

Art Unit 1502

Paper No. 32

MAILED

Appeal No. 93-1711

JUL 30 1993

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ON BRIEF

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte Harry Hind

Application for Patent filed May 18, 1990, Serial No. 07/526,771, which is a Continuation of Serial No. 07/325,373, filed March 17, 1989, now abandoned. Method For Treating Pain Associated With Herpes-Zoster And Post-Herpetic Neuralgia.

Bertram I. Rowland, for appellant.

Primary Examiner - Thurman K. Page.
Examiner - L. Horne.

Before Goldstein, Lovell and Steiner, Examiners-in-Chief.

Lovell, Examiner-in-Chief.

This is an appeal from the examiner's refusal to allow claims 1 and 3-12, all the claims in the subject application.

Claim 1 is representative of the appealed claims:

1. A method for reducing pain associated with herpes-zoster and post herpetic neuralgia, said method comprising:

applying to the skin at the site of pain a composition comprising an lidocaine in a physiologically acceptable vehicle capable of transdermal penetration over an extended period of time in an amount sufficient to relieve pain and covering dressing.

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The references of record relied upon by the examiner are:

Dixon	4,499,084	Feb. 12, 1985
Powers et al. (Powers)	4,786,277	Nov. 22, 1988

Reference cited by the Board under 37 CFR 1.196(b):

British	1,108,837	Apr. 3, 1968
EPA	331,392	Sep. 6, 1989

The issue on appeal is the correctness of the examiner's rejection of claims 1 and 3-12 for obviousness under 35 U.S.C. 103 in view of Powers and Dixon.

After careful review of all the facts and arguments, we conclude that the examiner's decision is correct and we therefore affirm.

Powers teaches the transdermal delivery of lidocaine via a propylene glycol matrix (hydrogel) but does not specifically teach that such a delivery system is useful in treating pain associated with herpes zoster and post-herpetic neuralgia (PHN). But appellant has acknowledged (specification, page 2) that it was known in the art to administer lidocaine to relieve the pain of herpes zoster and PHN by epidural infusion and by direct subcutaneous infiltration. The Dixon reference is also evidence of the prior art's topical administering of percutaneous anesthetics in gel form for relieving the pain of herpes. Accordingly, we agree that one skilled in the art would

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have found it obvious to use Powers' transdermal delivery system in the treatment of pain associated with herpes zoster and thus arrive at the invention of claim 1.

As regards the inventions of claims 7-12, while the examiner did not see fit to address the limitations of these claims, the use of an occlusive or covering dressing is so common in the topical administration of pharmacologically active agents that we take judicial notice of such use. As regards the specific vehicle called for by claim 10, the record does not show that the selection of the particular proportions of ingredients for making up the vehicle involved anything more than an obvious matter of choice. Powers teaches that the ranges of proportions of the ingredients i.e propylene glycol, cross-linker, surface active agent, making up the matrix can be varied to change its characteristics. Powers also teaches that the lidocaine can either be added to the polymer matrix during formation or after formation prior to its use by inhibition or solvent transfer.

Further, we have reviewed the Great Britain 1,108,837 and EPA 331,392 references, which were included in appellant's Information Disclosure Statement, Paper No. 20, filed April 26, 1991. These references, which carry publication dates of April 3, 1968 and September 6, 1989 respectively, show that it was known to provide a transdermal delivery system for lidocaine

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comprising incorporating the lidocaine in a polymeric matrix and providing an occlusive backing member positioned behind the skin distal surface of said matrix. In view of the admission by appellants that it was known to administer lidocaine to relieve the pain of herpes zoster and PHN, we are persuaded that it would have readily occurred to one skilled in the art apprised of the prior art as a whole to have used the lidocaine containing transdermal delivery systems of the British and EPA references in treating pain resulting from herpes zoster and PHN.

We have carefully considered the Fields' declaration but do not find that it compels us to reach a different result. Declarant states that it was unexpected that combining lidocaine with a transdermal vehicle in conjunction with an occlusive dressing would provide long term relief. We note that such observation only applies to the subject matter of claims 7-12. In any event, the British and EPA references disclose the advantages to be expected when employing lidocaine with a transdermal vehicle in combination with an occlusive covering, which advantages include prolonged anesthetic effects. Accordingly, we find that appellants' evidence is insufficient to support a legal conclusion of unobviousness.

Because we have additionally relied upon the British and EPA references in affirming the examiner's rejection of claims 7-12, we delineate our affirmance of the §103 rejection of

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these claims as constituting a new ground of rejection under 37 CFR 1.196(b).

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date hereof (37 CFR 1.197).

With respect to the new rejection under 37 CFR 1.196(b), should appellant elect the alternate option under that rule to prosecute further before the Primary Examiner by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision. In the event appellant elects this alternate option, in order to preserve the right to seek review under 35 U.S.C. 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to us for final action on the affirmed rejection, including any timely request for reconsideration thereof.

