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In re Application of :
Urvashi Bhagat :
Application No.: 13/332,251 : DECISION ON PETITION
Filed: December 20, 2011 :
For: LIPID-CONTAINING :
COMPOSITIONS AND METHODS OF
USE THEREOF

This is a decision on the petition filed on June 6, 2017 under 37 CFR 1.181, requesting that the Director exercise his supervisory authority and overturn the decision of May 31, 2017 by the Director of Technology Center 1600 (Technology Center Director), which decision refused petitioner's request that the examiner be directed to withdraw finality of the Office action of December 21, 2016, consider the declarations filed on May 2, 2015, and respond to each of petitioner's arguments.

The petition to overturn the Technology Center Director's decision of May 31, 2017 and withdraw the finality of, or otherwise disturb, the Office action of December 21, 2016 is **DENIED**.

RELEVANT BACKGROUND

The above-identified application was filed on December 20, 2011, and claims benefit as a divisional application of prior-filed application No. 12/426,034.

Prosecution of the above-identified application resulted in a non-final Office action being mailed on April 14, 2015. The Office action of April 14, 2015 included, *inter alia*, a rejection of claims 94 and 101 under 35 U.S.C. § 102(b)[1] as being anticipated by U.S. Patent No. 5,549,905 to Mark

[1] Section 4 of the Leahy-Smith America Invents Act (AIA) designated 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

et al. The Office action of April 14, 2015 also stated that claims 1 through 93 were previously cancelled, and claims 95, 102 through 104, 107, 108, 112 through 114, 116, 118, 119, 121 through 125, 128 through 137, 139, 140, and 142 through 174 were previously withdrawn from consideration.

A response to the Office action of April 14, 2015 was filed on May 2, 2015 and a supplemental response was filed on June 13, 2015. The reply of May 2, 2015 stated that "at least claims 95, 119, 123, 125, 137, 145, 148-150, 153-155, 157, 161-163, and 168were improperly withdrawn, because they encompass elected species, *i.e.* fatty acids prepared/selected based on the factors" (page 20 of the remarks, 1st paragraph). The reply of May 2, 2015 also included declarations under 37 CFR 1.132 by Undurti N. Das (Das), Robert B. Rucker (Rucker), and Pradip K. Rustagi (Rustagi) traversing the rejection of claims 94 and 101 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,549,905 to Mark et al.

A Notice of Non-Responsive amendment was mailed on September 30, 2015 due to an apparent disagreement between petitioner and examiner to clarify the record of petitioner's election with respect to the species election requirement so that all of claims reading on the election were examined in the next Office Action. A response to the Notice of Non-Responsive amendment of September 30, 2015 was filed on September 30, 2015 (the same day), confirming the election to the species and indicating that "all of the claims 94-172 and 177-178 encompass the elected species," noting that the "ingredients/components in the dependent claims are not mutually exclusive."

A non-final Office action was mailed on March 4, 2016. The Office action of March 4, 2016 included, *inter alia*: (1) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145 through 150, 153 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 101 as not directed to patent eligible subject matter; (2) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145 through 150, 153 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 112, ¶ 2, for failing to comply with its definiteness requirement; (3) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145, 147, 148, 153 through 157, 159 through 161, 164 through 166, 171, 177, and 178 under 35 U.S.C. § 102(b) as being anticipated by "Olives" (published March 14, 2006), as evidenced by "Olives Nutrient Analysis" (published March 14, 2006); and (4) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, , 139, 140, 145, 147 through 149, 153 through 157, 159 through 162, 164

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 having any claim with an effective filing date on or after March 16, 2013. *See* Pub. L. No. 112-29, § 3, 125 Stat. at 285-293. Since the above-identified application was filed prior to September 16, 2012, and has only claims with an effective filing date prior to March 16, 2013, this decision refers to the pre-AIA versions of 35 U.S.C. §§ 102, 103, and 112.

through 166, 171, 177, and 178 under 35 U.S.C. §102(b) as being anticipated by "Walnuts" (published November 9, 2006), as evidenced by "Walnuts Nutrient Analysis" (published November 9, 2006). The Office action of March 4, 2016 also acknowledged the declarations by Das, Rucker, and Rustagi filed on May 2, 2015.

A response to the Office action of March 4, 2016 was filed on July 24, 2016 amending claims 94 and 101 as follows:

> 94. A method of preparing a lipid-containing formulation for a subject, comprising:
>
> combining daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area,
>
> wherein the formulation comprises omega-6 and omega-3 fatty acids, and wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of:
>
> ~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or
>
> ~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or
>
> ~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or
>
> ~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 2:1 to 30:1 if the subject has a diet of high seafood; or
>
> ~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 1:1 to 45:1 based on lipid tolerance of the subject; or

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or

wherein, the fatty acid content is matched to Table 6;

wherein the product produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

101. A method of selecting a lipid-containing formulation for administering to a subject, comprising:

a) evaluating the subject on the basis of one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area, and

b) combining daily amounts of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 2:1 to 30:1 if the subject has a diet of high seafood; or

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 1:1 to 45:1 based on lipid tolerance of the subject; or

~~the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of~~ 1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or

wherein, the fatty acid content is matched to Table 6;

wherein the product produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

A final Office action was mailed on December 21, 2016.

The final Office Action of December 21, 2016 included, *inter alia*: (1) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145, 147 through 149 153 through 157, 159 through 162, 164 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 101 as not directed to patent eligible subject matter; (2) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145 through 150, 153 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 112, ¶ 2, for failing to comply with its definiteness requirement; and (3) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145, 147 through 149, 153 through 157, 159 through 162, 164 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 102(b) as being anticipated by "Olive oil" (published July 14, 2007), as evidenced by Olive Oil Nutritional Profile (published July 14, 2007).

A reply under 37 CFR 1.116 to the final Office action of December 21, 2016 was filed on February 21, 2017. The reply under 37 CFR 1.116 of February 21, 2017 proposed to amend claims 94 and 101 as follows:

94. A method of preparing a lipid-containing formulation for a subject, comprising:

combining daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area,

wherein the formulation comprises omega-6 and omega-3 fatty acids, and wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of:

4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or

1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or

4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or

2:1 to 30:1 if the subject has a diet of high seafood; or

1:1 to 45:1 based on lipid tolerance of the subject; or

1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or

wherein, the fatty acid content is matched to Table 6;

wherein the ~~product~~ formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

101. A method of selecting a lipid-containing formulation for administering to a subject, comprising:

a) evaluating the subject on the basis of one or more factors selected from: age of the subject, gender of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area, and

b) combining daily amounts of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and/or their amounts are controlled based on the one or more factors; wherein, the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of

4:1 or greater, wherein dosage of omega-6 fatty acids is not more than 40 grams; or

1:1 to 10:1 if the subject has a diet of low antioxidants and/or low phytochemicals; or

4:1 to 45:1 if the subject has a diet of high antioxidants and/or high phytochemicals; or

2:1 to 30:1 if the subject has a diet of high seafood; or

1:1 to 45:1 based on lipid tolerance of the subject; or

1:1 to 50:1 if the subject has a condition wherein gradual increase of omega-6 and/or gradual withdrawal of omega-3 is necessary; or

wherein, the fatty acid content is matched to Table 6;

wherein the ~~product~~ formulation produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed.

An advisory action was mailed on March 17, 2017. The advisory action of March 17, 2017 indicated that the amendment of February 21, 2107 would be entered for purposes of appeal.

A petition under 37 CFR 1.181was filed on May 9, 2017, and supplemented on May 21, 2017, requesting that the finality of the Office action of December 21, 2016 be withdrawn.

A decision by Technology Center Director was mailed on May 31, 2017, the decision of May 31, 2017 denied the petition of May 9, 2016.

A petition under 37 CFR 1.181 filed on June 5, 2017, and replaced by the petition under 37 CFR 1.181 filed on June 6, 2017, requests that the Director exercise his supervisory authority over the Technology Center Director, and specifically requests that the examiner be directed to withdraw finality of the Office action of December 21, 2016, consider the declarations filed on May 2, 2015, and respond to each of petitioner's arguments.

STATUTES AND REGULATIONS

35 U.S.C. § 132(a) states:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the

application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 134 provides that:

> (a) PATENT APPLICANT — An applicant for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the Patent Trial and Appeal Board, having once paid the fee for such appeal.
>
> (b) PATENT OWNER — A patent owner in a reexamination may appeal from the final rejection of any claim by the primary examiner to the Patent Trial and Appeal Board, having once paid the fee for such appeal.

37 CFR 1.104(b) provides that:

> *Completeness of examiner's action.* The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

37 CFR 1.181(a) provides that:

> Petition may be taken to the Director:
>
> (1) From any action or requirement of any examiner in the *ex parte* prosecution of an application, or in *ex parte* or *inter partes* prosecution of a reexamination proceeding which is not subject to appeal to the Patent Trial and Appeal Board or to the court;
>
> (2) In cases in which a statute or the rules specify that the matter is to be determined directly by or reviewed by the Director; and
>
> (3) To invoke the supervisory authority of the Director in appropriate circumstances. For petitions involving action of the Patent Trial and Appeal Board, see § 41.3 of this title.

37 CFR 41.31 provides that:

> (a) Who may appeal and how to file an appeal. An appeal is taken to the Board by filing a notice of appeal.
>
> (1) Every applicant, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal

accompanied by the fee set forth in § 41.02(b)(1) within the time period provided under§ 1.134 of this title for reply.

(2) Every owner of a patent under ex parte reexamination filed under § 1.510 of this title before November 29, 1999, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the· fee set forth in § 4 l .20(b)(1) within the time period provided under § 1.134 of this title for reply.

(3) Every owner of a patent under ex parte reexamination filed under § 1.510 of this title on or after November 29, 1999, any of whose claims has been finally (§ 1.113 of this title) rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 4 l .20(b)(1) within the time period provided under § 1.134 of this title for reply.

(b) The signature requirements of §§1.33 and 11.18(a) of this title do not apply to a notice of appeal filed under this section.

(c) An appeal, when taken, is presumed to be taken from the rejection of all claims under rejection unless cancelled by an amendment filed by the applicant and entered by the Office. Questions relating to matters not affecting the merits of the invention may be required to be settled before an appeal can be considered.

(d) The time periods set forth in paragraphs (a)(l) through (a)(3) of this section are extendable under the provisions of §1.136 of this title for patent applications and§ 1 .550(c) of this title for ex parte reexamination proceedings.

OPINION

Petitioner argues that: (1) the examiner introduced new grounds of rejection not necessitated by thc amendment of the claims and thus the finality of the Office action of December 21, 2017 is not consistent with section 706.07(a) of the Manual of Patent Examining Procedure (MPEP); (2) the examiner does not answer the substance of several arguments advanced by applicant and thus violates MPEP § 707.07(f); (3) the examiner does not honor testimony of skilled persons thus violating MPEP § 2107.II; (4) the examiner is applying a "public use" rejection without providing any evidence or providing the applicant with an opportunity to respond in violation of MPEP § 706.07(c).

With respect to petitioner's argument that the examiner introduced new grounds of rejection not necessitated by amendment in the final Office action of December 21, 2017 final:

Petitioner specifically contends that the examiner introduced two new grounds of rejection in the Office action of December 21, 2016 that are not necessitated by amendment (nor based on information submitted in an information disclosure statement): (1) the rejection under 35 U.S.C.

§ 101; and (2) the rejection under 35 U.S.C. § 102 based upon "Olive Oil." Petitioner also contends that the rejection under 35 U.S.C. § 112, ¶ 2, in the Office action of December 21, 2016 was not necessitated by amendment. Petitioner argues that the amendment to claims 94 and 101 of the phrase "wherein the product produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or a seed" did not change the substance of the claim and therefore did not necessitate new grounds of rejection, as the amendment merely clarifies that a specific variety of a fruit, a vegetable, a grain, a legume, a nut, or seed cannot achieve the processes being claimed.

United States Patent and Trademark Office (USPTO) final action practice is set forth in MPEP § 706.07, which provides in part that:

> Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, *i.e.*, either an allowance of the application or a final rejection.
>
> While applicant does not have the right to amend as often as the examiner presents new references or reasons for rejection, examiners should not make hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application.
>
> The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal. However, it is to the interest of the applicants as a class as well as to that of the public that prosecution of an application be confined to as few actions as is consistent with a thorough consideration of its merits.

MPEP § 706.07(a) specifically set forth the USPTO's second action final practice, and provides in part that:

> Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). Where information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, *e.g.*, a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP § 609.04(b). Furthermore, a second or any subsequent action on the merits in any application will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art. Where information is submitted in a reply to a requirement under 37 CFR 1.105, the examiner may NOT make the next Office action relying on that art final unless all instances of the application of such art are necessitated by amendment.

In the above-identified application, the amendment to add the phrase "wherein the product produced by the method is not a specific variety of a fruit, a vegetable, a grain, a legume, a nut or a seed" to each of claims 94 and 101 changed the scope of the claims from covering a process that may produce a fruit (olives) or nut (walnuts) to a process that may not produce a fruit, a vegetable, a grain, a legume, a nut or a seed. This change to claims 94 and 101 goes directly to the basis for the examiner's modification of the patent eligibility rejection under 35 U.S.C. § 101, and to the basis for the examiner's change in rejection under 35 U.S.C. § 102 based upon prior art pertaining to "Olives" and "Walnuts" to a prior art pertaining to "Olive oil."

Finally, petitioner's arguments concerning the rejection under 35 U.S.C. § 112, ¶ 2, in the Office action of December 21, 2016 go to the propriety of the rejection, not whether the rejection was necessitated by the amendment. Again, the change to claims 94 and 101 goes directly to the basis for the examiner's inclusion of a rejection under 35 U.S.C. § 112, ¶ 2, in the Office action of December 21, 2016.

Petitioner is reminded that the review of the propriety of a rejection *per se* (and its underlying reasoning) is by way of an appeal as provided by 35 U.S.C. § 134 and 37 CFR 41.31, and not by way of petition under 37 CFR 1.181, even if a petitioner frames the issues as concerning procedure as set forth in the MPEP versus the merits. *See Boundy v. U.S. Patent & Trademark*

Office, 73 USPQ2d 1468, 1472 (E.D. Va. 2004). As stated by the Court of Customs and Patent Appeals (a predecessor of the U.S. Court of Appeals for the Federal Circuit), the adverse decisions of examiners which are reviewable by the Board are those which relate, at least indirectly, to matters involving the rejection of claims. *See In re Hengehold*, 440 F.2d 1395, 1404 (CCPA 1971). That an applicant casts the argument as directed to the *prima facie* case requirement (rather than the merits of the rejection) does not untether the review of the *prima facie* case from the review of the merits of the rejection. *See In re Jung*, 637 F.3d 1356, 1363 (Fed. Cir. 2011) (applicant's procedural arguments concerning the *prima facie* case requirement are the same arguments that would have been made on the merits). An applicant dissatisfied with an examiner's decision in the second or subsequent rejection may appeal to the Patent Trial and Appeal Board. *See* 37 CFR 41.31(a)(1). It is well settled that the Director will not, on petition, usurp the functions or impinge upon the jurisdiction of the Patent Trial and Appeal Board. *See In re Dickerson*, 299 F.2d 954, 958 (CCPA 1962) (The Board will not ordinarily hear a question that should be decided by the Director on petition, and the Director will not ordinarily entertain a petition where the question presented is a matter appealable to the Board). *See also* MPEP § 1201.

As the amendment to claims 94 and 101 sufficiently modified these claims as to require the change in rejections as between the Office action of March 4, 2016 and the Office action of December 21, 2016, the examiner's action is making the Office action of December 21, 2016 as final Office action was consistent with MPEP § 706.07(a). *See Ex parte Morris*, 159 USPQ 127, 128 (Comm'r Pat. 1968).

With respect to petitioner's argument that the examiner did not answer the substance of several arguments advanced by applicant:

MPEP § 707.07(f) provides, in part, that:

> In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application.
>
> Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment.

A review of the final Office action of December 21, 2016 reveals that: (1) the examiner has addressed petitioner's arguments regarding the "controlled" ratio of omega-6 to omega-3 fatty acids and/or their amounts are not features of nature (see, *e.g.*, pages 15-16, carry-over paragraph; page 16, second and third paragraphs; page 24, second paragraph; and pages 25-27); (2) the examiner has addressed petitioner's arguments regarding the term "evaluating a subject" recited in claim 101 (see, *e.g.*, page 29, second full paragraph); and (3) the examiner has

indicated that petitioner's arguments regarding the "Olives" reference is moot as the rejections based on this reference were withdrawn in the final Office action mailed on December 16, 2016 (see pages 3-4, carry-over paragraph).

Petitioner should note that differences in opinion between an applicant and the examiner as to the nature of the invention, scope of the claims, adequacy of the disclosure, or scope and content of the prior art are typical during the patent examination process. Such differences of opinion are not, however, the basis for a petition under 37 CFR 1.181. Petitioner is free to challenge the reliability, accuracy, and weight of the evidence by: presenting arguments that the rejections made fail to establish a *prima facie* case of unpatentability; presenting evidence in support of patentability; or presenting both arguments and evidence in a reply under 37 CFR 1.111. Petitioner is again reminded that in the event that an examiner is not persuaded by the arguments and/or evidence presented by an applicant to withdraw the rejections, review of the propriety of a rejection *per se* (and its underlying reasoning) is by way of an appeal as provided by 35 U.S.C. § 134 and 37 CFR 41.31, and not by way of petition under 37 CFR 1.181, even if an applicant frames the issues as concerning procedure as set forth in the MPEP versus the merits. *See Boundy*, 73 USPQ2d at 1472 (E.D. Va. 2004).

With respect to petitioner's argument that the examiner has not considered the declarations under 37 CFR 1.132 by Das, Rucker, and Rustagi:

MPEP 716.01(c) III provides, in part, that:

> Although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue. While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. *In re Chilowsky,* 306 F.2d 908, 134 USPQ 515 (CCPA 1962) (expert opinion that an application meets the requirements of 35 U.S.C. 112 is not entitled to any weight; however, facts supporting a basis for deciding that the specification complies with 35 U.S.C. 112 are entitled to some weight); *In re Lindell,* 385 F.2d 453, 155 USPQ 521 (CCPA 1967) (Although an affiant's or declarant's opinion on the ultimate legal issue is not evidence in the case, "some weight ought to be given to a persuasively supported statement of one skilled in the art on what was not obvious to him." 385 F.2d at 456, 155 USPQ at 524 (emphasis in original)).

The examiner has considered the declarations under 37 CFR 1.132 by Das, Rucker, and Rustagi filed on May 2, 2015 and has addressed these declarations in the non-final Office action of March 4, 2016 (see, *e.g.*, page 2, second paragraph), the final Office action of December 21, 2016 (see, *e.g.*, page 7, second paragraph), and the advisory action mailed on March 17, 2017 (see, *e.g.*, page 17, paragraph 3). Again, differences in opinion between an applicant and the examiner as to the weight or persuasive value of evidence submitted in support of patentability

are typical during the patent examination process. Such differences of opinion are not, however, the basis for a petition under 37 CFR 1.181. Petitioner is again reminded that in the event that an examiner is not persuaded by the arguments and/or evidence presented by an applicant to withdraw the rejections, review of the propriety of a rejection *per se* (and its underlying reasoning) is by way of an appeal as provided by 35 U.S.C. § 134 and 37 CFR 41.31, and not by way of petition under 37 CFR 1.181, even if an applicant frames the issues as concerning procedure as set forth in the MPEP versus the merits. *See Boundy*, 73 USPQ2d at 1472 (E.D. Va. 2004).

With respect to petitioner's argument the examiner is applying a "public use" rejection without providing any evidence or providing the applicant with an opportunity to respond:

The rejections pending in the above-identified application are the rejections set out in the final Office Action of December 21, 2016, namely: (1) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145, 147 through 149, 153 through 157, 159 through 162, 164 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 101 as not directed to patent eligible subject matter; (2) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145 through 150, 153 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 112, ¶ 2, for failing to comply with its definiteness requirement; and (3) a rejection of claims 94, 95, 101, 108, 116, 119, 122 through 125, 128 through 132, 134, 137, 139, 140, 145, 147 through 149, 153 through 157, 159 through 162, 164 through 166, 168, 171, 177, and 178 under 35 U.S.C. § 102(b) as being anticipated by "Olive oil" (published July 14, 2007), as evidenced by Olive Oil Nutritional Profile (published July 14, 2007). Any positions concerning the patentability of the claims in the above-identified application advanced during interviews do not amount to a "rejection" unless and until such position is stated in an Office action. Therefore, there are no rejections (*e.g.*, a "public use" rejection) of the claims in the above-identified application other than those rejections stated the final Office Action of December 21, 2016.

DECISION

For the previously stated reasons, the petition to withdraw the finality of, or otherwise disturb, the final Office action of December 21, 2016 is **DENIED**.

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 above-identified application is being returned to Technology Center 1600. Petitioner is reminded that the failure to timely reply within the meaning of 37 CFR 1.113 to the final Office action of December 21, 2016 will result in abandonment of the above-identified application.

Telephone inquiries concerning this decision may be directed to Vanitha Elgart whose telephone number is 571.272.7395.

Robert W. Bahr
Deputy Commissioner for
Patent Examination Policy