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

MEDTRONIC XOMED, INC,
Plaintiff/Counter Defendant.
v.
GYRUS ENT LLC,
Defendant/Counterclaimant.

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

Aug. 1, 2006.

Background: Patentee brought action against competitor, alleging infringement of patent describing a method and an instrument for performing sinus surgery using a powered sinus debrider instrument with blades. Parties filed cross motions for summary judgment on patentee's claims and competitor's affirmative defenses and counterclaims asserting that patent was invalid and unenforceable.

Holdings: The District Court, Corrigan, J., held that:
(1) summary judgment in favor of competitor was precluded on patentee's claims for direct infringement, contributory infringement, indirect infringement, and wilful infringement;
(2) neither party was entitled to summary judgment on competitor's anticipation defense and counterclaim;
(3) patentee was not entitled to summary judgment on competitor's derivation defense and counterclaim;
(4) neither party was entitled to summary judgment on competitor's invalidity counterclaim and defense;
(5) claims of patent were not invalid for indefiniteness; and
(6) summary judgment in favor of competitor was precluded on its infringement defense and counterclaim that patent was unenforceable because of patentee's alleged inequitable conduct.

Plaintiff's motion granted in part and denied in part; defendant's motion denied.

6,293,957. Cited.

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

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

ORDER FN1

FN1. Under the E-Government Act of 2002, this is a written opinion and therefore is available electronically. However, it is intended to decide the motions addressed herein and is not intended for official publication or to serve as precedent.

CORRIGAN**, District Judge.**

This Order addresses the parties' cross motions for summary judgment filed in this patent infringement case involving a sinus surgical instrument and method of performing sinus surgery. Specifically, before the Court are Defendant's Motion for Summary Judgment (Doc. 161-2) and Plaintiff Medtronic Xomed Inc.'s Motion For Summary Judgment On Defendant's Section '02, '03 and 112 Defenses And Counterclaim. (Doc. 147-1.) The parties have filed multiple legal memoranda addressing the motions (Docs.161-2, 174-1, 187, 147-1, 170, 186-1), and voluminous exhibits (see Docs. 144, 147, 155, 156, 166, 167, 174, 181, 182), which the Court has reviewed. The Court held oral argument on the motions on May 25, 2006.

I. *BACKGROUND*

Plaintiff Medtronic Xomed, Inc. ("Xomed"), alleges that Gyrus ENT LLC ("Gyrus") is infringing on its U.S. Patent No. 6,293,957 (filed Jan. 26, 1999)(issued Sept. 25, 2001) ("'957 Patent") entitled "Method of Performing Sinus Surgery Utilizing & Sinus Debrider Instrument." FN2 (Doc. 41-1.) Xomed alleges that Gyrus has used, sold, offered for sale and/or distributed allegedly infringing products, the ESSential(R) Shaver System (also used with the Turbo 7000) and Diego Powered Dissector System, and that Gyrus' actions constitute direct, contributory, and willful infringement, and inducement to infringe under 35 U.S.C. s. 271. (Doc. 41-1, para.para. 8, 12, 15.) Gyrus denies the allegations, asserts that the ' 957 Patent is invalid, and alleges that the patent is unenforceable because of Xomed's alleged inequitable conduct. (Doc. 119.) The Court has construed the ' 957 Patent claims. (Doc. 77.)

FN2. Xomed represents that it is the assignee of the '957 Patent. (See Doc. 144, Ex. 1)

As told by the parties, the '957 Patent describes a method and an instrument for performing sinus surgery using a powered sinus debrider instrument with blades, having a tube-within-a tube design. The rotating inner tube with blades is encased within a stationary outer tube. Unwanted tissue is dissected from the surgical site by a cutting surface at the end of the rotating inner tube; the instrument provides a suction passage through it for removing cut tissue from a sinus.FN3 Irrigating fluid is supplied to the tissue cutting surface through the annular space between the two tubes, such that the irrigating fluid "remains essentially within" the instrument during the dissection of the tissue, "to facilitate the removal of cut tissue without introducing fluid to the operative site." (Docs. 144, Ex. 1 ("Abstract"), 77 at 30; *see also* Doc. 161-2 at 13.) The debrider was designed to alleviate the problem caused when the arthroscopic surgical cutting instruments used in sinus surgery "clog or jam from tissue buildup as there is little fluid present at the sinus surgery site," and to account for the problem of excessive fluid to the surgical site when fluid is used with such instruments. (Doc. 144, Ex. 1, col.1, ll.17-26.)

FN3. "[S]eparate passageways for suction and fluid are provided in the invention." (Doc. 144, Ex. 1, col.2, ll.39-40.)

The application for the '957 Patent was filed with the Patent and Trademark Office ("PTO") on January 26, 1999. (Doc. 77 at 6.) FN4 The ' 957 patent was issued by the PTO September 25, 2001. (Doc. 144, Ex. 1, Ex. 16, para. 14.)

FN4. The PTO prosecution history of the '957 Patent is set forth in the Court's Claim Construction Order. (Doc. 77 at 6-11.)

The '957 Patent makes three claims:

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 rotatably disposed within the outer tubular member with a tissue cutting surface of the inner member adjacent to 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.

2. 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 member.

3. 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 the 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, said step of supplying fluid including supplying fluid

from the fluid passage directly to the tissue cutting surface.

(Doc. 244, Ex. 1, Col. 6, Lines 17-65.)

The Court construed the language "supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument," found in claims 1 and 3 of the '957 Patent, 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.

(Doc. 77 at 30.)

Gyrus and its predecessor have made, sold and distributed three basic debrider systems, consoles, hand pieces, and blades named the ESSential(R) Shaver System, Turbo 7000 and Diego(TM) Powered Dissector System surgical instruments. According to Xomed, the three instruments are essentially the same when used in sinus surgery. (See Docs. 41-1 at para. 8; 119 at para. 8; 155, S-6, Ex. 2, para. 12; 155, S-6, Ex. 12 at 94; 155, S-6, Ex. 13 at 81; 161-2 at 14 n. 2; 161-2 at 16 n. 4; 174-1 at 12.) The ESSential and Turbo 7000 debrider systems were distributed by Gyrus prior to and after the issuance of the '957 Patent on September 25, 2001. Gyrus began distributing the Diego debrider system in August 2002. (Doc. 155, S-6, Ex. 2, para. 13.) At issue is whether the Gyrus debrider systems are designed such that, when used to cut tissue in sinus surgery, they can be and are indeed used in such a manner so as to infringe upon Xomed's '957 patent.

II. ***Summary Judgment Legal Standard***

Summary judgment is appropriate in a patent case where the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc., 911 F.2d 670, 672-73 (Fed.Cir.1990)(citing Fed.R.Civ.P. 56(c)). "The party moving for summary judgment carries the burden of demonstrating the absence of any genuine issue of material fact, and that the party so moving is entitled to judgment as a matter of law." C.R. Bard, Inc., 911 F.2d at 672. "In ruling on a motion for summary judgment, the district court is required to view the evidence presented in a light most favorable to the nonmoving party and to draw all reasonable inferences in favor of the nonmoving party." C.R. Bard, Inc., 911 F.2d at 672. "[S]ufficient evidence must be forthcoming such as to allow a reasonable jury to return a verdict in favor of the nonmoving party." C.R. Bard, Inc., 911 F.2d at 673. "Summary judgment is therefore appropriate when there is no genuine issue of material fact or when, drawing all factual inferences in favor of the nonmoving party, no 'reasonable jury could return a verdict for the nonmoving party.' " Upsher-Smith Laboratories, Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1322 (Fed.Cir.2005). " 'In rendering a decision on a motion for summary judgment, a court must "view the evidence presented through the prism of the substantive evidentiary burden" that would inhere at trial.' " Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14, 20 (Fed.Cir.2000) (citation omitted).

III. ***The Parties' Claims and Defenses***

Xomed, in its Amended Complaint, alleges that Gyrus directly, contributorily, and willfully infringed upon the '957 patent, and that it induced others to infringe. (Doc. 41-1, para.para. 12, 15.) Gyrus has moved for summary judgment on Xomed's claims. (Doc. 161-2.) Both Gyrus and Xomed have moved for summary judgment on Gyrus' affirmative defenses and counterclaim asserting that the '957 Patent is invalid and unenforceable (Docs.147-1, 161-1). The Court will address each claim and defense, but will do so briefly

when it finds triable issues.

A. ***Direct Infringement***

Determining whether a patent has been infringed requires a two-step analysis of (1) claim construction and (2) comparison of the properly construed claims to the accused product. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995)(en banc), aff'd, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In this case, the first step of claim construction is completed. (Doc. 77.) In the second step of comparing claims, a patentee must show, by a preponderance of the evidence, that the accused device contains each limitation of the asserted claim (i.e. literally infringes) or an equivalent of each such limitation (i.e. infringes by equivalents). "To prove infringement, the patentee must show that the accused device meets each claim limitation, either literally, or under the doctrine of equivalents." Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1273 (Fed.Cir.2004).

[1] Gyrus argues that it is entitled to judgment as a matter of law because its products, the ESSential(R) Shaver System, Turbo 7000 and Diego(TM) Powered Dissector System surgical instruments do "not include the 'supplying step' of the 957 patent claims." (Doc. 161-2 at 14.) FN5 Gyrus argues that its instruments differ from '957 because "fluid continually exits the blades of the Diego [Gyrus] debrider systems and irrigates the surgical site," as compared to the Xomed sinus debrider, in which " 'fluid is intended for the tissue cutting surface, but that an incidental amount may go beyond the tissue cutting surface to the operative site.' " (Doc. 161-2 at 14-16 (and citing Claim Construction Order, (Doc. 77 at 25).)) Gyrus contends that while fluid "remains essentially within the [Xomed] instrument," according to Xomed's patent documents and this Court's claim construction, the fluid does not remain within the Diego [Gyrus] debrider systems when used in sinus surgery. (Doc. 161-2 at 15-16.)

FN5. Gyrus inserts in a footnote that none of its instruments infringe upon the '957 Patent under any theory "because it does not perform sinus surgery, or make, use or sell a method of performing sinus surgery." (Doc. 161-2 at 14 n. 1). Gyrus itself appears to recognize this assertion is without merit as a basis for summary judgment, acknowledging its debrider systems are indeed used in sinus surgery. (See Doc. 161-2 at 15.)

Gyrus relies upon the experimentation and reports of its experts, Dr. Daniel G. Becker, M.D., ("Dr.Becker"), a sinus surgeon, and Steven B. Kushnick, P.E., a registered professional engineer with expertise in fluid flow. Both simulated surgery and use of the Gyrus debrider instruments on a chicken breast, dying the irrigating fluid dark blue to illustrate its flow. Dr. Becker also performed experimentation on a cadaver head. Dr. Becker concluded that based on his experimental use of the Diego debrider,

irrigating fluid exited the window in the outer tube of the Diego debrider blade during these tests and irrigated the surgical site. Specifically, more than a few drops and more than an incidental amount of irrigating fluid left the tip of the Diego debrider blade during these tests. Rather, the irrigating fluid continuouslyexited the blade tip and wetted the surgical site.

(Doc. 144, Ex. 3, para. 19; *see also* Doc. 144, Ex. 6, para. 33 (conclusions of Steven B. Kushnick: "The irrigant continuously exited the blade tip. More than a few drops of irrigant exited the blade tip and wetted the tissue. Much more than an incidental amount of irrigant exited the blade tip").) Further, Dr. Becker testified that he "observed an amount of fluid that wet the tissue in a continuous way and ... it facilitated

cutting." (Doc. 182, Ex. 94 at 66.) "[I]t was functioning as described as a suction irrigator, that it was wetting the tissue in a functional way and allowing me-you know, facilitating cutting." (Id. at 68.) He later described it as more than "an inconsequential amount," more than a "drip or a drop;" "more than a few drips" exited the Gyrus debrider. (Id. at 311-12.)

Xomed refers to its expert Dr. Donald A. Leopold.FN6 In his expert report, Dr. Leopold said that based upon his testing and use of the Gyrus instruments, the ESSential, Diego, and the Turbo 7000, "[i]rrigating fluid is supplied to the tissue cutting surface through this fluid passage in the sinus debrider instrument such that fluid remains essentially within the instrument, to be removed through the suction passage." (Doc. 175, S-11, Ex. 1 at 14, 20.)

FN6. Gyrus urges the Court to not consider Dr. Leopold's opinion letter, citing Jones v. Menard, 559 F.2d 1282, 1285 n. 5 (5th Cir.1977) and Lugue v. Hercules, Inc., 12 F.Supp.2d 1351, 1357-58 (N.D.Ga.1997) for the proposition that unsworn expert reports should not be considered on summary judgment because they are not in the form of admissible evidence. (Doc. 187 at 7.) See Fed.R.Civ.P. 56(e). Neither the Federal Circuit or the Eleventh has ever cited the *Jones* case for this proposition Second, Gyrus submitted as support for its motion for summary judgment the December 2, 2005 deposition of Dr. Leopold in which the expert report was marked as an exhibit and Dr. Leopold identified the report. (Doc. 144, Ex. 11 at 7.) The Court finds that Dr. Leopold's report is properly before it in considering the motions for summary judgment.

Dr. Leopold disputes that the Gyrus debrider is different from the Xomed debrider, calling Gyrus' contention that its debrider irrigates the surgical site "illogical." " 'In a normal surgical setting, the flow of irrigating fluid must be set such that the vast majority of irrigating fluid reaches the tissue cutting surface and is then suctioned into the inner lumen of the blade without reaching the surgical site. If the flow of irrigating fluid exceeds that necessary to irrigate the tissue cutting surface, the surgical site will become flooded with the irrigating fluid....' " (Doc. 175, S-11, Ex. 1 at 25). Dr. Leopold observed that in cadaver dissection courses where he has used the system, "the irrigation settings controlled by the Gyrus company representatives were always set such that little or no irrigating fluid exited the instrument." (*Id*.)

Furthermore, Xomed argues that Gyrus' Diego device can be used such that "fluid remains essentially within the instrument, and that, as Gyrus is well aware, such manner of use is the way surgeons in fact use the device." (Doc. 174-1 at 11.) Xomed cites to the deposition testimony of Gyrus employee Perry Mykleby who worked on the Diego project, (Doc. 174-1 at 11) and who acknowledged that a surgeon can adjust the irrigation flow on the Diego (Gyrus) instrument so that the irrigation fluid could be provided to the blades only, and not to the surgical site. (Doc. 175, S-11, Ex. 2 at 228-29.) There is other disputed testimony of a similar sort.

A fact question emerges as to how much irrigating fluid flows from the Gyrus debrider during normal sinus surgery, and whether this is the equivalent of the Xomed debrider. The parties proffer competing expert testimony on this question. These differing conclusions create a genuine issue of material fact; drawing reasonable inferences in favor of Xomed, a reasonable juror could conclude that the Gyrus debriders infringed upon the '957 Patent. *See* Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052, 1079-80 (Fed.Cir.2005)(disagreement between experts may create genuine dispute for infringement if there is some foundation or basis for the opinion). Gyrus' motion for summary judgment as to direct infringement will be denied.

B. ***Contributory Infringement***

[2] Contributory infringement liability arises when one "sells within the United States ... a component of a patented machine ... constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. s. 271(c). The language of the contributory infringement statute "deals with the material actually sold by the accused and the uses made of it by its purchasers." Hodosh v. Block Drug Co., 833 F.2d 1575, 1578 (Fed.Cir.1987). "[O]nly proof of a defendant's knowledge, not *intent,* that his activity cause[s] infringement [is] necessary to establish contributory infringement." Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed.Cir.1990)(emphasis in original).

[3] [4] The "substantial, non-infringing use" defense to contributory infringement FN7 requires "a qualitatively significant noninfringing use ... before a defendant can be fully absolved from contributory infringement liability.... Whether a use is 'substantial' or not depends on how likely and often the use will occur." Hoffmann-La Roche, Inc. v. Promega Corp., No. C-93-1748-VRW, 33 U.S.P.Q.2d 1641, 1648, 1994 WL 761241 (N.D.Cal. June 13, 1994). This element additionally requires that the item sold not be a "staple article or commodity of commerce" suitable for such use. See 35 U.S.C. s. 271(c). A "staple" article of commerce " 'is one that was not specifically designed for use with a patented process [or combination] and has substantial, efficient, and feasible uses outside of the patent. If the practice of the patented method [or combination] is incidental and necessary to the practice of the unpatented methods, the device is a staple and there can be no contributory infringement.' " McKesson Information Solutions, Inc. v. Bridge Medical, Inc., Case No. CIV-S-02-2669, 2005 WL 2346919, at (E.D.Cal. Sept. 23, 2005)(citing 4 Patent Law Fundamentals s. 20:7 (citations omitted)). A finding of contributory infringement must be predicated on a direct infringement. C.R. Bard, Inc., 911 F.2d at 673.

FN7. Gyrus has denied that contributory infringement can be found with regard to its products, and asserts an affirmative defense to that effect. (Doc. 119, para. 12, and at 3 ("Second Affirmative Defense").) It does not specifically plead a defense to contributory infringement that its debriders have a "substantial noncompeting use."

[5] To survive a challenge to contributory infringement on summary judgment, a patentee must be able to demonstrate there is a genuine factual dispute as to whether the accused device has no "substantial noninfringing uses." Golden Blount, Inc. v. Robert H. Peterson Co., 365 F.3d 1054, 1061 (Fed.Cir.2004). Thus, to have contributory infringement, Section 271(c) requires a finding that Gyrus sold a sinus debrider for use in practicing the ' 957 process, which use constitutes a material part of the invention, knowing that the debrider is especially made or adapted for use in infringing the patent, and that the Gyrus debrider is not a staple article or commodity of commerce suitable for substantial noninfringing use. *See* C.R. Bard, Inc., 911 F.2d at 674-75.

Gyrus contends that it is entitled to summary judgment on Xomed's contributory infringement claim because the Gyrus debrider systems are "staple articles or commodities of commerce 'suitable for substantial non-infringing use.' " (Doc. 161-2 at 17.) While the '957 Patent claims are all limited to a method of performing sinus surgery, the Gyrus debriders "are intended to be and have been regularly used to perform non-sinus surgery." (Id. at 17-18.) Gyrus notes that (1) its Turbo 7000 and Diego Debrider systems can be used for otologic (ear) surgery, by using an otology handpiece and an otology blade or bur instead of a sinus

handpiece and an irrigating sinus blade (Doc. 161-2 at 18); (2) all three of the Gyrus debrider systems may be used for laryngeal and adenoid surgeries, when used with laryngeal blades and adenoid (including tonsil) blades instead of irrigating sinus blades (Id. at 18-19); (3) all three Gyrus debrider systems can be used with burs attached to the sinus hand pieces instead of irrigating blades (Id. at 19); and (4) the ESSential and Turbo 7000 debrider systems are intended to and have been used with non-irrigating sinus blades. (Id. at 19-20.) Each of these alternative adaptations and uses of the debrider systems are noninfringing uses, as admitted by Xomed. (Id. at 18-20 (citing Doc. 144, Ex. 11; Doc. 155, S-6, Exs. 12, 13 (depositions of Dr. Leopold and Xomed corporate representative Mark Fletcher.))) Thus, argues Gyrus, "[t]he uses of the Gyrus debrider systems in otologic, laryngeal and adenoid surgeries and with burs and non-irrigating blades are intentional, actual, numerous, and not occasional or aberrant." (Doc. 161-2 at 20.)

Xomed counters that Gyrus' sinus debriders were specifically designed, marketed and sold for use in sinus surgery as covered by the claims of the ' 957 Patent. (Doc. 174-1 at 14.) First, Xomed cites to Gyrus' marketing materials for the ESSential(R) Shaver System, Turbo 7000 and Diego(TM) Powered Dissector System surgical instruments which it says "place an almost exclusive emphasis on use of its debriders in sinus surgery," as "designed exclusively for otolaryngologists"; "designed exclusively for Endoscopic Sinus Surgery"; designed for "Faster, More Efficient Sinus Procedures"; "The Ultimate in Powered Sinus Instrumentation"; "sinus application blades"; and as providing "profoundly improved experience for sinusitis patients and surgeons." (Doc. 174-1 at 15; Docs. 174-7-13 (Exs.6-11).) For example, the Enhanced ESSential (TM) Shaver System provides, according to Gyrus' promotional materials, "power and control for Endoscopic Sinus Surgery," providing "[q]uick and easy flushing of the handpick and blade," and that "[h]elps eliminate clogging during removal of fluids and dissected tissue from the operative site." (Doc. 174-7.) The Turbo 7000 system provides "[a] 'Flush' mode designed to provide extra irrigant to the blade when needed." (Doc. 174-10.) The Diego(TM) provides as a feature "1 combined Irrigation and Suction Tube, 1 Blade Insertion." (Doc. 174-13 at 6.)

Moreover, Gyrus' sales figures comparing percentages of sales of non-sinus blades versus sinus blades for the years 2001 through 2005, have been provided under seal. (Doc. 155, S-6, Ex. 2, para.para. 25.C.D.) For purposes of this Order, and viewing the evidence in a light most favorable to Xomed, the nonmoving party, it suffices that the Court finds that these sales figures do not establish, as a matter of law, that Gyrus' sale of non-infringing non-sinus blades is "substantial" to bar a claim for contributory infringement. Accordingly, Gyrus' motion for summary judgment as to contributory infringement will be denied. *See* Mentor H/S, Inc. v. Medical Device Alliance, Inc., 244 F.3d 1365, 1379 (Fed.Cir.2001)(defendant's manual states that instrument specifically manufactured for plastic and cosmetic surgical method at issue); Pollock v. Thunderline-Z, Inc., No. 98-1191, 215 F.3d 1351, 1999 WL 710262 (Fed.Cir. Sept.1, 1999)(unpublished opinion)(defendant's own sales belie the conclusion that its product is a staple article)

C. *Induced Infringement*

[6] Under the principles of indirect infringement, "[W]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. s. 271(b). "To succeed on this theory, a plaintiff must prove that the defendants' 'actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement.' " Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed.Cir.2003) (citation omitted). *See also* Alloc, Inc. v. Internat'l Trade Commission, 342 F.3d 1361, 1374 (Fed.Cir.2003). A person induces infringement under s. 271(b) "by actively and knowingly aiding and abetting another's direct infringement." C.R. Bard, Inc., 911 F.2d at 675 "[T]he patentee must show both direct infringement and a certain level of intent on the part of the alleged inducer that the patent be infringed." Insituform

Technologies, Inc. v. CAT Contracting, Inc., 385 F.3d 1360, 1377 (Fed.Cir.2004).

[7] [8] In order to succeed on a claim of inducement, the patentee must show first, that there has been a direct infringement, and second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement. Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1312 (Fed.Cir.2005). Proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement. Warner-Lambert Co., 316 F.3d at 1363. Intent may be established by direct and circumstantial evidence. Warner-Lambert Co., 316 F.3d at 1363. "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." Warner-Lambert Co., 316 F.3d at 1364 (if physician, without inducement from defendant, prescribes use of drug in an infringing manner, defendant's knowledge of this is irrelevant).

[9] Gyrus argues that there is no induced infringement as a matter of law because its operations manual does not instruct users of Gyrus debrider systems "to use the systems in such a manner that the fluid remains essentially within the systems." (Doc. 161-2 at 21.) Specifically, Gyrus cites the Diego (TM) System Powered Dissector's Owner's Manual, which it says instructs users to irrigate the surgical site during use. (Doc. 161-2 at 22 (citing Doc. 144, Ex. 14).) The manual advises users to "[s]et pump flow so that irrigation is seen at the surgical site. (The flow of irrigating solution must exceed the level of suction.)." (Doc. 144, Ex. 14, Bates No. D000917.) The manual instructs that the irrigating pump flow rate is adjustable, (*id*. at Bates No. D000925), and that "[t]o *ensure* irrigation of the surgical site, the flow of irrigating solution must exceed the level of suction." (*Id*. at D000927.)

Further, Gyrus argues that, as a matter of law, it cannot be held liable for inducing infringement because it reasonably relied on an opinion from a competent outside patent counsel and in-house counsel, and thus it reasonably believed that the use of the Diego debrider systems would not infringe upon the '957 patent. As a result, Gyrus argues, it had no "intent" to induce, a necessary element. (Docs. 161-2 at 22 (citing Doc. 144, Exs. 2, 16, 17; Doc. 187 at 11.))

Finally, Gyrus contends that there is no affirmative evidence of inducement: "[t]here are no documents by Gyrus, no instructions by Gyrus, etc. that induce use of the Gyrus debriders in an infringing manner." (Doc. 187 at 10.)

"Intent is a factual determination particularly within the province of the trier of fact and may be inferred from all of the circumstances." Insituform Technologies, Inc., 385 F.3d at 1378. Whether Gyrus knew that physicians are using the Gyrus debrider instruments, with adjustable irrigation flow, in such a manner as to infringe upon the '957 Patent process, and intended for physicians to do so, while a close question, may be inferred from the circumstances. There is a genuine issue of material fact both as to whether Gyrus "knowingly induced infringement" and as to whether Gyrus "possessed specific intent to encourage [the surgeons'] infringement." Cross Medical Products, Inc., 424 F.3d at 1312. Drawing reasonable inferences in favor of Xomed, as the Court must on Gyrus' motion for summary judgment, a reasonable juror could find that Gyrus designed its debrider devices to function in such a manner as its use would infringe upon the '957 Patent process, anticipated that surgeons would use it in such a manner, and thus intended for the surgeon to use the apparatus as claimed. *See* Cross Medical Products, Inc., 424 F.3d at 1314; *See also* C.R. Bard, Inc., 911 F.2d at 675 (having positioned apparatus components so as to allow the user to infringe the claim, the evidence was at best ambiguous regarding the fact pattern under which the catheter was to be used creating genuine issue of material fact).

D. ***Willful Infringement***

[10] "A determination of willfulness is made on consideration of the totality of the circumstances." Insituform Technologies, Inc., 385 F.3d at 1377. The patentee bears the burden of persuasion and must prove willful infringement by clear and convincing evidence. Golden Blount, Inc. v. Robert H. Peterson Co., 438 F.3d 1354, 1368(Fed.Cir.2006). Willful infringement is not established by the simple fact of infringement, even where the accused has knowledge of the patents. *Id*.

The issue of "willful" infringement measures the infringing behavior, in the circumstances in which the infringer acted, against an objective standard of reasonable commercial behavior in the same circumstances. Willful infringement is thus a measure of reasonable commercial behavior in the context of the tort of patent infringement. The extent to which the infringer disregarded the property rights of the patentee, the deliberateness of the tortious acts, or other manifestations of unethical or injurious commercial conduct, may provide grounds for a finding of willful infringement and the enhancement of damages.

Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1583 (Fed.Cir.1996).FN8

FN8. Factors considered when determining whether an infringer has acted in bad faith include: " '(1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; ... (3) the infringer's behavior as a party to the litigation;' (4) 'defendant's size and financial condition;' (5)'closeness of the case;' (6) 'duration of defendant's misconduct;' (7) 'remedial action by the defendant;' (8) 'defendant's motivation for harm;' and (9)' whether defendant attempted to conceal its misconduct.' " Liquid Dynamics Corp. v. Vaughan Co., 449 F.3d 1209, 1225 (Fed.Cir.2006) (citation omitted).

[11] "As a general matter, a potential infringer with actual notice of another's patent has an affirmative duty of care that usually requires a potential infringer to obtain competent legal advice before engaging in any activity that could infringe another's patent rights." Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1190 (Fed.Cir.1998). *See also* Vulcan Engineering Co. v. Fata Aluminium, Inc., 278 F.3d 1366, 1378 (Fed.Cir.2002). "Although reliance on competent counsel's opinion is evidence of good faith, it is not conclusive." In re Hayes Microcomputer Products, Inc. Patent Litigation, 982 F.2d 1527, 1543 (Fed.Cir.1992). "Obtaining an objective opinion letter from counsel ... provides the basis for a defense against willful infringement." Comark Communications, Inc., 156 F.3d at 1191. "However, legal advice is only one factor to be considered, and an opinion of counsel does not guarantee against a finding of willfulness." Minnesota Mining and Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1580 (Fed.Cir.1992). The patentee may establish willfulness by challenging the competence of attorney opinions produced. Golden Blount, Inc., 438 F.3d at 1368. "[T]he legal opinion must be 'competent' or it is of little value in showing the good faith of the infringer." Comark Communications, Inc., 156 F.3d at 1191.

" 'There continues to be an "affirmative duty of due care to avoid infringement of the known patent rights of others." ' " Golden Blount, Inc., 438 F.3d at 1368 (citations omitted). The standard is whether the alleged infringer had a " 'reasonable good faith belief' in noninfringement." Hoechst Celanese Corp., 78 F.3d at 1583 (citation omitted). "The issue of willfulness of wrongdoing is a question of fact." Hoechst Celanese Corp., 78 F.3d at 1583.

[12] Gyrus contends that, as a matter of law, Xomed's willful infringement claim should fail because, upon learning of Xomed's '957 patent, and before marketing the Diego debrider systems, it sought an opinion from outside patent counsel who concluded that the Diego product does not infringe upon Xomed's patent. (Docs. 161-2 at 23; 187 at 12.) Gyrus cites the declaration of its vice president for Group Legal and Intellectual Property Affairs, Robert Gadsden, who said that he learned about the '957 Patent within a week of its September 25, 2001 patent date, and after study and comparison, concluded that the Diego did not infringe upon the '957 process. Mr. Gadsden also requested an independent legal opinion from outside counsel Thomas J. Pardini, Esquire. (Doc. 144, Ex. 16 at para.para. 13-27). Gyrus senior vice president of business development Brad Beale states that Gyrus relied upon the opinions Messrs. Pardini and Gadsden during the development of the Diego debrider system prior to the initial marketing of the Diego in August 2002. These opinions were that the Gyrus debriders do not infringe upon the '957 Patent because Gyrus' systems are designed such that, when used to cut tissue in sinus surgery, the irrigation fluid intentionally exits the blades and irrigates the surgical site rather than remaining "essentially within" the system. (Doc. 155, S-6, S-6, Ex. 2 at para.para. 18-19; *see also* Doc. 144, Ex. 16, para.para. 28, 29 (Mr. Gadsden reviewed Mr. Pardini's opinion).)

Xomed argues that the Pardini opinion letter, (Doc. 144, Ex. 17), is the only evidence proffered by Gyrus to defeat Xomed's claim of willful infringement. Xomed contends that attorney Pardini's opinion on noninfringement is not objective because Mr. Pardini advised Gyrus how to avoid infringement by including surgical site irrigation language in its product instructions. FN9 It also cites to its expert Dr. Leopold's report in which he opines that " 'Gyrus and its management and technical personnel could have anticipated no result other than that sinus surgeons would use all of these Gyrus products in a manner that would infringe the claims of the ' 957 patent.' " (Doc. 174-1 at 22 (citing Doc. 175, S-11, Ex. 1 at 3).)

FN9. For purposes of the question of willful infringement, the Court does not consider the fact that Gyrus disputes the production of documents, as Xomed urges. (Doc. 174-1 at 22.) *See* Golden Blount, Inc., 438 F.3d at 1368.

The entire premise of attorney Pardini's opinion letter is that Xomed's device embodied in the '957 Patent, supplies fluid "to the tissue cutting surface without introducing fluid to the operative site," (Doc. 144, Ex. 17 at Bates No. D029422 (emphasis deleted)), while the Diego debrider does not prevent irrigation fluid from being supplied to the area and, as recommended by the owner's manual, irrigation must exceed the level of suction. (Doc. 144, Ex. 17 at Bates No. D029429; *see also* Bates No. D029406-407.) However, Mr. Pardini notes that

The amount of irrigation fluid that is supplied to the cutting surface and surgical site is controlled by the surgeon via a controller. The controller has 10 irrigation settings, each of which incrementally increases the amount of irrigation fluid. However, there is a standard level of suction which is not controlled by the Diego controller. Instead, the amount of suction is dependent on the hospital's suction source. (Doc. 144, Ex. 17 at Bates No. D029406.)

Given that the Diego debrider is designed such that a using physician may alter the amount of irrigating fluid vis a vis the level of suction, and that attorney Pardini was aware that "[t]o avoid induced infringement, U.S. law requires Gyrus to not give the impression of inviting or encouraging any use where suction exceeds irrigation," (Doc. 175, S-11, Ex. 15 at Bates No. 029483), the objectivity and competence of

Mr. Pardini's opinion letter, *see generally* In re Hayes Microcomputer Products, Inc., 982 F.2d at 1543, the circumstances surrounding Gyrus' obtaining that opinion letter, and the reasonableness of Gyrus alleged good faith belief in noninfringement are questions of fact. Accordingly, Gyrus' motion for summary judgment as to willful infringement will be denied.

E. ***Defenses and Counterclaim***

1. ***Validity***

"The criteria set forth in section 337 require not only proof of patent infringement, but also a showing that the infringed patent is valid and enforceable." Alloc, Inc., 342 F.3d at 1374 (citing 19 U.S.C. s. 1337(a)(1)(B)(i)). Xomed's patent claims are entitled to a presumption of validity, and Gyrus bears the burden of showing, by clear and convincing evidence, the invalidity of the Xomed's claims. Hewlett-Packard Co., 909 F.2d at 1467; *see also* 35 U.S.C. s. 282. "[Gyrus'] burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." Hewlett-Packard Co., 909 F.2d at 1467. Both Xomed and Gyrus seek judgment as a matter of law on Gyrus' validity defenses and counterclaim. (Docs. 119 at 3; 161-2 at 23-38; 147-1 at 14-47.)

a. ***Invalidity for "Anticipation"*** *(*35 U.S.C. s. 102(b)*)*

Section 102(b) provides that "a person shall be entitled to a patent unless ... the invention was patented or described in a printed publication ... more than one year prior to the date of the application for patent." 35 U.S.C. s. 102(b). "Accordingly, invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Systems, Inc. v. Kent State University, 212 F.3d 1272, 1282 (Fed.Cir.2000). A determination that a patent is invalid as being anticipated under 35 U.S.C. s. 102 requires a finding that " 'each and every limitation is found either expressly or inherently in a single prior art reference.' " Transclean Corp. v. Bridgewood Services, Inc., 290 F.3d 1364, 1370 (Fed.Cir.2002) (citation omitted). Conversely, absence from the prior art of any claimed element negates anticipation. Minnesota Mining and Mfg., 976 F.2d at 1572.

[13] [14] A claim may be "anticipated" if the prior art functions or may be used as the patented product; that is, that the patented process is indeed inherent in the prior art. " 'Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.' " Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327 (Fed.Cir.2001) (citation omitted). Restated, "[i]nherency occurs when the invention described by the prior art necessarily functions in accordance with a claim limitation, even if the limitation is not expressly mentioned in the art." Ricoh Co., Ltd. v. Katun Corp., 380 F.Supp.2d 418, 438 (D.N.J.2005). "[A] limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373, 1379 (Fed.Cir.2003).

[15] The evidence of inherency "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed.Cir.1991). " 'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.' " Continental Can Co., 948 F.2d at 1269 (citation omitted)(emphasis in original).

"Whether a claim limitation is inherent in a prior art reference is a question of fact." Telemac Cellular Corp., 247 F.3d at 1328. The Court compares the properly constructed Xomed '957 patent claims with the subject matter described in the prior art reference, and identifies the elements disclosed in the allegedly anticipating reference. Ricoh Co., 380 F.Supp.2d at 438. "[S]ummary judgment is inappropriate if a trier of fact applying the clear and convincing standard could find for either party." Oney v. Ratliff, 182 F.3d 893, 895 (Fed.Cir.1999).

[16] Gyrus contends that the so-called Frost article,FN10 and the Frost patent,FN11 are anticipatory prior art under 35 U.S.C. s. 102(b) because they were published more than one year before the April 17, 1995 earliest possible filing date of Xomed's ' 957 patent application, they each disclose every element of the '957 claims, and the instrument described can be used in sinus surgery. (Doc. 161-2 at 24-254 & n. 6; Doc. 170 at 16-23.) FN12 Gyrus cites to the work of its expert, Dr. Rodney J. Schlosser, a sinus surgeon, who compared the Frost article and patent with Xomed's ' 957 patent claims. (Doc. 161-2 at 24 (citing Doc. 144, Exs. 21-23).) Gyrus cites the following passage in the Frost article:

FN10. R.B. Frost, et al., "The Design and Development of an Irrigating Sucking Cutter for Neurosurgical Use," *Engineering in Medicine,* Vol. 15, No. (1): 9-12 (Jan.1986). (Doc. 144, Ex. 18.)

FN11. U.S. Patent No. 4,517,977 (filed July 24, 1981)(issued May 21, 1985), entitled "Co-Axial Tube Surgical Infusion/Cutter Tip." (Doc. 144, Ex. 20.)

FN12. Gyrus limits its s. 102 anticipation defense and counterclaim to being based upon the Frost Article and the Frost Patent.

Initially the device was run at a low speed, approximately 300 revs/min. A good flow of water was obtained for irrigation. With the suction bypass slot blocked, a good suction effect was obtained at the probe tip, which drew most of the irrigating water back down the inner tube before it emerged at the probe tip.

...

In each case the excised tissue debris was satisfactorily conveyed from the site via the inner probe tube by the suction and the irrigating fluid.... As soon as the suction ceased at the probe tip the tissue being cut moved slightly away from the probe tip due to the re-emergence of the irrigating water. (Doc. 144, Ex. 18 at Bates No. D001121.)

The Frost patent, '977, provides:

The duct means to direct a stream of liquid to the said one ends of the tubes preferably comprises an annular space between the two tubes. It is however important that the liquid stream ... is directed so that the area of tissue to be removed is irrigated before the liquid is sucked up by the suction source acting through the interior of the second tube. (Doc. 144, Ex. 20 col.2 ll.15-23).

The Frost patent provides for the surgeon to control the amount of air flowing in the annular recess, which in turn controls the amount of suction. (Doc. 144, Ex. 20, col.3 ll.45-54.) Gyrus argues that based on this feature, the surgeon using the Frost instrument can control the amount of irrigating fluid leaving the instrument, (Doc. 161-2 at 25), and that "most of the irrigating fluid stays within the Frost debrider." (Doc. 187 at 13 (emphasis omitted).) Thus, argues Gyrus, because the Frost article and the Frost patent each

disclose all of the elements of the '957 patent claims, the claims are invalid under 35 U.S.C. s. 102(b). At minimum, Gyrus argues, the Frost debrider's use in sinus surgery, if not explicit, is inherent in that it naturally occurs from the teachings and disclosure of the prior art reference. (Doc. 170 at 18, 21.) Xomed contends that summary judgment in its favor is appropriate on Gyrus' s. 102 anticipation defense and counterclaim because Gyrus has failed to show that use in sinus surgery was inherently and " 'necessarily' " present in the Frost '977 patent or in the Frost article. (Doc. 147-1 at 14-17.) Xomed argues that the Frost instrument described in the Frost Article and Patent does not address sinus surgery, which element appears in all three ' 957 Patent constructed claims. (Doc. 174-1 at 23; see Doc. 77 at 12-13, 17.) Rather, the Frost instrument as described in the Frost Article and Frost Patent is designed as a suction cutter for use in neurosurgery. (Doc. 147-1 at 15-16.) Xomed cites to the deposition of Gyrus' expert Dr. Schlosser, who testified that he did not know "of a specific case that was written by a sinus surgeon using this specific [Frost] device." (Docs. 147-1 at 16-17; 147-16 at 128 (Ex. 15, Schlosser deposition); *See also* Doc. 167, Ex. 90 at 39, 124.)

Xomed says that Gyrus' argument is flawed because it focuses only upon the Frost article and patent description of the Frost surgical infusion/suction cutter tip "supplying step," that is, whether the irrigating fluid remains within the instrument. (Doc. 174-1.) Furthermore, as to the "supplying step," Xomed cites the Frost article which says the Frost debrider " 'provide[s] a flow of isotonic saline solutionto allow irrigation of the surgical field,' " while the '957 Patent "teaches to keep the fluid essentially within the instrument in order to minimize the contact of the fluid with the surgical field." (Doc. 174-1 at 23-24 (citing Doc. 144, Ex. 18 at 9).) Xomed contends that Gyrus has failed to prove by clear and convincing evidence that "use in sinus surgery" and the "supplying" step are disclosed in the Frost Patent or the Frost Article.

[17] Anticipation by prior art cannot be established by probabilities or possibilities, or require "undue experimentation." Genuine issues of material fact are present as to whether the Frost article and the '977 Patent retains irrigating fluid "essentially within" the instrument and may be adapted to sinus surgery, and thus disclose and anticipate, either expressly or inherently, the '957 Patent. *See* Continental Can Co., 948 F.2d at 1269. The parties' motions for summary judgment on this issue will be denied.

b. *Invalidity for "Derivation" (*35 U.S.C. s.s. 102(f) ***and* (g)*)***

[18] Xomed moves for summary judgment in its favor on Gyrus' Section 102(f) and (g) defense, which seeks to invalidate the '957 patent based upon derivation.FN13 (Doc. 147-1 at 20.)

FN13. Xomed contends that Gyrus should not be permitted to assert a s. 102(f) and (g) co-inventor claim or defense because in answer to Xomed's interrogatory asking Gyrus to detail every basis for the contention that the '957 Patent is invalid, Gyrus discussed references that "anticipated" the '957 claims, and did not mention derivation under s. 102(f) and (g). (Doc. 147-1 at 8-9 (citing Doc. 147-3 at 9 (Ex. 2, Answers to Interrogatories))); (Doc. 186-1 at 11-12.) Gyrus' Third Affirmative defense recites that the '957 Patent is invalid and/or unenforceable for failure to comply with the conditions of patentability specified in 35 U.S.C. s.s. 102, 103 and 112. (Doc. 119 at 3.) Count I of its Counterclaim seeks a declaration that the '957 Patent is invalid for not complying with these sections. (Doc. 119 at 4.) Count II of Gyrus' Counterclaim seeking a declaration that the '957 Patent is unenforceable for alleged inequitable conduct does detail Gyrus' allegations of derivation under Sections 102(f) and (g). (Doc. 119 at 7-8, para.para. 28, 29.) While not set forth as a separate claim, the Court concludes that Xomed was on sufficient notice that it was faced with a section 102(f) and (g) derivation defense.

[19] Section 102(f) provides that "[a] person shall be entitled to a patent unless ... he did not himself invent the subject matter sought to be patented." 35 U.S.C. s. 102(f). "To prove derivation under s. 102(f), 'the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee' by clear and convincing evidence." Eaton Corp. v. Rockwell International Corp., 323 F.3d 1332, 1334 (Fed.Cir.2003) (citation omitted). The communication to the patentee "must be sufficient to enable one of ordinary skill in the art to make the patented invention." Eaton Corp., 323 F.3d at 1344.

"Inventorship is a question of who actually invented the subject matter claimed in a patent." Acromed Corp. v. Sofamor Danek Group, Inc., 253 F.3d 1371,1379 (Fed.Cir.2001). Inventorship requires a determination of underlying factual issues. Checkpoint Systems, Inc. v. All-Tag Sec. S.A., 412 F.3d 1331, 1338 (Fed.Cir.2005)

[20] [21] [22] " '[S]ince the word "he" refers to the specific inventive entity named on the patent, [Section 102(f)] mandates that a patent accurately list the correct inventors of the claimed invention.' " Checkpoint Systems, Inc., 412 F.3d at 1338 (citation omitted). "When an invention is the work of several inventors, they must jointly apply for the patent.... Omission of an inventor can invalidate a patent unless the omission was an error 'without any deceptive intention.' " Acromed Corp., 253 F.3d at 1379. " 'If nonjoinder of an actual inventor is proved by clear and convincing evidence, a patent is rendered invalid.' " Checkpoint Systems, Inc., 412 F.3d at 1338 (quoting Pannu v. Iolab Corp., 155 F.3d 1344, 1349 (Fed.Cir.1998)). "However, '[i]f a patentee can demonstrate that inventorship can be corrected as provided by [35 U.S.C. s. 256], a district court must order correction of the patent, thus saving it from being rendered invalid.' " Checkpoint Systems, Inc., 412 F.3d at 1338 (quoting Pannu, 155 F.3d at 1350).

[23] Testimonial evidence alone is not sufficient to invalidate a patent. " 'The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony.' " Checkpoint Systems, Inc., 412 F.3d at 1339 (citation omitted). This " 'rule of reason' " standard requiring corroborating evidence extends to claims by individuals purporting to be co-inventors. "Physical, documentary, or circumstantial evidence, or reliable testimony from individuals other than the alleged inventor or an interested party, may corroborate." *Id*. *See also* Sandt Technology, Ltd. v. Resco Metal and Plastics Corp., 264 F.3d 1344, 1350 (Fed.Cir.2001)(setting forth corroborating factors by which to judge inventor's testimony).

Closely related is section 102(g), which Gyrus asserts renders Xomed's ' 957 Patent invalid. Xomed moves for summary judgment on this defense and counterclaim as well. Section 102(g) provides that a person shall be entitled to a patent unless "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. s. 102(g). Section 102(g) " 'relates to prior inventorship by another in this country' and 'retains the rules governing the determination of priority of invention.' " Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed.Cir.1986) (citation omitted). " 'In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.' " *Id*.

Gary Peters ("Peters") and John T. Cleveland ("Cleveland") of Jacksonville, Florida, are the named inventors on Xomed's '957 Patent. (Doc. 147-2.) FN14 Peters and Cleveland were Xomed employees at the

time of the invention. (Doc. 147-1 at 20.) Xomed asserts that the evidence establishes that Cleveland conceived the invention between June 1, 1994 and October 31, 1994, and reduced it to practice between September 1, 1994 and December 31, 1994. (Doc. 147-1 at 21 (citing Doc. 156, S08, Ex. 18 at 312) (Peters deposition.)); Doc. 147-22, Ex. 19 (Xomed supplemental response to interrogatories). Xomed acknowledges that there is little documentation by Peters and Cleveland describing the invention, but adds that there is documentation by the Xomed team of which Peters and Cleveland were a part, citing a June 20, 1994 memorandum which states that Peters and Xomed employee Ben Rubin created a prototype to run debrider tips, including a Stryker tip and a "modified (irrigating style)" tip. (Doc. 147-1 at 21-22.)

FN14. Medtronic Xomed, Inc., Jacksonville, Florida, is listed as the Assignee. (Doc. 147-2.)

Gyrus responds that the inventor (or co-inventor) was Robert Mericle ("Mericle") and that Mericle's invention was communicated to Xomed before the June 1994 alleged conception of the invention leading to the '957 Patent. Specifically, according to Gyrus, Mericle was a consultant to Xomed's predecessor, Merocel Corp., and in March 1994, conceived the debrider system recited in the '957 patent, and developed it into a prototype. (Doc. 170 at 23 (citing Doc. 166, S-12; Ex. 70; Doc. 167, Exs. 71-88, 91).) Mericle communicated his newly designed debrider to Merocel on March 18, 1994. (Doc. 170, Ex. 81.) On April 15, 1994, Merocel's parent company acquired Xomed. (See Doc. 147-1 at 23 (citing Doc. 147-28 at 177).) Because Mericle is not listed as an inventor on the '957 Patent claims, there exists, at minimum a genuine issue of material fact as to the patent's validity, Gyrus argues. (Doc. 170 at 23.)

Evidence proferred by Gyrus that Mericle conceived of a surgical debrider with the irrigating fluid remaining "essentially within" the debrider is:

(1) Mericle's recognition after observing sinus surgery with a Hummer debrider on March 1, 1994 that "too much irrigating fluid within the sinus would flood the surgical site, which would impair the surgeon's ability to see and potentially drown the patient if fluid flowed into the patient's lungs (Doc. 166, S-12, Ex. 70, para. 26);

(2) a March 2, 1994 hand drawing of an instrument, communicated to Merocel on March 18, 1994, which mistakenly says: "Tip Plugging Will Will Occur As Frequently As Present Aspiration Tips," which Mericle states should say: "Tip Plugging Will *Not* Occur: (Doc. 166, S-12, Ex. 70, para.para. 34, 37; Doc. 167, Exs. 80, 81.A);

(3) a handwritten note of a June 30, 1994 conference call with the notation: Ben Rubin: Gary-Test Run

Full Radius Cutter No Cutting

Gator Would Cut

Irrigation-Sample, Look Good-No Drip

Micro No Motor

which Mericle states "advises that my new sinus debrider invention functioned with the irrigating fluid remaining in the instrument." (Doc. 166, S-12, para. 53; Doc. 167, Ex. 87);

(4) A July, 1994 memorandum by Ben Rubin [the same cited by Xomed] of Xomed concerning the June 30, 1994 conference call which said:

3. The Stryker aggressive (3.5 mm) cutter cut ok dry but did not carry debris away. When irrigation was connected to the port we built into the cutter, the debris was carried away (without drippage at the tip). Additionally, the suction provided for the debris was sufficient to draw the irrigation from a syringe (the syringe closed itself).

(Doc. 166, S-12, para. 54; Doc. 167, Ex. 88.)

Gyrus also points to the deposition testimony of Mericle employee (and Xomed consultant) Dom Gatto ("Gatto") as underscoring the similarities between the ' 957 Patent and Mericle's March 1994 debrider. (Doc. 170 at 29-30 (citing Doc. 167, Ex. 91 at 139-150).) As to whether it was his understanding in March 1994 that the Mericle debrider's irrigating fluid remained "essentially within" the instrument, Gatto testified:

Q: When you received [the March 1994 Mericle drawing], did you understand the concept on page 3 to be used in a surgical procedure involving the step of supplying fluid to the tissue-cutting surface through the fluid passage and the sinus debrider instrument such that fluid remains essentially within the instrument to be removed through the suction passage?

A. At this point in time, no. I'm not sure exactly what irrigation controls were required as specified at this point in time in terms of being contained within the unit or not.

Q: At this point in time was it the understanding that the fluid would exit the instrument into the surgical site?

...

A: No
Q: If it wasn't to be-if it wasn't intended to exit, then it was going to remain essentially with the instrument, correct?

...

A: Or exited and then vacuumed out.
(Doc. 167, Ex. 91 at 149-50.)

Xomed's employee Peters, on the other hand, states that Mericle did not perform any role in the development of the method of performing sinus surgery which is set forth in Claims 1 through 3 of the '957 Patent. (Doc. 147-1 at 23 (citing Doc. 156, S-8, at 309, 312).) Xomed contends that 1) Mericle's testimony that he was the inventor cannot be considered competent to establish that point, and: 2) the evidence proffered by Gyrus does not establish Mericle was the individual who conceived of the "essentially within" element of the supply step on the '957 Patent claims. (Doc. 186-1 at 8-11.) At best, argues Xomed, Mericle contributed only elements that were already in the prior art. (Doc. 186-1 at 12.)

Undisputed is that on April 15, 1994, Merocel's parent company acquired Xomed. From that point, the paths of Merocel's consultant Mericle, and Xomed's employees Peters and Cleveland crossed. The question of

who ultimately conceived of and invented the product that became the '957 Patent is rife with unresolved material factual questions. Indeed, Mericle and Peters attended the same June 30, 1994 conference call (see Doc. 147-24, Ex. 21), and Gyrus and Xomed both cite to the same March 18, 1994 and June 30, 1994 memoranda as support for their respective positions. Xomed's motion for summary judgment as to Gyrus' s. 102(f) and (g) derivation defense and counterclaim is denied.

c. *Invalidity for "Obviousness" Defense (*35 U.S.C. s. 103(a)*)*

[24] A patent claim is invalid "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." 35 U.S.C. s. 103(a). Several factual inquiries underlie the determination of obviousness. SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp., 225 F.3d 1349, 1355 (Fed.Cir.2000). These factual inquiries include (1) scope and content of the prior art, (2) the level of ordinary skill in the field of invention, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of nonobviousness, including commercial success, long-felt but unresolved need, failure of others copying, and unexpected results. Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); Ruiz v. A.B. Chance Co., 234 F.3d 654, 662-63 (Fed.Cir.2000).

[25] "In making the assessment of differences, section 103 specifically requires consideration of the claimed invention 'as a whole.' Inventions typically are new combinations of existing principles or features. [Citation omitted.] The 'as a whole' instruction in [T]itle 35 prevents evaluation of the invention part by part" and recognizes "the value of combining various existing features or principles in a new way to achieve a new result-often the very definition of invention." Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed.Cir.2004). In making this "as a whole" assessment, the court requires "a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner." Ruiz, 357 F.3d at 1275.

[26] "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed.Cir.1998). "A court must consider what the prior art as a whole would have suggested to one skilled in the art." Environmental Designs, Ltd. v. Union Oil Co. of Calif., 713 F.2d 693, 698 (Fed.Cir.1983). "The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence." Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1334 (Fed.Cir.2002).

[27] As with any invalidity claim, because an issued patent is presumed valid, there must be clear and convincing evidence supporting the obviousness determination. SIBIA Neurosciences, Inc., 225 F.3d at 1355. Both Xomed and Gyrus move for summary judgment on this issue.

[28] As prior art, Gyrus cites to an instrument known as the Hummer debrider, discussed in a 1994 article ("Hummer Article") FN15 and the Frost Article and Frost Patent, discussed above. *See supra* at 1317 n. 11, 12. (Doc. 161-2 at 26.)

FN15. Reuben C. Setliff, III, M.D. et al., "The 'Hummer': New Instrumentation For Functional Endoscopic

Sinus Surgery," *American Journal of Rhinology,* Vol. 8, No. 6 at 275-78 (Nov.-Dec.1994). (Doc. 144, Ex. 25.)

The Hummer debrider is a powered rotary microdebrider system used in sinus surgery, having a "tube within a tube" design, that is, an inner member rotatably disposed within the outer tubular member with the cutting surface of the inner member adjacent to the opening in the outer tubular member, with an annular space between the inner and outer tubes. (See Doc. 144, Ex. 26, p. 64.) It was designed to provide "[s]imultaneous continuous suction at the operative site", cutting the tissue with a rotary blade, and pulling it into the hollow center shaft. (Doc. 144, Ex. 25 at 275-76, Bates No. XO 26087071.) "Prevention of line obstruction is managed by intermittent irrigation down the shaft of either the telescope or the 'Hummer,' " or alternatively, by "dipping the tip of the 'Hummer' in saline or water after each withdrawal, allowing the suction line to be flushed." (Doc. 144, Ex. 25 at 277, Bates No. XO 260872.)

Significantly, as acknowledged by Gyrus, the "prior art use of the Hummer debrider in sinus surgery includes all of the elements of the claims of the ' 957 Patent, except that the Hummer debrider did not have internal irrigation, i.e., the Hummer debrider did not use the existing annular space between its inner member and its outer tubular member as a fluid passageway to deliver fluid to the tissue cutting surface of the inner member." (Doc. 161-2 at 27; *see also* Doc. 144, Ex. 26 at 64.) "[T]he existing annular space between the inner member and the outer tubular member of the Hummer debrider was not employed as a fluid passage to deliver fluid to the tissue cutting surface of the inner member." (Doc. 161-2 at 28.)

However, argues Gyrus, the fluid delivery through the annular space element "is disclosed by the Frost article and the Frost patent, each of which discloses this missing claim element in a similarly sized tube-within-a-tube debrider, the same as the Hummer debrider and the claimed debrider." (Doc. 161-2 at 29-30.) "One of ordinary skill in the art in June-October 1994 would have been motivated to use the annular space between the inner member and outer tubular member in the Hummer debrider as a fluid passageway in view of the Frost article or the Frost patent." (Doc. 161-2 at 30.)

Gyrus relies upon the affidavit of sinus surgeon Dr. Schlosser who opined that the claims of the '957 Patent would have been obvious to one of ordinary skill in 1994 in view of the Frost and the Hummer prior art. (Docs. 161-2 at 30, 170 at 35-40 (citing (Doc. 144, Ex. 21, para.para. 36-61)).) Gyrus concludes, inasmuch as doctors sometimes use instruments designed for one type of surgery in other surgeries, "it would have been obvious to use the Frost debrider in sinus surgery" and that "[s]uch use of the Frost debrider in sinus surgery includes all of the elements of the '957 patent claims." (Doc. 161-2 at 31.) Thus, "[t]he combination of (1) the Hummer prior art and (2) the Frost article or the Frost patent includes all of the elements of the 957 patent claims." (Id.)

Xomed contends that Gyrus has failed to establish by clear and convincing evidence that the subject matter as a whole of the '957 Xomed debrider would have been obvious to a person of ordinary skill in the art at the time of the invention. Specifically, Xomed contends that Gyrus' expert's (Dr. Schlosser) opinion that the invention was obvious, was based upon hindsight; "Dr Schlosser was not one of ordinary skill in the art, under his own definition of the term and never asked anyone who was skilled in the art in the June to October 1994 time period what they recall about the state of the art." (Doc. 174-1 at 26.) Finally, Xomed argues that Gyrus offers no evidence of motivation references, nor does it identify specifically how the Frost Article or Frost Patent "teach" a combination with the Hummer device for use in sinus surgery. (Doc. 174-1 at 27.)

Neither reference provided by Gyrus-the Hummer debrider, and the Frost Article and Frost Patent-disclose every element of Xomed's '957 Patent as to Claims I through 3. The Hummer instrument does not provide irrigating fluid to the cutting blades through the annular space; and the Frost instrument was labeled as being for neurological surgery, not designed specifically for sinus surgery. The possibility that there was motivation to combine elements of the two-the desire to develop a debrider which could accurately remove tumors from delicate sinus structures, and to reduce surgery time (Doc. 161-2 at 30.)-is tenuous, at best.FN16

FN16. Indeed, in all of their submissions on the derivation defense, neither party adduced any evidence that any of the proffered inventors considered the Hummer and Frost instruments in combination when developing a new sinus debrider.

"Inventions typically are new combinations of existing principles." *Princeton Biochemicals, Inc.*, 411 F.3d at 1337. "[S]imply identifying all of the elements in a claim in the prior art does not render a claim obvious." *Id.* at 1338. However, because the Court cannot find, as a matter of law, that no reasonable jury could find for either Gyrus or Xomed on the question whether the '957 Patent was an obvious combination of the Hummer and Frost prior art, the parties' motions for summary judgment on Gyrus' invalidity counterclaim and defense will be denied.

d. *Invalidity for "Indefiniteness" (*35 U.S.C. s. 112*)*

[29] [30] Every patent's specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. s. 112, para. 2. "Because the claims perform the fundamental function of delineating the scope of the invention, [citation omitted], the purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." Datamize, LLC. v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed.Cir.2005). The Federal Circuit, in *Datamize, supra,* advises the Court of the requirements of definiteness in patent claims.

[T]he definiteness of claim terms depends on whether those terms can be given any reasonable meaning. Furthermore, a difficult issue of claim construction does not *ipso facto* result in a holding of indefiniteness. [Citation omitted.] "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held a claim sufficiently clear to avoid invalidity on indefiniteness grounds." [Citation omitted.] In this regard it is important to note that an issued patent is entitled to a statutory presumption of validity. *See* 35 U.S.C. s. 282. "By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of validity and we protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal." [Citation omitted.] In this way we also follow the requirement that clear and convincing evidence be shown to invalidate a patent.

Datamize, LLC, 417 F.3d at 1347-48. The definiteness requirement does not require absolute clarity; "[o]nly claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." Id. at 1347.

[31] [32] [33] "A determination that a patent claim is invalid for failure to meet the definiteness requirement of 35 U.S.C. s. 112, para. 2 is 'a legal conclusion that is drawn from the court's performance of its duty as

the construer of patent claims [, and] therefore, like claim construction, is a question of law.' " All Dental Prodx, LLC and DMG v. Advantage Dental Products, Inc., 309 F.3d 774, 778 (Fed.Cir.2002). In the face of an allegation of indefiniteness, general principles of claim construction apply, which involves a review of intrinsic evidence and extrinsic evidence such as expert testimony. Datamize, LLC, 417 F.3d at 1348; Exxon Research and Engineering Co. v. U.S., 265 F.3d 1371, 1376 (Fed.Cir.2001). "The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification." *Union Pacific Resources Co.,* 236 F.3d at 692. Disagreement between the parties concerning the meaning of the claims does not automatically render the claims so lacking in clarity as to be invalid for indefiniteness. Personalized Media Communications, LLC v. International Trade Commission, 161 F.3d 696, 705 (Fed.Cir.1998). Respecting the statutory presumption of patent validity, " 'close questions of indefiniteness in litigation involving issued patents are properly resolved in favor of the patentee.' " Bancorp Services, L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1372 (Fed.Cir.2004) (citation omitted). Both parties seek summary judgment on this issue.

[34] Gyrus contends that the "supplying step" elements of Claims 1 and 3 fail to meet the definiteness requirement of 35 U.S.C. s. 112, second paragraph. (Doc. 161-2 at 33.)

Independent Claims 1 and 3 of the '957 Patent recite a step of

supplying fluid to the tissue cutting surface through the fluid passage in the sinus debrider instrument. (Doc. 144, Ex. 1, col.6 ll.35-36, 61-62.)

In its claim construction Order, dated May 23, 2005, the Court construed this element as follows:

"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. (Doc. 77 at 30.)

Gyrus argues that the terminology that fluid "remains essentially within the instrument" is ambiguous and indefinite as a matter of law. Citing to the deposition testimony of Xomed's sinus surgeon expert, Dr. Leopold, Xomed's corporate designee Mark Fletcher, and one of Xomed's patent applicants Gary Peters, Gyrus contends that the phrase is defined differently by Xomed's own witnesses, as being "less than a few drops" or a "trace" of fluid exits the instrument; to "any quantity can exit the instrument so long as it does not obfuscate the surgeon's view." For this reason, "remains essentially within" is indefinite because the step's "boundary" cannot be deciphered; competitors cannot determine whether they infringe; there is no objective standard; the step has different meanings to persons skilled in the art. (Docs. 161-2 at 33-38; 187 at 15.)

Xomed responds, arguing that the term "essentially" is not indefinite in claim construction proceedings. (Doc, 174-1 at 30.) Second, the patent's specification and the prosecution history provide ample guidance to determine whether fluid remains essentially within the instrument. (Doc. 174-1 at 31.) The '957 Patent specifies the problem to be solved by the Xomed debrider invention, that is "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" requiring "frequent cleaning or substitution of the prior art." (Doc. 144, Ex. 1, col.1 ll. 17-26.) Third, Xomed argues that of the extrinsic evidence relied upon by Gyrus to attempt to establish "indefiniteness, only the testimony of Xomed's own expert, Dr. Leopold, qualifies as

one "skilled in the art" able to discuss the definiteness of the patent term, and that Dr. Leopold understood the so-called "supplying step" " term. (Doc. 174-1 at 33-34.)

Dr. Leopold was questioned repeatedly about the phrase "remains essentially within," and he gave repeated answers, sometimes with varying terminology. It is these distinctions that Gyrus seizes upon to argue that the term is indefinite and thus the '957 Patent is invalid. To summarize, Dr. Leopold said, "Most of the time, with a device that's performing under the essentially within format, the fluid-there will be no fluid escaping. There are times there will be, due to temporary blockages to the opening of the inner lumen that there will be fluid escaping. These are temporary blockages that may result in some fluid escaping-some irrigation fluid escaping the instrument, but they are momentary, and, over time, not a significant part of the surgical experience." (Doc. 144. Ex. 11, at 97.)

The Court, in construing the patent element "supplying fluid to the cutting surface," accepted the definition of "essentially" 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." (Doc. 77 at 25.) "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. 77 at 29-30.)

While the witnesses used different terminology to describe the small and insignificant amounts of irrigating fluid that may escape from the Xomed debrider, their testimony does not, as a matter of law, render the term "such that fluid remains essentially within the instrument" indefinite such as to invalidate the '957 Patent. *See* Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333, 1337 (Fed.Cir.2001)(construing antibiotic " 'in amorphous form essentially free from crystalline material' " for purposes of patent claim, as describing antibiotic with maximum crystalline content of less than 10%); In re Marosi, 710 F.2d 799, 802-03 (Fed.Cir.1983)(phrase " 'essentially free of alkali metal' " means material is present only as an unavoidable impurity, and is not indefinite where specification defined it as containing only residual impurities); Chimie v. PPG Industries, Inc., Case No. Civ.A. 01-389, 2003 WL 22400215, at *8, 9 (D.Del.2003)(term " 'essentially spheroidal in geometical configuration' " construed to embody "less than perfect" spheres); Apotex Corp. v. Merck & Co., Inc., Case No. 96 C 7375, 2000 WL 97582, at (N.D.Ill.2000)(interpreting claim term " 'essentially complete' " to mean " 'virtually complete' " and " 'mostly complete but not entirely complete' "); Thermal Engineering Corp. v. Clean Air Systems, Inc., 706 F.Supp. 436, 445-46 (W.D.N.C.1987)(term " 'essentially unobstructed path' " in high heat transfer oven and process of drying articles not vague and indefinite). The meaning of the '957 Patent claims are "reasonably discernible." *See* Bancorp Services, L.L.C., 359 F.3d at 1372. Gyrus' motion for summary judgment on this issue will be denied; Xomed's motion for summary judgment will be granted.

2. ***Inequitable Conduct***

[35] [36] Patent applicants FN17 owe a " 'duty of candor and good faith' to the PTO." Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348, 1351 (Fed.Cir.2005)(citing 37 C.F.R. s. 1.56(a)). "A breach of this duty may constitute inequitable conduct, which can arise from a failure to disclose information material to patentability, coupled with an intent to deceive or mislead the PTO." Bruno, 394 F.3d at 1351. *See also* Ferring B.V. v. Barr Laboratories, Inc., 437 F.3d 1181, 1186 (Fed.Cir.2006). "While inequitable conduct includes affirmative misrepresentations of material facts, it also arises when the patentee fails to disclose material information to the PTO." *Id*. A showing of inequitable conduct involves two steps: (1) a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and (2) a weighing of materiality and intent in light of all the circumstances to determine

whether the applicant's conduct is so culpable that the patent should be held unenforceable. Ferring B.V., 437 F.3d at 1186. *See also* ATD Corp., 159 F.3d at 546. The Court must balance the levels of materiality and intent, " 'with the greater showing of one factor allowing a lesser showing of the other.' " Digital Control, Inc. v. Charles Machine Works, 437 F.3d 1309, 1313 (Fed.Cir.2006).(citation omitted). The evidence is then weighed " 'to determine whether the equities warrant a conclusion that inequitable conduct occurred.' " Bruno Indep. Living Aids, Inc., 394 F.3d at 1351. A patent may be valid yet be rendered unenforceable due to inequitable conduct. Digital Control Inc., 437 F.3d at 1318.

FN17. In the context of an inequitable conduct determination, "applicant" includes anyone under a duty to disclose material information to the PTO, including the inventor, the prosecuting attorney or agent, and anyone associated with the inventor or the assignee who is substantially involved in the preparation or prosecution of the application. Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348 1351 n. 3 (Fed.Cir.2005)(citing 37 C.F.R. s. 1.56).

[37] Gyrus moves for summary judgment on its defense and counterclaim that the '957 Patent is not enforceable because of Xomed's alleged inequitable conduct in intentionally "withhold[ing] highly material prior art, in violation of their obligations under 37 C.F.R. s. 1.56 and common law." (Doc. 119, at 3 (Fifth Affirmative Defense) and at, para.para. 26-30.) To prove inequitable conduct for failure to disclose material information, Gyrus must establish by clear and convincing evidence "(1) prior art that was material; (2) knowledge chargeable to [Xomed] of that prior art and of its materiality; and (3) failure of [Xomed] to disclose the art resulting from an intent to mislead the [PTO]." Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed.Cir.1999). *See also* Bruno Indep. Living Aids, Inc., 394 F.3d at 1351 (materiality and intent must be established by clear and convincing evidence); Mentor H/S, Inc. v. Medical Device Alliance, Inc., 244 F.3d 1365, 1377 (Fed.Cir.2001); ATD Corp., 159 F.3d at 546.

[38] A piece of prior art is material if "there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Elk Corp. of Dallas, 168 F.3d at 31. *See also* Liquid Dynamics Corp., 449 F.3d at 1226-27 ("the correct analysis asks whether a reasonable examiner would find it important"). " '[A]ffirmative misrepresentations ... in contrast to misleading omissions, are more likely to be regarded as material.' " Digital Control Inc., 437 F.3d at 1318 (citation omitted). "[A]n otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed." Elk Corp. of Dallas, 168 F.3d at 31. *See also* Mentor H/S, Inc., 244 F.3d at 1378.

[39] As to intent, "even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive." Ferring B.V., 437 F.3d at 1191. Because intent can rarely be proven by direct evidence, " 'intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.' " Ferring B.V., 437 F.3d at 1191 (citation omitted; emphasis omitted).

"In the summary judgment context, all inferences must be made in favor of the nonmovant; thus, it is often improper to determine at summary judgment that a patentee made intentional misstatements or omissions to the PTO." Digital Control Inc., 437 F.3d at 1317 (issue of intent is inherently factual). "[S]ummary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a

credible explanation for the withholding." Ferring B.V., 437 F.3d at 1191. Summary judgment may be refused where the plaintiff submits evidence that sets forth " 'a non-frivolous explanation that could lead a finder of fact to determine that his declaration [to the PTO] was not false or misleading.' [citation omitted], or where the plaintiff 'state[d] facts supporting a plausible justification or excuse for the misrepresentation.' " Digital Control Inc., 437 F.3d at 1314 (citation omitted).

[40] Determination of inequitable conduct is an equitable issue committed to the discretion of the district court. Elk Corp. of Dallas, 168 F.3d at 30.

Gyrus contends that Xomed's failure to disclose the Hummer prior art to the PTO constitutes inequitable conduct which renders the '957 Patent unenforceable. (Doc. 161-2 at 40.) As to the Hummer debrider's materiality, Gyrus cites to deposition testimony by Xomed applicant Gary Peters, that the Xomed Wizard debrider was designed to perform powered sinus surgery without clogging the inner member of the instrument. (Doc. 161-2 at 40 (citing Doc. 144, Ex. 26 at 122)). Thus, argues Gyrus, the '957 Patent was to improve on the Hummer prior art. (Doc. 161-2 at 40.)

Gyrus proffers the following evidence of Xomed's alleged intent to deceive. (Doc. 161-2 at 41.) First, testimony of Xomed's corporate officers and the Xomed "Wizard" inventor acknowledge that they knew of the existence of the Hummer when they participated in the '957 Patent application, and the similarities and differences between the two devices. (Doc. 144, Ex. 26 at 65, 68, 108; Ex. 34 at 279; Ex. 35 at 99-100.) Inventor Peters called the Hummer "prior art" (Doc. 144, Ex. 26 at 61-68), and acknowledged that the task at hand was to improve upon the Hummer clogging problems, and thus was the impetus for developing the Xomed Wizard debrider. (See Doc. 187 at 17; Doc. 144, Ex. 26 at 124-27). The Xomed witnesses testified that the "Hummer" was not disclosed to the PTO in conjunction with the '957 patent application.

Second, the Hummer debrider was cited by Xomed to the PTO as prior art in connection with six other Xomed sinus debrider patent applications. (See Doc. 161-2 at 41-42 & n. 16.)

Third, and particularly significant to Gyrus' argument, Xomed disclosed to the FDA, when seeking FDA approval for use of the '957 Patent debrider system, that the '957 Patent was "substantially similar" to the Hummer debrider system. (Doc. 161-2 at 42-43 (citing Doc. 144, Ex. 26 at 185-86; Doc 155, S-6, Ex. 43 at Bates No. XO 054626, 054656).) Gyrus argues that Xomed's inconsistency in disclosing the Hummer to the FDA in an attempt to obtain approval of its debrider, and nondisclosure of the prior art to the PTO is evidence of intent to deceive. *See* Bruno Indep. Living Aids, Inc., 394 F.3d at 1352; Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1420 (Fed.Cir.1989).

Xomed responds that the Hummer debrider is cumulative to the prior art that was disclosed to the PTO, and thus not material, and that Gyrus has failed to establish by clear and convincing evidence Xomed's intent to deceive. (Doc. 174-1 at 34.) Xomed does not rebut the evidence that it knew of the Hummer device prior to its '957 Patent application, but contends that Gyrus has not established by clear and convincing evidence that it intended to mislead the PTO by not disclosing the Hummer as a prior art.

Because the scope and content of prior art and what the prior art teaches are disputed, there are genuine issues of material fact as to whether failure to disclose the Hummer was a material omission, not properly decided on summary judgment. *See* Digital Control Inc., 437 F.3d at 1319. There is also a fact issue whether the undisclosed prior art reference was cumulative of other prior art already before the patent examiner. *See* Elk Corp. of Dallas, 168 F.3d at 31.

Furthermore there are factual disputes concerning whether Xomed had the intent to deceive the PTO. Xomed advances a plausible explanation for its nondisclosure of the Hummer prior art-that it would have been cumulative of the disclosures made to the PTO. Xomed's disclosure of the Hummer debrider to the FDA but not to the PTO, while relevant, does not establish, as a matter of law, inequitable conduct. Further, Gyrus has not established as a matter of law that Xomed's patentability argument to the PTO could not have been made had the Hummer prior art been disclosed. Accordingly, Gyrus' motion for summary judgment as to inequitable conduct is denied.

3. *Lost Profits*

Gyrus moves for summary judgment on Xomed's claim for lost profit damages. Gyrus contends that Xomed is not entitled to recovery of lost profits due to alleged lost sales because "there is at least one available, acceptable non-infringing substitute." (Doc. 161-2 at 45.) Gyrus cites the so-called *Panduit* factors for a patent owner to receive lost profit recovery, focusing on the requirement that the patent owner establish that "there is an absence of acceptable non-infringing substitutes." (Doc. 161-2 at 45) (referring to Panduit Corp. v. Stahlin Brothers Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir.1978)).

[41] [42] " 'To recover lost profits damages, the patentee must show a reasonable probability that, 'but for' the infringement, it would have made the sales that were made by the infringer.' " Golden Blount, Inc. v. Robert H. Peterson Co., 438 F.3d 1354, 1371 (Fed.Cir.2006)(citing Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed.Cir.1995)(en banc)). "The patentee may rely upon the four-factor test articulated in *Panduit* to prove entitlement to lost profits damages." Golden Blount, Inc., 438 F.3d at 1371. The *Panduit* test has been "accepted as a useful, but nonexclusive, way for a patentee to prove entitlement to lost profits damages." Rite-Hite Corp., 56 F.3d at 1545. The *Panduit* test requires that the patentee establish:

(1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit it would have made. Rite-Hite Corp., 56 F.3d at 1545 (citing Panduit, 575 F.2d at 1156).

A showing of these four factors permits a court to reasonably infer the lost profits claimed were caused by the infringing sales, establishing the patentee's *prima facie* case with respect to lost profits. Rite-Hite Corp., 56 F.3d at 1545. "The patentee need only show that there was a reasonable probability that the sales would have been made 'but for' the infringement." *Id*. *See also* Ericsson, Inc. v. Harris Corp., 352 F.3d 1369, 1377 (Fed.Cir.2003); Grain Processing Corp. v. American Maize-Products Co., 185 F.3d 1341, 1349 (Fed.Cir.1999)("patent owner has an initial burden to show a reasonable probability that he would have made the asserted sales 'but for' the infringement."). In order to show "but for" causation, "the patentee must reconstruct the market to determine what profits the patentee would have made had the market developed absent the infringing product." Ericsson, Inc., 352 F.3d at 1377.

" 'The burden then shifts to the infringer to show that the inference is unreasonable for some or all of the lost sales.' " Golden Blount, Inc., 438 F.3d at 1372 (citing Rite-Hite Corp., 56 F.3d at 1545). *See also* Grain Processing Corp., 185 F.3d at 1349 ("but for" causation claim is "unreasonable for some or all of the lost sales").

[43] Gyrus first contends that lost profits are not available to Xomed as a matter of law because Gyrus had available an alternative design sinus debrider with a substituted new pump module. The alternative design

would clearly be noninfringing because with the alternative pump module, irrigating fluid would more readily exit the surgical instrument and irrigate the surgical site. (Doc. 161-2 at 46-47.) Gyrus did not "attempt to implement" the design alternative, however, because of its aesthetics coupled with "legal opinions that there was no infringement when using the original Diego pump module." (Doc. 161-2 at 46 (citing Doc. 155, S-6, Ex. 2, para.para. 33, 34) (Declaration of Gyrus senior vice president Brad W. Beale); Doc. 155, S-6, Ex. 45, para. 14 (Declaration of Gyrus director of research and development Phillip A. Ryan).)

Xomed disputes Gyrus' interpretation of the law, contending that lost profits are recoverable even if substitutes are available. (Doc. 174-1 at 40.) Furthermore, Xomed contends that the evidence does not establish as a matter of law that Gyrus' proffered substitute, a debrider with an alternative pump module, was or is even now actually available. (Doc. 174-1 at 40-41 (citing Doc. 175, S-11, Ex. 29 (July 28, 2005 Gyrus memorandum stating that availability of alternative motors and gear heads not identified and may require software changes)); Doc. 155, S-6, Ex. 69 (February 16, 2006 Gyrus memorandum stating that extensive validation testing had not yet been done on the alternative design).) Xomed further argues that Gyrus' proffered alternative Diego debrider is not acceptable as an alternative to the Xomed debrider because the modified Diego permits the irrigating fluid to "flood" the surgical site, rendering it "unacceptable for use in sinus surgery." (Doc. 174-1 at 42-43.) Xomed also argues that Gyrus has presented no competent evidence that the alternative Diego does not infringe upon the '957 patent. (Doc. 174-1 at 43-44.)

[44] "When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time." Grain Processing Corp. 185 F.3d at 1353. Likewise, to be acceptable to potential customers, the alternative design must not " 'possess characteristics significantly different from the patented product.' " BIC Leisure Products, Inc. v. Windsurfing Internat'l, Inc., 1 F.3d 1214, 1219 (Fed.Cir.1993) (citation omitted). Inasmuch as factual issues remain as to whether Gyrus' alternative design was available, and whether or not it was "acceptable" as an alternative sinus surgical instrument, the Court denies Gyrus' motion for summary judgment as to lost profits damages on this basis.

[45] Alternatively, Gyrus says that assuming *arguendo* that Xomed is entitled to some lost profit damages, that award should be reduced to account for the fact that Xomed's expert's calculations include alleged lost profits for non-infringing accessories, specifically non-infringing blades and bur attachments. (Doc. 161-2 at 47-48.) Gyrus argues that to be a basis of recovery, a component part must be physically part of the same machine. (Doc. 161-2 at 48-49.)

Xomed responds that its and Gyrus' blades and burs have a "functional relationship" with the other components of the patented/infringing debrider systems because the "blades and burs are ... used with the same system that infringes when used with blades in sinus surgery." (Doc. 174-1 at 45.) Xomed argues that it is the systems that drives the sales, not the blade and bur attachments, and that Xomed loses a sale each time Gyrus sells a blade or bur to be used with the infringing system, because that customer cannot use and thus will not purchase a Xomed blade or bur. (Doc. 174-1 at 46.)

[46] Unpatented components may be considered as relevant to the patentee's damages when "the components together constitute[ ] one functional unit." Rite-Hite Corp., 56 F.3d at 1550 (citing cases). This so-called "entire market value rule" "is appropriate where both the patented and unpatented components together are 'analogous to components of a single assembly,''parts of a complete machine,' or 'constitute a

functional unit,' but not where the unpatented components 'have essentially no functional relationship to the patented invention, and ... may have been sold with an infringing device only as a matter of convenience or business advantage.' " Tec Air, Inc. v. Denso Manufacturing Michigan Inc., 192 F.3d 1353, 1362 (Fed.Cir.1999)(quoting Rite-Hite Corp., 56 F.3d at 1550). "[A] functional relationship between a patented device and an unpatented material used with it is not precluded by the fact that the device can be used with other materials or that the unpatented material can be used with other devices." Juicy Whip, Inc. v. Orange Bang, Inc., 382 F.3d 1367, 1372 (Fed.Cir.2004).

While it may argue this issue at trial, Gyrus has failed to establish as a matter of law that Xomed should not recover lost profits for lost sales of blade and bur attachments and its motion for summary judgment as to lost profits is denied on this point.

Finally, Gyrus argues that Xomed should not be entitled to lost profit damages for fiscal years 2004 through 2006 for "increased placements" (free product) which it could have otherwise sold in order to compete with Gyrus' free placement of allegedly infringing debriders. Gyrus contends that its free placements actually declined in 2005 and 2006, while Xomed's placements of its debrider unnecessarily increased. (Doc. 161-2 at 50.)

Xomed responds that it is seeking recovery of lost profits for increased placements from 2002 through 2006, that between 2002 and 2005, Gyrus' free placements were very high necessitating Xomed to also increase its free placements, that Xomed was unaware that Gyrus pulled back on its placement rate in 2005; and that the aggregate in increased placements between 2002 and 2006 should be the basis for an award of lost profits. (Doc. 174-1 at 46-47.)

Again, the facts surrounding the increased placements and whether lost profits are recoverable are in dispute. The Court denies Gyrus' motion for summary judgment as to lost profits damages for Xomed's increased placements.

For the foregoing reasons, and upon due consideration, it is hereby **ORDERED:**

1. Defendant/Counterclaimant Gyrus ENT LLC's Motion for Summary Judgment (Doc. (161-2)) is **DENIED.**

2. Plaintiff/Counterdefendant Medtronic Xomed, Inc.'s Motion For Summary Judgment On Defendant's Section 102, 103 and 112 Defenses And Counterclaim (Doc. 147-1) is **GRANTED IN PART AND DENIED IN PART,** consistent with this opinion. Specifically,

A. Xomed's Motion For Summary Judgment as to Gyrus' "Anticipation" (35 U.S.C. s. 102(b)) Defense and Counterclaim is **DENIED.**

B. Xomed's Motion For Summary Judgment as to Gyrus' "Derivation" (35 U.S.C. s. 102(f) and (g)) Defense and Counterclaim is **DENIED.**

C. Xomed's Motion For Summary Judgment as to Gyrus' "Obviousness" (35 U.S.C. s. 103(a)) Defense and Counterclaim is **DENIED.**

D. Xomed's Motion For Summary Judgment as to Gyrus' "Indefiniteness" (35 U.S.C. s. 112) Defense and

Counterclaim is **GRANTED.**

DONE AND ORDERED.

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