

Appeal No. 1996-2910
Application 07/825,488

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 39

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAYMOND M. XHONNEUX and GUY R.E. VAN LOMMEN

Appeal No. 1996-2910
Application 07/825,488

HEARD: January 13, 2000

Before WINTERS, GRON and ROBINSON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 21, 22, 24, 25 and 26, appeal having been withdrawn with respect to claims 20 and 23.

Claims 25, 26 and 22 are representative and a copy of same is appended to this decision.

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The reference relied on by the examiner is:

Van Lommen et al. (Van Lommen) 4,654,362 March 31, 1987

PRELIMINARY MATTERS

Claims 20 through 26 were finally rejected under 35 U.S.C. §§ 102 (a) and (b) as described by Van Lommen (Paper no. 14, February 15, 1994), but both rejections were expressly withdrawn in the Examiner's Answer (page 3).

In the final rejection, claims 20 through 26 were also rejected under 35 U.S.C. § 103 as unpatentable over Van Lommen together with Van de Water.¹ In their Brief, appellants argued that Van de Water "was not a proper reference because the Van de Water et al. article was published [after] . . . the filing date of their parent application Serial No. 07/172,747" and pointed to portions of the parent disclosure that supported the claims on appeal (Brief, pages 12 through 14). The examiner continued the rejection in the Examiner's Answer without addressing appellant's argument. Following an exchange of Reply Briefs (paper nos. 23 and 26) and Supplemental Examiner's Answers (paper nos. 25 and 27), the examiner apparently conceded the issue ("Appellant has provided information indicating the Van de Water et al publication was issued after the effective date of the parent application . . . The Van de Water et al teaching . . . is not required to obviate the presented claims"). See the Supplemental

¹ Van de Water et al., Chem Abstracts No. 110:50943v (1989).

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Examiner's Answer, paper no. 27. Therefore, we shall treat this rejection as having been withdrawn.

During oral argument counsel for appellants, Ellen Ciambrone Coletti, withdrew the appeal with respect to claim 20. Appeal was also withdrawn with respect to claim 23 (which depends from claim 20) pursuant to a telephone conversation with counsel on February 16, 2000.

Accordingly, the appeal with respect to claims 20 and 23 is dismissed, and the only rejection remaining for our consideration is that of claims 21, 22, 24, 25 and 26 under 35 U.S.C. § 103 as unpatentable over Van Lommen. For the reasons set forth below, we reverse the rejection. In addition, we raise several issues for consideration on return of the application to the examining group.

DISCUSSION

Van Lommen discloses unresolved stereoisomeric mixtures of the antihypertensive compound α,α' -[iminobismethylene]bis[6-fluoro-3,4-dihydro-2*H*-1-benzopyran-2-methanol] (compounds 84 and 87, column 21). The compound has four chiral carbons, and ten possible stereoisomers. As acknowledged in the Brief (page 7) and oral argument, compound 84 is an unresolved mixture of four of the ten isomers, designated RSSS, SRRR, RSRR and SRSS. At column 4, lines 40-58, Van Lommen states that "[p]ure stereochemically isomeric forms of the compounds . . . may be obtained by the application of art-known procedures" and "[s]tereochemically isomeric

forms of the compounds . . . are naturally intended to be embraced within the scope of the invention.”

Claim 25 is directed to “[a] composition consisting essentially of” the RSSS stereoisomer of α,α' -[iminobismethylene]bis[6-fluoro-3,4-dihydro-2*H*-1-benzopyran-2-methanol], while claim 26 is directed to “[a] pharmaceutical composition consisting essentially of” a combination of the RSSS stereoisomer and its enantiomer, SRRR.

The examiner’s statement of the rejection is as follows:

Van Lommen et al and Van de Water et al teach the claim designated compounds as old, well known and in combination with various carriers and excipients as useful for the claimed utility. This teaching includes all position isomers inherent in the claimed compound. The skilled artisan would have known that various isomers would exhibit biological activity at various levels. . . [T]he skilled artisan would have seen optical isomer separation as a routine procedure leading to the compounds claimed herein . . . such artisan would have expected the various biological activity levels set forth herein. It would follow therefore that the instant claims recite prima facie obvious subject matter and are properly rejected under 35 USC 103. (Final Rejection, page 3.)

For purposes of this appeal we accept, without deciding, that the examiner has established a prima facie case of obviousness against claims 21, 22 and 24 through 26. Nevertheless, a conclusion of prima facie obviousness does not end a patentability determination under 35 U.S.C. § 103. 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. (Citations omitted).

The Declaration of Raymond Xhonneux, filed January 24, 1992 under the provisions of 37 CFR § 1.132, presents evidence supporting a conclusion that the RSSS stereoisomer, unlike its enantiomer, SRRR, “only minimally affects blood pressure when administered alone” but significantly “potentiates the antihypertensive effects of the (SRRR)-compound, but not the bradycardiac affects [sic] of the (SRRR)-compound.” See page 4 of the Declaration. The examiner does not propose any reason why a person having ordinary skill in the art would have expected the RSSS stereoisomer to have such properties. Nor does the examiner contend that the potentiating property, described in the declaration, is insignificant. Therefore, we reverse the rejection of the claims under 35 U.S.C. § 103 on the strength of appellants’ rebuttal evidence establishing that the claimed subject matter possesses unexpectedly superior results.

OTHER ISSUES

As stated previously, the appealed claims were finally rejected under 35 U.S.C. §§ 102 (a) and (b) (Paper no. 14, February 15, 1994). The claims were said to be described by Van Lommen, without clarification or explanation. On pages 6 through 9 of their Brief, appellants argue that Van Lommen discloses only unresolved mixtures of stereoisomers, and so does not anticipate the RSSS stereoisomer alone (claim 25), or in combination with its enantiomer, SRRR (claim 26). The examiner was persuaded by that argument, and both rejections were expressly withdrawn in the Examiner’s Answer (page 3).

Inasmuch as the rejections under 35 U.S.C. §§ 102 (a) and (b) were entered and withdrawn without meaningful explanation from the examiner, it is unclear on the record (1) whether independent claim 25 was evaluated under the appropriate legal standards; or (2) whether the scope of independent claim 26 was properly interpreted.

(1) Claim 25 is directed to a composition consisting essentially of the R₁R₂S₁S₂ stereoisomer of α,α' -[iminobismethylene]bis[6-fluoro-3,4-dihydro-2*H*-1-benzopyran-2-methanol] or a pharmaceutically acceptable acid addition salt thereof. Van Lommen discloses compound 84, which has a bilaterally symmetrical structure identical to the compound of claim 25, but has the isomeric designation "AB" (column 21). As explained in the paragraph bridging columns 4 and 5 of Van Lommen, "A" and "B" specify the stereochemical configuration at the compound's four chiral centers. Because "A" corresponds to the RS or SR configuration, and "B" corresponds to the SS or RR configuration, the "AB" designation indicates that compound 84 is an unresolved mixture of four stereoisomers: R₁R₂S₁S₂, S₁R₁R₂R₂, R₁S₁R₂R₂ and S₁R₁S₂S₂. Appellants' argument at pages 7 through 9 of the Brief is consistent with this. Moreover, at column 4, lines 40-58, Van Lommen states that "[p]ure stereochemically isomeric forms of the compounds . . . may be obtained by the application of art-known procedures" and "are naturally intended to be embraced within the scope of the invention."

As stated in In re Schaumann, 572 F.2d 312, 315, 197 USPQ 5, 8 (CCPA 1978), a "fundamental question presented by this appeal is whether the disclosure of a chemical genus may ever constitute a description of a specific compound falling within

the ambit of the genus.” That case involved a generic prior art disclosure embracing seven compounds. The court held that the genus “embrace[d] a very limited number of compounds closely related to one another in structure” and “led inevitably to the conclusion that the reference provide[d] a description of those compounds just as surely as if they were identified in the reference by name.” In re Schaumann, 572 F.2d at 1316-17, 197 USPQ at 9. Under this reasoning, Van Lommen’s disclosure of compound 84, together with its designation “AB,” appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers “just as surely as if they were identified in the reference by name.” On return of this application, the examiner should consider whether a person having ordinary skill in the art would have envisioned each individual stereoisomer (RSSS, SRRR, RSRR, SRSS) in light of Van Lommen’s disclosure of compound 84; and whether Van Lommen constitutes an enabling disclosure, i.e., puts a person having ordinary skill in possession of each stereoisomer.

Appellants, on the other hand, cite In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) for the proposition that “the novelty of an optical isomer is not negated by the prior art disclosure of its racemate.” According to appellants, “a reasonable interpretation of the holding in May et al. is that the disclosure in the prior art of a base compound that has stereoisomeric configurations is not an anticipation of particular stereoisomers of that base compound.” See Appendix II, accompanying appellants’ main Brief, page 29, last paragraph.

On return of this application, we recommend that the examiner reevaluate the patentability of claim 25 under 35 U.S.C. § 102 in light of the Van Lommen reference, the decisions in Schaumann and May, and the foregoing remarks.

(2) In making a patentability determination, “[a]nalysis begins with a key legal question -- what is the invention claimed?” since “[c]laim interpretation . . . will normally control the remainder of the decisional process,” Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987).

Claim 26 is directed to a pharmaceutical composition “consisting essentially of” a pharmaceutically acceptable carrier, and as active ingredients, (a) the blood pressure reducing SRRR stereoisomer of α,α' -[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] or a pharmaceutically acceptable acid addition salt thereof and (b) its enantiomer, RSSS, or a pharmaceutically acceptable acid addition salt thereof; the RSSS stereoisomer being present in an amount capable of potentiating the blood pressure lowering effect of the SRRR stereoisomer. It is well settled that “the phrase ‘consisting essentially of’ limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition.” In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). Here, a basic and novel characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity.

Van Lommen's antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. Because the RSRR and SRSS stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the composition of claim 26. On return of the application, we recommend that the examiner reevaluate the patentability of claim 26, and any claims depending therefrom, under 35 U.S.C. § 102 in light of Van Lommen. Specifically, the examiner should consider whether claim 26 "reads on" Van Lommen's compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

It is axiomatic that one cannot patent what is old. If, on return of this application to the examining group, the examiner determines that any claim or claims are described by Van Lommen within the meaning of 35 U.S.C. § 102, we emphasize that "[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) (citations omitted). In other words, if the examiner determines that the claimed subject matter is described by Van Lommen under 35 U.S.C. § 102, declaration evidence establishing unexpectedly superior results would be unavailing to

the appellants. See In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962) (Even though appellants' claimed compound may exhibit antivitamin activity, a property not disclosed by Karrer, this fact is not significant here because appellants' invention *as defined in these claims is described* in the Karrer patent.). Emphasis original. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Without novelty, evidence of unobviousness is superfluous.)

CONCLUSION

In conclusion, for the reasons set forth in the body of this opinion, the appeal with respect to claims 20 and 23 is dismissed. The rejection of claims 21, 22 and 24 through 26 under 35 U.S.C. § 103 as unpatentable over Van Lommen is reversed. In addition, we raise several issues for consideration on return of this application to the examining group.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
TEDDY S. GRON)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
DOUGLAS W. ROBINSON)

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Administrative Patent Judge)

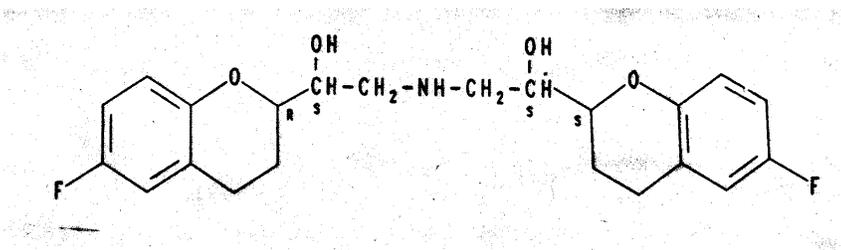
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APPENDIX A

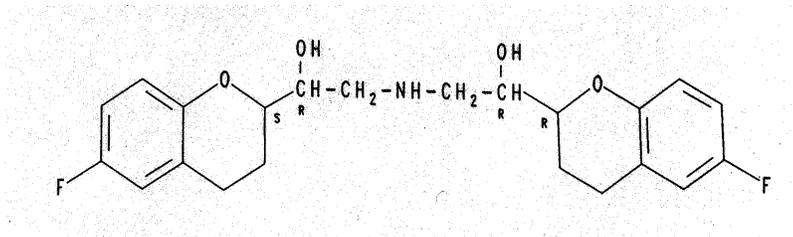
25. A composition consisting essentially of the compound [2R,αS,2'S,α'S]-α,α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof.

26. A pharmaceutical composition consisting essentially of a pharmaceutically acceptable carrier and, as active ingredients:

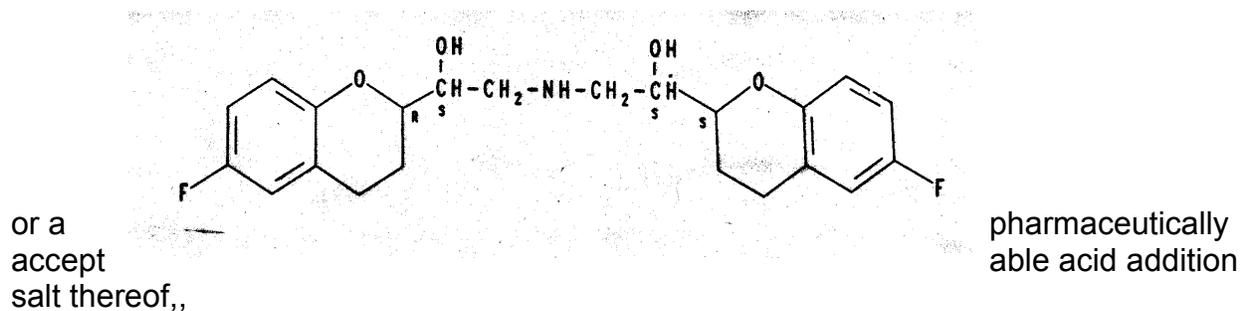
(a) the blood pressure reducing compound [2S,αR,2'R,α'R]-α,α'-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof; and

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(b) the compound [2R,αS,2'S,α'S]-α,α'-[iminobismethylene]bis [6-fluoro -3,4-dihydro-2H- 1-benzopyran-2-methanol] having the formula:



Compound (b) being present in an amount capable of potentiating the blood pressure lowering effect of compound (a), above.

22. A method of treating hypertension in warm blooded animals in need of such treatment which comprises administering to said warm blooded animals an effective amount of the pharmaceutical composition of Claim 26.