

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte ALFRED J. NIJERK and
JOHANNA M.P. VERMEER

Appeal No. 2001-1162
Application No. 08/726,803

HEARD: March 6, 2003

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

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2 and 5 through 17, all the claims remaining in the application.

Claims 10 and 11 are representative of the subject matter on appeal and read as follows:

10. An aqueous folinate solution for pharmaceutical applications consisting essentially of

(i) sodium folinate, said sodium folinate being present in an effective amount in a concentration of up to 400 mg folinic acid per ml,

- (ii) a stabilizer selected from the group consisting of sodium citrate, sodium acetate, and mixtures thereof,
- (iii) optionally, an isotonizing agent, and
- (iv) optionally, a buffer selected from the group consisting of tris, phosphate and carbonate buffers.

11. An aqueous folinate solution of sodium salts for pharmaceutical applications, consisting of
sodium folinate in a concentration of about 15 to 400 mg folinic acid per ml,
a stabilizer selected from the group consisting of sodium citrate, sodium acetate, and mixtures thereof,
optionally, an isotonizing agent,
optionally, a buffer selected from the group consisting of tris, phosphate and carbonate buffers, and optionally, a pH adjusting agent.

The references relied upon by the examiner are:

Mueller et al. (Mueller)	5,134,235	Jul. 28, 1992
Haeger	5,173,488	Dec. 22, 1992
Eur. Pat. App. (Buchs)	0 667 159 A2	Aug. 16, 1995 ¹

Hoover, Remington's Pharmaceutical Sciences (Remington's), 15th edition, pp. 268-270 and 283-284 (Easton, Pa; Mack Pub. Co. 1975)

Hagers Handbook (Hagers), 4th edition, Vol. 7, P+. A, page 368 (1971)

Claims 2 and 5 through 17 stand rejected under 35 U.S.C. § 103(a). As evidence of obviousness, the examiner relies upon Haeger, Buchs, Mueller, Remington's, and Hagers. We reverse.

Discussion

¹ The examiner's rejection as stated in the Examiner's Answer is based upon the English abstract provided in this German language document. However, in response to a remand from the board, the examiner obtained a full-text translation of Buchs. Our consideration of the issues raised in this appeal is based upon the full text translation.

This board serves as a board of review. 35 U.S.C. § 6(b) ("The [board] shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents . . ."). In this case, the examiner's statement of the rejection which appears on pages 3-9 of the Examiner's Answer is essentially unreviewable. In the paragraph bridging pages 3-4 of the Examiner's Answer, the examiner first makes references to the individual references applied and concludes "[t]he claimed invention differs primarily in that it employs a sodium folinate solution. One of ordinary skill would have been motivated to employ a sodium folinate solution in the prior art solution composition since the prior art clearly suggests the same."

First, the examiner makes reference to the "claimed invention" instead of discussing the requirement set forth in any individual claim pending in the application. Patentability is determined on a claim-by-claim basis not by making a broad reference to the "claimed invention." Second, the examiner only states what one of ordinary skill in the art would presumably have been "motivated" to do, not what would have been obvious to this hypothetical person. The statutory standard of patentability under 35 U.S.C. § 103 is obviousness, not motivation. Third, it is unclear what the examiner means by his suggestion that one would have been motivated to employ a sodium folinate solution in the "prior art solution composition." Simply put, what is the "prior art solution composition" which the examiner seeks to modify by using sodium folinate? The examiner cites to column 16, lines 65-70 of Haeger in support of this conclusion. This portion of Haeger states that sodium folinate can be used in that invention. Thus, it does not appear that it is necessary to substitute sodium folinate into an unknown "prior art solution composition" since the prior art apparently describes the use of

sodium folinate.

Another difficulty in reviewing the examiner's statement of the rejection is that it appears to contain the examiner's response to arguments which were made in response to previous submissions by appellants apart from the present Reply Brief. See pages 5-9 of the Examiner's Answer. It is unclear from the record why the examiner would structure a statement of rejection in this manner. The statement of a rejection should include the facts and reasons why the individual claims being reviewed are unpatentable, not responses to arguments set forth in previous Office actions.

Our best guess as to the examiner's position is that each of Haeger, Buchs, and Mueller would be considered a so-called primary reference to be modified on the basis of the teachings in Remington's and Hagers. We believe the examiner's position is that each of Haeger, Buchs, and Mueller describes a sodium folinate composition but not the use of a stabilizer selected from the group consisting of sodium citrate, sodium acetate, and mixtures thereof as required by the claims on appeal. The examiner would then rely upon Remington's and Hagers to provide the teaching, suggestion, and motivation to use such a stabilizer in the compositions of the so-called primary references, thus making the subject matter of the claims as a whole obvious to one of ordinary skill in the art. If this is in fact the examiner's position, we disagree that these references establish a prima facie case of obviousness.

Turning to Haeger first, the sodium folinate compositions of that reference must contain tromethamine as a buffer and 3-mercapto-1,2-propanediol as a antioxidant. Claim 10 states that the claimed composition is one "consisting essentially of" the recited components while claim 11 on appeal states that the composition is one

"consisting of" the recited components. One of the optional components encompassed by claims 10 and 11 is a buffer known as tris. Tris is a synonym for tromethamine.² Thus, the first issue to be resolved in considering Haeger as a primary reference is whether claims 10 and 11 are open to the inclusion of 3-mercapto-1,2-propanediol as an antioxidant.

In regard to "consisting of" claim 11, the examiner has not explained how this closed claim is open to the inclusion of 3-mercapto-1,2-propanediol. Nor has the examiner explained how a "consisting essentially of" claim such as claim 10 on appeal is open to the inclusion of this compound. Absent a more specific explanation by the examiner as to how either claim 10 or 11 should be read as to include the presence of 3-mercapto-1,2-propanediol, we do not find that the examiner has established a prima facie case of obviousness on this basis. Thus, any rejection premised upon Haeger is reversed.

Turning to Buchs, we find that the full text translation of this reference, if anything, teaches away from the claimed invention. As seen from page 5 of the translation, the goal of the Buchs invention "is to make a concentrated, stable solution based upon folates available, which contains neither a stabilizing agent nor a complexing agent." Buchs found that sodium folinate solutions according to that invention were stable for at least 12 months at temperatures from 0°C to 5°C "without the addition of stabilizing agents and/or complexing agents." Translation, page 5. Since the examiner's statement of rejection is nonspecific as to how the teachings of

² See the attached printout of information derived from the web site of the Massachusetts General Hospital. The URL was accessed on March 7, 2003.

any individual reference are to be combined with the disclosure of another reference, it is unclear why the examiner believes the subject matter of any claim on appeal would have been obvious from a consideration of Buchs as a so-called primary reference. To the extent the examiner's rejection under 35 U.S.C. § 103 is premised upon a combination of references using Buchs as a so-called primary reference, such a rejection is reversed.

It cannot be gainsaid that Mueller describes sodium folinate solutions. See, e.g., Example 4. However, the examiner has not explained, and it is not apparent from reading Mueller, how Mueller in and of itself teaches, suggests, or motivates one of ordinary skill in the art to formulate the sodium folinate solutions of that reference in the manner required by the claims on appeal. The examiner has not pointed to any passage of Mueller, nor do we find any, which suggests that the sodium folinate solutions of that reference should be used in combination with sodium citrate, sodium acetate or mixtures thereof, or for that matter, any stabilizer. To the extent the examiner's rejection is premised upon the use of Mueller as a so-called primary reference, any such rejection under 35 U.S.C. § 103 is reversed.

The examiner's reliance upon Remington's and Hagers is unavailing as these references do not provide the needed reason, suggestion or motivation to use sodium citrate or sodium acetate in compositions which consist essentially of or consist of sodium folinate.

We are aware that applicants rely upon a declaration filed under 37 CFR § 1.132 by J.J. Scherpbier. However, since we have determined that the references relied upon

by the examiner do not establish a prima facie case of obviousness, we need not consider this evidence of nonobviousness.

The decision of the examiner is reversed.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
Lora M. Green)	
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