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Abel Schillinger, LLP
12414 Alderbrook Drive
Suite 201
Austin, TX 78758

EXAMINER	
WANG, SHENGJUN	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RAINER KROEPKE, LUDGER KOLBE, ANETTE BUERGER, and CLAUDIA MUNDT

Appeal 2021-003549
Application 11/004,617
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and TAWEN CHANG, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from Examiner's decision to reject claims 101–138 (Final Act.[2] 1). 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 "Beiersdorf AG of Hamburg, Germany" (Appellant's January 14, 2021, Appeal Brief (Appeal Br.) 3).

[2] Examiner's June 16, 2020, Final Office Action.

STATEMENT OF THE CASE

Appellant's disclosure "relates to cosmetic or dermatological preparations that include a combination of a dye and an anti-inflammatory active ingredient, and particularly to preparations for the prophylaxis and treatment of sun-irritated skin that aid the body's own repair mechanisms" and "to the use of such preparations comprising such combinations" (Spec.[3] 1:6–10).

This is the fourth Appeal of the subject matter of this Application (*see* Appeal Br. 3).[4] Of the prior Appeals, we find Appeal 2018-008640 particularly relevant to the issues presented in this Appeal (*see* Decision on Appeal 2018-008640, mailed August 12, 2019 ("2018-008640 Decision")). The 2018-008640 Decision affirmed the non-statutory double patenting and obviousness rejections of record therein (*see generally id.*). The 2018-008640 Decision found claim 101, reproduced below, representative of the subject matter in that Appeal:

> 101. A cosmetic or dermatological preparation, wherein the preparation comprises from 0.01 % to 5 % by weight of at least one red light-filtering dye, at least one white pigment, and from 0.0001 % to 10 % by weight of at least one anti-inflammatory active ingredient which comprises at least one aqueous extract of Glycyrrhiza inflata.

(2018-008640 Decision 2.)

Claim 101 presented for our review in this Appeal differs from claim 101 of the 2018-008640 Appeal by additionally requiring that the

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[3] Appellant's December 3, 2004, Specification.

[4] We note that although Appellant acknowledges Appeals 2015-002324 and 2018-008640, Appellant did not acknowledge Appeal 2011-008403, which Appellant subsequently withdrew from Appeal prior to a decision on the merits (*see* ORDER DISMISSING APPEAL, mailed April 26, 2013).

preparation does not contain strontium cations. In fact, each of Appellant's independent claims, claims 101, 123, and 133, reproduced below, presented for our review in this Appeal include this additional limitation as highlighted with italics:

> 101. A cosmetic or dermatological preparation, wherein the preparation comprises from 0.01 % to 5 % by weight of at least one red light-filtering dye, at least one white pigment, and from 0.0001 % to 10 % by weight of at least one anti-inflammatory active ingredient which comprises at least one aqueous extract of Glycyrrhiza inflata, and *wherein the preparation does not contain strontium cations*.

(Appeal Br. 31 (emphasis added).)

> 123. A cosmetic or dermatological preparation, wherein the preparation comprises from 0.01 % to 0.25 % by weight of at least one green pigment, at least 2.25 % by weight of at least one white pigment, at least one blue pigment, a weight ratio of the at least one blue pigment to the at least one green pigment being from 1:1 to 1:100, and from 0.0001 % to 10 % by weight of at least one anti-inflammatory active ingredient which comprises at least on aqueous extract of Glycyrrhiza inflata, and *wherein the preparation does not contain strontium cations*.

(*Id.* at 34 (emphasis added).)

> 133. A cosmetic or dermatological preparation, wherein the preparation comprises from 0.1 % to 0.2 % by weight of at least one green pigment selected from CI 77288 and CI 77289, at least one blue pigment in a weight ratio of the at least one blue pigment to the at least one green pigment of from 1:1 to 1:100, and from 0.0001 % to 10 % by weight of at least one anti-inflammatory active ingredient which comprises at least one aqueous extract of Glycyrrhiza inflata, and *wherein the preparation does not contain strontium cations*.

(*Id.* at 35–36 (emphasis added).)

Grounds of rejection before this Panel for review:

I. Claims 101–138 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

II. Claims 101–117, 119–131, 133, 134, and 136–138 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hahn,[5] Shibata,[6] Nagatani,[7] Wenninger,[8] Millikan,[9] Demko,[10] Bara,[11] Oto,[12] and Bikowski.[13]

III. Claims 118, 132, and 135 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, Bikowski, and Krzysik.[14]

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[5] Hahn et al., US 5,804,203, iss. Sept. 8, 1998.
[6] Shoji Shibata et al. *Inhibitory Effects of Licochalcone A Isolated from* Glycyrrhiza inflata *Root on Inflammatory Ear Edema and Tumor Promotion in Mice*, 57 Planta Med., 221–224 (1991).
[7] Nagatani et al., US 2001/0007677 A1, pub. July 12, 2001.
[8] International Cosmetic Ingredient Dictionary and Handbook, 301–307 (John A. Wenninger & G.N. McEwen, Jr., Ph.D., J.D. eds., 7th ed. 1997).
[9] Larry Millikan, *The Proposed Inflammatory Pathophysiology of Rosacea: Implications for Treatment,* Skinmed., 43–47 (2003).
[10] Demko, US 3,873,687, iss. Mar. 25, 1975.
[11] Bara et al., US 5,478,555, iss. Dec. 26, 1995.
[12] Oto et al., JP 2001-170226, pub. Dec. 18, 2002 (as translated).
[13] J. Bikowski, *The Use of Therapeutic Moisturizers in Various Dermatologic Disorders,* 68 Cutis 3–11 (2001).
[14] Krzysik et al., US 6,440,437 B1, iss. Aug. 27, 2002.

I

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention?

ANALYSIS

Examiner finds that Appellant's disclosure "as a whole does not conceptualize that the preparation should or should not contain strontium cation. Further, as to the sixty examples disclosed in the application, no explicit[] disclosure of strontium cation does not mean that exemplified preparations do not contain strontium cation" (Ans.[15] 15 (emphasis omitted)). Thus, Examiner find that "[t]he recitation 'wherein the preparation does not contain strontium cations' in claims 101, 123 and 133 lack[s] support from the application as originally filed" (Ans. 3). We are not persuaded.

As our reviewing court recently explained:

> "[A] reference need not state a feature's absence in order to disclose a negative limitation." *AC Techs., S.A. v. Amazon.com, Inc.*, 912 F.3d 1358, 1367 (Fed. Cir. 2019). Instead, it was reasonable for the Board to find that, in the context of Garrett, a skilled artisan would recognize that the reference discloses a complete formulation—excluding the possibility of an additional active ingredient. *See, e.g., Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1373 (Fed. Cir. 2022) (recognizing that for negative limitations, "the disclosure must be read from the perspective of a person of skill in the art"). It is undisputed that Garrett discloses dapsone formulations that lack adapalene. The Board thus did not err in

[15] Examiner's March 12, 2021, Answer.

> concluding that Garrett discloses the negative adapalene claim limitation.

Almirall, LLC v. Amneal Pharms. LLC, 28 F.4th 265, 273–274 (Fed. Cir. 2022) (alteration in original).

Similarly, on this record, Appellant explains that although "it is correct that the application as originally filed does not explicitly disclose the absence of strontium cations in the claimed preparation, sixty exemplified (most diverse) preparations, none of which contains strontium cations, speak for themselves" (Appeal Br. 9). Thus, Appellant contends,

> the fact that the sixty Examples of the instant application comprise "various specific ingredients", i.e., exemplify preparations which are diverse, and that none of these diverse compositions contains strontium cations is an indication that regardless of their specific composition, the preparations of the present invention do not contain strontium ions.

(*Id.* at 10 (emphasis omitted).) We find that Appellant has the better position on this record and, therefore, reverse the written description rejection. *See Almirall*, 28 F.4th at 273–274.

CONCLUSION

The preponderance of evidence on this record fails to support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention. The rejection of claims 101–138 under the written description provision of 35 U.S.C. § 112, first paragraph, is reversed.

II–III

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

ANALYSIS

Examiner relies upon the same prior art combinations of the same claims for rejections II–III, on this record, as was relied upon in the 2018-008640 Decision. We, therefore, direct attention to the 2018-008640 Decision for factual findings and analysis relevant to Appellant's claimed subject matter, with the exception of the additional limitation in the claims presented for our review on this record, which requires that "*the preparation does not contain strontium cations*" (emphasis added) (*see* 2018-008640 Decision 4–13). Of particular interest, in the 2018-008640 Decision, we acknowledged Appellant's contention that Hahn's composition included strontium cations, but found that as Appellant recognized, its claim 101 did not, at that time, exclude strontium cations, and, therefore, found Appellant's contentions regarding strontium cations not persuasive on that record (*see id.* at 10).

As discussed above, the claims now before this Panel expressly require that the preparation does not contain strontium cations. "As to the limitation of 'wherein the preparation does not contain strontium cations', [Examiner notes that] it has been well-established that omission of an element and its function is obvious if the function of the element is not desired" (Ans. 13 (citing *Ex parte Wu*, 10 USPQ 2031, 2032 (BPAI 1989))). Thus, Examiner finds "[i]n instant case *Hahn . . . does teach the requirement of strontium for its anti-irritation activity in topical composition against skin irritation*, particularly for those with sensitive skin, caused by irritant chemicals such as retinoids, carboxylic acid, capsaicin, along with other well-known excipients for topical composition" (Ans. 13 (emphasis added)). Examiner, therefore, concludes that, at the time Appellant's claimed

invention was made, it would have been prima facie obvious to those of ordinary skill in this art exclude "strontium cations" from the composition made obvious by the combination of Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, and Bikowski, with or without Krzysik, "if it does not have the characteristics rendered by strontium cation, i.e. anti-irritation function" (*id.*). We are not persuaded.

Hahn discloses:

> Many ingredients used in topical products are known irritants or are potentially irritating, especially to people with "sensitive skin". These *irritating ingredients include fragrances, preservatives, solvents, propellants and many other ingredients that might otherwise be considered inert components of the products*. Additionally, many topical product active ingredients, including chemicals that may also be classified as drugs, produce irritation when applied to the skin. These include, but are not limited to, such ingredients as exfoliants and skin cell renewal agents, anti-acne drugs, antiperspirant compounds, antihistamines, *anti-inflammatory agents*, skin protective agents, insect repellent chemicals, sunscreens and many others. Where more than one chemical irritant is present, their irritating effects may be additive. Furthermore, chemical ingredients may react with one another, or in the environment of the skin, to form new chemicals which are irritating. The vehicles in which the active drug ingredients are formulated may also produce irritation in sensitive people, especially in drugs such as topical corticosteroids.
>
> In addition to chemicals which directly trigger skin irritation, some chemicals indirectly cause the skin to become more sensitive to other chemicals or environmental conditions which would not normally cause irritation. Many chemicals which act as skin "exfoliants" such as retinoids (e.g. tretinoin, retinol and retinal), carboxylic acids including α-hydroxy acids (e.g. lactic acid, glycolic acid), β-hydroxy acids (e.g. salicylic acid), α-keto acids, acetic acid and trichloroacetic acid, 1-pyrrolidone-5-carboxylic acid, capryloyl salicylic acid, α-

> hydroxy decanoic acid, α-hydroxy octanoic acid, gluconolactone, methoxypropyl gluconamide, oxalic acid, malic acid, tartaric acid, mandelic acid, benzylic acid, gluconic acid, benzoyl peroxide and phenol, among others, may cause the skin to become more sensitive to irritation triggered by other topically-applied chemicals such as *moisturizers*, sunscreens, fragrances, preservatives, surfactants (e.g. soaps, shaving cream) and other topical products. Exfoliants and other ingredients may also increase the skin's sensitivity to environmental conditions such as sunlight, wind, cold temperature and dry air, or may exacerbate the irritation attributable to a pre-existing skin disease.

(Hahn 2:30–3:4 (emphasis added).)

As discussed in the 2018-008640 Decision:

> "[B]ased on the combination of Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, and Bikowski, [with or without Krzysik,] we [found] no error in Examiner's conclusion [in the 2018-008640 Decision] that, at the time Appellants' [sic] invention was made, it would have been *prima facie obvious to prepare a cosmetic or dermatological composition comprising a moisturizer*, 0.5-20% of at least one red light-filtering dye, at least one white pigment, *and* 1 % or 5% by weight of *an anti-inflammatory agent*, such as an aqueous extract of *Glycyrrhiza inflata.*

(2018-008640 Decision 8 (emphasis added).)

Hahn discloses, however, that its invention "involves the surprising discovery that the inclusion of strontium metal cation in the topical product formulations of the present invention is useful in reducing the incidence and severity of irritation associated with topically applied skin irritants, including irritation caused by various ingredients of the topical product," which, as discussed above, include, *inter alia*, moisturizers and anti-inflammatory agents (Hahn 5:6–13). As we found in the 2018-008640 Decision, the combination of references relied upon by Examiner include,

inter alia, moisturizers and anti-inflammatory agents (*see* 2018-008640 Decision 4–7). In addition, Appellant's claimed invention requires, *inter alia*, *an anti-inflammatory active ingredient* (*see* Appeal Br. 31, 34, 35). Thus, it is unclear what ingredient(s) Examiner proposes to remove from the composition made obvious by the combination of prior art relied upon by Examiner, which Hahn discloses would benefit from the presence of strontium cations, i.e. moisturizer and anti-inflammatory agents, while still allowing such a composition to read on Appellant's claimed invention.

Examiner's reliance on *Wu* is unavailing on this record. The issue in *Wu* was whether "it would have been obvious to omit . . . [the prior art's] polybasic acid salts when the function attributed to these salts is not desired or required." *See Wu*, 10 USPQ2d at 2032. In *Wu*, the prior art at issue disclosed "that the[] salts are beneficial when the composition is employed in contact with fresh water." *Id.* Thus, in *Wu*, the Board found that the "[o]mission of the salt component in preparing compositions to be used to provide corrosion resistance to metals in environments which do not encounter fresh water would have been obvious." *Id*. On this record, and in contrast to *Wu*, Examiner's conclusion of obviousness is based on a composition that includes reagents, e.g., moisturizers and anti-inflammatory agents, that Hahn expressly discloses would benefit from the presence of a strontium metal cation (*see* Ans. ¶¶ 19–23; *cf.* Hahn 2:30–3:4, 5:5–13; 2018-008640 Decision 4–7; *see also* Appeal Br. 13).

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness.

The rejection of claims 101–117, 119–131, 133, 134, and 136–138 under 35 U.S.C. § 103(a) as unpatentable over the combination of Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, and Bikowski is reversed.

The rejection of claims 118, 132, and 135 under 35 U.S.C. § 103(a) as unpatentable over the combination of Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, Bikowski and Krzysik is reversed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
101–138	112	Written Description		101–138
101–117, 119–131, 133, 134, 136–138	103(a)	Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, Bikowski		101–117, 119–131, 133, 134, 136–138
118, 132, 135	103(a)	Hahn, Shibata, Nagatani, Wenninger, Millikan, Demko, Bara, Oto, Bikowski Krzysik		118, 132, 135
Overall Outcome				101–138

REVERSED