

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHIRO MITA and EIICHI SCHIRASAWA

Appeal No. 1997-3135
Application 08/208,497

ON BRIEF

Before WINTERS, ROBINSON, and LORIN, Administrative Patent Judges.

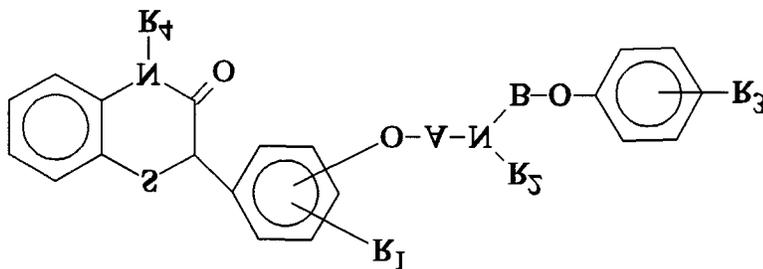
WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 9-14 and 21-29, which are all of the claims remaining in the application.

Claim 9, which is illustrative of the subject matter on appeal, reads as follows:

9. A method for treating glaucoma which comprises administering an effective amount of a therapeutic agent for glaucoma comprising, as active ingredient, a compound of the following formula (I) or its salt:



wherein R¹ represents one or more groups selected from the group consisting of a hydrogen atom, lower alkyl groups, halogen atoms, a nitro group, a hydroxyl group, lower alkoxy groups, lower alkanoyloxy groups, an amino group, lower alkylamino groups and lower alkoxycarbonyl groups, R² represents a hydrogen atom, a lower alkyl group or a cycloalkyl group having 3 to 6 carbon atoms, R³ represents one or more groups selected from the group consisting of a hydrogen atom, lower alkyl groups, a hydroxyl group, lower alkoxy groups, halogen atoms, a nitro group, lower alkylendioxy groups, lower alkanoyl groups, lower alkanoyloxy groups, an amino group, lower alkylamino groups, lower alkanoylamino groups and lower alkoxycarbonyloxy groups, or a group of $-(CH_2)_n-$, R⁴ represents a hydrogen atom or a lower alkyl group, A and B may be the same or different from each other and each represent a lower alkylene group having 1 to 6 carbon atoms, and n represents 3 or 4, and pharmaceutically acceptable diluent and/or carrier to a patient suffering from glaucoma.

The prior art references relied on by the examiner are:

Fujita et al. (Fujita), "Synthesis and Ca²⁺ Antagonistic Activity of 2-[2-[(Aminoalkyl)oxy]-5-methoxyphenyl]-3,4-dihydro-4-methyl-3-oxo-2H-1,4-benzothiazines," *J. Med. Chem.*, Vol. 33, pp. 1898-1905 (1990)

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Abelson et al. (Abelson), "Sustained Reduction of Intraocular Pressure in Humans With the Calcium Channel Blocker Verapamil," American Journal of Ophthalmology, Vol. 105, pp. 155-59 (Feb. 1988)

The issue presented for review is whether the examiner erred in rejecting claims 9-14 and 21-29 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Fujita and Abelson.

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief and Reply Brief; (3) the Yamauch declaration, filed under the provisions of 37 CFR § 1.132, dated November 14, 1994; (4) the Examiner's Answer and the communication mailed by the examiner March 19, 1996; and (5) the above-cited references relied on by the examiner.

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection under 35 U.S.C. § 103.

DISCUSSION

The appealed claims relate to a method for treating glaucoma by administering an effective amount of a therapeutic agent comprising, as the active ingredient, a specified 2-phenyl-3-oxo-2H-1,4-benzothiazine compound and a pharmaceutically acceptable diluent and/or carrier to a patient suffering from glaucoma.

The active ingredient 2-phenyl-3-oxo-2H-1,4-benzothiazine compounds are spelled out by way of chemical formula in claim 9 on appeal.

According to the examiner, Fujita discloses that applicants' 2-phenyl-3-oxo-2H-1, 4-benzothiazine compounds are Ca^{2+} antagonists or calcium channel blockers. The examiner argues that Abelson discloses the use of calcium channel blockers for treating glaucoma by the sustained reduction of intraocular pressure in humans. The examiner concludes that the combined disclosures of Fujita and Abelson would have led a person having ordinary skill to the claimed invention because: (1) it was known, at the time the invention was made, that applicants' 2-phenyl-3-oxo-2H-1,4-benzothiazine compounds were calcium channel blockers (Fujita); (2) it was known that calcium channel blockers were useful for treating glaucoma by the sustained reduction of intraocular pressure in humans (Abelson); and (3) therefore, it would have been obvious to a person having ordinary skill in the art to use applicants' 2-phenyl-3-oxo-2H-1,4-benzothiazine compounds for treating glaucoma by administering an effective amount of such compound in combination with a pharmaceutically acceptable diluent or carrier to a patient suffering from glaucoma. We disagree.

The examiner's argument is flawed because it is unsupported by evidence of record. The examiner's position to the contrary, notwithstanding, Abelson does not disclose using calcium channel blockers, generically, for treating glaucoma. Rather,

Abelson reports that topical administration of the calcium channel blocker Verapamil elicited a significant and sustained reduction of intraocular pressure in human subjects with ocular hypertension. According to Abelson, this finding is supported by a previous study where oral administration of the calcium channel blocker Nitrendipine caused a significant drop in intraocular pressure. See Abelson, page 157, left-hand column, last paragraph, referring to Monica et al. “the effect of a calcium-channel blocking agent on intraocular pressure,” American Journal of Ophthalmology, 96:814 (1983). On the other hand, Abelson acknowledges that his results conflict with those of Beatty and Associates,¹ who found a slight increase in pressure (1 or 2mm Hg) in humans who had received topical Verapamil. See Abelson's discussion of the Beatty reference at page 155, right-hand column, first full paragraph; and the paragraph bridging pages 157-58. Abelson also discloses that Diltiazem, another calcium channel blocker, did not lower intraocular pressure in a pilot study of ten ocular hypertensive subjects (unpublished data). See Abelson, page 158, left-hand column, last full paragraph.

In sum, Abelson does not disclose using calcium channel blockers, generically, for treating glaucoma. According to Abelson, the topical administration of Verapamil elicited a significant and sustained reduction of intraocular pressure in human subjects with ocular

¹ Beatty et al., “Elevation of intraocular pressure by calcium channel blockers,” Arch. Ophthalmol., 102:1072 (1984).

hypertension, and this finding is supported by a previous study where oral administration of Nitrendipine caused a significant drop in intraocular pressure. On the other hand, Abelson's results conflict with those of Beatty and Associates, who found a slight increase in pressure in humans who had received topical Verapamil. Abelson also discloses that Diltiazem did not lower intraocular pressure in a pilot study of ten ocular hypertensive subjects (unpublished data). This means to say that some calcium channel blockers cause a decrease in intraocular pressure and others do not, and these facts were known to persons having ordinary skill in the art at the time applicants' invention was made. As stated by Abelson, page 158, left-hand column, last full paragraph, "[t]he pharmacologic profile of different calcium channel antagonists is varied."

Where, as here, the cited prior art does not disclose using calcium channel blockers, generically, for treating glaucoma by the sustained reduction of intraocular pressure in humans, the premise of the examiner's rejection is unsupported by evidence and the rejection must fall. At the time applicants' invention was made, it was known that some calcium channel blockers cause a decrease in intraocular pressure and others do not. On this record, the examiner has not established that when all of the prior art is considered together, a person having ordinary skill would have had a sufficient basis for the necessary predictability of success to sustain a rejection under 35 U.S.C. § 103. In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). The examiner has not

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established that a person having ordinary skill in the art would have reasonably expected that applicants' 2-phenyl-3-oxo-2H-1,4-benzothiazine compounds would be useful in a method for treating glaucoma.

The examiner's error, we believe, stems from focusing on those portions of Abelson which support the rejection under 35 U.S.C. § 103 but ignoring other portions of the reference which do not support the rejection. In other words, the examiner misapprehends the scope and content of the prior art, considerably overstates the significance of Abelson, and does not adequately evaluate the Abelson reference in its entirety. As stated in In re Hedges, 783 F.2d 1038, 1049, 228 USPQ 685, 687 (Fed. Cir. 1986), quoting from In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965),

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.

Accordingly, on this record, the examiner has not established a prima facie case of obviousness of the appealed claims. We find it unnecessary to discuss the Yamauch declaration, dated November 14, 1994, relied on by the applicants as rebutting any such prima facie case.

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For the reasons set forth above, and those presented more fully in applicants' Appeal Brief and Reply Brief, we reverse the rejection of claims 9-14 and 21-29 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Fujita and Abelson.

The examiner's decision is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Douglas W. Robinson)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Hubert C. Lorin)	
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