IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 07-468-JJF
	:	
RYMED TECHNOLOGIES, INC.,	:	
	:	
Defendant.	:	

James Pooley, Esquire; Kimberly N. Van Voorhis, Esquire; Marc David Peters, Esquire; Diana Luo, Esquire; Katharine Nolan-Stevaux, Esquire; and Daniel Wan, Esquire of MORRISON & FOERSTER, LLP, Palo Alto, California.
Laura L. Kohut, Esquire and Sarah K. Kohut, Esquire, of KOHUT & KOHUT LLP, Costa Mesa, California.
Richard L. Horowitz, Esquire; David E. Moore, Esquire; and D. Fon Muttamara-Walker, Esquire of POTTER ANDERSON & CORROON LLP, Wilmington, Delaware.

Attorneys for Plaintiff.

Henry Bunsow, Esquire; K.T. Cherian, Esquire; and Scott Wales, Esquire of HOWREY LLP, San Francisco, California.
Mark L. Levine, Esquire; Chris Lind, Esquire; and Christopher Landgraff, Esquire of BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP, Chicago, Illinois.
Stanley L. Amberg, Esquire, Chappaqua, New York.
Richard D. Kirk, Esquire and Stephen B. Brauerman, Esquire of BAYARD, P.A., Wilmington, Delaware.

Attorneys for Defendant.

MEMORANDUM OPINION

December 3, 2009
Wilmington, Delaware

Farnan, District Judge.

Plaintiff ICU Medical, Inc. ("ICU") filed this case against Defendant RyMed Technologies, Inc. ("RyMed") alleging infringement of United States Patent Nos. 5,865,866 (the "'866 Patent"); 5,873,862 (the "'862 Patent"); 5,928,204 (the "'204 Patent"); and 6,572,592 (the "'592 Patent") (collectively, "the patents-in-suit"). The parties briefed their respective positions on claim construction, and the Court conducted a Markman hearing on the disputed terms. This Memorandum Opinion provides constructions of the disputed terms.

BACKGROUND

The patents-in-suit relate to needleless intravenous medical connector valves. Such valves are used to facilitate both the transmission of medication and fluids into a patient's bloodstream, as well as the withdrawal of a patient's blood. Before the patents-in-suit, the traditional technique for changing or adding fluid bags to an existing intravenous line required the insertion of an external needle into a needle access port, which was then connected to the existing intravenous line. Numerous problems existed with this traditional practice, for example, detachment of the needle, or contamination of the needle posed serious safety risks to patients, and accidental needle sticks posed the risk of infection to medical personnel.

DISCUSSION

I. The Legal Principles of Claim Construction

Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 388-90, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Id. at 979. Of these sources, the specification is "always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005)(citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). However, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004)(citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002).

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 1318-19; Markman, 52

F.3d at 979-80 (citations omitted). However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 1318-19 (discussing "flaws" inherent in extrinsic evidence, and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of the intrinsic evidence").

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). The ordinary and accustomed meaning of claim terms denotes the meaning that a person having ordinary skill in the pertinent art would ascribe to the terms in the context of the entire patent, including its specification. Phillips, 415 F.3d, at 1313. If the inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984) (citations omitted).

II. Decision

ICU has asserted against RyMed the following claims of the patents-in-suit: claims 1, 2, 3, 5, and 6 of the '866 Patent; claims 1-3 of the '862 Patent; claims 1, 2, 3, 6, and 9- 12 of the '204 Patent; and claim 45 of the '592 Patent. (D.I. 116, at 1.) Although the patents contain different claims, they share a common specification (the "Common Specification").[1] From these claims, the parties have identified several disputed claim terms and/or phrases, but have been unable to reach agreement as to whether all require interpretation by the Court.

Several of the disputed terms have been considered or construed by other courts in prior proceedings concerning this family of ICU patents. See ICU Med., Inc. v. Alaris Med. Sys., Inc., No. CV04-0689 MRP, 2007 U.S. Dist. LEXIS 96077(C.D. Cal. Jul. 17, 2006), aff'd, 558 F.3d 1368 (Fed. Cir. 2009) [hereinafter Alaris]; ICU Med., Inc. v. B. Braun Med., Inc., 344 F. Supp. 663 (N.D. Cal. 2004) [hereinafter Braun]. The Court has determined that the doctrine of collateral estoppel is inapplicable, but that the Alaris and Braun claim constructions are persuasive authority. For the reasons that follow, the Court construes the disputed terms as follows:

A. Compressed State/ Decompressed State

[1]Any references to the Common Specification will be based on the specification found in the '866 Patent.

ICU's Construction	RyMed's Construction
Compressed State The position of the [flexible element] seal when it is under axial compression from a medical implement and opens the valve ***Decompressed State*** The position of the [flexible element] seal when it is not under axial compression from a medical implement	***Compressed State*** A state (i.e. condition) of axial compression ***Decompressed State*** A state (i.e. condition) of no axial compression

The terms "compressed state" and "decompressed state" appear in the asserted claims in the '866, '862, and '592 Patents. ICU contends that a compressed state is created upon insertion of the medical implement's delivery end into the opening of the valve's internal cavity. (D.I. 118, at 12.) Conversely, it contends that a decompressed state is created upon the removal of the medical implement from the valve's internal cavity. (D.I. 118, at 13.) Essentially, the crux of ICU's contention is that the states of compression and decompression referred to in the patents-in-suit are "about what happens when you push a medical implement in, and take it out," rather than abstract notions about the existence or absence of some compression. (D.I. 232, at 7:7-12.) RyMed contends that compressed and decompressed states refer to the condition of the seal when under axial compression and when under no axial compression, respectively. (D.I. 116, at 9.) RyMed opposes ICU's contention that compressed

and decompressed states are to be understood in relation to the insertion or removal of a medical implement. (D.I. 116, at 9-10.) Specifically, RyMed argues that constructing the claim terms according to ICU's proposal improperly rewrites the claim language to allow for relative or partial states of compression. (D.I. 165, at 5-6.)

The Court concludes that ICU's proposed construction is more consistent with both the literal claim language and the Common Specification. The patent repeatedly and clearly explains that the resilient seal is compressed upon insertion of the medical implement, and decompressed upon its removal. See '866 Patent, col. 15: 41-46 ("a resilient seal which is adapted to be moved distally in the cavity into a compressed state upon insertion of the delivery end of the medical implement . . ., said seal . . . returning to a decompressed state upon removal of said delivery end"); '862 Patent, col. 15:37-43 ("a resilient seal . . . adapted to be moved distally in the cavity into a compressed state upon insertion of the delivery end of the medical implement . . ., said seal . . . returning to a decompressed state upon removal of said delivery end"); '592 Patent, col. 15: 49-53 ("a resilient seal which is adapted to be moved into a compressed state upon insertion of the of the [sic] medical implement into said opening to open the valve and returns to a decompressed state upon removal of said tip to close said valve"). RyMed's

proposed construction ignores the integral role of the medical implement in what is claimed about the seal's condition.

Additionally, the Common Specification provides clear support for this interpretation. See Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1379-80 (Fed. Cir. 2001)(stating that the specification should be read, "if possible, in a manner that renders the patent internally consistent"). The claim term "compressed state" is consistently described by reference to the behavior of the seal when a medical implement is inserted into the cavity. See '866 Patent, col. 3, 37-39 ("In the compressed state, the seal section is pushed by the delivery end of the medical implement away from the opening and into the cavity."); id. at col. 1, 17-19 (the valve includes a "seal which, upon being compressed by the medial implement, is pierced to open the valve and reseals upon being decompressed").

RyMed's argument that ICU's construction allows for relative states of compression is not persuasive. In Alaris, Judge Pfaelzer stated that "[b]oth the concept of the medical implement as the source of the compression and the concept of the valve being opened as a result of the compression are already included in the applicable claim language and thus do not need to be included in the construction of compression." Alaris, 2007 U.S. Dist. LEXIS 96077, at *16. However, concerns over relative or partial compression being read into the claim language are

precisely why "compressed state" and "decompressed state" must be construed with reference to the source of the compression, as well as to the condition of the seal. See Braun, 344 F. Supp. 2d, at 671-72 (noting that the claim term "uncompressed" in the '673 Patent clearly referred to a lack of compression, but that the relevant question was what source of compression was being referenced). Thus, in light of the claim language and Common Specification, the Court concludes a "compressed state" means the state of the seal when a medical implement causes axial compression; a "decompressed state" means the state of the seal when a medical implement is not causing axial compression. Whether any compression exists in the valve in the abstract, not in relation to the medical implement, is outside the scope of the claim.

B. O-Ring Elements

ICU's Construction	**RyMed's Construction**
Portions having a circular outer surface that is wider at the middle than at the top or bottom	Ring-Shaped elements wherein the cross section of the ring taken perpendicular to the plane of the ring is circular in shape

The term "O-ring elements" appears in the asserted claims in the '866, '862, and '592 Patents.[2] ICU emphasizes the importance

[2] In the '866 and '592 Patents, the term "O-ring elements" appears in an identical phrase: "a series of O-ring elements stacked together and connected to form a unitary structure." '866 Patent, col. 15: 52-54; '592 Patent, col. 15: 63-65. In the

of the word *elements* in its proposed construction. ICU contends that because the term used is "O-ring *elements*," it does not mean the seal is comprised of actual O-rings. (D.I. 232, at 14: 18-22.) Rather, a person of ordinary skill in the art would understand that this term describes what the seal looks like from the outside. (Id.) In support of this position, ICU contends that the Detailed Description of the Preferred Embodiments proves at least two different types of "O-ring elements" (namely those in Figures 9-12 and 13-19) can form the seal of the patents-in-suit. (D.I. 118, at 18.) Further, ICU argues that the '862 Patent prosecution history demonstrates that the "ringed wall portions" of Figures 9-12 are included within the meaning of "O-ring elements." (Id. at 19-20.)

RyMed responds that ICU's emphasis on the word "elements" in construing the claim term "O-Ring elements" is inappropriate, (See D.I. 232, at 50:11-14), because it allows ICU to construe "O-ring elements" significantly more broadly than the actual term "O-ring." (D.I. 116, at 21.) RyMed also argues that ICU's construction is confusing, unclear, and will be unhelpful to the jury. (Id.) RyMed contends its construction is appropriate because it reflects the ordinary meaning of "O-ring," and is

---

'862 patent, the term appears in the following phrase: "wherein said seal has at least one groove defined by at least two O-ring elements forming a portion of said seal[.]" '862 Patent, col. 16, 17-19.

consistent with the patent disclosure. (Id. at 20.)

Both parties agree as to the ordinary meaning of O-ring. (Compare D.I. 232, at 52:7-10 (RyMed stating that an O-ring is a "circular torus or doughnut-shaped ring") with id. at 83:23-25 (ICU stating "we agree an O-ring is like a doughnut").) The issue is whether the term "O-ring elements" has a different meaning than "O-ring," namely as a description of the seal's appearance rather than as a description of its structure. The Court is persuaded that ICU's construction is more appropriate because support for their position can be found in the Common Specification and prosecution history.

There is limited use of the term "O-ring elements" in the Common Specification. The Summary of the Invention states, "[a] preferred embodiment of the seal comprises a series of O-ring elements stacked together and connected to form a unitary structure." '866 Patent, col. 3: 63-66. A description of a preferred embodiment can help define what is claimed, but without a specific declaration, it does not limit what the patent claims. See Liebel-Flarsheim Co., 358 F.3d at 906. In fact, both Figures 9 and 13 illustrate features of the preferred embodiment. See '866 Patent, col. 5: 19-20, 47-48, 58-59. Figure 9 displays a "seal wall consisting of a plurality of ringed wall portions 94 that expand and collapse in an accordian like fashion." Id. at col. 12:4-5. Figure 13 displays a seal with a "wall 150

comprised on circular tires 100 stacked in a series one on top of an adjacent larger diameter tire." Id. at col. 12:47-49. Therefore, ICU's contention that "O-ring elements" should not be construed as merely a device of actual O-rings is supported in the Common Specification.

The prosecution history of the '862 Patent provides additional confirmation that RyMed's more limited construction is unsupported. "In order to disavow claim scope during prosecution 'a patent applicant must clearly and unambiguously express surrender of the subject matter.'" Voda v. Cordis Corp., 536 F.3d 1311, 1321 (Fed. Cir. 2008)(citations omitted). During the course of the '862 Patent's prosecution, the Examiner rejected claims 70 and 71 (which ultimately issued as claims 2 and 3) for indefiniteness because it was unclear whether the "at least two O-ring elements" were on the seal or made up the seal. (D.I. 120, Ex. D, at 1236.) ICU clarified that the O-ring elements form a portion of the seal, and further stated that "[s]upport for amended Claim 70 can be found on page 15, lines 27-29, which disclose that the 'seal wall' consists 'of a plurality of ringed wall portions 94 that expand and collapse in an accordian like fashion.'" (Id.) With regard to amended Claim 71, ICU stated, "the Examiner's attention is respectfully drawn to Figure 9 which illustrates a plurality of O-ring elements. . ." (Id.)

Although RyMed contends these statements were irrelevant to

the indefiniteness rejection, the prosecution history, at a minimum, demonstrates that the ICU patentee did not explicitly disavow the claim scope currently advocated by ICU's proposed construction. In sum, nothing in the Common Specification or prosecution history supports a reading of "O-ring elements" which gives no meaning to "elements," a word included in the disputed term. Thus, the Court concludes "O-ring elements" means "portions having a circular outer surface that is wider at the middle than at the top or bottom."

C. Resilient Seal/ Resilient Seal Elements

ICU's Construction	**RyMed's Construction**
Resilient Seal A seal capable of returning to its original position after being bent, compressed or stretched	***Resilient Seal*** Wherein, upon compression, the structure changes shape and, upon removal of the compression, the structure returns to its original shape
Resilient Seal Element A sealing portion capable of returning to its original position after being bent, compressed, or stretched	***Resilient Seal Element*** A single sealing structure wherein, upon compression, the structure changes shape and, upon removal of the compression, the structure returns to its original shape

The terms "resilient seal" and "resilient sealing element" appear in the asserted claims of all four of the patents-in-suit. The parties agree two separate inquiries must be made: 1) what does "resilient" mean?; and 2) does the claim language indicate the limitation of a "single sealing structure"?

1. What Does "Resilient" Mean?

ICU contends that their construction is closely tied to the language of the patent, and is consistent with the ordinary meaning of the term "resilient." (D.I. 118, at 15.) RyMed contends their construction is supported by the Common Specification, and asserts that ICU's construction improperly allows the seal to be considered "resilient" if, "outside of its use in the invention, it could be bent or stretched and return to its original form." (D.I. 116, at 24-25.)

In the Court's view, RyMed's proposed construction is more persuasive because it mirrors the language used in the Common Specification. In contrast, ICU's proposed construction adds terms, such as "bent" or "stretched," which do not appear anywhere in the intrinsic record of the patents-in-suit. Further, ICU proposes the construction of the Braun court, which relied on the dictionary meaning of "resilient." See Braun, 344 F. Supp. at 668. Currently, dictionary definitions are not favored as a source of ordinary meaning. See Phillips, 415 F.3d 1303, 1320-23 (discussing problems with approach of Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002)). Rather, the ordinary meaning of claim terms is to be determined by reference to the context provided by the intrinsic record. Id. at 1313.

When read in the context of the intrinsic record, the Court

concludes RyMed's construction is fully supported. The Common Specification states, "[u]pon removal of the syringe from spike. . . the seal 36 is free to return to its original shape," and "[t]he ability of the seal 36 to return to its original shape is determined by the resiliency of the material used to prepare the seal." ('866 Patent, col. 9:14-18.) Therefore, if a seal is made of resilient material, it is able to return to its original shape. The seal is free to return to its original shape when the syringe is removed, or in other words, when the source of compression is removed.

2. Does the Claim Language Indicate the Limitation of a "Single Sealing Structure"?

ICU contends that RyMed's proposed limitation of a "single sealing structure" is neither inherent in the claim language, nor supported by the intrinsic record. (D.I. 118, at 16.) ICU asserts that RyMed's emphasis on the article "a" in the claim language is ineffective, and that the Common Specification contemplates multi-component sealing structures. (D.I. 172, at 14.) RyMed contends there is no disclosure in the patents that two or more seals can be used to perform the specifically claimed functions, and accordingly, a single resilient seal must perform the functions. (D.I. 116, at 24.) Further, RyMed contends that this single sealing structure is disclosed as "the invention" in the preferred embodiment, and that the claims cannot have a broader scope than the embodiment. (Id. at 23.)

The Court concludes that ICU's construction is more appropriate for two reasons. First, the claim language and Common Specification appear to contemplate multi-component sealing structures. In general, the indefinite article "a" or "an" in a patent claim means "one or more." Baldwin Graphic Sys., Inc. v. Siebert, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008). "[This] is particularly true when those words are used in combination with the open-ended antecedent 'comprising.'" Tivo, Inc. v. Echostar Commc'n Corp., 516 F.3d 1290, 1303 (Fed. Cir. 2008). When the articles "the" and "said" refer back to the same claim terms, the general non-singular meaning still applies. Baldwin, 512 F.3d at 1342. However "a" or "an" can mean "only one" when the context dictates a singular meaning. Id. at 1342-43. RyMed notes that neither the patent claims nor the Common Specification discloses more than one sealing structure. This reading is accurate, but RyMed fails to cite any context from the claims or Common Specification that supports deviating from the general meaning of the article "a." Additionally, the claim language "a resilient seal" is preceded by the open-ended term "comprising" in the '866, '862 and '592 Patent claims, thus providing further support to use the general meaning of the article "a."

Second, the contention that a "single sealing element" is the invention itself is not convincing. "Where the specification

makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent." SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001). As discussed above, the Common Specification does *not* make clear that the invention does not include multi-component sealing structures, and accordingly, a multi-component sealing structure should not be deemed to be a feature outside the reach of the claims. Thus, the Court concludes that "resilient seal" means "wherein, upon compression, the structure changes shape and, upon removal of the compression, the structure returns to its original shape." The Court concludes that "resilient seal element" means "a sealing structure wherein, upon compression, the structure changes shape and, upon removal of the compression, the structure returns to its original shape."

D. Generally Arcuate Segments

ICU's Construction	**RyMed's Construction**
Naturally separated divisions, portions or sections of the walls that are bent, curved like a bow or arc-sharped	Segments wherein the inner and outer surfaces of the wall are curved in the same direction.

The term "generally arcuate segments" appears in independent claim 1 of the '204 Patent. ICU contends that the Court should adopt the construction used in the Braun case because it reflects the plain meanings of "arcuate" and "segment." (D.I. 118, at 21.)

ICU also contends that RyMed's proposed construction ignores or excludes dependent claim language which further defines the disputed term, (D.I. 172, at 18), and that RyMed's proposed construction contains limitations not warranted by the claim language or Common Specification. (Id. at 21.)

RyMed contends that ICU's construction is "confusing, redundant, and inconsistent with the intrinsic evidence." (D.I. 116, at 28.) RyMed further contends that Figure 9 is the only support in the Common Specification for the term "generally arcuate segments," and that a prosecution history disclaimer should apply to prevent ICU from arguing that additional support exists in the Common Specification. (See D.I. 116, at 29 ("ICU is. . . estopped by its statements in the prosecution history from arguing that a seal such as the O-ring based seal of Figure 13 has 'arcuate segments.'").)

As an initial matter, the Court finds that prosecution history disclaimer is inapplicable. In order for the Court to find a prosecution history disclaimer, the patentee must have limited the meaning of a claim term by making a "clear and unmistakable disavowal" of claim scope during prosecution. Purdue Pharma, L.P. v. Endo Pharm., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). During the prosecution of the '204 Patent, the Examiner rejected the term "arcuate segments" for lack of support in the specification. (D.I. 117, Ex. 23, at 49.) The patentee

replied, "Figure 9 clearly discloses a seal element 36a having the arcuate segments." (Id.) Because it is not apparent whether the patentee meant Figure 9 as one of multiple examples of "arcuate segments," or as the only example of them, no "clear and unmistakable disavowal" was made. See SanDisk Corp. v. Memorex Prod., Inc., 415 F.3d 1278, 1287 (Fed. Cir. 2005)("[t]here is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation"). The fact that the patentee had the opportunity to cite Figure 13 in support of "generally arcuate segments," but chose not to, does not change the foregoing analysis.

As ICU points out in their Opening Brief, both parties are in relative agreement as to the meaning of "arcuate." (Compare D.I. 118, at 21 (ICU construing "arcuate" as "bent, curved like a bow, or arc-shaped") with D.I. 232, at 72:20-21 (RyMed stating "arcuate means curved like a bow. Bow means something bent into a simple curve.").) However, the parties dispute whether or not RyMed's proposed limitation concerning "the inner and outer surfaces of the wall" is appropriate. In the Court's view, this limitation is unwarranted. Even if RyMed were correct that the Figure 9 embodiment is the only support for "generally arcuate segments" in the Common Specification- which is a contested point- they provide no justification for reading a limitation about the inner surface walls into Figure 9.

ICU relies in large part on the Braun construction of "generally arcuate segments." In Braun, the parties stipulated to the construction, and it was based on dictionary definitions, a now-disfavored practice. Accordingly, it is unclear how persuasive an authority Braun is on the construction of this term. However, if prosecution history disclaimer does not apply and the proposed RyMed limitation is not accepted, ICU's proposed construction is more persuasive. Thus, the Court concludes that "generally arcuate segments" means "naturally separated divisions, portions or sections of the walls that are bent, curved like a bow or arc-shaped."

E. Arcuate Segments Intersecting One Another

ICU's Construction	**RyMed's Construction**
Arcuate segments that meet or touch	Successive arcuate segments touch each other

The term "arcuate segments intersecting one another" appears in independent claim 1 of the '204 Patent. ICU contends that this term is plain on its face and does not require construction. (D.I. 118, at 22.) To the extent it requires construction, ICU contends that "meet or touch" is the common understanding of "intersect." (Id.) Further, ICU criticizes RyMed's proposed construction, contending that the limitation of "successive" is both unwarranted by the claim language, as well as redundant. (Id.) RyMed contends that ICU's use of the word "meet" to

construe the word "intersect" is ambiguous, and that "intersect" means only that the arcuate segments "touch." (D.I. 116, at 30-31.) Further, RyMed contends that its use of the word "successive" is supported by, and required by, Figure 9. (D.I. 165, at 28.)

In the Court's view, ICU's construction is more persuasive because RyMed offers no support to read in the "successive" limitation. This limitation is not grounded in the claim language or in the Common Specification, since the words "intersect" or "intersecting" do not appear anywhere in the Common Specification. Accordingly, the limitation seems to be based on nothing more than RyMed's interpretation of what Figure 9 illustrates. Thus, the Court concludes that "arcuate segments intersecting one another" means "arcuate segments that meet or touch."

F. Fills Essentially Completely

ICU's Construction	**RyMed's Construction**
Fills all or almost all	(No construction necessary) Fills all of or almost all of the cavity adjacent to the opening to prevent fluid from leaking between the seal and the wall structure

The claim term "fills essentially completely" appears in claim 1 of the '866 Patent, and claims 1 and 2 of the '862 Patent. RyMed contends the claim term need not be construed, but

that ICU had insisted it needs construction. (D.I. 116, at 32.) However, in its Answering Brief, ICU concedes that, "in an effort to reduce the number of terms for the Court to consider, and because it appears that this will not make a difference in the infringement or invalidity analysis, ICU can agree to the construction proposed by RyMed." (D.I. 172, at 20.) Thus, the Court concludes that "fills essentially completely" means "fills all of or almost all of the cavity adjacent to the opening to prevent fluid from leaking between the seal and the wall structure."

G. Bearing Against Said Wall Structure Near Said Opening to Seal Said Opening

ICU's Construction	**RyMed's Construction**
The seal presses against the wall structure near the opening to prevent leakage of the fluid into the valve when the seal is in the decompressed state	The seal is situated in contact with the wall structure [of the housing] near the opening of the proximal end of the housing to make the opening fluid tight

The claim term "bearing against said wall near said opening to seal said opening" appears in claim 1 of the '866 Patent, and claims 1 and 2 of the '862 Patent. RyMed contends that its proposed construction, which is identical to the one adopted in Alaris, is correct. (D.I. 116, at 3.) RyMed contends that the Common Specification dictates that the seal in this claim term is always fluid tight, and that the claim term applies to both the compressed and decompressed states. (Id. at 31-32.)

ICU contends that the "fluid tight" requirement is inappropriate because the seal's fluid tight condition is only relevant in the compressed state. (D.I. 118, at 25.) Further, ICU criticizes the Alaris construction as ignoring the context of the claims and the Common Specification. (Id.) ICU contends that the claim language limits the condition of "bearing against said wall near said opening to seal said opening" as a position of the seal in its decompressed state. (Id.) According to ICU, the Alaris construction also "ignores the expressed function of this claim limitation, which is to allow for swabbing with alcohol or other disinfectant without leakage of disinfectant into the valve." (Id.)

The Alaris case dealt with almost identical issues regarding construction of this claim term: 1) whether the claim term only refers to when the valve is in a decompressed state; and 2) whether the claim term requires that the opening be fluid tight or just that it be sufficient to prevent leakage. Alaris, 2006 U.S. Dist. LEXIS, 96077, at *20. Judge Pfaelzer construed the claim term to refer to both the decompressed and compressed states, and to require that the opening be fluid tight.

As Judge Pfaelzer noted, in regard to whether this claim term is only applicable to the decompressed state, the claim language is somewhat ambiguous. Alaris, 2006 U.S. Dist. LEXIS 96077, at *21. "[T]he context in which a term is used in the

asserted claim can be highly instructive." Phillips, 415 F.3d at 1314. Even when read in the context of the broader claim language, it is not entirely clear whether the phrase containing this claim term refers only to the decompressed state, or to both the decompressed and compressed states. Claim 1 of the '862 Patent reads:

> ... [S]aid [resilient] seal moving proximally in the cavity and returning to a decompressed said upon removal of said delivery end from said opening, said seal in the decompressed state having a section which fills essentially completely a portion of the cavity adjacent to said opening, *said seal bearing against said wall structure near said opening to seal said opening*, and in the compressed state, said seal being located in the cavity distal said opening, said seal being preslit at the proximal end thereof...

'862 Patent, col. 15: 41-49 (emphasis added). Claim 1 of the '866 Patent reads substantially the same:

> ... [S]aid [resilient] seal moving proximally in the cavity and returning to a decompressed said upon removal of said delivery end from said opening, said seal in the decompressed state having a section which fills essentially completely a portion of the cavity adjacent to said opening, *said seal bearing against said wall structure near said opening to seal said opening*, and in the compressed state, said seal being located in the cavity distal said opening, said seal comprising a series of O-ring elements stacked together and connected to form a unitary structure...

'866 Patent, col. 15: 44-54 (emphasis added). It is apparent that the claims set forth a list of the resilient seal's characteristics. The placement of the disputed claim term between descriptions of the seal in the decompressed and compressed states arguably creates confusion as to whether the

claim term is referring to one or both of these states. In one way, the context suggests that the claim term refers to both the compressed and decompressed states, as RyMed contends. The last sentence in each of the claims is preceded by a description of the seal's location in the compressed state, yet both sentences seem to provide general descriptions of the seal *not* limited in reference to the compressed state. In another way, the context suggests that the claim term is limited in reference to the decompressed state, as ICU contends. In the disputed claim term, the seal section bears against said wall structure "*near said seal opening* to seal said seal opening." Immediately following this term, the claim states that, in the compressed state, said seal section is "located in the cavity *distal said opening*." If the seal section is distal to the opening while in the compressed state, the logical conclusion is that the seal section is near the opening in the decompressed state.

When the language used by the patentees deprives the claim of clarity, courts should look to the specification to determine a disputed term's construction. Rexnord Corp. v. Laitrop Corp., 274 F.3d 1336, 1343 (Fed. Cir. 2001). The Common Specification supports the conclusion that the disputed claim term is limited in reference to the decompressed state. The relevant language from the Common Specification is as follows:

> The seal in the decompressed state has a section which fills essentially completely a portion of the cavity adjacent the

> opening. The seal section bears against the wall structure near the opening to seal the opening. In the compressed state, the seal section is pushed by the delivery end of the medical implement away from the opening and into the cavity. . . The seal section bears against the wall structure as the seal is moved inward into the cavity by the tip of the medical implement .

'866 Patent, col. 3: 33-43. As in the claim language, the Common Specification dictates that the medical implement pushes the seal section away from the opening in the compressed state. Further, while the seal is being moved into the compressed state, the seal section is still "bear[ing] against the wall structure," but it is no longer "bear[ing] against the wall structure near the opening." Accordingly, ICU's proposed construction, which limits the claim term by reference to the decompressed state, is persuasive.

The Common Specification also supports RyMed's contention that the seal is required to be fluid tight, even when in the decompressed state. ICU points to language in the Common Specification which states that the seal should be able to the swabbed with disinfectant without the disinfectant leaking into the valve. See '866 Patent, col. 8: 8-13. Based on this alleged expressed function, ICU claims that nothing more is required than "a seal section that fills all or almost all of the cavity, enough to seal the opening, [and] to prevent this type of swabbing fluid from entering the valve." (D.I. 118, at 25.) However, RyMed refers to another part of the Common Specification

which states that one of the claimed invention's features is that the seal has a "pressure responsive element" on its proximal end which "in the decompressed state closes any orifice in the seal at the proximal end of the seal to provide an essentially fluid tight seal while in the decompressed state." '866 Patent, col. 4: 35-41. Further, the Common Specification states that "[a] fluid tight seal is maintained between the seal section and the wall structure as the seal is moved into the compressed state." Id. at 3:39-41. As Judge Pfaelzer noted in Alaris, the use of the word "maintained" is important because it makes clear that the seal described in the claim term was in a fluid tight condition before being moved into a compressed state. Alaris, 2006 U.S. Dist. LEXIS, 96077, at *21. Accordingly, the Court agrees with RyMed's proposed construction which includes the fluid tight condition. Thus, the Court concludes that "bearing against said wall near said opening to seal said opening" means "the seal is situated in contact with the wall structure [of the housing] near the opening of the proximal end of the housing to make the opening fluid tight."

H. Pre-Slit

ICU's Construction	**RyMed's Construction**
An opening made beforehand	An opening cut in the seal before the seal was axially compressed

The claim term "preslit" appears in claims 1 and 2 of the

'862 Patent. RyMed contends that if construction of this claim term is required, then construction in Alaris should be adopted. (D.I. 116, at 33.) In particular, RyMed contends that this construction is correct because the Common Specification's antecedent bases for the term "preslit" all refer to cutting of the seal before activation of the valve. (Id. at 33-34.) ICU takes issue with the Alaris construction for its use of the word cut, which ICU contends is an improper limitation on how the opening is formed. (D.I. 118, at 27.) Further, ICU contends that the Common Specification only requires the slit to be placed in the seal "prior to use," not "before axial compression." (Id. at 27-28.)

In the Court's view, ICU's proposed construction is more appropriate. As the Alaris court noted, the word "preslit" does not appear anywhere in the Common Specification, yet the word "precut" appears numerous times. See '866 Patent, col. 4: 1-4 ("The proximal end of the seal may be precut to form a tiny orifice therein that allows the tip of the spike to pass therethrough easily upon compression of the seal"; id. at col. 4: 47-49 ("Typically, the pressure responsive element is a section of the seal having an entryway into a precut orifice."). However, "[w]here a specification does not *require* a limitation, that limitation should not be read from the specification into the claims." E.I. DuPont de Nemours & Co., v. Phillips Petroleum

Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988)(citing Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)(emphasis in original)). Despite several uses of this word, the Common Specification does not require that "preslit" can only mean "precut," and in fact, suggests that the preslit can be made through piercing. See '866 Patent, col. 14: 3-7 ("Prior to the use of valve 10, it is preferable that the seal caps 40 or 92 be pierced centrally by a steel needle in the axial direction, precutting the seal to provide the slit 11 in order to allow for more rapid decompression. . ."). Accordingly, it is unnecessary to use the Common Specification to impose a limitation on how the preslit must be made.

Although RyMed contends that construing "preslit" to mean "beforehand" is nebulous and offers no real construction, (D.I. 165, at 34), the Common Specification provides clear guidance on when the slit must be made: "[p]rior to use of the valve." '866 Patent, col. 14: 3. Thus, the Court concludes that "preslit" means "an opening made beforehand."

I. Horizontal Groove

ICU's Construction	**RyMed's Construction**
One or more non-vertical indentations that extend from one side to another	At least one groove which is perpendicular to an axis defined by the proximal and distal ends

The claim term "horizontal groove" appears in claim 1 of the

'862 Patent within the phrase "wherein said seal has at least one horizontal groove to facilitate the movement of the seal." '862 Patent, col. 1:49-51. Both parties acknowledge that neither "horizontal" nor "horizontal groove" appear anywhere in the Common Specification. (D.I. 116, at 26; D.I. 118, at 29.) ICU contends that the word "horizontal" merely "explains the overall orientation of the groove in facilitating the function," which is to facilitate movement of the seal. (D.I. 118, at 28.) Further, ICU contends that "horizontal" need not be given a precise geometric meaning because it should be construed as broadly as its functional requirements allow (id. at 29), and because other directional terms in the Common Specification are not limited to precise geometric meanings. (D.I. 172, at 16.) RyMed contends that ICU's construction improperly reads out the word "horizontal," substituting it with "non-vertical." (D.I. 116, at 27.) Additionally, RyMed contends that ICU has selectively chosen the dictionary definition most helpful to them, ignoring other definitions defining "horizontal" as "at right angles to the vertical." (D.I. 165, at 24-25.)

As ICU points out, the surrounding context of the claim language demonstrates that the function of the "horizontal groove" is to facilitate the movement of the seal. (D.I. 118, at 28.) Although ICU has supplied the Declaration of Mr. Claude Vidal (D.I. 173) to support its contention that a person of

ordinary skill in the art would understand "horizontal" as meaning "from one side of the seal to another" in this context, nothing in the intrinsic record counsels such a broad understanding. "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 the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. The plain meaning of "horizontal" is perpendicular to, or at right angles from, a vertical axis, and there is no support for broadening that term to include anything "non-vertical." See Nystrom v. TREX Co., Inc., 424 F.3d 1136, 1145 (Fed. Cir. 2005)("in the absence of something in the written description. . . to provide explicit or implicit notice to . . . the public- i.e., those of ordinary skill in the art- that the inventor intended a disputed term to cover more that the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source"). Thus, the Court concludes that "horizontal groove" means "at least one groove which is perpendicular to an axis defined by the proximal and distal ends."

J. Seated Within the Cavity

ICU's Construction	RyMed's Construction
Situated, positioned or located within the cavity	Sitting in a seat [the annular cuff] of housing walls forming the cavity

The claim term "seated within the cavity" appears in claim 1 of the '866 Patent. RyMed contends that construction of this term is not necessary. (D.I. 116, at 34.) ICU apparently concurs, but has submitted a proposed construction to the Court because RyMed allegedly claims that this element is not present in the accused device. (D.I. 118, at 29.) ICU contends that "in this way RyMed will be forced to provide some hint about why construction of this term matters." (Id.) ICU contends their construction is consistent with the plain meaning of "seated," and is supported by the Common Specification. (Id. at 30.) In response, RyMed contends that ICU's construction is unsupported by intrinsic or extrinsic evidence, and that RyMed's construction is actually supported by the Common Specification. (D.I. 165, at 35.)

In the Court's view, it is not entirely clear that this term needs to be construed, as both parties seem to indicate that construction is only necessary because of the other party. (See D.I. 118, at 29-30 and D.I. 165, at 36.) To the extent that construction is necessary, the Court is persuaded that ICU's construction is more appropriate because it does not limit the claim language to a preferred embodiment in the Common

Specification. Admittedly, none of ICU's citations to the Common Specification directly support the construction of "seated" as "situated, positioned, or located." However, RyMed's construction principally relies on a sentence in the Detailed Description of the Preferred Embodiments in the Common Specification which reads, "the spike 24, with contiguous inner conduit 18, is affixed to the housing 12 through the association of the external portion of annular cuff 28 and the internal portion of annular ring 14." '866 Patent, col. 8: 13-17. Broader claim language should generally not be limited to a preferred embodiment in the patent specification. See Phillips, 415 F.3d at 1323 ("although the specification often describes the very embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments")(citations omitted). Thus, the Court concludes, if a construction is necessary, the term "seated within the cavity" means "situated, positioned or located within the cavity."

III. Conclusion

For the reasons discussed, the Court has construed the disputed terms and/or phrases of the '866, '862, '204, and '592 patents as provided herein. An Order consistent with this Memorandum Opinion will be entered setting forth the meanings of the disputed terms and/or phrases in the '866, '862, '204, and '592 patents.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 07-468-JJF
	:	
RYMED TECHNOLOGIES, INC.,	:	
	:	
Defendant.	:	

O R D E R

At Wilmington, this 3 day of December 2009, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the following terms and/or phrases in U.S. Patent Nos. 5,865,866 (the "'866 Patent"); 5,873,862 (the "'862 Patent"); 5,928,204 (the "'204 Patent"); and 6,572,592 (the "'592 Patent") are assigned the following meanings:

1. The term "**compressed state**" means "the position of the seal when it is under axial compression from a medical implement and opens the valve."

2. The term "**decompressed state**" means "the position of the seal when it is not under axial compression from a medical implement."

3. The term "**O-ring elements**" means "portions having a circular outer surface that is wider at the middle than at the top or bottom."

4. The term "**resilient seal**" means "wherein, upon compression, the structure changes shape and, upon removal of the

compression, the structure returns to its original shape."

5. The term **"resilient seal element"** means "a sealing structure wherein, upon compression, the structure changes shape and, upon removal of the compression, the structure returns to its original shape."

6. The term **"generally arcuate segments"** means "naturally separated divisions, portions or sections of the walls that are bent, curved like a bow or arc-shaped."

7. The term "**arcuate segments intersecting one another**" means "arcuate segments that meet or touch."

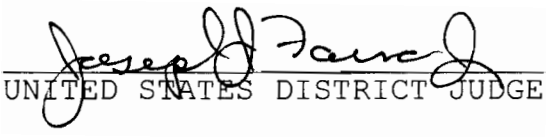
8. The term "**fills essentially completely**" means "fills all of or almost all of the cavity adjacent to the opening to prevent fluid from leaking between the seal and the wall structure."

9. The term "**bearing against said wall structure near said opening to seal said opening**" means "the seal is situated in contact with the wall structure [of the housing] near the opening of the proximal end of the housing to make the opening fluid tight."

10. The term "**preslit**" means "an opening made beforehand."

11. The term "**horizontal groove**" means "at least one groove which is perpendicular to an axis defined by the proximal and distal ends."

12. The term "**seated within the cavity**" means "situated, positioned or located within the cavity."



UNITED STATES DISTRICT JUDGE