IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

BAXTER INTERNATIONAL, INC.,))
Plaintiff,)
v.) No. 15 C 9986
CAREFUSION CORPORATION, and BECTON, DICKINSON and COMPANY,) Judge Virginia M. Kendall))
Defendants.))

MEMORANDUM OPINION AND ORDER

Plaintiff Baxter International, Inc. ("Baxter") sued Defendants CareFusion Corporation and Becton, Dickinson and Company (collectively "CareFusion") for infringement of United States Patent Nos. 5,782,805 (the "805 Patent") and 6,231,560 (the "560 Patent"). The Court held a claims construction hearing, at which time it heard evidence and argument regarding the various claims in dispute in the '805 and '560 Patents. The Court's construction of these terms is set forth below.

BACKGROUND

The '805 and '560 Patents at issue are concerned with medical infusion pumps which deliver medication to patients. The '805 Patent generally relates to a medical infusion pump with a display area to facilitate the display of user interface information. The '560 Patent relates to an infusion pump which collects patient condition information and adjusts medication doses as needed to optimize treatment. Baxter asserts that Defendants have infringed on the Patents by engaging in the manufacture, use, sale, and/or offer for sale of their own infusion system, the Alaris System.

LEGAL STANDARD

Claim construction resolves disputed meanings in a patent to clarify and explain what the claims cover. See Terlep v. Brinkmann Corp., 418 F.3d 1379, 1382 (Fed. Cir. 2005). The construction of the claims at issue is a legal determination to be made by the court. See id. (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995)). Generally, the terms of a claim are given the ordinary and customary meaning that the terms would have to a person of ordinary skill in the art at the time of the filing date of the patent application. See Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). When interpreting an asserted claim, the court looks first to intrinsic evidence: the words of the claims, the patent specification, and the prosecution history. See id. at 1316-18.

The claim language is the starting point for claim construction analysis because it frames and ultimately resolves all issues of claim interpretation. *See Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharmaceuticals Limited*, 887 F.3d 1153, 1157-58 (Fed. Cir. 2018); *Robotic Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370, 1375 (Fed. Cir. 1997). In some cases, the "ordinary and customary" meaning of the claim language may be readily apparent, even to lay judges, and the court applies the widely accepted meaning of the commonly understood words. See Phillips, 415 F.3d at 1314. In such cases, a general-purpose dictionary may be helpful. *See id*. In many cases, however, the court must proceed beyond the bare language of the claims and examine the patent specification. See id. at 1314-15. "The 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." Id. at 1313. The specification is usually dispositive; "it is the single best guide to the meaning of a disputed term." Id. at 1315 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). In the specification, the patentee provides a written description of the invention that allows a person of ordinary skill in the art to make and use the invention. See id. at 1323. At times, the patentee uses the specification to "set forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001).

The court may also look to the patent's prosecution history. See Phillips, 415 F.3d at 1317. While the prosecution history often lacks the clarity of and is less useful than the specification, it may inform the court of the meaning of a claim term by illustrating how the inventor understood the invention as well as how the inventor may have limited the scope of the invention. See id. The prosecution history is generally relevant if a particular interpretation of the claim was considered and specifically disclaimed during the prosecution of the patent. See Schumer v. Lab. Comp. Sys., 308 F.3d 1304, 1313 (Fed. Cir. 2002). Finally, a court may also consult "extrinsic evidence," such as dictionaries, treatises, and expert testimony, to "shed useful light on the relevant art." *Phillips*, 415 F.3d at 1317-18. Generally, extrinsic evidence is "less reliable" than intrinsic evidence and is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. With respect to the use of dictionaries, technical or general, a court may consult such evidence "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Id.* at 1322-23.

DISCUSSION

I. Agreed-Upon Terms

The parties agree upon the construction of certain terms in the disputed patents. The Court adopts the agreed-upon constructions, as set forth in the Parties' Joint Claim Construction Chart and supplemental Notice of Agreed-Upon Construction. (Dkts. 169, 188).

II. The '805 Patent

A. Microprocessor Terms

The parties agree that each of the following four terms are means-plus function claims governed by 35 U.S.C. § 112 ¶ 6, and further agree on the function of each.

- "microprocessor means contained in the main body portion for generating user interface information on the display areas" (claim 1)
- "microprocessor means for generating user interface information on the display" (claim 24)

- "means for generating a plurality of pictoral graphic representations as user interface information on the main display" (claim 1)
- "means responsive to the entered values for calculating a dose of the beneficial agent to be infused into the patient" (claims 3 and 31)

The parties disagree however as to the structure of each term. Baxter presents its own proposed construction for each while CareFusion argues "[t]here is no algorithm disclosed in the specification explaining how the microprocessor calculates doses of medication, and accordingly this element is indefinite." (Dkt. 169, pgs. 4-5).

§ 112(f) provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

As a result of permitting such means-plus claiming, "the specification must contain sufficient descriptive text by which a person of skill in the field of the invention would 'know and understand what structure corresponds to the means limitation." *Typhoon Touch Technologies, Inc. v. Dell, Inc.*, 659 F.3d 1376, 1383-84 (Fed. Cir. 2011) (quoting *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008)). In reviewing a means-plus claim, "[t]he court must first identify the claimed function. ... Then, the court must determine what structure, if any, disclosed in the specification corresponds to the claimed function." *Williamson v. Citrix-Online, LLC,* 792 F.3d 1339, 1351 (Fed. Cir. 2015). Further, in cases such as here, where the claim limitation is implemented using a microprocessor, the specification must disclose the algorithm necessary to perform the claimed function. *Id.* at 1352. "The algorithm may be expressed as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure." *Id.* "In turn, the amount of detail that must be included in the specification depends on the subject matter that is described and its role in the invention as a whole, in view of the existing knowledge in the field of the invention." *Typhoon*, 659 F.3d at 1385. "[T]he patent need only disclose sufficient structure for a person of skill in the field to provide an operative software program for the specified function." *Id.*

An infringer challenging claims as being indefinite has "the burden of proving indefiniteness by clear and convincing evidence." United Access Technologies, LLC v. AT&T Corp., 2019 WL 326120, at *6 (Fed. Cir. 2019). Generally, "[c]laims are invalid for indefiniteness if, when viewed in light of the specification and the prosecution history, they 'fail to inform, with reasonably certainty, those skilled in the art about the scope of the invention." Id. (quoting Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014).

The crux of the four microprocessor claims listed above is whether Figure 7 of the '805 Patent discloses the algorithm necessary to perform the described function. The '805 Patent refers to Figure 7 as "a user interface navigation flow diagram ... depict[ing] an overview of the user interface routine." (Dkt. 159, pg. 38). The flow diagram in Figure 7 displays certain routines such as "power on" (element 302), "select personality" (element 306), "view personality" (element 308), change occlusion settings" (element 313), "primary rate-volume programming" (element 339), "piggyback rate-volume programming" (element 347), "primary volume-time programming" (element 341), and "primary 'dose' programming" (element 343), among others. *Id.* at pgs. 9-10. Baxter concedes that a detailed computer code does not appear in Figure 7 nor anywhere else in the '805 Patent. *See* (Dkt. 161, pg. 16). However, providing the computer code is not a necessity to survive an indefiniteness challenge. *Typhoon*, 659 F.3d at 1385 ("For computer-implemented procedures, the computer code is not required to be included in the patent specification."). Rather, the patent need only "disclose, at least to the satisfaction of one of ordinary skill in the art, enough of an algorithm to provide the necessary structure under § 112, $\P6$." *Finisar Corp.*, 523 F.3d at 1340.

Under this flexible standard, the Court finds that the algorithm at issue here has been presented in sufficiently understandable terms such that a person of ordinary skill in the art would understand what structure corresponds to the limitation. *See Finisar*, 523 F.3d at 1340. The flow diagram in Figure 7 displays a step by step process of how the claimed function operates. CareFusion demands more, but it is difficult to imagine precisely what else could have been disclosed short of the actual computer code, which, as discussed above, is not necessary. *Typhoon*, 659 F.3d at 1385. Accordingly, the Court adopts Baxter's proposed structure construction in the Joint Claim Construction Chart (Dkt. 169) with respect to the above listed claim terms for the '805 Patent.

B. "Means for sensing tube restrictions" (claims 5 and 24)

The parties next dispute the proposed structure of the "means for sensing tube restrictions" term found in claims 5 and 24. The agreed upon function is "sensing tube restrictions." (Dkt. 169, pg. 5). CareFusion argues that the Patent specification does not disclose any structure and therefore the limitation is indefinite. Baxter suggests that "a pressure sensor" is the disclosed structure found in the '805 Patent. Again, the question before the Court is "whether the specification discloses sufficient structure that corresponds to the claimed function." Williamson, 792 F.3d at 1351. A claim without adequately disclosed structure will be deemed indefinite. *Id.* at 1352. There is no question that the words "pressure sensor" do not appear in the '805 Patent. The Patent reads: "The flow check display feature provides the user with a graphical display of the downstream resistance to flow. ... When one triangle is filled, normal flow conditions are present. When all of the triangles are filled, the downstream flow has been occluded." (Dkt. 159, pgs. 40-41). The specification also provides that the user can change the display to pounds per square inch or millimeters of mercury. Id. at pg. 41. Instead, Baxter selects certain phrases and argues that "[a] person of ordinary skill in the art at the time would have readily recognized that measuring pressure necessarily involves employing a device to sense pressure." (Dkt. 161, pg. 25). To overcome this deficit, this contention makes unsound leaps and inferences from the actual specifications within the Patent to its conclusion that a pressure sensor is the disclosed structure.

A structure is considered disclosed "only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc. (d/b/a The Home Depot), 412 F.3d 1292, 1298 (Fed. Cir. 2005). While it is true that the precise term, "pressure sensor," need not appear in the specification, a total omission of any structure is fatal to Baxter's claim. Id. The specification here is analogous to the circumstances in Robert Bosch, LLC v. Snap-On Inc. 769 F.3d 1094 (Fed. Cir. 2014). There, the proposed structure was not explicitly present in the Patent and all cited specifications served to explain the function, rather than the structure. Id. at 1099-100; see also Home Depot, 412 F.3d at 1301. Here, the specifications are focused on the function of the user interface and the varying displays a medical professional would observe while engaging with the unit. The mere fact that the unit would display a value in terms of pounds per square inch or millimeters of mercury is not sufficient disclosure of structure. Baxter attempts to overcome the shortfall of a complete lack of structure by relying on expert declarations. However, this practice is prohibited and the testimony of an expert "cannot create structure where none otherwise exists." Williamson, 792 F.3d at 1354. Because the '805 Patent is completely lacking in structure for "means for sensing tube restrictions," the limitation is indefinite.

C. "Means for applying pumping action to the tube" (claims 1 and 24)

The parties again agree that this claim term is a means-plus function term governed by § $112 \$ 6. They further agree that the function is "applying pumping

action to the tube." (Dkt. 169, pg. 5). Baxter's proposed construction is "a mechanism that imparts propulsion to a fluid" and CareFusion proposes "a peristaltic-type or Id. The dispute centers on precisely which valve-type pumping mechanism." pumping mechanisms are disclosed in the '805 Patent. The Patent clearly articulates two types of pumping mechanisms—peristaltic-type and valve-type. (Dkt. 159, pg. 36) ("Such pumps include, for example, peristaltic-type pumps and valve-type pumps."). Baxter suggests that a third pumping technology is disclosed in the patent, which reads: "While the pump modules depicted in the preferred embodiment described herein are standard IV pump modules, the present invention contemplates use of alternative pump modules employing alternative pumping technology, such as, for example, syringe pump modules." Id. at pg. 37. Reading syringe pumps into the structure would be impermissibly expansive as "a bare statement that known techniques or methods can be used does not disclose structure." Biomedino, LLC v. Waters Techs. Corp., 490 F.3d 946, 953 (Fed. Cir. 2007). The patent discloses and describes only peristaltic-type and valve-type pumping mechanisms and the Court will not read in new structures not described in the '805 Patent itself. Accordingly, the Court adopts CareFusion's proposed construction of "a peristaltic-type or valvetype pumping mechanism."

D. "A plurality of sets of configuration parameters..." (claim 1)

The term "a plurality of sets of configuration parameters are included as user interface information such that a user can select which of the plurality of sets of configuration parameters to configure the infusion pump" appears in claim 1 of the

'805 Patent. Baxter proposes a lengthy construction while CareFusion suggests that no construction is necessary and that the "phrase has its plain and ordinary English meaning." (Dkt. 169, pg. 6). Baxter argues that the words "plurality," "sets," "configuration," and "parameters" are confusing terms to those not of ordinary skill. (Dkt. 161, pg. 27). While the Court must be cognizant of the jury's ability to understand claim construction rulings, Power-One, Inc. v. Artesyn Techs., Inc., 599 F.3d 1343, 1348 (Fed. Cir. 2010), Baxter's proposed construction does more to advocate its case than provide clarification to the jury. Baxter's construction would have the Court read in limitations not present in the '805 Patent. For example, instead of "of sets of configuration parameters," Baxter proposes "collection of drugs' parameters that determines the overall pump operating characteristics for a given clinical context." (Dkt. 169, pg. 6). This construction adds terms and limitations not previously present in the Patent. When a claim has a facially plain and ordinary meaning, the Court's inquiry ends. Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 711 F.3d 1348, 1361 (Fed. Cir. 2013); see also ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1326 (Fed. Cir. 2012). Here, the claim is "comprised of commonly used terms; each [] used in common parlance and has no special meaning in the art." Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1291 (Fed. Cir. 2015). The contested claim requires no further construction and the terms will be given their plain and ordinary meaning.

III. The '560 Patent

A. "Automatically changing the rate and amount..."

The term "automatically changing the rate and amount of the liquid medicant to be administered to the patient in accordance with the set of patient specific, predetermined ranges of medication" appears in claim 9 of the '506 Patent. Baxter asserts that no construction is necessary, and the term should be given its plain and (Dkt. 169, pg. 6). To the contrary, CareFusion's proposed ordinary meaning. construction reads: "Automatically increasing or decreasing the amount and duration of the patient's ongoing delivery of medication in accordance with a set of patient specific, predetermined ranges of medication." Id. Essentially, the dispute between the parties boils down to whether the claim covers the stopping or pausing of the infusion of a dose. CareFusion attempts to limit the claim to only increasing or decreasing the dose, while arguing that it is not broad enough to cover the stopping/starting of a dose. To do so, CareFusion proposes the addition of the terms "increasing or decreasing" and "ongoing delivery." CareFusion's proposed construction would require the Court to impermissibly read terms in to the '560 Patent and restrict the plain meaning of the claim. The specifications of the Patent anticipate that "changing the rate and amount of the liquid medicant" include increasing and decreasing, but also the stopping and starting. For example, the specification lists modes of infusion which include "an intermittent mode in which the pump delivers discrete liquid volumes spaced over relatively long periods of time, such as a liquid volume every three hours" and "a custom mode in which the pump can be programmed to deliver a unique infusion rate during each of 25 different time periods." See e.g. (Dkt. 159, pg. 61). The specifications further detail that in certain scenarios, "the motor is not activated continuously, but is instead turned on periodically ... and then is turned off." *Id.* Accepting CareFusion's proposed language would restrict the claim in a way inconsistent with the plain wording of the Patent.

CareFusion next proposes to change the term "rate" to "duration," but withdrew this specific proposal at the claim construction hearing. (Dkt. 190, pg. 123:14-23). Finally, CareFusion alters "the set of patient specific, predetermined ranges of medication" to "a set of patient specific, predetermined ranges of medication." (Dkt. 169, pgs. 6-7) (emphasis added). Such a change is not justified here where the specification clearly relates back to the language in Claim 9. See e.g., (Dkt. 159, pgs. 63:36-39, 63:65-67, 65:7-32). The claim term for claim 9 is sufficiently clear and will be given its plain and ordinary meaning with no further construction. See Power Integrations, 711 F.3d at 1361.

B. "Obtaining information pertaining to the patient's pain level" (claim 9)

The final term in dispute, "obtaining information pertaining to the patient's pain level," comes from claim 9 of the '560 Patent. CareFusion's proposed construction of the term is: "obtaining data specifically related to the patient's pain level, such as by querying the patient directly or by analyzing whether the patient makes a significant number of bolus requests over the maximum permitted in a short period of time." Baxter contends that CareFusion's construction improperly adds restrictive limitations to the claim and instead the term should be given its plain and ordinary meaning. CareFusion's construction essentially parrots limitations from the dependent Claims 12 and 13. *See* (Dkt. 159, pg. 65) ("The infusion pump of claim 11

wherein data pertaining to the patient's pain level comprises the number of bolus requests made by the patient which exceed the maximum number of boluses. ... The infusion pump of claim 11 wherein data pertaining to the patient's pain level, side effects and impairment of functionalities comprises data stored in response to querying the patient..."). This claim contains no technical terms of art and is not facially confusing. *See Power Integrations*, 711 F.3d at 1361. A person of ordinary skill in the art could easily discern the term and therefore no further construction of the term is needed. CareFusion's proposed construction serves to impermissibly limit the claim and CareFusion supplies no convincing reason for doing so. "Obtaining information pertaining to the patient's pain level" will be given its plain and ordinary meaning.

CONCLUSION

For the reasons stated within, the Court construes the disputed terms as set forth above.

United States District Judge

Date: April 29, 2019