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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NEIL ROBERT BUCK, WOUTER CLAERHOUT, BRUNO H. LEUENBERGER, ELISABETH STOECKLIN, KAI URBAN, and SWEN WOLFRAM[1]

Appeal 2017-005470
Application 13/446,128
Technology Center 1600

Before LORA M. GREEN, RICHARD M. LEBOVITZ, and JOHN G. NEW, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1]Appellants identify DSM IP ASSETS B.V. as the real party-in-interest. App. Br. 3.

SUMMARY

Appellants file this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 7–10.

Claims 7–10 stand rejected as unpatentable under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

Claims 7–10 stand rejected as unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite.

Claims 7–10 also stand rejected 35 U.S.C. § 102(b) as being anticipated by, and/or under 35 U.S.C. § 103(a) as obvious over, Chung et al. (WO 2007/020042 A1, February 22, 2007) ("Chung").

Claims 7–10 also stand rejected 35 U.S.C. § 103(a) as being obvious over Krammer et al. (US 2007/0082089 A1, April 27, 2007) ("Krammer").

Claims 7–10 also stand rejected 35 U.S.C. § 103(a) as being obvious over Krammer and Nduaka et al. (US 2005/0101578 A1, May 12, 2005) ("Nduaka").[2]

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellants' claimed invention is directed to compositions comprising Vitamin D (cholecalciferol and /or ergocalciferol) and 25-OH D3 (calcifediol), and use of those compositions to affect at least the

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[2] The Examiner also rejected claims 7-10 as unpatentable under the nonstatutory doctrine of obviousness-type double patenting over copending US Appl. Ser. No. 12/867,372 and Chung. Final Act. 14. The Examiner has withdrawn this rejection. Ans. 2.

concentration, bioavailability, metabolism, or efficacy of vitamin D in a human. Abstract.

REPRESENTATIVE CLAIM

Claim 7 is representative of the claims on appeal and recites:

> 7. A kit comprising multiple, separate weekly or monthly dosages of
>
> a) Vitamin D, and
>
> b) 25-OH D3,
>
> wherein a dosage ratio of the Vitamin D3 to the 25-OH D3 is from about 6:1 to 1:6; a single weekly dosage contains from 7µg to 350 µg each of Vitamin D and 25-OH D3; and a single monthly dosage contain from 30 µg.

App. Br. 24.

A. Rejection of claims 7–10 under 35 U.S.C. § 101

Issue

Appellants argue that the Examiner erred in finding that the claims are directed to a judicially-created exception to Section 101, *viz.*, a phenomenon of nature. App. Br. 7.

Analysis

The Examiner finds the claims are directed to a judicially-created exception to natural phenomenon. The Examiner finds claims 7–10 are directed to a kit comprising vitamin D and 25-OH D3, both of which are natural products, and the Examiner finds the characteristics of each component are not significantly different from their naturally-occurring counterparts because they have the same structure and function as they do in nature. *Id.* The Examiner additionally finds that the limitations recited in

claim 8 do not add significantly more to the judicial exception because the recited container or instructions for use are generic kit elements that do not add significantly more to the natural product because they would be routine in any kit. *Id.*

Appellants respond that the claimed invention, a kit comprising multiple, separate weekly or monthly dosages of Vitamin D, and 25-OH D3 cannot be found in nature. App. Br. 7. Appellants assert that, in finding that the claims are directed to a natural phenomenon, the Examiner has failed to provide a single example of a natural product, that comes in multiple separate weekly or monthly dosages, and which satisfies all the features of the claims. *Id.*

Furthermore, argue Appellants, the claimed kit has characteristics that are not found in a natural product and which would be unexpected in a natural product. App. Br. 7. According to Appellants, the two claimed compounds, Vitamin D3 and 25-OH D3, exhibit in combination synergistic effects, synergistically raising and sustaining 25-OH D3 levels in an individual and allowing weekly and/or monthly dosing, which is not possible using the single ingredients. *Id.* at 7–8.

We are not persuaded by Appellants' arguments. It is indisputable that both vitamin D3 and 25-OH D3 are naturally-occurring chemicals that co-exist in biological systems and, by themselves, are products of nature and consequently unpatentable. *See, e.g.*, Spec. 2. However, all inventions, at some level, embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012). Consequently, we must determine whether the: "claims do significantly more than simply describe these

natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?" *Mayo*, 566 U.S. at 77.

We conclude that they do not. Appellants' claims are directed to a composition of matter, i.e., a kit containing dosages of Vitamin D3 and 25-OH D3 such that the dosage ratio of Vitamin D3 to 25-OH D3 is from about 6:1 to 1:6; and that a single weekly dosage contains from 7μg to 350 μg each of Vitamin D and 25-OH D3, and a single monthly dosage contains from 30 μg. *See* claim 7. However, we cannot structurally distinguish the chemical compositions recited in the claims from those occurring naturally in biological systems. Nor does the fact that Appellants claim different dosage amounts or ratios suffice to add significantly more to the naturally-occurring substances than the administration of the same naturally-occurring substances themselves. *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948). *See also In re Bhagat*, Appeal No. 2016-2525 at 11–12, decided March 16, 2018 (Fed. Cir. 2018) (nonprecedential).

Consequently, we find that the claims are directed to a judicially-created exception to Section 101 and that the remaining claims, taken individually and as a whole, do not add significantly more to the claim than reciting the phenomenon of nature itself. We affirm the Examiner's rejection of the claims on this ground.

B. Rejection of claims 7–10 under 35 U.S.C. § 112, second paragraph

Issue

Appellants argue the Examiner erred in finding the limitations reciting "from 30 μg" and weekly and monthly dosages without concurrent weight ratios are indefinite. App. Br. 9.

Analysis

The Examiner finds that, from the language of the claims when viewed in light of the Specification, it is unclear what is the end amount starting "from 30 μg," as recited in independent claim 7. Final Act. 3. The Examiner also finds indefinite the limitations of claim 7 reciting single weekly and monthly dosage of vitamin D and 25-OHD3 omitting a dosage-to-patient mass ratio, e.g., dose/kg body mass, because the recited dosage could read on any dose-to-weight ratio. *Id.*

Appellants argue that the phrase "from 30 μg" is not indefinite because it defines the lower value limit of the related monthly dosage. App. Br. 9. Appellants note that the phrase "from 30 μg" is also used when referring to the lower limit of the weekly dosage range. *Id.*

With respect to the claims being indefinite because they fail to prescribe a ratio such as dosage unit per/kg body mass, Appellants argue that the claim is directed to a kit with weekly or monthly doses and that the range of amounts in each dose is expressly claimed. App. Br. 9. According to Appellants, this is a common practice in the art of describing a dose to one of ordinary skill. *Id.* Appellants note that many over-the-counter

medications, intended for sale to the public, are prescribed in dosage without reference to dosages per body mass. *Id.*

The test for definiteness under the second paragraph of 35 U.S.C. § 112 is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification," such that a skilled artisan may understand the metes and bounds of the claim. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986); *Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 899 (Fed. Cir. 2013).

With respect to the Examiner's rejection based upon a supposed requirement that the claim recited a dosage-to-body mass ratio, or some similar measure, we are not persuaded that the lack of such a ratio, by itself, is sufficient to render the claim indefinite. Claim 7 recites, in relevant part: "a single weekly dosage contains from 7 μg to 350 μg each of Vitamin D and 25-OH D3," and we construe the plain language of the claim to mean exactly that: a dosage of between 7 μg to 350 μg each of Vitamin D and 25-OH D3 per week, independent of any other factors. The lack of an additional limitation reciting: "per kilogram of body mass" or some such related language, is not sufficient to render the claim incomprehensible to a person of ordinary skill in the art.

Nor do we agree that the limitation reciting "from 30 μg" is indefinite. Appellants argue, and we agree, that the phrase defines the lower value limit of the related monthly dosage. We find that, used as such, the phrase defines a dosage that is equivalent to "at least 30 μg" and that, although broad, such usage is not indefinite. *See In re Miller*, 441 F.2d 689, 693 (C.C.P.A. 1971) ("breadth is not to be equated with indefiniteness"); *see also In re Hyatt*, 708

F.2d 712, 714-15 (Fed. Cir. 1983). We consequently reverse the Examiner's rejection based upon this ground.

C. Rejection of claims 7–10 under 35 U.S.C. §§ 102 and 103(a) over Chung

Issue

Appellants next argue the Examiner erred because Chung neither discloses nor suggests the dosages or ratios of Vitamin D to 25–OH D3 that are recited in the claims. App. Br. 10.

Analysis

The Examiner finds that Chung discloses combination of both 25-OH D3 and vitamin D in a ratio of 1:1 (0.08%:0.08%). Final Act. 4 (citing Chung ex. 3). The Examiner also finds that Chung discloses, in Example 1, a food composition containing 1000 IU/kg dog food of vitamin D3, supplemented by 50-80 μg/kg dog food of 25-OH D3. *Id.* (citing Chung 3, 44, Table 1). The Examiner calculates that these concentrations read on the ratios of Vitamin D and 25-OH D3 and the ranges of 7 μg to 350 μg recited in the claims.[3] *Id.*

With respect to the obviousness rejection, the Examiner also finds that Chung discloses that the term "dietary supplement" refers to a small amount

[3] The Examiner notes that, for both vitamin D3 and 25-OH d3, 1.0 μg equals 40 IU, and therefore calculates that 50–80 μg equals 2000–3000 IUs. *See* Krammer ¶ 4. The Examiner therefore finds the ratios of Vitamin D to 25-OH D3 to be between 1:2 and 1:3, which is within the range of ratios recited in the claim. Final Act. 4.

of a compound for supplementation of a human or animal diet packaged in single or multiple dose units, and that these do not generally provide significant amounts of calories but may contain other micronutrients. *Id.* at 6–7. The Examiner finds that, although Chung does not explicitly state that at least 7 or at least 30 separate dosages are present, however, the reference renders obvious multiple separate dosages as claimed, and would therefore render obvious at least 7 or at least 30 separate multiple dosages since a daily dosage is suggested and 7 or 30 dosages would provide daily dosages for up to a week or up to a month. *Id.* at 7.

The Examiner concludes that a person of ordinary skill in the art would have been motivated to use the disclosures and suggestions of the prior art and prepare a kit comprising separate dosage in the container, and instructions for the administration. Final Act. 8.

With respect to the rejection under 35 U.S.C. § 102, Appellants respond that Chung is directed to a method involving a different ratio of 25-OH D3 and Vitamin D than is recited in the claims. App. Br. 10. Referring to the table of Example 3, Appellants point out that the Chung discloses using 0.08% ROVIMIX with 1.25% 25-OH D3 and 0.08% Vitamin D3 (100%). Appellants therefore calculate that Chung discloses a ratio of 1:80, which is well outside the range of ratios of 1:6 to 6:1 recited in claim 7. *Id.* at 11.

Appellants contend that Chung further discloses that the daily dose of 25-OH D3 for a human is from about 5-15 μg/kg body weight (Appellants note that, for the average 70 kg human, this equates to 350–1050 μg/day), whereas the claims require a substantially lower dose of 7–350 μg/week or 30–1500 μg/month. App. Br. 12 (citing Chung 2). According to Appellants,

Chung does not teach that if one lowers the dosage, then the combination can be used for a totally different purpose, nor is it suggested that the combination of 25-OH D3 and Vitamin D3 can be successfully administered on a weekly or monthly basis. *Id.* Finally, Appellants contend that Chung nowhere discloses a kit with weekly or monthly doses in the same range recited by Appellants claims. *Id.* at 12–13.

With respect to the Examiner's obviousness rejection, Appellants repeat their argument that Chung discloses different amounts of 25-OH D3 and Vitamin D that those recited in the claims. App. Br. 13. Furthermore, argue Appellants, the Examiner points to no teaching or suggestion of Chung that would have motivated a person of ordinary skill in the art to alter the dose, ratio, or frequency of administration, nor any that would lead a skilled artisan to expect that the fertility treatment method taught by Chung would have different effects. *Id.* at 16.

Appellants argue further that Chung does not disclose weekly or monthly dosages but, rather, teaches food and feed mixes and, therefore, daily dosages. App. Br. 16. Appellants contend that a person of ordinary skill in the art would have no basis to relate these teachings to the feeding of humans or animals once weekly or monthly because food is generally taken multiple times per day. *Id.*

Finally, Appellants argue, there is no factual basis that would lead a skilled artisan to reasonable assume that an ingredient fed to humans and animals once per day would also be effective if fed once weekly or monthly as the Examiner finds. App. Br. 16. According to Appellants, a person of ordinary skill in the art would have known that daily doses of beneficial ingredients (including vitamins and foods) cannot be linearly multiplied by

seven or thirty into weekly doses and monthly doses without possible toxic or lethal side effects. *Id.*

We are persuaded by Appellants that the Examiner has failed to establish a *prima facie* case of anticipation under Section 102. "For a claim to be anticipated, each claim element must be disclosed, either expressly or inherently, in a single prior art reference, and the claimed arrangement or combination of those elements must also be disclosed, either expressly or inherently, in that same prior art reference." *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1325, 1332–33 (Fed. Cir. 2010).

As an initial matter, Chung is principally directed to additives to animal food. *See* Spec. 2 ("For the purposes of the invention, 25-hydroxy vitamin D_3 is suitably administered as supplement to food"). The Examiner did not direct our attention to where Chung discloses a kit, nor where it expressly discloses "multiple, separate weekly or monthly dosages of Vitamin D, and 25-OH D3," as recited in the claims. (Ans. 2)

With respect to the rejection under Section 103, Appellants acknowledge that administration of Vitamin D and 25-OH D3 for therapeutic purposes is well-known in the art. *See* Spec. 1–2. According to Appellants, their claimed invention is based upon the synergistic effects of co-administration of Vitamin D and 25-OH D3. *Id.* at 3.

Chung discloses:

> For the purposes of the invention, 25-[OH] D_3 is suitably administered in amounts from about 0.112 [μ]g to about 1.120 [μ]g, especially about 0.560 [μ]g to about 0.784 [μ]g per kg body weight of an individual animal per day. Thus, 25-[OH] vitamin D_3 is suitably added to the food in an amount to satisfy such dosage requirement. Typically, a boar food may contain from

> about 10 [µ]g to about 100 [µ]g, especially of from about 50 [µ]g to about 80 [µ]g 25-[OH] vitamin D_3 per kg food.

Chung 3. Chung also teaches further dosages of approximately 0.125–1.00 µg/kg body mass/day for dogs, 0.112–1.120 µg/kg body mass/day for horses, and 5–15 [µ]g/kg body mass/day for humans. *Id.*

With respect to the latter, by way of example, if we assume that the average mass of a human adult is 70 kg, then Chung teaches a daily dosage of 350–1050 µg/day, or 2450–7350 µg/week. This greatly exceeds the weekly dosage recited in the claims of 7–350 µg/week. Moreover, none of these examples teach 25-OH D3 administered in combination with Vitamin D.

Examples 1, 4, and 5 of Chung disclose combining 25-OH D3 with Vitamin D. Example 1 teaches adding "50 to 80 µg of 25-[OH] D3 per kg of food to a food composition comprising, in relevant part of 1000 IUs of Vitamin D3 per kg of food, or 25 µg of Vitamin D3 per kg. Chung 3–4. This results in ratios of 25-OH D3 to Vitamin D of 1:2–1:3.2, which is within the range of ratios required by the claims. However, without knowing the amount of food daily consumed by the subject, or the identity of the subjects (which information is not disclosed by Chung) it is impossible to know the daily, weekly, or monthly dosage administered. Examples 4 and 5 of Chung yield similar results; Example 5 teaches a supplement to a horse food composition of approximately 0.112–1.120 µg/kg body weight mixed with an "inclusion level" of 3000 IUs (75 µg). Again it is impossible to know, based upon these disclosures of Chung, how this recipe translates into a weekly or monthly dosage.

In summary, the Examiner did not establish that Chung teaches a kit comprising multiple, separate weekly or monthly dosages of Vitamin D, and 25-OH D3 at the dosages required by the claims. Nor, for the same reasons, does the Examiner identify any teaching or suggestion of Chung that would lead a person of ordinary skill to understand that Appellants' claimed invention would be obvious over the teachings of Chung. We consequently conclude that the claims are neither anticipated nor obvious over Chung, and we reverse the Examiner's rejection on these grounds.

D. Rejection of claims 7–10 under 35 U.S.C. § 103(a) over Krammer

Issue

Appellants argue the Examiner erred because Krammer neither teaches nor suggests the dosages of Vitamin D and 25–OH D3 recited in the claims. App. Br. 17.

Analysis

Appellants argue that, although Krammer teaches large amounts of vitamin D and 25-OH D3/kilo of food, the daily dose is given for dogs is only 5–20 IU each for 25-OH D3 and vitamin D3, which is equivalent to 0.125 –0.5 μg/day. App. Br. 17. Appellants point out that the rejected claims recite a weekly dosage of 7–350 μg/week or 30–1500 μg/month, which equates to 1–50μg/day, which is substantially different from the dosages/taught by Krammer. *Id.*

Appellants argue further that, based upon the teachings of Krammer, there is no basis to assume that pet food, which is given to pets multiple times, or at least once, a day, can be effective if given to an animal on a

weekly or monthly basis. App. Br. 17. Nor, Appellants contend, can pets be fed only once per week or month. *Id.* at 18.

The Examiner responds that Krammer teaches that the ratio of 25-OH D3 and vitamin D3 in a preferred ratio of 1:1 and a range of ratios of 1:9 to 9:1, which overlaps the claimed ratios 1:6 or 6:1. Ans. 10. The Examiner points to paragraph [0003] of Krammer, which teaches coadministering 25-OH D3 at about 500–5000 IU/kg dog food (preferably – 2000 IU/kg food) and vitamin D3 at about the same concentrations. *Id.* The Examiner therefore concludes that it would have been obvious to one of ordinary skill in the art to prepare an animal feed with vitamin D and 25-OH vitamin D3 in a 1:1 or within the range of ratios recited in the claims. *Id.* at 11. The Examiner additionally concludes that it would have been obvious to a skilled artisan to prepare a kit for the combination of 25-OH D3 and vitamin D3 with reasonable expectation of success, because Krammer teaches administering a combination of both vitamin and the preparation of a kit of known active ingredients and how to use them would have been known by a person of ordinary skill in the art. *Id.*

We are not persuaded by the Examiner's *prima facie* conclusion of obviousness. Krammer teaches:

> In yet another aspect, the present invention relates to a pet food, comprising 25-[OH-D3] in a concentration of from about 500 IU to about 5000 IU per kg food, particularly from about 500 IU to about 2000 IU per kg food and vitamin D_3 in a concentration of from about 500 IU to about 5000 IU per kg food, particularly from about 500 IU to about 2000 IU per kg food, the total amount of 25-[OH D3] and vitamin D_3 not exceeding 5000 IU per kg food.

Krammer ¶ 3. Krammer further teaches:

> For treatment and prevention of joint diseases in pets, especially dogs, an appropriate daily dosage for a dog would be from about 5-20 IU of 25-[OH D3] and, optionally, 5-20 IU of vitamin D_3, 25-[OH D3] and, optionally, vitamin D_3 are suitably administered as a food supplement.

Id. at ¶ 12. Calculating that 1μg equals 40 IU (*see* Krammer ¶ 4), we can then determine that the daily dosages taught by Krammer equate to 0.125–0.5 μg/day, or 0.875–3.5 μg/week, which are an order of magnitude or more below the claimed values of "a single weekly dosage contains from 7μg to 350 μg each of Vitamin D and 25-OH D3." *See* claim 7. Although we agree with the Examiner that Krammer teaches the claimed relative ratios of Vitamin D and 25-OH D3, the range of daily dosage amounts taught by Krammer fails to coincide, or even overlap with, the claimed dosages.

Nor can one successfully extrapolate a weekly or monthly dosage from the remaining teachings of Krammer. Krammer teaches adding Vitamin D and 25-OH D3 at concentrations of "500 IU to about 5000 IU per kg food" (12.5–125 μg/kg food), but without knowing how much food a given dog consumes per unit time, a value that is not taught by Krammer or by any other evidence of record and which undoubtedly varies widely from Chihuahua to Great Dane, one can only guess at a daily, weekly or monthly dosage. We consequently reverse the Examiner's rejection on this ground.

E. Rejection of claims 7–10 under 35 U.S.C. § 103(a) over Krammer and Nduaka

Appellants rely upon the arguments presented with respected to the Examiner's rejection of claims 7–10 over Krammer alone, contending that

Nduaka fails to cure the alleged deficiencies of Krammer. App. Br. 19. The Examiner relies upon Nduaka as teaching Nduaka teaches kits for use by a consumer to which comprise vitamin D compounds. Final Act. 11. We agree with Appellants that Nduaka neither teaches nor suggests the dosages or dosage ratios of 25-OH D3 and vitamin D recited in the claims and, for the reasons explained *supra*, we also reverse the Examiner's rejection of those claims.

DECISION

The Examiner's rejection of claims claims 7–10 as unpatentable under 35 U.S.C. § 101 is affirmed.

The Examiner's rejection of claims claims 7–10 as unpatentable under 35 U.S.C. § 112, second paragraph is reversed.

The Examiner's rejections of claims claims 7–10 as unpatentable under 35 U.S.C. § 102(b) is reversed.

The Examiner's rejections of claims claims 7–10 as unpatentable under 35 U.S.C. § 103(a) is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). See 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED