

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte STANLEY W. HUTH, OREST OLEJNIK,
and ZHI-JIAN YU

Appeal 2008-3489
Application 10/349,466
Technology Center 1600

Decided: September 30, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and MELANIE L.
McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an ophthalmic composition and method. The Examiner has rejected the claims as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

INTRODUCTION

The Specification discloses “[o]phthalmic compositions comprising oil-in-water emulsions” (Spec. 3). In particular, the Specification discloses that the “compositions preferably include self-emulsifying emulsions. That is, the present oil-in-water emulsions preferably can be formed with reduced amounts of dispersion mixing at shear speed, more preferably with substantially no dispersion mixing at shear speed.” (*Id.*).

In addition, the Specification discloses that the oil-in-water emulsions comprise “a surfactant component which includes at least three emulsifiers or surfactants” (*id.* at 5). The Specification also discloses that “each surfactant includes a hydrophobic constituent and a hydrophilic constituent, with the hydrophobic constituent of the first surfactant and the hydrophobic constituent of the second surfactant being substantially similar, or even substantially identical, in chemical structure” (*id.* at 6). Additionally, the Specification states that “the hydrophobic constituent of the third surfactant may be shorter in overall length in fully extended conformation than the hydrophobic constituents of the first and second surfactants by an equivalent length of about 3 to about 10 methylene groups” (*id.* at 7).

Claims 1-52 and 64-69 are pending and on appeal (App. Br. 5). We will focus on independent claims 1, 13, 24, and 39, which read as follows:

1. An ophthalmic composition comprising an oil-in-water emulsion including an oily component, an aqueous component, and a surfactant component including a first surfactant, a second surfactant and a third surfactant, wherein each of the surfactants is different from the other surfactant, and wherein each surfactant includes a hydrophobic constituent and a hydrophilic constituent, and the hydrophobic constituent of the first surfactant and the hydrophobic constituent of the second surfactant are substantially similar in chemical structure.

13. An ophthalmic composition comprising an oil-in-water emulsion including an oily component, an aqueous component, and a surfactant component including a first surfactant, a second surfactant and a third surfactant, each surfactant includes a hydrophobic constituent and a hydrophilic constituent, the hydrophobic constituent of the first surfactant and the hydrophobic constituent of the second surfactant are substantially similar in chemical structure, and the hydrophilic constituent of the second surfactant and the hydrophilic constituent of the third surfactant are substantially similar in chemical structure.

24. An ophthalmic composition comprising a therapeutic component and an oil-in-water emulsion including an oily component, an aqueous component and a surfactant component including a first surfactant, a second surfactant and a third surfactant, wherein each of the surfactants is different from the other surfactants, and wherein each surfactant includes a hydrophobic constituent and a hydrophilic constituent, and the hydrophobic constituent of the first surfactant and the hydrophobic constituent of the second surfactant are substantially similar in chemical structure.

39. An ophthalmic composition comprising a therapeutic component, and an oil-in-water emulsion including an oily component, an aqueous component and a surfactant component including a first surfactant, a second surfactant and a third surfactant, each surfactant includes a hydrophobic constituent and a hydrophilic constituent, the hydrophobic constituent of the first surfactant and the hydrophobic constituent of the second surfactant are substantially similar in chemical structure, and the hydrophilic constituent of the second surfactant and the hydrophilic constituent of the third surfactant are substantially similar in chemical structure.

ANTICIPATION

Claims 1, 2, and 24-27¹ stand rejected under 35 U.S.C. § 102(b) as anticipated by Kunz (WO 99/21533, May 6, 1999) (Ans. 3). The Examiner

¹ In the Examiner's Answer, claims 53, 54, and 63 are also listed as rejected on this basis (Ans. 3). However, claim 53, 54, and 63 were canceled in the June 2006 Amendment (App. Br. 5).

relies on Kunz for disclosing “a composition comprising of an emulsion that includes a therapeutic agent, an oily phase, an aqueous phase, and three surfactants of non-identical structure” (*id.* at 4).

Appellants argue that “Kunz does not disclose an ophthalmic emulsion comprising an oil-in-water emulsion including . . . a surfactant component including three different surfactants . . . wherein the hydrophobic constituent[s] of the first and second surfactant[s] are substantially similar in chemical structure” (App. Br. 21 (emphasis omitted)).

Findings of Fact

1. Kunz discloses “a composition for transporting a bioactive agent across a biological barrier . . . includ[ing] a bioactive agent, an oil, an oil-immiscible compound and a noncationic surface active agent” (Kunz 3: 7-10). In particular, Kunz discloses “compositions having an aqueous continuous phase, which may take the form of an oil-in-water (O/W) emulsion or microemulsion” (*id.* at 28: 26-27).

2. As a “surface active agent,” Kunz refers to “a chemical that has both hydrophilic and hydrophobic portions” (*id.* at 10: 13-14). Kunz discloses that the “surface active agent may be a noncationic surface active agent,” preferably a nonionic surface active agent (*id.* at 11: 3-10).

3. Kunz also discloses:

In one embodiment, the nonionic surface active agent contains a hydrophobic organic group in covalent attachment to a hydrophilic polyol. In general, the hydrophobic organic group can be, for example, an alkyl chain. . . . An alkyl chain can be chosen of any desired size, depending on the hydrophobicity desired and the hydrophilicity of the polyol moiety. A preferred range of alkyl chains is from 4 to 24 carbon atoms.

(*Id.* at 11: 11-16.)

4. In addition, Kunz discloses that “[t]he above examples are illustrative of the types of surfactants to be used in the compositions and methods claimed herein; however, the list is not exhaustive” (*id.* at 12: 26-27).

5. Kunz also discloses that “the surface active agent may encompass . . . first, second and third surface active agents of non-identical structures” (*id.* at 27: 19-20).

Analysis

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). We agree with Appellants that the Examiner has not set forth a prima facie case that Kunz discloses three different surfactants where the hydrophobic constituents of the first and second surfactants are substantially similar in chemical structure, as recited in claims 1 and 24.

Kunz discloses a composition comprising an oil-in-water emulsion and three different surface active agents (Findings of Fact (FF) 1 & 5). As a “surface active agent,” Kunz refers to “a chemical that has both hydrophilic and hydrophobic portions” (FF 2). Kunz also discloses that the “surface active agent may be a noncationic surface active agent,” preferably a nonionic surface active agent (FF 2). As one example, Kunz discloses a “nonionic surface active agent contain[ing] a hydrophobic organic group in covalent attachment to a hydrophilic polyol[,] . . . the hydrophobic organic group [being], for example, an alkyl chain . . . [having a] preferred range of

. . . from 4 to 24 carbon atoms” (FF 3). In sum, while Kunz identifies several examples of surface active agents, Kunz states that “[t]he above examples are illustrative of the types of surfactants to be used in the compositions and methods claimed herein; however, the list is not exhaustive” (FF 4).

Although Kunz discloses including three different surface active agents in its composition (FF 5), the Examiner has not shown that Kunz discloses a composition comprising at least two surfactants having hydrophobic constituents that are substantially similar in chemical structure. In particular, although we agree with the Examiner that surfactants having a hydrophobic group having an alkyl chain length of 4 to 24 carbon atoms encompasses surfactants that are “substantially similar in chemical structure” (Ans. 9), the Examiner has not identified any teaching, or preference, in Kunz to prepare a composition wherein at least two surfactants are substantially similar in chemical structure. Therefore, we agree with Appellants that the Examiner has not met his burden of establishing a prima facie case that Kunz anticipates claims 1 and 24 and claims 2 and 25-27, which depend from claims 1 or 24.

OBVIOUSNESS I

Claims 1-11, 13-22, 24-37, and 39-51² stand rejected under 35 U.S.C. § 103(a) as obvious in view of Reed (US 6,770,675 B2, Aug. 3, 2004), Simonnet (US 6,375,960 B1, Apr. 23, 2002), and Kawashima (US 6,582,718

² In the Examiner’s Answer, claims 53-61 and 63 are also listed as rejected on this basis (Ans. 4). However, claim 53-61 and 63 were canceled in the June 2006 Amendment (App. Br. 5).

B2, Jun. 24, 2003) (Ans. 4). The claims have been argued in four groups – claims 1-11, claims 13-22, claims 24-37, and claims 39-51 (App. Br. 25-36). The claims within each group have not been argued separately³ and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner relies on Reed for disclosing “an ophthalmic composition comprising . . . [a] therapeutic agent . . . and two or more surfactants”; for disclosing that “the combination of two or more non-ionic surfactants, as opposed to a single surfactant, can reduce the total concentration of surfactant required”; and for disclosing “examples of surfactants, such as Cremophors, Brij 97 and Brij 98” (Ans. 5).

The Examiner relies on Simonnet for teaching “a composition for ophthalmic usage comprising an oily phase, aqueous phase, and at least one surfactant”; for disclosing “examples of surfactants such as Brij 72”; and for disclosing “that microemulsions or self-emulsions are well known in the art” (*id.*).

The Examiner relies on Kawashima for disclosing “an ophthalmic composition comprising cyclosporine and a surfactant selected from polyoxyethylene fatty acid esters, polyoxyethylene alkylphenyl ethers, and polyoxyethylene alkyl ethers, or mixtures thereof” (*id.*).

³ In the Appeal Brief, Appellants state that the combination of references do not suggest the features of claims 2, 3, 4, 5, 6, “and so forth” (App. Br. 28). Appellants do not explain why the features of these claims would not have been obvious over the applied references. Therefore, this statement is not being considered an argument for the separate patentability of these claims pursuant to 37 C.F.R. § 41.37(c)(1)(vii). Thus, these claims stand or fall with claim 1.

The Examiner concludes:

[I]t is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually or in combination in the prior art.

(*Id.* at 6.) The Examiner also concludes that “selecting a surfactant from a group of similar surfactants in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize” and that it “would have been customary for an artisan of ordinary skill to determine the optimal ingredient to add in order to best achieve the desired results” (*id.* at 6-7).

Appellants argue that the Examiner erred in concluding that claims 1, 13, 24, and 39 would have been obvious over the applied references (App. Br. 25-36; Reply Br. 8-13).

Findings of Fact

6. Simonnet discloses a nanoemulsion including “an oily phase dispersed in an aqueous phase; and at least one surfactant . . . selected from the group including ethoxylated fatty ethers and ethoxylated fatty esters, and mixtures thereof” (Simonnet, Abstract).

7. Simonnet discloses that the “nanoemulsion is particularly useful in compositions, including topical, pharmaceutical, cosmetic, ophthalmic, [and] ophthalmologic. The composition is also particularly useful in applications to the . . . eyes.” (*Id.*)

8. Simonnet also discloses that the nanoemulsions can “be used as ophthalmic vehicles” and that the nanoemulsions “may optionally contain

water-soluble or fat-soluble active principles having a[n] . . . ophthalmic activity” (*id.* at col. 5, l. 57, to col. 6, l. 14).

9. In addition, Simonnet discloses that the ethoxylated fatty ethers “are preferably ethers formed of 1 to 100 ethylene oxide units and of at least one fatty alcohol chain having from 16 to 22 carbon atoms” and that the ethoxylated fatty esters “are preferably esters formed of 1 to 100 ethylene oxide units and of at least one fatty acid chain having from 16 to 22 carbon atoms” (*id.* at col. 3, ll. 23-45).

10. In its Background section, Simonnet discloses that microemulsions have a “high proportion of surfactants, leading to intolerance and resulting in a sticky feel during application to the skin” and that “their formulation range is generally very narrow and their temperature stability very limited” (*id.* at col. 1, ll. 51-56). Simonnet also discloses that “[n]anoemulsions stabilized by a lamellar liquid crystal coating . . . exhibit a waxy and film-forming feel, which is not very pleasant, for the user” and that “nanoemulsions based on fluid non-ionic amphiphilic lipids . . . hav[e] a sticky effect during application to the skin” (*id.* at col. 1, l. 64, to col. 2, l. 7).

11. Reed discloses “an ophthalmic composition which includes a docosanoid, a non-ionic surfactant (e.g., a CREMOPHOR) and a preservative” (Reed, col. 2, ll. 5-7).

12. Reed also discloses that “the combination of two or more non-ionic surfactants, as opposed to a single surfactant, can reduce the total concentration of surfactant required to achieve a given level of solubility of the docosanoid active agent” (*id.* at col. 3, ll. 47-50).

13. Kawashima discloses an ophthalmic composition containing “cyclosporine and a surfactant selected from polyoxyethylene fatty acid esters, polyoxyethylene alkylphenyl ethers and polyoxyethylene alkyl ethers, or mixtures thereof” (Kawashima, Abstract).

14. The Specification discloses creating an oil-in-water emulsion by gently mixing the oil phase into an aqueous phase (Spec. 44: 3-7).

15. The Specification states that the emulsions “advantageously have a shelf life exceeding one year at room temperature” (*id.* at 45: 8-10).

Analysis

Simonnet discloses a composition comprising an oil-in-water emulsion and mixtures of surfactants, specifically an ophthalmic composition (FF 6-7). In particular, Simonnet discloses emulsions containing “active principles having a[n] . . . ophthalmic activity” (FF 8). Reed and Kawashima also disclose including mixtures of surfactants in ophthalmic compositions (FF 11-13). Based on these disclosures, we agree with the Examiner that it would have been prima facie obvious to include a mixture of three surfactants in Simonnet’s ophthalmic compositions.

In addition, Simonnet discloses surfactants “selected from the group including ethoxylated fatty ethers and ethoxylated fatty esters, and mixtures thereof” (FF 6). Based on this teaching, we agree with the Examiner that it would have been prima facie obvious to include any three of these surfactants, including at least two surfactants having hydrophobic constituents that are substantially similar in chemical structure, because the surfactants taught by Simonnet have similar (fatty alcohol or acid) hydrophobic constituents. (See FF 9.) “The combination of familiar

elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007). *Cf. In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980) (“It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.”).

Appellants argue, however, that *Simonnet* “is drawn to transparent nanoemulsions . . . [and] makes clear that ‘in contrast to nanoemulsions, microemulsions are spontaneously formed by mixing the constituents, without contributing mechanical energy other than simple magnetic stirring.’ . . . Therefore, to follow the obviously implicit syllogism, the nanoemulsions of *Simonnet* cannot be formed except by contributing mechanical energy.” (App. Br. 26 (quoting *Simonnet*, col. 1, ll. 48-51).)

In addition, Appellants argue:

Simonnet’s emulsions are formed by homogenizing an aqueous phase and an oily phase at high pressure ($1-18 \times 10^7$ Pa) and shear (2×10^6 /sec to 5×10^8 /sec). . . . In contrast, “to create an oil in water emulsion” . . . according to the present invention “the final oil phase is gently mixed into an aqueous phase” without the need for elevated temperature. Specification at 28, lines 19-29. This is not merely a difference in the method of making the emulsions; it is a difference in the physical properties of *Simonnet*’s emulsion as compared to the claimed composition.

(App. Br. 27.)

We are not persuaded. Independent claims 1, 13, 24, and 39 each recite an oil-in-water emulsion. They do not exclude emulsions that are formed by contributing mechanical energy.

Appellants also argue that, like Reed, the compositions of Kawashima “are solutions rather than emulsions, as can be seen from the Examples. Indeed, Kawashima actually teaches away from the present invention, since [Kawashima’s] claims 1 and 11 specify ‘an oil free composition’.” (App. Br. 26 (emphasis omitted).)

We are not persuaded. In particular, we are not relying on either Reed or Kawashima to disclose an emulsion.

In addition, Appellants argue that Reed “is not concerned with the same subject matter as the presently pending claims” (Reply Br. 11). In particular, Appellants argue that Reed states that “the combination of two or more non-ionic surfactants . . . can reduce the total concentration of surfactant required to achieve a given level of solubility of the docosanoid active agent,” but that a “docosanoid is not a required element of any of the pending claims” (*id.*).

We are not persuaded by this argument. First, we conclude that including three different surfactants would have been obvious based on the disclosure of Simonnet alone, which specifically discloses mixtures of surfactants (FF 6). Second, based on the “comprising” language, claims 1, 13, 24, and 39 are all open to including a docosanoid.

Appellants also argue that, “[e]ven assuming *arguendo* that a *prima facie* presumption of obviousness had been established . . . , the surprising properties of the presently claimed emulsions would successfully rebut such a presumption” (App. Br. 31). Appellants argue that “[t]hese surprising properties are described in the patent specification” (*id.*). In particular, Appellants argue:

The present specification describes emulsions that can be formed from the ingredients set forth in [claim 1]. . . . The emulsion is made by gently mixing the final oil phase with either an intermediate or final aqueous phase. Specification at 44, lines 3-15. Surfactants are first dissolved into the oil phase. *Id.* at 43, lines 12-31. The resulting emulsions, unlike the self-emulsifying microemulsions described by *Simonnet*, have a shelf life at room temperature of more than one year. *Id.* at 45, lines 8-10.

(App. Br. 32.)

We are not persuaded. The Specification discloses creating an oil-in-water emulsion by gently mixing the oil phase into an aqueous phase and that the emulsion “advantageously [has] a shelf life exceeding one year at room temperature” (FF 14-15). However, Appellants have not provided any evidence that the claimed compositions provide unexpectedly superior results as compared to the compositions of *Simonnet*. “[I]t is well settled that unexpected results must be established by factual evidence. ‘Mere argument or conclusory statements in the specification does not suffice.’” *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (quoting *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984)).

With regard to claim 13, Appellants additionally argue that “the combination of *Reed*, *Kawashima*, and *Simonnet* does not disclose or suggest either expressly or inherently . . . an ophthalmic composition comprising an emulsion necessarily having three surfactants in which one surfactant has a hydrophobic constituent that is substantially similar to the other two surfactants” (App. Br. 33).

We are not persuaded. First, claim 13 does not recite an emulsion “having three surfactants in which one surfactant has a hydrophobic

constituent that is substantially similar to the other two surfactants.” In addition, for substantially the same reasons that it would have been prima facie obvious to include first and second surfactants having hydrophobic constituents that are substantially similar in chemical structure, we also agree with the Examiner that it would have been prima facie obvious for the second and third surfactants to have hydrophilic constituents that are substantially similar in chemical structure, as recited in claim 13, because the ethoxylated fatty ethers and ethoxylated fatty esters disclosed by Simonnet all have a similar (poly(ethoxy)) hydrophilic group. (See FF 9.)

With regard to claim 24, Appellants additionally argue that “*Simonnet* discloses that certain emulsions, such as the microemulsions and nanoemulsions of the prior art, may be unsuitable as drug vehicles for topical or ophthalmic use” (App. Br. 35). We are not persuaded. Although *Simonnet* discusses some disadvantages of prior art microemulsions and nanoemulsions (FF 10), *Simonnet* specifically discloses using its compositions as a vehicle, specifically for carrying “active principles having a[n] . . . ophthalmic activity” (FF 8).

With regard to claim 39, Appellants argue that this claim is patentable for the reasons set forth with regard to claims 13 and 24 (App. Br. 36). We are not persuaded by these arguments for the reasons discussed above.

We conclude that the Examiner has set forth a prima facie case that claims 1, 13, 24, and 39 would have been obvious in view of Reed, *Simonnet*, and Kawashima, which Appellants have not rebutted. We therefore affirm the rejection of claims 1, 13, 24, and 39 under 35 U.S.C.

§ 103(a). Claims 2-11, 14-22, 25-37, and 40-51 fall with claims 1, 13, 24, and 39.

OBVIOUSNESS II

Claims 12, 23, 38, 52, and 64-69⁴ stand rejected under 35 U.S.C. § 103(a) as obvious over Reed, Simonnet, and Kawashima in view of Chou (US 5,310,429, May 10, 1994) and Remington⁵ (Ans. 7). Claims 12, 23, 38, and 52 depend from claims 1, 13, 24, and 39, respectively, and additionally require that the composition is sterilized by filtering. Claims 64, 65, 68, and 69 are directed to methods comprising administering “to an eye of a subject” the compositions of claims 1, 13, 24, and 39, respectively. Claims 66 and 67 are directed to methods comprising contacting a contact lens with the compositions of claims 1 and 13, respectively.

The Examiner relies on Remington for disclosing that, “[v]ery frequently, the best results are obtained from blends of nonionic emulsifiers [surfactants]” and for demonstrating that “the method of sterilizing ophthalmic compositions by filtering was well known in the prior art” (*id.*).

The Examiner relies on Chou for disclosing “a method of cleaning contact lens using a composition comprising . . . three different surfactants” (*id.*). Based on this knowledge, the Examiner concludes that “an artisan of ordinary skill would have been motivated to administer the composition . . . as claimed by Applicant[s]” (*id.* at 7-8).

⁴ In the Examiner’s Answer, claims 62 and 70 are also listed as rejected on this basis (Ans. 7). However, claim 62 and 70 were canceled in the June 2006 Amendment (App. Br. 5).

⁵ Remington: The Science and Practice of Pharmacy, vol. II (19th ed. 1995).

Appellants argue that the Examiner erred in concluding that claims 12, 23, 38, 52, and 64-69 would have been obvious over the applied references (App. Br. 36-40).

Findings of Fact

16. Remington discloses using filtration to sterilize an ophthalmic composition (Remington 1570).

17. Chou discloses rubbing a solution containing three surfactants against a hard contact lens to remove surface deposits thereon (Chou, Abstract).

18. After cleaning the contact lens, Chou discloses rinsing the lens with water or placing it in a soaking and/or wetting solution prior to insertion into the eye (*id.* at col. 5, ll. 14-20).

Analysis

Claims 64, 65, 68, and 69 are directed to methods comprising administering the compositions of claims 1, 13, 24, and 39, respectively, “to an eye of a subject in an amount effective to provide at least one benefit to the eye” or “a desired therapeutic effect to the subject.” As discussed above, the Examiner has set forth a prima facie case that the compositions of claims 1, 13, 24, and 39 would have been obvious in view of Reed, Simonnet, and Kawashima, which Appellants have not persuasively rebutted. In addition, Simonnet discloses administering the compositions to an eye of a subject (FF 7). Thus, we agree that the Examiner has set forth a prima facie case that the methods of claims 64, 65, 68, and 69 would have been obvious.

Appellants argue that “*Chou* discloses hard contact lens cleaning solutions and suspensions which preferably contain abrasives. *Chou* teaches away from using the emulsion-containing compositions of the present invention for administration to the eye, since it teaches rinsing the contact lens cleaning solution from the lens before inserting the lens in the eye.” (App. Br. 38.) In addition, Appellants argue that “Remington does not disclose or suggest the present invention” (*id.* at 39).

However, we do not find it necessary to rely on either *Chou* or Remington to render claims 64, 65, 68, and 69 *prima facie* obvious. In addition, although *Chou* discloses rinsing the contact lens before inserting it into an eye (FF 18), we do not agree that *Chou* teaches away from administering to the eye the compositions of claims 1, 13, 24, and 39. Thus, we are not persuaded by Appellants’ argument. We therefore affirm the rejection of claims 64, 65, 68, and 69.

Claims 66 and 67 are directed to methods comprising contacting a contact lens with the compositions of claims 1 and 13, respectively, “in an amount and at conditions effective to provide at least one benefit to the contact lens or to the wearer of the contact lens.” As discussed above, the Examiner has set forth a *prima facie* case that the compositions of claims 1 and 13 would have been obvious in view of Reed, Simonnet, and Kawashima, which Appellants have not rebutted. In addition, *Chou* discloses rubbing a solution containing three surfactants against a hard contact lens to remove surface deposits thereon (FF 17). In view of this teaching, we agree that the Examiner has set forth a *prima facie* case that the methods of claims 66 and 67 would have been obvious.

Appellants argue that “*Simonnet* does not . . . suggest tha[t] an emulsion may be used for contact lens care” and that “*Reed, Kawashima* and *Chou* do not discuss emulsions at all” (App. Br. 39). We are not persuaded. In particular, we do not rely on *Chou* for teaching an emulsion, nor do we rely on *Simonnet* for disclosing using an emulsion for contact lens care. Instead, we find that the combination of these references renders obvious using an emulsion for contact lens care. We therefore affirm the rejection of claims 66 and 67.

Claims 12, 23, 38, and 52 depend from claims 1, 13, 24, and 39, respectively, and additionally require that the composition is sterilized by filtering. As discussed above, the Examiner has set forth a prima facie case that the compositions of claims 1, 13, 24, and 39 would have been obvious in view of *Reed*, *Simonnet*, and *Kawashima*, which Appellants have not rebutted. In addition, *Remington* discloses using filtration to sterilize an ophthalmic composition (FF 16). In view of this teaching, we agree that it would have been obvious to sterilize the composition suggested by *Simonnet*, *Reed*, and *Kawashima* by filtering, as taught by *Remington*. Therefore, the Examiner has set forth a prima facie case that the compositions of claims 12, 23, 38, and 52 would have been obvious.

Appellants argue that *Chou* “adds nothing that would render the present invention obvious” (App. Br. 37). However, we do not find it necessary to rely on *Chou* to render claims 12, 23, 38, and 52 prima facie obvious. Thus, we are not persuaded by Appellants’ argument. We therefore affirm the rejection of claims 12, 23, 38, and 52.

Appeal 2008-3489
Application 10/349,466

CONCLUSION

We reverse the anticipation rejection of claims 1, 2, and 24-27.
However, we affirm the obviousness rejections of claims 1-52 and 64-69.
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

dm

ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599