IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CONCEPTUS, INC.,

Plaintiff,

v.

HOLOGIC, INC.,

Defendant.
_____/

No. C 09-02280 WHA

ORDER DENYING MOTIONS FOR JUDGMENT AS A MATTER OF LAW AND MOTIONS FOR A NEW TRIAL

INTRODUCTION

In this patent infringement action, defendant moves for judgment as a matter of law, or in the alternative for a new trial, on grounds of lack of enablement and non-infringement after a jury found infringement and awarded $18 million in damages. For the reasons set forth below, the motions are **DENIED**.

STATEMENT

The history of this action has been explained in prior orders (Dkt. Nos. 131, 356). In brief, defendant Hologic, Inc. owned and marketed the Adiana contraceptive system, which involved minimally invasive transcervical placement of a contraceptive device into a woman's fallopian tubes. Combined with the use of radiofrequency energy, the Adiana system produced intrafallopian occlusion, which either prevented conception from occurring or blocked the passage of a fertilized ovum to the uterus.

A jury trial found that the Adiana system directly and indirectly infringed the '361 patent, entitled "Contraceptive Transcervical Fallopian Tube Occlusion Devices And Methods," which was assigned to plaintiff Conceptus, Inc. Claims 37 and 38 (not claim 36) of U.S. Patent 6634361 were asserted and had the following language:

> 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.
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> 37. A method as claimed in claim 36, wherein the affixing step comprises promoting tissue ingrowth of the tubal wall surrounding the resilient structure.
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> 38. A method as claimed in claim 37, wherein the tissue ingrowth occludes the fallopian tube to inhibit contraception

(col. 23:38–53).

After a two-week trial, the jury found Hologic liable for direct and indirect infringement and awarded Conceptus $18,807,241 in damages. Hologic now moves for judgment as a matter of law for lack of enablement and for no indirect infringement, and for a new trial (Dkt. Nos. 494, 495).

ANALYSIS

Judgment as a matter of law may be granted against a party if it "has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Rule 50(a). "Judgment as a matter of law may be granted only where, so viewed, the evidence permits only one reasonable conclusion, and that conclusion is contrary to the jury's verdict." *Wallace v. City of San Diego*, 479 F.3d 616, 624 (9th Cir. 2007).

"A district court may order a new trial based on insufficient evidence only if it finds that the jury's verdict is against the great weight of the evidence, or it is quite clear that the jury has reached a seriously erroneous result." *Ace v. Aetna Life Ins. Co.*, 139 F.3d 1241, 1248 (9th Cir. 1998).

The final charge to the jury was and remains the complete statement of the law governing the trial issues unless a timely and proper objection to the instructions was made and the Court now agrees that the objection has merit. The post-trial motions under Rule 50 must be evaluated,

therefore, in light of that statement of the law and not in light of new citations, new legal theories and/or legal variations. Rule 50 is not an occasion for yet another round of summary judgment based on new slants on the case law. Of course, an appellate court might later find that an objection to an instruction was preserved, well-taken and not harmless and so require a new trial. But until then, this Court is satisfied that the jury instructions were proper and both sides are bound by the jury instructions as the exclusive statement of the governing law for the instant action.

1. ENABLEMENT.

To be enabling, as the jury was instructed, 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. The purpose of the enablement requirement is to make sure that a patent specification and figures, as originally filed, disclosed how to practice the full invention in return for the limited monopoly granted by the government to the inventor. The question of whether a patent is enabling is judged as of the date the original application for the patent was first filed. It is presumed that all relevant prior art was already known to those practicing in the field (Dkt. No. 475 [jury instructions] at ¶ 42).

In determining whether excessive experimentation would have been required, the following factors may be considered: (1) the scope of the claimed invention; (2) the amount of guidance presented in the patent; (3) the amount of experimentation necessary; (4) the time and cost of any necessary experimentation; (5) how routine any necessary experimentation was in the field; (6) whether the patent disclosed specific working examples of the claimed invention; (7) the nature and predictability of experimentation and variations of the field; and (8) the level of ordinary skill in the field (*id.* at ¶ 44). With respect to the first factor, the scope of the claimed invention, a patentee who chooses broad claim language must make sure the broad claims are fully enabled. The scope of the claims must be less than or equal to the scope of the enablement to ensure that public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. Put differently, the narrower the claims, the easier it is to sustain enablement (*id.* at ¶ 45).

By analogy, suppose that an inventor created a particular method for fuel efficiency and described the method in such detail in the specification that a person of ordinary skill in the art would be able to achieve fuel efficiency. Although the specification would meet the requirements of enablement with respect to a claim directed to that particular method, it would not necessarily support a broad claim to every possible type of method to achieve fuel efficiency no matter how different in operation from the claimed invention. A single embodiment would support such a generic claim only if the specification would enable a person skilled in the art to use the full scope of the claimed invention at the time of application without undue experimentation (*id.* at ¶ 46). The appendix includes the full jury instructions on enablement.

In its motion, Hologic proceeds as if issues of law were not determined for the jury in the instructions. Hologic seeks to conduct a de novo and post hoc inquiry into the legal standard of enablement. The jury instructions were proper and Hologic acquiesced to those instructions (*see* Tr. 1324:19–1328:10).

A. Use of Radiofrequency Energy Was Enabled.

Hologic argues that the '361 patent specification did not give "guidance as to the parameters that could be employed in order to use energy to permanently affix a device in the fallopian tube" (Reply Br. 1). True, there were no examples of radiofrequency use and no disclosure of parameter settings for use in the specification. Conceptus argues, however, that testimony and evidence at trial sufficiently established that these omissions could have been filled in by the knowledge of one skilled in the art without undue experimentation (*see* Tr. 1415:8–1439:10).[1] This order agrees.

[1]In its opposition, Conceptus also argues that Hologic's generic objection on enablement was nonspecific and therefore Hologic waived its enablement objection on radiofrequency energy. This order disagrees. The pre-verdict objection together with other trial filings were specific enough to notify Conceptus that Hologic's post-verdict Rule 50 motion would challenge whether the use of radiofrequency energy was enabled.

The specification described one embodiment of the invention as using an electrical current to attach the device to the surrounding lumenal wall (col. 3:52–62). For example, the specification contained the following:

> In some embodiments, electrosurgical attachment of an intraluminal device to a surrounding lumenal wall may provide effective anchoring even without loops and other anchoring structures. Electrical current may also be used to decouple the intrafallopian device from the delivery system, typically by electrolytically dissolving a solder bond. Current may also actuate an anchor, such as by releasing a resilient radially expandable tubular structure within the fallopian tube.
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> * * *
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> Alternatively, an electrical current is applied to the device after it is positioned within the fallopian tube, providing permanent sterilization. Electrical current might also effect detachment of the device from the delivery system using a system similar to that described in U.S. Pat. No. 5,624,449, the full disclosure of which is incorporated herein by reference. In situ actuation of an anchor might be effected by releasing a resilient structure to expand in situ with a similar mechanism, or by a current induced phase change of a shape memory alloy (for example, causing a straight Nitinol® ribbon to curl within the fallopian tube with a current)
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> * * *
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> The present invention further encompasses permanent sterilization by passing a current through the corewire to the intrafallopian device prior to withdrawing the corewire. Fallopian tube tissue in contact with the intrafallopian device is desiccated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the corewire/primary coil interadiofrequencyace must be conductive to allow the present non-surgical method of permanent sterilization.
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> * * *
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> In some embodiments, corewire will be capable of transmitting heat, electrical current, and/or some other energy which induces scarring, electrocautery, or the like, so as to attach the contraceptive device within the fallopian tube. Alternatively, the transmitted energy may decouple the device from the corewire, for example, by melting a coupler.

(col. 3:52–62, 8:62–9:6, 11:8–18, 12:58–64). The ’361 patent also referenced the Vancaille patent, which provided more details of how to apply energy to promote tissue ingrowth in fallopian tubes: “bipolar coagulation current of approximately 5 watts for a duration between 5 and 15 seconds is sufficient to produce irreversible but shallow thermal damage of the tubal mucosa” (TX 197 at 3:10–14).

Conceptus’s expert Dr. John Webster testified that one skilled in the art would have been able to use radiofrequency energy as an embodiment of the invention based on the specification

without undue experimentation. Dr. Webster testified that in September 1997, "the word 'current' immediately [came] to one skilled in the art that they should use radio frequency current" (Tr. 1428:24–1429:13). In addition, Dr. Webster testified that references to electrosurgery, electrocautery, dessicated, electric current, electrode in the specification would have been understood by people skilled in the art to mean methods of using radiofrequency energy to promote tissue ingrowth into the resilient structure (*see, e.g.*, Tr. 1430:5–23). Dr. Webster also identified other patents and patent applications incorporated by reference in the '361 patent that discussed radiofrequency energy use (Tr. 1430:24–1433:13).

Dr. Webster testified that one skilled in the art would have known how to find the right level of radiofrequency energy to apply to the fallopian tubes based on the specification's description to use an "electrosurgical attachment to produce current to actuate an anchor and damage the surround tissue to promote tissue ingrowth" (Tr. 1429:15–24). That is, although the specification did not describe what power level, duration, or wave form should be used, Dr. Webster testified that the experimentation necessary to use radiofrequency energy would not be undue at the time of the patent application. He testified that one skilled in the art would have known to use the "Goldilocks" approach to determine the parameters of radiofrequency energy use (Tr. 1432:19–1433:7). Dr. Webster described the approach as follows: "I think in all ablation work done by everyone, there's a routine method that you follow. You start low, and you find you haven't heated it up enough. And then you go up high and you find you heated it too much, that you've charred the tissue, or something you don't want to do. And so you try a series of levels in between those two limits until you find the optimal level for application" (Tr. 1418:9–15). To support his testimony, Dr. Webster showed the jury a number of prior art publications discussing radiofrequency use on tissue (Tr. 1420:6–1425:9).

There was also evidence at trial on how to set up the necessary testing. Dr. Webster explained how one skilled in the art could have slightly modified ablation generators to generate the correct radiofrequency energy to practice the claims (Tr. 1433:15–1434:22). He also discussed resources available to guide one skilled in the art on how to do this (Tr. 1434:23–1439:10; TX 212, 215, 216, 222, 224).

Dr. Webster testified that it would take approximately four months to perform the necessary testing to use radiofrequency energy to promote tissue ingrowth in fallopian tubes, and that this amount of time and experimentation was not undue (Tr. 1438:4–21, 1473:13–1474:15). True, this admission possibly bespeaks more than undue experimentation, but given the presumption of validity, the clear and convincing standard, and the other trial evidence, it cannot be said as a matter of law that the jury got it wrong, given the deference we must accord jury verdicts. *See AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1238–39 (Fed. Cir. 2003). The jury's decision was supported by substantial evidence. However, this could be one where the Federal Circuit has a different view.

To sum up, the specification, supplemented with evidence about one skilled in the art, provided a sufficient basis to conclude that the following *Wands* factors weighed in favor of enablement: quantity of experimentation, amount of direction or guidance presented, the nature of the invention, the state of the prior art, the relative skill of those in the art, and the predictability of the art. The evidence was sufficient to support the jury's finding of enablement. Hologic has not met its burden of showing by clear and convincing evidence that the patent claims were not enabled and a jury could not have reasonably found enablement.

Hologic asserts that the jury's finding was contrary to *Automotive Technologies Intern., Inc. v. BMW of North America, Inc.*,501 F.3d 1274 (Fed. Cir. 2007). Even taking Hologic's new legal arguments into account, this order finds them unpersuasive and *Automotive Technologies* consistent with this holding. In *Automotive Technologies*, the technology at issue involved side-door crash-sensing devices. The patentee argued for, and district court agreed, that the patent claimed not only mechanical switch assemblies, but also electronic switch assemblies to serve as a sensing device. Subsequently, the district court found that an electronic switch assembly was not enabled. The Federal Circuit reviewed de novo and affirmed.

In *Automotive Technologies*, the specification stated that an electronic sensor assembly could be used to sense side impacts. The specification contained a figure of an electronic sensor with the accompanying text:

> [The figure] is a conceptional view of an electronic sensor assembly built according to the teachings of this invention. This sensor contains a sensing mass which moves relative to

> housing in response to the acceleration of housing which accompanies a side impact crash. The motion of the sensing mass can be sensed by a variety of technologies using, for example, optics, resistance change, capacitance change or magnetic reluctance change. Output from the sensing circuitry can be further processed to achieve a variety of sensor response characteristics as desired by the sensor designer.

The Federal Circuit held that the figure and text only provided an overview of an electronic sensor without providing any details of how the electronic sensor operated. *Automotive Technologies*, 501 F.3d at 1282–83. Noticeably absent was any discussion of the circuitry involved in the electronic side-impact sensor that could provide more detail on how the sensor operated. *Id.* at 1283.

The patentee contended that electronic sensors, albeit for sensing *frontal* impacts, were widely known at the time of filing and therefore there was no need for the specification to describe them in detail. *Id.* at 1281. Its expert testified that one skilled in the art would have known how to adapt then-existing technology to create an electronic side-impact sensor. The patentee argued that this testimony created a genuine issue of material fact. The court, however, found that the expert's testimony failed to discuss what types of tests would have been needed to adapt existing electronic sensors for side-impact sensing, and the testimony did not provide any detail on how to adapt the existing technology. *Id.* at 1285–86.

Automotive Technologies is distinguishable. Here, Conceptus's expert, Dr. Webster, *did* discuss what type of testing would be needed for radiofrequency energy use and how to adapt then-existing ablation generators for that purpose; the Federal Circuit in *Automotive Technologies* found patentee's expert's testimony lacking on this point. In *Automotive Technologies*, the specification cautioned that the figure depicting the use of an electronic sensor was a "conceptional view." There is no similar description for using a current in the '361 patent. In *Automotive Technologies*, the Federal Circuit based its holding, in part, on the finding that "the novel aspect of this invention [was] using a velocity-type sensor for side impact sensing" and that "given that the novel aspect of the invention [was] side impact sensors, it [was] insufficient to merely state that known technologies can be used to create an electronic sensor." *Id.* at 1283. In the instant action, the novel aspect of the '361 patent was the intrafallopian device *and* methods for affixation. The use of radiofrequency energy as a mechanism of injury was only a portion of

the invention, not the entire novel aspect. Therefore, it was appropriate for the jury to supplement the specification on how to use radiofrequency energy with the knowledge of one skilled in the art.

B. The Finding of Enablement Was Not a Seriously Erroneous Result or Against the Great Weight of the Evidence.

As discussed, Conceptus presented sufficient evidence for the jury to reasonably find that the claims were enabled. For the same reasons, the result was not seriously erroneous. Nor was it against the great weight of evidence.

Hologic argues that the *Wands* factors weigh against enablement because: *first*, the claims were broad because Conceptus prevailed on three phrases during claim construction (Br. 5–6); *second*, the mechanism of affixation was the novel aspect of the invention (Br. 6–7); *third*, the application of energy to tissue had inherent risks (Br. 7); *fourth*, there was no disclosure of power level, duration, and wave form in the specification (Br. 8–9); *fifth*, Conceptus did not conduct experiments using radiofrequency energy (Br. 9); *sixth*, Conceptus did not demonstate that the Vancaillie patent was in common knowledge (Br. 13); *seventh*, Dr. Vancaillie and Hologic had taken years to develop the Adiana system (*ibid.*); and *eighth*, Dr. Webster's description of how to test radiofrequency energy use required undue experimentation because the project would have taken four months under the best estimate, eight months if there were normal problems, and ten years under the worst case scenario (Tr. 1460:6–1464:14).

The evidence against enablement did not greatly outweigh the jury's finding: *First*, the fact that Conceptus prevailed at claim construction did not necessarily mean that the patent claims were broader than the specification. *Second*, as discussed above, the novel aspect of the patent was the entire system of intrafallopian occlusion, including the device and the mechanism for stimulating tissue ingrowth; radiofrequency energy only dealt with the mechanism of affixation. *Third*, Conceptus did not have to demonstrate that the Vancaillie patent prior art was in the common knowledge of one skilled in the art (Dkt. No. 475 at ¶ 42). *Fourth*, the inherent risks of energy ablation and lack of parameter settings in the specification did not necessarily mean that it would take undue experimentation to use radiofrequency energy. Dr. Webster testified that testing was necessary to calculate the proper parameters and concluded that this testing did not

constitute undue experimentation. Dr. Webster also said that testing could be finished in four months, and perhaps finished in eight months if "normal troubles" arise (Tr. 1460:6–1464:14); the jury could have reasonably relied on that testimony. The *Wands* factors did not greatly weigh in favor of non-enablement. To sum up, the jury's finding of enablement was not against the great weight of the evidence.

2. INDIRECT INFRINGEMENT.

The jury found that Hologic either contributed to or induced infringement (Dkt. No. 478). Thus, the jury's verdict must stand if substantial evidence supported either finding. *See McCord v. Maguire*, 873 F.2d 1271, 1273–74 (9th Cir. 1989).

The jury was instructed that induced infringement requires three elements: (1) that Hologic intentionally took action that actually induced direct infringement by doctors; (2) that Hologic knew of the '361 patent; and (3) that Hologic knew its action would cause direct infringement by the doctor (Dkt. No. 475 at ¶ 26). Contributory infringement, it was instructed, requires the following four elements: (1) that the asserted claims were directly infringed by doctors performing the Adiana procedure; (2) that Hologic supplied an important component of the infringing part of the procedure; (3) that the component had no substantial non-infringing use; and (4) that Hologic supplied the component with knowledge of the '361 patent and knowledge that the component was especially made or adapted for use in an infringing manner (*id.* at ¶ 27).

At the charging conference, Hologic objected to a phrase in the draft jury instructions: "Regarding the knowledge component, Conceptus need not prove that Hologic specifically intended to infringe the asserted claims" (Tr. 1123:6–1143:12). Hologic cited *Global-Tech Appliances, Inc., v. SEB S.A.*, 131 S.Ct. 2060, 2068-71 (2011), for the legal argument that indirect infringement required specific intent of infringement. The judge suggested to take out that phrase in both inducement and contributory infringement instructions. Hologic agreed (Tr. 1129:9–10, 1142:18). The finalized jury instructions did not contain that phrase (Dkt. No. 475 at ¶ 26, 27). Hologic, therefore, acquiesced in the final instructions on indirect infringement.

In its motion, Hologic again proceeds as if issues of law were not determined by the instructions. Hologic again raises *Global-Tech Appliances* to argue that specific intent is required

for indirect infringement. This order is unpersuaded by Hologic's argument and stands by the knowledge requirement as set forth in the jury instructions, which Hologic acquiesced in at trial. Even taking Hologic's new legal arguments into account, the finding of indirect infringement was substantiated and not against the great weight of the evidence.

A. Sufficient Facts to Support Finding of Indirect Infringement.

Hologic admits there was sufficient evidence to show that it knew of the '361 patent when it began selling the Adiana system, knew the manner in which the Adiana system operated, and knew the Adiana system was accused of infringement by Conceptus (Reply Br. 11). Hologic, however, argues that this knowledge is insufficient because indirect infringement requires that the accused infringer specifically intended to infringe (*see* Reply Br. 2). Hologic is implicitly arguing that to show indirect infringement, there must be direct evidence that the accused infringer conducted an infringement analysis, knew that there was infringement based on that analysis, and continued its infringing acts (*see* Br. 17–18). Hologic is mistaken; circumstantial evidence of intent will suffice. *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1342 (Fed. Cir. 2008) ("Specific intent may be inferred from circumstantial evidence where a defendant has both knowledge of the patent and specific intent to cause the acts constituting infringement.").

At trial, Hologic admitted that it received notice of the patent-in-suit before this action was filed (Tr. 1011:6–9). Hologic admitted that it specifically considered whether the Adiana system practiced the claims of the '361 patent before launching their products (Tr. 1032:11–1033:14). And Hologic admitted that it sold the Adiana system before receiving its patent attorney's opinion letter that the '361 patent was likely invalid (Tr. 1034:1–12). This evidence was certainly enough to satisfy the elements of indirect infringement as laid out in the jury instructions. And this was sufficient circumstantial evidence of specific intent under Hologic's interpretation of the law.

B. Finding of Indirect Infringement Was Not Against the Great Weight of the Evidence.

In its motion, Hologic argues that because its executives and patent counsel believed the '361 patent was invalid and not infringed, there was insufficient evidence to show intent or

knowledge of infringement (Br. 20–21; Tr. 942:15–943:4, 1033:7–14, 1090:19–25, 1095:13–1096:3). Stated another way, Hologic argues that its good faith belief of non-infringement precluded a finding of indirect infringement (Br. 23). Also related to establishing good faith belief, Hologic argues that this Court "must consider" now the preliminary injunction ruling that was excluded at trial (*see* Br. 24–25).

The jury's finding of indirect infringement was not against the great weight of the evidence. The jury could have disbelieved Hologic's pure-heart, empty-head explanation. The jury could have found that the opinions of patent counsel were unreliable or biased. For example, the first opinion letter by attorney David Crocket did not include an analysis of the patent file history and failed to undertake an anticipatory analysis of the claims asserted at trial (TX 744 at 107862; Tr. 1012:18–1013:16). The second opinion letter by attorney David Burse was given to defendant *after* sale of the Adriana device began (Tr. 1033:19–1034:21). Mr. Burse knew that his client had spent significant resources to research and develop the Adiana system and would have been disappointed if the system was infringing (Tr. 1091:11–1092:21). The jury may have found Mr. Burse's opinion biased. The jury also learned that Mr. Burse lacked important facts regarding hysterosalpingogram testing with the Adiana system, which would have suggested that the Adiana system operated in an infringing manner (Tr. 1102:16–1103:5). Finally, the jury could have concluded that Hologic's reliance on the opinions of counsel was not reasonable. The jury's finding of indirect infringement was not against the great weight of the evidence.

3. DIRECT INFRINGEMENT.

A. Hologic Preserved Its *Daubert* Objections.

Hologic argues that the finding of direct infringement was against the great weight of the evidence because the jury should not have accepted the unreliable testimony of Conceptus's infringement expert, Dr. Mark Glasser (Br. 1). In response, Conceptus argues that Hologic failed to preserve any objections to Dr. Glasser's testimony (Opp. 3).

"[W]here the substance of an objection has been thoroughly explored and the trial court's ruling [on a motion in limine] was explicit and definitive, the issue is preserved for appeal." *U.S. v. Pablo Varela-Rivera*, 279 F.3d 1174, 1177 (9th Cir. 2002).

Hologic's pretrial motion in limine number one sought to exclude Dr. Glasser's testimony as unreliable. The motion was denied on the record and in a written order (Dkt. No. 433; Dkt. No. 429 at 12:19-13:2). Hologic sufficiently preserved its objections to Dr. Glasser's testimony.

B. Finding of Direct Infringement Was Not Seriously Erroneous or Against the Great Weight of the Evidence.

Hologic argues that the finding of direct infringement was against the great weight of the evidence because the jury improperly relied on Dr. Glasser's unreliable testimony (Br. 1). Specifically, Hologic argues that Dr. Glasser's testimony that the accused device performed the step of "permanently affixing the resilient structure . . . so that at least a portion of the fallopian tube is open" was unreliable under *Daubert* (*ibid.*). Hologic advanced a similar argument in its motion for summary judgment and motion in limine to exclude Dr. Glasser's testimony (*see* Dkt. No. 356 at 12; Dkt. No. 385). The order denying summary judgment held that when permanent affixation occurred was a question of medical fact on which reasonable jurors could disagree (Dkt. No. 356 at 12).

Hologic argues that Dr. Glasser's testimony was not reliable because his opinion on "permanent affixation" did not clearly define the standard to apply for the limitation, was not supported by peer-reviewed articles, and was not based on testing (Br. 9–13). This order disagrees. Hologic would have required Dr. Glass do the impossible and unnecessary. The task was impossible because there were no scientific journals devoted to the study of permanent affixation, and science had not come up with a method for determining permanent affixation. The task was unnecessary because Dr. Glasser did not need to pinpoint the precise moment of permanent affixation to help the jury on the issue of direct infringement. To find direct infringement, the jury only needed to rely on evidence showing that the Adiana device was permanently affixed *before* complete occlusion of the fallopian tube occurred.

Dr. Glasser's testimony was reliable and helpful to the jury. Dr. Glasser defined "permanently affixation" as when the Adiana matrix was held within the tube lumen by tissue ingrowth (Tr. 517:9–12). Dr. Glasser explained that the onset of tissue ingrowth, which permanently affixed the device, began in approximately one week, was variable by patient, and could not be determined with precision (*see, e.g.*, Tr. 597:24–599:15; 613:8–614:19; 616:2–12;

633:6–634:7). Dr. Glasser based his estimate, in part, on his personal experience using the Adiana system and ultrasound visibility of tissue ingrowth (Tr. 618:14–19; 636:9–637:7). Hologic's own stipulation to the FDA supported this estimate (*see, e.g.*, Tr. 662:22–663:2).

Dr. Glasser testified and presented evidence that complete occlusion occurred months after ingrowth maintains the matrix position in the tubal lumen (*see, e.g.*, TX 9 at 104858; TX 25 at 67832; Tr. 1185:20–1191:2). Hologic's own instructions for using the Adiana system suggested that complete occlusion occurred over time as tissue ingrowth progressed (Tr. 661:13–662:15; Tr. 1183:18–1184:16; TX 9 at 104858). The hysterosalpingogram and ultrasound results from the Adiana clinical trials showed that there were no reported expulsions of the Adiana matrix despite the fact that women had open fallopian tubes for months after the procedure and while tissue ingrowth was proceeding (Tr. 516:3–24; 640:20–641:17; 642:2–24).

In addition to Dr. Glasser's opinion, Hologic's own presentation to the FDA explaining the mechanism of Adiana showed that permanent affixation occurred before complete occlusion: "we observed a normal biomaterial response, which leads to fibrous integration of the Adiana implant in the tube, *which, in turn, results* in tubal occlusion . . . . we are confident that the Adiana device results in permanent integration of the device within the tissue, *leading to* tubal occlusion" (Tx 56 at 4797–800) (emphasis added). In turn, the FDA itself noted a difference in the timing of matrix fixation and total occlusion: "[O]n [ultrasound], 598/604 subjects had devices visualized bilaterally. From the HSG results, however, we know that 551/604 had confirmed occlusion. Therefore, [ultrasound] should not be the sole basis for assessing the likelihood of tubal occlusion for the purposes of relying on the Adiana System for contraception" (TX 25 at 67831; *see also* Tr. 1185:20–1188:22).

To sum up, there was more than enough evidence to show that Adiana met the claim limitation because permanent affixation occurred before complete occlusion.

At trial, Hologic's position was that permanent affixation of the Adiana matrix only occurred when tissue ingrowth was complete and the risk of expulsions and migrations were eliminated, which only happened upon complete occlusion of the fallopian tube (Br. 2). The Court, however, did not construe the term "permanent affixation" to require complete tissue

ingrowth and zero risk of expulsion and migration. The jury could have, and likely did, reject Hologic's definition of permanent affixation.

The jury could have discounted Hologic's evidence at trial. Hologic presented to the jury its "epithelial race mechanism" explanation for why permanent affixation occurred only at the time of complete occlusion. The "epithelial race mechanism" theory explained that the delivery of radiofrequency energy removed the epithelium, an aggressive tissue, whose growth would act to keep the fallopian tube open (Tr. 875:25–878:1). New tissue grew into the pores of the matrix and all the way around it and eventually the epithelium growth would meet the ends of the healed tissue and form cul-de-sacs. Hologic explained that it was only when those cul-de-sacs formed that one could be certain that the risk of migrations or expulsions was eliminated and thus that permanent affixation had occurred (*see* Tr. 875:25–878:1, 883:13–24, 935:20–936:2, 1174:1–20). The jury could have discounted this explanation of permanent affixation because the opinions were proffered by Mr. Harrington, who was not a physician and not a disclosed expert, but had a direct and substantial financial stake in the outcome of the case (Tr. 1016:13–1018:8).

The jury's finding of direct infringement was not seriously erroneous or against the great weight of the evidence.

CONCLUSION

For the reasons stated above, motions for judgment as a matter of law and new trial are **DENIED**.

IT IS SO ORDERED.

Dated: January 9, 2012.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE