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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FRANZ LAERMER, MICHAEL STUMBER, DICK SCHOLTEN,
and CHRISTIAN MAEURER

Appeal 2011-004602
Application 11/897,299
Technology Center 3700

Before ERIC GRIMES, MELANIE L. McCOLLUM, and SHERIDAN K.
SNEDDEN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a drug delivery device, which have been rejected for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification discloses a carrier substrate having on it an array of microneedles with preset breaking points, so that the microneedles can be broken off after being placed into the skin (Spec. 4:17-30). “The

introduction of [] active agents can be managed either through active agents already held in reserve in the porous needle material or through active agent preparations applied from the outside, via the needles” (*id.* at 4:30 to 5:3). The microneedles can be made so that they “will dissolve after a pre-determined time, so that they do not have to be actively removed” (*id.* at 5:12-14).

Claims 1-8 and 15-22 are on appeal. Claim 1 is representative and reads as follows:

1. An array to be placed on the skin of a human patient or an animal patient for transdermally applying pharmaceuticals, toxins or active agents, comprising:
a carrier substrate; and
microneedles situated on the carrier substrate, the microneedles having a present breaking point in an area of a transition to the carrier substrate, the present breaking point including one of (a) a material tapering and (b) a constriction.

Claim 8, the only other independent claim, is directed to an array kit comprising the same array recited in claim 1, and a cover material.

The Examiner has rejected claims 1-6, 8, and 15-20 under 35 U.S.C. § 102(b) as anticipated by Prausnitz¹ (Answer 4). The Examiner has rejected claims 7, 21, and 22 under 35 U.S.C. § 103(a) as obvious based on Prausnitz combined with Kingsford,² Golubovic-Liakopoulos,³ or Delmore,⁴ respectively (Answer 6-7). The same issue is dispositive for all of the rejections.

¹ Prausnitz et al., US 2005/0137531 A1, June 23, 2005

² Kingsford, US 2005/0118388 A1, June 2, 2005

³ Golubovic-Liakopoulos et al., US 2006/0030812 A1, Feb. 9, 2006

⁴ Delmore et al., US 2003/0045837 A1, Mar. 6, 2003

The Examiner finds that Prausnitz discloses an array comprising “a carrier substrate (Fig. 9, #11), and microneedles situated on the carrier substrate (Fig. 9, #12), the microneedles having a preset breaking point in an area of a transition to the carrier substrate (para. 190, lines 1-3), the preset breaking point including one of (a) a material tapering and (b) a constriction (para. 191, lines 2-5)” (*id.* at 4).

Appellants argue that “[t]he cited sections of Prausnitz merely describe that the microneedles may be sheared off from the substrate, and that the microneedles may include a notch to control breakage of the microneedles” (Appeal Br. 4). Appellants argue that “although Prausnitz refers to a notch to control breakage, . . . Prausnitz does not disclose any location for its notch, and does not further describe the structure of its notch as constituting a material tapering or a constriction” (*id.*).

We agree with Appellants that the Examiner has not shown that Prausnitz discloses a microneedle array meeting all the limitations of claim 1. Prausnitz discloses a microneedle device for drug delivery (Prausnitz 13, ¶¶ 179, 184). In one embodiment, “these microneedles may be purposefully sheared off from the substrate after penetrating the biological barrier. In this way, a portion of the microneedles would remain within or on the other side of the biological barrier and a portion of the microneedles and their substrate would be removed.” (*Id.* at 14, ¶ 190.) Prausnitz discloses that the “[m]icroneedle shape and content can be designed to control the breakage of microneedles. For example, a notch can be introduced into microneedles either at the time of fabrication or as a subsequent step. In this way,

microneedles would preferentially break at the site of the notch.” (*Id.* at 14, ¶ 191.)

The Examiner reasons that the notch disclosed by Prausnitz is a type of constriction in a surface and therefore meets the “preset breaking point” limitation of the claims (Answer 8). Appellants argue that Prausnitz does not describe “its notch as constituting a material tapering or a constriction” (Appeal Br. 4).

Regardless of whether or not the notch described by Prausnitz would be considered a “constriction,” however, we agree with Appellants (Appeal Br. 4) that Prausnitz does not disclose a specific location for its notch; specifically, an embodiment in which the notch is located “in an area of a transition to the carrier substrate,” as required by the claims on appeal. Instead, Prausnitz describes shearing off the microneedle tip, for example by introducing a notch, and then removing “a portion of the microneedles and their substrate” (Prausnitz 14, ¶ 190). The Examiner has not shown that a skilled worker would recognize this disclosure as expressly or inherently describing microneedles having a preset breaking point in an area of transition to the carrier substrate.

Although Prausnitz states that microneedles “may break at the juncture of the microneedle and substrate due to mechanical stresses at the sharp angle formed there” (*id.* at 13, ¶ 178), that disclosure relates to a different embodiment than the one described as having a preset breaking point. In addition, Prausnitz describes breakage at the base of the microneedles as undesirable and states that it can be avoided by reinforcing the base of the microneedles (*id.*). The Examiner has not established that a

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skilled worker reading Prausnitz's ¶¶ 178, 190, and 191 would have recognized an express or inherent description of the preset breaking point required by the claims on appeal.

The rejections for obviousness rely on the Examiner's finding that Prausnitz identically discloses the products of claims 1 and 8, and therefore suffer from the same deficiency.

SUMMARY

We reverse all of the rejections on appeal.

REVERSED

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