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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 90/009,487 | 07/16/2009 | 6136349 | STU775/48001 | 7695 |

27723 7590 11/06/2009

KEVIN FARRELL
PIERCE ATWOOD
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PORTSMOUTH, NH 03801

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 11/06/2009

Please find below and/or attached an Office communication concerning this application or proceeding.



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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

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AUSTIN, TX 78746-7568

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NOV 06 2009

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/009,487.

PATENT NO. 6136349.

ART UNIT 3991.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

| | | | |
|--|---------------------------|---------------------------------------|--|
| Office Action in Ex Parte Reexamination | Control No. 90/009,487 | Patent Under Reexamination 6136349 | |
| | Examiner BRUCE CAMPELL | Art Unit 3991 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

- a Responsive to the communication(s) filed on _____. b This action is made FINAL.
c A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 3. <input type="checkbox"/> Interview Summary, PTO-474. |
| 2. <input type="checkbox"/> Information Disclosure Statement, PTO/SB/08. | 4. <input type="checkbox"/> _____. |

Part II SUMMARY OF ACTION

- 1a. Claims 1-14 are subject to reexamination.
 - 1b. Claims _____ are not subject to reexamination.
 2. Claims _____ have been canceled in the present reexamination proceeding.
 3. Claims _____ are patentable and/or confirmed.
 4. Claims 1-14 are rejected.
 5. Claims _____ are objected to.
 6. The drawings, filed on _____ are acceptable.
 7. The proposed drawing correction, filed on _____ has been (7a) approved (7b) disapproved.
 8. Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the certified copies have
 - 1 been received.
 - 2 not been received.
 - 3 been filed in Application No. _____.
 - 4 been filed in reexamination Control No. _____.
 - 5 been received by the International Bureau in PCT application No. _____.
- * See the attached detailed Office action for a list of the certified copies not received.
9. Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
 10. Other: _____

cc: Requester (if third party requester)

Art Unit: 3991

***Ex Parte Reexamination
Detailed Non-Final Office Action***

This is a reexamination of U.S. Patent 6,136,349, issued October 24, 2000. A Request pursuant to 37 CFR 1.510 for *ex parte* reexamination of claims 1-14 of U.S. Patent 6,136,349 was filed on July 16, 2009 by Third Party Requester and assigned control number 90/009,487. An Order granting *ex parte* reexamination of claims 1-14 of U.S. Patent 6,136,349 was mailed on August 13, 2009.

Patent Owner's Statement

No Patent Owner's Statement under 37 CFR 1.530 was received.

Status of the Claims

Claims 1-14 of U.S. Patent 6,136,349 are subject to reexamination.

Scope of the Claims

In reexamination, patent claims are construed broadly. *In re Yamamoto*, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984) (claims given "their broadest reasonable interpretation consistent with the specification"). Claims 1 and 13, the independent claims, read as follows:

1. A method of treating a food seasoning, food ingredient or food composition such that upon ingestion it results in a decrease in serum cholesterol and blood pressure relative to an otherwise identical, untreated food seasoning, food ingredient, or food composition, wherein said treatment consists essentially of adding to said food seasoning, food ingredient, or food composition at least one material that provides for an increase in the amount of plant sterol/stanol, wherein said material is selected from the group consisting of beta-sitosterol, stigmasterol, campesterol, dihydrobrassicasterol, hardened stanol forms of said sterols, and fatty acid esters of said sterols and stanols, and at least one material that provides for an increase in a mineral nutrient selected from the group consisting of magnesium, calcium and potassium, and wherein the combined amounts of said material that provides for increased sterol/stanol and said material that provides for an increase in said mineral are sufficient to result in greater serum cholesterol and blood pressure lowering activity when ingested than the additive effect of either material if utilized singularly.

13. A treated food seasoning, food ingredient, or food composition which, upon ingestion, results in a decrease in serum cholesterol and blood pressure relative to an otherwise identical but untreated food seasoning, ingredient, or composition, wherein said treatment consists essentially of adding to a food seasoning, food ingredient, or food composition that is to be ingested, at least one material that

Art Unit: 3991

provides for an increase in the amount of plant sterol/stanol, wherein said material is selected from the group consisting of beta-sitosterol, stigmasterol, campesterol, dihydrobrassicasterol, hardened stanol forms of said sterols, and fatty acid esters of said sterols and stanols, and at least one material that provides for an increase in a mineral nutrient selected from the group consisting of magnesium, calcium and potassium, and wherein the combined amounts of said material which provides for increased sterol/stanol and said material and which provides for an increase in said mineral are sufficient to result in greater serum cholesterol and blood pressure lowering activity than the additive effect of either material if utilized singularly.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Thus any composition that can lower serum cholesterol and blood pressure, and contains the recited minerals and sterols in combination with any other edible material, would appear to meet the limitations of the claim.

Claim 1 is a process for making a product similar to that of claim 13. Any edible material is considered a "food ingredient" within the meaning of claim 1.

Claim 10 requires providing a decreased level of sodium chloride in a food composition. Since no standard of comparison is given in the claim or specification, it can not be determined what constitutes a decreased level of sodium chloride.

Therefore this claim limitation does not affect the scope of the claim.

Claims 4 and 11 recite the concentration of various components "in the diet." The claims are drawn to a method of treating food. When treating food, it is impossible to know what else a subject might consume in their diet along with said treated food. Moreover, later consumption of the treated food and/or other foods is an intended use which does not further limit the claimed process of treating food, i.e. the claims do not include a step of feeding the treated food to a subject. Therefore these claim limitations do not affect the scope of the claims.

Claim 14 recites lowering serum cholesterol in a subject. Neither the specification nor the claims defines "serum cholesterol." This term could refer to free cholesterol, HDL-cholesterol, LDL-cholesterol, total cholesterol, etc. Prior art that shows a decrease in any of these parameters would meet this claim limitation. Claim

Art Unit: 3991

14 also recites "elevated" blood pressure. Since neither the specification nor the claim provides a criterion for what is considered "elevated," any decrease in blood pressure would meet this claim limitation.

Prior Art Documents

The following prior art documents were submitted by Requester.

1. Peterson, D.W. "Effect of Soybean Sterols in the Diet on Plasma and Liver Cholesterol in Chicks," Proceedings for the Society for Experimental Biology and Medicine, Vol. 78, pp. 143-147 (1951).
2. Miller, Jonathan, et al. "Regression Studies with Safflower Oil and Sitosterol in Rabbit Atherosclerosis," Circulation Research, Vol. 7, pp. 779-786 (1959).
3. U.S. Patent No. 3,004,043 (Stern).
4. Beveridge, J.M.R., et al. "Magnitude of the Hypocholesterolemic Effect of Dietary Sitosterol in Man," Journal of Nutrition, Vol. 83, p. 119-122 (1964).
5. Mattson, Fred, et al. "Effect of Plant Sterol Esters on the Absorption of Dietary Cholesterol," Journal of Nutrition, Vol. 107, pp. 1139-1146 (1977).
6. O'Brien, Barbara, et al. "Interrelated Effects of Food Lipids on Steroid Metabolism in Rats," Journal of Nutrition, Vol. 107, pp. 1444-1454 (1977).
7. Sugano, Michihiro, et al. "A Comparison of Hypocholesterolemic Activity of β -Sitosterol and β -Sitostanol in Rats," Journal of Nutrition, Vol. 107, pp. 2011-2019 (1977).
8. Ikeda, Ikuo and Michihiro Sugano, "Comparison of Absorption and Metabolism of β -Sitosterol and β -Sitostanol in Rats," Atherosclerosis, Vol. 30, pp. 227-237 (1978). ("Ikeda I")
9. Ikeda, Ikuo, et al. "Inhibition of Cholesterol Absorption in Rats by Plant Sterols," Journal of Lipid Research, Vol. 29, pp. 1573-1582 (1988). ("Ikeda II")
10. Ikeda, Ikuo, et al. "Effects of Sitosterol and Sitostanol on Micellar Solubility of Cholesterol," Journal of Nutritional Science and Vitaminology, Vol. 35, pp. 361-369 (1989). ("Ikeda III")

Evidentiary Documents

The following prior art documents were submitted by Requester to provide evidence clarifying the disclosure of certain prior art documents:

Art Unit: 3991

1. Peterson, D.W., Effect of Sterols on the Growth of Chicks Fed High Alfalfa Diets or a Diet Containing Quillaja Saponin, Journal of Nutrition, 1950, pages 597-607, USA ("Peterson 1950")
2. Mattson, Fred H., et al, The Effect of a Nonabsorbable Lipid, Sucrose Polyester, on the Absorption of Dietary Cholesterol by the Rat, Journal of Nutrition, 1976, pages 747-752, Vol. 106, USA ("Mattson 1976")
3. Harper, A.E., Amino Acid Balance and Imbalance, Journal of Nutrition, 1958, pages 405-418, USA
4. Rogers And Harper, Amino Acid Diets and Maximal Growth in the Rat, Journal of Nutrition, 1965, pages 267-273, Vol: 87, USA
5. Committee Of The Council Of American Institute Of Nutrition, Report of the American Institute of Nutrition Ad Hoc Committee on Standards for Nutritional Studies, Journal of Nutrition, pages 1340-1348, USA ("AIN")

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Peterson**, as evidenced by Peterson 1950, USDA I, USDA II and USDA III.

Peterson discloses an experimental diet fed to young chickens. The diet contains mixed soy sterols comprising mainly sitosterol and stigmasterol (paragraph bridging pp. 143-144). Peterson 1950 discloses the other ingredients of the diet. These include limestone (calcium carbonate), bone meal (source of calcium and magnesium), barley, corn, wheat, soybean meal, fish meal, dried whey, dried skim milk, liver meal and sodium chloride (p. 598). USDA I, II and III show that many of these ingredients contain calcium, magnesium and potassium. With regard to the specific compounds recited in claims 7-9, chloride, phosphate, carbonate, sulfate, hydroxide and amino acids are all anions commonly found in biological materials, so it is expected that the cations recited in the claims would be associated with one or more of these anions. The

Art Unit: 3991

diets containing 1% or 1.3% soy sterols were found to lower plasma cholesterol in chicks relative to chicks receiving the same diet without sterols (Tables I and II).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Miller**.

Miller discloses experimental diets which comprise salts of sodium, calcium, magnesium and potassium, and may contain safflower oil (which contains β -sitosterol) or safflower oil supplemented with additional β -sitosterol (p. 779, col. 2). Diets containing sitosterol lowered serum cholesterol in rabbits more than the same diet without sitosterol.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Stern** as evidenced by Mattson 1976 and Peterson.

Stern discloses experimental diets which comprise salts of sodium, calcium, magnesium and potassium (U.S.P. Salt XIV; see Mattson 1976, footnote on p. 748) and may contain 1% soybean sterols (Example 3). Soy sterols comprise sitosterol, as noted in Peterson (p. 143, see footnote). The diet containing soy sterols lowered serum cholesterol in rats more than the same diet without sterols.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Beveridge**, as evidenced by USDA I-III.

Beveridge discloses an experimental diet fed to human subjects. The diet contains sodium chloride and skim milk powder, which provides calcium, magnesium and potassium (see USDA I-III), and could be supplemented with varying amounts of plant β -sitosterol (p. 120). With regard to the specific compounds recited in claims 7-9, chloride, phosphate, carbonate, sulfate, hydroxide and amino acids are all anions commonly found in biological materials, so it is expected that the cations recited in the claims would be associated with one or more of these anions in milk. The diet containing sitosterol was found to lower serum cholesterol relative to subjects receiving the same diet without sitosterol (Table 2).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Mattson**, as evidenced by Mattson 1976.

Mattson discloses experimental diets fed to rats. The diets contain salts of sodium, calcium, magnesium and potassium (U.S.P. XIV, see Mattson 1976), and some were supplemented with plant β -sitosterol, stigmasterol, campesterol and fatty acid esters of these sterols (p. 1141). Diets containing sterols and sterol esters were found to inhibit absorption of dietary cholesterol. While serum cholesterol was not measured directly, Mattson teaches that serum cholesterol level depends on absorption of dietary cholesterol, among other factors (p. 1144, col. 2).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **O'Brien**.

O'Brien discloses experimental diets which comprise salts of sodium, calcium, magnesium and potassium, and may contain phytosterols (p. 1445, Table 1). The diet containing phytosterols (sterols derived from plants) lowered serum cholesterol in female rats compared to the same diet without phytosterols (Fig. 1).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Sugano** as evidenced by Harper.

Sugano discloses experimental diets which comprise salts of sodium, calcium, magnesium and potassium (see pp. 2012-2013 and Harper, p. 408), and may contain the phytosterols sitosterol or sitostanol. When cholesterol was added to the feed, diets containing sitosterol or sitostanol lowered blood cholesterol in male rats compared to the same diet without sitosterol or sitostanol (Table 1).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Ikeda II**, as evidenced by Rogers.

Ikeda II discloses experimental diets which comprise salts of sodium, calcium, magnesium and potassium, and may contain sitosterol (see p. 1575, col. 1, and Rogers

Art Unit: 3991

p. 268, footnote 3). While serum cholesterol was not measured directly, it was found that sitosterol inhibits absorption of cholesterol in the intestines (p. 1576, col. 2). Ikeda II teaches that because they inhibit cholesterol absorption, plant sterols are considered hypocholesterolemic (cholesterol lowering; p. 1573, col. 1).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Ikeda III**, as evidenced by AIN.

Ikeda III discloses experimental diets which comprise salts of sodium, calcium, magnesium and potassium, and may contain sitosterol or sitostanol (see pp. 362-363, AIN). Sitosterol and sitostanol were both shown to decrease solubility of cholesterol in the intestine. While serum cholesterol level was not measured, Ikeda III acknowledges that both sitosterol and sitostanol are potent hypocholesterolemic agents (p. 361).

Prior Art Documents Not Relied Upon

Ikeda I is not applied in any rejection primarily because significant parts of the reference, including data and conclusions, are illegible. The reference appears to be cumulative to the other cited references in its use of a diet containing mineral salts in combination with sterols and stanols, but neither serum cholesterol nor blood pressure was measured in test subjects.

Conclusion

Claims 1-14 are rejected.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)).

Art Unit: 3991

Extension of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and 37 CFR 41.33 after appeal, which will be strictly enforced.

Duty to Disclose

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving U.S. Patent No. 6,136,349 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRUCE CAMPELL whose telephone number is (571)272-0974. The examiner can normally be reached on Monday - Thursday from 8:00 to 5:00. The examiner can also be reached on alternate Fridays.

Art Unit: 3991

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

All correspondence relating to this ex parte reexamination proceeding should be directed:

By EFS: Registered users may submit via the electronic filing system EFS-Web at


<https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html>


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/Bruce Campell/
Primary Examiner, Art Unit 3991


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PRIMARY EXAMINER
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DEBORAH D. JONES
CRU SPE-AU 3991



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 90/009,487 | .07/16/2009 | 6136349 | STU775/48001 | 7695 |

21839 7590 08/13/2009

BUCHANAN, INGERSOLL & ROONEY PC
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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 08/13/2009

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VINSON & ELKINS LLP

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AUSTIN, TX 78746-7568

MAILED

AUG 13 2009

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/009,487.

PATENT NO. 6136349.

ART UNIT 3991.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

| | | | |
|--|----------------------------------|--|--|
| Order Granting / Denying Request For Ex Parte Reexamination | Control No. 90/009,487 | Patent Under Reexamination 6136349 | |
| | Examiner BRUCE CAMPELL | Art Unit 3991 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 16 July 2009 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) PTO-892, b) PTO/SB/08, c) Other: _____

1. The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): **TWO MONTHS** from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): **TWO MONTHS** from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within **ONE MONTH** from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) by Treasury check or,
b) by credit to Deposit Account No. _____, or
c) by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

| | | |
|--|--|--|
| /Bruce Campell/ Primary Examiner, Art Unit 3991 | | |
| cc:Requester (if third party requester) | | |

Art Unit: 3991

Request for Ex Parte Reexamination

A request for ex parte reexamination of claims 1-14 of U.S. Patent 6,136,349 was filed July 16, 2009 by a third party requester.

Decision on Request

A substantial new question of patentability (SNQ) affecting claims 1-14 of United States Patent Number 6,136,349 is raised by the request for ex parte reexamination.

Claims

Patent 6,136,349 comprises 14 claims and this Request is directed to claims 1-14. Claims 1 and 13, the independent claims, read as follows:

1. A method of treating a food seasoning, food ingredient or food composition such that upon ingestion it results in a decrease in serum cholesterol and blood pressure relative to an otherwise identical, untreated food seasoning, food ingredient, or food composition, wherein said treatment consists essentially of adding to said food seasoning, food ingredient, or food composition at least one material that provides for an increase in the amount of plant sterol/stanol, wherein said material is selected from the group consisting of beta-sitosterol, stigmasterol, campesterol, dihydrobrassicasterol, hardened stanol forms of said sterols, and fatty acid esters of said sterols and stanols, and at least one material that provides for an increase in a mineral nutrient selected from the group consisting of magnesium, calcium and potassium, and wherein the combined amounts of said material that provides for increased sterol/stanol and said material that provides for an increase in said mineral are sufficient to result in greater serum cholesterol and blood pressure lowering activity when ingested than the additive effect of either material if utilized singularly.

13. A treated food seasoning, food ingredient, or food composition which, upon ingestion, results in a decrease in serum cholesterol and blood pressure relative to an otherwise identical but untreated food seasoning, ingredient, or composition, wherein said treatment consists essentially of adding to a food seasoning, food ingredient, or food composition that is to be ingested, at least one material that provides for an increase in the amount of plant sterol/stanol, wherein said material is selected from the group consisting of beta-sitosterol, stigmasterol, campesterol, dihydrobrassicasterol, hardened stanol forms of said sterols, and fatty acid esters of said sterols and stanols, and at least one material that provides for an increase in a mineral nutrient selected from the group consisting of magnesium, calcium and potassium, and wherein the combined amounts of said material which provides for increased sterol/stanol and said material and which provides for an increase in said mineral are sufficient to result in greater serum cholesterol and blood pressure lowering activity than the additive effect of either material if utilized singularly.

Documents Submitted by Requester

Art Unit: 3991

The following documents were submitted by Requester as the basis for this Request.

1. Peterson, D.W. "Effect of Soybean Sterols in the Diet on Plasma and Liver Cholesterol in Chicks," Proceedings for the Society for Experimental Biology and Medicine, Vol. 78, pp. 143-147 (1951).
2. Miller, Jonathan, et al. "Regression Studies with Safflower Oil and Sitosterol in Rabbit Atherosclerosis," Circulation Research, Vol. 7, pp. 779-786 (1959).
3. U.S. Patent No. 3,004,043 (Stern).
4. Beveridge, J.M.R., et al. "Magnitude of the Hypocholesterolemic Effect of Dietary Sitosterol in Man," Journal of Nutrition, Vol. 83, p. 119-122 (1964).
5. Mattson, Fred, et al. "Effect of Plant Sterol Esters on the Absorption of Dietary Cholesterol," Journal of Nutrition, Vol. 107, pp. 1139-1146 (1977).
6. O'Brien, Barbara, et al. "Interrelated Effects of Food Lipids on Steroid Metabolism in Rats," Journal of Nutrition, Vol. 107, pp. 1444-1454 (1977).
7. Sugano, Michihiro, et al. "A Comparison of Hypocholesterolemic Activity of β -Sitosterol and β -Sitostanol in Rats," Journal of Nutrition, Vol. 107, pp. 2011-2019 (1977).
8. Ikeda, Ikuo and Michihiro Sugano, "Comparison of Absorption and Metabolism of β -Sitosterol and β -Sitostanol in Rats," Atherosclerosis, Vol. 30, pp. 227-237 (1978). ("Ikeda I")
9. Ikeda, Ikuo, et al. "Inhibition of Cholesterol Absorption in Rats by Plant Sterols," Journal of Lipid Research, Vol. 29, pp. 1573-1582 (1988). ("Ikeda II")
10. Ikeda, Ikuo, et al. "Effects of Sitosterol and Sitostanol on Micellar Solubility of Cholesterol," Journal of Nutritional Science and Vitaminology, Vol. 35, pp. 361-369 (1989). ("Ikeda III")

Mattson was cited by Applicant in the prosecution of the application that matured into the '349 patent (09/106,094, "the '094 application"). This will be discussed further below. None of the other references were considered in the prosecution of the '094 application.

Requester's Proposed SNQs

Requester considers claims 1, 2, 4, 8, 10 and 12-14 unpatentable over **Peterson**.

Peterson discloses an experimental diet fed to young chickens. The diet contains minerals in the form of ground limestone and bone meal, each of which provides at least calcium, and may contain mixed soy sterols comprising mainly sitosterol and stigmasterol (paragraph bridging pp. 143-144). The diet containing soy sterols was found to lower serum cholesterol in chicks relative to chicks receiving the same diet without sterols.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Peterson can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the Peterson disclosure important in determining whether claims 1, 2, 4, 8, 10 and 12-14 are patentable. Accordingly, Peterson raises a SNQ regarding claims 1, 2, 4, 8, 10 and 12-14.

Requester considers claims 1-14 unpatentable over **Miller**.

Miller discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain safflower oil supplemented with β -sitosterol (p. 779, col. 2). Diets containing sitosterol lowered serum cholesterol in rabbits more than the same diet without sitosterol.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more

Art Unit: 3991

minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Miller can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the Miller disclosure important in determining whether claims 1-14 are patentable. Accordingly, Miller raises a SNQ regarding claims 1-14.

Requester considers claims 1-14 unpatentable over **Stern**.

Stern discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain 1% soybean sterols (Example 3). The diet containing soy sterols lowered serum cholesterol in rats more than the same diet without sterols.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Stern can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the Stern disclosure important in determining whether claims 1-14 are patentable. Accordingly, Stern raises a SNQ regarding claims 1-14.

Requester considers claims 1-4, 10 and 12-14 unpatentable over **Beveridge**.

Art Unit: 3991

Beveridge discloses an experimental diet fed to human subjects. The diet contains skim milk powder and calcium caseinate, each of which provides at least calcium, and was supplemented with varying amounts of β -sitosterol (p. 120). The diet containing sitosterol was found to lower serum cholesterol relative to subjects receiving the same diet without sitosterol.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Beveridge can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the Beveridge disclosure important in determining whether claims 1-4, 10 and 12-14 are patentable. Accordingly, Beveridge raises a SNQ regarding claims 1-4, 10 and 12-14.

Requester considers claims 1-14 unpatentable over **Mattson**.

This proposed SNQ is based solely on patents and/or printed publications already cited/considered in an earlier examination of the patent being reexamined. On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a

Art Unit: 3991

SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. A discussion of the specifics now follows:

Mattson was cited by Applicant in the prosecution of the '094 application. See response of October 18, 1999, p. 5. Applicant relied on Mattson for the teaching, "If only a single sterol is present in the oil phase, whether it is the cholesterol or beta-sitosterol, the precipitate is the hydrated species of that sterol. If the oil phase contains both sterols, both will be present in the precipitate."

Mattson discloses an experimental diet fed to rats. The diet contains salts of calcium, magnesium and potassium, and was supplemented with β -sitosterol, stigmasterol, campesterol and fatty acid esters of these sterols (p. 1141). Diets containing sterols and sterol esters were found to inhibit absorption of dietary cholesterol.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Mattson can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

Thus Mattson is being presented/viewed in a new light, or in a different way, as compared with the earlier concluded examination, in view of a material new argument or interpretation presented in the request which was not present in the prosecution of the application which became the '349 patent. There is a substantial likelihood that a reasonable examiner would consider the disclosure of Mattson, when viewed in this light, important in determining whether claims 1-14 are patentable. Accordingly, Mattson raises a SNQ regarding claims 1-14.

Requester considers claims 1-14 unpatentable over **O'Brien**.

Art Unit: 3991

O'Brien discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain phytosterols (p. 1445). The diet containing phytosterols lowered serum cholesterol in rats compared to the same diet without sterols.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," O'Brien can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the O'Brien disclosure important in determining whether claims 1-14 are patentable. Accordingly, O'Brien raises a SNQ regarding claims 1-14.

Requester considers claims 1-14 unpatentable over **Sugano**.

Sugano discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain sitosterol or sitostanol (pp. 2012-2013). When cholesterol was added to the feed, diets containing sitosterol or sitostanol lowered blood cholesterol in rats compared to the same diet without sitosterol or sitostanol.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Sugano can be said to disclose adding minerals and

Art Unit: 3991

sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the Sugano disclosure important in determining whether claims 1-14 are patentable. Accordingly, Sugano raises a SNQ regarding claims 1-14.

Requester considers claims 1-14 unpatentable over **Ikeda I**.

Ikeda I is difficult to understand because part of each page is illegible. The reference discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain sitosterol or sitostanol (p. 229). There does not appear to be any evidence that ingestion of sitosterol or sitostanol lowers serum cholesterol, but that would be an inherent characteristic of the dietary composition if it falls within the parameters specified by the claims and specification of the '349 patent.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," **Ikeda I** can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the **Ikeda I** disclosure important in determining whether claims 1-14 are patentable. Accordingly, **Ikeda I** raises a SNQ regarding claims 1-14.

Requester considers claims 1-14 unpatentable over **Ikeda II**.

Ikeda II discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain sitosterol (p. 1575, col. 1). While serum

Art Unit: 3991

cholesterol was not measured directly, it was found that sitosterol inhibits absorption of cholesterol in the intestines (p. 1576, col. 2).

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Ikeda II can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

There is a substantial likelihood that a reasonable examiner would consider the Ikeda II disclosure important in determining whether claims 1-14 are patentable. Accordingly, Ikeda II raises a SNQ regarding claims 1-14.

Requester considers claims 1-14 unpatentable over **Ikeda III**.

Ikeda III discloses an experimental diet which comprises salts of calcium, magnesium and potassium, and may contain sitosterol or sitostanol (pp. 362-363). While serum cholesterol was not measured, reduction in serum cholesterol would be an inherent characteristic of the dietary composition if it falls within the parameters specified by the claims and specification of the '349 patent.

Claim 13 is essentially a product-by-process claim. The process involves adding minerals and sterols to an undefined starting material. The resulting product has more minerals and sterols than an undefined, arbitrary comparison product and can lower serum cholesterol and blood pressure upon ingestion. Claim 1 is a process for making a product similar to that of claim 13. Any component of the experimental diet is a "food ingredient" within the meaning of claim 1. Thus if any component of the diet is arbitrarily designated the "food ingredient," Ikeda III can be said to disclose adding minerals and sterols to that ingredient to produce a product which lowers serum cholesterol upon ingestion.

Art Unit: 3991

There is a substantial likelihood that a reasonable examiner would consider the Ikeda III disclosure important in determining whether claims 1-14 are patentable. Accordingly, Ikeda III raises a SNQ regarding claims 1-14.

Conclusion

In view of the analysis above, the request for reexamination is **GRANTED**. Claims 1-14 of US Patent 6,136,349 will be reexamined.

Duty to Disclose

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 6,136,349 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Waiver of Right to File Patent Owner Statement

In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The waiver document must contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester (see 37 C.F.R 1.550(f)).

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

Service of Papers

Art Unit: 3991

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRUCE CAMPELL whose telephone number is 571-272-0974. The examiner can normally be reached on Monday - Thursday from 8:00 to 5:00. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

All correspondence relating to this ex parte reexamination proceeding should be directed:

By EFS: Registered users may submit via the electronic filing system EFS-Web at

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