

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte KARL T. WEBBER

Appeal No. 2003-1024
Application No. 09/556,352

ON BRIEF

Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

GREEN, 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 5 and 6, which are reproduced below.

5. An article of manufacture comprising a pharmaceutical tablet or capsule for oral ingestion, comprising spironolactone in an amount within a range of 10 to 20 milligrams.

6. An article of manufacture comprising a pharmaceutical tablet or capsule for oral ingestion, comprising spironolactone in an amount within a range of 10 to 20 milligrams, so as to be therapeutically effective in suppressing aldosterone-mediated myocardial fibrosis without substantially increasing sodium excretion and without substantially reducing potassium retention by the body.

The examiner relies upon the following references:

Greenberger et al. (Greenberger) "Readministration of Spironolactone in the Spironolactone-Intolerant Patient," NER Allerge Proc, pp. 343-345 (1986)

Remington's Pharmaceutical Sciences, XIVth edition, Mark Publishing Company, pp. 867-868

The claims stand rejected under 35 U.S.C. § 103(a) as being obvious over Greenberger or Remington's Pharmaceutical Sciences. After careful review of the record and consideration of the issues before us, we affirm the rejection over Greenberger, and thus need not reach the rejection over Remington's Pharmaceutical Sciences.

DISCUSSION

Claims 5 and 6 stand rejected under 35 U.S.C. § 103(a) as being obvious over either Greenberger or Remington's Pharmaceutical Sciences. As we are affirming the rejection over Greenberger, we need not reach the rejection over Remington's Pharmaceutical Sciences, and thus we limit our analysis on the rejection over Greenberger.

According to the Answer:

Greenberger [] disclose[s] that readministration of spironolactone is done by serially increasing doses from 1mg to 400 mg. The instant claims differ over Greenberger [] in reciting an article of manufacture comprising a pharmaceutical tablet or

capsule for oral ingestion comprising spironolactone in an amount within a range of 10 to 20 mg. However, it would have been obvious to one of ordinary skill in the art to administer a tablet or capsule having 10 to 20 mg or to break the available 25 mg tablet into smaller pieces, including a piece within the recited range of 10 to 20 mg. One would be motivated to do so because of the desire to desensitize the spironolactone intolerant patient.

Examiner's Answer, pages 3-4.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with

evidence or argument shift to the applicant.” In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citations omitted). The test of obviousness is “whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention.” In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Moreover, changes in dosages are normally not patentable unless “the results achieved at the designated concentration are ‘unexpectedly good.’” Merck & Co. Inc. v. Biocraft Laboratories, Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847 (Fed. Cir. 1989) (quoting In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977)).

Greenberger set forth a protocol for readministering spironolactone to a patient who initially had an adverse reaction. The reference states that such readministration requires that “1) there be a current essential indication for the drug; 2) there be no suitable pharmacologic alternatives; and 3) the patient or family understand the risks involved.” Id. at 343, col. 2. The protocol describes dissolving a 25 mg tablet in 25 ml of water, and teaches administration of a 20 mg dose, which is within the claimed range. See id. at 344, Table I. Thus, as noted by the rejection, the reference does not specifically describe an article of manufacture comprising a pharmaceutical tablet or capsule for oral ingestion consisting of spironolactone in an amount within a range of 10 to 20 mg. It would have been obvious to one of ordinary skill in the art, however, to provide such an article of manufacture rather than the use of the 20mg of liquid prepared by dissolving a 25mg for use in the protocol described by Greenberger, as the tablet allows for ease of use and less opportunity for dosing error, such as if the tablet does not completely dissolve or if too little water is used to dissolve the tablet. The ordinary artisan would have been further motivated to produce such a tablet because, as taught by Greenberger, such a readministration protocol is necessary when there is a current essential indication for the drug and when there are no suitable pharmacologic alternatives. Therefore, the rejection of claims 5 and 6 under 35 U.S.C. § 103(a) over Greenberger is affirmed.

Appellant argues that Greenberger does not disclose a tablet or capsule for oral ingestion

containing 10 to 20 mg of spironolactone as required by the claims. Appellant contends that “[a] tablet or capsule containing 10 to 20 milligrams of an aldosterone antagonist has been found . . . to serve the important function of inhibiting myocardial fibrosis without the adverse side effects that are typically incurred at dosages large enough to control hypertension.” Appeal Brief, page 6. Appellant asserts further that nothing in Greenberger suggests that an aldosterone antagonist should be produced in the form of a tablet or capsule in a 10 to 20 mg dosage, as that dosage is not effective for the control of blood pressure, the primary purpose for the administration of aldosterone antagonists. See id.

As has already been noted, Greenberger discloses the administration of a spironolactone in the claimed dosage. Admittedly, Greenberger does not specifically describe an article of manufacture comprising a pharmaceutical tablet or capsule for oral ingestion comprising a pharmaceutical tablet or capsule for oral ingestions comprising spironolactone in an amount within a range of 10 to 20 mg, but it would have been obvious to one of ordinary skill in the art to provide such an article of manufacture for use in the protocol described by Greenberger in order to desensitize the spironolactone intolerant patient. Appellant’s argument that Greenberger does not teach the administration of a spironolactone in the claimed dosage for the treatment of myocardial fibrosis is also not found to be convincing, as the treatment of myocardial fibrosis is intended use and not a patentable limitation. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Moreover, according to appellant, in Greenberger small dosages are only administered for a short amount of time, providing no motivation for tablets or capsules to be manufactured in such dosages. Appellant contends that the claims are patentable over Greenberger as unexpectedly favorable results are obtained, i.e., control of myocardial fibrosis without the adverse side effects usually experienced during aldosterone treatment for hypertension.

Greenberger describes readministration of a spironolactone for a single patient. But, Greenberger

Demetra J. Mills
Administrative Patent Judge

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