



Asha Nutrition Sciences, Inc.  
P.O. Box 1000  
Palo Alto CA 94302

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 August 27, 2016, which is being treated as a petition under 37 CFR 1.181(a)(3) requesting that the Director exercise her supervisory authority and overturn the decision of July 8, 2016, of the Director of Technology Center 1600 (Technology Center Director), which decision refused to withdraw the final restriction requirement in the Office action of March 4, 2016.

The petition to overturn the Technology Center Director's decision of July 8, 2016 and withdraw the final restriction requirement in the Office action of March 4, 2016 is **DENIED**.

### BACKGROUND

1. The instant application was filed on December 20, 2011, as a divisional of U.S. patent application 12/426,034.
2. In the Office action mailed July 31, 2012, restriction to one of the following inventions was required under 35 U.S.C. 121:
  - I. Claims 42, 44-51, 56-57, 63-64, 66, 68, 73, 80-83, 85-86, 92, and 120, drawn to methods of treatment of medical conditions, classified in class 514, multiple subclasses.
  - II. Claims 94-95, drawn to methods for preparing lipid-containing compositions, classified in classes 426 and 554, multiple subclasses.
  - III. Claims 96-100, drawn to methods of administering formulations to a subject, classified in class 514, multiple subclasses.
  - IV. Claims 101-104, 107-108, 111-114, and 116-119, drawn to methods of selecting a lipid formulation, classified in class 514, multiple subclasses.

Petitioner also was required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In addition, the species election was required to identify one specific composition including all components thereof (regardless of which of Groups I-IV was elected), and, if either Group I or Group III was elected, the species election was required to also identify one specific medical condition within the scope of the claims.

3. Petitioner filed a reply on August 31, 2012, electing the invention of Group II (claims 94-95 and new claims 121-137) with traverse. Petitioner argued in the traversal that groups II and IV should be rejoined as the search involved would not be burdensome for the examiner. Petitioner also elected without traverse the species pertaining to the composition determined by the factor - climate of the subject's living area.
4. A non-final Office action was mailed on November 8, 2012. The non-final Office action of November 8, 2012: (1) indicated that the arguments traversing the restriction were persuasive and thus claims corresponding to groups II and IV were rejoined consistent with the species that was elected without traverse; and (2) maintained and made final the restriction requirement with respect to Groups I and III as petitioner did not specifically traverse the restriction requirement with respect to these groups. The non-final Office action of November 8, 2012 indicated that claims 94, 95, 101-104, 107, 108, 111-114, 116-119 and 121-143 were pending, and of these claims 94 and 137 were rejected, and claims 95, 101-104, 107, 108, 111-114, 116-119, 121-136 and 138-143 were withdrawn from consideration.
5. Petitioner filed a reply on January 4, 2013, confirming the previous species election of "climate of the subject's living area," but disagreeing that the species election does not include any of the ingredients recited in the dependent claims. Petitioner indicated that at least claims 94, 95, 121-125, 137, and 145-149 encompassed the elected species.
6. A final Office action was mailed on April 16, 2013. The final Office action of April 16, 2013 acknowledged applicant's election with traverse of Group II, drawn to methods of preparing lipid-containing compositions, indicated that claims 173-174 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention (i.e., the invention of Group I), there being no allowable generic or linking claim, and indicated that amended claims 94 and 101 read on the elected species and were examined on the merits (and rejected) in that Office action. Thus, in the final Office action of April 16, 2013: claims 94, 95, 101-104, 107, 108, 112-114, 116, 118, 119, 121-125, 128-137, 139, 140 and 142-174 were pending, and, of these, claims 94 and 101 were rejected, and claims 95, 102-104, 107, 108, 112-114, 116, 118, 119, 121-125, 128-137, 139, 140, and 142-174 were withdrawn from consideration.

7. Petitioner filed a request for continued examination under 37 CFR 1.114 on May 22, 2013, including arguments that requested rejoinder of claims 173-176, which correspond to the invention of Group I, on the basis that all claims directed to the elected invention are in condition for allowance as they have been accepted by Australian patent office.
8. A non-final Office action was mailed on April 14, 2015. The Office action of April 14, 2015 indicated disagreement with petitioner's request to rejoin the newly added claims 174-176, and that these claims were withdrawn from examination as being directed to non-elected invention. Thus, in the Office action of April 14, 2015, claims 94, 95, 101-104, 107, 108, 112-114, 116, 118, 119, 121-125, 128-137, 139, 140 and 142-176 were pending, and, of these, claims 94 and 101 were rejected, and claims 95, 102-104, 107, 108, 112-114, 116, 118, 119, 121-125, 128-137, 139, 140, and 142-176 were withdrawn from consideration.
9. Petitioner filed a reply to the Office action of April 14, 2015 on May 2, 2015, and supplemented that reply on June 13, 2015. Petitioner argued in the reply of May 2, 2015 that "at least claims 95, 119, 123, 125, 137, 145, 148-150, 153-155, 157, 161-163, and 168 are improperly withdrawn, because they encompass elected species, i.e. fatty acids prepared/selected based on the factors" (page 20 of the remarks, 1st paragraph).
10. A Notice of Non-Responsive amendment was mailed on September 30, 2015 due to the apparent disagreement between petitioner and examiner to clarify the record of petitioner's election with respect to the species election requirement so that all claims reading on said election are examined in the next Office Action.
11. Petitioner filed a reply to the Notice of Non-Responsive amendment of September 30, 2015 on September 30, 2015 (the same day), confirming the election to the species identified as "A . . . lipid-containing formulation for . . . , a subject, comprising: combining daily amounts of fatty acids for the subject based on . . . 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 . . ." This election, however, was made with traverse on the basis that the factors "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" are not mutually exclusive. (MPEP 806.04(f))." Petitioner further indicated 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. (MPEP 806.04(f))."
12. A non-final Office action was mailed on March 4, 2016. The Office action of March 4, 2016 indicated that the requirement to elect "one specific composition including all

components thereof” “was withdrawn<sup>1</sup> and dependent claims that appear to read on the elected “factor” “have been rejoined and examined with independent claims 94 and 101. The Office action of March 4, 2016 indicated that the requirement to elect a single “factor” from those recited in Claims 94 and 101 was proper in that each factor is distinct (with reasons) in response to petitioner’s arguments that the factors recited in the claims are not mutually exclusive. The Office action of March 4, 2016 further indicated there was no need to “correct the record” because it was clear, in the response filed August 31, 2012, that applicant elected the species “climate of the subject’s living area” without traverse in response to petitioner’s statement concerning the change in the nature of the election of species to one with traverse. The species election requirement directed to a single “factor” was made final in the Office action of March 4, 2016.

13. A petition was filed on June 16, 2016, requesting the Technology Center Director to reconsider and withdraw the finality of the species election requirement on the basis that the search of all species and all claims jointly would not impose a serious burden and also because the application is to be considered special as it has been pending since 2009.
14. In a decision mailed July 8, 2016, the Technology Center Director dismissed the petition filed June 16, 2016 stating that by electing the species of ‘climate’ without traverse in the response to the restriction requirement of August 31, 2012, the applicant waived the right to later petition the election of species.
15. The instant petition was filed on August 27, 2016, seeking supervisory review of the decision of the Technology Center Director that upheld the finality of the restriction requirement by the examiner.

#### 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

---

<sup>1</sup> The indication by the examiner in the Office action mailed March 4, 2016 on the withdrawal of the requirement to elect is limited to the portion of the requirement pertaining to “all components thereof.” Accordingly, the requirement to elect a specific composition still remains, as evident from the examiner’s statement in the same Office action that “requirement to elect a single “factor” from those recited in Claims 94 and 101 was proper.”

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.

**37 CFR 1.141 provides that:**

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.

(b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.

**37 CFR 1.142 provides that:**

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

**37 CFR 1.143 provides that:**

If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefor. (See § 1.111). In requesting reconsideration the applicant must indicate a provisional election of one invention for prosecution, which invention

shall be the one elected in the event the requirement becomes final. The requirement for restriction will be reconsidered on such a request. If the requirement is repeated and made final, the examiner will at the same time act on the claims to the invention elected.

**37 CFR 1.144 provides that:**

After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181).

**37 CFR 1.145 provides that:**

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144.

**37 CFR 1.146 provides that:**

In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable. However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application.

**OPINION**

Petitioner specifically requests that the Director<sup>2</sup> overturn the Technology Center Director's decision of July 8, 2016 and that "all "factors" in claims 94 and 101, and all dependent claims be

---

<sup>2</sup> The Director of the USPTO, pursuant to 37 CFR 1.181(g), has delegated decisions on petitions seeking to invoke the supervisory authority of the Director of the USPTO in reviewing a decision of a Group Director to the Deputy Commissioner for Patent Examination Policy. *See* MPEP § 1002.02(b).

examined together because it does not impose serious examination burden, and because the application is entitled to "special" advancement having been pending for over five years."

Petitioner initially elected a species for examination without traverse in a reply filed on August 31, 2012. The examiner, however, withdrew the initial election of species requirement,<sup>3</sup> and petitioner subsequently elected with traverse in the reply of September 30, 2015 on the basis that the species are not mutually exclusive. Therefore, petitioner is **not** being treated as having elected a species without traverse, and thus having waived the right to petition the election of species requirement under the provisions of 37 CFR 1.144.

**Petitioner's contention that serious burden does not exist:**

Pursuant to MPEP § 803, "a serious burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02."

MPEP § 803 specifically provides, in part, that:

For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant.

In the initial requirement of restriction mailed July 31, 2012, the examiner stated that the species are independent or distinct and that there is a search and/or examination burden for the patentably distinct species as set forth because at least the following reason(s) apply: The claims are directed to a wide range of different medical conditions, involving unrelated different pathological processes, and the use of many different compositions in the treatment of these conditions, each of which will require separate searches of the prior art. Thus, this initial determination of a serious burden on the examiner was in accordance with the guidelines set forth in MPEP § 808.02.

MPEP § 808 specifically provides that:

Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the examiner if restriction is not required, i.e., the reasons for insisting upon restriction therebetween as set forth in the following sections.

MPEP § 808.02 specifically provides, in part, that:

---

<sup>3</sup> See Office action mailed March 4, 2016, where examiner indicates that the requirement to elect "one specific composition including all components thereof" is withdrawn.

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

(A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(B) **A separate status in the art when they are classifiable together:** Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(C) **A different field of search:** Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Thus, under MPEP § 808.02, in order to show "serious burden" the examiner must show by appropriate explanation one of the following: that the restricted inventions (1) have separate classifications, (2) have separate status in the art, or (3) require different fields of search. Initially, there is no showing of error in the examiner's position that each species (*i.e.*, "factor") is distinct because the factors are directed to different patient populations (*i.e.*, climate, diet, medical conditions are directed to different patient (subject) populations). In addition, these species do not appear to be obvious variants of each other based on the current record. *Cf. In re Lee*, 199 USPQ 108, 109 (Comm'r Pat. 1978) (providing for withdrawal of a restriction requirement due to the applicant's express admission that the inventions are obvious variants of each other within the meaning of 35 U.S.C. § 103). Moreover, it is readily apparent that search queries directed to the factor of "ambient temperature range of the subject's living area" will not encompass additional searches that would be necessary the species directed to the alternative "factors": *i.e.*, 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, and family medical history of the subject.

**Petitioner's contention that application is entitled to special status as a reason for withdrawal of the restriction requirement:**

Nonprovisional applications are ordinarily taken up for examination by the examiner to whom they have been assigned in the order in which they have been filed except for those applications in which examination has been advanced pursuant to 37 CFR 1.102. Subject alone to diligent

prosecution by the applicant, an application for patent that has once been made special and advanced out of turn for examination by reason of a ruling made in that particular case will continue to be special throughout its entire course of prosecution in the U.S. Patent and Trademark Office, including appeal, if any, to the Patent Trial and Appeal Board. Applications pending more than 5 years, including those which, by relation to a prior United States application, have an effective pendency of more than 5 years, are regarded automatically as special.

The instant application has been made special (see the decisions mailed February 1, 2016 and October 5, 2015 on petitions to make special filed October 3, 2015 and September 29, 2015, respectively). The special status of the application has also been acknowledged in the decision of the Technology Center Director mailed July 8, 2016 through reference to the decision mailed February 1, 2016. Petitioner should note that the special status of the application is for the purpose of advancing the examination of the application in that the examination of the application is being taken up out of its regular turn. Such special status, however, does not entitle an applicant to withdrawal of requirements for restriction or election of species that may be made as part of the examination process.

### DECISION

The petition is granted to the extent that the decision of the Technology Center Director of July 8, 2016 has been reviewed, but is **DENIED** with respect to withdrawing the restriction requirement that was made final in the Office action of March 4, 2016.

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 Ramesh Krishnamurthy at (571) 272-4914.

The application is being forwarded to the Technology Center 1600 for appropriate action on the reply filed July 24, 2016.



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