United States Court of Appeals for the Federal Circuit

00-1393

BALLARD MEDICAL PRODUCTS,

Plaintiff-Appellant,

v.

ALLEGIANCE HEALTHCARE CORP.
and SORENSON CRITICAL CARE, INC.,

Defendants-Appellees.

Roy W. Hardin, Locke Liddell & Sapp LLP, of Dallas, Texas, argued for plaintiff-appellant. With him on the brief were Craig L. Weinstock, John Wilson Jones, and Steven S. Boyd.

David V. Trask, Trask Britt, of Salt Lake City, Utah, representing Sorenson Critical Care, Inc., argued for defendants-appellees. With him on the brief was John P. Aston, Prince, Yeates & Geldzahler, of Salt Lake City, Utah, representing Allegiance Healthcare Corp.

Appealed from: United States District Court for the District of Utah

Judge Bruce S. Jenkins

United States Court of Appeals for the Federal Circuit

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BALLARD MEDICAL PRODUCTS,

Plaintiff-Appellant,

v.

ALLEGIANCE HEALTHCARE CORP.,
and SORENSON CRITICAL CARE, INC.,

Defendants-Appellees.

DECIDED: October 9, 2001

Before MAYER, Chief Judge, BRYSON, and DYK, Circuit Judges.

BRYSON, Circuit Judge.

Ballard Medical Products owns U.S. Patent Nos. 4,569,344 ("the '344 patent") and 4,696,296 ("the '296 patent"), which are drawn to ventilating and aspirating tracheobronchial catheters. Ballard sued Sorenson Critical Care, Inc., and Allegiance Healthcare Corp. (collectively "Sorenson") for infringement of multiple claims of the '344 and '296 patents. On summary judgment, the district court ruled that Sorenson had not infringed the disputed patents either literally or under the doctrine of equivalents. We affirm.

I

A tracheobronchial catheter of the type at issue in this case performs both ventilation and aspiration of a patient's breathing passages. During ventilation, the catheter pumps air into and out of the patient's respiratory system. During aspiration, the catheter uses vacuum pressure to evacuate fluids that have accumulated in the patient's lungs.

The two claims that Ballard treats as representative for purposes of appeal are claim 1 of the '344

patent and claim 4 of the '296 patent. Claim 1 of the '344 patent reads as follows, in pertinent part:

> 1. An indwelling ventilating/aspirating apparatus by which a medical patient is subjected to involuntary respiratory therapy and by which fluids from the trachea and/or bronchi are evacuated, the apparatus comprising:
>
> * * * * *
>
> normally closed normally internal sealed and internally sterile vacuum control mechanism sealed against external entry of contamination, the vacuum control mechanism comprising valve means . . . the valve means comprising biased normally closed internal seal means, means by which the valve may be selectively manually locked in a closed position to prohibit inadvertent as well as intentional actuation of the valve means, means by which the valve means may be selectively manually place[d] in an unlocked closed position accommodating subsequent selective manual actuation of the valve means, means by which the valve means are manually displaced from the unlocked closed position to an unlocked open position accommodating aspiration of fluids from the trachea-bronchi of the patient along the catheter tube and across the valve means responsive to communication of said vacuum suction to the distal tip of the catheter tube, as long as the valve means are manually retained in the open position counter to the bias imposed upon the biased seal means, and means which isolate said vacuum suction from atmospheric contamination.

Claim 4 of the '296 patent reads as follows, in pertinent part:

> 4. An indwelling ventilating aspirating apparatus by which a medial patient is subjected to involuntary respiratory therapy and by which secretions from the trachea and/or bronchi are evacuated, the apparatus comprising:
>
> * * * * *
>
> vacuum control valve structure comprising valve body means having fluid flow passageway means and valve means operable within the valve body means between non-activated and activated positions to respectively prohibit and accommodate vacuum caused fluid flow along the passageway means, the control valve structure further comprising (a) means biasing the valve means into the non-activated vacuum prohibiting position, (b) actuator means for manually displacing the valve means from the non-activated to the activated position counter to the bias, means and the valve means and thus prevents bacterial contamination within the passageway means and along the catheter tube, and (c) means by which said valve structure is connected to the other end of the envelope.

Figure 1 below, which is taken from the '344 and '296 patents, depicts the structure of the Ballard invention that is the subject of the asserted patents:

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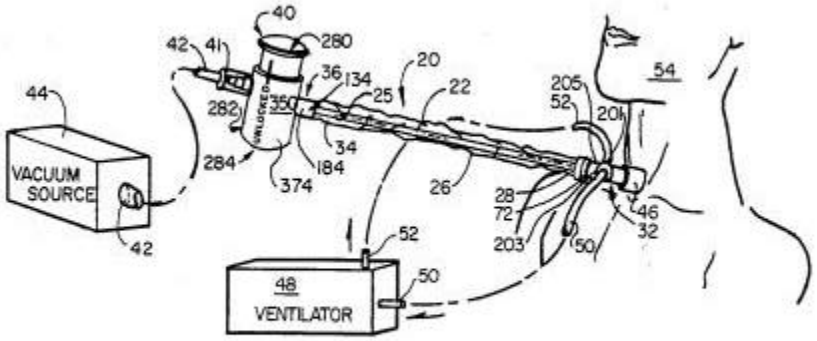

FIG. 1

Fig ard

valve in the closed and open positions, respectively.

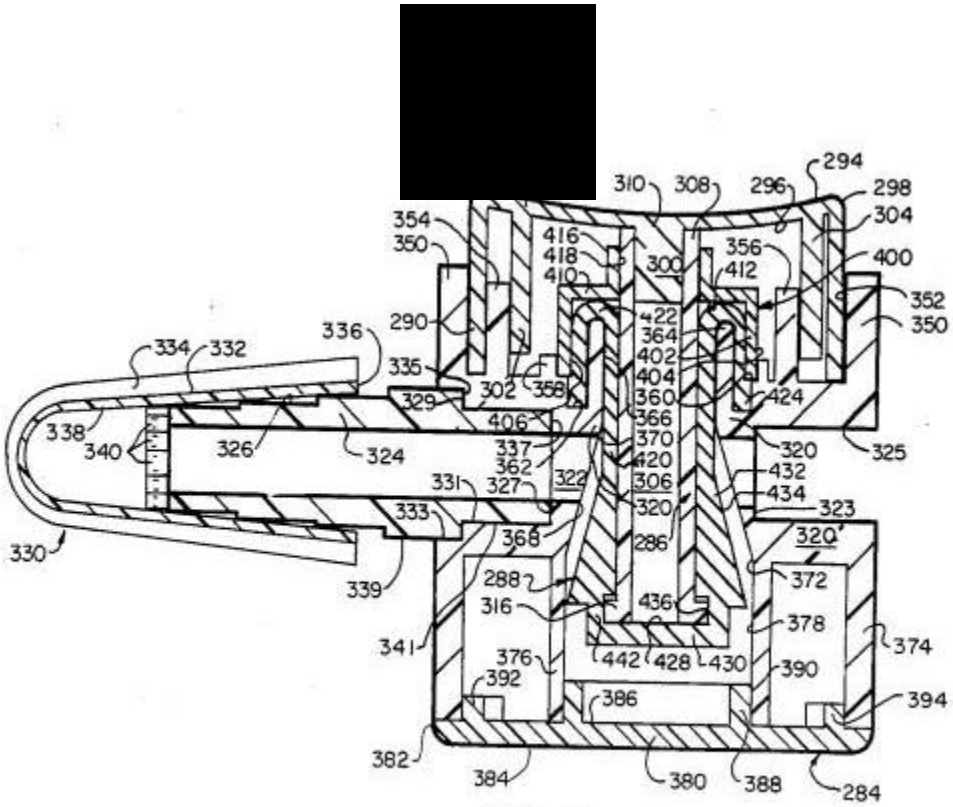

FIG. 8

body posts 354 and 356, which prevents the actuator from being depressed.

The accused TRACH-EZE device made by defendant Sorenson is shown in the following figure, taken from Sorenson's U.S. Pat. No. 5,919,174:

In the c eal 38 is positione he open position, hen flow through w of fluid up into tl e rotated to a posi position.

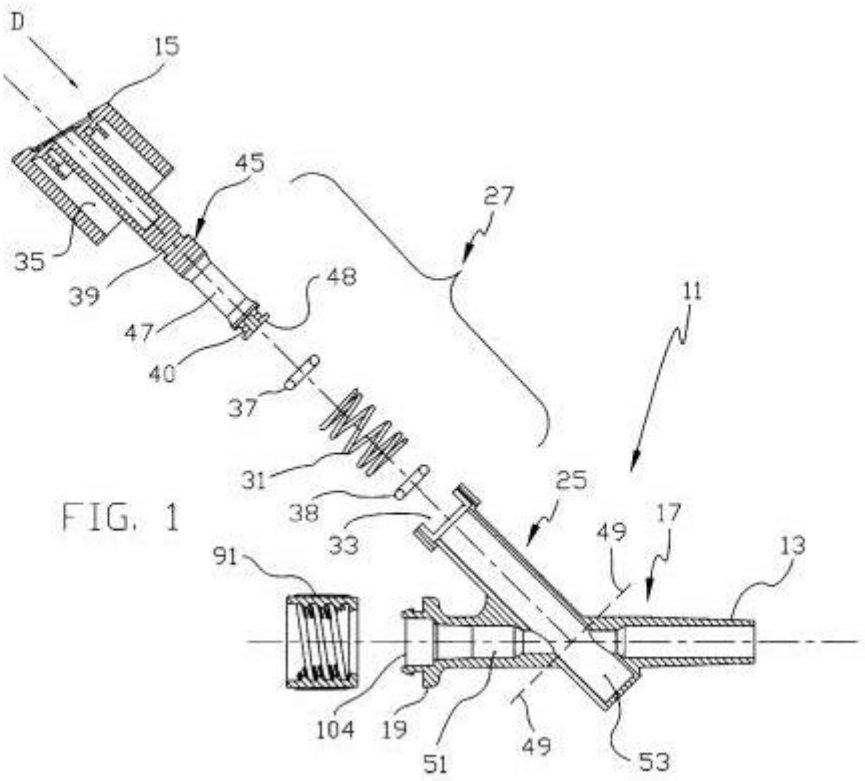

FIG. 1

Ballard f the ’344 patent a nference at which ntly, the court iss ent. The court ba rk Office (“PTO”) during the prosecution of the ’344 patent distinguishing the valve of the claimed catheter from various prior art devices. Those statements, the court concluded, required that the ’344 and ’296 patents be construed to exclude catheter systems having a valve structure of the sort used in the accused Sorenson device. The court also concluded that prosecution history estoppel foreclosed Ballard from establishing infringement based on the doctrine of equivalents.

II

A

Ballard first argues that the district court improperly failed to conduct a detailed, limitation-by-limitation construction of each of the asserted claims. According to Ballard, this court’s decision in Markman v. Westview Instruments, Inc., 52 F.3d 967, 34 USPQ2d 1321 (Fed.

Cir. 1995), aff'd, 517 U.S. 370 (1996), required the district court to conduct a complete claim construction of the asserted claims before addressing the issue of infringement.

Contrary to Ballard's contention, Markman does not require a district court to follow any particular procedure in conducting claim construction. It merely holds that claim construction is the province of the court, not a jury. To perform that task, some courts have found it useful to hold hearings and issue orders comprehensively construing the claims in issue. Such a procedure is not always necessary, however. If the district court considers one issue to be dispositive, the court may cut to the heart of the matter and need not exhaustively discuss all the other issues presented by the parties. District courts have wide latitude in how they conduct the proceedings before them, and there is nothing unique about claim construction that requires the court to proceed according to any particular protocol. As long as the trial court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best.

Nor do Ballard's arguments concerning the terminology in the district court's opinion suffice to overturn the judgment. Ballard complains that the district court incorrectly invoked prosecution history estoppel to limit claim scope for literal infringement despite our case law that holds prosecution history estoppel to be inapplicable to literal infringement. See, e.g., Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578, 34 USPQ2d 1673, 1679 (Fed. Cir. 1995); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1571, 219 USPQ 1137, 1141 (Fed. Cir. 1983).

It is true that the district court at one point in its opinion referred to prosecution history estoppel in the context of claim construction. What is important, however, is the analysis, not the nomenclature, and we are satisfied that in relying on the prosecution history as an aid to claim construction, the district court did not err. In similar circumstances, the court in Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 20 USPQ2d 1252 (Fed. Cir. 1991), acknowledged that

prosecution history estoppel does not apply to the determination of literal claim scope, but noted that "a particular interpretation of a claim term may have been disclaimed by the inventor during prosecution." Id. at 863, 20 USPQ2d at 1262. See also McGill Inc. v. John Zink Co., 736 F.3d 666, 673, 221 USPQ 944, 949 (Fed. Cir. 1984) ('Prosecution history may be used not only in an estoppel context but also as a claim construction tool."). In this case, the district court held that in the course of the prosecution the patentee disclaimed a particular claim interpretation. The court concluded that because of that disclaimer Ballard could not assert that interpretation as the basis for literal infringement and could not invoke the doctrine of equivalents to reach a device covered by the disclaimer. Because the substance of the district court's analysis was sound, we disregard the fact that the court used the term "prosecution history estoppel" in an unconventional manner.

B

Focusing on claim 1 of the '344 patent and claim 4 of the '296 patent, Ballard next contends that the district court erred in concluding that the valve element of those claims did not read on the accused device. The parties agree that the disputed valve limitation of those two claims is drafted in means-plus-function format, governed by 35 U.S.C. § 112 ¶ 6, and we concur. For that reason, the scope of the valve limitation must be confined to the valve structure disclosed in the specification, plus its equivalents. The drawings above depict the structure of the only disclosed embodiment as well as the structure of the accused Sorenson device. Because there are plainly differences between the disclosed valve structure and the valve of the Sorenson device, Ballard must rely on the theory that the Sorenson valve is equivalent to the valve structure disclosed in the written description of the '344 and '296 patents.

An inventor may use the specification and prosecution history to define what his invention is and what it is not—particularly when distinguishing the invention over prior art. "[J]ust as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under §

112, ¶ 6." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1454, 1457, 46 USPQ2d 1169, 1175 (Fed. Cir. 1998) (quoting Alpex Computer Corp. v. Nintendo Co., 102 F.3d 1214, 1221, 40 USPQ2d 1667, 1673 (Fed. Cir. 1996)). Statements detailing the shortcomings of the relevant prior art have often proved useful in construing means-plus-function claims. For example, in Signtech USA, Ltd. v. Vutek, Inc., 174 F.3d 1352, 50 USPQ2d 1372 (Fed. Cir. 1999), the patentee, which had used means-plus-function claim format, noted that the structure used by certain prior art was "incapable" of achieving the desired results of the invention. That was held to be an "explicit disavowal of prior art structure," which was properly used in construing the means-plus-function claims. See 174 F.3d at 1357, 50 USPQ2d at 1375. When a patentee advises the examiner (and the public after patent issuance) that a particular structure is not within his invention, the patentee is not permitted to assert in a subsequent infringement action that the same structure is equivalent to the structure described in the patentee's specification for purposes of section 112 paragraph 6.

Sorenson asserts that in the course of prosecuting the 633,570 application, which issued as the '344 patent, the applicant, Darrel Palmer, offered an amendment and an inventor's affidavit in which he disavowed certain structures by characterizing them as falling outside the scope of his invention. With regard to how his valve opened and closed, Palmer stated that the prior art valves that the examiner had cited were "pressure valves," while the valve disclosed and claimed in the 633,570 application was a "vacuum valve." Palmer asserted that his vacuum valve mechanism for stopping the flow of liquid through the catheter, which is perpendicular to the direction of fluid flow in the catheter, was not affected by pressure through the catheter from either direction. He explained that the prior art pressure valve devices, in contrast, would seal if vacuum pressure were applied to one end of the catheter, but would tend to open or leak if vacuum pressure were applied to the opposite end.

Palmer also distinguished his valve from the prior art valves based on the type of seal that his

valve used to preserve the sterility of the catheter. Palmer explained that his valve "uses a static seal feature to eliminate bacterial contamination." As such, it "has no shaft-seal interface which would, if such existed, allow contaminants to enter the sterile interior of the claimed apparatus." As explained in the written description of the '344 and '296 patents, when the valve is in the closed position, the elastic sealing member entirely blocks the flow of fluid through the catheter. When the actuator that is built into the middle of the sealing member is depressed, the sealing member stretches and permits fluid to flow through the catheter. An advantage of that design, the specification recites, is that only the interior portion of the seal is exposed to the fluid flow and there is no access point through which bacteria can travel between the outside environment and the interior of the catheter. The cited prior art devices, Palmer explained, use a "dynamic seal-to-shaft interface," which "would allow entry of contaminating bacteria between the valve body and the shaft into the fluid flow region of said prior art devices."

Finally, Palmer distinguished the prior art valves on the ground that they lacked a locking mechanism. His valve, he explained, could be locked in the closed position (but not in the open position) to prevent the valve from accidentally opening, leading to inadvertent aspiration of the patient.

Ballard asserts that Palmer's statements distinguishing his valve from the prior art valves applied only to the claims 27-29 of the application, which were introduced with the amendment in which the disputed statements were made. Those claims eventually became claims 1-3 of the '296 patent, which are not at issue in this case. Under Ballard's theory, the statements that Palmer made in his affidavit and in the amendment distinguishing the prior art valves have no effect on claims 4-6 of the '296 patent or any of the claims of the '344 patent.

We disagree. Palmer and his counsel repeatedly characterized the control valve that was described in his affidavit and the amendment as the "control valve of the present invention," "the control valve structure of the above-identified application," and "the control valve disclosed in the

above-identified application," i.e., the 633,570 application that ultimately became the '344 patent. Indeed, through counsel he referred in his statement to "the pending claims [particularly Claims 27-29]," which makes it clear that his remarks applied to all pending claims, not just claims 27-29.

Furthermore, in prosecuting the '296 patent Palmer noted that "[t]he present invention is . . . patentable over the same [prior art] for reasons stated in the parent case." It was therefore appropriate for the district court to treat the distinction of the prior art valves that Palmer made in the amendment to the 633,570 application as applying equally to the related application that became the '296 patent.

Because means-plus-function claims derive their scope from the structure disclosed in the written description, and because the two patents share the same written description, all of the means-plus-function claims at issue in this case derive their scope from the same disclosed structure. For that reason, Palmer's characterizations of the valve described in the original specification of the 633,570 application presumably apply to all of the means-plus-function claims at issue in this case, at least in the absence of some indication that the structure referred to in the means-plus-function limitations should be construed differently for some claims than for others. Nothing in the patent or the prosecution history provides any reason to conclude that the disclosed structure to which the means-plus-function limitations refer differs for purposes of the two patents. In light of the identical disclosures of the two patents, it was therefore appropriate for the district court to construe the means-plus-function claims of the two patents in pari material. See Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1384, 53 USPQ2d 1161, 1165 (Fed. Cir. 1999) (noting that for subject matter common to related patents arguments concerning prior art are "correctly viewed as applying to the common subject matter"); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980, 52 USPQ2d 1109, 1114 (Fed. Cir. 1999) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same

claim limitation."); see also Augustine Med., Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1300, 50 USPQ2d 1900, 1907 (Fed. Cir. 2000) ("[T]he prosecution history of a parent application may limit the scope of a later application using the same claim term.").

Ballard cites Cybor for the proposition that specific statements in the prosecution history should not be generalized into broad disclaimers, and argues that in this case the prosecution history disclaims only those dynamic seals that do not contain means for avoiding bacterial contamination between the interior of the catheter and the outside environment. In Cybor, the court carefully considered the patentee's arguments during prosecution and concluded that the arguments distinguishing a prior art reference did not preclude coverage of any fluid dispensing device that used an external reservoir. Instead, the court agreed with the district court that the patentee disclaimed only "a physically unattached reservoir which has independent functionality." Cybor, 138 F.3d at 1458, 46 USPQ2d at 1176. The court emphasized that the scope of the disclaimer must be determined by what "a competitor would reasonably believe that the applicant had surrendered." 138 F.3d at 1457-58, 46 USPQ2d at 1175. Applying that standard in this case, the district court concluded, as do we, that Palmer's statements identifying his invention as a vacuum valve with a static seal had the effect of disclaiming pressure valves ("[t]he control valve disclosed in the . . . application is not a pressure valve. It is strictly a vacuum valve wherein vacuum pressure, if desired, can be applied to either end with the same result") and dynamic seals ("[t]he present vacuum control valve uses a static seal feature to eliminate the bacterial contamination. It has no shaft/seal interface along which bacterial contamination can pass into the sterile interior").

As for Ballard's contention that the '344 and '296 patents apply to any valve structure that minimizes the cross-contamination between the interior of the catheter and the outside environment, that functional characterization of the scope of the claims is inconsistent with the statutory provision that limits means-plus-function claims to the disclosed structure and equivalents, rather than covering any structure that performs the recited function. In addition,

Ballard's argument is inconsistent with Palmer's representations before the PTO. Palmer did not suggest that his claims extended to any valve structure that served the function of preventing or inhibiting cross-contamination. Instead, he stated that his vacuum control valve "uses a static seal feature to eliminate the bacterial contamination." Other structures, whether or not they served the same function, were thereby excluded.

Finally, Ballard contends that even if the claims of the '344 patent are construed narrowly in light of the prosecution history, claim 4 of the '296 patent should not be subject to the same narrow construction because it lacks two critical limitations found in the '344 claims—the "locking" feature and the "internal seal means." While it is true that claim 4 of the '296 patent does not specifically recite those features, the "valve means" limitation of that claim is nonetheless written in means-plus-function format, and it contains several subordinate limitations that are also written in means-plus-function format. As such, the scope of the "valve means" limitation of claim 4, like the scope of the other means-plus-function limitations at issue in this case, is limited to the structures disclosed in the written description that correspond to the recited functions, plus their equivalents. See Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1257-58, 52 USPQ2d 1258, 1263 (Fed. Cir. 1999). The structure that corresponds to the recited functions, as we have explained, does not read directly on the Sorenson device, and by virtue of Palmer's characterization of his valve structure, the disclosed structure—a vacuum control valve with a static internal seal—cannot be regarded as equivalent to a dynamic pressure valve with a shaft-to-seal interface.

C

Because there is no dispute over the structure of the accused device, resolution of the claim construction issue in this case dictates the outcome of the infringement inquiry. The trial court correctly concluded that the "valve means" limitation cannot encompass the accused device, because the accused device includes structural features that the applicant represented were

different from the invention. Palmer gave specific, detailed reasons for distinguishing his valve from the prior art valves, and in light of those statements no reasonable jury could find that the disclosed valve is equivalent to the valve structure in the accused devices.

The valve of the Sorenson device has a biasing means that applies force at about a 45-degree angle to the fluid flow. Because the biasing means in the Sorenson device is not perpendicular to the fluid flow, the biasing means can be overcome by vacuum pressure in the catheter, as in the case of the prior art devices. Thus, the accused device is a "pressure valve" within the meaning of Palmer's affidavit. That is, the accused device suffers from the very shortcoming described by Palmer in the disputed amendment: the vacuum side (i.e., the direction of fluid flow) is opposite to the biasing means, which can potentially cause the valve to "open or leak," as Palmer warned.

The sealing structure of the accused device also cannot be considered equivalent to the disclosed structure. The accused valve has a plunger shaft with seals on its upper and lower portions. The seals slide with the plunger along the shaft walls as the plunger is actuated. The Sorenson seals thus display exactly the type of dynamic seal-to-shaft interface that Palmer said his device did not have. Palmer argues that the Sorenson device, unlike the prior art devices, has an upper O-ring seal that helps prevent cross-contamination into and out of the interior of the catheter in the accused device. As we have noted, however, Palmer did not disclose or claim all structures that impede contamination, nor is Ballard entitled to have the means-plus-function claims of the two patents construed to cover all structures that perform that function. The fact that Sorenson used an additional structure to attempt to maintain sterile conditions within the catheter does not make the Sorenson structure equivalent to the structure set forth in the specification of the Ballard patent.

D

Having concluded that the Sorenson device is not equivalent to the structure disclosed in

the '344 and '296 patents for purposes of section 112 paragraph 6, we also hold that the Sorenson device does not infringe under the doctrine of equivalents. The same distinctions of the prior art that inform the claim construction in this case give rise to prosecution history estoppel and prevent the doctrine of equivalents from capturing structure that the patentee surrendered during prosecution. Moreover, where the claim of infringement under section 112 paragraph 6 fails on the ground that the accused device is not equivalent to the structure disclosed in the specification, the doctrine of equivalents is available only if, unlike in this case, the accused device represents new technology developed after the issuance of the patent. Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1311, 46 USPQ2d 1752, 1758 (Fed. Cir. 1998).

E

We note that claim 26 of the '344 patent, unlike the other asserted claims, is a method claim and is not in means-plus-function form. Ballard notes that claim 26 was asserted below, but all of the arguments in Ballard's brief focus on the construction of the means-plus-function limitation of the other asserted claims. Since Ballard has presented no argument to us directed particularly to claim 26, the question of the proper construction of that claim has been waived. See Disabled Am. Veterans v. Gober, 234 F.3d 682, 688 n.3 (Fed. Cir. 2000) ("Even though Petitioners challenge multiple rules in their petitions, we will only address those challenges that were briefed."); Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 800, 17 USPQ2d 1097, 1103 (Fed. Cir. 1990) ("An issue not raised by an appellant in its opening brief . . . is waived.").

We also decline to address Ballard's contention that the seal of the '344 and '296 patents is not static, but is at least partly dynamic, so that the district court's construction of the claims at issue as excluding dynamic seals had the effect of making the patent not read on the only disclosed embodiment. Ballard's counsel did not raise that contention until oral argument in this case, and even then only on rebuttal. That is far too late to raise an argument for reversal on appeal.

Ballard has characterized its seal as static throughout the proceedings in this case, and we reject Ballard's eleventh-hour effort to alter that characterization.

III

Because the patentee explicitly represented during prosecution that his claims differed from structures in the prior art, we construe the disputed claims to exclude the disclaimed structures. Based on that construction, we uphold the district court's summary judgment of noninfringement.

AFFIRMED.