

The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte RAJIV JANJIKHEL, PHILIP IZEVBEHAI,
MAHENDRA G. DEDHIYA, and CHARLES LINDAMOOD III

Appeal 2007-3734
Application 11/286,137
Technology Center 1600

Decided: September 25, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a pharmaceutical composition. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

The Specification describes “a pharmaceutical formulation comprising ibuprofen . . . , oxycodone . . . , and 14-hydroxycodeinone . . . , and its use for the treatment of pain” (Specification 2). The Specification states that the

“formulation is preferably an oral dosage form” (*id.* at 3). In addition, the Specification states that, “[s]urprisingly, it has been found that 14-hydroxycodeinone at doses up to 125 mg/kg in mice does not exhibit mutagenic properties” (*id.*).

DISCUSSION

1. CLAIMS

Claims 1-7 are on appeal. Claims 8 and 9 are also pending but have been withdrawn from consideration by the Examiner.

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, the broadest claim on appeal, which reads as follows:

1. A solid oral dosage form comprising oxycodone or a pharmaceutically acceptable salt thereof, ibuprofen or a pharmaceutically acceptable salt thereof, and 14-hydroxycodeinone or a pharmaceutically acceptable salt thereof.

2. REFERENCES

The Examiner relies on the following references:

Baker	US 4,569,937	Feb. 11, 1986
Chiu	US 6,177,567 B1	Jan. 23, 2001
Newman	US 2004/0186122 A1	Sep. 23, 2004

The Examiner also refers to the following references:

Chapman	US 2005/0222188 A1	Oct. 6, 2005
Freiha	WO 2005/098414 A1	Oct. 20, 2005

3. OBVIOUSNESS

Claims 1-7 stand rejected under 35 U.S.C. § 103 as obvious over Baker or Newman in view of Chiu. The Examiner relies on Baker for

teaching “an analgesic mixture of oxycodone and ibuprofen that has a synergistic analgesic effect” and for exemplifying “oral tablet compositions having 5 mg of oxycodone HCl and 300 mg of ibuprofen” (Answer 4). The Examiner relies on Newman for teaching “a composition for pain relief comprising oxycodone and ibuprofen for acute pain relief” and for exemplifying “oral tablet compositions having 400 mg ibuprofen and 5.17 mg of oxycodone hydrochloride” (*id.* at 5).

The Examiner relies on Chiu for teaching “a method for the preparation of oxycodone,” which “proceeds via synthesis of 14-hydroxycodeinone and subsequent hydrogenation to form the oxycodone product” (*id.*). The Examiner concludes that it would have been obvious

to provide an oral composition for pain relief comprising ibuprofen, oxycodone and 14-hydroxycodeinone, because Baker et al. and Newman et al. teach that it is known to provide a combination of ibuprofen and oxycodone for the treatment of pain, and Chiu et al. teaches that oxycodone is prepared by a synthetic pathway that . . . necessarily results in an amount of remaining 14-hydroxycodeinoene as a part of the oxycodone product.

(*Id.* at 6.)

The Examiner also finds that “the state of the prior art at the time of filing of Appellants[’] application was that 14-hydroxycodeinone was known to be an impurity present in oxycodone formulations that those of ordinary skill in the art desired to remove and were finding difficult to do so” (*id.* at 15). In support of this position, the Examiner refers to Chapman and Freiha, which are of record and “were published shortly before the filing date of [Appellants’] application” (*id.*).

We conclude that claim 1 is anticipated by Baker or Newman, and therefore would have been obvious over the applied references. Anticipation is the epitome of obviousness. *In re McDaniel*, 293 F.3d 1379, 1385-1386 (Fed. Cir. 2002).

Baker describes “a pharmaceutical composition comprising a combination of synergistically effective analgesic amounts of oxycodone, . . . and ibuprofen” (Baker, col. 2, ll. 19-22). Specifically, Baker describes tablets containing oxycodone hydrochloride and ibuprofen (*id.* at col. 4, ll. 20-59).

Newman describes “a unitary formulation (or oral dosage form) containing an effective analgesic amount of (a) oxycodone or a pharmaceutically acceptable salt thereof and (b) ibuprofen or a pharmaceutically acceptable salt thereof” (Newman ¶ 8). Specifically, Newman describes tablets containing oxycodone hydrochloride and ibuprofen (*id.* at ¶¶ 59 and 60).

Neither Baker nor Newman specifically recites that 14-hydroxycodeinone or a pharmaceutically acceptable salt thereof is present in their compositions. However, Chapman states that “[c]urrent commercially-available oxycodone hydrochloride API [active pharmaceutical ingredient], and oxycodone hydrochloride prepared by known procedures, have a level of 14-hydroxycodeinone of greater than 100 ppm” (Chapman ¶ 13). Thus, we find that Chapman provides evidence that the oxycodone hydrochloride-containing tablets described in Baker and Newman inherently contain 14-hydroxycodeinone.

Appellants argue that Chiu cannot be relied upon to overcome the deficiencies of Baker and Newman (Br. 9-11). However, because we do not find it necessary to rely on Chiu, we are not persuaded by these arguments.¹

Appellants also argue that “the potential toxicity of 14-hydroxycodeinone would teach one skilled in the art away from providing oral dosage forms comprising oxycodone, ibuprofen, and 14-hydroxycodeinone” (Br. 11). Because we find that Baker and Newman anticipate claim 1, we are not persuaded by this argument. “[T]he question whether a reference ‘teaches away’ from the invention is inapplicable to an anticipation analysis.” *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

In addition, Appellants argue that “the present inventors have unexpectedly found that oral dosage forms comprising oxycodone, ibuprofen and 14-hydroxycodeinone may be used for the management of pain” (Br. 12). Because we find that Baker and Newman anticipate claim 1, we are not persuaded by this argument. “Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.” *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

¹ As pointed out by Appellants (Br. 9), Chiu states that “[t]he disappearance of 14-hydroxycodeinone was determined” (Chui, col. 15, l. 62, to col. 16, l. 1). However, we do not find that this statement provides sufficient evidence to overcome the position that oxycodone hydrochloride inherently contains 14-hydroxycodeinone. As pointed out by the Examiner, Chiu “monitors the presence of 14-hydroxycodeinone *to the extent it is detectable by HPLC* to ascertain reaction completeness” (Answer 12). Chiu does not claim that *all* of the 14-hydroxycodeinone is converted to oxycodone.

Appellants also argue that “14-hydroxycodeine is a known impurity that one skilled in the art would remove from an oral dosage form” (Reply Br. 6). We are not persuaded by this argument. We agree with Appellants that the evidence of record suggests that one of ordinary skill in the art would like to remove 14-hydroxycodeine from oxycodone hydrochloride preparations. However, the evidence of record indicates that, at the time of Appellants’ invention, not all of the 14-hydroxycodeine was removed (Chapman ¶¶ 13 and 14, which state that “[t]here is a continuing need in the art to provide an oxycodone hydrochloride composition that contains reduced amounts of 14-hydroxycodeinone as compared to compositions known in the art”). Thus, for the reasons discussed above, we find that Baker and Newman each anticipate claim 1.

We conclude that claim 1 is anticipated by, and therefore would have been obvious over, Baker or Newman. As a result, we affirm the rejection of claim 1 under 35 U.S.C. § 103. Claims 2-7 fall with claim 1. However, because our reasoning differs from that of the Examiner, we designate our affirmation of the rejection as a new ground of rejection under 37 CFR § 41.50(b) in order to give Appellants a fair opportunity to respond.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

Appeal 2007-3734
Application 11/286,137

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

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

AFFIRMED, 37 C.F.R. § 41.50(b)

Ssc

FOREST LABORATORIES, INC.
ATT: MICHAEL CIRAOLO
48 MALL DRIVE
COMMACK, NY 11725