

United States District Court,
S.D. Florida.

WHITE WATER INVESTMENTS, INC,
Plaintiff.

v.

ETHICON ENDO-SURGERY, INC,
Defendant.

No. 04-81178-CIV

Sept. 1, 2005.

John Scarola, Searcy Denney Scarola Barnhart & Shipley, West Palm Beach, FL, Joseph S. Beckman, The Intellect Law Group, Palm City, FL, for Plaintiff.

David R. Bennett, Harry J. Roper, Timothy J. Barron, Roper & Quigg, George S. Bosy, Raymond N. Nimrod, Jenner & Block, Chicago, IL, Eric Christu, Ruden McClosky Smith Schuster & Russell, P.A., West Palm Beach, FL, Rudolph F. Aragon, White & Case, Miami, FL, for Defendant.

ORDER CONSTRUING U.S. PATENT NO. 6,214,045

DONALD M. MIDDLEBROOKS, District Judge.

THIS CAUSE comes before the court upon the Plaintiff's Motion for a Markman Hearing [**DE # 33**] and the parties' filings of "Markman" Briefs, proposing constructions of the patent at issue [**DE # 130, 136**]. *See* Markman v. Westview Instruments, Inc. 52 F.3d 967 (Fed.Cir.1995) (*en banc*), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The Court has reviewed the Record and is fully advised in the premises.

Plaintiff White Water Investments, Inc. (White Water) accuses Defendant Ethicon Endo-Surgery, Inc. (EES) of infringing upon claims of U.S. Patent No. 6,214,045 ("the '045 patent") by manufacture and sale of two biopsy site identifier products: MammoMark and CorMark. The patent concerns a resorbable breast implant which is sized and shaped to replace excised tissue, support the surrounding tissue after implementation, and permit the in-growth of fibrous replacement tissue. *See* U.S. patent No. 6,214,045 (issued April 10,2001).

White Water specifically alleges infringement of the following claims in the ' 045 patent: independent claim 9 and dependent claims 10, 11, and 16; independent claim 17 and dependent claims 18, 19, and 20; and independent claim 22 and dependent claims 23 and 24. The claim language is as follows:

Claim 9:

A method for replacing excised human breast tissue with an implant comprising the steps of:

forming a cavity having surrounding tissue within a breast;

forming the implant entirely of resorbable material and sizing the implant to occupy the cavity; and

implanting the implant in the cavity, the implant supporting the surrounding tissue and allowing for in-growth of fibrous tissue into and replacing the resorbable material wherein the resorbable material is elastically compressible, and the step of implanting includes the step of compressing the resorbable material.

'045 patent, col. 5, 11.17-28.

Claim 10:

The method of claim 9, further comprising the step of introducing into the implant at least one of a medicinal, therapeutic or diagnostic substance.

'045 patent, col. 5, 11.29-31.

Claim 11:

The method of claim 9, wherein the at least one substance is selected from the group consisting of radiation material, antibiotics, chemotherapies, cancer therapies, hemostatic material, hormone therapies, and radiographic markers.

'045 patent, col. 5, 11.32-36.

Claim 16:

The method of claim 9, wherein the step of implanting the implant in the cavity comprises expanding the implant within the cavity.

'045 patent, col. 6, 11.6-8.

Claim 17:

A breast implant comprising a self-expanding matrix of biocompatible material, the expanded matrix having a porous structure for supporting surrounding tissue of a breast and configured to provide a framework for the in-growth of fibrous tissue into the matrix.

'045 patent, col. 6, 11.9-13.

Claim 18:

The breast implant of claim 17, wherein the biocompatible material is resorbable.

'045 patent, col. 6, 11.14-15.

Claim 19:

The breast implant of claim 17, wherein the self-expanding matrix comprises a foam.

'045 patent, col. 6, 11.16-17.

Claim 20:

The breast implant of claim 17, wherein the self-expanding matrix comprises a resilient framework for implantation by compressing the matrix into a smaller volume, the matrix expanding resiliency within the breast.

'045 patent, col. 6, 11.18-21.

Claim 22:

A method for replacing excised human breast tissue with an implant comprising the steps of:
forming a cavity having surrounding tissue within a breast;

forming the implant entirely of resorbable material and implanting the implant in the cavity, the implant supporting the surrounding tissue and allowing for in-growth of fibrous tissue into and replacing the resorbable material, wherein the resorbable material is formed from a self-expanding foam and the step of implanting is performed by injection of the self-expanding foam.

'045 patent, col. 6, 11.25-36.

Claim 23:

The method of claim 22, further comprising the step of introducing into the implant at least one of a medicinal, therapeutic or diagnostic substance.

'045 patent, col. 6, 11.37-39.

Claim 24:

The method of claim 23, wherein the at least one substance is selected from the group consisting of radiation material, antibiotics, chemotherapies, cancer therapies, hemostatic material, hormone therapies, and radiographic markers.

'045 patent, col. 6, 11.40-44.

LEGAL BACKGROUND

Claim construction analysis begins by looking to the words of the claims. *Teleflex, Inc. v. Ficosa North Am. Corp.*, 299 F.3d 1313, 1324 (Fed.Cir.2002); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). The words of the claims 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 at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed.Cir.2005) (*en banc*); *Vitronics*, 90 F.3d at 1582; *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed.Cir.2004). The Court assumes that a person of ordinary skill would read the terms in the context of the entire patent. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998). For example, if a dependent claim adds a limitation, there is a presumption that the limitation is not included in the independent claim. *Phillips*, 415 F.3d at 1314-1315 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed.Cir.2004)). Furthermore, the Court assumes the patent uses terms consistently throughout. *Phillips*, 415 F.3d at 1314.

The Court must also read claims in light of the specification. "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." *Vitronics*, 90 F.3d at 1582. If the specification indicates that the patentee has given a term a special definition different from its ordinary definition, the patentee's definition governs. *Phillips*, 415 F.3d at 1316. Similarly, if the specification contains an intentional disclaimer of claim scope, the inventor's definition of claim scope governs. *Id.*

In addition to the claims themselves and the specification, the Court should also look to the patent's prosecution history for further evidence of what the patentee understood the claims to mean. *Id.* at 1317. The Federal Circuit warns that the patent prosecution might be ambiguous, and thus less relevant to claim construction. *See Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380-82 (Fed.Cir.2002). The patent prosecution particularly aids construction by indicating whether the inventor limited the claim scope or disclaimed any particular interpretations. *Vitronics*, 90 F.3d at 1582-83. However, in order to conclude that a patentee narrowed his claim, the disclaimer must have been with "reasonable clarity and deliberateness." *Superguide Corp. v. Directv Enterprises, Inc.*, 358 F.3d 870, 875 (Fed.Cir.2004)

(quoting *N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294 (Fed.Cir.2000)).

Finally, the Court may look to extrinsic evidence, such as dictionaries, treatises, or expert testimony. Phillips, 415 F.3d at 1317. However, extrinsic evidence is considered less significant than the intrinsic evidence. *Id.* A Court should not rely on extrinsic evidence if intrinsic evidence can resolve an ambiguity. Vitronics, 90 F.3d at 1583. Furthermore, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court." Phillips, 415 F.3d at 1318.

ANALYSIS

The analysis will proceed by construing each debated term in each claim at issue. Many of the relevant claims use the same terms, particularly claims 9 and 22. The Court presumes that identical terms are used consistently throughout the patent. Phillips, 415 F.3d at 1314. Consequently, construction of terms from one claim will not be re-explained for purposes of a later claim unless there is evidence to indicate the term has a different meaning in the later claim.

Claim 9

"A METHOD FOR REPLACING EXCISED HUMAN BREAST TISSUE WITH AN IMPLANT"

There is no real dispute between the parties as to the meaning of "implant." "Implant" means "something implanted in tissue." This construction is consistent with the specification's statement that the invention replaces excised tissue by "implanting an implant." '045 patent, col. 1, 11. 66-67.

"FORMING A CAVITY HAVING SURROUNDING TISSUE WITHIN A BREAST"

The Plaintiff defines "cavity" as an "unfilled space within a mass; especially a hollowed out space." Pl. Mot. Summ. J. at 4. Although Plaintiff takes this definition from the Merriam-Webster Dictionary, which is a source of *extrinsic* evidence, this definition is consistent with the intrinsic evidence as well. The specification indicates that the invention is meant for replacing tissue after a biopsy. '045 patent, col. 1, 11. 15-55. The defendant does not dispute this definition.

The Plaintiff defines "surrounding tissue" as "human breast tissue that surrounds a cavity in the breast." Pl. Mot. Summ. J. at 4. The Defendant does not challenge this definition either, and the definition is consistent with the intrinsic evidence.

"FORMING THE IMPLANT ENTIRELY OF RESORBABLE MATERIAL"

There is no dispute that "resorbable" means "to break down and assimilate; to undergo absorption." The dispute here regards what exactly must be "entirely resorbable." The Defendant argues that the limitation requires *everything* that is implanted into the body be resorbable. Specifically, Defendant argues that its MammoMark, which is made mostly of resorbable collagen but contains a nonresorbable titanium clip, is not an "implant [made] entirely of resorbable material."

The Plaintiff, however, argues that the patent explicitly contemplates having a resorbable "implant" which contains a nonresorbable "substance." The Plaintiff points to dependent claim 10, which adds to claim 9 the possibility of "introducing into the implant at least one of a medicinal, therapeutic, or diagnostic *substance*." (emphasis added). Claim 11 further describes possible "substances" as including "radiographic markers."

Thus, the plain language of the claim indicates a difference between the "implant"-which must be made "entirely of resorbable material"-and a "substance" introduced into that implant. The patent specification also lists "metallic material" as a potential substance to instill into the implant. '045 patent, col. 4, 1.36. Thus, the patent specification also contemplates including a nonresorbable "substance" in the "implant."

The Defendant argues that, during the patent prosecution, the '045 patentee added the word "entirely" to the description of "implant" in order to distinguish from an earlier patent (the "Naficy" patent), which apparently had a non-absorbable inner core. EES argues that, in doing so, Plaintiff "disclaimed an implant that was not formed 'entirely of resorbable material.'" Def. Mot. Summ. J. at 6. In support of this argument, the Defendant offers testimony from its own expert, Dr. Ian Grady, and deposition testimony of '045 co-inventors Dr. John Corbitt and Ms. Lori Loretta Anthony.

However, even if the White Water added the word "entirely" to distinguish its application from the Naficy patent, this act alone is not sufficiently clear to disclaim the plain meaning interpretation of the patent claims. The only evidence the Defendant presents from the patent prosecution itself is a form showing the insertion of the word "entirely." The Defendant supplements this evidence with extrinsic evidence-testimony, taken in preparation for this litigation-indicating that "entirely" was inserted to distinguish from the Naficy patent. Even accepting Defendant's assertion that "entirely" was inserted to distinguish the '045 patent application from the Naficy patent, none of the Defendant's evidence demonstrates the patentee's unambiguous intent to disclaim the interpretation indicated by the plain language. Even if the patentee was attempting to distinguish from an implant with a "non-absorbable inner core," this action does not explicitly disclaim a distinction between a resorbable implant with a nonresorbable substance added to it. Subsequently, the term "entirely resorbable" should be construed to apply to the "implant" but *not* to a "medicinal, therapeutic, or diagnostic substance" introduced into the implant.

"SIZING THE IMPLANT TO OCCUPY THE CAVITY"

The Plaintiff defines "sizing" as "to make a particular size; bring to a suitable size," and defines "occupy" as "to take up (a place or extent in space)." Pl. Mot. Summ. J. at 4 (citing Merriam-Webster's Dictionary). The Defendant responds that this entire phrase should mean "to form the implant to the proper size and shape to fill up the breast cavity." Def. Mem. Opp'n. Summ. J. at 11. Under the Plaintiff's definition, an implant would merely need to be purposefully made small enough to fit into a cavity, but not necessarily fill up the entire cavity. The Defendant's construction would require the implant to fill the entire cavity.

The intrinsic evidence, particularly the purpose of the invention described in the specification, indicates that "fill up" is the proper definition of "occupy." The specification suggests that one purpose of the invention is to replace small amounts of excised tissue in order to prevent dimpling. '045 patent, col. 1, 11.25-26, 44-46. Both the specification and the claims themselves state that the implant is supposed to "support[] the surrounding tissue." '045 patent, col. 2, 1.2, col. 5, 11.23-24. In order to provide such support and prevent dimples in the overlying skin, the implant would have to fill up the entire cavity. Otherwise, space would remain in the cavity and some of the surrounding tissue would receive no support. Consequently "sizing the implant to occupy the cavity" should mean "making the implant a particular size in order to fill the cavity."

"SUPPORTING THE SURROUNDING TISSUE"

The parties appear to agree on the definition of "supporting the surrounding tissue." The Defendant defines it as "to hold up and bear the weight of the tissue surrounding the entire cavity." Def. Mem. Opp'n. Summ. J. at 13 (citing *Webster's Third New Int'l Dictionary Unabridged* (2002)). The Plaintiff defines "support" as "to

bear the weight of, especially from below" or "to hold in position so as to keep from falling, sinking, or slipping." Pl. Mot. Summ. J. at 6 (citing *Stedman's Medical Dictionary*). The Plaintiff further defines "the surrounding tissue" as the "tissue that surrounds a cavity in the breast." Pl. Mot. Summ. J. at 4. Defining "support" to mean "bear the weight of" and defining "surrounding tissue" as "the tissue surrounding the entire cavity in the breast" is consistent with the invention's purpose, indicated in the specification, to prevent dimpling in the overlying skin. Therefore, the phrase should mean "bearing the weight of the tissue surrounding the entire cavity."

"ALLOWING FOR IN-GROWTH OF FIBROUS TISSUE INTO AND REPLACING THE RESORBABLE MATERIAL"

There is also no dispute over this phrase's definition. The phrase means "allowing for the development or proliferation of connective tissue elements and fibers inward into the resorbable material."

"ELASTICALLY COMPRESSIBLE"

The Plaintiff defines "elastically compressible" as "capable of recovering size and shape after deformation; capable of ready change or easy expansion or contraction; capable of being compressed ." Pl. Mot. Summ. J. at 4 (citing *Merriam-Webster's Dictionary*). The Defendant says it means a substance that "after compression forces are removed *springs back* to its pre-compression shape and size." Def. Mem. Opp'n. Summ. J., at 15 (emphasis added). Thus, the parties agree that the term means "capable of recovering size and shape."

The dispute seems to be over *when* the recovery occurs. While Plaintiff's construction would allow for recovery of size and shape at any time, Defendant's definition implies that the recovery must occur immediately and spontaneously after compression forces are removed. Defendant bases its construction on a description of a preferred embodiment in the specification, which states that the implant is "compressed as to fit within a cannula for insertion" and after insertion "expands to fill the implant site space." '045 patent, col. 3, 11.34-35, 39.

However, nothing in the patent claims or specification suggests that the expansion must occur immediately after implantation. The quoted preferred embodiment suggests that the material should expand at some point, but does not require that it must "spring back" immediately after leaving the cannula. The Federal Circuit has suggested that the scope of a patent is determined by "giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.' " Phillips, 415 F.3d at 1317 (quoting *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed.Cir.2004)). Although the Defendant's construction is not a wholly unreasonable interpretation of the phrase "elastically compressible," the Plaintiff's broader construction is the proper one in absence of narrowing language in the specification. Thus, "elastically compressible" should be construed as "capable of recovering size and shape after deformation after implantation."

"THE STEP OF IMPLANTING INCLUDES THE STEP OF COMPRESSING THE RESORBABLE MATERIAL"

The dispute over this term also involves timing. Both parties apparently agree that this term describes compressing the implant in order to fit it into a cannula for insertion. Plaintiff's construction seems to allow for compression at any time before insertion, while the Defendant insists that the compression occur at the actual time of implantation.

The plain meaning of the phrase favors the Defendant. The phrase specifically states that the step of implanting *includes* the step of compressing; the word "includes" suggests that the compressing occurs *during* the step of implanting. If the patent intended the Plaintiff's meaning, the phrase would more clearly have read "the resorbable material is compressed before implanting" or "is compressed in preparation for implanting." Nothing in the specification or other claims suggests a construction other than the plain meaning. Therefore, the phrase should be defined as "the implant is compressed during or immediately before implantation."

Claim 10

"DIAGNOSTIC SUBSTANCE"

There is no apparent dispute over this term. "Diagnostic" means "used in diagnosis." "Diagnosis" is "the determination of the nature of a disease, injury, or congenital defect." *See* Pl. Mot. Summ. J. at 5. The specification lists a number of examples, including "x-ray opaque or metallic material for identification of an area." '045 patent, col. 4, 11.36-37. However, the patent clearly indicates that its list is non-exhaustive.

Claim 11

"RADIOGRAPHIC MARKERS"

There is no dispute over this term. A "Radiographic marker" is "material detectable by radiation, other than visible light." Again, the patent gives "x-ray opaque or metallic material for identification of an area" as non-limiting examples. '045 patent, col. 4, 11.36-37.

Claim 16

There are no terms specific to this claim which need construction.

Claim 17

"A BREAST IMPLANT"

The Defendant argues that a "breast implant" is necessarily "formed to prevent cosmetic deformity that may arise from breast capsular or cavity contraction." Def. Mem. Opp'n. Summ. J. at 18. Plaintiff offers no additional specific construction of "breast implant."

The Defendant does not sufficiently support its proposed construction. As described above, the parties agree that "implant" means "something implanted in tissue." Thus the ordinary meaning of "breast implant" would be "something implanted into breast tissue." While "preventing cosmetic deformity" may be the overall purpose of the '045 patent's invention, the patented invention acquires this character through the other claim terms. "Breast implant" is more properly construed as a general term meaning "something implanted into breast tissue."

"SELF-EXPANDING"

The parties agree that "self-expanding" means "to become greater in size, volume, quantity or scope by itself." The Plaintiff argues that the ordinary meaning of "self-expanding" in the medical community

includes devices that expand when they come in contact with fluid in a body cavity. The Plaintiff offers testimony by its expert witness Dr. Edward Dauer to support its construction. The Defendant argues that during the patent prosecution, the '045 patentees narrowed the scope of "self-expanding" to exclude expanding by absorbing fluid *in situ* (within the human body). The Plaintiff counters that the Defendant's evidence is insufficient to demonstrate a clear and deliberate intent to narrow the claim's scope.

The Defendant cites the Patent Applicant October 19, 2000, response to the Patent Examiner's July 19, 2000, Office Action as a disclaimer of self-expansion by fluid. The Patent Examiner had rejected a claim of the '045 patent application because the previous "Wallace" patent included a hydrogel that "has the ability to be extruded through a syringe thus being able to conform to holes, pockets, divots which give it a *self-expanding capability*." App. Def. Mot. Summ. J., Tab 13, at EES 094288 (emphasis added)). The '045 Patent Applicant replied:

Wallace discloses that the hydrogel has "flowability" sufficient that the material can be injected through a syringe. In addition, the hydrogel can be used in a partially-hydrated form and allowed to *swell in situ by absorbing water* from a moist environment. Wallace et al. *does not disclose or suggest, however, that the hydrogel is self-expanding*.

Id. at EES 094302-3 (emphasis added).

As stated above, in order to find that a patentee limited or narrowed the definition of a claim term from its ordinary meaning during the patent prosecution, there must be a clear, unambiguous, and deliberate statement to that effect. *Superguide Corp. v. Directv Enterprises, Inc.*, 358 F.3d 870, 875 (Fed.Cir.2004). Plaintiff argues that the Patent Applicant response was only clarifying that "flowability" is not properly defined as "self-expanding," and that self-expansion is not limited to water absorption. The Plaintiff's explanation creates too much doubt about the Patent Applicant response to establish a clear and unambiguous disclaimer. While one could read the response standing alone to imply that "absorbing water" is not "self-expansion," that conclusion is not clear in light of the statement's context. Therefore, "self-expanding" should include expanding by absorbing water or bodily fluid *in situ*.

"MATRIX"

There is no dispute on this term. "Matrix" means "the intercellular substance in which tissue cells are embedded; something (as a surrounding or pervading substance or element) within which something else originates or takes form or develops." Pl. Mot. Summ. J. at 5-6, (citing *Merriam-Webster's Medical Dictionary*).

"POROUS"

There is no real dispute on this term either. The parties agree that "porous" means "full of or possessing pores."

"FRAMEWORK"

There is no real dispute on this term. "Framework" means "a skeletal structure or network of tissue that provides support."

Claim 18

All terms in this claim have been defined above.

Claim 19

"FOAM"

The Plaintiff defines "foam" as "masses of air cells or air pockets in a solid or semisolid substance." Pl. Mot. Summ. J. at 6. It takes this definition from the report of its expert Dr. Edward Dauer, who cites *Stedman's Medical Dictionary*, 27th Edition. The Defendant defines "foam" as "a stabilized frothy substance generated by either a chemical reaction or by mechanical agitation," citing *Webster's Third International Dictionary Unabridged*. The Defendant further argues that the patent specification clearly treats "foam" and "sponge" as different terms.

The patent clearly indicates that "foam" and "sponge" are different. The specification uses both terms in the same sentence, offering both forms as alternatives. *See* '045 patent, col. 2, 11. 4-6, col. 3, 11. 22-28. Nothing in the patent itself suggests which of the offered dictionary definitions is more appropriate. The Federal Circuit has warned against taking dictionary definitions, which may reflect a more general definition, rather than the one used in the patent or the relevant art. *Phillips*, 415 F.3d at 1320. The Federal Circuit has also admonished "arbitrarily pick[ing] and choos[ing] from various accepted definitions." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir.1998). The dicta in *Phillips* indicates a slight preference for technical dictionaries, since they "endeavor to collect the accepted meanings of terms used in various fields of science and technology." 415 F.3d at 1318.

The medical dictionary cited by the Plaintiff is more likely than a general dictionary to reflect the definition of foam as used in the relevant art and in the patent. Furthermore, because the Plaintiff's definition appears slightly broader, using this definition is less likely to improperly narrow the patent's intended definition. Therefore, "foam" is defined as "masses of air cells or air pockets in a solid or semisolid substance." However, this definition does *not* include the term sponge.

Claim 20

"RESILIENT FRAMEWORK"/"EXPAND RESILIENTLY"

There is no dispute over the terms "resilient" or "resiliently ." They refer to a framework or matrix's "the ability to return to its original or normal size after having been compressed."

Claim 22

All of the terms in claim 22 have already been defined above. Claim 22 is identical to claim 9, except that it adds the term "self-expanding foam." "Self-expanding foam" is defined by combining the definitions of "self-expanding" and "foam" discussed above under claims 17 and 19 respectively.

Claim 23

All the terms in claim 23 have already been defined above.

Claim 24

All the terms in claim 24 have already been defined above.

It is hereby **ORDERED AND ADJUDGED** that the '045 patent should be construed as explained above. It is **FURTHER ORDERED AND ADJUDGED** that Plaintiff's Motion for a Markman Hearing [**DE # 33**] is **DENIED** as moot.

S.D.Fla.,2005.

White Water Investments, Inc. v. Ethicon Endo-Surgery, Inc.

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