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

MEDTRONIC XOMED, INC,
Plaintiff.
v.
GYRUS ENT LLC,
Defendant.

No. 3:04-cv-400-J-32MCR

May 23, 2005.

A. James Anderson, Christopher T. Nace, Marla R. Butler, Robins, Kaplan, Miller & Ciresi, LLP, Atlanta, GA, Jeffrey S. York, Robert Eric Bilik, McGuire Woods, LLP, Jacksonville, FL, for Plaintiff.

Darle M. Short, Kristin K. Vidovich, Stephen T. Owen, Thomas J. Pardini, William J. Utermohlen, Oliff & Berridge, PLC, Alexandria, VA, Thomas Edward Bishop, Tanner Bishop, Jacksonville, FL, for Defendant.

ORDER

TIMOTHY J. CORRIGAN**, District Judge.**

Medtronic Xomed, Inc. ("Xomed"), alleges that Gyrus ENT LLC ("Gyrus") is infringing on U.S. Patent No. 6,293,957 B1 ("'957 Patent") entitled, "Method of Performing Sinus Surgery Utilizing & Sinus Debrider Instrument." FN1 The parties have presented sixteen claim terms for construction. They disagree on proposed constructions for seven of them. The Court has reviewed the parties' briefs, examined their exhibits, and considered their arguments made at the April 21, 2005 claim construction hearing.

FN1. Xomed represents that it is the assignee of the '957 Patent.

I. ***Claim Construction Standards***

A patent specification must conclude "with one or more claims particularly pointing out and distinctly claiming the subject matter" that the applicant regards as his invention. 35 U.S.C. s. 112, para. 2. Determination of patent infringement involves two steps: (1) construing the meaning and scope of the claims, and (2) comparing the allegedly infringing device to the construed claims. Novartis Pharms. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306, 1308 (Fed.Cir.2004). The first step, claim construction, is a matter of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

Claim construction is "the process of giving proper meaning to the claim language." Abtox, Inc. v. Exitron

Corp., 122 F.3d 1019, 1023 (Fed.Cir.1997); *see also* SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1339 (Fed.Cir.2005) (describing claim construction as "contextual interpretation of language"). Courts construe claim terms "in order to assign a fixed, unambiguous, legally operative meaning to the claim." Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1377 (Fed.Cir.2005).

In construing a claim term, a court should consider the claim language, the specification,FN2 and the prosecution history.FN3 Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd,* 517 U.S. at 370. Collectively, these are considered intrinsic evidence of the claim term meaning.FN4 *Id*. The intrinsic evidence allows a court to "place the claim language in its proper technological and temporal context." SmithKline, 403 F.3d at 1338.

FN2. "The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention ." 35 U.S.C. s. 112, para. 1.

FN3. The prosecution history consists of the record of the proceedings before the Patent and Trademark Office ("PTO"), including any express representations made by the applicant regarding the scope of a claim as well as prior art cited therein that may give an indication as to what a claim does not cover. Bell Atlantic Network Servs., Inc. v. Covad Comm. Group, Inc., 262 F.3d 1258, 1268 (Fed.Cir.2001); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996).

FN4. If intrinsic evidence does not resolve an ambiguity relating to a claim term, a court may resolve the ambiguity by considering extrinsic evidence such as inventor or expert testimony. Vitronics Corp., 90 F.3d at 1583; Markman, 52 F.3d at 980-81. The parties have not asked the Court to consider extrinsic evidence.

Claim construction "begins and ends in all cases with the actual words of the claim." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998). A claim term should be given its "ordinary and accustomed" construction to one of ordinary skill in the art as a "touchstone" for meaning. FN5 Nazomi Comms., Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1369 (Fed.Cir.2005). Dictionary definitions provide evidence of a claim term's ordinary meaning.FN6 Inverness Med. Switzerland GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378 (Fed.Cir.2002). "Potentially relevant dictionaries include dictionaries of the English language (providing general definitions and usages) FN7 and technical dictionaries, encyclopedias, and treatises (providing specialized meanings as used in particular fields of art)." *Id*.

FN5. At the hearing, the parties agreed that, with respect to the ' 957 Patent, a physician licensed to perform sinus surgeries would be one of ordinary skill in the art.

FN6. There is a case pending before an en banc panel of the Federal Circuit to address numerous claim construction issues including, "Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee's use of the term in the specification? If both sources are to be consulted,

in what order?" *See* Phillips v. AWH Corp., 376 F.3d 1382, 1383 (Fed.Cir.2004). Gyrus asserts that determination of these issues will not affect claim construction in this case.

FN7. The Federal Circuit has cautioned against using non-scientific dictionaries, "lest dictionary definitions ... be converted into technical terms of art having legal, not linguistic significance." Dow Chem. Co. v. Sumitomo Chem. Co., Ltd., 257 F.3d 1364, 1372 (Fed.Cir.2001) (quotations omitted). The Federal Circuit also has warned that its cases cannot be read to mean that a dictionary definition trumps the intrinsic record. C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed.Cir.2004).

Claims must be read "in view of the specification, of which they are a part." Markman, 52 F.3d at 979. The purpose of this review is "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Vitronics, 90 F.3d at 1582. The specification "may act as a sort of dictionary, which explains the invention and may define terms used in the claims." Markman, 52 F.3d at 979. The specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. "When the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1347 (Fed.Cir.2004) (quotations omitted). However, the specification may not be used to "enlarge, diminish, or vary the limitations in the claims." Markman, 52 F.3d at 979-80 (quotations omitted).

Finally, claims should be read in light of the prosecution history, if introduced by either party. Vitronics, 90 F.3d at 1582. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995). Accordingly, if an applicant takes a position before the PTO such that a "competitor would reasonably believe that the applicant had surrendered the relevant subject matter," the applicant may be barred from asserting an inconsistent position on claim construction. Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1457 (Fed.Cir.1998). Only clear positions will suffice; ambiguous statements in the prosecution history are insufficient to surrender claim scope. Kumar v. Ovonic Battery Co. ., Inc., 351 F.3d 1364, 1371 (Fed.Cir.2003). As with the specification, the prosecution history may not be used to "enlarge, diminish, or vary the limitations in the claims." Markman, 52 F.3d at 980 (quotations omitted).

II. ***The*** '957 Patent ***& the Prosecution History***

On January 26, 1999, a patent application was filed with the PTO for a "Method of Performing Sinus Surgery Utilizing a Sinus Debrider Instrument" invented by Gary Peters and John Cleveland, both of Jacksonville. The application explained that the "present invention generally relates to the field of tissue removal and more specifically relates to sinus debriders used for tissue removal during sinus surgery."

The background explained the problems sought to be addressed by the invention:

Generally in the field of sinus surgery, arthroscopic cutting instruments have been used which instruments have encountered numerous problems, the primary one being that the instruments clog or jam from tissue buildup as there is little fluid present at the sinus surgery site unlike the abundance of fluid which occurs in the joints of a human being. Furthermore, when fluid is used with such instruments, it is excessively applied

at the surgical site. The tissue jamming or clogging requires frequent cleaning or substitution of the prior art instruments which is not only time consuming thus increasing the time of the procedure as well as decreasing the number of procedures possible in a given operating room facility but also contributes to physician fatigue thus increasing the chances of error.

(Doc. 61, Ex. E, Bates XO275090; Doc. 41, Ex. A, Col. 1, Lines 17-31.) The background explained that the invention has overcome the problems in the prior art devices by:

providing a dual passage, removable manifold which can be easily removed, cleaned or replaced and a double lumen flexible tube. The cutter head body into which the manifold is mounted is also easily removed from the apparatus.

The double lumen flexible tube which supplies both the suction and fluid is mounted in a channel cut into the instrument body with the tube terminating at one end of the removable manifold. Thus, separate passageways for suction and fluid are provided in the invention. It should be noted that in [arthoscopic] surgery, there is normally a great deal of fluid present at the site of the surgery so that fluid is not required, but in sinus surgery which is the primary direction of the present invention, there is little moisture, so moisture must be supplied to keep the tissue material from clogging up the device.

The instrument is also provided with a nipple projection extending into the tube channel so that a surgeon can easily grasp the flexible tube and with slight finger pressure, decrease the amount of suction or the amount of fluid going to the operation site.

(Doc. 61, Ex. E, Bates XO275093-94; Doc. 41, Ex. A, Col. 2, Lines 31-52.) A stated object of the invention was "to provide an instrument which allows the surgeon to manually change the amount of fluid delivered to the surgical site ...." (Doc. 61, Ex. E, Bates XO275095; Doc. 41, Ex. A, Col. 3, Lines 7-9.)

The application initially presented claims 1 through 20. The application was amended to cancel claims 1 through 20 and add claims 21 and 22. Claim 21 recited:

A method of performing sinus surgery utilizing a sinus debrider instrument having an outer tubular member with an opening at a distal end thereof, an inner member rotatably disposed within the outer tubular member with a tissue cutting surface of the inner member adjacent the opening in the outer tubular member, and an annular space between the outer tubular member and the inner member forming a fluid passage to deliver fluid to the tissue cutting surface, said method comprising the steps of positioning a distal end of the sinus debrider instrument at an operative site within a sinus;

cutting tissue at the operative site within the sinus with the tissue cutting surface by rotating the inner member relative to the outer tubular member;

removing tissue cut by the tissue cutting surface from the sinus through a suction passage from the sinus in the sinus debrider instrument; and

supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument to facilitate the removing of cut tissue from the sinus *without introducing fluid to the operative site*.

(Doc. 61, Ex. E, Bates XO275139 (emphasis added).) Claim 22 recited: "The method of performing sinus

surgery as recited in claim 21 wherein the inner member is tubular and has a lumen therein and wherein said step of removing cut tissue from the sinus includes aspirating the cut tissue through the lumen in the inner member." (Doc. 61, Ex. E, Bates XO275139.) In presenting the amendment, Xomed's patent attorney remarked:

Claims 21 and 22 remain in the subject application and are directed specifically to sinus surgery. As explained in the specification, there is little moisture available at an operative site in a sinus, and the method of performing sinus surgery in accordance with the present invention supplies fluid to a tissue cutting surface of a sinus debrider instrument without introducing fluid to the operative site.

(Doc. 61, Ex. E, Bates XO275140.)

In PTO action dated November 20, 1999, the examiner rejected claims 21 and 22 on the grounds that they were obvious FN8 over U.S. Patent No. 5,254, 115 ("Bhatta et al."). Xomed's patent attorney responded with many reasons why the invention was not obvious over Bhatta et al., including the fact that Bhatta et al. "introduces irrigating solution or fluid to the surgical field" while claim 21 recites "supplying fluid to the tissue cutting surface ... without introducing fluid to the operative site." (Doc. 61, Ex. E, Bates XO275200-01.)

FN8. The basis for an obviousness rejection is 35 U.S.C. s. 103(a), which states that "[a] patent may not be obtained though the invention is not identically disclosed or described ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains...."

In PTO action dated April 12, 2000, the examiner applied another rejection of claims 21 and 22, this time explaining:

Claims 21-22 is [sic] rejected under 35 U.S.C. s. 112, first paragraph, as containing subject matter which was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 21, the limitation in the method of "supplying fluid to the tissue cutting surface ... without introducing fluid to the operative site" is a) inconsistent with the applicant's disclosure and b) not clear to the examiner how one would practice this step of the claimed method to insure no fluid would be introduced. While it is understood that suction is provided, this limitation is nebulous.

The applicant discloses in the *Summary of the Invention* that one advantage of this invention is to "manually change the amount of fluid delivered to the surgical site ...." Examiner suggests applicant remove said limitation from the method claim to overcome this rejection.

(Doc. 61, Ex. E, Bates XO275206-207.) Following this suggestion, Xomed's patent attorney amended the claims to delete the words "without introducing fluid to the operative site," but traversed the rejection:

The rejection of claims 21-22 under 35 U.S.C. s. 112 is respectfully traversed in that it is clear from the drawings and the specification that the fluid is supplied to the tissue cutting surface through the fluid passage between the outer tubular member and the inner member in a fashion to deliver the fluid to the

tissue cutting surface such that the fluid remains essentially within the instrument to be removed through the suction passage. In any event, applicant has adopted the Examiner's suggestion and deleted the words "without introducing fluid to the operative site". It is noted that the references in the specification relating to changing the amount of fluid delivered to the surgical site relate to fluid supplied to the tissue cutting surface as opposed to the operative site.

(Doc. 61, Ex. E, Bates X0275219.) In what Xomed believes was an oversight, the phrase "without introducing fluid to the operative site" was not deleted from the abstract when it was deleted from the claims.

The examiner determined that the applicant's response was persuasive, but applied another rejection in agency action dated December 27, 2000, this time on the grounds that claims 21 and 22 were obvious over U.S. Patent No. 5,490,860 (Middle et al.). The examiner explained that Middle et al. had "a fluid passageway to deliver fluid to the tissue cutter ... wherein fluid is supplied to the cutter through the passageway and tissues cut are removed through an aspiration passageway ...." (Doc. 61, Ex. E, Bates X0275228.) Xomed's patent attorney amended the application to add claim 23 and filed a response in which he distinguished Middle et al. by explaining:

Since irrigation fluid discharged from orifice 112 in the distal end 60 of sheath 50 is supplied to the surgical area forwardly or in front of the distal end 60, no positive step is taught or suggested by Middle et al. of supplying the irrigation fluid to the tissue cutting edges 116, which are disposed within sheath 50 proximally of distal end 60 (Fig.10)....

...

In addition to the foregoing deficiencies, Middle et al. fail to disclose the step of supplying irrigation fluid from the fluid passage directly to the tissue cutting surface in that orifice 112 [of the Middle patent] is not adjacent the tissue cutting edges 116 (Fig.10) [of the Middle patent]. In Middle et al, irrigation fluid is supplied from the orifice 112 adjacent the distal end 60 of sheath 50 and is not supplied from the orifice 112 directly to the cutting edges 116 as is required for the supplying step recited in independent claim 23. Accordingly, independent claim 23 is submitted to be clearly patentable over Middle et al and should be allowed.

(Doc.61, Ex. E, Bates X0275236-238 (emphasis in original.) Persuaded by this response, the examiner thereafter withdrew his objection, closed prosecution on the merits, and issued a notice of allowability.FN9

FN9. At the hearing, counsel for Xomed represented that the '957 Patent "revolutionized sinus surgery" and that "today the overwhelming majority of sinus surgeons use the method of the '957 Patent. It represented a sea change in sinus surgery." (Doc. 76, 8:38-40, 52-56.)

III. *The Claims*

In the '957 Patent, claims 21, 22, and 23 were issued as claims 1, 2, and 3 respectively. Claims 1 and 3 are independent; claim 2 is dependent on claim 1. FN10 Claim 1 recites (with emphasis on the claim terms and phrases that the parties present for construction):

FN10. "A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.... [A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. s. 112 para.para. 3-4.

1. A method of performing *sinus surgery* utilizing a *sinus debrider instrument* having an outer tubular member with an opening at a *distal end* thereof, an inner member ratably disposed within the outer tubular member with a *tissue cutting surface* of the inner member adjacent the opening in the outer tubular member, and an *annular space* between the outer tubular member and the inner member forming a *fluid passage* to *deliver fluid to the tissue cutting surface,* said method comprising steps of
positioning a *distal end* of the *sinus debrider instrument* at an *operative site within a sinus:*

cutting *tissue* at the operative site within the *sinus* with the *tissue cutting surface* by rotating the inner member relative to the outer tubular member;

removing *tissue* cut by the *tissue* cutting surface from the *sinus* through a *suction passage* in the *sinus debrider instrument;* and

supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument to facilitate the removing of cut tissue from the sinus.

(Doc. 41, Ex. A, Col. 6, Lines 17-37 (emphasis added).) Claim 2 recites: "The method of performing *sinus surgery* as recited in claim 1 wherein *the inner member is tubular and has a lumen therein* and wherein said step of removing cut *tissue* from the *sinus* includes *aspirating the cut tissue through the lumen* in the inner tube." (Doc. 41, Ex. A, Col. 6, Lines 38-42 (emphasis added).) Claim 3 is identical to claim 1, except that it adds the following phrase at the end: "*said step of supplying fluid including supplying fluid from the fluid passage directly to the tissue cutting surface*." (Doc. 41, Ex. A, Col. 6, Lines 63-65 (emphasis added).)

IV. *Claims Construction*

A. *Construction of Disputed Claim Terms and Phrases*

1. Construction of "Sinus"

Xomed's Proposed Construction	Gyrus's Proposed Construction
Any of various air-filled cavities in the bones of the skull, especially one communicating with the nostrils.	A cavity, recess, or depression in an organ, tissue or other part of the body.

Independent claims 1 and 3 recite a method of performing "sinus surgery." The parties agree to a proposed construction of "sinus surgery" as "a surgical operation or procedure involving the removal of tissue from the sinus on which the operation or procedure is being performed." (Doc. 62.) They disagree, however, on a proposed construction of "sinus," with Xomed arguing for a narrow construction and Gyrus arguing for a broad construction.FN11

FN11. Xomed asserts that Gyrus wants a broad construction in order to envelop certain prior art related to

surgery performed in other areas of the body and thus support its invalidity defense. The Court notes this, but applies the Federal Circuit's caution to refrain from the temptation to "put the validity cart before the claim construction horse." Nazomi, 403 F.3d at 1369.

Xomed asserts that its narrow construction provides the ordinary and accustomed meaning of "sinus." Xomed points out that the '957 Patent uses "sinus" in conjunction with "surgery," and that "sinus surgery" communicates surgery related to cavities that communicate with the nostrils as opposed to surgery in other body cavities. Xomed also points to narrow definitions of "sinus" found in dictionaries. Xomed asserts that to the extent there is any ambiguity over the meaning of "sinus," the specification resolves the ambiguity in favor of its proposed construction as the specification teaches away from art relating to surgery in other body cavities:

Generally in the field of sinus surgery, arthroscopic cutting instruments have been used which instruments have encountered numerous problems, the primary one being that instruments clog or jam from tissue buildup as there is little fluid present at the sinus surgery site unlike the abundance of fluid which occurs in the joints of a human being. Furthermore, when fluid is used with such instruments, it is excessively applied at the surgical site.

...

It should be noted that in arthroscopic surgery, there is normally a great deal of fluid present at the site of the surgery so that fluid is not required, but in sinus surgery which is the primary direction of the present invention, there is little moisture, so moisture must be supplied to keep the tissue material from clogging up the device.

(Doc. 41, Ex. A, Col. 1, Lines 18-25; Col. 2, Lines 41-46.) Xomed further asserts that the specification informs the reader that the patent is seeking to address two problems with arthroscopic devices for sinus surgery-that there is little fluid at the operative site which leads to clogging or jamming of instruments and that the arthroscopic devices apply more fluid to the operative site than appropriate for sinus surgery. Xomed argues that these problems are relevant only because the sinuses in the skull that communicate with the nostrils do not contain fluid and because too much fluid in those sinuses can choke or drown a patient.

Gyrus counters with the broad definition of "sinus" that appears alongside the narrow definition in medical dictionaries. Gyrus argues that neither the claim language nor the specification limit "sinus" to a sinus in the skull that communicate with the nostrils. Gyrus points out, moreover, that the specification states that the "invention generally relates to the field of tissue removal" (Doc. 41, Ex. A, Col. 1, Lines 12-13), which Gyrus contends supports a broad meaning of "sinus."

Many of the dictionary entries for "sinus" offered by the parties present multiple meanings. One of these definitions is the narrow one proposed by Xomed; one is the broad one proposed by Gyrus. For example, *Meriam-Webster's Medical Desk Dictionary* defines "sinus" as:

a cavity or hollow in the body: as a: a narrow elongated tract extending from a focus of suppuration and serving for the discharge of pus ... **b** (1): a cavity in the substance of a bone of the skull that usu. communicates with the nostrils and contains air (2): a channel for venous blood (3) a dilation in a bodily canal or vessel

MERIAM-WEBSTER'S MEDICAL DESK DICTIONARY 759 (2002). This definition, and those found in other dictionaries, do not limit "sinus" to one meaning.

When a claim term has multiple dictionary definitions, the Court should review the intrinsic evidence to identify which of the definitions is most consistent with the use of the words of the applicant. *See* Brookhill-Wilk 1, LLC, v. Intuitive Surgical, Inc., 334 F.3d 1294, 1300 (Fed.Cir.2003) ("ln construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor."); *see also* Renishaw, 158 F.3d at 1250 (explaining that a court may resort to the specifications if a claim term lends itself to several common meanings; in such a situation "the patent disclosure serves to point away from the improper meanings and toward the proper meaning"). "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Id*. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id* .

The Court agrees with Xomed's proposed construction and construes the term "sinus" in the '957 Patent as "any of various air-filled cavities in the bones of the skull, especially one communicating with the nostrils." The patent's use of "sinus" in conjunction with "surgery," which ordinarily connotes surgery relating to sinuses in the skull that communicate with the nostrils, together with the specification that states that the '957 Patent seeks to address the very problems encountered in such surgeries when ordinary arthroscopic surgery instruments are used, demonstrate that the narrow meaning was both intended and conveyed.

2. Construction of "Distal End"

Xomed's Proposed Construction	**Gyrus's Proposed Construction**
The end which is remote, or farther from the point of reference, as opposed to proximal.	Tip portion

Independent claims 1 and 3 recite: "a sinus debrider instrument having an outer tubular member with an opening at a *distal end* thereof" and "positioning a *distal end* of the sinus debrider instrument at an operative site within a sinus." (Doc. 41, Ex. A, Col. 6, Lines 17-19, 26-27, 43-45, 52-53 (emphasis added).) Again, the parties argue whether "distal end" should be construed in a narrow or broad way; this time Xomed is arguing for the broad construction and Gyrus is arguing for the narrow construction.FN12

FN12. Xomed asserts that Gyrus seeks a narrow construction so that it can argue that its device, which has an opening on the side of the distal end of the outer tubular member, does not meet this claim limitation.

Xomed asserts that "tip portion," as proposed by Gyrus, is limited to the farthest end or "absolute extremity" while "distal" connotes something that is farther as opposed to closer. (Doc. 61, p. 12.) Xomed asserts that its proposed construction accords with the ordinary meaning of "distal end," pointing to dictionary definitions that define "distal" as: "anatomically located far from a point of reference, such as an origin or a point of attachment," THE AMERICAN HERITAGE DICTIONARY 540 (3d ed.1992), and as: "remote;

farther from any point of reference; opposed to proximal," DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 534 (29th ed.2000).

Gyrus responds that Xomed's construction begs the questions: "Remote from what? What point of reference?" (Doc. 60, p. 24.) Relying on figures in the drawings sheets, Gyrus argues that the specification uses the terms "distal portion," "distal end," and "distal tip" synonymously to mean "tip portion." Gyrus points out that the "distal portion" of coupler member 62 has a bore of 70, shown in figure 13 as:

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(Doc. 41, Ex. A.) Gyrus argues that it is clear from the description and figure 13 that "distal portion" means "tip portion." Gyrus further points out that cutting tube 110 has knurled "distal end portion 114" and a "distal cutting tip 112," both of which are tip portions of cutting tube 110, shown in figure 15 as:

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(Doc. 41, Ex. A.)

Xomed responds that the "point of reference" in its proposed construction is apparent when the context of the claims is considered. Xomed asserts that the "point of reference for a surgical method and device is the physician's hand. It's the doctor holding [the] device. The proximal end is the end closer to his hand. And the distal end is that farther away." (Doc. 76, 83:42-48.) Xomed asserts that Gyrus's proposed construction is the one that would raise a "point of reference" concern because the device pictured in figure 1 of the patent has two "tip portions":

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(Doc. 41, Ex. A.) Xomed argues that defining "distal end" as "tip portion" would create confusion in determining which of the "tip portions" in figure 1 is the "distal end."

The Court agrees with Xomed's construction and construes the term "distal end" in the '957 Patent as "the end which is remote, or farther from the point of reference, as opposed to proximal." The Court finds that this construction incorporates the ordinary meaning of "distal end" and that the specification does not indicate that "distal end" is used in a manner inconsistent with its ordinary meaning or intended to mean only the tip portion. *See* SmithKline, 403 F.3d at 1339 ("Unless the intrinsic evidence compels a contrary conclusion, the claim language carries the meaning accorded those words in the usage of skilled artisans at the time of invention."). The Court also agrees with Xomed that defining "distal end" as "tip portion" could cause confusion. This would be counterproductive to the claim construction process, which seeks to apply an unambiguous meaning to the claims. *See* Chimie, 402 F.3d at 1377.

3. Construction of "Annular Space"

Xomed's Proposed Construction	**Gyrus's Proposed Construction**
A space that is shaped like or forming a ring.	The space between the outer tubular member and the inner tubular member is shaped like or forms a ring in the cross section.

Independent claims 1 and 3 recite "a sinus debrider instrument having an outer tubular member ... an inner member rotatably disposed within the outer tubular member ... and an *annular space* between the other tubular member and the inner member forming a fluid passage ...." (Doc. 41, Ex. A, Col. 6, Lines 18-24, 44-50 (emphasis added).)

At the hearing, counsel for Xomed indicated that he did not think the term "annular space" needed construction, but since Gyrus asserted that it did, Xomed was proposing a construction based on the ordinary and accustomed meanings of "annular" and "space." Xomed cites a definition of "annular" as "shaped like or forming a ring." THE AMERICAN HERITAGE DICTIONARY 540 (3d ed.1992). Xomed argues that Gyrus's construction "confuses what is otherwise a simple and unambiguous construction." (Doc. 61, p. 13-14.) Xomed argues further that Gyrus's proposed construction improperly imports a limitation that the inner member be tubular.

Gyrus argues that the dictionary definition proposed by Xomed is only correct in the context of the '957 Patent if a cross-sectional slice of the annular space is considered. According to Gyrus, the use of "space" with "annular" adds "a three dimensional component in that the annular space has a length along the coaxial tubes" or, as counsel for Gyrus stated at the hearing, "annular space travels the length of the blade." (Doc. 76, 90:26.) Gyrus asserts that Xomed's construction ignores the word "space" and the modifier " 'between the outer tubular member and the inner tubular member." (Doc. 60 p. 26.)

The Court agrees with Gyrus's construction and construes the term "annular space" in the '957 Patent as "the space between the outer tubular member and the inner tubular member is shaped like or forms a ring in the cross section." This construction accounts for the claim language that the "annular space" is the fluid passage formed by the inner and outer members, which necessarily includes a three dimensional component. Given Xomed's position at the hearing that a ring can be irregularly shaped, the Court does not agree that Gyrus's proposed construction limits the inner member to a tubular shape.

4. Construction of "Supplying Fluid to the Tissue Cutting Surface Through the Fluid Passage in the Sinus Debrider Instrument"

Xomed's Proposed Construction	Gyrus's Proposed Construction
Providing fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument such that fluid remains essentially within the instrument to be removed through the suction passage.	Making fluid available through the fluid passage such that the fluid reaches as far as the tissue cutting surface while remaining essentially within the instrument to be removed through the suction passage. This claim limitation excludes supplying fluid beyond the tip of the instrument to the surgical area located outside the instrument.

Independent claims 1 and 3 recite a step of "supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument." (Doc. 41, Ex. A, Col. 6, Lines 35-36, 61-62.) The parties dedicated much of their briefs and hearing time to the construction of this phrase and the phrase "deliver fluid to the tissue cutting surface" discussed in section IV(A)(5) immediately below.

In its initial claims construction brief, Xomed proposed a different construction of the phrase from the one it now proposes, as set forth in the box above. Xomed initially had asserted that the term "essentially" in the construction proposed by Gyrus was too indefinite as "one of ordinary skill may not know how much fluid must reach the operative site before this limitation is avoided." (Doc. 61, p. 20.) However, in its responsive brief and at the hearing, Xomed asserted that it accepted the term "essentially" in Gyrus's proposed construction after learning that "essentially" had an understood meaning of "less than perfect" in the patent context. Xomed would like the word "essentially" in its proposed construction to speak for itself to mean "less than perfect" in order to convey that fluid is intended for the tissue cutting surface, but that an incidental amount may go beyond the tissue cutting surface to the operative site. Xomed asserts that Gyrus actually agrees with Xomed's position, citing Gyrus's responsive brief in which Gyrus indicated: "Stated differently, the words 'remains essentially within the instrument' simply mean that there can be less than perfect containment of the fluid in the instrument." (Doc. 68, p. 15.) Xomed disagrees only with Gyrus's proposed inclusion of the phrase: "[t]his claim limitation excludes supplying fluid beyond the tip of the instrument to the surgical area located outside the instrument," arguing that Gyrus is attempting to improperly import a limitation into the claims.

Gyrus makes several arguments in support of the inclusion of this phrase. First, Gyrus asserts that dictionary definitions and Federal Circuit precedent support its proposed construction. Gyrus points to the definition of "to" as "reaching as far as," THE AMERICAN HERITAGE DICTIONARY 1274 (2d coll. ed.1982), and to Cybor Corp., 138 F.3d at 1451, 1458-59, and Application of Gabrielsen, 41 C.C.P.A. 942, 213 F.2d 545, 546 (C.C.P.A.1954), for the proposition that "to" should be construed to convey that something reaches a destination without going further.

Second, Gyrus points to the portion of the abstract that states, "to facilitate the removal of the cut tissue *without introducing fluid to the operative site*." (Doc. 41, Ex. A (emphasis added).) Gyrus cites to Tate Access Floors, Inc. v. Maxcess Techs., Inc., 222 F.3d 958, 965 n. 2 (Fed.Cir.2000), for the proposition that "in determining the scope of a claim, the abstract of a patent is a potentially useful source of intrinsic evidence as to the meaning of a disputed claim term."

Third, Gyrus argues that claim construction must consider the purposes or objectives of the invention. Gyrus points out that the '957 Patent sought to solve the problem of jamming or clogging of conventional

arthroscopic cutting instruments when used for sinus surgery and the related problem of excessively applying fluid at the surgical site by delivering fluid to the tissue cutting surface and not beyond. According to Gyrus, Xomed's proposed construction addresses the first problem (clogging) but not the second problem (excessive fluid).

Fourth, Gyrus argues that the doctrine of prosecution disclaimer applies. Gyrus argues that although Xomed's patent attorney deleted, at the examiner's suggestion, the limitation in claims 21 and 22 "without introducing fluid to the operative site," Xomed's patent attorney also traversed the examiner's rejection by stating that the step of supplying fluid to the tissue cutting surface implied that fluid would not reach the operative site. And, Gyrus says, Xomed's patent attorney later distinguished Middle et al. by relying on the very limitation that it had deleted. Gyrus cites Omega Enq'r, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed.Cir.2003) (quotations omitted), for the proposition that "explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim," and Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 835 (Fed.Cir.2003), for the proposition that a limitation that has been deleted during the prosecution history may nevertheless apply to the claims if the applicant clearly indicated during the prosecution history that the limitation still applies.

The Court is unpersuaded by Gyrus's arguments and agrees with Xomed that including the phrase "This claim limitation excludes supplying fluid beyond the tip of the instrument to the surgical area located outside the instrument" in the claim construction would add a limitation to the claims without justification. Preliminarily, the Court declines Gyrus's invitation to construe "to" to mean "reaching as far and no further" on the basis that two other patent cases may have construed "to" in a similar manner. While some transition words or phrases may have well-accepted meanings in the patent world, *see, e.g.,* Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc., 246 F.3d 1336, 1347-48 (Fed.Cir.2001), the Court does not think that the word "to" has any such a well-accepted meaning. As the Federal Circuit has explained, "A particular term used in one patent need not have the same meaning when used in an entirely separate patent ... Even absent an express definition of a term in the specification or prosecution history, or a clearly established understanding of the meaning of the term in the art, the manner in which the term is used in the patent may dictate a definition that differs from the definition that would be given to the same term in a different patent with a different specification or prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1318 (Fed.Cir.2005).

The manner in which the phrase "supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument" is used in the '957 Patent does not dictate a limitation that fluid does not go beyond the instrument. As Xomed points out, during the prosecution history, Xomed's patent attorney deleted the words "without introducing fluid to the operative site" from claims 21 and 22 (which became claims 1 and 2 respectively) while at the same time explaining that the fluid would be delivered to the tissue cutting surface "such that the fluid remains essentially within the instrument to be removed through the suction passage." (Doc. 61, Ex. E, Bates X0275219.) The construction now proposed by Xomed captures exactly what Xomed's patent attorney told the examiner. It is clear that there was recognition that the invention intended fluid to go to the tissue cutting surface but recognized, through the deletion, that an incidental amount of fluid might go beyond the instrument. As explained by Xomed, keeping the phrase "to facilitate the removal of the cut tissue without introducing fluid to the operative site" in the abstract after the deletion of "without introducing fluid to the operative site" from the claims was an oversight. It does not, as Xomed points out, serve to add a limitation to the claim. Moreover, Xomed's patent attorney distinguished Middle et al. on the ground that Middle et al. was designed such that fluid goes only to the surgical site and, therefore, not to the tissue cutting surface. The Court agrees with Xomed that this distinction was nothing

more than Xomed's patent attorney pointing out that the structure of the Middle et al. patent does not allow it to meet the limitation of "supplying fluid from the fluid passage directly to the tissue cutting surface." By reminding the examiner that, under the '957 Patent claims, fluid must be supplied to the tissue cutting surface, it was not disavowing any construction that would permit some fluid to go beyond the tissue cutting surface. The Court does not find that Xomed's patent attorney "has unequivocally disavowed a certain meaning to obtain [the] patent," and therefore concludes that the doctrine of prosecution disclaimer does not apply. *See* Omega, 334 F.3d at 1324.

Finally, while the Court agrees with Gyrus that claim construction should take into account the purposes or objectives of the invention, the Court disagrees with Gyrus that a construction that does not include a limitation that fluid does not go beyond the instrument fails to account for the problem of excessive fluid to the surgical site sought to be addressed by the invention. The invention sought to address "excessive" fluid to the surgical site and not to eliminate any and all fluid from being introduced to the surgical site. (Doc. 41, Ex. A, Col. 1, Line 24.)

To summarize, the intrinsic evidence as a whole accords with the construction proposed by Xomed. The Court notes that the term "supplying" does not need to be construed as "providing" since the terms are synonymous. Accordingly, the Court construes "supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument" as "supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument such that fluid remains essentially within the instrument to be removed through the suction passage."

5. Construction of "Deliver Fluid to the Tissue Cutting Surface."

Xomed's Proposed Construction	**Gyrus's Proposed Construction**
Transport fluid to the tissue cutting surface	To send fluid to the tissue cutting surface and not beyond the tissue cutting surface.

The preamble of independent claims 1 and 3 recites, "an annular space between the outer tubular member and the inner tubular member forming a fluid passage to *deliver fluid to the tissue cutting surface* ...." (Doc. 41, Ex. A, Col. 6, Lines 22-24, 48-50 (emphasis added).) The parties agree to a proposed construction of "tissue cutting surface" as "that portion at the distal end of the inner member of the sinus debrider instrument which performs the tissue cutting function." (Doc. 62.) The parties disagree on the construction of "deliver" and whether the limitation "and not beyond the tissue cutting surface" should be included in the construction. For the reasons stated in section IV(A)(4) immediately above, the Court will not include the phrase "and not beyond the tissue cutting surface" as proposed by Gyrus. The Court will focus on the claim term "deliver."

Xomed argues for a passive construction of "deliver," pointing out that the term is used with reference to the route that the fluid travels and not with reference to someone or something acting on the fluid. Xomed explained at the hearing that the only agent acting on the fluid is gravity or a pump, neither of which are relevant to the claim, which focuses on the method of containment of the fluid introduced to the tissue cutting surface. Xomed references the definition of "transport" as "to carry from one place to another; convey," THE AMERICAN HERITAGE DICTIONARY 1903 (3d ed.1992), and asserts that this definition accurately portrays the idea in the claim; i.e., that fluid is conveyed or carried along the fluid passage. Xomed argues Gyrus's proposed use of "send" as "to cause to be conveyed by an intermediary to a

destination," THE AMERICAN HERITAGE DICTIONARY 1642 (3d ed.1992), improperly implies action by some outside force.

Gyrus argues for an active construction of "deliver," pointing to the dictionary definition of "deliver" as "to send to an intended goal or target" and "to take to the intended recipient," THE AMERICAN HERITAGE DICTIONARY 378 (2d coll. ed.1982), and contends that there are no dictionary definitions to support Xomed's use of "transport." Gyrus argues that, contrary to Xomed's assertion, the fluid passage does act on the fluid in that the "walls of the inner and outer members that define the annular space *constrain* the fluid, thus conveying or carrying it to its destination, the tissue cutting surface." (Doc. 68, p. 10-11.)

The Court agrees with Xomed that the intrinsic evidence indicates that the annular space is passive in nature, serving only to contain the fluid that is being delivered to the tissue cutting surface, but the Court is not convinced that "transport" necessarily conveys passivity. The Court believes that "deliver," "transport," and "send" mean essentially the same thing in this context. Accordingly, the Court construes "deliver fluid to the tissue cutting surface" in the '957 Patent as "to contain fluid being delivered to the tissue cutting surface."

6. Construction of "To Facilitate the Removing of Cut Tissue From the Sinus"

Xomed's Proposed Construction	**Gyrus's Proposed Construction**
To make easier the process of removing cut tissue from the sinus.	Fluid is supplied to the tissue cutting surface to reduce clogging caused by the tissue at the tissue cutting surface.

Independent claims 1 and 3 recite, "supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument *to facilitate the removing of cut tissue from the sinus*." (Doc. 41, Ex. A, Col. 6, Lines 35-37, 61-63.)

Xomed does not believe this phrase needs construction and would be content to let the phrase speak for itself but, to the extent the phrase needs construction, says that "facilitate" simply means to make easier. Xomed argues that Gyrus, through its proposed construction, "is attempting to import a benefit, or convert, rather, a benefit of the invention [set forth in the specification], namely that it reduces clogging, into a claim limitation." (Doc. 76, 86:14-18.)

Gyrus contends that the claim language, the specification, and the prosecution history support its construction. Gyrus argues that the phrase, "to facilitate" modifies the step "supplying fluid to the tissue cutting surface." Gyrus further argues that the background of the invention in the '957 Patent describes the problem of instruments clogging or jamming from tissue build-up, and teaches that reducing the clogging at the tissue cutting surface "facilitates" the removal of cut tissue from the sinus." Finally, Gyrus points out that Xomed told the PTO that the references in the '957 Patent specification to supplying fluid to the "surgical site" actually relate to fluid supplied to the tissue cutting surface rather than to the operative site within the sinus because, according to Gyrus, supplying fluid to the tissue cutting surface reduces clogging at the tissue cutting surface, which facilitates the removal of cut tissue from the sinus.

The Court agrees with Xomed and finds that the phrase "to facilitate the removing of cut tissue from the sinus" in the '957 Patent does not need construction. The claim term "facilitate" speaks for itself. The intrinsic evidence does not compel the limitation sought by Gyrus. *See* Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002) (explaining that presumption in favor of dictionary definition will be overcome when patentee serves as own lexicographer or uses "words or expressions of manifest

exclusion or restriction, representing clear disavowal of claim scope").

7. Construction of "Said Step of Supplying Fluid Including Supplying Fluid From the Fluid Passage Directly to the Tissue Cutting Surface"

Xomed's Proposed Construction	Gyrus's Proposed Construction
Said step of supplying fluid including supplying fluid from the fluid passage in a direct line or manner to the tissue cutting surface.	In the "supplying fluid" step (defined above), the fluid is delivered from the fluid passage immediately adjacent to the tissue cutting surface.

Independent claim 3 is identical to claim 1 except that it adds at the end, "said step of supplying fluid including supplying fluid from the fluid passage *directly* to the tissue cutting surface." (Doc. 41, Ex. A, Col. 6, Lines 63-65 (emphasis added).) The parties agree that their dispute here focuses on the word "directly ."

Xomed asserts that its construction should be used because it is based on the ordinary and accustomed definition of "directly" as "in a direct line or manner; straight." THE AMERICAN HERITAGE DICTIONARY 527 (3d ed.1992). Gyrus does not disagree with this definition, but argues that Xomed narrowed the ordinary meaning of "directly" during the prosecution by taking the position that "directly" requires an "adjacent" location. Gyrus cites the following portion of the prosecution history in which Xomed's patent attorney sought to distinguish Middle et al.:

In addition to the foregoing deficiencies, Middle et al fail to disclose the step of supplying fluid from the fluid passage directly to the tissue cutting surface in that orifice 112 [of the Middle patent] is not adjacent the tissue cutting edges 116 (Fig.10) [of the Middle patent]. In Middle et al, irrigation fluid is supplied from the orifice 112 adjacent the distal end 60 of sheath 50 and is not supplied from the orifice 112 directly to the cutting edges 116 as is required for the supplying step recited in independent claim 23 [which issued as claim 3 of the '957 Patent] According, independent claim 23 is submitted to be clearly patentable over Middle et al and should be allowed.

(Doc. 61, Ex. E, Bates X0275238 (emphasis in original).) Gyrus also argues that its construction is consistent with the use of the word "adjacent" in the preambles of claims 1 and 3. Gyrus asserts that it is used in a locational sense to recite that the tissue cutting surface of the inner member is adjacent the opening of the outer tubular member and the outlet of the fluid passage is adjacent the tissue cutting surface for supplying fluid directly to the tissue cutting surface.

The Court rejects Gyrus's arguments. In distinguishing Middle et al., Xomed's patent attorney explained to the examiner that the structure of the device in Middle et al. precluded fluid from being supplied directly to the tissue cutting surface. For fluid to be supplied directly to the tissue cutting surface in the Middle et al. device, the orifice from which the fluid was supplied would have had to be adjacent to the tissue cutting surface. As Xomed points out, claim 3 in the '957 does not include a limitation that fluid be delivered from a point adjacent to the tissue cutting surface; it need only be supplied directly to the tissue cutting surface. The Court does not find that the prosecution history or the preamble compels the limitation that Gyrus seeks to add. The Court finds that the phrase "said step of supplying fluid including supplying fluid from the fluid passage directly to the tissue cutting surface" in the '957 Patent does not need construction. The construction of "directly" as "in a direct line or manner" does not serve to clarify or give a contextual meaning to the phrase. Counsel for Xomed conceded as much at the hearing.

B. ***Jointly Proposed Claim Term Constructions***

The parties agree with proposed constructions of the remaining nine claim terms and phrases. The Court finds that construction of these claim terms and phrases is warranted and that the jointly proposed constructions are supported by the intrinsic evidence. Accordingly, the Court construes these claims terms and phrases as follows:

TERM/PHRASE	CONSTRUCTION
"Sinus surgery"	A surgical operation or procedure involving the removal of tissue from the sinus on which the operation or procedure is being performed.
"Sinus debrider instrument"	A tool used for the surgical cutting and removal of tissue from the sinus on which the operation or procedure is being performed.
"Tissue"	An aggregation of similar cellular matter.
"Fluid passage"	A path, channel, or duct through or along which fluid may pass.
"Operative site within a sinus"	That location within the sinus where the surgical operation is performed.
"Suction passage"	A path, channel, or duct through or along which a fluid and/or solid may pass as a result of a suction force.
"The inner member is tubular and has a lumen therein"	The inner member is a hollow cylinder that has an inner open space or cavity.
"Aspirating the cut tissue through the lumen."	Removing the cut tissue through the inner open space or cavity by suction.

V. ***Conclusion***

A. It is **HEREBY ORDERED** that the meaning and scope of the patent claims presented by the parties for construction are determined by the Court as set forth in this order.

B. The Court expects that the parties will engage in a mediation conference with Brian Gilchrist, the appointed mediator, within 45 days of this order, as they represented they would do at the April 21, 2005 hearing.

C. A telephone status conference to discuss dispositive motion deadlines, pre-trial deadlines, and a trial term will be held on **July 18, 2005 at 1:30 p.m.** before the undersigned. **Counsel for Xomed shall initiate the telephone conference by first contacting counsel for Gyrus then calling the Court's audio conference number at (904) 549-1949.**

DONE AND ORDERED.

M.D.Fla.,2005.
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