

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HIDEAKI OKABE, ICHIRO
TSUCHIDA and TAKANORI SAITO

Appeal No. 94-3575
Application 07/929,044¹

ON BRIEF

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges
and McKELVEY, Senior Administrative Patent Judge.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision finally rejecting claims 1 through 22, which are all of the claims in the application.

¹ Application for patent filed August 13, 1992.

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REPRESENTATIVE CLAIM

Claim 1, which is illustrative of the subject matter on appeal reads as follows:

1. In a transdermal therapeutic adhesive composition comprising an adhesive layer containing a pharmacologically active agent and adapted to adhere the composition to the skin, the improvement wherein the adhesion of the composition to the skin is provided by a polymer having lipophilic monomer units and hydrophilic monomer units in a weight ratio in the range from 98:2 to 0:100, wherein the composition has an adhesive strength of at least 25 g/12 mm and wherein the composition comprises 5 to 100 weight parts of a C₂-C₃ alcohol, 0 to 50 weight parts of a percutaneous absorption promoter and 10 to 40 weight parts of water, respectively based on 100 weight parts of the polymer.

THE REFERENCES

The prior art references relied on by the examiner are:

Song et al. (Song)	4,789,547	Dec. 6, 1988
Petereit et al. (Petereit)	5,133,970	Jul. 28, 1992
Sablotsky et al. (Sablotsky)	5,186,938	Feb. 16, 1993

THE ISSUES

The issues presented for review are:

(1) Whether the examiner erred in finally rejecting claims 1 through 9, 11 through 19, 21, and 22 under 35 USC § 103 as

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unpatentable over the combined disclosures of Sablotsky and
Petereit; and

(2) Whether the examiner erred in finally rejecting claims
10 and 20 under 35 USC § 103 as unpatentable over the combined
disclosures of Sablotsky, Petereit, and Song.

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) Appellants' main Brief and Reply Brief before the Board;

(3) The Examiner's Answer and the communication mailed by
the examiner September 13, 1994; and

(4) The above-cited references relied on by the examiner.

On consideration of the record, including the above-listed
materials, we reverse the examiner's prior art rejections.

DISCUSSION

As recited in independent claim 1, appellants' transdermal
therapeutic formulation contains 5 to 100 weight parts of a C₂-C₃

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alcohol based on 100 weight parts of polymer. In our judgment, the prior art relied on by the examiner is insufficient to support a conclusion of obviousness of claims containing that limitation.

First, the examiner relies on Sablotsky's disclosure of "about 9% methanol" in column 6, lines 52 and 53. That disclosure, however, relates to the amount of methanol in the cross-linking agent, which is present in an amount of 0.2 to about 1% by weight based on the total weight of Sablotsky's first component layer. See Sablotsky, column 6, lines 27 through 29. The examiner's reliance on this portion of Sablotsky is misplaced, because Sablotsky does not disclose or suggest 5 to 100 weight parts of methanol based on 100 weight parts of polymer as recited in independent claim 1. As correctly argued by appellants in their Brief before the Board, page 5, footnote 1, the amount of methanol disclosed by Sablotsky is well below the amount of alcohol required by the appealed claims. Furthermore, methanol is not a C₂-C₃ alcohol.

Second, the examiner relies on Sablotsky's disclosure of a sequence of steps for producing a bilayer transdermal dosage system. Specifically, the examiner refers to column 10, lines 4

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through 13, disclosing the use of ethanol. According to the examiner, Sablotsky discloses removing 85 to 95% of the ethanol (column 10, lines 11 through 13), and thus implies retaining 5 to 15% which meets the terms of the claims. See the Examiner's Answer, page 3, first paragraph, and page 5, lines 1 through 4. As correctly pointed out by appellants, however, Sablotsky's multi-step method is not complete until the cross-linked adhesive containing pharmaceutically active drug is transferred to a coating station. There, Sablotsky discloses a heating means to remove water and/or solvents which may have been included in the mixing procedure; and

(11) after the heating is completed and the solvents are removed, the first component layer will be firmly adhered to the second component layer and the system can be wound into rolls for storage.

See Sablotsky, column 9, lines 20 through 27. Considering the Sablotsky patent in its entirety, we agree with appellants that (1) Sablotsky discloses removing ethanol in the coating station, and (2) the examiner's reliance on Sablotsky's interim step of removing only 85 to 95% ethanol (column 10, lines 11 through 13) is misplaced. Appellants argue this point strenuously in their Reply Brief, pages 1 and 2. In response, the examiner states

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only that "[t]he reply brief filed August 29, 1994 has been entered and considered but no further response by the Examiner is deemed necessary".

The examiner does not rely on any disclosure in Petereit or Song, and we find none, which would compensate for the above-noted deficiencies in Sablotsky. Again, the combined disclosures of Sablotsky, Petereit, and Song are insufficient to support a conclusion of obviousness of claims requiring 5 to 100 weight parts of a C₂-C₃ alcohol based on 100 weight parts of the polymer.

We further note the examiner's statement that "Sablotsky does not disclose the presence of a lipophilic monomer unit". See the Examiner's Answer, page 3, first paragraph. In this regard, independent claim 1 recites "a polymer having lipophilic monomer units and hydrophilic monomer units in a weight ratio in the range from 98:2 to 0:100", i.e., claim 1 does not require lipophilic monomer units. Furthermore, the examiner's statement is factually incorrect because Sablotsky discloses adhesives containing about 5 to about 20% by weight of a C₄ to C₁₂ alkyl acrylate. See Sablotsky, column 5, lines 52 through 59. Compare the instant specification, page 5, last paragraph, disclosing

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that preferred examples of the lipophilic monomer from which the lipophilic monomer units are derived are acrylic ester monomers, such as esters of acrylic acid or methacrylic acid with an alcohol having 1 to 14 carbon atoms. The examiner's position to the contrary, notwithstanding, Sablotsky discloses lipophilic monomer units.

The examiner's rejections under 35 USC § 103 are reversed.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
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)
) BOARD OF PATENT
WILLIAM F. SMITH)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES

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FRED E. MCKELVEY, Senior)
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