

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL L. FLYNN
and ROBERT L. SHONE

Appeal No. 94-3351
Application 07/919,679¹

ON BRIEF

Before JOHN D. SMITH, WARREN and WALTZ, Administrative Patent Judges.

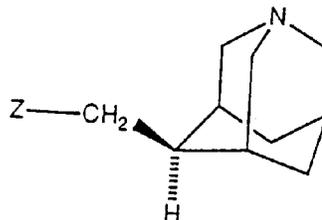
JOHN D. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

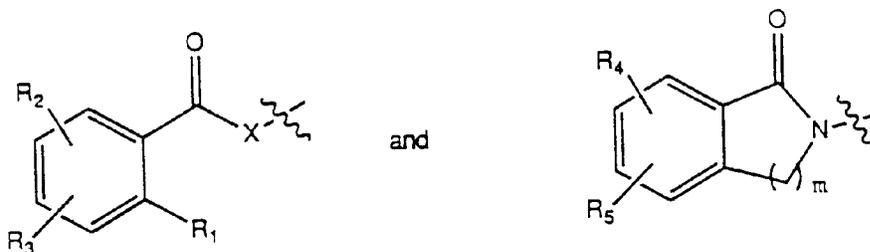
This is an appeal pursuant to 35 USC § 134 from the final rejection of claims 1 through 16. Claim 1 is representative and is reproduced below:

¹ Application for patent filed July 27, 1992.

1. A compound of the formula:



or a pharmaceutically acceptable salt thereof
wherein Z is selected from the group consisting of



R_1 is alkoxy of one to six carbon atoms;
 R_2 , R_3 , R_4 and R_5 are the same or different and are selected from the group consisting of hydrogen, halogen, CF_3 , hydroxy, alkoxy of one to six carbon atoms, acyl of two to seven carbon atoms, amino, amino substituted by one or two alkyl groups of one to six carbon atoms, C_2-C_7 acylamino, aminocarbonyl, aminosulfone optionally substituted by one or two alkyl groups of one to six carbon atoms, C_1-C_6 alkylsulfone and nitro;
 m is 1 or 2;
 X is O or NR_7 ; and
 R_7 is hydrogen or alkyl of 1 to 6 carbon atoms.

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The references of record relied upon by the examiner are:

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| Watts | 4,816,453 | Mar. 28, 1989 |
| King | 4,853,376 | Aug. 1, 1989 |
| Buchheit | 4,910,193 | Mar. 20, 1990 |

Claims 1 through 5 and 9 through 13 stand rejected under 35 USC § 112, first paragraph, enablement requirement.

Additionally, all appealed claims stand rejected under 35 USC § 103 over Watts in view of King and Buchheit.

THE REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH

According to the examiner, the "how to make and use requirement" of 35 USC § 112, first paragraph requires an enabling disclosure commensurate in scope with the protection sought by the claims. The examiner further alleges that appellants, "it appears," have not enabled and disclosed "how to make, test and use" the compounds claimed in the generic scope for the presently claimed invention. See the Answer at page 3. We reverse.

It is well settled law that the examiner has the "burden of

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giving reasons, supported by the record as whole, why the specification is not enabling....Showing that the disclosure entails undue experimentation is part of the PTO's initial burden....? In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). In determining whether a disclosure would require undue experimentation to make and use claimed subject matter, the examiner must consider not only the breadth of the claims but also other factors such as the predictability or unpredictability of the art in question, the relative skill of those in the art, the state of the prior art, the nature of the invention, the presence or absence of working examples, the amount of direction or guidance presented, and the quantity of experimentation necessary. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), citing with approval Ex parte Forman, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986). The examiner has failed to adequately address any of the above considerations.

In neither his statement of rejection, nor his response to appellants' arguments, has the examiner provided a single persuasive reason as to why the specification fails to enable one skilled in the art to disclose how to make and use the compounds claimed ?in the generic scope?. Indeed, the examiner acknowledges that the cited prior art shows that the activity

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(utility) of the type of compounds claimed is predictable. Moreover, it is apparent that the examiner has given no weight to the statements in the Flynn declaration (paragraphs 2.1 through 2.8) regarding the question of undue experimentation. Accordingly, the examiner's rejection under 35 USC § 112, first paragraph, is reversed.

THE REJECTION UNDER 35 USC § 103

The subject matter on appeal is directed to a certain class of pharmaceutical compounds referred to as serotonergic agents as defined by the generic formula in appealed claim 1 (and compositions) which act as 5-HT₄ agonists or antagonists and/or 5-HT₃ antagonists in mammals. As set forth in the specification at page 9, the compounds of the claimed invention are said to be useful in treating conditions such as gastrointestinal motility disorders, emesis, anxiety, cognitive and other CNS disorders. Gastrointestinal motility disorders said to be responsive to treatment with 5-HT₄ agonists include reflux esophagitis, non-ulcer dyspepsia, gastroparesis, ileus, irritable bowel syndrome (constipation predominant), constipation, and the like. Gastrointestinal motility disorders said to be responsive to treatment with 5-HT₄ antagonists include diarrhea, irritable bowel syndrome (diarrhea predominant) and the like. Disorders

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responsive to 5-HT₃ antagonist include emesis due to either cancer chemotherapy or post-operative, anxiety, cognitive disorders, drug abuse (either cravings or withdrawal syndrome), irritable bowel syndrome (diarrhea predominant) and the like.

In rejecting the appealed claims over the cited prior art references, the examiner indicates in the Answer at page 8 that

Clearly, the cited prior art compounds and the instant compounds are vastly structurally similar or identical.

As an initial matter, we have independently reviewed each of the relied upon prior art references. However, we have been unable to discover any compounds described in these prior art references which are ?identical? to the claimed compounds. Accordingly, this application is remanded to the examiner to point out where in the relied upon references such identical compounds are disclosed. Further, if identical compounds are disclosed in the prior art, the examiner should reject the relevant claims as anticipated (35 USC § 102) by the prior art.

We agree with the examiner that there is a adequate factual

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basis to support the contention that the cited prior art compounds are structurally similar to the instantly claimed compounds. However, statements by the examiner that the claimed serotonergic agents act as 5-HT₄ antagonists or agonist are not germane to any issue at hand (Answer, page 8) and the statement that the methods of using the claimed compounds (the utility of a compound is based on its properties) are not under consideration (Answer, page 5) are inconsistent with legal theories of structural obviousness. In this regard, we point out to the examiner that an obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound in the expectation that compounds similar in structure will have similar properties. In re Gyurik, 596 F.2d 1012, 1018, 201 USPQ 552, 557 (CCPA 1979); In re May, 574 F.2d 1082, 1094, 197 USPQ 601, 611 (CCPA 1978); In re Hoch, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970). Thus, the expectation that compounds similar in structure will have similar properties leads one to the conclusion that the compounds will have similar utilities.

In the case before us, the relied upon prior art references to Watts and King describe their compounds as having multiple identical utilities (see Watts at column 4, lines 47 through 56

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and King at column 7, lines 38 through 54), albeit neither Watts nor King specifically indicates that these prior art compounds exhibit 5-HT₄ agonist activity, as possessed by some of the compounds covered by the appealed claims. In this regard, on remand, the examiner should indicate why appellants' finding at paragraphs 4.6 and 4.7 of the Flynn declaration that a compound covered by the appealed claims exhibits approximately 3.5 times more 5-HT₄ agonist activity than the preferred compound of Watts would not have been unexpected to a person of ordinary skill in this art. Compare In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439, (Fed. Cir. 1987) wherein the court held that evidence that a compound is unexpectedly superior in one of a spectrum of common properties can be enough to rebut a prima facie case of obviousness.

The examiner should also consider, on remand, whether or not the comparative showing in the Flynn declaration, which is limited to a single compound covered by the claims (a salt having 0.4 H₂O), is reasonably commensurate in scope with any claim presented on appeal.

On remand to the examiner, the examiner should consider whether there is any factual support for rejection of the appealed claims based on the relied upon prior art references

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under 35 USC § 102. The examiner should also reevaluate the prima facie case of obviousness based on structural obviousness legal theories giving appropriate consideration to the properties and uses of the claimed compounds and the prior art compounds. Finally, the examiner should reevaluate the evidence of record and specifically the evidence in the Flynn declaration as to whether or not any prima facie case of obviousness has been adequately rebutted and particularly whether such evidence is reasonably commensurate in scope with any claim on appeal.

Accordingly, in summary, the examiner's rejection of certain appealed claims under 35 USC § 112, first paragraph, is reversed. With respect to the examiner's obviousness rejection of the appealed claims, this application is remanded to the examiner for further consideration.

REVERSED & REMANDED

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| JOHN D. SMITH |) | |
| Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
| CHARLES F. WARREN |) | |
| Administrative Patent Judge |) | APPEALS AND |
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