United States District Court,
N.D. California.

ICU MEDICAL, INC,
Plaintiff.
v.
B. BRAUN MEDICAL, INC,
Defendant.

No. C 01-3202 CRB

March 13, 2003.

MEMORANDUM AND ORDER

BREYER**, J.**

This suit involves the alleged infringement of U.S. Patent No. 5,928,204 ("the '204 patent"). The patent relates to a valve for medical use in administering or withdrawing fluids from a patient. The alleged infringing device is defendant's Ultrasite valve. The Ultrasite valve contains a piston made of flexible material. When the piston is in its uncompressed state, it seals against the housing of the valve preventing fluid flow through the valve. In this state, the wall of the piston is relatively flat. When a syringe or other appropriate medical device is connected to the valve, the piston is compressed causing the piston wall to buckle. The compressed piston no longer completely seals against the valve housing because the portion of the piston that seals against the housing is moved to a location where there are channels in the housing. Thus, when the piston is compressed, fluid can flow through the valve.

Now before the Court is defendant's motion for summary judgment of invalidity of Claims 1-5 of the '204 patent and plaintiff's motion for summary judgment of infringement of the same claims. The Court issued its claim construction order on November 27, 2002. A key finding of the Court's construction was that Claim 1 refers to a seal either in its ordinary uncompressed state or in its compressed state. Independent Claim 1 and dependent Claims 2-5 are directed to a seal having a particularly shaped wall. Specifically, generally arcuate segments are required in the seal wall. In both the prior art asserted for invalidity and the allegedly infringing Ultrasite piston, the walls of the seals are generally flat in their uncompressed state. Thus, it is the compressed state of these devices that is relevant for the present motions.

Independent Claim 1 reads: "A seal for use in selectively opening and closing a fluid pathway through a medical connector comprising a resilient seal element having a wall having a top end and a bottom end, said wall including at least two generally arcuate segments each having an outwardly extending portion, said segments intersecting one another and defining at least one space between where said segments intersect and a line tangential to the outwardly extending portion of both segments, and 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." Claims 2-5 depend from Claim 1.

DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). An issue is "genuine" only if there is sufficient evidence for a reasonable fact finder to find for the non-moving party. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986). A fact is "material" if the fact may affect the outcome of the case. *See* id. at 248. "In considering a motion for summary judgment, the court may not weigh the evidence or make credibility determinations, and is required to draw all inferences in a light most favorable to the non-moving party." Freeman v. Arpaio, 125 F.3d 732, 735 (9th Cir.1997). A principal purpose of the summary judgment procedure is to identify and dispose of factually unsupported claims. *See* Celotex Corp. v. Cattrett, 477 U.S. 317, 323-24 (1986).

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *See* id. at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *See id*. Once the moving party meets this initial burden, the non-moving party must go beyond the pleadings and by its own evidence "set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). The non-moving party must "identify with reasonable particularity the evidence that precludes summary judgment." Keenan v. Allan, 91 F.3d 1275, 1279 (9th Cir.1996) (quoting Richards v. Combined Ins. Co., 55 F.3d 247, 251 (7th Cir.1995), and noting that it is not a district court's task to "scour the record in search of a genuine issue of triable fact"). If the non-moving party fails to make this showing, the moving party is entitled to judgment as a matter of law. *See* Celotex, 477 U.S. at 323.

II. Invalidity

Defendant's invalidity contentions are that Claims 1-5 of the '204 patent are anticipated by U.S. Patent No. 2,847,995 ("Adams") and U.S. Patent No. 4,512,766 ("Vailancourt"), and are therefore invalid under 35 U.S.C. s. 102. Adams discloses a sheath covering a hypodermic needle. Upon usage, the needle pierces through the sheath and the sheath is compressed to expose the needle. Vailancourt discloses a catheter valve containing a valve member that compresses to open the valve. Both Adams and Vailancourt were before the PTO during the examination of the '204 patent. The examiner did not reject Claims 1-5 based on either Adams or Vailancourt.

A. Legal Standard for Invalidity

Issued patents are presumed to be valid and the burden of establishing invalidity rests on the party asserting it. *See* 35 U.S.C. s. 282. Thus, defendant must show invalidity by "clear and convincing evidence." American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed.Cir.1984). Furthermore,

[w]hen no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the

art and whose duty it is to issue only valid patents.... When an attacker simply goes over the same ground travelled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent.

Id. at 1359-1360 (emphasis in original). Since both Vailancourt and Adams were before the examiner during prosecution, the defendant must overcome the additional burden of deference to the PTO.

Claims 1-5 will be found invalid due to anticipation if either Vailancourt or Adams discloses every element found in the claims. *See* In re Schreiber, 128 F.3d 1473, 1477 (Fed.Cir.1997) ("To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently ."). The analysis for anticipation is similar to that of infringement. It is a two-step process. *See* In re Cruciferous Sprout Litig., 301 F.3d 1343, 1346 (Fed.Cir.2002). The first step is claim construction, which is question of law. *Id*. The second step is to compare the properly construed claim to the prior art, which is a question of fact. *Id*. Summary judgment is appropriate only if no reasonable trier of fact could conclude that the patent is valid.

B. The Vailancourt Patent

Plaintiff contends that Vailancourt does not anticipate Claim 1 because Vailancourt does not disclose "generally arcuate segments." The parties agree that "generally arcuate segments" means naturally separated divisions, portions, or sections of the walls that are bent, curved like a bow, or arc-shaped. Revised Joint Claim Construction Statement ["RJCCS"] at 14. Vailancourt discloses a seal identified as a valve member that can be compressed "causing the valve member to buckle or collapse axially against the resilient bias which continuously urges the valve member ... to its extended or closed position." Vailancourt at 5:47-57. Figure 2 of Vailancourt illustrates the compressed state of the valve member. Figure 2 clearly shows that portions of the wall are bent and arc-shaped. However, because the wall is flat in its uncompressed state, the buckling of the valve member wall depicted in Figure 2 is not regular. Furthermore, since the uncompressed walls of Vailancourt contain no natural divisions that would predetermine the locations that the arcuate portions will form, it is reasonable to infer that each time Vailancourt's valve member is compressed, there may be a different number of arcuate portions formed in different locations. Vailancourt's specification provides no evidence to counter this inference. Given that the adopted claim construction requires naturally separated divisions, a reasonable trier of fact, considering the burden required to overcome the presumption of validity, could find that Vailancourt does not disclose "segments," and therefore that is does not anticipate Claim 1 of the '204 patent.

C. The Adams Patent

Plaintiff takes the position that Adams does not anticipate Claim 1 because Adams does not disclose at least one arcuate segment "having a larger maximum diameter than a second [arcuate] segment." The Court construed "maximum diameter" as the longest straight line passing through the center of an arcuate segment. The Court further noted that since a given segment may compress to a slightly different diameter each time it is compressed, "maximum diameter" refers to the largest diameter that the segment will ever achieve when compressed. Claim Construction Order at 7-8. Figures 5-8 of Adams disclose a sheath that is corrugated. The corrugation results in the sheath naturally dividing into arcuate segments upon compression, as depicted in Figure 7. Figure 7 shows one particular state of compression in which some arcuate segments have larger diameters than others. However, Adams does not teach that the state of compression depicted in Figure 7 necessarily causes the arcuate segments to obtain their maximum diameters. As such, a different state of compression could result in arcuate segments having larger diameters than depicted in Figure 7. Thus,

Adams does not provide enough information to determine if a particular arcuate segment would have a larger maximum diameter than another. Moreover, since the corrugations of the sheath in the uncompressed state are uniform, one might expect that the maximum attainable diameters of the corresponding arcuate segments formed in the compressed state would also be uniform. Therefore, a reasonable trier of fact, considering the high invalidity standard, could find that this element is not present in Adams, making summary judgment of invalidity due to Adams inappropriate.

Since a reasonable trier of fact could find that Vailancourt and Adams do not anticipate Claim 1 of the '204 patent, the same is true of dependent Claims 2-5. *See* In re Royka, 490 F.2d 981, 983-84 (Cust. & Pat.App.1947). Accordingly, plaintiff's motion for summary judgment of invalidity will be denied.

III. Infringement

Plaintiff bases its infringement contentions in large part on diagrams contained in defendant's marketing literature and FDA submissions. Pl.'s Motion at 7, illustration 2. The diagrams purportedly show the Ultrasite piston in its compressed state. The depiction shows the piston collapsing into regular folds that appear to be radially symmetric. In contrast, defendant has submitted photographic evidence of an actual Ultrasite valve in its compressed state as well as physical samples of the Ultrasite valve. This evidence reveals that when the piston is compressed, it collapses in an irregular fashion with no radial symmetry.

Infringement analysis requires comparing the "*device* accused of infringing" with the properly construed claims. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (emphasis added). The device that plaintiff accuses of infringement is the Ultrasite valve. Therefore, the Court's infringement analysis will focus on the Ultrasite valve itself and accurate depictions of the Ultrasite valve as it is actually manufactured. FN1

FN1. The diagram relied upon by plaintiff was submitted to the FDA for the purpose of showing the fluid flow path through the Ultrasite valve and not to depict the precise shape of the collapsed piston. Where, as here, the crucial information required for infringement analysis is the shape of the collapsed piston, no better evidence than the actual device exists. It would not be logical to rely on diagrams whose purpose is not to precisely depict the shape of the collapsed piston when the shape of the collapsed piston can be directly observed in the actual device. *See* Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., 63 F.Supp.2d 1064, 1078 (N.D.Cal.1999).

In its motion for summary judgment of infringement, plaintiff does not argue that the Ultrasite seal infringes Claims 1-5 under the doctrine of equivalents. Therefore, only literal infringement will be considered. The Ultrasite valve will literally infringe the claims only if every element of the claims, as construed by the Court, is found to exist in the valve. *See* TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1371 (Fed.Cir.2002). If a reasonable factfinder could conclude that any claim element does not exist in the accused device, summary judgment will be denied.

A. "at least two generally arcuate segments"

While the parties disagree as to whether "segments" must be discrete, they agree that "generally arcuate segments" are naturally separated divisions, portions, or sections of the walls that are bent, curved like a bow, or arc-shaped. RJCCS at 14. Upon compression, the Ultrasite piston forms bent portions that appear generally arc-shaped. Defendant argues that there is no arc-shape because the outermost portion of the folds

is flattened by the housing wall. As plaintiff points out, however, at low states of compression the folds do not contact the housing walls, and the extent of any flattening appears to be small. Accordingly, the folds could be found to be "generally arcuate."

A key issue is whether or not the folds formed in the piston may be considered "segments." As mentioned above, the parties have agreed that a "segment" should be construed as one of the parts into which something naturally separates or is divided; a division, portion, or section. RJCCS at 14. Examination of the nature of the folds of the Ultrasite compressed piston reveals that no folds remain separated from adjacent folds around the entire circumference of the piston, i.e., there are no completely separate segments. While two folds may be clearly separated on some portion of the circumference, those same two folds may join together at another portion of the circumference. A fold may also divide into two folds. Thus, it may not be possible to identify a particular fold as a segment because it is not naturally separated from other folds. Furthermore, the Ultrasite piston does not necessarily produce the same number of folds in the same locations each time it is compressed. A reasonable trier of fact could therefore find that this claim element is lacking in the Ultrasite valve.

In the absence of segments, the remaining elements of Claim 1-"segments intersecting one another ..." and "at least one segment ... having a larger maximum diameter"-also cannot be present. Accordingly, summary judgment of literal infringement of Claim 1 is inappropriate.

B. "at least one segment ... having a larger maximum diameter than a second segment"

As indicated above, this claim element is necessarily lacking in the Ultrasite valve if the piston is found not to contain segments. Furthermore, a reasonable trier of fact could find this claim element lacking insofar as it may not be possible to define the maximum diameter of a particular fold in the compressed Ultrasite piston. Since the folds are not separated from other folds around the entire circumference of the piston, the points that define a diameter are uncertain. Moreover, due to the irregularity with which the piston folds, a reasonable factfinder could find that it is not possible to determine the maximum attainable diameter of any particular fold relative to another. For this additional reason, summary judgment of literal infringement of Claim 1 is inappropriate.

C. Claims 2-5

If a reasonable trier of fact finds that the Ultrasite valve does not literally infringe Claim 1, it must also find that the Ultrasite valve does not literally infringe dependent Claims 2-5. *See* Wahpeton Canvass Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed.Cir.1989) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed."). Since a reasonable trier of fact could find that the Ultrasite valve does not infringe Claim 1, summary judgment of infringement is inappropriate for Claims 2-5 as well.

CONCLUSION

For the reasons stated above, defendant's motion for summary judgment of invalidity and plaintiff's motion for summary judgment of infringement are hereby DENIED.

IT IS SO ORDERED.

N.D.Cal.,2003.

ICU Medical, Inc. v. B. Braun Medical, Inc.

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