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31781	7590	06/18/2020	EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* JINYU HUANG, DAQING WU, UWE HAKEN,  
HORNGYIH HUANG, and VENKAT SHANKAR

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Appeal 2019-005335  
Application 14/108,426  
Technology Center 1700

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Before JEFFREY B. ROBERTSON, JAMES C. HOUSEL, and  
CHRISTOPHER C. KENNEDY, *Administrative Patent Judges*.

ROBERTSON, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>2</sup> appeals from the Examiner's decision to reject claims 1, 3–5, and 7. Appeal Br. 2. We have jurisdiction under 35 U.S.C. § 6(b).

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<sup>1</sup> This Decision includes citations to the following documents: Specification filed December 17, 2013 (“Spec.”); Final Office Action mailed June 26, 2018 (“Final Act.”); Appeal Brief filed November 19, 2018 (“Appeal Br.”); Examiner's Answer mailed May 2, 2019 (“Ans.”); and Reply Brief filed July 2, 2019 (“Reply Br.”).

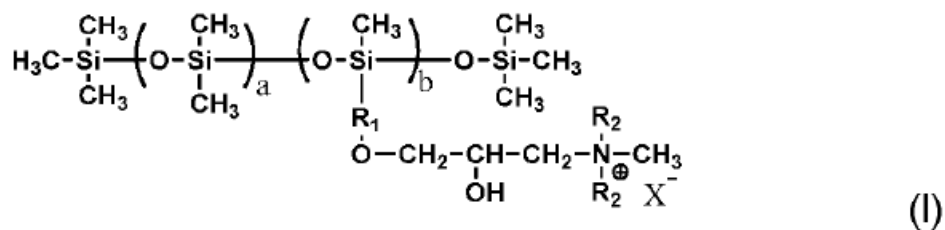
<sup>2</sup> We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Novartis AG. Appeal Br. 2.

We affirm.

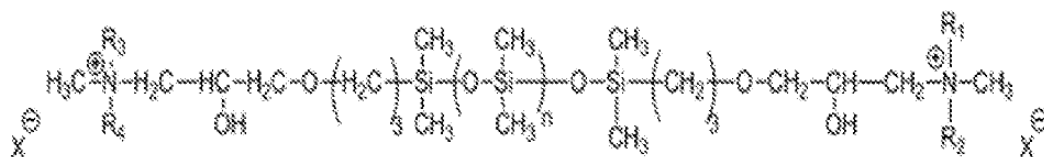
### CLAIMED SUBJECT MATTER

Appellant states the invention relates to a method for making contact lenses using quaternary ammonium cationic group containing silicone surfactants as mold releasing agents. Spec. 1. Claim 1, reproduced below, is illustrative of the claimed subject matter (Appeal Br., Claims Appendix 11):

1. A method for producing silicone hydrogel contact lenses, the method comprising the steps of:
  - (1) providing a mold for making soft contact lenses, wherein the mold has a first mold half with a first molding surface for defining an anterior surface of a contact lens and a second mold half with a second molding surface for defining an opposite posterior surface of the contact lens, wherein said first and second mold halves are configured to receive each other such that a cavity is formed between said first and second molding surfaces;
  - (2) introducing a fluid polymerizable composition comprising at least one actinically-crosslinkable water processable siloxane-containing prepolymer and at least one water soluble and/or dispersible quaternary ammonium cationic group containing silicone surfactant into the cavity, wherein the quaternary ammonium cationic group containing silicone surfactant comprises a cationic surfactant which is represented by formula (I)



in which  $R_1$  is  $C_1-C_8$  alkylene divalent radical,  $R_2$  is  $C_1-C_8$  alkyl radical,  $X^-$  is a  $Cl^-$ ,  $Br^-$ , or  $I^-$ ,  $a$  is an integer of from 10 to 50, and  $b$  is an integer of from 2 to 8,  
or a cationic surfactant which is represented by formula (II)



(II)

in which  $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$ , independently of each other, is a  $C_1-C_8$  alkyl radical,  $X^-$  is  $Cl^-$ ,  $Br^-$ , or  $I^-$ , and  $n$  is an integer of from 10 to 50;

(3) curing the fluid polymerizable composition in the mold to form a silicone hydrogel contact lens, wherein the formed silicone hydrogel contact lens comprises the anterior surface defined by the first molding surface and the opposite posterior surface defined by the second molding surface; (4) separating the mold from the formed lens; and

(5) repeating steps (1) to (4) at least three times;

wherein the water soluble/dispersible silicone surfactant is present in the fluid polymerizable composition in an amount sufficient to reduce an averaged mold separation force between the mold and formed lens by at least about 30% in comparison to a control composition comprising all components of the fluid polymerizable composition with exception of any mold releasing agent and wherein the averaged mold separation force is obtained from an average of the at least three instances of repetition.

## REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Pruitt et al. hereinafter “Pruitt”	US 7,780,879 B2	August 24, 2010
Xie et al. hereinafter “Xie”	CN 102675538 A English Translation	September 19, 2012
Siltech	“Innovative Silicone Specialties” (Archived from <a href="http://www.siltech.com/index.php/siliconequatarnary-compounds-silquat">www.siltech.com/index.php/siliconequatarnary-compounds-silquat</a> to 2003, Retrieved on December 7, 2016	2003

## REJECTIONS

1. The Examiner rejected claims 1, 3–5, and 7 under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Xie, Siltech, and Pruitt. Final Act. 8–11.
2. The Examiner rejected 1, 3–5, and 7 under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Pruitt and Siltech. Final Act. 12–14.

## OPINION

In view of our disposition with respect to Rejection 2, discussed *infra*, we find it unnecessary to reach a decision as to Rejection 1.

### *Rejection 2*

Appellant states that claims 1, 3, and 7 and claims 4 and 5 are argued as separate groups. *See* Appeal Br. 8. We select claims 1 and 4 as representative for disposition of this rejection, with the patentability of the

other claims standing or falling with claims 1 and 4. 37 C.F.R.  
§ 41.37(c)(1)(iv).

*The Examiner's Rejection*

Regarding claim 1, the Examiner found that Pruitt discloses providing a contact lens mold, introducing a siloxane-containing prepolymer and an alkyl quaternary ammonium cationic group containing surfactant as an internal release agent into a mold, curing the lens-forming material, and separating the mold with a reduction in mold separation force falling into the claimed range. Final Act. 12–13, citing Pruitt, col. 2, ll. 60–67, col. 9, ll. 22–24, col. 16, Formula I, col. 17, ll. 25–31, col. 18, l. 55–col. 19, l. 14.

The Examiner found Pruitt's alkyl quaternary ammonium cationic surfactant lacks silicone backbone portions, and relied on Siltech for the quaternary ammonium cationic group containing silicone surfactants having the formulas recited in claim 1. *Id.* The Examiner found the surfactants disclosed in Siltech are similar to the quaternary ammonium cationic group containing phospholipids disclosed in Pruitt, because both contain hydrophilic and hydrophobic groups (each are amphipathic), both are alkyl quaternary ammonium cationic group-containing materials including oxygen-containing substituents, and both are recognized as mold release agents. *Id.* at 13, citing Siltech, 1, 2, 12–13.

The Examiner determined it would have been obvious to incorporate the quaternary ammonium cationic group containing silicone surfactants disclosed in Siltech having the formulas recited in claim 1 into Pruitt, because they are interchangeable for or would improve the “remarkably similar surfactant release agents already disclosed by Pruitt.” *Id.* at 13.

As to the reduction in mold separation force recited in claim 1, as discussed above, the Examiner found Pruitt discloses values falling within the claimed range. *Id.*, citing Pruitt, col. 17, ll. 25–31. The Examiner determined that because the compounds disclosed in Siltech are similar to Pruitt’s mold release agents, such would be expected to have the same or similar mold separation-force-reducing effect. *Id.* The Examiner also determined that because Pruitt discloses a correlation between release agent amount and mold separation force (Pruitt, Table 1), one of ordinary skill in the art would have optimized the amount of the surfactants disclosed in Siltech in order to obtain the greatest possible reduction in mold separation force without negatively impacting quality or utility of the resulting product. *Id.* at 13–14.

*Appellant’s contentions*

Appellant argues the Examiner has failed to provide sufficient reasoning as to why one of ordinary skill in the art, when faced with Pruitt’s disclosure of a phospholipid internal mold releasing agent, would have turned to Siltech and chosen the specific quaternary ammonium cationic group containing silicone surfactants of Formulas I and II from among all the silicone products disclosed therein. Appeal Br. 9. Appellant contends not every mold release agent would result in the reduction of average mold separation force recited in claim 1, such that employing the quaternary ammonium cationic group containing silicone surfactants of Formulas I and II led to unexpected results. *Id.* at 8, citing Spec., Table 1.

*Issue*

Has Appellant identified reversible error in the Examiner's position that it would have been obvious to have incorporated the surfactants disclosed in Siltech falling within Formulas I and II recited in claim 1 in the method of making silicone hydrogel contact lenses disclosed in Pruitt, and obtain the recited mold separation force reduction?

*Discussion*

We are not persuaded by Appellant's contention that the Examiner has failed to provide sufficient reasoning to support the position that one having ordinary skill in the art would have looked to the specific surfactants disclosed in Siltech and having the formulas recited in claim 1 in order to modify Pruitt's phospholipid mold releasing agent.

Although Appellant argues Siltech discloses a number of silicone products and Pruitt's mold releasing agent "has a totally different property and structure" from the quaternary ammonium cationic group containing silicone surfactants (Appeal Br. 9–10), Appellant does not address to any particular extent, the Examiner's findings with respect to the chemical similarities between the two structures. Specifically, Appellant does not address the presence of alkyl quaternary ammonium cationic groups and oxygen-containing substituents in the surfactants of both Pruitt and Siltech, as well as the identification of both as mold releasing agents. Final Act. 13; Ans. 8–9, 13–14; Pruitt, col. 15, ll. 50–52; col. 16, ll. 40–54, Formula I; Siltech, 1, 2, 12–13.

As the Examiner explains, such similarities in structure and function between the quaternary ammonium cationic group containing silicone



surfactants in Siltech and the phospholipid mold release agent in Pruitt provide support for the position that one of ordinary skill in the art would have employed the alkyl quaternary ammonium surfactants in Siltech in Pruitt, including those having Formulas I and II recited in claim 1, with a reasonable expectation of success. Ans. 14–15. Appellant’s general arguments that Pruitt’s phospholipids have a different structure and property do not sufficiently address the Examiner’s rationale.

We are also not persuaded by Appellant’s argument that not every mold releasing agent would yield the mold separation force reduction recited in the claim. Although Appellant points to Table 1 of the Specification for support (Appeal Br. 8), we agree with the Examiner (Ans. 11–13) that Table 1 is insufficient to outweigh the evidence applied in the Examiner’s rejection. In particular, we observe that the Examiner found that Pruitt suggests a correlation between the amount of mold release agent and separation force (Final Act. 13, citing Pruitt, Table 1), and as a result one of ordinary skill in the art would have optimized the amount of releasing agent to achieve the greatest possible reduction in separation force without negatively impacting quality of utility of the resulting product. Final Act. 13–14.

We agree with the Examiner that Pruitt appears to show a decrease in mold separation force (MSF) as the amount of mold release additive is increased. *See* Pruitt, Table 1, Exs. 4 (additive amount 2.5% by weight, MSF 13 N), 5 (additive amount 2.0% by weight, MSF 21 N) as compared to control Ex. 6 (additive amount 0% by weight, MSF 131 N). Appellant does not address the Examiner’s position in this regard. Given Pruitt’s disclosure that the mold separation force is reduced by at least 40% (col. 17, ll. 25–31)

along with the Examiner's findings of the similarity between quaternary ammonium cationic group containing silicone surfactants in Siltech and the phospholipid mold release agent in Pruitt discussed above, we are not persuaded by Appellant's argument.

Regarding the data in Table 1, we agree with the Examiner that Table 1 is insufficient to establish unexpected results in reducing mold separation force by at least about 30%. Ans. 11–13. As the Examiner points out, a number of other surfactants also appear to meet the claimed reduction in mold separation force. *Id.*; see Table 1, where the mold release agent (MRA) is PVP-PVAc-45KDa, PVP-40kDa, H<sub>2</sub>N-PDMS-NH<sub>2</sub>. In addition, in order to prove unexpected results, the invention must be compared with the closest prior art. *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). Table 1 does not compare the closest prior art, which are compositions in Pruitt where the mold release agent is a phospholipid.

#### *Claim 4*

Although Appellant lists claim 4, which recites the mold is “a reusable mold,” under a separate heading, Appellant does not contest the Examiner's finding that Pruitt discloses a reusable mold. Appeal Br. 9–10; Final Act. 12, citing Pruitt col. 18, l. 55 –col. 19, l. 10. Rather, Appellant again argues the Examiner's rationale in combining Pruitt and Siltech as addressed above.

In view of the above discussion, we affirm the Examiner's rejection of claims 1, 3–5, and 7 as obvious over Pruitt and Siltech.

DECISION SUMMARY

In summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1, 3-5, 7	103	Xie, Siltech, Pruitt <sup>3</sup>		
1, 3-5, 7	103	Pruitt, Siltech	1, 3-5, 7	
<b>Overall Outcome</b>			<b>1, 3-5, 7</b>	

<sup>3</sup> As explained above, because we affirm the Examiner's rejections of all the claims based on Rejection 2, we do not reach this rejection.

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED