United States District Court,
C.D. California.

ICU MEDICAL, INC,
Plaintiff.
v.
ALARIS MEDICAL SYSTEMS, INC,
Defendant.

No. SA CV 04-0689 MRP (VBKx)

July 17, 2006.

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CLAIM CONSTRUCTION ORDER

MARIANA R. PFAELZER**, District Judge.**

I. Introduction

In this case, plaintiff ICU Medical, Inc., a Delaware corporation ("ICU"), alleges infringement of four of its patents by defendant Alaris Medical Systems, Inc., a Delaware corporation ("Alaris"): United States Patent Nos. 5,685,866 ("the '866 patent"), 5,873,862 ("the '862 patent"), 6,572,592 ("the '592 patent") and 6,682,509 ("the '509 patent"). All four patents relate to a medical device-a needle-free valve which, when opened, can deliver drugs, blood and other fluids to and from a patient through intravenous tubing. Although the four patents in suit differ from one another in terms of scope and specific claim language, they all relate to this same technology, claim priority from the same original application, and share a common specification (the "Common Specification"). Before the court is the task of construing certain disputed claim terms of the patents in suit.

In arriving at the claim constructions set forth herein, the court has reviewed and considered various briefs submitted by the parties, including those submitted by both parties in connection with Alaris's motion for Partial Summary Judgment of Noninfringement of "Spike" Claims, as well as those submitted in connection with this Claim Construction Order ("Order"). On June 21 and 22, 2006, a Markman hearing was held in the

matter, and the court heard extensive oral argument from the parties with respect to the terms construed in this Order.

II. Background

In June of 2004, ICU filed this lawsuit against Alaris, initially alleging that Alaris's SmartSite (R) Valve and SmartSite (R) Plus Valve infringe ICU's ' 509 patent. ICU asserted only the '509 patent, which the parties characterize as "spike-less" because its claims, unlike those of the '862, '866 and '592 patents, do not recite a "spike" element. Although the SmartSite (R) Valve had been on the market since 1996, immediately upon the filing of this lawsuit ICU also filed an *ex parte* application for a temporary restraining order and order to show cause why Alaris should not be preliminarily enjoined from making, using and selling SmartSite Valves. On July 30, 2004, Judge Stotler issued an Order Denying Plaintiff's Motion for a Preliminary Injunction and Findings of Fact and Conclusions of Law (the "July 2004 Order"), which denied ICU's application, and which construed, as conclusions of law, three of the terms at issue in the present Order: "preslit"; "into an axially compressed state"; and "returning to an axially decompressed state". Upon denial of its preliminary injunction application, ICU subsequently amended its complaint to add claims for infringement of its '862, '866 and '592 "spike" patents. In September of 2005, Alaris filed a Motion for Partial Summary Judgment of Noninfringement of "Spike" Claims, which seeks the dismissal of those claims from the more recently added patents reciting a "spike" element. That motion is pending before this court.

III. Legal Standard

"The words of a [patent] claim are generally given their ordinary and customary meaning," i.e. "the meaning that the term would have to a person of ordinary skill in the art in question ... as of the [patent's] effective filing date." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed.Cir.2005) (en banc). The patent specification is central to a determination of "the meaning of a claim term as it is used by the inventor in the context of the entirety of his invention[.]" Comark Comm'ms v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998). The patent 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, 415 F.3d at 1315 (quoting Vitrioncs Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention [in the specification] will be, in the end, the correct construction." *Id*. at 1316 (quoting Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998). Although a patent claim may at times contain terms that do not appear in the specification, all "terms and phrases used in the claims must find clear support or antecedent basis in the [specification] so that the meaning of the terms in the claims may be ascertainable by reference to the [specification]." Tandon Corp. v. U.S.I.T.C., 831 F.2d 1017, 1024 (Fed.Cir.1987); *see* Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed.Cir.1997).

IV. Claim Construction

A. "Spike"

The term "spike" appears in the claims recited in the '592, '862 and '866 patents, and throughout the Common Specification. Alaris proposes that the term "spike" be defined as: "An elongated structure having a pointed tip for piercing the seal. The pointed tip may be sharp or slightly rounded." ICU proposes the broader definition, "an upward projection."

In terms of its focus on a pointed tip and the purpose of piercing, the definition proposed by Alaris comports more closely with the ordinary meaning of the word "spike." However, as *Phillips* instructs, in construing a disputed term the court must look to the specification to see whether a different or more specific meaning is given to the term therein. In fact, the specification repeatedly and uniformly describes the spike as a pointed instrument for the purpose of piercing a seal inside the valve. For example, under the section entitled "Background of the Invention," the Common Specification states that "[t]his invention relates to ... [a] two-way valve ... which includes a seal which, upon being compressed by the medical implement, is pierced to open the valve." ' *862 Patent* at 1:18-25. FN1 Under the section entitled "Summary of the Invention," the Common Specification states that "[a] two-way valve is employed utilizing a reusable seal that may be repeatedly pierced by an enclosed, protected, non-metallic spike rather than an exposed needle." *Id*. at 2:40-43. Under the section entitled "Operation," the Common Specification states that the "nose of the medical implement is inserted into the valve ..., pushing the nose against the seal to compress the seal sufficiently to allow the tip of the spike to pierce the seal ..." *Id*. at 14:67-71. Furthermore, all of the figures in the Common Specification that depict a spike portray it as elongated and pointed, and the two figures that show an activated valve show the spike piercing the seal. Nowhere in the Common Specification is piercing described as optional, or is any non-piercing item described as a spike. The Summary of the Invention also states that the "tip [of the spike] may be sharp or slightly rounded." *Id*. at 3:10.

FN1. Except where otherwise noted, all references herein to the Common Specification shall be to the '862 patent.

Nevertheless, ICU contends that the Common Specification discloses a wider array of possible spikes, of which the pointed piercing version is only one, albeit the preferred, embodiment. However, ICU's position finds little support in the Common Specification. ICU argues, for example, that claim 1 of the '866 patent, which recites "a spike having a tip, at least one hole located at or near said tip," describes a spike that is flat on top instead of being pointed. ' *866 Patent* at 15:36-37. But Alaris's definition, which includes the sharp or slightly rounded language from the Common Specification, does allow for the possibility of a hole at the tip of the spike. Moreover, as Alaris notes, spikes featuring an angled tip allowing for a hole at the end while still having an acute tip were well-known at the time the original patents were filed in the early 1990's.

ICU devotes considerable attention to a single instance in the Common Specification in which the preferable distance from the spike tip to the lip of the housing is said to be approximately from 0.525" to 0.1". ' *862 Patent* at 8:28-29. According to ICU, focusing on the longer end of this range, the Common Specification discloses a short, "stubby" spike that would be incapable of piercing or even reaching the seal. This argument fails for three reasons. First, in the context of a patent that repeatedly and consistently describes and portrays the operation of the patented device in terms of the piercing function of the spike, it is not reasonable to expect that even a person skilled in the art would be able to extrapolate from a single reference to a particular dimensional range a spike of a completely different purpose than that otherwise disclosed throughout the patent. Second, even if one were able to extrapolate the short, non-piercing spike from the reference to this dimensional range, it is not at all clear how such a spike would operate or function in the context of the device disclosed. Finally, ICU's extrapolation of a short, non-piercing spike from the 0.525" to 0.1" range conflicts with another statement in the Common Specification, only two sentences later: "The spike tip is thus embedded in the seal cap prior to use or may be approximately 0.025" distal the seal cap when the valve is in the closed position." *Id*. at 8:21-24. As Alaris correctly points out, the only way to reconcile the so-called short spike with the 0.025" distal requirement would be for the seal cap itself to be at the longer end of its range disclosed in the Common Specification, thereby closing the gap

between the spike and the seal and preserving the critical piercing function of the spike. The Common Specification does not disclose an unpointed and/or non-piercing spike.

ICU also draws attention to dependent claim 13 of the '592 patent, which recites, in relevant part, that the end of the spike 'is pointed so that it can pierce [the] seal." ' *592 Patent* at 16:44-45. It argues that because this dependent claim recites the concepts of pointed and piercing, those concepts cannot be part of the proper construction of the term "spike" under the doctrine of claim differentiation. However, these concepts are not the only limitations contained in claim 13, which also requires that the end of the spike "enter into a portion of [the] medical implement when said medical implement is connected to [the] valve." *Id.* at 16:45-47. Because "pointed" and "piercing" are not the only differences distinguishing dependent claim 13, the claim would not be rendered superfluous by including these concepts in the construction of "spike." *See, e.g.,* Kraft Foods Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed.Cir.2000)("[T]hat the claims are presumed to differ in scope does not mean that every limitation must be distinguished from its counterpart in another claim, but only that at least one limitation must differ."). Moreover, dependent claim 13 was only added to the '592 patent in 2001, years after the filing date of the original patents, the issuance of the '866 and '862 patents, and the introduction of the allegedly infringing Alaris products.

The Common Specification clearly and uniformly describes a spike as having a pointed tip and being for the purpose of piercing the seal. Accordingly, the court finds that the proper construction for the term "spike" is "an elongated structure having a pointed tip for piercing the seal, which tip may be sharp or slightly rounded."

B. "Preslit Orifice"/"Seal Being Preslit"

Either or both of the terms "preslit orifice" and "seal being preslit" appear in claims recited in the '509, '592 and '862 patents, although neither term or any variation thereof appears in the Common Specification. Alaris proposes the following definition for these terms: "an opening that is cut in the seal before the seal is axially compressed." ICU in turn proposes the following definition: "an opening made or formed beforehand."

ICU added the "preslit" terms to its patent claims several years after filing the original application from which the Common Specification derives, and as such the word "preslit" does not appear in the Common Specification. However, every claim term must have an antecedent basis in the specification. *See* Tandon, 831 F.2d at 1024; Lockwood, 107 F.3d at 1572 ("[A]ll the limitations must appear in the specification.").

The seal disclosed in ICU's original 1991 application contained no orifice at all until punctured by the spike during use. However, in 1992 ICU added new matter to the Common Specification containing various references to the term "precut". For example, the following references to precutting were added to the Summary of the Invention: "[t]he 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"; and "[t]ypically, the pressure responsive element is a section of the seal having an entryway into a *precut* orifice." ' *862 Patent* at 4:3-6, 4:49-51 (emphasis added). Under the "Detailed Description of the Preferred Embodiment" section, the Common Specification states that "[p]rior to the use of the 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 and reformation of the seal upon piercing by the spike." *Id.* at 14:3-8 (emphasis added). These and other similar references to "precutting" are the only antecedent bases in the specification for "preslit", making clear that the term refers to cutting of the seal prior to axial compression, i.e., before activation of the valve. This meaning also comports with the ordinary meanings of

the component prefix "pre-" and word "slit. The court thus agrees with Judge Stotler's July 2004 Order that ICU's proposed construction, which would encompass any opening in the seal, however made, finds no support in the Common Specification. *See July 2004 Order* at Sec. III, para.para. 13-22.

The court therefore finds that the proper construction for the term "preslit orifice" is "an opening that is cut in the seal before the seal is axially compressed," and that the proper construction for "being preslit" is "having had an opening cut in the seal before the seal was axially compressed."

C. "Compressed State/Position" and "Decompressed State/Position"

The terms "compressed state" or "compressed position" and "decompressed state" or "decompressed position" appear in different forms in all four patents in suit. The Common Specification and the earlier issued '866 and '862 patents use the term "state," whereas the more recently issued '562 and '509 patents contain claims that employ the term "position." Although the parties have agreed that "state" and "position" should be construed consistently with one another, Alaris emphasizes "state" and ICU emphasizes "position" in their respective proposed constructions. The patents also use the terms "uncompressed" and "decompressed," apparently interchangeably, and the court will treat these words as synonymous for purposes of claim construction.

The parties disagree on the precise claim language to be construed. Alaris urges the court to construe the term "into a compressed state" as "from a state (i.e condition) of no axial compression to a state of axial compression" and the term "returning to a decompressed state" as "returning to a state (i.e.condition) of no axial compression." ICU urges the court to construe the term "compressed position" as "the position of the seal when it is under axial compression from a medical implement and opens the valve" and the term "decompressed position" as the position of the seal when it not under axial compression from a medical implement and closes the valve." Because the words "into a" and "returning to a" from the claim language are not technical or obscure in their meaning, the court will follow ICU's lead and restrict its construction to "compressed position/state" and "decompressed position/state."

As noted above, although the parties agree that "state" and "position" should be construed similarly, they disagree over which word better captures the proper manner of viewing the role of axial compression in the claim language. Alaris, in focusing on the word "state," attempts to define compression in terms of the condition of the seal, i.e., either under axial compression or not. ICU, in focusing on the word "position," highlights the actual position of the seal and attempts to incorporate into the definitions the source of the compression, i.e. a medical implement, and the status of the valve, i.e. open or closed. A plain reading of the claim language itself makes clear that there is no need to import the source and valve status limitations into the construction of these terms, because they are already present in the claim language itself. For example, claim 1 of the '862 patent requires a seal that moves distally "into a compressed state upon insertion of the delivery end of the medical implement ... and returning to a decompressed state upon removal of said delivery end from said opening ..." Claim 1 goes on to describe the device in terms of "pushing said delivery end into the cavity to compress said seal sufficiently to allow the fluid to flow from said medical implement through [the] valve to the patient." Id. at 15:38-43 and 15:54-56. Both the concept of the medical implement as the source of 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; indeed, to do so would render certain portions of the claim language superfluous or redundant.

Furthermore, the "into a" and "returning to a" language preceding the respective terms under construction make clear that what is at issue in the use of the terms "compressed state/position" and "decompressed state/position" in the claim language is best understood as referring to the condition of the seal, irrespective of the source or purpose of the compression. As Judge Stotler concluded in the July 2004 Order,

... to move into an axially compressed state the claimed seal must first start in a state in which it is not axially compressed. Logically, the claim language describing the seal as "returning to an axially decompressed state" must then mean that the seal returns to the original state of no compression from which it moved initially."

July 2004 Order at Sec. III, para. 27. Nothing in this claim language discloses or suggests any intermediate condition of relative or partial compression.

Every claim term must have an antecedent basis in the specification. *See* Tandon, 831 F.2d at 1024; *Lockwood,* 107 F.3f at 1572. Here, the antecedent basis in the Common Specification for both "state" and "position" is "state," and the use of the term in the Common Specification confirms that the terms in question are best understood as referring to the condition of the seal. As an example, the Summary of the Invention mirrors the claim language in describing the seal as moving "into a compressed state upon insertion of the tip of the medical implement into the opening and returns to a decompressed state upon removal of the tip." *Id*. at 3:32-35. The Common Specification further states that "[the application of pressure on the syringe ... creates pressure on [the] seal cap," thereby suggesting that the seal was not initially under any pressure at all. *Id*. at 9:1-3. The Common Specification thus supports a straightforward reading of the claim language that suggests that "compressed state/position" and "decompressed state/compression" are best understood in terms of the presence or absence of axial compression.

The proper construction of "compressed state/position" is thus "a state (i.e.condition) of axial compression," and the proper construction of "decompressed state/position" is thus "a state (i .e. condition) of no axial compression."

D. "Fills Essenially Completely"

Alaris's proposed claim construction for this term is "fills almost entirely a portion of the cavity adjacent to the opening to prevent fluid from leaking between the seal and the wall structure." At the Markman hearing in connection with this Order, attorneys for ICU indicated that they were amenable to this definition provided that the words "fills almost entirely" be replaced with "fills all of or almost entirely," and the word "swabbing" be inserted before the word "fluid." To the court's knowledge, no final agreement was reached between the parties. Nevertheless, the court will use the proposed ICU changes to the Alaris definition as a basis for discussing the construction of the claim.

The issue with respect to ICU's first proposed change is easily resolved. The words "essentially completely," while embracing a seal that allows for a slight gap between the seal and the wall so long as leakage is prevented, certainly does not foreclose the possibility of a complete seal. As to ICU's second proposed change, while swabbing fluid is likely to be the main concern in terms of leakage, the court finds no compelling reason why the seal function should not-and in fact would not-also apply to blood, pharmaceuticals, water, or any other fluid matter.

The proper construction of "fills essentially completely" is thus "fills all of or almost entirely a portion of

the cavity adjacent to the opening to prevent fluid from leaking between the seal and the wall structure."

E. "Bearing Against Said Wall Structure Near Said Opening to Seal Said Opening"

Alaris proposes the following definition for this claim term: "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." ICU in turn proposes the following definition: "the seal presses against the wall structure near the opening to prevent leakage of fluid into the valve when the seal is in the decompressed state." At issue between the parties with respect to this term is (1) whether the verb "seal" requires that the opening be fluid tight or just that it be sufficient to prevent leakage and (2) whether this claim term refers only to when the valve is in a decompressed state.

With respect to the first issue, the applicable passage from the Common Specification makes clear that the seal in question is intended to be a fluid tight seal:

The seal in the decompressed state has a section which fills essentially completely a portion of the cavity adjacent to 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. *A fluid tight seal is maintained between the seal section and the wall structure as the seal is moved into the compressed state*. The seal section bears against the wall structure as the seal is moved inward into the cavity by the tip of the medical implement ... *A fluid tight seal is maintained over repeated opening and closing of the valve ...*

Id. At 3:35-57 (emphasis added). The use in two instances of the word "maintained" in describing the fluid tight nature of the seal thus makes clear that the seal described in this claim term is fluid tight at all times.

Although the claim language itself with respect to the second point is somewhat ambiguous, the above quoted passage from the Common Specification also makes clear that this claim term is not limited to the decompressed state. In particular, the assertion that "the seal section bears against the wall structure as the seal is moved inward into the cavity by the tip of the medical implement"-i.e., when the valve is in the compressed state-makes plain that this claim term is applicable to both the compressed and decompressed states.

The proper construction of "bearing against said wall structure near said opening to seal said opening" is thus "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."

IT IS SO ORDERED.

C.D.Cal.,2006.
ICU Medical, Inc. v. Alaris Medical Systems, Inc.