

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

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LEO MARTIS, RON BURKE, TY SCHOCKLEY
LEE W. HENDERSON, BERNADETTE FALLER

Appeal No. 1999-0342
Application 08/184,813

HEARD: June 14, 2001

Before WINTERS, SCHEINER and MILLS, Administrative Patent Judges.

MILLS, 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 1-22, which are all of the claims pending in this application.

We reverse.

Appeal No. 1999-0342
Application 08/184,813

Claims 1-22 are illustrative of the claims on appeal and read as in the attached appendix of pending claims as originally presented with the Appeal Brief.

The prior art reference relied upon by the examiner is:

Eur. Pat. Appl. (Alsop)	0 207 676	Jan. 7, 1987
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Ground of Rejection

Claims 1-22 stand rejected under 35 U.S.C. § 103 over Alsop.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied prior art reference, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejection, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief and Reply Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

The claimed invention is directed to a peritoneal dialysis solution containing maltodextrins of a specific molecular weight and amino acids, each in specific amounts. The specification acknowledges that one of the difficulties of peritoneal dialysis is providing a suitable osmotic agent. Specification, page 2. One of the problems associated with the use of dextrose as an osmotic agent is that it is rapidly taken up by the blood from the dialysate. Because dextrose crosses the peritoneum so rapidly, the osmotic gradient is dissipated within two to three hours of infusion. This can cause reversal of the direction of ultrafiltration, causing water to be reabsorbed from the dialysate toward the end of the time allowed for exchange. Specification pages 2-3.

According to the specification, appellants' invention provides an improved dialysis solution, including a mixture of amino acids and maltodextrins as the osmotic agent. The addition of amino acids to glucose polymers, such as maltodextrins, resulted in a 46% reduction in the quantity of glucose polymers required to produce an equivalent net ultrafiltration at 8 hours. Specification page 22. Moreover the percent adsorption of glucose polymers used in combination with amino acids was significantly lower than that of glucose or maltodextrin alone at the end of 8 hours. Specification, pages 13 and 23.

35 U.S.C. § 103

Claims 1-22 stand rejected under 35 U.S.C. § 103 over Alsop.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

The examiner suggests that Alsop establishes knowledge in the art of a peritoneal dialysis composition containing a glucose polymer, wherein at least 80% by weight of the polymer is of molecular weight in the range of 5000 to 50,000, also including electrolytes, buffers, and amino acids. Answer, page 3. The examiner acknowledges that Alsop does not disclose the claimed specific amounts of glucose polymers (note that maltodextrin is a glucose polymer) and amino acids. Answer, pages 3-4.

Alsop, in fact, describes a peritoneal dialysis solution including maltodextrins in a particular molecular weight distribution. Alsop appears to cursorily mention that amino acids may be included in the composition to function as an electrolyte or other additive/adjuvant. Alsop, pages 10-11 and 38.

The examiner summarizes that “one of ordinary skill in the art at the time the instant invention was made would have been motivated to vary the amounts of glucose polymer and amino acids in order to prepare a composition having optimal results.” Answer, page 4.

Appellants respond, arguing that the examiner has failed to establish a prima facie case of obviousness as the examiner has failed to meet the burden of showing 1) a two component osmotic agent for peritoneal dialysis containing both maltodextrins and amino acids in the claimed amounts (Brief, page 13) and 2) the defined degree of polymerization of the maltodextrins (Brief, page 14). Appellants also argue the evidence provided in the specification shows unexpected and improved peritoneal dialysis osmotic results when maltodextrin is combined with amino acids (Id.).

We agree with appellants that the examiner has not established a prima facie case of obviousness. The motivation to combine references was discussed in Ecolochem Inc. v. Southern California Edison, 227, F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000). Ecolochem stated that the:

“[S]uggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved.” ... However, there still must be 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.” ... “[A] rejection cannot be predicated on the mere identification ... of individual components of claimed limitations.

[Citations omitted]. Further, as set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. [] Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher. @ []

Most if not all inventions arise from a combination of old elements. [] Thus, every element of a claimed invention may often be found in the prior art. [] However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. [] Rather, to 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. [citations omitted]

In other words, there still must be evidence that a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. @ Ecolochem Inc. v. Southern California

Appeal No. 1999-0342
Application 08/184,813

Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000). At best, the statement of the rejection establishes that individual parts of the claimed invention were known in the prior art.

We have no doubt that the prior art could be modified in a manner consistent with appellant's specification and claims. The mere fact that the prior art could be so modified, however, would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

In the present case the examiner has not provided an evidentiary basis for concluding that the amino acids described in Alsop function, in combination with maltodextrin, as an osmotic agent. All of the independent claims of the application require approximately 2-6% w/v of maltodextrins having a specific weight average molecular weight and 0.25-2% w/v of amino acids. In our view the examiner has failed to present evidence that one of ordinary skill in the art, upon reading the disclosure of Alsop, would be motivated to use the amino acids disclosed in Alsop which function as "electrolytes" (in no specific amounts), as part of a two component osmotic agent having the specifically claimed amounts. The amount of maltodextrin required by the claims is significant, according to appellants' specification, because the addition of amino acids to maltodextrins resulted in a 46% reduction in the quantity of glucose polymers required to

Appeal No. 1999-0342
Application 08/184,813

produce an equivalent net ultrafiltration at 8 hours and the percent adsorption of glucose polymers was significantly lower than glucose or maltodextrin alone at the end of 8 hours. The examiner has not established that Alsop provides a suggestion of the claimed amounts of maltodextrin, such that the amount of maltodextrin required for ultrafiltration is reduced by the presence of the amino acid electrolytes, or that the amino acids of Alsop additionally function as an osmotic agent in combination with maltodextrin.

After evidence or arguments are submitted by the appellants in response to rejection based on obviousness, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of the argument. On balance, we believe that the totality of the evidence presented by the examiner and appellants weighs in favor of finding the claimed invention to be non-obvious in view of the cited references. We find the examiner has not established on the record before us that the cited references both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. The rejection of the claims for obviousness of the claimed invention is reversed.

CONCLUSION

The rejection of claims 1-22 under 35 U.S.C. § 103 over Alsop is reversed.

Appeal No. 1999-0342
Application 08/184,813

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

REVERSED

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Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Appeal No. 1999-0342
Application 08/184,813

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