

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte ELIZABETH WOLDEMUSSIE and  
GUADALUPE RUIZ

\_\_\_\_\_  
Appeal No. 95-4823  
Application 07/856,012<sup>1</sup>

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ON BRIEF  
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Before STONER, Chief Administrative Patent Judge, and WINTERS and WILLIAM F. SMITH, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

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<sup>1</sup> Application for patent filed March 19, 1992.

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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 11, 12, 14, 17, 19, 21, and 22, all the claims remaining in the application. Claims 11 and 14 are illustrative of the subject matter on appeal and read as follows:

11. A method of treating animals of the mammalian species, including humans, for the purpose of reducing intraocular pressure in the eye of the mammal, the method of treatment comprising the steps of administering to the mammal an ophthalmic solution which comprises as its active ingredient one or more gamma aminobutyric acid agonist compounds and wherein the active ingredient is present in the range of approximately 0.1 to 5 per cent weight by volume.

14. A method of treating animals of the mammalian species, including humans, for the purpose of reducing intraocular pressure in the eye of the mammal, the method of treatment comprising the steps of administering to the mammal an ophthalmic composition in the form of eye droplets which comprises as its active ingredient one or more gamma aminobutyric acid agonist compounds selected from a group consisting of:

gamma aminobutyric acid (**GABA**),  
5-(aminomethyl)-3(2H)-isoxazolone (**muscimol**),  
4,5,6,7-tetrahydroisoxazolopyridin-3-ol (**THIP**) and a pharmaceutically acceptable salt of 4,5,6,7-tetrahydroisoxazolopyridin-3-ol,  
piperidine-4-sulfonic acid and a pharmaceutically acceptable salt of piperidine-4-sulfonic acid,  
3-(2H)-isothiazolone, 5-(aminomethyl) (**thiomuscimol**),  
7-chloro-1-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one (**flurazepam**) and a pharmaceutically acceptable salt of 7-chloro-1-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one, and  
7-chloro-N-methyl-5-phenyl-3H-1,4-benzodiazepin-2-amine 4-oxide (**chlordiazepoxide**) and a pharmaceutically acceptable salt of 7-chloro-N-methyl-5-phenyl-3H-1,4-benzodiazepin-2-amine 4-oxide the concentration of the gamma aminobutyric acid agonist in the eye droplets being in the range of approximately 0.1 to 5 per cent, weight by volume.

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The references relied upon by the examiner are:

Kastner, Embase Abstract of Klin, MBL, Augeheilk (Germany West), (Embase Abstract) 165, pages 946-47, 1974<sup>2</sup>

J.A. Pino Capote (Pino Capote), British Journal of Anesthesia, Vol. 50, No. 8, page 865 (1978)

Claims 11, 12, 14, 17, 19, 21, and 22 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Kastner and Pino Capote. We reverse.

#### Discussion

Simply put, we reverse the rejection in view of the numerous procedural and substantive errors committed by the examiner on appeal. By statute, this board serves as a board of review, not a de novo examination tribunal. 35 U.S.C. § 7(b) ("The [board] shall . . . review adverse decisions of examiners upon applications for patents . . ."). Here, we have little of substance to review. We will discuss some of the more serious errors.

#### 1. Separate argument of claims.

On pages 3-4 of the Appeal Brief, appellants make clear that the claims do not stand or fall together for the purposes of this appeal, setting forth three groups of claims: Group 1 consisting of claims 11, 12, and 21; Group 2 consisting of claims 14 and 22; and

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<sup>2</sup> We have obtained a full text translation of the German language document which is the subject of this abstract. A copy of the translation is attached to this opinion.

Group 3 consisting of claims 17 and 19. As required by the then existing provisions of 37 CFR § 1.192(c)(5), appellants presented arguments directed to each separate group of claims. See pages 7-17 of the Appeal Brief for arguments directed to the claims of Group 1, and pages 17-18 of the Appeal Brief for arguments directed to the claims of Groups 2 and 3.

In response, the examiner stated at page 2 of the Examiner's Answer that appellants' statement that the claims do not stand or fall together is "not agreed with because all the claims can be rejected over the combination of the relied upon references." The examiner's statement falls from its own weight. Taking the examiner's statement at face value, it means that anytime an examiner's rejection includes more than one claim, an appellant is estopped from separately arguing the patentability of the claims included in that rejection. This flies in the face of the rule.

The examiner's failure to separately consider the patentability of the three groups of claims delineated by appellants in the Appeal Brief constitutes error.

## 2. Statement of the Rejection.

In view of its brevity, we reproduce the statement of the rejection as it appears at page 4 of the Examiner's Answer as follows:

Kastner teaches the use of the claimed type diazepam derivatives for the treatment of intraocular pressure. Pino Capote teaches the effect of topical and intravenous diazepam on reducing intraocular pressure.

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One skilled in the art would have been motivated to combine the teaching of the above references, since one relates to the claimed type compounds in lowering intraocular pressure and the other relates to the use of diazepam a well known GABA agonist for reducing intraocular pressure. The above references make clear that diazepam having GABA agonist activity has been previously used for lowering intraocular pressure. Such teaching reads on the generic claim which is directed to the use of a GABA agonist for the treatment of glaucoma. The specific amino butyric agonists are also rejected over the combination of the relied upon reference, since it would have been obvious to a person skilled in the art to substitute one GABA agonist for another. Thus, for the above reasons and in view of relied upon references, the claimed use does not patentably distinguish over the state of the art, and claims 11, 12, 14, 17, 19, 21 and 22 are properly rejected under 35 USC 103.

First, while the statement of the rejection proposes to combine "the teaching [sic] of [Kastner and Pino Capote]" the examiner has not explained which portions of the references are to be combined and in what manner. As set forth in the Manual of Patent Examining Procedure (MPEP) § 706.02(j) (6th ed., no. 3, July 1997), in making a rejection under 35 U.S.C. § 103,

the examiner should set forth . . . (1) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, (2) the difference or differences in the claim over the applied reference(s), (3) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and (4) an explanation why such proposed modification would have been obvious to one of ordinary skill in the art at the time the invention was made.

Failure of the examiner to identify the difference or differences in the claims over the applied references and clearly communicating the proposed modification of the applied

references needed in order to arrive at the claimed subject matter constitutes error on the part of the examiner.

Second, the examiner has not properly considered those claims which are limited to specific gamma aminobutyric acid agonists [GABA] such as claim 14 on appeal. The examiner has merely concluded that "it would have been obvious to a person skilled in the art to substitute one GABA agonist for another." However, the examiner has not relied upon any facts in support of this conclusion. Where does Kastner or Pino Capote describe the use of any of the specific GABA agonists required by claim 14 on appeal? Failure for the examiner to consider the subject matter as a whole in making a rejection under 35 U.S.C. § 103 constitutes error.

3. Kastner.

As is clear from the citation of Kastner at page 3 of the Examiner's Answer, the examiner is relying upon an "Embase Abstract" of the document, not the document itself. Appellants confirm at pages 8-9 of the Appeal Brief that the examination of the application up to the filing the Appeal Brief had been premised upon the abstract of Kastner, not the complete document. In the Appeal Brief, appellants made of record the original German language reference and premised their argument on partial translations of the document. It does not appear that appellants or the examiner have had the full text German language document translated.

Despite being presented with an Appeal Brief in which appellants rely upon partial translations of the full text Kastner article, the examiner continued to rely upon the Embase Abstract of Kastner. In fact, the examiner did not acknowledge in the Examiner's Answer appellants' reliance upon the partial translation of the full text Kastner article.

By relying upon the partial translation of Kastner in pursuing their case on appeal, appellants changed the factual setting in which the patentability determination under 35 U.S.C. § 103 takes place. The examiner's failure to acknowledge and take into account this shift in the factual base of the 103 analysis constitutes error.

4. WoldeMussie Declaration.

Appellants rely upon a declaration filed under 37 CFR § 1.132 by co-appellant Dr. Elizabeth WoldeMussie, dated August 3, 1993. See pages 14-16 of the Appeal Brief. The examiner did not acknowledge or discuss this declaration in the Examiner's Answer. As stated in In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986):

If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

The failure of the examiner to consider the WoldeMussie declaration constitutes error.

5. Appellants' discussion of other references.

At pages 12-13 of the Appeal Brief, appellants discuss other references of record which they believe are relevant in determining the patentability of the claims on appeal. Once again, the examiner has ignored a substantiative portion of the Appeal Brief. This constitutes yet another error on the part of the examiner. In re Hedges, supra.

The rejection is reversed.

Other Issue

Notwithstanding our disposition of the examiner's rejection, there are significant issues of patentability present in this record which have not been properly considered by the examiner. We direct attention to Pino Capote. This reference describes administering diazepam either intravenously or by eye drop into the conjunctival sac of cats in order to determine if diazepam will decrease intraocular pressure. Diazepam is a GABA agonist according to the present invention. See page 4, lines 27-28 of the supporting specification. Pino Capote reports that diazepam was found to significantly reduce intraocular pressure by either mode of administration.

In comparing the subject matter of claim 11 on appeal with the described procedure in Pino Capote, it is not clear whether the diazepam was present in the compositions used by Pino Capote "in the range of approximately 0.1 to 5 per cent weight by volume" as

required by claim 11 on appeal. Thus, it is not readily apparent from this record whether the dosages of diazepam used in Pino Capote fall within or without the claimed range.

Upon return of the application, the examiner should consider this relevant disclosure of Pino Capote and determine whether the dosages of diazepam used in the reference fall within or without the range required by claim 11 on appeal. If a dosage used by Pino Capote falls within the range required by claim 11 on appeal, Pino Capote might be anticipatory of claim 11. If the dosages used by Pino Capote all fall outside the range required by claim 11, the examiner should determine whether it would have been obvious to one of ordinary skill in the art to adjust the dosage to a value within the claimed range. In so doing, the examiner should take into account Pino Capote's finding that "diazepam was found to reduce [intraocular pressure] in a dose-dependent manner (fig. 2)."

We also take this opportunity to comment upon some of appellants' arguments presented in regard to Pino Capote in the Appeal Brief. Appellants argue at page 8 of the Appeal Brief that Pino Capote only discloses reduction of intraocular pressure in the experimental cats for up to 20 minutes. Appellants believe that reducing intraocular pressure for only 20 minutes is of no practical significance. We have two problems with appellants' argument. First, Pino Capote only measured intraocular pressure for 20 minutes which appears to be the reason why values are only reported in that time frame. This does not mean that intraocular pressure was not reduced beyond 20 minutes. It only

means that for Pino Capote's purposes this parameter was only measured for 20 minutes. Second, claim 11 on appeal does not require any particular length of time for intraocular pressure to be reduced as a result of the claimed treatment. Thus, a procedure which falls within the scope of claim 11 on appeal would not be outside the scope of claim 11 on appeal merely because that procedure resulted in reducing intraocular pressure for less than 20 minutes.

Appellants also criticize Pino Capote in that the reference does not purportedly describe an ophthalmic composition as required by claim 11 on appeal. Appellants point out that Pino Capote describes a solution of diazepam and dimethylacetamide, which appellants assert is not suitable for administration into the eye for therapeutic purposes. Upon return of the application the examiner should determine whether the specific solution used by Pino Capote would reasonably be considered an "ophthalmic" solution. In making this determination, the examiner should take into account that the cats treated in the reference were "decerebrated." If the specific solution used in the reference can not be reasonably described as "ophthalmic" the examiner should consider whether one of ordinary skill in the art would have found it obvious to formulate diazepam in an ophthalmic form in view of the successful results reported by Pino Capote.

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The decision of the examiner is reversed.

REVERSED

	)	
Bruce H. Stoner, Jr., Chief	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Sherman D. Winters	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
William F. Smith	)	
Administrative Patent Judge	)	

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