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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JUTTA PASSLICK-DEETJEN, THOMAS P. SCHAUB, and GEORG TOPP[1]

Appeal 2017-000440
Application 11/596,181
Technology Center 1600

Before DEMETRA J. MILLS, ERIC B. GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a set for use in peritoneal dialysis, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

The Specification states that, "[d]uring the dialysis treatment, there is a transfer of numerous blood components, inter alia of sodium ions, from the

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[1] Appellants identify the Real Party in Interest as Fresenius Medical Care Deutschland GmbH. Appeal Br. 3.

blood of the patient to the dialysate via the peritoneum." Spec. 1. The Specification discloses that known peritoneal dialysis solutions having sodium concentrations of 120 mmol/l[2] or 134 mmol/l have disadvantages. *Id.* at 2–3. The Specification discloses "a solution for peritoneal dialysis which has a blood pressure-lowering effect and in which the side effects known by the use of peritoneal dialysis solutions with a low sodium content do not occur." *Id.* at 3.

Claims 1, 3, 6–8, 14, 15, and 17 are on appeal. Claim 1 is illustrative and reads as follows:

> 1. A set for use in peritoneal dialysis, the set comprising two separate solutions, a first separate solution and second separate solution, wherein the first separate solution includes an osmotic agent and a physiolocially [sic, physiologically] compatible acid,
>
> wherein when the two separate solutions are mixed to form a mixed solution, the mixed solution contains sodium ions in a concentration in the range from 124 to 126 mmol/l and chloride ions in a concentration in the range from 91-94 mmol/l.

DISCUSSION

The Examiner has rejected all of the claims on appeal under 35 U.S.C. § 103(a) as obvious based on Duponchelle,[3] Elisabettini,[4] and Shockley[5] (Non-Final Action[6] 3). The Examiner finds that Duponchelle discloses "a

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[2] The terms "mmol/l," "mmol/L," and "mM" are equivalent and are used interchangeably in this opinion.
[3] US 6,309,673 B1; Oct. 30, 2001.
[4] US 2003/0138501 A1; July 24, 2003.
[5] US 5,589,197; Dec. 31, 1996.
[6] Office Action mailed June 9, 2015.

two part peritoneal dialysis solution which is contained in a two-chambered container where . . . one chamber can contain dextrose, calcium chloride, magnesium chloride and an acid and the other chamber can contain sodium chloride, lactate and bicarbonate." *Id.* The Examiner finds that Duponchelle also discloses that the solution obtained by mixing the contents of the two chambers contains 100–150 mM sodium and 70–120 mM chloride, among other things. *Id.*

The Examiner finds that Elisabettini similarly discloses a two-part dialysis solution, where the mixed solution contains 100–600 mmol/L sodium and 70–130 mmol/L chloride. *Id.* at 3–4. The Examiner finds that Shockley discloses "discloses a low sodium peritoneal dialysis solution" containing, among other things, about 125 meq/L[7] sodium and 0–100 meq/L chloride. *Id.* at 4. The Examiner concludes that the set of claim 1 would have been obvious based on the teachings of the cited references. *Id.* at 3–5.

We agree with the Examiner that the cited references support a prima facie case of obviousness with respect to claim 1. Duponchelle discloses "peritoneal dialysis solutions . . . formulated and stored in at least two parts—an alkaline bicarbonate concentrate and an acidic concentrate." Duponchelle 4:17–22. Duponchelle discloses that the solutions can be stored in a container having a first chamber and a second chamber. *Id.* at 4:33–44.

> [I]n an embodiment, the first chamber **12** contains a dextrose concentrate, whereas the second chamber contains a

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[7] Appellants acknowledge that "1 mEq of Na^+ is equal to 1 mmol thereof. Similarly, 1 mEq of Cl^- is equal to 1 mmol thereof." Appeal Br. 15, footnote 4. Thus, Shockley's units of mEq/L are equivalent to claim 1's units of mmol/l.

> bicarbonate concentrate. In a preferred embodiment, the first chamber **12** further includes calcium chloride, magnesium chloride and a physiologically tolerable acid to adjust the pH of the acidic concentrate. The second chamber **14** can further include sodium chloride and lactate.

Id. at 6:60–66. Dextrose is an osmotic agent, as recited in claim 1. *See* Spec. 5 ("osmotic agent (for example glucose)"; dextrose (as disclosed in Duponchelle) is simply the D-isomer of glucose; *see* Elisabettini ¶ 29 ("In an embodiment, the bicarbonate-based solution includes . . . anhydrous glucose or dextrose, hydrous glucose or dextrose.").

Thus, Duponchelle discloses a set for peritoneal dialysis comprising a first separate solution that includes an osmotic agent and a physiologically compatible acid. Duponchelle also discloses that, when the two solutions in its set "are mixed together to form a ready-to-use solution for peritoneal dialysis . . . the subsequent dialysis solution contains the following ingredients in the identified amount: . . . sodium (100 to 150 mM); . . . chloride (70 to 120 mM)." *Id.* at 7:53–63. Duponchelle therefore discloses a set for peritoneal dialysis having solutions that include the same components as recited in claim 1 on appeal, and combine to form a dialysis solution having amounts of sodium and chloride that encompass those recited in claim 1.

Elisabettini similarly discloses a solution that "includes at least two separate components including a bicarbonate concentrate and an electrolyte concentrate which can be readily and sterilely mixed to form a ready-to-use formulation for patient administration" for "dialysis therapy." Elisabettini ¶ 26. Elisabettini discloses that an embodiment of its solution contains about 100–160 mmol/L sodium and about 70–130 mmol/L chloride, among other things. *Id.* ¶ 30.

Shockley discloses "an improved peritoneal dialysis solution." Shockley 2:15–16. Shockley discloses "specific examples of peritoneal solutions of [its] invention" that include sodium concentrations of 125 mEq/L and chloride concentrations of 88 mEq/L. *Id.* at Table 1, solutions 4, 9, 13, and 17. As noted above, Appellants agree that, for sodium and chloride, units of mEq/L are equivalent to the mmol/l units recited in the claims.

The cited references disclose sets comprising two separate solutions comprising the components recited in claim 1, and disclose that the mixed solutions contain a range of sodium and chloride ions that encompasses the range recited in claim 1. The set recited in claim 1 thus would have been obvious in view of the cited references. *See In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious.").

Appellants argue that "[n]either the Duponchelle nor Elisabettini reference teaches or suggests either one of narrow range of 124-126 mmol/1 for sodium and the narrow range of 91-94 mmol/l for chloride ions in a PD [peritoneal dialysis] solution, nor their combination to which the claims on appeal are limited." Appeal Br. 15.

This argument is unpersuasive.

> [W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness. But the presumption will be rebutted if it can be shown: (1) That the prior art taught away from the claimed invention, *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997); or (2) that there are new and unexpected results relative to the prior art, *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004). Here, there are ranges of sodium and chloride concentrations disclosed in the prior art, for a peritoneal dialysis solution, that encompass the ranges recited in claim 1. The burden therefore falls on Appellants to show that the prior art taught away from the claimed invention or that the claimed invention achieved unexpected results.

To that end, Appellants argue that "the objective evidence of nonobviousness in the present application and the Passlick-Deetjen Declaration[8] are adequate to rebut any . . . *prima facie* obviousness." Appeal Br. 20. Appellants argue that "[w]ith regard to the objective evidence in the present application, a comparison is made between the Phase II Study table in the present application and Shockley Figure 4." *Id.* Appellants argue that

> [t]he comparison of the results in Fig. 4 Shockley with the results for the dialysis patients treated with a PD solution of the present invention in the Phase II Study shows that the ultrafiltration volume achieved in accordance with the presently claimed invention is remarkably higher than that obtained according to Shockley.

Id. at 22.

Appellants also argue that "Dr. Passlick-Deetjen details a clinical study comparing the safety and efficacy of a peritoneal dialysis solution ('PD solution') according to the present invention with a similar PD solution according to the alleged prior art with a higher sodium content" and that "Dr. Passlick-Deetjen concludes that the presently claimed PD solution

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[8] Declaration under 37 C.F.R. § 1.132 of Jutta Passlick-Deetjen, filed Sept. 12, 2013.

markedly improved the patients' blood pressure, while providing adequate dialysis." *Id.* at 23. Appellants contend that "the unexpected advantage achieved by the presently claimed invention, demonstrated by the clinical study described in the Passlick-Deetjen Declaration, is not specifically the lowering of blood pressure, but instead is the constant tolerability and efficiency of PD therapy in addition to the lower blood pressure." *Id.* at 24.

We are not persuaded that Appellants' evidence of unexpected results is sufficient to overcome the prima facie case of obviousness. The Specification presents evidence that a peritoneal dialysis solution having 125 mmol/l produced better results than a similar one having 120 mmol/l sodium. Spec. 8. The Passlick-Deetjen Declaration presents a comparison of a peritoneal dialysis solution having 125 mmol/L sodium with one having 134 mmol/L sodium. Appeal Br. 45 (Passlick-Deetjen Decl., Exh. A). Dr. Passlick-Deetjen states that, "[i]n respect to sodium removal and blood pressure control a major improvement could be seen with the PD solution of the invention." Passlick-Deetjen Decl. ¶ 11.

However, "[t]o be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the *closest prior art*, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) (emphasis added). Here, the closest prior art embodiment is disclosed by Shockley, which provides "Examples of Specific Compositions" that include ones having 125 mEq/L (mmol/L) of sodium and 88 mEq/L (mmol/L) of chloride. Shockley Table 1. These prior art compositions thus differ from those of claim 1 only in the amount of

chloride included, and are closer prior art embodiments than those compared to the claimed composition in the Specification and in the Passlick-Deetjen Declaration. Appellants' evidence of unexpected results are therefore not persuasive of nonobviousness.

Appellants argue, however, that "Shockley[] is **not** directed to multiple part solutions for PD, nor PD solutions that contain a physiolocially [sic] compatible acid in one of the separated solution parts." Appeal Br. 25.

This argument is unpersuasive, because both the Specification and the Passlick-Deetjen Declaration describe only the results of administering a single, mixed solution to patients. *See* Spec. 8; Passlick-Deetjen Declaration ¶¶ 4, 6, 11. The Specification states that a two-part solution "produces the advantage that, on the one hand, the degradation of glucose is prevented during the heat sterilization and that, on the other hand, no special demands have to be made on the pouch material with respect to the CO_2 barrier properties due to the low CO_2 partial pressure." Spec. 4. Appellants, however, have not pointed to evidence of record that shows that a two-part solution provides different results, after mixing, compared to a similar one-part solution.

We therefore affirm the rejection of claim 1 under 35 U.S.C. § 103 as obvious based on Duponchelle, Elisabettini, and Shockley. Claims 3, 6, 7, and 17 fall with claim 1 because they were not argued separately. Appellants rely on the same arguments with respect to claim 15. Appeal Br. 31–32. We therefore affirm the rejection of claim 15 for the reasons discussed above.

With regard to claim 8, Appellants argue that the claim specifies that the first separate solution includes specific components in specific mmol/l

ranges, and that the cited references do not suggest the recited composition. Appeal Br. 28–29.

We agree with Appellants that the Examiner has not shown that the cited references support a prima facie case of obviousness with respect to claim 8, which requires that the first separate solution comprises, in addition to an osmotic agent and a physiologically compatible acid, 172–200 mmol/l sodium. Duponchelle discloses that its first separate solution, containing dextrose and an acid, does not contain sodium. Duponchelle 8:50–63. The Examiner has not identified any specific disclosure in the cited references that would make obvious an embodiment in which a separate solution includes an osmotic agent, a physiologically compatible acid, and 172–200 mmol/l sodium. *See* Ans. 8–9. The Examiner reasons that "one of ordinary skill in the art would expect that one chamber can contain sodium, calcium, magnesium, H+ access [sic, excess?], chloride, glucose at various concentrations, including the claimed concentrations, so long that when combined, the use solution contains physiologically acceptable concentrations of the constituents." Ans. 9. However, the Examiner has not pointed to evidence of record to support the position that it would have been obvious to provide sodium in the solution comprising an osmotic agent and a physiologically compatible acid that is disclosed by Duponchelle. We therefore reverse the rejection of claim 8.

Regarding claim 14, Appellants argue:

> In the cited part, Duponchelle does not describe the structure and function of the "peel seal" mentioned at column 6, lines 53-55 in any detail. The patent cited at column 6, lines 49-52 by Duponchelle as providing an example of the multi-chambered container does not appear to describe the peel seal. As indicated, claim 14 on appeal specifies a separation of the first

> and second chambers "by weld seam dimensioned such that the welded seam opens on pressure on one of the chambers filled with liquid so that the content of the two chambers can be mixed with one another."

Appeal Br. 30–31.

This argument is not persuasive. Duponchelle states that "[a] variety of containers can be used to house the two parts of the bicarbonate-containing solution, such as separate containers (i.e. flasks or bags) that are connected by a suitable fluid communication means." Duponchelle 6:31–34. Duponchelle exemplifies a container having two chambers connected by a frangible connector (*id.* at 6:37–42) but also states that "[a]lternatively, both containers can be separated by a peel seal, which is broken before use by the patient" (*id.* at 53–55). Based on these disclosures, we agree with the Examiner that the "weld seam" recited in claim 14 would have been obvious to a person of ordinary skill in the art.

SUMMARY

We affirm the rejection of claims 1, 3, 6, 7, 14, 15, and 17 under 35 U.S.C. § 103(a) based on Duponchelle, Elisabettini, and Shockley.

We reverse the rejection under 35 U.S.C. § 103(a) based on Duponchelle, Elisabettini, and Shockley as applied to claim 8.

TIME PERIOD FOR RESPONSE

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

AFFIRMED-IN-PART