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for publication and is not binding precedent of the Board.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.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES H. PICKAR

Appeal No. 2004-1478
Application No. 10/099,356

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, 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 12-15. Claims 1-11 and 16-51 are also pending but have been withdrawn from consideration. Claim 12 is representative of the appealed claims and reads as follows:

> 12. A method of inhibiting or retarding bone demineralization or treating or inhibiting osteoporosis in a perimenopausal, menopausal, or postmenopausal women in need thereof, which comprises orally providing to said woman continuously and uninterruptedly over the treatment period, a daily dosage of between 0.25mg and 0.1mg conjugated estrogens, wherein the conjugated estrogens are provided without concomitant administration of a progestin.

The examiner relies on the following reference:

Plunkett et al. (Plunkett)	Re. 36,247	Jul. 6, 1999

Claims 12-15 stand rejected under 35 U.S.C. § 103 as obvious in view of Plunkett.

We reverse.

Background

The specification discloses that estrogen replacement therapy (ERT) is known to be beneficial for, among other thing, prevention of postmenopausal osteoporosis (page 2) and that ERTs available in the United States and/or Europe include conjugated equine estrogens, which are sold under the brand name Premarin® and available in dosages of 0.3, 0.625, 0.9, 1.25, and 2.5 mg (page 3).

The specification also discloses that the lowest effective does of estrogen should be used in order to reduce side effects and that administration of a progestin along with estrogen prevents endometrial cancer. Page 4. Co-administration of progestin, however, can cause other undesirable effects. Id. Appellants sought "to provide the significant benefits of a commercially successful ERT product, such as PREMARIN . . ., while lowering the dosage of conjugated estrogens below that which has previously been demonstrated to be effective." Id., page 5.

Discussion

Claim 12, the only independent claim on appeal, is directed to a method of treating or preventing, for example, osteoporosis by administering 0.1 to 0.25 mg/day of conjugated estrogens "without concomitant administration of a progestin."

The examiner rejected the claims as obvious in view of Plunkett, because Plunkett teaches that estrogens such as conjugated equine estrogens had been used (without added progestin) in estrogen replacement therapy, and Plunkett teaches that effective dosages of various estrogens range from 0.005 to 2.5 mg/day. See Paper No. 7, mailed February 11, 2003, pages 3-5.

Appellants argue that the examiner "has relied upon selected language from the reference . . ., without considering the teaching of the Plunkett et al. reference as a whole. When properly read, the Plunkett et al. reference not only fails to teach or suggest the present invention, but in fact teaches away from the present invention." Appeal Brief, page 3. Appellants review the teachings of Plunkett and conclude that "[t]here is no teaching or suggestion in Plunkett et al. of the use of conjugated estrogens in the range recited in the claims on appeal (0.1 –0.25 mg), much less that such a low range can be successfully utilized in the absence of a co-administered progestogen." Id., page 5 (emphasis added). (According to Appellants, Plunkett's "progestogen" and claim 12's "progestin" are synonymous. See the Appeal Brief, footnote 1.)

We agree with Appellants. When determining obviousness, "the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill." In re Hedges, 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1986). "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." Id.

When considered as a whole, Plunkett does not support the examiner's rejection. It is true that Plunkett teaches that "[e]strogen alone, given in small doses on a continuous basis, is effective for most patients. Column 2, lines 8-10. Plunkett does not, however, define what dosage was considered "small". In addition, Plunkett goes on to explain that using estrogen alone has serious drawbacks. See column 2, lines 11-21.

Plunkett teaches that these drawbacks can be avoided by administering estrogen in combination with a progestogen, and discloses that co-administration of both agents has advantages over administration of estrogen alone. We agree with Appellants that Plunkett therefore teaches away from administering estrogen without concomitant administration of a progestogen, as required by claim 12.

We also agree that Plunkett does not suggest the dosage range recited in claim 12. The examiner relies on Plunkett's disclosure that estrogen should be used in the dosage range of 0.005 to 2.5 mg/day (column 3, line 66). However, that disclosure must be viewed in combination with Plunkett's Table 1A, which shows dosage ranges for various estrogens that vary from a minimum dosage of 0.005 mg/day (see, e.g., column 5, line 15) to a maximum dosage of 2.5 mg/day(see, e.g., column 4, line 66). Importantly, Plunkett discloses that the dosage range for "conjugated equine estrogen" is 0.3 to 2.5 mg/day. Column 4, line 66. The examiner has pointed to nothing in the reference that suggests the dosage range recited in claim 12 for the specific estrogen recited in the claim.

Therefore, we agree with Appellants that Plunkett would not have suggested the method defined by claim 12 to a person of ordinary skill in the art who had no knowledge of the instant disclosure. The rejection under 35 U.S.C. § 103 is reversed.

Other Issues

During prosecution, Appellants submitted a copy of an International Search Report listing numerous references that were each individually deemed to render certain claims unpatentable. To take just one example, the International Search Report lists PCT patent application WO 92/22457 (Morris) as an "X" category document; i.e., a document that renders the claims lacking in novelty or inventive step.

Morris discloses treatment of osteoporosis by administration of estrogens in combination with ipriflavone. See the abstract. See also pages 5-6: "The effect of the combined administration of ipriflavone and estrogens were shown in a one year study carried out in corresponding groups of patients, in physiological menopause for 12-24 months. . . . Each group was treated according to a different therapeutic scheme: . . . group 4: CE [conjugated estrogens] 0.15 mg/day + ipriflavone 600 mg/day." Morris discloses that "in the group of patients treated with Ip+CE 0.15 [i.e., ipriflavone plus 0.15 mg/day conjugated estrogens, see page 7] an effective control of the bone mass is attained after 6 months." Page 8.

We are unable to discern any difference between the method defined by instant claim 12 and the method described by Morris in 1992, well before the filing date of the present application. We have not reviewed any of the other references cited in the International Search Report but they may also be more applicable to the present claims than Plunkett.

Thus, it appears to us that the examiner has not applied the most relevant prior art. We encourage the examiner, on return of this application, to review the prior art of record. If the examiner concludes that the record contains prior art that anticipates or

renders obvious the instant claims, a rejection under 35 U.S.C. §§ 102 or 103 would be appropriate.

Summary

The reference relied on by the examiner does not support a prima facie case of obviousness. We therefore reverse the rejection of record. However, we recommend that the examiner review the other references that have been made of record to determine if they would support a rejection under 35 U.S.C. §§ 102 or 103.

REVERSED

Toni R. Scheiner Administrative Patent Judge	))))) BOARD OF PATENT
Eric Grimes Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
Lora M. Green Administrative Patent Judge	)))

EG/jlb

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