

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte ANDREW X. CHEN, JUN FAN, XI-YUN YU, and
MARTHA J. WHITEHOUSE

Appeal 2007-1073
Application 10/308,176
Technology Center 1600

Decided: May 23, 2007

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness, indefiniteness, and lack of written description. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the obviousness rejection.

Claim 104 is representative.

104. A unit dosage form consisting essentially of about 10 µg to about 70 µg of calcitrol, about 50% MIGLYOL 812 by weight, about 50% tocopherol PEG-1000 succinate by weight, butylated hydroxyanisole and butylated hydroxytoluene.

Grounds of Rejection

1. Claims 104-108 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the invention.

2. Claims 104-108 stand rejected under 35 U.S.C. § 112, second paragraph, for claim indefiniteness.

3. Claims 104-108 stand rejected under 35 U.S.C. § 103 for obviousness over Barbier in view of Chen and admissions in Appellants' Specification, page 2.

Cited References

Barbier	US 5,919,986 A	July 6, 1999
Chen	US 6,267,985 B1	July 31, 2001

DISCUSSION

1. WRITTEN DESCRIPTION

Claims 104-108 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the invention.

The Examiner contends that Appellants' preliminary amendment of May 19, 2004 inserted new matter into the claims because the specification as filed does not support the claim limitation, "about 50% MIGLYOL 812 by weight, about 50% tocopherol PEG-1000 succinate by weight." Answer 4. The Examiner acknowledges the original specification disclosed in claim 48, "MIGLYOL 812 is present in an amount from 60-80% by weight" and "tocopherol PEG.-1000 succinate is present in an amount of 25% at page 23 of the specification or 15%, 24%, 22%, 20% at page 25 of the specification." (*Id.*)

Appellants contend that because each of the limitations was present in the specification, Appellants were in possession of the subject matter of the invention at the time of filing the application. (Br. 10.)

Appellants further argue that, "[t]he value of 'about 50% by weight' for the lipophilic phase component and the surfactant is expressly stated in the specification. '[T]he literal description of a species provides the requisite legal foundation for claiming that species.'" *Snitzer v. Etzel*, 465 F.2d 899, 902, 175 USPQ 108, 111 (CCPA 1972)." (Br. 11.)

We agree with Appellants that the specification describes that the unit dosage form of the invention may include a lipophilic agent in an amount from 50 to 85% (Specification 18: 63), and further describes that the lipophilic agent may be MIGLYOL 812 (Specification 11: 40). Furthermore, the Specification, paragraph 50 describes that the surfactant may be tocopherol PEG 1000 (TPGS) and that the surfactant may be present in the composition from 1-50% (Specification 19: 64; Br. 9-10). In Table 2 of the Specification on page 25, compositions L1 and L2 describe unit dosage forms containing MIGLYOL and (TPGS), albeit not in 50% amounts.

In *In re Wertheim*, 541 F.2d 257, 256, 191 USPQ 90, 98 (CCPA 1976), a disclosure of 25-60% solids content taught those skilled in the art that 35-60% solids was part of the invention in Wertheim, although the latter range was not expressly mentioned therein. *In re Blaser*, 556 F.2d 534, 538, 194 USPQ 122, 125 (CCPA 1977). See also, *In re Schaumann*, 572 F.2d 312, 316, 197 USPQ 5, 9 (CCPA 1978).¹

We similarly find that the disclosure of a specific unit dosage form containing each of the MIGLYOL 812 and TPGS surfactant when read in view of the range of amounts for each ingredient, and literally reciting a

¹ In *Schaumann*, claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. In *Schaumann*, the facts substantiated that one of ordinary skill in the art would “at once envisage the subject matter within the reference.” *Schaumann*, 572 F.2d at 316, 197 USPQ at 9 (CCPA 1978).

50% amount, separately provided for in the specification, provides written description for a claim including about 50% MIGLYOL and about 50% TPGS.

In view of the above, the written description rejection is reversed.

INDEFINITENESS

2. Claims 104-108 stand rejected under 35 U.S.C. § 112, second paragraph, for claim indefiniteness.

The Examiner contends that the phrase "about 50% MIGLYOL by weight, about 50% tocopherol PEG-1000 succinate by weight" renders the claims indefinite since it leaves 0% for other ingredients, about 0% for calcitriol and about 0% BHA or BHT, ingredients also recited in the claim. The Examiner argues that one of ordinary skill in the art would not understand the scope of the claims because they do not leave room for the other three specified ingredients. (Answer 6.)

Appellants contend that the term "about" implies a range of numbers and that the descriptive word "about" is not indefinite, rather, the term is clear but flexible and is deemed to be similar in meaning to terms such as "approximately" or "nearly". *Citing, Ex parte Eastwood*, 163 USPQ 316, 317 (BPAI 1968). (Br. 15.)

We do not find the claims indefinite. The Specification indicates, especially in the examples of the invention present in Tables 2 and 3 (Specification 25 and 26), that the amounts of calcitriol, BHT and BHA present in the claimed unit dosage form are very small, relative to the amounts of MIGLYOL and TPGS. In our view, one of ordinary skill in the

art, upon reading the Specification, would understand that the unit dosage form includes MIGLYOL and TPGS in nearly or approximately 50% amounts with the small difference being made up by the calcitriol, BHT and BHA ingredients.

The rejection of the claims for indefiniteness is reversed.

OBVIOUSNESS

3. Claims 104-108 stand rejected stand rejected under 35 U.S.C. § 103 for obviousness over Barbier in view of Chen and admissions in Appellant's Specification, page 2.

The Examiner contends

Barbier et al. discloses that exemplified compositions in a soft gelatin capsule comprise vitamin D3 compound such as calcitriol (see col. 1, line 7-10) in an effective amount of 0.0001-1 mg/capsule which equals to 0.1-1000 µg/capsule (which encompasses the instant claimed range), α -tocopherol (known as vitamin E oil) in an amount of 0.016 mg/capsule, Miglyol 812 in an amount of 160 mg/capsule as a solubilizer (see col. 23 line 40-41), butylated hydroxytoluene (BHT) in an amount of 0.016 mg/capsule, and butylated hydroxyanisole (BHA) in an amount of 0.016 mg/capsule (see Example A and B compositions at col. 24 line 21-39). . . . Barbier et al. does not expressly disclose the employment of tocopherol PEG-100 succinate (also known as vitamin E TPGS) in lieu of α -tocopherol or polyethylene glycol (PEG) in the gelatin capsule therein. Barbier et al. does not expressly disclose the particular amounts of calcitriol, Miglyol 812, and tocopherol PEG-1000 succinate, and the total volume of the capsule as instantly claimed.

(Answer 7-8.)

The Examiner relies on Chen for the disclosure of

clear oil containing pharmaceutical compositions and methods for improving solubilization and delivery of therapeutic agents including calcitriol (see col. 29, l. 20), wherein tocopherol PEG-1000 succinate is used therein as a preferred surfactant (see col. 25, ll. 25-38). Miglyol 812 (also known as glyceryl tricaprylate/caprate, see col. 6, l. 53), [is used] as a preferred carrier for the compositions of Chen et al. (see col. 7, ll. 52-66).

(Answer 8.)

The Examiner concludes:

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tocopherol PEG-1000 succinate in lieu of α -tocopherol or polyethylene glycol (PEG) in the gelatin capsule composition of Barbier et al, since tocopherol PEG-1000 succinate (vitamin E TPGS) is known to be used as a preferred surfactant for improving solubilizaton and delivery of therapeutic agents including calcitriol according to Chen et al.

(Answer 9.)

Appellants contend that the Examiner has failed to establish a prima facie case of obviousness. (Br. 19.) In particular, Appellants argue that there is no motivation to combine Barbier with Chen. (Br. 22.)

We agree with Appellants that the Examiner has failed to establish a prima facie case of obviousness on the evidence before us.

Appellants succinctly argue

It is clear that Barbier [] used α -tocopherol as an antioxidant and not as a surfactant in the composition of Example B as the α -tocopherol is present at a level of 0.01% by weight (column 24, lines 32-39), a level that is too low to be useful as a surfactant but typically used for an antioxidant. Thus, one of ordinary skill in the art would not think to replace the α -tocopherol in Example B with a surfactant, even a surfactant that has a tocopherol moiety in it. Second, Barbier [], list PEG as one of a laundry list of possible components in an oral dosage form and do not disclose compositions comprising a solubilizer such as MIGLYOL 812 with PEG. In fact, Barbier [] do not disclose any specific compositions comprising PEG. Thus, no motivation is provided to replace PEG with tocopherol PEG-1000 succinate. Moreover, even assuming, *arguendo*, that one would replace PEG with tocopherol PEG-1000 succinate, there is no direction in Barbier [] to combine MIGLYOL 812 and tocopherol PEG-1000 succinate in the form of a composition comprising about 50% of each. (Br. 22.)

The legal conclusion of unpatentability for obviousness depends on four factual inquiries identified by *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). These inquiries concern: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness. Against this background, the obviousness or nonobviousness of the subject matter is determined. *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1388 (2007).

“The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art.” In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991). However, “before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references.” Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). “[E]vidence of a motivation to combine [references] need *not* be found in the prior art references themselves, but rather may be found in ‘the knowledge of one of ordinary skill in the art or, in some cases, from the nature of the problem to be solved.’” *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1366, 80 USPQ2d 1641, 1649 (Fed. Cir. 2006) (emphasis in original, quoting *In re Dembicza*k, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)).

In the present case, we do not find that the Examiner has provided evidence of a sufficient reason, suggestion or motivation to combine the cited references arising either from the prior art, from the nature of the problem solved, or from the knowledge of one of ordinary skill in the art. We particularly find no teaching in Barbier or Chen that would have led one of ordinary skill in the art to substitute a small amount of tocopherol antioxidant with a large amount of TPGS surfactant, as claimed. Nor do we find motivation to replace the polyethylene glycol emulsifier described in Barbier with tocopherol PEG-1000 succinate surfactant as taught by Chen, or an indication that one of ordinary skill in the art would have been led to

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combine MIGLYOL 812 and tocopherol PEG-1000 succinate in the form of a composition comprising about 50% of each.

In view of the above, the rejection of the claims for obviousness is reversed.

SUMMARY

The rejection of claims 104-108 under 35 U.S.C. § 112, first paragraph, as containing new matter is reversed. The indefiniteness rejection of the claims is reversed. The obviousness rejection of the claims is reversed.

REVERSED

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