

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN W. DOHNER, SCOTT A. BURA
and RICHARD E. FORD

Appeal No. 2001-1235
Application No. 08/951,943¹

ON BRIEF

Before: TORCZON, SPIEGEL and GARDNER-LANE, Administrative Patent Judges.
SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 26, which are all of the claims pending in this application.

Claims 1-4, 8, 9 and 26 are illustrative and read as follows:

1. An improved method for manufacturing delivery devices for the transdermal administration of a liquid drug capable of forming a crystalline structure, the method comprising:
 - a) heating, to a predetermined temperature, each individual film or laminate of a transdermal delivery device which comprises a dispersion of said liquid drug in a matrix immediately following film formation or lamination;
 - b) maintaining each film or laminate at the desired temperature for

¹ Application for patent filed October 17, 1997. According to appellants, this application is a continuation of application 08/566,228, filed December 1, 1995, now abandoned.

a period of time sufficient to prevent the formation and/or growth of a crystalline structure in any film or laminate; and

c) allowing each film or laminate to cool to ambient conditions.

2. The method according to claim 1 further comprising the step of providing that each dispersion of said liquid drug in a matrix is placed between two non-porous substrates prior to heating.

3. The method according to claim 2 further comprising the steps of:

c) laminating the individual films or laminates to form a final laminate;

d) heating the final laminate to said predetermined temperature immediately following lamination and maintaining the final laminate at the temperature for a period of time sufficient to prevent formation and/or growth of a crystalline structure in the final laminate; and

e) allowing the final laminate to cool to ambient conditions.

4. The method according to claim 3 further comprising the steps of:

e) cutting subunits from said final laminate and forming said delivery devices;

f) packaging said delivery devices in sealed containers;

g) heating the devices in said containers to a predetermined temperature and maintaining the devices at the temperature for a period of time sufficient to prevent formation and/or growth of a crystalline structure in the devices; and

h) allowing the sealed devices to cool to ambient conditions.

8. The method of claim 2 wherein the drug is scopolamine.

9. The method of claim 8 wherein the predetermined temperature is within the range of 75-90° C and the period of time is 2-10 minutes.

26. A drug delivery device for the transdermal administration of scopolamine manufactured by the method according to any one of claims 1, 14, or 25.

The examiner relies on the following reference as evidence of obviousness:

Campbell et al. (Campbell)

4,832,953

May 23, 1989

Claims 1-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Campbell. We reverse.

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art reference and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper 12, mailed September 29, 1999) for the examiner's reasoning in support of the rejection, and to the appellants' brief (Paper 11, filed May 28, 1999)² for the appellants' arguments thereagainst.

Discussion

Campbell discloses a method for manufacturing transdermal delivery devices having at least one lamina formed from a dispersion of a liquid drug capable of forming a crystalline hydrate comprising (i) forming a laminate, (ii) cutting the laminate to shape the device, (iii) heating the device, preferably after packaging, to a predetermined temperature, preferably above the melting point of the hydrate, for a period of time sufficient to prevent formation of said crystalline hydrate, and (iv) cooling the heated device to ambient conditions (abstract; c. 3, ll. 16-43). Campbell further discloses heating five-layer laminated scopolamine delivery devices to 60° C for 24 hours after packaging the devices and then cooling them to ambient conditions (EXAMPLE 1, c. 3, l. 65 - c. 4, l. 38; see also c. 3, ll. 43-48).

According to the examiner, "Applicants' broad recitation of the heating step is

² Two additional copies of appellants' brief were filed September 30, 1999 as Paper 13.

inherent to the disclosure of Campbell” (answer, p. 3). The examiner maintains that the method disclosed by Campbell and appellants’ claimed method “appear to be equivalent” (answer, p. 4).

The examiner is not convinced of any patentable differences because Campbell’s specification include the limitations claimed by appellants, as is noted above [i.e., the articles are heated to a temperature above the melting point of the crystalline hydrate]. It is inherent that the heating of each individual laminate can be performed immediately following lamination. Although, the reference prefers to heat the laminations after being placed in their packages. Therefore, the claimed limitations are seen to be inherent over the Campbell reference. [Answer, p. 5, emphasis in the original.]

First, anticipation requires that all elements of the claimed invention be described, either expressly or under the principles of inherency, in a single prior art reference. In re Paulsen, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); In re Spada, 911 F.2d 705, 708 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

Second, it is well established that inherency cannot be established by probabilities or possibilities. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) citing Hansgirk v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939).

Here, as pointed out by appellants, “Campbell does not disclose annealing each individual film or laminate nor performing the annealing immediately following formation and/or lamination” (brief, p. 7). Moreover, to the extent that Campbell suggests “crystallization seemed to appear after the step in which the multilaminate film is cut into individual devices” (c. 2, ll. 36-38), the examiner has not explained why one of ordinary skill in the art would have been motivated to employ one or more heating steps prior to cutting laminated films into individual devices as required by all the independent

claims on appeal, i.e., claims 1, 11 and 14. In addition, the examiner has not pointed out, and we do not find, where Campbell discloses or suggests additionally claimed limitations of (i) placing the film or lamina between two non-porous substrates to protect the film or laminate from environmental exposure or (ii) heating scopolamine containing laminates to 75-90° C for 2-10 minutes as expressly argued by appellants (brief, pp. 9-10). Furthermore, it is unclear whether, or on what basis, the examiner might consider heating scopolamine laminates to 75-90° C for 2-10 minutes as claimed to be functionally equivalent to heating laminated scopolamine delivery devices to 60° C for 24 hours after packaging as disclosed by Campbell. (The examiner has not separately argued that the claimed device is identical or substantially identical with the device of Campbell). Finally, we noted that Campbell is expressly directed to preventing formation of crystalline hydrates (e.g., Campbell at c. 3, ll. 17), whereas appellants invention relates to preventing formation of anhydrous scopolamine base in transdermal devices (appellants' specification at p. 5, ll. 14-19).

Therefore, based on the foregoing, the examiner's rejection of claims 1-26 as anticipated by Campbell is reversed.

OTHER MATTERS

Upon return of this application to the jurisdiction of the examiner, it is suggested that both appellants and the examiner review the pending claims for proper antecedent basis. For example, independent claim 1 recites "a predetermined temperature" in line 3 and "the desired temperature" in line 6, while dependent claim 3/1 recites "said

predetermined temperature” in line 3.

It is also suggested that the examiner take a look at U.S. Patent 6,238,700 to Dohner et al., which issued from an application which is a continuation-in-part of the instant application, to see if a double patenting rejection might be appropriate, especially in view of appellants arguments above that placing the film or lamina between two non-porous substrates protects it from environmental exposure.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1-26 under 35 U.S.C. §102(b) as anticipated by Campbell is reversed.

REVERSED

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RICHARD TORCZON)	
Administrative Patent Judge)	
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SALLY GARDNER-LANE)	
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