

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* LTS LOHmann THERAPIE-SYSTEME AG,  
Appellant

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Appeal 2007-3160

Reexamination Control 90/006,899<sup>1</sup>  
U.S. Patent 5,393,529<sup>2</sup>  
Technology Center 1700

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Decided: October 09, 2008

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Before CAROL A. SPIEGEL, MICHAEL P. TIERNEY, and  
MARK NAGUMO, *Administrative Patent Judges*.

NAGUMO, *Administrative Patent Judge*.

DECISION ON REQUEST FOR RECONSIDERATION<sup>3</sup>

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<sup>1</sup> Request for Reexamination filed 31 December 2003 by the Patent Owner.

<sup>2</sup> Patent 5,393,529, *Estrogen-Containing Active Substance Plaster*, issued 28 February 1995.

<sup>3</sup> *Request for Rehearing Pursuant to 37 C.F.R. § 41.52*, filed 19 November 2007 (“Request”).

## A. Introduction

Appellant (“LTS”) timely requests reconsideration under 37 C.F.R. § 41.42 of the Decision<sup>4</sup> of the Board in this appeal. We have considered the arguments presented but do not grant the requested relief.

The claimed invention relates to a transdermal drug delivery system for the controlled release of estrogen, hereafter referred to as a “transdermal patch.”

LTS argues that the Board “misapprehended and/or overlooked several points from the Chiang and Kim references as is evidenced by the statements made in their ‘Findings of Fact.’” (Request 2.) LTS contrasts (a) findings (“FF”) relating to the presence of solvents for polymers that form matrices described by Chiang, which solvents are subsequently “substantially eliminated from the matrix during fabrication” (Chiang 4:31-32; FF 9) with (b) findings that Kim requires the continued presence of a solvent used to dissolve the active substance in the transdermal patch (Kim 3:16-21; FF 19). (Request 2-3.) According to LTS, “Chiang and Kim represent fundamentally different inventions . . . [because] the solvents are removed from the matrix of Chiang whereas solvents are an integral part of the matrix for Kim to delivery [*sic*] their drug.” (Request 4.) LTS argues further that “there is no rational underpinning in light of the differences in the inventions between Chiang and Kim, i.e., there can be no assertion of predictable results or reasonable expectation of success when comparing a transdermal drug delivery system **with** a skin permeation

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<sup>4</sup> *Decision on Appeal*, mailed 18 September 2007.

Appeal 2007-3160  
Reexamination Control 90/006,899  
Patent 5,393,529

enhancer vs. a transdermal drug delivery system *without* a skin permeation enhancer and where the mechanism of action for one transdermal drug delivery system keeps the active ingredient in *solid form* whereas the other transdermal drug delivery system keeps the active ingredient in *dissolved form.*” (Request 6, original emphasis.)

## B. Discussion

The Board regulation governing requests for rehearing provides in relevant part:

The request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board. Arguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for hearing except as permitted by paragraphs (a)(2) and (a)(3) of this section.

37 C.F.R. § 41.52(a) (2008). Paragraph (a)(2) provides that upon showing of good cause, a new argument may be presented based on a recent relevant decision of either the Board or a Federal Court. Paragraph (a)(3) provides that new arguments may be presented responding to a new ground of rejection made pursuant to § 41.50(b).

LTS has not directed our attention to arguments in its principal brief on appeal that the presence of solvents for the active ingredient estrogen in the matrix of Kim’s transdermal patches would have been incompatible with the absence of solvents for the polymer matrices in the completed transdermal patches described by Chiang. Thus, we cannot have misapprehended or overlooked this argument. Moreover, we did not enter a new ground of rejection, nor has LTS requested that we denominate our

Appeal 2007-3160  
Reexamination Control 90/006,899  
Patent 5,393,529

affirmance as a new ground. Accordingly, neither basis for raising a new argument has been satisfied, and we therefore DENY the request for relief on that basis.

In any event, LTS has not supported its allegations of the fundamentally different characters of the inventions of Chiang and Kim with credible evidence. Indeed, LTS appears to have conflated solvents for polymers with solvents for the active agent (estrogen). In particular, LTS appears to have overlooked the similarities of the materials and procedures used in Chiang Example 1 (Chiang 6:61-8:19) and Kim Example 1 (Kim 4:21-37).

In Chiang Example 1, an estradiol was mixed, with or without polyethylene glycol monolaurate (“PGML,” said to be a skin penetration enhancer (Chiang 1:40-45)), with a vinyl acetate acrylate copolymer pressure sensitive adhesive (Monsanto GELVA® 737 solution in typical solvents such as ethanol and ethylacetate (Chiang 7:1-5)), cast in a film, and dried at 75° C for 15-20 minutes to remove the solvents. The fluxes of all the drugs tested were reportedly not affected by the incorporation of the enhancer (PGML) in the acrylate matrix, although an enhancement was noted when silicone matrices were used. (Chiang 7:31-36.)

In Kim Example 1, a matrix was prepared by dissolving an estradiol in polyethylene glycol 200, polypropylene glycol, and polysorbate 80 (a nonionic surfactant obtained by esterification of sorbitol with fatty acids) (Kim 4:23-25), and adding the solution to a polymer solution (Monsanto GELVA® 737), cast to form a film on a backing material, and dried for 30 minutes at 45° C. According to Kim, polyethylene glycol esters such

Appeal 2007-3160  
Reexamination Control 90/006,899  
Patent 5,393,529

as polyethylene glycol monolaurate are also solvents for the active substance (estradiol). (Kim 3:41-51.)

Thus, rather than being “fundamentally different,” the transdermal drug delivery systems described by Chiang and Kim appear to be very much alike.

We conclude that LTS has failed to show that the Board misapprehended or overlooked points raised in the appeal or that the Decision to AFFIRM the Examiner was erroneous.

#### **D. Summary**

In view of the record and the foregoing considerations, it is:

ORDERED that the request for rehearing is granted to the extent that we have fully considered the arguments advanced by LTS;

FURTHER ORDERED that the request for relief is DENIED; and

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

**DENIED**

Appeal 2007-3160  
Reexamination Control 90/006,899  
Patent 5,393,529

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