

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte DILEEP BHAGWAT, BRADLEY P. GLASSMAN
and DANIEL GLASSMAN

Appeal No. 2003-1424
Application No. 09/961,623

HEARD January 6, 2004

Before WILLIAM F. SMITH, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-13, all of the claims remaining. Claims 12 and 13 are representative and read as follows:

12. A topical composition comprising:
 - (a) about 0.5 to about 20 weight % benzoyl peroxide;
 - (b) about 0.1 to about 40 weight % urea; and
 - (c) a dermatologically acceptable carrier.

13. The composition of claim 12, wherein the pH of the composition is below about 9.

combine the benefits of urea and benzoyl peroxide and yet achieve a stable formulation. See page 1.

Discussion

Claim 12, the broadest claim on appeal, is directed to a composition comprising benzoyl peroxide (0.5 to 20 weight percent), urea (0.1 to 40 weight percent), and a dermatologically acceptable carrier. The examiner rejected all of the claims as obvious in view of Klein and Gennaro. The examiner cited Klein as teaching an anti-acne composition comprising, among other things, 5% benzoyl peroxide, and cited Gennaro for its teaching that urea is a mild keratolytic agent used in a concentration of 2-20%. See the Examiner's Answer, page 4. The examiner acknowledged that, as the basis of an obviousness rejection, Klein and Gennaro leave something to be desired:

The references do not expressly teach that urea is useful in treating acne. The references do not expressly teach that the pH of the composition is in a range of about 4 to about 9. The references do not expressly teach that the topical composition comprises an additional keratolytic agent.

Examiner's Answer, page 5.¹

In the examiner's view, however, a person of ordinary skill in the art would have been motivated to add urea to Klein's anti-acne composition, because urea is a keratolytic agent and "keratolytic agents are known to be useful in treating acne." The examiner concluded that "[c]ombining two agents, which are known

¹ The examiner's last point—regarding an additional keratolytic agent—is implicated only by dependent claim 6 and need not concern us here.

to be useful to treat acne individually, into a single composition and method useful for the very same purpose is prima facie obvious.” Id.

Appellants dispute the examiner’s basis for combining the references.

See the Reply Brief, pages 2-3:

[T]he Examiner makes a general statement that all keratolytic agents are known to be useful in treating acne. However, in the first full paragraph describing keratolytic agents in general, Gennaro does not mention acne as a specific primary treatment for such an agent. Although benzoyl peroxide . . . [is] stated to be possibly useful for treating acne, the Examiner has not demonstrated that all keratolytic agents are useful for treating acne. In fact, there is no indication in Gennaro that urea can be used for treating acne. Notably, it is stated to be used to treat dry skin.

Appellants also argue that the references do not provide a reasonable expectation of success. See the Appeal Brief, page 8:

The success to be expected here is whether a single stable combination providing compatibility for the two active ingredients benzoyl peroxide and urea could actually have been made providing treatment of dermatological disorders. There is no expectation of success that a single composition could be made which would be stable with these two ingredients. In fact, Klein et al. would teach away from such a single stable composition.

The examiner bears the initial burden of showing unpatentability. See, e.g., In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness requires evidence that the prior art disclosed or suggested all of the elements of the claimed invention, and that those skilled in the art would have been motivated to combine those elements with a reasonable expectation of success. See In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) (“All words in a claim must be considered in judging the patentability of the claim against the prior art.”); In re Vaeck, 947 F.2d 488, 493,

20 USPQ2d 1438, 1443 (Fed. Cir. 1991) (prima facie obviousness requires, inter alia, motivation to combine and reasonable expectation of success, both founded on the prior art).

We agree with Appellants that the examiner's references do not support a prima facie case of obviousness. The examiner has not adequately explained why those skilled in the art would have been led to combine Gennaro's urea with Klein's anti-acne composition. Neither Klein nor Gennaro expressly suggest that urea would be effective in treating acne, or that it would impart any other desirable quality to Klein's composition.

While Gennaro discloses that urea is a mild keratolytic agent, and discloses that some other keratolytic agents are useful in treating acne, these disclosures do not support the examiner's position that it would have been obvious to combine urea with Klein's anti-acne composition. First, Gennaro does not disclose that all keratolytic agents are useful in treating acne. See pages 767-768: in the general discussion of keratolytics, Gennaro states only that they are useful for "treatment of epidermophytosis [i.e., fungal infections] . . . [and] to thin hyperkeratotic areas." The examiner has not explained how this disclosure would have suggested treatment of acne to those of ordinary skill in the art.

In addition, Klein teaches away from combining other active agents with its disclosed benzoyl peroxide-containing composition. See column 2, lines 7-12: "[B]ecause of the powerful oxidizing properties of the peroxide component, the inclusion of this substance . . . with other active ingredients results in unstable compositions that soon display an unacceptable loss in keratolytic potency."

Klein's solution to this problem is to store the second active agent (erythromycin) separately from the benzoyl peroxide-containing composition.

Thus, Klein would have led those skilled in the art to expect that combining urea with Klein's benzoyl peroxide composition would have produced an unstable composition that would soon display an unacceptable loss of keratolytic potency. It would seem, therefore, that Klein would have discouraged those of skill in the art from making the combination required by the instant claims. Such a disclosure is evidence of unobviousness. See *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 119 F.3d 953, 957-58, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements. . . . The evidence that the combination was not viewed as technically feasible must be considered, for conventional wisdom that a combination should not be made is evidence of unobviousness.").

Other Issues

According to the "Search Notes" section of the file wrapper, the examiner's search of the patent and non-patent literature consisted of the keywords "benzoyl peroxide", "urea", and "keratolytic". Notable by its absence is the keyword "acne". We recommend that, upon return of this case and before issuing a Notice of Allowability, the examiner re-search the relevant databases and include "acne" as a search term. Such a search may well turn up more relevant prior art than is currently in the record.

For example, a search of the publicly accessible PubMed database (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>), using the keywords “benzoyl peroxide”, “urea”, and “acne” turned up a reference entitled “Comparative trial of benzoyl peroxide versus benzoyl peroxide with urea in inflammatory acne.”² The most relevant passage from the reference’s abstract states:

A clinical trial was performed to evaluate an improved vehicle for topical benzoyl peroxide. Thirty-nine subjects participated in a split-face, double-blind trial of topical benzoyl peroxide 5 percent versus benzoyl peroxide 5 percent in 8 percent urea.

The study found “[n]o overall differences” between the effects of the two compositions (that is, no added efficacy due to the addition of urea). However, that makes no difference with respect to patentability if the disclosed composition meets the limitations of Appellants’ claims. See Celeritas Techs. Ltd. v. Rockwell Int’l Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998) (“A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it.”).

Upon return of this case, the examiner should consider the patentability of the instant claims over the reference discussed above and any other references discovered using “acne” as a search term along with other relevant keywords.

² The reference citation is Prince et al., Cutis, Vol. 29, No. 6, pp. 638-40 and 644-45 (1982). A copy of the abstract from the PubMed database is attached to this opinion.

Summary

The references relied upon by the examiner do not support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Eric Grimes)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Lora M. Green)	
Administrative Patent Judge)	

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