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1 2 3 4 5 IN THE UNITED STATES DISTRICT COURT 6 7 FOR THE NORTHERN DISTRICT OF CALIFORNIA 8 9 10 CONCEPTUS, INC., No. C 09-02280 WHA 11 Plaintiff, 12 ORDER GRANTING v. PARTIAL SUMMARY 13 HOLOGIC, INC., JUDGMENT AND DENYING MOTIONS TO STRIKE AND 14 Defendant. LIMIT TRIAL TESTIMONY 15 16 INTRODUCTION 17 In this patent infringement action involving intrafallopian contraceptive devices, the 18 parties each move for summary judgment. Plaintiff Conceptus, Inc. requests summary 19 adjudication of the following: 20 1. That defendant Hologic, Inc. has contributed to the direct 21 infringement of method claims 37 and 38 of U.S. Patent No. 6,634,361 through 22 the sale of its Adiana Permanent Contraception System since July 6, 2009; 23 2. That Conceptus's Essure procedure practices method claims 37 24 and 38 of the '361 patent; 25 3. That there were no acceptable and available non-infringing 26 alternatives to the claimed inventions during the relevant damages period; and

That for the purposes of a reasonable royalty assessment, the

hypothetical negotiation would have occurred in mid-2009.

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Defendant Hologic, on the other hand, requests summary adjudication that claims 8, 37, and 38 of the '361 patent are not infringed and are invalid. Additionally, each party moves to strike a portion of its opponent's submissions and to limit trial testimony.

For the reasons stated below, both motions are **Granted in Part** and **Denied in Part**. The motions to strike are **DENIED AS MOOT**. The motions to limit trial testimony are **DENIED WITHOUT PREJUDICE.** This order follows full briefing and a hearing on the motions.

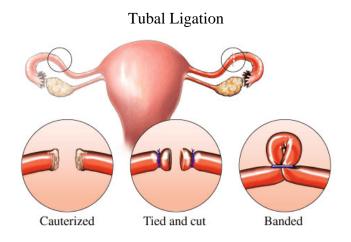
STATEMENT

Plaintiff Conceptus sells a transcervically introduced permanent contraceptive product called Essure. It received FDA approval in 2002 and is Conceptus's only marketed product at present. Unlike tubal ligation, the Essure system allegedly requires no incisions and is minimally invasive. According to Conceptus, Essure can be placed within a woman's fallopian tubes 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 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 a woman's fallopian tubes. Combined with the use of radiofrequency energy, the Adiana matrix — 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. Under the basics of reproductive biology, sperm enter the fallopian tubes by way of the uterus. Ova, on the other hand, travel in the opposite direction toward the uterus from the ovaries. Thus, blocking the fallopian tubes is a sensible way to prevent sperm from meeting and fertilizing an ovum.

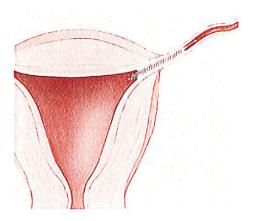
Tubal ligation, a longstanding but highly invasive procedure for permanent female sterilization, works similarly to the invention in the asserted patent; it physically prevents the meeting of sperm and ova. Tubal ligation can be performed in a variety of ways, including by clipping the fallopian tubes,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



Unlike tubal ligation, the asserted patent covers an intrafallopian contraceptive system in which a contraceptive device is placed within the reproductive system via the cervix using specially adapted tools. No cutting, banding, or cauterizing is supposedly necessary. Rather than blocking the fallopian tubes using external mechanical methods (as done in tubal ligation),

the devices in the asserted patent serve their intended purposes by blocking the fallopian tubes *from within*. The illustration below illustrates the concept of intrafallopian contraception (Compl. \P 12):

Intrafallopian Contraception



Conceptus asserted five patents in its initial complaint, which was filed in May 2009 (Dkt. No. 1). 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). Before the claim construction hearing, the parties stipulated to eliminating three of the five asserted patents (including the '904 patent) from the dispute, which left only two patents and five claims (Dkt. No. 140). After the claim construction order issued, the parties stipulated to eliminating additional patent claims from the dispute. The only asserted patent claims that now remain in this action are claims 8, 37, and 38 of the '361 patent (Dkt. No. 219). Additionally, claims and counterclaims regarding unfair competition have been raised and dropped by the parties (Dkt. No. 241). The Court thanks counsel for streamlining the case.

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. Of the three claims from this patent that are asserted in this litigation, one (claim 8) is an independent claim, and two (claims 37 and 38) are dependent claims that depend from an independent claim (claim 36) that is not asserted here. Five of the six disputed terms and phrases that were construed in the claim construction order came from these three patent claims. The construed terms and phrases are italicized in the claims below.

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Claim 8 covers a contraceptive device:

A tissue ingrowth contraceptive device for use in a fallopian tube, the contraceptive device comprising:

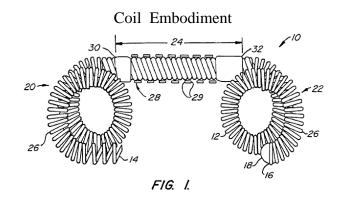
> a resilient elongate body having a proximal end and a distal end and defining an axis therebetween;

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.

(col. 20:21–33). To provide a visual reference, two embodiments of the invention (a coil embodiment and an elongated embodiment) are depicted below:







Claims 37 and 38 (as well as independent claim 36, which they reference) cover a contraceptive method:

> An intrafallopian contraceptive method comprising: 36.

> > 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.

(col. 23:38-53).

The Court construed these disputed terms and phrases to have the following meanings:

DISPUTED TERM OR PHRASE	CONSTRUED MEANING
Claim 8: "a resilient elongate body"	Claim 8: "a resilient elongate intrafallopian device"
Claims 37 and 38: "pre-formed resilient structure"	Claims 37 and 38: "pre-formed resilient intrafallopian device"
Claim 8: "a bond affixing the retention structure to the resilient body"	Claim 8: "a bond affixing the retention structure to the resilient body, where without the bond, the retention structure and resilient body would be unaffixed components"
Claims 37 and 38: "permanently affixing the resilient structure within the fallopian tube"	Claims 37 and 38: "permanently affixing the resilient structure within the fallopian tube" (plain and ordinary meaning)
Claims 37 and 38: "lumen-traversing region of the resilient structure"	Claims 37 and 38: "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"
Claims 37 and 38: "so that at least a portion of the fallopian tube is open"	Claims 37 and 38: "so that at least a portion of the fallopian tube is not completely occluded"

(Dkt. No. 189). With this background in place, this order now turns to the instant summary judgment motions.

ANALYSIS

"One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24

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(1986). Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" only if there is sufficient evidence for a reasonable fact finder to find for the non-moving party, and "material" only if the fact may affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248–49 (1986). In this analysis, all reasonable inferences must be drawn in the light most favorable to the non-moving party. Johnson v. Racnho Santiago Cmty. Coll. Dist., 623 F.3d 1011, 1018 (9th Cir. 2010). Unsupported conjecture or conclusory statements, however, cannot defeat summary judgment. Surrell v. Cal. Water Serv. Co., 518 F.3d 1097, 1103 (9th Cir. 2008).

"Summary judgment is as appropriate in a patent case as in any other." Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 835 (Fed. Cir. 1984). Although the determination of patent infringement usually is a fact-intensive issue, "comparison of a properly interpreted claim with a stipulated or uncontested description of an accused device or process would reflect such an absence of material fact issue as to warrant summary judgment of infringement or noninfringement." D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1573 (Fed. Cir. 1985).

1. Requirements of Claim 36.

Before proceeding to the summary judgment motions, a matter of claim interpretation that arose in the summary judgment briefs must be addressed. 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." *Phillips*, 415 F.3d at 1314. Additionally, a patent's specification "is always highly relevant to the claim construction analysis." Id. at 1315 (quoting Vintronics, 90 F.3d at 1582). Indeed, claims "must

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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 also should consider the patent's prosecution history, which "can often 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 1317 (citations omitted). These components of the intrinsic record are the primary resources in properly construing claim terms. *Id.* at 1312–18.

First, much of the briefing and hearing concerned Hologic's position that independent method claim 36 of the '361 patent (from which asserted method claims 37 and 38 depend) requires permanent affixation of the resilient structure within the fallopian tube while at least a portion of the fallopian tube is open. During the hearing, however, Conceptus explicitly and repeatedly conceded that claim 36 does in fact require permanent affixation while the fallopian tube remains at least partially open (Dkt. No. 355 at 8:18–19). Given the plain language of the claim and its prosecution history, the Court is convinced that claim 36 does require permanent affixation while the tube is at least partially open, but since Conceptus no longer is arguing the contrary, this order need not further address the issue.

Second, much of the briefing and hearing also concerned Hologic's position that claim 36 requires contraception to occur while at least a portion of the fallopian tube is open. In fact, the first point Hologic briefed in support of its noninfringement argument is "the Adiana device does not provide for contraception while 'at least a portion of the fallopian tube is open," and Conceptus countered that "claim 36 does not require contraception prior to occlusion" (Hologic Br. 10; Conceptus Opp. 1). At the hearing, Hologic clarified its position. Hologic conceded that claim 36 does not require a contraceptive effect *immediately* upon permanent affixation of the resilient structure (disavowing that position as a straw man set up by Conceptus) but maintained that claim 36 does require the fallopian tube to be at least partially open when contraception takes

¹ As with the constructions set forth in the claim construction order in this action (Dkt. No. 189), the Court reserves the authority to modify the interpretations set forth herein if further evidence warrants such a modification. Again, however, the parties should be aware that they are not invited to ask for reconsideration outside the applicable rules of procedure.

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effect (Dkt. No. 355 at 18:7–20:1; 26:6–8; 31:3–19). This order therefore turns to the question of whether claim 36 of the '361 patent requires a contraceptive effect to be provided while at least a portion of the fallopian tube is open.

A. Plain Language

As an initial matter, the plain language of the claim compels this interpretation. Claim 36 claims "[a]n intrafallopian contraceptive method," the last step of which is "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" (col. 23:38–47). The last step of the method is the only place in the claim that the limitation "so that at least a portion of the fallopian tube is open" appears. Grammatically, this description modifies the act of permanently affixing the resilient structure — meaning that permanent affixation must happen while the tube is open — but there is no indication that it applies to the other method steps, or indeed to the preamble of the claim.

Hologic uses the word "while" to join phrases from the preamble ("contraceptive method") and final method step ("at least a portion of the fallopian tube is open") without providing any reason why doing so might be appropriate (Hologic Reply Br. 3). Conceptus does not dispute that the preamble of claim 36 ("[a]n intrafallopian contraceptive method comprising:") is a limitation of the claim (Hologic Opp. 3). On the contrary, Conceptus addresses the preamble as a distinct element of the claim in its infringement contentions (e.g., Dkt. No. 277-1, Scott Corrected Exh. J at 3). Thus, this order finds that the method claimed in claim 36 must, of course, provide contraceptive effect at some point, but it need no do so while the fallopian tube is still open.

В. **Patent Claims and Specification**

The context of the other claims and specification of the '361 patent supports this reading of claim 36 as well. The four dependent claims that depend from claim 36 add limitations relating, for example, to "promoting tissue ingrowth" (claim 37) that "occludes the fallopian tube to inhibit conception" (claim 38). This specific means of inhibiting contraception provides an example of how an embodiment of claim 36 might provide contraception only after long-term

tissue growth has closed the fallopian tube. Hologic argues that this analysis improperly imports the limitations of dependent claims into the independent claim from which they depend (Hologic Reply Br. 3). Not so. The logic of this analysis is not that claim 36 *requires* tissue ingrowth that occludes the fallopian tube to inhibit contraception, but rather that one possible embodiment of the invention claimed in claim 36 involves tissue ingrowth that occludes the fallopian tube to inhibit contraception.

Moreover, the specification of the '361 patent does not limit the claimed invention to only those devices and methods that provide contraception while the fallopian tube remains open. For example, it states: "The intrafallopian contraceptive methods and devices of the present invention can provide highly effective contraception even when the contraceptive device does not totally occlude the lumen of the fallopian tube." (col. 11:19–22). This characterization recognizes that embodiments of the invention *may* provide contraception while the fallopian tube remains open, but it does not dictate that they *must* do so. Other passages throughout the specification take this same approach, singling out embodiments that provide contraception while the fallopian tube is open as the exception rather than the rule (*see* col. 4:30–34 ("In many embodiments, the presence of the contraceptive device in combination with the tissue reaction can provide effective contraception without having to rely on total occlusion of the fallopian tube."); col. 5:11–14 ("Such tubular devices will often effect contraception by disrupting the architecture and/or transport mechanisms of the tubal tissues, rather than relying entirely on total blockage of the tube.")). This specification language implies that at least some embodiments of the invention do rely entirely on total occlusion of the fallopian tube for contraception.

C. Prosecution History

Amendments to claim 36 made during prosecution also support this construction.

Originally, the claim did not include the limitation "so that least a portion of the fallopian tube is open." Rather, this limitation was added in an amendment made after the claim was rejected as anticipated (Dkt. No. 275-9, Scott Exh. I at CON00028921). The applicant argued that the supposedly anticipating reference did not predate the effective priority date for this claim, but the amendment nonetheless was made (*ibid.* at CON00028916). By adding this limitation to the final

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step of claim 36 — and only to the final step of the claim — the applicant narrowed the claim to encompass only contraceptive methods in which "at least a portion of the fallopian tube is open" when the final method step of "permanently affixing the resilient structure" is performed.

Having considered the plain language of independent claim 36, the context of its dependent claims and the '361 patent specification, the prosecution history, and Hologic's counterarguments, this order finds that claim 36 does not require provision of any contraception while the fallopian tube is open — so long, of course, as contraception is the eventual result of the procedure.

Infringement or Noninfringement of Claims 8, 37, and 38 of the '361 Patent. 2.

The parties' motions regarding infringement and noninfringement will be analyzed concurrently, on a claim-by-claim basis.

Method Claims 37 and 38 A.

Conceptus moves for summary adjudication that "Hologic contributes to the direct infringement of claims 37 and 38 of the '361 patent' (Conceptus Br. 25). Hologic moves for summary adjudication that claims 37 and 38 of the '361 patent are not infringed (Hologic Br. 25). Both motions are **DENIED**.

"[W]hen simultaneous cross-motions for summary judgment on the same claim are before the court, the court must consider the appropriate evidentiary material identified and submitted in support of both motions, and in opposition to both motions, before ruling on each of them." Fair Housing Council of Riverside County, Inc. v. Riverside Two, 249 F.3d 1132, 1134 (9th Cir. 2001). Having considered all of the briefs and supporting materials submitted by Conceptus and Hologic in relation to the cross-motions for summary judgment and the motions to strike, this order will address the summary judgment motions in turn.

(1) Direct Infringement

Conceptus moves for summary judgment of infringement. Granting this motion would require finding that no reasonable juror, when drawing all reasonable inferences in favor of Hologic, could return a verdict of no infringement. That finding is not warranted on this record.

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For its part, Hologic moves for summary judgment of noninfringement. Granting this motion would require finding that no reasonable juror, when drawing all reasonable inferences in favor of Conceptus, could return a verdict of infringement. Again, such a finding is not warranted.

The crux of the argument is on the facts, and the question of whether the Adiana procedure satisfies the requirements of the asserted method claims is a fact issue for the jury to decide. Specifically, the question of when the Adiana matrix becomes "permanently affixed" is one on which reasonable jurors could disagree. By way of simple analogy, if one were to permanently affix two foot-long steel bars to each other by welding them together lengthwise, reasonable jurors could disagree as to how much of the foot-long weld joint must be completed before the bars are permanently affixed. So too here; reasonable jurors could disagree as to how much (if any) tissue ingrowth must take place before the Adiana matrix is permanently affixed within the fallopian tube. Because the parties disagree as to this question of medical fact, both summary judgment motions fail, and the question of direct infringement of method claims 37 and 38 will go to the jury.

(2) Indirect (Induced and Contributory) Infringement

A finding of direct infringement is a prerequisite to a finding of indirect infringement. Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1033 (Fed. Cir. 2002). Since summary judgment regarding direct infringement is not appropriate on the current record, summary judgment regarding indirect infringement is not appropriate either.

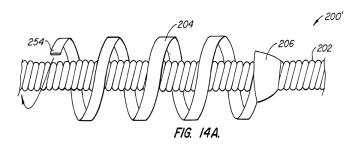
В. **Device Claim 8**

Hologic moves for summary adjudication that device claim 8 is "not infringed" (Hologic Br. 25). A patent claim may be infringed literally — i.e., by practicing every limitation of the claim — or under the doctrine of equivalents, which "allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." Honeywell Int'l Inc. v. Hamilton Sndstrand Corp., 370 F.3d 1131, 1139 (Fed. Cir. 2004). Hologic's motion is **GRANTED**.

(1) Literal Infringement

As explained in the claim construction order, claim 8 separately lists three distinct components of the invention: "a resilient elongate body," "a retention structure," and "a bond affixing the retention structure to the resilient body" (col. 20:21–33). To provide a visual example, FIG. 14A from the '361 patent is reproduced below. This figure shows a "bond" (206) affixing "a retention structure" (204) to a "resilient body" (202) in a particular embodiment of the '361 patent's invention:

Embodiment from FIG. 14A of the '361 Patent



Given this language, the claim construction order found 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. The order therefore construed "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." This construction responded in part to Hologic's concern that the term "bond" could be stretched to encompass bonds on a molecular level, and that 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 (Dkt. No. 189 at 11–12).

Based on the evidence that has come forth, no reasonable trier of fact could now find that the Adiana matrix includes all three distinct components of claim 8. *Hologic has presented sworn testimony that the Adiana matrix is a single unitary device made of the same material throughout, and Conceptus has not challenged this evidence*. Hologic's evidence shows that the Adiana

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matrix is formed through an injection molding process that involves a single injection of a liquid silicone rubber material into a mold that creates a unitary structure (Martin Decl. ¶¶ 7–12). The shape of this molded structure is defined by a "solid core through the center" and a "porous architecture which surrounds the center core" (Williams Exh. 7 at HOL-CON 0004788). Because the Adiana matrix is, according to Hologic's evidence, a single unitary device, it cannot literally infringe a claim that requires three separate components, one of which bonds the other two together.

Despite its best efforts, Conceptus has not identified any admissible evidence that would permit a reasonable trier of fact to read the limitations of claim 8 onto the Adiana matrix. First, Conceptus attempts to map the claim limitations onto the Adiana matrix by identifying the matrix's "solid core" as the resilient elongate body, its "microporous architecture" as the retention structure, and "bonds between them" as the required bond (Conceptus Opp. 5). There are at least two problems with this attempt. One is that "microporous architecture" is a style description, not a component. Just as a Gothic cathedral is Gothic, the Adiana matrix is microporous. A specified architectural style is a modifier of the structure to which it is applied, not a separate structure. The other problem is that any "bonds" between the inner (solid) and outer (microporous) regions of the Adiana matrix would be akin to the nominal molecular bonds that the claim term "bond" was construed to avoid. Calling out "bonds between them" as the bond element is a vague, conclusory statement — not evidence. These two problems cripple Conceptus's further arguments on the subject.

Second, Conceptus cites evidence that when the Adiana matrix is formed in the mold, the microporous portion solidifies first, followed later by the solid core, and that as the matrix solidifies, "bonds form between the microporous architecture and the matrix core" (Conceptus Opp. 6). Even if a trier of fact interpreted this sequential solidification to create two separate components, however, there still is no evidence to support a finding that the "bonds" between them are a separate, third component as required by the claim. *Third*, Conceptus emphasizes what the claim limitations and claim constructions do not require — such as that the components be separately manufactured or made from different materials (Conceptus Opp. 5–6). But the

point is rather what the claim limitations and claim construction *do* require — three separate components. Conceptus's exclusionary analysis does not cite any evidence that would enable a reasonable trier of fact to identify the three components required by the elements of claim 8 and a bond of the nature required by the claim construction. Accordingly, summary judgment of no literal infringement of claim 8 is appropriate.

(2) Doctrine of Equivalents

"[I]f two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). To determine the question of infringement under the doctrine of equivalents, "[t]he trier of fact, applying the claims as construed, finds whether the accused device, element by element, is equivalent to that which has been patented." *Multiform Desiccants, Inc.v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998). "An equivalent must be found for every limitation of the claim somewhere in an accused device, but not necessarily in a corresponding component, although that is generally the case." *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1259 (Fed. Cir. 1989).

No reasonable trier of fact could identify an equivalent to the "bond" element of claim 8 anywhere in the Adiana product. The "bonds" Conceptus identifies between the inner and outer portions of the Adiana matrix are simply molecular bonds of the sort the claim construction order sought to exclude by identifying the bond as a third distinct component of the invention (Dkt. No. 189 at 12). Conceptus attempts to avoid this problem through deposition testimony characterizing these "bonds" as "a sufficient aggregation of chemical bonds that it rises to the level of a physical bond," but this testimony is unavailing (Williams Exh. 5 at 270:24–271:4). Once the Adiana matrix is divided into its solid inner core (the supposed equivalent to "a resilient elongate body") and its microporous outer region (the supposed equivalent to "a retention structure"), there simply is nothing left for a trier of fact to point to as a bond between them. Allowing a fact finder to infer "bonds between them" out of nothing would impermissibly vitiate the bond element of claim 8. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29–30 (1997). Summary judgment of noninfringement is therefore appropriate.

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3. Validity or Invalidity of Claims 8, 37, and 38 of the '361 Patent.

Hologic moves for summary adjudication that "claims 8, 37, and 38 of U.S. Patent No. 6,634,351 . . . are invalid" (Hologic Br. 25). This motion is **DENIED**. Hologic advances three grounds on which the asserted claims are allegedly invalid: inadequate written description, lack of enablement, and anticipation by prior art. Hologic is not entitled to summary judgment of invalidity on any of these theories, but it may present evidence of invalidity to the jury at trial.

Α. **Inadequate Written Description**

A patent specification must include "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. 112 ¶ 1. "[A] patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification." Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927 (Fed. Cir. 2004). If no reasonable juror could find that a patentee's disclosure was sufficiently detailed to enable one of skill in the art to recognize that the patentee invented what the patent claimed, then a grant of summary judgment of invalidity is appropriate. *Ibid.* Such is not the case here. Accordingly, summary judgment of invalidity is not appropriate on the grounds of inadequate written description.

В. **Enablement**

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation." ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010). Enablement is a question of law, but it is based on underlying factual inquiries. "[W]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." Ibid. Conceptus has identified admissible evidence in the record that at least creates a genuine issue of material fact as to whether the '361 patent is sufficiently enabled. As such, summary judgment of lack of enablement would be inappropriate.

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C. **Anticipation and Obviousness**

Hologic argues that only claim 8 of the '361 patent "is also invalid as anticipated and/or obvious as a matter of law in light of U.S. Patent No. 3,687,129" (Hologic Br. 16). Because this invalidity argument is limited to claim 8 and because this order already found that the Adiana product does not infringe claim 8 as a matter of law, this order need not reach the anticipation/obviousness portion of Hologic's invalidity defense.

4. Whether Essure Practices Claims 37 and 38 of the '361 Patent.

Conceptus moves for summary adjudication that "Conceptus' own Essure procedure practices claims 37 and 38 of the '361 patent" (Conceptus Br. 25). Conceptus represented at the hearing that this determination would be relevant to its reasonable royalty analysis of damages. This motion is **DENIED**. The question of whether Essure practices claims 37 and 38 of the '361 patent is a question of fact appropriate for the jury on the well-developed instant record.

5. Whether Alternatives to the Claimed Invention Existed

Conceptus moves for summary adjudication that "there were no acceptable and available, non-infringing alternatives to the claimed inventions during the relevant damages period" (Conceptus Br. 25). This motion is **GRANTED**.

"When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time." Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1353 (Fed. Cir. 1999). In such cases, the burden shifts to the infringer to show that a substitute nonetheless was "available" during this period, for example based on alternative actions the infringer reasonably could have taken to avoid infringement. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1331 (Fed. Cir. 2009). Having the necessary materials, equipment, know-how, and experience to make an alternative product during the relevant time frame may render that product "available." Grain Processing Corp., 185 F.3d at 1353–55. But "[m]ere speculation or conclusory assertions will not suffice to overcome the inference. . . . [T]he trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement." *Ibid.* at 1353.

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In this action, Hologic does not dispute the fact that Conceptus's Essure product and Hologic's Adiana product were the only two transcervical intrafallopian contraception methods on the U.S. market during the relevant time period (Hologic Opp. 22–24; Glasser Decl. ¶ 98). Hologic — the alleged infringer — therefore bears the burden of proving the availability of some other acceptable noninfringing alternative. Hologic, however, has not proffered any admissible evidence to rebut the inference that no acceptable noninfringing substitutes were available. Hologic argues that two specific alternatives were available because Adiana, Inc. (Hologic's predecessor) designed them and had the materials, equipment, and know-how to "implement" them during the period of alleged infringement (Hologic Opp. 23). But the only support Hologic cites for this argument is a portion of the unsworn report of its own expert that relies exclusively on private conversations with Hologic personnel (Hologic Opp. 22–24; Ascolese Exh. 7 at ¶¶ 42–47). As Conceptus cogently notes, that is not evidence; it is double hearsay. Hologic does not point to any research-and-development documentation, deposition testimony, or sworn declarations that might demonstrate Hologic's capacity to "implement" noninfringing alternatives during the period of alleged infringement. Accordingly, Conceptus is entitled to judgment as a matter of law on this point.

6. When the Hypothetical Negotiation Would Have Taken Place

Conceptus moves for summary adjudication that "for the purposes of a reasonable royalty assessment, the hypothetical negotiation would have occurred in mid-2009" (Conceptus Br. 25). This motion is **Granted in Part and Denied in Part**. This order finds that the hypothetical negotiation would have occurred in July 2009.

"To determine a reasonable royalty, a jury must find the royalty that would have been agreed to in a hypothetical negotiation between a willing licensee and willing licensors at the time the infringement began." *Fujifilm Corp. v. Benun*, 605 F.3d 1366, 1372 (Fed. Cir. 2010). Assuming the Adiana product is found to infringe the '361 patent, Conceptus argues that infringement began when Adiana first was offered for sale in the U.S. — July 2009 (Conceptus Br. 24–25). Hologic does not dispute that Adiana was offered for sale in the U.S. for the first time in July 2009. Nor does Hologic dispute that, assuming the Adiana product is found to

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infringe, the infringement began when Adiana first was offered for sale in the U.S. (Hologic Opp. 24–25). Thus, if the Adiana product is found to infringe, and if a reasonable royalty must be determined, a negotiation in July 2009 shall be hypothesized for this purpose.

Hologic resists this conclusion on the grounds that the hypothetical negotiation must take place between willing parties, but by July 2009 Conceptus and Hologic were embroiled in litigation, with Hologic facing the likelihood of protracted costs and the possibility of a monetary judgement or injunction. According to Hologic, "[t]hese facts would certainly skew the results of the hypothetical negotiation, if it were deemed to occur in July 2009" (Hologic Opp. 25). Hologic's argument completely misses the point of the counterfactual exercise. The Sixth Circuit has explained this principle with particularly colorful language:

> Determination of a "reasonable royalty" after infringement, like many devices in the law, rests on a legal fiction. Created in an effort to "compensate" when profits are not provable, the "reasonable royalty" device conjures a "willing" licensor and licensee, who like Ghosts of Christmas Past, are dimly seen as "negotiating" a "license." There is, of course, no actual willingness on either side, and no license to do anything

Panduit Corp. v. Stahlin Bros. Fire Works, Inc., 575 F.2d 1152, 1159 (6th Cir. 1978). In this instance, Conceptus and Hologic did not negotiate a license in July 2009. And, as Hologic suggests, they may very well have been unwilling to negotiate a license in July 2009. If the Adiana product is found to infringe the '361 patent, however, then the infringement began in July 2009, and a reasonable royalty rate would be the one hypothetically negotiated between hypothetically willing parties at that time. The jury will be asked to imagine that a negotiation took place in lieu of this litigation and to reconstruct how a royalty negotiation in July 2009 would have gone.

CONCLUSION

For the reasons provided herein, Conceptus's motion for summary judgment is **GRANTED** IN PART AND DENIED IN PART. Conceptus's motion for summary adjudication that "Hologic contributes to the direct infringement of claims 37 and 38 of the '361 patent" is **DENIED**. Conceptus's motion for summary adjudication that "Conceptus' Essure procedure practices claims 37 and 38 of the '361 patent" is **DENIED**. Conceptus's motion for summary adjudication

that "there were no acceptable and available, non-infringing alternatives to the claimed inventions during the relevant damages period" is **GRANTED**. Conceptus's motion for summary adjudication that "for the purposes of a reasonable royalty assessment, the hypothetical negotiation would have occurred in mid-2009" is GRANTED IN PART AND DENIED IN PART. This order finds that for the purposes of a reasonable royalty assessment, the hypothetical negotiation would have occurred in July 2009.

For the reasons provided herein, Hologic's motion for summary judgment is **GRANTED IN** PART AND DENIED IN PART. Hologic's motion for summary adjudication that claim 8 of the '361 patent is not infringed is **GRANTED**. Hologic's motion for summary adjudication that claims 37 and 38 of the '361 patent are not infringed is **DENIED**. Hologic's motion for summary adjudication that claims 8, 37, and 38 of U.S. Patent No. 6,634,351 are invalid is **DENIED**.

Because this order does not rely on any of the material identified therein, Conceptus's motion to strike and Hologic's motion to strike are both **DENIED AS MOOT**.

The motions to limit trial testimony are **DENIED WITHOUT PREJUDICE**. The parties may renew such motions at the appropriate time.

IT IS SO ORDERED.

Dated: December 16, 2010.

UNITED STATES DISTRICT JUDGE