --assignee--, --applicant--, or --joint inventor--.
- 8. This form paragraph must be preceded by form paragraph 7.12.aia.
- 9. Under 35 U.S.C. 101, two patents are not permitted to issue on identical subject matter. Any claims in the instant application directed to the same invention claimed in the reference should be rejected (or provisionally rejected if the reference has not yet issued as a patent) on the grounds of statutory double patenting using form paragraphs 8.30 8.32. Additionally, the applicant should be required to amend or cancel claims such that the reference and the instant application no longer contain claims directed to the same invention using form paragraph 8.27.aia.
- 10. Any claims in the instant application that are directed to subject matter that is not patentably distinct from an invention claimed in the reference should be rejected (or provisionally rejected if the reference has not yet issued as a patent) on the grounds of nonstatutory double patenting using form paragraph 8.33 and at least one of form paragraphs 8.34 8.39.
- 11. For applications claiming priority to, or the benefit of, an application filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.

¶ 7.15.02.fti Rejection, Pre-AIA 35 U.S.C. 102(e), Common Assignee, Applicant, or Joint Inventor

Claim(s) [1] is/are rejected under <u>pre-AIA 35 U.S.C. 102(e)</u> as being anticipated by [2].

The applied reference has a common [3] with the instant application. Based upon the pre-AIA 35 U.S.C. 102(e) date of the reference, it constitutes prior art. This rejection under pre-AIA 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor or joint inventors (i.e., the inventive entity) of this application and is thus not the invention "by another," or if the same invention is not being claimed, by an appropriate showing under 37 CFR 1.131(a).

- 1. This form paragraph is used to reject over a patent or patent application publication that is prior art under pre-AIA 35 U.S.C.
 102(e) to the claimed invention. The patent or patent application publication must have either a common assignee, a common applicant (35 U.S.C. 118), or a common (joint) inventor.
- 2. Pre-AIA 35 U.S.C. 102(e) as amended by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 (form paragraph 7.12.fti) must be applied if the reference is by another and is one of the following:
- a. a U.S. patent or a publication of a U.S. application for patent filed under 35 U.S.C. 111(a);

- a U.S. patent issued directly or indirectly from, or a U.S. or WIPO publication of, an international application (PCT) if the international application has an international filing date on or after November 29, 2000;
- c. a U.S. patent issued from, or a WIPO publication of, an international design application that designates the United States. See the Examiner Notes for form paragraph 7.12.fti to assist in the determination of the <u>pre-AIA 35 U.S.C. 102(e)</u> date of the reference.
- 3. **Pre-AIPA** 35 U.S.C. 102(e) (form paragraph 7.12.01.fti) must be applied if the reference is a U.S. patent issued directly, or indirectly, from an international application filed prior to November 29, 2000. See the Examiner Notes for form paragraph 7.12.01.fti to assist in the determination of the **pre-AIPA** 35 U.S.C. 102(e) date of the reference.
- 4. In determining the pre-AIA 35 U.S.C. 102(e) date, consider benefit claims to earlier-filed U.S. provisional applications under 35 U.S.C. 119(e), and to earlier-filed U.S. nonprovisional applications and international applications under 35 U.S.C. 120, 121, 365(c), or 386(c) if the subject matter used to make the rejection is appropriately supported in the relied upon earlier-filed application's disclosure (and any intermediate application(s)). A benefit claim to a U.S. patent of an earlier-filed international application, which has an international filing date prior to November 29, 2000, may only result in a prior art date under pre-AIPA 35 U.S.C. 102(e) as of the date the requirements of <u>35 U.S.C. 371(c)(1)</u>, (2) and (4) were fulfilled. Do NOT consider any benefit claims to U.S. applications which are filed before an international application that has an international filing date prior to November 29, 2000. Do NOT consider foreign priority claims under <u>35 U.S.C. 119(a)</u> - (d), <u>365(a)</u> or (b), or 386(a) or (b).

In addition, a reference (i.e., a U.S. patent, published U.S. patent application, or WIPO publication) is entitled to the benefit of the filing date of a provisional application only if at least one of the claims in the reference is supported by the written description of the provisional application in compliance with pre-AIA 35 U.S.C. 112, first paragraph or 35 U.S.C. 112(a). See *Dynamic Drinkware*, *LLC*, *v. National Graphics*, *Inc.*, 800 F.3d 1375, 116 USPQ2d 1045 (Fed. Cir. 2015) and *Amgen v. Sanofi*, 872 F.3d 1367, 1380 (Fed. Cir. 2017).

- 5. If the reference is a publication of an international application (PCT), including voluntary U.S. publication under 35 U.S.C. 122 of the national stage or a WIPO PCT publication, that has an international filing date prior to November 29, 2000, did not designate the United States or was not published in English by WIPO, do not use this form paragraph. Such a reference is not a prior art reference under pre-AIA 35 U.S.C. 102(e). The reference may be applied under pre-AIA 35 U.S.C. 102(a) or (b) as of its publication date. See form paragraphs 7.08.fti and 7.09.fti.
- 6. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 7. This form paragraph must be preceded by either of form paragraphs 7.12.fti or 7.12.01.fti.

- 8. Patent application publications may only be used if this form paragraph was preceded by form paragraph 7.12.fti.
- 9. For applications with an actual filing date on or after March 16, 2013, that claim priority to, or the benefit of, an application filed before March 16, 2013, this form paragraph must be preceded by form paragraph 7.06.
- 10. Under 35 U.S.C. 101, two patents are not permitted to issue on identical subject matter. Any claims in the instant application directed to the same invention claimed in the reference should be rejected (or provisionally rejected if the reference has not yet issued as a patent) using form paragraphs 8.30 8.32. Additionally, the applicant should be required to resolve any issue of priority under pre-AIA 35 U.S.C. 102(g) and possibly pre-AIA 35 U.S.C. 102(f) using form paragraph 8.27.fti. See MPEP § 804, subsection II.A.
- 11. Any claims in the instant application that are directed to subject matter that is not patentably distinct from an invention claimed in the reference should be rejected (or provisionally rejected if the reference has not yet issued as a patent) on the grounds of nonstatutory double patenting using form paragraph 8.33 and at least one of form paragraphs 8.34 8.39.

¶ 7.21.01.aia Provisional Rejection, 35 U.S.C. 103, Common Assignee, Common Applicant, or at Least One Common (Joint) Inventor

Claim [1] is/are provisionally rejected under 35 U.S.C. 103 as being obvious over copending Application No. [2] which has a common [3] with the instant application. The copending application would constitute prior art under 35 U.S.C. 102(a)(2) if published or patented. This provisional rejection under 35 U.S.C. 103 is based upon a presumption of future publication or patenting of the copending application. [4]

This provisional rejection might be overcome by: (1) a showing under 37 CFR 1.130(a) that the subject matter disclosed in the copending application was obtained directly or indirectly from the inventor or a joint inventor of this application and is thus not prior art in accordance with 35 U.S.C. 102(b)(2)(A); (2) a showing under 37 CFR 1.130(b) of a prior public disclosure under 35 U.S.C. 102(b)(2)(B); or (3) a statement pursuant to 35 U.S.C. 102(b)(2)(C) establishing that, not later than the effective filing date of the claimed invention, the subject matter disclosed in the copending application and the claimed invention either were owned by the same person or subject to an obligation of assignment to the same person or subject to a joint research agreement. See generally MPEP § 717.02.

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. This form paragraph is used to provisionally reject claims over a copending application that discloses the claimed invention and would constitute prior art under 35 U.S.C. 102(a)(2) if published under 35 U.S.C. 122 or patented. The copending application must have either a common assignee, common applicant (35 U.S.C. 118) or at least one common (joint) inventor.

- 3. If the claimed invention is fully disclosed in the copending application, use form paragraph 7.15.01.aia.
- 4. In bracket 1, insert the claim number(s) which is/are under rejection.
- 5. In bracket 2, insert the application number.
- 6. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 7. In bracket 4, insert an explanation of obviousness. See MPEP § 2144.
- 8. If the claimed invention is not patentably distinct from the invention claimed in the copending application, a provisional nonstatutory double patenting rejection should additionally be made using form paragraphs 8.33 and 8.37.

¶ 7.21.01.fti Provisional Rejection, Pre-AIA 35 U.S.C. 103(a), Common Assignee, Common Applicant, or at Least One Common (Joint) Inventor

Claim [1] is/are provisionally rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over copending Application No. [2] which has a common [3] with the instant application. The copending application would constitute prior art under pre-AIA 35 U.S.C. 102(e) if published or patented. This provisional rejection under pre-AIA 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the copending application. [4]

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor or joint inventors (i.e., the inventive entity) of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the pre-AIA 35 U.S.C. 102(e)date of the copending application under 37 CFR 1.131(a). This rejection might also be overcome by showing that the copending application is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP § 2146 et seq.

Examiner Note:

- 1. This paragraph is used to provisionally reject claims not patentably distinct from the disclosure in a copending application that would be prior art under pre-AIA 35 U.S.C. 102(e) to the claimed invention if published or issued as a patent and also has either a common assignee, a common applicant (35 U.S.C. 118), or at least one common (joint) inventor. This form paragraph should not be used when the copending application is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection. See MPEP § 2146.03(a).
- 2. Use pre-AIA 35 U.S.C. 102(e) as amended by the American Inventors Protection Act (AIPA) to determine the copending application's prior art date, unless the copending application is based directly, or indirectly, from an international application which has an international filing date prior to November 29, 2000. If the copending application is either a national stage of an international application (application under 35 U.S.C. 371) which has an international filing date prior to November 29, 2000, or a continuing application claiming benefit under 35

- U.S.C. 120, 121, 365(c), or 386(c) to an international application having an international filing date prior to November 29, 2000, use pre-AIPA 35 U.S.C. 102(e) to determine the copending application's prior art date. See the Examiner Notes for form paragraphs 7.12.fti and 7.12.01.fti to assist in the determination of the reference's pre-AIA and pre-AIPA 35 U.S.C. 102(e) dates, respectively.
- 3. If the claimed invention is fully disclosed in the copending application, use paragraph 7.15.01.fti.
- 4. In bracket 1, insert the claim number(s) which is/are under rejection.
- 5. In bracket 2, insert the application number.
- 6. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 7. In bracket 4, insert an explanation of obviousness. See MPEP § 2144.
- 8. If the claimed invention is not patentably distinct from the invention claimed in the copending application, a provisional obviousness double patenting rejection should additionally be made using form paragraphs 8.33 and 8.37.
- 9. A rejection should additionally be made under <u>pre-AIA 35</u> <u>U.S.C. 103(a)</u> using form paragraph 7.21.fti if:
- a. evidence indicates that the copending application is also prior art under <u>pre-AIA 35 U.S.C. 102(f)</u> or (g) (e.g., applicant has named the prior inventor in response to a requirement made using form paragraph 8.28.fti); and
- b. the copending application has not been disqualified as prior art in a <u>pre-AIA 35 U.S.C. 103(a)</u> rejection pursuant to <u>pre-AIA 35 U.S.C. 103(c)</u>.

¶ 7.21.02.aia Rejection, 35 U.S.C. 103, Common Assignee, Common Applicant, or at Least One Common (Joint) Inventor

Claim [1] is/are rejected under 35 U.S.C. 103 as being obvious over [2].

The applied reference has a common [3] with the instant application. Based upon the earlier effectively filed date of the reference, it constitutes prior art under 35 U.S.C. 102(a)(2). [4]

This rejection under 35 U.S.C. 103 might be overcome by: (1) a showing under 37 CFR 1.130(a) that the subject matter disclosed in the reference was obtained directly or indirectly from the inventor or a joint inventor of this application and is thus not prior art in accordance with 35 U.S.C. 102(b)(2)(A); (2) a showing under 37 CFR 1.130(b) of a prior public disclosure under 35 U.S.C. 102(b)(2)(B); or (3) a statement pursuant to 35 U.S.C. 102(b)(2)(C) establishing that, not later than the effective filing date of the claimed invention, the subject matter disclosed and the claimed invention were either owned by the same person or subject to an obligation of assignment to the same person or subject to a joint research agreement. See generally MPEP § 717.02.

Examiner Note:

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. This paragraph is used to reject over a reference (patent or published application) that discloses the claimed invention, and that ONLY qualifies as prior art under 35 U.S.C. 102(a)(2). If the reference qualifies as prior art under 35 U.S.C. 102(a)(1), then this form paragraph should not be used (form paragraph 7.21.aia should be used instead). The reference must have either a common assignee, a common applicant (35 U.S.C. 118), or at least one common (joint) inventor. This form paragraph should **not** be used in applications when the reference is not prior art in view of the 35 U.S.C. 102(b)(2)(C) exception.
- 3. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 4. In bracket 4, insert an explanation of obviousness. See MPEP § 2144.

¶ 7.22.aia Rejection, 35 U.S.C. 103, Further in View Of

Claim [1] is/are rejected under 35 U.S.C. 103 as being unpatentable over [2] as applied to claim [3] above, and further in view of [4].

Examiner Note:

- 1. This form paragraph should only be used in an application filed on or after March 16, 2013, where the claims are being examined under 35 U.S.C. 102/103 as amended by the Leahy-Smith America Invents Act. This form paragraph must be preceded by form paragraph 7.03.aia.
- 2. This form paragraph must be preceded by form paragraph 7.21.aia.
- 3. An explanation of the rejection must follow this form paragraph. See MPEP § 2144.

¶ 7.21.02.fti Rejection, pre-AIA 35 U.S.C. 103(a), Common Assignee, Common Applicant, or at Least One Common (Joint) Inventor

Claim [1] is/are rejected under <u>pre-AIA 35 U.S.C. 103(a)</u> as being obvious over [2].

The applied reference has a common [3] with the instant application. Based upon the pre-AIA 35 U.S.C. 102(e) date of the reference, it constitutes prior art. This rejection under pre-AIA 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the pre-AIA 35 U.S.C. 102(e) date of the reference under 37 CFR 1.131(a); or (3) an oath or declaration under 37 CFR 1.131(c) stating that the application and reference are currently owned by the same party and that the inventor or joint inventors (i.e., the inventive entity) named in the application is the prior inventor under pre-AIA 35 U.S.C..

104 as in effect on March 15, 2013, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP § 2146 et seq. [4]

Examiner Note:

- 1. This paragraph is used to reject over a reference (patent or published application) that discloses the claimed invention, and that only qualifies as prior art under pre-AIA 35 U.S.C. 102(e). If the reference qualifies as prior art under pre-AIA 35 U.S.C. 102(a) or (b), then this form paragraph should not be used (form paragraph 7.21.fti should be used instead). The reference must have either a common assignee, a common applicant (35 U.S.C. 118), or at least one common (joint) inventor. This form paragraph should not be used in applications when the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a pre-AIA 35 U.S.C. 103(a) rejection. See MPEP § 2146.03.
- 2. Pre-AIA 35 U.S.C. 102(e) as amended by the American Inventors Protection Act of 1999 (AIPA) must be applied if the reference is by another and is one of the following:
- a. a U.S. patent or a publication of a U.S. application for patent filed under 35 U.S.C. 111(a);
- a U.S. patent issued directly or indirectly from, or a U.S. or WIPO publication of, an international application (PCT) if the international application has an international filing date on or after November 29, 2000;
- c. a U.S. patent issued from, or a WIPO publication of, an international design application that designates the United States. See the Examiner Notes for form paragraph 7.12.fti to assist in the determination of the pre-AIA 35 U.S.C. 102(e) date of the reference.
- 3. **Pre-AIPA 35 U.S.C. 102(e)** must be applied if the reference is a U.S. patent issued directly, or indirectly, from an international application filed prior to November 29, 2000. See the Examiner Notes for form paragraph 7.12.01.fti to assist in the determination of the **pre-AIPA 35 U.S.C. 102(e)** date of the reference.
- 4. In bracket 1, insert the claim number(s) which is/are under rejection.
- 5. In bracket 2, insert the prior art reference(s) relied upon for the obviousness rejection.
- 6. In bracket 3, insert --assignee--, --applicant--, or --joint inventor--.
- 7. In bracket 4, insert an explanation of obviousness. See MPEP § 2144.

804.04 Submission to Technology Center Director [R-07.2015]

In order to promote uniform practice, every Office action containing a rejection on the ground of nonstatutory double patenting which relies on the parent application to reject the claims in a divisional application where the divisional application was filed because of a requirement to restrict made by the examiner under 35 U.S.C. 121, including a requirement to elect species, must be submitted to the Technology Center Director for approval prior to mailing. If the rejection on the ground of double patenting is disapproved, it shall not be mailed but other appropriate action shall be taken. Note MPEP § 1003.

When a claimed invention that was the subject of a restriction requirement in one application is presented in a divisional application, a nonstatutory double patenting rejection cannot be applied to that claimed invention unless the restriction requirement was withdrawn. A nonstatutory double patenting rejection may be appropriate in situations in which the invention presented in the divisional is not the same invention that was the subject of the restriction requirement. "When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application.... [I]f an examiner issues a restriction requirement between patentably indistinct claims, two patents may issue and prolong patent protection beyond the statutory term on obvious variants of the same invention. This prolongation would occur because <u>section 121</u> would immunize the restricted application against nonstatutory double patenting rejections." Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1381, 68 USPQ2d 1865, 1869 (Fed. Cir. 2003).

"[W]hen the existence of multiple patents is due to the administrative requirements imposed by the Patent and Trademark Office, 35 U.S.C. Section 121 provides that the inventor shall not be prejudiced by having complied with those requirements. Thus when two or more patents result from a PTO restriction requirement, whereby aspects of the original application must be divided into separate applications, Section 121 insulates the ensuing patents from the charge of double patenting." Applied Materials Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1568, 40 USPQ2d 1481, 1484 (Fed. Cir. 1996) (citing Studiengesellschaft

Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 354, 228 USPQ 837, 840 (Fed. Cir. 1986)).

"Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement. If a restriction requirement does not clearly set forth the line of demarcation, then challenged claims could not satisfy the consonance requirement." *Geneva Pharm*, 349 F.3d at 1381, 68 USPQ2d at 1871.

"Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained ... Where that line is crossed the prohibition -[against double patenting in] the third sentence of Section 121 does not apply." Symbol Techs, Inc. v. Opticon, Inc., 935 F.2d 1569, 1579, 19 USPQ2d 1241, 1249 (Fed. Cir. 1991) (quoting Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1440 (Fed. Cir. 1990)); see also MPEP § 804.01. " However, even if such consonance is lost, double patenting does not follow if the requirements of Section 121 are met or if the claims are in fact patentably distinct.... The purpose of Section 121 is to accommodate administrative convenience and to protect the patentee from technical flaws based on this unappealable examination practice." Applied Materials, 98 F.3d at 1568, 40 USPQ at 1484.

804.05 Impact of Patent Term Extension under 35 U.S.C. 156 on Nonstatutory Double Patenting [R-10.2019]

Nonstatutory double patenting does not invalidate any patent term extension (PTE) granted under 35 U.S.C. 156, if the claims are otherwise valid under its pre-PTE expiration date. See *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 128 USPQ2d 1752 (Fed. Cir. 2018). "For example, if a patent, under its original expiration date without a PTE, should have been (but was not) terminally disclaimed because of obviousness-type double patenting, then this court's obviousness-type double patenting case law would apply, and the patent could be invalidated. However, if a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE." *Id.* at 1374, 128

USPQ2d at 1757. The Novartis court upheld the validity of a PTE even when the PTE created a potential nonstatutory double patenting issue due to the later date of enforceability of applicable claims of the patent resulting from the PTE finding that the earlier-expired, patentably indistinct patent was "not a double patenting reference" to extended patent. Id. at 1375, 128 USPQ2d at 1757. Specifically, the court held "[b]y applying statutory construction principles, following this court's precedent in [Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007)], and addressing traditional obviousness-type double patenting principles, we hold that a PTE pursuant to § 156 is valid so long as the extended patent is otherwise valid without the extension." Id. Thus, the court declined to allow "a judge-made doctrine" regarding double patenting to "cut off a statutorily-authorized time extension." Id. at 1375, 128 USPQ2d at 1757.

805 Effect of Improper Joinder in Patent [R-07.2015]

35 U.S.C. 121, last sentence, provides "the validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention." In other words, under this statute, no patent can be held invalid for improper joinder of inventions claimed therein.

806 Determination of Distinctness or Independence of Claimed Inventions [R-08.2012]

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

- (A) Where inventions are independent (i.e., no disclosed relation therebetween), restriction to one thereof is ordinarily proper, MPEP § 806.06.
- (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.
- (D) A reasonable number of species may be claimed when there is an allowable claim generic thereto. 37 CFR 1.141, MPEP § 806.04.

Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct. For (B) and (C) see MPEP § 806.05 - § 806.05(j) and § 809.03. See MPEP § 802.01 for criteria for patentably distinct inventions.

806.01 Compare Claimed Subject Matter [R-07.2022]

In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence. However, a provisional election of a single species may be required where only generic claims are presented and the generic claims recite or encompass such a multiplicity of species that an unduly extensive and burdensome search is necessary. See MPEP \& 803.02 and \& 808.01(a).

806.02 [Reserved]

806.03 Single Embodiment, Claims Defining Same Essential Features [R-07.2022]

Where the claims of an application define the same essential characteristics of a *single* disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.

Where such claims are voluntarily presented in different applications having at least one common (joint) inventor or a common assignee (i.e., no restriction requirement was made by the Office), disclosing the same embodiments, see MPEP \& 804
- \& 804.02.

806.04 Genus and/or Species Inventions [R-08.2012]

Where an application includes claims directed to different embodiments or species that could fall within the scope of a generic claim, restriction between the species may be proper if the species are independent or distinct. However, <u>37 CFR 1.141</u> provides that an allowable generic claim may link a reasonable number of species embraced thereby. The practice is set forth in <u>37 CFR 1.146</u>.

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.

See MPEP § 806.04(d) for the definition of a generic claim, and MPEP § 806.04(e) for a discussion of claims that include one or more species.

806.04(a) [Reserved]

806.04(b) Species May Be Independent or Related Inventions [R-07.2022]

Species may be either independent or related under the particular disclosure. Where species under a claimed genus are not connected in any of design, operation, or effect under the disclosure, the species are independent inventions. See MPEP \& 802.01 and \& 806.06. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP \& 806.05 - \& 806.05(j). If restriction is improper under either practice, it should not be required.

For example, two different subcombinations usable with each other may each be a species of some common generic invention. If so, restriction practice under election of species and the practice applicable to restriction between combination and subcombinations must be addressed.

As a further example, species of carbon compounds may be related to each other as intermediate and final product. Thus, these species are not independent and in order to sustain a restriction requirement, distinctness must be shown. Distinctness is proven if the claims to the intermediate and final products do not overlap in scope (i.e., a claim to the final product does not read on the intermediate, and vice versa) and are not obvious variants and it can be shown that the intermediate product is useful other than to make the final product. Otherwise, the disclosed relationship would preclude their being issued in separate patents. See MPEP § 806.05(j) for restriction practice pertaining to related products, including intermediate-final product relationships.

806.04(c) [Reserved]

806.04(d) Definition of a Generic Claim [R-08.2012]

In an application presenting three species illustrated, for example, in Figures 1, 2, and 3, respectively, a generic claim should read on each of these views; but the fact that a claim does so read is not conclusive that it is generic. It may define only an element or subcombination common to the several species.

In general, a generic claim should require no material element additional to those required by the species claims, and each of the species claims must require all the limitations of the generic claim.

Once a generic claim is allowable, all of the claims drawn to species in addition to the elected species which require all the limitations of the generic claim will ordinarily be allowable over the prior art in view of the allowability of the generic claim, since the additional species will depend thereon or otherwise require all of the limitations thereof. When all or some of the claims directed to one of the species in addition to the elected species do not require all the limitations of the generic claim, see MPEP § 821.04(a).

806.04(e) Claims Limited to Species [R-08.2012]

Claims are definitions or descriptions of inventions. Claims themselves are never species. The scope of a claim may be limited to a single disclosed embodiment (i.e., a single species, and thus be designated a specific species claim). Alternatively, a claim may encompass two or more of the disclosed embodiments (and thus be designated a generic or genus claim).

Species always refer to the different embodiments of the invention.

Species may be either independent or related as disclosed (see MPEP § 806.04 and § 806.04(b)).

806.04(f) Restriction Between Mutually Exclusive Species [R-08.2012]

Where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope.

806.04(g) [Reserved]

806.04(h) Species Must Be Patentably Distinct From Each Other [R-07.2022]

In making a requirement for restriction in an application claiming plural species, the examiner should group together species considered clearly unpatentable over each other.

Where generic claims are allowable, applicant may claim in the *same application* additional species as provided by 37 CFR 1.141. See MPEP § 806.04. Where an applicant files a divisional application claiming a species previously claimed but nonelected in the parent case pursuant to and consonant with a

requirement to restrict, a double patenting rejection of the species claim(s) would be prohibited under 35 U.S.C. 121. See MPEP § 821.04(a) for rejoinder of species claims when a generic claim is allowable.

Where, however, claims to a different species, or a species disclosed but not claimed in a parent case as filed and first acted upon by the examiner, are voluntarily presented in a different application having at least one common (joint) inventor or a common assignee (i.e., no requirement for election pertaining to said species was made by the Office) there should be close investigation to determine whether a double patenting rejection would be appropriate. See MPEP § 804.01 and § 804.02.

806.04(i) Generic Claims Presented In a Separate Application After Issuance of Species Claims [R-07.2022]

If a generic claim is presented in a separate application after the issuance of a patent claiming one or more species within the scope of the generic claim, the Office may reject the generic claim on the grounds of nonstatutory double patenting when the patent and application have at least one common (joint) inventor and/or are either (1) commonly assigned/owned or (2) non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3). See MPEP § <u>804</u>. Applicant may overcome such a rejection by filing a terminal disclaimer. See In re Goodman, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967).

806.05 Related Inventions [R-08.2012]

Where two or more related inventions are claimed, the principal question to be determined in connection with a requirement to restrict or a rejection on the ground of double patenting 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. If nondistinct inventions are claimed in separate applications or patents, double patenting must be held, except where the

additional applications were filed consonant with a requirement to restrict.

Various pairs of related inventions are noted in the following sections. In applications claiming inventions in different statutory categories, only one-way distinctness is generally needed to support a restriction requirement. See MPEP § 806.05(c) (combination and subcombination) and § 806.05(j) (related products or related processes) for examples of when a two-way test is required for distinctness. Related inventions in the same statutory class are considered mutually exclusive, or not overlapping in scope, if a first invention would not infringe a second invention, and the second invention would not infringe the first invention

806.05(a) Combination and Subcombination [R-08.2012]

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

806.05(b) [Reserved]

806.05(c) Criteria of Distinctness Between Combination and Subcombination [R-07.2022]

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 as evidenced by separate classification, status, or field of search and/or a serious examination burden as evidenced by, for example, non-prior art issues relevant to one invention that are not relevant to the other invention. See MPEP § 808.02.

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.

When these factors cannot be shown, such inventions are not distinct.

The following examples are included for general guidance.

I. SUBCOMBINATION ESSENTIAL TO COMBINATION

ABsp/Bsp No Restriction

Where a combination *as claimed* requires the details of a subcombination *as separately claimed*, there is usually no evidence that combination AB_{sp} is patentable without the details of B_{sp} . The inventions are not distinct and a requirement for restriction must not be made or maintained, even if the subcombination has separate utility. This situation can be diagrammed as combination AB_{sp} ("sp" is an abbreviation for "specific"), and subcombination B_{sp} . Thus the specific characteristics required by the subcombination claim B_{sp} are also required by the combination claim. See <u>MPEP § 806.05(d)</u> for situations where two or more subcombinations are separately claimed.

II. SUBCOMBINATION NOT ESSENTIAL TO COMBINATION

A. ABbr/Bsp Restriction Proper

Where a combination as claimed does not require the details of the subcombination as separately claimed and the subcombination has separate utility, the inventions are distinct and restriction is proper if reasons exist for insisting upon the restriction, i.e., there would be a serious search burden as evidenced by separate classification, status, or field of search and/or a serious examination burden as evidenced by, for example, non-prior art issues relevant to one invention that are not relevant to the other invention. See MPEP § 808.02.

This situation can be diagramed as combination AB_{br} ("br" is an abbreviation for "broad"), and subcombination B_{sp} ("sp" is an abbreviation for "specific"). B_{br} indicates that in the combination the subcombination is broadly recited and that the specific characteristics required by the subcombination claim B_{sp} are not required by the combination claim.

Since claims to both the subcombination and combination are presented, the omission of details of the claimed subcombination B_{sp} in the combination claim AB_{br} is evidence that the combination does not rely upon the specific limitations of the subcombination for its patentability. If subcombination B_{sp} has separate utility, the inventions are distinct and restriction is proper if reasons exist for insisting upon the restriction.

In applications claiming plural inventions capable of being viewed as related in two ways, for example, as both combination-subcombination and also as species under a claimed genus, both applicable criteria for distinctness must be demonstrated to support a restriction requirement. See also MPEP § 806.04(b).

Form paragraph 8.15 may be used in combination-subcombination restriction requirements.

¶ 8.15 Combination-Subcombination

Inventions [1] and [2] are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because [3]. The subcombination has separate utility such as [4].

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present

application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to both **combination(s)** and **subcombination(s)** (MPEP § 806.05(c)).
- 2. In bracket 3, specify the limitations of the claimed subcombination that are not required by the claimed combination, or the evidence that supports the conclusion that the combination does not rely upon the specific details of the subcombination for patentability. See MPEP \& 806.05(c), subsection II and \& 806.05(d).
- 3. In bracket 4, suggest utility other than used in the combination.
- 4. Conclude restriction requirement with form paragraph 8.21.

The burden is on the examiner to suggest an example of separate utility. If applicant proves or provides an argument, supported by facts, that the utility suggested by the examiner cannot be accomplished, the burden shifts to the examiner to document a viable separate utility or withdraw the requirement.

B. ABsp/ABbr/Bsp Restriction Proper

The presence of a claim to combination AB_{sp} does not alter the propriety of a restriction requirement properly made between combination AB_{br} and subcombination B_{sp} . Claim AB_{br} is an evidence claim which indicates that the combination does not rely upon the specific details of the subcombination for its patentability. If a restriction requirement can be properly made between combination AB_{br} and subcombination B_{sp} , any claim to combination AB_{sp} would be grouped with combination AB_{br} .

If the combination claims are amended after a restriction requirement such that each combination, as claimed, requires all the limitations of the subcombination as claimed, i.e., if the evidence claim AB_{br} is deleted or amended to require B_{sp} , the restriction requirement between the combination and subcombination should not be maintained.

If a claim to B_{sp} is determined to be allowable, any claims requiring B_{sp} , including any combination claims of the format AB_{sp} , must be considered for rejoinder. See MPEP § 821.04.

III. PLURAL COMBINATIONS REQUIRING A SUBCOMBINATION COMMON TO EACH COMBINATION

When an application includes a claim to a single subcombination, and that subcombination is required by plural claimed combinations that are properly restrictable, the subcombination claim is a linking claim and will be examined with the elected combination (see MPEP § 809.03). The subcombination claim links the otherwise restrictable combination inventions and should be listed in form paragraph 8.12. The claimed plural combinations are evidence that the subcombination has utility in more than one combination. Restriction between plural combinations may be made using form paragraph 8.14.01. See MPEP § 806.05(j).

806.05(d) Subcombinations Usable Together [R-07.2022]

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.

To support a restriction requirement where applicant separately claims plural subcombinations usable together in a single combination <u>and</u> claims a combination that requires the particulars of at least one of said subcombinations, both two-way distinctness and reasons for insisting on restriction are necessary. 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.

See MPEP § 806.05(c). Furthermore, restriction is only proper when there would be a serious search and/or examination burden if restriction were not required. A serious search burden can be evidenced by separate classification, status, or field of search and a serious examination burden can be evidenced

by, for example, non-prior art issues relevant to one invention that are not relevant to the other invention. See MPEP § 808.02.

Where claims to two or more subcombinations are presented along with a claim to a combination that includes the particulars of at least two subcombinations, the presence of the claim to the second subcombination is evidence that the details of the first subcombination are not required for patentability (and vice versa). For example, if an application claims ABC/B/C wherein ABC is a combination claim and B and C are each subcombinations that are properly restrictable from each other, the presence of a claim to C provides evidence that the details of B are not required for the patentability of combination ABC.

Upon determining that all claims directed to an elected combination invention are allowable, the examiner must reconsider the propriety of the restriction requirement. Where the combination is allowable in view of the patentability of at least one of the subcombinations, the restriction requirement between the elected combination and patentable subcombination(s) will be withdrawn; furthermore, any subcombinations that were searched and determined to be allowable must also be rejoined. If a subcombination is elected and determined to be allowable, nonelected claims requiring all the limitations of the allowable claim will be rejoined in accordance with MPEP § 821.04.

Form paragraph 8.16 may be used in restriction requirements between subcombinations.

¶ 8.16 Subcombinations, Usable Together

Inventions [1] and [2] are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case subcombination [3] has separate utility such as [4]. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim

may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to subcombinations usable together (MPEP § 806.05(d)).
- 2. In bracket 3, insert the appropriate group number or identify the subcombination.
- 3. In bracket 4, suggest utility other than with the other subcombination.
- 4. Conclude restriction requirement with form paragraph 8.21.

The examiner must show, by way of example, that one of the subcombinations has utility other than in the disclosed combination.

Care must be taken to determine if the subcombinations are generically claimed.

Where subcombinations as disclosed and claimed are both (a) species under a claimed genus and (b) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to related inventions. If restriction is improper under either practice, it should not be required (MPEP § 806.04(b)).

If applicant proves or provides an argument, supported by facts, that the other use, suggested by the examiner, cannot be accomplished or is not reasonable, the burden is on the examiner to document a viable alternative use or withdraw the requirement.

806.05(e) Process and Apparatus for Its Practice [R-08.2012]

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.

Form paragraph 8.17 may be used to make restriction requirements between process and apparatus.

¶ 8.17 Process and Apparatus

Inventions [1] and [2] are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another materially different process. (MPEP § 806.05(e)). In this case [3].

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to both a **process** and **apparatus for its practice** (MPEP § 806.05(e)).
- 2. In bracket 3, use one or more of the following reasons:
- (a) --the process as claimed can be practiced by another materially different apparatus such as.....-,
- (b) -- the process as claimed can be practiced by hand--,
- (c) --the apparatus as claimed can be used to practice another materially different process such as.....--.
- 3. A process can be practiced by hand if it can be performed without using any apparatus.
- 4. Conclude restriction requirement with form paragraph 8.21.
- 5. All restriction requirements between a process and an apparatus (or product) for practicing the process should be followed by form paragraph 8.21.04 to notify the applicant that if an apparatus claim is found allowable, process claims that depend from or otherwise require all the limitations of the patentable apparatus may be rejoined.

The burden is on the examiner to provide reasonable examples that recite material differences.

If applicant proves or provides convincing argument that there is no material difference or that a process cannot be performed by hand (if examiner so argued), the burden is on the examiner to document another materially different process or apparatus or withdraw the requirement.

806.05(f) Process of Making and Product Made [R-08.2012]

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.

Allegations of different processes or products need not be documented.

A product defined by the process by which it can be made is still a product claim (*In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)) and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process; defining the product in terms of a process by which it is made is nothing more than a permissible technique that applicant may use to define the invention.

If applicant convincingly traverses the requirement, the burden shifts to the examiner to document a viable alternative process or product, or withdraw the requirement.

Form paragraphs 8.18 and 8.21.04 should be used in restriction requirements between product and process of making.

¶ 8.18 Product and Process of Making

Inventions [1] and [2] 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 another materially different product or (2) that the product as claimed can be made by another materially different process (MPEP § 806.05(f)). In the instant case [3].

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to both a **product** and the **process of making** the product (MPEP § 806.05(f)).
- 2. In bracket 3, use one or more of the following reasons:
- (a) --the process as claimed can be used to make a materially different product such as.....--,
- (b) --the product as claimed can be made by a materially different process such as.....--.
- 3. Conclude the basis for the restriction requirement with form paragraph 8.21.
- 4. All restriction requirements between a product and a process of making the product should be followed by form paragraph 8.21.04 to notify the applicant that if a product claim is found allowable, process claims that depend from or otherwise require all the limitations of the patentable product may be rejoined.

¶ 8.21.04 Notice of Potential Rejoinder of Process Claims

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are

subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with <u>37 CFR 1.104</u>. 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 all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. Failure to do so may result in no 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.

Examiner Note:

This form paragraph should appear at the end of any requirement for restriction between a process and a product/apparatus for practicing the process (see form paragraph 8.17), a product/apparatus and a process of making the product/apparatus (see form paragraph 8.18) or between a product/apparatus and a process of using the product/apparatus (see form paragraph 8.20). See MPEP § 821.04 for rejoinder practice.

806.05(g) Apparatus and Product Made [R-08.2012]

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.

Form paragraph 8.19 may be used for restriction requirements between apparatus and product made.

¶ 8.19 Apparatus and Product Made

Inventions [1] and [2] are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a materially different product or (2) that the product as claimed can be made by another materially different apparatus (MPEP § 806.05(g)). In this case [3].

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to both the **apparatus** and **product made** (MPEP § 806.05(g)).
- 2. In bracket 3, use one or more of the following reasons:
- (a) --the apparatus as claimed is not an obvious apparatus for making the product and the apparatus as claimed can be used to make a different product such as.....-,
- (b) --the product can be made by a materially different apparatus such as.....-.
- 3. Conclude restriction requirement with form paragraph 8.21.

The examiner must show by way of example either (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.

The burden is on the examiner to provide an example, but the example need not be documented.

If applicant either proves or provides convincing argument that the alternative example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement.

806.05(h) Product and Process of Using [R-08.2012]

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.

The burden is on the examiner to provide an example, but the example need not be documented.

If the applicant either proves or provides a convincing argument that the alternative use

suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement.

Form paragraphs 8.20 and 8.21.04 should be used in restriction requirements between the product and method of using.

¶ 8.20 Product and Process of Using

Inventions [1] and [2] 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. See MPEP \& 806.05(h). In the instant case [3].

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to both the **product** and **process of using the product** (MPEP § 806.05(h). If claims to a process specially adapted for (i.e., not patentably distinct from) making the product are also presented such process of making claims should be grouped with the product invention. See MPEP § 806.05(i).
- 2. In bracket 3, use one or more of the following reasons:
- (a) --the process as claimed can be practiced with another materially different product such as.....--,
- (b) --the product as claimed can be used in a materially different process such as.....-.
- 3. Conclude the basis for the restriction requirement with form paragraph 8.21.
- 4. All restriction requirements between a product and a process of using the product should be followed by form paragraph 8.21.04 to notify the applicant that if a product claim is found allowable, process claims that depend from or otherwise require all the limitations of the patentable product may be rejoined.

¶ 8.21.04 Notice of Potential Rejoinder of Process Claims

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus 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 all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. Failure to do so may result in no 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.

Examiner Note:

This form paragraph should appear at the end of any requirement for restriction between a process and a product/apparatus for practicing the process (see form paragraph 8.17), a product/apparatus and a process of making the product/apparatus (see form paragraph 8.18) or between a product/apparatus and a process of using the product/apparatus (see form paragraph 8.20). See MPEP § 821.04 for rejoinder practice.

806.05(i) Product, Process of Making, and Process of Using [R-08.2012]

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 (i.e., not patentably distinct from, as defined in MPEP § 806.05(f)) 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 cannot make a showing of distinctness between the process of using and the product (MPEP § 806.05(h)), restriction cannot be required.

Form paragraph 8.20 (See MPEP § 806.05(h)) may be used in product, process of making and process of using situations where the product cannot be restricted from the process of making the product.

See MPEP § 821.04(b) for rejoinder practice pertaining to product and process inventions.

806.05(j) Related Products; Related Processes [R-07.2022]

To support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, both two-way distinctness and reasons for insisting on restriction are necessary, i.e., separate classification, status in the art, or field of search. See MPEP \structure 808.02. See MPEP \structure 806.05(c) for an explanation of the requirements to establish two-way distinctness as it a pplies to inventions in a combination/subcombination relationship. For other 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 (i.e., a claim to the final product does not read on the intermediate, and *vice versa*);
- (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. See <u>MPEP § 802.01</u>.

The burden is on the examiner to provide an example to support the determination that the inventions are distinct, but the example need not be documented. If applicant either proves or provides convincing evidence that the example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement.

As an example, an intermediate product and a final product can be shown to be distinct inventions if the intermediate and final products are mutually exclusive inventions (not overlapping in scope) that are not obvious variants, and the intermediate product as claimed is useful to make something other than the final product as claimed. Typically, the intermediate loses its identity in the final product. See also MPEP § 806.05(d) for restricting between subcombinations disclosed as usable together. See MPEP § 809 - § 809.03 if a generic claim or claim

linking multiple products or multiple processes is present.

Form paragraph 8.14.01 may be used to restrict between related products or related processes; form paragraph 8.14 may be used in intermediate-final product restriction requirements; form paragraph 8.16 may be used to restrict between subcombinations.

¶ 8.14.01 Distinct Products or Distinct Processes

Inventions [1] and [2] are directed to related [3]. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP \u2288 806.05(j). In the instant case, the inventions as claimed [4]. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Examiner Note:

- 1. This form paragraph may be used when claims are presented to two or more related product inventions, or two or more related process inventions, wherein the inventions as claimed are mutually exclusive, i.e., there is no product (or process) that would infringe both of the identified inventions. Use form paragraph 8.15 to restrict between combination(s) and subcombination(s).
- 3. In bracket 3, insert --products -- or --processes--.
- 4. In bracket 4, explain why the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect.
- 5. Conclude restriction requirement with form paragraph 8.21.

¶ 8.14 Intermediate-Final Product

Inventions [1] and [2] are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as [3] and the inventions are deemed patentably distinct because there is nothing of record to show them to be obvious variants.

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to both **an intermediate** and **final product** (MPEP § 806.05(j)).
- 2. Conclude restriction requirement with form paragraph 8.21.

¶ 8.16 Subcombinations, Usable Together

Inventions [1] and [2] are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case subcombination [3] has separate utility such as [4]. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Examiner Note:

- 1. This form paragraph is to be used when claims are presented to subcombinations usable together (MPEP § 806.05(d)).
- 2. In bracket 3, insert the appropriate group number or identify the subcombination.
- 3. In bracket 4, suggest utility other than with the other subcombination.
- 4. Conclude restriction requirement with form paragraph 8.21.

806.06 Independent Inventions [R-07.2022]

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 search and/or examination 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.

Form paragraph 8.20.02 may be used to restrict between independent, unrelated inventions. Form paragraph 8.20.03 may be used to restrict between an unrelated product and process.

¶ 8.20.02 Unrelated Inventions

Inventions [1] and [2] are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01 and MPEP § 806.06). In the instant case, the different inventions [3].

Examiner Note:

- 1. This form paragraph is to be used only when claims are presented to unrelated inventions, e. g., a necktie and a locomotive bearing not disclosed as capable of use together.
- 2. In bracket 3, insert reasons for concluding that the inventions are unrelated.
- 3. This form paragraph must be followed by form paragraph 8.21.

¶ 8.20.03 Unrelated Product and Process Inventions

Inventions [1] and [2] are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP \& 802.01 and <a href=\& 806.06. In the instant case, [3].

Examiner Note:

- 1. In bracket 3, insert reasons for concluding that the inventions are unrelated.
- 2. This form paragraph must be followed by form paragraph 8.21.

807 Patentability Report Practice Has No Effect on Restriction Practice [R-08.2012]

Patentability report practice (MPEP § 705), has no effect upon, and does not modify in any way, the practice of restriction, being designed merely to facilitate the handling of cases in which restriction cannot properly be required.

808 Reasons for Insisting Upon Restriction [R-07.2022]

Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention *as claimed* is either independent or distinct from the other(s); and

(B) the reasons why there would be a serious search and/or examination burden on the examiner if restriction is not required, i.e., the reasons for insisting upon restriction therebetween as set forth in the following sections.

808.01 Reasons for Holding of Independence or Distinctness [R-08.2012]

The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given.

For example, relative to a combination and a subcombination thereof, the examiner should point out the reasons why he or she considers the subcombination to have utility by itself or in other combinations, and why he or she considers that the combination as claimed does not require the particulars of the subcombination as claimed.

Each relationship of claimed inventions should be similarly treated and the reasons for the conclusions of distinctness or independence set forth. Form paragraphs 8.01, 8.02, and 8.14 - 8.20.02 may be used as appropriate to explain why the inventions as claimed are independent or distinct. See MPEP \mathbb{8} 806.05 - \mathbb{8} 806.06.

808.01(a) Species [R-07.2022]

Where there is no disclosure of a relationship between species (see MPEP § 806.04(b)), they are independent inventions. A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious search and/or examination burden on the examiner if restriction is not required. See MPEP § 803 and § 808.02.

Where there is a relationship disclosed between species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction.

When a requirement for restriction between either independent or distinct species is made, applicant must elect a single disclosed species even if applicant disagrees with the examiner's restriction requirement.

Election of species should not be required between claimed species that are considered clearly unpatentable (obvious) over each other. In making a requirement for restriction in an application claiming plural species, the examiner should group together species considered clearly unpatentable over each other.

Election of species may be required prior to a search on the merits (A) in applications containing claims to a plurality of species with no generic claims, and (B) in applications containing both species claims and generic or Markush claims.

In applications where only generic claims are presented, restriction cannot be required unless the generic claims recite or encompass such a multiplicity of species that an unduly extensive and burdensome search would be necessary to search the entire scope of the claim. See MPEP \\$ 803.02 and <a href="\$\\$ 809.02(a). If applicant presents species claims to more than one patentably distinct species of the invention after an Office action on only generic claims, with no restriction requirement, the Office may require the applicant to elect a single species for examination.

In all applications where a generic claim is found allowable, the application should be treated as indicated in MPEP \& 803.02 and & 809.02(a) for guidance regarding how to require restriction between species.

808.02 Establishing Burden [R-07.2022]

Where, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U.S.C. 121 is never proper (MPEP § 806.05). If applicant voluntarily files claims to such related inventions in different applications, double patenting may be held.

Where the inventions as claimed are shown to be independent or distinct under the criteria of MPEP § 806.05(c) - § 806.06, the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious search and/or examination burden on the examiner if restriction is not required. In order to demonstrate a serious search burden, the examiner must show by appropriate explanation one of the following:

- (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. Patents need not be cited to show separate classification.
- (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. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.
- (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. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions.

To demonstrate serious examination burden separate from a serious search burden, the examiner must show by appropriate explanation that the inventions are likely to raise serious examination issues, such as non-prior art issues under 35 U.S.C. 101, pre-AIA 35 U.S.C. 112, first paragraph and/or 35 U.S.C. 112(a). In this situation, a serious examination

burden may exist where issues relevant to one invention are not relevant to the other invention.

809 Linking Claims [R-08.2012]

Linking claims and the inventions they link together are usually either all directed to products or all directed to processes (i.e., a product claim linking properly divisible product inventions, or a process claim linking properly divisible process inventions). The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims; and
- (B) subcombination claims linking plural combinations.

Where an application includes claims to distinct inventions as well as linking claims, restriction can nevertheless be required.

The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions. Where such withdrawn claims have been canceled by applicant pursuant to the restriction

requirement, upon the allowance of the linking claim(s), the examiner must notify applicant that any canceled, nonelected claim(s) which depends from or requires all the limitations of the allowable linking claim may be reinstated by submitting the claim(s) in an amendment. Upon entry of the amendment, the amended claim(s) will be fully examined for patentability. See MPEP § 821.04 for additional information regarding rejoinder.

809.01 [Reserved]

809.02 Election of Species Required [R-07.2022]

809.02(a) Election of Species Required [R-07.2022]

Where restriction between species is appropriate (see MPEP § 808.01(a)) the examiner should send a letter including only a restriction requirement or place a telephone requirement to restrict (the latter being encouraged). See MPEP § 812.01 for telephone practice in restriction requirements.

Action as follows should be taken:

- (A) Identify generic claims or indicate that no generic claims are present. See MPEP § 806.04(d) for definition of a generic claim.
- (B) Clearly identify each (or in aggravated cases at least exemplary ones) of the disclosed species, to which claims are to be restricted. The species are preferably identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, respectively. In the absence of distinct figures or examples to identify the several species, the mechanical means, the particular material, or other distinguishing characteristic of the species should be stated for each species identified. If the species cannot be conveniently identified, the claims may be grouped in accordance with the species to which they are restricted. Provide reasons why the species are independent or distinct.
- (C) Applicant should then be required to elect a single disclosed species under 35 U.S.C. 121, and

advised as to the requisites of a complete reply and their rights under 37 CFR 1.141.

To be complete, a reply to a requirement made according to this section should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added.

In those applications wherein a requirement for restriction is accompanied by an action on the elected claims, such action will be considered to be an action on the merits and the next action may be made final where appropriate in accordance with MPEP \sigma 706.07(a).

For treatment of claims held to be drawn to nonelected inventions, see MPEP § 821 et seq.

¶ 8.01 Election of Species; Species Claim(s) Present

This application contains claims directed to the following patentably distinct species [1]. The species are independent or distinct because [2]. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under <u>35 U.S.C. 121</u> to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, [3] generic.

There is a serious search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: [4].

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, 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.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election

is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them 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 species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Examiner Note:

- 1. In bracket 1, identify the species and/or grouping(s) of patentably indistinct species from which an election is to be made. The species may be identified as the species of figures 1, 2, and 3, for example, or the species of examples I, II, and III, respectively. Where the election requirement identifies a grouping of patentably indistinct species, applicant should not be required to elect a specific species within that grouping.
- 2. In bracket 2 insert the reason(s) why the species or grouping(s) of species are independent or distinct. See MPEP § 806.04(b), § 806.04(f) and § 806.04(h). For example, insert --the claims to the different species recite the mutually exclusive characteristics of such species--, and provide a description of the mutually exclusive characteristics of each species or grouping of species.
- 3. In bracket 3 insert the appropriate generic claim information.
- 4. In bracket 4 insert the applicable reason(s) why there is a serious search and/or examination burden as listed below.
- -For a serious search burden list one or more of the following:
- --the species or groupings of patentably indistinct species have acquired a separate status in the art in view of their different classification;
- --the species or groupings of patentably indistinct species have acquired a separate status in the art due to their recognized divergent subject matter; and/or
- --the species or groupings of patentably indistinct species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).
- -For a serious examination burden explain the reason, such as non-prior art issues under 35 U.S.C. 101, pre-AIA 35 U.S.C. 112, first paragraph, and/or 35 U.S.C. 112(a) are relevant to one species or grouping of patentably indistinct species that are not relevant to the other species or grouping(s) of patentably indistinct species.
- 5. This form paragraph does not need to be followed by form paragraph 8.21.

\P 8.02 Requiring an Election of Species; No Species Claim Present

Claim(s) [1] is/are generic to the following disclosed patentably distinct species: [2]. The species are independent or distinct because [3]. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under <u>35 U.S.C. 121</u> to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a serious search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: [4]

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement <u>may</u> be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, 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.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them 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 species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Examiner Note:

- 1. This form paragraph should be used for the election of species requirement described in MPEP § 803.02 (Markush group) and MPEP § 808.01(a) where only generic claims are presented.
- 2. In bracket 1, insert the claim number(s).

- 3. In bracket 2, clearly identify the species and/or grouping(s) of patentably indistinct species from which an election is to be made. The species may be identified as the species of figures 1, 2, and 3, for example, or the species of examples I, II, and III, respectively. Where the election requirement identifies a grouping of patentably indistinct species, applicant should not be required to elect a specific species within that grouping.
- 4. In bracket 3 insert the reason(s) why the species or groupings of species as disclosed are independent or distinct. See MPEP § 806.04(b), § 806.04(f) and MPEP § 806.04(h). For example, insert --as disclosed the different species have mutually exclusive characteristics for each identified species--, and provide a description of the mutually exclusive characteristics of each species or grouping of species.
- 5. In bracket 4 insert the applicable reason(s) why there is a serious search and/or examination burden as listed below.
- -For a serious search burden list one or more of the following:
- --the species or groupings of patentably indistinct species have acquired a separate status in the art in view of their different classification;
- --the species or groupings of patentably indistinct species have acquired a separate status in the art due to their recognized divergent subject matter; and/or
- --the species or groupings of patentably indistinct species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).
- -For a serious examination burden explain the reason, such as non-prior art issues under 35 U.S.C. 101, pre-AIA 35 U.S.C. 112, first paragraph, and/or 35 U.S.C. 112(a) are relevant to one species or grouping of patentably indistinct species that are not relevant to the other species or grouping(s) of patentably indistinct species.
- 6. This form paragraph does <u>not</u> need to be followed by form paragraph 8.21.

809.03 Restriction Between Linked Inventions [R-07.2022]

Where an application includes two or more otherwise properly divisible inventions that are linked by a claim which, if allowable, would require rejoinder (See MPEP § 809 and § 821.04), the examiner should require restriction, either by a written Office action that includes only a restriction requirement or by a telephoned requirement to restrict (the latter being encouraged). Examiners should use form paragraph 8.12 to make restrictions involving linking claims when the linking claim is other than a genus claim linking species inventions. When the linking claim is a genus claim linking species inventions,

examiners should use form paragraph 8.01 or 8.02 (see MPEP § 809.02(a)).

¶ 8.12 Restriction, Linking Claims

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 indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with <u>37 CFR 1.104</u>. Claims that require all the limitations of an allowable linking claim 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 <u>37 CFR 1.116</u>; amendments submitted after allowance are governed by <u>37 CFR 1.312</u>.

Applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim 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, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. This form paragraph must be included in any restriction requirement with at least one linking claim present.
- 2. In bracket 4, insert either --between-- or --among--.
- 3. In bracket 5, insert the claim number(s) of the linking claims.
- 4. See related form paragraphs 8.45, 8.46 and 8.47.

Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions.

For traverse of a restriction requirement with linking claims, see <u>MPEP § 818.01(d)</u>.

For treatment of claims held to be drawn to nonelected inventions, see <u>MPEP § 821</u> et seq.

810 Action on the Merits [R-07.2015]

In general, in an application when only a nonfinal written requirement to restrict is made, no action on

the merits is given. A 2-month 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 <u>37 CFR 1.136(a)</u>. The Office action making the restriction requirement final also ordinarily includes an action on the merits of the claims of the elected invention. See <u>37 CFR 1.143</u>. In those applications wherein a requirement for restriction is made via telephone and applicant makes an oral election of a single invention, the written record of the restriction requirement will be accompanied by a complete action on the merits of the elected claims. See MPEP § 812.01. The restriction requirement should be made final as soon as reasonably possible. If the election is made with traverse, it is proper to make the restriction requirement final after consideration of the reasons for traversal. See MPEP § 821.01.

811 Time for Making Requirement [R-07.2022]

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 requiring restriction of claims previously examined on the merits, the examiner must consider whether there will be a serious search and/or examination burden if restriction is not required.

811.01 [Reserved]

811.02 New Requirement After Compliance With Preceding Requirement [R-08.2012]

Since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 OG 1588 (Comm'r Pat. 1904).

811.03 Repeating After Withdrawal Proper [R-08.2012]

Where a requirement to restrict is made and thereafter withdrawn as improper, if restriction becomes proper at a later stage in the prosecution, restriction may again be required.

811.04 Proper Even Though Grouped Together in Parent Application [R-08.2012]

Even though inventions are grouped together in a requirement in a parent application, restriction or election among the inventions may be required in the divisional applications, if proper.

812 Who Should Make the Requirement [R-07.2022]

The examiner to which the application has been assigned will make the restriction requirement, unless the classification is not reasonably correct and complete. In this instance the examiner assigned the application will submit a C-Star (C*) classification challenge on the unrestricted application to have the C* classification picture corrected. If the C* challenge is proper, the application may be reassigned to another examiner whose portfolio matches the new classification picture. The newly assigned examiner would then make the restriction requirement, if appropriate.

812.01 Telephone Restriction Practice [R-07.2022]

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 and/or generic. Thereupon, the examiner should telephone the attorney or agent of record and request an oral election, with or without traverse. The examiner should arrange for a second telephone call within a reasonable time, generally within 3 working days, to provide time for the attorney or agent to consider the requirement. If the attorney or agent objects to making an oral election, or fails to respond, a restriction requirement will be mailed, and should contain reference to the

unsuccessful telephone call. When an oral election is made, the examiner will then proceed to incorporate into the next 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 and/or generic claims if present. 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.

Form paragraphs 8.23 or 8.23.01 should be used to make a telephone election of record.

¶ 8.23 Requirement, When Elected by Telephone

During a telephone conversation with [1] on [2] a provisional election was made [3] traverse to prosecute the invention of [4], claim [5]. Affirmation of this election must be made by applicant in replying to this Office action. Claim [6] withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Examiner Note:

- 1. In bracket 3, insert --with-- or --without--, whichever is applicable.
- 2. In bracket 4, insert either the elected group or species.
- 3. An action on the merits of the claims to the elected invention should follow.

¶ 8.23.01 Requirement, No Election by Telephone

A telephone call was made to [1] on [2] to request an oral election to the above restriction requirement, but did not result in an election being made.

Examiner Note:

- 1. In bracket 1, insert the name of the applicant or attorney or agent contacted.
- 2. In bracket 2, insert the date(s) of the telephone contact(s).
- 3. This form paragraph should be used in all instances where a telephone election was attempted and the applicant's representative did not or would not make an election.
- 4. This form paragraph should **not** be used if no contact was made with applicant or applicant's representative.

Registered attorneys or agents not of record in a patent application should not be contacted for restriction requirements. See MPEP § 408. If an Application Data Sheet lists one or more attorneys or agents under representative information, but a

valid power of attorney has not been filed in the application, telephone restriction practice is not permitted, and form paragraph 8.23.03 should be used.

\P 08.23.03 No Telephone Restriction Permitted, No Attorney or Agent of Record, Practitioner Included in ADS

Telephone restriction practice is not permitted because it appears applicant has legal representation but a valid power of attorney has not been filed in the present application. Providing representative information in an Application Data Sheet (ADS) does not constitute a power of attorney. See 37 CFR 1.76(b)(4) and MPEP § 408. For information on appointing a power of attorney, see MPEP § 402.02 et seq.

Examiner Note:

This form paragraph should be used ONLY when a practitioner or customer number is identified in the ADS but no power of attorney is of record.

If, on examination, the examiner finds the claims to an invention elected without traverse to be allowable and no nonelected invention is eligible for rejoinder (see MPEP § 821.04), the restriction requirement should be attached to the Notice of Allowability form PTOL-37 and should include cancelation of the nonelected claims, and a statement that the prosecution is closed and that a notice of allowance will be sent in due course. Correction of formal matters in the above-noted situation which cannot be handled by a telephone call and thus requires action by the applicant should be handled under the *Ex parte Quayle* practice, using Office Action Summary form PTOL-326.

Should the elected invention as claimed be found allowable in the first action, and an oral traverse was noted, the examiner should include in the action a statement under MPEP § 821.01, making the restriction requirement final and giving applicant two months to either cancel the claims drawn to the nonelected invention or take other appropriate action. (37 CFR 1.144). Failure to take action will be treated as an authorization to cancel the nonelected claims by an examiner's amendment and pass the application to issue. Prosecution of the application is otherwise closed.

In either situation (traverse or no traverse), caution should be exercised to determine if any of the allowable claims are linking and/or generic claims, or if any nonelected inventions are eligible for rejoinder (see MPEP § 821.04), before canceling claims drawn to the nonelected invention.

When a telephonic election results in the withdrawal of claims such that the assigned examiner believes that the C* classification picture is incorrect, the examiner should enter a C* classification challenge. In this instance, the examiner must document the complete restriction requirement using the internal "Telephonic Restriction and Election Summary" form indicating: the groups and species of invention(s) and, if necessary, the classification thereof; the claims corresponding to each group; the elected invention and/or species; the date of the election; the applicant or applicant representative making the election; and whether the election was with or without traverse. This form is not mailed and is used only to document the restriction requirement until such time as an action on the merits of the elected claims is mailed. After completion of the form the assigned examiner will submit a C* classification picture challenge indicating that the challenge was the result of an election.

If the C* classification challenge results in the application remaining with the examiner, the examiner will incorporate the written restriction and election into the next Office action. If the C* classification challenge results in the application being reassigned, the newly assigned examiner will document the substance of the internal "Telephonic Restriction and Election Summary" form in the next Office action as indicated above. If the newly assigned examiner disagrees with the original restriction requirement, differences should be settled by the existing chain of command, e.g., supervisory patent examiner or TC Director.

Telephone restriction practice is limited to use by examiners who have at least negotiation authority. Other examiners must have the prior approval of their supervisory patent examiner or their reviewing primary examiner. See MPEP \sigma 707.01.

813 [Reserved]

814 Indicate Exactly How Application Is To Be Restricted [R-07.2022]

The examiner must provide a <u>clear and detailed record</u> of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a divisional application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under <u>35 U.S.C. 121</u>. *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381, 68 USPQ2d 1865, 1871 (Fed. Cir. 2003). See also MPEP § 804.01.

I. SPECIES

The mode of indicating how to require restriction between species is set forth in MPEP § 809.02(a).

The particular limitations in the claims and the reasons why such limitations are considered to support restriction of the claims to a particular disclosed species should be mentioned if necessary to make the requirement clear. Form paragraph 8.01 or 8.02 may be used to require an election of species.

II. INVENTIONS OTHER THAN SPECIES

It is necessary to read all of the claims to determine what the claims cover. When doing this, the claims directed to each separate invention should be noted along with a statement of the invention to which they are drawn.

In setting forth the restriction requirement, separate inventions should be identified by a grouping of the claims with a short description of the total extent of the invention claimed in each group, specifying the type or relationship of each group as by stating the group is drawn to a process, or to a subcombination, or to a product, etc., and should indicate the classification or separate status of each group, as for example, by class and subclass. See MPEP \\$ 817 for additional guidance.

While every claim should be accounted for, the omission to group a claim, or placing a claim in the wrong group will not affect the propriety of a final requirement where the requirement is otherwise proper and the correct disposition of the omitted or erroneously grouped claim is clear.

III. LINKING CLAIMS

The generic or other linking claims should not be associated with any one of the linked inventions since such claims must be examined with the elected linked invention. See MPEP § 809.

815 Make Requirement Complete [R-07.2022]

When making a restriction requirement, every effort should be made to have the requirement be complete. If some of the claimed inventions are classifiable in a technology that the examiner does not examine and the examiner has any doubt as to the proper restriction among the claimed inventions, the application should be referred to an examiner who regularly examines that technology, and such examiner should render the necessary assistance.

816 [Reserved]

817 Outline of Letter for Restriction Requirement [R-07.2022]

The following outline should be used to set forth a requirement to restrict.

OUTLINE OF RESTRICTION REQUIREMENT

- (A) Statement of the requirement to restrict and that it is being made under <u>35 U.S.C. 121</u>.
 - (1) Identify each group by Roman numeral.
- (2) List claims in each group. Check accuracy of numbering of the claims; look for same claims in two groups; and look for omitted claims.
- (3) Give short description of total extent of the subject matter claimed in each group, pointing out critical claims of different scope and identifying whether the claims are directed to a combination, subcombination, process, apparatus, or product.

(4) Classify each group.

Form paragraphs 8.08-8.11 should be used to group inventions.

¶ 8.08 Restriction, Two Groupings

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

- I. Claim [1], drawn to [2], classified in [3].
- II. Claim [4], drawn to [5], classified [6].

Examiner Note:

In brackets 3 and 6, insert CPC subclass and main group/subgroup if classified in the Cooperative Patent Classification or USPC class and subclass if classified in the United States Patent Classification. For example, if examined in CPC, enter CPC main group xxx, subgroup yyy.

¶ 8.09 Restriction, 3rd Grouping

III. Claim [1], drawn to [2], classified in [3].

Examiner Note:

In bracket 3, insert CPC subclass and main group/subgroup if classified in the Cooperative Patent Classification or USPC class and subclass if classified in the United States Patent Classification. For example, if examined in CPC, enter CPC main group xxx, subgroup yyy.

¶ 8.10 Restriction, 4th Grouping

IV. Claim [1], drawn to [2], classified in [3].

Examiner Note:

In bracket 3, insert CPC subclass and main group/subgroup if classified in the Cooperative Patent Classification or USPC class and subclass if classified in the United States Patent Classification. For example, if examined in CPC, enter main group xxx, subgroup yyy.

¶ 8.11 Restriction, Additional Groupings

[1]. Claim [2], drawn to [3], classified in [4].

Examiner Note:

- 1. In bracket 1, insert the appropriate roman numeral, e.g., --V--, --VI--, etc.
- 2. In bracket 4, insert CPC subclass and main group/subgroup if classified in the Cooperative Patent Classification or USPC class and subclass if classified in the United States Patent Classification or. For example, if examined in CPC, enter CPC main group xxx, subgroup yyy.

If restriction is required between species, form paragraph 8.01 or 8.02 should be used to set forth the species from which applicant is required to elect and the reasons for holding the species to be independent or distinct. See MPEP § 809.02(a).

- (B) Take into account claims not grouped, indicating their disposition.
 - (1) Linking claims
 - (i) Identify
- (ii) Statement of groups to which linking claims may be assigned for examination
 - (2) Other ungrouped claims
- (3) Indicate disposition, e.g., improperly dependent, canceled, etc.
 - (C) Allegation of independence or distinctness
- (1) Point out facts which show independence or distinctness
- (2) Treat the inventions as claimed, don't merely state the conclusion that inventions in fact are independent or distinct, e.g.,
- (i) Subcombination Subcombination disclosed as usable together

Each usable alone or in other identified combination

Demonstrate by examiner's suggestion

(ii) Combination - Subcombination

Combination as claimed does not require subcombination AND subcombination usable alone or in other combination

Demonstrate by examiner's suggestion

(iii) Process - Apparatus

Process can be carried out by hand or by other apparatus

Demonstrate by examiner's suggestion OR Demonstrate apparatus can be used in other process (rare)

(iv) Process of making and/or Apparatus for making - Product made

Claimed product can be made by other process (or apparatus)

Demonstrate by examiner's suggestion OR Demonstrate process of making (or

apparatus for making) can produce other product (rare)

(v) Process of making - Process of using

Product used in claimed process can be made by process materially different from that claimed

Demonstrate by examiner's

suggestion

OR

Product made by claimed process of making can be used in a process materially different from that claimed

Demonstrate by examiner's suggestion.

- (D) Provide reasons for insisting upon restriction
 - (1) Separate status in the art
 - (2) Different classification
- (3) Same classification but recognition of divergent subject matter
 - (4) Divergent fields of search, or
- (5) Search required for one group not required for the other
 - (E) Summary statement
- (1) Summarize (i) independence or distinctness and (ii) reasons for insisting upon restriction
- (2) Include paragraph advising as to reply required
- (3) Indicate effect of allowance of linking claims, if any present
- (4) Indicate effect of cancelation of evidence claims (see MPEP § 806.05(c))
- (5) Indicate effect of allowance of product claims if restriction was required between a product and a process of making and/or using the product.

Form paragraphs 8.14-8.20.02 may be used as appropriate to set forth the reasons for the holding of independence or distinctness. Form paragraph 8.13 may be used as a heading.

¶ 8.13 Distinctness (Heading)

The inventions are independent or distinct, each from the other because:

Examiner Note:

This form paragraph should be followed by one of form paragraphs 8.14-8.20.02 to show independence or distinctness.

Form paragraph 8.21 must be used at the conclusion of all restriction requirements other than those containing only election of species, with or without an action on the merits.

\P 8.21 To Establish Burden AND Requirement for Election and Means for Traversal for all Restrictions, other than an Election of Species

Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

[1].

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of an invention to be examined even though the requirement may be traversed (37 <u>CFR 1.143</u>) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. 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 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Examiner Note:

1. THIS FORM PARAGRAPH MUST BE ADDED TO ALL RESTRICTION REQUIREMENTS <u>other than</u> those containing **only election of species**, with or without an action on the merits, or an those containing only an election by original presentation requirement. This form paragraph only needs to be used once, after all restriction requirements are set out.

- 2. In bracket 1 insert the applicable reason(s) why there is a serious search and/or examination burden.
- -For a serious search burden list one or more of the following:
- -- the inventions have acquired a separate status in the art in view of their different classification;
- --the inventions have acquired a separate status in the art due to their recognized divergent subject matter; and/or
- --the inventions require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).
- -For a serious examination burden explain the reason, such as non-prior art issues under 35 U.S.C. 101, pre-AIA 35 U.S.C. 112, first paragraph, and/or 35 U.S.C. 112(a) are relevant to one invention that are not relevant to the other invention(s).

¶ 8.27.aia Different Inventors, Common Assignee, Same Invention, Examined under First Inventor To File (FITF) Provisions of the AIA

Claim [1] directed to the same invention as that of claim [2] of commonly assigned [3]. Under 35 U.S.C. 101, more than one patent may not be issued on the same invention.

The USPTO may not institute a derivation proceeding in the absence of a timely filed petition. The U.S. Patent and Trademark Office normally will not institute a derivation proceeding between applications or a patent and an application having common ownership (see <u>37 CFR 42.411</u>). The applicant should amend or cancel claims such that the reference and the instant application no longer contain claims directed to the same invention.

Examiner Note:

- 1. Form paragraph 7.03.aia must be included in any Office action that contains this paragraph.
- 2. In bracket 3, insert the U.S. patent number or the copending application number.
- 3. The claims listed in brackets 1 and 2 must be for the same invention. If one invention would have been obvious in view of the other, do not use this form paragraph; see form paragraph 8.28.aia.
- 4. A provisional or actual statutory double patenting rejection should also be made using form paragraph 8.31 or 8.32.
- 5. If the commonly assigned application or patent is prior art under 35 U.S.C. 102(a)(2), a rejection may also be made using form paragraph 7.15.01.aia or 7.15.02.aia.

¶ 8.28.aia Different Inventors, Common Assignee, Inventions Not Patentably Distinct, No Evidence of Common Ownership Not Later Than the Effective Filing Date of the Claimed Invention, Examined Under First Inventor to File (FITF) Provisions of the AIA

Claim [1] directed to an invention not patentably distinct from claim [2] of commonly assigned [3]. Specifically, [4].

Examiner Note:

- 1. This form paragraph should be used when the application being examined is commonly assigned with an application or patent that includes claims patentably indistinct from those in the present application, but it has not been established that they were commonly owned or deemed to have been commonly owned not later than the effective filing date under 35 U.S.C. 100(i) of the claimed invention. See 35 U.S.C. 102(b)(2)(C) and 35 U.S.C. 102(c).
- 2. A rejection under 35 U.S.C. 102(a)(2)/103 using form paragraph 7.21.aia, 7.21.01.aia or 7.21.02.aia also should be made, as appropriate.
- 3. In bracket 3, insert the number of the patent or application that includes claims patentably indistinct from those in the present application.
- 4. A nonstatutory double patenting rejection should also be included in the action using one of form paragraphs 8.34 to 8.37.
- 5. In bracket 4, explain why the claims in the present application and the reference patent or application are patentably indistinct.
- 6. Form paragraph 8.28.01.aia MUST follow this paragraph.

Form paragraph 8.23.02 must be included in all restriction requirements for applications having joint inventors.

¶ 8.23.02 Joint Inventors, Correction of Inventorship

Applicant is reminded that upon the cancelation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Examiner Note:

This form paragraph must be included in all restriction requirements for applications having joint inventors.

818 Election and Reply [R-07.2022]

Election is the designation by applicant of the one of two or more inventions or patentably distinct species, or of the group of patentably indistinct species, that will be prosecuted in the application. See MPEP § 803.02.

When two or more independent and distinct inventions are presented for examination, the examiner may make a restriction requirement if a serious search and/or examination burden exists. In the reply to the restriction requirement, applicant

must elect one invention for examination. If applicant wishes to traverse the restriction requirement, the reply must also include a traversal with specific reasons why applicant believes the restriction requirement is in error. See 37 CFR 1.111 and MPEP § 818.01. Applicant must make their own election; the examiner will not make the election for the applicant.

Election becomes fixed when the claims in an application have received an action on their merits by the Office. If, after receiving an action on the merits of an invention, one or more properly divisible additional inventions are subsequently presented for examination, the examiner may deem the examined invention to be the invention elected by original presentation. See MPEP § 818.02(a).

818.01 Election in Reply to a Restriction Requirement: Express [R-07.2022]

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 therefor. (See § 1.111). 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 for restriction may be made either with or without an accompanying traverse of the requirement. A complete reply to a restriction requirement must include an election even if applicant traverses the requirement.

A traverse is a request for reconsideration of a requirement to restrict that must include a written statement of the reasons for traverse, distinctly and specifically pointing out the supposed errors upon which the applicant relies for concluding that the requirement is in error. The absence of any statement indicating whether the requirement to restrict is traversed or the failure to provide reasons for traverse will be treated as an election without traverse.

Where a rejection or objection is included with a restriction requirement, applicant, besides making a proper election, must also distinctly and specifically point out any supposed errors in the examiner's rejection or objection, or amend and argue that as amended the objection or rejection is moot. See 37 CFR 1.111.

Applicant must make their own election; the examiner will not make the election for the applicant. See 37 CFR 1.142 and 37 CFR 1.143.

818.01(a) Reply Must be Complete [R-07.2015]

As indicated in the first sentence of 37 CFR 1.143, the traverse to a requirement for restriction must be complete as required by 37 CFR 1.111(b). Under this rule, the applicant is required to specifically point out the reason(s) on which he or she bases his or her conclusion(s) 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 (see MPEP § 818.01(b)) becomes an election without traverse if accompanied by an incomplete traversal of the requirement for restriction.

818.01(b) Election is Required, Even When Requirement Is Traversed [R-07.2015]

As noted in the second sentence of <u>37 CFR 1.143</u>, a provisional election must be made even if the requirement is traversed.

All requirements for restriction, other than those containing only an election of species, should include form paragraph 8.21. For election of species, form paragraph 8.01 or 8.02 should be used. These form paragraphs include the above notice.

818.01(c) Traverse is Required To Preserve Right of Petition [R-07.2022]

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 (see § 1.181).

To preserve the right to petition from the requirement for restriction, including an election of species requirement, all errors to be relied upon in the petition must be distinctly and specifically pointed out in a timely filed traverse by the applicant. The petition may be deferred until after final action on or allowance of the claims to the elected invention. In any event, the petition must not be filed later than the filing date of the notice of appeal. 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 and be so indicated to the applicant by use of form paragraph 8.25.02.

\P 8.25.02 Election Without Traverse Based on Incomplete Reply

Applicant's election of [1] in the reply filed on [2] is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.01(a)).

818.01(d) Traverse of Restriction Requirement With Linking Claims [R-07.2015]

Regardless of the presence of a linking claim, a proper traverse must include a written statement of the reasons for traverse, distinctly and specifically pointing out the supposed errors upon which the applicant relies for his or her conclusion that the requirement is in error. If restriction is made final following consideration of a traverse, the right to petition is preserved even if all linking claims are canceled. When a final restriction requirement is contingent on the nonallowability of the linking claims, applicant may petition from the requirement under 37 CFR 1.144 without waiting for a final action on the merits of the linking claims or applicant may defer his or her petition until the linking claims have been finally rejected, but not later than the notice of appeal. See 37 CFR 1.144 and MPEP § 818.01(c).

An election combined with an argument that the linking claim is allowable is not a traversal of the restriction requirement. The Office considers such a response to be a concession that restriction is proper if the linking claim is not allowable. If the linking claim is allowable, the restriction is improper and should be withdrawn. If the Office allows the linking claim, the restriction requirement must be withdrawn and claims to all linked inventions that depend from or otherwise include all the limitations of the allowable linking claim must be acted upon.

818.02 Election Other Than Express [R-07.2015]

Election may be made in ways other than by explicitly or expressly identifying the elected invention or in reply to a requirement as set forth in MPEP § 818.02(a) and § 818.02(d).

818.02(a) Election By Originally Presented Claims [R-07.2015]

Where claims to another invention are properly added and entered in the application before the earlier of the mailing of a first restriction requirement or the mailing of a first Office action on the merits, those claims, along with the ones presented upon filing the application, will be considered originally presented 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) filed for the application. Subsequently presented claims to an invention other than that acted upon should be treated as provided in MPEP § 821.03.

For reissue practice, see MPEP Chapter 1400.

818.02(b) Generic Claims Only — No Election of Species; Linking Claims Only – No Election of Invention [R-07.2022]

Where only generic claims are first presented and prosecuted in an application in which no election of a single species of that genus or of a group of patentably indistinct species has been required, and applicant later presents species claims to two or more independent or distinct species of the invention, the examiner may require applicant to elect a single

species or of a group of patentably indistinct species. The practice of requiring election of species in cases with only generic claims is discussed in MPEP § 808.01(a). Where only linking claims are first presented and prosecuted in an application in which no election of a single linked invention has been made, and applicant later presents claims to two or more linked, independent or distinct inventions, the examiner may require applicant to elect a single invention.

818.02(c) Election By Optional Cancelation of Claims [R-07.2015]

Where applicant claims two or more independent or distinct inventions and as a result of amendment to the claims, he or she cancels the claims to one or more of such inventions, leaving claims to one invention, and such claims are acted upon by the examiner, the claimed invention thus acted upon is elected.

818.02(d) Election By Cancelation of Claims, Lacking Express Election Statement [R-07.2015]

If applicant's reply to a requirement for restriction does not expressly state the invention elected, but cancels claims to all but one of the inventions, the remaining invention will be deemed to be the elected invention.

819 Office Generally Does Not Permit Shift [R-07.2022]

The general policy of the Office is that applicants are not permitted to shift to claim another invention after an election is made and an Office action on the merits is made on the elected invention. Specifically, the applicant may not disaffirm or change their election, as a matter of right, after making an oral election and receiving an Office action based upon that oral election in a pending application. See 37 CFR 1.142(b). In addition, the applicant cannot, as a matter of right, file a request for continued examination (RCE) on 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). See MPEP

§ 706.07(h), subsection VI.(B). When claims are presented which the examiner finds are drawn to an invention other than the one elected, he or she should treat the claims as outlined in MPEP § 821.03.

A restriction requirement (and election thereto) made in a parent application does not carry over to a continuation, CIP, or divisional application. See Bristol-Myers Squibb Co. v. Pharmachemie BV, 361 F.3d 1343, 1348, 70 USPQ2d 1097, 1100 (Fed. Cir. 2004) (An original restriction requirement in an earlier filed application does not carry over to claims of a continuation application in which the examiner does not reinstate or refer to the restriction requirement in the parent application.). In design not international applications, but applications, where a continued prosecution application (CPA) filed under 37 CFR 1.53(d) is a continuation of its parent application and not a divisional, an express election made in the prior (parent) application in reply to a restriction requirement does carry over to the CPA unless otherwise indicated by applicant.

While applicant, as a matter of right, may not shift from claiming one invention to claiming another, the examiner is not precluded from permitting a shift. The examiner is most likely to do so where the shift results in no additional burden, and particularly where the shift reduces work by simplifying the issues.

820 [Reserved]

821 Treatment of Claims Held To Be Drawn to Nonelected Inventions [R-07.2022]

Claims found 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 finds are not directed to the elected invention are withdrawn from further consideration by the examiner in accordance with 37 CFR 1.142(b). See MPEP § 821.01 through § 821.04. The examiner should clearly set forth in the

Office action the reasons why the claims withdrawn from consideration are not readable on the elected invention. Applicant may traverse the requirement pursuant to <u>37 CFR 1.143</u>. If a final requirement for restriction is made by the examiner, applicant may file a petition under 37 CFR 1.144 for review of the restriction requirement if the applicant made a timely traversal. See In re Hengehold, 440 F.2d 1395, 169 USPQ 473 (CCPA 1971). When an election results in the withdrawal of claims such that the assigned examiner believes the C* classification picture is incorrect, the examiner should submit a C* classification challenge prior to an action on the merits of the elected claims to ensure the C* classification picture on the application appropriately reflects the elected invention.

821.01 After Election With Traverse [R-07.2015]

Where the initial requirement is traversed, the examiner should reconsider it. If, upon reconsideration, the examiner is still of the opinion that restriction is proper, the examiner should maintain the restriction requirement and make it final in the next Office action. See MPEP \\$ 803.01. In doing so, the examiner should reply to the reasons or arguments advanced by applicant in the traverse. Form paragraph 8.25 should be used to make a restriction requirement final.

¶ 8.25 Answer to Arguments With Traverse

Applicant's election with traverse of [1] in the reply filed on [2] is acknowledged. The traversal is on the ground(s) that [3]. This is not found persuasive because [4].

The requirement is still deemed proper and is therefore made FINAL.

Examiner Note:

- In bracket 1, insert the invention elected.
- 2. In bracket 3, insert in summary form, the ground(s) on which traversal is based.
- 3. In bracket 4, insert the reasons why the traversal was not found to be persuasive.

If the requirement is made final, the claims to the nonelected invention should be clearly indicated as being withdrawn from consideration. In this situation, the examiner should use form paragraph 8.05.

¶ 8.05 Claims Stand Withdrawn With Traverse

Claim [1] withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected [2], there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on [3].

Examiner Note:

In bracket 2, insert --invention-- or --species--.

This form paragraph will show that applicant has retained the right to petition from the requirement under 37 CFR 1.144. See MPEP § 818.01(c).

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 reinstated, and give an action on the merits of all the claims directed to the elected invention and any invention reinstated with the elected invention.

When the application is otherwise in condition for allowance, the examiner should contact applicant and advise him or her of his or her options with regard to any pending claims withdrawn from consideration. Alternatively, applicant may be notified using form paragraph 8.03.

\P 8.03 In Condition for Allowance, Non-elected Claims Withdrawn with Traverse

This application is in condition for allowance except for the presence of claim [1] directed to an invention non-elected with traverse in the reply filed on [2]. Applicant is given TWO MONTHS from the date of this letter to cancel the noted claims or take other appropriate action (37 CFR 1.144). Failure to take action during this period will be treated as authorization to cancel the noted claims by Examiner's Amendment and pass the case to issue. Extensions of time under 37 CFR 1.136(a) will not be permitted since this application will be passed to issue.

The prosecution of this case is closed except for consideration of the above matter.

See also MPEP § 821.04 for rejoinder of certain nonelected inventions when the claims to the elected invention are allowable.

When preparing a final action in an application where there has been a traversal of a requirement for restriction, the examiner should indicate in the Office action which claims, if any, remain withdrawn from consideration.

Note that the petition under 37 CFR 1.144 must be filed not later than appeal. This is construed to mean on or before the date the notice of appeal is filed. See MPEP § 1204. If the application is ready for allowance on or after the date of the notice of appeal and no petition has been filed, the examiner should simply cancel nonelected claims that are not eligible for rejoinder by examiner's amendment, calling attention to the provisions of 37 CFR 1.144.

821.02 After Election Without Traverse [R-07.2022]

¶ 8.25.01 Election Without Traverse

Applicant's election without traverse of [1] in the reply filed on [2] is acknowledged.

\P 8.25.02 Election Without Traverse Based on Incomplete Reply

Applicant's election of [1] in the reply filed on [2] is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.01(a)).

Claims to the nonelected invention should be treated by using form paragraph 8.06.

¶ 8.06 Claims Stand Withdrawn Without Traverse

Claim [1] withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected [2], there being no allowable generic or linking claim. Election was made without traverse in the reply filed on [3].

Examiner Note:

In bracket 2, insert --invention--, or --species--.

This form paragraph will show that applicant has not retained the right to petition from the requirement under 37 CFR 1.144.

When applicant has not retained the right to petition the restriction requirement and the application is otherwise ready for allowance, the claims to the nonelected invention, except for claims directed to nonelected species and nonelected inventions eligible for rejoinder, may be canceled by an examiner's amendment, and the application passed to issue.

The examiner should use form paragraph 8.07 in this situation.

See also MPEP § 821.01 and § 821.04 et seq.

\P 8.07 Ready for Allowance, Non-elected Claims Withdrawn Without Traverse

This application is in condition for allowance except for the presence of claim [1] directed to [2] nonelected without traverse. Accordingly, claim [3] been canceled.

Examiner Note:

In bracket 2, insert --an invention--, --inventions--, --a species--, or --species--.

Note that even if an election was made without traverse, claims directed to nonelected species and nonelected inventions that are eligible for rejoinder should be rejoined; if not rejoined, such claims that are eligible for rejoinder may only be canceled by examiner's amendment when the cancelation is expressly authorized by applicant. If claims are directed to nonelected species and/or nonelected inventions that are not eligible for rejoinder, see form paragraph 8.07 and its associated guidance above for when claims may be canceled by an examiner's amendment, and the application passed to issue.

821.03 Claims for Different Invention Added After an Office Action [R-07.2022]

Claims added by amendment following action by the examiner, as explained in MPEP § 818.02(a), and drawn to an invention other than the one previously claimed, should be treated as indicated in 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.

The action should include form paragraph 8.04.

¶ 8.04 Election by Original Presentation

Newly submitted claim [1] directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: [2]

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

To preserve a right to petition, the reply to this action must distinctly and specifically point out supposed errors in the restriction requirement. Otherwise, the election shall be treated as a final election without traverse. Traversal must be timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are subsequently added, applicant must indicate which of the subsequently added claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. 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 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Examiner Note:

- 1. In bracket 2, insert the particular reason(s) why the newly submitted claim(s) is/are directed to independent or distinct invention(s).
- -For patentably distinct species, see MPEP §§ 806.04(b), 806.04(f) and 806.04(h). For example, insert --the claims to the different species recite the mutually exclusive characteristics of such species--, and provide a description of the mutually exclusive characteristics of each species or grouping of species.
- -For patentably distinct inventions, see $\underline{MPEP \S\S 806.05(a)}$ and $\underline{806.05(c)}$ $\underline{806.05(j)}$.
- -For unrelated inventions, see MPEP §§ 802.01 and 806.06.

A complete action on all claims to the elected invention should be given.

If the applicant fails to request reconsideration of the election by original presentation in reply to the Office action containing the requirement, the examiner should treat the application as if the election was made without traverse. See MPEP \sigma 821.02.

If the examiner finds all elected claims allowable following the amendment that added claims drawn to a new invention, the examiner cannot cancel the withdrawn claims without obtaining the applicant's express authorization. The applicant must be provided the opportunity to seek reconsideration of the election by original presentation. In this situation, the examiner may obtain express authorization to cancel the withdrawn claims via an interview prior to mailing a notice of allowability with an examiner's amendment canceling the withdrawn claims. If applicant's express authorization is not obtained, then the examiner should issue an Exparte Ouayle action that requires cancelation of the withdrawn claims. In reply, the applicant can either cancel the withdrawn claims or traverse the election by original presentation requirement. If applicant traverses the election, the examiner must reconsider the election by original presentation and address applicant's arguments if the election by original presentation is maintained. See MPEP § 821.01.

An amendment canceling all claims drawn to the elected invention and presenting only claims drawn to the nonelected invention should not be entered. Such an amendment is nonresponsive. Applicant should be notified by using form paragraph 8.26. Examiners should take care to correctly designate the issue as a non-responsive amendment, which is not be confused with a notice of non-compliant amendment. Examiners may use a PTOL-90 with form paragraph 8.26 to create a notice of non-responsive amendment. Such Office Action may be designated "Informal or Non-Responsive Amendment After Examiner Action."

¶ 8.26 Canceled Elected Claims, Non-Responsive

The amendment filed on [1] canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03) and has not been entered. The remaining claims are not readable on the elected invention because [2].

Since the above-mentioned amendment appears to be *a bona fide* attempt to reply, applicant is given a shortened statutory period of **TWO (2) MONTHS** from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER <u>37 CFR 1.136(a)</u> ARE AVAILABLE but in no case can any extension carry the date for reply to this letter beyond the maximum period of SIX MONTHS set by statute (<u>35 U.S.C.</u> 133).

Examiner Note:

This form paragraph should not be used for an application filed on or after August 25, 2006 that has been granted special status under the accelerated examination program or other provisions under 37 CFR 1.102(c)(2) or (d). Form paragraph 8.26.AE should be used instead. See MPEP § 708.02, subsection IX.

The practice set forth in this section is not applicable where a provisional election of a single species or a group of patentably indistinct species was made in accordance with MPEP § 803.02 and applicant amends the claims such that the elected species or group is canceled, or where applicant presents claims that could not have been restricted from the claims drawn to the elected invention had they been presented earlier.

821.04 Rejoinder [R-07.2022]

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.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder. See MPEP § 821.04(b). In order to retain the right to rejoinder,

applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. Failure to do so may result in a loss of the right to rejoinder.

Rejoined claims must be fully examined for patentability in accordance with <u>37 CFR 1.104</u>. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of <u>35 U.S.C. 101</u>, <u>102</u>, <u>103</u>, and <u>112</u>.

The requirement for restriction between the rejoined inventions must be withdrawn. Any claim(s) presented in a divisional application that are anticipated by, or rendered obvious over, the claims of the parent application may be subject to a double patenting rejection when the restriction requirement is withdrawn in the parent application. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §§ 804.01 and 821.04(a).

The provisions of MPEP § 706.07 govern the propriety of making an Office action final in rejoinder situations. If rejoinder occurs after the first Office action on the merits, and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final where the new ground of rejection was necessitated by applicant's amendment (or based on information submitted in an IDS filed during the time period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)). See MPEP § 706.07(a).

If restriction is required between product and process claims, for example, and all the product claims would be allowable in the first Office action on the merits, upon rejoinder of the process claims, it would not be proper to make the first Office action on the merits final if the rejoined process claim did not comply with the requirements of 35 U.S.C. 112, first paragraph. This is because the rejoinder did not occur after the first Office action on the merits. Note that the provisions of MPEP § 706.07(b) govern the propriety of making a first Office action on the merits final.

Amendments submitted after final rejection are governed by <u>37 CFR 1.116</u>.

Where applicant voluntarily presents claims to the product and process, for example, in separate applications (i.e., no restriction requirement was made by the Office), and one of the applications issues as a patent, the remaining application may be rejected under the doctrine of obviousness-type double patenting, where appropriate (see MPEP § 804 - § 804.03), and applicant may overcome the rejection by the filing of a terminal disclaimer under 37 CFR 1.321(c) where appropriate. Similarly, if copending applications separately present product and process claims, provisional obviousness-type double patenting rejections should be made where appropriate. However, once a determination as to the patentability of the product has been reached, any process claim directed to making or using an allowable product should not be rejected over prior art without consultation with a Technology Center Director.

See MPEP § 2147 for the applicability of 35 U.S.C. 103(b) to biotechnological processes and compositions of matter.

See MPEP § 2116.01 for guidance on the treatment of process claims which make or use a novel, nonobvious product.

Upon rejoinder of a nonelected invention, the assigned examiner should reconsider whether the C* classification picture is correct. If the assigned examiner believes that the C* classification picture is incorrect, the examiner should enter a C* classification challenge at the time of rejoinder

821.04(a) Rejoinder Between Product Inventions; Rejoinder Between Process Inventions [R-07.2022]

Where restriction was required between independent or distinct products, or between independent or distinct processes, and all claims directed to an elected invention are allowable, the examiner should withdraw any restriction requirement between the elected invention and any nonelected invention that depends from or otherwise requires all the limitations of an allowable claim. For example, a requirement for restriction should be withdrawn when a generic claim, linking claim, or subcombination claim is allowable and any previously withdrawn claim

depends from or otherwise requires all the limitations thereof. Claims that require all the limitations of an allowable claim will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that do not require all the limitations of an allowable claim remain withdrawn from consideration. However, in view of the withdrawal of the restriction requirement, if any claim presented in a divisional application includes all the limitations of a claim that is allowable in the parent application, such claim may be subject to a double patenting rejection over the claims of the parent application. Once a restriction requirement is withdrawn, the provisions of <u>35 U.S.C. 121</u> are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Additionally, a patentably indistinct claim in a child application would be subject to a double patenting rejection over the claims of the parent application when the child application is a continuation or continuation-in-part application or is a divisional application without consonance. The prohibition against double patenting rejections under 35 U.S.C. 121 is limited to divisional applications with consonance. See MPEP § 804.01

An amendment presenting additional claims that depend from or otherwise require all the limitations of an allowable claim 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.

When *all* claims to the nonelected invention(s) depend from or otherwise require all the limitations of an allowable claim, applicant must be advised that claims drawn to the nonelected invention have been rejoined and the restriction requirement has been withdrawn in its entirety. Form paragraph 8.45 may be used.

\P 8.45 Elected Invention Allowable, Rejoinder of All Previously Withdrawn Claims

Claim [1] allowable. Claim [2], previously withdrawn from consideration as a result of a restriction requirement, [3] all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), the restriction requirement [4] inventions [5], as set forth in the Office action mailed on [6], is hereby withdrawn and claim [7] hereby rejoined and fully

examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. Where the elected invention is directed to a product and previously nonelected process claims are rejoined, form paragraph 8.43 should be used instead of this paragraph.
- 2. This form paragraph should be used whenever ALL previously withdrawn claims depend from or otherwise require all the limitations of an allowable claim (e.g., a generic claim, linking claim, or subcombination claim) and wherein the non-elected claims have NOT been canceled. Use form paragraph 8.46, 8.47, or 8.47.01 as appropriate where the nonelected claims HAVE BEEN canceled. Use form paragraph 8.50 when the elected invention is allowable and the restriction requirement is withdrawn in part. Use form paragraph 8.49 when the elected invention is allowable and the restriction requirement is maintained without modification.
- 3. In bracket 2, insert the number(s) of the rejoined claim(s) followed by either -- is-- or -- are--.
- 4. In bracket 3 insert-- requires-- or -- require--.
- 5. In bracket 4, insert either --between-- or --among--.
- 6. In bracket 5, insert the group(s), species, or subject matter of the invention(s) being rejoined.
- 7. In bracket 7, insert the number(s) of the rejoined claim(s) followed by either --is-- or --are--.

When *no* claims directed to the nonelected invention(s) depend from or otherwise require all the limitations of an allowable claim, form paragraph 8.49 should be used to explain why all nonelected claims are still withdrawn from further consideration.

¶ 8.49 Elected Invention Allowable, Claims Stand Withdrawn, Restriction Maintained

Claim [1] allowable. The restriction requirement [2], as set forth in the Office action mailed on [3], has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement is maintained because the nonelected claim(s) do not require all the limitations of an allowable claim.

Examiner Note:

1. This form paragraph is applicable where a restriction requirement was made between related product inventions or

between related process inventions. See MPEP §§ 806.05(j) and 821.04(a).

- 2. This form paragraph should be used upon the allowance of a linking claim, generic claim, or subcombination claim when none of the nonelected claims require all the limitations of an allowable claim and wherein the nonelected claims have NOT been canceled. Use form paragraph 8.46, 8.47, or 8.47.01 as appropriate where the nonelected claims HAVE BEEN canceled. Use form paragraph 8.45 when the elected invention is allowable and the restriction requirement is withdrawn in its entirety. Use form paragraph 8.50 when the elected invention is allowable and the restriction requirement is withdrawn in part.
- 3. In bracket 2, insert -- between-- or --among-- followed by identification of the inventions (i.e., groups or species) restricted.
- 4. In bracket 3, insert the date of the restriction requirement being maintained.

Note that each additional invention is considered separately. When claims to one nonelected invention depend from or otherwise require all the limitations of an allowable claim, and claims to another nonelected invention do not, applicant must be advised as to which claims have been rejoined and which claims remain withdrawn from further consideration. Form paragraph 8.50 may be used.

¶ 8.50 Elected Invention Allowable, Some Claims No Longer Considered Withdrawn

Claim [1] allowable. The restriction requirement [2], as set forth in the Office action mailed on [3], has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim. Specifically, the restriction requirement of [4] is [5]. Claim [6], directed to [7] no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claim [8], directed to [9] withdrawn from consideration because [10] require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

1. This form paragraph is applicable where a restriction requirement was made between related product inventions or between related process inventions. See MPEP §§ 806.05(j) and 821.04(a).

- 2. This form paragraph should be used upon the allowance of a linking claim, generic claim, or subcombination claim when some, but not all, of the nonelected claims require all the limitations of an allowable claim and wherein the nonelected claims have NOT been canceled. Use form paragraph 8.46, 8.47, or 8.47.01 as appropriate where the nonelected claims HAVE BEEN canceled. Use form paragraph 8.45 when the elected invention is allowable and the restriction requirement is withdrawn in its entirety. Use form paragraph 8.49 when the elected invention is allowable and the restriction requirement is maintained without modification.
- 3. In bracket 2, insert -- between-- or --among-- followed by identification of the inventions (i.e., groups or species) restricted.
- 4. In bracket 4, insert the date of the restriction requirement being fully or partially withdrawn.
- 5. In bracket 5, insert "withdrawn" if the restriction requirement is no longer in effect at all or "partially withdrawn" if the restriction requirement is still partially in effect. If the restriction requirement is still partially in effect, state the claim(s) to which it still applies.
- 6. In bracket 7, insert the subject matter of the claimed invention or species being rejoined followed by either -- is-- or -- are--.
- 7. In bracket 9, insert the subject matter of the claimed invention or species not being rejoined followed by -- remains-- or --remain--.
- 8. In bracket 10, insert --it does not-- or --they do not all--.
- 9. If all of the claims are in proper form, i.e., they include all the limitations of an allowable claim, one of form paragraphs 8.45, 8.46 or 8.47 must be used.

Where the application claims an allowable invention and discloses but does not claim an additional invention that depends on or otherwise requires all the limitations of the allowable claim, applicant may add claims directed to such additional invention by way of amendment pursuant to <u>37 CFR 1.121</u>. Amendments submitted after allowance are governed by <u>37 CFR 1.312</u>; amendments submitted after final rejection are governed by <u>37 CFR 1.116</u>.

Form paragraph 8.46 (or form paragraph 8.47 or 8.47.01 if appropriate) must be used to notify applicant when nonelected claim(s) which depended from or required all the limitations of an allowable claim were canceled by applicant and may be reinstated by submitting the claim(s) in an amendment.

¶ 8.46 Elected Invention Allowable, Non-elected Claims Canceled, Other Issues Remain Outstanding

Claim [1] allowable. The restriction requirement [2] inventions [3], as set forth in the Office action mailed on [4], has been reconsidered in view of the allowability of claims to the elected

invention pursuant to MPEP § 821.04(a). The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim. Specifically, the restriction requirement of [5] is [6]. Claim [7], which required all the limitations of an allowable claim, previously withdrawn from consideration as a result of the restriction requirement, [8] canceled by applicant in the reply filed on [9]. The canceled, nonelected claim(s) may be reinstated by applicant if submitted in a timely filed amendment in reply to this action. Upon entry of the amendment, such amended claim(s) will be examined for patentability under 37 CFR 1.104.

In view of the withdrawal of the restriction requirement as set forth above, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. This form paragraph is applicable where a restriction requirement was made between related product inventions or between related process inventions. See MPEP §§ 806.05(j) and 821.04(a).
- 2. This form paragraph (or form paragraph 8.47 or 8.47.01) **must** be used upon the allowance of a linking claim, generic claim, or subcombination claim following a restriction requirement with at least one of these claim types present and wherein the non-elected claims requiring all the limitations of an allowable claim HAVE BEEN canceled. Use form paragraph 8.45 where the nonelected claims have NOT been canceled and all previously withdrawn claims are rejoined. Use form paragraph 8.50 when the elected invention is allowable and the restriction requirement is withdrawn in part.
- 3. If no issues remain outstanding and application is otherwise ready for allowance, use form paragraph 8.47 or 8.47.01 instead of this form paragraph.
- 4. In bracket 2, insert either --between-- or --among--.
- 5. In bracket 3, insert the group(s), species, or subject matter of the invention(s) that were restricted.
- 6. In bracket 5, insert the date of the restriction requirement being fully or partially withdrawn.
- 7. In bracket 6, insert "withdrawn" if the restriction requirement is no longer in effect at all or "partially withdrawn" if the restriction requirement is still partially in effect. If the restriction requirement is still partially in effect, state the claim(s) to which it still applies.
- 8. In bracket 7, insert the number of each claim that required all the limitations of an allowable claim but was canceled as a result of the restriction requirement.
- 9. In bracket 8, insert either --was-- or --were--.

¶ 8.47 Elected Invention Allowable, Non-elected Claims Canceled, Before Final Rejection, No Outstanding Issues Remaining

Claim [1] allowable. The restriction requirement [2] inventions [3], as set forth in the Office action mailed on [4], has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim. Specifically, the restriction requirement of [5] is [6]. Claim [7], which required all the limitations of an allowable claim, previously withdrawn from consideration as a result of the restriction requirement, [8] canceled by applicant in the reply filed on [9]. The canceled, nonelected claim(s) may be reinstated by applicant if submitted in an amendment, limited to the addition of such claim(s), filed within a time period of TWO MONTHS from the mailing date of this letter. Upon entry of the amendment, such amended claim(s) will be examined for patentability under 37 CFR 1.104. If NO such amendment is submitted within the set time period, the application will be passed to issue. PROSECUTION ON THE MERITS IS OTHERWISE CLOSED.

In view of the withdrawal of the restriction requirement as to the linked inventions, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. This form paragraph is applicable where a restriction requirement was made between related product inventions or between related process inventions and the application has not been finally rejected. See MPEP §§ 806.05(j) and 821.04(a). After final rejection, use form paragraph 8.47.01 instead of this form paragraph.
- 2. This form paragraph (or form paragraph 8.46 or 8.47.01) **must** be used upon the allowance of a linking claim, generic claim, or subcombination claim following a restriction requirement with at least one of these claim types present and wherein the non-elected claims requiring all the limitations of an allowable claim HAVE BEEN canceled. Use form paragraph 8.45 where the nonelected claims have NOT been canceled and all previously withdrawn claims are rejoined. Use form paragraph 8.50 when the elected invention is allowable and the restriction requirement is withdrawn in part.
- This form paragraph should be used only when there are no outstanding issues remaining and is to be used with only a PTO-90C cover sheet.
- 4. In bracket 2, insert either --between-- or --among--.
- 5. In bracket 3, insert the group(s), species, or subject matter of the invention(s) that were restricted.

- 6. In bracket 5, insert the date of the restriction requirement being fully or partially withdrawn.
- 7. In bracket 6, insert "withdrawn" if the restriction requirement is no longer in effect at all or "partially withdrawn" if the restriction requirement is still partially in effect. If the restriction requirement is still partially in effect, state the claim(s) to which it still applies.
- 8. In bracket 7, insert the number of each claim that required all the limitations of an allowable claim but was canceled as a result of the restriction requirement.
- 9. In bracket 8, insert either --was-- or --were--.

¶ 8.47.01 Elected Invention Allowable, Non-elected Claims Canceled, After Final Rejection, No Outstanding Issues Remaining

Claim [1] allowable. The restriction requirement [2] inventions [3], as set forth in the Office action mailed on [4], has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim. Specifically, the restriction requirement of [5] is [6]. In view of the withdrawal of the restriction requirement as set forth above, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. This form paragraph is applicable where a restriction requirement was made between related product inventions or between related process inventions and the application has been finally rejected. See MPEP §§ 806.05(j) and 821.04(a). Before final rejection, use form paragraph 8.47 instead of this form paragraph.
- 2. This form paragraph (or form paragraph 8.46) **must** be used upon the allowance of a linking claim, generic claim, or subcombination claim following a restriction requirement with at least one of these claim types present and wherein the non-elected claims requiring all the limitations of an allowable claim HAVE BEEN canceled. Use form paragraph 8.45 where the nonelected claims have NOT been canceled and all previously withdrawn claims are rejoined. Use form paragraph 8.50 when the elected invention is allowable and the restriction requirement is withdrawn in part.
- 3. This form paragraph should be used only when there are no outstanding issues remaining and is to be used with only a PTO-90C cover sheet.
- 4. In bracket 2, insert either --between-- or --among--.
- 5. In bracket 3, insert the group(s), species, or subject matter of the invention(s) that were restricted.

- 6. In bracket 5, insert the date of the restriction requirement being fully or partially withdrawn.
- 7. In bracket 6, insert "withdrawn" if the restriction requirement is no longer in effect at all or "partially withdrawn" if the restriction requirement is still partially in effect. If the restriction requirement is still partially in effect, state the claim(s) to which it still applies.

If the election is traversed, an additional paragraph worded as form paragraph 8.03 should be added to the holding.

\P 8.03 In Condition for Allowance, Non-elected Claims Withdrawn with Traverse

This application is in condition for allowance except for the presence of claim [1] directed to an invention non-elected with traverse in the reply filed on [2]. Applicant is given TWO MONTHS from the date of this letter to cancel the noted claims or take other appropriate action (37 CFR 1.144). Failure to take action during this period will be treated as authorization to cancel the noted claims by Examiner's Amendment and pass the case to issue. Extensions of time under 37 CFR 1.136(a) will not be permitted since this application will be passed to issue.

The prosecution of this case is closed except for consideration of the above matter.

821.04(b) Rejoinder of Process Requiring an Allowable Product [R-07.2022]

Where claims directed to a product and to a process of making and/or using the product are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or a process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 821 through § 821.03. However, if applicant elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must depend from or otherwise require all the limitations of an allowable product claim for that process invention to be rejoined. Upon rejoinder of claims directed to a previously nonelected process invention, the restriction requirement between the elected product and rejoined process(es) will be withdrawn.

If applicant cancels all the claims directed to a nonelected process invention **before** rejoinder occurs, the examiner should not withdraw the restriction requirement. This will preserve applicant's rights under 35 U.S.C. 121.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, applicant may present claims directed to the process of making and/or using the allowable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise require 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. However, if applicant files an amendment adding claims to a process invention, and the amendment includes process claims which do not depend from or otherwise require all the limitations of an allowable product, all claims directed to that newly added invention may be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03).

Amendments submitted after allowance are governed by <u>37 CFR 1.312</u>. Amendments to add only process claims which depend from or otherwise require all the limitations of an allowed product claim and which meet the requirements of <u>35 U.S.C. 101</u>, <u>102</u>, <u>103</u>, and <u>112</u> may be entered.

Amendments submitted after final rejection are governed by <u>37 CFR 1.116</u>. When all claims to the elected product are in condition for allowance, all process claims eligible for rejoinder (see <u>MPEP § 821.04</u>) must be considered for <u>patentability</u>.

If an amendment after final rejection that otherwise complies with the requirements of 37 CFR 1.116 would place all the elected product claim(s) in condition for allowance and thereby require rejoinder of process claims that raise new issues requiring further consideration (e.g., issues under 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph), the

amendment could be denied entry. For example, if pending nonelected process claims depend from a finally rejected product claim, and the amendment (or affidavit or other evidence that could have been submitted earlier) submitted after final rejection, if entered, would put the product claim(s) in condition for allowance, entry of the amendment (or evidence submission) would not be required if it would raise new issues that would require further consideration, such as issues under 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph necessitated by rejoinder of previously nonelected process claims.

Before mailing an advisory action in the above situation, it is recommended that applicant be called and given the opportunity to cancel the process claims to place the application in condition for allowance with the allowable product claims, or to file an RCE to continue prosecution of the process claims in the same application as the product claims.

In after final situations when no amendment or evidence is submitted, but applicant submits arguments that persuade the examiner that all the product claims are allowable, in effect the final rejection of the product claims is not sustainable, and any rejection of the rejoined process claims must be done in a new Office action. If the process claims would be rejected, applicant may be called before mailing a new Office action and given the opportunity to cancel the process claims and to place the application in condition for allowance with the allowable product claims. If a new Office action is prepared indicating the allowability of the product claim and including a new rejection of the process claims, the provisions of MPEP § 706.07 govern the propriety of making the Office action final.

Form paragraph 8.21.04 should be included in any requirement for restriction between a product and a process of making or process of using the product. See MPEP § 806.05(f) and § 806.05(h).

Form paragraph 8.42 or 8.43 should be used to notify applicant of the rejoinder of process inventions which depend from or otherwise require all the limitations of an allowable product claim.

\P 8.42 Allowable Product, Rejoinder of at Least One Process Claim, Less Than All Claims

Claim [1] directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claim [2], directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, [3] hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claim [4], directed to the invention(s) of [5] require all the limitations of an allowable product claim, and [6] NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, the restriction requirement [7] groups [8] as set forth in the Office action mailed on [9] is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. If ALL previously withdrawn process claims are being rejoined, then form paragraph 8.43 should be used instead of this form paragraph. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. See MPEP \struct \text{821.04(b)}.
- 2. In bracket 1, insert the claim number(s) of the allowable product claims followed by either -- is-- or -- are--.
- 3. In bracket 2, insert the claim number(s) of ALL the rejoined process claims.
- 4. In bracket 3, insert either --is-- or --are--.
- 5. In bracket 4, insert the number(s) of the claims NOT being rejoined followed by either -- is-- or -- are--.
- 6. In bracket 5, insert the group(s) or subject matter of the invention(s) to which the claims NOT being rejoined are directed, followed by either --, do not all-- or --, does not--.
- 7. In bracket 6, insert --has-- or --have--.
- 8. In bracket 7, insert either -- among -- or -- between--.
- 9. In bracket 8, insert group numbers of the elected product and rejoined process.

\P 8.43 Allowable Product, Rejoinder of All Previously Withdrawn Process Claims

Claim [1] directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claim [2], directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a

restriction requirement, [3] hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on [4] is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner Note:

- 1. If LESS THAN ALL previously withdrawn claims are being rejoined, then form paragraph 8.42 should be used instead of this form paragraph. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. See MPEP § 821.04(b).
- 2. In bracket 1, insert the claim number(s) of the allowable product claim(s) followed by either -- is-- or -- are--.
- 3. In bracket 2, insert the claim number(s) of the process claim(s) previously withdrawn from consideration.
- 4. In bracket 3, insert either --is-- or --are--.
- 5. If rejoinder occurs after the first Office action on the merits and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final if proper under MPEP § 706.07(a).

822 Claims to Inventions That Are Not Patentably Distinct in Plural Applications of Same Applicant or Assignee [R-07.2022]

37 CFR 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(f) Applications containing patentably indistinct claims. Where two or more applications filed by the same applicant or assignee contain patentably indistinct claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

Where claims in two or more applications filed by the same applicant or assignee are patentably indistinct, a complete examination should be made of the claims of each application and all appropriate rejections should be entered in each application, including rejections based upon prior art. The claims of each application may also be rejected on the grounds of provisional double patenting based on the claims of the other application whether or not any claims avoid the prior art. Where appropriate, the same prior art may be relied upon in each of the applications. See also MPEP § 804.01.

The provisional double patenting rejection should continue to be made by the examiner in each application as long as there are patentably indistinct claims in more than one application unless that provisional double patenting rejection is the only rejection remaining in one of the applications. See MPEP \sigma 1490 when the provisional double patenting rejection is the only rejection remaining in at least one application.

See MPEP § 804.03 for conflicting subject matter, different inventors, common ownership.

See MPEP § 608.01(m) for rejection of one claim over another in the same application.

See MPEP § 2190, subsection II, for res judicata.

See <u>MPEP § 709.01</u> for one application in interference.

See MPEP § 806.04(h) to § 806.04(i) for species and genus in separate applications.

Wherever appropriate, such conflicting claims should be moved to a single application. This is particularly true where the two or more applications are due to, and consonant with, a requirement to restrict which the examiner now considers to be improper.

Form paragraph 8.29 should be used when the conflicting claims are identical or conceded by applicant not to be patentably distinct.

\P 8.29 Patentably Indistinct Claims, Copending Applications

Claim [1] of this application is patentably indistinct from claim [2] of Application No. [3]. Pursuant to 37 CFR 1.78(f), when two or more applications filed by the same applicant or assignee contain patentably indistinct claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either

cancel the patentably indistinct claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

823 Unity of Invention Under the Patent Cooperation Treaty [R-07.2015]

The analysis used to determine whether the Office may require restriction differs in national stage applications submitted under 35 U.S.C. 371 (unity of invention analysis) as compared to national applications filed under 35 U.S.C. 111(a) (independent and distinct analysis). See MPEP Chapter 1800, in particular MPEP § 1850, § 1875, and § 1893.03(d), for a detailed discussion of unity of invention under the Patent Cooperation Treaty (PCT). However, the guidance set forth in this chapter with regard to other substantive and procedural matters (e.g., double patenting rejections (MPEP § 804), election and reply by applicant (MPEP § 818), and rejoinder of nonelected inventions (MPEP § 821.04) generally applies to national stage applications submitted under 35 U.S.C. 371.