

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte PATRICK S. L. WONG, FELIX THEEUWES,
GEORGE V. GUITTARD and ATUL D. AYER

Appeal No. 2001-1027
Application No. 08/442,210

ON BRIEF

Before WINTERS, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, 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, 2, and 4-15, all of the claims remaining. Claim 1 is representative and reads as follows:

1. An osmotic solid caplet for delivering a maximum dose of a drug to a patient, the osmotic caplet comprising:
 - (1) a cylindrical body;
 - (2) a dose of 300 ng to 1,200 mg of drug in the caplet;
 - (3) a semipermeable wall that defines the caplet; and, wherein the osmotic caplet is characterized by:

(4) a lead end comprising a convex surface for eliminating residual drug inside the caplet, which convex surface possesses a radius of curvature equal to, but not exceeding, twice the radius of the cylindrical body, for maximizing the dose of drug delivered from the osmotic caplet; and

(5) a passageway in the convex surface for delivering the drug to the patient.

The examiner relies on the following reference:

Eckenhoff et al. (Eckenhoff) 4,612,186 Sept. 16, 1986

Claims 1, 2, and 4-15 stand rejected under 35 U.S.C. § 102(b) as anticipated by Eckenhoff.

We reverse.

Discussion

The claims are directed to a caplet for delivering a drug to a patient. The claims define a caplet comprising a cylindrical body, a dose of drug, and a semipermeable wall. The claims also state that the caplet has a convex surface on the lead end of the caplet, "which convex surface possesses a radius of curvature equal to but not exceeding twice the radius of the cylindrical body," and a passageway in the convex surface through which the drug is delivered. The specification makes clear that the convex surface referred to in the claims is a curved depression in one end of the caplet. See the specification, pages 8-9 (numbers refer to reference numerals in the specification's Figure 2):

Osmotic dosage caplet 10 comprises a dispensing passageway 19 that communicates the interior of compartment 15 with the exterior of solid dosage caplet 10. Dispensing passageway 19 is present in

wall 14 in the area where wall 14 is curved upward and outward from inside compartment 15 for directing the maximum movement or flow of drug 16 from compartment 15. The curved, inside surface 20 and its continual rate of curved change eliminates sharp breaks, angularity, or corners thereby substantially eliminating drug 16 entrapment at the inside surface 20 of caplet 10. The caplet drug delivery end 12 improves the flow profile resulting in a minimum to none amount of residual drug 16 in caplet 10.

This design is disclosed to improve the efficiency with which the drug is delivered to the patient, i.e., to result in less drug remaining undispensed from the caplet. See the specification, page 3: “The present invention advances the state of the drug delivery art by providing a novel and unique dosage form manufactured as an osmotic caplet for optimizing therapy by delivering essentially the full dose of drug present in the osmotic caplet.”

The examiner rejected the claims as anticipated by Eckenhoff. The explanation of the rejection, in its entirety, reads as follows: “Eckenhoff et al. teach an osmotic device with a convex end, semipermeable outer wall (Figure. 3), and a gelatin inner wall.” Examiner’s Answer, page 4.

Appellants argue that

[t]he reference does not anticipate a delivery end with a passageway in said end that reduces residual drug retention in the osmotic caplet to provide for the delivery of the preferred dose of drug. The Eckenhoff et al. dispenser depicts an ellipse with a continuous surface, and this patent does not anticipate an osmotic caplet with a convex end with a passageway designed to both eliminate drug retention and to deliver the drug.

Appeal Brief, page 9.*

* Appellants also argue that Eckenhoff discloses only capsules, not caplets as required by the claims. Appeal Brief, page 8. The examiner has responded that the dictionary definition of “caplet” is broad enough to encompass Eckenhoff’s product. Examiner’s Answer, page 4. For reasons that will become apparent, we find it unnecessary to decide this issue.

“[I]n an ex parte proceeding to obtain a patent, . . . the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty.” In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). The standard under § 102 is one of strict identity. “Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim.” Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). “Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

We agree with Appellants that the examiner has not met his burden of showing that the products disclosed by Eckenhoff meet all of the limitations of the instant claims. We note that the examiner’s explanation of the rejection does not address several limitations of the instant claims. For example, the examiner does not address the requirements for a “solid caplet” or for a particular dosage of drug contained therein

Particularly glaring is the examiner’s failure to point to a specific passage in the reference showing a caplet having a convex surface on one end, with a specific radius of curvature relative to the radius of the caplet. In reviewing the reference ourselves, we have been unable to find such a disclosure.

Thus, the examiner has not shown that the prior art disclosed a drug-delivery system, whether characterized as caplet or capsule, having the particular geometric limitations recited in the instant claims. The examiner has

therefore not met his burden of showing that the claimed invention was identically disclosed in the prior art. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”). The rejection under 35 U.S.C. § 102(b) is reversed.

Summary

We reverse the rejection under 35 U.S.C. § 102(b) because the examiner has not established that the claimed invention was disclosed in the prior art.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Donald E. Adams)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Eric Grimes)	
Administrative Patent Judge)	

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