From:
Sent: Friday, August 13, 2010 11:34 AM
To: Restriction_Comments
Cc: Matt Rainey; Steve Malaska
Subject: Docket No. PTO-P-2010-0030; Intellectual Ventures Comments on Proposed Changes to Restriction Practice

Attention: Linda S. Therkorn
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Ms. Therkorn,

Please enter the attached document titled "Comments on Proposed Changes to restriction Practice in Patent Applications" filed on behalf of Intellectual Ventures, LLC.

Thank you for your attention to this.

Sincerely,

Stephen L. Malaska
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Docket No. PTO-P-2010-0030

75 Fed. Reg. 113
(June 14, 2010)

Comments on Proposed Changes to Restriction Practice in Patent Applications

Attention:

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments - Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Linda S. Therkorn

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Practice in Patent Applications	)
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The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments - Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Linda S. Therkorn

By email to:Restriction_comments@uspto.gov

Dear Under Secretary Kappos:

In reply to the Request for Comments on Proposed Changes to Restriction Practice in Patent Applications published June 14, 2010, at 75 Fed. Reg. 113, at pages 33584-33587 (the "Request"), Intellectual Ventures, LLC submits the following comments.

I. Introductory Comments and Proposals

Intellectual Ventures, LLC, based in Bellevue Washington, is in the business of creating and investing in new ideas. We create ideas in-house and seek to protect them through the patent system. We work with inventors both inside and outside of the company—some of the brightest minds of today's inventive society—to create our new ideas. In addition, Intellectual Ventures also builds upon our own ideas by licensing and acquiring intellectual property from industrial, government and academic partnerships.

Our inventions span a diverse range of technologies, including software, semiconductors, medical devices and biotechnology. Intellectual Ventures is in the business of ideas, and we rely on a strong patent system to protect the innovation our company fosters. In short, we create, and

invest in, inventions with the mission to energize and streamline an invention economy that will drive innovation around the world.

Intellectual Ventures offers these comments with the goal of building a long-term constructive partnership with the Patent and Trademark Office ("Office") in its aim to improve restriction practice. We support a strong patent system, and are a substantial customer of the Office's services.

We believe that appropriate and consistent standards for restriction practice are an important part of the patent system because they help achieve high-quality patents and public reliance upon those patents, and we offer our comments in the furtherance of these goals.

In the Request, the Office identified five specific aspects of restriction practice for which it sought comments. Before addressing each of the five aspects, we provide our overall view of the current state of restriction practice.

Intellectual Ventures appreciates the efforts of the Office to review current restriction practice and to seek alternatives to improve efficiency and consistency for the Office and the community. Our experience demonstrates that current restriction practice is inconsistent and seemingly arbitrary. It is clear that examiners are imposing restriction requirements using varying standards. A summary of our proposals follows.

a. Do Not Implement a PCT-style "Lack of Unity" Practice

We do not believe major revision of the MPEP is necessary in order to return consistency and predictability back to restriction practice. We also do not believe that the replacement of current restriction practice with a PCT-style "lack of unity" practice will reduce the Office's workload or case pendency. Indeed, we believe implementation of a "lack of unity" practice will not be easily implemented by the community nor will it increase certainty. Further, without clear standards for what constitutes a "lack of unity," the PCT-style system might provide additional room for abuse.

b. Require Examiners to Follow the Law

Fundamentally, we believe a significant improvement in restriction practice—to the Office and to the community—can be obtained by requiring examiners to follow the Patent Statute and the Patent Office Rules of Practice. That is, examiners must be required to provide more than mere conclusory statements when issuing a restriction requirement. We encourage the Office to require examiners to establish that the inventions are both independent *and* distinct and support any such allegation with a detailed analysis of each restricted claim. Further, examiners must be required to provide evidence that they would incur a serious burden if restriction is not required. It has become normal practice to merely cut-and-paste MPEP form paragraphs when asserting

that a "serious burden" exists. Indeed, we have been informed by Office personnel that examiners are being trained to do such that.

i. Examiners Are Using Certain MPEP Form Paragraphs That Are Not Consistent with the Law and Impose Improper "Requirements" Upon Applicants

Some of the Office's training materials, MPEP and internal memoranda[1] provide guidance to examiners that stray from the requirements clearly set forth in the Statute and Rules. During a recent conversation with a Supervisory Patent Examiner, the undersigned was told that examiners are being trained to not provide any reasoning or evidence in support of the "serious burden" requirement because "most applicants do not traverse restriction requirements, thus saving the examiners extra work." Further, the MPEP "Form Paragraphs" that examiners are required to use, improperly attempt to shift the burden of proof upon an applicant and are, therefore, not consistent with the Statute or Rules.

We have seen a strong trend of restrictions that require us to restrict between disclosed figures or examples. These types of restriction requirements improperly restrict based on what is disclosed as opposed to what is claimed. Some examiners have conceded that they do not read the claims before issuing such restrictions.

Finally, many examiners attempt to require an applicant identify claims that encompass the elected species or invention. Indeed, the MPEP form paragraphs include such a requirement. This is improper practice because the examiner has the burden of providing a clear demarcation between restricted inventions, as claimed. This is so the applicant can determine whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. § 121. *See*, for example, MPEP § 814(I). Moreover, requiring the applicant to identify claims that encompass elected species is tantamount to forcing an applicant to create prosecution estoppel.

c. Credit or Refund Applicant-Paid Excess Claim Fees

We encourage the Office to implement a policy to credit or refund to an applicant excess claim fees paid prior to a restriction requirement. When an applicant files an application it pays fees to the Office according to 37 CFR § 1.16. If an application contains an "excessive number of claims," the applicant is required to pay fees for the excess claims. When claims are subject to a restriction requirement and an applicant is required to file a divisional application to have those claims examined, the applicant is required to pay another basic filing fee. However, the applicant had already paid the fees necessary to have such claims examined. Such fees should be credited or refunded to the applicant.

[1] See, e.g., USPTO Memorandum from Robert Bahr, dated January 21, 2010, attached hereto as Appendix I.

d. Eliminate Incentives to Restrict

There are various incentives to restrict claims in applications, including reducing the workload per application and potentially increasing the total number of "counts" the examiner could be awarded. To reduce the incentive to restrict an application, we suggest the Office consider revising the count system regarding the examination of divisional applications. A count system that factored in the size of the application and the number of claims examined would likely reduce the number of restriction requirements.

e. Optionally Select Up to Five "Inventions" in a Single Application for an Additional Fee

In a manner similar to how the Office handles nucleotide sequences under MPEP § 804.03, restriction practice could be improved by allowing an applicant to optionally select up to a certain number (e.g., five) of restricted inventions for examination in a single application. The applicant would pay a nominal examination fee for each group selected.

f. Constructive Election

The Office should instruct examiners that when practicing under 37 CFR § 1.145 and MPEP §§ 819 and 821.03, they still must follow the law and demonstrate that the new claims are are directed to "an invention distinct from and independent of the invention previously claimed."

II. What Should Be Included In An Office Action That Sets Forth A Restriction Requirement?

We appreciate the request from the Office for suggestions to improve Office actions that set forth a restriction requirement. Restriction practice has become increasingly complex and inconsistent. Our practice has seen a dramatic increase in the number of restriction requirements and a correspondingly dramatic increase in the number of traversals filed. We recently have filed a number of Petitions to the Director for reconsideration of the restriction requirements, and without a change to the current practice, we will continue to file such Petitions in the future. Like the Office, we have an acute interest in seeing an improvement in the consistency and quality of the restrictions.

a. Office Actions Should Demonstrate that Restricted Inventions are "Independent and Distinct" and Provide Evidence Supporting an Allegation of "Serious Burden"

i. The Patent Statute and Patent Rules Require Inventions be "Independent and Distinct," not "Independent or Distinct"

It is noted that the Request uses both the phrase "independent and distinct" and the phrase "independent or distinct." Throughout the MPEP, the phrase "independent or distinct" is used

when providing guidance to examiners. However, this is *not* the standard. The Patent Statute and Patent Rules require the Office to demonstrate that restricted inventions be both independent *and* distinct. Despite the long-standing practice within the Office of applying the incorrect "independent or distinct" standard, Office practice today generally involves analyzing inventions under the "distinct" standard. The word "distinct" is vaguely defined in the MPEP and has been applied with enormous breadth in restriction practice. This broad and vague standard has contributed to tremendous inconsistency in restriction requirements and uncertainty in determining whether an examiner has correctly identified independent and distinct inventions. We demonstrate this in detail below.

1. The Basis for Restriction Practice

The basis for restriction practice can be found in the Patent Statute and Patent Rules:

35 U.S.C. § 121

> If two or more *independent and distinct* inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. 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 (emphasis added).

The Patent Rules state:

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 (emphasis added).

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 (emphasis added).

2. The Office Unilaterally *Lowered* the Standard From "Independent and Distinct" to "Distinct"

Section 802.01 was added to the MPEP in 1957. Section 802.01 acknowledged that interpretation of the phrase "independent and distinct" is key to successful restriction practice according to the Statute: "[t]his 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." These statements have been substantially maintained for over 50 years up to the current Section 802.01 of the MPEP. Section 802.01 further explains:

> "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.
>
> ... 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* (emphasis added).

The Office states that it would restrict claims that it considers to be "independent" inventions because such independent inventions are "accurately termed 'distinct.'"[2] As a result, the Office effectively concludes that "independent and distinct" really means just "distinct." The MPEP provides no explanation to support the Office's view that Congress intended the lower standard "distinct" when they drafted "independent and distinct." This important change to the interpretation of the Patent Statute, as well as other phrases introduced by the Office into restriction practice have lead to numerous errors and increasing confusion within the Office and community, and a misapplication of the Statute and Rules.

In 1950, draft Section 120 "Divisional applications" of H.R. 9133 permitted restriction between "two or more independent *or* distinct inventions claimed" (emphasis added). The Bill was not acted on by Congress. In 1951, draft H.R. 3760 stated in Section 121: "two or more independent *and* distinct inventions are claimed ..." (emphasis added) may be restricted. House Bill 3760 was revised in H.R. 7794; however, it retained the "independent and distinct" language for Section 121. Then H.R. 7794 passed the House and Senate and is now known as the 1952 Patent Act. Clearly, Congress intended that the disjunctive "or" be changed to conjunctive "and."[3]

3. The Office Introduces the Extra-Statutory Phrase "Related But Distinct" and Defines "Distinct"

The Office amended Section 802.01 of the MPEP in 2005 to introduce the extra-statutory phrase "related but distinct." The Office's rationale to restrict "related but distinct" inventions is described as follows:

> *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*

[2] MPEP 802.01 Rev. 3, June 1957

[3] Information obtained from the Life Science Law & Industry Report, 3 LSLI 491 (May 8, 2009), attached hereto as Appendix II.

> *term related is used as an alternative for dependent in referring to inventions other than independent inventions* (emphasis added).
>
> 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 (emphasis added).
>
> 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.

According to the Office, inventions that are not independent (i.e., that are dependent or "related") will be restricted if they are *distinct*. Related inventions are "distinct" if they "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)."

Therefore, test is effectively, whether claims are "distinct." That is, they "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." It is not clear why the Office goes through the trouble of describing "related but distinct" when "distinct" appears to be the Office's sole standard. That is, the Office has already concluded that "independent" inventions are, by definition, "distinct." See, for example, MPEP §§ 806, 806.03, and 806.05:

> 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. (MPEP § 806.05, emphasis added)

The word "distinct" as used in 35 U.S.C. § 121 was not defined by Congress. Moreover, Congress clearly did not intend simply to use the single word "distinct." The Office's definition of *distinct*: "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)" has no basis in the legislative history. Unfortunately, this definition, without additional specific Office guidance, opens the door for myriad examiner interpretations and applications. For example, examiner often state that inventions are "distinct" when "the inventions can be used in a materially different process." When faced with a restriction formed on this basis, the

applicant has no reasonable avenue to argue this point, other than argue that such a basis is not in accord with the Statute. Moreover, since one could argue that *any* two things can be used in materially different processes, such a basis has become commonplace and hence, "normal" restriction practice. Importantly, this Office-created standard does not reliably determine whether two or more claims in a single application recite independent and distinct inventions.

A. Examiners Typically Provide Only Conclusory Statements Using MPEP Form Paragraphs

As demonstrated above, the test of whether claims recite "distinct" inventions is highly subjective and provides an incentive for abuse. Office Actions that contain an allegation of distinct inventions typically contain conclusory statements asserting, e.g., that the claims recite inventions that "can be used in a materially different process." Moreover, such conclusory statements are copied from the MPEP's form paragraphs. Often, the applicant is given no specific evidence or reasoning *why* the claimed inventions are considered "distinct."

MPEP Section 817 states "Form paragraphs 8.14-8.20.02 may be used as appropriate *to set forth* the reasons for the holding of independence or distinctness" (emphasis added). The USPTO Memorandum of January 21, 2010, authored by Robert W. Bahr,[4] is an example of the Office's improper guidance for examiners. Specifically, the Memorandum states:

> First, it is never appropriate to require an election between species (or inventions) that are *not patentably distinct*[5] (page 1, emphasis added).
>
> Second, form paragraphs 8.01 and 8.02 as set forth in the April 25, 2007 memo and in OACS specify that the species are independent or distinct "because claims to the different species recite the mutually exclusive characteristics of such species."
>
> To help ensure that all restriction requirements, including election of species requirements, *set forth the requisite burden,* and to give the applicant notice of why there is a burden, form paragraphs 8.01, 8.02, and 8.21 have been revised to provide for the examiner to specify at least one applicable reason (page 2, emphasis added).

Form Paragraph 8.01 states:

> *8.01 Requiring an 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.

---

[4] Attached as Appendix I

[5] We assume the Office's use of "Patentably Distinct" is essentially the same definition as used for "distinct" since the definition of "distinct" includes the requirement that at least one invention be *patentable* over the other.

The "Examiner Note" associated with Form Paragraph 8.01 states:

> 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* (page 3, emphasis added).

Examiners cannot comply with the Patent Statute and Rules through rote use of MPEP form paragraphs. Indeed, it is our experience that of the numerous patent applications we file covering a variety of technologies, the written basis for restriction requirements in these cases is *largely the same*. This tells us that the improper practice is not confined to specific art units.

The Office must revise the MPEP form paragraphs according to statutory standards and must encourage examiners to use properly drafted form paragraphs as a guide in preparing restriction requirements. Furthermore, the Office should consider subjecting to public comment any proposed new or revised MPEP form paragraph. In effect, the drafters of MPEP form paragraphs have been allowed to unilaterally change the standards for restriction practice.

1. A New Criterion for Distinctness is Introduced: "Mutually Exclusive Characteristics"

As shown above, examiners are being instructed to utilize form paragraphs to "ensure … that all restriction requirements set forth the requisite burden … ." Indeed, Form Paragraph 8.01 provides a new (or additional) standard for distinctness: whether the claims recite inventions (or species) that include "mutually exclusive characteristics." This recently added criterion, or test, for distinctness appears to have been added into Form Paragraph 8.01 via a USPTO Memorandum from John Love, Deputy Commissioner for Patent Examination Policy dated April 25, 2007.[6] This criterion was maintained in Form Paragraph 8.01 by Robert Bahr in his USPTO Memorandum of January 21, 2010.

[6] Attached hereto as Appendix III

In addition, Form Paragraph 8.14.01 states:

> Inventions **[1]** and **[2]** are directed to related **[3]**. The related inventions are distinct if the (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 § 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.

However, this explanation in MPEP Form Paragraph 8.14.01 is not consistent with the Office's own MPEP at Section 802.01 under the heading "Related But Distinct" quoted above. For ease of comparison, the two are reproduced here.

> *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) (Section 802.01, emphasis added).

> The *related inventions are distinct if* the (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 (Form Paragraph 8.14.01, emphasis added).

It is apparent that the revisions to the MPEP and its form paragraphs do not provide consistent guidance to examiners or to the community for Office actions that set forth a restriction requirement. We encourage the Office to revise the MPEP and the form paragraphs to be compliant with the Patent Statute.

ii. Examiners Should Be Required to Demonstrate Why a Serious Burden Exists if Restriction is Not Required.

The second prong *necessary* to establish a restriction requirement is the demonstration of a "serious burden" on the examiner if restriction is not required. MPEP § 808.02 states:

> *808.02 Establishing Burden [R-5]*
>
> * * *
>
> 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*

burden on the examiner if restriction is not required. Thus 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 (emphasis added).

Simply requiring examiners to comply *fully* with MPEP § 808.02 would be a significant help to applicants. Many restriction requirements do not come with *any* justification for alleging a "serious burden." Indeed, in our experience, the majority of restriction requirements merely include Form Paragraph 8.21.01 (found in MPEP § 817) as the alleged "justification":

8.21.01 Conclusion to All Restriction Requirements: Different Classification

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required *because* the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper (emphasis added).

However, sometimes when an examiner attempts to demonstrate that a "serious burden" exists, the examiner almost always provides the general search classification of the groups of inventions. Typically, no other information is provided. While we appreciate the examiner's effort to classify the restricted inventions, examiners must be reminded that restriction is *never* proper when the groups are classified in the same class and field of search, and no other justification is provided. *See* MPEP § 808.02 "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."

In addition, the Office is instructing examiners to use form paragraphs to ensure demonstration of the "serious burden" prong. *See* Form Paragraphs 8.01, 8.02 and 8.21 as described in the Robert W. Bahr USPTO Memorandum of January 21, 2010. For example:

> Note that form paragraphs 8.01 and 8.02 as set forth in MPEP Chapter 800 do not include an explanation regarding burden, however the restriction requirement is to be concluded with one of form paragraphs 8.21.01-8.21.03 as set forth in that chapter. Revised form paragraphs 8.01 and 8.02 as set forth below *include the burden explanation*; furthermore, revised form paragraph 8.21 consolidates and replaces form paragraphs 8.21.01-8.21.03 and 8.22 as set forth in MPEP Chapter 800 (emphasis added).
>
> 8.21 To Establish Burden AND Requirement for Election and Means for Traversal for all Restriction, other than an Election of Species
>
> 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**]·
>
> (emphasis added)

In the Examiner Note for paragraph 8.01, the following four burden explanations are provided for the examiner:

> 4. In bracket 4 *insert the applicable reason(s) why* there is a search and/or examination burden:
>
> --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
>
> --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).
>
> (emphasis added)

Clearly, examiners are being improperly instructed to satisfy their "serious burden" requirement by simply reciting any one of the four possible choices listed above. This is not consistent with Statute or even the Office's own MPEP. Based on this instruction, no classification actually needs to be performed, no analysis of the field of search is performed, and no analysis of whether the inventions have achieved a separate status in the art needs to be done.

As stated in the Introductory Comments of this paper, the undersigned was informed by a Supervisory Patent Examiner that examiners are being taught to use *only* form paragraphs and

not to provide any support for an allegation of "serious burden." This is reportedly due to the Office's position that most applicants do not traverse restriction requirements and, therefore, examiners can avoid justifying the "serious burden" requirement until an applicant traverses. It is our experience that even under traversal and when pressed for evidence of "serious burden" most examiners do not provide the required information and simply deem the restriction as "final"—apparently hoping the applicant will drop the traversal. In this situation, an applicant is left to decide whether to pay counsel to file a Petition, or simply comply with the improper requirement. We believe most applicants simply comply because it is a less expensive alternative to filing a Petition with the Director—especially when it is generally regarded that efforts to traverse and petition a restriction requirement are not typically successful.

The Office and the patent community would greatly benefit from consistency in the standards applied when determining whether claims are directed to "independent and distinct" inventions. If the Office continues to utilize "distinct" as opposed to the statutory "independent and distinct," then the Office should issue a new clear and straightforward definition that does not open the door to myriad interpretations and potential abuse by examiners. Further, there should be an emphasis on requiring examiners to follow the MPEP and to demonstrate, with evidence, the "distinctness" of the inventions, as well as the demonstration of a "serious burden." Consistency between the form paragraphs and the Statute, Rules and even the MPEP itself would improve the practice.

b. Lowering the Standards in the MPEP for Establishing "Serious Burden" Will Add Further Uncertainty and Inconsistency

The removal of current standards for establishing serious burden, as is being considered by the Office, will impose additional uncertainty and inconsistency on an applicant, and will create more work for an examiner. Indeed, the Request notes that the Office is considering removing the current standards for establishing "serious burden" and instructing examiners that a "serious burden" can be established "when the prior art applicable to one invention would not likely be applicable to another invention (e.g., because of a different field of art or different effective filing date)." This proposed revision is completely unnecessary if the examiners are merely instructed to *follow the Law and Rules*.

The proposed revision appears to require an examiner to actually perform a search of all claims in advance of requiring the restriction in order to determine whether "prior art applicable to one invention is not likely applicable to another invention." If the examiner performs a search of prior art *vis-à-vis* all of the originally filed claims (as presumably would be necessary to meet this standard), then there can be *no future* serious burden on an examiner since the search has already been performed.

If the proposed revision does not require an examiner to perform a search prior to making the allegation that "prior art applicable to one invention is not likely applicable to another invention," then such an allegation amounts to mere *speculation.* The Request implies that the proposed revision: "when the prior art applicable to one invention would not likely be applicable to another invention" could be satisfied by showing a "different field of art" or "different effective filing date." Therefore, the proposed revision would instruct examiners to establish "serious burden" by *merely alleging* "different field of art" or "different effective filing date."

We respectfully submit that this proposed revision is not an improvement to current practice. Indeed, it is ripe for at least as much abuse as the current open-ended Office definition of "distinct." Moreover, it is not clear from the Request how a "different effective filing date" would *per se* indicate that "the prior art applicable to one invention would not likely be applicable to another invention." The Request did not provide examples of such a scenario. Again, the idea behind 35 U.S.C. § 121 is to prevent an applicant from claiming two or more independent and distinct inventions in one application. It is not clear how the mere determination of "different effective filing date" indicates that two or more independent and distinct inventions are being claimed in one application.

Further, the proposed revision provides no real concrete standard for an applicant to judge whether an examiner is correct in his or her allegation. The allegation that prior art applicable to one invention would not *likely* be applicable to another invention is not a determinative indicator of independent and distinct inventions. One can imagine an examiner might always find prior art that is applicable to one invention but would not *likely* be applicable to another invention. Moreover, it is unknown what he term "applicable" actually means in this context. Does this mean applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103? If the examiner makes such an allegation regarding on the merits of a claim, then we submit that the examiner provide objective evidence to support the allegation. Again, if an examiner is required to do more than merely allege "applicability" of the reference, then we believe then examiner will have to examine the claims on the merits. And no "serious burden" can be demonstrated since the search has already been performed on all claims.

Lastly, by allowing examiners to justify the "serious burden" by including language from a newly revised form paragraph—as opposed ot providing objective evidence—does not further the purpose of the Request, which is to "improve the quality and consistency of restriction requirements."

c. "Examination Burden" is not Consistent with Historic Practices nor with Patent Statute or Patent Rules

The Request indicates that the Office is considering revising the MPEP to specify that "a serious burden on the examiner" encompasses search burden and/or examination burden." As

shown above in the USPTO Memorandum from Robert W. Bahr, some MPEP form paragraphs *already* utilize the "search and/or examination" burden as justification. This standard is clearly not in accord with Statute or historical practice. Changing the MPEP to lower the burden level for establishing a restriction requirement would mean that a restriction requirement could conceivably be used in every patent application. The Request indicates that:

> However, the determination of whether a claimed invention is *allowable* requires both a search of the prior art and an examination of the application to determine whether the claimed invention meets the statutory requirements for patentability. The burden imposed by the examination of patentably distinct inventions is, in many cases, as serious as the burden imposed by searching for such inventions.

We agree that the searching and examination of two applications is more burdensome than searching and examination of a single application. However, this does not indicate that an application contains claims to *separately patentable inventions*—which is the basis of the restriction practice (see 35 U.S.C. § 121, 37 CFR §§ 1.141, 1.142). We submit that this proposed revision runs counter to statutory mandate.

It is noted that the examiner must *first* make the case that separately patentable inventions are claimed in a single application. In other words, the burden described by the Request is a burden assumed after-the-fact. Examination of two applications *does not establish* that two "patentably distinct" inventions actually exist in the application. Further, the proposed revision provides no firm standard for an applicant to judge whether an examiner is correct in his allegation. Examiners are always burdened with examination of an application during prosecution; however, this is not a *per se* indicator of separately patentable inventions. One can imagine an examiner might easily allege that an examination burden exists in an application, whether or not the claims are directed to two or more separately patentable inventions. This proposed revision of the MPEP will certainly lead to less consistency and possibly significant abuse.

d. Restricting Claims Based on Non-Prior Art Issues Such as Under 35 U.S.C. §§ 101, 112, First Paragraph Does Not Indicate that an Application *per se* Contains Claims to *Separately Patentable Inventions*

The Request also states that the Office is considering revising the MPEP to indicate that a "serious burden" can be established when inventions "are *likely* to raise different non-prior art issues under 35 U.S.C. §§ 101, 112, first paragraph" (emphasis added).

We agree that certain claims may raise different issues under 35 U.S.C. §§ 101, 112, first paragraph. However, this is not a *per se* indicator that an application contains claims to *independent and distinct inventions*—which is the basis of the restriction practice (see 35 U.S.C.

§ 121, 37 CFR §§ 1.141, 1.142). We submit that this proposed revision runs counter to statutory mandate.

Whether or not two or more claims are *likely* to satisfy both the written description and enablement requirements is immaterial to the analysis of whether those claims recite separately patentable inventions. The written description and enablement requirements are determined based on whether the subject matter *disclosed in the Specification* is sufficient to satisfy the requirements. The legal inquiry under § 112, first paragraph, examines the Specification text as opposed to examining claim text. Claim text is examined to determine whether two or more claims recite separately patentable inventions. What a Specification *discloses* is not a *per se* indicator relevant to whether independent and distinct inventions are *claimed.*

Similarly to the above, an analysis of a claim for *patentable subject matter eligibility* under 35 U.S.C. § 101 is a legal inquiry that is distinct from the legal inquiry of whether two or more claims recite independent and distinct inventions. Subject matter *eligibility* does not involve determining whether two or more claims recite *independent and distinct inventions*. This also is not an indicator relevant to restriction practice.

e. Grouping of Species Together

The Request notes that the Office is considering revising the MPEP to instruct examiners to "group together species that are not patentably distinct from each other." It also states that "the examiner should require election of either a single species [sic] or a single grouping of patentably indistinct species, and the applicant should not be required to elect a specific species within a grouping of patentably indistinct species."

We agree with this proposed revision with the caveat that examiners be required according to statute to set forth, in every restriction requirement, the evidence and reasoning for alleging "independent and distinct" inventions as well as evidence and reasoning supporting the assertion of a "serious burden," as we have detailed *supra*.

Summary

The MPEP *already* mandates that examiners *must always* set forth the reasons why the inventions are independent or distinct and why there would be a serious burden on the examiner if restriction was not required. Changing the MPEP and its form paragraphs to guide examiners based on statutory standards "independent and distinct" would be well-received by the community. Lowering the standard for establishing "serious burden" using immaterial rationale such as 35 U.S.C. §§ 101, 112, first paragraph, or using a purported "examination burden" would lead to *less* consistency and empower examiner's to restrict claims based on indeterminate criteria. Moreover, the applicant has little recourse against such reasoning, other than to traverse, which is generally regarded as unlikely to be successful.

III. How Should The Process Of Traversing Or Requesting Reconsideration Be Changed To Achieve More Consistent, Accurate, Timely and Cost-Effective Review?

a. The Practice of "Requiring" an Applicant Identify Claims Encompassing the Elected Invention is Improper and Must be Stopped

Rule 143 provides the authorization for an applicant to traverse a restriction requirement. The MPEP's "requirements" for traversing a restriction requirement have become increasingly complex and can impose severe restrictions on an applicant's ability to respond properly. For example, MPEP § 818.03(b) mandates the examiner use of Form Paragraph 8.22 in every restriction requirement. Form Paragraph 8.22 states:

> *8.22 Requirement for Election and Means for Traversal*
>
> Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and *(ii) identification of the claims encompassing the elected invention.*
>
> The election of an invention or species 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.
>
> Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention (emphasis added).

The MPEP Form Paragraph 8.22 is at odds with the other requirements of the MPEP and the Statute. By *requiring* an applicant to provide the claim listing that identifies the "claims encompassing the elected invention," the Office has taken the MPEP form paragraphs and *improperly* given them the effect of the Statute or the Rules[7]. In addition, the MPEP fails to cite any binding legal authority to support the "requirement" that an applicant *must* include "a listing of all claims encompassing" an elected species. Because the asserted "requirement" is stated in a MPEP form paragraph, it does not impose a legal obligation on an applicant to provide such listing.

[7] By its own admission, the MPEP "does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations," *see* MPEP Foreword)

If the Office requires a listing of claims readable thereon, the Office should instruct examiners to provide their own claim listing. The examiner must have *already* identified the claims associated with the various species groups. As described above, the examiner typically states as the *basis* for the restriction requirement "[t]he species are independent or distinct because claims to the species recite the mutually exclusive characteristics of such species." We believe this conclusory statement could not have been made without first identifying each specific claim and its respective claim "characteristics." Because the examiner *must* perform this claim review in order to make the statement, the examiner must have drawn his *own* view of a relationship of the claims to the various species. Thus, this information is already available to the examiner. We believe that the "requirement" imposed on an applicant to provide the claim listing to be an improper shifting of burden that is not in accord with Statute or MPEP § 814.

Moreover, by requiring an applicant to identify claims that "encompass" an elected invention invites the applicant to make potentially claim scope-limiting statements in the record. Such pre-issuance claim interpretation statements could possibly be used against an applicant under post-issuance claim interpretation rules. Applicants are well-advised to not characterize their claims, especially since the Office is required to identify the claims associated with each purported species or group. *See* MPEP §§ 806.01, and 814. *See*, in particular MPEP § 806.04(e) wherein it is stated "claims are definitions of inventions." Since "inventions" are to be restricted, "[t]he examiner must provide a clear and detailed record of the restriction requirement *to provide a clear demarcation between restricted inventions* so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121" (MPEP § 814, emphasis added). A "clear demarcation" requires the examiner identify the claims associated with each group or species.

b. It is Improper to Restrict the Claims Based on Figures or Examples of the Specification

We receive a significant number of restriction requirements that are based solely on the allegation that patentably distinct inventions are *disclosed* in the figures or examples—not the claims. We traverse each of these requirements, resulting in a minority (certainly not all) of such restriction requirements being withdrawn or modified. However, the practice continues even with the same examiners. Since the *claims* define the invention that an applicant seeks to patent (*see* MPEP § 608.01(k)), MPEP § 806.01 requires an examiner to consider the claims:

> *806.01 Compare Claimed Subject Matter [R-3]*
>
> 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 such a multiplicity of species that an unduly extensive and burdensome search is necessary (emphasis added).

By *only* referring to the figures of the as-filed application, examiners are requiring restriction of inventions (or species) that are *disclosed*, as opposed to inventions (or species) that are *claimed*. It is clear from the discussion above that an applicant may *claim* "more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims" in one national application (see 37 CFR § 1.141). See also 37 § CFR 1.146: "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.... However, if such application contains *claims directed to* more than a reasonable number of species..." (emphasis added). Clearly, claims are to be restricted, not figures or examples.

Restriction based on figures is a relatively recent phenomenon. Indeed, we believe a source of the inconsistency and confusion is the USPTO Memorandum from John Love, dated April 25, 2007, that was supported by the USPTO Memorandum by Robert W. Bahr, dated January 21, 2010. Both are referenced above. In the Memoranda, regarding the "Examiner Note" associated with at least Form Paragraph 8.01, examiners are instructed that "[t]he 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" (emphasis added). As shown above, this is without any basis in law and confuses both examiners and applicants, thus causing a great deal of improper and unnecessary restrictions and traversals.

Restriction practice based on anything other than the *claimed* subject matter, e.g., figures and examples, is improper and not in accord with the Statute, Rules, or even the Office's own MPEP. We encourage the Office to instruct examiners and management of the USPTO to cease the practice of requiring restriction between figures or examples.

IV. How Could the Office Clarify Requirements for Restriction Between Related Product Inventions or Related process Inventions Where the Relationship is not Specifically Provided in MPEP Chapter 800?

The Request states that the Office is "considering providing for a new section in the MPEP to address restriction between related product inventions or related process inventions not otherwise provided for in MPEP Sec. Sec. 806 through 806.05(j)." Specifically, the Request states:

> Specifically, the Office is considering explaining that to support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, that are not otherwise provided for in MPEP Sec. Sec. 806 through 806.05(j), there must be two-way distinctness (see MPEP Sec. 802.01) and a serious burden if restriction were not required. The Office is

considering explaining that for such related product inventions or such related process inventions, the *inventions are distinct* if: (1) The inventions as claimed have *mutually exclusive characteristics* (see MPEP Sec. Sec. 806 through 806.05(f)); (2) the inventions as claimed are *not obvious variants* over each other; and (3) each invention as claimed can be made by, or used in, a *materially different process or product.* In an effort to reduce the number of improper requirements for restriction between related product inventions or related process inventions, the Office is considering explaining that where claims of an application define the same essential characteristics of a single invention, e.g., the claims vary from each other only in breadth or scope (ranging from broad to detailed), the examiner should not require restriction between such claims (emphasis added).

We agree with and applaud the Office for its efforts to reduce the number of improper requirements for restriction between related product inventions or related process inventions. Further, we commend the Office in its efforts to instruct examiners to consider explaining that where claims of an application define the same essential characteristics of a single invention, e.g., the claims vary from each other only in breadth or scope (ranging from broad to detailed), the examiner should not require restriction between such claims.

Regarding the related product inventions or related process inventions, we do not believe the proposed revision to the MPEP will provide clarity, consistency or reduced workload. Indeed, the standard used in the proposed revision is essentially the same as described above for Form Paragraph 8.14.01. As demonstrated above, the standard of distinctness defined by Form Paragraph 8.14.01 is *different* from the definition in MPEP Section 802.01. If this revision is implemented, examiners would receive guidance that is not consistent with the MPEP, Patent Statute or the Patent Rules. The guidance offered to examiners would create more ambiguity regarding the meaning of the term "distinct." An easy solution would be for the Office to restate the standard (as "independent *and* distinct"), maintain that standard in all Office guidance to examiners, and require examiners to prove independence and distinctness instead of instructing examiners to use form paragraphs as a way to satisfy their legal burden.

V. How Could the Office Modify Markush Practice?

The Request states:

First, if the examiner determines that the elected species is allowable, the Office is considering specifying that the examination of the Markush-type claim will be extended to the extent necessary to determine the patentability of the claim, i.e., to determine whether any nonelected species is unpatentable for any reason (35 U.S.C. 101, 102, 103, or 112, or nonstatutory double patenting). If a nonelected species is determined to be unpatentable, the Markush-type claim would be rejected, and the search and examination would not be extended to cover all nonelected species.

We agree with the analysis and support the Office's efforts to clarify this aspect of Markush practice.

The Request also states:

> Next, the Office is considering revising the treatment of amended Markush-type claims to clarify that whether an Office action may be made final is determined by whether the conditions in MPEP Sec. 706.07 for making a second or subsequent Office action final are met and is not dependent upon whether the examiner previously required a provisional election of species.

We agree with the analysis and support the Office's efforts to clarify this aspect of Markush practice.

The Request also states:

> Lastly, the Office is considering situations where restriction may be proper between a subcombination and a combination when a subcombination sets forth a Markush grouping of alternatives. In particular, the Office is referring to a subcombination that (1) encompasses two or more subcombination embodiments within its scope, and (2) lists those embodiments using Markush-type claim language, i.e., lists the embodiments as a group of alternatives from which a subcombination embodiment is selected. For example, the Office is considering whether restriction would be proper between a subcombination claim to an individual DNA molecule selected from a list of alternative embodiments and a combination claim to an array comprising a plurality of DNA molecules wherein one or more of the DNA molecules are selected from the list of alternative embodiments set forth in the subcombination claim. In such a situation, the combination claim does not require all the elements of any particular claimed subcombination to be present in the claimed array.

We believe the decision whether to restrict "between a subcombination and a combination when a subcombination sets forth a Markush grouping of alternatives" is entirely a fact-specific determination. We do not believe every subcombination that sets forth a Markush grouping should *automatically* be restricted from the combination. Indeed, the Office should reinforce requirements that restricted inventions must be demonstrated, by the examiner, to be *independent and distinct* and that a serious burden would exist in order to justify the restriction.

Importantly, in the fact situation described in the Request, the Office states its justification for why it believes restriction is proper: "In such a situation, the combination claim does not require all the elements of any particular claimed subcombination to be present in the claimed array." However, only do we believe this statement to be factually incorrect, but it is an inaccurate paraphrasing of the actual test in MPEP § 806.05(c). The Office failed to also

consider the other prong of the test set forth in MPEP § 806.05(c). That is, whether "(B) the subcombination can be shown to have utility either by itself or in another materially different combination." It is not apparent whether the Office simply ignored the second part of the test, or if the Office is proposing modifying the test to include only the Office's inaccurate paraphrasing of the first prong.

While it is not clear in the example provided whether the combination claim is dependent upon the subcombination claim, we take this opportunity to express our belief that it is improper to restrict a dependent claim from its respective independent claim. Because a dependent claim, by definition, includes all of the recitations of the claim from which it depends, the dependent and independent claims cannot be considered to be independent and distinct inventions. *See*, for example, 37 CFR § 1.141(a); and MPEP 806.03:

> *§ 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 (emphasis added).

> *806.03 Single Embodiment, Claims Defining Same Essential Features [R-3]*
>
> 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 inventor or a common assignee (i.e., no restriction requirement was made by the Office)<, disclosing the same embodiments, see MPEP § 804 - § 804.02.

Further, while not stated in the example provided, it appears that the claim the Office considers a "combination" is a dependent claim to "an array comprising a plurality of DNA molecules wherein one or more of the DNA molecules are selected from the list of alternative embodiments set forth in the subcombination claim." The "subcombination" claim is an independent claim to an "individual DNA molecule selected from a list of alternative embodiments." MPEP Section § 806.05(c) requires a "two-way distinctness" test to restrict such claims. That is, "[t]he 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." Using this two-way test, and assuming the DNA molecules are novel, it would be evident that the DNA molecule "subcombination" and the array "combination" would *not* be distinct and should not be restricted. This is similar to *Example I* given in MPEP § 806.05(c).

The applicant could have drafted claims to each individual DNA molecule as opposed to using a Markush-style claim. This is a matter of style, not substance. Claim scope remains the same. Logically, if an individual DNA molecule presented in a single claim cannot be restricted from the array claim, then a Markush claim to multiple DNA molecules should not be restricted. Again, the Office should not automatically restrict between a combination and a subcombination *merely* because the subcombination recites a Markush grouping. The restriction should never be proper if the claims have a dependency relationship.

The Office also stated in the Request:

> Apart from these specific considerations, the Office invites suggestions from the public regarding changes to the practice of requiring election/restriction of Markush claims in a manner that balances the interests of the Office and those of the public in the context of the current statutory and regulatory framework.

We appreciate the Office's effort to solicit suggestions to improve the practice in a way that balances the Office's interests and those of the public. However, we believe it is in the best interests of both the public and the Office to consistently follow the Statute and Rules. Further, the Office's own MPEP § 803.02 provides relevant guidance:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner *must* examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require provisional election of a single species. >See MPEP § 808.02.<
>
> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). *Broadly, unity of invention exists where compounds*

included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility (emphasis added).

Section 2172 of the MPEP states that: "the invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which applicants regard as their invention. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971)." Because applicants chose to claim their invention in a Markush-style, a presumption exists that the applicant intended each specie listed in the Markush group to possess a "common utility" and "share a substantial structural feature essential to that utility." Restriction of a Markush group *may* be proper if the examiner *proves* using objective evidence, as opposed to mere conclusory statements, that the species in the grouping lack such characteristics. See *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980), wherein the benefits of Markush-type claims are described:

> The allowance of a Markush type claim under a true genus claim would appear to be beneficial to the applicant without imposing any undue burden on the Patent and Trademark Office or in any way detracting from the rights of the public. Such a subgenus claim would enable the applicant to **[*724]** claim all the disclosed operative embodiments and afford him an intermediate **[**24]** level of protection in the event the true genus claims should be subsequently held invalid.

VI. How Could the Office Improve Rejoinder Practice?

MPEP § 821.04 provides guidance to examiners regarding rejoinder practice. MPEP § 821.04 provides, in part:

> 821.04 Rejoinder [R-3]
>
> **>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.

The Request stated:

> The Office is considering changes to rejoinder practice as part of an effort to institute more uniform treatment of claims directed to nonelected subject matter upon the determination that all claims to the elected invention are allowable. The Office is considering whether to define "rejoinder" as the practice of withdrawing a restriction requirement as between some or all groupings of claims and reinstating certain claims previously withdrawn from consideration that occurs when the following conditions are met: (1) All claims to the elected invention are allowable; and (2) it is readily apparent that all claims to one or more nonelected inventions are allowable for the same reasons that the elected claims are

> allowable. Claims that meet the second condition for rejoinder may include, for example, those that (1) properly depend from an allowable elected claim; (2) include all of the limitations of an allowable elected claim; or (3) require no further search and/or examination. Claims that may not be eligible for rejoinder would include, for example, those that require additional consideration of the prior art or raise utility, enablement, or written description issues not considered during examination of the allowable elected claims.

We agree with the most of the proposed changes to rejoinder practice that are mentioned above. However, as discussed above, we do not believe that rejoinder of claims "that (1) properly depend from an allowable elected claim; [or] (2) include all of the limitations of an allowable elected claim" is necessary because it is improper to restrict such dependent claims away from the independent claim. Similarly, claims that require all the limitations of an elected claim should not be restricted away from the elected claim. *See*, for example, 37 CFR § 1.141(a); and MPEP § 806.03.

We do not agree, however, that claims should not be rejoined due to "additional consideration of the prior art or raise utility, enablement, or written description issues not considered during examination of the allowable elected claims." These considerations are certainly relevant to the *patentability* of the non-elected claims, but are immaterial to whether such non-elected claims recite a separately patentable invention from the elected claims. As stated in the Request and in MPEP § 821.04, rejoinder practice is the practice where *the propriety* of a restriction requirement *is reconsidered* upon allowance of the elected claims. If it is determined that such non-elected claims are directed to an independent and distinct invention and there would be a serious burden on the examiner if rejoinder was made, then rejoinder is not necessary. However, if the examiner determines that a serious burden on the examiner would not occur if non-elected claims were rejoined, then rejoinder of such claims should be made.

Lastly, the Request stated:

> Separately, the Office is also considering instructing examiners that when all claims directed to an elected invention are allowable, nonelected claims must be considered for rejoinder and withdrawal of the restriction requirement. In making this decision, examiners must reevaluate both aspects of the restriction requirement, i.e., whether the nonelected invention(s) as now claimed are independent or distinct from the claim(s) to the allowable elected invention and whether there would be a serious burden if the nonelected inventions were rejoined.

We agree with the Office's proposed instructions to examiners, with the caveat that the standard be changed from "independent or distinct" to "independent and distinct."

VII. What Other Areas of Restriction Practice Can the Office Improve and How?

We appreciate the Office's efforts to improving restriction practice and its efforts to solicit ideas and suggestions from the community. We believe the suggestions provided hereinabove will significantly improve the consistency, quality and predictability of restriction requirements. Other suggestions not already discussed include:

a. Election of Species/Linking Claims

There seems to be considerable confusion regarding restriction of "species" *vis-a-vis* restriction of "inventions" and vis-à-vis "linking claims." Many Office actions that set forth a restriction requirement are based on "patentably distinct species" within dependent claims. The independent claim usually is considered as a genus claim, and yet the dependent claim species are treated as though they are "patentably distinct inventions." In such a situation, restriction is improper for the reasons set forth above regarding improper restrictions of dependent claims from their independent claims.

Further, many restriction requirements confusingly interchange the terms "species" and "inventions." It is clear from 37 CFR § 1.141(a) that the Patent Rules intend to give "species" a different meaning and treatment as compared to "inventions." Consistent and appropriate use of the terminology "species" and "inventions" will help improve restriction practice.

In addition, "linking claim" restriction practice is in effect the same as genus/species restriction practice. MPEP § 806.04 indicates that a genus claim may "link a reasonable number of species encompassed thereby." However, under MPEP § 809, such a claim may be considered as a "linking claim." We recommend that the Office clarify the distinction between linking claim restriction practice and genus/species restriction practice, or simply eliminate the confusing "linking claim" restriction practice altogether.

b. Credit or Refund Applicant-Paid Excess Claim Fees

We encourage the Office to implement a policy to credit or refund to an applicant excess claim fees paid prior to a restriction requirement. When an applicant files an application it pays fees to the Office according to 37 CFR § 1.16. If an application contains an "excessive number of claims," the applicant is required to pay fees for the excess claims. When claims are subject to a restriction requirement and an applicant files a divisional application, the applicant is required to pay another basic filing fee.

Under these circumstances, an applicant should be entitled to a credit or a refund of the excessive claim fees paid in the original application for claims subsequently filed in the

divisional application. For example, in an original application "(A)" containing five independent claims and 100 dependent claims, the non-small entity applicant pays excessive claim fees of $4420 [$420 (two extra independent claims x $210) plus $4000 (80 extra dependent claims x $50)]. If the examiner requires restriction and the applicant files a divisional application "(B)" for two independent claims and 40 dependent claims, the excess claim fees for such divisional application (B) would total $1000 (20 extra dependent claims x $50). After restriction, the applicant will have paid a total of $5420 in excess claim fees.

However, after restriction, application (A) now contains three independent and 60 dependent; and application (B) now contains two independent and 40 dependent claims. If applications (A) and (B) were originally filed as two applications with this claim configuration, the *total* excess claim fees for such applications would be $3000: (A) 40 x $50 = $2000; and (B) 20 x $50 = $1000. Therefore, because of the restriction, the applicant paid $2420 more in excess claim fees than without the restriction requirement. This is a significant amount and the Office should implement a policy whereby an applicant is able to obtain a credit or a refund of the excess claim fees already paid in the applications.

c. Constructive Election

When claims are presented following an earlier restriction requirement, an examiner may find that the new claims are directed to an invention other than the one elected. This practice is generally described in MPEP §§ 819 and 821.03 and 37 CFR § 1.145. It is our experience, however, that examiners will hold *as a matter of course* that such newly presented claims are directed to an invention other than the one elected. It is our experience that examiners will constructively elect claims even if the originally elected claims are canceled and new claims added, no matter how similar the claim sets may be. The examiner will refuse to examine the new claims under the rubric of restriction practice. We have encountered examiners that simply allege the new independent claim is directed to a different invention or directed to a non-elected invention and they fail to provide any evidence to support their assertions. We encourage the Office to instruct examiners to comply with 37 CFR § 1.145—to demonstrate that the new claims are directed to "an invention distinct from and independent of the invention previously claimed."

VIII. Other Suggestions for Improvement

a. Eliminate Incentives to Restrict

We believe various incentives exist for the Office to restrict claims, including increased revenue from divisional application filing fees. However, one of the largest incentives may come from the examiner "Count System."

i. Revise the "Count System" With Respect to Divisional Applications

An examiner facing an application containing a large number of claims has a strong incentive to force the restriction of claims. With relatively few applicants traversing restriction requirements, an examiner can easily create a potential multiple "count" family. The examiner's work would be reduced over the entire family since each application has the same specification and would likely involve the same prior art search and issues. Receiving those examination "counts" depends, of course, on the applicant actually filing divisional applications on the non-elected claims. Thus, for essentially little additional work, an examiner can turn a "two count" application into a potential four, six or more count "family." If the applicant does not file a divisional application on the non-elected claims, the examiner still can receive the same count number for examining the reduced claim set (i.e., the elected claims). Thus, the restriction gives the examiner an easy vehicle to receive the same award for less work.

To reduce the incentive to restrict an application, we suggest the Office consider revising the count system regarding the examination of divisional applications. For example, a count system that factored in the size of the application and the number of claims examined would likely reduce the number of restriction requirements.

b. Allow an Applicant to Optionally Select a Number of (e.g., five) "Inventions" in a Single Application for an Additional Fee

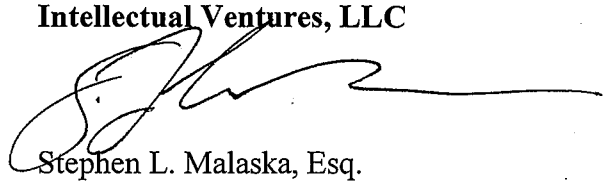
In a manner similar to how the Office handles nucleotide sequences under MPEP § 804.03, restriction practice could be improved by allowing an applicant to optionally select up to a certain number (e.g., five) of restricted inventions for examination in a single application. The applicant could pay a nominal examination fee for each group selected.

c. Provide a Mechanism for Expedited Administrative Review of Traversed Restriction Requirements

Currently, an applicant that is unhappy with a final restriction requirement may petition the Technology Center Director (37 CFR § 1.144; MPEP § 1002.02(c)(2)). This is a costly and time consuming process for any applicant. We recommend the Office provide the applicant with a more time-sensitive and cost-effective administrative review procedure. For example, by filing a simple request, the applicant could have the record reviewed by the Supervisory Patent Examiner. If the applicant is still unhappy with the administrative review, the applicant then can petition the Director.

Consideration of the above comments is respectfully requested.

Respectfully submitted,
Intellectual Ventures, LLC



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APPENDIX I

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

Date: January 21, 2010

To: Technology Center Directors
Patent Examining Corps

From: Robert W. Bahr
Acting Associate Commissioner
for Patent Examination Policy

Subject: Changes to Restriction Form Paragraphs

The purpose of this memorandum is to clarify Office policy with respect to communicating election of species requirements to applicants and with respect to establishing burden in the context of a restriction requirement. The guidance and form paragraphs set forth herein supersede the April 25, 2007 memorandum regarding changes to restriction form paragraphs, form paragraphs 8.01, 8.02, and 8.21 currently in the Office Action Correspondence Subsystem (OACS), and form paragraphs 8.01, 8.02, 8.21.01-8.21.03, and 8.22 currently in MPEP Chapter 800 (8th Ed., rev. 7, July 2008).

Form paragraphs 8.01 and 8.02 concerning election of species have caused confusion for some patent examiners and applicants with regard to (1) whether the applicant must always elect a single species, (2) why the species from which applicant is required to elect are independent or distinct, and (3) why there would be a burden on the examiner if an election of species were not required.

First, it is never appropriate to require an election between species (or inventions) that are not patentably distinct. In setting forth the species from which an applicant is required to elect, the examiner should group together species that are not patentably distinct from each other. Form paragraphs 8.01 and 8.02 have been revised by adding references to "grouping(s) of patentably indistinct species" so as to permit examiners to require election of either a single species or a single grouping of patentably indistinct species. As explained in the examiner notes, where the election requirement identifies a grouping of patentably indistinct species, applicant should not be required to elect a specific species within that grouping.

Second, form paragraphs 8.01 and 8.02 as set forth in the April 25, 2007 memo and in OACS specify that the species are independent or distinct "because claims to the different species recite the mutually exclusive characteristics of such species." However, this exemplary language is inadequate in certain cases, and it may be necessary to set forth additional details and/or different reasons to support the requirement for election. Therefore, form paragraphs 8.01 and 8.02 have been revised to permit the

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examiner to set forth an explanation as to why the species or grouping(s) of species are independent or distinct.

Third, with regard to the burden requirement, form paragraphs 8.01 and 8.02 as set forth in the April 25, 2007 memo and in OACS presume there is a burden to search and/or examine patentably distinct species "due to their mutually exclusive characteristics," and assert that at least one of several possible reasons apply. Similarly, form paragraph 8.21, which concludes all restriction requirements other than those setting forth only an election of species, explains that there would be a serious search and/or examination burden if restriction were not required because one or more of reasons listed therein apply. None of these form paragraphs currently provide for the examiner to identify the specific reason(s) why there would be a search and/or examination burden if restriction were not required in the application under examination.

As noted in MPEP §§ 803 and 808.02, if the examination and search of all the claims in an application can be made without serious burden, restriction should not be required, even though they are drawn to independent or distinct inventions, including species. To help ensure that all restriction requirements, including election of species requirements, set forth the requisite burden, and to give the applicant notice of why there is a burden, form paragraphs 8.01, 8.02, and 8.21 have been revised to provide for the examiner to specify at least one applicable reason. Possible applicable reasons are listed in the examiner notes to the form paragraphs, and are consistent with MPEP § 808.02.

Note that form paragraphs 8.01 and 8.02 as set forth in MPEP Chapter 800 do not include an explanation regarding burden, however the restriction requirement is to be concluded with one of form paragraphs 8.21.01-8.21.03 as set forth in that chapter. Revised form paragraphs 8.01 and 8.02 as set forth below include the burden explanation; furthermore, revised form paragraph 8.21 consolidates and replaces form paragraphs 8.21.01-8.21.03 and 8.22 as set forth in MPEP Chapter 800.

The following form paragraphs will be available as custom form paragraphs until the release of the next OACS update.

Revised form paragraphs 8.01, 8.02 and 8.21

¶ *8.01 Requiring an 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 35 U.S.C. 121 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 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 must include (i) an election of a species or a grouping of patentably indistinct 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(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 search and/or examination burden:

--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

--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).

5. This form paragraph does not need to be followed by form paragraph 8.21.

¶ *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 35 U.S.C. 121 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 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 must include (i) an election of a species or a grouping of patentably indistinct 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(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 § 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 search and/or examination burden:

--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

--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).

6. This form paragraph does not need to be followed by form paragraph 8.21.

¶ *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 these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply:

[1].

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

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(a) of the other invention.

Examiner Note:

1. THIS FORM PARAGRAPH MUST BE ADDED TO ALL RESTRICTION REQUIREMENTS **other than** those containing **only election of species**, with or without an action on the merits. 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 search and/or examination burden:

--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

--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).

APPENDIX II

BNA, INC.

LIFE SCIENCES LAW & INDUSTRY

VOL. 2, NO. 9 | REPORT | MAY 8, 2009

Patents

When asked by BNA to discuss major issues in life sciences patent prosecutions, attorneys responded emphatically, "Restrictions." Particular attention was paid to the PTO's interpretation of the phrase "independent and distinct" in the section of the patent law on divisional applications. Attorneys told BNA that as a result of the interpretation many life sciences patent applications may be unnecessarily restricted. Investigation by BNA and comments by life sciences attorneys show that the history of confusion over the interpretation runs deep. And a solution may be complicated.

Life Sciences Patent Restrictions Depend on Meaning of Word 'And'

U.S. Patent Law on divisional applications, 35 U.S.C. § 121, reads, "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."

The PTO has long held that "independent and distinct" means "independent or distinct." A slide from the Sept. 13, 2006, meeting of the PTO's Biotechnology/Chemical/Pharmaceutical Customer Partnership (BCP) meeting on restriction petitions references 35 U.S.C. § 121 states, "Historically the phrase 'two or more independent and distinct inventions' has been interpreted to mean two or more independent or distinct inventions."[1]

Karen Canaan, a partner in the intellectual property practice group of Sheppard Mullin Richter & Hampton LLP, Menlo Park, Calif., told BNA, "Many life sciences patent applications, which typically include composition, method, assay, and device claims, are probably being restricted unnecessarily as a result of the PTO's use of the 'independent or distinct' standard."

Jane M. Love, partner and co-vice chair of the intellectual property department of Wilmer Hale, New York, told BNA, "The PTO interpretation, which is broader than the plain language, is a problem for applicants with claims in the area of life sciences. There seem to be increasingly more restriction requirements among claims in the life sciences technologies than in other technologies. This causes increased cost for applicants to prosecute claims in separate applications that could have been retained in one application had there been a different interpretation of the language. It also causes great delay in prosecution of the restricted subject matter since a new divisional application would need to be filed prior to examination of the restricted claims."

Love continued, "In some cases, the number of restriction groups set out by the PTO in one application is high—it can be over 20 groups. The PTO often includes in their reasoning underlying the restriction requirement that it would be an 'undue burden' on the examiner to search. However, over the past five or so years, the search engines available to the public have improved tremendously, and nucleic acid sequence databases and peptide sequence databases have also improved dramatically."

PTO's Definitions. The PTO justifies its interpretation of "independent and distinct" in comments on restrictions and double patenting in Chapter 800 of the Manual of Patenting Examining Procedures:

> If "distinct" means the same thing [as independent], then its use in the statute and in the rule is redundant. . . . If section 121 of the 1952 Act were intended to direct the Director never to approve division between dependent inven-

[1] *See* http://www.cabic.com/bcp/091306.

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APPENDIX II, continued

> tions, 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) [may] be properly divided if they are, in fact, "distinct" inventions, even though dependent.[2]

The MPEP goes on to characterize inventions as "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)."

In an April 25, 2007, internal PTO memo from the deputy commissioner for patent examination policy on communicating election of species requirements and establishing examination burden to applicants, a copy of which was obtained by BNA, the PTO appeared to be further standardizing restriction requirements regarding "independent and distinct."[3]

The memo states that, while the then-current form required an examiner to provide an explanation as to why the species are "independent or distinct," the new form already provides the three most common reasons, requiring the examiner only to identify the species and the generic claims.

Patent Act's Legislative History. However, an examination of the legislative history of the Patent Act of 1952, which was the first revision of U.S. patent law since 1836 and was codified as Title 35 of the U.S. Code, suggests a different conclusion as to the meaning of "independent and distinct" than the one arrived at by the PTO.

The "Proposed Revision and Amendment of the Patent Laws" by the House Judiciary Committee, which was printed by the Government Printing Office in 1950 during the 81st Congress, shows that the wording of Section 121 on divisional applications was, "If two or more independent or distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions; and the other invention or inventions may only be made the subject of divisional applications." The phrase used is "independent or distinct." The same phrase appears in H.R. 9133[4], introduced on July 17, 1950. The bill was not acted on in the 81st Congress.

H.R. 3760[5] was introduced in the House on April 18, 1951, in the 82nd Congress by Rep. Joseph R. Bryson (D-NC), chairman of a subcommittee of the House Judiciary Committee that was in charge of the patent law revisions. In this bill, the section reads, "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; and the other invention or inventions may only be made the subject of divisional applications." The phrase used in this bill and in the revised bill H.R. 7794[6], which was passed by the House and Senate is "independent and distinct."[7]

In other words, "or" was changed to "and."

In an address on the Patent Act of 1952, delivered at the Nov. 6, 1952, meeting of the New York Patent Law Association prior to the new law's taking effect, one of the two people on the law's drafting committee discussed "independent and distinct."[8]

Giles S. Rich,[9] indicates in the speech that the change from "or" to "and" was deliberate and that without a doubt "and" means "and."

Rich said, "Section 121 is a tightening up of the law on division in favor of the patentees. The present statutes [i.e., before the 1952 amendments] do not refer to the subject. Note the conjunctive expression 'independent and distinct inventions.' Requiring the inventions be both independent and distinct makes it easier to keep two of them in one case."

Rich went on to specifically discuss the applicability of the section to the double patenting issue.

> I believe that one patent or application may still be cited against the other for this purpose. You should not have two patents on one invention, but you should not be required to show "invention" in one over what is disclosed in the other where they are copending and where you have been forced to file a plurality of applications on the theory that a plurality of inventions are being claimed.

Rich acknowledged that there should not be two patents on one invention and his comments on forcing the filing of "a plurality of applications on the theory that a plurality of inventions are being claimed" anticipate the complaints about current PTO practices by life sciences patent attorneys.

Finally, while some have suggested that the switch from "and" to "or" was a typographical error, Rich's highlighting of the phrase indicates that it was not.[10]

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[2] MPEP, "Chapter 800 Restriction in Applications Filed Under 35 U.S.C. 111; Double Patenting." *See* http://www.uspto.gov/web/offices/pac/mpep/old/E8R3_800.pdf.

[3] Memorandum from PTO Deputy Commissioner for Patent Examination Policy John Love to Technology Center Directors, Re: Changes to Restriction Form Paragraphs, April 25, 2007.

[4] *See* http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file11.pdf.

[5] *See* http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file14.pdf.

[6] *See* http://www.ipmall.info/hosted_resources/lipa/patents/patentact/file12.pdf.

[7] The Senate report on the bill, which can be found at http://www.ipmall.info/hosted_resources/lipa/patents/patentact/senate_report_1979.htm, states the following about Sections 120 and 121: "Sections 120 and 121 express in the statute certain matters which exist in the law today but which had not before been written into the statute, and in so doing make some minor changes in the concepts involved."

[8] The speech was reprinted in 1993 in a special issue of the *Journal of the Patent and Trademark Office Society*, Vol. 75, pp. 1-24.

[9] Although Bryson died in 1953, Rich lived another 46 years, serving on the U.S. Court of Appeals for the Federal Circuit where he sometimes commented in opinions on the history of the drafting the 1952 Patent Act. He also authored the opinion in *State Street & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), which allowed the patentability of business methods. He died the following year at the age of 95. In March 2009, the Federal Circuit in *In re Bilski* struck down the underpinnings of *State Street*, which attorneys indicated could have a negative effect on the life sciences industry (2 LSLR 947, 11/7/08).

[10] Note also should be made of Rich's use of the phrase "conjunctive expression." A book currently available to read

LSLR ISSN 1935-7257

APPENDIX II, continued

Calls to Reinterpret 'And.' The variance of the PTO's current practice with the evident intent of those who drafted the legislation has been noted before. In an Oct. 15, 2007, letter to the PTO offering comments on proposed rules related to the examination of patent applications that include claims containing alternative language, Intellectual Property Owners Association President Marc S. Adler wrote,

> We note that in many cases the Office continues to restrict applications where the inventions are independent or distinct from one another, which is contrary to the statements made in the Proposed Rules and in the plain language of 35 U.S.C. 121. We encouraged the Office to follow the language of 35 U.S.C. 121 and only restrict claims which are directed to inventions that are both independent and distinct.

In an April 9, 2008, letter commenting on the same proposed rules, David E. Boundy of Cantor Fitzgerald, New York, also noted that "as a practical matter, the effect of Chapter 800 of the MPEP is to permit restriction if two inventions are independent or distinct. Chapter 800 should be redrafted to conform PTO policy to statute."

Even the PTO has considered reinterpreting its definition of "independent and distinct." In the 2005 "Green Paper Concerning Restriction Practices,"[11] the PTO presented four options for the "independent and distinct" standard, the last of which was as follows:

> Under this option, the 35 U.S.C. § 121 standard would be reinterpreted to require that inventions subject to restriction be both "independent and distinct" (rather than "independent or distinct" per current practice).

Some life sciences attorneys complained that in its description of the options the PTO modified the definitions of "independent" and of "distinct." But, regardless, the PTO rejected option 4, citing comments from reviewers that the proposal for implementing such a standard was too difficult and unpredictable to be practical.[12]

In its response to the PTO's request for comments on the Green Paper, the government affairs committee of the National Association of Patent Practitioners wrote,

> In contrast to the clear intent of the law, the PTO has, on its own initiative, erroneously interpreted the law to apply a standard in the alternative, viz, "independent or distinct." The PTO has no authority to fail to adhere to that which Congress has enacted as law. Therefore, we urge the PTO to follow the law and apply the 'independent and distinct' standard for restriction, rather than risk the possibility of facing challenges in court.

The NAPP derided the PTO's "summary dismissal" of option 4 in the Green Paper and urged the PTO to reconsider it.

In a Sept. 14, 2005, letter responding to the Green Paper, Lila Feisee, director for intellectual property for the Biotechnology Industry Organization (BIO), also complained about the dismissal of option 4. She wrote,

> BIO finds the PTO's proposal for implementing this option unnecessarily complicated. Standards for both independence and distinctness already exist and standards for distinctness are already being applied by examiners. All that is necessary is additionally to apply standards for independence and to ensure that both requirements are met before an application is restricted.

Feisee concluded, "Thus, many BIO members see merit in this proposal simply because it would result in fewer restriction requirements and consequently would help minimize the costs associated with fragmentary patent protection."

Effect on Life Sciences. Sheppard Mullin's Canaan told BNA that the PTO presumes the terms "independent" and "distinct" mean the same thing and therefore are redundant. "We disagree because you can have independent and non-distinct and independent and distinct inventions. For example, if you have two separate independent claims that have the same limitations, such as a diagnostic assay and a medical device that recite the same structural limitations, then the inventions will be independent but not distinct. By contrast, if you have a diagnostic assay with structural recitations and a diagnostic method directed to the use of the assay, then the inventions will be independent and distinct."

Canaan continued, "Under its current system, the PTO will classify the assay and medical device claims in two different search classifications and assert that the searches impose a serious burden on the examiner. In response, practitioners may argue that the limitations are the same and therefore there is no serious burden, but under current PTO practice, the fact that the two claims fall under different classifications is sufficient to warrant the serious burden."

Canaan added that, under the current system, if the medical device theoretically can be used for screening as well as diagnostic purposes and the assay can be used only for diagnostic purposes, then the PTO can take the position that the medical device can be used in a materially different process, which further supports the restriction of the claims."

Canaan concluded, "Consequently, many life sciences patent applications, which typically include composition, method, assay, and device claims, are probably being restricted unnecessarily as a result of the PTO's use of the 'independent or distinct' standard."

Don Pelto, a partner in the intellectual property and litigation department of Sheppard Mullin Richter & Hampton LLP, Washington, added, "With respect to life sciences companies, the PTO's use of the term 'or' may result in restriction where restriction is not necessary or appropriate and indeed my position is that this is a real problem for life sciences companies—especially in the current economic environment where the U.S. government should be putting money into the pockets of life sciences companies to stimulate research and the economy, rather than taking it out."

Hans Sauer, BIO's associate general counsel for intellectual property, told BNA that it has been BIO's view that PTO restrictions actually generate more work for

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on google.com that was in the Harvard library when Rich was an undergraduate there, *Reports of Cases in Equity, Argued and Determined in the Court of Appeals [of South Carolina], Nov. 1854 to May 1855, Vol. 17*, indicates that, while "and" was always considered "conjunctive," "or" was not. On p. 316 in the case *Heyward v. Heyward*, there is the statement, "The usual and natural expression of the word 'or' is disjunctive." More recently, Vrae Crabbe in a book titled *Legislative Drafting*, Cavendish Press, 1993, indicates that this classification still exists: "The use of the words 'and' and 'or' has given rise to many different problems The difference in meaning lies in this: 'or' is disjunctive and 'and' is conjunctive. 'And' connotes togetherness, 'or' tells you, take your pick (pp. 34-5)."

[11] U. S. Patent and Trademark Office, "Notice of Availability of and Request for Comments on Green Paper Concerning Restriction Practice," 70 Fed. Reg. 32761 (June 6, 2005) (request for comments).

[12] *See* http://www.uspto.gov/web/patents/greenpaper.pdf.

the agency, "more and repetitive work, work that could be reduced if not eliminated if the claims were processed together."

As for the motivation behind the PTO's definition of "independent and distinct" meaning "independent or distinct," Sauer said that "the motivation runs through the PTO's activity since 2006, including its promulgation of new rules that limit the number of claims and continuations [1 LSLR 526, 9/28/07 and 3 LSLR 268, 3/27/09]. The motivation is trying to save work."

Sauer concurred with Love's comment that the PTO's reasoning underlying the restriction requirement that it would be an 'undue burden' on the examiner to search should be mitigated by more efficient search engines. "Genomic inventions can now be searched extremely efficiently," Sauer said.

Change Might Not Solve Problem. As to the effect on PTO workloads and on backlogs if "independent and distinct" was defined by the PTO as "independent and distinct," Sauer said that on the one hand, "since the PTO has indicated that the increase of filings last year was largely attributable to continuation applications and that divisionals have not been a big part of that, the impact of the change might not be enormous.

"On the other hand," Sauer continued, "there may be some self-interest on the PTO's part in downplaying the impact on the backlog of divisionals, so what the PTO has said here may be taken with a grain of salt."

Janet McLeod, a partner with Crowell & Moring LLP, New York, told BNA that under the PTO's interpretation of "independent and distinct," an "undocumented example of an alternative process for making or using the product is sufficient to show that the inventions are distinct. Thus, a requirement for restriction between claims directed to a product and process of using the product may be supported by a simple allegation that, for example, 'the product as claimed can be used in a materially different process such as a detection assay.' "

But McLeod cautioned that a change in interpreting the phrase "independent and distinct" might not benefit applicants for life sciences-related patents because the reworked interpretation still would be contingent on the PTO's definition of "independent."

As previously noted, in the 2005 Green Paper the PTO presented the possibility of differing definitions of "independent." McLeod noted, "The MPEP describes independent inventions as 'unconnected in design, operation, and effect.' However, the 2005 Green Paper states that an examiner could establish that inventions are independent by showing that the inventions do not share a common feature, or that there is a common feature but it does not 'define over the prior art and/or satisfy the enablement or written description requirements.' If there is a common feature and the elected invention is found to be patentable, the examiner would then search a nonelected invention that requires the common feature, or the common feature itself. This proposed methodology for examination would significantly increase the time and cost of prosecution."

McLeod concluded, "In addition, an applicant could not be certain whether a requirement for restriction would be maintained or withdrawn until completion of prosecution of the initially elected invention. An applicant who is unwilling to risk loss of patent term on important embodiments of an invention would thus need to file divisional applications well before a determination that the requirement would be maintained or withdrawn."

However, Love concludes, the problem with restrictions continues. "I've seen one patent application with 46 divisionals! Reconsideration of PTO's patent restriction policies could be beneficial to life sciences, if it is done the right way."

In response to BNA's request for comments on the PTO's interpretation of "independent and distinct" and on the requests by patent and life sciences organizations that the PTO reconsider its interpretation of the phrase, a PTO spokesperson May 4 e-mailed BNA portions of Chapter 800 of the MPEP.

BY JOHN T. AQUINO

The 2005 FDA Green Paper on restrictions can be found at http://www.uspto.gov/web/patents/greenpaper.pdf.
The NAPP and BIO comments on the Green Paper can be found at http://www.uspto.gov/web/offices/pac/dapp/opla/comments/restriction/napp.pdf and http://www.uspto.gov/web/offices/pac/dapp/opla/comments/restriction/bio.pdf, respectively.

APPENDIX III

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

Date: April 25, 2007

To: Technology Center Directors
Patent Examining Corps

From: John Love
Deputy Commissioner for Patent Examination Policy

Subject: Changes to Restriction form paragraphs

The purpose of this memorandum is to clarify Office policy with respect to communicating election of species requirements to applicants and with respect to establishing burden in the context of election of species requirements and restriction requirements.

Current form paragraphs 8.01 and 8.02 concerning election of species have caused confusion for some patent examiners and applicants. The current form paragraphs require an examiner to provide an explanation as to why the species are independent or distinct; the revised form paragraphs provide such explanation (i.e., "the mutually exclusive characteristics"). Using the revised form paragraphs, the examiner need only identify the species and identify the generic claim(s) (if present). However, as the Examiner Notes state, it is useful to describe the mutually exclusive characteristics of each species, if these characteristics are not readily apparent by the designation of the species by the figures or examples in the specification.

As noted in MPEP §§ 803 and 808.02, if the examination and search of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they are drawn to independent or distinct inventions, including species. To help ensure that an election of species requirement sets forth the requisite burden, the statement of search and examination burden is now incorporated directly into form paragraphs 8.01 and 8.02. These form paragraphs have been amended to include the three most common reasons for this burden in an election of species. In most cases at least two, if not all three, of these reasons will apply for patentably distinct species. If the applicant argues that the restriction is improper because there is no burden, the examiner should specify which one(s) of the reasons apply. The examiner should be able to readily identify with specificity which reason(s) apply when responding to applicant's arguments, since the search and FAOM will have been done.

New form paragraph 8.21 consolidates and replaces previous form paragraphs 8.21.01- 8.21.03 and 8.22. This new form paragraph will be for use at the end of all restriction requirements which require restrictions between inventions other than election of species, and lists the most common reasons for the search and examination burden.

The next revision of the MPEP will be amended to incorporate these changes. Examiners should seek assistance from knowledgeable TC personnel if questions arise.

Members of the MPEP Chapter 800 Review workgroup include:

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TC 1600-	Julie Burke, Christopher Low	TC 1700-	Gladys Corcoran
TC 2100-	Pat Salce	TC 2800-	Hien Phan, Bill Baumeister
TC 2600-	Ken Vanderpuye	TC 3600-	Terry Melius, Vinnie Millin
TC 3700-	Tom Hughes	OPLA-	Kathleen Fonda, Karen Hastings

The following form paragraphs will be available as "custom form paragraphs" until the release of next OACS update in July 2007.

Amended form paragraphs 8.01, 8.02 and new form paragraph 8.21
¶ 8.01 Requiring an 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 claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **[2]** generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must 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**, 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 of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the 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.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other 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 from which an election is to be made. The species are preferably identified as the species of figures 1, 2, and 3, for example, or the species of examples I, II, and III, respectively. It would be useful to describe the mutually exclusive characteristics of each species if these characteristics are not readily apparent. Or, it may be useful to explain in more detail why the species are

independent or distinct using, for example only, the definition of independent or distinct inventions at MPEP § 802.01 or form paragraphs 8.14.01 or 8.20.02. However, it is not necessary to use form paragraphs 8.14.01 or 8.20.02 here.

2. In bracket 2 insert the appropriate generic claim information.
3. This form paragraph does not need to be followed by form paragraph 8.21.

4. If applicant traverses the requirement on the basis that there is no search burden, the examiner will explain specifically which reason(s) apply.

¶ 8.02 Requiring an Election of Species; No Species Claim Present

Claim [1] generic to the following disclosed patentably distinct species: [2]. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must 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,** 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 of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the 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.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other 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 requirement described in MPEP § 803.02 (Markush group) and MPEP § 808.01(a) where only generic claims are presented.

2. In bracket 2, clearly identify the 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. It would be useful to describe the mutually exclusive characteristics of each species if these characteristics are not readily apparent. Or, it may be useful to explain in more detail why the species are

independent or distinct using, for example only, the definition of independent or distinct inventions at MPEP § 802.01 or form paragraphs 8.14.01 or 8.20.02. However, it is not necessary to use form paragraphs 8.14.01 or 8.20.02 here.
3. This form paragraph does not need to be followed by form paragraph 8.21.

4. If applicant traverses the requirement on the basis that there is no search burden, the examiner will explain specifically which reason(s) apply.

New form paragraph 8.21 replaces previous form paragraphs 8.21.01 - 8.21.03 and 8.22:

¶ 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 these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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

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 on the elected invention.

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(a) of the other invention.

Examiner Note:

1. THIS FORM PARAGRAPH MUST BE ADDED TO ALL RESTRICTION REQUIREMENTS **other than** those containing **only election of species,** with or without an action on the merits. This form paragraph only needs to be used once, after all restriction requirements are set out.

2. If applicant traverses the requirement on the basis that there is no search burden, the examiner will explain specifically which reason(s) apply.

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