United States District Court,
D. Utah, Central Division.

CLINICAL INNOVATIONS, LLC, dba Clinical Innovations, Inc., a Delaware limited liability company,
Plaintiff and Counterclaim Defendant.
v.
TYCO HEALTHCARE GROUP LP, a Delaware corporation; Tyco International Ltd., a Bermuda based corporation. Tyco International (US), Inc., a Massachusetts corporation,
Defendants and Counterclaimants.

Civil No. 2:05-CV-00633 BSJ

July 6, 2007.

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MEMORANDUM OPINION & ORDER

BRUCE S. JENKINS**, Senior United States District Judge.**

This matter is before the court on plaintiff Clinical Innovations, LLC's ("Clinical Innovations") Motion for Claim Interpretation and for Partial Summary Judgment of Infringement (dkt. no. 146) and on defendants Tyco Healthcare Group LP's and Tyco International (US) Inc.'s (hereinafter collectively referred to as "Tyco" FN1) Motion for Summary Judgment of Non-Infringement (dkt. no. 158). The court heard oral argument on these motions during a hearing on November 9, 2006, as well as during the pretrial conference held on March 23, 2007. The court has carefully considered the parties' briefs relating to claim construction and infringement, the arguments made by the parties during the November 9, 2006 and March 23, 007 hearings, and the relevant law and facts. Now being fully advised, the court enters the following Memorandum Opinion & Order.

FN1. Based on the parties' representations, the court understands that Tyco International Ltd. has never been served and has not appeared in this matter. Thus, Tyco International Ltd. is not a party to this matter.

I. BACKGROUND[FN2]

FN2. Unless otherwise indicated, the following facts are taken from the parties' memoranda in support of their respective motions or are based on Clinical Innovations' representations during the March 23, 2007 hearing. (*See generally* Memorandum in Support of Motion for Claim Interpretation and for Partial Summary Judgment of Infringement (dkt. no. 147) ("C.I.'s Memo. in Supp."), at 1-7; Tyco Healthcare Group LP.'s and Tyco Int'l (US) Inc.'s Memorandum of Points and Authorities in Support of Motion for Summary Judgment of Non-Infringement (dkt. no. 159) ("Tyco's Memo. in Supp."), at 1-5; Transcript of Hearing, dated March 23, 2007 (dkt. no. 109) ("Tr.3/23/07"), at 8:14-14:5 (Mr. Mangum).)

Clinical Innovations makes and sells certain medical devices, including intrauterine pressure catheters. Clinical Innovations is the owner of the patent-in-suit, U.S. Patent No. 6,231,524 (the "'524 patent"), which is titled "Pressure Catheter Device with Enhanced Monitoring Features." The ' 524 patent is a continuation of the application that became U.S. Patent No. 5,951,497 (the "'497 patent"), and the '497 patent, in turn, is a continuation-in-part of U.S. Patent No. 5,984,879 (the "'879 patent"). FN3

FN3. ('524 patent, col. 1, ll. 5-10.)

The technology of the '524, '879, and '497 patents concerns a catheter that can be used as an intrauterine pressure catheter (an "IUPC") that monitors an expectant mother's uterine contractions during labor. IUPCs, which generally include a long tube with pressure detection technology located at the distal end of the tube, are intended to be inserted into the uterus and in the amniotic fluid space surrounding the fetus. Because the clinician cannot view the distal end of an IUPC during insertion, however, IUPCs are sometimes unintentionally inserted into a so-called "extraovular" location outside of the amniotic membrane, in which case the catheter may not accurately detect amniotic pressures and can cause tissue damage.

According to Clinical Innovations, after the '879 patent was issued, the inventors discovered that extraovular placement of their IUPCs was occurring. Recognizing the problems associated with such extraovular placement, the inventors identified the need to provide the clinician with some type of feedback to ensure the proper insertion of the IUPC. The solution devised by the inventors was to incorporate the use of light-transmissive material in the wall of the catheter tube, allowing the color and characteristics of the fluid flowing into the catheter's fluid passageway to be observed as amniotic fluid before the catheter was completely inserted. In the application that ultimately issued as the '497 patent (a continuation-in-part of the '879 patent), the inventors added this feedback feature to ensure proper placement of the IUPC. After the '497 patent was issued, the inventors filed a continuation application, which later issued as the '524 patent.FN4

FN4. According to Clinical Innovations, the purpose of the '524 patent was to claim the feedback feature of the '497 patent (*i.e.* the use of light-transmissive material in the wall of the tube) in integrated pressure catheters that used different types of pressure detectors than the one claimed in the '879 patent.

In this case, Clinical Innovations claims that the Accu-Trace intrauterine pressure catheters made and sold by Tyco infringe a number of claims of the '524 patent.FN5 The Accu-Trace, like the invention claimed in the ' 524 patent, includes a long tube with pressure detection technology located at the distal end of the tube. The tube used in the Accu-Trace is entirely clear.

FN5. After reviewing the material filed by the parties in this matter, the court is unaware of any specific product besides the Accu-Trace that Clinical Innovations has identified as infringing the '524 patent. The court, therefore, will only consider the Accu-Trace in its infringement analysis.

In its motion for summary judgment of infringement, Clinical Innovations asks the court to adopt its proposed construction for a number of disputed claim terms and argues that under such construction, the Accu-Trace product literally infringes claims 1-3, 5, 8, 11, 13-16, 18, 21, 24-26, 29-30, 32-33, 36, and 39-40 of the '524 patent as a matter of law.

Tyco, on the other hand, argues in its motion for summary judgment of non-infringement that the only claim element that the court needs to analyze is the "window" limitation, which is included in each claim of the '524 patent. According to Tyco, because the Accu-Trace's entirely clear catheter tube does not meet the "window" limitation either literally or under the doctrine of equivalents, Clinical Innovations cannot prove that the Accu-Trace contains each element of any of the asserted claims, and therefore, cannot establish infringement.

II. STANDARD OF REVIEW

Summary judgment is appropriate in a patent case, as in any other type of case, where there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law .FN6 In order to determine whether or not the Accu-Trace infringes the ' 524 patent, the court must apply a two-part analysis.FN7 First, as a matter of law, the court must construe the ' 524 patent to determine the scope and meaning of its claims.FN8 Next, the claims of the ' 524 patent, as construed by the court, must be compared to the Accu-Trace to determine whether the patent's claims are infringed.FN9 The "determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact." FN10 However, both literal infringement and infringement under the doctrine of equivalents may be decided on summary judgment .FN11 The issue of literal infringement "is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." FN12 A claim of infringement under the doctrine of equivalents may also be decided on summary judgment " 'where the evidence is such that no reasonable jury could determine two elements to be equivalent....' " FN13

FN6. Fed.R.Civ.P. 56(c); TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1369 (Fed.Cir.2002).

FN7. C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 861 (Fed.Cir.2004).

FN8. *Id*.

FN9. *Id*.

FN10. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed.Cir.1998).

FN11. *Id*.

FN12. *Id*.

FN13. *Id*. at 1353-54 (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 n. 8 (1997)).

The parties agree that there are no disputed issues of fact regarding the structure and operation of Tyco's Accu-Trace product and that once the court construes the disputed claim terms as a matter of law, the issue of infringement should be determined on summary judgment.FN14

FN14. (Motion for Claim Interpretation and for Partial Summary Judgment of Infringement (dkt. no. 146) ("C.I.'s Mot."), at 21 ("[T]he structure and operation of Tyco's accused infringing intrauterine catheters is not in dispute."); C.I.'s Memo. in Supp., at 1 ("The only infringement issue is the purely legal issue of interpretation of the '524 patent's claims."); Tyco Healthcare Group LP.'s and Tyco International (US) Inc.'s Motion for Summary Judgment of Non-Infringement (dkt. no. 158) ("Tyco's Mot."); Tyco Healthcare Group LP.'s and Tyco International (US) Inc.'s Reply Memorandum of Points and Authorities in Support of Motion for Summary Judgment of Non-Infringement (dkt. no. 180) ("Tyco's Reply"), at 1 ("This case is ripe for entry of summary judgment of non-infringement. There is no factual dispute regarding the relevant structure of the accused Accu-Trace product...."); Tr. 3/23/07, at 8, 65, 70, 72.)

III. CLAIM CONSTRUCTION

In construing the claims of a patent, the court must first consider the intrinsic evidence of record, which "is the most significant source of the legally operative meaning of disputed claim language." FN15 Intrinsic evidence comes from three sources: the words of the claims in the patent, the patent specification, and the prosecution history.FN16

FN15. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

FN16. *Id*.

The claims of a patent define the scope of the invention by "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." FN17 Thus, in construing a claim term, the court should first look to the words of the claims.FN18 "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." FN19 "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention...." FN20

FN17. 35 U.S.C.A. s. 112 (2001).

FN18. Vitronics, 90 F.3d at 1582.

FN19. *Id*.

FN20. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed.Cir.2005).

"The claims, of course, do not stand alone. Rather, they are part of 'a fully integrated written instrument....' " FN21 Thus, the court must also review the patent specification-"the single best guide to the meaning of a disputed term"-"to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." FN22 The court must read the claims and construe the terms of a patent in view of, and consistent with, the specification of which they are a part.FN23

FN21. *Id*. at 1315 (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed.Cir.1995) (en banc)).

FN22. Vitronics, 90 F.3d at 1582.

FN23. Phillips, 415 F.3d at 1315.

Finally, the court should also consider the prosecution history of the patent. FN24 The prosecution history

FN24. Vitronics, 90 F.3d at 1582.

contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims. *See* Markman, 52 F.3d at 980, 34 USPQ2d at 1330; Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 USPQ2d 1673, 1676 (Fed.Cir.1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.") (citations omitted). Included within an analysis of the file history may be an examination of the prior art cited therein. Autogiro Co. of America v. United States, 181 Ct.Cl. 55, 384 F.2d 391, 399, 155 USPQ 697, 704 (1967) ("In its broader use as source material, the prior art cited in the file wrapper gives clues as to what the claims do not cover.").FN25

FN25. *Id*. at 1582-83; Phillips, 415 F.3d at 1317 (providing that the prosecution history "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent").

Generally, "an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." FN26 In cases where the intrinsic evidence does not resolve the ambiguity in a claim term, the court may rely on extrinsic evidence, which includes all evidence that is external to the patent and prosecution history, such as expert testimony, dictionaries, and learned treatises.FN27 But extrinsic evidence is less significant than the intrinsic record in determining the meaning of a disputed claim.FN28

FN26. Vitronics, 90 F.3d at 1583.

FN27. *Id*.

FN28. Phillips, 415 F.3d at 1317.

In determining whether or not the Accu-Trace infringes the '524 patent, the court must construe the terms of the patent only to the extent necessary to resolve the controversy regarding infringement.FN29 In this case, the parties disagree about the proper construction of a number of terms used in the ' 524 patent, including the term "window." FN30 The parties agree that the court's construction of the term "window" may be dispositive of the infringement issue for the reason that if the court construes the "window" limitation as not being satisfied by an entirely clear tube, the Accu-Trace will not meet every element of the asserted claims.FN31 Thus, the court will begin its claim construction process by construing the term "window."

FN29. Vivid Tech., Inc. v. Am. Science & Eng'g, Inc., 200 F.3d 795, 803 (Fed.Cir.1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

FN30. (*See* Joint Claim Construction Statement (dkt. no. 126), Ex. B.)

FN31. (Tr. 3/23/07, at 70 ("It's absolutely a legal issue. And I think both sides agree that if you adopt our interpretation [of the term "window"], they infringe-at least some of the claims they infringe. If you adopt their interpretation [of the term "window"], we agree that we-they do not infringe." (Mr. Mangum); Tyco's Reply, at 1 ("The outstanding issue presented by Tyco's motion for summary judgment is the meaning of the single term 'window,'.... The court's determination that an entirely clear tube is not a 'window' will dispose of C.I.'s entire case because a 'window' is required in each claim.").)

A. Construction of the "Window" Limitation

The three independent claims of '524 patent, each of which has been asserted against Tyco, contains a "window" limitation. Independent claim 1 provides:

1. A catheter for detecting changes in pressure within a body comprising;

an elongated outer tube defined by a circumferential wall, having ... at least a portion of said circumferential wall of said elongated outer tube ... located at least in part remote from said first, distal end and including at least a medial portion of said elongated outer tube *being formed of a light-transmissive material comprising at least one window* along a length of said elongated outer tube;.... FN32

FN32. ('524 patent, at col. 18 (emphasis added).)

Independent claim 13 provides:

13. An intrauterine pressure catheter comprising:

an elongated outer tube having ... at least a portion of a wall of said elongated outer tube ... located at least in part remote from the distal end thereof and including at least a medial portion thereof *comprising at least one window of light-transmissive material* along a length of said elongated outer tube;.... FN33

FN33. ('524 patent, at col. 18-19 (emphasis added).)

And independent claim 25 provides:

25. A pressure catheter for detecting changes in pressure within a body comprising:

an elongated tube structure ... including a wall ... at least a portion of said wall located at least in part remote from said first, distal end of said elongated tube structure and including at least a medial portion of said elongated tube structure *comprising a light-transmissive material providing at least one light-transmissive window* along a length of said elongated tube structure;.... FN34

FN34. ('524 patent, at col. 19-20 (emphasis added).)

Because a dependent claim, by definition, includes each element of the independent claim from which it depends, each dependent claim of the '524 patent also contains a window limitation.FN35

FN35. 35 U.S.C.A. s. 112 ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.").

Clinical Innovations argues that the term "window" means that at least some portion of the catheter tubing, including at least somewhere generally in the middle part of the tube, cannot be opaque, but instead must be made of light-transmissive material that acts as a means of observation.FN36 Under Clinical Innovations' proposed construction, the catheter tube is not precluded from being entirely light-transmissive (*i.e.*, entirely clear).FN37

FN36. (Joint Claim Construction Statement, at Ex. B, 10-13, 15-20; C .I.'s Memo. in Supp., at 48-49.)

FN37. (C.I.'s Memo. in Supp., at 48-49.)

Tyco, on the other hand, argues that the "window" limitation of the ' 524 patent means "an opening made of light-transmissive material in the circumferential wall of the outer tube that is bounded by material that is not light-transmissive, either in circumference around the outer tube and/or longitudinally along the length of the outer tube." FN38 Under Tyco's proposed claim construction, the term "window" means something less than the entire outer tube such that the "window" limitation cannot be met by a tube made entirely of light-transmissive material.FN39

FN38. (Joint Claim Construction Statement, at Ex. B, 15-20.)

FN39. (Id.)

1. The Claim Language

It is not entirely clear based on the claim language of the '524 patent alone what the term "window" means, and, critically for this case, whether the "window" limitation can be satisfied by an entirely clear tube.

The independent claims repeatedly use the qualifying language "at least" in describing the window limitation. The independent claims require: " *at least* one" "window," that the "window" be located " *at least* in part remote from" the distal end of the tube, and that the "window" be located " *at least* [in] a medial portion" of the tube. Based on this language, Clinical Innovations argues that the claims do not limit the use of light-transmissive material in the tube and merely require that, at a minimum, light-transmissive material be located in the middle part of the tube.FN40 According to Clinical Innovations, as long as there is some light-transmissive material in at least the middle portion of the tube, and regardless of how much other light-transmissive material is used in the tube, the window limitation is met.

FN40. (C.I.'s Memo. in Supp., at 48; Tr. 3/23/07, at 6-7 (Mr. Mangum).)

In the court's opinion, while the "at least" language provides that the claimed catheter tube may contain more than one "window" and may contain such window or windows in particular locations of the tube, it does not negate the requirement that the tube contain the specific structure of a " *window*." The independent claims do not simply require that "light-transmissive material" be used somewhere in the tube. Instead, the independent claims specifically require that "light-transmissive material" "compris[e]" or "provid[e]" a " *window*." FN41 This language suggests that the applicants deliberately used the different terms "window" and "light-transmissive material" to represent different things. The "window," one thing, is a distinct structure that is made from the "light-transmissive material," a different thing.

FN41. In fact, as discussed below, during the prosecution of the ' 497 patent, two of the original independent claims initially required only that "at least a portion" of the tube wall be light-transmissive. However, after the Patent Examiner rejected the claims and before the claims were allowed, the applicants amended the

claims to include the "window" limitation.

Ordinarily, the term "window" is used to describe a transparent opening that is inserted in, or framed by, non-light-transmissive material.FN42 As discussed above, the claim language clearly teaches that a "window" is made from "light-transmissive material" and is therefore transparent. However, it is not entirely clear from the language of the claims alone whether the term "window" is used in a manner that is consistent with the ordinary meaning of the term and requires that the transparent structure be inserted in opaque material.

FN42. In its supporting memorandum, Clinical Innovations relies on the following dictionary definition for the word "window," which is consistent with the court's understanding of the ordinary meaning of the term: "A 'window' is '[a] means of ... observation,' 'a transparent opening,' and 'a transparent panel ... *inserted in an otherwise opaque material*.' The American Heritage Dictionary of the English Language, Exh. 12 (4th ed.2000); WordNet 2.0 (2003). 'Opaque' means '[i]mpenetrable by light; neither transparent nor translucent." The American Heritage Dictionary of the English Language, Exh. 12 (4th ed.2000)."

(C.I.'s Memo. in Supp., at 45-46 (emphasis added).) While the court, in construing the term "window," is relying on the intrinsic evidence of the ' 524 patent (the claims, the patent specification, and prosecution history) and not extrinsic evidence, the court finds it interesting that Clinical Innovations relies on a dictionary definition of the term "window" that seems to support Tyco's proposed construction.
On the one hand, certain of the unasserted, dependent claims that add to the "window" limitation in the independent claims, such as claims 9-10, 22-23, and 37-38, describe a "window" as a portion of light-transmissive material that is bounded (either circumferentially, longitudinally, or both) by non-light-transmissive material. These dependent claims support the notion that the term "window" requires opaque material around the light-transmissive material and means something different from an entirely clear tube.FN43

FN43. For instance, claims 9, 22, and 37 provide that the "at least one" "window comprises a plurality of longitudinally-spaced windows of light-transmissive material." ('524 patent, at col. 18-20.) Claims 10, 23, and 38 provide that the "at least one" "window" "extends through about a 75 degree arc circumferentially" of the outer tube wall. ('524 patent, at col. 18-20.)

Other of the asserted, dependent claims require that light-transmissive material comprise "substantially an entire wall" of the catheter tube, FN44 which Clinical Innovations interprets as meaning "that the width of a window in the catheter wall extends at least to a great extent around the outer circumference of the wall" and as claiming an entirely clear tube. FN45

FN44. (*See* '524 patent, at col. 18-20 (providing in claim 11 that "light-transmissive material comprises substantially an entire wall of said elongated outer tube;" providing in claim 24 "wherein substantially an entire wall of said elongated outer tube comprises a light-transmissive material;" and providing in claim 39 that "at least one light-transmissive wall portion comprises substantially an entire exterior wall of said elongated tube structure").)

FN45. (C.I.'s Memo. in Supp., at 49; Memorandum in Opposition to Tyco Healthcare Group LP.'s and Tyco International (US) Inc.'s Motion for Summary Judgment of Non-Infringement (dkt. no. 176) ("C.I.'s Memo. in Opp.), at 22.)

In the court's opinion, neither the language of the independent claims, nor the language of the dependent claims, nor both considered together, clearly define the term "window." The lack of guidance in the claims regarding the meaning of "window" raise at least some question as to whether the "window" limitation is satisfied by an entirely clear tube, or whether it requires that the light-transmissive material be bounded in some way by non-light-transmissive material.

However, as discussed below, the specification of the '524 patent and the prosecution history of the '524 and '497 patents both provide compelling evidence that a person of skill in the art would understand that the "window" in the '524 patent is a distinct structure in the outer tube that is made from light-transmissive material, is bounded in some way by opaque material, and is different than an entirely clear tube.

2. The '524 Patent **Specification**

The '524 patent specification discloses two distinct catheter tubing embodiments: a tube with one or more windows, and a tube made entirely of light-transmissive material. While the specification provides that the function of the two embodiments is the same-to allow the fluid in the tube to be viewed by the clinician-the structures of the two embodiments, as described in the specification, are clearly different.FN46 The catheter tube with the claimed "window" or "windows" is illustrated and described in the specification as a tube containing a discrete portion of light-transmissive material in the wall of the tube that is framed to some extent by non-light-transmissive material.FN47 The entirely clear outer tube, on the other hand, is illustrated and described as a tube made entirely of light-transmissive material, with no opaque material in the wall of the tube.FN48

FN46. (*See* '524 patent, col. 7, ll. 14-23 (providing that "[t]he *view window* provides a view of amniotic fluid traveling from the distal end of the catheter toward the proximal end, through the channel defined between the outer tube and the inner tube" and that " *[a]lternatively, the entire outer tube* may be made of an ambient light-penetrable material for easy viewing of amniotic fluid" (emphasis added)); col. 16, ll. 5-9 ("Use of a window structure *or* other light-transmissive configuration for the outer catheter tube permits early viewing of amniotic fluid prior to discharge thereof from the proximal end of the catheter, and thus facilitates safe confirmation of proper catheter placement." (emphasis added)).)

FN47. Figure 13 is described in the specification as a "view of a catheter structure including a view *window* " and as a "tube 216 including a light-transmissive *window* 220 extending about a 75 degree circumferential arc along the tube wall." ('524 patent, col. 8, ll. 41-43 (emphasis added); col. 15, ll. 56-58 (emphasis added).) Figure 13B is similarly described in the specification as a side "view of an outer tube structure including a plurality of longitudinally-spaced view *windows* " and as a depiction of "an outer tube 216 including discontinuous distal, medial and proximal *windows* 220 *a,* 220 *b,* and 220 *c,* respectively." ('524 patent, col. 8, ll. 46-48 (emphasis added); col. 16, ll. 3-5 (emphasis added).) Both figures 13 and 13B clearly depict a tube where a portion of light-transmissive material is bounded in some way by opaque material.

FN48. Figure 13A, which shows an entirely clear tube, is not described as, referred to, or labeled as depicting a "window." Instead, the specification describes figure 13A as a "view of a light-transmissive outer tube structure" and as an "entire tube 216 ... formed of a light-transmissive material ...." ('524 patent, col. 8, ll. 44-45; col. 15, ll. 62-63.)

The specification repeatedly distinguishes between, and treats in the alternative, a catheter tube with one or more windows and a catheter tube made entirely of light-transmissive material. For example, the "Summary of the Invention" section of the specification explains:

An additional benefit is provided in one embodiment of the catheter of the invention in the form of a transparent or translucent view window extending longitudinally along at least a portion of the wall of the hollow outer tube.... The window may extend longitudinally along substantially the entire length of the outer tube, and circumferentially along a suitable arc, for example 75 degrees, of the outer tube wall. *Alternatively,* the entire outer tube may be made of an ambient light-penetrable material for easy viewing of amniotic fluid.

...

Further, a single tube, two-lumen catheter may be fabricated with a view window extending along an exterior wall of one lumen, *or* the entire tube fabricated of a light-transmissive material. Alternatively, two adjacent tubes may be employed, with at least one formed of light-transmissive material *or* having a longitudinally-extending view window or windows." FN49

FN49. ('524 patent, col. 7, ll. 10-23, 61-67 (emphasis added).)

Similarly, the "Detailed Description of the Invention" section of the specification provides:

The window 220 of the outer tube may be formed of clear PELLETHANE 2363 elastomer, while the remainder of the tube wall may be formed of HYTREL G6356 elastomer, by an extrusion process as known in the art. *Alternatively,* the entire tube 216 may be formed of a light-transmissive material 222 as shown in FIG. 13A." FN50

FN50. ('524 patent, col. 15, ll. 58-64 (emphasis added); *see also* '524 patent, col. 16, ll. 5-9 ("Use of a window structure *or* other light-transmissive configuration for the outer catheter tube permits early viewing of amniotic fluid ...." (emphasis added)).)

Clinical Innovations argues that this language is a description of one embodiment and two types of windows: bounded windows and entirely clear tube windows.FN51 The court disagrees. The terms "alternatively" and "or" are normally used to designate an alternative between different things, and there is no basis for the court to determine that those words were intended to have a different meaning in the ' 524 patent.FN52 Thus, the court determines that the specification's repeated use of the terms "alternatively" and "or" in referring to an entirely clear tube clearly teaches that a catheter tube made entirely of light-transmissive material is different from a catheter tube containing one or more windows.

FN51. (Tr. 3/23/07, at 18-19, 66-67 ("And their suggestion that when the specification talks about the use of partially clear tubes and then says alternatively you can have an entirely clear tube, their position is that that is in contradistinction to a window, and our position is that it's listing two types of windows. There are bounded windows and there are entirely clear tube windows.") (Mr. Mangum).)

FN52. *See* Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1311-12 (Fed.Cir.2002).

The applicants, in drafting the claims that define the scope and extent of their invention, specifically included the term "window" as a limitation in each of the independent claims. Had the applicants meant for the term "window" to have a meaning that included an entirely clear tube, they should have clearly explained their special definition in the patent specification. FN53 But they did not do so.

FN53. *See* Vitronics, 90 F.3d at 1582.

Nowhere in the specification is an entirely clear tube described, referred to, or labeled as a "window." Instead, each reference to an entirely clear tube in the specification is prefaced as an *alternative* to a window. Thus, the court finds that the specification supports Tyco's position that the "window" limitation in the '524 patent requires a portion of light-transmissive material that is bounded in some way by opaque material and is, therefore, not satisfied by an entirely clear tube.

3. The Prosecution History

Relevant sections of the prosecution history of the '524 patent and its parent, the '497 patent, also present compelling evidence that the term "window" was understood by both the Patent Examiner and the applicants as meaning a discrete portion of light-transmissive material inserted in opaque material and as being something different than an entirely clear tube. FN54

FN54. As mentioned above, the application for what became the '524 patent is a continuation from the application that became the '497 patent. The independent claims of both the '497 and '524 patents require the use of a "window" in the outer tube. Thus, the prosecution history of the '497 patent is relevant to an understanding of the term "window" as that term is used in the '524 patent. *See* Jonsson v. The Stanley Works, 903 F.2d 812, 818 (Fed.Cir.1990).

The Examiner's citations to the prior art illustrates how she understood the term "window." FN55 During the prosecution of the patents, the Examiner repeatedly and consistently distinguished between prior art that depicted a "window" and prior art that depicted an entirely clear tube. In discussing the concept of a "window," the Examiner repeatedly cited to Ouchi (U.S. Patent No. 4,407,273) and Herrmann, *et al*. (U.S. Patent No. 5,421,323) as prior art.FN56 Both of these prior art references disclose an endoscope having a "window" formed of light-transmissive material that is bounded by opaque material.FN57 However, in discussing the concept of an entirely clear tube, the Examiner did not refer to either Ouchi or Herrmann, but instead referred to Kolff (U.S. Patent No. 5,370,640), which discloses a "light-transmissive wall"- *i.e* . an entirely clear tube-not a "window." FN58 Based on the Examiners' citations to the Ouchi and Herrmann patents in referring to a "window," in comparison to her reliance on Kolff when referring to an entirely clear

wall, it is apparent to the court that the Examiner understood an entirely clear tube to be something different than a "window."

FN55. *See* Nazomi Communications, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed.Cir.2005) ("[T]he prior art is often a reliable source of the understanding of one of ordinary skill in the art.").

FN56. (Declaration of David C. Bohrer in Support of Defendants' Motion for Summary Judgment of Non-Infringement ("Bohrer Decl.") (dkt. no. 164), at Ex. D ('497 file history), TYCO 6866 (stating that "figure 10 of Ouchi shows an endoscope having a substantially transparent viewing windows 2 and a substantially transparent illuminating window 3"), TYCO 6868 (same), TYCO 6873 (providing that "Herrmann et al (Pat. No. 5,421,323) is cited to show the window"); Ex. B ('524 file history), TYCO 7164-65 ("Ouchi teaches an endoscope comprising an elongated outer tube 104, ... a wall (103, 104) having a substantially transparent viewing windows 2 and a substantially transparent illuminating window 3...."), TYCO 7200 ("Ouchi teaches an endoscope comprising an elongated outer tube 104, ... a wall (103, 104) having a substantially transparent viewing windows 2 (remote from distal end)....").)

FN57. (Id.; *see also* id. at Ex. D ('497 file history), TYCO 6883-84, TYCO 6890 (Ouchi patent (col. 6, ll. 21-37 and Figs. 2-3)), TYCO 6970, TYCO 6973, TYCO 6975 (Herrmann patent (col.4, ll.45-49, figs.6-7)).)

FN58. (Id. at Ex. D ('497 file history), TYCO 6873 (specifying that "Kolff (Pat. No. 5,370,640) is cited to show the light transmitting wall"), TYCO 6957, TYCO 6958, TYCO 6963 (Kolff patent (Figs. 1-3 and col. 6, ll. 30-33 ("The light-transmitting wall 44 is typically made of clear plastic, but may alternatively be made of any transparent or translucent material, or any other preferably flexible material penetrable by light"))); Ex. B ('524 file history), TYCO 7206 ("Applicant further argues that neither Ouchi nor Daw teaches the portion forming a light transmissive window comprising substantially an entire wall of the outer tube. While it is true that neither Ouchi nor Daw disclose such an outer tube. However, the feature of fabricating the tube from transmissive material is notoriously old and well known in the surgical instrument art. See teaching in column 6, lines 30-33 Kolff reference.").)

Amendments that the applicants made during the prosecution of the '497 and ' 524 patents also support this conclusion. The application that ultimately became the '497 patent originally contained three independent claims: 1, 21, and 43. Each of these original independent claims included the limitation that "at least a portion" of the catheter tube wall be "light-transmissive." Claims 1 and 43, which respectively recited "at least a portion of said wall of said outer tube being light-transmissive" FN59 and "at least a portion of said wall being light-transmissive," FN60 did not contain a window limitation and were broad enough to cover an entirely clear tube. Claim 21 recited "at least a portion of a wall of said outer tube ... comprising a window." FN61 These original claims show that the applicants understood there to be a difference in meaning between a tube with one or more windows and a tube with "at least a portion" of the wall being "light-transmissive" and were seeking to incorporate both the "window" embodiment and the entirely clear tube embodiment in the original claims.

FN59. (Id. at Ex. D ('497 file history), TYCO 6745.)

FN60. (Id. at Ex. D ('497 file history), TYCO 6750.)

FN61. (Id. at Ex. D ('497 file history), TYCO 6747.)

The Examiner, however, rejected each of the original independent claims as being obvious given the prior art.FN62 In response, the applicants amended the independent claims to more particularly define the claims and to make "clear that the light-transmissive portion or window in the tube wall had to be a 'material' that 'formed' or 'comprised' the tube wall...." FN63 After the applicants filed this amendment, and before the Examiner issued a new Office Action, the applicants agreed during a telephone interview to "[f]urther define the nature of the tube by adding limitation such as 'comprising at least one window along a length of the outer tube (or tubes)' to claims 1, 21, and 43." FN64 Thus, while two of the three original independent claims did not contain a "window" limitation and would have been broad enough to cover an entirely clear tube, the Examiner required the applicants to further clarify the nature of the tube by adding the limitation of "at least one *window* along a length of the outer tube [or tube structure]" before she allowed the claims to issue.FN65

FN62. (Id. at Ex. D ('497 file history), TYCO 6865-69.)

FN63. (C.I.'s Memo. in Opp. at 16; *see* Bohrer Decl., at Ex. D ('497 file history), TYCO 6983, TYCO 6986-87 (setting forth the applicants' amendments in response to the Examiner's rejection).)

FN64. (Id. at Ex. D ('497 file history), TYCO 7006.)

FN65. Clinical Innovations argues that during the prosecution of the '497 patent, the Examiner considered the term "light-transmissive and "light-transmissive window" in the original claims as being broad enough to cover a hole or opening in the wall of the tube and that the applicants amended the independent claims to include the term "window" in order to make "it absolutely clear that the light-transmissive portion of the tube could not encompass a hole or opening." (C.I.'s Memo. in Opp. at 15-17.) However, before the Examiner's Interview, at which time the applicants agreed to add the term "window" to each of the independent claims, the applicants already had amended the claims to make "clear that the light-transmissive portion or window in the tube wall had to be a 'material' that 'formed' or 'comprised' the tube wall, and thus could not be an opening or hole because air is not a material that can form or comprise a wall." (Id. at 16; *see* Bohrer Decl., at Ex. D ('497 file history), TYCO 6983, TYCO 6986, TYCO 6989.) After reviewing the prosecution history in detail, the court determines that the Examiner did not require the addition of the term "window" to the independent claims merely to indicate that the claims did not encompass a hole or opening in the tube.

During the prosecution of the '524 patent, the applicants again attempted to broaden their claims to include the entirely clear tube embodiment. Dependent claims 11, 24, and 39 of the '524 patent each claim a catheter wherein "substantially an entire" wall is formed of "light-transmissive material." FN66 In the Examiner's

first Office Action during the prosecution of the ' 524 patent, the Examiner interpreted these dependent claims as an attempt by the applicants to claim an entirely clear tube. Based on this understanding, the Examiner rejected the dependent claims on the basis that an entirely clear tube was an obvious design choice.FN67

FN66. ('524 patent, col. 18-20.)

FN67. In specifically rejecting claims 11 and 24, the Examiner stated that "the feature of fabricating an entire wall of the outer tube from light-transmissive material is considered as an obvious design choice since such feature is well know [sic] in the medical art." (Bohrer Decl., at Ex. B ('524 file history), TYCO 7165.) In specifically rejecting claim 39, the patent examiner stated that the feature "of choosing the entire exterior wall from light-transmissive material" was considered an "obvious design preference[ ] within the knowledge of one skilled in the art since such features are well known in the art." (Id. at Ex. B ('524 file history), TYCO 7167.) The Examiner's indication that an entirely clear tube was unpatentable, by itself, is a clear indication that she believed that the term "window," which was already allowed to be claimed in the '497 patent, meant something different from, and did not encompass, an entirely clear tube.

The applicants responded to the Examiner's rejection by claiming that the recited feature was not an obvious design choice and by arguing that

[a]llowing the entire wall to be a window provides the advantage that the clinician not search for the a[sic] specifically located window while the catheter is in use. A specifically placed window may be difficult to locate requiring physical handling, such as rotation, of the tube by a clinician each time the window is needed for viewing purposes.FN68

FN68. (Id. at Ex. B ('524 file history), TYCO 7182-83, TYCO 7189.)

By their response, the applicants clearly encouraged the Examiner to interpret the term "window" as encompassing an entirely clear tube.

After "fully consider[ing]" the applicants' arguments and finding them to be "not persuasive," the Examiner again rejected dependent claims 11, 24, and 39. FN69 In rejecting the dependent claims as being obvious under 35 U.S.C. s. 103, the examiner repeated her previous determination that fabricating an entire wall of the outer tube from light-transmissive material was an obvious design preference that was well known in the medical art.FN70

FN69. (Id. at Ex. B ('524 file history), TYCO 7200-01, TYCO 7203, TYCO 7205-06 ("Applicant further argues that neither Ouchi nor Daw teaches the portion forming a light transmissive window comprising substantially an entire wall of the outer tube. While it is true that neither Ouchi nor Daw disclose such an outer tube. However, the feature of fabricating the tube from transmissive material is notoriously old and well known in the surgical instrument art.").)

FN70. (Id. Ex. B ('524 file history), TYCO 7201 ("In regard to claims 11 and 24, the feature of fabricating

an entire wall of the outer tube from light-transmissive material is considered as an obvious design choice since such feature is well know [sic] in the medical art."), TYCO 7203 (indicating that with respect to claim 39, the feature "of choosing the entire exterior wall from light-transmissive material ... [is] considered as [an] obvious design preference[ ] within the knowledge of one skilled in the art since such feature[ ][is] well known in the art").)

The Examiner's response explicitly provided that an entirely clear tube was unpatentable, and implicitly indicated that she did not accept the applicants' argument that the term "window" means the same thing as, or includes, an entirely clear tube. Ultimately, the dependent claims were allowed to issue without amendment, but only after the applicants amended the independent claims to further define the "window" limitation and reassured the Examiner that the dependent claims were patentable as depending upon the independent claims, all of which contained the "window" limitation.FN71

FN71. (Id. at Ex. B ('524 file history), TYCO 7222-23, TYCO 7226, TYCO 7228.) Clinical Innovations argues that in response to the Examiner's rejection, the applicants disputed the assertion that the configuration in claims 11, 24, or 39 is a matter of obvious design choice and thus "refuted the examiner's contention that these claims would have been obvious based on a combination of the use of clear tubes in prior art with other prior art that the examiner used to reject the independent claims." (C.I.'s Opp., at 21). According to Clinical Innovations, the "examiner then allowed the claims without additional comment or rejections. She did not repeat, and thus ceased, the basis for her rejection of all of those claims." (Id.) A review of the prosecution history, however, shows that while Clinical Innovations disputed the obviousness rejection with respect to claims 10, 23, and 38, which are directed to a "window" extending through a 75-degree circumferential arc, it did not dispute the obviousness rejection of claims 11, 24, and 39. Instead, their only response to the rejection of those claims was that such claims were allowable because they depended upon the independent claims, each of which included the "window" limitation. (Bohrer Decl., at Ex. B ('524 file history), TYCO 7216, TYCO 7218, TYCO 7226, TYCO 7228; *see also* Tyco's Reply, at 24.) This history shows that the Examiner allowed independent claims 11, 24, and 39 because they depended on independent claims that included the amended "window" limitation, not because the applicants had persuasively refuted her position that such claims were unpatentable as an obvious design choice.

After carefully analyzing the intrinsic evidence, the court determines that the patent specification and the prosecution history of the '524 and '497 patents provide compelling evidence that the term "window" in the '524 patent means something different than and does not encompass an entirely clear tube.FN72 Relying on the intrinsic evidence alone, the court adopts Tyco's proposed construction and construes the term "window" as meaning "an opening made of light-transmissive material in the circumferential wall of the outer tube that is bounded by material that is not light-transmissive, either in circumference around the outer tube and/or longitudinally along the length of the outer tube." FN73 Therefore, "[a] window is less than the entire outer tube such that it cannot be a tube made entirely of light-transmissive material." FN74

FN72. The court's consideration of the intrinsic evidence has resolved any ambiguity in the term "window." The court, therefore, has not relied on any extrinsic evidence. *See* Vitronics, 90 F.3d at 1583.

FN73. (Tyco's Memo. in Supp., at 8.)

FN74. (*Id.*)

IV. INFRINGEMENT ANALYSIS

Having determined the scope and meaning of the "window" limitation that is included in each of the asserted claims, the court now compares the asserted claims to the accused device.

"To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system ." FN75 It is undisputed that Tyco's accused Accu-Trace contains an elongated tube that is entirely clear. Because the term "window," as properly construed, means something different than an entirely clear tube, no reasonable jury could find that every limitation recited in the asserted claims of the ' 524 patent are literally satisfied by the accused product. Thus, Clinical Innovations cannot establish literal infringement of the ' 524 patent, and summary judgment in Tyco's favor is appropriate.

FN75. TechSearch, 286 F.3d at 1371.

The court also determines that Clinical Innovations cannot establish infringement under the doctrine of equivalents because no reasonable fact finder could find equivalence.FN76

FN76. In its Complaint, Clinical Innovations alleged that Tyco was infringing the '524 patent either literally or under the doctrine of equivalents. (Complaint (dkt. no. 1), at 4, para. 16.) While Clinical Innovations' motion for summary judgment of infringement was limited to the issue of literal infringement, Tyco raised the issue of infringement under the doctrine of equivalents in its motion for summary judgment of non-infringement. Clinical Innovations' only response to Tyco's arguments regarding non-infringement under the doctrine of equivalents was that Tyco's arguments were based upon Tyco's incorrect proposed construction of the word "window." (*See* C.I.'s Memo. in Opp., at 24-25.)

"The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." FN77 "Equivalence is shown by evidence that the accused device contains an element that is not 'substantially different' from any claim element that is literally lacking, or that the claimed limitation and the accused component 'perform[ ] substantially the same function in substantially the same way to achieve substantially the same result[.]' " FN78

FN77. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U . S. 722, 733 (2002).

FN78. Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1371 (Fed.Cir.2000) (citations omitted); Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed.Cir.1997) ("A claim element is equivalently present in an accused device if only 'insubstantial differences' distinguish the missing claim element from the corresponding aspects of the accused device." (quoting Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1517-18 (Fed.Cir.1995) (en banc))).

An entirely clear tube is not an insubstantial alteration of the "window" limitation that was not captured in drafting the original patent claim. To the contrary, the applicants of the '524 patent were clearly aware of and disclosed the use of an entirely clear tube in the patent's specification as an alternative to an outer tube with a "window." However, because the Patent Examiner would not allow the applicants to claim an entirely clear tube, the independent claims (upon which all of the dependent claims depend) more narrowly claimed only the "window" embodiment.

"A patentee may not write narrow claims for allowance by the [Patent and Trademark Office] and subsequently attempt to broaden the claims in a court by using the doctrine of equivalents." FN79 Because the applicants specifically identified the clear tube embodiment, but excluded it from the claims, Clinical Innovations cannot now invoke the doctrine of equivalents to embrace that embodiment. The court will not improperly enlarge the ' 524 patent beyond the scope of its claims as allowed by the Patent Office by determining that an entirely clear tube is the equivalent of the "window" limitation in the ' 524 patent.FN80

FN79. PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1357 (Fed.Cir.2004); Johnson & Johnston Assoc., Inc. v. R.E. Serv. Co., Inc., 285 F.3d 1046, 1054-55 (Fed.Cir.2002) ("[A] patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents. 'Such a result would merely encourage a patent applicant to present a broad disclosure in the specification of the application and file narrow claims, avoiding examination of broader claims that the applicant could have filed consistent with the specification.' " (quoting Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1107 (Fed.Cir.1996))).

FN80. *See* Johnson & Johnston, 285 F.3d at 1055.

In addition, while a catheter tube with one or more windows and a catheter tube with an entirely clear wall both achieve a similar result-allowing the clinician to view the contents inside the catheter tube-the court determines that an entirely clear catheter tube is substantially different than a catheter tube with one or more windows and that the claimed "window" is a meaningful structural limitation on which the public is entitled to rely in avoiding infringement.FN81

FN81. *See* Sage Prods., 126 F.3d at 1424-25.

Without the "window" limitation in the independent claims, the claims would merely require that "at least a medial portion" of the outer tube be made from light-transmissive material, and accordingly, would be broad enough to cover an entirely clear tube. However, as discussed above, the independent claims do not simply require that "light-transmissive material" be used in "at least a portion" tube, but instead specifically include the structural limitation that the "light-transmissive material" comprise a " *window*." The court must deem the "window" limitation of the '524 patent, like each element contained in a patent claim, as "material to defining the scope of the patented invention." FN82 Construing the term "window" as the equivalent of an entirely clear tube would read the "window" limitation out of the claims and would render the "window" limitation surplusage of the "light-transmissive material" language. The court may not apply the doctrine of equivalents so broadly as to effectively eliminate the "window" element in its entirety. FN83

FN82. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997).

FN83. *See id.*

For these reasons, the court determines as a matter of law that an entirely clear tube, such as the one used in the accused Accu-Trace product, is not the equivalent of the "window" limitation in the '524 patent.

V. CONCLUSION

The court determines that the term "window," as construed by the court as meaning an opening made of light-transmissive material in the circumferential wall of the outer tube that is bounded by material that is not light-transmissive, either in circumference around the outer tube and/or longitudinally along the length of the outer tube, and as less than the entire outer tube such that it cannot be a tube made entirely of light-transmissive material, precludes a finding that the accused Accu-Trace infringes the '524 patent either literally or under the doctrine of equivalents.

For all of the foregoing reasons,

IT IS ORDERED that Tyco Healthcare Group LP's and Tyco International (US) Inc.'s Motion for Summary Judgment of Non-Infringement (dkt. no. 158) is GRANTED, and Clinical Innovations, LLC's Motion for Claim Interpretation and for Partial Summary Judgment of Infringement (dkt. no. 146) is DENIED.

IT IS FURTHER ORDERED that the substantive matter having been decided, all other pending motions, procedural or otherwise, are irrelevant at this point and are stricken.

LET JUDGMENT BE ENTERED ACCORDINGLY.

D.Utah,2007.
Clinical Innovations, LLC v. Tyco Healthcare Group LP