

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LEO MARTIS, RON BURKE and DIRK FAICT

Appeal No. 95-2970
Application No. 07/995,106¹

ON BRIEF

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

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 27 and 35 through 43. Claims 28

¹ Application for patent filed December 22, 1992.

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through 34 and 44 through 46, which are the only other claims remaining in the application, stand withdrawn from further consideration by the examiner as directed to a non-elected invention.

Claims 1, 10, 35 and 41, which are illustrative of the subject matter on appeal, read as follows:

1. A peritoneal dialysis solution comprising as osmotic agents:

approximately 0.25 to about 4.0% (w/v) polypeptides; and
approximately 0.5% to about 4.0% (w/v) dextrose.

10. A peritoneal dialysis solution comprising a polypeptide mixture as an osmotically active agent in an osmotically effective amount, the polypeptide mixture consisting of:

not more than approximately 0.10% of polypeptides having a molecular weight of greater than 1200;

not more than approximately 25% of polypeptides having a molecular weight of less than 400; and

the weight average of the polypeptide mixture being within the range of approximately 400 to about 900 daltons.

35. A peritoneal dialysis solution comprising as an osmotic agent synthetic polypeptides that are approximately 4 to about 10 amino acids long and dextrose.

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41. A peritoneal dialysis solution comprising as one of at least two osmotic agents a polypeptide having the following amino acid composition:

ASX	10.3
GLX	20.3
SER	4.5
GLY	2.3
HIS	2.4
ARG	2.3
THR	5.7
ALA	6.4
PRO	5.8
TYR	3.7
VAL	4.6
MET	2.3
ILE	4.7
LEU	11.7
PHE	3.4
LYS	9.7

and including 50 to 150 mg of valine and 15 to 30 mg tryptophan per gm of polypeptide.

The references relied on by the examiner are:

Steudle et al. (Steudle)	5,011,826	Apr. 30, 1991
Klein	5,039,609	Aug. 13, 1991

The issues presented for review are: (1) whether the examiner erred in rejecting claims 10 through 20 under 35 U.S.C. § 103 as unpatentable over Klein; and (2) whether the examiner erred in rejecting claims 1 through 9, 21 through 27 and

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35 through 43 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Klein and Steudle.

On consideration of the record, including appellants' Appeal Brief, Reply Brief and Supplemental Reply Brief, and the Examiner's Answer and Supplemental Answer, we reverse these prior art rejections.

DISCUSSION

As stated in the Appeal Brief, section V, "[a]ppellants do not argue for the patentability of the dependent claims apart from the independent claims from which they depend." In other words, for the purposes of this appeal, appellants group the independent claims separately. Further, in section VI of the Appeal Brief, appellants argue that (1) specific limitations in the independent claims are not described in the prior art relied on by the examiner; and (2) those limitations render the claimed subject matter unobvious over the prior art. For example, see the Appeal Brief, paragraph bridging pages 9 and 10.

In light of the foregoing, we find that this statement in the Examiner's Answer, page 2, is clearly erroneous:

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The rejection of claims 1-27 and 35-43 stand or fall together, as indicated by appellants['] statement.

Where, as here, the examiner has entered separate rejections under 35 U.S.C. § 103, and where the appellants have grouped and argued the independent claims separately, the examiner's statement that "[t]he rejection of claims 1-27 and 35-43 stand or fall together" is manifestly incorrect. In our deliberations, we have reviewed and considered each independent claim separately.

Turning to the merits, we first consider the rejection of claims 10 through 20 under 35 U.S.C. § 103 as unpatentable over Klein. We agree with the examiner that Klein discloses a peritoneal dialysis solution which comprises, as an osmotically active agent, an osmotically effective amount of a mixture of peptides, the mixture consisting substantially of peptides having a molecular weight of about 300 to about 2000 daltons, and an equivalent weight between about 150 to about 1500. We disagree, however, with the unsupported conclusion that:

[I]t would have been obvious to one of ordinary skill to employ a molecular weight range somewhat narrower than that suggested (300-2000 daltons) in

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order to optimize the ultrafiltration profile, thus arriving at substantially the molecular weight range recited in the instant claims. [Examiner's Answer, page 4, first full paragraph].

Simply stated, the foregoing is an example of ipse dixit reasoning. On this record, it is the appellants' specification, not Klein's disclosure, which provides the guidelines and direction leading to a polypeptide mixture having the specific molecular weight characteristics recited in independent claim 10. The examiner's conclusion of obviousness is not supported by an adequate factual foundation, and cannot stand. This rejection is reversed.

Claims 21 through 27 depend directly or indirectly from claim 10 and, therefore, include the limitations pertaining to molecular weight recited therein. Again, the examiner has not established that the Klein reference is sufficient to support a conclusion of obviousness of claims containing those limitations. Nor does the Steudle reference cure that deficiency in Klein. Accordingly, the rejection of claims 21 through 27 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Klein and Steudle is reversed.

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In setting forth the statement of rejection of claims 1 through 9, 21 through 27, and 35 through 43 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Klein and Steudle (Examiner's Answer, pages 4 and 5), the examiner does not refer to independent claim 41. Rather, the examiner discusses claim 41 in the context of the § 103 rejection of claims 10 through 20 over Klein. See the Examiner's Answer, paragraph bridging pages 3 and 4. This is, to say the least, unorthodox. In any event, we have carefully reviewed the Klein reference, including column 6, TABLE 1, referenced by the examiner, but find that the amino acid composition there set forth bears little relationship to the amino acid composition recited in claim 41. On this record, the examiner has not established how a person having ordinary skill would have been led from "here to there," i.e., from the amino acid composition disclosed by Klein in column 6, TABLE 1, to a polypeptide having the amino acid composition recited in claim 41. The examiner has not established a prima facie case of obviousness of independent claim 41 or the claims depending directly or indirectly therefrom (claims 42 and 43).

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In setting forth the rejection of claims 1 through 9, 21 through 27, and 35 through 43 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Klein and Steudle (Examiner's Answer, pages 4 and 5), the examiner does not come to grips with the limitation in independent claim 35 requiring "synthetic polypeptides that are approximately 4 to about 10 amino acids long." The examiner does not explain how a person having ordinary skill in the art would have been led from the disclosures of Klein and Steudle to a peritoneal dialysis solution comprising, as an osmotic agent, synthetic polypeptides that are approximately 4 to about 10 amino acids long and dextrose. Again, the examiner has not established a prima facie case of obviousness of claim 35 or claims 36 through 40 depending therefrom. The rejection of claims 35 through 40 on prior art grounds is reversed.

Independent claim 1 defines a peritoneal dialysis solution comprising, as osmotic agents, specific concentrations of polypeptides and dextrose. In setting forth the rejection of claims 1 through 9, 21 through 27, and 35 through 43 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Klein and Steudle (Examiner's Answer,

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pages 4 and 5), the examiner does not come to grips with those recited concentrations. In the Answer, page 5, line 4, the examiner states that "extensive information is available in the art" respecting the concentrations of components in the dialysis solution. A reference to "extensive information . . . available in the art," however, is insufficient to support a conclusion of obviousness. The Klein and Steudle references, coupled with uncited and unretrieved "information . . . available in the art" do not provide an adequate factual foundation serving to support a conclusion of obviousness. Accordingly, the examiner has not established a prima facie case of obviousness of claim 1 or claims 2 through 9 which depend directly or indirectly therefrom. The rejection of claims 1 through 9 over the cited prior art is reversed.

OTHER ISSUES:

Upon the return of this case to the examining group, we urge the examiner to step back and consider anew the question of patentability of at least claims 1 and 10 in light of Klein (5,039,609) and the below noted case law.

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With regard to claim 1, we note initially that the claim is directed to a peritoneal dialysis solution comprising specific proportions of polypeptide in combination with specific proportions of dextrose.² However, the claim does not contain any limiting language with regard to the molecular weight of the polypeptide. It reasonably appears that the polypeptide of this claim would "read on" the polypeptide of Klein (note: In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989), and In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969)). The examiner should make the factual inquiries necessary to determine whether the Klein disclosure, at column 12, lines 39-65, would have reasonably suggested the combination of the polypeptide and dextrose in the claimed proportions. In presenting his case before the Board, the examiner did not rely on that portion of the reference.

With regard to claim 10, we note that the claim is directed to a peritoneal dialysis solution which does not require the ingredient dextrose. We note a number of

² We note The Merck Index, item 4353 (11th ed., Merck & Co. 1989) as indicating that glucose and dextrose are the same chemical compound. (Copy attached).

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similarities between the claimed polypeptide composition and the polypeptide composition disclosed by Klein. The examiner should weigh the significance of such similarities as: (1) the source of the two polypeptides appear to be the same, compare Klein at column 5, line 24 through column 6, line 23, with appellants' specification, pages 9-10; (2) the disclosed utility is the same; and (3) the parameters of molecular weight, although not identical, appear to be closely related. We are mindful that, in the specification, appellant suggests that the molecular weight in claim 10 is critical or gives rise to unexpected results. Yet the specification contains no specific comparison of the claim designated polypeptide mixture, without dextrose, with the closest prior art mixture disclosed by Klein. Taking into consideration these similarities, the examiner should re-evaluate patentability of claim 10 in light of Kline.³ In so doing, the examiner should consider the claimed subject matter as compared to Klein in light of the legal principles discussed in such cases as: In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997); In

³ These points were not relied upon or addressed by the examiner in this appeal.

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re Malagari, 499 F.2d 1297, 182 USPQ 549 (CCPA 1974); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

CONCLUSION

In conclusion, we do not sustain either of the examiner's prior art rejections. The examiner's decision, rejecting claims 1 through 27 and 35 through 43, is reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
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