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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GERHARD SAUERMAN, VOLKER SCHREINER, THOMAS DORING, WILFRIED SIEFKEN, CORNELIA GATERMANN, STEFANIE CARSTENSEN, and HELGA BIERGIESSER¹

Appeal 2015-005017
Application 10/482,164
Technology Center 1600

Before DONALD E. ADAMS, RICHARD J. SMITH, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a cosmetic or dermatologic composition that includes at least one L-carnitine compound or derivative, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

One of the many functions of the skin is its barrier function, including preventing skin from drying out. (Spec. 1.) The epidermis is the thinnest

¹ Appellants identify the Real Party in Interest as Beiersdorf AG. (Appeal Br. 3.)

layer of the skin but forms the “protective sheath against the environment” effecting the barrier function of the skin. (*Id.*) The outer layer of the epidermis becomes worn away from contact with the environment and is in a “continuous process of renewal, where, on the outside, fine flakes are continuously shed and, on the inside, keratinized cell and lipid material is subsequently produced.” (*Id.*) “[T]he protective mechanism on the surface of the skin is impaired” in environmentally damaged skin and ageing skin. (Spec. 3.) Appellants’ invention is aimed at providing “skincare compositions which retain or restore the barrier properties of the skin.” (Spec. 5.)

Claims 95–97, 99–102, 107, 108, 110–112, 124–126, 128, 129, 136–138, 140, 141, 143, 144, 146, and 147 are on appeal. Claims 95, 107, and 125 are representative and read as follows:

95. A cosmetic or dermatological composition, wherein the composition comprises from 0.001 % to 30 % by weight of at least one substance which is a carboxylic acid ester of L-carnitine selected from propionyl-L-carnitine, L-carnitine fumarate, and L-carnitine galactarate or is an ester of carnitine with an alkanol and wherein the composition is present as at least one of an anhydrous preparation, an emulsion, a microemulsion, a multiple emulsion, a cream, a milk, a lotion, an ointment, a gel, a solid stick, and an aerosol.

107. A cosmetic or dermatological composition, wherein the composition comprises from 0.05 % to 10 % by weight of at least one substance which is an ester of carnitine with a carboxylic acid or is an ester of carnitine with an alkanol and wherein the composition has a pH of from 5 to 7.

125. A cosmetic or dermatological composition, wherein the composition comprises from 0.1 % to 5.0 % by weight of at least one substance which is carnitine, an ester of carnitine with

a carboxylic acid, or an ester of carnitine with an alkanol, has a pH of from 5 to 6, and is present as at least one of an anhydrous preparation, an emulsion, a microemulsion, a multiple emulsion, a cream, a milk, a lotion, an ointment, a gel, a solid stick, and an aerosol.

(Appeal Br. 20–22.)

The following ground of rejection by the Examiner is before us on review:

Claims 95–97, 99–102, 107, 108, 110–112, 124–126, 128, 129, and 136–147 under 35 U.S.C. § 103 as unpatentable over Hamilton,² Fitton,³ Santaniello,⁴ and de Witt.⁵

DISCUSSION

The Examiner finds that Hamilton, which “is directed to cosmetics to support skin metabolism,” teaches a composition that includes “a carnitine such as L-carnitine or acetyl-L-carnitine (carboxylic acid ester of carnitine).” (Final Action 4; Ans. 3.) The pH of the formulation is taught to be from about 4 to about 8. (*Id.*) Hamilton’s “Example 3 provides several oil-in-water based emulsions” and the carnitine is present in an amount of 1.0% by weight. (*Id.*) The “carnitine and its derivatives are useful for slowing or reversing mitochondrial age related dysfunction.” (*Id.*) According to the Examiner, “[a]lthough all of the Examples of Hamilton employ L-carnitine, rather than acetyl-L-carnitine,” the selection of acetyl-L-carnitine would

² Hamilton, US 2002/0044913 A1, published Apr. 18, 2002.

³ Fitton, US 4,485,091, issued Nov. 27, 1984.

⁴ Santaniello et al. US 6,051,608, issued Apr. 18, 2000.

⁵ de Witt, US 4,401,827, issued Aug. 30, 1983.

have been obvious because “the genus of Hamilton is sufficiently small (suggests using one of L-carnitine or acetyl-L-carnitine) that one of ordinary skill would envisage its use in the composition.” (Final Action 5; Ans. 3.)

The Examiner notes that Hamilton does not “teach the composition as including a carboxylic acid ester of L-carnitine selected from L-carnitine fumarate and propionyl-L-carnitine.” (Final Action 5; Ans. 4.) The Examiner notes, however, that Santaniello, which is directed to compositions comprising L-carnitine or an alkonyl-L-carnitine (such as acetyl-L-carnitine and propionyl-L-carnitine), teaches that “salts of L-carnitine and alkonyl-L-carnitine esters provide the exact same therapeutic and nutritional activities as those of the inner salts and do not provide unwanted or toxic side effects.” (*Id.*) In other words, the Examiner finds “Santaniello teaches that the biological activity of propionyl-L-carnitine is equivalent to that of acetyl-L-carnitine.” (Ans. 8.) Thus, the Examiner finds that “it would have been obvious to use propionyl-L-carnitine of Santaniello in the composition of Hamilton with a reasonable expectation for success as propionyl-L-carnitine exhibits the same therapeutic benefits of L-carnitine (and acetyl-L-carnitine) and are well tolerated physiologically.” (Final Action 5–6; Ans. 8.)

The Examiner further finds that it would have been obvious to use fumarate monoester of L-carnitine in Hamilton in light of the teachings of de Witt. (Final Action 6; Ans. 4–5.) In particular, the Examiner finds de Witt to be “directed to novel acyl-derivatives of carnitine [that] are useful as therapeutic agents . . . and are well tolerated,” and the “[e]xemplified acyl derivatives includes fumarate monoester of L-carnitine.” (*Id.*) The

Examiner finds that, similar to Santaniello, de Witt establishes that acyl derivatives of carnitine “have the same biochemistry as that of L-carnitine.” (Ans. 8.) Thus, according to the Examiner, one of ordinary skill in the art would have a reasonable expectation of success of using the fumarate ester in the Hamilton composition because de Witt indicates such a compound “exhibit[s] therapeutic benefits . . . and are well tolerated physiologically.” (Final Action 6; Ans. 5.)

The Examiner further finds, that while Hamilton does not teach a pH buffer in the exemplified compositions, such would have been obvious in light of Fitton to ensure “that rapid changes in pH could be avoided and the active ingredients contained therein can remain chemically unaffected. (Final Action 5; Ans. 4.) In particular, the Examiner finds that Fitton teaches “a dermatological composition wherein the composition is to comprise a buffer that maintains an acid pH, i.e. less than 7” and exemplifies buffers such as lactic acid, and citric acid, among others, as well as the acid salt. (*Id.*)

In sum, the Examiner concludes:

it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the formulation of Hamilton such that the composition comprised a pH buffer, as taught by Fitton, so as to provide a stable chemical environment wherein the carnitine species with the propionyl-L-carnitine species (Santaniello) or the fumarate ester (de Witt) with a reasonable expectation that the combination in arriving at a composition exhibiting dermatological/cosmetic benefit to the user thereof, in view of the similar physiological/biological benefits for each of the carnitine species separately taught in the art.

(Final Action 6; Ans. 5.)

We agree with the Examiner's factual findings and conclusions as they pertain to composition claims that indicate the composition can contain carnitine or, generally, "an ester of carnitine with a carboxylic acid," e.g., independent claims 107 and 125. We, however, disagree with the Examiner's findings and conclusion of obviousness as to claims that require there be a carboxylic acid ester of L-carnitine "selected from propionyl-L-carnitine, L-carnitine fumarate, and L-carnitine galactarate" or "an ester of carnitine with an alkanol," e.g., independent claim 95 and dependent claims 110, 137, 138, 143, and 144.

Appellants assert that "[i]ndependent claims 95 and 107 and dependent claims 136–138 each recite that the claimed cosmetic or dermatological composition comprises at least one substance which is an ester of carnitine with a carboxylic acid or is an ester of carnitine with an alkanol." (Appeal Br. 7.) We find the foregoing to be an overgeneralization and that these claims, instead, include important differences on what is required by the composition. For example, claim 107 recites that the composition comprises at least one substance "which is an ester of carnitine with a carboxylic acid or is an ester of carnitine with an alkanol." (Claim 107.) Claim 136, on the other hand, recites that the composition "comprises at least one of acetyl-L-carnitine, propionyl-L-carnitine, L-carnitine fumarate, and L-carnitine galactarate," whereas claims 137 and 138 specify that the ester of carnitine in the composition comprises propionyl-L-carnitine or L-carnitine fumarate, respectively. (Appeal Br. 22 (Claims 136–138).) Claim 95 recites that the composition comprises at least one substance "which is a carboxylic acid ester of L-carnitine selected from propionyl-L-

carnitine, L-carnitine fumarate, and L-carnitine galactarate or is an ester of carnitine with an alkanol.” (Claim 95.) Thus, while Appellants argue claims 95, 107, and 136–138 as a group (Appeal Br. 7–15), we note that the group of carnitine compounds of claim 107 is far broader than that of claims 95 and 136–138. Moreover, the carnitine compounds included in claim 136, which depends from independent claim 125, is broader than that of claim 95 in that claim 136 includes “acetyl-L-carnitine” as one of the carboxylic acid esters. We will address the broader claims first.

Independent Claims 107 and 125: “an ester of carnitine with a carboxylic acid”

Appellants concede that Hamilton discloses the use of acetyl-L-carnitine for use in topical cosmetic compositions. (Appeal Br. 7.) Appellants argue that Hamilton “does not render it obvious to one of ordinary skill in the art to use any derivative of carnitine that is different from acetyl-L-carnitine in the topical cosmetic compositions disclosed therein.” (*Id.*) As noted above, claim 107 recites that the composition comprises at least one substance “which is an ester of carnitine . . . or is an ester of carnitine with an alkanol.” (Claim 107.) Because claim 107 permits the use of acetyl-L-carnitine without also requiring an alkanol, we are not persuaded that the Examiner erred in rejecting claim 107 for obviousness over Hamilton.

Similarly, claim 136 also permits the use of acetyl-L-carnitine without also requiring an alkanol; consequently, we are also not persuaded that the Examiner erred in rejecting claim 136 for obviousness over Hamilton.

Claim 136 depends from independent claim 125. Appellants do not contest the Examiner's rejection of claim 125. We believe that is for good reason because, similar to claim 107, claim 125 permits the composition to include carnitine or an ester of carnitine with a carboxylic acid without also requiring an alkanol. (Claim 125.) Appellants concede that Hamilton discloses the use of both carnitine and acetyl-L-carnitine for use in topical cosmetic compositions. (Appeal Br. 7.)

Moreover, we agree with the Examiner that claim 125, which requires the composition to have a pH of from 5 to 6, would have been obvious from Hamilton's teachings. Hamilton teaches that the compositions are preferably between a pH of about 4 to about 9. (Hamilton ¶ 63.) Fitton teaches common buffers used in dermatological compositions for maintaining pHs within a range of pH 2.5 and 6.5 were well known in the art. (Fitton 3:20–27.) Thus, while Hamilton does not disclose the pH of the compositions of Example 3, we agree with the Examiner that it would have been obvious to one of ordinary skill in the art to ensure the pH of these compositions were at the disclosed preferred range. (Ans. 9.) Thus, we conclude that the Examiner has established a *prima facie* case of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness.”). Appellants do not argue to the contrary.

Claims 108, 111, 112, and 124 have not been argued separately from independent claim 107 and, therefore, fall with claim 107. 37 C.F.R.

§ 41.37(c)(1)(iv). Claims 126, 128, and 129 have not been argued separately from independent claim 125 and, therefore, fall with claim 125. *Id.*

Independent claim 95 and dependent claims where the carboxylic acid ester of L-carnitine is not acetyl-L-carnitine but is propionyl-L-carnitine or L-carnitine fumarate.

Claim 95 recites that the carboxylic acid ester of L-carnitine is “selected from propionyl-L-carnitine, L-carnitine fumarate, and L-carnitine galactarate or is an ester of carnitine with an alkanol.” (Claim 95.) While Hamilton teaches a composition that includes acetyl-L-carnitine, the Examiner does not contend that Hamilton also discloses an alkanol. Consequently, we discern the Examiner’s rejection of claim 95 requires substitution of propionyl-L-carnitine, which the Examiner contends is obvious from Santaniello, or the substitution of L-carnitine fumarate, which the Examiner contends is obvious from de Witt. (Final Action 5–6.) In reaching this conclusion, the Examiner contends that “Santaniello teaches that the biological activity of propionyl-L-carnitine is equivalent to that of acetyl-L-carnitine.” (Ans. 8; Final Action 5 (citing Santaniello 1:27–31).) The Examiner further finds that, similar to Santaniello, de Witt’s teaching that acyl-derivatives are useful as therapeutic agents indicates that “acyl derivatives of carnitine (i.e. acetyl, propionyl, fumaryl, etc.) have the same biochemistry as that of L-carnitine” and “if one desired a more stable and more active alternative to L-carnitine or acetyl-L-carnitine, then one of ordinary skill in the art would turn to other L-carnitine ester actives, such as the fumarate ester of L-carnitine, where the resulting modification would provide topical cosmetic benefit.” (Ans. 8; Final Action 6.)

We disagree with the Examiner. In particular, as Appellants explain, Santaniello states that “the salts of L(-)-carnitine and its alkanoyl derivatives present the same therapeutic or nutritional activities as those of the so-called inner salts” not that the therapeutic or nutritional activities of L(-)-carnitine are equivalent to the therapeutic or nutritional activities of the alkanoyl derivatives of L(-)-carnitine. (Appeal Br. 12; Santaniello 1:27–31.) That the equivalent activity statement is directed to L-carnitine and its salts or alkanoyl derivatives of L-carnitine and its salts is further evidenced by the preceding paragraphs of Santaniello, which indicate that “L-carnitine has been used in the cardiovascular field for the treatment of acute and chronic myocardial ischaemia, angina pectoris, heart failure and cardiac arrhythmias” (Santaniello 1:13–16), in the nephrological field “to combat myasthenia and the onset of muscular cramps” (Santaniello 1:17–20), as well as “the normalization of the HDL:LDL+ VLDL ratio and total parenteral nutrition” (Santaniello 1:21–22), whereas acetyl-L-carnitine has been used in Alzheimer’s disease and diabetic neuropathy (Santaniello 1:23–26) and propionyl-L-carnitine has been used for treating vascular disease and congestive heart failure (Santaniello 1:26–27). The foregoing belies any conclusion that Santaniello teaches the biological activity of propionyl-L-carnitine is equivalent to that of acetyl-L-carnitine. And for this reason, we disagree with the Examiner that it would have been obvious to substitute propionyl-L-carnitine for acetyl-L-carnitine in the composition of Hamilton with the expectation that “that despite the difference in purpose, the proposed modification wherein Hamilton employs the propionyl ester would provide the biological benefits espoused” (Ans. 7–8).

We also do not find that de Witt teaches therapeutic equivalence of L-carnitine, acetyl-L-carnitine and L-carnitine-fumarate, much less indicating that L-carnitine-fumarate is more stable than either acetyl-L-carnitine or L-carnitine. de Witt merely teaches “the compounds of formula (I) and their pharmaceutically acceptable salts have shown interesting cardiotropic hyperlipoproteinemic and hyperlipidaemic properties.” (de Witt 1:55–58.) And for this reason, we disagree with the Examiner that it would have been obvious to substitute L-carnitine fumarate for L-carnitine or acetyl-L-carnitine in the composition of Hamilton with the expectation that it would provide topical cosmetic benefit (much less that it would be more stable). (Ans. 8–9).

Consequently, we reverse the Examiner’s rejection of claim 95 for obviousness over Hamilton, Santaniello, and de Witt.

Claim 110, like claim 95, recites that the composition “comprises at least one of propionyl-L-carnitine, L-carnitine fumarate, and L-carnitine galactarate.” Claims 137 and 143 require that the composition comprises propionyl-L-carnitine. Claims 138 and 144 require that the composition comprises L-carnitine fumarate. For the reasons just discussed, we also reverse the Examiner’s rejection of these claims for obviousness over Hamilton, Santaniello, and de Witt.

Dependent Claims 146 and 147: “a buffered preparation”

Appellants argue that it would not have been obvious for the Hamilton composition to be a buffered preparation in light of Fitton. (Appeal Br. 16–17.) According to Appellants, Fitton incorporates a buffer in its

compositions because it “is essential for stabilizing hydrogen peroxide in the compositions disclosed therein.” (Appeal Br. 17.) Appellants contend that “it is not seen that compositions which comprise carnitine or acetyl-L-carnitine require the presence of a buffer in order to stabilize these compounds” and none of the examples including carnitine contain any buffer, nor is there “any other indication in HAMILTON to the effect that the presence of a buffer in the compositions disclosed therein might be beneficial.” (*Id.*) According to Appellants, because the pH of the Hamilton compositions is disclosed to “vary over a wide range from acidic to basic,” it is “reasonable to assume for one of ordinary skill in the art that the presence of a buffer in these compositions is superfluous because the pH apparently does not affect the stability of carnitine and the other compounds which are required to be present in the compositions.” (Appeal Br. 17–18.)

We do not find Appellants’ arguments persuasive. We agree with the Examiner that pH stability is a desirable condition for dermatological compositions (Ans. 9), and is conceptually disclosed in Hamilton. While Hamilton indicates the range of acceptable skin compositions is between about 4 to about 9, Hamilton further indicates that it is more preferable to maintain a more neutral pH of from about 6 to about 8. (Hamilton ¶ 63.) Thus, that Hamilton may not expressly indicate “the presence of a buffer in the compositions disclosed therein might be beneficial” (Appeal Br. 17), we find the preference for maintaining a relatively neutral pH of the composition is a sufficient implication of the benefit of including a pH buffer in the carnitine compositions disclosed in Hamilton. As the Examiner noted, “Fitton is cited to demonstrate that a) pH buffers are common in

dermatological compositions and b) maintain the pH of the composition such that rapid changes are avoided and the active ingredients are not chemically affected.” (Ans. 9.) As the Examiner aptly explained, that Fitton’s composition includes hydrogen peroxide “is of little to no significance as the basic principle of Fitton remains[, namely,] that pH buffers provide stability to topical dermatological compositions by resisting change in pH.” (*Id.*) In view of the foregoing, we conclude that the Examiner has established a prima facie case of obviousness of including a pH buffer in a composition of Hamilton that includes L-carnitine or acetyl-L-carnitine. Thus, we affirm the Examiner’s rejection of claims 146 and 147 for obviousness over Hamilton and Fitton.

SUMMARY

We affirm the rejection of claims 107, 108, 111, 112, 124–126, 128, 129, 136, 146, and 147 under 35 U.S.C. § 103 as unpatentable over Hamilton, Fitton, Santaniello, and de Witt.

We reverse the rejection of claims 95–97, 99–102, 110, 137, 138, 140, 141, and 144 under 35 U.S.C. § 103 as unpatentable over Hamilton, Fitton, Santaniello, and de Witt.

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-IN-PART