

United States District Court,
N.D. California.

BAXTER HEALTHCARE CORPORATION,
Plaintiffs.

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC., dba Fresenius Medical Care North America, et al,
Defendants.

No. C 07-1359 PJH

Feb. 10, 2009.

David K. Callahan, Garret Alan Leach, Helen Istvan Odom, Mary Elizabeth Zaug, Matthew James Shiels, Meredith Lee Krannich, Michael Ira Cohen, Reid Phillip Huefner, Robin Ann McCue, Serena Jean Gondek, Aaron D. Charfoos, Bryce Alison Mautner, Kirkland & Ellis, LLP, Chicago, IL, Kenneth Howard Bridges, Kirkland & Ellis, San Francisco, CA, Robert G. Krupka, Kirkland & Ellis, Los Angeles, CA, for Plaintiff, Baxter Healthcare Corporation.

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ORDER CONSTRUING CLAIMS

PHYLLIS J. HAMILTON, District Judge.

Plaintiffs Baxter Healthcare Corporation, Baxter International, Inc., and Baxter Healthcare SA (collectively, "Baxter"), and DEKA Products Limited Partnership ("DEKA") assert nine patents against defendants Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, and Fresenius USA, Inc. (collectively, "Fresenius").

The patents at issue in this action involve or relate to systems and methods for performing peritoneal dialysis ("PD"), to assist patients suffering from end-stage renal disease. Such patients' kidneys do not function properly in that they fail to remove harmful waste products from the blood. PD is an alternative to hemodialysis, which pulls blood out of the body, filters the waste in a machine, and returns the cleansed blood to the body.

By contrast, PD does not directly filter the waste directly out of the blood. Rather, a sterile solution known as "peritoneal dialysis solution" or "dialysate" is infused into the patient's peritoneal, or abdominal, cavity by way of a catheter surgically implanted into the abdomen. The dialysate remains in the peritoneal cavity for a prescribed amount of time, during which time diffusion and osmosis exchanges take place between the solution and the bloodstream across the natural body membranes. These exchanges remove the waste products that kidneys normally excrete. The dialysate (including the filtered waste) is then drained from the peritoneal cavity.

PD was initially performed by hand, using a syringe, or by using the force of gravity to help the dialysate fill into and drain from the patient's peritoneal cavity. Machines were eventually developed to assist patients with this process. These "Automated Peritoneal Dialysis" or "APD" machines are sometimes referred to as "cyclers" because they cycle dialysate through the dialysis treatment. APD cyclers are particularly attractive to some PD patients because the machines can work while the patients sleep at home.

Baxter is a leading provider of dialysis-related products and services, including PD systems, disposables, and related equipment. One of the first cyclers for personal home use was Baxter's PAC-XTRA(TM), which was introduced in the 1980s. The PAC-XTRA(TM) was a large and complicated device, which used gravity to help fill the patient's peritoneal cavity and drain the dialysate. In 1994, Baxter introduced the HomeChoice(TM). Instead of gravity, the HomeChoice (TM) uses air pressure and diaphragm pump technology to move dialysate in and out of the patient's peritoneal cavity. DEKA is an engineering design company that owns a number of the patents used in the HomeChoice(TM) machine.

The HomeChoice(TM) dialysis machine resulted from a collaboration between Baxter and inventor Dean Kamen (one of the principals of DEKA), after Baxter sought DEKA's help in improving the PAC-XTRA(TM). Baxter wanted a machine that was smaller, easier for patients to use, and more fool-proof. Plaintiffs claim that the HomeChoice(TM) machine is now considered the standard for PD.

The nine patents at issue in the present action are U.S. Patent No. 5,324,422 ("the '422 patent"); U.S. Patent No. 5,421,823 ("the '823 patent"); U.S. Patent No. 5,431,626 ("the '626 patent"); U.S. Patent No. 5,438,510 ("the '510 patent"); U.S. Patent No. 6,503,062 ("the '062 patent"); U.S. Patent No. 6,808,369 ("the '369 patent"); U.S. Patent No. 6,814,547 ("the '547 patent"); U.S. Patent No. 6,929,751 ("the '751 patent"); and U.S. Patent No. 7,083,719 ("the '719 patent").

The '422, '823, '626, and '510 patents comprise the '823 patent family, also referred to the "1993 patents" or the "HomeChoice patents." The '369 and '062 patents comprise the '062 patent family, also referred to as the "2000 patents" or the "system calibration patents." The '719, '751, and '547 patents are referred to as "2002 patents." Of this last group, only the '547 patent is at issue in the present claims construction, as the parties have agreed to stay the action, both as to claims and counterclaims, relating to the '751 patent and the '719 patent.

The parties now seek an order construing nine disputed terms. FN1 The first six terms appear variously in

the four patents that comprise the ' 823 patent family (the '422, '823, '626, and ' 510 patents). The next two terms appear in the two patents comprising the ' 062 patent family (the '062 and ' 369 patents). The last term appears in patents across all three patent groups.

FN1. The parties originally sought construction of a tenth term-"calibrating" ('062 patent, claims 10, 10, 16, 21)-but subsequently advised the court that they had reached agreement as to the construction of this term.

DISCUSSION

A. Legal Standard

Patent infringement analysis involves a two-step process. First, the court must determine as a matter of law the correct scope and meaning of disputed claim terms. Second, the properly construed claims are compared to the accused device to see whether the device contains all the limitations (literally or by equivalents) in the claims at issue. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (citation and quotation omitted); see also *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998) (claim construction "begins and ends" with the actual words of the claims). The terms used in the claims bear a "heavy presumption" that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002) (citation omitted).

A patentee is presumed to have intended the ordinary meaning of a claim term in the absence of an express intent to the contrary. *See York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572 (Fed.Cir.1996). The ordinary and customary meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313. The person of ordinary skill in the art is "deemed to read the claim term not only in the context of the particular claim ... but in the context of the entire patent, including the specification." *Id.* The words in the claim may also be interpreted in light of the prosecution history, if in evidence. *Teleflex, Inc. v. Ficosa North Am. Corp.*, 299 F.3d 1313, 1324-25 (Fed.Cir.2002).

"[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). Only if an analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language may the court then rely on extrinsic evidence, such as expert declarations. *Id.* at 1583 (in cases where public record unambiguously describes scope of patented invention, "reliance on any extrinsic evidence is improper").

B. The Disputed Terms and the Claims Construction

1. applying fluid pressure to the diaphragm to operate the pump chamber ('823 patent, claims 1, 10, 16, 21, and 25)

This term appears only in the '823 patent, and is asserted in independent claims 1, 10, 16, 21, and 25, all of which are "method" claims. The parties dispute whether "to operate" is adequately explained by the words

of the claims; or, conversely, whether "to operate" necessitates (a) the application of alternating positive and negative fluid pressure, (b) in pulses, (c) such that the diaphragm is flexed in and out.

Plaintiffs propose that this term means "applying pressure through a gas or liquid to the diaphragm to operate the pump chamber ." Fresenius proposes that this term means "applying alternating positive and negative fluid pressure pulses to the diaphragm such that the diaphragm is flexed in and out and liquid moves through the pump chamber."

Thus, both sides agree that "applying" means "applying;" that "fluid pressure" means either "fluid pressure" or "pressure through a gas or liquid;" FN2 that "to the diaphragm" means "to the diaphragm;" and that "pump chamber" means "pump chamber ." What is left is the construction of the two words-"to operate." Plaintiffs contend that "to operate" should be construed as having its ordinary and customary meaning. Fresenius asserts, however, that under *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351 (Fed.Cir.2008), the court is required to construe "to operate" because the parties have raised an actual dispute regarding the proper scope of the term. *See id.* at 1361.

FN2. Plaintiffs note that Fresenius appears to accept plaintiffs' construction of "fluid" as "a gas or a liquid."

The claim language provides the starting point for analysis of the words "to operate." Claim 1 discloses that the pump chamber "operates" by the application of "fluid pressure to the diaphragm ." The claim language also makes clear that "operation" of the pump chamber "either move[s] dialysis solution fluid from the peritoneal cavity" - "or move[s] dialysis solution into the peritoneal cavity." Thus, the meaning of "to operate" is explained by the claim language itself.

Nothing in the specification suggests that the patentees intended a meaning of "to operate" other than the plain and ordinary meaning of those words as used in the claims. The specification identifies preferred embodiments in which both positive and negative pressures are applied. *See, e.g.*, '823 patent, 8:60-68, 13:22-29; 20:48-58; 21:40-50.

In addition, the "Summary of the Invention" explicitly identifies the embodiment in which both positive *and* negative pressures are applied as a preferred embodiment. *See id.*, 2:52, 3:16-20). Because that configuration is described as "preferred" only (not required), and does not avow a broader claim scope, this claim term cannot be limited to require both positive and negative pressure. Where there is no narrowing limitation in the claim language and no express disavowal of broader language in the written description, it is error to rely on a preferred embodiment to limit the claim term. *Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1368-69 (Fed.Cir.2004)

Neither the claims themselves nor the specification support Fresenius' narrow construction, and Fresenius has pointed to no language in either the claims or specification clearly limiting the claims to embodiments disclosed in the '823 specification. The '823 patent claim language itself is not limited to pneumatics, is not limited to alternating positive and negative fluid pressure pulses, and is not limited to flexing the diaphragm in and out.

Absent any indication that the patentees intended to define the phrase "to operate" to require both positive and negative fluid pressure pulses, the court will not read into the claim language limitations taken from the preferred embodiments. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed.Cir.2004). In

addition, the doctrine of claim differentiation precludes Fresenius' proposed addition of the words "alternating positive and negative fluid pressure."

Under the doctrine of claim differentiation, when one claim does not recite a particular limitation that is recited in another claim, "that limitation cannot be read into the former claim." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1326 (Fed.Cir.2003). Each claim is presumed to be different in scope, and that presumption "is especially strong where there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between two claims." *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1375 (Fed.Cir.2002); *see also* *Liebel-Flarsheim*, 358 F.3d at 909.

Here, independent claims 1, 10, 16, 21, and 25 of the '823 patent all recite "applying fluid pressure" generally, and do not specify any particular type of fluid pressure. However, claims that depend from those independent claims narrowly recite the specific types of fluid pressure. Dependent claims 5, 14, and 19 specify a "fluid pressure that is below atmospheric pressure"-that is, negative pressure. Dependent claims 6, 15, and 20 specify a "fluid pressure that is above atmospheric pressure"-that is, positive pressure. Thus, under Fresenius' proposed construction, the limitation of negative pressure in dependent claims 5, 14, and 19, and the limitation of positive pressure in dependent claims 6, 15, and 20, would be redundant and superfluous.

It is true that the doctrine of claim differentiation is a rebuttable presumption, which may be overcome "by a contrary construction dictated by the written description or the prosecution history." *Seachange, Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1368-69 (Fed.Cir.2005). Here, however, Fresenius has pointed to no evidence from the intrinsic record to overcome this presumption.

With regard to the second and third limitations proposed by Fresenius-"pulses" and "such that the diaphragm is flexed in and out"- "fluid pressure" is used generically in independent claims 1, 10, 16, 21, and 25. Nothing in the patent dictates that the "fluid pressure" be applied in "pulses" or that it "flex" the diaphragm "in and out."

In short, nothing in the specification of the '823 patent indicates that the patentees intended to give some special meaning to the words "to operate." The claim language preceding and following "to operate"- "applying fluid pressure to the diaphragm" and "to either move dialysis solution fluid from the peritoneal cavity or move dialysis fluid into the peritoneal cavity-clearly explains how the "operation" occurs and what it accomplishes.

"Applying fluid pressure to the diaphragm to operate the pump chamber" means "applying pressure through a gas or liquid to the diaphragm to operate the pump chamber."

2. *actuator means* for operating the pumping mechanism to (i) drain spent dialysis liquid from the peritoneal cavity through, and (ii) infuse fresh dialysis liquid from a source into the peritoneal cavity ('422 patent, claim 1)

***actuator means* for operating the pumping mechanism to emulate gravity flow conditions independent of head height conditions** ('510 patent, claim 1)

This term appears in claim 1 of the '422 patent and in claim 1 of the ' 510 patent, both of which are part of

the '823 patent family. The parties agree that these claims recite means-plus-function limitations under 35 U.S.C. s. 112 para. 6.

In construing a means-plus-function term, the court must first determine the claimed function, and must then "identify the corresponding structure in the written description" for performing the recited function. *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1240 (Fed.Cir.2007). That structure, along with its equivalents, are within the literal scope of the claim. 35 U.S.C. s. 112 para. 6. When construing a means-plus-function term, "a court may not import functional limitations that are not recited in the claim, or structural limitations from the written description that are unnecessary to perform the claimed function." *Wenger Mfg. ., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed.Cir.2001).

Here, the parties agree that the applicable functions are recited in the claim terms themselves, after the words "means for." That is, the function of "actuator means" in the '422 patent is "operating the pumping mechanism to (1) drain spent peritoneal dialysis liquid from the peritoneal cavity through, and (2) infuse fresh dialysis liquid from a source into the peritoneal cavity;" and the function of "actuator means in the '510 patent is "operating the pumping mechanism to emulate gravity flow conditions independent of head height conditions."

The parties disagree, however, as to which structure or structures described in the specifications of the '422 and '510 patents perform the stated functions. Plaintiffs propose that the corresponding structure is the "piston element, port and pump actuator components of the piston head assembly, and equivalents thereof." Fresenius proposes that the corresponding structure is the "first and second pressure actuating networks (230 and 232), the pump actuators (PA1 and PA2), the valve actuators (VA1-VA10), and the associated valves (A0, A3, A4, B0, B1, B4, C0-C4, D1-D5)."

The specification links a structure (the pump actuators) to the claimed function ("operating the pump mechanism"). *See* '510 patent, Fig. 8A. Both sides agree that the pump actuators PA1 and PA2 are corresponding structure to perform the necessary function of the actuator means. Accordingly, the court finds that the pump actuators are part of the structure.

In addition, the structure that the specification identifies as operating the pumping mechanism to move dialysate to and from the patient, and to emulate gravity flow conditions independent of head height, is pump chambers P1 and P2, the corresponding pump actuator cavities PA1 and PA2, and the ports 120 that supply fluid pressure to those PA1 and PA2 cavities. '510 patent, 2:61-64, 13:5-9, 14:1-14; '422 patent, 12:16-20, 13:12-26. These structures are illustrated in Figs. 8A and 13.

The patents describe Fig. 8A as "a plan view of the one side of the cassette shown in Fig. 8, showing the liquid paths within the cassette." Fig. 13 is "a perspective view of the operative front side of the fluid pressure piston housed within the cassette module." Fig. 8A shows the pump chambers P1 and P2. A "piston element," 102 in Fig. 13, sits behind the cassette and operates the pumps. '510 patent, 12:64-13:4 ("piston element 102 comprises a molded or machined plastic or metal body" containing "two pump actuators PA1 and PA2" and ten valve actuators); '422 patent, 12:7-15 (same).

Because the piston element 102 is a solid piece of material, fluid pressure must necessarily flow through ports 120 to operate the pumps and perform the claimed function. *See* '510 patent, 13:5-9 ("Each actuator PA1/PA2 ... includes a port 120); 14:1-14 ("... This, in turn, moves liquid through the cassette."); *see also* id. 20:17-23 ("These actuators [pump actuator PA1 and associated valve actuators], in turn, operate cassette

pump station P1 and valve stations V1, V2, V8, and V10, respectively, which serve pump station P1."); 20:24-30 (same for PA2 and P2), Fig. 8A; and Fig. 13; and '422 patent, 12:7-15, 13:12-26, 19:38-51 (same as for '510 patent); Fig. 8A; Fig. 13.

The court finds that the piston element (which actually forms the pump actuators PA1 and PA2) and the ports inside the pump actuators (through which pressure fills and exits the pump actuators) are also, therefore, necessary corresponding structure.

Fresenius seeks to add additional structure beyond those actually necessary to operate the pumping mechanism—including entire pressure networks and twenty-six valves. However, the specification expressly distinguishes between "pump actuators," which operate the pump, and the other structure Fresenius proposes to add, such as the "first and second pressure actuating networks" and "valve actuators and associated valves," which serve or work with the pump actuators and pump. *See* '510 patent, 20:17-23 ("The first pressure actuating network 230 distributes negative and positive pressures to the first pump actuator PA1 and the valve actuators that serve it (namely, VA1; VA2; VA8; VA9; and VA10). These actuators, in turn, operate cassette pump station P1 and valve stations V1; V2; V8; V9; and V10, respectively, which serve pump station P1"); '422 patent, 19:38-44 (same).

"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 Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1371 (Fed.Cir.2001). Here, while the additional structure identified by Fresenius—the valves (which work with the pump chambers), the valve actuators (which are also formed by the piston element and correspond to the valve stations much as the pump actuators correspond to the pump stations), and the pressure actuating networks (which distribute the fluid pressure from the air pump to the pump and valve actuators using tubing)—all enable the pumping mechanism to operate, they do not actually *perform* the claimed function of operating the pumping mechanism.

Indeed, the specification states that the valves and valve actuators merely "serve" the pump actuators, and that the pressure actuating network merely "distributes" pressure to the pump actuators. *See* '510 patent, 20:17-23 ("The first pressure actuating network 230 distributes negative and positive pressures to the first pump actuator PA1 and the valve actuators that serve it (namely, VA1; VA2; VA8; VA9; and VA10). These actuators, in turn, operate cassette pump station P1 and valve stations V1; V2; V8; V9; and V10, respectively, which serve pump station P1."); '422 patent, 19:38-44 (same); *see also* '510 patent, 20:49-55 ("first actuating network 230 provides" pressure valve actuators and first pumping actuator). Accordingly, the valves, valve actuators, and pressure actuating network are not corresponding structure to the claimed "actuator means."

The court adopts the parties' agreed function for the term "**actuator means**" in the '422 patent as

"operating the pump mechanism to (i) drain spent peritoneal dialysis liquid from the peritoneal cavity through, and (ii) infuse fresh dialysis liquid from a source into the peritoneal cavity."

The court also adopts the parties' agreed function for the term "**actuator means**" in the '510 patent as

"operating the pumping mechanism to emulate gravity flow conditions independent of head height conditions."

The corresponding structure for the "**actuator means**" of both the '422 and the '510 patents is

"piston element, port and pump actuator components of the piston head assembly, and equivalents thereof."

3. **pressure conveying element** ('626 patent, claims 34, 38, 41, 44)

This term appears in asserted independent claims 34, 38, 41, and 44 of the '626 patent. The parties' dispute centers on whether this term requires construction, and, if so, whether the patent requires specific pressure-conveying components.

Plaintiffs propose that "pressure conveying element" means "a pressure conveying element." Fresenius proposes that "pressure conveying element" means "an assembly including at least (1) a pressure transfer element (*e.g.*, 102) in contact against the diaphragm of the pump chamber to apply positive and negative fluid pressure to the diaphragm; (2) pneumatic control valves; (3) inflatable reservoir/main bladder (*e.g.*, 128; (4) a conduit for transporting positive pneumatic pressure from the source to the inflatable reservoir (*e.g.*, 216); (5) a pressure regulator communicating with the inflatable reservoir; and (6) a carrier (*e.g.*, 104) that moves the pressure transfer element."

The court finds that the claims and specification support the plain and ordinary meaning. In some cases, "the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and ... involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. Here, the widely accepted and commonly understood meaning of "pressure conveying element" makes sense in conjunction with the rest of the asserted claims in the '626 patent.

For example, claim 34 recites "a pressure conveying element carried within the housing for conveying fluid pressure to the diaphragm to operate the pump chamber and valve" '626 patent, 42:66-43:2. In other words, the claim itself explains that the "pressure conveying element" is for "conveying fluid pressure to the diaphragm to operate the pump chamber and valve." Similarly, claims 38, 41, and 42 all recite "a pressure conveying element carried within the housing for conveying fluid pressure ... to operate the pump chamber and valve" '626 patent, 43:59-64, 44:23-31, 44:56-61. The claim language therefore suggests that the court should not further limit this term.

Nothing in the specification indicates that any further limit should be placed on this term. The patent describes several different types of pressure-conveying elements. *See* '626 patent, 13:50-57 ("As Fig. 15B shows, when the main bladder 128 inflates, it presses the plate 104 against the spring element 132. The open cell structure of the spring element 132 resiliently deforms under the pressure. The piston element 102 moves within the window 134 into pressure contact against the cassette diaphragm 59.") and Fig. 15B; '626 patent, 13:6-8 ("The ports 120 convey positive or negative pneumatic pressures from the pneumatic pressure distribution module 88 (as will be described in greater detail later)"); *id.*, 19:66-68 ("Valve A6 is either opened to convey air in the main branch line 216 to the low pressure reservoir 214 or closed to block this conveyance.")

However, because the '626 patent does not suggest that the "pressure conveying element" is limited to any particular embodiment, specific "pressure conveying" components cannot be read into the claim. Fresenius' proposed construction would improperly exclude the above-described embodiment, because the embodiment

lacks the six specific features Fresenius has included in its proposed construction.

The doctrine of claim differentiation also precludes Fresenius' attempt to read the additional specific components into the general and straightforward term "pressure conveying element." Dependent claims 2 and 3, which depend from independent claim 1 (not asserted here), recite the same structural limitations on "pressure conveying element" that Fresenius proposes to read into claim 1 (except for the second item- "pneumatic control valves").

Under the doctrine of claim differentiation, the "pressure conveying element" in claim 1 must have a broader and different scope than the specific configuration claimed in claims 2 and 3. The additional limitations claimed in claims 2 and 3 would be redundant if "pressure conveying element" itself necessarily included these structures. *See SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed.Cir.2003). Fresenius points to no language in either the claims, the specification, or the prosecution history that expressly requires that the additional limitations to "pressure conveying element" in dependent claims 2 and 3 be imported into the construction of "pressure conveying element" generally. *See id.*

"Pressure conveying element" means **"pressure conveying element."**

4. **drain[s] spent peritoneal dialysis liquid from the peritoneal cavity *through*** ('422 patent, claim 1)

This term appears in asserted independent claim 1 of the '422 patent (and, without the "through," in claim 1 of the '510 patent). Claim 1 of the '422 patent recites, in relevant part,

actuator means for operating the pumping mechanism to:

(i) drain spent peritoneal dialysis liquid from the peritoneal cavity *through*, and

(ii) infuse fresh dialysis liquid from a source into the peritoneal cavity,

'422 patent, 38:25-30 (emphasis added).

The parties agree that claim 1 of the '422 patent contains a typographical error. They dispute whether the error is the addition of the preposition "through," or the failure to append a noun phrase that serves as a complement to the preposition "through" (that is, the failure to add an object to the preposition); and, if the latter, whether the claim term is indefinite because there is no possible way that is obvious on the face of the patent to correct the error.

Plaintiffs assert that the typographical error is the addition of "through" to this claim language. They advocate simply removing the word "through," and propose that the term means "drain spent peritoneal dialysis liquid from the peritoneal cavity."

Fresenius argues that the typographical error is the failure to append an object to the preposition "through," and asserts that this term cannot be construed because it is incomplete. According to Fresenius, a person of skill in the art would not know "through" what structure the peritoneal dialysis liquid is drained-whether it is a pumping mechanism, a conduit, or something else. Fresenius claims that the limitation therefore does not satisfy the statutory requirements of s. 112 of the Patent Act.

Fresenius asserts in addition that regardless of whether "through" was intentionally or inadvertently included, a reader cannot determine whether it was intentional (thus necessitating an object after the "through") or inadvertent (thus necessitating the removal of the "through"). Thus, Fresenius argues, since the reader cannot know what correction is necessary or how the claim should be interpreted, the claim is not amenable to the correction.

The court may correct obvious minor typographical and clerical errors in patent claims when the correction is not subject to reasonable debate based on consideration of the claim language and the specification; and the prosecution history does not suggest a different interpretation of the claims. *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed.Cir.2003); *see also* *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1331 (Fed.Cir.2005) ("When a harmless error in a patent is not subject to reasonable debate, it can be corrected by the court.").

The definiteness of a claim term depends on whether that term can be given "any reasonable meaning." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed.Cir.2005). Moreover, a difficult issue of claim construction does not automatically result in a holding of indefiniteness. *Id.* "Only claims not amenable to construction or insolubly ambiguous are indefinite." *Id.* (quotation and citations omitted).

The court finds that Fresenius has failed to carry its burden of showing by clear and convincing evidence that the disputed term in claim 1 is "not amenable to construction" or is "insolubly ambiguous," and has also failed to show that the correction is subject to reasonable debate.

Fresenius cites to the deposition of Daniel Ryan, the attorney who prosecuted the '422 patent, claiming that when Ryan was asked "through what" spent dialysate was drained, he responded that the intent of the claim was that spent dialysate be drained through something- "Through a pumping mechanism, through a conduit, through something, didn't just go through the air."

However, Fresenius has taken the Ryan comments out of context. Immediately before the excerpt quoted by Fresenius, Ryan stated that he assumed the word "through" was a typographical error that was correctable. He also stated that he could not say what the "through" meant unless he could see what the claims said when they were presented to the PTO.

Fresenius also asserts, citing *Novo*, that the court cannot consider any other patent when looking to see whether the correction is subject to reasonable debate, but must look only at the patent in which the disputed term appears. It is true that the Federal Circuit in *Novo* looked only at the language of the patent in which the disputed term appeared. However, there was only one patent at issue in *Novo*. *See id.*, 350 F.3d at 1349. *Novo* provides no authority for a finding that it would be improper to compare the identical claim in two patents filed on the same date, with almost identical specifications.

During the claim construction hearing, Fresenius cited a recent Federal Circuit decision, *Fargo Elecs., Inc. v. Iris Ltd., Inc.*, 287 Fed. Appx. 96, 2008 WL 2570822 (Fed.Cir., June 27, 2008), to support its contention that there is no proper way to correct the error in claim 1 of the '422 patent. However, the facts in the *Fargo* decision are distinguishable. In *Fargo*, the plaintiffs did not propose a single way to correct the error, but rather proposed multiple possible ways. All the possible corrections were supported by the claim language and the specification. Because the plaintiffs themselves could not determine what the patentee had intended, the matter was subject to reasonable debate.

Here, by contrast, Baxter proposes that the obvious error be corrected by eliminating the extraneous word "through," a construction that is supported both by the claim language and the prosecution history. A person of ordinary skill in the art would understand that this limitation recites two parallel phrases describing fluid movement, one relating to draining dialysate and the other relating to infusing dialysate. Thus, a person of ordinary skill in the art would readily recognize that the addition of the word "through" in the first of the two parallel phrases is extraneous—a typographical error. This conclusion is reinforced by the fact that the '510 patent, the specification for which is nearly identical to the specification for the '422 patent, recites the same two parallel fluid movement phrases without the "through" error. *See* '510 patent, 38:52-55. Moreover, Fresenius points to nothing in the prosecution history indicating that the patentee intended the word "through" to be followed by an object.

"Drain spent peritoneal dialysis liquid from the peritoneal cavity through" means "drain spent peritoneal dialysis liquid from the peritoneal cavity."

5. means responsive to first alarm signal ('510 patent, claim 6)

This term appears in asserted claim 6 of the '510 patent. Claim 6 depends from independent claim 1. The invention claimed in the '510 patent relates to systems and methods for performing PD. One aspect of the invention provides an automated PD system that discriminates between alarm conditions that require user intervention to correct, and alarm conditions that reflect conditions that are anomalies but typically correct themselves with minimum or no user intervention. '510 patent, 2:55-60.

Claim 1 recites "an automated peritoneal dialysis system" that includes "means for establishing flow communication with the patient's peritoneal cavity catheter through a pumping mechanism;" "actuator means for operating the pumping mechanism;" "control means for directing operation of the actuator means;" and "means for monitoring system operation."

The "means for monitoring system operation" in turn includes "means for generating a first alarm signal" when system operation fails to satisfy a "predetermined set of criteria;" "means for generating a second alarm signal" when system operation fails to satisfy a "second predetermined set of criteria;" "means for suspending system operation in response to the first alarm signal" and for "requiring user intervention to resume system operation;" and, finally, "means for continuing system operation" in response to the second alarm signal, "canceling the second alarm condition without user intervention" if system operation satisfies a second set of criteria, and initiating a first alarm condition if system operation fails to satisfy the second set of criteria.

Dependent claim 6 recites

[a] system according to claim 1 wherein the means responsive to first alarm signal includes an interface having input means through which the user intervenes.

The parties agree that the term "means responsive to first alarm signal" is a means-plus-function limitation under 35 U.S.C. s. 112 para. 6, and that the applicable function is recited in the claim itself, after the word "means"—"respon[ding] to first alarm signal."

The dispute involves which structure, identified in the specification, performs the stated function. Plaintiffs propose that the identified structure is the "key(s) and display screen, and equivalents thereof." Fresenius

proposes that the identified structure is the "controller with special purpose software that, in response to the first alarm signal, sounds an audible alarm and displays an ALARM MENU."

The language of claim 6 requires that the structure for "means responsive to first alarm signal" include "an interface through which the user intervenes." The specification explains that, in the event of a first alarm signal, the controller gives the user information about the error, and the options for responding:

The controller 16 raises ALARM 1 in situations that require user intervention to correct.... The controller 16 also displays an ALARM MENU that informs the user about the condition that should be corrected. The ALARM MENU gives the user the choice to correct the condition and CONTINUE; to END the therapy; or to BYPASS (i.e., ignore) the condition and resume the therapy session.

Id., 31:53-64. The specification further explains that, using the information gleaned from the display screen, the user can then utilize the keypad and, in particular, the key(s), to issue commands:

The controller 16 includes a user interface 367 with a display screen 370 and keypad 368. The user interface 367 receives characters from the keypad 368, displays text to a display screen 370, and sounds the speaker 372 (shown in Figs. 9 and 10). The interface 367 presents status information to the user during a therapy session. The interface 367 also allows the user to enter and edit therapy parameters, and to issue therapy commands.

Id., 26:26-34; *see also* Figs. 2, 9, 10.

In other words, the "interface having input means" through which-or by means of which-the user responds to the first alarm signal is the key(s) and display screen. This is the only structure necessary for performing the claimed function. *See* Wenger Mfg., 239 F.3d at 1233.

Fresenius contends that because claim 6 recites "a system according to claim 1 wherein *the* means responsive to first alarm signal ..." (emphasis added), the claim is indefinite, or, if the claim is not indefinite, it is not clear what the corresponding structure is. Fresenius asserts that a claim may be indefinite if a term lacks proper antecedent basis, where such basis is not otherwise present by implication or the meaning is not readily ascertainable.

Fresenius contends that in this case, claim 1 includes no "means responsive to first alarm signal," and the basis is not present by implication and is not readily ascertainable from the claim. Fresenius argues that neither claim 6 nor claim 1 identifies in any way "the means responsive to first alarm signal," and asserts that as a result, claim 6 is indefinite.

"The requirement of antecedent basis is a rule of patent drafting, administered during patent examination." *Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed.Cir.2006). In *Patent Law Fundamentals*, the editors explain the concept of "antecedent basis" as follows:

An ambiguity would exist if an element were preceded by the definite article [e.g., *the* filament] when first mentioned in the claim. The question which would naturally enter one's mind would be: "What filament?" Accordingly, a foundation or antecedent basis must be laid for each element recited. This can be done, usually in the preamble, by introducing each element with the indefinite article ("a" or "an"). Subsequent mention of the element is to be modified by the definite article or by "said" or "the said," thereby making

later mention(s) of the element unequivocally referable to its earlier recitation.

Mills, Reiley, and Highley, *Patent Law Fundamentals* (2008) s. 14.13.

Claim indefiniteness is not analyzed "in a vacuum," but rather "in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *Energizer Holdings*, 435 F.3d at 1370 (quotation and citation omitted). To show a claim indefinite, the accused infringer must "show by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton Energy Servs., Inc. v. M-1 LLC*, 514 F.3d 1244, 1244 (Fed.Cir.2008).

The mere fact that there may not be an explicit antecedent basis for the term does not render it indefinite. *See Energizer Holdings*, 435 F.3d at 1370 (citing *Manual of Patent Examining Procedure* s. 2173.05(e) (8th ed. Rev.2, May 2004)). Even lacking an explicit antecedent basis, a claim will not be indefinite "[i]f the scope of the claim would be reasonably ascertainable by those skilled in the art." *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359 (Fed.Cir.2001), *quoted in Energizer Holdings*, 435 F.3d at 1370-71. Moreover, an antecedent basis can be present by implication. *Slimfold Manufacturing Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1116 (Fed.Cir.1987).

In *Energizer Holdings*, the Federal Circuit overturned a ruling by the International Trade Commission that *Energizer's* claim for "zero-mercury-added" alkaline batteries was indefinite because the claim lacked antecedent basis for the term "said zinc anode." The court held that the lack of antecedent basis did not render the claim so indefinite that it could not be reasonably understood and that it was reasonably ascertainable that "said zinc anode" referred to the "anode gel" recited earlier in the claim. *Id.* at 1370-71.

In the present case, the term that Fresenius asserts lacks an antecedent basis is a means-plus-function limitation in dependent claim 6 ("the means responsive to first alarm signal"), which clearly refers back to the language in independent claim 1 ("means for (i) suspending system operation in response to the first alarm signal; and (ii) requiring user intervention to resume system operation"). So even though there may not be an explicit antecedent basis for "the means responsive to first alarm signal" recited in the patent, the court finds that independent claim 1 provides sufficient antecedent basis for the term, either directly or by implication. *See id.* at 1370 (finding antecedent basis by implication).

The specification provides additional context. *See* '510 patent, 3:8-11 ("the monitoring mechanism [that] works to: (i) suspend system operation in response to the first alarm signal, requiring user intervention to resume system operation"). Accordingly, the court finds that Fresenius has not established that this term is indefinite for lack of antecedent basis.

Fresenius argues in the alternative that if the claim is not indefinite, the only disclosed structure "responsive to first alarm signal" is the cyclor's controller and its special purpose software. Fresenius cites the specification, "When ALARM1 [first alarm signal] occurs, the controller 16 suspends the therapy session and sounds an audible alarm. The controller 16 also displays an ALARM MENU that informs the user about the condition that should be corrected." *Id.*, 31:56-60. Fresenius contends that if the claim is to be construed, that is the corresponding structure.

Fresenius claims that keys and a display screen cannot be the corresponding structure because they can do

nothing without a controller and software. Fresenius also notes that the specification specifically states that "[t]he controller 16 includes a user interface 367 with a display screen 370 and keypad 368." Id., 26:26-28.

As noted above, however, the specification clearly explains that the user responds to the first alarm signal by using the keys/keypad and display screen "interface." Fresenius' proposed construction is both too broad and too narrow. It is too broad because it includes structure that is not necessary to performing the claimed function—the audible alarm and the alarm menu. It is too narrow because it excludes the key(s) and the display screen, which are necessary for the patient to respond to an alarm signal.

The court adopts the parties' agreed function for the term "**means responsive to the first alarm signal**" in the '510 patent as

"responding to first alarm signal."

The corresponding structure for the "**means responsive to first alarm signal**" is

"key(s) and display screen, and equivalents thereof."

6. means for (i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) canceling the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria ('510 patent, claim 1)

One aspect of the invention claimed in the '510 patent "provides an automated peritoneal dialysis system that discriminates between alarm conditions that require user intervention to correct and alarm conditions that reflect conditions that are anomalies but typically correct themselves with minimum or no user intervention." '510 patent, 2:55-60.

The disputed term appears in asserted claim 1 of the '510 patent. The parties agree that this is a means-plus-function limitation under 35 U.S.C. s. 112 para. 6, and that the applicable function is recited in the claim itself, after the words "means for"—

(i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) canceling the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria.

The parties dispute which structure, identified in the specification, performs the stated function; and whether the lack of antecedent basis for "the second alarm condition" (in subpart ii) renders the claim indefinite.

Plaintiffs propose that the corresponding structure is a controller with software that is tailored to perform the various steps set forth in the agreed-upon function. Specifically, plaintiffs propose that the structure is

a controller with software for (i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) canceling the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first

alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria, and equivalents thereof.

Fresenius, on the other hand, asserts that the limitation is indefinite because the phrase "the second alarm condition" of subpart (ii) of the limitation lacks antecedent basis. In the alternative, to the extent that the court finds the limitation not indefinite, Fresenius proposes that the corresponding structure is as follows:

As to function (i) controller 16 and special purpose software performing the following algorithm: in response to ALARM2 continue system operation for 30 seconds and if the alarm condition persists after 30 seconds continue system operation for an additional 30 seconds. As to function (ii) controller 16 and special purpose software performing the following algorithm: if during the first or second 30 second periods of continued operation the condition that generated the ALARM2 no longer exist, cancel the ALARM2. As to function (iii) controller 16 and special purpose software performing the following algorithm: if ALARM2 condition persists at the end of a second 30-second period, raise an ALARM 1.

As an initial matter, the court finds that the claim is not indefinite for lack of antecedent basis. As with the prior term ("means responsive to first alarm signal," No. 5, above), the court finds that "the second alarm condition" can easily be understood by reference to the language in the remainder of claim 1 of the '510 patent.

Taken in context, the phrase "the second alarm condition" clearly refers to the status or condition of having been alerted by the second alarm signal. The specification provides additional context. *See* '510 patent, 32:5-13 ("When ALARM2 occurs, the controller 16 generates a first audible signal The controller 16 then mutes the audible signal for 30 seconds If the condition still exists after 30 second [sic], the controller 16 generates a second audible signal").

Turning to the question of what structure corresponds to the claimed function, the court notes that each side's proposed structure includes a "controller" and "software," and that the specification identifies a controller with software for performing the claimed function as the corresponding structure for this term. The mechanism for monitoring system operation

includes a monitoring element for generating a first alarm signal when system operation fails to satisfy a first predetermined set of criteria. It also includes another monitoring element for generating a second alarm signal when system operation fails to satisfy a second predetermined set of criteria different than the first set of criteria.

Id., 3:1-7. The specification identifies the cyclor controller 16 as the structure that carries out such monitoring functions. *Id.*, 26:25-26 ("The controller 16 carries out process control and monitoring functions for the cyclor 14.").

Figs. 9, 10, 17, and 18 show the controller 16. *Id.*, 26:24. As illustrated, "the controller 16 comprises a central microprocessing unit (CPU) 358 [which] employs conventional real-time multi-tasking to allocate CPU cycles to application tasks" and "includes a user interface 367 with a display screen 370 and keypad 368." *Id.*, 26:26-42.

"In 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." *WMS Gaming, Inc. v. International Game Technology*, 184 F.3d 1339, 1349 (Fed.Cir.1999); *quoted in Aristocrat Techs. Australia Pty Ltd. v. International Game Tech.*, 521 F.3d 1328, 1333 (Fed.Cir.), *cert. denied*, --- U.S. ----, 129 S.Ct. 754, --- L.Ed.2d ---- (2008). "Thus the patent must disclose ... enough of an algorithm to provide the necessary structure under s. 112, para. 6." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1340 (Fed.Cir.), *cert. denied*, --- U.S. ----, 129 S.Ct. 754, --- L.Ed.2d ---- (2008).

An algorithm is a set of well-defined rules for the solution of a problem in a finite number of steps. IEEE 100, *The Authoritative Dictionary of IEEE Standard Terms* (7th ed.2000), at 25. In software, an algorithm is "any sequence of operations for performing a specific task." *Id.* Courts permit a patentee to express an algorithm "in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure." *Finisar*, 523 F.3d at 1340. Where software is involved, the "algorithms in the specification need only disclose adequate drafting structure to render the bounds of the claim understandable to one of ordinary skill in the art." *AllVoice*, 504 F.3d at 1245.

Here, the controller uses an algorithm set forth in the specification and via an exemplary embodiment in Fig. 30. The specification explains that the monitoring mechanism works to

(1) suspend system operation in response to the first alarm signal, requiring user intervention to resume system operation, (ii) continue system operation for a predetermined time period in response to the second alarm signal, then canceling the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and (iii) initiate a first alarm condition when, after the predetermined period, system operation fails to satisfy the second set of criteria.

Id., 3:8-20, and Fig. 30.

Fig. 30 is labeled "Alarm Routines," and is described in the specification as "a flow chart showing the operation of the alarm routines that the controller for the cyclor shown in Fig. 1 employs." '510 patent, 5:57-59; *see also id.*, 31:51-52 (Fig. 30 shows the ALARM1 and ALARM2 routines). "The controller 16 raises ALARM1 in situations that require user intervention to correct ..." and "raises ALARM2 in situations which are anomalies but will typically correct themselves with little or no user intervention" *Id.*, 31:53-32:4. If the situation that triggers ALARM2 is not corrected within a predetermined amount of time, following two distinct audible signals, the controller will raise an ALARM 1, and "[t]he user is then required to intervene using the ALARM MENU." *Id.*, 32:5-13.

The algorithm disclosed in the '510 patent for performing the three functions recited in the disputed term in (i) through (iii) is the description of the monitoring mechanism in the "Summary of the Patent," and the "alarm routines" described in Fig. 30. Fresenius' proposed construction impermissibly seeks to limit the claim term by adding limitations to its proposed structure which are beyond the requirements of the claim term-"ALARM1," "ALARM2," and defined time periods of 30 seconds. None of these structures is necessary to perform the claimed function, as it requires only a "first alarm condition," a "second alarm condition," and a "predetermined time period," respectively.

The court adopts the parties' agreed function for the disputed term in claim 1 of the '510 patent as

(i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) canceling the second alarm condition without user intervention when, after the

predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria.

The corresponding structure for this term is

a controller with software as illustrated in Fig. 30 that suspends system operation in response to the first alarm signal, requiring user intervention to resume system operation; that continues system operation for a predetermined time period in response to the second alarm signal, then cancels the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and that initiates a first alarm condition when, after the predetermined period, system operation fails to satisfy the second set of criteria; and equivalents thereof.

7. **control volume** ('062 patent, claims 1, 16)

This term appears in independent claims 1 and 16 of the '062 patent. The '062 patent "relates to fluid flow control devices and, more specifically, to regulating pump pressures. In particular, the invention provides a method and apparatus for increasing the fluid flow rate in a fluid flow control device while maintaining desired pressure levels." '062 patent, 1:6-10.

Claim 1 recites

A method for regulating pressure at a distal end of a fluid line, the method comprising:

providing a fluid control system, the fluid control system having at least one liquid volume in valved communication with the distal end, a control volume in pressure communication with the liquid volume, means for measuring pressure in the control volume, and means for adjusting the pressure in the control volume;

calibrating the means for measuring the pressure;

establishing communication between the liquid volume and the distal end;

measuring a pressure of the control volume; and

adjusting the pressure in the control volume in accordance with the measured pressure.

Claim 16 recites

A method for regulating pressure at the distal end of a fluid line, the method comprising:

providing a fluid flow control system, the fluid flow control system having at least one liquid volume in valved communication with the distal end, a control volume in pressure communication with the liquid volume, a pressure transducer in communication with the control volume, and a pressure adjuster in communication with the control volume;

calibrating the pressure traducer;

establishing communication between the liquid volume and the distal end;

measuring a pressure of the control volume; and

adjusting the pressure in the control volume in accordance with the measured pressure.

The parties dispute whether "control volume" simply refers to a "volume" of gas or liquid that "regulates" or "guides" the flow control system; or whether "control volume" more specifically refers to that portion of the "pump chamber" that contains the pressurizing fluid, and which is separated (in that pump chamber) from the "liquid volume" by the "membrane."

Plaintiffs propose that "control volume" means "a volume of gas or liquid used in regulating and guiding the fluid flow control system." Plaintiffs also accept Fresenius' expert's definition of "control volume," which is "a region in space which is mathematically defined with the purpose of analyzing the region." Fresenius proposes that "control volume" means "the portion of the pump chamber that contains the pressurizing fluid and is separated from the liquid volume by the membrane."

The claims and specification of the '062 patent do not explicitly define "control volume" to have a special meaning, but instead use "control volume" to refer broadly to a volume of fluid (gas or liquid, as the parties agree) used in regulating and guiding operation of the claimed device.

For example, Claim 1 recites "[a] method for regulating pressure at a distal end of a fluid line, the method comprising ...," and includes the step of "measuring a pressure of the control volume," and then, to control the liquid flow control device, requires "adjusting the pressure in the control volume in accordance with the measured pressure." *Id.*, 7:1-3.

In certain preferred embodiments, pressure measurements are taken at the control volume and used in calculations that form the basis for system adjustments—that is, to regulate and guide the fluid flow control system. The specification states that a "control volume" can be used to identify pressure correlations and calculate pressure values, which values the processor then uses to control the fluid flow control device:

The fluid flow control device preferably includes a control volume for each liquid volume, a transducer for each control volume, and a processor for reading and storing pressure values, computing and identifying a correlation between pressure values, and calculating pressure values based on identified correlations. The processor may estimate the elevation differential based upon the pressure values, and/or regulate fluid pump pressures.

Id., 2:8-15; *see also id.*, 5:51-56 ("In process 514, the pressure transducer 315 measures the pressure in the second control volume 311, and the relative elevation is estimated in process 515 based on the pressure in the second control volume and the calibration constants generated during calibration"). In other words, the "pressure in the second 'control volume' " is used to estimate the relative elevation between the fluid control device and the distal end of the fluid line.

Fresenius' proposed construction ignores distinctions made by the claims and specifications. Fresenius argues that the claimed "control volume" must be "a portion of the pump chamber." However, this proposal

is directly contradicted by the patent, as the specification clearly indicates that the control volume need not be a portion of the pump chamber. *See id.*, 6:38-43 ("separate pumps, control volumes, and liquid volumes may be provided and ... the liquid volumes and control volumes may be located at a different point from the pumps along the fluid pathway to the distal end of the fluid line"); *id.*, 2:23-24 (in one preferred embodiment, "the liquid volume and the control volume themselves are parts of a pump").

Similarly, Fresenius defines "control volume" as containing "the pressurizing fluid" (*e.g.*, only a gas or a liquid). However, the specification states that while pressurizing "may occur" through the use of a gas or a liquid, it may also occur through "other methods known in the art, such as pumps, pistons, pressurized reservoirs, valves, and vents." *Id.*, 3:35-38. A construction that excludes embodiments of the invention described in the specification "is rarely, if ever, correct and would require highly persuasive evidentiary support." *Vitronics*, 90 F.3d at 1583. Fresenius offers no such highly persuasive support here.

Fresenius' proposal that the control volume must be "separated from the liquid volume by the membrane" is also contradicted by the patent. For example, claim 2, which depends from claim 1, requires that "the liquid volume includes a flexible membrane that separates the liquid volume from the control volume." Under the doctrine of claim differentiation, the requirement that the control volume is separated from the liquid volume by a flexible membrane cannot be read into claim 1, because it is a limitation that is recited in claim 2. *See, e.g.*, *Phillips*, 415 F.3d at 1314-15 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim"); *Liebel-Flarsheim*, 358 F.3d at 910 ("where the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest").

"Control volume" means "a volume of gas or liquid used in regulating and guiding the fluid flow control system."

8. **calibrating** ('062 patent, claims 1, 10, 16, 21)

This term appears in the '062 patent. The parties have agreed that "calibrating" should be construed in accordance with the definition the patentees provided to the PTO during the prosecution of the patent. Thus, no dispute remains as to the construction of this term.

"Calibrating" means "to standardize (as a measuring instrument) by determining deviation from a standard so as to ascertain the proper correction factors."

9. **adjusting the pressure in the control volume in accordance with the measured pressure** ('062 patent, claims 1, 16)

adjusting the pressure in accordance with the measured pressure ('062 patent, claims 10, 21)

adjusts the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end ('369 patent, claim 1)

adjusting the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end ('369 patent, claim 7)

In this disputed term, the phrase "adjusting the pressure" is part of four phrases appearing in two different patents, as noted above. The parties dispute whether these four phrases are sufficiently related to be construed as one term, or whether they should be construed separately. They also dispute whether "adjusting" should be construed as having its ordinary meaning, or whether the "adjusting" can be done only at a particular step, as part of an ordered sequence of steps.

Plaintiffs argue that the four phrases actually comprise four terms in four distinct claims. Plaintiffs assert that the court should decline to construe these terms, asserting that they are not sufficiently closely related for joint construction as a single term, that they contain many potential claims for construction, and that Fresenius appears to be attempting to get around the court's ten-term limit.

In addition, however, plaintiffs contend that these terms do not require construction because they are plain and unambiguous. Thus, plaintiffs propose that the two terms from the '062 patent be construed as "adjusting the pressure in the control volume in accordance with the measured pressure" and "adjusting the pressure in accordance with the measured pressure;" and that the two terms from the '369 patent be construed as "adjusts/adjusting the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end."

Fresenius, on the other hand, proposes that the two terms from the '062 patent be construed as "adjusting the pressure in the control volume based on (1) the system correction factors obtained during calibration and (2) the measured pressure in the control volume after the liquid is placed in fluid communication with the distal end of the fluid line;" and that the two terms from the '362 patent be construed as "adjusting the pressure in the control volume based on the estimate provided by the controller of the height differential between the pump and the distal end of the fluid line [to obtain a desired pressure at the distal end]."

Both sides proffer proposed constructions that include the words "adjusting the pressure" to explain the meaning of "adjusting the pressure," and "adjusting the pressure in the control volume" to explain the meaning of "adjusting the pressure in the control volume." Thus, it cannot be that they seek a judicial construction of "adjusting the pressure" or "adjusting the pressure in the control volume."

While plaintiffs argue that the words in the claims themselves are sufficient ("in accordance with the measured pressure" in the '062 patent, and "in accordance with the relative elevation to obtain a desired pressure at the distal end" in the '369 patent), it appears that Fresenius seeks construction of the words that follow "adjusting the pressure" in claims 1 and 16 of the '062 patent; the words that follow "adjust[ing] the fluid pump pressure" in claims 1 and 7 of the '369 patent; FN3 and the words that follow "adjusting the pressure in the control volume" in claims 10 and 21 of the '062 patent.

FN3. Fresenius proposes construing "adjust[ing] the fluid pump pressure" as "adjusting the pressure in the control volume."

In other words, Fresenius proposes a construction of the phrases "in accordance with the measured pressure" ('062 patent) and "in accordance with the relative elevation" ('369 patent). Specifically, Fresenius asserts that "in accordance with the measured pressure" means "based on (1) the system correction factors obtained during calibration and (2) the measured pressure in the control volume after the liquid is placed in fluid communication with the distal end of the fluid line," and that "in accordance with the relative elevation" means "based on the estimate provided by the controller of the height differential between the pump and the

distal end of the fluid line."

The court finds that the claims and specifications of the two patents do not suggest a construction other than the plain and ordinary meaning of the words "in accordance with the measured pressure" and "in accordance with the relative elevation." The specification does not support Fresenius' additions to the claim terms, but rather mirrors the claim language itself. Thus, there is no need for the court to construe these terms.

Both the '062 patent and the '369 patent "relate to fluid flow control devices, and, more specifically, to regulating pump pressure." '062 patent, 1:6-7; '369 patent, 1:10-11. In claims 1, 10, 16, and 21 of the '062 patent, a "method for regulating pressure" in a fluid line or at the distal end of a fluid line comprises "a fluid flow control system" with "means for measuring pressure." Each of these claims also includes the step of "measuring pressure," and the step of "adjusting the pressure in accordance with the measured pressure."

In claims 1 and 7 of the '369 patent, a "system for regulating fluid pump pressures" comprises "a fluid flow control device" that includes "pressure means for pressurizing ... at least one liquid volume;" "a transducer ... for measuring pressure;" and "a controller" used "for controlling the fluid pump pressure," for estimating "a relative elevation between the fluid control device and the distal end" based on information received from the transducer; and for "adjusting the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end."

In both the '062 patent and the '369 patent, the "Summary of the Invention" states that the inventions provide a method for "regulating fluid pump pressures based on the relative elevation between a fluid flow control device and a distal end of a fluid line by providing at least one liquid volume in valved communication with the distal end." '062 patent, 1:56-60; '369 patent, 1:60-64. After "[t]he pressure measurement of the liquid volume is calibrated, ... valving is opened to establish communication between the liquid volume and the distal end of the fluid line." '062 patent, 1:60-63; '369 patent, 1:64-67. "A pressure associated with the one liquid volume is measured, and the fluid pump pressure is adjusted in accordance with the measured pressure." '062 patent, 1:63-65; *see also id.*, 2:5-7 (same); '369 patent, 1:67-2:2 (same); *id.*, 2:9-11 (same).

The "Detailed Description of Specific Embodiments" describes "[a] computer program product" which "may be employed for implementing the methods" of the invention. This computer program product may include "program code for calculating a desired fluid pump pressure" as well as "program code for adjusting the pump pressure in accordance with the desired pump pressure." '062 patent, 6:5-20; '369 patent, 6:9-24 (same); *see also* '062 patent, 6:21-28 ("The computer program product may be run on a data processing unit, which acts as a controller. Such a unit may be capable of adjusting the flow rate of fluid being pumped to the distal end 208 by adjusting the pump pressure. For example, if the calculation determined that the distal end 208 of the fluid line 204 and the fluid control system were at the same height, the pump pressure might be safely increased above 75 mm Hg resulting in faster flow rate."); '369 patent, 6:25-32 (same).

Both patents also explain that "the pressure in the pumps 300 and 310 may be adjusted in process 517 to accommodate the height differential." '062 patent, 6:2-4; '369 patent, 6:6-8; *see also* '062 patent, 4:52-54; '369 patent, 4:46-58 ("... the pump pressure may be adjusted to accommodate the height differential in process 405").

While it is true, as Fresenius asserts, that "adjusting the pressure" in the '062 patent occurs only after the calibration step, and after pressure in the control volume is measured after the liquid volume is placed in fluid communication with the distal end, *see id.*, 6:55-7:3; *id.*, 7:9-26; *id.*, 8:52-67, it does not follow that

"adjusting the pressure" should be construed as requiring adjustments based on (1) system correction factors obtained through calibration, and (2) measured pressure in the control volume after establishing fluid communication with the fluid line's distal end. The pressure is simply adjusted "in accordance with the measured pressure."

Fresenius' proposed construction of the terms from the '369 patent also reflects an improper attempt to import limitations from the '369 specification into the claims—specifically, the inclusion of "control volume" in their proposed construction. While "control volumes" are claimed in the '062 patent, they do not appear in any claim limitation in the '369 patent.

In addition, Fresenius has chosen to substitute "relative elevation" in the claim with "estimate provided by the controller of the height differential between the pump and the distal end of the fluid line." The words used in the patent are sufficiently concise without the additional words that Fresenius has improperly attempted to import from the specification. *See, e.g.*, '369 patent, 6:4-8 ("Subsequently, the pressure at the distal end 208 of the fluid line 204, P (distal end), due to the elevation differential may be calculated in process 516. Finally, the pressure in the pumps 300 and 310 may be adjusted in process 517 to accommodate the height differential.").

"Adjusting the pressure in the control volume in accordance with the measured pressure" means "adjusting the pressure in the control volume in accordance with the measured pressure."

"Adjusting the pressure in accordance with the measured pressure" means "adjusting the pressure in accordance with the measured pressure."

"Adjust[ing] the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end" means "adjust[ing] the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end."

10. **membrane** ('547 patent, claim 12)

This term, as asserted, appears in the '547 patent, the '369 patent, and the '626 patent. At the claim construction hearing, Fresenius adopted plaintiffs' proposed construction of "membrane" to mean "barrier" in the '369 and '626 patents. Thus, the parties' dispute focuses on the construction of "membrane" in asserted independent claim 12 of the '547 patent.

The parties dispute whether the "membrane" must be "flexible" and "capable of being deformed," or whether it should simply be defined as a "barrier" without those limitations. Plaintiffs propose that "membrane" means "barrier." Fresenius proposes that "membrane" as used in the '547 patent means "a flexible sheet capable of being deformed under the disclosed pressures."

The '547 patent claims a method, system, and apparatus for performing PD. To that end, a medical fluid pump for a dialysis system is provided. *See* '547 patent, 1:4-8.

Claim 12 of the '547 patent recites:

A pump connected to at least one vacuum source for use in a system for providing dialysis treatment, the pump comprising:

a first chamber wall;

a second chamber wall, the second chamber wall defining an aperture;

first and second fluid receiving membranes disposed between the first and second chamber walls, the [sic] at least one vacuum source operable to apply a vacuum between the membrane and the walls;

a piston, at least a portion of which moves through the aperture, the piston including a piston head having an external shape substantially similar to a mating internal shape of the first chamber wall, the piston in operation contacting one of the membranes; and

a dialysis fluid opening enabling dialysis fluid to be pulled in between the first and second membranes upon movement of the piston.

Fresenius contends that claim 12 of the '547 patent requires that the two "membranes" form a dialysate receptacle, and that in operation, the membranes be pulled apart from one another by application of the vacuum and movement of the piston, which allows the receptacle to fill with dialysate. Thus, Fresenius asserts, the "membranes" recited in claim 12 must be flexible, and must permit deformation in response to the pressures applied by the piston and the pneumatic vacuum.

The court finds, however, that none of the claims of the '547 patent-including claim 12-suggests that the ordinary and customary meaning of the term "membrane" as a "barrier" should be given a construction other than the agreed-upon construction for the '369 and '626 patents. In particular, there is no indication in the language of the claims of the '547 patent that the generic word "membrane" should be given any special meaning, or that it should be construed as being "flexible." In claim 12, both a rigid and a flexible membrane can be "fluid receiving," and both can "contact" the piston.

"[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. The '547 patent specification refers both to generic membranes and to specific types of membranes. The specification uses the term "membrane" to refer not only to the disposable layers between which fluid flows during pump operation, but also to a patient's peritoneum, *see* '547 patent, 1:44-46 ("dialysate contacts the patient's peritoneal membrane in the peritoneal cavity"); to a flexible housing, *see id.*, 6:12-17 (the disposable unit in one embodiment of the invention "includes a first flexible membrane and a second flexible membrane that house the pump receptacle, the fluid heating path and the rigid valve manifold" and a "rigid frame that attaches to at least one of the first and second flexible membranes"); and to hydrophobic tips that form a liquid barrier between the patient line and the atmosphere, *see id.*, 22:32-40 (Fig. 12 illustrates cross section of tip protector 280, and a "hydrophobic membrane" is placed on outer edge of tip protector).

Fresenius argues, however, that the only "membranes" recited in claim 12 of the '547 patent are the "first and second fluid receiving membranes" that form the fluid receptacle within the pump chamber. Fresenius contends that the claimed "fluid receiving membranes" are different from the "hydrophobic membranes," which are located completely outside of the pumping chamber and are not claimed in the '547 patent, but are only mentioned in the specification.

Fresenius suggests, therefore, that only those portions of the specification that discuss the operation of the fluid-receiving membranes in the disposable unit are the portions that are relevant to the meaning of "membrane" in claim 12. Fresenius points to the "Summary of the Invention," which describes the invention as a dialysis system with a "disposable unit" that "has at least two flexible membranes that bond together at selected locations and to a rigid plastic piece or manifold ... The membranes seal to one another so as to define a pump receptacle and a fluid heating pathway." *Id.*, 3:32-37.

Fresenius also notes that the "Summary of the Invention" explains that "[t]he heater heats the fluid heating pathway defined by the flexible membranes of the disposable unit," *id.*, 5:18-19; and that "[t]he disposable unit in another embodiment includes a first flexible membrane and a second flexible membrane that house the pump receptacle, the fluid heating path and the rigid valve manifold. The disposable unit also includes a rigid frame that attaches to at least one of the first and second flexible membranes," *id.*, 6:12-17.

Based on the above-cited portions of the specification, Fresenius asserts that the specification explicitly distinguishes between the "flexible membranes" and the rigid plastic to which they are attached. Fresenius contends, moreover, that every embodiment disclosed in the '547 patent specification describes disposable unit 160 as including "a pair of flexible membranes, including an upper flexible membrane 162 and a lower flexible membrane 164," *see, e.g., id.*, 15:38-47, 33:8-11; and that no broader category of "membrane" as part of a fluid receptacle is mentioned anywhere in the patent.

Fresenius contends in addition that the specification explicitly requires that the "membranes" of the fluid receptacle be capable of deformation by application of vacuum and mechanical pressure. The patent describes Fig. 13 as "a sectional view of one embodiment of a single layer film structure for the disposable unit membranes of the present invention," and describes Fig. 14 as "a sectional view of one embodiment of a multiple layer film structure for the disposable unit membranes of the present invention." *Id.*, 8:25-30. The "Detailed Description of the Invention" refers to Figs. 13 and 14 in a section entitled "Membrane Material for the Disposable Unit," explaining that

upper and lower membranes 162 and 164 can be fabricated from a monolayer film structure 312 (Fig.13) or a multiple layer film structure (Fig.14). The film 312 is constructed from a non-PVC containing polymeric material and must satisfy numerous physical property requirements. The film 312 must have a low modulus of elasticity so that it can be deformed under low pressure to function as a pumping element. What is meant by low modulus is the film 312 has a modulus of elasticity when measured in accordance with ASTM D882, of less than 10,000 psi, more preferably less than about 8,000 psi and even more preferably less than about 5,000 psi and finally, less than 3,000 psi, or any range or combination of ranges defined by these numbers.

Id., 23:60-24:8.

In addition, Fresenius notes, the membrane must be sufficiently flexible so that "it can be deformed under a pressure of 5 psi." *Id.*, 29:14-15. "The film maintains its low modulus and deformability properties even after sterilization to continue to meet the pumping requirement." *Id.*, 29:15-17. Fresenius contends that this is an express definition, and that it controls the meaning of the term "membrane" as used in the '547 patent.

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. The word "membrane" is a widely understood term that means "barrier." Where a disputed claim term is

accompanied by a clarifying adjective, that clarifying adjective may assist the court in construing the disputed term. *See id.*

Here, however, Fresenius is attempting to confine the construction to one embodiment in the specification. The specification for the '547 patent does not require that the "membrane" in claim 12 be flexible. In every reference cited by Fresenius, the specification clearly indicates that the description applies to one or more embodiments-not that it applies to every possible embodiment of the invention.

For example, while it is true, as Fresenius asserts, that the specification states with reference to Figs. 13 and 14 that the "film" from which the membranes may be fabricated "must have a low modulus of elasticity so that it can be deformed under low pressure to function as a pumping element, *id.*, 23:67-24:2, the patentees earlier clarify that they are describing only one of many kinds of membranes that may be used in the invention:

Referring now to Figs. 3A, 4A, 4B, 5, and 6, various embodiments of the disposable unit 160 are illustrated. In each of the embodiments, the disposable unit 160 includes a pair of flexible membranes, including an upper flexible membrane 162 and a lower flexible membrane 164.... The flexible membranes 162 and 164 can be made of any suitable sterile and inert material, such as a sterile and inert plastic or rubber.... One preferred material for the flexible membrane is described below in connection with Figs. 13 and 14.

Id., 15:39-56.

Fresenius has established that at least one embodiment utilizes two (or more) flexible membranes, capable of deformation. However, the specification also discloses embodiments in which only one of two (or more) membranes is flexible, while the other may not be. For example, the "Summary of the Invention" describes an embodiment in which only one of the two membranes has these characteristics:

Thus, in an embodiment, the system maintains a negative pressure on one of the membranes of the fluid receptacle of the disposable unit to pull same away from the other membrane and draw dialysis fluid into the fluid receptacle.

Id., 4:64-67; *see also id.*, 5:1-7 ("The negative pressure on the active membrane is then released, which pushes the membrane toward the other membrane and dispels the dialysis fluid from the pump receptacle. In another embodiment, a mechanical pump piston can be pneumatically attached to one of the membranes, wherein the system mechanically pulls the membrane away from the other membrane.")

In examining the specification for proper context, the court should avoid importing limitations from the specification into the claims. *See Varco, L.P. v. Pason Sys. USA Corp.*, 436 F.3d 1368, 1373 (Fed.Cir.2006). Even if every disclosed embodiment uses flexible membranes, *Phillips* squarely rejects limiting the claim on that basis, unless the specification makes clear that "the patentee ... intends for the claims and the embodiments in the specification to be strictly coextensive." *Phillips*, 415 F.3d at 1323, *quoted in JWV Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed.Cir.2005).

"Membrane" means "barrier."

CONCLUSION

In accordance with the foregoing, the court finds as follows:

1. **"Applying fluid pressure to the diaphragm to operate the pump chamber" means "applying pressure through a gas or liquid to the diaphragm to operate the pump chamber."**
2. The function for the term **"actuator means"** in the '422 patent is **"operating the pump mechanism to (i) drain spent peritoneal dialysis liquid from the peritoneal cavity through, and (ii) infuse fresh dialysis liquid from a source into the peritoneal cavity."** The function for the term **"actuator means"** in the '510 patent is **"operating the pumping mechanism to emulate gravity flow conditions independent of head height conditions."** The corresponding structure for the **"actuator means"** of both the '422 and the '510 patents is **"piston element, port and pump actuator components of the piston head assembly, and equivalents thereof."**
3. **"Pressure conveying element" means "pressure conveying element."**
4. **"Drain spent peritoneal dialysis liquid from the peritoneal cavity through" means "drain spent peritoneal dialysis liquid from the peritoneal cavity."**
5. The function for the term **"means responsive to the first alarm signal"** in the '510 patent is **"responding to first alarm signal."** The corresponding structure for the **"means responsive to first alarm signal"** is **"key(s) and display screen, and equivalents thereof."**
6. The function for the term **"means for (i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) canceling the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria"** in the 510 patent is **(i) continuing system operation for a predetermined time period in response to the second alarm signal; (ii) canceling the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and (iii) initiating a first alarm condition when, after the predetermined time period, system operation fails to satisfy the second set of criteria."**

The corresponding structure for the above-described function is **a controller with software as illustrated in Fig. 30 that suspends system operation in response to the first alarm signal, requiring user intervention to resume system operation; that continues system operation for a predetermined time period in response to the second alarm signal, then cancels the second alarm condition without user intervention when, after the predetermined time period, system operation satisfies the second set of criteria; and that initiates a first alarm condition when, after the predetermined period, system operation fails to satisfy the second set of criteria; and equivalents thereof.**
7. **"Control volume" means "a volume of gas or liquid used in regulating and guiding the fluid flow control system."** Alternatively, to the extent that the parties agree, **"control volume" means "a region in space which is mathematically defined with the purpose of analyzing the region."**
8. **"Calibrating" means "to standardize (as a measuring instrument) by determining deviation from a standard so as to ascertain the proper correction factors."**

9. "Adjusting the pressure in the control volume in accordance with the measured pressure" means "adjusting the pressure in the control volume in accordance with the measured pressure." "Adjusting the pressure in accordance with the measured pressure" means "adjusting the pressure in accordance with the measured pressure." "Adjust[ing] the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end" means "adjust[ing] the fluid pump pressure in accordance with the relative elevation to obtain a desired pressure at the distal end."

10. "Membrane" means "barrier."

The date for the trial of this action, previously set for April 6, 2009, is VACATED, as is the March 12, 2009, date for the pretrial conference. The parties are directed to meet and confer; and, no later than March 3, 2009, to submit a jointly proposed schedule for future litigation, or a request for a case management conference.

IT IS SO ORDERED.

N.D.Cal.,2009.

Baxter Healthcare Corp. v. Fresenius Medical Care Holdings, Inc.

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