

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SANDRA BROWN

Appeal No. 2000-0643
Application 08/273,423¹

HEARD: January 25, 2001

Before WINTERS, SCHEINER and MILLS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed July 11, 1994. According to appellant, this application is a continuation-in-part of application serial no. 07/943,853, filed September 11, 1992, now abandoned, and a continuation-in-part of application serial no. 08/207,821, filed March 7, 1994, now abandoned.

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 16, all the claims in the application. Claims 1 and 15 are representative and read as follows:

1. A composition for the treatment of hair loss comprising effective amounts of:
a corticosteroid,
a Vitamin A derivative, and
a carrier agent for said corticosteroid and said Vitamin A derivative.

15. A method of treatment for hair restoration of a patient comprising the steps of:
administering a corticosteroid to a hairless area of the skin of the patient; and
administering a Vitamin A derivative to said hairless area of the skin of the patient.

The references relied on by the examiner are:

Kligman	5,026,691	Jun. 25, 1991
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Lesnik et al. (Lesnik), "Topical all-*trans*-retinoic acid prevents corticosteroid-induced skin atrophy without abrogating the anti-inflammatory effect," J. Am. Acad. Dermatol., Vol. 21, pp. 186-190 (1989)

Bazzano et al. (Bazzano), "Effect of Retinoids on Follicular Cells," J. Invest. Dermatol., Vol. 101, pp. 138S-142S (1993)

The claims stand rejected as follows:²

- I. Claims 1 through 9 under 35 U.S.C. § 103 as unpatentable over Lesnik.

² According to the Advisory Action (paper no. 16, mailed April 16, 1997), the rejection of claims 1 through 16 under the first paragraph of 35 U.S.C. § 112 (as based on a non-enabling disclosure), and the rejection of claims 15 and 16 under the second paragraph of 35 U.S.C. § 112 have been withdrawn.

Appeal No. 2000-0643
Application 08/273,423

II. Claims 10 through 16 under 35 U.S.C. § 103 as unpatentable over Bazzano, Kligman and Lesnik.

We reverse Rejection I, and affirm Rejection II.

DISCUSSION

Initially, we note the somewhat confusing statement on page 3 of the Brief regarding the grouping of claims:

Claims 1-9 comprise one group. The claims of this group do not stand or fall together. Claims 10-16 comprise a second group. The claims of this group do not stand or fall together.

During the hearing on January 25, 2001, appellant's counsel confirmed that the claims within each group stand or fall together. Therefore, we shall limit our consideration of the issues raised by this appeal as they pertain to independent claims 1 and 15.

Rejection I

Claim 1, which represents the claimed composition in its broadest aspect, is directed to a composition comprising a carrier, a corticosteroid and a vitamin A derivative, in amounts effective to treat hair loss.

Topical corticosteroids are used extensively to treat inflammatory skin disorders, despite their numerous undesirable side effects (skin thinning, increased transparency, telangiectasia, etc.). Lesnik investigates the ability of the vitamin A derivative, all-*trans*-

retinoic acid (RA), to prevent corticosteroid-induced skin atrophy without compromising the anti-inflammatory properties of the steroids. Page 186.

The examiner cites a single example in Lesnik wherein betamethasone valerate cream was applied to mouse skin “in the AM,” followed by RA “in the PM” (page 187, column 1, paragraph 2) and concludes that “[o]ne of ordinary skill would have been motivated to employ both agents together in a skin-treating composition since they are known to be useful in a single therapeutic regimen for the treatment of the skin.”

In addition, we note that Lesnik describes other protocols, which differ from that cited by the examiner, in that RA is administered immediately after fluocinolone acetonide or triamcinolone acetonide (both of which are corticosteroids). Regardless of the timing, administration of RA prevents corticosteroid-induced skin atrophy. Further examples demonstrate that administration of RA does not interfere with the anti-inflammatory effects of the corticosteroids. Page 187. Thus, applying a corticosteroid and RA together would not appear to present a problem, and the examiner’s proposed reason for combining them in a single composition for the treatment of inflammatory skin disorders seems plausible at first blush.

Nevertheless, claim 1 requires a composition containing a corticosteroid and a Vitamin A derivative in amounts effective for the treatment of hair loss. The examiner touches on this briefly; on the one hand dismissing the recitation “for the treatment of hair loss” as a mere statement of intended use, while on the other hand asserting that “[t]he

Appeal No. 2000-0643
Application 08/273,423

optimization of amounts of ingredients is deemed within the skill of the artisan.”

Examiner’s Answer, pages 3 and 2, respectively.

The question that comes to mind is, optimization for what? Contrary to the examiner’s assertion, the recitation “effective amounts” coupled with the recitation “for the treatment of hair loss” confers a functional limitation on the claimed composition; in this case, the preamble of the claim is not merely a statement of intended use. The examiner does not allege that the levels of corticosteroid and RA in Lesnik’s examples, would, if combined, be effective in treating hair loss. Nor has the examiner explained why one skilled in the art would optimize, or adjust, the corticosteroid and RA amounts used in Lesnik to levels effective to treat hair loss, when Lesnik does not mention hair loss at all.

35 U.S.C. § 103 requires that obviousness be determined based on the claimed subject matter as a whole. Where, as here, the determination of obviousness is based on less than the entire claimed subject matter, the examiner’s conclusion of obviousness is unsound and cannot stand. On this record, we hold that the examiner has not established a prima facie case of obviousness for claim 1, the broadest of the composition claims; that being the case, we are constrained to reverse the examiner’s rejection of claims 1 through 9 under 35 U.S.C. § 103 as unpatentable over Lesnik.

Rejection II

Claim 15, directed to a “method of treatment for hair restoration” comprising administering a corticosteroid and a Vitamin A derivative to hairless skin, stands rejected as unpatentable over Kligman, Bazzano and Lesnik.

Bazzano teaches that topical application of all-*trans*-retinoic acid alters the hair-growth cycle in the C₃H mouse model by prolonging the anagen phase and shortening the telogen phase. According to the reference, “[t]his effect is similar to the effect of minoxidil on the hair cycle dynamics in this animal model.” Abstract.

Kligman discloses a method of treating alopecia (hair loss) comprising topical application of a composition comprising minoxidil and a corticosteroid to affected areas of the human scalp. According to Kligman, the method prevents the “chronic inflammatory process, subtending to the hair bulbs, in patterned alopecia, [which] lead[s] to eventual scarring of the lower follicle, making regrowth impossible.” Abstract, and the paragraph bridging columns 3 and 4. In addition, we note that Kligman reports that “[t]he use of retinoids alone or in combination with minoxidil . . . to increase hair growth” is known. Paragraph bridging columns 2 and 3.

We agree with the examiner that it would have been obvious for one skilled in the art “to employ corticosteroids and all-*trans*-retinoic acid together in a single hair loss treatment since each was known separately for the same purpose.” Examiner’s Answer, page 3. (“[T]he idea of combining them flows logically from their having been individually taught in the in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072

Appeal No. 2000-0643
Application 08/273,423

(CCPA 1980)). Moreover, in our view, one skilled in the art would have had a reasonable expectation that Kligman's corticosteroids and Bazzano's all-*trans*-retinoic acid would complement each other, as corticosteroids and minoxidil do, inasmuch as Bazzano suggests that all-*trans*-retinoic acid and minoxidil have similar effects on hair cycle dynamics.

The matter does not end here, however. As stated in In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986):

If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

Appellant argues that "experimental evidence . . . encompassing two double blind studies unequivocally shows the unexpected results of Applicant's claimed . . . method to treat alopecia." Brief, page 12. The results of the two double blind studies, in which a corticosteroid and a vitamin A derivative were administered together, are reported and analyzed in the declarations of Drs. Alan H. Greenspan and Jules T. Mitchel. The declarants concluded that the results "are suggestive of treatment efficacy,"³ i.e., that the combination "display[s] a favorable trend toward hair growth for patients diagnosed with . . . male pattern baldness, and is potentially effective in the treatment of male pattern

³ Declaration of Alan H. Greenspan, M.D., executed March 18, 1997 (page 5, paragraph 21).

Appeal No. 2000-0643
Application 08/273,423

alopecia.”⁴ The issue, however, is whether the “favorable trend toward hair growth” attributed to administering all-*trans*-retinoic acid and a corticosteroid would have been unexpected.

Appellant’s burden to make adequate rebuttal under these circumstances is described in In re Freeman, 474 F.2d 1318, 1324, 177 USPQ 139, 143 (CCPA 1973):

In order for a showing of “unexpected results” to be probative evidence of non-obviousness, it falls upon the applicant to at least establish: (1) that there actually is a difference between the results obtained through the claimed invention and those of the prior art: and (2) that the difference actually obtained would not have been expected by one skilled in the art at the time of the invention (citations omitted).

To the extent that appellant relies on the results of the two double blind studies to demonstrate a difference between the invention and the prior art, we are not persuaded. Appellant acknowledges that at least one of the components used in the claimed method is recognized as promoting hair growth (“[Bazzano] does teach that retinoic acid has utility in promoting hair growth” Brief, page 8). Nevertheless, in each of the double blind studies described in the declarations, the effect of administering all-*trans*-retinoic acid in combination with a corticosteroid is compared with the effect of administering a placebo. It cannot be established from these results whether there is any difference between administering the combination and administering all-*trans*-retinoic acid alone, much less whether any difference, if it exists, would have been unexpected. Having carefully reviewed

⁴ Declaration of Dr. Jules T. Mitchel, executed September 2, 1995 (page 3, paragraph 22).

Appeal No. 2000-0643
Application 08/273,423

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