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

This is a decision on the petition under 37 CFR 1.181(a)(3) filed August 25, 2016, to invoke the supervisory authority of the Director to review the August 17, 2016 and July 5, 2016 decisions of a Director of Technology Center 1600 (Technology Center Director), and withdraw the restriction requirement made final in the Office action of February 9, 2016.

The petition is **GRANTED** to the extent that the restriction requirement is withdrawn as between the inventions of Groups I, II and III (which are determined to have unity of invention).

The petition is **DENIED** with respect to withdrawing the restriction requirement with respect to the invention of Group IV.

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) mailed 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 mailed 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 mailed 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 mailed on February 9, 2016. The Office action of February 9, 2016 indicated that claims 82 through 112 were pending, of which claims 99 through 111 were rejected, and claims 82 through 98 and 112 were withdrawn from consideration. The restriction/election requirement was made **final** in the Office action of February 9, 2016.

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.

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.

13.3. 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 II and III have unity of invention.

Whether there is unity of invention between the inventions of Group I and the inventions of Groups II and III:

Petitioner argues that the inventions of Groups I and II (claims 82 and 99) share the same special technical feature, namely “omega-6 fatty acids, antioxidants, and polyphenols.” Petitioner contends that in the absence of any prior art evidence in the record that these groups lack unity of invention *a posteriori* (i.e., evidence that the special technical feature is not novel or is obvious), the inventions of Groups I and II cannot be treated as lacking unity of invention.

The Technology Center Director determined that the inventions of Group II and Group III do share unity of invention because they share a special technical feature, namely “a source of omega-6 fatty acids, a source of antioxidant, and polyphenols.” See decision of July 5, 2016 at 2. The Technology Center Director, however, determined that the inventions of Group I and the inventions of Groups II and III do not share unity of invention because: (1) the invention of Group I does not share the same technical features as Group II and Group III; and (2) the method of Group I falls outside of the categories of permissible groups presented under MPEP 1850.

Petitioner’s argument that Group I and Group II share this same special technical feature is persuasive. The expression “special technical features” means “those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” See PCT Rule 13.2; *see also* 37 CFR 1.475(a). Claim 99 (and thus claims 110 through 112 via their dependency upon claim 99) requires “selecting and preparing a one or more nutritional formulations for the individual, including at least one **formulation** comprising phytochemicals, **omega-6 fatty acids**, and **antioxidants**; wherein the one or more formulations collectively provide a daily dosage of 1 to 40g of **omega-6 fatty acids**, 25mg-10g of **antioxidants**, and one or more phytochemicals comprising one or more polyphenols which provide a daily dosage of greater than 5mg of **polyphenols**.” Since the invention of Group I shares the features identified in the decision of July 5, 2016 as the special technical features that provide unity of invention to the inventions of Group II and III, unity of invention exists among the inventions of Group I, II, and III (collectively claims 82 through 111 as they appear in the amendment filed on October 30, 2015).

The position that the method of Group I falls outside of the categories of permissible groups presented under MPEP 1850 appears to be directed to the provisions of 37 CFR 1.475(b), which is reproduced at MPEP 1850. The provisions of 37 CFR 1.475(b), however, simply present situations in which claims to different categories of invention will be considered to have unity of invention. *See* 37 CFR 1.475(b). 37 CFR 1.475 does **not** indicate that these categories of inventions are the **only** categories of invention considered to have unity of invention. *See* 37 CFR 1.475(c) (indicating that unity of invention may (but not shall) not be present if an application contains claims to more or less than one of the combinations of categories of invention set forth in 37 CFR 1.475(b)). Thus, neither the order in which claims or groups of claims is presented, nor the particular combination of categories of claims that are present, is dispositive of whether different categories of invention have unity of invention. As explained at MPEP 1850:

In applying PCT Rule 13.2 to international applications as an International Searching Authority, an International Preliminary Examining Authority and to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2.

PCT Rule 13.2, as it was modified effective July 1, 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Chapter 10 of the International Search and Preliminary Examination Guidelines, may be obtained from the Patent Examiner's Toolkit link or from WIPO's website (www.wipo.int/pct/en/texts/gdlines.html). The categories of invention in former PCT Rule 13.2 have been replaced with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Chapter 10 of the International Search and Preliminary Examination Guidelines also contains examples concerning unity of invention.

See MPEP 1850.

Whether there is unity of invention between the inventions of Groups I, II, and III and the invention of Group IV:

Petitioner argues in part that there is unity of invention between the inventions of Group I and Group IV because the invention of Group IV is defined by claim 112, and claim 112 is dependent upon claim 99 (Group I), thus showing clear unity of invention between the inventions of Groups I and IV. Petitioner also asserts that, according to Chapter 10 of the International Search and Preliminary Examination Guidelines ("ISPE Guidelines"): "There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then there is unity of invention and an objection of lack of unity does not arise . . . the benefit of any doubt being given to the applicant."

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.

Petitioner's argument that the claim of Group IV (claim 112) is a "dependent claim," dependent on claim 99 (Group I), and thus could be examined together with other claims without imposing an undue burden, is noted. Claim 112, however, is not properly treated as a dependent claim for the purposes of assessing unity of invention under the ISPE Guidelines. ISPE Guideline 5.19 provides that:

A claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, in a situation like a plug and socket example, a claim to the one part referring to the other cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...," is not a dependent claim as it does not expressly contain the limitations of the earlier claim from which it depends, rather it only has a functional relationship to that earlier claim.

ISPE Guideline 10.06 further elaborates that:

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, in a situation like the plug and socket example in paragraph 5.19, a claim to the one part referring to the other cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim.

ISPE Guideline 10.25 Example 5, specifically illustrates that

Claim 1: A process for treating textiles comprising spraying the material with a particular coating composition under special conditions (for example, as to temperature, irradiation).

Claim 2: A textile material coated according to the process of claim 1.

Claim 3: A spraying machine for use in the process of claim 1 and characterized by a new nozzle arrangement providing a better distribution of the composition being sprayed.

The process according to claim 1 imparts unexpected properties to the product of claim 2.

The special technical feature in claim 1 is the use of special process conditions corresponding to what is made necessary by the choice of the particular coating.

Unity exists between claims 1 and 2. The spraying machine in claim 3 does not correspond to the above identified special technical feature. Unity does not exist between claim 3 and claims 1 and 2.

Claim 112 (drawn to a computer system) of the above-identified application contains a reference to claim 99 (drawn to a method for providing nutritional management to an individual), which is in a different category of invention. While claim 112 may suggest a cooperation with the method according to claim 99, this does not render claim 112 dependent upon claim 99 within the sense of ISPE Guideline 10.06. As such, it would **not** be appropriate to deem claim 112 dependent upon claim 99 for purposes of the unity of invention analysis. For at least these reasons, unity of invention is not found to exist *a priori* between the inventions of Groups I, II, and III, and the invention of Group IV because claim 112 does not share a special technical feature with the inventions of Groups I, II, and III.

DECISION

The petition is **GRANTED** to the extent that unity of invention is found to exist among the inventions of Groups I, II, and III, and therefore the requirement for restriction as between the inventions of Groups I, II, and III (claims 82 through 111, 113 and 114) is withdrawn.

The petition is **DENIED** to the extent that 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 therefore the requirement for restriction as to the invention of Group IV (claim 112) will **not** be withdrawn.

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.

Telephone inquiries concerning this decision should be directed to George Dombroske at (571) 272-3283.

This application is being returned to Technology Center 1600 for further proceedings in accordance with this decision. An Office action on the merits of claims 82 through 111, 113 and 114 will follow in due course.

A handwritten signature in black ink, appearing to read 'R. Bahr', is written over the printed name.

Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy
United States Patent and Trademark Office