

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte GEORGE E. DECKNER  
and BRIAN S. LOMBARDO

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Appeal No. 1997-2750  
Application 08/191,734

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HEARD: December 7, 2000

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Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 24, which are all of the claims pending in the application.

## THE INVENTION

The present invention relates to topical pharmaceutical compositions having enhanced penetration through the skin. These compositions comprise a safe and effective amount of a "pharmaceutical active" or drug and from about 0.1% to about 10% of a high molecular weight crosslinked cationic polymer. The crosslinked polymer is defined by way of formula in the appealed claims.

Claims 1, 4, 5, and 23, which are illustrative of the subject matter on appeal, read as follows:

1. A topical pharmaceutical composition having enhanced penetration through the skin comprising:

(a) a safe and effective amount of a pharmaceutical active; and

(b) from about 0.1% to about 10.0% of a high molecular weight crosslinked cationic polymer of the formula:  $(A)_l(B)_m(C)_n$  wherein (A) is a dialkylaminoalkyl acrylate monomer or its quaternary ammonium or acid addition salt, (B) is a dialkylaminoalkyl methacrylate monomer or its quaternary ammonium or acid addition salt, (C) is acrylamide, l is an integer of 0 or greater, m is an integer of 1 or greater, and n is an integer of 0 or greater, wherein said polymer contains a crosslinking agent.

4. The composition of Claim 3 wherein said pharmaceutical active is selected from the group consisting of anti-acne drugs, non-steroidal anti-inflammatory drugs, steroidal anti-inflammatory drugs, sunless tanning agents, sunscreen agents, wound healing agents, skin bleaching or lightening agents, antihistaminic drugs, antitussive drugs, antipruritic drugs, anticholinergic drugs, anti-emetic and antinauseant drugs,

anorexic drugs, central stimulant drugs, antiarrhythmic drugs, B-adrenergic blocker drugs, cardiogenic drugs, antihypertensive drugs, diuretic drugs, vasodilator drugs, vasoconstrictor drugs, anti-ulcer drugs, anesthetic drugs, antidepressant drugs, tranquilizer and sedative drugs, antipsychotic drugs, antimicrobial drugs, antineoplastic drugs, antimalarial drugs, muscle relaxant drugs.

5. The composition of Claim 4 wherein said pharmaceutical active is an anti-acne drug selected from the group consisting of salicylic acid, sulfur, resorcinol, N-acetylcysteine, octopriox, retinoic acid and its derivatives, benzoyl peroxide, erythromycin, zinc, tetracyclin, azelaic acid and its derivatives, phenoxy ethanol and phenoxy propanol, ethylacetate, clindamycin and meclocycline, flavinoids, lactic acid, glycolic acid, pyruvic acid, urea, scymnol sulfate and its derivatives, deoxycholate and cholate and mixtures thereof.

23. The composition of Claim 4 wherein said drug active is a sunless tanning agent selected from the group consisting of dihydroxyacetone, indole derivatives and mixtures thereof.

### THE REJECTIONS

The prior art references relied on by the examiner are:

Kligman et al. (Kligman)	4,355,028	Oct. 19, 1982
McShane	4,434,154	Feb. 28, 1984
Bhattacharyya	4,806,345	Feb. 21, 1989
Turner et al. (Turner)	5,073,372	Dec. 17, 1991
Miller	5,009,969	Apr. 23, 1991
Hawe et al. (Hawe)	5,100,660	Mar. 31, 1992
Lew et al. (Lew)	5,162,043	Nov. 10, 1992

Allied Colloids Brochure, "SALCARE SC92 For Cosmetic/Personal Care Applications," undated (SALCARE SC92).

The appealed claims stand rejected as follows:

(1) claims 1 through 10 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Bhattacharyya, Kligman, Hawe, and SALCARE SC92;

(2) claims 1 through 4, 11, 16, 19, 21 and 22 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Bhattacharyya, Turner, Hawe, and SALCARE SC 92;

(3) claims 1 through 4, 12 through 15, 17, 18, and 20 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Bhattacharyya, Lew, Hall, and SALCARE SC92; and

(4) claims 1 through 4, 23 and 24 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Bhattacharyya, Miller, McShane, Hawe, and SALCARE SC92.

#### DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) the instant specification, including all of the claims on appeal;
- (2) applicants' Appeal Brief (Paper No. 20) and the Reply Brief (Paper No. 23);
- (3) the Examiner's Answer (Paper No. 21) and the Supplemental Answer (Paper No. 24); and

(4) the above-cited prior art references.

On consideration of the record, including the above-listed materials, we affirm the examiner's decision rejecting claims 1 through 10. We also affirm the examiner's decision rejecting claims 11 through 22, however, with respect to the latter claims, applicants may treat our "affirmance" as though it were a new ground of rejection entered under the provisions of 37 CFR § 1.196(b). We reverse the examiner's decision rejecting claims 23 and 24.

#### DISCUSSION

Kligman discloses a topical pharmaceutical composition in the form of an aqueous gel comprising (a) a safe and effective amount of an anti-acne drug; and (b) a suitable quantity, for example, from about 0.1% to 5.0% by weight, based on the total weight of the composition, of a gelling or thickening agent. Non-limiting examples of such gelling or thickening agents are enumerated in Kligman, column 3; Example 2A bridging columns 6 and 7; and Example 2T bridging columns 10 and 11. Note particularly polyacrylamide listed at column 10, line 66.

The SALCARE SC92 brochure discloses that SALCARE SC92 is a gelling agent or thickener useful in formulating aqueous gels to be administered topically for cosmetic or

personal care applications.<sup>1</sup> According to information provided in this brochure, under the heading “KEY HIGHLIGHTS OF SALCARE SC92,” using this product provides a number of benefits associated with liquid dispersed polymer technology, for example, ease of finished product manufacture; finished product versatility; cold mixing process; compatible with other cationics and nonionics; low use level for many applications; and attractive price. Again, in describing a cosmetic “cream/gel” base formed with SALCARE SC92, the brochure lists a number of advantageous performance characteristics, for example, the “cream/gel” base spreads easily; possesses “elegant” residual skin feel; conditions and moisturizes; and is non-oily and non-sticky.

We are persuaded that a person having ordinary skill in the art, armed with the disclosure of the SALCARE SC92 brochure, would have found it obvious to use a suitable quantity of SALCARE SC92 as the gelling or thickening agent in the topical pharmaceutical composition of Kligman. By thus modifying the composition of Kligman, per the teachings of the “secondary” reference, a person having ordinary skill in the art

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<sup>1</sup> As made clear in the instant specification, page 16, lines 5 through 11, Polyquaternium 32, also referred to as SALCARE SC92, is a cationic polymer useful in applicants' invention. SALCARE SC92 was commercially available at the time applicants' invention was made. Also see Exhibit 1 attached to the Appeal Brief, illustrating the formula of Polyquaternium 32 or SALCARE SC92.

would have arrived at the subject matter sought to be patented in claim 1 with a reasonable expectation of achieving the benefits and performance characteristics associated with the known gelling agent/thickener SALCARE SC92. In our judgment, the combined disclosures of Kligman and SALCARE SC92 provide the requisite reason, suggestion, or motivation, and reasonable expectation of success, to here sustain a rejection under 35 U.S.C. § 103. We note that the examples of gelling or thickening agents set forth in Kligman are non-limiting in nature; that the particular agent polyacrylamide illustrated by Kligman in column 10, line 66, is related to SALCARE SC92, a copolymer containing acrylamide as a monomeric component; and that the “secondary” reference discloses that SALCARE SC92 is a gelling agent or thickener useful in formulating aqueous gels for topical administration, possessing a number of benefits and advantageous performance characteristics.

For the same reasons, the subject matter sought to be patented in claims 4 and 5 would have been prima facie obvious in view of the combined disclosures of Kligman and the SALCARE SC92 brochure. Claim 4 “reads on” a topical pharmaceutical composition wherein the pharmaceutical active is an anti-acne drug. Claim 5 depends from claim 4 and requires that the pharmaceutical active is an anti-acne drug selected from the group consisting of, inter alia, salicylic acid, benzoyl peroxide, and mixtures thereof. The active ingredient disclosed by Kligman is a combination of salicylic acid and benzoyl peroxide.

We find, therefore, no limitation in claims 4 or 5 serving to patentably distinguish over the combined disclosures of Kligman and the SALCARE SC92 brochure.

Considering now claim 11, the format or structure of this claim is different from that of claim 5. The latter claim depends from claim 4 and requires that the pharmaceutical active is an anti-acne drug selected from a Markush group of specific drugs. Claim 11, however, does not require that the pharmaceutical active is an anti-histaminic drug. Rather, claim 11 specifies that, when the pharmaceutical active is an antihistaminic drug, that drug is selected from a Markush group of specific antihistamines. Claim 11, like claim 4, “reads on” a topical pharmaceutical composition wherein the pharmaceutical active is an anti-acne drug. The same infirmity plagues claims 12 through 22. All of those claims, like claim 11, “read on” a topical pharmaceutical composition wherein the pharmaceutical active is an anti-acne drug. Accordingly, claims 11 through 22 would have been prima facie obvious in view of the combined disclosures of Kligman and the SALCARE SC92 brochure for the same reasons previously discussed with respect to claims 1 and 4.

Applicants' main argument is that their combination of a safe and effective amount of a pharmaceutical active, and from about 0.1% to about 10.0% of a high molecular weight crosslinked cationic polymer having the formula spelled out in claim 1, provides enhanced penetration of a pharmaceutical active through the skin during transdermal administration of the claimed composition. According to applicants, the cited prior art

would not have suggested the property of “enhanced penetration through the skin.” The argument lacks merit.

First, even though applicants' composition may possess an advantageous property, which is unobvious (unexpected) in view of the disclosures of the prior art references, it does not follow that the prima facie case of obviousness has been overcome. On this record, applicants do not rely on objective evidence of non-obviousness, for example, a showing of substantial, actual differences in properties between the claimed composition and the closest prior art composition, which would serve to rebut the examiner's prima facie case. See In re Hoch, 428 F.2d 1342, 1343-44, 166 USPQ 406, 409 (CCPA 1970). Second, although the motivation to combine references here differs from that of applicants, nevertheless, the motivation in the prior art to combine references does not have to be identical to that of the applicant to establish obviousness. In re Kemps, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996).

In view of the foregoing, we conclude that the subject matter sought to be patented in claims 1, 4 and 5 would have been obvious in view of the combined disclosures of Kligman and the SALCARE SC92 brochure. Based on applicants' grouping of claims in their Appeal Brief, page 3, we shall not discuss claims 2 or 3 separately. Those claims fall together with claim 1. Likewise, claims 6 through 10 fall together with claim 5. The examiner's rejection under 35 U.S.C. § 103 with respect to claims 1 through 10 is affirmed.

As previously indicated, claims 11 through 22 also would have been prima facie obvious in view of the combined disclosures of Kligman and the SALCARE SC92 brochure. Again, applicants do not rely on objective evidence of non-obviousness, for example, a showing of substantial, actual differences in properties between the claimed composition and closest prior art composition which would serve to rebut the prima facie case.

Accordingly, we affirm the examiner's decision rejecting claims 11 through 22 under 35 U.S.C. § 103. In so doing, we note that the examiner did not include Kligman in rejecting these claims and that we rely on the combined disclosures of Kligman and the SALCARE SC92 brochure. This being the case, we advise applicants that they may, if desired, treat our "affirmance" of the examiner's rejection of claims 11 through 22 as though it were a new ground of rejection under the provisions of 37 CFR § 1.196(b).

Claim 23 depends from claim 4 and recites a topical pharmaceutical composition wherein the pharmaceutical active is a sunless tanning agent selected from the group consisting of dihydroxyacetone, indole derivatives, and mixtures thereof. Claim 24 depends from claim 23 and recites that the topical composition further comprises a sunscreen active. In our judgment, the combined disclosures of the references cited and

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relied on by the examiner are insufficient to support a conclusion of obviousness of claims containing these limitations. Accordingly, the examiner's section 103 rejection of claims 23 and 24 is reversed.

In conclusion, for the reasons set forth in the body of this opinion, we affirm the examiner's rejection of claims 1 through 10 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of the Kligman and the SALCARE SC92 brochure. We also affirm the rejection of claims 11 through 22 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of the same references but, if desired, applicants may treat our “affirmance” of the latter claims as though it were a new ground of rejection under the provisions of 37 CFR § 1.196(b). We reverse the rejection of claims 23 and 24 under 35 U.S.C. § 103.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, “A new ground of rejection shall not be considered final for purposes of judicial review.”

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37 CFR § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

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The examiner's decision is affirmed-in-part.

AFFIRMED-IN-PART  
37 CFR § 1.196(b)

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Demetra J. Mills	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
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