

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ULRICH SPECK

Appeal No. 95-5133
Application 08/135,523¹

ON BRIEF

Before WINTERS, WILLIAM F. SMITH and ROBINSON, , Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of

¹ Application for patent filed October 12, 1993. According to appellant, the application is a continuation of Application 07/365,935, filed June 15, 1989, now U.S. Patent No. 5,288,716 issued February 22, 1994; which is a continuation-in-part of Application 07/156,990, filed February 18, 1988.

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claims 1, 5-8, 10-12 and 14, all of the claims pending in the application.

Claims 1 and 14 are illustrative of the claims on appeal and are appended to this decision.

The references relied upon by the examiner are:

A. H. Merrill et al. (Merrill), "Diseases Associated with Defects in Vitamin B6 Metabolism or Utilization", Ann. Rev. Nutr. , Vol. 7, pages 144-147 (1987)

A. Osol et al. (Remington's), Remington's Pharmaceutical Sciences, 16th edition, Merck Publishing Co. (PA.), pages 960-961 (1980)

M. Windholz et al. (Merck), The Merck Index, Merck & Co., page 1151, cit. 7878 (1983)²

Grounds of Rejection

Claim 14 stands rejected under 35 U.S.C. § 102, as anticipated by Merck.

Claims 1, 5-8, and 10-12 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Merrill and Remington's

We affirm the rejection under 35 U.S.C. § 102 and reverse the rejection under 35 U.S.C. § 103.

Claims:

² The examiner in his answer and appellant in his principal brief have referred to The Merck Index, page 1151, item 7880. However, item 7880 describes "Pyridoxamine Dihydrochloride", while item 7878 at page 1151 describes "pyridoxal". In our consideration of this reference, we have considered the disclosure and the examiner's reliance on the reference to be directed to item 7878 as it relates to the compound pyridoxal.

Claim 1 is directed to a method of preventing atherosclerosis and/or treating hyperlipidemia or atherosclerosis using structurally defined pyridoxine derivatives. Claim 14 is directed to a composition comprising a pharmaceutically acceptable carrier in combination with the structurally defined pyridoxine derivatives. The pyridoxine derivative are stated to be present in the composition in an amount effective to prevent atherosclerosis and/or to treat hyperlipidemia or atherosclerosis. In both claims 1 and 14, when R₁ and R₂ together are oxygen and X is H, the pyridoxine derivative is pyridoxal.

BACKGROUND

The applicant's invention, as described at page 1 of the specification, is directed to use of pyridoxine derivatives in the prevention and treatment of hyperlipidemia and atherosclerosis.

The Rejection under 35 U.S.C. § 102

Claim 14 stands rejected under 35 U.S.C. § 102 as anticipated by Merck. The examiner relies on Merck as disclosing an aqueous and alcoholic composition comprising 1 gram of pyridoxal dissolved in 2ml. of water. The examiner compares the composition of Merck to the composition of claim 14 and refers to the specification, page 12, last 2 lines through page 13, first 2 lines, which discloses daily dosages of 20mg and 1000mg in 1-3 doses, as supporting the determination that the amount of pyridoxal disclosed in the aqueous composition of the reference corresponds to the claimed "amount . . . effective to prevent atherosclerosis and/or to treat hyperlipidemia or atherosclerosis" required by claim 14. Where functional language is used, it is appropriate to look to the specification

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for guidance in determining the finite amounts which correspond to the functional language. See In re Woodruff, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); In re Herz, 537, f.2d 549, 190 USPQ 461 (CCPA 1976). On the

record before us, we find that the examiner has established a prima facie case of unpatentability of the claimed composition over the disclosed composition of the reference.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In rebuttal, appellant urges that Merck does not anticipate the composition of claim 14 and points to the lack of a disclosed utility which would suggest a pharmaceutical composition as claimed. However, a disclosure which disclosed products and a method of making the product but lacks a teaching of how to use the product for a specific, substantial utility is entirely adequate to anticipate a claim to the product. In re Schoenwald, 964 F.2d 1122, 1123, 22 USPQ2d 1671, 1673 (Fed. Cir. 1992), In re Hafner, 410 F.2d 1403, 1405, 161 USPQ 783, 785 (CCPA 1969). A new use for an

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old product will not render that product patentable as such. In re Spada, *supra*. Thus, appellant's arguments are not persuasive of error in the examiner's determination that claim 14 does not patentably distinguish over Merck. We affirm the rejection of claim 14 under 35 U.S.C. § 102(b).

The Rejection under 35 U.S.C. § 103

Claims 1, 5-8, and 10-12 stand rejected under 35 U.S.C. § 103 as obvious over Merrill in view of Remington's.

The examiner cites Merrill as establishing a causal relationship between deficient vitamin B₆ levels in mammals and atherosclerosis. He notes, particularly, page 144, last paragraph which states:

The first association of vitamin B₆ and vascular disease was the observation . . . that monkeys fed a diet deficient in this nutrient developed atherosclerosis.

The examiner relies on Remington's as disclosing that pyridoxal is an active form of vitamin B₆.

The examiner concludes (Answer, page 4) that:

it would have been obvious to administer pyridoxal for treating and/or preventing atherosclerosis and/or hyperlipidemia associated with low vitamin B₆ levels.

It is the initial burden of the patent examiner to establish that claims presented in an application for patent are unpatentable. In re Oetiker, 977 F.d. 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). On the record before us, we agree that the examiner has made out a prima facie case of unpatentability of the claimed subject matter. Where, as here, a prima facie case of obviousness has

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been established, the burden of going forward shifts to the appellants. In re Piasecki, 745 F.2d. 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984), In re Rinehart, 531 F.2d. 1048, 1052, 189 USPQ 143, 147, (CCPA 1976).

While conceding that vitamin B₆ is a collective term for the naturally occurring pyridines: pyridoxine, pyridoxal and pyridoxamine, appellant urges that the combination of Merrill and Remington's do not suggest the use of the claim designated pyridine derivatives for the treatment and prevention of atherosclerosis and/or hyperlipidemia. (principal brief, page 4). More persuasive is the evidence of record, in the form of the two declarations filed under 37 CFR §1.132 by Dr. Schneider. In evaluating this evidence, particularly Tales 1 and 2, of the declaration filed October 11, 1994, copies of which are attached to appellant's principal brief, we find that the declaration evidence demonstrate that the three natural ccurring pyridine derivatives demonstrate widely varying effects on the factors associated with atherosclerotic and hyperlipidemia. Considered in the most favorable light, the facts established by the examiner would have suggested that administration of any one of the three known vitamin B₆ components would have been expected to be result in substantially equal effectiveness in treating or preventing atherosclerosis. There is nothing of record, and the examiner points to no facts, which would have suggested that the three components of vitamin B₆ would have been expected to give

such varying results as demonstrated in Tables 1 and 2 of the Schneider declaration.

In response to the declaration evidence, the examiner initially (Answer, page 8) states that "the data, taken as a whole, does not clearly provide a basis for concluding non-obviousness." The examiner concludes that "the values were not shown to be statistically significant and thus no different than the control group." However, the examiner fails to provide any facts or reasons as to why the data is considered to lack statistical significance. In addition the examiner (Answer, page 9) points to inconsistencies between the first Declaration, originally filed in the parent application, and the second declaration filed in this application. At page 2 of the Reply Brief, appellant explains these inconsistencies and urges that the second Declaration provides a more appropriate comparison in that the side-by-side comparison with a single control provides a more valid comparison. The examiner fails to respond to this point in the letter of May 5, 1995. For many inventions that seem quite obvious, there is no absolute predicatability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

On the record before us, we find the evidence presented by appellant is sufficient to overcome

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the prima facie case of unpatentability over Merck and Remington's. See In re Papesch, 315 F.2d 381, 386, 137 USPQ 43, 47 (CCPA 1963).

The rejection of claims 1, 5-8, and 12 under 35 U.S.C. § 103 is reversed.

Other Matters:

Should further prosecution take place before the examiner, we urge the examiner to step back and consider, anew, the disclosure of French Patent 2,255,883³. While the invention described in the French patent is to a combination of clofibric acid and at least one substance with vitamin B₆ activity, it would appear that the patent also discloses that “substances with B₆ action had a good hypocholesterolemic . . . action.” Such a disclosure might reasonably suggest the use of this compound in the treatment and prevention of atherosclerosis and/or hyperlipidemia. The examine should note particularly pages 2 and 3 of the translation. See also Table 1 where the effect of vitamin B₆ per se, i.e., not co-administered with clofibric acid, on levels of serum cholesterol and serum lipids is

³ A translation of this reference has been prepared for the PTO by Diplomatic Language Services, Inc., in March 1999, a copy of which is attached to this decision.

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described in “Lot D.” Since Lot D includes active agents required by the claims on appeal, that example might anticipate or render obvious the claims on appeal.

SUMMARY

To summarize, the decision of the examiner to reject claim 14 under 35 U.S.C. § 102 is affirmed. The decision of the examiner to reject claims 1, 5-8, and 10-12 under 35 U.S.C. § 103 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

SHERMAN D. WINTERS)
Administrative Patent Judge)
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) BOARD OF PATENT

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WILLIAM F. SMITH
Administrative Patent Judge

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) APPEALS AND

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) INTERFERENCES

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DOUGLAS W. ROBINSON
Administrative Patent Judge

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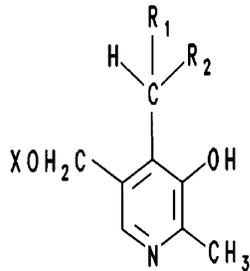
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APPENDIX

1. A
atherosclerosis
or
administering to
amount of a
according to



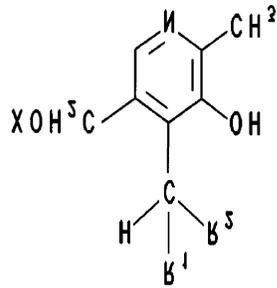
(I)
method for prevention of
and/or for treatment of hyperlipidemia
atherosclerosis comprising
a host in need thereof an effective
compound or a mixture of compounds
formula (I)

wherein
R₁ and R₂ together are oxygen

and X is $\begin{matrix} \text{O} \\ | \\ \text{2} \end{matrix}$ hydrogen or -C-R₃, R₃ being independently,
hydrogen, C₁₋₆-alkyl, C₂₋₆-alkenyl, (hydroxy or
C₁₋₄-alkoxy) -C₁₋₆-alkyl or C₆₋₁₄-aryl or
substituted aryl,

or a pharmaceutically acceptable salt of said compound;
with the proviso that:

when X is H, then the resultant compounds is not coadministered with clofibric acid or an ester
or salt thereof.



(I)

14. A pharmaceutical amount of effective to treat hyperlipidemia or atherosclerosis,

composition comprising a pharmaceutically acceptable carrier and a compound of the formula (I) to prevent atherosclerosis and/or to

wherein R₁ and R₂ together are oxygen

and X is hydrogen or $-\overset{\text{O}}{\underset{2}{\text{C}}}-\text{R}_3$, R₃ being independently, hydrogen, C₁₋₆-alkyl, C₂₋₆-alkenyl, (hydroxy or C₁₋₄-alkoxy) -C₁₋₆-alkyl or C₆₋₁₄-aryl or substituted aryl,

or a pharmaceutically acceptable salt of said compound; with the proviso that:

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when X is H, then the resultant compounds is not coadministered with clofibric acid or an ester or salt thereof.