

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

FRESENIUS USA, INC.
and FRESENIUS MEDICAL CARE HOLDINGS, INC.,

Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,

Defendants-Cross Appellants.

Juanita R. Brooks, Fish & Richardson P.C., of San Diego, California, argued for plaintiffs-appellants. With her on the brief were Michael E. Florey, Mathias W. Samuel and Deanna J. Reichel, of Minneapolis, Minnesota, and Robert E. Hillman, of Boston, Massachusetts.

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Appealed from: United States District Court for the Northern District of California

Judge Sandra Brown Armstrong

United States Court of Appeals for the Federal Circuit

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Appeals from the United States District Court for the Northern District of California in case no. 03-CV-1431, Judge Sandra Brown Armstrong.

DECIDED: September 10, 2009

Before NEWMAN, GAJARSA, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA. Concurring opinions filed by Circuit Judge NEWMAN and Circuit Judge DYK.

GAJARSA, Circuit Judge.

In this patent infringement case, Plaintiffs Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively “Fresenius”) appeal and Defendants Baxter International, Inc. and Baxter Healthcare Corporation (collectively “Baxter”) cross appeal from the final judgment of the United States District Court for the District of California, which was based on findings that Fresenius infringed claims of three patents asserted

by Baxter—U.S. Patent Nos. 5,247,434 (“the ’434 patent”), 5,744,027 (“the ’027 patent”), and 6,284,131 (“the ’131 patent”)—all of which disclose and claim a hemodialysis machine integrated with a touch screen user interface. Fresenius Med. Care Holdings, Inc. v. Baxter Int’l, Inc., No. 03-CV-1431 (N.D. Cal. Feb. 12, 2007) (“JMOL Opinion”). We affirm in part, reverse in part, vacate in part, and remand for further proceedings consistent with this opinion.

BACKGROUND

I. The Technology and Patents

When a person’s kidneys fail to function properly, a hemodialysis machine can function in place of the kidneys to cleanse the blood of toxins. During hemodialysis, the person’s blood is pumped through a hemodialysis machine, which contains a dialysate—a solution formulated to draw toxins out of the blood. Inside the machine, the blood is separated from the dialysate by a semi-permeable membrane that allows toxins to pass from the blood into the dialysate. Because it is important to ensure that toxins are removed without inadvertently filtering essential nutrients out of the blood, the hemodialysis machine must facilitate the monitoring and control of numerous parameters.

All of the patents at issue derived from a parent patent application filed in 1991, and all of the relevant claims are directed to a hemodialysis machine integrated with a touch screen user interface. At the time the parent application was filed, touch screens were known and had been used on other medical devices, such as a heart-lung machine, but a touch screen had not been integrated with a hemodialysis machine. The System 1000, which embodies the patents at issue, was introduced in 1991 and was a

commercial success.¹ In 1998, Fresenius introduced the alleged infringing device, a hemodialysis machine with a touch screen interface called the 2008K machine.

A. The '027 Patent

The only '027 patent claim at issue in this appeal is claim 11, which is dependent on claim 10, which is in turn dependent on claim 7. Claim 7 reads:

A kidney dialysis machine, comprising:

(a) a dialysate pump for circulating dialysate at a dialysate conductivity through a dialysate circuit including a dialysate compartment for a dialyzer; and

(b) a controller operable to receive non-conductivity data concerning a particular selection of dialysate to be circulated and to calculate from the data an expected conductivity reading of the dialysate.

'027 Patent col.36 ll.14–21. Dependent claim 11 additionally requires only a “data input device” that “comprises a touch screen.” Id. at col.36 l.32–33. The additional limitation of claim 10 is not at issue in this appeal.

B. The '131 Patent

Regarding the '131 patent, independent claim 1 and claims 2, 3, and 13–16, which are dependent on claim 1, are at issue in this appeal. Claim 1 reads:

A hemodialysis apparatus, comprising:

(a) 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; and

(b) a user/machine interface operably connected to the dialysate-delivery system, the user/machine interface

¹ Althin filed the relevant patent applications and introduced the System 1000. Baxter purchased Althin and the patents at issue in March 2000.

comprising a touch screen that displays information corresponding to a setting of a parameter pertinent to operation of the hemodialysis apparatus, the touch screen being operable to display an indicium permitting the user to perform, using the touch screen, at least one step of a procedure for changing the setting of the parameter, and to display a time-variable profile of the operational parameter, the profile being representable as a plot of coordinates, the plot being with respect to an ordinate of values of the operational parameter and a time-based abscissa.

'131 Patent col.36 ll.1–21. Claim 14 additionally requires only that “the touch screen is operable to display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter.” Id. at col.36 ll.64–67. Claim 16 additionally requires that “the user/machine interface is operable to require the user to verify a parameter after a value of the parameter is selected.” Id. at col.37 ll.4–6. The additional limitations recited in claims 2, 3, 13, and 15 were not argued on appeal.

C. The '434 Patent

Regarding the '434 patent, independent claim 26 and claims 27–31, which are dependent on claim 26, are at issue in this appeal. Claim 26 reads:

A hemodialysis machine comprising:

(a) 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; and

(b) a user/machine interface operably coupled to said dialysate-delivery means, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine for performing hemodialysis and to permit the user, by touching the indicium, to cause a change in the parameter.

'434 Patent col.40 ll.29–42. Dependent claims 27–31 include additional limitations, but only the additional limitation in claim 30 is relevant to this appeal. That limitation

requires a “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.” Id. at col.40 ll.61–64.

II. Litigation Background

Fresenius initially filed suit against Baxter in 2003, seeking a declaratory judgment that the '027, '131, and '434 patent claims are invalid and not infringed by Fresenius's hemodialysis machines.² Baxter counterclaimed, alleging that Fresenius infringes claims 7, 11, and 14–16 of the '027 patent; claims 1–3 and 13–16 of the '131 patent; and claims 26–31 of the '434 patent. On Baxter's motion, the district court granted partial summary judgment that Fresenius infringes claim 1 of the '131 patent and claim 26 of the '434 patent. Baxter continued to allege that Fresenius infringes the other asserted claims, and Fresenius continued to allege that all asserted claims are invalid. Following claim construction, Fresenius stipulated that it infringes Baxter's remaining asserted claims. A jury trial on validity followed, and the jury found claims 7 and 14–16 of the '027 patent invalid as anticipated and all asserted claims invalid as obvious.

The district court determined that substantial evidence does not support the jury's obviousness verdict and granted Baxter's motion for judgment as a matter of law (“JMOL”) that its asserted patent claims are not invalid as obvious. Namely, the district court found that Fresenius had not presented evidence that specified limitations of claim 11 of the '027 patent, claims 1 and 14 of the '131 patent, and claims 26–31 of the '434

² The original filings included two additional patents—neither of which is relevant to this appeal.

patent were present in the prior art. JMOL Opinion, slip op. at 8–13, 18–19. In addition, the district court found that Fresenius did not present substantial evidence of a motivation to combine the elements of the prior art to produce the invention claimed in the '131 and '434 patents. Id. at 13–16. The court did not evaluate the jury's findings that claims 7 and 14–16 of the '027 patent are invalid as anticipated, stating that Baxter had not challenged the anticipation verdict. Id. at 6 n.1.

After a jury trial on damages, the jury awarded Baxter a total of \$14,266,000 in damages, \$91,000 of which was attributable to unpatented disposable products. The district court, after considering the four factors articulated in eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006), concluded that injunctive relief was appropriate and permanently enjoined Fresenius. Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc., No. 03-CV-1431, slip. op. at 8–10 (N.D. Cal. March 21, 2008) ("Injunction Order"). The district court ordered that the injunction take effect on January 1, 2009, because Fresenius indicated it could develop a non-infringing machine by that date. Id. at 8–9. The district court also ordered Fresenius to pay an ongoing royalty of 10% of the sales price for any infringing machines sold before January 1, 2009, and a royalty of 7% of the sales price for all disposable products linked to infringing machines that were sold from November 7, 2002, until the patents expire. Id. at 9–10. The district court imposed the royalty rates without explaining the bases for its calculations.

Fresenius appeals the district court's grant of JMOL, entry of a permanent injunction, royalty award, and constructions of specified claim terms. Baxter cross appeals the jury's determination that the asserted '027 patent claims are invalid as anticipated. This court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

Following the procedural law of the Ninth Circuit, we review the district court's grant or denial of JMOL de novo. Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1370 (Fed. Cir. 2009) (citing Theme Promotions, Inc. v. News Am. Mktg. FSI, 546 F.3d 991, 999 (9th Cir. 2008)); see also Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1149 (Fed. Cir. 2004) (reviewing without deference JMOL decisions of a district court in the Ninth Circuit). "The party requesting the JMOL . . . must show that substantial evidence did not support the jury's findings, where 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.'" Koito, 381 F.3d at 1149 (quoting Tex. Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1563 (Fed. Cir. 1996)); see also Revolution Eyewear, 563 F.3d at 1370–71.

As we have explained, "[t]his court reviews a jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001). Where, as here, the jury made no explicit factual findings regarding obviousness, we must determine whether the implicit findings necessary to support the verdict are supported by substantial evidence. Upjohn Co. v. Mova Pharm. Corp., 225 F.3d 1306, 1310 (Fed. Cir. 2000). "[T]he verdict of obviousness must be supported by facts of (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention

and the prior art, and (4) any objective indicia such as commercial success or long-felt need.” Id.

Each patent claim is presumed valid, and as the party contending that the asserted claims are invalid, Fresenius was required to prove invalidity of each claim by clear and convincing evidence. See 35 U.S.C. § 282; Lisle Corp. v. A.J. Mfg. Co., 398 F.3d 1306, 1316 (Fed. Cir. 2005). Thus, in reviewing the jury’s verdict, “we must determine whether the jury had substantial evidence upon which to conclude that [the party alleging invalidity] met its burden of showing invalidity by clear and convincing evidence.” Koito, 381 F.3d at 1149.

In this appeal, we also consider the district court’s entry of a permanent injunction and royalty award. We review the district court’s grant of a permanent injunction for abuse of discretion. Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1379 (Fed. Cir. 2008); see also eBay, 547 U.S. at 391. Regarding the district court’s royalty award, “we review the trial court’s determinations for erroneous conclusions of law, clearly erroneous factual findings, and clear errors of judgment amounting to an abuse of discretion.” Mitutoyo Corp. v. Cent. Purchasing, LLC, 499 F.3d 1284, 1292 (Fed. Cir. 2007).

II. Baxter’s Cross Appeal Regarding Anticipation of Claim 7 of the ’027 Patent

As the sole issue in its cross appeal, Baxter asserts that substantial evidence does not support the jury’s finding that claim 7 of the ’027 patent is invalid as anticipated. By failing to properly raise that argument before the district court, Baxter has waived it, and we decline to consider it. See Golden Bridge Tech., Inc. v. Nokia, Inc., 527 F.3d 1318, 1323 (Fed. Cir. 2008) (declining to consider a new argument the

party could have raised before the district court); Sw. Software, Inc. v. Harlequin Inc., 226 F.3d 1280, 1290 (Fed. Cir. 2000) (“Failing to properly move for JMOL at the close of the evidence precludes a challenge to the sufficiency of the evidence underlying fact findings.”); Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1426 (Fed. Cir. 1997) (declining to consider a novel infringement argument raised on appeal).

In Baxter’s Rule 50(a) motion for JMOL and Rule 50(b) renewed motion for JMOL, Baxter only briefly mentioned the jury’s anticipation verdict, and in each motion, Baxter relegated its discussion of that verdict to a single footnote. In its Rule 50(a) motion, Baxter merely stated that “[t]o preserve its rights, Baxter also moves for JMOL on Fresenius’ defense that the Seratron System anticipates the asserted claims of the ’027 patent because Fresenius has failed to prove that System is prior art with sufficient corroborating evidence.” J.A. at 21588. Baxter provided no further explanation in the Rule 50(a) motion and did little to develop the anticipation argument in its Rule 50(b) motion. In that motion, also in a footnote, Baxter stated that it “renews its JMOL on Fresenius’ defense that the Seratron System anticipates and/or renders obvious the remaining asserted claims of the ’027 Patent,” and then provided a minimal explanation regarding how “Fresenius failed to prove by clear and convincing evidence that that Seratron System is prior art with sufficient corroborating evidence.”

On appeal, Baxter argues that the Seratron System lacks two of the required claim limitations because “it is not operable to receive non-conductivity data concerning a particular selection of dialysate, and it does not use non-conductivity data to calculate an expected conductivity reading.” Cross Appellant’s Rep. Br. at 5–6. Baxter asserts that its limited statements to the district court preserved those arguments for appeal, but

we disagree. Before the trial court, Baxter argued that it is entitled to JMOL because Fresenius failed to prove that the Seratron System is prior art—Baxter did not argue that the Seratron System lacked specified claim limitations. Contrary to Baxter’s assertions, one specific challenge to an anticipation finding does not preserve all possible challenges to that finding. If a party fails to raise an argument before the trial court, or presents only a skeletal or undeveloped argument to the trial court, we may deem that argument waived on appeal, and we do so here. See CBOCS W., Inc. v. Humphries, 128 S. Ct. 1951, 1963 n.2 (2008) (declining to consider a claim while noting the appellate court had deemed that claim waived because it was presented as “only a skeletal argument” to the district court) (citing Humphries v. CBOCS W., Inc., 474 F.3d 387, 407 (7th Cir. 2007)); Golden Bridge Tech., 527 F.3d at 1323 (“This is an appellate court and as such we abide by the general rule that new arguments will not be decided in the first instance on appeal.”); SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1320 (Fed. Cir. 2006) (deeming an argument waived because it was not presented as a developed argument in the opening brief); Sage Prods., 126 F.3d at 1426 (“With a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party’s new theories, lodged first on appeal. If a litigant seeks to show error in a trial court’s overlooking an argument, it must first present that argument to the trial court.”).

Moreover, the new anticipation argument Baxter presents on appeal includes factual assertions regarding the information contained in the Seratron manual. See Cross Appellant’s Rep. Br. at 7–15. Fresenius contests those factual assertions, arguing that the technical statements in the Seratron manual cannot be interpreted in

the manner proposed by Baxter. See Appellant's Rep. Br. at 18–20. Thus, the parties present a new factual dispute on appeal. Such a factual dispute should have been presented to the district court for its consideration in the first instance.

For the foregoing reasons, we conclude that Baxter did not properly present its argument regarding the claim 7 anticipation verdict to the district court, and thus, Baxter has waived that argument.

III. Obviousness

The district court determined that Fresenius failed to present substantial evidence that various non-touch-screen limitations of the asserted claims were present in the prior art. The district court also found that Fresenius did not present substantial evidence of a motivation to combine the elements of the prior art to achieve the invention claimed in the '131 and '434 patents. Fresenius argues that the non-touch-screen limitations in the asserted claims were standard in prior art hemodialysis machines and that it presented substantial evidence of such to the jury. Baxter contends the asserted claims are nonobvious, or at a minimum, that Fresenius failed to meet its burden of proving invalidity by clear and convincing evidence. For the following reasons, we reverse the district court's grant of Baxter's JMOL motion, except as to claims 26–31 of the '434 patent.

A. Claim 11 of the '027 Patent

Because claim 11 is dependent on claim 7, it includes all limitations recited in claim 7. The district court determined that Fresenius had not presented any testimony regarding the obviousness of claim 7, and thus concluded that Fresenius necessarily failed to demonstrate that all limitations of claim 11 were in the prior art. JMOL Opinion,

slip op. at 19. Specifically, the district court determined that because Mr. Causey—Fresenius’s only expert witness to testify that claim 11 is obvious—did not discuss the claim 7 limitations, Fresenius had failed to meet its burden of proving by clear and convincing evidence that claim 11 is obvious. Id. We disagree.

As Fresenius notes, although Mr. Causey did not discuss the claim 7 limitations, Mr. Ragsdale, another expert witness for Fresenius, had previously discussed those limitations when he testified that claim 7 is invalid as anticipated. In determining whether Fresenius presented substantial evidence to support the jury’s verdict that claim 11 is obvious, we must consider all evidence that was before the jury and draw all reasonable inferences from that evidence in the light most favorable to Fresenius. See Koito, 381 F.3d at 1149. From Mr. Ragsdale’s testimony, a reasonable jury could conclude that all limitations of claim 7 were present in the prior art. Claim 7 is divided into elements (a) and (b), and Mr. Ragsdale separately testified about each element, explaining how each was present in the prior art Seratron machine. J.A. at 14342–43. Fresenius also offered the Seratron’s operating manual. Thus, when the jury was assessing the obviousness of dependent claim 11, it could reasonably conclude that all limitations of claim 7 were in the prior art based on Mr. Ragsdale’s testimony.

Baxter argues that Fresenius failed to carry its burden because it did not properly connect all of the evidence regarding the obviousness of claim 11, namely because Mr. Causey never referred to Mr. Ragsdale’s testimony. Cross Appellant’s Br. at 40. That argument fails. Although it would have been advisable for Fresenius to ensure that Mr. Causey discussed all limitations of claim 11 when he testified regarding the obviousness of that claim, Fresenius was not required to do so. When, as here, the

question of obviousness is submitted to the jury, we must review the jury's implicit factual findings for substantial evidence. Upjohn Co., 225 F.3d at 1310. Here, the jury implicitly found that all limitations of claim 7 were present in the prior art, and as explained above, substantial evidence supports that finding. Thus, a reasonable jury could conclude that the non-touch-screen limitations of claim 11 were in the prior art by considering Mr. Causey's testimony in combination with Mr. Ragsdale's testimony and the Seratron manual. Because substantial evidence supports the jury's implicit finding, JMOL was inappropriate.

B. Claims 1–3 and 13–16 of the '131 Patent

On appeal, the parties limit their arguments to element (a) of claim 1 and specified additional limitations of claims 14 and 16.

1. Element (a) of Claim 1

Element (a) of claim 1 requires:

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.

'131 Patent col.36 ll.1–8. The district court concluded that substantial evidence does not support the jury's verdict because Mr. Causey, Fresenius's expert who testified that claim 1 is obvious, did not specifically analyze element (a). Because Mr. Causey's "testimony did not analyze and explain the claim language and which components of the prior art embodied each element of the asserted claim," the district court determined that Fresenius had not met its burden of proving that claim 1 is invalid. JMOL Opinion, slip op. at 13. Because all the asserted claims of the '131 patent contain the element

(a) limitation, the district court granted JMOL for all of the asserted claims. We disagree with the district court.

Element (a) is written in Markush form, such that the entire element is disclosed by the prior art if one alternative in the Markush group is in the prior art. See Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003) (holding a claim invalid as anticipated when it claimed compounds in Markush form and a prior art reference disclosed one of the claimed compounds); In re Skoll, 523 F.2d 1392, 1397 (CCPA 1975); see also Titanium Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) (“It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.”). Thus, a prior art device discloses element (a) if it contains a dialysate-delivery system for supplying dialysate to a hemodialyzer comprising only a dialysate-circulation unit (or any one of the other three listed alternatives).

It is clear that the prior art disclosed a hemodialysis machine containing a dialysate-circulation unit. Mr. Kelly, Baxter’s witness, admitted and agreed that all hemodialysis machines—which the jury could reasonably presume would include those in the prior art—must have “some way of circulating the dialysate through a dialysate circuit.” J.A. at 14399. In addition, Mr. Ragsdale testified that in his opinion, “the Seratron system includes a dialysate pump for circulating dialysate . . . through a circuit including a dialysate compartment for a dialyzer.” J.A. at 14342. Finally, Mr. Causey testified that the limitations of element (a) of the ’131 patent are present in the CMS 08 prior art hemodialysis machine.

Based on the totality of the testimony presented by Messrs. Kelly, Ragsdale, and Causey, the jury could reasonably conclude that the limitations of element (a) were known in the prior art. Specifically, the jury could conclude that the prior art contained a hemodialysis machine with a dialysate-delivery system that supplies dialysate to a hemodialyzer and comprises a dialysate-circulation unit. Because substantial evidence supports the jury's finding, JMOL was inappropriate.

2. Claim 14

Claim 14 of the '131 patent depends from claim 1 and adds one additional limitation: "wherein the touch screen is operable to display a plurality of indicia, each corresponding to a different time-variable hemodialysis parameter." '131 Patent col.36 ll.64–67. Although the district court noted that the manual for the Cobe C3 prior art machine—which was in evidence and had been submitted to the jury—disclosed "an indicium corresponding to a time-variable hemodialysis parameter," the district court concluded that Fresenius failed to present any evidence that the "plurality of indicia" limitation of claim 14 was present in the prior art. JMOL Opinion, slip op. at 8–9. We disagree.

Mr. Causey testified, using an explanatory demonstrative, that the inventors of the prior art Cobe C3 machine had provided for more than one time-variable parameter. The demonstrative indicated that the prior art machine allowed for multiple indicia, each corresponding to a different time-variable hemodialysis parameter. The jury could have reasonably credited Mr. Causey's testimony and concluded that the relevant limitation was present in the prior art Cobe C3 machine. Because substantial evidence supports

the jury's implicit finding that the plurality of indicia limitation existed in the prior art, JMOL was inappropriate.

3. Claim 16

Baxter additionally asserts that Fresenius failed to demonstrate that the following limitation of claim 16 existed in the prior art: “the user/machine interface is operable to require the user to verify a parameter after a value of the parameter is selected.” '131 Patent col.37 ll.4–6. That argument is unpersuasive. Fresenius's expert testified that the CMS 08 prior art machine contains the limitation described in the claim, referring specifically to a page of the CMS 08 manual that supports the testimony. J.A. at 14455, 19935. Thus, substantial evidence supports the jury's implicit finding that the claim limitation at issue existed in the prior art.

C. Claims 26–31 of the '434 Patent

Claims 26–31 contain means-plus-function limitations, and all require a “means for delivering the dialysate to a dialysate compartment of a hemodialyzer.” '434 Patent col.40 ll.33–35. The district court granted Baxter's motion for JMOL of no invalidity based in part on its conclusion that Fresenius failed to prove that the means for delivering dialysate limitation was present in the prior art. We agree, though for somewhat different reasons than those articulated by the district court. Namely, Fresenius failed to present any evidence—let alone substantial evidence—that the structure corresponding to the means for delivering dialysate limitation, or an equivalent thereof, existed in the prior art.

It is firmly established in our precedent that a structural analysis is required when means-plus-function limitations are at issue; a functional analysis alone will not suffice.

See, e.g., CytoLogix Corp. v. Ventana Med. Sys., 424 F.3d 1168, 1178 (Fed. Cir. 2005) (“To establish infringement under § 112, ¶ 6, it is insufficient for the patent holder to present testimony ‘based only on a functional, not a structural, analysis.’” (quoting Alpex Computer Corp. v. Nintendo Co., 102 F.3d 1214, 1222 (Fed. Cir. 1996))). Just as a patentee who seeks to prove infringement must provide a structural analysis by demonstrating that the accused device has the identified corresponding structure or an equivalent structure, a challenger who seeks to demonstrate that a means-plus-function limitation was present in the prior art must prove that the corresponding structure—or an equivalent—was present in the prior art. See In re Donaldson Co., 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc) (“[W]e hold that paragraph six applies regardless of the context in which the interpretation of means-plus-function language arises, i.e., whether as part of a patentability determination in the PTO or as part of a validity or infringement determination in a court.”); see also McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1361 (Fed. Cir. 2001) (Michel, J., dissenting) (“Of course, in the context of a means-plus-function claim, the invalidating prior art must disclose not simply a means for achieving the desired function, but rather the particular structure recited in the written description corresponding to that function, or an equivalent thereof.”).

Here, Fresenius neither identified the structure in the specification that corresponds to the means for delivering dialysate nor compared it to the structures present in the prior art. See CytoLogix, 424 F.3d at 1178 (“Here, CytoLogix failed to identify the structure in the specification that is the ‘temperature controller means’ and compare it to the structure of the accused device. Accordingly, because CytoLogix failed to present substantial evidence of infringement of claim 13 of the ’693 patent, the

jury verdict of infringement of claim 13 must be reversed.”). At most, the evidence of record supports a finding that some structures that could perform the claimed function existed in the prior art. Under our precedent, it is clear that such a finding is insufficient. Thus, as in CytoLogix, the jury’s verdict as to claims 26–31 cannot stand.

We note also that there is an additional reason for affirming the district court’s grant of JMOL regarding dependent claim 30, which requires a “means for delivering an anticoagulant to a patient.” The district court instructed the jury that the corresponding structure is a microprocessor and stepper motor. Fresenius USA, Inc. v. Baxter Int’l, Inc., No. 03-1431, at 21 (N.D. Cal. July 5, 2006) (Dkt. No. 825) (“Jury Instructions”). Because Fresenius failed to present any evidence that the required stepper motor structure existed in the prior art, the district court correctly granted JMOL. Fresenius has cited no testimony wherein any witness discussed a “stepper motor.” Fresenius contends that the Cobe C3 manual, which was submitted to the jury, discloses the necessary structure, but notably, Fresenius has cited no manual pages that reference a “stepper motor.” After independently reviewing the record, this court notes that the CMS 08 manual briefly mentions a “stepper motor” but does not discuss that structure in the context of the claimed function—delivering an anticoagulant. Moreover, even if the CMS 08 manual disclosed a stepper motor for delivering an anticoagulant, it was Fresenius’s burden to clearly disclose, discuss, and identify for the jury the supporting evidence upon which it was relying to prove that the claim limitation was present in the prior art. See Koito, 381 F.3d at 1151 (holding that a challenger failed to meet its burden of proving a prior art reference anticipated the patent claims when it “failed to provide any testimony or other evidence that would demonstrate to the jury how that

reference met the limitations of the claims”). Here, as with the means for delivering dialysate limitation discussed above, the evidentiary burden of proof cannot be carried without clearly identifying the corresponding structure in the prior art. Thus, substantial evidence does not support the jury’s implicit finding that the prior art contained a stepper motor means for delivering an anticoagulant, and the district court correctly granted JMOL.

For the foregoing reasons, we affirm the district court’s grant of JMOL as to claims 26–31 of the ’434 patent.

D. Motivation to Combine

All of the claims on appeal are directed to a hemodialysis machine integrated with a touch screen user interface, which Baxter contends was novel and nonobvious at the time the relevant patent applications were filed. Fresenius contends that touch screens were well-known in the prior art and had been widely employed—even on other medical devices—such that Baxter’s addition of a touch screen interface to an otherwise conventional hemodialysis machine would have been obvious and thus unpatentable.

The district court conducted the trial and issued its JMOL opinion before the Supreme Court decided KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007). Thus, the district court applied the teaching-suggestion-motivation test for obviousness as it existed before it was modified by KSR. The district court granted JMOL and overturned the jury’s verdict that all asserted claims of the ’131 and ’434 patents are invalid as obvious because it determined that Fresenius had failed to demonstrate the required motivation to combine.

We first note that it remains appropriate for a post-KSR court considering obviousness “to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” KSR, 550 U.S. at 418. Thus, the jury’s obviousness verdict remains relevant to our review because we will not overturn the implicit factual findings underlying the jury’s verdict so long as they are supported by substantial evidence. See LNP Eng’g Plastics, 275 F.3d at 1353. As explained below, Fresenius presented substantial evidence to support the jury’s implicit factual finding that the prior art suggested the combination of a touch screen user interface with known elements of prior art hemodialysis machines.³ Thus, we reverse the district court’s grant of JMOL as to the asserted claims in the ’131 patent.

Baxter concedes that Fresenius presented a prior art publication that disclosed the use of a touch screen interface on a medical device—specifically an anesthesia-delivery system. That publication noted hemodialysis as one rapidly advancing area of medicine, stated that complex technologies have fueled such rapid advances, and then disclosed that the equipment necessary to practice those complex technologies could benefit from an improved user interface. J.A. at 18048. The publication then specifically described the integration of a touch screen interface with an anesthesia-delivery system. Dr. Rau, the author of the publication, explained to the jury where his publication mentioned hemodialysis and pointed to other sections of the publication that, in his opinion, suggested the addition of a touch screen to a hemodialysis machine. J.A. at 14373–75. Specifically, Dr. Rau testified that his publication “gave numerous

³ The jury was instructed that “[t]he claimed invention is not obvious unless there was something in the prior art or within the understanding of a person of ordinary skill in the field that would suggest the claimed invention.” Jury Instructions at 26.

examples of where you can use [touch screen technology] beneficially” and stated that “one of the examples which I mentioned was hemodialysis and a hemodialysis machine.” J.A. at 14373–75. Dr. Phares, another Fresenius witness, described the ease and prevalence of “integrating a touch screen into some kind of a computer-controlled machine” and opined that as of the relevant filing date, it would not have been difficult for one to integrate a touch screen interface into a hemodialysis machine. J.A. at 14321–22.

Under KSR, “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” 550 U.S. at 417. In addition, “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” Id. at 416. Here, the jury implicitly found that the prior art suggested combining a touch screen with known elements of a hemodialysis machine. That finding is supported by substantial evidence because a reasonable jury could conclude that Dr. Rau’s publication contained an explicit suggestion to combine the disclosed benefits of a touch screen interface with a hemodialysis machine. In addition, the jury could reasonably conclude, based on Dr. Phares’s testimony, that an ordinarily skilled artisan would have known how to make that combination. Thus, substantial evidence supports the jury’s findings that the limitations of the ’131 patent claims were known in the prior art, that the prior art suggested combining those elements to arrive at the claimed invention, and that the ordinarily skilled artisan would have known how to make that combination. Therefore, JMOL is inappropriate under KSR, and we reverse

the district court's grant of JMOL regarding all asserted claims of the '131 patent. However, as discussed above, Fresenius failed to present evidence that all limitations present in claims 26–31 of the '434 patent were present in the prior art—thus, we affirm the district court's grant of JMOL as to those claims.

Baxter argues it presented objective evidence sufficient to demonstrate that its invention was not obvious. However, it was the proper role of the jury to assess the credibility and weight of Baxter's evidence regarding the difficulties of integrating a hemodialysis machine with a touch screen interface and the commercial success of an embodiment of the patents. The jury was instructed that it must consider that evidence. Jury Instructions at 26–27. Therefore, to render its verdict on obviousness, the jury necessarily determined that Baxter's evidence was insufficient to overcome Fresenius's showing that the claims are invalid as obvious. We will not disturb that implicit factual finding because it is supported by substantial evidence.

IV. The Permanent Injunction and Royalty Award

Fresenius argues that the district court abused its discretion when it permanently enjoined Fresenius and awarded Baxter a royalty on hemodialysis machines sold before January 1, 2009, and disposables linked to those machines. Although we hold that the district court did not err when it determined that injunctive relief is appropriate, we vacate the injunction and remand for the district court to revise or reconsider the injunction in light of our reversal of JMOL. We likewise vacate the royalty award and remand for the district court to reconsider that award in view of this opinion.

A. The Permanent Injunction

To obtain a permanent injunction, the prevailing patentee must demonstrate:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay, 547 U.S. at 391.

The district court performed the appropriate analysis required by eBay. It weighed all of the factors and explained why it ultimately determined that injunctive relief is appropriate. Injunction Order, slip op. at 3–8. Contrary to Fresenius’s assertion, the district court did not consider the permanent injunction to be “all but inevitable” following the infringement determination.⁴ Fresenius asserts several additional challenges to the district court’s analysis, but it cites no legal error and fails to demonstrate that the district court made any clearly erroneous factual determinations. For example, Fresenius asserts that the district court “ignored” evidence, see Appellant’s Br. at 50–52, but there is no requirement that the district court’s opinion discuss every single fact alleged by Fresenius. In addition, the record contains support for the district court’s factual determinations; the district court did not clearly err. Thus,

⁴ The district court did discuss an injunction as “all but inevitable,” but it did so in the context of balancing the relative hardships to the parties and did not commit legal error. The district court noted that it was “somewhat bewildering that, having admitted to infringing the patents nearly two years ago and having known for at least a year that an injunction was all but inevitable, Fresenius has apparently done nothing to implement any alternative to the [accused infringing device].” Injunction Order, slip op. at 7 (emphasis added). The district court then found that the balance of hardships favored Baxter because “[i]t is Fresenius’s burden, and not Baxter’s, to taste the bitter fruit of its own inaction.” Id. Read in context, the “all but inevitable” statement does not amount to legal error, particularly in light of the fact that the district court applied the correct four-factor test and explained its analysis. The district court was likely merely acknowledging, as did Chief Justice Roberts in eBay, that “courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases.” eBay, 547 U.S. at 395 (Roberts, C.J., concurring).

we conclude that the district court did not abuse its discretion when it granted permanent injunctive relief. Nonetheless, we vacate the injunction and remand for the district court to revise or reconsider the injunction in light of our reversal of the district court's grant of JMOL regarding the '027 and '131 patents.

B. The Royalty Award

The district court ordered Fresenius to pay an ongoing royalty of 10% of the sales price for any infringing machines sold before January 1, 2009, and a royalty of 7% of the sales price for all disposable products linked to infringing machines that were sold from November 7, 2002, until the patents expire. Injunction Order, slip op. at 9–10. Fresenius argues the district court abused its discretion by imposing the ongoing royalty without explaining the bases for its royalty rate determinations. See Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1315 (Fed. Cir. 2007) (remanding because, absent an explanation of the selection of the royalty rate, this court cannot determine whether the district court abused its discretion) (citing Hensley v. Eckerhart, 461 U.S. 424, 437 (1983) (“It [is] important . . . for the district court to provide a concise but clear explanation of its reasons for the fee award.”)).

We do not decide today whether the district court's royalty award was proper. Instead, we vacate the royalty award and remand for the district court to consider whether the previous award is proper in light of this court's modification of the district court's judgment. In particular, we note that our reversal of JMOL may affect the district court's consideration of the putative royalty rate that would result from a hypothetical negotiation between Baxter and Fresenius. That analysis is influenced by the Georgia Pacific factors, see Minks v. Polaris Indus., 546 F.3d 1364, 1372 (Fed. Cir. 2008), and

our decision here may affect how the district court weighs one of more of those factors, see Georgia-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

Fresenius also argues that the district court erred by imposing a royalty on post-verdict sales of disposables linked to machines that were sold pre-verdict. According to Fresenius, that portion of the royalty is inappropriate because the jury had already awarded Baxter damages based on machines sold pre-verdict. We disagree because the district court acted within its discretion. A damages award for pre-verdict sales of the infringing product does not fully compensate the patentee because it fails to account for post-verdict sales of repair parts. See Carborundum Co. v. Molten Metal Equip. Innovations, Inc., 72 F.3d 872, 881–82 (Fed. Cir. 1995). Although the jury had awarded damages for Fresenius's pre-verdict sales of machines and disposable products, Fresenius cites no evidence indicating that the jury also considered post-verdict sales of disposable products linked to machines sold pre-verdict. The district court was within its discretion to impose a royalty on those sales of disposable products in order to fully compensate Baxter for the infringement.

V. Other Arguments

We have considered the parties' other arguments and find them unpersuasive. For example, Fresenius asserts that the district court erred in construing two claim terms: the "means for controlling a dialysate parameter" term in claim 26 of the '434 patent and the "time variable profile" term in all asserted claims of the '131 patent. We decline to consider those arguments. First, Fresenius failed to clearly explain what result would occur if this court adopted Fresenius's proposed claim constructions.

Fresenius gave this court little guidance and cited no record support regarding why a modified claim construction would affect the infringement judgment, the validity judgment, or both. For that reason alone, we may decline to consider Fresenius's claim construction arguments. See Jang v. Boston Sci. Corp., 532 F.3d 1330, 1336 (Fed. Cir. 2008) ("The Supreme Court has explicitly held that Article III does not permit the courts to resolve issues when it is not clear that the resolution of the question will resolve a concrete controversy between interested parties." (citing Coffman v. Breeze, 323 U.S. 316, 322–24 (1945))). In addition, to the extent Fresenius contends a modified claim construction may affect the infringement judgment, we disagree. Fresenius unconditionally stipulated that its accused infringing device contains each and every element of the claims, J.A. at 13721, and then proceeded to argue invalidity at trial. That stipulation in no way stated or indicated that it was conditioned upon the district court's claim construction, and thus, the infringement judgment cannot be altered by a modified claim construction. Finally, to the extent Fresenius's proffered claim constructions would support its invalidity arguments, we note that we have not relied on the contested claim terms for any holdings adverse to Fresenius, and thus, the claim construction arguments are moot as to the issue of validity.

Baxter asserts that it is entitled to a new trial if this court determines that the district court's grant of JMOL was erroneous. We disagree. We have decided the invalidity issues as a matter of law, and no new trial is warranted.

VI. CONCLUSION

Because Fresenius failed to demonstrate that the structures corresponding to certain means-plus-function claim limitations were present in the prior art, we affirm the

district court's judgment that Fresenius failed to prove that claims 26–31 of the '434 patent are invalid. We reverse the district court's grant of JMOL as to all other asserted claims. In addition, although we hold that the district court did not abuse its discretion when it permanently enjoined Fresenius, we vacate the injunction and remand so that the court may revise or reconsider the injunction in light of the fact that only claims 26–31 of the '434 patent remain valid and infringed. Finally, we vacate the royalty award entered by the district court and remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

FRESENIUS USA, INC.
and FRESENIUS MEDICAL CARE HOLDINGS, INC.,
Plaintiffs-Appellants,

v.

BAXTER INTERNATIONAL, INC.
and BAXTER HEALTHCARE CORPORATION,
Defendants-Cross Appellants.

Appeals from the United States District Court for the Northern District of California in Case no. 03-CV-1431, Judge Sandra Brown Armstrong.

NEWMAN, Circuit Judge, concurring.

I join the court's opinion, but I write separately to respond to Judge Dyk's separate opinion, in which he proposes that the district court should stay completion of this litigation, in view of the pending reexamination proceeding. Although this proposal is not adopted it warrants response, for at this stage in this protracted litigation, after full trial and decision in the district court, after full appeal and ruling of the appellate court and with only a modified remedy remaining on remand, such an action would be inappropriate. Further, this question has been neither briefed nor debated. Its sua sponte presentment as available at this stage is irregular.

This litigation began in 2003. Only an issue of adjustment of damages and a modification of the permanent injunction to reflect our reversal of JMOL remain on remand. Meanwhile, the reexamination has yet to be finally decided at the PTO, and remains subject to judicial review, on the same issues of validity as have been litigated. The proposal would entail several years' additional delay, if the court were now to stay the action at this final stage.¹

The relationship between reexamination and litigation is not new to the courts, and precedent reflects the variety of responses in particular situations, as summarized in Slip Track Systems, Inc. v. Metal Lite, Inc., 159 F.3d 1337, 1341 (Fed. Cir. 1998) with respect to concurrent proceedings including PTO reexamination and PTO interference proceedings. It is established that a “court is not required to stay judicial resolution in view of the reexaminations.” Viskase Corp. v. American Nat’l Can Co., 261 F.3d 1316,1328 (Fed. Cir. 2001). The corollary rule is that the PTO has no authority to stay reexamination pending the outcome of district court litigation. Ethicon, Inc. v. Quigg,

¹ Our colleague in concurrence appears to believe that a PTO decision on reexamination will override a judicial decision reached after trial and appeal. That is incorrect. All that can be accomplished is delay. In exercising its discretion to deny or grant a stay pending reexamination, a district court should consider the effect of delay upon a patentee. With respect to inter partes reexamination, 35 U.S.C. §318 commits the grant of a stay to the district court’s discretion with special heed to the concerns of the patentee:

Once an order for inter partes reexamination of a patent has been issued under section 313, the patent owner may obtain a stay of any pending litigation which involves an issue of patentability of any claims of the patent which are the subject of the inter partes reexamination order, unless the court before which such litigation is pending determines that a stay would not serve the interests of justice.

(emphasis added).

849 F.2d 1422 (Fed. Cir. 1988). A stay of finality, after the issues of validity and infringement have been litigated and decided by the district court and appealed to the Federal Circuit, is a distortion of the role of reexamination.

I remain a strong supporter of the principle of reexamination. It can be a useful and powerful tool for the benefit of both patentees and those interested in restricting or eliminating adversely held patents. However, if routinely available to delay the judicial resolution of disputes, the procedure is subject to inequity, if not manipulation and abuse, through the delays that are inherent in PTO activity. The statistical data of the Patent and Trademark Office place this aspect in sharp relief, for the number of reexamination requests is increasing, as is the time for completion of reexamination and appeal in the PTO, as well as the right of judicial review. In its recent statistical summaries, the PTO reports a 54% increase in filing of ex parte reexaminations since 2004 (from 441 in 2004 to 680 in 2008, and with 481 filings through June 2009). See USPTO, Reexamination Operational Statistics (June 30, 2009), available at http://www.uspto.gov/web/patents/documents/reexam_operations_06-09.pdf. Of these filings 31% were reported to be in litigation. Id. Inter partes reexaminations are increasing rapidly, from 168 in 2008 to 195 filings through June of 2009, with 66% reported to be in litigation. Id. The PTO also reports that as of the third quarter of 2009, the average pendency for ex parte reexamination is 36.1 months, an increase from the 34.6 months at December 2008. Id. The pendency of inter partes reexamination is reported to average 41.7 months. Id.

Decisions on reexamination can be appealed to the Board and are subject to judicial review. The PTO reports that the Board is still experiencing a heavy increase in

appeals and the backlog of appeals. In contrast, the present case is over but for review of the remedy on remand. The suggestion that the district court should now stay the proceedings, at this final stage, is contrary to the precepts of expeditious and just resolution of disputes.

United States Court of Appeals for the Federal Circuit

2008-1306, -1331

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DYK, Circuit Judge, concurring.

I join the majority opinion on the understanding that it does not foreclose the district court in its discretion from staying further proceedings pending the outcome of the reexamination before the U.S. Patent and Trademark Office. While Fresenius did not establish the invalidity of claims 26–31 of the '434 patent in the district court proceeding, those claims on their face are of dubious validity in light of our holding that claims 1–3 and 13–16 of the '131 patent and claim 11 of the '027 patent are invalid. It is entirely possible that the U.S. Patent and Trademark Office will finally conclude that claims 26–31 of the '434 patent are also invalid.