

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

Ex parte TSUNG-MIN HUS and  
TUNG F. CHEN

---

Appeal No. 95-3461  
Application 08/056,076<sup>1</sup>

---

ON BRIEF

---

Before STONER, Chief Administrative Patent Judge, and WINTERS and WILLIAM F. SMITH, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 15 and 29 through 41, all the claims remaining in the application.

---

<sup>1</sup> Application for patent filed April 30, 1993. According to appellants, this application is a continuation-in-part of Application 07/956,635, filed October 5, 1992.

Appeal No. 95-3461  
Application 08/056,076

Claim 15 is illustrative of the subject matter on appeal and reads as follows:

15. A transdermal patch comprising a laminated composite of:

a backing layer and

a sustained release drug formulation layer comprising a matrix of:

(a) a continuous hydrophobic polymer phase;

(b) a particulate phase dispersed in the continuous polymer phase comprised of:

(i) a hydrated inorganic silicate;

(ii) a water-soluble drug at least partly dissolved in the aqueous phase of (i);

and

(c) a dispersing agent for dispersing (a) in (b), wherein the particular phase defines at least a portion of the surface area of the matrix and provides a diffusion pathway for the drug in the matrix;

wherein the continuous hydrophobic polymer phase is a pressure sensitive adhesive; and

wherein the drug constitutes about 1% to 20% by weight of the matrix and the inorganic silicate (unhydrated) constitutes about 2% to 20% by weight of the matrix.

The references relied upon by the examiner are:

Cleary et al. (Cleary)	4,906,463	Mar. 6, 1990
Johnson et al. (Johnson)	5,071,645	Dec. 10, 1991
Kon et al. (Kon)	5,166,341	Nov. 24, 1992

Claims 15 and 29 through 41 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Cleary, Johnson, and Kon. We reverse.

#### Discussion

The initial burden of establishing reasons for unpatentability rests on the examiner. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Where, as here, a conclusion of obviousness is premised upon a combination of references, the

examiner must identify a reason, suggestion, or motivation which would have led an inventor to combine those references. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629, (Fed. Cir. 1996).

Here, in relevant part<sup>2</sup> the examiner proposes to modify the pressure-sensitive adhesive layer 17 of Cleary which can contain a drug by incorporating the hydrated inorganic silicate described in Johnson. See, e.g., column 4, lines 13-35, of Johnson. As stated at page 4 of the Examiner's Answer,

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the particulate phase of Johnson et al. in the hydrophobic phase of Cleary et al. Motivation lies in Johnson et al. who clearly suggests use of the matrix comprising the particulate material in devices including transdermal patches (see especially Johnson et al. at column 14, lines 20-23).

In our view, the reason given by the examiner for combining the two references in this manner, i.e., Johnson suggests use of silicate in transdermal patches, is premised upon a too expansive reading of the references. Taken to its logical conclusion, the examiner's so-called motivation means that it would have been prima facie obvious to use any material used in a specific transdermal device in any other transdermal device. We do not subscribe to such a sweeping generalization. Rather, the total disclosure of the

---

<sup>2</sup> The examiner relies upon Kon for its description of specific active agents, not the silicate filler required by the claims on appeal.

relevant references must be analyzed in order to find fact-based reasons to combine teachings from the references.

Here, Johnson does not teach that silicates can be used generally in transdermal patches. Rather, the invention described in Johnson involves a microporous material which comprises linear ultrahigh molecular weight polyolefin, finely-divided silicate filler, and a high void content. See, e.g., column 1, lines 14-19, of Johnson. In other words, Johnson describes the use of a silicate filler in a very specific environment. Thus, the subsequent suggestion in Johnson that the microporous material of that reference may be used in transdermal patches, column 14, lines 20-23, must be viewed in the context of the specific environment of Johnson.

The environment of Cleary into which the examiner proposes to insert the silicate filler he has extracted from the microporous material of Johnson is described at column 5, lines 26-54, where Cleary describes the polymers which are useful in providing the pressure-sensitive adhesive layer 17. This portion of the reference first sets forth functional definitions for the polymers which are useful in this layer followed by descriptions of specific polymer types which have the required properties. The examiner has not explained on this record how the ultrahigh molecular weight polyolefin of Johnson meets the functional characteristics required by Cleary. The specific polymer types described in this portion of Cleary do not appear to include ultrahigh molecular weight polyolefin as

required by Johnson. Thus, it is not clear on what basis the examiner concludes that the silicate of Johnson, described to be useful in transdermal devices only when used in conjunction with ultrahigh molecular weight polyolefin, would be similarly useful in layer 17 of Cleary which does not use the ultrahigh molecular weight polyolefin.

What is needed on this record is a more in-depth, fact-based analysis by the examiner of the specific references relied upon. Absent such an explanation, we are constrained to reverse the rejection of record.

The decision of the examiner is reversed.

REVERSED

Bruce H. Stoner, Jr., Chief	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Sherman D. Winters	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
William F. Smith	)	

Appeal No. 95-3461  
Application 08/056,076

Administrative Patent Judge )

Cygnus, Inc.  
Intellectual Property Department  
400 Penobscot Drive  
Redwood City, CA 94063

dem