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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 39

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS J. HARTRANFT and CHARLES J. DUBAUSKAS

Appeal No. 96-0881
Application No. 07/795,908[1]

HEARD: March 2, 1998

Before JOHN D. SMITH, GARRIS, and PAK, Administrative Patent Judges.

JOHN D. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the final rejection of claims 1-26. Claim 1 and 14 are representative and are reproduced below:

1. A method of mixing dialysate in a hemodialysis machine, comprising:

[1] Application for patent filed November 15, 1991.

determining the actual concentration of individual concentrate components to be mixed as a dialysate;

determining the actual conductivity of a dialysate to be formed by the concentrate components and water;

combining said concentrate components with said water to form said dialysate;

sensing the conductivity of said dialysate and comparing said sensed conductivity of said dialysate with said determined actual conductivity of said dialysate; and

contolling the proportions of said concentrate components and said water in accordance with said comparison to obtain said determined actual dialysate conductivity.

14. An apparatus for mixing dialysate in a hemodialysis machine, comprising:

means for determining the actual concentration of individual concentrate components to be mixed in a dialysate;

means for determining the actual conductivity of a dialysate to be formed by the concentrate components and water;

means for combining said concentrate components with said water to form said dialysate;

means for sensing the conductivity of said dialysate and means for comparing said sensed conductivity of said dialysate with said determined actual conductivity; and

means for controlling the proportions of said concentrate components and said water in accordance with said comparison to obtain said determined dialysate conductivity.

The references of record relied upon by the examiner are:

Storey et al.(Storey)	4,202,760	May 13, 1980
Babb et al.(Babb)	4,399,036	August 16, 1983

The appealed claims stand rejected under 35 U.S.C. § 102(b) as anticipated by Babb. Claims 1, 3-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, and 26 stand rejected under35 U.S.C. § 102(b) as anticipated by Storey.

The subject matter on appeal is broadly directed to a method and an associated apparatus for mixing dialysate in a hemodialysis machine. As explained in appellants' specification, hemodialysis machines are utilized by persons having insufficient kidney function and are attached to the person through an extracorporeal circuit of blood tubing connected to a dialyzer having a pair of chambers separated by a thin semi-permeable membrane. In operation, the person's blood is circulated through one of the chambers while a flow of a dialysate is circulated through the other chamber. The semi-permeable ultrafiltration membrane passes waste materials and water from the person's blood to the dialysate. The composition of a dialysate is typically an aqueous solution of

an alkalizing salt. For example, a bicarbonate dialysate is typically formed by sequentially volumetrically proportioning two concentrates and water into a single solution by first mixing an acid concentrate with water to form a first mixed solution and then adding a bicarbonate concentrate to the first solution. Appellants explain that such prior art "Bicarbonate and Acidified concentrates" are available in many different concentrations to allow a dialysate solution to be tailored for an individual patient, and that such solutions are designated by the final concentrations of the chemicals based on nominal proportioning ratios (specification, page 2, lines 15-21). In some prior art cases, it is desirable that the final "Sodium and Bicarbonate" concentrations differ form the nominal values and to achieve this result, the volumetric mixing ratios are varied from the nominal values[2].

Appellants acknowledge that prior art servo-proportioning/feedback control systems have been utilized

[2] The nominal volumetric proportioning ratio for water to "Acidified concentrate" is 34:1 while the the nominal volumetric proportioning ratio for "Water/Acidified" solution to "Bicarbonate concentrate" is 19.13:1.

which are based upon and controlled by nominal conductivity values which are attained from the concentration labels of the concentrates. However, according to appellants, such concentration values have been found to vary as much as plus or minus five percent which "produce errors in the actual final concentrations achieved"(specification, page 3, lines 11-20). Appellants' invention is said to solve the above problem by calculating the actual conductivity contributions of the individual chemical components of the concentrate being utilized(Abstract of the Disclosure).

Appealed claim 1 is directed to a method of mixing dialysate comprising, inter alia, the steps of "determing the actual concentration of individual concentrate components to be mixed as a dialysate[emphasis added]" and "determining the actual conductivity of a dialysate to be formed by the concentrate components and water[emphasis added]". It is these steps[3] which appellants contend are not described or carried out in the prior art systems. Thus, in the brief at

[3] Similar claim language is present in the apparatus claims on appeal. Claim 14, for example, requires "means for determining the actual concentration of individual components to be mixed."

page 14, appellants contend that there is nothing in Storey that teaches the claimed preliminary steps of "actually measuring concentrations of components to be combined into a dialysate as well as determining the actual(or desired) conductivity of the dialysate to result from the combination of components[emphasis added]." With respect to Babb, appellants argue that Babb simply assumes that the value of the concentrate components is that which is found on the label of the containers prior to mixing (brief, page 10). These arguments by appellants' counsel lead one to believe that the claimed "determining" steps of appellants' method involve some quantitative measurement of the concentrates to determine the "actual concentrate components" to solve the prior art problem wherein reliance is placed on data on the labels of the concentrate which may vary as much as plus or minus five percent from the actual values. On the other hand, appellants' specification does not describe any actual measurement to determine "the actual concentration of individual concentrate components", but instead indicates that the "concentrate components are expressed in terms of the final nominal diluted concentrations" (i.e., the values on the

label) which "must be converted to the actual concentrations of the concentrate components"(specification, page 6, lines 19-22). This conversion or calculation is apparently effected by entering the "erroneous" data from the concentrate labels into a monitor **14** and a controller **16** (Figure 2). Thus, based on the specification, it appears that the claimed step of "determining the actual concentration of individual concentrate components to be mixed as a dialysate" covers a step in which theoretical concentration values of concentration components, not actual concentration values, are simply calculated. Moreover, such theoretical concentration values necessarily are based on the erroneous label data.

In light of the above, it appears that appellants have chosen to give the claim language "actual concentration" an uncommon meaning, i.e., a theoretical calculated concentration based on a label value which appellants acknowledge varies as much as plus or minus five percent from its actual value. In the present case, however, this uncommon meaning of the claim language has not been set forth "with reasonable clarity, deliberateness, and precision" as required. In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed Cir 1994). Indeed,

the claim language is used in a manner contrary to its accepted meaning in the art. See the MPEP § 2173.01. Moreover, further ambiguity is raised by the arguments of counsel which imply that the claimed step in question alternatively covers a step of actually measuring the concentrations of the concentrate components to be combined. In light of the foregoing, we find that the claims on appeal do not define the metes and bounds of the invention with a reasonable degree of precision and particularity. Therefore, pursuant to our authority under 37 C.F.R.§ 1.196(b), we enter a new rejection against the appealed claims under 35 U.S.C. § 112, second paragraph.

We now turn to the prior art rejections before us. Under the circumstances recounted above, it is our view that the metes and bounds of the appealed claims cannot be readily ascertained. Thus, the prior art can only be applied against the claims based on conjecture and supposition and this is not a proper basis for a rejection under 35 U.S.C. § 102(b). Compare In re Steele, 305 F2d 859, 862, 134 USPQ 292, 295 (CCPA 1962). Accordingly, we reverse the prior art rejections of the claims. We make clear, however, that we are not

determining whether the subject matter of the appealed claims is patentable over the references, only that the subject matter of the claims cannot be reasonably ascertained. Thus, this determination cannot be properly made on this record. In any subsequent prosecution of this application, the examiner should reconsider the relied upon references as well as the the prior art references which form the basis of an opposition proceeding in the European Patent Office. See the references discussed in Paper No. 34.

The decision of the examiner is reversed and a new rejection has been entered against the appealed claims.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that [a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new

ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

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

REVERSED 37 CFR § 196 (b)

JOHN D. SMITH)
Administrative Patent Judge)

BRADLEY R. GARRIS Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
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Application No. 07/795,908

APJ SMITH

APJ PAK

APJ GARRIS

DECISION: REVERSED 196 b
Send Reference(s): Yes No
or Translation (s)
Panel Change: Yes No
Index Sheet-2901 Rejection(s): _____

Prepared: November 16, 2000

Draft Final

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OB/HD GAU

PALM / ACTS 2 / BOOK
DISK (FOIA) / REPORT