

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte MICHAEL A. ZELIGS

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Appeal No. 95-2688  
Application No. 07/845,560<sup>1</sup>

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ON BRIEF

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Before WINTERS, JOHN D. SMITH, and WALTZ, Administrative Patent Judges.

JOHN D. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the final rejection of claims 1-49 and 83-90.

The subject matter on appeal relates to compositions and methods of using dehydroepiandrosterone (DHEA) and its derivatives in combination with vitamin A

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<sup>1</sup> Application for patent filed March 4, 1992.

Appeal No. 95-2688  
Application No. 07/845,560

derivatives (retinoids) for the treatment and prevention of disorders of epithelial tissues.

Representative composition claim 1 is reproduced below:

1. A composition for the treatment of epithelial damage in a mammal comprising a pharmacologically active retinoid and pharmacologically active DHEA wherein the combination is effective in preventing or reversing damage to the epithelium due to environmental oxidative agents and wherein the proportion of retinoid and DHEA is sufficient to overcome the undesirable side effects of each composition when used alone.

The references of record relied upon by the examiner are:

Orentreich (Orentreich '556)	4,496,556	Jan. 29, 1985
Orentreich (Orentreich '129)	4,542,129	Sep. 17, 1985
Kligman et al. (Kligman)	4,889,847	Dec. 26, 1989

References of record relied upon by the appellant are:

Greenspan (Editor), "Disorders of Adrenal Cortex," in Review of Endocrinology, Lange, 818, 819 and 275, undated publication.

Martin Bohl et al (Editor), "Molecular Structure and Biological Activity of Steroids" 2, 3, 4, 16, 17 (Boca Raton, FL, CRC Press, 1992).

Louis S. Goodman et al., Chap. 60 "Adrenocortical Steroids: "Inhibitors of Synthesis," in 60 Goodman and Gilman's The Pharmacological Basis of Therapeutics, 554-557 (8th ed., New York, Pergamon Press, 1990).

Emil L. Smith et al., PRINCIPLES OF BIOCHEMISTRY: Mammalian Biochemistry 498-567 (7th ed., New York, McGraw-Hill Book Company, undated publication).

Mary May et al.(May), "PROTECTION FROM GLUCOCORTICOID INDUCED THYMIC INVOLUTION BY DEHYDROEPIANDROSTERONE," 46 Life Sciences, 1627-1631 (1990).

Raymond A. Daynes et al., "Regulation of murine lymphokine production *in vivo* II. Dehydroepiandrosterone is a natural enhancer of interleukin 2 synthesis by helper T cells\*," 20 Eur. J. Immunol. 793-802 (1990).

Appeal No. 95-2688  
Application No. 07/845,560

Arthur G. Schwart et al., "Novel Dehydroepiandrosterone Analogues with Enhanced Biological Activity and Reduced Side Effects in Mice and Rats," 48, Cancer Research 4817-4822 (1988)

The appealed claims stand rejected for obviousness (35 U.S.C. § 103) over Kligman in view of the Orentreich patents.

We cannot sustain the stated rejection.

#### OPINION

The examiner's rejection of the appealed claims is predicated on his assertion that it would have been obvious to a person of ordinary skill in this art to substitute "the DHEA of the secondary references for the steroids" of Kligman "in view of their similar activity and structure," thereby arriving at the claimed invention, since Kligman teaches a "composition containing steroids and retinoids" (answer, page 3).

Initially, we point out that Kligman's disclosure is directed to compositions containing glucocorticoids, not steroids in a generic sense, as held by the examiner. Secondly, the examiner has provided no factual support for the contention that glucocorticoids and DHEA have similar activity and structure. Indeed, as appellant has argued, glucocorticoids and DHEA are chemically distinct and are not functionally equivalent, and appellant has cited multiple publications in this record in support of his assertions. In this regard, the May publication relied upon by appellant indicates that

Appeal No. 95-2688  
Application No. 07/845,560

DHEA blocks the effects of glucocorticoids on the immune system. See May at page 1628.

Accordingly, the stated rejection of the appealed claims is reversed.

#### OTHER ISSUES

In the answer at page 3, the examiner states that no new ground of rejection has been imposed in the answer. The examiner then proceeds to raise a new rationale for the rejection of the appealed claims based on the holding of In re Kerkhoven, 626 F.2d 848, 850, 205 USPQ 1069, 1072, (CCPA 1980) that 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.

According to the examiner, the instant claims define nothing more than the concomitant use of two conventional epithelial damage medicaments. See the answer at page 5. As evidence of the "conventional" individual use of DHEA and retinoids, the examiner refers to the respective disclosures of Kligman at column 2, lines 19-30, and Orentreich '551 at column 2, lines 56-63.

Appellant has not responded to the specific theory of rejection based on the In re Kerkhoven rationale. However, since this rationale was not set forth in the examiner's final rejection, it constitutes a new ground of rejection, notwithstanding the examiner's contention that no new rejection was stated in the answer. On these facts, the Kerkhoven issue has not been properly joined.

Appeal No. 95-2688  
Application No. 07/845,560

This application is remanded to the examiner to reconsider the issues raised by the Kerkhoven theory of rejection in light of the following. Orentreich '556 teaches the use of DHEA to prevent and/or treat dry skin (xeroderma) and loss of natural oiliness. See this reference at column 1, lines 12-16 and column 2, lines 56-58. Xeroderma or xerosis is defined as the pathologic dryness of skin. See Stedman's Medical Dictionary, 24th ed., Williams & Wilkins, page 1582, copyright 1982, copy attached. Vitamin A (retinoic acid) has been recommended for the treatment of xerosis (asteatosis). See Modern Dermatology and Syphilology, 2nd ed., pages 65-69, copyright 1947, copy attached. However, retinoic acid topical therapy is said to often cause dryness of the skin. See appellant's specification at page 3, lines 6-17.

In light of the above disclosures and upon reconsideration of the entire record, the examiner is required to reweigh all disclosures (inclusive of the fact that retinoic acid therapy often causes dryness of the skin) which are relevant to a rejection based on the grounds that DHEA and vitamin A (retinoic acid) have been individually used for "the very same purpose" as required by the holding in In re Kerkhoven. Upon reweighing all the relevant facts in this record, the examiner should restate a rejection of appealed claim 1, if appropriate. Consideration of a rejection to any other appealed claim should be made on a claim-by-claim basis.

Appeal No. 95-2688  
Application No. 07/845,560

In summary, the decision of the examiner is reversed. This application is remanded to the examiner for reconsideration of the above issues.

This application, by virtue of its "special" status requires an immediate action. Manual of Patent Examining Procedure § 708.01(d) (7th ed., July 1998). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REVERSED/REMANDED

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
JOHN D. SMITH	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
	)	
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	)	
THOMAS A. WALTZ	)	
Administrative Patent Judge	)	

Appeal No. 95-2688  
Application No. 07/845,560

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Appeal No. 95-2688  
Application No. 07/845,560

APJ JOHN D. SMITH

APJ WINTERS

APJ WALTZ

DECISION: REVERSED/REMANDED

Send Reference(s): **Yes** No  
or Translation (s)

Panel Change: Yes No

Index Sheet-2901 Rejection(s):103

Prepared: July 25, 2000

Draft      Final

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OB/HD      GAU: 1205

PALM / ACTS 2 / BOOK  
DISK (FOIA) / REPORT