UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

FRESENIUS MEDICAL CARE HOLDINGS, INC., *et al.*,

Plaintiffs,

v.

BAXTER INTERNATIONAL, INC., *et al.*,

Defendants.

No. C 03-1431 SBA

ORDER

[Docket Nos. 845, 847]

This matter comes before the Court on defendants Baxter International, Inc. and Baxter Healthcare Corporation's (Baxter) Rule 50(b) Renewed Motion for Judgment as a Matter of Law [Docket No. 847], and Baxter's Motion for a New Trial Pursuant to Rule 59 [Docket No. 845]. Baxter seeks judgment as a matter of law (JMOL) that all of the asserted claims of U.S. Patent No. 5,247,434 (the '434 Patent), U.S. Patent No. 6,284,131 (the '131 Patent), U.S. Patent No. 5,326,476 (the '476 Patent), and U.S. Patent No. 5,744,027 (the '027 Patent) are not invalid. After reading and considering the arguments presented by the parties, the Court finds this matter appropriate for resolution without a hearing. For the reasons that follow, the Court GRANTS Baxter's renewed JMOL [Docket No. 847] and GRANTS Baxter's motion for a new trial [Docket No. 845].

PROCEDURAL HISTORY

On April 4, 2003, plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (Fresenius) filed a complaint seeking declaratory judgment of invalidity and non-infringement of five patents held by Baxter. One of the patents, U.S. Patent No. 5,486,286, is no longer at issue. Baxter commercialized the inventions of the patents through hemodialysis instruments, such as the Drake Willcock™ System 1000 Dialysate Delivery System (System 1000). A hemodialysis machine is a kidney dialysis machine that removes metabolic waste from a patient's blood by circulating the blood through an extracorporeal circuit. *See* Docket 835-1 (Jury Instr. at 19). On May 14, 2003,

Baxter answered and counterclaimed that Fresenius's 2008H and/or 2008K hemodialysis machines infringe four of the five patents. Fresenius responded by identifying the Sarns 9000 as prior art that invalidated the patents held by Baxter.

On September 2, 2005, the Court granted in part Baxter's motion for partial summary judgment and granted in part Fresenius's cross-motion for summary judgment, and held that Fresenius's 2008K hemodialysis infringed claim 26 of the '434 patent and claim 1 of the '131 patent. *See* Docket No. 370. The Court also held that the SVS, Kt/V, and Blood Pressure screens of the 2008K did not infringe claim 1 of the '131 patent.

On March 10, 2006, pursuant to a stipulation between the parties, the Court issued an order dismissing with prejudice: (1) all claims, counterclaims, and defenses of the parties concerning the '286 patent and claims 1 and 6 of the '476 patent; (2) all claims, counterclaims, and defenses of the parties concerning Fresenius's 2008H hemodialysis machine; (3) Fresenius's affirmative defenses of laches, estoppel, failure to mark, and prosecution laches with respect to all the patents-in-suit; (4) Fresenius's affirmative defense of unenforceability with respect to the '286 patent and the '027 patent; (5) Fresenius's defense of improper inventorship based on the alleged contribution by Ziba Design with respect to all of the patents-in-suits; and (6) Fresenius's defense of indefiniteness as to claims 1, 13, and 14 of the '131 patent. *See* Docket No. 484.

On May 16, 2006, the Court found that the '434 patent was not anticipated by the Sarns 9000. *See* Docket No. 661. On June 15, 2006, Fresenius stipulated that its 2008K hemodialysis machine meets every claim limitation of the '434, '131, and '027 patents. *See* Docket No. 755. The Court then entered a judgment of partial infringement reflecting this stipulation. *See* Docket No. 770.

The remaining dispute for the jury to resolve was whether Fresenius's 2008K hemodialysis machine infringed upon claims 26 through 31 of the '434 patent, claims 1, 2, 3, 13, 14, 15, and 16 of the '131 patent, claims 7, 11, 14, 15, and 16 of the '027 patent, and claims 5 and 7 of the '476 patent. Fresenius asserted that the claims of these patents were invalid either because they were obvious in light of prior art or because they were anticipated by prior art.

The jury returned a unanimous verdict on June 30, 2006, finding in favor of Fresenius on all

issues submitted to it. *See* Docket No. 829. The jury found that all remaining claims were either invalid as obvious and/or invalid as anticipated, and that the Fresenius 2008K did not infringe on either claim 5 or 7 of the '476 patent. Specifically, the jury found that Fresenius proved by clear and convincing evidence that claims 26, 27, 28, 29, 30, and 31 of the '434 patent were invalid as obvious based on prior art; that Fresenius proved by clear and convincing evidence that claims 1, 2, 3, 13, 14, 15, and 16 of the '131 patent were invalid as obvious based on prior art; that Fresenius proved by clear and convincing evidence that claims 5 and 7 of the '476 patent were invalid as obvious based on prior art; and that Fresenius proved by clear and convincing evidence that claims 7, 11, 14, 15, and 16 of the '027 patent were invalid as obvious based on prior art. With respect to the '027 patent, the jury also held that Fresenius proved by clear and convincing evidence that claims 7, 14, 15, and 16 were invalid as anticipated based on prior art. The jury next determined that Baxter failed to prove by a preponderance of the evidence that the Fresenius 2008K hemodialysis machine literally infringes on claim 5 or 7 of the '476 patent. *See* Docket No. 829 (Jury Verdict Form).

LEGAL STANDARDS

Federal Rule of Civil Procedure 50(a) governs judgments as a matter of law. This rule provides that "If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may . . . grant a motion for judgment as a matter of law." FED. R. CIV. P. 50(a)(1). A party may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of judgment. *See* FED. R. CIV. P. 50(b). A party may alternatively request a new trial under Rule 59. *See id*.

The party requesting the JMOL must show that substantial evidence does not support the jury's findings. *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1149 (Fed. Cir. 2004). "Substantial evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1362 (Fed. Cir. 2001) (citation omitted). The Court considers all evidence before

the jury and draws all reasonable inferences from the evidence in the light most favorable to the prevailing party on that issue. *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (en banc); *Koito Mfg.*, 381 F.3d at 1149. A jury verdict on obviousness, however, is reviewed without deference because obviousness is a question of law. *See Koito Mfg.*, 381 F.3d at 1149.

Because a patent is presumed valid, the quantum of proof required at trial for a finding of invalidity is clear and convincing evidence. 35 U.S.C. § 282 ("A patent shall be presumed valid"); *see also Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 736 (Fed. Cir. 2002). This burden "shall rest on the party asserting such invalidity." 35 U.S.C. § 282. The validity of each claim of a patent is evaluated independently of the others and the party challenging the validity of a claim must submit evidence supporting a conclusion of invalidity of each claim the challenger seeks to destroy. *Id.*; *see also Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992).

Under 35 U.S.C. § 103, patent claims are rendered invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The "party seeking a judgment that a patent is obvious bears the burden of demonstrating by clear and convincing evidence that the teachings of the prior art would have suggested the claimed subject matter to one of ordinary skill in the art." *Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1187 (Fed. Cir. 2002). "Invalidity based on obviousness is a question of law based on the underlying facts. The relevant facts relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying." *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1351 (Fed. Cir. 1998) (citations omitted). Knowledge in the prior art of every element of a patent claim by itself is not sufficient to render a claim obvious. *Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1357 (Fed. Cir. 2003); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987).

Invalidity due to obviousness may result from a combination of prior art references. When prior art references are combined to invalidate a claim under 35 U.S.C. § 103, the prior art must provide some teaching, suggestion, or motivation to combine the references. *Akamai Techs., Inc. v. Cable Wireless Internet Serv., Inc*., 344 F.3d 1186, 1196 (Fed. Cir. 2003); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001). A party may not use hindsight analysis to show that, in light of the patented invention, it would have been obvious to combine prior art references. *Crown Operations Int'l, Ltd. v. Solutia Inc*., 289 F.3d 1367, 1376 (Fed. Cir. 2002). The teaching, suggestion, or motivation to combine references may come from the teachings of the references themselves, from the knowledge generally available to one of ordinary skill in the art, or may "flow from the nature of the problem." *Akamai*, 344 F.3d at 1196 (citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2002). A showing, teaching, or motivation to combine prior art references must be clear and particular, and must be supported by actual evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1334 (Fed. Cir. 2002). Broad, conclusory statements about the teaching of prior art are insufficient. *Brown & Williamson*, 229 F.3d at 1125. Moreover, a prior art reference that merely offers an "invitation to try" for improvements in the relevant art, without suggesting a means to accomplish such improvement, is insufficient to prove obviousness. *See In re O'Farrell*, 853 F.2d 894, 903 (Fed Cir. 1988) (discussing "obvious to try" cases); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986).

ANALYSIS

A. Motion for Judgment as a Matter of Law

Baxter proffers seven arguments in its motion for judgment as a matter of law. Baxter maintains that:

1. Fresenius failed to offer any combination of prior art teaching of all of the claim limitations for claim 14 of the '131 patent;
2. Fresenius failed to offer any combination of prior art teaching of all of the claim limitations for claims 28, 29, and 30 of the '434 patent;
3. Fresenius failed to offer any evidence on element (a) of claim 26 of the '434 patent and element (a) of claim 1 of the '131 patent;
4. Fresenius failed to offer clear and convincing evidence of a motivation to

combine the '131 and '434 patents;

5. Fresenius failed to identify evidence of obviousness and failed to identify a motivation to combine claim 7 of the '476 patent;
6. Fresenius missed claim elements and offered no evidence of a motivation to combine for claim 5 of the '476 patent; and
7. Fresenius failed to address the entirety of dependent claim 11 of the '027 patent and failed to provide a motivation to combine.[1]

As an initial matter, Fresenius contends the first two contentions are precluded because Baxter failed to raise them in its original JMOL, as it never specifically mentioned dependent claims 28, 29, and 30 of the '434 patent or claim14 of the '131 patent. A party cannot raise arguments in its post-trial JMOL under Rule 50(b) that it did not raise in its pre-verdict Rule 50(a) motion. *Freund v. Nycomed Amersham*, 347 F.3d 752, 761 (9th Cir. 2003).

In Baxter's Rule 50(a) Motion for Judgment as a Matter of Law, it did not specifically break out claim 14 of the '131 patent or claims 28, 29, and 30 of the '434 patent from its general contention that "For the Claims of the '131 and '434 Patents, Fresenius Has Failed to Offer Clear and Convincing Evidence of Motivation to Combine." *See* Docket No. 808. In its motion Baxter stated:

> For the '131 and '434 patents, Fresenius offered Dr. Rau and Mr. Causey.
> Dr. Rau never offered the opinion that any *claim* of the '131 or '434 patents was obvious. Rather, he testified that *element (b)* of 131:1 and *element (b)* of 434:26 were obvious.
> . . . .
> Mr. Causey's testimony fails to provide the type of clear and convincing evidence required to invalidate Baxter's patent claims as obvious, and the Court may grant JMOL to Baxter.

Docket 808 at 10, 14 (emphasis in original).

The language recited above is broad enough to encompass claim 14 of the '131 patent and claims 28, 29, and 30 of the '434 patent. The issue is whether it was specific enough to give Fresenius notice that Baxter was challenging the sufficiency of evidence with respect to those particular claims. *See Duro-Last, Inc. v. Custom Seal, Inc*., 321 F.3d 1098, 1105-06 (Fed. Cir. 2003).

Although JMOL issues are generally governed by regional circuit law, Federal Circuit law

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[1] Baxter does not challenge the jury's verdict that claims 7, 14, 15, and 16 of the '027 patent are invalid as anticipated by prior art. *See* Docket No. 829 (Jury Verdict at 3).

governs whether arguments made in pre-verdict JMOLs are sufficient enough to preserve specific patent law issues for a post-verdict JMOL. *See Junker v. Eddings*, 396 F.3d 1359, 1363 (Fed. Cir. 2005); *Duro-Last*, 321 F.3d at 1106. Rule 50(a) provides that a motion for JMOL made before the case is submitted to the jury "shall specify . . . the law and the facts that entitle the movant to the judgment." FED. R. CIV. P. 50(a)(2). Like other circuits, the Federal Circuit requires that a Rule 50(a) motion be sufficiently specific regarding its factual basis to inform the opposing party of exactly what is alleged to be deficient in its evidence, thereby giving the opposing party an opportunity to cure the defects in proof. *See Junker*, 396 F.3d at 1363. The district court is in the best position to judge the sufficiency of the Rule 50(a) motion in the context of the trial. *See Gaus v. Conair Corp.*, 363 F.3d 1284, 1287 (Fed. Cir. 2004).

In *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1107 (Fed. Cir. 2003), the Federal Circuit noted, for instance, that a pre-verdict JMOL on the issue of anticipation would not be sufficient to support a post-verdict JMOL on obviousness because they are legally distinct and separate challenges to a patent's validity. And in *Junker v. Eddings*, 396 F.3d 1359, 1363 (Fed. Cir. 2005), the Federal Circuit found that a post-verdict JMOL raising specific elements of the patent in question were not supported by the pre-trial JMOL that referred only in general terms to the "design claimed in the patent."

Three other cases reached the opposite result. In *Gaus v. Conair Corp.*, 363 F.3d 1284, 1287 (Fed. Cir. 2004), the Federal Circuit upheld a district court's decision that a party did not waive its non-infringement claim in its post-verdict motion for JMOL where it raised the same arguments earlier, although in an abbreviated and terse form. In *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566 n.6 (Fed. Cir. 1996), and in *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1324-25 (Fed. Cir. 1991), the court held that very brief, oral pre-verdict motions for JMOL were sufficient to support a renewed JMOL. From these authorities, it appears the Federal Circuit follows

most circuits in liberally allowing renewed JMOLs,[2] as long as they do not raise issues entirely distinct and separate from the original JMOL.

In this case, there is no dispute that Baxter raised the issue of obviousness in its original Rule 50 motion. It also challenged the sufficiency of evidence with regard to obviousness specifically concerning patents '131 and '434. Obviousness was a major issue at the trial. Thus, the Court finds this situation more analogous to *Gaus*, *Texas Instruments*, and *Malta* rather than *Duro-Last* and *Junker*. Accordingly, the Court will review the merits of Baxter's arguments concerning claim 14 of the '131 patent and claims 28, 29, and 30 of the '434 patent.

1. Claim 14 of the '131 Patent

Claim 14 of the 131 patent requires that the "touch screen is operable to display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter." Docket 835-1 (Jury Instr. at 15). Baxter contends that Fresenius has failed to establish the invalidity of claim 14 because it relied only on the combination of the Cobe Manual and the Sarns 9000 to meet the claim elements. This Court has found that the Sarns 9000 Manual does not disclose the display of any indicium corresponding to time-variable hemodialysis parameters. As the Court has previously noted, the Sarns 9000 is a heart-lung machine and not a hemodialysis apparatus, and the Sarns 9000 "does not meet the 'time-variable profile' claim limitation." Docket No. 661, at 25-28. And Baxter points out that the Cobe Manual shows only one indicium relating to a time-variable hemodialysis parameter—programmable sodium. *See* PTX 240, Cobe Manual at F0145546.

For its part, Fresenius notes that its witness, James Causey, testified that claim 14 is obvious in view of prior art. Tr. at 835:13-836:21. Causey testified that "the engineers that developed the Cobe Machine have provided opportunities to add more time-variable parameter within this –." Tr. at 836:8-10. It adds that the Cobe C3 Manual discloses an indicium corresponding to a time-variable

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[2] *See* 9A C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2537 (3d ed. 1998); *see also Farley Transp. Co. v. Santa Fe Trail Transp. Co.*, 1342, 1347 (9th Cir. 1985).

hemodialysis parameter and that the Sarns 9000 has a touch screen. From this the jury could have reasonably concluded that it would have been obvious to add indicia corresponding to other time-variable parameters. It also notes the testimony of Charles Ragsdale that the Seratron Modeling Programmer Manual allows for UF profiling and sodium profiling and that the Modeling Programmer has several buttons corresponding to different time-variable hemodialysis parameters. Fresenius also relies on the testimony of Robert Pares that touch screens have been integrated into computer-controlled machines hundreds of times.

Fresenius did not show any of the cited pages of the Seratron Modeling Programmer Manual to the jury nor offered any expert testimony explaining the buttons on the modeling programmer to it. Moreover, the Seratron Modeling Programmer does not have a touch screen or any CRT display and therefore this reference fails to teach the missing claim elements because it does not "display" any indicia. Accordingly, Fresenius has not identified any prior art that would "display a plurality of indicia each corresponding to a different time variable hemodialysis parameter," and thereby provide substantial evidence supporting the jury verdict. The Cobe C3 Manual discloses a single indicium. The Sarns 9000 Manual discloses none. The Seratron Modeling Programmer does not have a touch screen or any CRT display. *See* PTX 1213C; *see also* PTX 380. The Federal Circuit has held that where no combination of prior art references describes the particular functions recited in a claim, a jury's verdict on obviousness must fall. *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997). With respect to Causey's testimony that "the engineers that developed the Cobe Machine have provided opportunities to add more time-variable parameter within this –", such confusing or generalized testimony as evidence of invalidity is improper. *See Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002). Therefore, there is not substantial evidence to support the jury's finding on claim 14 of the '131 patent.

2. Claims 28, 29, and 30 of the '434 Patent

Claim 28 of the '434 patent requires "means for delivering blood at a prescribed flow rate from

a patient, through a blood compartment of a hemodialyzer, and back to the patient, wherein the touch screen further provides a visual display of a parameter associated with said means for delivering blood." Docket No. 835-1 (Jury Instr. at 14). Claim 29 provides that "the parameter associated with said means for delivering blood is selected from a group consisting of blood flow rate, arterial blood pressure, and venous blood pressure." Docket No. 835-1 (Jury Instr. at 14). Claim 29 is dependent on claim 28. Claim 30 requires "means for delivering an anticoagulant to a patient, wherein the touch screen further provides an indicium soliciting input from the user corresponding to a rate of anticoagulant delivery." Docket No. 835-1 (Jury Instr. at 14). For claim 30, the Court instructed the jury that the structure corresponding to the "means for delivering an anticoagulant" is a microprocessor and a stepper motor. *See* Docket 835-1 (Jury Instr. at 21).

Baxter argues that Fresenius's witness Causey failed to discuss the means-plus-function claim elements or the structures required by them and that his testimony was therefore insufficient to prove obviousness. *See* Tr. at 824:2-827:24. Baxter also maintains that the single page of the Cobe Manual relied upon by Causey lacks any mention of a structure meeting either party's construction for "means for delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient" and that Causey offered no testimony regarding this claim limitation.

Causey testified that claim 28 is obvious in light of prior art—the Cobe C3 Manual (which displays venous and arterial pressure) and the Sarns 9000 (which has a touch screen). Tr. at 824:2-825:6. Baxter contends that none of the pages of the Cobe C3 Manual cited by Fresenius in its response were shown to the jurors or discussed in front of them by any of the eleven witnesses called by Fresenius. Fresenius does not rebut or effectively dispute this. Moreover, Fresenius does not identify any evidence given to the jury describing a microprocessor or a microprocessor with a blood pump performing the claimed function, *i.e.*, "delivering blood at a prescribed flow rate from a patient, through a blood compartment of a hemodialyzer, and back to the patient." Title 35 U.S.C. § 103 requires that the entire claim, or the "subject matter as a whole" be analyzed. Because not all of claim 28 was

analyzed, evidence of invalidity is lacking.

Causey also testified that claim 29 is invalid in view of prior art. Tr. at 825:7-826:13. Baxter contends that claim 29 is dependent on and includes all of the limitations of claim 28. Thus, a failure of proof on claim 28 would extend to claim 29 as well. Fresenius simply counters that there is sufficient evidentiary support for claim 28, and therefore claim 29 is also met. As the Court has found otherwise, sufficient evidence is also lacking to support the jury's finding on claim 29, and it too must be set aside.

Causey testified that claim 30 is invalid in view of prior art, namely the Cobe C3 Manual, which shows that the Cobe machine allows the controlled delivery of the anticoagulant heparin. Tr. at 826:14-827:24. However, the jury was instructed that "means for delivering an anticoagulant" is a microprocessor and a stepper motor. In its response to Baxter's motion, Fresenius makes no argument and indeed identifies no prior art that meets this construction. Fresenius response is that other machines delivered anticoagulants. This is insufficient evidence to support the jury's finding with respect to claim 30 because the prior art relied upon by Fresenius did not contain an equivalent structure to the disclosed structure for the means-plus-function claim term. *See Kahn v. General Motors Corp*., 135 F.3d 1472, 1480 (Fed. Cir. 1998). Accordingly, the jury's findings on claims, 28, 29, and 30 must fall.

3. Element (a) of Claim 26 of the '434 Patent and Element (a) of Claim 1 of the '131 Patent

Element (a) of claim 26 requires "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer." Docket No. 835-1 (Jury Instr. at 14). The jury was instructed that the function associated with the "means for controlling a dialysate parameter" is "controlling dialysate temperature and/or controlling dialysate concentration," and that the structure for controlling dialysate temperature is a "microprocessor, a heater, and a temperature sensing device;" the structure for controlling dialysate concentration is a "microprocessor and a concentrate pump." Docket No. 835-1 (Jury Instr. at 21). Element (a) of claim 1 of the '131 patent provides "a dialysate-delivery system for supplying dialysate to a hemodialyzer, the dialysate-delivery system comprising at least one

unit selected from the group consisting of (i) a dialysate-preparation unit, (ii) a dialysate-circulation unit, (iii) an ultrafiltrate-removal unit, and (iv) a dialysate-monitoring unit." Docket No. 835-1 (Jury Instr. at 15).

Baxter maintains that neither expert offered by Fresenius to prove the invalidity of the '131 and '434 patents—Dr. Gunter Rau or Causey—sufficiently addressed element (a) of claim 26 or element (a) of claim 1 because Dr. Rau only testified that element (b) of each claim was obvious, not element (a), and because Causey improperly "boiled down" element (a) in contravention of Federal Circuit law.

Fresenius offers little argument that Dr. Rau offered testimony on element (a) of either claim, only that his testimony in combination with all of the other evidence supports the verdict. A review of the record does show that Dr. Rau's testimony is limited to an analysis of element (b) of claim 1 and element (b) of claim 26. *See* Tr. 594:6-11; 599:20-600:10; 601:6-21.

Causey testified that claim 26 is obvious, pointing to the Cobe C3 Manual, the CMS 08 Manual, in combination with the Sarns 9000. Tr. at 821:6-822:17. The Cobe C3 Manual, however, does not appear to disclose the required structure for element (a) of claim 26. The pages cited by Fresenius do not mention a microprocessor and a heater and/or a temperature sensing device, or a microprocessor and a concentrate pump. *See* Docket No. 849, Ex. 5 (Abernathy Decl.). Nor does the CMS 08 Manual appear to provide disclosure of the required structure. The cited pages do not disclose a microprocessor, a heater, or a temperature sensing devices or the required "means for delivering the dialysate to a dialysate compartment of a hemodialyzer."

Fresenius further maintains that the limitations of element (a) of claim 26 are met by the Seratron System. Dr. Ben J. Lipps testified that the Seratron marketing literature describes the requirements of element (a) at a high level [Tr. at 222:5-19, 224:7-225:5] and that the Seratron Technician's Manual describes the inner workings of the machine. But this evidence is flawed. While the Seratron Technician's Manual was admitted into evidence, the only witness testimony concerning it was offered by Ragsdale who discussed one page of the Manual in reference to the '027 patent. Tr. at 549:10-552:2.

There was no witness testimony connecting it to the '434 patent. *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1325 (Fed. Cir. 2005) (expert's direct testimony was conclusory and failed to analyze and explain the claim language and which components of the prior art embodied each element of the asserted claim); *Koito*, 381 F.3d at 1152-54. Conclusory evidence is insufficient to meet Fresenius's burden of clear and convincing evidence. Nor is it convincing that the page mentioned (PTX 383 at F006581) discloses the required structure of element (a).

Turning next to claim 1 of the '131 patent, Causey testified that it is obvious based on the CMS 08/A2008 system or the CMS 08 Manual, in combination with the Sarns 9000. Tr. at 829:16-830:12. His testimony on this point was rather brief; he testified simply that it claimed "basically the functions of most of the hemodialysis machines." Tr. at 830:8-12. His testimony did not analyze and explain the claim language and which components of the prior art embodied each element of the asserted claim. *Cf. NTP*, 418 F.3d at 1325; *Koito Mfg*., 381 F.3d at 1152 n.4. Moreover, Fresenius has not identified any testimony from Causey where he specifically analyzes element (a). Fresenius further argues that by identifying the Cobe C3 Manual as invalidating prior art with respect to claims in the '131 patent that are dependent on claim 1, Causey implicitly identified the Cobe C3 Manual as meeting element (a) of claim 1 as well. This argument is vague at best and fails to identify substantial evidence given to the jury as required.

Fresenius also points to the Seratron System, as described in the Seratron Technician's Manual, as meeting the limitations of element (a) of claim 1 of the '131 patent. Reliance on the Seratron Manual, however, is problematic for the reason discussed above with respect to claim 26 (there was no testimony connecting it to the '131 patent). Therefore, Fresenius has not identified substantial evidence supporting the jury's verdict that the claims of the '131 and '434 patents are invalid because a necessary element of both was not addressed.

4. Motivation to Combine the Claims of the '131 and '434 Patents

Baxter argues that Fresenius failed to meet its burden to show a motivation to combine the

claims of the '434 and '131 patents. Fresenius witness Causey testified that the motivation to combine the claims of the '434 and '131 patents came from "Dr. Rau's article teaching touch screens on complex medical machines, including hemodialysis machines and a knowledge of those skilled in the art of touch screens as input devices." Tr. at 822:1-14.

As evidence of a motivation to combine, Fresenius relies heavily upon Dr. Rau's article entitled *Ergonomics and Aspects of Application in Medicine*. The article discusses "proposals regarding more sophisticated and complicated instrument systems" for complex medical devices and describes an anaesthesia information system with a touch screen interface. Dr. Rau testified that his article "gave numerous examples of where you can use [touch screen] technology beneficially," and that "one of the examples which I mentioned was hemodialysis and a hemodialysis machine." Tr. at 598:23-599:2.

Fresenius, however, offers little contention that the Rau article does in fact provide a motivation to combine. The article mentions "extracorporeal dialysis" a single time on page seven (F067208). There is no clear and particular showing, teaching, or motivation to combine the use of touch screen technology with a hemodialysis machine. At most, the Rau article is an "obvious to try" situation: it may have been obvious to try implementing a touch screen interface together with numerous medical devices, including a hemodialysis machine, but the article in context merely suggests this might be "a promising field of experimentation." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Federal Circuit precedent establishes that where the reference gives only general guidance or a suggested approach, this is insufficient to make the claim "obvious." *See, e.g., In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995); *O'Farrell*, 853 F.2d at 903 (listing cases).

Turning next to Causey's general citation of the "knowledge of those skilled in the art of touch screens as input devices" this also fails to show a motivation to combine. As specific examples, Fresenius relates the following testimony:

> Mr. Phares testified that by the late 1980s, Elographics was selling "several thousand" touch screen kits per month and was specifically targeting the medical device industry to get them to use touch screens. [*Id*. at 454:6-455:9.] He testified that Elographics "did a significant amount of advertising and participated in—in many trade shows" to encourage the use of touch screens. [*Id*. at 449:25-450:5.]
>
> Perry Guinn, the original project manager for the SATRN project, testified that

> the SATRN design team "would be getting, on a regular basis, trade magazines that had advertisements for all of the latest, you know, gee-whiz features that were coming along that were available to designers of equipment. And so [touch screens] were well-known, and—and well—they were very available. They just weren't cheap." [Ex. B, 7/22/2005 Depo. Tr. of Perry Guinn at 44:25-45:7.]
> Mr. Kelly testified that the System 1000 used an IBM compatible personal computer [Ex. A, Tr. at 986:10-17; Ex. I, PTX 157 at BA 184055] and conceded that touch screens were one of the well-known user interfaces that could be used to allow a person to interact with a computer [Ex. A, Tr. at 709:6-21.]
>
> Mr. Kelly also testified that using a touch screen could simplify the user interface. [Ex. A, Tr. at 900:4-5 ("by using touch screens, I felt we could potentially simplify the user interface".] Mr. Ferraro then later conceded that it would make sense to make the user input device for a hemodialysis machine as simple as possible for the technician. [Id. at 1274:22-1275:2.]
>
> The Sarns 9000 manual touts the supposed advantages of touch screens. [*See* Ex. J, PTX 342 at F298964 ("The unique S9000 touchscreen allows at-a-glance monitoring of critical information. Additional data can be displayed and manipulated as required, without losing sight of critical values"); *see also* F298967 ("The S9000 integrates advanced pumping technologies with computer-aided monitoring and efficient touchscreen controls for more assured decision-making and top perfusion performance. . . . Critical monitoring information is continuously displayed on the S9000 touchscreen, eliminating the need to scroll though menus to access the information needed.").]

Docket No. 860 at 18-19.

The difficulty with this evidence is that it merely demonstrates knowledge of touch screens in prior art. *See, e.g., Smiths Indus. Med. Sys. Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999) (emphasis in original) ("That knowledge *may* have been within the province of the ordinary artisan does not in and of itself make it so, absent clear and convincing evidence of such knowledge"). It fails to establish the clear and particular "reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). It is not disputed that the use of touch screens as inputs were known in the art; the issue Fresenius needed to prove was that there was a motivation to combine the touch screen in the manner claimed in the patents. *Id.* ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"). Even knowledge in the prior art of every element of a patent claim is not itself sufficient to render a claim obvious. *See Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1357 (Fed. Cir. 2003); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987). The cited evidence is deficient in this respect for establishing such a

motivation to combine the claims of the '131 and '434 patents. Therefore Fresenius has not shown there is substantial evidence adequately supporting the jury's decision on this point.

5. Claim 7 of the '476 Patent

Element (e) of claim 7 of the '476 patent requires "means, responsive to the entered time period and entered proposed profile, for comparing the profile cumulative value with the target cumulative value." Docket No. 835-1 (Jury Instr. at 17). The "means . . . for comparing" is a microprocessor. *See* Docket No. 701, at 30 (Order on Mot. Sum. Judg.). On the CMS 08, it is the user of the machine that does the "comparing" rather than a microprocessor. *Id*. Dr. Richard A. Ward testified on behalf of Fresenius with regard to claim 7. Dr. Ward testified that it would have been obvious to modify the CMS 08 to have the machine perform the "comparing" step of element (e) automatically rather than requiring the user to perform this function. Tr. at 537:11.

Baxter complains that Dr. Ward's testimony was conclusory and failed to identify anything suggesting such a modification, and that his testimony failed to explain how or why one of ordinary skill in the art would have made the modification in 1991. Fresenius counters that it is well known that steps performed manually may be automated using a computer and maintains that the single reference of the CMS 08 was enough to show automatic comparing. This is not persuasive. A broad, conclusory statement that such a modification was "obvious" is not enough to demonstrate by clear and convincing evidence that the teachings of the prior art would have suggested this modification. There must be factual support for an expert's conclusory opinion. *See Upjohn Co. v. MOVA Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000).

It is true that under some circumstances, a single prior art reference, such as the CMS 08, may be sufficient to render a claim obvious. *See, e.g., SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). However, there must still be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion.

SIBIA, 225 F.3d at 1356. Dr. Ward's brief testimony failed to address precisely where this suggestion or motivation was found in the prior art.

6. Claim 5 of the '476 Patent

Claim 5 of the '476 patent requires:

> A method of providing operational instructions to a dialysate-producing machine having a memory and a capability of ultrafiltrating fluid from a patient according to a time-variable ultrafiltration profile, so as to enable the machine to produce dialysate having particular ultrafiltration characteristics at various times during use of the machine for a dialysis procedure, the method comprising:
>
> > (a) providing a user/machine interface configured as a touch screen operably connected to the dialysate-producing machine;
> > (b) programming into the memory a first ultrafiltration profile;
> > (c) providing on the touch screen an indicium enabling a user of the machine to recall the first ultrafiltration profile from memory;
> > (d) using the touch screen, displaying on the touch screen first and second intersecting axes defining a ultrafiltration profile region, the first axis corresponding to ultrafiltration rate, and the second axis corresponding to time; and
> > (e) touching the indicium provided in step (c) to cause the touch screen to display within the ultrafiltration profile region a second ultrafiltration profile substantially conforming to the first ultrafiltration profile.

Docket No. 835-1 (Jury Instr. at 16).

Dr. Ward opined that claim 5 of the '476 patent is invalid as obvious. Baxter argues that Fresenius was obliged but failed to show that one of ordinary skill in the art would be motivated to combine a touch screen with the CMS 08 to display and control the function described in the elements of claim 5 of the '476 patent. *Cf. Koito*, 381 F.3d at 1151.

Fresenius maintains that it demonstrated that the CMS 08 meets all the elements of claim 5 except for the touch screen. It then notes that Dr. Ward concluded that claim 5 is invalid over a combination of the CMS 08 and a touch screen and that this conclusion is supported by evidence that touch screens "were known as input devices for medical devices at the time the patents were filed." Docket No. 860 at 23.

As related in the discussion of claim 7, when relying on a single reference to prove obviousness, "there must be a showing of a suggestion or motivation to modify the teachings of that reference to the

claimed invention in order to support the obviousness conclusion." *SIBIA Neurosciences*, 225 F.3d at 1356. Again, Dr. Ward did not offer testimony that the prior art contained a suggestion or motivation to combine the CMS 08 with a touch screen.

Fresenius further relies on the testimony of Phares and Causey with respect to claim 5. Causey testified that it would have been "exceptionally straightforward" to add a touch screen input device to the CMS 08. Tr. at 841:21-25. Phares testified that integrating a touch screen into a computer-controlled machine had been done hundreds of time before. Tr. at 468:13-25. This testimony too fails to show substantial evidence of a motivation to combine. "[O]pinion evidence that is connected to existing data only by the *ipse dixit* of the expert" is of little value. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). More particularly, the motivation to combine must be supported by actual evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1334 (Fed. Cir. 2002). Nothing beyond conclusory opinions were offered. Therefore, substantial evidence is missing to support the jury findings on claims 5 and 7 of the '476 patent.

7. Claim 11 of the '027 Patent

Baxter maintains that the testimony of Ragsdale and Causey was legally insufficient to prove obviousness of claim 11 of the '027 patent. Baxter contends that Causey addressed only claim 11 of the '027 patent, and reasons that because he did not address the limitations of independent claim 7, upon which claim 11 depends, he therefore failed to examine claim 11 "as a whole" as required by 35 U.S.C. § 103. Baxter also argues that Ragsdale's testimony about the '027 patent was limited to the issue of anticipation, not obviousness.

Fresenius counters that Ragsdale testified unequivocally that claim 7 was anticipated by the Seratron, citing this declaration: "everything that is written here is exactly what the Seratron did." Tr. at 549:2-550:13. And Fresenius reasons that this "anticipation" testimony necessarily extends to obviousness, citing the proposition that "[i]t is well settled that 'anticipation is the epitome of obviousness.'" *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (quoting *Connell v. Sears Roebuck*

& Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983)). This legal maxim, however, does little to overcome the statutory requirements of 35 U.S.C. § 282 that

> Each claim of a patent (whether in independent, dependant, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.

Claim 11 is dependent on claim 7. *See* Docket No. 835-1 (Jury Instr. at 18). Accordingly, claim 11 includes claim 7. Thus if 7 was not addressed, then all of the elements of 11 were not addressed. Fresenius therefore did not offer substantial evidence that one of skill in the art would, at the time the inventions were made, have recognized that each limitation of claim 11 were in the prior art or would have been motivated to combine the prior art. The jury's decision on this issue must be set aside as a result.

B. Motion for a New Trial Pursuant to Rule 59

Baxter has also submitted a Motion for a New Trial Pursuant to Rule 59 [Docket No. 845]. Federal Rule of Civil Procedure 59(a) provides that a "new trial may be granted . . . on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States." FED. R. CIV. P. 59(a). A new trial is appropriate if the verdict is contrary to the clear weight of the evidence, or is based upon evidence which is false, or to prevent, in the sound discretion of the trial judge, a miscarriage of justice. *See Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1005 (9th Cir. 2004); *City Solutions, Inc. v. Clear Channel Communications*, 365 F.3d 835, 843 (9th Cir. 2004). A new trial is generally not granted unless the court "is left with the definite and firm conviction that a mistake has been committed." *Landes Constr. Co. v. Royal Bank of Can.*, 833 F.2d 1365, 1372 (9th Cir. 1987).

In its motion, Baxter seeks a new trial on three issues: (1) the validity of the '434 patent, the '131 patent, the '476 patent, and the '027 patent; (2) on its allegations that the patents were infringed; and (3) damages. As discussed, the jury found that the various claims of the four patents were invalid as

either obvious or as anticipated. The Court has determined that the jury's determination of invalidity on the claims is not supported by substantial evidence and accordingly, as a matter of law, must be set aside. Therefore many of the arguments in Baxter's motion for a new trial are rendered moot by the Court's findings on Baxter's motion for judgment as a matter of law. A new trial is appropriate nevertheless.

The jury held that Baxter did not prove by a preponderance of the evidence that the Fresenius 2008K hemodialysis machine literally infringes claim 5 or 7 of the '476 patent. *See* Docket No. 829 (Jury Verdict at 4). The finding of non-infringement necessarily followed the determination of invalidity. As the Court has found that Fresenius has not proven by clear and convincing evidence the invalidity of the patents, the issues of validity, infringement, and possible damages are still left for resolution. A new trial to determine these matters is necessary.

CONCLUSION

IT IS HEREBY ORDERED THAT Baxter's Motion for Judgment as a Matter of Law [Docket No. 847] is GRANTED and that Baxter's Motion for a New Trial Pursuant to Rule 59 [Docket No. 845] is also GRANTED.

IT IS SO ORDERED.

February 12, 2007

Saundra Brown Armstrong
United States District Judge