

United States District Court,
N.D. California.

ICU MEDICAL, INC,
Plaintiff.

v.

B. BRAUN MEDICAL, INC,
Defendant.

No. C 01-03202 CRB

Nov. 27, 2002.

Christopher B. Hockett, Bingham McCutchen LLP, San Francisco, CA, Mary T. Huser, Bingham McCutchen LLP, Thomas Eilif Kuhnle, Adrienne L. Taclas, East Palo Alto, CA, Sean Christian Platt, Paul, Hastings, Janofsky & Walker LLP, San Diego, CA, Carolyn Chang, Fenwick & West LLP, Mountain View, CA, Kevin A. Fitzgerald, Las Vegas, NV, Mary A. Fuller, Maxim Integrated Products, Sunnyvale, CA, Susan Vastano Vaughan, Morrison & Foerster, LLP, Palo Alto, CA, for Plaintiff.

Tony Leroy Richardson, Kirkland & Ellis, Los Angeles, CA, Daniel F. Attridge, Edward C. Donovan, Gregory Corbett, John Thomas Battaglia, Justin P.D. Wilcox, Kirkland & Ellis LLP, Washington, DC, for Defendant.

CLAIM CONSTRUCTION ORDER

CHARLES R. BREYER, District Judge.

This suit involves the alleged infringement of United States Patent No. 5,928,204 (the "'204 Patent"). This patent relates to technology for administering or withdrawing fluids from medical patients by means of valves that do not require needles or numerous mechanical parts. Specifically, the '204 Patent discloses a "closed system, needleless valve device" that includes, *inter alia*, a resilient silicone seal that facilitates the smooth flow of fluids from a blunt cannula through a catheter to the patient. Now before the Court is the task of construing certain claim terms over which the parties remain in dispute.

CLAIM CONSTRUCTION

A. Legal Standards for Claim Construction

Patent infringement analysis involves two steps. The first step is to construe the asserted claims, and the second step is to determine whether the accused method or product infringes any of the claims as properly construed. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The first step, construction of the patent claims, is a matter of law and thus the responsibility of the court. *See id.* at 979.

Extrinsic evidence, such as expert and inventor testimony, dictionary definitions, and learned treatises, may be admitted in the court's discretion "for background and education on the technology implicated by the presented claim construction issues." *Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed.Cir.1998). However, "[i]n interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996).

In examining the intrinsic evidence, the court should first look to the words of the claims themselves to define the scope of the patented invention. *See id.* Words in a claim "are generally given their ordinary and customary meaning." *Id.*

Second, the court should review the patent specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id.* "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* The Federal Circuit teaches that "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." *Id.* Drawings included in the patent application have the same effect on claim language as other portions of the specifications. *See Autogiro Co. of America v. United States*, 384 F.2d 391, 398 (Ct.Cl.1967).

The third type of intrinsic evidence that the Court may consider is the prosecution history of the patent, if it is in evidence. *See Vitronics*, 90 F.3d at 1582. The prosecution history contains the entire record of the prosecution of the patent claim before the patent office, including any representations about the scope of the claim or the meaning of certain terms made by the applicant.

Ordinarily, the intrinsic evidence alone will resolve any ambiguity in a disputed term. By relying first on the claim language, the specification, and the prosecution history, a court can protect a patentee's rights while at the same time enabling the public to rely on the public record of the patentee's claim. "In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." *Vitronics*, 90 F.3d at 1583 (citing *Markman*, 52 F.3d at 978-79). For these reasons, "[o]nly if there [is] still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court [] resort[] to extrinsic evidence." *Id.* at 1584; *See Key Pharm.*, 161 F.3d at 716 (noting that extrinsic evidence is appropriate if the intrinsic evidence "does not answer the question").

B. Does Claim 1 Require That The Seal Have Arcuate Segments In Its Uncompressed State?

The central dispute between the parties is whether Claim 1 refers only to a seal in its ordinary uncompressed state or refers as well to a seal in its compressed state. Stated differently, the issue is whether Claim 1 reads on a seal that is arcuate only when compressed. Because the accused device is arcuate when compressed but flat-walled when decompressed, this determination is highly significant to the outcome of the litigation.

Neither the claim language nor the specification is helpful in this regard. Contrary to defendant's assertions, the ordinary meaning of the word "seal" conveys nothing about relative states of compression. While addition of the modifier "resilient" may connote a particular variety of seal that is subject to compression, by itself it does not indicate whether the rest of the claim pertains to the seal in its compressed state, its uncompressed state, or both. The specification describes the seal in both compressed and uncompressed states.

The parties offer conflicting interpretations of the prosecution history. In particular, they differ with respect to the implications of the examiner's initial determination that the claim that later became Claim 1 FN1 was anticipated by the Armao patent (the "'380 Patent," or "Armao"). That patent, which was directed toward shielded hypodermic needles, disclosed at least one exemplary embodiment having arcuate segments only in the compressed state, *see* '380 Patent, Figs. 4-5, and another embodiment having arcuate segments when compressed and arcuate segments housed in a flat-walled sheath when uncompressed. *See id.* Figs. 6-7.

FN1. Prior to issuance, Claim 1 of the '204 Patent was claim 67 of the patent application. For ease of reference, this Order will refer to the claim as Claim 1 both before and after it issued.

Plaintiff argues that the examiner's rejection of Claim 1 signified his determination that the claim was anticipated by-and hence read on-seals having arcuate segments only when compressed. Although plaintiff subsequently distinguished Claim 1 from Armao, it did so by not by amending this aspect of the claim, but rather by adding a limitation directed toward the relative diameters of the various seal segments. Plaintiff therefore argues that the claim as it emerged from patent prosecution covered seals that were arcuate only when compressed as well as seals that were arcuate in both their compressed and uncompressed states.

Defendant objects to this characterization of the prosecution history. According to defendant, the examiner rejected Claim 1 only in light of Figure 6 of the Armao patent-that is, the figure depicting arcuate segments in the seal's uncompressed state. The examiner did *not* find, argues defendant, that Claim 1 was anticipated by the embodiment of Armao having arcuate segments only when compressed. Moreover, the fact that the examiner did not reject the amended Claim 1 as anticipated by other prior art references having arcuate segments only when compressed demonstrates, according to defendant, that the claim is limited to a seal that is arcuate in its uncompressed state.

Examination of the file wrapper lends no support to defendant's characterization of the patent examiner's thought processes. The Court must presume that the examiner gave the term "seal" its broadest reasonable interpretation. *See* Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1347 (Fed.Cir.2001). While it is true that the examiner directed the applicant's attention to Figure 6 of Armao in connection with its statement that Claim 1 was "rejected ... as being clearly anticipated by Armao," *see* Ex. P to Taclas Decl., at ICU-BB 00686, the full extent of the examiner's commentary to this effect was the notation "Note figure 6." This falls short of establishing that the examiner believed that the claim was anticipated *only* by seals having arcuate segments in both compressed and uncompressed states.

Defendant's argument premised on the fact that the examiner did not reject Claim 1 as anticipated by other prior art references is also unconvincing. The file wrapper is understandably silent as to what the examiner did *not* do, and the universe of possible reasons for the examiner's allowance of Claim 1 over the prior art includes many having nothing to do with whether a seal is arcuate in a particular state. *See* Verdegall Bros. v. Union Oil Co., 814 F.2d 628, 631 (Fed.Cir.1987) (pending claims should be allowed unless "each and every element of the claimed invention [is] disclosed" by the prior art). As such, it is impossible to conclude that the claim's allowance signifies the examiner's determination that the claim does not read on seals that are arcuate only when compressed. *See* Inverness Med. Switzerland v. Warner Lambert Co., 309 F.3d 1373, 1382 (Fed.Cir.2002) ("It is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous.").

For these reasons, the Court declines to construe this claim as limited to seals having arcuate segments in their uncompressed state.

C. Other Disputed Terms

1. "A seal for use in selectively opening and closing a fluid pathway through a medical connector"

Plaintiff argues that this phrase, which appears in Claim 1, refers simply to a seal that is deployed in the context of opening and closing a fluid pathway through a medical connector. Defendant argues that any device that opens and closes a fluid pathway functions as a valve, and therefore proposes that "seal" be construed to mean "a seal that must be capable of the additional function of acting as a valve to selectively open and close a fluid pathway through a medical connector."

Whether or not defendant is correct that a device that opens and closes a pathway is necessarily a valve, defendant's proposed construction completely ignores the words "use in." That is, whereas the claim discloses "a seal *for use in* ... opening and closing a fluid pathway," defendant's construction reads the claim to disclose "a seal *for* opening and closing a fluid pathway." As defendant would construe the claim, it would suggest that the seal itself is the device that opens and closes the pathway. However, the abstract and specification plainly teach that the seal is to be incorporated into a valve, not that it is to function as a valve on its own. *See, e.g.*, Abstract ("The valve also *includes* a plastic, resilient silicone seal..."); Col. 2:41-42 ("A two-way valve is employed *utilizing* a reusable seal..."). The specification further reveals that it is only when the seal interacts with other elements of the valve assembly that fluid is able to flow through the pathway. *See* Col. 8:66-9:15.

As such, there is no reason to insert defendant's proposed limitation into Claim 1. The Court will construe this term in the manner proposed by plaintiff.

2. "resilient seal element"

The parties also dispute the meaning of the term "resilient seal element" in Claim 1. According to plaintiff, the term refers to "a sealing portion capable of returning to its original position after being bent, compressed or stretched." Defendant contends that the seal must be "prepared from a resilient material that is flexible, inert, and impermeable to fluid." The question is thus whether the word "resilient" refers to the behavior of the seal or its composition.

Defendant's proposed construction strains the term's ordinary meaning. Unlike a term such as "rubber seal" or "silicone seal," the term "resilient seal," absent more, does not connote a seal element that is made of a particular material. As such, defendant's construction seeks to add a limitation that is neither inherent in the claim language nor suggested by the specification or prosecution history. Indeed, the specification reveals that the invention is not limited to seals of a particular composition. *See* Col. 3:63-63 ("*In one embodiment, ... the seal is made of a material having a hardness of from 30 to 70 Shore units such as, for example, a silicone polymer.*") (emphasis added). "[C]laim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate ... by redefining the term ... in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear *disavowal of claim scope.*" *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002). Here, there is no indication that plaintiff meant to disclaim seals of any particular composition.

Defendant also seeks to read into the term a requirement that the seal element "act[] as a pierceable or pre-

slit valve to selectively open and close a fluid pathway." There is no basis for incorporating this limitation into the term. Since the proper construction of "seal" does not include defendant's proposed limitation that the seal itself must open and close a fluid pathway, defendant's attempt to read a similar limitation into the phrase "resilient seal element" must necessarily fail as well. Accordingly, this term will be construed in the manner proposed by plaintiff.

3. "Top end" and "bottom end"

The next dispute involves the proper construction of the terms "top end" and "bottom end" in the phrase "a resilient seal element having a wall having a top end and a bottom end." Defendant argues that the "top end" is the end that consists of an arcuate segment having a smaller maximum diameter than the arcuate segment at the "bottom end," and that the "bottom end" is the end opposite the "top end." By contrast, plaintiff seeks to construe "top" and "bottom" by reference to the point in the system where the fluid pathway is opened and closed.

Although the end of the seal containing the narrower arcuate segment may, in practice, be the end nearest to where the fluid pathway is opened and closed, the claim language does not require such a result. Claim 1 discloses "a wall having a top end and a bottom end, said wall including ... at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." As written, therefore, the claim identifies the "bottom end" as the end proximate to the segment with the larger maximum diameter, and the "top end" as the end proximate to the segment with the shorter maximum diameter. Nothing about this language requires that the seal be oriented in any particular direction vis-a-vis the point at which the fluid pathway is opened.

Plaintiff further argues that the specification indicates that the "top end" of the seal is always the end nearest where the fluid pathway is opened and closed. In fact, however, the specification reveals only that the "proximal" end of the internal cavity of the valve body is nearest that point, not that the top end of the seal is necessarily near it as well. *See* Col. 2: 52-54. Given the heavy presumption that a claim term takes on its ordinary meaning, *See* *Teleflex*, 299 F.3d at 1327, the Court declines to construe the "top end" of the seal as interchangeable with the "proximal end" of the internal cavity.

Moreover, the prosecution history reveals that the portion of the claim containing the references to the top and bottom ends of the seal wall was added in order to distinguish over Armao's non-tapered seal. As such, the terms "top end" and "bottom end" are more properly defined by reference to the tapering of the seal than in terms of their location vis-a-vis the fluid pathway.

Accordingly, "top end" and "bottom end" will be construed in the manner proposed by defendant.

4. "Maximum diameter"

Finally, the parties disagree as to the meaning of the term "maximum diameter" in the phrase "at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." Whereas plaintiff contends that the term should be given its ordinary meaning, defendant submits that the proper construction is "the diameter to the outside surface of the outwardly extending portion of each discrete, arcuate segment." Plaintiff objects to defendant's proposed construction because it would allegedly read the word "maximum" out of the term. Defendant objects to plaintiff's proposed construction because it allegedly implies that a particular arcuate segment can have multiple maximum diameters.

In fact, plaintiff does not suggest that any one segment can have multiple maximum diameters; rather, plaintiff's position is that a given segment of a resilient seal may compress to a slightly different diameter each time it is compressed, such that "maximum diameter" refers to the largest diameter that the segment will ever achieve when compressed. In this sense, the claim allows for the possibility that on any given compression, the seal might not taper perfectly. Meanwhile, defendant's construction does not ignore the word "maximum." Rather, defendant's proposed construction specifies that the measurement should be taken to the outermost portion of a given segment, and defendant explicitly states that "the 'maximum diameter' refers to the largest straight line passing through the center of the ... 'arcuate segment [].' " Def.'s Br. in Opp., at 33. When the parties' respective positions are properly understood, therefore, they are not inconsistent: Both parties understand the term to refer to the characteristic of the seal whereby the arcuate segments at the bottom end have larger maximum diameters than the segments at the top end.

Accordingly, the term "maximum diameter" will be construed to mean "the longest straight line passing through the center of an arcuate segment."

CONCLUSION

In addition to the construction of disputed terms and phrases supplied above, the Court adopts the agreed construction of the parties as set forth in the "Amended Joint Claim Construction Statement" filed July 3, 2002.

IT IS SO ORDERED.

N.D.Cal.,2002.

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