

United States District Court,
M.D. Florida, Tampa Division.

THERMO-PLY, INC,
Plaintiff.

v.

The OHIO WILLOW WOOD COMPANY, et al,
Defendants.

No. 8:05-CV-779-T-17MAP

Sept. 29, 2008.

Richard E. Fee, Kathleen M. Wade, Fee & Jeffries, PA, Tampa, FL, for Plaintiff.

Benjamin H. Hill, III, Patrick J. Risch, William Cooper Guerrant, Jr., Hill Ward Henderson, Tampa, FL, F. Michael Speed, James L. Kwak, Jeffrey S. Standley, Michael Stonebrook, Standley Law Group LLP, Dublin, OH, Steven E. Lipman, Darby & Darby, PC, New York, NY, Michael Gay, Foley & Lardner, LLP, Orlando, FL, for Defendants.

ORDER

ELIZABETH A. KOVACHEVICH, District Judge.

This cause is before the Court on:

Dkt. 82 Report and Recommendation

Dkt. 83 Objections

Dkt. 91 Response

Dkt. 94 Reply

The assigned Magistrate Judge conducted a Markman hearing and has issued a Report and Recommendation on claim construction. Defendants object to the Report and Recommendation and request a *de novo* review.

In the Report and Recommendation, the assigned Magistrate Judge recommends that the disputed terms in claims 1 and 17 be construed according to the proposed construction of Plaintiff Thermo-Ply, Inc. The Report and Recommendation includes sections directed to background information, claim construction standards, identification of terms to which the parties have stipulated as to construction, identification of disputed terms, and reasons for the specific recommendations as to the disputed terms.

The Court has independently reviewed the pleadings, including the Transcript of the Markman hearing, the objections, response and reply.

I. Dkt. 83-Objections

A. Background Issues

1. Wires Slipping; Radial Expansion

2. Commercial Embodiment as Limiting to Disclosure of '474 Patent

The Court has reviewed the '474 Patent. (Dkt.83-3). The invention covered by the '474 patent is described with regard to some particular, non-limiting embodiments with reference to the drawings included. The Court notes that the invention is "not limited to the particularly illustrated and above described embodiments, but many modifications and variations are obvious to the person skilled in the art and are within the scope of the following claims." (Dkt.83-3, p. 7).

The statements to which Defendant objects are included in the "Background" section of the Report and Recommendation, which provides context and informs the Court of how the assigned Magistrate Judge reached the proposed recommendations. The "Background" section is intended to be preliminary and descriptive. After consideration, the Court **overrules** Defendant's objections as to background issues.

B. Objection to Proposed Definition for "Prosthetic Liner"

Defendant objects to the proposed definition for "prosthetic liner" as "a soft interface between the structural prosthetic socket and the amputee's residual limb." Defendant proposes that the proper definition is "a non-fabric coated device formed of a cushioning material that is worn on a residual limb to cushion the contact area between the residual limb and a prosthetic socket." Defendant argues that the '617 patent discloses that a prosthetic liner is formed solely from silicone, urethane, a thermoformable gel, or other suitable cushioning material which may be of the thermoplastic or thermosetting type, and is not fabric-coated.

Plaintiff argues that a person of ordinary skill in the art in 1999 would understand that a "cushion" prosthetic liner may or may not have a fabric cover on the outside of the liner. Plaintiff further argues that a construction of the '617 Patent that includes liners with a fabric cover conforms with the language of the Patent itself. Plaintiff argues that the term "prosthetic liner" is used to describe the invention disclosed in the '237 Patent, which expressly claims a fabric-coated gel liner as its invention. Plaintiff further argues that the '617 Patent's specification describes how to make an embodiment of the Patent which includes an instruction on how to make a fabric-coated gel liner. Plaintiff further argues that the prosecution history of the '617 Patent does not bar the recommended definition of "prosthetic liner", as the Lohmann Patent claims a sock, not a prosthetic liner.

After consideration of the meaning a person of ordinary skill in the art at the time of the invention would assign to the term "prosthetic liner," the words of the claims, the remainder of the specification, the

prosecution history, and extrinsic evidence, the Court **overrules** Defendant's objection to the recommended definition of "prosthetic liner."

C. Objection to Proposed Definition for "A Predetermined Material That is Substantially Non-Stretchable in the Axial Direction"

Defendant objects to the recommended definition for the phrase "a predetermined material that is substantially non-stretchable in an axial direction" of "a material (or composite of materials bonded together) chosen in advance that exhibits very little longitudinal stretch when attached to the claimed prosthetic liner and used for its intended purpose." Defendant asks the Court to adopt its interpretation "a preselected material that is incapable of elongation."

1. Construction of "Substantially"

Defendant objects to the recommendation that "substantially non-stretchable" should be construed as "stretches very little," and argues that "substantially non-stretchable" should be construed as "incapable of elongation."

The Magistrate Judge discusses "substantially" as a word of approximation, which is a "descriptive term commonly used in patent claims to avoid a strict numerical boundary to the specified parameter" and which also serves to reasonably describe the subject matter so that its scope would be understood by persons in the field of the invention, and to distinguish the claimed subject matter from the prior art. *Playtex Products, Inc. v. Proctor & Gamble Co.*, 400 F.3d 901, 907 (Fed.Cir.2005); *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed.Cir.2002).

In construing disputed claim terms, the words in a patent claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005). Where the "ordinary meaning" is not readily apparent, the Court may consult the same resources that a person of ordinary skill in the art would: "the words of the claims themselves, the remainder of the specification, the prosecution history and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Timecertain, LLC v. Authentidate Holding Corp.*, 2006 WL 3804830, (M.D.Fla. Dec.22, 2006).

The Magistrate Judge did not err in according "substantially" its ordinary meaning. Further, a person of ordinary skill in the art would understand the term "substantially non-stretchable" to include material having some stretch. After consideration, the Court **overrules** Defendant's objection as to this issue. Accordingly, it is

ORDERED that Defendant's objections are **overruled**. The Report and Recommendation is **adopted** and incorporated herein by reference. The recommended definitions, set forth above, are **adopted**.

DONE and ORDERED.

REPORT AND RECOMMENDATION

MARK A. PIZZO, United States Magistrate Judge.

Thermo-Ply is the assignee and owner of U.S. Patent No. 6,231,617 ("the '617 patent"), a prosthetic liner having longitudinal inelasticity. It claims Ohio Willow Wood (OWW), a competitor, manufactures or distributes prosthetic liners or apparatuses that infringe its '617 patent. Because both sides dispute the meaning of certain claim terms, the parties jointly moved for a *Markman* hearing, a matter the district judge referred to me for a report and recommendation (docs. 62 and 66). *See Markman v. Westview, Inc.*, 571 U.S. 370 (1995). Having the benefit of such a hearing and the parties' supporting briefs (docs. 68 and 69), this report recommends appropriate claim construction for the disputed terms applying the principles outlined in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002); *Markman*; and *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir.2005) (*en banc*).

A. Background

A residual limb, or residuum, expands and contracts throughout the day and over long periods. A prosthetic liner is a sock-like device about fourteen inches in length pulled over the residuum. It cushions the residuum's contact with the prosthetic socket or receptacle which attaches to the prosthetic limb. The art of prosthetic liners has progressed from no liners at all, to a leather cushion or socket, to foam or plastic liners, and finally to ones made of synthetic gels. Fabric or a cloth-like material often covers the cushioning substance; however, some liners omit this thereby avoiding an allergic reaction to the fabric. Until the 1980s, at least in the United States, an amputee needed a third prosthetic device (a suspension sleeve) to ensure appropriate fitting and hinder the milking of the residuum caused by walking. FN1 This sleeve, which is made of a stretchable material, slips over the prosthetic socket and the limb. But by the mid to late 1980s, a second approach developed, one that did not use a suspension sleeve. Instead, the prosthetic liner had a distal attachment to the prosthetic limb. Hence, by 1999, the applicable period here, prosthetic liners came in two varieties: cushioned and distal-attachment types.FN2

FN1. The swinging of the prosthetic creates a piston-type force, much like the milking of a teeter, that grips or suctions the residuum. This action produces fluid build-up or edema in the residuum, a well-known complication to prosthetists.

FN2. At the *Markman* hearing, the parties, through their experts, presented a tutorial of the state of the art as of the '617's application date. Both experts essentially agreed and my findings here comport with their views.

The '617 liner addresses the adverse effects of milking. Thus, its sleeve expands radially to accommodate the residuum's day-to-day changes yet limits the longitudinal (axial) expansion thereby inhibiting milking. Prior efforts in the art such as the Klasson sleeve (the '474 patent) embedded a wire in the cushioning material to reduce milking. However, the wire either slipped from the embedding material or, particularly if multiple wires were used, inhibited radial expansion. Other embodiments of Klasson used an open-mesh fabric laminated onto a silicone prosthetic liner, but that also had disadvantages. Because it had the same shape as the liner and covered only the distal end of the sleeve up to one-third to one-half of the sleeve length (i.e., the extra fabric essentially serves as a supportive cup to the sleeve's distal end), this embodiment limited radial expansion. It also resisted longitudinal stretching to the distal area of the extra fabric but did not inhibit milking above that area. *See* doc. 1 ('617 patent at columns 1 and 2 describing the "background of the invention")

In contrast, the '617 addresses both the need for radial expansion and the inhibition of longitudinal expansion by using a plurality of elongate arms (ribbon-like or strips of material). These strips, which are equidistantly and circumferentially spaced apart, extend from or across a distal attachment in a distal-to-proximal direction. This provides a prosthetic liner having a structure that effectively harnesses substantially the entire surface area of the liner to support the swing weight of the prosthesis during walking thereby greatly inhibiting milking. *Id.* at column 3.

B. Claim Construction Standards

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.' " *Phillips*, 415 F.3d at 1312 (citations to quoted material omitted). The words of a claim are generally to be given their ordinary and customary meaning using the perspective of someone of ordinary skill in the applicable art. *Phillips*, 415 F.3d 1312-1313. With this same perspective, a court tasked with resolving a claims construction dispute studies the claims and specification, the patent's prosecution history, and, if necessary consults with outside relevant sources. But not all these sources stand on equal footing. The last two are less reliable and persuasive than the first. While the patent's prosecution history can potentially reveal how the PTO and the inventor understood the patent, their dialogue often lacks clarity, particularly when compared to the specification. *Phillips*, 415 F.3d at 1317. Therefore, a patent's prosecution history is less useful than the specification. *Id.* Instead, the file wrapper primarily serves to exclude any interpretation the patentee disclaimed during prosecution. *Id.* citing *Chimie v. PPG, Indus., Inc.*, 402 F.3d 1371, 1384 (Fed.Cir.2005); *see also Festo*, supra, 535 U.S. at 733-737 (prosecution history estoppel requires that the claims of a patent be interpreted by reference to those that have been cancelled or rejected during the proceedings before the PTO). And while the court can in its discretion look to extrinsic evidence, like expert and inventor testimony, dictionaries, and learned treatises, such evidence is less persuasive and reliable than the intrinsic record. *Phillips*, 415 F.3d at 1317-1318 (citing reasons why).

C. Discussion

In an effort to narrow the justiciable issues, I directed the parties to produce a joint claims construction statement (docs.72), a process that yielded some agreement and narrowed those terms at issue (*see* joint claims construction chart at doc. 76). At the *Markman* hearing, the parties further refined their joint claims chart by stipulating that claim 1's language, "circumferentially spaced apart with respect to one another," needed no construction. Both agreed and disputed constructions are noted below.

1. agreed construction

The parties agree to the following construction of these terms in claims 1 and 17.

Claim 1 (terms at issue in italics)	Agreed Construction
1. A prosthetic apparatus, comprising:	
a <i>distal attachment plate</i> secured to said prosthetic line at said end thereof;	"A structure affixed to the distal (or bottom) end of a prosthetic liner that provides mechanical connection between the liner-covered residual limb and the prosthesis."
said <i>elongate arms</i>	"A structure substantially longer than its width"
Claim 17 (terms at issue in italics)	Agreed Construction

17. A prosthetic liner of generally tubular shape having a rounded, closed distal end and an open proximal end for receiving a residuum, comprising: ^[FN3]

FN3. As further explained in the next section, the parties dispute the meaning of *prosthetic liner*, a term that is used in claim one. The parties, however, agree that its meaning in claims one and seventeen should be the same.

a plurality of elongate arms *extending continuously from said closed distal end* in a distal-to-proximal direction;

"Positioned in an uninterrupted manner from the bottom portion of the liner in an upward direction."

2. *disputed terms*

a. prosthetic liner

The parties dispute the meaning of *prosthetic liner* in claims in claims 1 and 17. Claim 1 claims a prosthetic apparatus comprising: "a *prosthetic liner* of generally tubular shape having a rounded, closed distal end and an open proximal end for receiving a residuum." *See* doc. at col. 9, line 24. Claim 17 says the same but adds, "comprising: said *prosthetic liner* formed of cushioning material selected from the group consisting of silicone, urethane, and thermoformable gels." *Id.* at col. 10, lines 48-50. Although both sides agree *prosthetic liner* should be read harmoniously, OWW contends Thermo-Ply surrendered fabric-coated liners during '617's prosecution; consequently, the term should be limited to a "non-fabric coated device." Thermo-Ply, on the other hand, denies this and urges *prosthetic liner* either needs no interpretation or deserves a broader scope: "a soft interface." As such, the claim would include fabric-covered liners and non-fabric varieties. After reviewing the file wrapper, I do not find OWW's argument persuasive.

The '617's prosecution history is fairly brief. The Patent and Trademark Office (PTO) examiner initially rejected the application, and claims 16 and 17 were specifically rejected under 35 U.S.C. s. 102(b) as being anticipated by U.S. Patent No. 5,728,167 ("Lohmann"). In short, Lohman describes a "sock" constructed of fabric to be worn on an amputee's residuum to inhibit movement whilst inserted into a prosthetic socket. In response to the initial rejection of the '617 application, the patentee requested reconsideration and withdrawal of the rejection of claims 16 and 17. The patentee distinguished the '617 patent from Lohmann, in part, on grounds that "Lohman [sic] discloses a prosthetic sock, made of fabric" whereas "[a]pplicant discloses a prosthetic liner, made of silicone, urethane, or a similar thermoformable gel." *See* OWW's exhibit B at p. 55. Accepting the amendment (*id.* at p. 63), the PTO issued the patent with much of the language from the initial draft of claims 16 and 17 preserved. Therefore, if the patentee surrendered anything, he surrendered those prosthetic liners constructed of fabric and therefore anticipated by Lohmann, but not those made of "silicone, urethane, or a similar thermoformable gel" coated with fabric. And someone of ordinary skill in the applicable art would read *prosthetic liner* to include those made of such substances that were either fabric-covered or without fabric. Hence, Thermo-Ply's proposed construction- *a soft-interface between the structural prosthetic socket and the amputee's residual limb*-adequately defines the term in keeping with the prosecution history and the perspective of a skilled prosthetist.

b. substantially non-stretchable

Both sides also dispute claim 1's language pertaining to the elongate arms designed to inhibit milking,

namely: "said elongate arms being formed of a *predetermined material that is substantially non-stretchable in axial direction.*" Their disagreement can be paired down to the use of the adverb, *substantially*. OWW, citing to repeated uses in the specification to "non-stretchable," "non-stretchability," and "not extensible or contractible in an axial direction," asserts the disputed term means *incapable*, as in "*incapable of elongation.*" See doc. 69 at pp. 15-16. Thermo-Ply assigns the customary definition: *very little*, as in "the predetermined material stretches *very little.*" Again, OWW's arguments are not particularly persuasive.

"The term 'substantial' is a meaningful modifier implying 'approximate,' rather than 'perfect.' " *Playtex Products, Inc. v. Proctor & Gamble Co.*, 400 F.3d 901,907 (Fed.Cir.2005) quoting *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1368 (Fed.Cir.2004). Like other words of approximation ("generally," "about," "almost," and "essentially"), they are "descriptive terms 'commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.'" *Id.* See also *LANDIS ON MECHANICS PAT. CLAIM DRAFTING*, s. 3:16. They also serve to reasonably describe the subject matter so that its scope would be understood by persons in the field of the invention, and to distinguish the claimed subject matter from the prior art. *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed.Cir.2002). In other words, the question is not whether the word, *substantially*, has a fixed meaning as applied to *non-stretchable* when referencing the "predetermined material" constituting the "elongate arms." Instead, it is "how the phrase would be understood by persons experienced in this field of [prosthetics], upon a reading of the patent documents." From this vantage, nothing in the specification nor the prosecution history suggests, as OWW purports, that *substantially non-stretchable* means *incapable of elongation*. See *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1329 (Fed.Cir.2006) (a "circular cross-section" "within the impact portion" of the frame does not mean the insert in this claim has to be "perfectly" circular); *Playtex, supra* at p. 907 ("The plain language of claim 1, *i.e.*, 'substantially flattened' [surface] requires neither a perfectly flat surface, nor one that is flat within manufacturing tolerance").

That said, the issue then becomes whether Thermo-Ply's proposed construction offers more understandable, yet equally accurate, terminology: "a material (or composite of materials bonded together) chosen in advance that exhibits very little longitudinal stretch to the claimed prosthetic liner and used for its intended purpose." This is as opposed to claim 1's current language: "being formed of a predetermined material that is substantially nonstretchable in an axial direction." See doc. 76 (Joint Claims Chart). Given that *Markman* rulings serve as the basis of the jury instructions should the case go to trial, Thermo-Ply offers equally accurate but more understandable language. See *AFG Industries, Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1247 (Fed.Cir.2001) (it is critical for trial courts to set forth an express construction of the material terms in dispute, in part because the claim construction becomes the basis of the jury instructions).

D. Conclusion

For the reasons, stated I recommend the disputed terms in claims 1 and 17 be construed as recommended above.

DONE AND ORDERED at Tampa, Florida on July 24, 2007.

M.D.Fla.,2008.

Thermo-Ply, Inc. Ohio Willow Wood Co.

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