

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANNMARIE L. SABB

Appeal No. 94-2100
Application 07/902,109¹

ON BRIEF

Before GRON, PAK and ELLIS, **Administrative Patent Judges**.

ELLIS, **Administrative Patent Judge**.

DECISION ON APPEAL

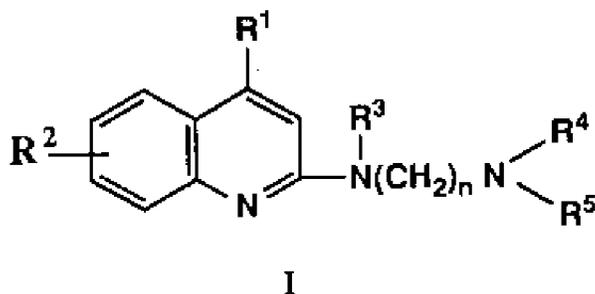
This is an appeal from the final rejection of claims 1, 2, 5, 8 and 10, all the claims pending in the application. Claim 1

¹ Application for patent filed June 22, 1992. According to the appellant, this application is a division of Application 07/794,227, filed November 19, 1991, now U.S. Patent 5,149,815, issued September 22, 1992, which is a division of Application 07/692,743, filed April 29, 1991, now U.S. Patent 5,093,333, issued March 3, 1992.

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is illustrative of the subject matter on appeal and reads as follows:

1. A compound of the formula I



wherein

R^1 is H, alkyl or cycloalkyl of 1 to 6 carbon atoms;

R^2 is H, alkyl of 1 to 6 carbon atoms, cyano, halo, nitro, amino or mono or dialkylamino in which the alkyl groups have 1 to 6 carbon atoms;

R^3 is H or alkyl of 1 to 6 carbon atoms;

n is 1 to 5

and R^4 and R^5 taken with the nitrogen atom to which they are attached are a piperazin-1-yl moiety in the 4-position of which is H, alkyl of 1 to 6 carbon atoms or unsubstituted or substituted pyrimidinyl, pyridinyl, or pyrazinyl wherein the substituents are alkyl of 1 to 6 carbon atoms, alkoxy of 1 to 6 carbon atoms, halo, cyano, nitro or trifluoromethyl or a pharmaceutically acceptable salt, hydrate or solvate thereof.

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A reference relied on by the appellant is:

Molchan, et al. (Molchan), "Increased Cognitive Sensitivity to Scopolamine With Age and a Perspective on the Scopolamine Model," **Brain Research Reviews**, vol. 17, pp. 215-226 (1992).

Claims 1, 2, 5, 8 and 10 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

We **reverse**.

The examiner argues that the specification fails "to **positively** assert that the claimed compounds have utility." Answer, p. 3. According to the examiner, "the evidence presented [in the specification] is not sufficient to demonstrate that the claimed compounds possess actual utility in currently available form." **Id.**

Although it appears that the rejection is based on the issue of whether the claims have a practical utility, a § 101 issue, the rejection in the Answer, and throughout prosecution of the application, has been under the first paragraph of § 112. Therefore, our consideration of the issues is limited to whether the specification would have enabled one skilled in the art to "make and use" the claimed compositions; i.e., whether the specification satisfies the requirements of § 112, first paragraph.

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To that end we point out that the specification is presumed to be "in compliance with the enablement requirement of § 112, first paragraph, unless there is reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). It is well established that when making a rejection under § 112, the examiner has the burden of presenting adequate reasons as to why the specification would not have enabled a person skilled in the art to make and use the full scope of the claimed invention. *In re Angstadt*, 537 F.2d 498, 502, 190 USPQ 214, 217 (CCPA 1976).

Turning to the specification, we find that it states that, based on the *in vitro* and *in vivo* data disclosed therein, the claimed compositions are

selective for central [nervous system] cholinergic M₁ receptors and are able to reverse scopolamine-induced hyperactivity and to improve scopolamine-induced amnesia in the radial arm maze in rats. Compounds having this activity may be useful for treatment of diseases involving hypofunction of the cortical cholinergic system [Specification, p. 2, lines 29-33].

Absent reasons or evidence to the contrary, the presumption is that this teaching, in conjunction with the rest of the specification which includes the methods of making the claimed compositions and the assays described in Examples 1 through 13, is sufficient to satisfy the enablement requirement of 35 U.S.C.

§ 112, first paragraph. However, in the case before us, we do not find that the examiner has provided a single reason as to why one skilled in the art would have doubted the truth of these statements or why the specification would not have enabled such person to "use" the claimed compositions.

As we understand it, the examiner's actual position is that the specification would not have enabled one skilled in the art to use the claimed compositions to cure Alzheimer's disease. However, such is not the utility asserted by the specification in the quoted section above. Rather, the quote only suggests that the claimed compositions, having the demonstrated utility of reversing scopolamine-induced hyperactivity and improving scopolamine-induced amnesia in rats, may be useful for treating diseases involving hypofunction of the cortical cholinergic system. With respect to Alzheimer's disease, the specification states that in view of the effectiveness of the tested compositions on M₁ receptors of the central nervous system, that "selective compounds may have therapeutic potential for the treatment of disease states in which cholinergic disfunction is apparent, such as senile dementia of the Alzheimer's type. No where in the specification, is it alleged that the claimed compounds are to be used exclusively for the cure, or treatment,

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of Alzheimer's. Thus, there is no need for the specification to positively demonstrate the successful treatment of Alzheimer's patients in order to satisfy the enablement requirement of § 112, first paragraph.

The examiner's contends that "scopolamine induced amnesia is only a **screening** test which screening test is deemed insufficient to employ [sic, comply?] with the statute." Answer, p. 3. Here, it appears that the examiner is questioning the relevance of the disclosed *in vitro* and *in vivo* screening assays with respect to the ability of the present compositions to treat Alzheimer's. Again, however, the examiner has not provided any reasons as to why the results of the screening tests do not correlate with the suggested utility of treating "diseases involving hypofunction of the cortical cholinergic system," or with the treatment of Alzheimer's. Specification, p. 2, lines 32-33. Moreover, we point out that the Federal Circuit recently addressed the issue of enablement with regard to screening assays in animals. In *In re Brana*, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995), the court stated that

proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility. *In re Krimmel*, 292 F.2d 948, 953, 130 USPQ 215, 219 (CCPA 1961); *see also In re Bergel*, 292 F.2d 958, 130 USPQ 205

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(CCPA 1961). In concluding that similar *in vivo* tests were adequate proof of utility the court in *In re Krimmel* stated:

We hold as we do because it is our firm conviction that one has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.

And

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of patent laws. *Scott*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.

Here, we find that the appellant has provided evidence that the screening assays which were employed to test the claimed compositions were performed using standard experimental animal models. See the Molchan publication. We note that Molchan recognizes that the scopolamine model has limitations, however, contrary to the examiner's assertion, we do not find that such acknowledgment in any way suggests that the models be discarded or the results obtained therefrom, disregarded. Rather, the Molchan studies indicate that the effects of scopolamine are age dependent. We direct attention to the concluding statements on p. 224 of Molchan (first complete paragraph) that

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older subjects were significantly more impaired than the younger by scopolamine on some tests of learning and memory. This increased sensitivity of the older group to scopolamine is consistent with studies in animals and humans showing decreased cholinergic system function with age. The findings also indicate that age is an important variable to consider in using the scopolamine model of memory impairment.

Thus, absent evidence to the contrary, we hold that the appellant's specification would have enabled one skilled in the art to "make and use" the claimed compositions at the time the application was filed.

Accordingly, decision of the examiner is reversed.

REVERSED

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TEDDY S. GRON)	
Administrative Patent Judge)	
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CHUNG K. PAK)	
Administrative Patent Judge)	APPEALS AND
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