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In re Application of
Urvashi Bhagat
Application No.: 13/877,847
PCT No.: PCT/US2011/056463
International Filing Date: October 14, 2011
Priority Date: October 14, 2010
For: **Optimized Nutritional Formulations, Methods for Selection of Tailored Diets Therefrom, And Methods of Use Thereof**

DECISION

ON

PETITION

This is a decision on the petition under 37 CFR 1.181 filed October 15, 2017, to invoke the supervisory authority of the Director to review the September 29, 2017 decision by the Director of Technology Center 1600 with respect to unity of invention between Groups I to IV and to request withdrawal of the requirement for restriction with respect to Group IV, and also to review the examiner's treatment of the species of claim 98.

The petition is **GRANTED** to the extent that the record of the above-identified application is clarified to indicate that there is no election of species restriction requirement currently in place with respect to the species of claim 98.

The petition is **DENIED** with respect to withdrawing the restriction requirement with respect to the invention of Group IV and with respect to the request for examination of all of the species of claim 98.

RELEVANT BACKGROUND

The above-identified application was filed as a Patent Cooperation Treaty (PCT) international application on October 14, 2011.

On June 27, 2013, the United States Designated/Elected Office (DO/EO/US) issued a NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.495 (Form PCT/DO/EO/903) reflecting a 35 U.S.C. 371(c)(1), (c)(2), and (c)(4) date of April 4, 2013.

An Office action was issued on March 20, 2015. The Office action of March 20, 2015 included a restriction requirement requiring petitioner to elect one of four groups: (1) Group I, claims 53 through 55 and 68 through 75, drawn to a method for selecting a nutritional formulation or plan for an individual; (2) Group II, claims 56 through 62, 65 and 79, drawn to a nutritional formulation for an individual comprising at least one module comprising at least one nutrient; (3) Group III, claims 66, 67, 80 and 81, drawn to a method of prophylaxis or treatment of a medical condition in a subject comprising administering a nutritional formulation for an individual comprising at least one module comprising at least one nutrient; and (4) Group IV, claim 76, drawn to a computer system. The Office action of March 20, 2015 also included an election of species requirement.

A reply to the Office action of March 20, 2015 was filed on September 18, 2015. The reply of September 18, 2015 included, *inter alia,* a preliminary amendment cancelling claims 1 through 81 and adding new claims 82 through 112, an election **with** traverse of Group I, claims 99 through 111 (indicated to correspond to previous claims 53 through 55 and 68 through 75), and an election in response to the election of species requirement.

A Notice of Non-Compliant Response concerning the reply of September 18, 2015 was issued on October 29, 2015.

A reply to the Notice of Non-Compliant Response of October 29, 2015 was filed on October 30, 2015. The reply of October 30, 2015 included an amended claim set, consisting of claims 82 through 112.

A non-final Office action was issued on February 9, 2016. The Office action of February 9, 2016 included, *inter alia*: (1) a rejection of claims 99 through 111 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter; (2) a provisional rejection of claims 99 through 111 under the judicially created double patenting doctrine over certain claims of copending application No. 13/332,251; and (3) a rejection of claims 99 through 111 under 35 U.S.C. § 112, ¶ 2,[1] as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Office action of February 9, 2016 indicated that claims 1 through 81 have been canceled, claims 82 through 112 are pending, and claims 82 through 98 and 112 are withdrawn from consideration. The restriction requirement was made **final** in the Office action of February 9, 2016; however, the requirement for an election of species was withdrawn.

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[1] Section 4 of the Leahy-Smith America Invents Act (AIA) designated pre-AIA 35 U.S.C. § 112, ¶¶ 1 through 6, as 35 U.S.C. §§ 112(a) through (f), effective as to applications filed on or after September 16, 2012. *See* Pub. L. No. 112-29, § 4, 125 Stat. 284, 293-97 (2011). Section 3 of the AIA revised 35 U.S.C. §§ 102 and 103, effective as to applications ever having a claim with an effective filing date on or after March 16, 2013, or ever having a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application that ever contained such a claim with an effective filing date on or after March 16, 2013. *See* Pub. L. No. 112-29, § 3, 125 Stat. at 285-293. The above-identified application was filed as a PCT application on October 14, 2011. Therefore, this decision refers to the pre-AIA versions of 35 U.S.C. §§ 102 and 112.

A petition under 37 CFR 1.144 and 1.181 was filed on June 18, 2016, requesting review, reconsideration and withdrawal of the final restriction requirement set forth in the Office action of February 9, 2016.

The petition of June 18, 2016 was granted in part and denied in part by the Technology Center Director in the decision of July 5, 2016. Specifically, the Technology Center Director determined that the inventions of Groups II and III have unity of invention, but that the elected invention of Group I (claims 99 through 111) lacked unity of invention with Groups II, III, and IV. The Technology Center Director thus concluded that it was unnecessary to examine additional Groups II, III, and IV.

A reply to the Office action of February 9, 2016 was filed on July 24, 2016, including an amendment to the claims. The amendment of July 24, 2016: (1) amended claims 82 through 97, 99 through 112; and (2) added new claims 113 and 114.

A renewed petition under 37 CFR 1.181 was filed on August 1, 2016, requesting review and reconsideration by the Technology Center Director of the restriction requirement.

The petition of August 1, 2016 was denied by the Technology Center Director in the decision of August 17, 2016.

A petition under 37 CFR 1.181(a)(3) was filed on August 25, 2016, requesting review of the August 17, 2016 and July 5, 2016 decisions of the Director of Technology Center 1600 and withdrawal of the final restriction requirement set forth in the Office action of February 9, 2016.

The petition of August 25, 2016 was granted in part and denied in part by the Deputy Commissioner for Patent Examination Policy in the decision of October 20, 2016. Specifically, the Deputy Commissioner determined that the inventions of Groups I, II, and III have unity of invention, and therefore, the requirement for restriction as between the inventions of Groups I, II, and III (claims 82 through 111, 113, and 114) was withdrawn. The Deputy Commissioner further determined that Group IV lacked unity of invention with Groups I, II, and II, and therefore, the requirement for restriction as to the invention of Group IV (claim 112) was not withdrawn.

A supplemental reply and amendment to the Office action of February 9, 2016 was filed on October 31, 2016, including an amendment to the claims. The amendment of October 31, 2016 (1) amended claims 82, 83, 95-100, 105, 109, and 112 and (2) argued that claim 112 as amended recites the common technical feature shared by Groups I, II, and III and requested examination of all claims.

A final Office action was issued on February 21, 2017. The Office action of February 21, 2017 included, *inter alia*: (1) a rejection of claims 99 through 111 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter; (2) a provisional rejection of claims 99 through 111 under the judicially created double patenting doctrine over certain claims of copending application No. 13/332,251; (3) a rejection of claims 99 through 112 under 35 U.S.C. § 112, ¶ 1, as failing to comply with its written description requirement; and (4) a rejection of claims 99

through 111 under 35 U.S.C. § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The final Office action of February 21, 2017 indicated that claims 1 through 81 have been canceled, claims 82 through 112, 113, and 114 are pending, and claims 82 through 98 and 112 through 114 are withdrawn from consideration. The restriction requirement was re-instituted based on the determination that the shared technical feature is disclosed in newly-cited prior art, and therefore, unity is lacking. Claims previously examined on the merits were considered constructively elected by original presentation and examined on the merits.

A petition was filed to the Technology Center Director on February 26, 2017, requesting withdrawal of the finality of the February 21, 2017 Office action, the issuance of a new non-final action addressing the unity of invention over cited art and addressing arguments and evidence of record, and a change of examiner.

The petition of February 26, 2017 was granted in part and denied in part by the Technology Center Director in the decision dated March 16, 2017. Specifically, the Technology Center Director granted the petition to the extent that it vacated the Office action of February 21, 2017 and required the examiner to abide by the final decision of the Deputy Commissioner for Patent Examination Policy on October 20, 2016 that there is unity of invention between Groups I, II, and III (claims 82 through 111, 113, and 114). The petition was denied to the extent that it requested reassignment to a new examiner.

A letter responding to the petition decision was filed March 22, 2017 indicating that the decision did not address remarks in the petition dated February 26, 2017 regarding unity of invention of Group IV (claim 112 as amended on October 21, 2016).

A reply pertaining to the vacated February 21, 2017 Office action was filed on March 26, 2017, including an amendment to the claims and additional remarks.

A non-final Office action was issued on July 11, 2017. The Office action of July 11, 2017 included, *inter alia*: (1) a rejection of claims 82 through 96, 113, and 114 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter; (2) a provisional rejection of claims 82 through 98, 113 and 114 under the judicially created double patenting doctrine over certain claims of copending application No. 12/426,034; (3) a provisional rejection of claims 82 through 98, 99 through 111, and 113 and 114 under the judicially created double patenting doctrine over certain claims of copending application No. 13/332,251; (4) a rejection of claims 82 through 111, 113 and 114 under 35 U.S.C. § 112, ¶ 1, as failing to comply with its written description requirement; (5) a rejection of claims 82 through 111, 113 and 114 under 35 U.S.C. § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention; (6) a rejection of claims 97 and 98 under 35 U.S.C. § 102(b) as being anticipated by Woods (Super Foods: walnuts [online]; 2006), in view of Anonymous (Whfoods [online]; 2009) and Chen *et al.* (*Asia Pac J Clin Nutr.* 2008; 17(S1): 329-332); and (7) a rejection of claims 82 through 96, 113, and 114 under 35 U.S.C. § 102(b) as being anticipated by Anonymous (Self Nutrition Data [online]; 2009), in view of Phillips *et al.* (*J Agric Food Chem.* 2005; 53: 9436-9445), Kornhteinber *et al.* (*Food Chemistry.* 2006; 98: 381-387), and Chen *et al.* (*Asia Pac J Clin Nutr.* 2008; 17(S1): 329-332). The Office action of July 11, 2017 also

indicated that: (1) claims 1 through 81 have been canceled; (2) claims 82 through 112, 113, and 114 are pending; (3) claim 112 is withdrawn from consideration; and (4) "species elections remain in effect."

A petition was filed to the Technology Center Director on August 30, 2017, requesting reconsideration and withdrawal of the restriction of Group IV (claim 112), in light of petitioner's amendments to claim 112 submitted on October 31, 2016.

The petition of August 30, 2017 was denied by the Technology Center Director in the decision dated September 29, 2017.

STATUTE AND REGULATION

35 U.S.C. § 121 provides that:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

35 U.S.C. § 372 provides that:

> (a) All questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office.
>
> (b) In case of international applications designating but not originating in, the United States—
>
> (1) the Director may cause to be reexamined questions relating to form and contents of the application in accordance with the requirements of the treaty and the Regulations;
>
> (2) the Director may cause the question of unity of invention to be reexamined under section 121, within the scope of the requirements of the treaty and the Regulations; and

(3) the Director may require a verification of the translation of the international application or any other document pertaining to the application if the application or other document was filed in a language other than English.

PCT Rule 13 provides that:

13.1. Requirement

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

13.2. Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

1*3.3. Determination of Unity of Invention Not Affected by Manner of Claiming*

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

13.4. Dependent Claims

Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.

13.5. Utility Models

Any designated State in which the grant of a utility model is sought on the basis of an international application may, instead of Rule 13.1 to 13.4 apply in respect of the matters regulated in those Rules the provisions of its national law concerning utility models once the processing of the international application has started in that State, provided that the applicant shall be allowed at least two months from the expiration of the time limit applicable under Article 22 to adapt his application to the requirements of the said provisions of the national law.

37 CFR 1.475 provides that:

> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
>
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
>
> (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
>
> (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
>
> (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

37 CFR 1.499 provides that:

> If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under §§ 1.143 and 1.144.

OPINION

Petitioner asserts that unity of invention should be found to exist among all of the claims currently present in the application, including: elected Group I (claims 99-111); Group II (claims 82-96,113 and 114); Group III (claims 97-98); and Group IV (claim 112). The Technology Center Director determined that the inventions of Groups I through III have unity of invention with each other, but not with the invention of Group IV. Petitioner also asserts that the election of species requirement with regard to the medical condition in Group III is improper.[2]

Whether there is unity of invention between the inventions of Groups I, II, and III and the invention of Group IV: The Deputy Commissioner for Patent Examination Policy determined that there is unity of invention between Groups I, and II, and III in the petition decision dated October 20, 2016.

The petition decision of October 20, 2016, at pages 7 through 8, states:

> A review of the invention of Group IV (claim 112) reveals that it does not recite the special technical feature common to Groups I, II and III: **a formulation** comprising omega-6 fatty acids, antioxidants, and polyphenols. This supports a finding that unity of invention does **not** exist between the inventions of Groups I, II, and III and the inventions of Group IV.

On October 31, 2016, petitioner submitted a supplementary amendment to claim 112 (among others), arguing that such amendment united Group IV with Groups I, II, and III. The amendments to the relevant paragraphs of claim 112 read as follows:

> 112. (Withdrawn, Currently Amended) A computer system configured to computationally implement a method according to claim 99, comprising:
>
> *****
>
> (f) a knowledge database having rules for manipulating the information in the database to provide a recommended future nutrition program for the individual, the nutrition program comprising one or more of nutrients selected from antioxidants, phytochemicals, lipids, vitamins and minerals in amounts that provide a beneficial effect to the individual, when a suitable daily dosage of omega-6 fatty acids and antioxidants including polyphenols is included in the program;
>
> *****
>
> (h) means for outputting the contents of the result database, under the direction of the second program module, wherein the nutrition program comprises a listing of formulations, and optionally food items comprising omega-6 fatty acids and antioxidants including polyphenols, when at least 5mg of one or more polyphenols are included in the program, for daily consumption by the individual.

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[2] This issue was not raised before the Technology Center Director.

In the Points and Evidence to be Reviewed section of the petition filed October 15, 2017, on page 8, petitioner asserts:

> [T]he amendments expressly incorporated the special technical feature in Claim 112 (Group IV): "formulations [] comprising omega-6 fatty acids and antioxidants including polyphenols" uniting Group IV with Groups I, II, and III, in accordance with guidance in the Petition Decision dated October 20, 2016.

and later states:

> Claims 82, 99, and 112(f)(h) recite the common technical feature "omega-6 fatty acids and antioxidants including polyphenols."

Chapter 10 of the International Search and Preliminary Examination Guidelines ("ISPE Guidelines") describes the method for determining whether the requirement for unity of invention under PCT Rule 13 is satisfied. In particular, ISPE Guidelines 10.12 through 10.16 are directed towards determining unity of invention when there are combinations of different categories of claims in an application.

ISPE Guideline 10.12 provides:

> The method for determining unity of invention under Rule 13 is construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
>
> (i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
>
> (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
>
> (iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process.
>
> A process is specially adapted for the manufacture of a product if it inherently results in the product and an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

Group I (claims 99-111) is directed to "[a] method for a preparing a product comprising one or more nutritional formulations…;" Group II (claims 82-96, 113, and 114) is directed to "[a] product comprising one or more nutritional formulations…;" and Group III (claims 97-98) is directed to "[a] method of prophylaxis and/or treatment of a medical condition … comprising administering a product…." The special technical feature shared by Groups I, II, and III is **a**

formulation comprising omega-6 fatty acids, antioxidants, and polyphenols. The claims of Groups I through III each require the presence of a formulation (product or composition) that is intended to be administered to an individual having the aforementioned components in specified dosages.

Group IV (claim 112), however, is directed to "[a] computer system configured to computationally implement a method" for a preparing a product comprising one or more nutritional formulations. The relationship between the inventions of Group I and Group IV most closely fits with the inventions described in ISPE Guideline 10.12, paragraph (ii), i.e., "an independent claim for a given process [and] an independent claim for an apparatus or means specifically designed for carrying out the said process." ISPE Guideline 10.14 explains in greater detail what is required for an apparatus or means to be "specifically designed for carrying out" a claimed process as follows:

> Also an apparatus or means is considered "specifically designed for carrying out" a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. **Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process.** However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means. [Emphasis added.]

Two components of the computer system of claim 112 recite the words "omega-6 fatty acids and antioxidants comprising (or including) polyphenols," namely component (f) which is a "knowledge database …to provide a **recommended future nutrition program** … **when** a suitable daily dosage of omega-6 fatty acids and antioxidants including polyphenols is included in the program" and component (h) which is a "means for outputting the contents of the resultant database … wherein the nutritional program comprises a **listing** of formulations, and optionally food items comprising omega-6 fatty acids and antioxidants comprising polyphenols, **when** at least 5mg of one or more polyphenols are included in the program …"

While it appears that the computer system of claim 112 would be capable of being used to carry out a portion of the process defined in Group I, claim 112 does not **require** a nutrition program that includes omega-6 fatty acids and antioxidants including polyphenols because these are optional elements of the nutrition program. ISPE Guideline 10.14 explains that "it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process."

Furthermore, claim 112 does not set forth any specified dosages for these components (a required element of each of the formulations in Groups I, II, and III) when they are included in a nutrition program. Petitioner's remarks in the July 24, 2016 reply to the rejections in the February 6, 2016 non-final Office action emphasize the importance of the dosages of the components (*see*, e.g., pages 28-30). The invention of Group IV is not "specifically designed for carrying out" the process of Group I because it is not similarly limited in scope.

In summary, because the recitation of "omega-6 fatty acids, antioxidants, and polyphenols" is not a positive limitation with regard to the computer system invention of Group IV, and because even when present the dosages of these components are not specified in accordance with the dosages in the invention of Groups I, II, and III, Group IV lacks unity with Groups I through III.

Assuming *arguendo* that claim 112 was amended such that the nutritional program required omega-6 fatty acids and antioxidants comprising polyphenols, and required them in the dosages specified in Groups I, II, and III, the claim would still not require the presence of the special technical feature shared by Groups I, II, and III, i.e., a **formulation** comprising omega-6 fatty acids, antioxidants, and polyphenols. Groups I, II, and III each require the presence of a formulation (product or composition) that is intended to be administered to, or consumed by, an individual. Claim 112 merely requires information in a knowledge database (component (f)) or a **listing** of formulations (component (h)), rather than formulations themselves. ISPE Guideline 10.14 explains that "an apparatus or means is considered 'specifically designed for carrying out' a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art." A computer system cannot make a contribution over the prior art in the same way that a product to be administered to, or consumed by, an individual can make a contribution to the prior art.

Petitioner also argues that there is no additional search burden on the examiner because the factors that the examiner would search for Groups I through III are substantially the same as Group IV. However, as noted above, Group IV is not specifically designed for carrying out the process of Group I, and Group IV does not require the same special technical feature as Groups I through III.

Whether the species restriction in claim 98 to "mood swings" is improper: The petition filed on October 15, 2017 is the allegation by petitioner that the species restriction in claim 98 to treatment of "mood swings" (Office action July 11, 2017, page 2) is improper. This issue should have been raised earlier, i.e., within two months of the mailing date of the action from which relief is requested; however, in view of the already lengthy petition process with regard to the restriction requirement, the propriety of the species restriction will be reviewed in this decision.

The Office action of March 20, 2015 included a restriction requirement requiring petitioner to elect one of four groups, and further required an election of species. A reply to the Office action of March 20, 2015 was filed on September 18, 2015. The reply of September 18, 2015 included, *inter alia,* a preliminary amendment cancelling claims 1 through 81 and adding new claims 82 through 112, an election **with** traverse of Group I, claims 99 through 111 (indicated to correspond to previous claims 53 through 55 and 68 through 75), and an election in response to the election of species requirement.

A non-final Office action was issued on February 9, 2016. On page 5 of the February 9, 2016 Office action the examiner stated that "[b]ecause the claims have been significantly amended since the restriction/election requirement of March 20, 2015, and the species identified as pertinent for the claim set originally presented are no longer as relevant ... the requirement for election of species is hereby withdrawn at this time." The examiner advised that future amendments may warrant a **new** requirement for election of species.

A final Office action was issued on February 21, 2017. The Office action of February 21, 2017 reinstituted the restriction requirement based on the determination that the shared technical feature is disclosed in newly-cited prior art, and therefore, unity is lacking; however, the Office action did not reinstitute the species election requirement.

In response to the petition of February 26, 2017 requesting withdrawal of the restriction requirement set forth in the final Office action, in the decision dated March 16, 2017, the Technology Center Director vacated the Office action of February 21, 2017 and required the examiner to abide by the final decision of the Deputy Commissioner for Patent Examination Policy on October 20, 2016 that there is unity of invention between Groups I, II, and III. The March 16, 2017 decision, however, referenced a "species election which appears to still be in place." The species election requirement, however, was withdrawn in the February 9, 2016 Office action, and thus, was no longer in place in the above-identified application. Because the species election requirement was previously withdrawn and the examiner did not impose a new requirement for an election of species in the July 11, 2017 Office action, **there is no election of species requirement in effect at this time**. Furthermore, claims 97 and 98 have been examined on the merits, and therefore, it would not be appropriate to impose a new election of species requirement on those claims on this record. If petitioner presents independent or dependent claims of more limited scope with regard to the medical condition treated, it would be appropriate for the examiner to reconsider whether an election of species requirement would be warranted at such time.

Whether the entire scope of claim 98 must be examined at this time: Although it is not necessary to address petitioner's specific argument that "[t]here is no specie restriction practice in ISPE Guidelines" in view of the correction of the record discussed previously, petitioner further asserts at page 12 of the petition that "[e]ven if Examiner believes that Claim 97 does not avoid prior art, Examiner needs to examine all species in Claim 98." This assertion is incorrect. ISPE Guidelines 10.07 and 10.08 provide in relevant part:

> 10.07 If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims.*****
>
> 10.08 If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.*****

In Species Election XII of the restriction requirement issued March 20, 2015, petitioner was required to elect "a single disclosed species of medical condition to which the claims shall be restricted if no generic claim is finally held to be allowable." This requirement is consistent with the ISPE Guidelines and consistent with the goals of compact prosecution. To avoid the necessity of making a restriction requirement later in prosecution if independent claim 97 does

not avoid the prior art, the examiner required a provisional election of a species to which claims 97 and 98 would be restricted if no generic claim is allowable. An election of species serves as a starting point for the search and examination of claims that encompass multiple alternative

species. Following an election of species, as explained in MPEP § 803.02, the claims that encompass multiple species (i.e., "Markush-type" claims)—

> would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and **claims to the nonelected species would be held withdrawn from further consideration.** *****
>
> On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and **claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.**

(Emphasis added).

Thus, in the absence of a requirement to elect a species (as is the case in the present application), claims to nonelected species would not be held withdrawn from further consideration. In the present application, claims 97 and 98 are rejected on prior art teaching the treatment of mood swings with a formulation that falls within the scope of the claims. Note that where a claim reads on multiple species, only one species needs to be taught or suggested by the prior art in order for the claim to be anticipated or rendered obvious. *See*, e.g., *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1298, 92 USPQ2d 1163, 1171 (Fed. Cir. 2009) (the entire element is disclosed by the prior art if one alternative in the Markush group is in the prior art). The examiner has provided a complete action on the merits for claims 97 and 98 and no claims have been withdrawn from consideration as being drawn to a nonelected species. Consistent with MPEP § 803.02, the prior art search will not be extended unnecessarily to search and examine additional species because claims 97 and 98 have been examined to the extent necessary to determine that the Markush-type claim is not patentable.

DECISION

The petition is **GRANTED** to the extent that the record of the above-identified application is clarified to indicate that there is no election of species restriction requirement currently in place with respect to the species of claim 98 (or the species of claim 97).

The petition is **DENIED** with respect to withdrawing the restriction requirement with respect to the invention of Group IV because unity of invention is found to be lacking as between the inventions of Groups I, II, and III and the invention of Group IV, and with respect to the request for examination of all species in claim 98 because the claim has been fully examined to the extent necessary to determine patentability.

This constitutes a final decision on this petition. No further requests for reconsideration will be entertained. Judicial review of this petition decision may be available upon entry of a final agency action adverse to the petitioner in the instant application (e.g., a final decision by the Patent Trial and Appeal Board). *See* MPEP § 1002.02.

The time period to respond to the non-final Office action of July 11, 2017 continues to run. Failure to file a timely reply under 37 CFR 1.111 to the Office action of July 11, 2017 will result in abandonment of the above-identified application (35 U.S.C. § 133).

Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy