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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/115,276	11/01/2013	John D. Blizzard	37461.0001U2	8408

23859 7590 01/16/2019

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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
01/16/2019	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN D. BLIZZARD

Appeal 2017-011206
Application 14/115,276
Technology Center 1600

Before JEFFREY N. FREDMAN, MICHAEL J. FITZPATRICK, and RYAN H. FLAX, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134 involving claims to a siloxane gel composition. The Examiner rejected the claims as obvious under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] Appellant identifies the Real Parties in Interest as "Quadsil, Inc., . . . and its licensee, Kimmerling Holdings Group LLC" (*see* Br. 2).

[2] We have considered and herein refer to the Specification of Nov. 1, 2013 ("Spec."); Final Office Action of Sept. 6, 2016 ("Final Act."); Appeal Brief of Mar. 13, 2017 ("Br."); and Examiner's Answer of June 16, 2017 ("Ans.").

Statement of the Case

Background

"The material of this invention is a siloxane polymer thixotropic base that is useful as an excipient for many actives or variable materials that can be compounded into it" (Spec. ¶ 2). "'Actives' for purposes of this invention means any material that will provide a benefit to a user, such as medicaments (e.g., triple antibiotic), pharmaceuticals (e.g., acetylsalicylic acid), cosmetics (e.g., colorants for the skin), and the like." (Spec. ¶ 2).

The Claims

Claims 1, 6, 7, 10–30, and 45 are on appeal. Claims 1 and 7 are representative and read as follows:

1. A composition, comprising:
A. a siloxane gel comprising:
   a. a first solvent selected from the group consisting of: methylsiloxane cyclics having 4 and 5 silicon atoms, a trimethylsiloxy end-blocked polydimethylsiloxane, ester of aromatic alkoxylated alcohol and fatty carboxylic acid, alkoxylated derivatives of benzyl alcohol, aromatic hydrocarbons, aliphatic hydrocarbons, alcohols, aldehydes, ketones, amines, esters, ethers, glycols, glycol ethers, alkyl halides, aromatic halides, and mixtures thereof;
   b. a siloxane copolymer comprising a reaction product of:
      i. an hydridopolysiloxane selected from the group consisting of:
         (a) $R_3SiO(R'_2SiO)_a(R"HSiO)_bSiR_3$;
         (b) $HR_2SiO(R'_2SiO)_cSiR_2H$; and
         (c) $HR_2SiO(R'_2SiO)_a(R"HSiO)_bSiR_2H$;
         wherein:
            R, R', R" are, each independently, C_1-C_6alkyl;
            a is about 0 to about 250;
            b is about 1 to about 250; and
            c is about 0 to about 250; and
      ii. an α,ω-diene having the general formula:

$$CH_2=CH(CH_2)_xCH=CH_2$$

wherein:

x is about 1 to about 20;

B. a first additional solvent selected from the group consisting of: methylsiloxane cyclics having 4 and 5 silicon atoms, a trimethylsiloxy endblocked polydimethylsiloxane, ester of aromatic alkoxylated alcohol and fatty carboxylic acid, alkoxylated derivatives of benzyl alcohol, aromatic hydrocarbons, aliphatic hydrocarbons, alcohols, aldehydes, ketones, amines, esters, ethers, glycols, glycol ethers, alkyl halides, aromatic halides, acetonitrile, nitromethane, dimethylforamide, propylene oxide, trioctyl phosphate, butyrolactone, furfural, pine oil, turpentine, m-creosol, volatile flavoring compound, volatile fragrance compound, and mixtures thereof; and

C. a second additional solvent selected from the group consisting of: methylsiloxane cyclics having 4 and 5 silicon atoms, a trimethylsiloxy endblocked polydimethylsiloxane, ester of aromatic alkoxylated alcohol and fatty carboxylic acid, alkoxylated derivatives of benzyl alcohol, aromatic hydrocarbons, aliphatic hydrocarbons, alcohols, aldehydes, ketones, amines, esters, ethers, glycols, glycol ethers, alkyl halides, aromatic halides, acetonitrile, nitromethane, dimethylforamide, propylene oxide, trioctyl phosphate, butyrolactone, furfural, pine oil, turpentine, m-creosol, volatile flavoring compound, volatile fragrance compound, and mixtures thereof; and

D. at least one antimicrobial agent;

wherein said antimicrobial agent is a silicon-containing antimicrobial agent.

7. A composition of claim 1,

wherein said at least one antimicrobial agent is 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.

The Rejections

A. The Examiner rejected claims 1, 6, 7, 10–25, and 27–30 under 35 U.S.C. § 103(a) as obvious over Mallard,[3] Schulz Jr.,[4] Avery '600,[5] and Sawaya[6] (Final Act. 3–7).

B. The Examiner rejected claim 45 under 35 U.S.C. § 103(a) as obvious over Mallard, Schulz Jr., Avery '600, Sawaya, and NYSCC[7] (Final Act. 7–9).

A. 35 U.S.C. § 103(a) over Mallard, Schulz Jr., Avery '600, and Sawaya

The Examiner finds that Mallard teaches "a pharmaceutical composition for topical application in the form of a gel" that comprises "an organopolysiloxane elastomer which reads on the claimed siloxane copolymers ([81] and [92]-[108])" and "solvents which read on the claimed solvents" (Final Act. 3). The Examiner acknowledges that Mallard does not teach "antimicrobial agents including 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride" (*id.* at 4).

The Examiner finds Avery '600 teaches "antimicrobial compositions comprising 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride" (Final Act. 4). The Examiner finds Sawaya teaches "topical formulations comprising at least one antibiotic and a triple antibiotic form" (*id.*). The Examiner finds Schulz, Jr. teaches "elastomers for thickening

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[3] Mallard et al., US 2007/0135379 A1, published June 14, 2007.
[4] Schulz, Jr. et al., US 5,654,362, issued Aug. 5, 1997.
[5] Avery et al., US 2003/0073600 A1, published Apr. 17, 2003.
[6] Sawaya et al., US 5,516,808, issued May 14, 1996.
[7] *NYSCC Showcases Global Technology Under One Roof*, 125 COSMETICS AND TOILETRIES MAGAZINE 12–14 (July 2010).

silicon oils and solvents including cyclic methyl siloxanes, trimethylsiloxy end-blocked PDMS, methanol, citronellol, and jasmine" (*id.*).

The Examiner finds it would have been obvious "to utilize the 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride of Avery ['600], in the formulations of Mallard et al. in order to further enhance the residual effectiveness of the antimicrobial components of Mallard" (Final Act. 5). The Examiner finds it would have been obvious "to utilize the triple antibiotic of Sawaya et al., in the formulations of Mallard et al. in order to produce a composition with broader antibiotic protection" (*id.*).

The issue with respect to these rejections is: Does a preponderance of the evidence of record support the Examiner's conclusion that the prior art renders claim 1 obvious?

Findings of Fact

1. Mallard teaches "stable, anhydrous pharmaceutical compositions combining at least one active ingredient and a silicone agent, said active ingredient being present in a solubilized form in said composition" (Mallard ¶ 1).

2. Mallard teaches "organopolysiloxane elastomer[s]" (Mallard ¶ 82) that may be formulated with "volatile silicone oils" (Mallard ¶¶ 90–92) and be "prepared by crosslinking reaction between polysiloxanes (A) containing ≡Si–H groups . . . an alpha,omega-diene (B) in the presence of a catalyst, and a low molecular weight linear or cyclic polysiloxane (C)" (Mallard ¶ 94).

3. Mallard teaches that active ingredients in the composition may include "antibacterial agents, antibiotics, antiparasitic agents, antifungal agents" (Mallard ¶ 61).

4. Avery '600 teaches "a hard surface antimicrobial cleaner with a residual antimicrobial effect, and [a] hard surface antimicrobial cleaner that inhibits the formulation of biofilm on the hard surface" (Avery '600 ¶ 4).

5. Avery '600 teaches that a "hard surface antimicrobial cleaner according to the invention may optionally include from 0 to about 5% by weight of the total weight of the cleaner of an organosilane" and "preferably, the organosilane is 3-trimethoxysilyl)propyldimethyloctadecyl ammonium chloride (commercially available as Dow Corning 5772) or 3-trimethoxysilyl)propylmethyldi(decyl)ammonium chloride. . . . The organosilane can further enhance the residual effectiveness against bacteria." (Avery '600 ¶ 38).

6. Sawaya teaches in "a 'triple antibiotic' form of the invention, i.e., including at least Polymyxin B, Neomycin Sulfate and Zinc Bacitracin, one or more agents are added to stabilize the Zinc Bacitracin" (Sawaya 4:30–33).

7. Schulz, Jr. teaches solvents including "furfural, pine oil, turpentine, and m-creosol" (Schulz, Jr. 5:27–28).

Principles of Law

"If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Analysis

We adopt the Examiner's findings of fact and conclusions of law (*see* Final Act. 3–7; FF 1–7) and agree that the combination of Mallard, Avery '600, Schulz, Jr., and Sawaya renders the claims obvious.

We address Appellant's arguments below.[8]

Appellant "submits that there would have been no reasonable expectation of success to reach the claimed invention because there is a teaching away" (Br. 5). Appellant specifically contends that

> Avery teaches away from the use of the silicon-containing antimicrobial agents in a composition for use on skin. Avery is directed to harsh, sprayable cleaners with residual effectiveness used in ***disinfecting hard surfaces***, such as glass, tile, porcelain, fiberglass composites, metallic surfaces, ceramic surfaces, laminate surfaces, hard polymeric surfaces. See paragraph [0006] of Avery. Appellant, in stark contrast, sought to develop a spreadable, thixotropic gel for ***topical use on a user's skin***.

(Br. 7). Appellant further contends the EPA requires "the label for Dow Corning 5772 (now Aegis AEM 5772) to state that the product is a 'poison'" and therefore "it is apparent that a skilled artisan reading the Avery patent would not consider Dow Corning 5772 to be suitable for use in composition to be used on skin as a hand sanitizer" (Br. 7–8). Appellant concludes "[b]ecause Avery ['600] teaches away from the use of the missing silicon-containing antimicrobial agents in a composition useful on skin, one of ordinary skill in the art would not modify the Mallard reference to incorporate the missing silicon-containing antimicrobial agents in an effort to arrive at the claimed invention" (Br. 8).

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[8] We limit our consideration of the merits of the appealed rejection to the elected species. *See Ex parte Ohsaka*, 2 USPQ2d 1460, 1461 (BPAI 1987). Thus, we read the claims as directed to the use of the elected 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride as the antimicrobial agent (*see* Resp. to Election/Restriction filed on Nov. 12, 2015 at 12).

We find the argument that Avery '600 teaches away unpersuasive for several reasons. First, we note that the AEM document on which Appellant relies also specifically states that approved uses include "non-woven disposable diapers," "wiping cloths," "pre-moistened towelettes and tissue wipes," and "socks, hosiery, undergarments" (Evidence Appendix, AEM 5772 Antimicrobial at 4). Thus, contrary to Appellant's arguments, the AEM document reasonably suggests that the compound may safely contact skin, including the skin of infants, when used in diapers, wiping cloths and moistened towelettes. Moreover, the AEM document state the antimicrobial "provides residual self-sanitizing activity against athlete's foot fungus . . . on treated socks" (Evidence Appendix, AEM 5772 Antimicrobial at 4). This indicates that the compound not only may safely contact skin, but that the compound retains activity while doing so.

Moreover, we agree with the Examiner that "many chemicals are considered a poison when stored separately in large amounts, however, many of said chemicals are suitable for topical formulations in small quantities" (Ans. 3). Indeed, the AEM document suggests to "[i]ncorporate AEM 5772 Antimicrobial directly into formulations used to make end-use products" (Evidence Appendix, AEM 5772 Antimicrobial at 5). Thus, we agree with the Examiner that the identified dangers of AEM 5772 in the document refer to the purified and isolated form, not to the compound when properly incorporated into final products for commercial application.

Second, the Examiner has cited Avery '585,[9] which teaches "aqueous compositions which can be used as antimicrobial hand cleaner formulations"

[9] Avery et al., US 5,411,585, issued May 2, 1995.

where Example 4 comprises Dow Corning 5772 (Avery '585 17:25–33). Avery '585 therefore reasonably suggests that the antimicrobial compound 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride in Dow Corning 5772 may be safely incorporated into compositions for external application to human skin (*see* Avery '585 17:25–33).

Third, Appellant does not identify any teaching in Avery '600 (or indeed in the EPA AEM 5772 Antimicrobial document itself) that criticizes, discredits, or discourages the use of the antimicrobial compound 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride in external use pharmaceutical compositions such as the composition of Mallard (FF 1–3). *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.").

Therefore, we conclude that neither Avery '600, nor the EPA AEM 5772 Antimicrobial document, teach away from the use of 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride in external use pharmaceutical compositions.

Appellant contends:

> Only after reading the cited references, with the benefit of the knowledge of Applicant's application, could the Office reach the conclusion that Applicant's pending claims are obvious in view of Mallard in view of Avery. However, that is not the standard for obviousness, and the use of hindsight is impermissible. "The tendency to resort to 'hindsight' based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process.

(Br. 6). Appellant also contends "there is no teaching, suggestion, or

motivation in the prior art that would have led one of ordinary skill . . . to combine the Mallard reference with the Avery reference" (*id.*).

We find these arguments unpersuasive. Although we are fully aware that hindsight bias may plague determinations of obviousness, *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966), we are also mindful that the Supreme Court has clearly stated that the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416. In the present case, Mallard teaches a silicone composition as required by claim 1 (FF 1–2) and specifically teaches inclusion of active agents including "antibacterial agents, antibiotics, antiparasitic agents, antifungal agents" (FF 3). Avery '600 teaches that one known agent that "can further enhance the residual effectiveness [of a composition] against bacteria" is "3-trimethoxysilyl) propyldimethyloctadecyl ammonium chloride (commercially available as Dow Corning 5772)" (Avery ''600 [0038], FF 5).

Therefore, the Examiner reasonably finds that inclusion of Avery '600's agent into Mallard's composition would have been obvious "in order to further enhance the residual effectiveness of the antimicrobial components of Mallard" (Final Act. 5). The Examiner provides a specific reason for the combination, and recognizes as well that the antimicrobial of Avery '600 is a well-known equivalent anti-microbial compound that was commercially available (FF 4). An "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

Conclusion of Law

A preponderance of the evidence of record supports the Examiner's

conclusion that the prior art renders claim 1 obvious.

B. 35 U.S.C. § 103(a) over Mallard, Schulz Jr., Avery '600, Sawaya, and NYSCC

Appellant does not argue this obviousness rejection. The Examiner provides sound fact-based reasoning for combining the teachings of NYSCC with Mallard, Schulz Jr., Avery '600, and Sawaya (*see* Final Act. 7–9). Having affirmed the obviousness rejection of claim 1 over Mallard, Schulz Jr., Avery '600, and Sawaya for the reasons given above, we also find that the further combination with NYSCC renders the rejected claim obvious for the reasons given by the Examiner.

SUMMARY

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over the combination of Mallard, Schulz Jr., Avery '600, and Sawaya. Pursuant to 37 C.F.R. § 41.37(c)(1), we also affirm the rejection of claims 6, 7, 10–25, and 27–30 as these claims were not argued separately.

We affirm the rejection of claim 45 under 35 U.S.C. § 103(a) as obvious over the combination of Mallard, Schulz Jr., Avery '600, Sawaya, and NYSCC.

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