

United States District Court,
S.D. Ohio, Western Division.

ETHICON ENDO-SURGERY, INC,
Plaintiff.

v.

TYCO HEALTHCARE GROUP LP, d/b/a United States Surgical,
Defendant.

July 26, 2006.

David Edward Schmit, Frost Brown & Todd, Cincinnati, OH, Angela Verrecchio, Barbara Lynn Mullin, David N. Farsiou, Dianne Brown Elderkin, Woodcock Washburn LLP, Philadelphia, PA, for Plaintiff.

Drew M. Wintringham, III, Mark A. Kirsch, Mark W. Rueh, Clifford Chance US, LLP, New York, NY, Robert Alexander Pitcairn, Jr., Katz, Teller, Brant & Hild, Jerome Bishop, Katz, Teller, Brant & Hild, Cincinnati, OH, for Defendant.

ORDER ON CLAIM CONSTRUCTION

SANDRA S. BECKWITH, Chief District Judge.

In this patent infringement action, Plaintiff claims that Defendant's DST Series surgical stapler systems infringe Claim 1 of U.S. Patent No. 4,805,823. Plaintiff claims to be the sole and exclusive assignee of the entire right, title, and interest in and to the '823 Patent. This matter is now before the Court for claim construction, as required by *Markman v. Westview Investments*, 52 F.3d 967 (1995), *aff'd* 517 U.S. 370 (1996).

The parties filed a Joint Claim Construction and Prehearing Statement (Doc. 52). The Court held a *Markman* hearing on June 16, 2006, during which counsel for both parties presented cogent arguments in support of their respective positions.

The Patent At Issue.

The '823 patent issued to Rothfuss, dated March 18, 1988, is titled "Pocket Configuration for Internal Organ Staplers." The invention concerns surgical staplers used for internal surgeries. The staples used by internal organ staplers are very small. These small staples pass through what are called "guiding pockets" which generally conform to the shape of an unformed staple. The stapler uses a driver to push the staple through the pocket and onto the anvil of the stapler, where the staple is formed. The staple must move freely through the staple pocket in the correct orientation, in order to properly meet the anvil and form the stapled connection.

The background of the invention describes the prior art staple pockets as "generally rectangular." (See Col.

1, lines 14-15 and 25-26.) Those prior art pockets are more particularly described:

... there are generally a first pair of parallel sides which are formed along the length of the unformed staple. This first pair of parallel sides is met by a second pair of parallel sides at right angles. This second pair of parallel sides generally corresponds to the width of the staple and staple driver.

Col. 1, lines 26-31. When a staple is loaded into a pocket at an angle to the generally parallel sides, the staple can jam into the pocket, or can be misformed when the driver pushes the staple against the anvil.

The invention of the patent is directed to an improved shape for the staple pocket, to overcome the problem of jammed staples, as well as to improve manufacturing, inspection and ease of staple loading. As described in the summary, the invention is a "self-centering pocket which is able to maintain the staples in proper alignment." (Col. 1, line 68-Col. 2, line 1.) The improved pocket

... comprises a pair of parallel sides each connected to a pair of tapered sides. This pair of tapered sides culminates at a second pair of parallel sides, situated at right angles to the first pair of parallel sides. Thus, the improved guiding pocket takes of a generally hexagonal shape. It is this hexagonal shape which allows the staple to center itself inside the pocket.

(Col. 2, lines 4-9.)

Claim 1, the only claim asserted by Ethicon in this action, states:

In a stapler having pockets through which pass staple drivers adapted to drive unformed staples, each said pocket generally conforming to the shape of one of said unformed staples, said pockets permitting said drivers to position said unformed staples on anvils for forming said staples, one of said pockets having first parallel sides generally corresponding to the length of said unformed staples, said first parallel sides connected by second parallel sides to form said pocket, said second parallel sides generally conforming to the width of said unformed staples, the improvement comprising the addition of a tapered side to each end of each first parallel side, each said tapered side diagonally approaching one of said second parallel sides, the resulting pocket formed with a generally hexagonal shape, wherein staples within said pocket become self-aligning.

Col. 3, line 39-Col. 4, line 13.

Claim Construction Issues.

The parties agree on the meaning of many of the terms used in Claim 1, as set forth in their Joint Statement (Doc. 52) at pg. 8. Those terms and agreements include the following:

"One of said pockets having first parallel sides generally corresponding to the length of said unformed staples" means that the length of each of the first parallel sides approximately corresponds to the length of an unformed staple.

"Parallel sides" means sides extending in the same direction and equidistant (but not with mathematical precision).

"**Connected by**" means "joined directly to" so that the two sets of parallel sides directly join to form the staple pocket generally conforming to the shape of an unformed staple.

"**Second parallel sides generally conforming to the width of said unformed staples**" means that the length of each of the second parallel sides approximately corresponds to the width of the unformed staple.

"**The addition of a tapered side to each end of each first parallel side**": The parties ascribe "ordinary meaning" to this phrase. "Tapered" is defined by Webster's Ninth as "to become progressively narrowed toward one end." The Oxford English Dictionary defines "tapered" as "diminished in breadth or thickness by degrees." The Court finds that the plain meaning of "tapered side" is a side that is progressively narrowed from one end to the other.

The Court adopts these constructions for these terms, finding no genuine dispute as to their meaning.

The parties disagree on the proper construction of the following claim terms.

I. "the improvement comprising".

The parties generally agree that Claim 1 is written in Jepson format. A Jepson format permits the applicant to include in the preamble all of the conventional, known elements of the claimed invention. See, e.g., *Kegel Co. v. AMF Bowling*, 127 F.3d 1420, 1426 (Fed.Cir.1997). The preamble is the material before the transitional phrase "the improvement comprising." The new or modified elements of the invention are contained in the body of the claim that follows the transitional phrase.

The parties also generally agree that "comprising" is a term of art used in patent claims to mean "including, but not excluding, additional unrecited elements." However, U.S. Surgical contends that "comprising" in a Jepson claim means everything in the preamble must be construed to be a part of, or limitation on, the entire claim.

Various cases have addressed the proper interpretation of a Jepson claim. U.S. Surgical cites *Epcon Gas Systems v. Bauer Compressors*, 279 F.3d 1022 (Fed.Cir.2002) for the proposition that the preamble must be construed as a limitation on the claim. *Epcon Gas* involved a patent claim for a method of providing gas assistance to a resin injection molding process. The claim preamble described that process in its various steps, and then described the improvement (varying the pressure of the gas injected into the mold). The infringer argued that the reference in the preamble to a "resin injection molding process" required the accused device to include a complete injection molding process, along with the improvement concerning variable gas pressures. The Federal Circuit disagreed. The Court first cited the general rule that a Jepson claim's preamble recites "elements or steps of the claimed invention which are conventional or known." The Court then noted its decision in *Rowe v. Dror*, 112 F.3d 473, 479 (Fed.Cir.1997), which stated that a Jepson claim preamble "defines not only the context of the claimed invention, but also its scope." *Epcon Gas* summarized these various authorities by stating that the preamble is a "limitation" on the claim (*Id.*, 279 F.3d at 1029), a phrase that U.S. Surgical argues applies here. What *Epcon Gas* actually held, however, is that the preamble "**helps define the scope** of the invention." *Id.* (emphasis added). In that case, the Court limited the claim to the improved method of providing gas assistance, and not that method plus an entire injection molding process, as the accused infringer urged.

A few months later, in *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed.Cir.2002),

the Federal Circuit observed that "no litmus test" determines the proper role of the preamble. The Court described Jepson claim format as "**generally** indicating an intent to use the preamble to define the claimed invention, thereby limiting claim scope." *Id.* (emphasis added). See also, *Vaupel Textilmaschinen KG v. Meccanica Euro Italia*, 944 F.2d 870, 879-881 (Fed.Cir.1991), construing a Jepson claim and holding that certain preamble terms were not "structural limitations" on the improvement, but rather provided "reference points" that helped define the patented improvement.

Ethicon notes that U.S. Surgical's limiting construction of the transition phrase could result in a direct conflict between the preamble and the body of the claim. For example, Claim 1 cannot be read to require that the first and second set of parallel sides are "connected" (as the preamble states) when the new, improved tapered sides are added to the first parallel sides. U.S. Surgical responds that it is not seeking an absurd construction, merely one that recognizes the importance of the elements contained in the preamble.

The Court concludes that this dispute cannot be resolved by formulating a general proposition concerning Jepson format construction. This disagreement must be resolved by applying these general rules to the resolution of the specific disputed claim terms in the body of Claim 1, addressed below.

II. "each tapered side diagonally approaching one of said second parallel sides"

Ethicon's proposed construction of this claim term is: "Each tapered side has a generally diagonal orientation and extends toward the second set of parallel sides. The term 'approaching' does not require connection of the tapered sides to the second parallel sides ." U.S. Surgical proposes the following: "'Diagonally approaching' means the tapered side constitutes a straight line displaced angularly between, and connecting, a first and second parallel side."

Thus, the first dispute is whether the term "approaching" as used in Claim 1 includes "connecting." Ethicon argues that the plain meaning of approaching is "to come nearer to," and that it does not require nor connote a "connection." Ethicon also relies on the doctrine of claim differentiation, a presumption that different patent claims have a different scope. See, e.g., *Kraft Foods, Inc. v. Int'l Trading*, 203 F.3d 1362, 1368 (Fed.Cir.2000). Independent and unasserted Claim 5 describes the tapered sides as "connected" to both sets of parallel sides, not "approaching" the second parallel sides as phrased in Claim 1. (While Claim 1 addresses a "stapler" and Claim 5 addresses a "staple cartridge," the parties do not address this possible difference in scope nor ascribe any distinction that might be relevant to the use of the words "approach" vs. "connect.") Ethicon also notes that the Summary of the Invention states the tapered side "culminates" at the second parallel side. This, says Ethicon, demonstrates that the drafter made deliberate, different choices in describing the connection of the two sides, with no intent to equate all of these terms. Ethicon admits that most specification references and the embodiments include connections between the tapered and second set of parallel sides. Indeed, other than the Summary's use of "culminates" and "approaching" used in Claim 1, the patent uniformly describes the tapered sides as connected to the second parallel sides. But Ethicon relies on the well-established rule that, absent explicit limiting language, claims are not limited to the specific embodiments, even if the patent describes only a single embodiment. See, e.g., *Altris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed.Cir.2003). Ethicon asserts that nothing in the specification **explicitly** limits "approaching" to "connecting" nor limits the claimed invention to the preferred embodiment.

U.S. Surgical argues that the repeated references in the specification to the "connection" between the tapered and parallel sides strongly expresses the inventor's intent and operates as a valid claim limitation. The Abstract describes the tapered sides as connected to both sets of parallel sides. And the specification states

that the "second parallel sides connect to both pairs of tapered sides ..." (Col. 2, lines 56-57). In addition, Claim 1 states "each said tapered side diagonally approaching one of said second parallel sides, **the resulting pocket** formed with a generally hexagonal shape, ..." (Col. 4, lines 10-12; emphasis added). A line that simply "approaches" without "connecting" cannot form a "resulting pocket." U.S. Surgical argues that, in view of this claim language, and the specification's failure to even suggest that the tapered sides are **not** connected to the first parallel sides, Ethicon's proposed construction is contrary to the specification. U.S. Surgical also argues that the proposed construction would violate 35 U.S.C. s. 112(1)'s requirement that the written description must enable a skilled person to make and use the invention.

Any potential challenges to the patent under 35 U.S.C. s. 112 are not before the Court. A general axiom of claim construction states that true ambiguity in a claim term should generally be resolved to preserve validity, so long as doing so does not read an improper limitation into the claim. See, *Texas Instruments v. U.S.I.T.C.*, 871 F.2d 1054, 1065 (Fed.Cir.1989). U.S. Surgical does not argue that "approaching" is ambiguous; it argues that the patent does not teach or suggest that "approach" means anything but "connect" so as to form a "pocket."

The Federal Circuit has often cautioned against importing unwarranted limitations from the specification when construing patent claims. See, e.g., *Arlington Indus. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed.Cir.2003). But simply reciting that rule does not resolve the dispute. As the Circuit has also observed, "[W]e recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed.Cir.2005) (en banc).

In *Microsoft Corp. v. Multi-Tech Systems*, 357 F.3d 1340 (Fed.Cir.2004), the Court affirmed a district court's noninfringement judgment based upon a claim construction that the patent holder argued was improperly limited by reliance on the specification. The dispute was whether the claims were limited to communications over a "telephone line" or could also include communications over a "packet-switched network" (e.g., the Internet). While a few of the claims explicitly used the term "telephone line," some were much broader, making no reference to a telephone line and, standing alone, did not exclude communications over a packet-switched network. The Court observed: "Nonetheless, the claims must be interpreted in light of the specification, which is identical for all three patents and which repeatedly and consistently describes the local and remote systems of the claimed inventions as communicating directly over a telephone line." *Id.* at 1347-1348. However, the Court also noted and relied on the extensive prosecution history of the patents, which explicitly supported the construction of the claims as limited to a telephone line. In **this** case, the claims were approved almost exactly as submitted by the applicant. (See Doc. 52, Exhibit 2, File Wrapper for the ' 823 patent, at pp. 19-20, which discloses only one Examiner's Amendment to Claim 5. Authorization for this amendment, adding the words "in a staple cartridge" to the claim, was given in an unrecorded telephone interview with the applicant's counsel.) Hence there is no prosecution history here that could assist in resolving this question.

More recently, in *Semitool, Inc. v. Dynamic Micro Systems*, 444 F.3d 1337 (Fed.Cir.2006), the Federal Circuit construed a claim term and affirmed a judgment of noninfringement based on the Circuit's own construction. The dispute concerned whether a condenser in a semiconductor cleaning machine was inside or outside of the machine's "processing chamber." The answer depended on whether the "chamber" was defined as the entire interior space of the "processing vessel," or some smaller portion of that interior. The disputed claim simply described the chamber as "within" the vessel. The Court turned to the specification, which the Court concluded clearly defined the chamber as coextensive with the vessel. Quoting from its

opinion in *Phillips*, the Court again noted 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. at 1346-1347. The Court limited the claim term "within the vessel" to mean that the chamber was co-extensive with the vessel.

Here, U.S. Surgical contends that the specification's consistent description of the "connecting" sides supports a conclusion that the claim term "approaching" must be limited to mean "connecting." While there is room for doubt, the Court is constrained to construe "approach" to have a meaning different from "connect." The drafter apparently intentionally used "approaching" in Claim 1, as distinguished from "connect" in Claim 5. "Approaching" is not ambiguous, and is not synonymous with "connecting." Whether the specification adequately supports this construction, or whether the claim may be invalid, are matters for another day.

The parties also dispute whether the tapered sides (described as "diagonally approaching" the second set of parallel sides) must be straight. Ethicon asserts that the plain meaning of "tapered" does not include nor require that the tapered side be straight. Ethicon admits that the specification and preferred embodiments depict a generally "straight" tapered, diagonal line. But Ethicon again argues that the claim cannot be limited by the specification or the preferred embodiment.

The Court previously construed "tapered" to mean progressively narrowed. While many things can "taper" (thunder storms, for instance, "taper" off), the question here is not the meaning of taper. The question is the construction of the phrase "diagonally approaches" to describe the tapered side's relationship to the second parallel side of the pocket.

Webster's Ninth defines the adjective diagonal as "joining two vertices of a rectilinear figure that are nonadjacent" or, "inclined obliquely from a reference line." When used as a noun, diagonal means a "diagonal straight line or plane." The Oxford English Dictionary similarly defines the words. "Diagonally" means "In a diagonal direction; so as to extend from one angle or corner to the opposite." "Diagonal" (n.) is defined as "Extending, as a line, from any angular point of a quadrilateral or multilateral figure to an opposite or non-adjacent angular point."

Every definition consulted, as well as common usage, confirms that "diagonal" is an obliquely inclined **line** that joins two defined points. The claim phrase "each tapered side diagonally approaching" is therefore construed as a generally (but not mathematically precise) straight line that lies at a measured angle of inclination from the first parallel side. This construction is also supported by the fact that "diagonally" describes a "side" of a pocket. "Side" commonly means a line or a surface that is more or less straight.

Ethicon argues that a construction requiring the diagonal, tapered lines to be "straight" imposes an extraneous limitation on the claim that finds no support in the patent language. The Court disagrees. There is nothing in the claim, or in the patent as a whole, that supports a construction other than that the tapered sides of the resultant pocket are generally straight.

III. "a generally hexagonal shape"

Ethicon contends that the phrase "generally hexagonal" means a staple pocket with "six major faces," similar to those shown in Figures 1, 2 or 3 of the patent. FN1 U.S. Surgical contends that the inventor's lexicography establishes that "generally hexagonal" means "octagonal." U.S. Surgical also contends that the claim term includes a limitation on both the shape (octagon) and the length of the parallel sides (conforming

to the staple size).

FN1. This proposal differs from the one contained in the Joint Claim Construction Statement (Doc. 52) at p. 12. The words "more or less" which appeared just before the words "six major faces" were omitted from the claim construction summary Ethicon presented at the *Markman* hearing on June 16, 2006. It is the amended proposal the Court will consider.

Ethicon argues that "generally hexagonal" as used in the claim does not mean a mathematically precise hexagon. Ethicon notes that the patent labels the prior art staple pockets as "generally rectangular" (Col. 1, lines 32-33), even though they are illustrated as having more than four sides (see Figures 2-a and 3-a). The patent improvement of adding the four tapered sides resulted in a pocket shape described as "generally hexagonal" because there are six major sides easily seen. The two smaller parallel sides are very tiny (as wide as a human hair, as long as .011 inches). The viewer thus perceives a "**generally** hexagonal" shape. (The Patent Examiner's reasons for allowance of the claims concludes that "the prior art does not disclose a pocket having a hexagonal shape as claimed" which also lends some support to Ethicon's argument. See Doc. 52, Exhibit 2, File Wrapper for the '823 Patent, at p. 20.)

U.S. Surgical responds that the specification and all figures clearly describe an octagon. The patent's claimed improvement avoids the close tolerances of the prior art end pockets, as illustrated in Figures 2-a and 3-a. Those prior art pockets actually had 12 sides, and so were not "rectangular" as described in the patent. U.S. Surgical posits that to accept Ethicon's definition would result in an unbounded claim: a pocket could have many more than six sides and still be "generally" hexagonal, and infringe the patent.

The specification describes prior art pockets as both "rectangular" (Col. 1, lines 14 and 25-26) and as "generally rectangular" (Col. 1, lines 16 and 32-33). Figures 2a and 3a illustrate prior art pockets that clearly are *not* precise rectangles. Figure 1a depicts an oval-shaped pocket with **no** straight sides. "Generally" is a term of approximation, and does not require mathematical precision. "Hexagonal" describes a figure having six angles and six sides. Figures 1, 2 and 3 of the patent illustrate the improved pocket with more than six angles and more than six sides. U.S. Surgical argues that the only way to reconcile this contradiction is to construe the drafter's use of "hexagon" to mean "octagon."

U.S. Surgical's argument contravenes two basic claim construction principles. First, as noted above, the Court may not limit construction of a claim term to the preferred embodiment or the specification, absent express language so limiting the claim. There is nothing in the specification **expressly limiting** the invention to an **eight**-sided pocket. Second, U.S. Surgical's proposal fails to explain the drafter's use of "rectangular" and "generally rectangular" to describe prior art staple pockets that are clearly not four-sided rectangles. This phrasing supports Ethicon's proposed construction, that it is the "major" faces of the pocket that are being described in the phrases "generally rectangular" and "generally hexagonal."

As to the question of the length of the parallel sides: Ethicon rejects U.S. Surgical's construction requiring the parallel sides to approximate the length and width of the unformed staple. The prior art descriptions in both the specification (Col. 1, lines 26-31) and the preamble of Claim 1 (Col. 4, lines 3-8) describe the two sets of parallel sides as conforming to the size of the staple. Ethicon argues that adding the tapered sides necessarily modifies the relationship between the size of the staple and the size of the parallel sides. Ethicon also notes that U.S. Surgical's construction would exclude the preferred embodiment, which explicitly states: "Of course, the length of the first parallel sides and tapered sides may have any dimension required to fit the

surgical staple." (Col. 3, lines 18-20.)

U.S. Surgical responds that a Jepson claim preamble acts as a claim limitation unless expressly modified by terms describing the improvement. Claim 1's preamble limits the length of the first parallel sides ("generally corresponding to the length of said unformed staples"). There is nothing in the improvement language stating that the length of those parallel sides would change, only that the tapered sides are added.

U.S. Surgical's proposed construction is unduly restrictive. It is true that the body of Claim 1 describing the improvement of tapered sides does not expressly modify the length of the first parallel sides after the tapered sides are added to the pocket. But the specification and the Figures clearly show that the staple is generally longer than the first parallel side. Indeed, that appears to be the essence of the "self-guiding feature" of the invention. Moreover, U.S. Surgical's construction would directly contradict the explicit description of the preferred embodiment, which is rarely if ever a proper construction of a claim.

The Court therefore construes the term "a generally hexagonal shape" to mean that the staple pocket is perceived by a viewer to have six major sides that can have varying lengths. This construction does not imply that "major" has any functional meaning, but is limited to a visual perception of the pocket's general shape.

IV. "wherein staples within said pocket become self-aligning"

The parties dispute whether this claim term requires the staples to touch, or physically contact, the new and improved tapered sides of the staple pocket. Ethicon posits that the phrase "self-aligning" simply means that the staple "is encouraged to move toward an aligned position." No "touching" is required, because the improved pocket shape is essentially "self-centering." Nothing in the claim terms or the specification requires the staples to physically contact the tapered sides each and every time a staple enters the guiding pocket in order to achieve proper alignment.

U.S. Surgical, on the other hand, argues the phrase means that the staples are "rotated" to proper alignment "by contact with the tapered sides." U.S. Surgical cites several passages from the specification which describes the tapered sides of the "hexagonal" pocket as **the** feature that permits the staple to self-center. See, e.g., Col. 2, line 66-Col. 3, line 13, describing the "geometry of the pocket" which lets the staple "slide against the sides of the guiding pocket wall so that it becomes properly aligned ." The specification also highlights the preferred angles of those tapered, diagonally placed sides to insure this self-alignment. See Col. 3, lines 22-25 describing the "optimal angle" to insure self alignment for differing staple wire diameters. If the staples do not have to "touch" the sides, U.S. Surgical argues that the specific angle between the first parallel side and the tapered side would not be important to achieving proper alignment.

The problem with the prior art pockets, as described in the background of the invention, is that the staple may jam in the pocket if it is loaded "at an angle to the generally parallel sides of the pocket." (Col. 1, lines 33-36.) If the staple is loaded correctly (e.g., not at an angle to the parallel sides), presumably the prior art pocket can perform its function correctly. The new, improved pocket claimed by the patent would also perform its function correctly if the staple is loaded correctly into the pocket. Ethicon persuasively argues that the claim term does not require **each** and **every** staple to "touch" the tapered sides **each** and **every** time a staple is loaded into the pocket. The invention is directed at avoiding a jammed staple caused by the incorrect loading of a staple into a pocket. This is made clear by the description in the specification, that "**should** the staple become placed in the pocket along the tapered sides ..." (Col. 2, line 67-Col. 3, line 1,

emphasis added), the staple will be guided to a correct alignment by contact with those tapered sides. But the claim term "self aligning" cannot be limited to require that **each** and **every** staple "touch" the tapered sides **each** and **every** time a staple is loaded.

CONCLUSION

For all of the foregoing reasons, the Court construes the disputed claim terms as stated in this Order.

S.D.Ohio,2006.

Ethicon Endo-Surgery, Inc. v. Tyco Healthcare Group LP

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