

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EDMUND P. HARRIGAN, JOTHAM W. COE,
BRIAN T.O'NEILL, STEVEN B. SANDS, and
ERIC JACOB WATSKY

Appeal No. 2006-0429
Application No. 10/348,399

ON BRIEF

Before ADAMS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to pharmaceutical compositions comprising a nicotine receptor agonist and either an antidepressant or anxiolytic agent. The examiner has rejected the claims as obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. Because we conclude that the references cited by the examiner support a prima facie case of obviousness, but for reasons different from those advanced by the examiner, we vacate the rejection on appeal and enter two new grounds of rejection.

Background

The specification discloses “pharmaceutical compositions for the treatment of nicotine dependence or addiction in a mammal (e.g. human) comprising a nicotine receptor partial agonist (NRPA) and an anti-depressant or anxiolytic agent. The term NRPA refers to all chemical compounds which bind at neuronal nicotinic acetylcholine specific receptor sites in mammalian tissue and elicit a partial agonist response.” Page 1.

“[P]articular NRPA compounds . . . which can be employed in the method and pharm[aceutical] compositions of this invention, can be made by processes known in the chemical arts, for example by the methods described in . . . WO 9935131-A1.”

Page 16, lines 16-17.

Discussion

1. Rejection on appeal

The examiner rejected claims 1-7 and 9 under 35 U.S.C. § 103 as obvious in view of Coe,¹ the PDR Sinequan[®] entry,² the PDR Zoloft[®] entry,³ and Cary.⁴ The examiner reasoned, basically, that the references teach that all of the compounds recited in the present claims are useful for treating depression and therefore those skilled in the art would have found it obvious to combine them into a single composition for treating depression. See the Examiner’s Answer, pages 3-4.

¹ Coe et al., WO 99/35131, published July 15, 1999.

² Physicians’ Desk Reference, pp. 2366-2367 (2000). Although the examiner cited the 2000 edition of the PDR, the Sinequan entry states that it was “[r]evised May 1996” and Appellants have not argued that Sinequan[®] was not known in the art prior to this application’s effective filing date.

³ Physicians’ Desk Reference, pp. 2051-2053 (1997).

⁴ Cary, WO 99/17803, published April 15, 1999.

Appellants have argued, however, that those skilled in the art would not have been led to combine all the cited references because the compounds taught by Coe are nicotine receptor agonists and the ones taught by Cary are nicotine receptor antagonists; given these directly conflicting modes of action, those skilled in the art would not have been led to combine them. See the Appeal Brief, pages 6-8.

Appellants' argument raises serious questions about whether the examiner's prima facie case could be sustained. We choose not to answer those questions, however, because we believe that the references provide more pertinent teachings than those relied on by the examiner. We therefore vacate the examiner's rejection and enter the following new grounds of rejection.

2. Claims

Claims 1-7 and 9 are on appeal. Claims 8 and 10-21 are also pending but have been withdrawn from consideration by the examiner.

Claims 1-5 and 9 read as follows:

1. A pharmaceutical composition for treating nicotine dependence or addiction, tobacco dependence or addiction, reducing nicotine withdrawal symptoms or aiding in the cessation or lessening of tobacco use or substance abuse, comprising a therapeutically effective combination of a nicotine receptor partial agonist and an anti-depressant or anxiolytic agent, and a pharmaceutically acceptable carrier.
2. The pharmaceutical composition according to Claim 1, wherein said anti-depressant is selected from tricyclic anti-depressant, a serotonin reuptake inhibitor anti-depressant, an atypical anti-depressant or a monoamine oxidase inhibitor, their pharmaceutically active salts and their optical isomers.
3. The pharmaceutical composition according to Claim 2, wherein said anti-depressant is selected from amitryptyline, imipramine, sertraline, paroxetine, fluoxetine, bupropion, nefazodone, tranylcypromine,

moclobemide, venlafaxine, or phenelzine, their pharmaceutically active salts and their optical isomers.

4. The pharmaceutical composition according to Claim 1 wherein said anxiolytic agent is selected from a benzodiazepine or a non-benzodiazepine anxiolytic, their pharmaceutically active salts and their optical isomers.
5. The pharmaceutical composition according to Claim 4, wherein the anxiolytic agents are selected from diazepam, alprazolam, hydroxyzine or doxepin, their pharmaceutically active salts and their optical isomers.
9. The pharmaceutically composition according to Claim 5, wherein the anxiolytic agent is doxepin.

Claim 6 depends on claim 1 and recites a list of specific nicotine receptor partial agonists. Claim 7 depends on claim 6 and recites a subset of the same compounds. Both lists include 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene and its pharmaceutically acceptable salts.

2. Claims 1-3, 6, and 7

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 1-3, 6, and 7 are rejected under 35 U.S.C. § 103 as obvious in view of Coe and the PDR Zoloft® entry. Coe discloses a group of aryl fused azapolycyclic compounds useful in treating a variety of conditions. See page 1, lines 7-22. One of the disclosed compounds is 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene hydrochloride. Page 6, line 13. Coe teaches that the disclosed compounds “may also be used in combination with an antidepressant such as, for example, a tricyclic antidepressant or a serotonin reuptake inhibiting antidepressant (SRI), in order to treat both the cognitive decline and depression associated with AD [Alzheimer’s disease], PD

[Parkinson's disease], stroke, Huntington's chorea or traumatic brain injury." Page 1, lines 23-26.

The PDR Zoloft® entry teaches that Zoloft® is a trade name for sertraline hydrochloride (page 2051, left-hand column, under "Description"), that it is a "selective serotonin reuptake inhibitor" (id., middle column, under "Warnings") and that it is useful in treating depression (id., middle column, under "Indications and usage").

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene hydrochloride disclosed by Coe with the serotonin reuptake inhibiting antidepressant sertraline hydrochloride, because Coe teaches that the combination is useful for treating the cognitive decline and depression associated with, for example, Alzheimer's disease.

A pharmaceutical composition comprising 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene hydrochloride and sertraline hydrochloride meets all the limitations of claims 1-3, 6, and 7. The preamble of claim 1 does not distinguish the claimed composition from the one made obvious by the prior art because it is merely a statement of intended use. See Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("Where . . . a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.").

3. Claims 1, 4-7, and 9

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 1, 4-7, and 9 are rejected under 35 U.S.C. § 103 as obvious in view of Coe, Cary, and the PDR Sinequan® entry. As discussed above, Coe discloses a group of aryl fused azapolycyclic compounds useful in treating a variety of conditions, including “chemical dependencies and addictions (e.g., dependencies on, or addictions to nicotine (and/or tobacco products) . . .).” See page 1, lines 7-17. See also page 76, lines 17-20 (claim directed to composition for treating nicotine addiction). One of the disclosed compounds is 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene hydrochloride. Page 6, line 13.

Cary teaches that “[a]nxiolytics have been administered to treat nicotine withdrawal. Anxiolytics counter the mild anxiety symptoms that occur during smoking cessation treatment.” Page 3, lines 20-22.

The PDR entry for Sinequan® (doxepin hydrochloride; page 2366, middle column under “Description”) discloses that it is useful in treating anxiety (page 2366, right-hand column, under “Indications”); i.e., it is an anxiolytic.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene hydrochloride disclosed by Coe with the anxiolytic doxepin hydrochloride because Coe teaches that the first compound is useful in treating nicotine addiction and Cary teaches that anxiolytics such as doxepin hydrochloride are useful in treating the anxiety that accompanies smoking cessation.

A pharmaceutical composition comprising 4,5-difluoro-10-aza-tricyclo [6.3.1.0^{2,7}] dodeca-2(7),3,5,-triene hydrochloride and doxepin hydrochloride meets all the limitations of claims 1, 4-7, and 9. The preamble of claim 1 does not distinguish the claimed composition from the one made obvious by the prior art because it is merely a statement of intended use. See Rowe v. Dror, 112 F.3d at 478, 42 USPQ2d at 1553.

Summary

We vacate the examiner's rejection and enter two new rejections based on obviousness. We have considered the arguments presented in the Appeal Brief and Reply Brief but do not find them relevant to the new grounds of rejection.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

VACATED, 37 CFR 41.50(b)

Donald E. Adams)
Administrative Patent Judge)
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)
) BOARD OF PATENT
Demetra J. Mills)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Eric Grimes)
Administrative Patent Judge)

Pfizer Inc.
150 East 42nd Street
5th Floor – Stop 49
New York, NY 10017-5612