IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CONCEPTUS, INC.,

Plaintiff,

v.

HOLOGIC, INC.,

Defendant.
_____/

No. C 09-02280 WHA

CLAIM CONSTRUCTION ORDER

INTRODUCTION

In this patent infringement action involving intrafallopian contraceptive devices, the parties seek construction of six terms and phrases found in asserted claims 8, 37, and 38 of U.S. Patent No. 6,634,361 and asserted claims 5 and 14 of U.S. Patent No. 7,506,650. On March 16, 2010, the Court issued a tentative claim construction order and invited the parties to file five-page critiques of the constructions therein. After consideration of voluminous briefing from both sides, final constructions are set forth below.

STATEMENT

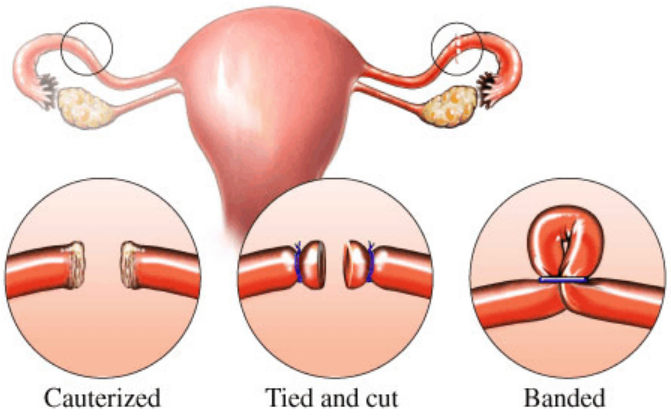
Plaintiff Conceptus, Inc. sells a transcervically introduced permanent contraceptive product called Essure. It received FDA approval in 2002, and is currently plaintiff's only marketed product. Unlike tubal ligation, the Essure system allegedly requires no incisions and is minimally invasive. According to plaintiff, Essure can be placed within the fallopian tubes of the

recipient by way of the cervix in a ten-minute, non-surgical procedure that can be performed in a doctor's office without general anesthesia. Essure's contraceptive efficacy is supposedly achieved through occlusion (*i.e.* blocking) of the fallopian tube.

Defendant Hologic, Inc. owns and markets the accused Adiana contraceptive system. The Adiana system, like the Essure system, supposedly involves the minimally invasive transcervical placement of a contraceptive device (referred to by Hologic as a "matrix") into the fallopian tubes of the recipient. Combined with the use of radiofrequency energy, the Adiana system — much like the Essure system — is intended to produce intrafallopian occlusion, which either prevents conception from occurring or blocks the passage of a fertilized ovum to the uterus. Adiana received FDA approval in July 2009.

Targeting the fallopian tubes is a well-known approach to permanent contraception. Referring to the basics of reproductive biology (and perhaps oversimplifying a bit), sperm enter the fallopian tubes by way of the uterus. Ova, on the other hand, travel in the opposite direction *towards* the uterus from the ovaries. Thus, blocking the fallopian tubes is a sensible way to prevent sperm from meeting and fertilizing an ovum.

Tubal ligation, a longstanding but highly invasive procedure for permanent sterilization, works similarly to the invention in the patents-in-suit; it physically prevents the meeting of sperm and ova. Tubal ligation can be performed in a variety of ways, including clipping the fallopian tubes, cutting and tying the fallopian tubes, banding the fallopian tubes, or cauterizing the fallopian tubes. An illustration of some of these techniques is shown below (Compl. ¶ 7):



Unlike tubal ligation, the patents-in-suit cover an intrafallopian contraceptive system where a contraceptive device is placed within the reproductive system via the cervix using specially adapted tools. No cutting, banding, or cauterizing is supposedly necessary. Additionally, rather than blocking the fallopian tubes using external mechanical methods (as done in tubal ligation), the devices in the asserted patents serve their intended purposes by blocking the fallopian tubes *from within*.

At the onset of this litigation, five patents were originally asserted by Conceptus (Dkt. Nos. 1, 12). Of these five patents, a single claim — claim 94 of U.S. Patent No. 7,428,904 — formed the basis for an unsuccessful preliminary injunction motion (Dkt. Nos. 91, 131). Thereafter, the parties stipulated to eliminating three of the five asserted patents (including the '904 patent) from the dispute (Dkt. No. 140). As such, only two patents and five claims currently remain. The Court thanks counsel for taking steps toward streamlining the case.

The '361 and '650 patents — the two remaining in this action — cover separate aspects of the contraceptive invention. The '361 patent covers the intrafallopian contraceptive device itself, as well as various methods for the device's placement within the fallopian tube. The '650 patent, by contrast, involves the deployment system for the device (meaning, the apparatus used to place the contraceptive device within the fallopian tubes). With this background in place, this order now turns to the disputed claim terms and phrases.

ANALYSIS

Courts must determine the meaning of disputed claim terms from the perspective of one of ordinary skill in the pertinent art at the time the patent was filed. *Chamberlain Group, Inc. v. Lear Corp.*, 516 F.3d 1331, 1335 (Fed. Cir. 2008). While claim terms "are generally given their ordinary and customary meaning," the "claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1314 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). As such, other claims of the patent can be "valuable sources of enlightenment as to the meaning of a claim term." *Vitronics*, 90 F.3d at 1582. Additionally, a patent's specification "is always highly relevant to [] claim construction[.]" *Phillips*, 415 F.3d at 1315 (quoting *Vintronics*,

90 F.3d at 1582). Indeed, claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Finally, courts should also consider the patent's prosecution history, which "can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1318 (citations omitted). These components of the intrinsic record are the primary resources in properly construing claim terms. *Id.* at 1317–18.

While this order acknowledges that the parties have a right to the construction of all disputed claim terms by the time the jury instructions are settled, the Court will reserve the authority, on its own motion, to modify the constructions in this order if further evidence — intrinsic or extrinsic — warrants such a modification. Given that claim construction is not a purely legal matter, but is (as the Supreme Court describes it) a "mongrel practice" with "evidentiary underpinnings," it is entirely appropriate for the Court to adjust its construction of claims prior to trial if the evidence compels an alternative construction. *Markman*, 517 U.S. at 378, 390. For the same reasons, this order will not be bound by prior constructions of similar terms in different patents, as urged by Hologic multiple times in its responsive brief (Resp. 5, 11–12). The '904 patent — the star of the preliminary injunction — is no longer being asserted in this action, and *preliminary* constructions of its terms have no bearing herein.

The parties should be aware, however, that they are *not* invited to ask for reconsideration of these constructions. Motions for reconsideration may only be made, if at all, in strict accordance with the rules of procedure.

1. THE '361 PATENT

The '361 patent, entitled "Contraceptive Transcervical Fallopian Tube Occlusion Devices And Methods," was issued on October 21, 2003. Conceptus is the assignee of the '361 patent. Three claims from this patent are asserted in this litigation: independent claim 8, and dependent claims 37 and 38. Five of the six disputed terms and phrases in this order are found in the '361 patent. These terms and phrases are italicized in the claims below.

Claim 8 covers (col. 20:21–33):

> 8. A tissue ingrowth contraceptive device for use in a fallopian tube, the contraceptive device comprising:
>
> *a resilient elongate body* having a proximal end and a distal end and defining an axis therebetween;
>
> a retention structure disposed along the resilient body, the retention structure adapted to restrain the resilient body within the fallopian tube;
>
> *a bond affixing the retention structure to the resilient body*;
>
> wherein at least one of the resilient body, the retention structure, and the bond comprises a microporous material which promotes tissue ingrowth therein.

Claims 37 and 38 (as well as independent claim 36, which they reference) cover (col. 23:38–53):

> 36. An intrafallopian contraceptive method comprising:
>
> transcervically introducing a *pre-formed resilient structure* into a target region of a fallopian tube;
>
> imposing an anchoring force against a tubal wall of the fallopian tube by resiliently engaging in inner surface of the tubal wall with the resilient structure; and
>
> *permanently affixing the resilient structure within the fallopian tube* with a *lumen-traversing region of the resilient structure so that at least a portion of the fallopian tube is open*.
>
> 37. A method as claimed in claim 36, wherein the affixing step comprises promoting tissue ingrowth of the tubal wall surrounding the resilient structure.
>
> 38. A method as claimed in claim 37, wherein the tissue ingrowth occludes the fallopian tube to inhibit contraception.

A. "resilient elongate body / pre-formed resilient structure"

The parties dispute the phrases "a resilient elongate body" and "pre-formed resilient structure." The former phrase is found in claim 8, while the latter phrase is found in claim 36 (upon which asserted claims 37 and 38 are dependent). The parties' proposed constructions are shown below.

CONCEPTUS'S PROPOSED CONSTRUCTION	HOLOGIC'S PROPOSED CONSTRUCTION
Claim 8: "a resilient elongate intrafallopian device"	*Claim 8:* "a resilient elongate intrafallopian device *that includes, at least in part, metal*" and
Claims 37 and 38: "pre-formed resilient intrafallopian device"	*Claims 37 and 38:* "pre-formed resilient intrafallopian device *that includes, at least in part, metal*"

Conceptus and Hologic agree that the terms "body" and "structure" in the above phrases refer to an "intrafallopian device." Where the parties disagree, however, is whether the intrafallopian device must be one "that includes, at least in part, metal." Conceptus points to the claim language and specification to argue that the claims never set forth a "metal" limitation, and the specification never evidenced a clear intent to limit the claims in such a manner. Hologic counters with the fact that every disclosed embodiment in the specification included a metal coil or component. Additionally, Hologic argues that the device in claim 36, which involves an "open" fallopian tube, must include copper to provide effective contraception. For the reasons explained below, this order finds that Hologic has failed to show an intent by the patentee to limit the claims in the manner proposed.

The language of claims 8 and 36 are entirely devoid of any limitation that the intrafallopian device "include[], at least in part, metal." Dependent claims 37 and 38 — which build upon claim 36 — similarly lack limitations involving metal. As such, Hologic's proposed construction immediately challenges the presumption that "the words of the claim . . . define the scope of the patent." *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*, 554 F.3d 1010, 1027 (Fed. Cir. 2009) (citing *Phillips*, 415 F.3d at 1312). Hologic must therefore show that despite the absence of such a limitation in the asserted claims, the intrinsic evidence shows that the patentee intended the contraceptive device to include metal.

On this point, a distinction must be drawn between the use of copper in the present invention, and the use of metal *in general* in the claimed device. The specification contained numerous references to "[t]he efficacy of the device [being] enhanced by forming the structure at least in part from copper or a copper alloy" (cols. 1:53–55, 3:7–9, 8:10–24, 9:34–46,

18:50–19:16). This is because copper provided "not fully understood" benefits in disrupting the reproductive process in the fallopian tube (col. 8:21–25). Indeed, three claims in the '361 patent — which are not being asserted here — included express limitations requiring the use of copper (cols. 24:32–34, 24:35–39). In sum, the specification discussed the use of copper in the device as a means to improve its contraceptive efficacy, but not as a required component in every embodiment. Hologic admitted as much at the claim construction hearing. It does *not* argue that copper must be present in all embodiments.[1]

Rather, Hologic's argument is directed towards the use of metal *in general* as a structural material in the device. To support its argument, Hologic notes that the specification never disclosed any embodiments that did not use metal (or, more specifically, a metal coil) to form the "resilient structure" — or backbone — of the device. This is true. The first embodiment of the contraceptive device, as disclosed by the specification, appeared to *require* the presence of metal in its primary coil component (*see* col. 9:34–46, noting that the primary coil is "preferably . . . formed from a beryllium copper alloy" or "[a]lternatively . . . from a resilient metal"). FIG. 1 below represents this first embodiment, with the primary coil denoted by the number 12.

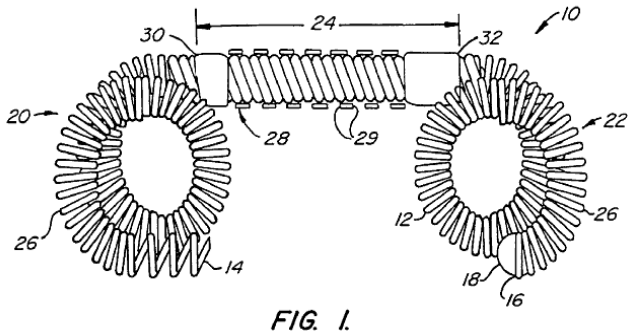


FIG. 1.

[1] In its critique brief, Hologic shifted its position by arguing that the device in claim 36 *must* include copper because the fallopian tube is "open" (Dkt. No. 178 at 1–3). This order disagrees. As explained in a later construction, an "open" fallopian tube simply means that the tube is not completely occluded. Under such conditions, effective contraception is still possible if "ovum transport, the process of fertilization, and/or cleavage of the ovum" is prevented (col. 8:15–21). While it is clear that the use of copper *enhances* contraceptive effectiveness, the specification sets forth other ways to "disrupt[] the architecture and/or normal functioning of the fallopian tube" (*see* cols. 8:21–35, 11:19–29). Indeed, a person having ordinary skill in the art at the time the patent application was filed would have understood that a device that allowed sperm to pass through the fallopian tube, but did not allow ova to reach the uterus, would provide effective contraception in an "open" tube whether or not copper was present. Moreover, the patentee clearly stated in the claims when copper was a required component in the claimed invention (*see* claims 44 through 46).

An alternative embodiment disclosed in the specification, referred to herein as the "straight" embodiment, similarly appeared to require the use of metal in its primary coil (*see* col. 11:52–12:19). This straight embodiment is shown in FIG. 11A below, with the primary coil denoted as 202.

FIG. IIA.

Indeed, all embodiments of the invention disclosed by the patent appeared to feature a "primary coil," and this coil appeared to be metallic when specifically described in the specification (*see* col. 19:19–24).

While this intrinsic evidence lends support to Hologic's proposed construction, it falls short of a "clear intention" by the patentee to limit the claim scope. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 905 (Fed. Cir. 2004) (holding that when the specification uses a single embodiment to enable the claims, broader claim language should not be limited to that embodiment "unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest execution or restriction"). As Conceptus pointed out at the claim construction hearing, the specification clearly stated that "[t]he intrafallopian device of the present invention . . . *often* comprises a resilient structure, *usually* a metallic coil . . . ideally comprising an alloy including at least 75% copper" (col. 3:14–17) (emphases added). Moreover, the specification itself noted that contraceptive devices in the prior art were made of non-metal materials, such as silicone (*see* col. 1:54–55, 2:33–36).[2]

Given this information, a person having ordinary skill in the relevant art at the time the patent was filed would have understood that metal coils were used in the disclosed embodiments because they were "biocompatible" while having the "strength" and "resiliency" to function, in

[2] While it is true, as Hologic's critique brief points out, that these prior art designs were criticized by the patentee, these criticisms were directed solely at prior designs being "less readily restrained" in the fallopian tube (*see* 3:9–14). This has no bearing on whether the present invention must include metal. Rather, the present invention improves upon the prior art because it is *more* readily restrained in the fallopian tube through the use of resilient structures, retention structures, and tissue ingrowth methods.

coil form, as the invention's "resilient structure" (*see* cols. 9:21–22, 9:35–38, 9:42–44). In other words, the specification disclosed using metal coils because they "provide[d] the *resilience* necessary to avoid expulsion of the device" (col. 9:35–38) (emphasis added). That said, the specification never stated that metal (or a metal coil) was required to provide this necessary resilience. Given that non-metallic devices were prevalent in the prior art at the time the patent application was filed, a person having ordinary skill in the art would have understood that the resilient structure could be made of *any* material so long as the structure was sufficiently resilient.

Indeed, the claims themselves support this conclusion. Claims 1 and 3 of the '361 patent contain an express "coil" limitation (cols. 19:33–45, 19:49–62). The asserted claims, however, do *not* (cols. 20:21–33, 23:38–53). Additionally, as Hologic admitted at the hearing, the *retention* structure of the device — which may (or may not) be a separate component from the resilient structure in various embodiments — does not need to be made out of metal (cols 13:57–60, 14:1–3, 13:14:6–10). Viewing this intrinsic evidence as a whole, this order cannot find that the patentee "demonstrated a clear intention to limit the claim scope" of the asserted claims to include, at least in part, metal. *See Liebel-Flarsheim*, 358 F.3d at 905.

None of the decisions cited by Hologic compels a contrary conclusion. In *Kinetic Concepts*, the court limited the claim term "wound" to "skin wounds" because the specification "in no way suggest[ed]" that non-skin wounds "[could] be treated according to the claimed invention." 554 F.3d 1010, 1018 (Fed. Cir. 2009). By contrast, the claims in the '361 patent clearly distinguished between coil-based and generic resilient structures, and the specification expressly left open the possibility of using resilient structures other than metal coils. Also distinguishable is *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, which relied upon an implied *functional* limitation in the specification to construe the claim term "spike." 558 F.3d 1368, 1374–76 (Fed. Cir. 2009). In *ICU Medical*, the specification made clear that the "spike" needed to be pointed, since its function was to pierce a seal. Thus, that limitation was properly read into the claim. Hologic fails to point to an equivalent functional limitation here. While it is true — at least based upon the specification — that certain metals provide the resilience necessary for the present device to function, resilience inhered in non-metal materials as well. Finally,

Netcraft Corp. v. eBay, Inc. is cited by Hologic without explanation, but it involved a patent where the term "present invention" was used with abandon through the specification, and the claims were limited to those features disclosed. 549 F.3d 1394, 1397–98 (Fed. Cir. 2008). *Netcraft*, however, expressly acknowledged that "use of the phrase 'the present invention' does not 'automatically' limit the meaning of claim terms in all circumstances, and that such language must be read in the context of the entire specification and prosecution history." *Id.* at 1398 (citing *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1094 (Fed. Cir. 2003)). As stated, this order gives full consideration to the entire specification, and finds that the intrinsic evidence does not support Hologic's argument that the claims be limited to the particular embodiments in the patent.

In sum, while all parties agree that the specification clearly set forth metallic *preferences* — copper for its contraceptive efficacy and metal coils for their "strength" and "resiliency" as a structural component — it expressly avoided setting forth a manifest limitation that the invention include metal. A person having ordinary skill in the relevant art at the time the application was filed would have understood that the "resilient structure" need only be resilient enough to serve its intended purpose. It need not be made out of metal coils, or even metal at all.

As such, this order adopts Conceptus's proposed constructions for the phrases "a resilient elongate body" and "pre-formed resilient structure" found in claims 8, 37, and 38.

B. "a bond affixing the retention structure to the resilient body"

The next disputed phrase, "a bond affixing the retention structure to the resilient body," is found solely in claim 8. Only Hologic seeks a construction of this particular phrase. Conceptus, by contrast, asserts that the phrase does not require construction, and that its plain meaning should apply (Br. 9–10). Hologic's proposed construction is shown below.

CONCEPTUS'S PROPOSED CONSTRUCTION	HOLOGIC'S PROPOSED CONSTRUCTION
Plain meaning applies. No construction necessary.	"solder or a similar type material for affixing the retention structure to the resilient body"

The term "bond" appears in various portions of the specification (*see, e.g.*, cols. 3:57–62, 4:55–57), as well as in the discussion and drawings of particular embodiments (*see, e.g.*, cols.

14:63–66, 15:3–7, 15:32–35, 15:66–16:2; FIGS. 14, 14A–C). To provide a visual example, FIG. 14A below shows a "bond" (206) affixing a retention structure (204) to the resilient body (202) in a particular embodiment of the present invention.

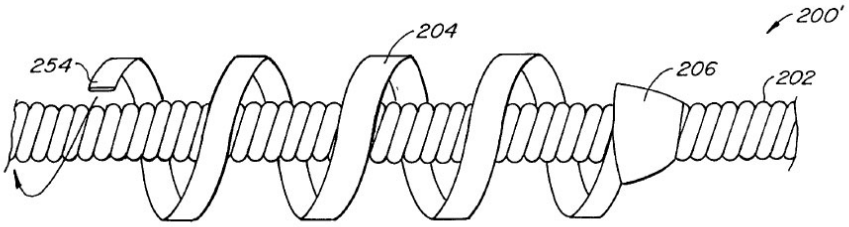


FIG. 14A.

Hologic's proposed construction attempts to limit the "bond" between the retention structure and resilient body of the present invention to a "solder or a similar type material" (Resp. 8–10). Nothing in the intrinsic evidence, however, supports such a limitation. While a "solder bond" is mentioned *once* in the specification, the context of its use has nothing to do with affixing the retention structure to the resilient body (*see* col. 3:57–62, using a "solder bond" to describe the attachment of the contraceptive device to an installation apparatus). As such, Hologic's construction improperly imports a limitation into the claim without *any* support in the specification, and must be rejected. *See Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (explaining that courts must be careful to *not* improperly import limitations from the specification into the claims); *Liebel-Flarsheim*, 358 F.3d at 905.

This does not mean, however, that plain meaning should apply (Br. 9–10). As Hologic explained at the claim construction hearing, it's underlying concern with respect to the term "bond" — reflected in its proposed construction — was that it could be stretched to encompass bonds on a molecular level (Resp. 8–9). Using such a construction, a unitary device, having no disparate parts that have ever been joined together, could still be argued to the jury as meeting the "bond" limitation. Given this dispute over the appropriate meaning of "bond," construction of the phrase is perhaps necessary. *See O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008) ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more

than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute.").

Looking to the language of claim 8, the context of the phrase "a bond affixing the retention structure to the resilient body" plainly contemplates the joining of two disparate components of the claimed device: namely, a retention structure and a resilient body. Adding support to this reading of claim 8 is the fact that it separately lists "a resilient elongate body," "a retention structure," and "a bond affixing the retention structure to the resilient body" as three distinct components of the invention (*see* col. 20:21–33). Given this language, this order finds that the patentee would not have called out "a bond affixing the retention structure to the resilient body" if the resilient elongate body and retention structure were already one and the same. Stated differently, the "bond" in claim 8 would serve no purpose if the retention structure and resilient body were already affixed to each other.

Since courts must interpret claim terms in the context of the claim as a whole, *see Kyocera Wireless Corp. v. International Trade Comm'n*, 545 F.3d 1340, 1347 (Fed. Cir. 2008), this order finds that a person of ordinary skill in the relevant art at the time the patent was filed would have construed the phrase "a bond affixing the retention structure to the resilient body" as meaning "a bond affixing the retention structure to the resilient body, where without the bond, the retention structure and resilient body would be unaffixed components."

C. "permanently affixing the resilient structure within the fallopian tube"

The third disputed phrase is "permanently affixing the resilient structure within the fallopian tube" found in claims 37 and 38. Proposed constructions are shown below:

CONCEPTUS'S PROPOSED CONSTRUCTION	HOLOGIC'S PROPOSED CONSTRUCTION
"affixing the resilient structure within the fallopian tube, such that it remains (or is intended to remain) affixed in the fallopian tube for a long, indefinite period"	"affixing the resilient structure within the fallopian tube so long as it is in the tube, *e.g.*, is not expelled or absorbed"

At the heart of this dispute is what is meant by the word "permanently." Both parties agreed during oral argument that the term pertains to permanent contraception — a conclusion

that finds ample support in the specification (*see, e.g.*, cols. 1:27–35, 1:57–58, 2:54–60, 7:65–67). Indeed, the specification frequently emphasized that one of the objects of the present invention was to improve upon the "unacceptably high percentage" of non-surgical intrafallopian contraceptive devices that became unintentionally dislodged (*i.e.*, did not remain in place and were expelled) after being inserted into the fallopian tube (cols. 2:1–4, 8:46–48).

Despite this agreement, Conceptus and Hologic nevertheless propose two different constructions commensurate with their respective strategic needs. Both constructions are confusing and flawed. For example, Conceptus's proposed construction inexplicably introduces a subjective element — "intended to remain" — into the claim, but never explains whose subjective intent is at issue. Additionally, Conceptus would require the contraceptive device to remain "affixed in the fallopian tube for a long, indefinite period." How one would go about proving that an accused device met such a limitation is a mystery to all involved.

Hologic's proposed construction is equally confusing. Not only does it inexplicably add the limitation that the contraceptive device not be "absorbed," it equates "permanently" with simply being "within the tube." This is contrary to the plain meaning of the word "permanently" as used in the context of the claim, and would only serve to confuse the jury.[3]

Having considered the context of the disputed phrase within the claim language, and the fact that the specification did not impart "permanently" with a definition that was different from its plain and ordinary meaning, this order finds that no construction is required for the phrase "permanently affixing the resilient structure within the fallopian tube."

D. "lumen-traversing region of the resilient structure"

The parties dispute the phrase "lumen-traversing region of the resilient structure" from claims 37 and 38. As explained in an earlier footnote, the lumen is the inner open space or cavity of a tubular organ. Used here, it is simply the open space within a fallopian tube.

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[3] Hologic's last-minute argument that this phrase is indefinite is both untimely and without merit. Both parties essentially agreed at oral argument on the basic meaning of the term "permanently." The parties merely differ over the details of its construction. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1374 (Fed. Cir. 2001) ("If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.").

CONCEPTUS'S PROPOSED CONSTRUCTION	HOLOGIC'S PROPOSED CONSTRUCTION
"region of the resilient structure that crosses the width of the fallopian tube"	"a section of the resilient structure that crosses the entire length of the fallopian tube lumen"

The parties could not be more diametrically opposed on the meaning of the phrase "lumen-traversing region." Conceptus argues that it refers to the part of the contraceptive device that traverses the entire *width* — meaning the diameter or cross-section — of the lumen, while Hologic contends that it pertains to the portion of the device traversing the entire *length* of the fallopian tube. As explained below, neither construction seems entirely correct.

Only *some* embodiments of the present invention have a clearly denoted "lumen-traversing region." In the embodiment shown in FIG. 1 (reproduced again below), the area denoted by number 24 is the "lumen-traversing region" (col. 9:7–12).

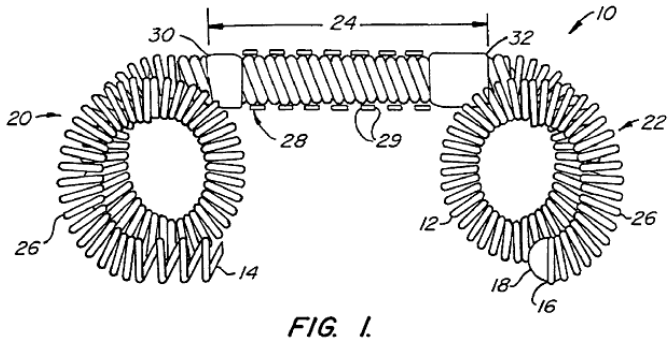

FIG. 1.

On either side of the lumen-traversing region are the "anchors" of the device, with the "proximal anchor" denoted by 20 and the "distal anchor" denoted by 22. These anchors serve their named purpose — they keep the contraceptive device "anchored" in the fallopian tube so that the device is not expelled.

When the embodiment shown in FIG. 1 is inserted into the fallopian tube, the anchors are actually not curled — rather, they held in a straight position to ease the insertion of the device. When the device is placed within the fallopian tube, the proximal and distal anchors are *ideally* placed on either side of the narrowest part of the tube (col. 8:43–53). That way, when the anchors are unfurled, the device is held snugly within the tube. FIG. 10 below illustrates the placement of the FIG. 1 embodiment within the fallopian tube.

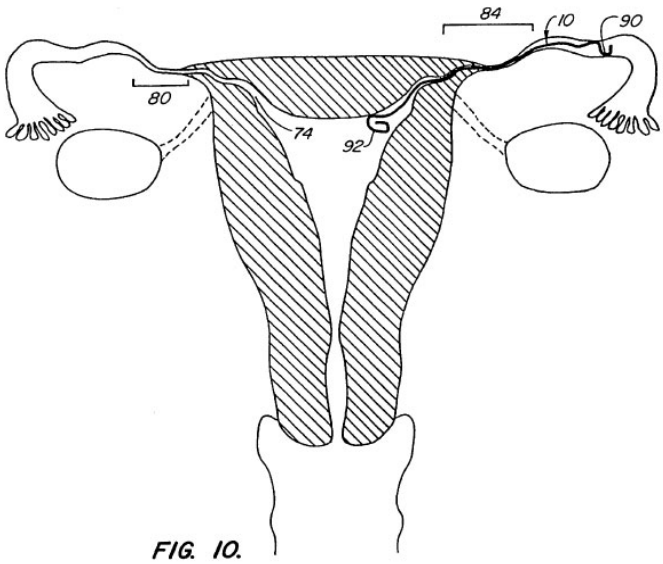

FIG. 10.

In FIG. 10 shown above, the narrowest part of the fallopian tube, called the "isthmus," is denoted by 80, while the proximal and distal anchors of the FIG. 1 embodiment are shown as 92 (the proximal anchor) and 90 (the distal anchor).

Given this intrinsic evidence, it is clear that Hologic's proposed construction cannot be correct. The device shown in FIG. 10 clearly does *not* traverse the entire length of the fallopian tube. Rather, there are portions of the fallopian tube beyond the distal anchor of the contraceptive device (shown in FIG. 10 as 90) that the device does not occupy. Moreover, the specification expressly stated that the invented device could span various other portions of the tubal lumen (*see* cols. 3:49–52, 8:55–58). In sum, Hologic's proposed construction is contrary to the teachings of the specification, and improperly excludes numerous disclosed embodiments. As such, it must be rejected. *See Vitronics*, 90 F.3d at 1583 (holding that a construction that excluded a preferred or disclosed embodiment would be "rarely, if ever, correct and would require highly persuasive evidentiary support"); *see also Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007) (if a disputed claim term has multiple ordinary meanings, the court should adopt the ordinary meaning that includes the disclosed examples in the specification).

Conceptus's proposed construction is also problematic. In claim 35 (which is not asserted in this action), the "lumen-traversing region" is expressly defined by the claim as the region

"extending between the proximal and distal anchors" (col. 23:31–37). This is exactly as the "lumen-traversing region" is described for the embodiments in FIGS. 1 and 6 (col. 9:11–13). By contrast, claim 36 — in the spotlight here — does *not* define the "lumen-traversing region" by reference to proximal and distal anchors. Rather, the "lumen-traversing region" is defined solely by claim 36 as the region of the resilient structure that is used to "permanently affix[] the resilient structure within the fallopian tube" (*see* col. 23:45–48).

Nothing in claim 36 or the specification *requires* that the contraceptive device "cross[] the width of the fallopian tube" to be permanently affixed within the fallopian tube. Granted, crossing the width of the fallopian tube might maximize the interaction of the device with the surrounding lumenal wall, which might be *ideal* in ensuring that the device is permanently affixed within the tube (especially for those embodiments that promote tissue ingrowth). The intrinsic evidence, however, does not require limiting the claims to such an ideal embodiment.

Indeed, a person having ordinary skill in the relevant art at the time the patent was filed would have understood, after reading the entire patent, that the lumen-traversing region of the contraceptive device could be lodged against one side of the fallopian tube (and *not* cross the entire width of the lumen) and still be entirely capable of becoming permanently affixed within the tube. This is because fallopian tube cross-sections can vary significantly in size, and the invention contemplates various means of affixing the device within the fallopian tube without mentioning any requirement that the device cross the entire width of the fallopian tube (*see* cols. 11:42–45, 16:52–54, 17:52–58). Moreover, it is unclear what Conceptus would consider the "width" of the lumen, given the fact that the lumen (depicted as "L" in FIG. 15A below) contains numerous folds.

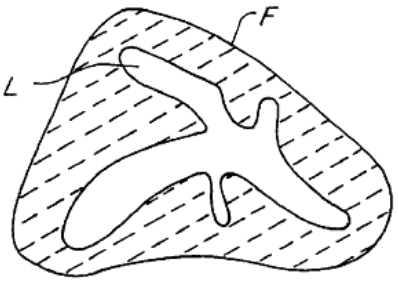

FIG. 15A.

Finally, in its critique brief, Hologic argues that the "lumen-traversing" region must be construed to traverse at least "a substantial portion" of the length of the fallopian tube lumen (Dkt. No. 178 at 4). This order disagrees. Asserted claims 37 and 38 cover a contraceptive device that promotes tissue ingrowth. The specification clearly states that "a relatively small device which promotes ingrowth may be capable of providing effective occlusion" (col. 11:43–45). Given this intrinsic evidence, a person having ordinary skill in the relevant art at the time the patent application was filed would not understand the "lumen-traversing region" as being required to traverse a "substantial portion" of the length of the tube.

Since the specification did not clearly define the term "lumen-traversing region" (and failed to denote such a region in all of the disclosed embodiments), this order will construe "lumen-traversing region" as it is defined by the language in claim 36. As such, the phrase "lumen-traversing region of the resilient structure" shall be construed as the "region of the resilient structure that interacts with the wall of the fallopian tube lumen to permanently affix the resilient structure within the fallopian tube lumen."[4]

E. "so that at least a portion of the fallopian tube is open"

The final disputed phrase from the '361 patent is "so that at least a portion of the fallopian tube is open" from claims 37 and 38. Proposed constructions are shown below.

CONCEPTUS'S PROPOSED CONSTRUCTION	HOLOGIC'S PROPOSED CONSTRUCTION
"so that at least a portion of the fallopian tube is not completely occluded"	Indefinite subject to 35 U.S.C. 112. Otherwise: "that there is no obstruction in the fallopian tube preventing the meeting of sperm and ovum"

As a preliminary matter, Hologic's indefiniteness argument must be rejected. As the analysis below illustrates, this phrase is amenable to construction in light of the specification.

[4] This order does not rely on the expert testimony of Dr. Mark Glasser to construe this, or any disputed phrase. As such, Hologic's evidentiary objections to Dr. Glasser's testimony are denied at moot.

Given this conclusion, the phrase is not indefinite. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1374 (Fed. Cir. 2001).

This construction boils down to the differences between complete (or total) occlusion of the fallopian tube and "functional occlusion" of the fallopian tube. As explained in the summary of the invention, while the contraceptive device in the asserted patent "will generally result in occlusion, *it need not completely occlude the fallopian tube* to prevent the meeting of the sperm and ovum" (col. 3:22–24) (emphasis added). "[C]ontraception can be provided by disrupting the architecture and/or function of the fallopian tube, *despite the presence of an open lumen*" (col. 3:27–29) (emphasis added). "This concept is referred to herein as 'functional occlusion'" (col. 3:29–30). In other words, the specification clearly taught that the intrafallopian contraceptive device need *not* block the entire lumenal cavity to provide effective contraception (*see* cols. 4:29–34, 11:27–34). Despite the presence of an open lumen, the device may still provide effective contraception so long as there is "functional occlusion" to "inhibit fertilization and/or conception" (col. 3:30–34).

With this definition of "functional occlusion" from the specification, the claims provide all the information necessary to properly construe this disputed phrase. Specifically, claim 40 — which is not asserted in this action — covers "[a] method as claimed in claim 36, wherein permanently affixing the resilient structure with the fallopian tube provides functional occlusion of the fallopian tube." Given that "functional occlusion" is only necessary when the fallopian tube is not completely occluded, this necessarily implies that the fallopian tube in claim 36 has this feature. Indeed, this is exactly what a person having ordinary skill in the relevant art at the time the patent was filed would have understood "so that at least a portion of the fallopian tube is open" to mean.

Moreover, asserted claims 37 and 38, which cover "tissue ingrowth," would *also* be meaningless if the fallopian tube in claim 36 were already completely occluded (*see* col. 4:21–22). Indeed, the specification stated that "[i]n many embodiments, the presence of the contraceptive device in combination with [] tissue reaction can provide effective contraception *without having to rely on total occlusion of the fallopian tube*" (col. 4:30–34) (emphasis added).

Stated differently, the promotion of tissue ingrowth into the device (claim 37) can produce sufficient ingrowth to inhibit contraception (claim 38), despite the fact that the fallopian tube was not completely occluded when the contraceptive device was initially affixed (claim 36).

As such, Conceptus's proposed construction is correct, and the phrase "so that at least a portion of the fallopian tube is open" from claims 37 and 38 patent shall mean "so that at least a portion of the fallopian tube is not completely occluded."[5]

2. THE '650 PATENT

The final construction in this order pertains to the '650 patent. The '650 patent, entitled "Deployment Actuation System For Intrafallopian Contraception," was issued on March 24, 2009. Unlike the prior patent, the '650 patent covers a "delivery mechanism" used to place contraceptive devices within the fallopian tube, rather than the contraceptive devices themselves (Br. 5). Conceptus is the assignee of this patent.

Two claims from the '650 patent — method claim 5 and apparatus claim 14 — are asserted in this litigation. The disputed phrases construed below are found in *both* of these claims.

Claim 5 covers (col. 19:41–20:8):

> 5. A contraceptive method comprising:
>
> inserting a contraceptive device transcervically into an ostium of a fallopian tube by gripping a handle with a hand and moving the hand, *the handle coupled to the contraceptive device by an elongate body*;
>
> Withdrawing a sheath surrounding the elongate body and at least a portion of the contraceptive device by moving the sheath proximally relative to the elongate body to expose the contraceptive device, such movement effected by moving an actuator on the handle with the hand while the hand grips the handle; and

[5] In its critique brief, Hologic stated that it no longer objects to the adoption of Conceptus's proposed construction (Dkt. No. 178 at 5). That said, both sides seek clarification of the term "completely occluded" as used in this order. Based upon the intrinsic evidence, a person having ordinary skill in the relevant art at the time the patent application was filed would have understood "complete occlusion" to mean that only a portion of the fallopian tube needs to be completely blocked. "Complete occlusion" does *not* require that the entire lumen of the fallopian tube, from the uterus to the fimbria, be completely blocked .

detaching the contraceptive device from the elongate body within the ostium to inhibit contraception.

Claim 14 (which is dependent upon claim 9) covers (cols. 20:19–32, 20:43–44):

> 9. A contraceptive delivery system comprising:
>
> a contraceptive device insertable into an ostium of a fallopian tube;
>
> *a deployment shaft having a proximal end and a distal end releasably coupled to the contraceptive device*;
>
> a proximal handle connected with the proximal end of the deployment shaft, the handle having a size and shape suitable for gripping with a single hand;
>
> an at least one actuator mounted on the handle, wherein movement of the at least one actuator by the hand while the hand grips the handle releases the contraceptive device from the distal end of the deployment shaft; and
>
> conductors extending along the deployment shaft to provide energy to at least a portion of the fallopian tube.
>
> * * *
>
> 14. The contraceptive delivery system of claim 9, wherein the conductors provide radiofrequency energy.

A. "the handle coupled to the contraceptive device by an elongate body" / "a deployment shaft having a proximal end and a distal end releasably coupled to the contraceptive device"

The parties have engineered a "two-for-one" deal with this final construction. While both Conceptus and Hologic framed this dispute as being centered on the term "coupled," two separate phrases — each using the term "coupled" in slightly different contexts — were targeted for construction. Specifically, the parties asked the Court to construe the phrases "the handle coupled to the contraceptive device by an elongate body" (from claim 5) and "a deployment shaft having a proximal end and a distal end releasably coupled to the contraceptive device" (from claim 9). Proposed constructions are shown below.

CONCEPTUS'S PROPOSED CONSTRUCTION	HOLOGIC'S PROPOSED CONSTRUCTION
Claim 5: "the handle paired to or joined with the contraceptive device by an elongate body"	*Claim 5:* "the handle is mechanically attached to the contraceptive device by the elongate body by threads, cooperating key/slots, connectors, or the like"
Claim 14: "a deployment shaft having a proximal end and a distal end paired to or joined with the contraceptive device"	*Claim 14:* "a deployment shaft having a proximal end and a distal end that is configured to mechanically attach and detach from the contraceptive device by threads, cooperating key slots, connectors, or the like"

Conceptus argues that "coupled" in both phrases means that the various components of the invented apparatus are simply "paired to or joined with" each other. Hologic, by contrast, asserts that when particular parts of the invention are "coupled" to each other, they must be "mechanically attached" using "threads, cooperating key/slots, connectors, or the like." As explained below, neither construction seems entirely correct.

The claims themselves provide guidance as to the meaning of the term "couple." For example, the method in claim 5 covers an apparatus having a handle with "an actuator," where manipulation of the actuator retracts a protective sheath surrounding the contraceptive device. Similarly, in the apparatus covered by claim 14, "movement" of an "actuator mounted on the handle . . . releases the contraceptive device from the . . . deployment shaft."

This "handle" and "actuator" are easily visualized by two disclosed embodiments shown below in FIGS. 7 and 11J.

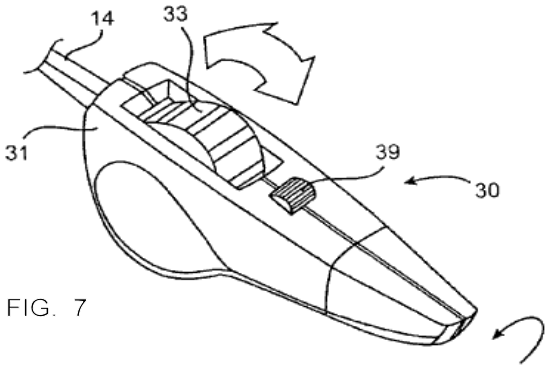

FIG. 7

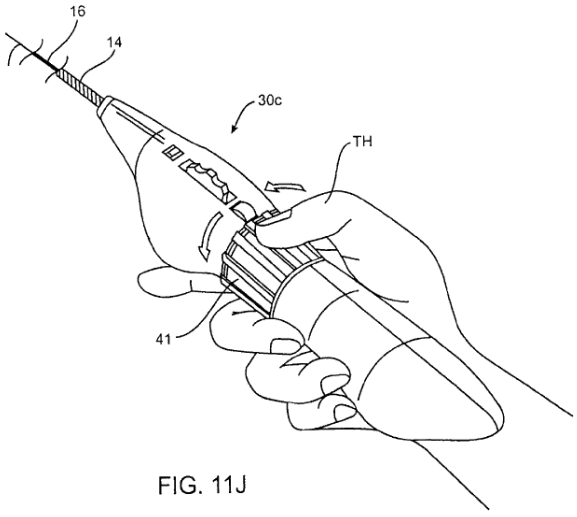

FIG. 11J

As shown in FIG. 7, the handle (denoted by 30) may contain numerous actuators (denoted by 33 and 39) that perform different actions once the contraceptive device is properly positioned within the fallopian tube. These actions may include the release of the contraceptive device from the installation apparatus or retraction of a protective sheath around the contraceptive device (col. 8:47–64). FIG. 11J shows an alternative embodiment of such a handle being held by the user, and illustrates how the actuators can moved (in this particular embodiment, the thumb rotates the actuator). To show how the handle fits in with the entire apparatus, an exemplary embodiment of the complete apparatus is shown below in FIG. 1B.

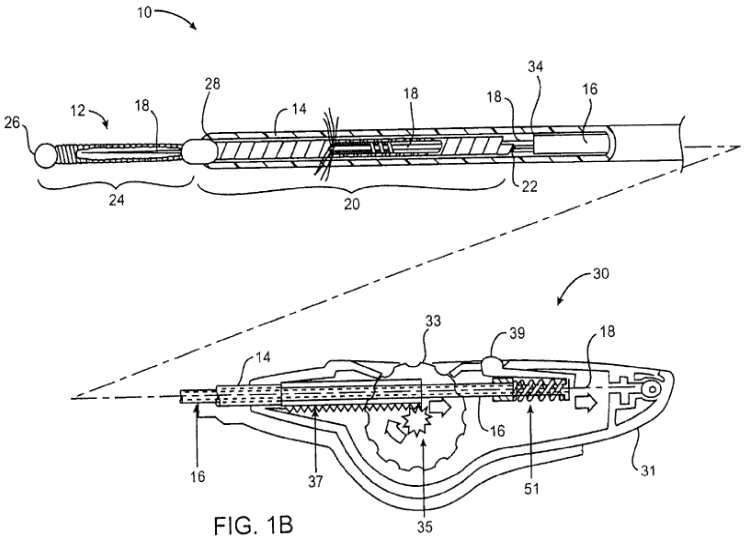

FIG. 1B

As seen in FIG. 1B above, the handle (denoted as 30) is only one component of the entire installation apparatus. On the opposite end of the apparatus is the contraceptive device (denoted by 12). Connecting the handle and contraceptive device to each other are various components, including a protective sheath (14), a release catheter (16), and a core shaft (18). Important to this order, however, is the fact that the various components are interconnected as to allow the actuators on the handle to retract the sheath (claim 5) or release the device within the fallopian tube (claim 14).

In light of this intrinsic evidence, it is clear that the term "coupled" as used in the asserted claims means something more than the components of the apparatus being simply "paired to or joined with" each other, as proposed by Conceptus. A person having ordinary skill in the relevant art at the time the patent was filed — after reading the entire patent — would have understood the

term "coupled" as used in the asserted claims as requiring a more interactive connection. Stated differently, the components of the device must be "coupled" together in a way that allows the actuator(s) on the handle to trigger activity elsewhere on the device. This is the principal object of the invention (col. 2:32–34).

The claims themselves, however, do not limit or describe how this interactivity between components of the invention must be achieved. Nevertheless, Hologic argues that the components of the invention must be "mechanically attached" to each other using "threads, cooperating key/slots, connectors, or the like." This construction of the term "coupled" was taken directly from the description of one particular embodiment of the present invention (*see* col. 10:30–33).

Hologic's proposed construction, however, is too limiting. While it is true that the specification only disclosed embodiments featuring mechanical attachments between the various components of the invention, a person having ordinary skill in the relevant art at the time the patent was filed would have understood that the required interactivity between various components could have been achieved by mechanical *or electronic* means. For example, nothing in the claims limit the "actuators" on the handle of the apparatus from being digital (*i.e.*, based on electronic circuitry) rather than mechanical. Pressing this button could send an electronic signal to the deployment shaft or contraceptive device, triggering the mechanical retraction of the sheath (in claim 5) or release of the device (in claim 14). Indeed, claim 14 also expressly covers an apparatus that can administer RF energy to a portion of the fallopian tube (to promote scar tissue formation). A person having ordinary skill in the relevant art at the time the patent was filed would have understood that triggering this RF energy would likely involve electronic, rather than mechanical, actuation.

In light of this analysis, this order finds that a person having ordinary skill in the relevant art at the time the patent was filed would have understood "coupled" in claims 5 and 14 to allow for the components of the apparatus to be mechanically or electronically connected to each other. Accordingly, the following constructions will govern:

The phrase "the handle coupled to the contraceptive device by an elongate body" from claim 5 will be construed as "the handle mechanically and/or electronically connected to the contraceptive device by the elongate body." Similarly, the phrase "a deployment shaft having a proximal end and a distal end releasably coupled to the contraceptive device" from claim 14 will be construed as "a deployment shaft having a proximal end and a distal end that is mechanically and/or electronically configured to attach to and detach from the contraceptive device."

In its critique brief, Conceptus sought clarification as to whether the "coupling" in claims 5 and 14 could be "indirect" in nature (Dkt. No. 177 at 1). This order takes no position on this inquiry, since (1) it is unclear what Conceptus means by "indirect" coupling, and (2) the claim language and above constructions provide sufficient guidance as to the nature of the "coupling" required. For example, claim 5 clearly requires that the handle and contraceptive device be "coupled" to each other "by an elongate body." The construction above would also require some form of mechanical and/or electronic connection between the handle and contraceptive device. There is no need to "clarify" whether any of these requirements be "direct" or "indirect." A jury, given the above information, can decide whether an accused device meets these limitations.

CONCLUSION

For the reasons provided herein, the constructions set forth above will apply in this dispute. The Court will reserve the authority, on its own motion, to modify these constructions if further evidence warrants such a modification.

IT IS SO ORDERED.

Dated: March 24, 2010.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE