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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEPHANIE KRAMMER-LUKAS, ELISABETH STOECKLIN,
JOSEPH SCHWAGER, and SWEN WOLFRAM

Appeal 2015-004491
Application 13/990,569
Technology Center 1600

Before DONALD E. ADAMS, RICHARD J. SMITH, and
TAWEN CHANG, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This appeal under 35 U.S.C. § 134(a) involves claims 1–4 and 13–16 (App. Br. 1). Examiner entered rejection under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellants' Specification "relates to treating/preventing conditions associated with an increased level of eotaxin in a human with 25-

¹ Appellants identify "[t]he real party in interest [as] DSM IP Assets, B.V." (Br. 2).

hydroxyvitamin D3 [(25-OH D3)] (calcifediol)” (Spec. 1:11–12). Claim 1 is representative and reproduced below:

1. A method of decreasing eotaxin levels in a human at risk for or experiencing symptoms of a disease or condition characterized by increased levels of eotaxin comprising administering, to a human patient at risk of or experiencing increased levels of eotaxin from a disease or condition selected from the group consisting of allergic rhinitis, sinusitis, nasal polyps, eosinophilic esophagitis, ulcerative colitis, gastric symptoms due to food allergies, gastric parasitic infections, and gastro-esophageal reflux, an eotaxin lowering effective amount of 25-OH D3, and observing or appreciating a lessening of the eotaxin levels of the patient.

(Br. 9.)

The claims stand rejected as follows:

Claims 1–4 and 13–16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Buck² and Bikle.³

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Appellants disclose that

[e]otaxins (also called CCL-11, CCL-24, and CCL-26) are three proteins which belong to the CC family of chemokines. They are selective recruiters of eosinophils, and also induce the aggregation of eosinophils. Eosinophils play an important beneficial role in killing some invasive microbes and helminths,

² Buck et al., US 2011/0052707 A1, published Mar. 3, 2011.

³ Daniel D Bikle, *Vitamin D Insufficiency/Deficiency in Gastrointestinal Disorders*, 22 *Journal of Bone and Mineral Research* V50–V54 (2007).

especially in the gut. Recent studies also suggest a role in organogenesis, tissue repair, and immune regulation.

(Spec. 6:8–12.)

FF 2. Buck “relates to a composition comprising Vitamin D (cholecalciferol/and/or ergocalciferol) and 25-hydroxyVitamin D3 (calcifediol), and [the] use of that composition to affect at least concentration, bioavailability, metabolism, or efficacy of vitamin D” (Buck ¶ 1).

FF 3. Buck discloses a composition that “comprises a combination of Vitamin D (cholecalciferol and/or ergocalciferol) and 25-OH D3 (calcifediol) for use as a pharmaceutical in a human,” which “is suitable for any indication where a Vitamin D[]or 25-OH D deficiency is implicated” (Buck ¶ 14; Ans. 2 and 3).

FF 4. Buck discloses that “[a] single weekly dosage may contain both Vitamin D and 25-OH D3 each in an amount from about 7 µg to about 350 µg” (Buck ¶ 60; Ans. 2–3; *cf.* Spec. 13:8–9 (“A single weekly dosage may contain both Vitamin D and 25-OH D3 each in an amount of from about 7 µg to about 350 µg.”)).

FF 5. Examiner finds that Buck fails to disclose the administration of 25-OH D3 to patients with “a disease or condition selected from the group consisting of allergic rhinitis, sinusitis, nasal polyps, eosinophilic esophagitis, ulcerative colitis, gastric symptoms due to food allergies, gastric parasitic infections, and gastro-esophageal reflux” (Ans. 3; *see also* Br. 9).

FF 6. Examiner finds that Bikle discloses, *inter alia*, that “celiac disease ([a gastrointestinal] disorder related to an allergic response to food) . . . cause[s] [a] deficiency in vitamin D and 25(OH) D and should be treated with vitamin D” (Ans. 3, citing Bikle, Abstract and V50–V52).

ANALYSIS

Based on the combination of Buck and Bikle, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious to administer a single weekly dosage of a composition comprising about 7–350 μg each of Vitamin D and 25-OH D3 for the treatment of a disease associated with a Vitamin D or 25-OH D deficiency, such as celiac disease (*see* Ans. 4; FF 2–6). Because the dosage suggest by the combination of Buck and Bikle is the same as Appellants' effective dosage, the dosage suggested by the combination of Buck and Bikle is necessarily an eotaxin-lowering effective amount of 25-OH D3 as required by Appellants' claimed invention (*see* FF 4). Therefore, we agree with Examiner's conclusion that Appellants' discovery of a new benefit (i.e., the lowering of eotaxin levels) of an old process (i.e., the administration of, *inter alia*, about 7–350 μg of 25-OH D3 to a subject experiencing a Vitamin D or 25-OH D deficiency, such as celiac disease) cannot render the old process patentable (*see* Ans. 5–6; FF 2–6). *See In re Huai-Hung Kao*, 639 F.3d 1057, 1071 (Fed. Cir. 2011); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

For the foregoing reasons, we are not persuaded by Appellants' contentions that Buck “does not disclose [] the use [of 25-OH D3] for decreasing eotaxin, or for diseases/conditions associated with eotaxin” and Bikle “is [] completely silent as to reducing eotaxin levels by administering 25-OH D3” (Br. 5 (emphasis removed); *id.* at 6–8).

Buck discloses that 25-OH D3 “affect[s] at least [the] concentration, bioavailability, metabolism, or efficacy of vitamin D” (FF 2). Thus, Buck suggests that when vitamin D therapy is indicated, 25-OH D3 will facilitate

that vitamin D therapy and vitamin D and 25-OH D3 are to be administered together (FF 2–4). Therefore, we are not persuaded by Appellants’ contention that Bikle suggests “Vitamin D therapy – significantly *not* 25-OH D3” and “only describes administering vitamin D3 for bone health” (Br 6; *id.* at 7).

For the reasons discussed above, the combination of Buck and Bikle suggest Appellant’s claim 1. Appellant’s claim 1 does not require an underlying disease be corrected (*see* Br. 9). Therefore, we are not persuaded by Appellant’s contention that while Bikle discloses the administration of vitamin D therapy for an individual experiencing, *inter alia*, a vitamin D deficiency due to a condition such as celiac disease, Bikle does not “correct the underlying disease” (Br. 6).

CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over the combination of Buck and Bikle is affirmed. Claims 2–4 and 13–16 are not separately argued and fall with claim 1.

TIME PERIOD FOR RESPONSE

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

AFFIRMED