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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 14/792,452 | 07/06/2015 | Eduardo Fernandez | 519902US | 7369 |

68850 7590 09/18/2020

DON J. PELTO
Sheppard, Mullin, Richter & Hampton LLP
333 South Hope Street
43rd Floor
Los Angeles, CA 90071

| EXAMINER | |
|---|---|
| GEORGE, PATRICIA ANN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1793 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 09/18/2020 | ELECTRONIC |

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SheppardMullin_Pair@firsttofile.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* EDUARDO FERNANDEZ and CHARLES BALZER

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Appeal 2019-005857
Application 14/792,452
Technology Center 1700

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Before LINDA M. GAUDETTE, N. WHITNEY WILSON, and BRIAN D. RANGE, *Administrative Patent Judges.*

RANGE, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 5–8, 14–17, 19–24, and 30. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Exeltis USA, Inc. Appeal Br. 2.

## CLAIMED SUBJECT MATTER[2]

Appellant describes the invention as relating to a gummy composition for a nutritional supplement. Spec. ¶ 2. Claim 1 is illustrative:

1. A method for treating a prenatal, pregnant or breastfeeding patient for a disease, condition or disorder that is associated with a nutritional deficiency in the patient, the method comprising:

> administering one or more gummy compositions to a patient, wherein the one or more gummy compositions consists of:
>
> a total dosing amount of about 1000 IU to about 2000 IU of vitamin A,
>
> a total dosing amount of about 1 mg to about 4 mg of vitamin B6,
>
> a total dosing amount of about 4 μg to about 15 μg of vitamin B12,
>
> a total dosing amount of about 0.5 mg to about 2.0 mg of encapsulated vitamin B9,
>
> a total dosing amount of about 5 mg to about 90 mg of vitamin C,
>
> a total dosing amount of about 500 IU to about 2000 IU of vitamin D,
>
> a total dosing amount of about 7.5 IU to about 22.5 IU of vitamin E,
>
> a total dosing amount of about 7 mg to about 23 mg of vitamin B3,
>
> a total dosing amount of about 75 μg to about 225 μg of iodine,

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[2] In this Decision, we refer to the Final Office Action dated March 8, 2018 ("Final Act."), the Appeal Brief filed May 6, 2019 ("Appeal Br."), the Examiner's Answer dated May 31, 2019 ("Ans."), and the Reply Brief filed July 31, 2019 ("Reply Br.").

a total dosing amount of about 5 mg to about 15 mg of choline,

a total dosing amount of about 1 mg to about 25 mg of encapsulated iron,

a total dosing amount of about 50 mg to about 500 mg of at least one omega-3 fatty acid,

water, and

one or more inactive ingredients selected from the group consisting of: sucrose, glucose, syrup, gelatin, lactic acid, citric acid, flavorants, colorants, and propylene glycol

to treat a disease, condition or disorder in the patient that is associated with a nutritional deficiency in the patient,

wherein the vitamins, minerals and omega-3 fatty acids in each of the one or more gummy compositions is provided in a single homogenous layer which is elastic and continuous.

Appeal Br. 22–23 (Claims App.).

REFERENCES

The Examiner relies upon the prior art below in rejecting the claims on appeal:

| **Name** | **Reference** | **Date** |
|---|---|---|
| Geuns et al. ("Geuns") | US 2010/0099640 A1 | Apr. 22, 2010 |
| Rifkin | US 2013/0287899 A1 | Oct. 31, 2013 |
| Dietary Reference Intskaes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, 1998 ("DRI") | | |
| Integrative Medicine Communications, Vitamin B9 (Folic Acid), Syrian Clinic, 2000 ("IMC") | | |
| Micronutrient Information Center: Vitamins, Oregon State University Linus Pauling Institute, April 15, 2003, lpi.oregonstate.edu/mic/vitamins ("OSU"). | | |
| H. Madziva et al, Alginate-pectin microcapsules as a potential for folic acid delivery in foods, 22 J. Microencapsulation 343 (2005) ("Madziva"). | | |
| J. Cox et al., Prenatal Nutrition: Special Considerations, 61 MINERVA | | |

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| GINECOLOGICA 373 (2009) ("Cox"). |
| Jaclyn M. Coletta et al., Omega-3 Fatty Acids and Pregnancy, 3(4) Rev. Obstretics Gynecology 163, 163–71, 2010 ("Coletta") |
| Michael B. Zimmermann & Erich J. Windhab, Encapsulation of Iron and Other Micronutrients for Food Fortification, Encapsulation Technologies for Active Food Ingredient and Food Processing (N.J. Zuidam & Victor Nedovic eds., 2010) ("Zimmermann"). |
| Spring Valley Prenatal Multivitamin/Multimineral with Folic Acid, www.amazon.com/Spring-Valley_Prenatal-Multivitamin-Multimineral/dp/B001QRRI88, March 5, 2010 ("Spring Valley").[3] |
| Vitafusion Prenatal Gummy Vitamins, 90 count, May 6, 2010 ("Vitafusion").[4] |
| Susan Enfield, ISO: A high-quality multivitamin my kids will actually eat!, deliciousliving.com/blog/iso-high-quality-multivitamin-my-kids-will-actually-eat, March 8, 2011 ("Enfield"). |
| Blake, How to Make Your Own Supplements, Building Muscle 101, Nov. 2, 2011, www.building-muscle101.com ("Blake")[5] |
| Elaine Laskowski, Homemade Gummy Vitamins, www.justapinch.com/recipes/non-edible/beauty-recipe/homemade-gummy-vitamins.html?p=1, Jan. 14, 2013 (last visited January 11, 2017) ("Laskowski").[6] |

## REJECTIONS

The Examiner maintains the following rejections on appeal:

A. Claims 5–8, 14–17, and 30 under 35 U.S.C. § 112 as indefinite. Ans. 4–5.

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[3] The Examiner relies on web.archive.org (i.e., The Wayback Machine) as archiving this reference. Ans. 6.
[4] The Examiner finds that this reference was online by at least May 6, 2010, as evidenced by an Amazon.com review by D. Won. Ans. 5.
[5] The Examiner relies on web.archive.org (i.e., The Wayback Machine) as archiving this reference. Ans. 6.
[6] The Examiner finds that this reference was published online on January 14, 2013. Ans. 5.

B. Claims 1, 5–8, 10, 14–17, 19–24, 29, and 30 under 35 U.S.C. § 103 as obvious over Laskowski, Rifkin, Vitafusion, Enfield, Spring Valley, Cox, Geuns, Appellant's Admitted Prior Art ("AAPA"), Madziva, Zimmerman, OSU, DRI, IMC, Coletta, and Blake. *Id.* at 5.

## OPINION

Rejection A, Indefiniteness. The Examiner rejects claims 5–8, 14–17, and 30 as indefinite. Ans. 4–5. During prosecution, "'[a] claim is indefinite when it contains words or phrases whose meaning is unclear.'" *Ex parte McAward*, Appeal No. 2015-006416, slip op. at 11 (quoting *In re Packard*, 751 F.3d 1307, 1314 (Fed. Cir. 2014) (per curiam)). Here, the Examiner asserts three different bases for rejecting claims as indefinite, and we address each basis below.

First, the Examiner rejects claims 5–8 and 14–17 as reciting broad ranges along with narrow ranges. Ans. 4. Claim 5 depends from claim 1 and recites, for example, "an individual dosing amount of vitamin A ranging from 275 IU [international units] to about 825 IU" and also recites "wherein the total dosing amount is two to four individual gummies." Appeal Br. 23–24 (Claims App.). Claim 1 recites, for example, "a total dosing amount of about 1000 IU to about 2000 IU of vitamin A." *Id.* at 22. In view of these recitations, the Examiner states, "[w]hen the claimed amount of gummies is multiplied by the individual dosages the total dosage does not equal to the total dosages of the independent claims." Ans. 4.

Appellant argues that the rejection does not establish that the claims are unclear. Appeal Br. 10–11. Appellant explains that the Specification

explains what the claims mean by "total dosing amount" and "individual dosing amount as follows:

> The gummy dosage forms and kits disclosed herein may also comprise multiple gummy compositions that provide **a total dosing amount** of each of the active ingredients. In these embodiments, each gummy composition is an "individual dosage form" that comprises an **"individual dosing amount**" of each of the active ingredients, and **the sum of the multiple individual dosing amounts approximately equals the total dosing amount**.

Spec. ¶ 55 (emphases added). In view of the Specification's disclosure above, "total dosing amount" refers to the amount of an ingredient a person ingests at one relatively discrete moment in time. "Individual dosing amount" refers to the amount in one individual gummy composition.

The Examiner's understanding of the claims is correct inasmuch as the individual dosing amount for an ingredient multiplied by the total number of gummies the person takes at one point in time will necessarily equal a total dosing amount. Ans. 4, 28–29. This, however, does not present any lack of clarity with respect to, for example, claim 5. Rather, claim 5's scope only encompasses methods that satisfy both claim 1's recited conditions and claim 5's recited conditions. For example, treating with one gummy of 275 IU vitamin A is outside the scope of claim 5 because it does not meet claim 1's criteria that the total dosing amount be at least 1000 IUs. Treating with four gummies of 275 IU vitamin A each in one dose, however, would meet both claim 5 and claim 1's criteria. We, therefore, do not sustain the Examiner's rejection on this basis.

As a second basis of indefiniteness, the Examiner determines that claims including claim 5 are unclear because they recite, for example, "the total dosing amount is two to four individual gummies." Ans. 4–5, 30.

Appellant argues the recitation is not unclear. Appeal Br. 11. Appellant's position is persuasive. The disputed phrase, in the context of claim 1, claim 5, and the Specification, means that the treated person ingests, at the time of dosing, two to four individual gummy compositions in total. The sum total dosing amount of each ingredient must be within the ranges recited in claim 1, and the individual dosing amount for each individual gummy composition must be within the range of claim 5. We also do not sustain the Examiner's rejection on this second basis.

Third, the Examiner determines that claim 30 is unclear because claim 30's recited "the single layer" lacks an antecedent basis. Ans. 5. Appellant argues the claim is clear. Appeal Br. 11–12. Appellant's argument is again persuasive. Claim 30 depends from independent claim 10. Claim 10 recites the term "layer" only one time: "wherein the vitamins, minerals and omega-3 fatty acids in each of the one or more gummy compositions is provided in **a single homogenous layer**." Appeal Br. 28 (Claims App.) (emphasis added). Because this is the only layer recited by claims 10 and 30 and because both claims 10 and 30 refer to the layer as being "single," claim 30's "the single layer" refers back to claim 10's only single layer. Because the Examiner does not establish a lack of clarity, we do not sustain this rejection.

Rejection B, obviousness. The Examiner rejects claims 1, 5–8, 10, 14–17, 19–24, 29, and 30 under 35 U.S.C. § 103 as obvious over Laskowski, Rifkin, Vitafusion, Enfield, Spring Valley, Cox, Geuns, AAPA, Madziva, Zimmerman, OSU, DRI, IMC, Coletta, and Blake. Ans. 5. We focus only on

the Appellant's identification of error in the rejection and the Examiner's related determinations.[7]

The Examiner finds that Laskowski teaches gummy vitamins for adults. Ans. 6. The Examiner finds that Laskowski does not teach ranges for claim 1 and claim 10's recited nutrients. *Id.* at 14. The Examiner finds that OSU teaches that tolerable upper level of intake for vitamin A is "result dependent based on the consumer's age." Ans. 14, 39. The Examiner finds that OSU's various tables teach a range that overlaps claim 1 and claim 10's recited vitamin A range of 1000 IU to 2000 IU. *Id.*

Appellant argues that OSU does not teach a total dosing amount of about 1000 IU to about 2000 IU as claims 1 and 10 recite. Appeal Br. 15. We agree. The OSU table entitled "Recommended Dietary Allowance (RDA) for Vitamin A as Preformed Vitamin A (Retinol)" only provides information about recommended dosage of Vitamin A *per day*. The table does not provide any information about what dosage is appropriate for a total dosing amount (i.e., amount of the ingredient a person should ingest at one time) or an individual dosing amount (i.e., amount of the ingredient that should be put in one dosing form).[8]

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[7] Appellant presents additional arguments as to why the Examiner's rejection is in error. We decline to address the additional arguments because resolution of error in one aspect of the Examiner's rejection is sufficient to reverse.

[8] Moreover, as Appellant's argue, this OSU table teaches 750–770 µg/day (equivalent to about 2500 IU per day) for pregnant females. That number is outside of claim 1's range. We note, however, that this issue may be less relevant for claim 10 because claim 10 is directed to a composition rather than a method.

Indeed, even if the evidence established that a "tolerable upper level of intake of vitamin A is result dependent, based on the consumer's age" (Ans.14) sufficiently to establish that "tolerable upper level of intake" is a result effective variable (*see, e.g.*, *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980) ("[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.")), this would not help the Examiner's position. Tolerable upper level of intake per day is not the same as total dosing amount. The Examiner, therefore, has not cited evidence to establish that "total dosing amount," as claims 1 and 10 recite, is a known result effective variable.

Similarly, the OSU table entitled "Tolerable Upper Level of Intake (UL) for Preformed Vitamin A (Retinol)" indicates toxicity in adults at 10,000 IU per day. The table again does not address how much Vitamin A should be provided in one total dose or in one dosing form.

We further note that OSU suggests that "toxicity may result acutely from high-dose exposure over a short period of time" and that "some populations may be more susceptible to toxicity at lower doses." *See* OSU SAFETY. Based on these teachings, we do not agree with the Examiner that OSU establishes that a person of skill in the art would have considered any total dosing amount below 10,000 IU appropriate. Ans. 38 ("using only the disclosure in OSU that daily amounts of ingested preformed vitamin A should not exceed 10,000 IU, the Examiner concludes that OSU teaches the claimed vitamin A ranges"). Rather, a person of skill in the art would have sought more specific guidance on dosing amounts while ensuring that the 10,000 IU per day maximum is not exceeded.

Because the Examiner has not adequately established that a person of skill in the art would have reached claim 1 or claim 10's total dosing amount of vitamin A, we do not sustain the Examiner's rejection of those claims or of the claims depending from claims 1 or 10.

## DECISION SUMMARY

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|---|---|---|---|---|
| 5–8, 14–17, 30 | 112 | Indefiniteness | | 5–8, 14–17, 30 |
| 1, 5–8, 10, 14–17, 19–24, 29, 30 | 103 | Laskowski, Rifkin, Vitafusion, Enfield, Spring Valley, Cox, Geuns, AAPA, Madziva, Zimmerman, OSU, DRI, IMC, Coletta, and Blake | | 1, 5–8, 10, 14–17, 19–24, 29, 30 |
| **Overall Outcome** | | | | **1, 5–8, 10, 14–17, 19–24, 29, 30** |

REVERSED