United States District Court,
N.D. California.

FRESENIUS MEDICAL CARE HOLDINGS, INC., et al,
Plaintiffs.
v.
BAXTER INTERNATIONAL, INC., et al,
Defendants.

No. C 03-1431 SBA

March 2, 2005.

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ORDER

SAUNDRA BROWN ARMSTRONG**, District Judge.**

This matter comes before the Court for construction of a certain limitation from element (a) of Claim 26 from U.S. Patent No. 5,247,434 ("'434 Patent"). Having read and considered the papers submitted, and being fully informed, the Court CONSTRUES this limitation as set forth below. FN1

FN1. The parties requested that the Court resolve this matter without oral argument [Docket No. 295]. After reviewing the papers presented by the parties, the Court finds this matter appropriate for resolution without a hearing.

BACKGROUND

Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc.

(collectively "Fresenius") initiated this suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity. Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 ("'434 Patent"); (2) U.S. Patent No. 5,326,476 ("'476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("'131 Patent"); (4) U.S. Patent No. 5,486,286 ("'286 Patent"); and (5) U.S. Patent No. 5,744,027 ("'027 Patent") (collectively "patents-in-suit").

On May 14, 2003, defendants and counter-plaintiffs Baxter International Inc. and Baxter Healthcare Corporation (collectively "Baxter") answered and counterclaimed that Fresenius' hemodialysis machines infringe four of the five patents. On October 20, 2003, Baxter amended its Answer and Counterclaims to assert infringement of the '286 Patent.

Each of the patents-in-suit relates to hemodialysis machines.

A claim construction hearing was held on October 14, 2004 on certain disputed terms. After the Court issued its claim construction ruling on November 22, 2004, the parties met and conferred in order to narrow the selection of additional terms to be construed by the Court.FN2

FN2. The meet and confer was conducted pursuant to the Court's October 8, 2004 Order.

On January 6, 2005, the parties requested that the Court construe one additional claim term: "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration" in Claim 26(a) of the '434 Patent.FN3 The parties agree that the claim term-at-issue is a means-plus-function claim.

FN3. Initially, Baxter contends that Fresenius waived this argument because the parties had originally submitted a joint construction for the claim term-at-issue. The Patent Local Rules were designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed. *See, e.g.,* Atmel Corp. v. Information Storage Devices, 1998 U.S. Dist. LEXIS 17564, at *7, 1998 WL 775115 (N.D.Cal.1998). In this case, however, the joint construction stemmed from a construction first proposed by Fresenius' prior counsel, McDermott, Will & Emery ("MWE"). On May 14, 2004, this Court granted Baxter's motion to disqualify MWE. Subsequently, Fresenius' current counsel, Keker & Van Nest LLP, transitioned into the lead counsel role. Moreover, pursuant to this Court's orders, the parties have met and conferred multiple times over the course of this action in order to reduce the number of disputed terms; it was during one of these supplemental meet and confers that Fresenius notified Baxter of its intention to assert the instant construction of the claim term-at-issue. Given the history of this case, coupled with the efforts of the parties to reduce the number of disputed terms, the Court finds that Fresenius has not waived its right to dispute the construction of the claim term-at-issue.

LEGAL STANDARDS

The first step in construing a means-plus-function claim limitation is to define the particular function of the claim limitation. Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376 (Fed.Cir.2001). "The court must construe the function of a means-plus-function limitation to include the limitations contained in the claim language, and only those limitations." Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106, 1113 (Fed.Cir.2002).

The next step in construing a means-plus-function claim limitation is to look to the specification and identify the corresponding structure for that function. Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1334 (Fed.Cir.2004). "Under this second step, 'structure disclosed in the specification is "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.' " Med. Instrumentation & Diagnostics Corp. v. Elekta AB, 344 F.3d 1205, 1210 (Fed.Cir.2003) (quoting B. Braun Med. Inc. v. Abbott Labs., 124 F.3d 1419, 1424 (Fed.Cir.1997)).

DISCUSSION

Claim 26(a) of the '434 Patent calls for:

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.

See 434.26 (term-at-issue emphasized).FN4

FN4. The format "XXX.YY" indicates the following: XXX is the patent number; YY is the number of the relevant claim in that patent. This format will be used to identify claims throughout this Order. The format "XXX:YY:ZZ" indicates the following: XXX is the patent number; YY is the relevant column number, and ZZ is the relevant line number. This format will be used to identify specification passages throughout this Order.

The parties agree on the first step of construction: identifying the recited functions. They are (1) controlling dialysate temperature; and/or (2) controlling dialysate concentration. However, the parties dispute the corresponding structures for those functions, and in particular whether the structures must include an algorithm.

Baxter contends that: (1) the corresponding structure for the control of dialysate temperature is a microprocessor, a heater, and a temperature-sensing device; and (2) the corresponding structure for the control of dialysate concentration is a microprocessor and a concentrate pump. Abernathy Decl., Exh. 10.

Fresenius argues that the corresponding structure for both functions is a heater and temperature sensing device (for temperature) and pump (for concentration) and a microprocessor, operably coupled together, the microprocessor processing an algorithm which allows an operator to change the dialysate temperature or concentration parameters by touching a series of windows and buttons displayed on a touch screen by the microprocessor. Id.

In support of its construction, Fresenius argues that because the recited functions require a microprocessor, WMS Gaming, Inc. v. Int'l Game Technology, 184 F.3d 1339 (Fed.Cir.1999) compels the Court to review the specification to determine the algorithm disclosed for performing the recited functions, and limit the claim accordingly.

In *WMS Gaming,* the Federal Circuit stated: "[i]n a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, *programmed to carry out an algorithm,* the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." *Id*. at 1348-49 (emphasis added); *see* Tehrani v. Hamilton Medical, Inc., 331 F.3d 1355, 1361-62 (Fed.Cir.2003) (remanding to the district court to determine the precise algorithm where *both parties and the district court agreed* that the structure referred to by a "means for processing" was "a processor running an algorithm as described in the specification.").

Based on *WMS Gaming,* Fresenius argues that merely because the disclosed structure includes a microprocessor "that implements an algorithm, the structure is limited to the microprocessor performing that specific algorithm." Fres. Supp. Br. at 3. However, Fresenius reads the rule too broadly. The cases cited by Fresenius specifically held that the corresponding structure for the claim limitations at issue *necessarily included* the particular algorithms. *See* Metrologic Instruments, Inc. v. PSC, Inc., 2004 U.S. Dist. LEXIS 24949, at *40, 2004 WL 2851955 (D.N.J.2004) (discussing and distinguishing *WMS Gaming* and *Tehrani*); *cf*. Anoto AB v. Sekendur, 2004 U.S. Dist. LEXIS 7950, at *37-38, 2004 WL 1102407 (N.D.Ill.2004). Here, the corresponding structure(s) do not *necessarily include* the algorithms advanced by Fresenius.

In *WMS Gaming,* the claimed function was "assigning a plurality of numbers to stop positions, where the plurality of numbers exceeds the number of stop positions and some stop positions are represented by more than one number." *Id*. at 1347. *The parties agreed* that the claimed function was performed according to an algorithm and that the corresponding structure needed both a microprocessor and an algorithm. *Id*. at 1348 (emphasis added).

The function of the disputed limitation in *Tehrani* also specified what and how data was manipulated:

processing data representing at least air viscosity factor in lungs of the patient, barometric pressure, lung elastance factor of the patient and measured levels of carbon dioxide and oxygen levels of the patient, and for providing, based upon said data, digital output data indicative of required ventilation and optimum frequency for a next breath of the patient.

Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1357 (Fed.Cir.2003). The court stated that "[t]he the claims must be construed to require that the device first process the five data values and then use those data values to calculate tidal volume and breath frequency." Id. at 1360. Critically, *the parties agreed,* and the court found, "that the structure corresponding to the processing function is the disclosed microprocessor *that is programmed to perform the disclosed algorithm*." Id. at 1362 (emphasis added); *see also Metrologic Instruments,* 2004 U.S. Dist. LEXIS 24949, at *41-42 (distinguishing *Tehrani*).

Here, the construction advanced by Fresenius improperly imports both functional and structural limitations.

With respect to the recited functions, unlike *WMS Gaming* and *Tehrani,* the recited functions of Claim 26(a) do not recite a specific software routine or data manipulation. The explicit claim language of Claim 26(a) does not suggest that the claimed functions include use of a touch screen. To the extent that Fresenius finds the function of using a touch screen in the patent specification, Fresenius cites no authority for importing functional language from the specification into the claim. *See* Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106, 1113 (Fed.Cir.2002); Creo Prods. v. Presstek, Inc., 305 F.3d 1337, 1346 (Fed.Cir.2002) ("[The Federal Circuit] has repeatedly held that it is improper to restrict a means-plus-function limitation by adopting a function different from that explicitly recited in the claim.").

With respect to the structures corresponding to the functions of Claim 26(a), while the disclosed structures include microprocessors, they do not require that the microprocessor process data that the operator enters using a touch screen. 35 U.S.C. s. 112 para. 6 does not "permit incorporation of structure from the written description beyond that necessary to perform the claimed function." Asyst Technologies, Inc. v. Empak, Inc., 268 F.3d 1364, 1369-70 (Fed.Cir .2001) (citing Micro Chem., Inc. v. Great Plains Chem. Co., 194 F .3d 1250, 1257-58 (Fed.Cir.1999)). "Structural features that do not actually perform the recited function do not constitute corresponding structure and thus do not serve as claim limitations." Id. at 1370 (citing Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1308-09 (Fed.Cir.1998), and B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1424 (Fed.Cir.1997)) ("[S]tructure disclosed in the specification is only 'corresponding' structure if the specification or prosecution history clearly links or associates that structure to the function recited in the claim."); *see also* Faroudja Lab., Inc. v. Dwin Elecs., Inc., 76 F.Supp.2d 999, 1010 (N.D.Cal.1999) (noting that *WMS Gaming* "does not lead to the conclusion that a court must, as a routine matter, limit the structural element to its functional purpose by importing functional language into the structure specification");.

Asyst provides a helpful example, corroborating its finding that "it is not necessary to claim in a patent every device required to enable the invention to be used":

An electrical outlet enables a toaster to work, but the outlet is not for that reason considered part of the toaster. *The corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to operate as intended*.

Asyst, 268 F.3d at 1371 (emphasis added) (citation omitted).

Although Fresenius concedes that the structure includes a microprocessor, a pump and a heater, it tries to add an algorithm, citing to the specification in support of its construction:

The microprocessor, using information pertaining to dialysate flow rate and concentrate parameters entered by the machine operator using a touch screen (described in detail hereinbelow), calculates the amount of concentrate necessary to achieve a correct ratio of water and "A" concentrate for hemodialysis therapy. The microprocessor thereby adjusts the angular velocity of the stepper motor.

See 434:2:57-64; Fres. Supp. Br. at 4.

This quote establishes that the microprocessor and the concentrate pump, not the touch screen, "actually perform" the function of controlling dialysate concentration. It is not "necessary" that the data come from the touch screen. The touch screen merely provides data, just like an outlet provides electricity.

Likewise, a microprocessor that "turns 'the heater on and off as required to maintain the water temperature at the proper level' " identifies the structure-a microprocessor and heater-which is "necessary to perform" the recited function of controlling dialysate temperature.FN5 *See* Fres. Supp. Br. at 5 (citing 434:2:29-43)). Despite this clear statement from the specification, Fresenius contends that the corresponding structure must include an algorithm enabling the microprocessor to determine the "proper level" of water temperature. *Id*. The recited function, however, is controlling dialysate temperature, not controlling dialysate temperature by determining the proper level of water temperature. The language Fresenius attempts to provide structure for is from the specification, not the claim. *Id*.

FN5. The passage that Fresenius cites in support of its proposition that corresponding structure for controlling dialysate temperature requires a touch screen does not mention a microprocessor or a heater. *See* Fres. Supp. Br. at 5.

For both controlling dialysate concentration and controlling dialysate temperature, the touch screen is akin to the "electrical outlet" of *Asyst, i.e.,* the touch screen enables the microprocessor, pump and heater to work but is not part of the microprocessor, pump and heater.

In addition to Fresenius' reliance on *WMS Gaming* and *Tehrani,* Fresenius contends that the prosecution history supports its position. However, review of the prosecution history for Claim 26 dictates otherwise. In distinguishing *Kerns,* the prosecuting attorney explicitly argued:

Claim 51 [which became Claim 26 in the issued patent] has been amended to include, in part (a), means for controlling a parameter of dialysate selected from a group consisting of dialysate temperature and concentration. Kerns et al. provides no hint whatsoever of controlling temperature and concentration of fluids being delivered. *Accomplishing these ends requires components such as a heater* (specification page 2, line 24) *and concentrate pump(s)* (specification page 2, line 24-25 and lines 28-29). Infusion pumps such as disclosed in Kerns et al. do not require such features. The Kerns et al. apparatus merely pumps. Therefore, claim 51 is not obvious from Kerns et al.

See Abernathy Reply Decl. Exh. 11 at BA 095364 (Amendment dated January 26, 1993 from the prosecution history of the '434 Patent (emphasis added)).

The prosecuting attorneys did not state that the claim required the use of a touch screen to control dialysate temperature and concentration. Instead, the prosecuting attorneys remarked that components such as a heater and concentrate pump are required to control dialysate temperature and concentration. The prosecution history, therefore, does not support Fresenius' proffered construction. *Cf.* Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed.Cir.2003) ("[F]or prosecution disclaimer to attach, [the Federal Circuit] requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.") (citations omitted).

Neither the cases relied on by Fresenius in support of its position that an algorithm must be included as corresponding structure for the limitation from Claim 26(a), the patent specification, nor the prosecution history, support Fresenius' construction.

CONCLUSION

Accordingly, the claim term "means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration" in Claim 26(a) of the '434 Patent is construed as follows:

1. The Court hereby CONSTRUES the function of "means for controlling a dialysate parameter selected from the group consisting of dialysate temperature and dialysate concentration" as **controlling dialysate temperature and/or controlling dialysate concentration.**

2. The Court hereby CONSTRUES the corresponding structure for the control of dialysate temperature as **requiring a microprocessor, a heater, and a temperature-sensing device.**

3. The Court hereby CONSTRUES the corresponding structure for the control of dialysate concentration as **requiring a microprocessor and a concentrate pump.**

IT IS SO ORDERED.

N.D.Cal.,2005.
Fresenius Medical Care Holdings, Inc. v. Baxter Intern., Inc.