

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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 CARL HENRY LAWYER, MATTHEW CARL LAWYER
and EDWARD ZADOK LAWYER

Appeal No. 2006-3260
Application No. 10/384,044

ON BRIEF

Before ADAMS, LINCK and LEBOVITZ, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-12, 14, 16-19, 21-29 and 31-36, which are all the claims pending in the application.¹

Claims 19 and 33 are illustrative of the subject matter on appeal and are reproduced below:

19. A pharmaceutical composition comprising an aqueous suspension of Modafinil for nasal administration, wherein said Modafinil has a particle size of 1 to 10 microns.

¹ Appellants assert that “[c]laims 13, 15 and 30 were withdrawn [from consideration] in Amendment B. Brief, page 2. However, upon review of “Amendment B”, received May 20, 2004, we note that claims 13, 15 and 30 were cancelled without prejudice. The Examiner acknowledged that these claims were cancelled at page 3 of the Office Action, mailed September 2, 2004.

33. The composition according to claim 19, wherein said composition also includes a solubility enhancer.

The references relied upon by the Examiner are:

Grebow et al. (Grebow)	GB 2 293 103	Mar. 20, 1996
(Remington's) <u>Remington's Pharmaceutical Sciences</u> , pp. 113-1134, 1613, 1629-1632 and 1694-1712 (Alfonso R. Gennaro, et al. eds., 18 th ed., Philadelphia College of Pharmacy and Science, 1990)		

GROUND OF REJECTION

Claims 1-12, 14, 16-19, 21-29 and 31-36 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Grebow and Remington's.

We affirm.

CLAIM GROUPING

We note that Appellants provide separate arguments for claims 17, 18, 33 and 34 in accordance with 37 CFR § 41.37(c)(1)(vii). See Brief, page 10.

Accordingly, we understand Appellants' Brief to set forth the following two groups of claims: I. Claims 1-12, 14, 16, 19, 21-29, 31, 32, 35 and 56; and II. Claims 17, 18, 33 and 34.² Accordingly, we limit our discussion to representative claims 19 and 33. Claims 1-12, 14, 16, 21-29, 31, 32, 35 and 56 will stand or fall together with claim 19. Claims 17, 18 and 34 will stand or fall together with claim 33.

² We recognize Appellants' statement at page 7 of the Brief, which merely points out what claims recite. We do not find this statement to be an argument for separate patentability of these claims. 37 C.F.R. § 41.37(c)(1)(vii).

DISCUSSION

Claims 1-12, 14, 16-19, 21-29 and 31-36 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Grebow and Remington's. As discussed above, we limit our discussion to representative claims 19 and 33.

The Examiner finds (Answer, page 4), Grebow teaches that Modafinil, having a particle size of 2 to 60 microns, can be formulated into powders, liquids, suspension and emulsions and administered topically or orally for the treatment of, inter alia, narcolepsy. In addition, the Examiner finds (*id.*), Grebow "teaches pharmaceutically acceptable carrier[s] that aid solubility . . . can be incorporated into the Modafinil formulation . . ."

The Examiner relies on Remington's to teach, inter alia, nasal administration of drugs, particle size and that caffeine is "useful as [a] CNS stimulant that aid[s] [in] staying awake . . ." Answer, page 5. For the reasons that follow we find that claims 19 and 33 are prima facie obvious in view of Grebow. Accordingly, we find it unnecessary to discuss the teachings of Remington's.

Claim 19:

As set forth above, claim 19 is drawn to a composition comprising an aqueous suspension of Modafinil having a particle size of 1 to 10 microns. In our opinion, the phrase "for nasal administration" (as it appears in claim 19) is a statement of the intended use of the claimed composition. In this regard, it has long been held that a claim to an otherwise old composition cannot be distinguished from the prior art simply by asserting a new use (e.g., nasal

administration) for the composition. See e.g., In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (“terms [that] merely set forth the intended use for ... an otherwise old composition ... do not differentiate the claimed composition from those known to the prior art.”). Accordingly, we construe claim 19 to read on a composition comprising an aqueous suspension of Modafinil having a particle size of 1 to 10 microns. Therefore, we disagree with Appellants’ intimation (Brief, page 9) that claim 19 is distinguished over the art because it “deal[s] with [a] previously undisclosed delivery route of a particular therapeutic compound, Modafinil . . .”

As discussed above, Grebow teaches a composition comprising Modafinil having a particle size of 2 to 60 microns. Grebow, page 4, lines 24-28. Appellants admit that the Modafinil particle size taught by Grebow overlaps the claimed particle range. See Brief, page 6, wherein Appellants assert “Grebow et al. does mention broadly a particle size range of 2 to 60 microns, which admittedly overlaps with Appellants’ claimed particle range. . . .” A prima facie case of obviousness exists where the claimed ranges overlap or lie inside ranges disclosed by the prior art. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

In addition, Grebow teaches that such a Modafinil composition can be formulated into a liquid/suspension – e.g., an aqueous suspension. Grebow, page 19, lines 10-13 and page 15, lines 10-26. Appellants do not dispute this teaching of Grebow.

Therefore, in our opinion, Grebow teaches a composition comprising an aqueous suspension of Modafinil having a particle size of 2 to 60 microns, and therefore renders obvious Appellants' narrower claim 19.

Emphasizing the nasal route of administration, Appellants assert (Brief, bridging sentence, pages 6-7) that their "invention is fundamentally different from Grebow et al., i.e. operates through a different absorption mechanism, at a particle size range (1 to 10 microns) significantly below the preferred ranges taught by Grebow et al." We do not find this argument persuasive.

As discussed above, we find the phrase "for nasal administration" to be a statement of intended use which is insufficient to distinguish the claimed composition from the Modafinil composition taught by Grebow. Regarding Appellants' reference to the preferred ranges taught by Grebow, we note that for an obviousness analysis, the fact that "a specific embodiment is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered." Merck & Co., Inc. v. Biocraft Labs., Inc., 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989) (internal quotations and alterations omitted). On this record, Appellants admit that their particle size range overlaps the range disclosed in the prior art. Brief, page 6. Accordingly, we do not find Appellants' focus on the preferred particle size ranges taught by Grebow persuasive.

We are also not persuaded by Appellants' assertion of unexpected results. See Brief, page 9, "the surprising and unexpected discovery that a therapeutically effective amount of Modafinil could successfully be administered

to a mammal by nasal delivery has absolutely no basis in the cited art.” As set forth above, claim 19 is drawn to a composition comprising Modafinil having a particle size of 1 to 10 microns. The phrase “for nasal administration” is merely a statement of the intended use of this composition. Accordingly, we are not persuaded by Appellants’ assertions regarding “nasal administration”. For the same reasons we are not persuaded by the Lawyer Declaration which addresses the nasal administration of Modafinil.³

On reflection, we find no error in the Examiner’s *prima facie* case of obviousness. Accordingly, we affirm the rejection of claim 19 under 35 U.S.C. § 103 as being unpatentable over the combination of Grebow and Remington’s. As discussed above, claims 1-12, 14, 16, 21-29, 31, 32, 35 and 56 fall together with claim 19.

Claim 33:

Claim 33 depends from and further limits the composition of claim 19 to further include a solubility enhancer. According to Appellants’ specification (page 8), “[s]ince Modafinil is practically insoluble in water and only slightly soluble in lower alcohols, solubility enhancers such as caffeine and/or dextrose may be included.” There can be no doubt that caffeine and dextrose as recited in Appellants’ specification are examples of “solubility enhancers”. Claim 33, before

³ In addition, we note that the Lawyer Declaration does not provide a comparison of the composition comprising the claimed particle with the composition set forth in Grebow.

us on appeal, does not require a specific “solubility enhancer,” but instead is open to include more than caffeine and dextrose.⁴

As discussed above, Grebow teaches a composition comprising an aqueous suspension of Modfinil having a particle size of 2 to 60 microns. According to Grebow, this composition “may comprise agents that aid solubility” Grebow, page 19, lines 15-16.⁵ Accordingly, we find that Grebow teaches a composition comprising an aqueous suspension of Modfinil having a particle size of 2 to 60 microns and further comprising a solubility enhancer. Therefore we find that Grebow renders the composition set forth in Appellants’ claim 33 *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made.

For their part, Appellants focus attention on nasal administration and caffeine asserting, inter alia, (Brief, page 10), “one skilled in the art would not be motivated to combine caffeine with Modafinil for nasal administration.” Claim 33 is not limited to a solubility enhancer that is caffeine, and nasal administration is merely the intended use of the composition. Accordingly, we do not find Appellants’ arguments persuasive.

On reflection, we find no error in the Examiner’s *prima facie* case of obviousness. Having found all the limitations of Appellants’ claim 33 in Grebow, we do not address Remington’s, which addresses, inter alia, caffeine.

⁴ In this regard, we note that claim 34 depends from and further limits the solubility enhancer of claim 33 to caffeine or dextrose.

⁵ See also, Answer, page 4, wherein the Examiner finds that “Grebow also teaches pharmaceutically acceptable carrier[s] that aid solubility . . . can be incorporated into the Modafinil formulation”

Accordingly, we affirm the rejection of claim 33 under 35 U.S.C. § 103 as being unpatentable over the combination of Grebow and Remington's. As discussed above, claims 17, 18 and 34 fall together with claim 19.

SUMMARY

We affirm the rejection of claims 1-12, 14, 16-19, 21-29 and 31-36 under 35 U.S.C. § 103 as being unpatentable over the combination of Grebow and Remington's.

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

AFFIRMED

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Donald E. Adams)
Administrative Patent Judge)
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