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

UTAH MEDICAL PRODUCTS, INC,
Plaintiff.
v.
CLINICAL INNOVATIONS ASSOCIATES, INC., William Dean Wallace, Christopher A. Cutler, Steven R. Smith, and Does 1-10,
Defendants.

No. 2:97-CV-0074 B

Oct. 28, 1999.

Owner of patent for intrauterine catheter sued former employees for infringement, false advertising, misappropriation of trade secrets and breach of fiduciary duty. On defendants' motion for summary judgment, the District Court, Benson, J., held that: (1) patent was not infringed; (2) defendant's advertising was not false; (3) no trade secrets were identified; and (4) breach of fiduciary duty claim was time-barred.

Motion granted.

5,573,007. Cited.

Richard Burbidge, Salt Lake City, UT, for plaintiff.

Raymond Etcheverry, Salt Lake City, UT, David Mangum, Salt Lake City, UT, for defendant.

MEMORANDUM OPINION & ORDER

BENSON**, District Judge.**

I. INTRODUCTION

This case is between plaintiff Utah Medical Products, Inc. ("Utah Medical") and defendants, Clinical Innovations Associates, Inc. ("Clinical"), Dr. William Wallace, Dr. Christopher Cutler, and Steven Smith. Clinical and Utah Medical compete with one another in the manufacturing and selling of medical products. The case primarily involves two competing intrauterine catheters which measure the pressure of amniotic fluid within the uterus during a pregnant woman's labor and delivery.

Utah Medical's complaint alleges claims against defendants for patent infringement, false advertising under the Lanham Act, misappropriation of trade secrets, and breach of fiduciary duty. Defendants move the Court for summary judgment on all claims. Defendants also filed two motionsin limine: (1) to exclude the expert

opinion testimony of Robert W. Hitchcock regarding plaintiff's Lanham Act claim, and (2) to exclude the expert opinion testimony of Roger W. Blakely, Jr. regarding his legal opinions on claim construction and other patent infringement issues. The Court considers these motions in limine contemporaneously with defendants' motion for summary judgment. Based upon the motions presently before the Court, the memoranda and exhibits submitted by both parties and the arguments presented in oral argument, the Court issues this Memorandum Opinion and Order.

II. BACKGROUND

Utah Medical is a publicly traded corporation that designs and manufactures medical products, including intrauterine catheters. In 1983, defendants, Dr. Wallace and Dr. Cutler, joined Utah Medical where they worked in a variety of positions, ultimately serving as Utah Medical's Chief Executive Officer and Vice President of Research and Development, respectively. During their time at Utah Medical, Wallace and Cutler invented and developed several products. Utah Medical obtained patents on many of Wallace's and Cutler's inventions, including the "161" intrauterine catheter at issue in this case.

In 1992, Wallace's career with Utah Medical took a turn for the worse. Wallace was indicted in federal district court for violations of securities laws and for tax evasion. Shortly after these charges were filed, Utah Medical's board of directors placed Wallace on administrative leave and appointed Cutler to serve as the acting president. Eventually, Utah Medical named Kevin Cornwall as Wallace's permanent replacement and as president of the company. After Wallace was placed on leave, but before a verdict was reached in the criminal case against him, Utah Medical's board of directors determined that Wallace's services were no longer needed and terminated his employment with Utah Medical. In December 1993, Cornwall instructed Wallace to clean out his office and asked Cutler to ensure that Wallace did not remove any trade secret or proprietary documents. Wallace took with him three boxes containing 17,000 pages of documents. Cutler issued a memorandum to the Utah Medical Board of Directors on January 4, 1993, attesting that no proprietary or trade secret materials were contained in the documents Wallace had taken. Utah Medical now alleges that Cutler did not actually review the documents and that many of the documents Wallace took contained proprietary information and trade secrets. Shortly after the appointment of Cornwall, Wallace's trial concluded and Wallace was acquitted of all charges by the jury.

On April 1, 1993, after Wallace's termination from Utah Medical, Wallace formed Clinical Innovations Associates, Inc. On June 1, 1993, Cutler also left Utah Medical and began work at Clinical. Steven Smith, who was a senior research and design engineer at Utah Medical from November, 1992 to May, 1993, also left Utah Medical in June 1993 and thereafter began working for Clinical. Wallace, Cutler, and Smith have equity ownership in Clinical and serve on its board of directors. One of Clinical's first products was its "Clearview" uterine manipulator, which is used to position the uterus to facilitate laparoscopic surgical procedures. Utah Medical alleges that Wallace took proprietary information from Utah Medical that aided Clinical in the development of this uterine manipulator. In June, 1996, Clinical began marketing the "Koala" intrauterine catheter, which Utah Medical alleges was developed from its trade secret and confidential information and infringes on one of Utah Medical's patents. Clinical advertised the Koala as being "sensor tipped." Utah Medical alleges that such advertising is false and misleading because the Koala does not contain a transducer in the tip of the catheter.

Ten years before Clinical released its Koala catheter, Utah Medical began work on a series of intrauterine catheters. Utah Medical's first line of intrauterine catheters was the Intran product line. The "Intran I" was developed by Wallace and was introduced to the market in 1987. The Intran I contained a pressure

transducer at the tip of the catheter and was patented by Utah Medical. In an effort to improve the Intran I, Utah Medical released the "Intran II" in 1989. The Intran II was patented under United States Patent No. 4966,161 (the "161 patent"). The 161 patent lists Wallace and Cutler as inventors and assigns the patent to Utah Medical. The Intran II removed the transducer from the tip of the catheter and placed it at the base of the catheter, outside of the patient's body. By removing the transducer from the catheter tip, Utah Medical was able to reduce the tip size and catheter stiffness. The Intran II was sold until 1995 when it was replaced by the "Intran Plus," which due to technological advances allowing for smaller pressure transducers, places the transducer in a disposable catheter tip. The Intran Plus remains Utah Medical's principal intrauterine catheter. Because of its disposable transducer tip, it is slightly more expensive than other catheters that can reuse the transducer. While the Intran product line has been on the market since 1987, and the Koala since 1996, these catheters were not the first to measure intrauterine pressure. Indeed, simple liquid or air-filled balloon catheters have been in existence for decades.

Although the Intran II (specifically the 161 patent claims) and the Koala will be analyzed in detail in this Opinion, as background to the discussion that will follow, the Court provides the following additional general description of the involved catheters. The Intran II, also know as the 161 device, is inserted into a woman's uterine cavity in order to monitor the intrauterine pressure during labor and delivery, as depicted below in Figure 1.

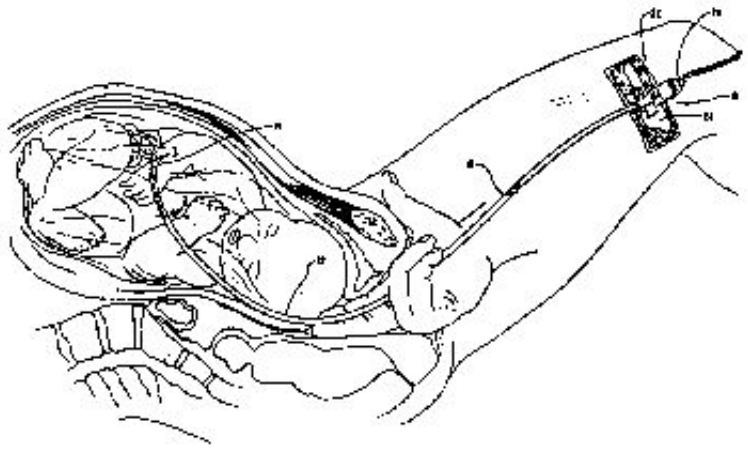

FIGURE 1 ('161 Patent Figure 10)

The 161 device is comprised of a catheter that is approximately 30 inches in length. The tip of the catheter that is inserted into the uterus contains several holes that allow amniotic fluid to enter the catheter. See Figure 2. Amniotic fluid enters the interior of the catheter into what is called the "first chamber." At that point the liquid fills the first chamber, but is prevented from traveling further up the catheter into the "second chamber" because of the air that is being sent into the second chamber through the "first lumen" of the catheter from the opposite end. The amniotic fluid forms a liquid column in the first chamber between

the holes that let in the liquid and the surface of the liquid-air interface. The amniotic fluid in the first chamber and the air coming from the second chamber come in direct contact with one another. This boundary between the first and second chamber is variable because it exists where the liquid column and the air come in contact and moves depending on the amount of pressure exerted from each side. The possible surfaces of this liquid-air interface, or boundary of the liquid column, can be seen below in Figure 3. As the uterus exerts pressure, the liquid column increases in size and as a result air pressure increases and is transmitted through a pressure sensitive diaphragm in the pressure transducer. The transducer converts the pressure reading into an electrical signal that is transferred to the patient monitor where the medical staff can monitor the uterine contractions.

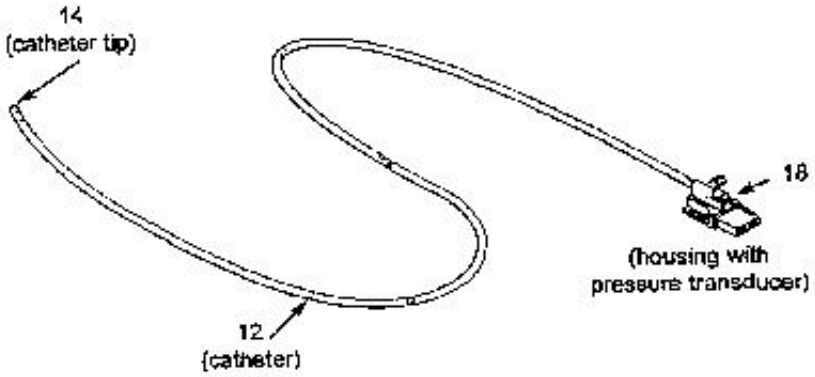

FIGURE 2 ('161 Patent Figure 1)

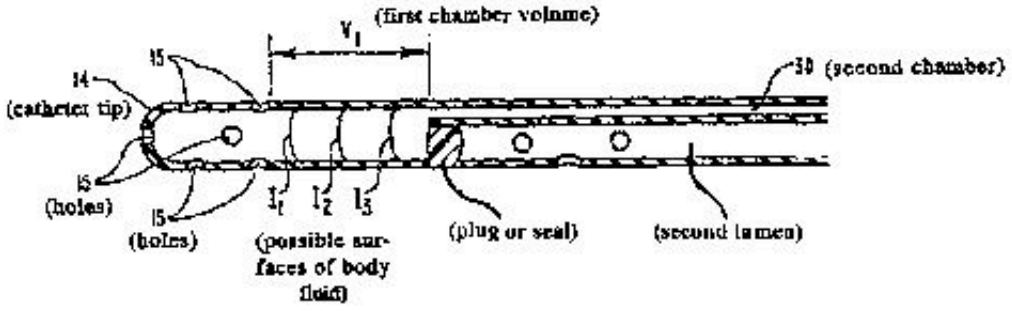

FIGURE 3 ('161 Patent Figure 3)

Beyond measuring intrauterine pressure, the 161 device provides a separate means for the infusion or withdrawal of liquids into or out of the uterus. There is another set of holes near the tip of the catheter that

allow amniotic fluid to enter what is called the "second lumen." The second lumen is sealed off by a plug from the first and second chambers of the catheter and is comprised of a separate tube that runs parallel to the first lumen from one end of the catheter to other end. This second lumen is completely separate from the first lumen, as depicted below in the cross section of the catheter in Figure 4. The second lumen provides access to the amniotic fluid through the catheter.

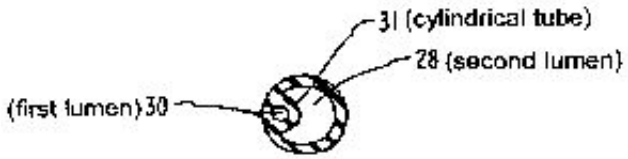

FIGURE 4 ('161 Patent Figure 7)

The accused device, the Koala, performs the same general function as the 161 device, monitoring intrauterine pressure. In developing the Koala catheter, Clinical consulted with Dr. Donald Bobo regarding the application of his patented technology that was assigned to his company, InnerSpace, Inc. The Bobo patent discloses the use of a gas-filled pressure flexible membrane at the end of a lumen to sense intracompartmental body cavity pressure. Clinical entered into an agreement with InnerSpace to license its rights under the Bobo patent for use in an intrauterine catheter. Using the technology license under the Bobo patent, as well as its own alleged innovations, Clinical developed and marketed the Koala. While in many ways the accused device is similar to the 161 device, there are several differences between the two catheters.

The Koala is comprised of a plastic housing that surrounds an air-pressurized balloon. Rather than allowing the air and amniotic fluid to come in direct contact with one another, the Koala isolates the air within the balloon structure. When amniotic fluid enters the plastic housing it surrounds and compresses the air contained within the balloon, thus, increasing air pressure within the balloon. The air pressure exerted by the contracting balloon is conducted to a pressure sensing diaphragm that transmits the information into an electrical signal and sends it to the patient's monitor, as depicted below in Figures 5 and 6.

FIGURE 5 (KOALA)

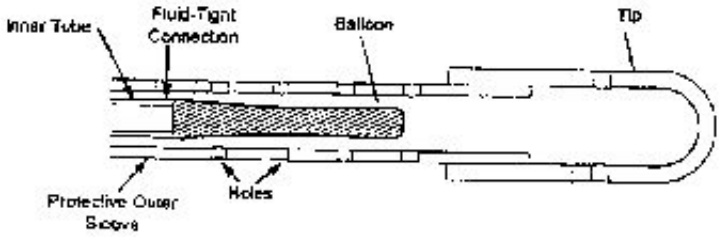

FIGURE 5 (Koala)

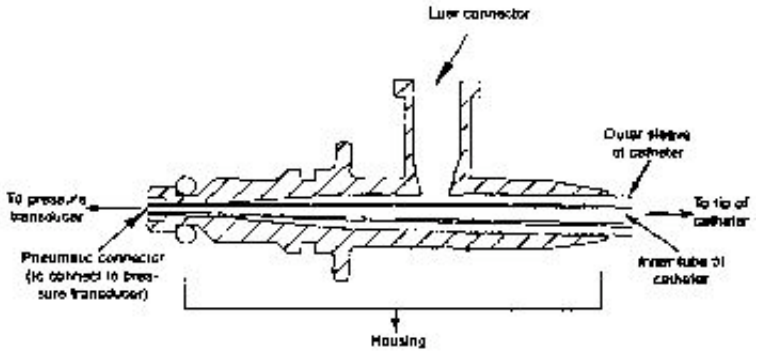

FIGURE 6 (Koala)

FIGURE 6 (KOALA)

The Koala transmits the air through an internal tube that is not attached to the interior of the catheter. Surrounding this internal tube, or first lumen, is a second lumen that allows amniotic fluid to flow around the inner tube and be removed from the catheter, similar to the 161 device, which also allows access to amniotic fluid. Clinical is in the process of registering its own patents on the Koala, and two patents are currently pending before the United States Patent and Trademark Office.

The Koala competes directly with Utah Medical's Intran Plus catheter. Utah Medical claims that Clinical is out to destroy Utah Medical. As a result, Utah Medical brought this suit against Clinical, alleging that the Koala infringes upon the patented technology of the Intran II. Additionally, Utah Medical alleges that Clinical misappropriated trade secrets in developing Clinical's medical products, that the advertising claims are false and misleading, and that Wallace and Cutler breached their fiduciary duties owed to Utah Medical while employed there. The current dispute illustrates the complexities that are often interwoven amidst competition and technology.

On July 20, 22, and 26, 1999, the Court heard oral argument on defendants's motion for summary judgment. Argument was presented by Raymond Etcheverry and David Mangum for the Defendants and by Richard Burbidge for the Plaintiff. After listening to the arguments advanced by both sides, the Court took defendants' motions under advisement.

III. DISCUSSION

Federal Rule of Civil Procedure 56(c) "mandates the entry of summary judgment ... against a party who fails to make a showing sufficient to establish the existence of an element essential to that party'scase, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 327, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Summary judgment is appropriate when no reasonable jury could return a verdict for the nonmoving party, the facts in the record show that there is no genuine issue of material fact, and the moving party is entitled to summary judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250-51, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). In making such a determination, the Court construes all justifiable factual inferences in the light most favorable to the nonmoving party. *See id.*

A. Summary Judgment as to Plaintiff's Patent Infringement Claims

Plaintiff alleges that Clinical's Koala catheter (the accused device) infringes literally, as well as under the doctrine of equivalents, on Claims 1 through 35 of Utah Medical's 161 patent. Defendants argue that plaintiff cannot establish that Clinical's Koala catheters infringes on any of the claims of the 161 patent either literally or under the doctrine of equivalents. Defendants contended that a comparison of the properly interpreted 161 patent claims with the accused device conclusively demonstrates that the Koala catheter does not have all of the requisite elements of the 161 patent claims and thus cannot infringe on that patent as a matter of law.

[1] [2] [3] Patent infringement can arise either literally or under the doctrine of equivalents. "To establish a literal infringement, a plaintiff must demonstrate that every limitation in the claim is literally met by the accused device." Enercon v. Int'l Trade Comm'n, 151 F.3d 1376, 1384 (Fed.Cir.1998). Accordingly, the absence of just one claim element mandates a determination of noninfringement by the Court. *See* Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed.Cir.1998). Utah Medical argues that even if a literal infringement is not found, the Koala infringes under the doctrine of equivalents. An accused device infringes under the doctrine of equivalents if every limitation in the claim or its equivalent is found in the accused device. An "equivalent" is something that only differs from the claim limitation insubstantially. *See* Valmont Industries, Inc. v. Reinke Manufacturing Co., Inc., 983 F.2d 1039, 1043 (Fed.Cir.1993). To find an infringement under the doctrine of equivalents, the Court must determine whether the accused device performs substantially the same overall function in substantially the same way to achieve substantially the same overall result as the element of the patented device, or whether the substitute element plays a role substantially different from the claimed element. *See* Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed.Cir.1998).

Before a determination can be made whether an infringement has taken place, the Court must first interpret the patent claims. *See* Markman v. Westview Instrs., Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Under *Markman,* the "construction of a patent, including the terms of art within its claims, is exclusively within the province of the court." Markman, 517 U.S. at 372, 116 S.Ct. 1384. When interpreting patent claims, the United States Court of Appeals for the Federal Circuit has instructed the district courts to "look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, specification and, if it is in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The "words in a claim are generally given their ordinary and customary meaning" unless "a special definition of the term is clearly stated in the patent specification or file history." *Id.*

[4] The Court recognizes that the patent at issue includes several "means-plus-function" claims. As set forth in 35 U.S.C. s. 112(6), a means-plus function is not limited to the structure described in the specifications.

The Federal Circuit has stated that when interpreting means-plus-function limitations such limitations shall be construed to cover the structure described in the specification and equivalents thereof. *See* D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1575 (Fed.Cir.1985). The Federal Circuit defines "equivalent" in the s. 112(6) context as "an insubstantial change which adds nothing of significance to the structure, material, or acts disclosed in the patent specification." Valmont Indus. v. Reinke Manf. Co., 983 F.2d 1039, 1043 (Fed.Cir.1993). Accordingly, in its analysis the Court must determine whether the accused device performs the same function as set forth in the claim with an equivalent structure to that described in the patent specification. *See* Cybor Corp. v. FAS Tech. Inc., 138 F.3d 1448, 1457 (Fed.Cir.1998).

Once the Court has interpreted the claims of the patent, the Court next compares the properly interpreted claims to the accused product to determine whether each element in the claims is present in the accused product. *See* Kahn v. GMC, 135 F.3d 1472, 1476 (Fed.Cir.1998). The second step is typically a factual question for a jury. However, if the Court finds that "no reasonable jury could find that every limitation recited in the properly construed claim is ... found in the accused device" and "where the evidence is such that no reasonable jury could determine two elements to be equivalent," summary judgment of noninfringement should be granted. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353-54 (Fed.Cir.1998). As a practical matter, this Court finds that combining the *Markman* hearing and the motion for summary judgment is an efficient and sensible approach to what could otherwise be an unnecessarily lengthy and multi-phased process.

As directed by *Markman,* the Court now proceeds to interpret Claims 1 through 35 of the 161 patent, as well as determining whether each element in these claims reads upon the accused Koala catheter.

1. Construction of Claim 1 and Its Application to the Koala

Under proper claim construction methodology, the Court begins its analysis of the 161 patent by examining the actual language of the claims. *See* Bell Comm. Research, Inc. v. Vitalink Comm., Corp., 55 F.3d 615, 619 (Fed.Cir.1995). Claim 1 reads:

An apparatus for continuously measuring intracomparmental fluid pressures exerted by a liquid contained within a body cavity comprising:

Pressure-sensing means for insertion into said body cavity so as to detect said intracompartmental fluid pressures therein, said pressure-sensing means comprising first chamber means for defining a first volume which is in fluid communication with said liquid such that said liquid will enter said first chamber means and form a liquid column therein having a liquid-air interface, and further comprising second chamber means for defining a second volume which is air-filled and is in fluid communication with said first chamber means;

Pressure transducer means attached to said pressure-sensing means for generating an electrical signal proportional to fluid pressure communicated by said pressure-sensing means to said pressure transducer means; and

Wherein a ratio is defined by said first and second volumes such that the ratio of said first volume to said second volume is such that, at maximum fluid pressures exerted within said body cavity, said liquid column in said first chamber means will tend to be minimized so as to minimize hydrostatic pressure error resulting therefrom and such that said liquid-air interface will be prevented from entering said second chamber

means.

Claim 1 has several distinct requirements that must read upon the Koala in order to find infringement. There is no question that the Koala is "an apparatus for continuously measuring intracompartmental fluid pressures exerted by a liquid contained within a body cavity," and it is undisputed that the Koala incorporates "pressure-sensing means for insertion into said body cavity so as to detect said intracompartmentalfluid pressures therein." However, the interpretation of several elements within Claim 1's "pressure sensing means" are disputed. Specifically, the parties dispute the interpretation of the elements requiring: (1) a first and second chamber means, (2) a liquid column, (3) fluid communication between the chambers, (4) a liquid-air interface, and (5) a ratio defined by first and second volumes. The Court now proceeds to interpret these disputed elements.

[5] Claim 1 requires that the pressure-sensing means is comprised of a "first chamber means for defining a first volume which is in fluid communication with said liquid such that said liquid will enter said first chamber means and form a liquid column therein having a liquid-air interface, and further comprising second chamber means for defining a second volume which is air-filled and is in fluid communication with said first chamber means." The first chamber must holds a volume of amniotic fluid that comes in contact with the air coming from the second chamber. The second chamber must contain air that is pumped into the catheter from an external source to provide a means of measuring the amount of pressure asserted against it from the first chamber when the air therein is compressed. Clinical contends that Claim 1 requires a first and second chamber means that are distinctive from the Koala. Clinical argues that the first chamber means must be interpreted to require a cavity inside of rigid, physical walls or other such surrounding structure so as to surround the first volume. However, Utah Medical argues all that is required is an area that holds amniotic fluid, such that when the amniotic fluid enters the Koala and surrounds the air-filled balloon, it comprises the first chamber and the air-filled balloon comprises the second chamber. While the Court finds Utah Medical's interpretation very broad, the specification appears to allow such a broad reading. However, the first chamber in Claim 1 must have the capacity to enclose within its surrounding structure a first volume of amniotic fluid, forming a liquid column that comes in contact with the air-filled second volume. In order to form a liquid column, the first chamber must be completely enclosed without any holes that would prevent a liquid column from functioning properly.

[6] [7] Claim 1 requires that the amniotic liquid will enter the first chamber and "form a liquid column therein." As established above, the first chamber must be enclosed by the walls of the catheter. This is because according to Claim 1 the liquid column forms below the section of the catheter where the holes allow the amniotic fluid to enter the catheter and is enclosed where it comes into contact with the air from the second chamber. The column must be formed on the inside of the plastic housing, as the claim requires it to be "therein." The column is an uninterrupted volume of liquid between the air from the second chamber and the free flowing amniotic fluid that enters the tip of the catheter through the holes in the tip. A column is defined as "a rigid, relatively slender, upright support, composed of relatively few pieces [or] a decorative pillar, most often composed of stone and typically having a cylindrical or polygonal shaft ...; any column like object, mass, or formation a column of smoke." THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 407 (2d ed.1987). Taken from the plain meaning of the word column, the liquid column-cylindrical in shape-must fill the interior of the first chamber and be bound by the cylindrical sidewalls of the first chamber. While Clinical argues that the accused device does not have a liquid column as required by Claim 1, Utah Medical argues that the Koala does in fact have a liquid column. Applying the Court's interpretation of the required liquid column to the accused device, the Court finds that a liquid column does not exist in the Koala, either literally or under the doctrine of equivalents. The Koala could

only be substantially equivalent by eliminating necessary structural and functional requirements from Claim 1, which would be improper. The "doctrine of equivalents cannot be used to erase 'meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement.' " Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1562 (Fed.Cir.1994). Utah Medical argues that the Koala has a column that is in fact a hollow cylinder that surrounds the air balloon within what Utah Medical argues is a first chamber. However, the area that Utah Medical argues is the liquid column is in reality the same as the area in the tip of the 161 device where the holes allow the amniotic fluid to enter the catheter. The housing around the Koala is for the purpose of inserting the catheter into the uterus. If the plastic housing were removed from the Koala once in the uterus, the device would still provide an accurate reading based on the amniotic pressure exerted on the balloon. Conversely, the 161 device is dependent upon the plastic housing wherein a liquid column is formed between the amniotic fluid and the air. Without such a housing, the 161 device would not operate.

[8] Clinical next argues that the Koala cannot infringe because it does not have any open passageway between any first chamber means and any second chamber means, and thus has no "fluid communication" between the first and second chamber means. Utah Medical counters by arguing that the term fluid communication is simply describing a smooth and continuous function of communicating intrauterine pressures from the first chamber means through the second chamber means to the pressure transducer. Thus, Utah Medical argues that this element of the claim reads upon the Koala. Claim 1 uses the term "fluid communication" twice. First, it requires that the first volume, which is in the first chamber, be in fluid communication with the amniotic liquid such that the amniotic liquid will enter the first chamber. Second, it requires that air-filled second volume be in fluid communication with the first chamber means. The Court finds that in order to be in fluid communication with the amniotic fluid, as in the first case or the air as in the second case, the amniotic fluid or air must be allowed to enter the first chamber and form, or come in contact with, the liquid column that has been created so that when the pressure changes the liquid column can move within the first chamber, as indicated by the possible surfaces of amniotic fluid depicted above in Figure 3. The term "fluid" is an adjective describing the ability for the liquid and air to move within the catheter, and, depending on the pressure exerted by the amniotic fluid, communicate that pressure to the transducer. Thus, all this element requires is that the amniotic pressure has the means to communicate with the air pressure so that pressures are able to be transmitted from one end of the catheter to the other end.

[9] Clinical next argues that Claim 1's requirement for a "liquid-air interface," cannot read upon the accused device because the Koala has an air-filled balloon that acts as a barrier between the air and liquid. According to Claim 1, the liquid column must have a "liquid-air interface" with the second air-filled volume. An interface is defined as "a surface regarded as the common boundary of two bodies, spaces, or phases." *Id*. at 993. There is no dispute that this liquid-air interface occurs in the first chamber of the 161 device between the amniotic liquid and the air from the second chamber. Clinical argues that such an interface requires molecule-to-molecule contact between the amniotic liquid and the air for such an interface to exist. Utah Medical asserts that such an interface is simply an exchange between two different surfaces, arguing that nothing in Claim 1 requires a direct molecule-to-molecule interface, and that the interface can exist even if a membrane (such as the balloon in the Koala) acts as a barrier between the air and the liquid. The description of the liquid-air interface in the claim specifications describe an interface between the partially filled liquid and air chamber (161 patent at column 5, line 68 to column 6, line 2), as well as a maintenance of pressure ratios between the air and the amniotic liquid to prevent the liquidfrom entering the air-filled second chamber (161 patent at column 13, lines 20-28). Because Claim 1 describes this interface in conjunction with the requisite liquid column, the Court finds that Claim 1 contemplates direct contact between the air and the amniotic liquid. Accordingly, the Court interprets Claim 1 to require an actual

interface-molecule-to-molecule-between the amniotic liquid and the air. Applying this claim interpretation to the accused device, the Court finds that the accused device does not involve such an air-liquid interface and therefore does not literally infringe on this aspect of the 161 patent. Whether the accused device infringes under the doctrine of equivalents is a question of fact.

[10] Claim 1 finally requires that there be a ratio volumes that will minimize hydrostatic pressure error and prevent the liquid-air interface from entering the second chamber means. Utah Medical argues that the Koala infringes upon this element of Claim 1 because the balloon must contain the same ratio to function properly. Clinical, however, argues that this element should be interpreted to mean that the ratio must be maintained so the liquid column will not be allowed to enter the second chamber, which, Clinical continues, is impossible to read on the accused device because no liquid can penetrate the balloon in the Koala. The Court finds that the ratio referred to in Claim 1 is generally indicating that the amount of pressure exerted by the amniotic fluid in the first chamber and the air in the second chamber must balance so the liquid column is contained within the first chamber. This is stating that Boyle's law (v1 x p1 = v2 x p2) must be complied with in order for the device to provide an accurate reading. Furthermore, the Court finds that this element of Claim 1 literally requires a device that would not allow the liquid to enter the second chamber. Any other interpretation would render the phrase "and prevent the liquid-air interface from entering the second chamber means" meaningless.

Additionally, although not briefed, at oral argument defendants pointed out that another purpose for maintaining the proper liquid-air ratio, pursuant to the language of Claim 1, is to minimize hydrostatic pressure by reducing the length of the liquid column, which cannot be done in the accused device because the Koala has no liquid column upon which hydrostatic pressure can be exerted upon it. The Court interprets Claim 1 to require a physical device that allows for a liquid column that can be adjusted to a height that will minimize the effect of any hydrostatic pressure. Because there is no question that the accused device does not contain such a liquid column, the Court finds as a matter of law that the accused device does not infringe this claim element either literally or under the doctrine of equivalents. On this point at oral argument, plaintiff argued that any hydrostatic pressure to which the column itself would be exposed would be so minimal as to be insignificant. Even if that is the case, it remains that such is a literal part of Claim 1, in words chosen by the plaintiff.

In accordance with the foregoing, after comparing the accused device to Claim 1 of the 161 patent, as construed by the Court, the Court finds that the elements requiring a liquid column are not present in the Koala either literally or under the doctrine of equivalents, and Claim 1's requirement of a liquid-air interface is not literally present in the Koala, but may be equivalent to the 161 device. Thus, as interpreted, the Court finds that plaintiff cannot demonstrate that every limitation in Claim 1 is literally or equivalently met by the accused device. Accordingly, the Court must find that the Koala does not infringe upon Claim 1 of the 161 patent. FN1 *See* Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed.Cir.1998) (holding that the absence of just one claim element mandates a determination of noninfringement by the Court).

FN1. In keeping with the above analysis, the Court notes that based upon its review, to interpret Claim 1's elements as plaintiff requests would require the Court to construe the elements of Claims 1 so broadly as to find that the 161 device essentially holds a patent on simple fluid mechanics. Were the Court to interpret the claims of the 161 patent as broadly as Utah Medical is requesting, it would appear to be tantamount to an invalidation of the 161 patent for prior art and obviousness. Claim 1 cannot be interpreted so broadly as to cover the fundamental laws of air pressure and fluid mechanics, including the basic principles used to measure those pressures within body cavities.

2. Construction of Claims 2 through 17 and Their Application to the Koala

[11] Claims 2 through 17 are dependent upon Claim 1 and incorporate the requirements of that claim. "One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1552 n. 9 (Fed.Cir.1998). Because the Court has found that Claim 1 is not infringed upon by the Koala, the Court similarly finds no infringement as to Claims 2 through 17.

3. Construction of Claims 18 through 32 and Their Application to the Koala

Plaintiff also alleges that the accused device infringes upon Claim 18 and its dependant claims 19 through 32. Claim 18 is very similar-in fact nearly identical-to much of Claim 1. Claim 18 reads as follows:

An apparatus for continuously measuring intrauterine fluid pressures exerted by amniotic fluid within the uterus comprising:

A catheter for insertion into said uterus so as to detect said pressures, said catheter comprising a first chamber formed in a distal end of said catheter at the interior thereof for defining a first volume, said catheter further comprising a plurality of apertures formed at said distal end of the catheter for providing fluid communication between said amniotic fluid in the uterus and said first chamber such that amniotic fluid will enter said first chamber and form a liquid column therein having a liquid-air-interface, and said catheter further comprising a second chamber formed with in the interior of said catheter for defining a second volume, said second chamber being airfilled, and wherein a ratio is defined by said first and second volumes such that the ratio of said first volume to said second volume is such that the ratio of said first volume to said second volume is such that at maximum fluid pressure exerted during a contraction of the uterus, said liquid column will tend to be minimized so as to minimize hydrostatic pressure error resulting therefrom and such that said liquid-air interface will not enter said second chamber; and

A pressure transducer means for generating an electrical signal proportional to said fluid pressures communicated to said transducer from said second chamber of the catheter.

Both parties present the same arguments as to Claim 18 as they did when arguing for and against infringement under Claim 1. Because the Court has found that under Claim 1 no reasonable juror could find literal infringement for each element of Claim 1, it is unnecessary to undertake the same analysis regarding Claim 18. Therefore, the Court finds that Claim 18, as well as its dependent Claims 19 through 32, do not read upon the Koala catheter for the same reasons articulated for Claims 1 through 17.

4. Construction of Claim 33 and Its Application to the Koala

Plaintiff further alleges that the accused device infringes on Claim 33 of the 161 patent. Claim 33 presents the Court with another substantial analytical challenge. It reads:

An apparatus for continuously measuring intrauterine fluid pressures exerted by amniotic fluid within a uterus, comprising:

a catheter for insertion into said uterus so as to detect said fluid pressures, said catheter comprising a

cylindrical tube formed a long an interior wall of said catheter so as to form a first lumen which extends through a substantial portion of the interior length of said catheter, said first lumen terminating at a distal end thereof a selected distance from a distal end of said catheter such that a chamber is formed in at least a portion of the interior space of said catheter defined by the space between the distal end of said first lumen and the distal end of said catheter, said chamber defining a first volume, and said first lumen defining a second volume, said catheter further comprising a second lumen formed in the remaining space between said cylindrical tube and said interior catheter wall and said second lumen being coextensive in length with said first lumen and said second lumen being sealed at a distal end thereof to prevent fluid communication between said chamber and said second lumen, said catheter further comprising a first plurality of apertures formed at said distal end of said catheter to provide fluid communication between said amniotic fluid and said chamber, and further comprising a second plurality of apertures formed through said catheter to provide fluid communication between said amniotic fluid and said second lumen;

a piezoresistive semiconductor pressure transducer comprising a pressure diaphragm for deflection in response to intrauterine fluid pressures exerted on one side of said diaphragm; and

connector means for housing said pressure transducer therein and for providing electrical between said transducer and an electrical cable, said connector means comprising means for continuously venting and opposite side of said diaphragm to atmospheric pressure, and said connector means further comprising a valve means for selective positioning between a first and second position such that when said valve means is in said first position, said one side of said diaphragm is vented through said connector means to atmospheric pressure, and when said valve means is in said second position, said one side of said diaphragm is in fluid communication with intrauterine fluid pressures communicated through said first lumen, and said connector means further comprising a fluid port through which amniotic fluids are infused into and through which amniotic fluid samples are withdrawn form said second lumen, and wherein fluid communication from said fluid port to said second lumen is provided by an aperture formed through said catheter at a location adjacent said fluid port.

While Claim 33 is similar in some respects to Claim 1, there are several additional elements that the Court must interpret and compare to the accused device. Specifically, Claim 33 has three major components: (1) "a catheter for insertion into said uterus so as to detect [ ] fluid pressures," comprised of a "first lumen" and a "second lumen," (2) a "pressure transducer," and (3) a "connector means for housing said pressure transducer therein and for providing electrical connection between said transducer and an electrical cable." Each of these major components has various sub parts. For example, the "connector means" also contains a "valve means" for venting the apparatus to atmospheric pressure. The parties dispute the interpretation of the following elements: (1) a first lumen, (2) a second lumen that is sealed and contains separate apertures, and (3) a valve means.

[12] Claim 33 requires a "first lumen" that runs throughout the interior of the catheter, having an opening in the chamber of the catheter. The claim describes the first lumen as "a cylindrical tube formed along an interior wall" of the catheter. The first lumen is essentially a passage way that transmits air from the air source into the second chamber as described in Claim 1. "Lumen" is defined as "the canal, duct, or cavity of a tubular organ." THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 1144 (2d ed.1987). The proper construction of the "first lumen" turns on the meaning of the phrase "formed along an interior wall." Clinical argues that this restriction requires the Court to interpret the claim as requiring the first lumen to be a cavity within rigid, physical cylindrical walls of a tube that is physically attached to the interior catheter wall as depicted by the cross-section of the 161 device in Figure 4 (161 Patent Figure 7).

See supra p. 1296. However, Utah Medical contends that all that Claim 33 requires is a cylindrical tube on the interior of the catheter capable of conveying air pressure from the chamber to the transducer. Utah Medical further argues that just because the tube is "formed along an interior wall" of the catheter does not require that the tube be attach to part of the catheter. The 161 specifications show that the actual design of the 161 device attached the first lumen to the wall of the catheter, stating: "As best illustrated in FIGS. 7 and 8, the first lumen [ ] is comprised of a cylindrical tube [ ] which is formed along the interior wall of the catheter...." (161 Specification at Column 10). Figure 7 of the 161 specifications clearly shows that the first lumen is attached to the interior wall of the catheter. However, Utah Medical argues that according to the Federal Circuit, such additional limitations appearing in the specification should not be read into the claim. *See* Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed.Cir.1998) (noting the "well-established principle that a court may not import limitations from the written description into the claims"); Electro Med. Sys. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994) (stating that "claims are not to be interpreted by adding limitations appearing only in the specification"). Accordingly, the Court does not look to how the device was actually constructed according to the specification, but rather looks to the language of the claim. The relevant meaning of "form," when used as a verb, is defined as "to give a particular form or shape to; fashion in a particular manner." THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 752 (2d ed.1987). "Along" is defined as "through, on, beside, over, or parallel to the length or direction of; from one end to the other of." *Id*. at 59. Based on the plain meaning of the claim language the Court finds that "formed along" only requires that a circular tube run within the catheter parallel to the interior walls of the catheter. The Koala has an interior tube that transmits air from the air pressure source into the balloon that is within the chamber of the catheter. Utah Medical argues that the Koala tube is in fact a first lumen and this portion of the claim reads literally on the Koala. There is no doubt that the Koala has a lumen that runs within the catheter walls. The Koala's air lumen is an independent tube. Although not attached to the interior wall of the catheter, it does run parallel to the interior walls of the catheter.

[13] Claim 33 next requires there to be a "second lumen." The second lumen performs a task separate from that of measuring intrauterine pressure. That purpose is for the infusion or withdrawal of liquids into or out of the uterus. Claim 33 requires that the "second lumen [be] formed in the remaining space between said cylindrical tube and said interior catheter wall" and be "coextensive in length with said first lumen." Simply put, the second lumen is comprised of the interior space of the catheter absent the first lumen and must run along the first lumen from one end of the catheter to the other end. Such a requirement initially appears to read upon the accused device. However, Claim 33 also requires that the "second lumen [be] sealed at the distal end thereof to prevent fluid communication between said chamber and said second lumen." The plain language of this element specifically requires that there be a seal between the chamber and the second lumen. Such a seal is created in the 161 device by the use of plug as depicted above in Figure 3. Such a seal or plug is absent from the accused device. Nevertheless, Utah Medical arguesthat the Koala has such a seal that restricts the amount of flow between the second lumen and the chamber in such a way that the fluid infusion and withdrawal does not interfere with the pressure measurement within the first chamber. Utah Medical acknowledges that the Koala does not have a "fluid tight seal," but argues that the Koala's "flexible seal" nevertheless infringes upon this element of the patent. The Court is not persuaded by Utah Medical's argument and interprets this element of Claim 33 to require a device that completely seals off the area between the chamber holding the amniotic fluid and the second lumen. The accused device has no such fluid-tight seal. Nor could any reasonable fact-finder find the equivalent of a fluid-tight seal in the accused device. Accordingly, the Court finds that the defendants' device does not infringe on this element of Claim 33 either literally or under the doctrine of equivalents.

[14] Finally, in relation to the second lumen, Claim 33 requires a "first plurality of apertures" allowing

amniotic fluid to enter the chamber, as well as a "second plurality of apertures" allowing amniotic fluid to enter the second lumen. The Court finds that Claim 33 requires two separate sets of apertures that function independently of one another. Indeed, the second set of apertures is required because the seal in the second lumen prevents any fluid from passing from the chamber that is fed by the first set into the second lumen. According to the Court's interpretation of Claim 33, these two sets of apertures must function independently of one another. Although plaintiff does not dispute this element in its brief, the accused device appears to have only one set of apertures that allow amniotic fluid to enter the chamber and also pass into the second lumen. Furthermore, because there is no fluid tight seal in the Koala, any apertures that may be located beyond the Koala's alleged "flexible seal" cannot be said to operate independently of the fist set of apertures. The Court, therefore, finds as a matter of law that the Koala does not literally infringe on this element of Claim 33. There is however, a factual dispute whether the Koala device infringes on this element under the doctrine of equivalents.

Claim 33 also requires a "connector means" that contains a pressure transducer, that mechanically joins together the transducer and the catheter, and the electrically connects or joins together the transducer and the patient monitor. Through this connection, intrauterine fluid pressures are communicated from the catheter through an internal pressure diaphragm to the patient monitor. While the connector means is generally undisputed as to its application to the Koala, the connector means further requires a "valve means," the application of which is disputed. The "valve means" language requires a means-plus-function analysis under section 112(6) to interpret this element of Claim 1. *See* York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1574 (Fed.Cir.1996). As stated above, means-plus-function analysis requires the court to determine whether the accused device performs the same function set forth in the claim with an equivalent structure-that is one with no substantial change-to that described in the specification.

[15] The "valve means" in both the 161 patent and the Koala undoubtably serve the same function. Claim 33 of the 161 patent states: "valve means for selective positioning between a first and a second position such that when said valve means is in said first position, said one side of said diaphragm is vented [opened to the outside air] through said connector means to atmospheric pressure, and when said valve means is in said second position, said one side of said diaphragm is in fluid communication with intrauterine fluid pressures communicated through said first lumen...." The pneumatic connector in a housing that mechanically joins the pressure transducer and the catheter in the Koala serves the same function. When the Koala is unconnected, it is basically in a first position, allowing the diaphragm to have contact with the outside air, and when the Koala is connected, it is in the second position due to the contact with the fluid pressure.

Thus, the Court turns to the specification to determine if the corresponding structure is defined by the language "valve means." The specification states the "valve means is comprised of a slide valve that is seated with a channel formed in the housing ... [and t]he slide valve has a knob at its upper end to permit movement back and forth of the slide valve within the channel." Additionally, the slide value is specified as having "a generally square cross-sectional shape as opposed to the circular shape of channel...." The Court construes the "valve means" element in Claim 33 to cover a structure equivalent to that described in the specification for the purpose stated in the claim and rejects Clinical's argument that the valve means requires a "mechanical switch."

Although the Koala's pneumatic connector serves the same function as the valve means in Claim 33, the pneumatic connector is not the same or an equivalent structure as that found in the 161 patent specification. The pneumatic connector is not a slide valve with a knob at its upper end that permits movement of the valve back and forth within the channel. To serve the same function of positioning between a first and

second position, the pneumatic connector must be disconnected not slid. The Koala pneumatic connector does not have a knob that permits movement back and forth within the channel. To be considered an "equivalent" of the specification structure under section 112(6), the pneumatic connector must only have "insubstantial change[s that] add[ ] nothing of significance to the structure...." *See* Valmont Industries, 983 F.2d at 1043. The pneumatic connector's structure is substantially and significantly different from the 161 specified structure. To perform the same function as the 161's motion along the channel, the pneumatic connector must be disconnected. Furthermore, the Koala is designed to switch between the two positions without some of the specifications of the 161 patent, such as the slide valve and the knob at the upper end of the slide valve. The two devices are neither structurally the same nor equivalents, thus, the court holds that the Koala does not literally infringe the 161 patent with respect to Claim 33's valve means element.

In sum, while under the Court's interpretation of Claim 33 the requirements of a first lumen may read upon the Koala, each and every element of a claim must read upon the infringing device in order for the Court to find infringement. *See* Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed.Cir.1998). Because the Court interprets that Claim 33 contains elements requiring the second lumen to be sealed and have a separate first and second pluralities of apertures for the first chamber and second lumen, as well as a valve means structure conforming to the patent specification, the Court holds that under its interpretation no reasonable jury could find that each element of Claim 33 reads literally upon the Koala. The Koala has neither an fluid-tight seal, nor a first and second plurality of apertures, and the pneumatic connector is not structurally identical or equivalent to the 161 specification. Consequently, the Court must find as a matter of law that the Koala does not literally infringe upon Claim 33 of the 161 patent. Additionally, because the Court cannot eliminate the necessary structural and functional requirements of the sealed second lumen, the Court finds that the accused device does not have all the necessary equivalent elements. *See* Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1562 (Fed.Cir.1994) (holding that the "doctrine of equivalents cannot be used to erase 'meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement' "). Thus, as to the absence of a fluid-tight seal, the Court finds that Koala device does not infringe under the doctrine of equivalents. Accordingly, the accused device cannot be found to infringe upon every element of Claim 33.

5. Construction of Claims 34 through 35 and Their Application to the Koala

Claims 34 and 35 are dependent upon Claim 33 and incorporate the requirements of that claim. "One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1552 n. 9 (Fed.Cir.1998). Because the Court has found that Claim 33 was not infringed upon by the accused device, the Court must find that Claims 34 and 35 are not infringed upon for the same reasons that no infringement was found for Claim 33.

In conclusion, plaintiff's patent infringement claim as to infringement of the 161 patent cannot stand as a matter of law. *See* Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353-54 (Fed.Cir.1998) (finding that when "no reasonable jury could find that every limitation recited in the properly construed claim is ... found in the accused device" and "where the evidence is such that no reasonable jury could determine two elements to be equivalent," summary judgment of noninfringement should be granted). Thus, defendants' motion for summary judgment will be granted.

B. Summary Judgment as to Plaintiff's False Advertising Claim Under the Lanham Act

Plaintiff alleges that Clinical's Koala promotional materials, particularly their reference to the Koala as

"sensor tipped," contain a false and misleading description of facts in violation of the Lanham Act, and that those descriptions are likely to cause confusion as to what is actually embodied at the tip of the Koala catheter. Plaintiff maintains that purchasers of the Koala will be mislead into believing that it has a pressure transducer located at the tip of the catheter. Ironically, Utah Medical advertised the Intran II (the 161 device) as sensor-tipped when that device also had the transducer in proximal end of the catheter outside of the patients body. Utah Medical now states that this too was false statement.

[16] Section 43(a) of the Lanham Act provides a cause of action against:

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.

15 U.S.C. s. 1125(a) (1994). In order to establish a claim under the false or deceptive advertising prong of the Lanham Act, a plaintiff must prove:

(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a loss of good will associated with its products.

United Industries Corp. v. Clorox Co., 140 F.3d 1175, 1180 (8th Cir.1998); *see also* Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc., 19 F.3d 125, 130 (3d Cir.1994) (further noting that "the Lanham Act plaintiff 'bears the burden of proving actual deception by a preponderance of the evidence' ").

[17] [18] To satisfy the first element and prove a statement is false within the meaning of the Lanham Act, "the plaintiff must demonstrate either that the challenged advertisement is literally false, or, although literally true, that it is still likely to mislead or confuse consumers." L & F Products v. Procter & Gamble, 45 F.3d 709, 711 (2d Cir.1995). Utah Medical pursues its Lanham Act claim only under the theory that defendants' claim that the Koala is "sensor-tipped" is literally false. Accordingly, plaintiff argues that by establishing that the commercial claim is literally false, consumer perception is irrelevant, and the Court should evaluate claims of literal falsity according to the objective industry standards without reference to consumer confusion. *See* Johnson & Johnson-Merck, 19 F.3d at 129 ("If a plaintiff proves a challenged claim is literally false, a court may grant relief without considering whether the buying public was misled. A determination of literal falsity rests on an analysis of the message in context."); United Industries, 140 F.3d at 1180 ("If a plaintiff proves that a challenged claim is literally false, a court may grant relief without considering whether the buying public was actually misled; actual consumer confusion need not be proved."). Defendants, however, argue that the law requires evidence of falsity based on the advertisements as a whole as viewed by the relevant consuming public. While actual consumer confusion is not necessary to assert a claim of literal falsity, the perspective of the relevant consumer population is necessary in determining whether the advertising could be viewed as false. Thus, in order to assess whether an advertisement is literally false, the Court must analyze the message conveyed within the full context of the

advertisement. Making such a determination as to the full context requires the Court to look at the audience. *See* Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 229 (3d Cir.1990) (noting that " '[c]ontext can often be important in discerning the message conveyed and this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience' [; h]ence, a target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product" (quoting Plough, Inc. v. Johnson & Johnson Baby Prods. Co., 532 F.Supp. 714, 717 (D.Del.1982))). This Court finds such an inquiry relevant in determining if advertising the Koala as sensor-tipped is literally false in light of its targeted audience. Plaintiff bears the burden to show that the Koala advertisements were false as commonly understood by the consuming population of obstetric and gynecologic clinicians based on their knowledge and experience.

[19] As an initial matter the Court finds that Utah Medical failed to produce sufficient evidence to find that the term "sensor-tipped" is literally false. The tip does in fact "sense" amniotic pressure. The advertisements do not state that the device is "transduce-tipped." Such a statement would be literally false as applied to the Koala. The inquiry thus becomes whether Utah Medical has sufficient evidence that the relevant consuming population interpreted "Sensor-tipped" as meaning the transducer was in the tip of the catheter. On this point, Utah Medical only offer Mr. Hitchcock's uncorroborated opinion.

Furthermore, Utah Medical's expert focuses only on the bald statement that the Koala is "sensor-tipped." In fact, it is undisputed that Koala's promotional materials fully describe the device and detail the respective locations of the pressure sensing membrane and the pressure transducer. In those advertisements, Clinical states that the Koala "senses the pressure at the catheter tip" and communicates amniotic pressure "to a transducer located in the reusable cable"; that the Koala system has a "pressure sensor in the uterus and external transducer in the reusable cable"; that "when pressure is exerted on the membrane, it is transmitted ... to the reusable connector which contains a pressure transducer"; and that "pressure [is] measured at the tip with internal sensing membrane; [and then] air-coupled to reusabletransducer located in interconnect cable." Plaintiff's expert admits that he viewed Clinical's advertisement statement in isolation and that the only thing he found important with respect to he Koala advertisements was that they used the term "sensor tip." Accordingly, the Court finds that plaintiffs argument does not take into account the proper context of the statement. Furthermore, plaintiff's expert offers no insight into how an educated and skilled labor and delivery clinician could misled into believing that there is a pressure transducer in the Koala catheter tip when the product literature repeatedly states that the external transducer is located in the reusable cable.

Utah Medical offers no support of its claim in context of the entire advertisement or as to the targeted audience. Utah Medical supports its allegations solely through the expert testimony of Robert W. Hitchcock, a biomedical engineer, who opines that the Koala advertisements are false because the "balloon at the tip of the Koala catheter is not a sensor according to industry definitions." Hitchcock claims that in order to be sensor-tipped under engineering parlance, an intrauterine pressure catheter must contain a silicon chip pressure transducer in the catheter tip. In his deposition, Hitchcock made several revealing admissions in connection with Utah Medical's false advertising claim: (1) that he had not done any research at all with respect to how a clinician in labor and delivery would understand the term sensor tip in conjunction with intrauterine catheters; (2) that he had not had any discussions with any intrauterine catheter consumer that expressed any confusion regarding the Koala's advertising; (3) that he had not talked to any purchasers of intrauterine catheters prior to putting his report together; and (4) that he was speculating with regard to the purchaser of an intrauterine catheter. As subsequently explained, the Court finds that the expert opinion of Robert Hitchcock regarding plaintiff's false advertising claim should be excluded under Federal Rule of Evidence 702. However, even if the Court were to allow Hitchcock's expert opinion regarding this issue, and

allow it to go to the weight of the issue, the Court finds that Hitchcock's testimony is not enough to allow plaintiff to present this claim to a jury.

Plaintiff must also prove that the challenged statement is material. *See* U.S. Healthcare, Inc. v. Blue Cross, 898 F.2d 914, 922 (3d Cir.1990) ("The [Lanham Act] plaintiff must ... show that defendant's misrepresentations material in that it is likely to influence the purchasing decision."). Plaintiff offers no such evidence. Nothing in plaintiff's expert report rises to the level that a reasonable juror could use in supporting a finding that the Koala advertisements was material and influenced purchasing decisions of relevant consumers.

Based upon all of the evidence submitted by plaintiff, the Court finds that no reasonable jury could find that defendants have falsely advertised the Koala as sensor-tipped when viewing the Koala advertisements as a whole in the relative context. The Koala advertisements clearly disclose that while the Koala is sensor-tipped it has a pressure transducer housed at the other end of the catheter. It would be another matter if the Koala advertisements read "transducer-tipped," but they do not. Thus, the Court finds that the sensor-tipped advertisements are not literally false as a matter of law. Even if plaintiff had claimed that the advertisements were misleading, plaintiff's claim would have failed because it has no support that consumers were confused or mislead. If there were some factual basis to support the claim that from the perspective of the relevant consumer the advertisements as a whole could be viewed as false, the Court would allow this claim to go to a jury. But, there is not. Hitchcock's claims are supported by nothing more than his opinion as an engineer that the term sensor-tipped does not mean what Clinical claims it does. Accordingly, the Court finds that no genuine issues of material fact exist and that summary judgmentis appropriate on plaintiff's false advertising claims under the Lanham Act.

C. Summary Judgment as to Plaintiff's Misappropriation of Trade Secrets Claim

[20] Plaintiff alleges that Clinical has misappropriated Utah Medical's trade secrets, specifically alleging that Clinical used its trade secrets and confidential information to develop and market Clinical's Clearview uterine manipulator and Koala catheter. To establish a claim for misappropriation of trade secrets, plaintiff must show "(1) the existence of a trade secret, (2) communication of the trade secret to [the defendant] under an express duty not to disclose or use it, and (3) [defendants'] use of the secret that injures [plaintiff]." Water & Energy Systems Tech., Inc., 974 P.2d 821, 822 (Utah 1999) (citing Microbiological Res. Corp. v. Muna, 625 P.2d 690, 697-98 (Utah 1981)). Clinical argues that it is entitled to summary judgment on plaintiff's misappropriation of trade secret claim because Utah Medical has not and cannot establish that its claimed information is a trade secret or that Clinical used any claimed trade secret information.

"The threshold issue in every case is whether, in fact, there is a trade secret to be misappropriate." Muna, 625 P.2d at 696. The Utah Supreme Court further recognized that "[t]he burden is upon the plaintiff to prove its existence as a secret, and there is no presumption in his favor." *Id*. a trade secret is statutorily defined. The Uniform Trade Secrets Act, which has been adopted by Utah, reads:

"Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process that:

(a) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and

(b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

UTAH CODE ANN. s. 13-24-2(4) (1999).

Plaintiff alleges that much of the 17,000 pages of documents in the three banker boxes that Wallace took from Utah Medical contained confidential trade secret information. According to one of plaintiff's expert reports, the documents that Wallace took from Utah Medical can be separated into the following five categories: (1) business strategy documents, including 1989-1993 company goals, 1993-1995 strategic plans, strategy regarding the Intran catheter, and a joint venture with Malinckrodt Medical regarding a pressure monitoring catheter which uses a "special membrane"; (2) market analysis documents, including development agreements, Dr. Buschmann agreement, documents relating to fetal oxymetry, Intran marketing and test research, Intran complaints, and Intran II specifications and market research; (3) product developing and testing documents, including the 1990 Intran Plus design and development, 1990 Intran II clinical trials, and Intran II design with balloon, analysis of Intran II clinical trial failures, and intrauterine catheter design suggestions for proximal sensor, air-filled catheter, and distally-mounted flexible membrane; (4) manufacturing and production documents, including standard operating procedure manufacturing documents, Intran Plus through-put and procedures, Intran II manufacturing through-put and vendors; and finally (5) sales and distribution documents, including Intran sales forecast, 1987 sales numbers, Deltran's sales strategy and marketing plan, Intran sales forecasts, and 1992 VP sales and marketing work objectives. *See* Hitchcock Trade Secret Report at 6-7. Utah Medical argues that having access to these documents would provide substantial assistance to Clinical in developing and introducing its Koala catheter by reducing the amount of time necessary to evaluate product opportunity, develop and test prototypes, and produce and distribute the product, as well as provide quicker market penetration, enhanced competitive strategies, and reduced development time and opportunity cost.

[21] Utah Medical further alleges that defendants had access to other unknown trade secret information that has been withheld by the defendants, as evidenced by information that appeared in Clinical's business plan regarding its uterine manipulator but was not in the documents turned over by Wallace to Utah Medical. Such allegations, lacking further support, will not be entertained by the Court. Without additional evidence, the Court will not infer trade secrets have been misappropriated. The burden is upon the plaintiff to establish the existence of a trade secret, and plaintiff must substantiate more than vague and unsupported allegations as to unknown trade secrets in order to satisfy its burden.

In determining whether the documents taken by Wallace constitute trade secrets, the Court looks to the Utah Supreme Court's decision in Microbiological Res. Corp. v. Muna, 625 P.2d 690 (Utah 1981), which is remarkably similar to the instant case. *Muna* involved a claim of misappropriation brought by a medical diagnostic kit company against its former president, a doctor and the developer of its diagnostic kits. While employed by plaintiff, the defendant conceived and developed diagnostic kits used to detect diseases, and the plaintiff manufactured these kits and sold them to hospitals and labs. The plaintiff terminated the defendant, and thereafter the defendant began plans to manufacture a line of products similar to the plaintiff's. The plaintiff sued, alleging misappropriation of its claimed trade secrets. *See Muna* at 692. Based on these facts, the Utah Supreme Court was faced with several of the same issues that this Court is now faced with regarding Utah Medical's claim. The *Muna* court offers several valuable insights as to Utah trade secret law. The court recognized the balance that must exist in this area, observing that the law encourages competition and supports an individual's right to exploit his own skill and knowledge, yet should grant established businesses reasonable protection against unfair trade practices. *See id.* at 697. Accordingly, the

court stated that "[u]pon termination of his employment, an employee has the prerogative to use his general knowledge, experience, memory and skill, however gained, provided he does not use, disclose, or impinge upon any of the secret process or business secrets of his former employer." *Id*. In *Muna,* the plaintiff failed to establish any claimed trade secret because the court found that the information the plaintiff claimed as its secret was expertise known to those in the industry such as Dr. Muna. The court concluded that it would be unfair to preclude Dr. Muna's use of his expertise, stating that he could not be enjoined from "using his knowledge, skill and experiences in an independent business." *Id*. at 699.

[22] Given Wallace, Cutler, and Smith's collective knowledge and experience with Utah Medical and its products, it is difficult to delineate what they knew and what would be a secret. *See id*. at 697 ("There must be a delineation between the general knowledge and experience of the employee and the trade secrets of the employer."). This is why the plaintiff has the burden to bring forth specific trade secret information that is not generally known or readily ascertainable. This standard cannot be viewed as whether the information is generally known and readily ascertainable to the general public, but, based on the defendants' knowledge and experience, whether the information was known or ascertainable to them. *See id*. at 699 (recognizing that information that was published and commonly known in the trade should not be considered a trade secret). Moreover, the "subject matter of the trade secret must be unknown; it should not be in the public domain or within the knowledge of the trade" *Id*. at 696.

Utah Medical must define its claimed trade secret with the precision and particularity necessary to separate it from the general skill and knowledge possessed by Wallace, Cutler, and Smith. The Court finds that the plaintiff has not done so. Simply identifying documents and claiming that they contain trade secret information is not enough. Plaintiff must establish that the information in the identified documents is not published or readily ascertainable information to those in the field. Additionally, plaintiff has reiterated in deposition and at oral argument that defendant could not help but use trade secret information in doing what they are doing. Yet, plaintiff has failed to identify with specificity exactly what trade secrets were used. Such vague assertions fall short of what is required by the law.

Even if Utah Medical could establish that defendants had trade secret information, it must be able to establish that defendants used such information. *See id*. at 696. Plaintiff claims Clinical's very products demonstrate the use of Utah Medical's trade secret information. Shortly after Clinical's inception in April of 1993, it developed its Clearview uterine manipulator. By June 11, 1993, Wallace developed a prototype for the Clearview without performing any marketing studies on the uterine manipulator. Clinical also generated a business plan in July of 1993, describing various potential products, including its uterine manipulator. Portions of the business plan, such as the product description and market analysis sections for a disposable uterine manipulator appear to have been copied nearly verbatim from Utah Medical documents. Clinical has admitted that it was able to avoid formal marketing evaluations for both the Koala and Clearview uterine manipulator. Clinical has acknowledged that it did not perform any marketing analysis for the Koala due to its principals' knowledge of Utah Medical's experience with the Intran I and Intran Plus. Certainly Clinical was able to circumvent some preliminary market research on the Koala and Clearview, allowing them to compete with Utah Medical sooner than someone who was just entering the market. However, Wallace, Cutler, and Smith were not just entering the market, and the law will not prevent competition just because a former employee has the potential to be an immediate competitor. Plaintiff's allegation regarding misappropriation of the uterine manipulator trade secret information falls short as a matter of law. Plaintiff does not identify any aspect of Clinical's Clearview product that it contends was a copy of any trade secret, but rather only identifies Clinical's business plan, which discusses general information about the purpose of uterine manipulators and the various competing uterine manipulators available to clinicians. From the record

in this case, the Court finds it is undisputed that such information is generally known or readily ascertainable to those in the industry.

Additionally, plaintiff alleges that Clinical's user specifications for the Koala are virtually identical to the user specification for the Intran II, which were among the documents taken by Wallace. Regarding the Intran II user specifications, that information contains general background information as to what intrauterine catheters are, their clinical use, and existing devices on the market. The Court is not satisfied that this information qualifies as a trade secret as a matter of law.

Finally, plaintiff alleges that the idea of placing a membrane in the tip of the Intran II was contained in the documents that Wallace had and that he used that idea in developing the Koala. However, the Court finds that given Wallace's expertise and experience with intrauterine catheters, plaintiff has not established that this idea to place a membrane or balloon in a catheter was a trade secret. *See id*. at 697 (finding that "the employee is protected by the rule that the owner may not arbitrarily pronounce anything a trade secret"). It is beyond any factual dispute that Wallace possessed this knowledge with or without any written reference there to in documentation he received from Utah Medical.

Other than plaintiff's two examples of Clinical's copying portions of its business plan discussing the uterine manipulator and the user specifications for the Koala, neither of which contain trade secret information, Utah Medical offers nothing more than argument for the proposition that the trade secret information contained in the Wallace documents and other trade secret information that Wallace, Cutler, and Smith left with in their heads must have been used by Clinical Innovations in its efforts to compete with Utah Medical. Plaintiff argues that the defendants' use of trade secrets was inevitable. Statements such as "I don't know how they couldn't have used trade secrets" are too tenuous to allow the Court to send such a claim to a jury. This case does not factually rise to the level of being an inevitable disclosure case. *See* PepsiCo v. Redmond, 54 F.3d 1262 (7th Cir.1995) (finding the at a former PepsiCo employee could not help but use time sensitive and highly specific marketing plans for the upcoming year in his new position with a competitor). Because plaintiff has failed to identify any trade secret with the particularly required by law, or adduced any evidence of use of any such trade secret, the Court finds that defendants are entitled to summary judgment on plaintiff's misappropriation of trade secrets claim.

D. Summary Judgment as to Plaintiff's Breach of Fiduciary Duty Claim

[23] Plaintiff's breach of fiduciary duty claim is based on Wallace's and Cutler's failure to sign an employee agreement and Wallace's possession of Utah Medical documents. Defendants assert, and this Court agrees, that plaintiff's breach of fiduciary duty claim is barred by the statute of limitations. There is a three-year statute of limitations applicable to plaintiff's claim. *See* UTAH CODE ANN. s. 78-12-27 (1999). For the statutory period to begin to run, "[t]he shareholders or directors must have knowledge of the wrongdoing or facts that put them on inquiry and must be sufficiently independent to be able to assert a claim on behalf of the corporation." United Park City Mines Co. v. Greater Park City Co., 870 P.2d 880, 885 (Utah 1993). The statute commences when the corporate officers obtain sufficient information "to put them on notice and to make further inquiry if they harbor doubts or questions." Id. at 886. In this case, plaintiffs did not file their claim until January 30, 1997. Accordingly, the question is whether Utah Medical had knowledge or notice of the wrongdoing before January 30, 1994. Based on the undisputed facts, Utah Medical had knowledge or notice sufficient to spur further inquiry in 1993.

Defendants assert that plaintiff had knowledge of Wallace and Cutler's alleged failure to sign the

employment agreement in 1993. At the latest, Utah Medical should have known or made further inquiry into this issue at the time Wallace filed his wrongful termination suit in the Spring of 1993, which should have provided Utah Medical with the opportunity to fully explore Wallace's employment terms. Utah Medical has not disputed that it had notice of Wallace's alleged failure to sign an employment agreement prior to 1994. In addition, Utah Medical's president admitted that he knew in May 1993 that Cutler had not signed an employee agreement. Plaintiff's memorandum in opposition does not address this aspect of defendants' argument. Therefore, it is undisputed that plaintiff had knowledge of these events prior to 1994.

[24] With respect to the second argument in plaintiff's breach of fiduciary duty claim, Utah Medical knew that Wallace had Utah Medical documents in his possession long before January of 1994. Plaintiff attempts to recast its claim as challenging Wallace's use of the documents, not his mere possession of the documents. However, this shift does not affect the statute of limitations defect. Under the standard set forth in *United Park City Mines,* the statute begins to run when corporate officers or directors obtain sufficient information "to put them on notice to make further inquiry if they harbor doubts or questions." *Id.* at 886. In *United Park City Mines,* the Utah Supreme Court makes no reference to any requirement that the officers have knowledge of actual "use" of the information. It is sufficient that Utah Medical had sufficient information that a reasonable person would "harbor doubts or questions." In July of 1993, Utah Medical obtained copies of all the documents Dr. Wallace had in his possession. Utah Medical had ample opportunity to review the documents for any alleged confidential and proprietary information. At that time they were put on notice of what the documents contained. As evidenced by plaintiff's trade secret claim, Utah Medical certainly claims that the documents contained alleged trade secrets. Therefore, Utah Medical had sufficient notice well before the January 1994 critical date, and their claim is barred.

[25] Even if the plaintiffs' claim was not precluded by the statute of limitations, summary judgment should be granted because Utah Medical cannot demonstrate that it suffered any harm as a result of any alleged breach. To avoid summary judgment on its breach of fiduciary duty claim, Utah Medical must demonstrate that it has suffered some harm as a result of the alleged breach. *See* Viernow v. Euripides Dev. Corp., 157 F.3d 785, 797-98 (10th Cir.1998) (upholding summary judgment where plaintiff could show no harm as a result of breach of fiduciary duty). Utah Medical has failed to substantiate that it suffered any harm from the alleged breach of fiduciary duty. Defendants argue that it is immaterial whether Wallace and Cutler signed an employment agreement. A formal employment agreement is not necessary under Utah law to create a duty of confidentiality. *See* Envirotech Corp. v. Callahan, 872 P.2d 487, 497 (Utah Ct.App.1994). Thus, a duty of confidentiality existed between Wallace and Cutler and Utah Medical under the Uniform Trade Secrets Act independent of any employment agreement. Therefore, Utah Medical suffered no harm even if Wallace and Cutler were obligated to sign the employment agreement, and failed to do so, as Utah Medical posits. Moreover, Utah Medical eviscerates its claim by admitting that the agreement contained no covenant not to compete. Even if Wallace and Cutler had signed the agreement, they were not forbidden to compete with Utah Medical. Plaintiff argues that because this is a bifurcated trial, they do not have to make a showing of damages. However, the fact of damages is an essential element of Utah Medical's cause of action that must be substantiated to overcome summary judgment. *See* Viernow, 157 F.3d at 797-98. Because damage is an essential element to a claim for breach of fiduciary duty, Utah Medical's claim fails as a matter of law.

Finally, any complaint as to the employment agreements would have been more appropriately brought under a breach of contract claim. No such cause of action was filed. The Court also finds that plaintiff's fiduciary duty argument is coextensive with its misappropriation of trade secrets claim. Plaintiff is simply attempting to recover under another theory that is improper. The law will not allow plaintiff to seek recovery by simply

repackaging their claim in another improper theory.

E. Defendants' Motions in Limine to Exclude Expert Testimony

Defendants move to exclude the expert opinion testimony of Robert W. Hitchcock regarding plaintiff's false advertising claim, and to exclude the expert opinion testimony of Roger W. Blakely, Jr. regarding his legal opinions on claim construction and other patent infringement issues. Defendants' argue that the proposed expert testimony does not satisfy, inter alia, the requirements of Federal Rule of Evidence 702.

Rule 702 states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

FED.R.EVID. 702. (1999). Under the Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), this Court is required to assume a "gatekeeping" role to guarantee that under Rule 702 an expert's testimony is "not only relevant, but reliable." *Id*. at 589, 113 S.Ct. 2786. Thus, the Court must determine first whether the expert's proposed testimony is scientific knowledge, and second, whether the evidence "fits" the current issue and will assist the jury. *See* id. at 592, 113 S.Ct. 2786; *see also* Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) (holding that *Daubert* 's gatekeeping obligation applies not only to scientific testimony, but also to all expert testimony, and that Rule 702 does not distinguish between scientific knowledge and technical or other specialized knowledge).

[26] Robert Hitchcock opines that advertising the Koala as "sensor-tipped" is literally false. As explained more fully in the false advertising section above, Hitchcock reaches this conclusion based on his engineering experience. In accordance with the Court's holding, plaintiff's Lanham Act claim is contingent on analyzing the advertisement in full context as viewed by those to whom the advertisement was directed. Hitchcock never analyzed the full context of the advertisements or how they were perceived among the clinicians whom the advertisements targeted. While Hitchcock's expert opinion may be reliable as to the methodology he used to opine on the meaning of "sensor-tipped" in the medical engineering industry, the Court does not need to address that issue. Even if Hitchcock's methodology for reaching his opinion is reliable, the opinion must be relevant. Hitchcock's testimony is deficient in this area. The Court finds that Hitchcock's testimony does not satisfy the relevance prong of admissibility under *Dauber* and *Kumho Tire* and will not be helpful in assisting a trier of fact as required under Rule 702. Therefore, the Court finds that Hitchcock's expert report as to plaintiff's false advertising claim is inadmissible and should be excluded.

[27] Next the Court turns to Roger Blakely's expert opinion. Plaintiff has designated Blakely, a patent attorney, as an expert witness to testify on claim construction, infringement, and the pioneer status of plaintiff's patented device. As stated earlier, patent claim construction is a question of law and "is exclusively within the province of the court." Markman v. Westview Instrs. Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Furthermore, patent claims generally will be construed solely upon intrinsic evidence, which includes the patent claims, the patent specification, and the prosecution history of the patent, without resort to extrinsic evidence, such as expert testimony. *See* Bell & Howell Document Mgt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997) (holding that "patents should be interpreted on the basis of their intrinsic record, not on the testimony of such after-the-fact 'experts' that played no part

in the creation and prosecution of the patent"); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed.Cir.1996) (holding that "where the patent documents are unambiguous, expert testimony regarding the meaning of a claim is entitled to no weight"). In this case, the Court sees no need to resort to any outside legal expert even one with Mr. Blakely's experience. Accordingly, Blakely's expert opinion as to claim construction is excluded.

Defendants next argue that Blakely's opinion should be excluded as to his testimony on whether the accused device infringes upon the 161 patent and as to the pioneer status of the 161 patent. The Court agrees that such legal opinions attempt to define the legal parameters which in this case should be left to the Court and to the jury. *See* Specht v. Jensen, 853 F.2d 805, 807-810 (10th Cir.1988) (allowing an expert to proclaim a legal conclusion would "circumvent the jury's decision-making function by telling it how to decide the case"). While arguing that this testimony should be admissible, plaintiff acknowledges that the admissibility of such testimony is within the discretion of the district court. *See* Markman v. Westview Inst., Inc., 52 F.3d 967, 980-81 (Fed.Cir.1995). Under its discretion, the Court finds that Blakely's testimony is unnecessary and not helpful to the Court or the fact finder pursuant to Rule 702. Accordingly, Blakely's expert opinion as to infringement and the pioneer status of the 161 patent is excluded.

IV. CONCLUSION

For the reasons stated above, the Court finds that in light of its interpretation of the 161 patent, no reasonable juror could find that the accused device infringes, either literally or under the doctrine of equivalents, upon Claims 1 through 35 of the 161 patent. Therefore, the Court GRANTS defendants' motion for summary judgment as to all of plaintiff's claims for patent infringement.

Additionally, the Court finds that the plaintiff has not presented sufficient evidence to sustain its false advertising, trade secrets, and fiduciary duty claims. Thus, the Court GRANTS defendants' motion for summary judgment as to plaintiff's claims for false advertising under the Lanham Act, misappropriation of trade secrets, and breach of fiduciary duty. Finally, the Court GRANTS defendants' motion in limine to exclude the expert testimony of Robert Hitchcock as to his expert report on the analysis of the term "sensor tip" as applied to the Koala device, as well as defendants' motion in limine to exclude the expert testimony of Roger W. Blakely regarding his legal opinions on claim construction, infringement, and the pioneer status of plaintiff's patented device.

It is so ORDERED.