

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte W. HARRY MANDEVILLE, and STEPHEN RANDALL

Appeal No. 2003-0564
Application No. 08/964,498

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

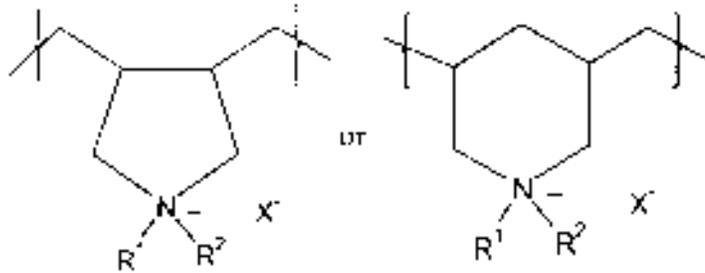
DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 9-18. Claims 1-8 and 19-28 are also pending but have been withdrawn from consideration. See Paper No. 19, mailed Nov. 7, 2000.

Claim 9 is representative of the claims on appeal and is reproduced in an appendix to this opinion.

1. A method for lowering the serum phosphate level of a patient comprising administering to the patient a therapeutically effective amount of a polymer characterized by a substituted or unsubstituted diallylamine repeat unit.

9. The method of Claim 1 wherein the polymer comprises a repeat unit of the general formula



wherein R¹ and R² are each, independently, is hydrogen, a substituted or unsubstituted, normal, branched or cyclic alkyl group, or a substituted or unsubstituted aryl group; or R¹, R² and the nitrogen atom together form a cyclic system; and X is a pharmaceutically acceptable anion.

The examiner relies on the following references:

Howes	2,090,605	Dec. 12, 1980
Holmes-Farley	WO 95/05184	Feb. 23, 1995

Claims 9-18 stand rejected under 35 U.S.C. § 103 as obvious in view of

Howes and Holmes-Farley.¹

We reverse.

Background

Elevated phosphate levels, or hyperphosphatemia, “frequently accompanies diseases associated with inadequate renal function, hypoparathyroidism, and certain other medical conditions.” Specification, page 1. The condition can cause “aberrant calcification in joints, lungs, and eyes.” Id.

¹ The rejection based on Howes and Holmes-Farley is the only rejection applied to the claims, despite the examiner’s statement that he “could just as well make the rejection combining newly submitted Patent Document EPA 793960.” Paper No. 19, mailed Nov. 7, 2000, page 2. The ‘960 reference was not cited as a basis for the rejection, nor did the examiner provide any explanation whatsoever of how it might form a basis for rejecting the claims. To the extent that the examiner

Treatments for hyperphosphatemia include “oral administration of insoluble phosphate binders to reduce gastrointestinal absorption.” Id. Phosphate binders that have been used in such therapies include calcium salts, aluminum salts, and ion exchange resins. See id., pages 2-3. All of these agents, however, can cause serious side effects. See id.

The specification discloses a method of lowering the serum phosphate level of a patient by administering a polymer having diallylamine repeat units. These poly(diallylamine) polymers are disclosed to have “excellent phosphate-binding activity.” Page 4.

Discussion

Claim 9, the broadest claim on appeal, is directed to a method for lowering the serum phosphate level in a patient by administering a therapeutically effective amount of a poly(diallylamine) that comprises repeat units having one of two recited structures. The structures comprise a heterocyclic, five- or six-membered ring that includes a quaternary ammonium group.

The examiner rejected the claimed method as obvious in view of Howes and Holmes-Farley. The examiner’s statement of the rejection reads as follows:

[Howes] teaches polymers comprising heterocyclic diallyl ammonium monomers (Abstract). [Holmes-Farley] teaches phosphate binding polymers for treating hyper phosphatemia (Abstract). Quaternary amines are specified (claim 31).

It would have been obvious to one of ordinary skill to use the polyallylamines of [Howes] to treat hyper phosphatemia in view of

intended to imply an alternative basis for the rejection, we vacate any implied rejection based on references other than Howes and Holmes-Farley.

the teaching of [Holmes-Farley] that quaternary polyallylamines are effective for so treating.

Paper No. 19, mailed Nov. 7, 2000, page 2.

Appellants argue that the cited references do not support a prima facie case of obviousness. See the Revised Brief on Appeal, page 5: Howes “discloses antimicrobial polymers with diallyl repeat units but does not suggest using the polymers for treating hyperphosphatemia,” while Holmes-Farley does not suggest using polymers of cyclic diallyl monomers, such as those of Howes, for treating hyperphosphatemia. Appellants conclude that, at best, “the Examiner has shown that the disease state is known to be treated by a different product and that a polymer falling within the scope of some of the claims is known to treat a different disease.” Id., page 7.

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). An adequate prima facie case requires, among other things, evidence showing that those of ordinary skill in the art would have been led to combine the elements known in the prior art in such a way as to yield the claimed invention. See In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (“[T]o establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or

teaching of the desirability of making the specific combination that was made by the applicant.”).

An adequate showing of motivation to combine requires “evidence that ‘a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.’” Ecolchem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000).

In this case, we agree with Appellants that the examiner has not shown that the claimed method would have been obvious based on the cited references. Howes discloses heterocyclic polymers comprising quaternary ammonium units that fall within the formulas recited in the instant claims. Howes, however, does not disclose that the polymers are useful for treating hyperphosphatemia or that they have properties (e.g., phosphate binding) that would suggested such a use. Instead, Howes discloses that the polymers have antimicrobial activity and are useful for sterilization of contact lenses and for treatment of bacterial infection of the skin. See the abstract.

Holmes-Farley teaches treatment of hyperphosphatemia using phosphate-binding polymers comprising tertiary or quaternary ammonium units. The polymers disclosed by Holmes-Farley, however, are made up of acyclic subunits and therefore do not fall within the formulas recited in the instant claims. See pages 3-7. Nor does Holmes-Farley suggest that all polymers comprising tertiary or quaternary ammonium units would work in the disclosed method.

Rather, the method is disclosed to require “oral administration . . . of a composition containing at least one phosphate-binding polymer that is non-toxic and stable once ingested.” Page 2. Holmes-Farley defines “non-toxic” to mean that “neither the polymers nor any ions released into the body upon ion exchange are harmful,” and defines “stable” to mean that “the polymers do not dissolve or otherwise decompose to form potentially harmful by-products, and remain substantially intact so that they can transport bound phosphate out of the body.” Page 3.

The examiner has argued that “the fact that both the polymers of [Holmes-Farley] and [Howes] contain quaternary amine groups would inform one of ordinary skill that, with regard to methods of use of [sic] implicating the quaternary amine, the polymers will be functionally similar.” Examiner’s Answer, page 4. We understand this to mean that, in the examiner’s view, those of skill in the art would have expected both Holmes-Farley’s polymers and Howes’ polymers (and any other polymer comprising quaternary ammonium units) to bind phosphate.

The examiner has presented no evidence to support this position, but it would make no difference if he had. Even assuming the examiner is correct, Holmes-Farley clearly discloses that not all phosphate-binding polymers are appropriate for use in treating hyperphosphatemia. In addition to binding phosphate, the polymers must also be non-toxic and stable, as those terms are defined by Holmes-Farley. The examiner has presented no evidence that those skilled in the art would have recognized Howes’ polymers as meeting these

criteria. Therefore, the examiner has not shown that the references would have suggested combining Howes' polymers with Holmes-Farley's method, in the manner required to yield the presently claimed invention. The rejection under 35 U.S.C. § 103 is reversed.

Summary

The references cited by the examiner, viewed without the benefit of hindsight, would not have suggested the method claimed by Appellants. We therefore reverse the rejection under 35 U.S.C. § 103.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Eric Grimes)	
Administrative Patent Judge)	

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