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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

CAYENNE MEDICAL, INC.,)
)
 Plaintiff,)
)
 vs.)
)
 MEDSHAPE, INC., a Georgia corporation,)
 KURT JACOBUS, KEN GALL, TIMOTHY)
 NASH, AND JOSHUA RAY,)
)
 Defendants.)
 _____)

No. 2:14-cv-0451-HRH

ORDER

Motion for Partial Summary Judgment

Defendant moves for summary judgment that Claims 6-11 and 13 of the '294 patent are invalid.¹ This motion is opposed.² Oral argument was requested and has been heard.

Facts

Plaintiff Cayenne Medical, Inc. has alleged that defendant MedShape, Inc. is infringing Claims 6-11, 13, and 16-18 of U.S. Patent No. 8,435,294. The '294 patent is directed to methods and devices for attaching soft tissue to bone.

¹Docket No. 133.

²Docket No. 134.

Claim 6 is an independent claim. Claims 7-11 and 13 are dependent on Claim 6 and thus include all claim limitations cited in Claim 6.

Claim 6 is an apparatus claim and reads:

A material fixation system, comprising an implant which is placeable in a space defined by bone, said implant comprising:

- a body having a longitudinal axis, a distal end, and proximal end;
- a first member on said body which is movably expandable outwardly;
- a second member on said body which is disposed axially from said first member and is also movably expandable outwardly, said second member being of a substantially different construction than said first member;
- a distal end of said body comprising a space for receiving soft tissue therethrough, said space being defined by surfaces of said body which are oriented both generally parallel to said longitudinal axis and generally transverse to said longitudinal axis; and
- a deployment device which is movable in a generally axial direction to deploy at least one of said first and second members.^[3]

During the prosecution of the '294 patent, the PTO examiner rejected the claims in view of a patent to Levy and others.⁴ To overcome the rejection, the inventors amended

³'294 Patent, col. 25, lns. 31-49, Exhibit C, Defendant MedShape Inc.'s Motion for Partial Summary Judgment [etc.], Docket No. 133.

⁴Non-Final Rejection (dated July 9, 2012), Exhibit 1, Cayenne Medical, Inc.'s Memorandum in Opposition [etc.], Docket No. 134.

what became Claim 6 to include the phrase “substantially different construction.”⁵ The inventors told the Examiner that

[t]he claim has been amended to now recite that the recited second member is of a substantially different construction than the recited first member.... [B]oth of the expandable members 210 of Levy are shown and disclosed as having a substantially identical construction,^[6] whereas the claim now requires the second recited member to have a substantially different construction than the first recited member.^[7]

After the inventors made this amendment, the Examiner issued a notice of allowance.⁸

On March 19, 2015, defendant petitioned for an inter partes review (IPR) before the Patent Trial and Appeal Board (PTAB) of Claims 6-11, 13, and 16-18 of the '294 patent. During an IPR, validity challenges are limited to anticipation and/or obviousness. Synopsys, Inc. v. Mentor Graphics Corp., 814 F.3d 1309, 1316 (Fed. Cir. 2016). The patent owner may “file a preliminary response to the petition, ... that sets forth reasons why no inter partes review should be instituted...” 35 U.S.C. § 313. “The response ... can include

⁵Amendment, Exhibit 2, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

⁶U.S. Patent No. 6,554,833 at Sheet 2 of 10, Exhibit 3, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

⁷Amendment at 9, Exhibit 2, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

⁸Exhibit 4, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

supporting evidence[.]” but it cannot include “new testimony evidence ... beyond that already of record[.]” 37 C.F.R. § 42.107(a), (c).

On September 14, 2015, the PTAB authorized the institution of an IPR as to Claims 16-18.⁹ The PTAB did not consider the merits of defendant’s arguments that Claims 6-11 and 13 were anticipated and/or obvious in part because the PTAB found that the phrase “substantially different construction” was indefinite.¹⁰ The PTAB explained that

[t]he phrase “substantially different” is highly subjective and, on its face, provides little guidance to one of skill in the art. Sufficient guidance is lacking in the written description of the ‘294 patent as well. The specification of the ‘294 patent does not contain the phrase “substantially different construction” outside of the claims, and neither party has directed us to any disclosure in the written description relevant to determining a standard for measuring the necessary degree of difference which is to be defined as “substantially different.” Likewise, neither party has directed us to any disclosure in the prosecution history that illuminates the relationship between the written description and the “substantially different construction” claim phrase. As noted above, the claim phrase was added in an amendment during prosecution, but the prosecution amendment at issue provides no disclosure to further illuminate the meaning of “substantially different construction.”^[11]

⁹Decision at 2, Exhibit A, Defendant MedShape Inc.’s Motion for Partial Summary Judgment [etc.], Docket No. 133.

¹⁰Id. at 6-10.

¹¹Id. at 9.

Defendant now moves for summary judgment that Claims 6-11 and 13 of the '294 patent are invalid. Defendant argues that the court, like the PTAB, should find the phrase "substantially different construction" indefinite, which would render Claims 6-11 and 13 of the '294 patent invalid.

Discussion

Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

A patent is presumed to be valid and "a defendant bears the burden of proving invalidity by clear and convincing evidence[.]" Shire LLC v. Amneal Pharmaceuticals, LLC, 802 F.3d 1301, 1306 (Fed. Cir. 2015) (citation omitted). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014). "The definiteness standard 'must allow for a modicum of uncertainty' to provide incentives for innovation, but must also require 'clear notice of what is claimed, thereby appris[ing] the public of what is still open to them.'" Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1370 (Fed. Cir. 2014) (quoting Nautilus, 134 S. Ct. at 2128, 2129). "What the statute requires ... 'is that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with

reasonable certainty.” Id. (quoting Nautilus, 134 S. Ct. at 2129). “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.” Id. at 1371. “Although absolute or mathematical precision is not required, it is not enough ... to identify some standard for measuring the scope of the phrase.” Id. at 1370-71 (citation omitted).

“There is no dispute that, under controlling precedent, the ultimate question of indefiniteness is one of law.” Dow Chemical Co. v. Nova Chemicals Corp. (Canada), 809 F.3d 1223, 1224-25 (Fed. Cir. 2015). But, “[i]ndefiniteness ... sometimes requires resolution of underlying questions of fact.” Id. at 1225. “There is likewise no dispute that, under controlling precedent, extrinsic evidence may play a significant role in the indefiniteness analysis.” Id.

Claims 6-11 and 13 of the ‘294 patent each require that the first and second members of the claimed implant have “substantially different construction.” Defendant argues that this phrase is indefinite. Plaintiff argues that it is not.

As an initial matter, the court notes that the phrase “substantially different construction” contains a term of degree. “[T]erms of degree” are not “inherently indefinite. Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.” Interval Licensing, 766 F.3d at 1370. Also, the fact that the parties offered proposed

constructions of this phrase during the Markman proceedings has no bearing on the issue of indefiniteness. “Even if a claim term’s definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.” Halliburton Energy Services, Inc. v. M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008).

Turning then to the question of whether the phrase “substantially different construction” is indefinite, plaintiff contends that defendant’s argument is based almost entirely on the PTAB’s decision. But, plaintiff reminds the court that the PTAB’s decision is not binding on this court, that the PTAB is not authorized to invalidate patent claims on indefiniteness grounds, and that defendant must present clear and convincing evidence to invalidate any of the claims of the ‘294 patent. Plaintiff also points out that it was not allowed to present rebuttal evidence (in the form of expert testimony) in the IPR proceeding, evidence which plaintiff contends demonstrates that the phrase “substantially different construction” can be understood by a person of ordinary skill in the art with reasonable certainty. Plaintiff also points out that the PTAB’s decision is unappealable. See St. Jude Medical, Cardiology Div., Inc. v. Volcano Corp., 749 F.3d 1373, 1375 (Fed. Cir. 2014) (holding that there is no appeal from a denial of a petition for inter partes review).

Although the PTAB’s finding on indefiniteness is not binding on this court, “[d]ecisions of the Patent Trademark Office Trademark Trial and Appeal Board ... are to

be given great weight.” Lahoti v. Vericheck, Inc., 636 F.3d 501, 506 n.1 (9th Cir. 2011). The PTAB’s finding is compelling evidence that the term “substantially different construction” is indefinite.

Plaintiff argues, however, that the ‘294 patent and its prosecution history include sufficient context for a person of ordinary skill in the art to understand the phrase “substantially different construction” with reasonable certainty. First, plaintiff argues that a skilled artisan could look to the claims themselves and find guidance as to the objective boundaries of the phrase. Plaintiff contends that Claims 9 and 12 provide examples of first and second members of substantially different construction. Claim 9 states that the “first member comprises an arm which is pivotable outwardly[.]”¹² Claim 12 states that the “second member comprises a mid-section which may be actuated to a collapsed orientation[.]”¹³ Plaintiff argues that these claims, which correspond to the embodiment depicted in Figure 48,¹⁴ offer a skilled artisan one example of members with “substantially different construction.” Plaintiff supports this argument with the declaration of Kevin L.

¹²’294 Patent at col. 26, lns. 2-3, Exhibit C, Defendant MedShape Inc.’s Motion for Partial Summary Judgment of Invalidity [etc.], Docket No. 133.

¹³Id. at col. 26, lns. 13-15.

¹⁴Id. at col. 22, ln. 66 - col. 23, ln. 14 and Sheet 48 of 50.

Ohashi, one of the named inventors of the '294 patent, and who avers that he has been retained by plaintiff to offer expert opinions in this case.¹⁵ Ohashi avers that

[o]ne of ordinary skill in the art would recognize that these dependent claims provide an example of a device with members having substantially different construction. As described above, these members have unique features and components based on their different shapes and position on the implant.^[16]

First of all, plaintiff's reliance on Ohashi's testimony¹⁷ is misplaced. "It is particularly inappropriate to consider inventor testimony obtained in the context of litigation in assessing validity under section 112, paragraph 2, in view of the absence of probative value of such testimony." Solomon v. Kimberly Clark Corp., 216 F.3d 1372, 1379 (Fed. Cir. 2000). Secondly, one example does not provide any limits as to the possible variations of the device being claimed. Dependent claims 9 and 12, at best, provide some standard for measuring the scope of the phrase "substantially different construction." But some standard is not sufficient. "The Supreme Court explained that a patent does not satisfy the definiteness requirement of § 112 merely because 'a court can ascribe some meaning to a patent's claims.' The claims, when read in light of the specification and the

¹⁵Declaration of Kevin L. Ohashi, PhD, MBA [etc.] at 1, ¶¶ 2 & 5, Exhibit 11, Cayenne Medical, Inc.'s Memorandum in Opposition [etc.], Docket No. 134.

¹⁶Id. at 10, ¶ 41.

¹⁷The court assumes without deciding that the extrinsic evidence offered by plaintiff in opposition to the instant motion is timely.

prosecution history, must provide objective boundaries for those of skill in the art.” Interval Licensing, 766 F.3d at 1371 (quoting Nautilus, 134 S. Ct. at 2130). The ‘294 patent’s specification and prosecution history do not provide objective boundaries as to the scope of the phrase “substantially different construction.” Plaintiff’s arguments to the contrary are unavailing.

Plaintiff argues that the specification for the ‘294 patent discloses numerous examples that a person of ordinary skill in the art could use to practice the invention and create implants with members of “substantially different construction.” Plaintiff again cites to Figure 48, contending that members 482 and 483 in the figure¹⁸ have a “substantially different construction” because they have different shapes and positions on the implant.

Ohashi avers that

[a] person of ordinary skill would be able to ascertain the boundaries of what constitutes components of “substantially identical construction” with what constitutes components of “substantially different construction” by simply comparing the shapes and functions of the two components. When compared to Levy, for example, Figure 48 of the ‘294 Patent would have been understood to have two engagement members with more than a minor difference in shape and structure. One of ordinary skill would have understood that the arms at the proximal end of the implant have a substantially different shape and structure than the collapsible middle portion of the implant, which is attached at either side of the implant and includes an equidistant notch that allows it to buckle outward

¹⁸’294 Patent at Sheet 48 of 50, Exhibit C, Defendant MedShape Inc.’s Motion for Partial Summary Judgment of Invalidity [etc.], Docket No. 133.

upon deployment. Further, one of ordinary skill would note that the first member identified in Figure 48, the pair of center arms, functions to press soft tissue against the bone while the second member, the collapsible middle portion, functions to directly engage the bone. This is significant when compared to Levy, where both sets of splines serve the same purpose and move the same way to do so.^[19]

Plaintiff also contends that Figures 39-47²⁰ depict embodiments that include first and second members with substantially different constructions. Plaintiff contends that these figures show devices that have lateral arms and center arms that are constructed with different shapes, unique extruding tabs, and differences in holes/facets.²¹ Ohashi avers that

a skilled artisan would have understood Figures 39-47 to depict expanding components that are substantially different constructions. The different positions and shapes of tabs and facets on the arms of the device cause the sets of arms to be substantially different constructions and allow the arms to perform their unique functions of either pressing the tendon into the bone or directly engaging the bone through varied forces.^[22]

¹⁹Ohashi Declaration at 12-13, ¶ 50, Exhibit 11, Cayenne Medical, Inc.'s Memorandum in Opposition [etc.], Docket No. 134.

²⁰294 Patent at Sheets 39-47, Exhibit C, Defendant MedShape Inc.'s Motion for Partial Summary Judgment of Invalidity [etc.], Docket No. 133.

²¹Id. at col. 21, lns. 35-47; col. 21, ln. 66- col. 22, ln. 5; col. 22, lns. 35-38; col. 22, lns. 44-45; col. 22, lns. 60-65.

²²Ohashi Declaration at 13, ¶ 51, Exhibit 11, Cayenne Medical, Inc.'s Memorandum in Opposition [etc.], Docket No. 134.

Plaintiff also offers the declaration of Dr. James Dreese in support of its argument.

Dreese, an orthopaedic surgeon, has been retained by plaintiff as an expert in this case.²³

Dreese avers that

Figures 39-47 show devices that include four expanding arms. The arms for each embodiment can be separated into two pairs: a “center arm” pair, and a “lateral arm” pair. The pairs are opposite to one another on the implant, so that adjacent arms alternate between being a center arm and a lateral arm. The center arms are designed to press the tendon into the bone. Thus, they generally include a flatter surface with fewer protrusions to avoid damaging the tendon graft. The lateral arms are designed to directly engage the bone. Thus, they may include additional tabs or tabs with more pronounced shapes. The sets of arms are substantially different constructions based on these differences in their shape and structure.^[24]

Plaintiff also points out that with respect to Figure 39, the specification states that “[t]he flattened or curvilinear shape of the center arms ... is designed to optimize the implant to tendon contact area” while “[t]he lateral arms ... directly contact the bone surface and can have various protrusions or extensions ... that anchor the implant ... into the bone.”²⁵

Plaintiff argues that a skilled artisan reviewing these embodiments would have been able

²³Declaration of James C. Dreese, MD [etc.] at 1, ¶¶ 2 & 6, Exhibit 12, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

²⁴Id. at 7, ¶ 25.

²⁵’294 Patent at col. 21, lns. 37-44, Exhibit C, Defendant MedShape Inc.’s Motion for Partial Summary Judgment of Invalidity [etc.], Docket No. 133.

to use these examples to understand the meaning of the phrase “substantially different construction” with reasonable certainty. In fact, Dreese avers that

when the claim talks about a second member that has a “substantially different construction” from the first member, the claim is referring to two sets of expanding components seen at least in figures 39-47 and 48 of the patent. As discussed above, those two sets of components have different shapes and structures that allow the two sets of components to engage with bone in different ways. I believe that my fellow orthopedic surgeons would appreciate this from reading the specification and claims. Thus, I believe orthopedic surgeons of ordinary skill would understand “substantially different construction” to mean having a “substantially different shape or structure compared to the other member.”^[26]

The problem with plaintiff’s argument is that there is nothing in the ‘294 patent specification that would direct a skilled artisan to focus on these specific figures. And even if a skilled artisan were to focus on these figures, the artisan would still be left to wonder what other possible features described in the ‘294 specification or other embodiments fall within the meaning and scope of the claim limitation. If the skilled artisan could tell by focusing on Figures 39-47 that “different construction” means “different shape or structure”, as plaintiff’s experts vaguely contend, there is still nothing in the figures or anywhere else in the specification that provides any objective boundaries for the term “substantially.” There is nothing in the intrinsic evidence that would allow one skilled in

²⁶Dreese Declaration at 9, ¶ 29, Exhibit 12, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

the art to determine, with reasonable certainty, when the magnitude of change in the “construction” of the first and second member is no longer insubstantial but rather has become “substantially” different.

Plaintiff’s reliance on the prosecution history is also unavailing. As set out above, the inventors amended what became Claim 6 by adding the phrase “substantially different construction” after the Examiner rejected the claims in view of Levy. Ohashi avers that

Levy discloses a device with components that would be understood to have substantially identical construction. Levy states that: “although the first and second sets of splines 710, 740 are shown as having substantially the same length, it will be appreciated that different length splines may be provided.” Cayenne Exhibit 3 at 16:5-7. Thus, we understood that amending the claims to recite merely “different construction” would not properly distinguish Levy. In light of this, we amended the claims to recite “substantially different construction.”^[27]

Plaintiff insists that the inventors’ comments distinguishing Levy, when considered in conjunction with Levy’s disclosure and the ‘294 patent embodiments, provides instructive guidance that allows a skilled artisan to understand the objective limits of the phrase “substantially different construction.” Plaintiff also argues that the fact that the Examiner withdrew his rejection and allowed the claims after receiving the inventors’ response and amendment supports the conclusion that the phrase “substantially different construction” is definite. See Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d 1358, 1367 (Fed. Cir. 2011)

²⁷Ohashi Declaration at 11, ¶ 45, Exhibit 11, Cayenne Medical, Inc.’s Memorandum in Opposition [etc.], Docket No. 134.

("a party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the U.S. Patent and Trademark Office").

Ohashi avers that the inventors added the term "substantially" to the phrase "different construction" in order to distinguish Levy. But this does not provide any guidance to one skilled in art as to the objective boundaries of the phrase. Nothing in the prosecution history informs the skilled artisan, with reasonable certainty, when the construction of the second member becomes sufficiently dissimilar to the construction of the first member to be considered "substantially different."

Conclusion

Defendant's motion for partial summary judgment²⁸ is granted. The phrase "substantially different construction" is indefinite, thereby rendering Claims 6-11 and 13 of the '294 patent invalid.

DATED at Anchorage, Alaska, this 6th day of May, 2016.

/s/ H. Russel Holland
United States District Judge

²⁸Docket No. 133.