

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte

JACOB RABER and LENNART MUCKE

Appeal 2008-2530

Application 10/256,676

Technology Center 1600

Decided: September 23, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
LORA M. GREEN, *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. We have jurisdiction under 35 U.S.C. § 6(b).

The following claim is representative.

34. A method of improving a cognitive function of a female human, said method comprising administering to said female human an effective amount of an androgenic agent to improve said cognitive function, wherein said female human has been identified as having an ApoE4 genotype, whereby cognitive function in the female human is improved.

Cited References

Aroonsakul	US 4,898,857	Feb. 6, 1990
Roses et al.	US 5,508,167	Apr. 16, 1996
White	US 5,935,949	Aug. 10, 1999

Grounds of Rejection

1. Claims 3-4, 8 and 34-36 are rejected under 35 U.S.C. § 103(a), for obviousness over Aroonsakul in view of Roses.
2. Claim 5 is rejected under 35 U.S.C. § 103(a), for obviousness over Aroonsakul in view of Roses and White.

DISCUSSION

Background

The present invention relates to the field of “cognition and methods for enhancing cognitive function, e.g., for treatment of cognitive decline disease conditions, such as neurodegenerative disease conditions.” (Spec. 1.)

1. Claims 3-4, 8 and 34-36 are rejected under 35 U.S.C. § 103(a), for obviousness over Aroonsakul in view of Roses.

The Examiner finds that:

Aroonsakul teaches the claimed androgen compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments’, androgens, (such as testosterone) to include

testosterone, are taught as useful for treating Alzheimer's disease (AD) (see claims 1-3). Examiner notes the use of these agents on female patients is disclosed at column 3, paragraph 1. Thus, this use disclosed by Aroonsakul would have been viewed by the skilled artisan as indistinguishable from that use herein claimed.

(Ans. 3.)

The Examiner acknowledges that "Aroonsakul does not teach expressly the identification of patient with ApoE4 genotype." (*Id.* at 4.) However, the Examiner finds that Roses discloses "that ApoE4 is an indicator for those who have Alzheimer's disease, or who is susceptible to Alzheimer's disease. See, particularly, the abstract, and the claims." (*Id.*)

The Examiner, therefore, concludes that

it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to confirm the diagnose of a Alzheimer's disease patient by detecting the presence or absence of ApoE4 genotype in the patient, and treat the patient with the method of Aroonsakul if ApoE4 genotype is confirmed.

A person of ordinary skill in the art would have been motivated to confirm the diagnose of a Alzheimer's disease patient by detecting the presence or absence of ApoE4 genotype in the patient, and treat the patient with the method of Aroonsakul if ApoE4 genotype is confirmed because the presence ApoE4 genotype is a known method to diagnose Alzheimer's patients.

(*Id.*)

Appellants contend that "Aroonsakul does not teach the identification of a patient with an [A]poE4 genotype" (App. Br. 7) and that Roses does not disclose "that [A]poE4 is an indicator for those who have AD, or who are

susceptible to AD.” (*Id.*) Appellants further argue that Aroonsakul does not disclose specifically selecting female patients with ApoE4 for treatment with androgen (Reply Br. 3).

However, “[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). 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 (Fed. Cir. 1991). For the reasons discussed by the Examiner, we conclude that the combined teachings of the cited references would have suggested the invention as claimed.

Appellants rely on the Declaration of Lennart Mucke as evidence of non-obviousness of the claimed invention. (App. Br. 9.) The Declaration states that only approximately 40-60% of female Alzheimer’s Disease patients have at least one ApoE4 gene. (Declaration ¶ 4.) The Declarant further argues that Aroonsakul does not mention treatment of female patients who have ApoE4 genotype, and concludes that it would not have been obvious to select female humans having an apoE4 genotype as a subpopulation for treatment with androgen. (Declaration ¶ 3 and 4.)

We are not persuaded by Appellant’s Declaration evidence. We find that Roses discloses that the presence of ApoE4 genotype indicates that a person is afflicted with Alzheimer’s Disease (AD) or at risk for AD. (Roses, abstract; col. 4, ll. 7-9.) We agree with the Examiner that one of ordinary skill in the art having diagnosed an individual with AD by the method of Roses, would have been motivated by the disclosure of Aroonsakul to treat

the female patients diagnosed with AD with androgen. (Aroonsakul, col. 3, ll. 1-12; col. 5, ll. 20-32.)

In view of the above, the rejection for obviousness is affirmed.

2. Claim 5 is rejected under 35 U.S.C. § 103(a), for obviousness over Aroonsakul in view of Roses and White.

The Examiner acknowledges that Aroonsakul and Roses together do not teach expressly dihydrotestosterone as in claim 5. (Ans. 4.)

However, the Examiner finds that “dihydrotestosterone is a well-known androgen and is known to be similarly useful as testosterone. See, e.g., col. 4, lines 4-15” of White. (*Id.*)

Thus, the Examiner concludes, “it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ dihydrotestosterone as androgen in Aroonsakul’s method because dihydrotestosterone is a well-known androgen and is known to be similarly useful as testosterone.” (*Id.*) We find no error in the Examiner’s *prima facie* case of obviousness.

Appellants argue that there is no motivation to combine Aroonsakul with Roses and White because White relates to treating chronic fatigue syndrome and fibromyalgia with androgens and does not disclose treating cognitive function. (App. Br. 12.) We are not persuaded by Appellants’ argument. White is relied on by the Examiner solely for its disclosure to one of ordinary skill in the art that testosterone and dihydrotestosterone are well known androgens.

We find in view of this disclosure of White, that one of ordinary skill in the art would have been motivated to substitute the testosterone of

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Aroonsakul with the dihydrotestosterone of White. “[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007). Appellants have presented no evidence that substitution of dihydrotestosterone for testosterone in the method of Aroonsakul would yield an unpredictable result.

The obviousness rejection is affirmed.

SUMMARY

The obviousness rejections are affirmed.

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

AFFIRMED

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