

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte DIETER ANHAUSER, LOTHAR DEURER,  
THOMAS HILLE, and PETER STEINBORN

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Appeal No. 1998-0244  
Application No. 08/531,890

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HEARD: Oct. 12, 2000

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Before FRANKFORT, MCQUADE, and LAZARUS, Administrative Patent Judges.

MCQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Dieter Anhauser et al. appeal from the final rejection of claims 2 through 4, all of the claims pending in the application. We reverse and enter new grounds of rejection.

THE INVENTION

The invention relates to "a process for the continuous production of transdermal therapeutic patches having a backing layer, a pressure-sensitive adhesive drug-reservoir-layer, and a removable protective layer, wherein the loss of active substance caused by production is minimized" (specification, page 1). Claim 3 is illustrative and reads as follows:

3. A process for the continuous production of transdermal therapeutic patches having a backing layer, a pressure-sensitive adhesive drug-reservoir-section and a removable protective layer, in which the loss of drug during fabrication is minimized, comprising the steps of

providing a laminate which is present in a tape form and comprises a pressure-sensitive adhesive drug-free backing layer and a removable protective layer,

inserting individual quadrangular pressure-sensitive adhesive drug-reservoir-sections lengthwise one after the other between the layers, the clearance between said drug-reservoir-sections in longitudinal direction remaining constant and the width thereof being dimensioned such that said backing layer and said removable protective layer project beyond said drug-reservoir-section at all sides thereof, whereafter the pressure-sensitive adhesive drug-free backing layer is cut by punching in such a manner that the punching line surrounds the external dimensions of the individual drug reservoir sections,

removing the resulting latticed refuse of the drug-free pressure sensitive adhesive backing layer, and

then cutting the protective layer in the resultant spaces between the drug-reservoir-sections.

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THE PRIOR ART

The references relied upon by the examiner as evidence of obviousness are:

Blackford et al. (Blackford) 2, 1958	2,862,846	Dec.
Szycher et al. (Szycher) 20, 1987	4,638,043	Jan.
Seth 4, 1989	4,844,903	Jul.
Morgan 1989	4,867,821	Sep. 19,
Sablotsky 19, 1991	4,994,267	Feb.

THE REJECTION

Claims 2 through 4 stand rejected under 35 U.S.C. 103 as being unpatentable over Seth in view of Szycher, Sablotsky, Morgan and Blackford.

Attention is directed to the appellants' brief (Paper No. 29) and to the examiner's Office action dated July 22, 1996 (Paper No. 23) and answer (Paper No. 30) for the respective positions of the appellants and the examiner with regard to the merits of this rejection.

DISCUSSION

Seth, the examiner's primary reference, discloses an adhesive plaster or patch for the transdermal administration

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of a pharmaceutical. The patch includes a pressure sensitive adhesive layer 1, an impermeable backing layer 2, a matrix layer 3 containing the pharmaceutical and an inert protective layer 4,

these components being arranged as shown in the drawing figure. Of the process by which the plaster is made, Seth states only that

[t]he [matrix] composition is applied at a temperature of about 45E-50E C. to the backing layer in a thickness which is calculated on the basis of the amount of active substance which is to be released per unit area and time (for example cm<sup>2</sup> and hour). The composition is then allowed to cool and solidify to result in a solid coated body. The coated body is then cut to the desired dimensions, and the cut pieces are provided with the pressure-sensitive adhesive layer on the side of the backing layer, and with the inert protective layer on the side of the matrix layer [column 4, lines 18 through 28].

As conceded by the examiner, the process disclosed by Seth fails to respond to the limitations in independent claim 3, and the corresponding limitations in independent claim 4, (1) requiring "pressure-sensitive adhesive" drug-reservoir-sections and (2) setting forth the particular manipulative steps by which the transdermal therapeutic patches are continuously produced. In essence, the examiner relies on

Szycher and Sablotsky to overcome the first deficiency and Morgan and Blackford to overcome the second.

Szycher discloses a transdermal patch 10 composed of a substrate 12, a pressure sensitive adhesive 14, a drug releasing member 16 and optionally a second layer of adhesive 18, these elements being arranged as shown in Figure 3. The optional second layer of adhesive 18 allows the patch to be adhered to the targeted site (see column 4, lines 45 through 54). Szycher indicates in very general terms that the patch is made by successively adding its constituent layers to the substrate 12 (see column 6, lines 40 through 59).

Sablotsky discloses "a dermal composition suitable for use in the transdermal delivery of drugs, which composition permits a high loading of medicament as well as a low loading of medicament into the formulation while maintaining acceptable shear, tack and peel adhesive properties" (column 2, lines 5 through 10). As for the system in which this composition is used, Sablotsky states that

[t]he transdermal drug delivery system of this invention has a defined geometric shape, with a release liner on one side. Removal of the liner exposes the pressure sensitive adhesive that functions as the drug carrier and as the means of applying the system to the patient. The pressure-

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sensitive adhesive is backed by a drug impermeable material that may be colored and labeled as appropriate [column 3, lines 17 through 24].  
Morgan discloses a process for fabricating self-adhesive

bandages. As described therein, the process comprises the steps of

continuously separating a lamination of a release strip component attached to the wound-side surface of a bandage strip component, the lateral portions of said surface being covered with a pressure-sensitive adhesive, thereafter scoring said release strip component while simultaneously depositing a gel coating on the middle portion of said wound-side surface, thereafter relaminating said components in their original relationship, and thereafter die-cutting said fabric bandage strip component of the relamination in a desired bandage shape and separating the selvage therefrom to form a strip of self-adhesive bandages [column 2, lines 13 through 25].

Blackford discloses a method for making plastic strip adhesive bandages wherein individual gauze pads 27 cut from a strip 30 are placed on a continuously running web of plastic film 12 having an adhesive 15 on its top surface, two continuous strips of facing material 36 are added over the gauze pads, and the resulting laminate is cut into individual bandages.

Notwithstanding the appellants' arguments to the contrary, the examiner's conclusion that Szycher and Sablotsky

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would have suggested providing Seth's matrix layer 3 with the characteristics of a pressure-sensitive adhesive to permit it to be adhered to the targeted site is tenable. The same cannot be said, however, for the examiner's application of Morgan and Blackford to overcome Seth's failure to meet the particular continuous production steps recited in claims 3 and 4. Seth, Szycher and Sablotsky pertain to transdermal patches and impart very little detail as to how such patches are made. Morgan and Blackford, on the other hand, relate to the mass production of adhesive bandages, and the continuous manufacturing methods disclosed therein are quite specific to this particular type of product. While we are not convinced that Morgan and Blackford are non-analogous to the claimed invention as argued by the appellants, we are satisfied that the only suggestion for selectively combining them with Seth, Szycher and Sablotsky in the manner proposed by the examiner to arrive at the continuous production processes recited in claims 3 and 4 stems from hindsight knowledge impermissibly derived from the appellants' own disclosure.

Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of independent claims 3 and 4, or of claim

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2 which depends from claim 3, as being unpatentable over Seth in view of Szycher, Sablotsky, Morgan and Blackford.

NEW GROUNDS OF REJECTION

The following rejections are entered pursuant to 37 CFR § 1.196(b).

Claims 2 through 4 are rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification which fails to comply with the written description requirement of this section of the statute.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

Independent claims 3 and 4 recite a continuous production process which includes, inter alia, the steps of (1) providing a laminate in tape form comprising a pressure-sensitive

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adhesive drug-free backing layer and a removable protective layer and (2) inserting individual quadrangular pressure-sensitive adhesive drug-reservoir-sections one after the other between the layers. According to the original disclosure (see pages 8 through 11), however, the individual quadrangular pressure-sensitive adhesive drug-reservoir-sections (5 and 6) are placed on the removable protective layer (3) before the pressure-sensitive adhesive drug-free backing layer (1 and 4) is ever laminated to the removable protective layer. In other words, the process described in the original specification does not contemplate the provision of a laminate of two layers in tape form and the insertion of quadrangular sections between the laminate layers. Thus, the disclosure of the application as originally filed would not reasonably convey to the artisan that the appellants had possession at that time of the process now recited in claims 3 and 4, and in claim 2 which depends from claim 3.

Claims 2 through 4 are also rejected under 35 U.S.C. § 112, second paragraph.

This statutory provision requires that the claims accurately define the invention. See In re Knowlton, 481 F.2d

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1357, 1366, 178 USPQ 486, 492-93 (CCPA 1973). For the reasons discussed above in connection with the 35 U.S.C. § 112, first paragraph, rejection, claims 2 through 4 do not accurately define the invention disclosed in the underlying specification considered as a whole.<sup>1</sup>

#### SUMMARY

The decision of the examiner to reject claims 2 through 4 under 35 U.S.C. 103 as being unpatentable over Seth in view of Szycher, Sablotsky, Morgan and Blackford is reversed; and new rejections of claims 2 through 4 are entered pursuant to 37 CFR § 1.196(b).

This decision contains new grounds of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)).

37 CFR

§ 1.196(b) provides that, "A new rejection shall not be considered final for purposes of judicial review."

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<sup>1</sup> Although the appellants have amended page 3 in the specification to include language corresponding to the problematic language in claims 2 and 3, this amendment clearly conflicts with the detailed description of the inventive process set forth on pages 8 through 11 in the specification.

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37 CFR § 1.196(b) also provides that the appellants,  
WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise  
one of

the following two options with respect to the new grounds of  
rejection to avoid termination of proceedings (§ 1.197(c)) as  
to the rejected claims:

(1) Submit an appropriate amendment of the  
claims so rejected or a showing of facts relating to  
the claims so rejected, or both, and have the matter  
reconsidered by the examiner, in which event the  
application will be remanded to the examiner. . . .

(2) Request that the application be reheard  
under § 1.197(b) by the Board of Patent Appeals and  
Interferences upon the same record. . . .

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b).

	Charles E. Frankfort	)	
	Administrative Patent Judge	)	
		)	
		)	
	John P. McQuade	)	BOARD OF
PATENT	Administrative Patent Judge	)	APPEALS AND
		)	INTERFERENCES
		)	
	Richard B. Lazarus	)	
	Administrative Patent Judge	)	

JPM:tdl

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