

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 BRUCE N. AMES and QING JIANG

Appeal 2007-1138
Application 10/301,918
Technology Center 1600

ON BRIEF

Before SCHEINER, ADAMS, and LEBOV ITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Claims 1 and 10 are appealed. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the rejection, but because the Examiner improperly interpreted the claims, we designate it as a new ground of rejection.

STATEMENT OF CASE

Claims 1-16 and 21-24 are pending (Br. 1). Claim 2-9, 11-16, and 21-24 are withdrawn from consideration (*id.*). Claims 1-10 stand finally rejected and subject of this appeal (*id.*).

“Chronic use of a number of medications is known to contribute to obesity.” (Specification 1: 21). Examples of “obesity-promoting drugs” include “corticosteroids and antidiabetes drugs like hypoglycemic drugs, starch blockers, glucose production blockers, and insulin sensitizers.” (*Id.* at 3: 27-29.) According to the instant specification, “tocopherol and tocotrienol compositions can be used to reduce triglyceride accumulation in adipocytes, particularly accumulation resulting from obesity-promoting drug use.” (*Id.* at 1: 29-31.) It is stated that the disclosed “formulations exert antiobesity effects *in vivo* as measured by reduced weight gain and reduced triglyceride accumulation. . . . Control mice treated with anti-diabetic drugs alone gained significantly more weight than either the no-trea[t]ment controls or the formulation-treated mice.” (*Id.* at 13: 4-8.) The specification also reports human trials of formulations of tocotrienol and an anti-diabetic drug in which “[n]o significant weight gain is observed in either the control or formulation treatment groups, whereas anti-diabetic drug treatment groups present significant weight gain.” (*Id.* at 13: 25-27.)

The Examiner relies on the following prior art in rejection the claims:

Perricone U.S. Pat. 5,376,361 Dec. 27, 1994

Drug Facts and Comparison (Drug Facts) 2950-51 (1997)

Claims 1 and 10 stand finally rejected under 35 U.S.C. § 103(a) as obvious over Perricone in view of Drug Facts. Because Appellants did not separately argue the patentability of the claims, we select claim 1 as representative for purpose of deciding this appeal. 37 C.F.R.

§ 41.37(c)(1)(vii). Claim 1 reads as follows:

1. An orally administrable medicament comprising predetermined amounts of a phytyl substituted chromanol and an obesity-promoting drug, wherein:

said medicament is in unit dosage form suitable for pharmaceutical administration;

said phytyl substituted chromanol is selected from the group consisting gamma-tocopherol, delta-tocopherol, alpha-tocotrienol, gamma-tocotrienol and delta-tocotrienol; and

said obesity-promoting drug is selected from the group consisting of a corticosteroid and an anti-diabetes drug selected from the group consisting of hypoglycemic drugs, starch blockers, glucose production blockers, and insulin sensitizers.

ISSUE ON APPEAL

The Examiner contends that the phrase “orally administrable” is not a patentable limitation of claim 1 because it “fails to impart any physical limitation” to the claimed medicament (Answer 4). Appellants contend that “orally administrable” is a “functional limitation” which “precludes the claims from reading on topical formulations.” (Reply Br. 1).

The issue in this appeal is whether the limitation in claim 1 that requires the medicament to be “orally administrable” distinguishes it from a composition for topical application to the skin.

CLAIM INTERPRETATION

The terms appearing in a preamble may be deemed limitations of a claim when they “give meaning to the claim and properly define the invention.” *Gerber Garment Technology, Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 896, 221 USPQ 669, 675

(Fed. Cir. [1984]), cert. denied, 469 U.S. 857 (1984)). Although no ‘litmus test’ exists as to what effect should be accorded to words contained in a preamble, review of a patent in its entirety should be made to determine whether the inventors intended such language to represent an additional structural limitation or mere introductory language.” *In re Paulsen*, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994).

In this case, our review of the specification indicates that the phrase “orally administrable” is one that “breathes life and meaning into the claims and, hence, is a necessary limitation to them.” *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 866, 228 USPQ 90, 92 (Fed. Cir. 1984). According to the specification, the claimed medicament can be administered by any effective route (Specification 6: 17-25). Oral administration is identified as one such route (at 5: 12 to 6: 2). 24 specific oral formulations are listed in the specification (6: 29 to 9: 24). These oral formulations are used to determine the efficacy of the medicament in reducing triglycerides and weight gain (11: 25 to 13: 27). Claims are interpreted in view of the specification as they would be understood by one of skill in the art. In view of the specification, we interpret the phrase “orally administrable” to mean that the medicament is in a physical form which could be administered by mouth.

PRIOR ART

Perricone teaches tocotrienol or tocotrienol-enriched vitamin E in “a dermatologically acceptable carrier or vehicle” for topical application to the skin to treat radiation skin burn (Col. 3, ll. 15-51). For example:

“Suitable carriers include water, alcohols, oils and the like.” (Col. 5, ll. 28-32.)

“[T]he carrier . . . can consist of a relatively simple solvent or dispersant such as water or oils.” (Col. 5, ll. 47-48.)

Drug Facts teaches topical corticosteroids as anti-inflammatory agents (Drug Facts at p. 2950). Topical corticosteroids are used to treat several different conditions, including sunburns (*id.* at 2951).

DISCUSSION

We find that the Examiner erroneously concluded (Answer 5) that “orally administrable” does not limit the scope of claim 1. Under its proper interpretation, this phrase requires the medicament of claim 1 to be in a physical form which can be ingested by mouth. Having adopted this interpretation, the question in this appeal is whether the cited combination of topical tocotrienol and topical corticosteroid as suggested by Perricone in view of Drug Facts would be in a physical form that is acceptable for oral administration. We conclude that it is.

Perricone teaches water at the top of its list of suitable carriers (Col. 5, ll. 28-32 and 47-48). Water is clearly compatible with oral administration. Among other carriers described in Perricone (col. 5, l. 28 to col. 6, l. 37), several are listed which appear suitable for oral use, *e.g.*, “vegetable, animal or marine fats or oils” at col. 5, ll. 60-61. When the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing patentability based on inherency under 35 U.S.C. § 102 or on *prima facie* obviousness under 35 U.S.C. § 103, “it possesses the authority to require the

applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.” *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). In view of Perricone’s teaching of carriers for topical compositions that also appear suitable for oral administration, we find there is sufficient evidence to reasonably presume that the suggested topical composition is “orally administrable,” shifting the burden to Appellants to show otherwise.

Appellants argue that the prior art relied upon by the Examiner teaches topical compositions which would be “incompatible with an orally administrable form.” (Br. 3.) We agree to the extent that when impregnated in a wound dressing, the composition would hardly be suitable for administration by mouth. However, Perricone teaches topical formulations, *e.g.*, using water, which are in a physical form compatible with oral administration. Appellants assert that “the disclosed topical vehicles” in the cited prior are not compatible with oral use, but provide no evidence to substantiate this position.

Accordingly, we affirm the rejection. Because our reasoning differs from the Examiner’s, we designate this as a new ground of rejection under 37 C.F.R. § 41.50(b) to provide Appellants with the opportunity to respond to it.

OTHER ISSUES

Should prosecution resume in this application, the Examiner should consider the relevance of the following prior art:

1. “Cortabs” comprise prednisone (“a corticosteroid”) and vitamin E for oral administration to dogs and cats (world wide web at vetcominc.com, accessed March 5, 2007). The Examiner should determine whether Cortabs were on sale prior to the filing date of the instant application.
2. “Drug Bank” (world wide web at redpoll.pharmacy.ualberta.ca/drugbank, accessed March 5, 2007) describes “Cortab,” “Predniderm Tab,” and “Sterolin Liq” as containing prednisone (“a corticosteroid”) and vitamin E. The Examiner should determine whether any of these formulations were on sale prior to the filing date of the instant application.
3. Serban (Serban, M.G., “Lipid Peroxidation in Autoimmune Systemic Vasculitides, Effect of Corticoid Treatment on Lipid Peroxidation, Antioxidant Protection with Vitamin E, *Rev. Roum. Med. Int.*, 32(2):137-142 (1994)), teaches administration of prednisone (“a corticosteroid”) and vitamin E (Serban at pp. 138, 139 (Table I)). The Examiner should determine whether the combination therapy described in Serban meets the claimed requirement of a “medicament,” anticipating the claimed subject matter, and/or whether it renders the claimed subject matter obvious, alone, or combined with other prior art references.

TIME PERIOD

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides “[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board.”

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

37 CFR § 41.50(b) also provides that the 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. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmation is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences

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for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv)(2006).

AFFIRMED; § 41.50(b)

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| Toni R. Scheiner |) | |
| Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
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| Administrative Patent Judge |) | APPEALS AND |
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