

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2019-2054, 2019-2081

 $\label{eq:hologic} \begin{aligned} \text{Hologic, Inc., Cytyc Surgical Products, LLC,} \\ & \textit{Plaintiffs-Appellants,} \end{aligned}$

v.

MINERVA SURGICAL, INC.,

 $Defendant ext{-}Cross ext{-}Appellant.$

Appeals from the United States District Court for the District of Delaware in No. 1:15-cv-01031-JFB-SRF, Senior Judge Joseph F. Bataillon.

Decided: April 22, 2020

Before WALLACH, CLEVENGER, and STOLL, Circuit Judges.

OPINION

Additional views filed by Circuit Judge STOLL. STOLL, Circuit Judge.

These appeals require us to grapple with the doctrine of assignor estoppel, an equitable doctrine that prevents a party who assigned a patent to another from later challenging the validity of the assigned patent in district court. There are two patents-in-suit and each presents a different assignor estoppel issue. For the first patent, we consider whether the district court erred in holding that assignor estoppel does not bar the assignor from relying on our court's affirmance of the Patent Trial and Appeal Board's final decision invalidating the asserted patent claims in an inter partes review proceeding. For the second patent, we review the district court's summary judgment that assignor estoppel bars the assignor from asserting invalidity of the assigned second patent in district court. Based on our precedent, which we are bound to follow, we conclude that the district court did not err in either respect.

BACKGROUND

T

Hologic, Inc. and Cytyc Surgical Products, LLC (collectively, "Hologic") sued Minerva Surgical, Inc. for infringement of certain claims of its U.S. Patent Nos. 6,872,183 and 9,095,348, which relate to procedures and devices for endometrial ablation. Endometrial ablation is a treatment wherein the lining of the uterus is destroyed in order to treat menorrhagia, or abnormally heavy menstrual bleeding.

The '183 patent is titled "System and Method for Detecting Perforations in a Body Cavity," and describes and claims methods for determining the presence of uterine perforations, or holes, prior to ablation. "[T]he presence of a perforation in the uterus could result in inadvertent passage of the ablation device through the perforation and out of the uterus

into the bowel." '183 patent col. 1 ll. 38–41. The '183 patent solves this problem by "provid[ing] a mechanism by which a physician can evaluate whether perforations are present in [the uterus] before" ablation. *Id.* at col. 1 ll. 43–46. Claim 9, the only asserted independent claim of the '183 patent, recites:

9. A method of detecting a perforation in a uterus, comprising the steps of:

passing an inflation medium into the uterus;

monitoring for the presence of a perforation in the uterus using a pressure sensor;

if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and

if a perforation is detected during the monitoring step, preventing ablation of the uterus.

Id. at col. 8 ll. 39–48.

The '348 patent is titled "Moisture Transport System for Contact Electrocoagulation," and describes and claims an ablation device. The claimed device eliminates the problem of "steam and liquid buildup at the ablation site" associated with prior art devices, and also "allows the depth of ablation to be controlled" and "automatically discontinues ablation once the desired ablation depth has been reached." '348 patent col. 2 ll. 25–30. Claim 1, the only claim of the '348 patent at issue in this appeal, recites:

1. A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus. *Id.* at col. 19 ll. 9–42 (emphases added to highlight disputed claim terms on appeal).

II

In 1993, Csaba Truckai co-founded the company NovaCept, Inc. In the late 1990s, Mr. Truckai and his design team at NovaCept developed a medical device called the NovaSure system. NovaSure, received approval for commercial distribution from the U.S. Food and Drug Administration in September 2001, detects perforations in the uterus by applying carbon dioxide gas to the uterus and measuring any flow of gas out of the uterus. NovaSure uses an application head with a triangular shape designed to conform to the shape of the uterus and which ablates the endometrial lining throughout the cavity in two minutes or less. NovaSure also provides a moisture transport function with a vacuum used to remove steam and moisture from the cavity during energy delivery. NovaSure is indicated for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. It is undisputed that NovaSure incorporates the patented technology in this case.

Both the '183 and '348 patents list Mr. Truckai as an inventor. In August 1998, Mr. Truckai assigned his interest in U.S. Patent Application No. 09/103,072, an application from which the '348 patent claims priority, as well as all continuation applications, to NovaCept. In February 2001, Mr. Truckai assigned his interest in U.S. Patent Application No. 09/710,102, an application from which the '183 patent claims priority, as well as all continuation applications, to NovaCept.

In 2004, Cytyc Corporation acquired NovaCept for \$325 million. NovaCept assigned its patent rights, including rights to continuation applications, to Cytyc.

Hologic acquired Cytyc in 2007. The continuation application that issued as the '183 patent was filed in May 2004 and issued in March 2005. The continuation application that issued as the '348 patent was filed in August 2013 and issued in August 2015. Hologic is the current assignee of the '183 and '348 patents and markets and sells the NovaSure system throughout the United States.

Mr. Truckai left NovaCept and, in 2008, founded the accused infringer in this case, Minerva. Mr. Truckai served as Minerva's President, Chief Executive Officer, and a member of its Board of Directors. Mr. Truckai and others at Minerva developed the Endometrial Ablation System (EAS), which received FDA approval in 2015. Minerva's EAS is approved for the same indication as Hologic's NovaSure system. Minerva began commercial distribution of the EAS in August 2015.

III

In November 2015, Hologic sued Minerva in the U.S. District Court for the District of Delaware, alleging that Minerva's EAS and the use thereof infringed certain claims of the '183 and '348 patents. In addition to asserting the invalidity defenses of lack of enablement and failure to provide an adequate written description in district court, Minerva also filed petitions for IPR in the Patent Office, challenging the patentability of the asserted '183 patent claims, as well as those of the '348 patent, in view of prior art. The Board instituted review of the '183 patent, but denied review of the '348 patent.

Shortly after the district court issued its claim construction decision in April 2017, the Board issued its final written decision in the parallel IPR proceeding, holding the '183 patent claims unpatentable

as obvious. See generally Minerva Surgical, Inc. v. Hologic, Inc., No. IPR2016-00868, 2017 WL 6404966 (P.T.A.B. Dec. 15, 2017). Hologic appealed the Board's decision to this court.

Around the same time, Minerva requested that the district court dismiss as moot Hologic's claim for infringement of asserted claims 7, 9, 11, 13, and 14 of the '183 patent. The district court denied Minerva's request, concluding that the "patent has not been cancelled" and the Board's "finding is on appeal and does not have preclusive effect as to this action unless and until the appeal is resolved." *Hologic, Inc. v. Minerva Surgical, Inc.*, 325 F. Supp. 3d 507, 519 (D. Del. 2018) (Summary Judgment Op.).

Hologic, for its part, moved for summary judgment that the doctrine of assignor estoppel bars Minerva from challenging the validity of the '183 and '348 patent claims in district court. The district court granted Hologic's motion for both patents. After "[c]onsidering the balance of equities and the relationship of Minerva and Truckai," the district court found that "Truckai is in privity with Minerva" and that "assignor estoppel applies to Minerva's defenses to Hologic's patent infringement claims." Summary Judgment Op., 325 F. Supp. 3d at 524–25. Specifically, the court relied on "[u]ndisputed evidence" that Mr. Truckai founded Minerva, he "used his expertise to research, develop, test, manufacture, and obtain regulatory approval for the Minerva EAS," his "job responsibilities as Minerva's President and CEO included bringing the accused product to market to directly compete with Hologic," and he "executed broad assignments of his inventions to NovaCept, which was then sold to Hologic's predecessor for \$325 million." Id. at 523. In addition, the district court granted summary judgment of no invalidity in Hologic's favor. The district court also granted summary judgment of infringement of the asserted '183 and '348 patent claims.

The case then proceeded to a jury trial on the issues of willful infringement, damages, and certain of Minerva's state law counterclaims. The jury found, in relevant part, that Hologic was entitled \$4,200,529.75 in lost profits and \$587,138.48 in royalties for sales not included in lost profits—for a total award of \$4,787,668.23—based on Minerva's infringement of the '183 and '348 patent claims. Over Minerva's objection, the jury was not asked to separately apportion damages between the two patents. The jury also found that Minerva's infringement of claim 1 of the '348 patent was not willful. On August 13, 2018, the district court entered judgment on the verdict, subject to revision pursuant to any rulings on post-trial motions. After trial, Hologic moved for a permanent injunction to enjoin Minerva from further infringement of the asserted '183 patent claims.

The '348 patent expired on November 19, 2018. Five months later, this court affirmed the Board's decision that the '183 patent claims are invalid as obvious under 35 U.S.C. § 103. See generally Hologic, Inc. v. Minerva Surgical, Inc., 764 F. App'x 873 (Fed. Cir. 2019) (Hologic). Thereafter, the district court denied Hologic's motion for a permanent injunction as moot in light of this court's Hologic decision. Hologic, Inc. v. Minerva Surgical, Inc., No. 15-1031, 2019 WL 1958020, at *4 (D. Del. May 2, 2019) (JMOL Op.). The district court also denied Hologic's motions for supplemental damages, enhanced damages, and ongoing royalties for infringement of the asserted '183 patent claims as moot. Id.

With respect to the '348 patent, the district court noted Minerva's argument that the jury had not even found willful infringement, id. at *2, and denied Hologic's motion for enhanced damages, finding that "the damages are adequate to compensate Hologic for infringement through the life of the patent," id. at *10. It awarded Hologic supplemental damages for Minerva's continued infringement of claim 1 of the '348 patent "from the last-produced date of sales (April 1, 2018) to the date the '348 patent expired (November 19, 2018)," determined that Hologic was "entitled to recover a 16.1% royalty for [those] infringing sales," and ordered Minerva to submit an accounting of those infringing sales. *Id.* at *10–11. The court declined, however, to award an enhanced royalty for the postverdict sales because "Hologic has not shown that enhanced damages are warranted." Id. at *10. The court also awarded Hologic \$270,533 in pre-judgment interest on the jury's damages award, and concluded that Hologic would be awarded post-judgment interest "at the legal rate from and after August 13, 2018." *Id*. The court denied Minerva's motion for judgment as a matter of law of no damages or, alternatively, for a new trial on reasonable royalty damages. The court then ordered the parties to each submit a proposed final judgment consistent with its decision.

Finally, the district court addressed the impact of this court's *Hologic* decision on the jury's damages award and the district court's ruling on assignor estoppel. Specifically, the district court determined that the *Hologic* decision "d[id] not affect the jury verdict" because "a finding that the method claims [of the '183 patent] are not valid does not affect the finding of infringement as to the apparatus claim" of the '348 patent, and the "jury's damages determination can be adequately supported by the finding of infringement of Claim 1 of the '348 patent." *Id.* at *3. The district court further held that this court's

"findings as to the '183 patent (method claims) do not affect the [district court's] findings of assignor estoppel on the asserted claim of the '348 patent." *Id.* at *4 (footnote omitted).

In its final judgment, the district court awarded Hologic pre-judgment interest on the \$4,787,668.23 damages award "in the amount of \$270,533, plus postjudgment interest at the statutory rate of 2.44% under 35 U.S.C. § 1961(a)" in accordance with its ruling on post-trial motions. Final Judgment at 1, Hologic, Inc. v. Minerva Surgical, Inc., No. 15-1031 (D. Del. June 3, 2019), ECF No. 621 (Final Judgment). The district court also awarded Hologic supplemental damages in the \$1,629,304.08—the amount proposed by Minerva in its proposed final judgment. The district court further awarded pre-judgment interest on the supplemental damages award calculated "from the date infringement to August 13, 2018, (D.I. 520), plus postjudgment interest thereafter at the legal rate under 28 U.S.C. § 1961 until such time as the judgment is paid." *Id.* at 1–2.

Hologic and Minerva appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

This case presents various issues on appeal and cross-appeal. We start by addressing the assignor estoppel issues. We then turn to Minerva's challenge to the district court's claim construction, Minerva's challenge to the jury's damages award, Hologic's appeal of the district court's supplemental damages award, and Hologic's challenge to the district court's award of pre- and post-judgment interest.

We first address Hologic's challenge to the district court's application of collateral estoppel based on our affirmance of the Board's holding of invalidity of the '183 patent claims in *Hologic*. Hologic asserts that assignor estoppel precludes Minerva from relying on this court's *Hologic* decision to escape liability for infringement. It argues that "the final outcome of the IPR is irrelevant to the district court proceeding" and that "[t]o hold otherwise would be to hold that the America Invents Act ('AIA') abrogated the assignor estoppel doctrine in a district court infringement action." Appellant's Br. 36. Based on our precedent, we disagree.

Α

This court first examined and affirmed the vitality of the doctrine of assignor estoppel in Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220 (Fed. Cir. 1988). We defined assignor estoppel as "an equitable doctrine that prevents one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity." Diamond Sci., 848 F.2d at 1224. We explained that the "estoppel also operates to bar other parties in privity with the assignor, such as a corporation founded by the assignor." Id. (citation omitted). We also cited early Supreme Court cases addressing the doctrine, including Westinghouse Electric & Manufacturing Co. v. Formica Insulation Co., 266 U.S. 342, 45 S.Ct. 117, 69 L.Ed. 316 (1924) and Scott Paper Co. v. Marcalus Manufacturing Co., 326 U.S. 249, 66 S.Ct. 101, 90 L.Ed. 47 (1945). See id. at 1222–23. In both Westinghouse and Scott Paper, the Supreme Court carved out exceptions to the general assignor estoppel doctrine. But the Court did not abolish the doctrine.

In *Diamond Scientific*, we recognized that some courts questioned the vitality of the assignor estoppel

doctrine following the Supreme Court's decision abolishing licensee estoppel in *Lear*, *Inc. v. Adkins*, 395 U.S. 653, 666, 89 S.Ct. 1902, 23 L.Ed.2d 610 (1969). *See id.* at 1223–24. We concluded, however, that nothing in *Lear* eliminated assignor estoppel and that an important distinction existed between assignors and licensees:

The public policy favoring allowing a licensee to contest the validity of the patent is not present in the assignment situation. Unlike the licensee, who, without *Lear* might be forced to continue to pay for a potentially invalid patent, the assignor who would challenge the patent has already been fully paid for the patent rights.

Id. at 1224.

We acknowledged the "public policy encouraging people to challenge potentially invalid patents" and "disfavoring the repression of competition by the enforcement of worthless patents," but we nonetheless held that assignor estoppel serves important purposes. *Id.* at 1224–25. In doing so, we identified four common justifications for applying the doctrine: "(1) to prevent unfairness and injustice; (2) to prevent one [from] benefiting from his own wrong; (3) by analogy to estoppel by deed in real estate; and (4) by analogy to a landlord-tenant relationship." Id. at 1224 (alteration in original) (quoting Cooper, Estoppel to Challenge Patent Validity: The Case of Private Good Faith vs. Public Policy, 18 Case W. Res. L. Rev. 1122 (1967)). We also emphasized the longstanding reasoning behind the doctrine that "an assignor should not be permitted to sell something and later to assert that what was sold is worthless, all to the detriment of the assignee." Id. Stated another way, "it is the implicit representation by the assignor that the patent rights that he is assigning (presumably for value) are not worthless that sets the assignor apart from the rest of the world and can deprive him of the ability to challenge later the validity of the patent." *Id.* Thus, it "could work an injustice against the assignee" to "allow the assignor to make that representation at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage)." *Id.*

Since Diamond Scientific, this court has continued to apply the doctrine in a variety of circumstances, often citing prevention of "unfairness and injustice" as the primary justification for its application. See, e.g., Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1280–83 (Fed. Cir. 2017) (affirming grant of summary judgment that a company founded by the patent's inventors was barred from challenging the validity of the patent asserted by the inventors' former employer and assignee); Pandrol USA, LP v. Airboss Ry. Prods., Inc., 424 F.3d 1161, 1166-67 (Fed. Cir. 2005) (affirming the district court's exclusion of an assignor-inventor's testimony as to the invalidity of his own patent on the ground of assignor estoppel); *Mentor* Graphics Corp. v. Quickturn Design Sys., Inc., 150 F.3d 1374, 1377-80 (Fed. Cir. 1998) (affirming grant of a preliminary injunction where the assignee showed a likelihood of success on validity based on the district court's grant of summary judgment that the original assignor and its wholly owned subsidiary were barred from challenging validity); Shamrock Techs., Inc. v. Med. Sterilization, Inc., 903 F.2d 789, 793–96 (Fed. Cir. 1990) (affirming grant of summary judgment that the patent's inventor and the company he joined as "Vice President in charge of Operations" were barred from challenging the validity of the patent asserted by the inventor's former employer and assignee).

Consistent with the Supreme Court's guidance in Westinghouse and Scott Paper, however, we have

recognized certain limits to the doctrine. For instance, although estopped parties "cannot challenge the validity of" the patent at issue, "assignor estoppel does not limit their ability to defend themselves in other ways," including "arguing that the patentee is itself collaterally estopped from asserting a patent found invalid in a prior proceeding." Mentor Graphics, 150 F.3d at 1379 (first citing Blonder-Tongue Lab., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971); then citing Foster v. Hallco Mfg. Co., 947 F.2d 469, 481–83 (Fed. Cir. 1991)). In addition, an estopped party "may also argue for a narrow claim construction, or that the accused devices are within the prior art and therefore cannot infringe." Id. at 1380 (first citing Westinghouse, 266 U.S. at 351, 45 S.Ct. 117; then citing Scott Paper, 326 U.S. at 257– 58, 66 S.Ct. 101).

В

Based on our precedent and the limits it places on the assignor estoppel doctrine, we conclude that assignor estoppel does not preclude Minerva from relying on the *Hologic* decision to argue that the '183 patent claims are *void ab initio*.

We are mindful of the seeming unfairness to Hologic in this situation. Although Minerva would have been estopped from challenging the validity of the '183 patent claims in district court, it was able to challenge their validity in an IPR proceeding and, hence, circumvent the assignor estoppel doctrine. Minerva had the right to do so under the AIA and this court's precedent. This court has held that the doctrine of assignor estoppel does not bar an assignor from filing a petition for IPR. Arista Networks, Inc. v. Cisco Sys., Inc., 908 F.3d 792, 804 (Fed. Cir. 2018). In Arista, the patent owner argued that assignor estoppel barred the assignor-petitioner's IPR challenge to the patent's

validity. *Id.* at 798. We interpreted the statute at issue, 35 U.S.C. § 311(a)—which provides that "a person who is not the owner of a patent" may file an IPR—to determine whether Congress intended for assignor estoppel to apply in an IPR proceeding. *Id.* at 802–03. We concluded that the plain language of the statute was unambiguous and provided that "an assignor, who is no longer the owner of a patent, may file an IPR petition as to that patent." *Id.* at 803.

While we understand Hologic's predicament, we nevertheless conclude that the district court did not abuse its discretion in denying Hologic its requested injunctive and monetary relief following a finding of patent infringement. See Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1147 (Fed. Cir. 2011) (denial of a permanent injunction is reviewed for abuse of discretion). Generally, "when a [patent] claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot." Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1340 (Fed. Cir. 2013). Because the '183 patent claims are invalid, Hologic cannot assert those claims or seek ongoing monetary or injunctive relief based on infringement. Our affirmance of the Board's invalidity decision in Hologic is dispositive of the validity of the '183 patent claims, regardless of how the validity question came to this court, and regardless of whether assignor estoppel bars Minerva from challenging the patent's validity in this district court case.

Our conclusion is further supported by XY, LLC v. Trans Ova Genetics, L.C., 890 F.3d 1282 (Fed. Cir. 2018), in which we addressed the impact of our concurrent affirmance of invalidity on other pending actions involving the same patent. XY involved an appeal from a district court's judgment following a jury

trial. *Id.* at 1285–86. Similar to this case, there was a parallel IPR proceeding involving the same patent, in which the Board had held the asserted claims invalid. *Id.* at 1294. This court held *sua sponte* that the patent owner was collaterally estopped from asserting the patent "in any further proceedings" in view of the court's concurrent affirmance of the Board's invalidity decision. *Id.* at 1294–95. As in *XY*, this court's affirmance of the Board's invalidity decision in *Hologic* "renders final a judgment on the invalidity of the ['183 patent], and has an immediate issue-preclusive effect on any pending or co-pending actions involving the patent," including the instant action. *Id.* at 1294.

Hologic cites American Fence Co. v. MRM Security Systems, Inc., 710 F. Supp. 37 (D. Conn. 1989), as an example of how "district courts have suggested that assignor estoppel would control" in district court even when there is a determination of invalidity in an IPR. Appellant's Br. 37. Similar to this case, the assignee in American Fence sued the assignor and the company the assignor created for patent infringement. 710 F. Supp. at 39. The district court held that assignor estoppel prevented the defendants from challenging the validity of the patents-in-suit. Id. at 42. The district court also denied the defendants' request to stay the proceedings pending reexamination of one of the patents, stating that "[e]ven if upon reexamination the U.S. Patent Office finds that the ... patent is invalid, the defendants will be unable to assert that finding" because of assignor estoppel. Id. But American Fence is not binding on this court, and the section of the opinion on which Hologic relies is contrary to *Mentor Graphics*. There, we held that even an estopped assignor may argue that "the patentee is itself collaterally estopped from asserting a patent found invalid in a prior proceeding." *Mentor Graphics*, 150 F.3d at 1379 (citations omitted).

Accordingly, we affirm the district court's denial of Hologic's motions for a permanent injunction, enhanced damages, and ongoing royalties for Minerva's infringement of the '183 patent claims because Hologic is collaterally estopped from asserting infringement of these claims.

TT

We next consider Minerva's assertion that the district court erred in holding that assignor estoppel precludes Minerva from challenging the validity of claim 1 of the '348 patent. We review a district court's application of the equitable doctrine of assignor estoppel for an abuse of discretion. *MAG Aerospace Indus., Inc. v. B/E Aerospace, Inc.*, 816 F.3d 1374, 1376 (Fed. Cir. 2016) (citing *Pandrol*, 424 F.3d at 1165). We conclude that the district court did not abuse its discretion in applying assignor estoppel here.

As an initial matter, we decline Minerva's invitation to "abandon the doctrine" of assignor estoppel entirely. Cross-Appellant's Br. 67. Minerva contends that the doctrine is inconsistent with Lear, in which the Supreme Court abolished the doctrine of licensee estoppel. Minerva argues that "[a]n assignee who seeks protection against future competition from an assignor need simply negotiate a covenant not to compete in their agreement." Id. When addressing this same argument in EVE-USA, we declined to read Lear as "demolish[ing] the doctrinal underpinnings of assignor estoppel." EVE-USA, 851 F.3d at 1283 (citation omitted). In EVE-USA, we noted that our Diamond Scientific decision "emphasized the continued vitality of the doctrine of assignor estoppel after Lear." Id. (citing Diamond Sci., 848 F.2d at 1222–26); see also Arista, 908 F.3d at 802. We similarly decline at this time to read *Lear* as eliminating the doctrine of assignor estoppel.

Although we recognize that assignor estoppel is not a "broad equitable device susceptible of automatic application," Diamond Sci., 848 F.2d at 1225–26, we agree with the district court that the equities weigh in favor of its application in this case. The facts here are analogous to those in Diamond Scientific, Shamrock, and other cases in which an inventor executes broad assignments to his employer, leaves his employer, founds or takes on a controlling role at a competing company, and is directly involved in the alleged infringement. Minerva disputed none of the pertinent facts below or on appeal. Mr. Truckai "executed a broad assignment of his patent rights to NovaCept and later sold NovaCept to Hologic's predecessor for \$325 million." Summary Judgment Op., 325 F. Supp. 3d at 524. Thus, NovaCept "received appreciable value" for the patents at issue. Mentor Graphics, 150 F.3d at 1378. Mr. Truckai then "founded Minerva" and "used his expertise to research, develop, test, manufacture, and obtain regulatory approval for the Minerva EAS." Summary Judgment Op., 325 F. Supp. 3d at 523. Mr. Truckai's "job responsibilities as Minerva's President and CEO included bringing the accused product to market to directly compete with Hologic." *Id.*

Minerva also does not challenge the district court's finding that Minerva is in privity with Mr. Truckai—the original assignor and Minerva's founder, President, and CEO. See Diamond Sci., 848 F.2d at 1224 ("[E]stoppel also operates to bar other parties in privity with the assignor, such as a corporation founded by the assignor." (citation omitted)). Instead, Minerva contends that "Hologic is deploying assignor estoppel to shield its unwarranted expansion of the

patent's scope from the invalidity arguments created by its own overreach." Cross-Appellant's Br. 68. Minerva emphasizes that Hologic, not Mr. Truckai, prosecuted claim 1 of the '348 patent. The continuation application from which the '348 patent issued was filed in 2013, after Mr. Truckai had left NovaCept and founded Minerva. Minerva asserts that Hologic broadened the claims during prosecution and after Mr. Truckai's assignment, and that it would be unfair to block Mr. Truckai (or Minerva) from challenging the breadth of those claims.

We find Minerva's argument unpersuasive. In Diamond Scientific, we considered it "irrelevant that, at the time of the assignment," the inventor's "patent applications were still pending" and that assignee Diamond "may have later amended the claims in the application process (a very common occurrence in patent prosecutions), with or without [the inventor's] assistance." 848 F.2d at 1226. It is true, as Minerva observes, that in *Diamond Scientific* we noted that the Supreme Court "observed that the scope of the right conveyed in the assignment of patent rights before the granting of the patent 'is much less certainly defined than that of a granted patent, and the question of the extent of the estoppel against the assignor of such an inchoate right is more difficult to determine than in the case of the patent assigned after its granting." Id. (quoting Westinghouse, 266 U.S. at 352–53, 45 S.Ct. 117). We also noted, however, that the Supreme Court "found it unnecessary to decide the question" and "merely suggested that '[t]his difference might justify the view that the range of relevant and competent evidence in fixing the limits of the subsequent estoppel should be more liberal than in the case of an assignment of a granted patent." Id. (alteration in original) (quoting Westinghouse, 266 U.S. at 353, 45 S.Ct. 117).

To the extent Hologic "may have broadened the claims" in the application that issued as the '348 patent after Mr. Truckai's assignment "beyond what could be validly claimed in light of the prior art," the Supreme Court's and this court's precedents allow Minerva to "introduce evidence of prior art to narrow the scope of" claim 1 so as to bring its accused product "outside the scope of" claim 1. *Id.* (citing *Westinghouse*, 266 U.S. at 350, 45 S.Ct. 117). Thus, "[t]his exception to assignor estoppel also shows that estopping [Minerva] from raising invalidity defenses does not necessarily prevent [it] from successfully defending against [Hologic's] infringement claims." *Id.*

Because the district court did not abuse its discretion in applying the doctrine of assignor estoppel, we affirm the district court's grant of summary judgment of no invalidity as to claim 1 of the '348 patent.

Ш

We next consider Minerva's challenge to the district court's constructions of two terms in claim 1 of the '348 patent. Claim construction based on the intrinsic evidence is a question of law that this court reviews de novo. Trustees of Columbia Univ. v. Symantec Corp., 811 F.3d 1359, 1362 (Fed. Cir. 2016) ("The construction of claim terms based on the claim language, the specification, and the prosecution history are legal determinations." (citing Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 328, 135 S.Ct. 831, 190 L.Ed.2d 719 (2015))). Minerva contends that the district court erred in its constructions of "applicator head" and "indicator mechanism" and further that Minerva's accused EAS product does not infringe under the proper constructions. Minerva requests that

this court remand to the district court with instructions to enter a judgment of noninfringement. Because we discern no error in either of the court's constructions, we deny Minerva's request.

The district court construed the term "applicator head" in claim 1 of the '348 patent to mean "[a] distal end portion of an ablation device that applies energy to the uterine tissue." Hologic, Inc. v. Minerva Surgical, Inc., No. 15-1031, 2017 WL 1483305, at *2 (D. Del. Apr. 24, 2017) (Claim Construction Op.). The court rejected Minerva's proposed construction of "applicator head" to require "an applicator having a permeable or absorbent tissue contacting surface into which moisture is drawn." Id. at *2 n.6. It noted that Minerva "presented extensive argument for reading [certain] limitations from the specification into the claims" relating to "shortcomings of the prior art methods" with respect to permeability, but concluded that "such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by" Minerva. Id. We agree. Neither the claim nor the specification describes the "applicator head" as being permeable or requiring moisture removal. To be certain, the specification emphasizes the importance of moisture removal. But neither the plain claim language "applicator head" nor the specification includes a moisture removal requirement in the applicator head. Minerva emphasizes that an embodiment of the invention includes an "electrode carrying means" formed of a material that is "permeable to moisture," '348 patent col. 5 ll. 52–57, but this appears to be a component of the ablation device other than the claimed "applicator head." For all these reasons, we agree with the district court's claim construction.

The district court construed the term "indicator mechanism" in claim 1 of the '348 patent to mean "[a] mechanism configured to indicate a dimension." Claim Construction Op., 2017 WL 1483305, at *3. Minerva argues, as it did below, that the court's construction is too broad and that the term requires displaying uterine widths in "units of measure." Id. at *3 n.10. To support its broader construction, the district court relied on the second embodiment described in the specification, wherein the "ablation device . . . includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge." Id. at *3 (emphasis added) (quoting '348 patent col. 14 ll. 33-36). The district court also cited Figure 32b of the '348 patent, which shows a "dial face" that "includes calibration markings corresponding to an appropriate range of uterine widths." Id. (emphasis added) (quoting '348 patent col. 14 ll. 47–49).

We adopt the district court's construction of "indicator mechanism." Like the district court, we are unpersuaded by Minerva's attempt to narrow the claim scope to require a dimension. First of all, Minerva's proposed construction is inconsistent with the plain language of claim 1. See '348 patent col. 19 ll. 40-42 (reciting "an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus"). Moreover, we agree with the district court that "[n]othing in the specification suggests that applicant intended to limit 'an indicator mechanism' to devices that solely display uterine widths in 'units of measure.'" Claim Construction Op., 2017 WL 1483305, at *3 n.10. Accordingly, we discern no error in the district court's claim construction.

We have considered Minerva's additional arguments in support of its proposed claim constructions, but do not find them persuasive. Because the district court correctly construed the disputed terms in claim 1 of the '348 patent, we affirm the district court's grant of summary judgment of infringement.

IV

We turn to Minerva's assertion that the district court erred in awarding damages to Hologic based on Minerva's infringement of claim 1 of the '348 patent alone, where the jury verdict did not apportion damages between the '348 and '183 patents and where the '183 patent claims were held invalid following the jury verdict. We discern no reversible error in the district court's decision.

"The general rule is that when a 'jury was told it could rely on any of two or more independent legal theories, one of which was defective,' the general verdict must be set aside." WesternGeco L.L.C. v. ION Geophysical Corp., 913 F.3d 1067, 1073 (Fed. Cir. 2019) (citations omitted). "In a situation—such as this one—where the jury rendered a single verdict on damages, without breaking down the damages attributable to each patent, the normal rule would require a new trial as to damages." Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1310 (Fed. Cir. 2007) (citing Memphis Cmty. Sch. Dist. v. Stachura, 477 U.S. 299, 312, 106 S.Ct. 2537, 91 L.Ed.2d 249 (1986)); see also DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1262 (Fed. Cir. 2014) (vacating the damages award upon holding the claims of one of the two patents-in-suit invalid as anticipated and noting that its decision "could warrant a new trial on damages" (citing Verizon, 503 F.3d at 1310)).

We have recognized, however, an exception to this general rule. A single damages award "can be sustained" if, despite the fact that some of the asserted claims were held invalid or not infringed subsequent to the award, "undisputed evidence" demonstrated that the sustained patent claim was necessarily infringed by all of the accused activity on which the damages award was based. WesternGeco, 913 F.3d at 1074. In such cases, "we apply a harmlessness analysis similar to our approach in the case of erroneous jury instructions." Id. (citation omitted); see also Chrimar Holding Co., LLC v. ALE USA Inc., 732 F. App'x 876, 886 (Fed. Cir. 2018) (holding that a new trial to determine damages on a patent-by-patent basis was unnecessary because the same royalty damages applied whether the claims of one or three asserted patents were infringed). For the reasons that follow, we conclude that a departure from the general rule is warranted in this case.

In each of WesternGeco, Verizon, and DDR, this court vacated the damages award and remanded to the district court to determine in the first instance whether a new trial on damages was warranted based on this court's invalidity or noninfringement ruling. See WesternGeco, 913 F.3d at 1075; Verizon, 503 F.3d at 1310; DDR, 773 F.3d at 1262. By contrast, the district court in this case addressed the issue of apportionment and determined that the jury verdict on damages was "adequately supported by the finding of infringement of Claim 1 of the '348 patent." JMOL Op., 2019 WL 1958020, at *3. The district court's determination is supported by undisputed evidence. Hologic's damages expert explained to the jury that the same royalty rate he used in his damages calculation would apply to either the '183 patent or '348 patent, "individually or the two patents collectively," since they "both cover the entire procedure and device respectively." J.A. 30439 at 1084:7–25. The expert was then cross-examined about his reasoning. Thus, Hologic presented evidence to the jury that the damages award could be supported if either or both of the '183 and '348 patents' claims were infringed and valid. Minerva did not present any contrary evidence. Accordingly, we conclude that a departure from the general rule requiring a new trial is warranted in this case.

Minerva asserts that it asked for a jury instruction on apportionment but that its request was denied. The district court reasoned, however, that Minerva had not presented any evidence to the jury explaining why apportionment was necessary. See J.A. 31961–64 at 2298:4–2301:5. When asked during oral argument on appeal whether there was any evidence on apportionment other than the testimony by Hologic's expert, Minerva's counsel could not identify anything in the record. Oral Arg. at 17:35–21:19, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2019-2054.mp3. Likewise, following oral argument, this court did not receive any supplemental briefing identifying any testimony or other evidence to rebut Hologic's expert's testimony.

Because Hologic's expert's testimony remains undisputed, we see no error in the district court's conclusion that the jury's royalty award should stand. We have considered Minerva's additional arguments concerning the jury's damages award, including its award of lost profits, but we do not find them persuasive. Accordingly, we affirm the district court's denial of Minerva's motion for judgment as a matter of law of no damages or, alternatively, for a new trial on reasonable royalty damages.

V

We next consider Hologic's assertion that the district court erred in denying Hologic's requests for: (1) supplemental damages based on all of Minerva's infringing sales prior to the expiration of the '348 patent; (2) an increase in the royalty rate for post-verdict infringing sales; and (3) an enhancement of that rate under 35 U.S.C. § 284. We review a district court's decision to award or deny supplemental or enhanced damages for an abuse of discretion. *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1382 (Fed. Cir. 2017) (citing *WBIP*, *LLC v. Kohler, Co.*, 829 F.3d 1317, 1339 (Fed. Cir. 2016)); see also Prism Techs. *LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1377–79 (Fed. Cir. 2017). We conclude that the district court did not abuse its discretion in its award of supplemental damages.

Hologic argues that the district court undercounted the number of infringing sales and, specifically, that the court should have included \$4.011 million from the sales of a certain "design-around" product that Minerva began selling in June 2018. Appellant's Br. 58–59. We disagree. Hologic is not entitled to supplemental damages based on sales of products that Hologic did not accuse of infringement. Indeed, the district court on summary judgment stated that it "need not address whether Minerva's 'new' handle design would infringe Hologic's '348 Patent" because the new product "is not alleged to be infringing Hologic's patent." Summary Judgment Op., 325 F. Supp. 3d at 529. The jury was not asked to consider the design-around product for purposes of either infringement or determining the damages award. Thus, the district court correctly excluded sales of Minerva's design-around product from its supplemental damages award.

Hologic next contends that the district court should have increased the royalty rate from 16.1% to 20% for infringing sales made after August 13, 2018—the date the district court entered judgment on the jury's

verdict. "[A]n assessment of prospective damages for ongoing infringement should 'take into account the change in the parties' bargaining positions, and the resulting change in economic circumstances, resulting from the determination of liability." ActiveVideo Networks, Inc. v. Verizon Comme'ns, Inc., 694 F.3d 1312, 1343 (Fed. Cir. 2012) (quoting Amado v. Microsoft Corp., 517 F.3d 1353, 1362 (Fed. Cir. 2008)). Here, the jury did not make any "determination of liability." Id. Instead, the district court entered summary judgment of infringement and thus it, rather than the jury, made the "determination of liability." We agree with Minerva that no change in the parties' bargaining positions or economic circumstances could have "result[ed] from the determination of liability" between the jury's verdict and the district court's ruling on post-trial motions because no determination of liability occurred during that time period. *Id.* Thus, the district court did not abuse its discretion in declining to increase the royalty rate for ongoing royalties for infringement of claim 1 of the '348 patent.

Lastly, Hologic contends that the district court should have enhanced the royalty rate for the supplemental damages from 20% to 30% pursuant to § 284. District courts have discretion to "increase the damages up to three times the amount found or assessed." 35 U.S.C. § 284. "Enhanced damages are generally only appropriate in egregious cases of misconduct, such as willful, wanton, or malicious behavior." *Presidio*, 875 F.3d at 1382 (citing *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, — U.S. ——, 136 S. Ct. 1923, 1932, 195 L.Ed.2d 278 (2016)). An award of enhanced damages, however, "does not necessarily flow from a willfulness finding." *Id.* (first citing *Halo*, 136 S. Ct. at 1932; then citing *WBIP*, 829 F.3d at 1341 n.13). Rather, "[d]iscretion remains with the court to

determine whether the conduct is sufficiently egregious to warrant enhanced damages," and "courts should consider the overall circumstances of the case." *Id.* (first citing *WBIP*, 829 F.3d at 1341 n.13; then citing *Halo*, 136 S. Ct. at 1933).

Here, the jury determined that Minerva did not willfully infringe claim 1 of the '348 patent. Additionally, there was neither a finding by the district court of any post-verdict willful infringement, nor a request by Hologic that the district court make such a finding. Contrary to Hologic's assertion, a district court is not required to award enhanced damages absent a finding of willful infringement. Nor is it required to discuss the factors set forth in Read Corp. v. Portec, Inc., 970 F.2d 816 (Fed. Cir. 1992), in deciding whether to award enhanced damages absent a finding of willful infringement. See Presidio, 875 F.3d at 1382. Moreover, we are not persuaded by Hologic's unsupported assertion, raised for the first time during oral argument, that the Read factors supplant a willfulness finding in the post-verdict context. See Oral Arg. at 8:26–9:33. Thus, the district court did not abuse its discretion in declining to enhance the royalty rate for ongoing royalties for infringement of claim 1 of the '348 patent.

For all these reasons, we affirm the district court's decision regarding supplemental damages.

VI

Finally, we hold that the district court erred by using an incorrect judgment date in its calculation of preand post-judgment interest on the supplemental damages award.

We apply regional circuit law in reviewing a determination of pre- and post-judgment interest on a damages award. *Taltech Ltd. v. Esquel Enters. Ltd.*,

604 F.3d 1324, 1335 (Fed. Cir. 2010). The Third Circuit reviews such determinations de novo. Addie v. Kjaer, 836 F.3d 251, 258 (3d Cir. 2016). The relevant statutory provision, 28 U.S.C. § 1961(a), provides that "[i]nterest shall be allowed on any money judgment in a civil case recovered in a district court," and that "[s]uch interest shall be calculated from the date of the entry of the judgment, at a rate equal to the weekly average 1-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the calendar week preceding[] the date of the judgment." 28 U.S.C. § 1961(a). Generally, "post-judgment interest on a particular award only starts running when a judgment quantifying that award has been entered." Travelers Cas. & Sur. Co. v. Ins. Co. of N. Am., 609 F.3d 143, 175 (3d Cir. 2010) (citation omitted).

In its May 2, 2019 ruling on post-trial motions, the district court determined that Hologic was entitled to supplemental damages and ordered Minerva to "submit an accounting of infringing sales from April 1, 2018, to November 19, 2018." JMOL Op., 2019 WL 1958020, at *10-11. In its opinion, however, the court did not quantify the amount of supplemental damages to which Hologic was entitled. Pursuant to § 1961(a), both parties then submitted proposed final judgments requesting that interest on the supplemental damages award be calculated from the "date of entry of this Final Judgment." J.A. 36251, 36259. Contrary to Minerva's assertion, in its submission to the district court, Hologic did not propose an August 13, 2018 date as the relevant date for interest on the *supplemental* damages award. Instead, it proposed August 13, 2018 as the relevant date for interest on the jury's damages award. See J.A. 36251.

The district court's final judgment specifies August 13, 2018 as the date for awarding pre- and postjudgment interest for supplemental damages for the '348 patent. Final Judgment at 1-2 (entering judgment in favor of Hologic for "supplemental damages for Minerva's infringing sales from April 1, 2018, through August 13, 2018, plus prejudgment interest on that amount at the prime rate compounded quarterly from the date of infringement to August 13, 2018, (D.I. 520), plus post-judgment interest thereafter at the legal rate under 28 U.S.C. § 1961 until such time as the judgment is paid" (emphasis added)). The "judgment quantifying [the supplemental damages] award," however, was not entered until June 3, 2019—the date of the final judgment. Travelers, 609 F.3d at 175. We agree with Hologic that the district court should have used June 3, 2019 as the relevant date for awarding pre- and post-judgment interest.

We conclude that the district court erred in determining the relevant date for calculating pre- and post-judgment interest on the supplemental damages award. We therefore vacate the district court's interest award and remand for the district court to award pre-judgment interest on the supplemental damages award from the date of infringement to June 3, 2019, and post-judgment interest thereafter.

CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Hologic's motions for a permanent injunction, enhanced damages, and ongoing royalties for infringement of the asserted '183 patent claims. We also affirm its denial of Hologic's requests for supplemental damages to include Minerva's redesigned product, and for increased and enhanced supplemental damages. Finally, we affirm the district court's summary judgment of no invalidity and infringement,

summary judgment that assignor estoppel bars Minerva from challenging the validity of the asserted '348 patent claim, and denial of Minerva's motion for judgment as a matter of law of no damages or, alternatively, for a new trial on reasonable royalty damages.

We vacate the district court's award of pre- and postjudgment interest on the supplemental damages award, and remand for the district court to calculate the interest award in accordance with this decision.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED.

Costs

No costs.

STOLL, Circuit Judge, additional views.

I write separately to highlight and question the peculiar circumstance created in this case by this court's precedent, which the panel is bound to follow. In Arista, we held that the judge-made doctrine of assignor estoppel does not apply in the context of an inter partes review. In other words, an assignor who sold his patent rights may file a petition for IPR challenging the validity of that patent. Arista Networks, Inc. v. Cisco Sys., Inc., 908 F.3d 792, 803-04 (Fed. Cir. 2018). At the same time, we continue to bar assignors from challenging in district court the validity of the patents they assigned. See, e.g., Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1280-83 (Fed. Cir. 2017). Our precedent thus presents an odd situation where an assignor can circumvent the doctrine of assignor estoppel by attacking the validity of a patent claim in the Patent Office, but cannot do the same in district court. Do the principles underlying assignor estoppel—unfairness in allowing one who profited from the sale of the patent to attack it—apply in district court but not in Patent Office proceedings? Should we change the application of the doctrine in district court, or should we revisit our construction of the America Invents Act and reevaluate our interpretation of the statute as prohibiting the doctrine of assignor estoppel?

Given the odd circumstance created in this case, I suggest that it is time for this court to consider en banc the doctrine of assignor estoppel as it applies both in district court and in the Patent Office. We should seek to clarify this odd and seemingly illogical regime in which an assignor cannot present any invalidity defenses in district court but can present a limited set of invalidity grounds in an IPR proceeding.¹

¹ A petitioner in an IPR proceeding may request to cancel as unpatentable one or more claims of a patent, but "only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b).

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1:15CV1031

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs,

v.

MINERVA SURGICAL, INC.,

Defendant.

Signed 06/28/2018

MEMORANDUM OPINION

Joseph F. Bataillon, Senior United States District Judge

This matter is before the court on the following motions: defendant Minerva Surgical, Inc.'s ("Minerva") Motion to Dismiss the '183 Patent and the '989 Patent under Federal Rule of Civil Procedure 12(b)(1) or for judgment on the pleadings under Rule 12(c) (D.I. 275); Minerva's motion for partial summary judgment on: invalidity; non-infringement; no willfulness; and no unfair competition (D.I. 277);

¹ The '989 Patent is no longer at issue. (D.I. 367, Joint [Proposed] Pretrial Order).

and plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's (collectively "Hologic") motions for summary judgment of no invalidity (D.I. 287); infringement (D.I. 288); and assignor estoppel (D.I. 289).² Minerva also seeks a summary judgment that the doctrine of equivalents does not apply to Minerva's redesign, arguing prosecution history estoppel ("PHE"). (D.I. 278, Brief at 44–47).³

I. FACTS

This is an action for patent infringement and related state-law claims.⁴ Hologic alleges that Minerva infringes U.S. Patent No. 6,872,183 ("the '183 Patent"),

² Also pending is Hologic's motion to strike Minerva's "Appendix A" (D.I. 278–1), "Supplemental Exhibit A" (D.I. 320–1), and "Second Supplemental Exhibit A" (D.I. 341–1) (D.I. 346). Hologic contends the exhibits should not be considered by the court in rendering its summary judgment decision because they include impermissible attorney argument and exceed the court's limits on page length. The court finds the exhibits are more in the nature of demonstrative exhibits. Whether properly the subject of a motion to strike or not, the court has not relied on the exhibits and the motion will be denied as moot. The parties also request oral argument on the pending motions (D.I. 354 and 359). The court finds oral argument is not necessary and the motion will be denied.

³ Minerva is relying on a redesign of its handle as a noninfringing alternative for purposes of damages.

⁴ Hologic also alleges Minerva has engaged in (i) unfair competition in violation of under 15 U.S.C. § 1125; (ii) deceptive trade practices under 6 Del. C. § 2532; (iii) unfair competition under Delaware common law; and (iv) tortious interference with Hologic's business relationships under Delaware common law. Counterclaims against Hologic, alleging that it has engaged in (i) unfair competition under 15 U.S.C. § 1125(a) & (c); (ii) deceptive trade practices under 6 Del. C. § 2532; (iii) unfair competition under the Delaware common law; (iv) interference with contract/business advantage; (v) breach of contract; and (vi) trade libel. Hologic has moved to bifurcate the trial with respect to those

titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004, and issued March 29, 2005, and U.S. Patent No. 9,095,348 ("the '348 Patent"), titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013, and issued August 4, 2015 (collectively "the Patents-in-Suit"). The asserted patent claims that remain at issue are claims 7, 9, 11, 13, and 14 of the '183 Patent and claim 1 of the '348 Patent.⁵ (D.I. 367, Joint [Proposed] Final Pretrial Order at 13; oral order dated June 15, 2018).

Additional facts are set out in the court's memorandum order on the plaintiff's motion for preliminary injunction (D.I. 127) and need not be repeated here. Briefly, the technology at issue in this litigation involves instruments and procedures for endometrial ablation, a treatment wherein the lining of the uterus is destroyed in order to treat Menorrhagia, or abnormally heavy menstrual bleeding. In the late 1990s, NovaCept Corporation ("NovaCept") under the direction of Csaba Truckai ("Truckai") and his design team developed the NovaSure system ("NovaSure") in the late-1990s. Prior to an ablation procedure, NovaSure uses computerized monitoring to detect perforations in the uterus, by applying C02 gas to the uterus and measuring any flow of gas out of the uterus. NovaSure employs an application head with a triangular shape designed to conform to the shape of the uterus, which ablates the endometrial lining throughout the cavity in two minutes or less. NovaSure also provides a "moisture transport" function with a vacuum used to remove steam and moisture from the cavity during energy delivery. Minerva has developed and brought

issues (D.I. 374). In light of this disposition, the court finds the motion should be denied.

⁵ Claim 1 of the '348 patent is a system claim.

to market a new technology for the treatment of abnormal uterine bleeding, the Minerva Endometrial Ablation System ("EAS" or "accused product").

The '348 patent is directed to "an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ." It uses "an electrode array," which "includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon." To use the apparatus, "the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." (D.I. 281–7, Ex. 40, '348 patent, 2:34–45). The specification describes two exemplary embodiments. The first embodiment describes an ablation device comprised generally of three major components—RF applicator head, main body, and handle. (Id. at 4:55-58) The applicator head includes an array of electrodes formed on the surface of an electrode carrying means. (Id. at 4:58–61). "The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array." (Id. 11:53-54). Aspects of the two "exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention." (Id. at 11:50–58).

Claim 1 of the '348 Patent states:

A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

(Id. at 19:9-42) (emphasis added).

The '183 patent is directed to "a system and method for detecting perforations in a body cavity." (D.I. 281–7, Ex. 39). The system delivers a fluid (either liquid or gas) "into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted." In the preferred form of the system, the perforation detection functionality is provided with an RF [radio frequency] ablation system. ('183 patent, 1:49–62).

What is claimed in Claim 1 of the '183 Patent is:

1. A method of ablating a uterus, comprising the steps of:

inserting an ablation device into a uterus;

flowing an inflation medium into the uterus;

monitoring for the presence of a perforation in the uterus using a pressure sensor; and

treating the interior of the uterus using the ablation device.

(Id. at 8:10–14). Asserted Claim 7 recites:

The method of claim 1, further including the step of preventing performance of the treating step until after the monitoring step has been carried out.

(Id. at 8:30-33) Asserted Claim 9 recites:

A method of detecting a perforation in a uterus, comprising the steps of:

passing an inflation medium into the uterus;

monitoring for the presence of a perforation in the uterus using a pressure sensor;

if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and

if a perforation is detected during the monitoring step, preventing ablation of the uterus.

(Id. at 8:39-48). Dependent claim 11 recites:

The method of claim 9, further including the step of:

if a perforation is detected during the monitoring step, activating a notification signal alerting t e user to the presence of a perforation in the uterus.

(*Id.* at 8:54–57). Dependent claim 13 limits claim 9 reciting, "wherein the inflation medium is introduced using the ablation device." (*Id.* at 8:60–61). Claim 14 states: "The method of claim 9, wherein the ablation device is an RF ablation device." (*Id.* at 8:63–65).

The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." (*Id.* at 2:36–44) The pressure sensor "monitors pressure in the pressure signal line . . . and delivers the signal to the microprocessor." (*Id.* at 5:23–25). The specification explains that during testing "[w]hen the

pressure at gauge 84 rises and remains above 50mmHg for 4 seconds", the test is passed.

The court has construed the relevant claims of the Patents-in-Suit as follows:

<u>Pressure sensor</u>: A device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

<u>Applicator head</u>:⁷ A distal end portion of an ablation device that applies energy to the uterine tissue.

<u>Indicator mechanism</u>:⁸ A mechanism configured to indicate a dimension.

One or more electrical conductors.

(D.I. 227, Memorandum Order at 2–5). In addition, the term "monitoring," found in the '183 patent, claims 7, 9, and 11, requires no construction. *Id.* at 3.

The parties agree to the following additional facts. (D.I. 367–1, Joint [Proposed] Final Pretrial Order, Ex. 1, Joint Statement of Uncontested Facts). Plaintiff Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Marlborough, Massachusetts. Plaintiff Cytyc Surgical Products, LLC ("Cytyc") is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business in Marlborough, Massachusetts. Cytyc is a wholly-owned subsidiary of Hologic.

⁶ Found in '183 patent, claim 9.

⁷ Found in '348 patent, claim 1.

⁸ Found in '348 patent, claim 1.

⁹ Found in '348 patent, claim 1.

Defendant Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Redwood City, California.

The parties agree the '183 Patent was issued by the United States Patent and Trademark Office ("USPTO") on March 29, 2005, and expires on November 10, 2020. Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller are the named inventors of the '183 Patent.

Csaba Truckai assigned his interest in the '183 Patent to NovaCept on February 9, 2001. In February 2001, Csaba Truckai assigned his interest in U.S. Application No. 09/710,102, an application to which the '183 Patent claims priority, to NovaCept. Hologic is the owner by assignment of the '183 Patent. Hologic acquired the '183 Patent from Cytyc on January 15, 2016.

The '348 Patent was issued by the USPTO on August 4, 2015 and expires on November 19, 2018. 11 Cytyc

¹⁰ The '183 Patent claims priority to Provisional Application No. 60/164,482, filed November 10, 1999 (i.e., the '183 Priority Date). Original Utility Application No. 09/710,102, filed November 10, 2000, issued as U.S. Patent No. 6,554,780 ("the '780 Patent"). Application No. 10/400,823, filed March 27, 2003, was a continuation of Application No. 09/710,102, and issued as U.S. Patent No. 6,743,184 ("the '184 Patent"). Application No. 10/852,684, filed May 24, 2004, was a continuation of Application No. 10/400,823, and issued as U.S. Patent No. 6,872,183 ("the '183 Patent"). The '780, '184, and '183 Patents all share a common specification. Only the claims of each are different.

¹¹ The '348 Patent claims priority to Provisional Application No. 60/084,791, filed May 8, 1998 (i.e., the '348 Priority Date). Original Utility Application No. 09/103,072, filed June 23, 1998, issued as U.S. Patent No. 6,813,520 ("the '520 Patent"). Application No. 10/959,771, filed October 6, 2004 was a divisional of Application No. 09/103,072, and issued as U.S. Patent No. 7,604,633 ("the '633 Patent"). Application No. 12/581,506, filed

listed Csaba Truckai, Russel Mahlon Sampson, Stephanie Squarcia, Alfonso Lawrence Ramirez, and Estela Hilario as named inventors on the face of the '348 Patent.

In August 1998, Csaba Truckai assigned his interest in U.S. Application No. 09/103,072, an application to which the '348 Patent claims priority, to NovaCept. Hologic is the owner by assignment of the '348 Patent. Hologic acquired the '348 Patent from Cytyc on January 15, 2016. In May 2004, Cytyc Corporation ("Cytyc") acquired NovaCept for \$325 million dollars. In 2007, Hologic acquired Cytyc Corporation.

In 1993, Csaba Truckai co-founded NovaCept, Inc. ("NovaCept") Csaba Truckai and others at NovaCept developed the NovaSure system. NovaCept received FDA premarket approval for commercial distribution of the NovaSure system on September 28, 2001. NovaCept assigned to Cytyc its patent rights including continuation applications. Hologic markets and sells the NovaSure system throughout the United States and in interstate commerce.

Csaba Truckai is a founder of Minerva. Minerva was founded in 2008. Csaba Truckai was involved in the development of the Minerva Endometrial Ablation System ("EAS"). Minerva received FDA premarket approval for commercial distribution of the Minerva EAS on July 27, 2015. Minerva began commercial distribution of the Minerva EAS in August 2015. Minerva markets and sells the Minerva EAS

October 19, 2009, was a continuation of Application No. 10/959,771, and issued as U.S. Patent No. 8,506,563 ("the '563 Patent"). Application No. 13/962,178, filed August 8, 2013, was a continuation of Application No. 12/581,506, and issued as U.S. Patent No. 9,095,348 ("the '348 Patent"). The '520, '633, '563, and '348 Patents all share a common specification. Only the claims of each are different.

throughout the United States and in interstate commerce. Both the Minerva EAS and the NovaSure system are indicated for use on premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete. The Array Opening Indicator of the Minerva EAS contains a Black Indicator Line that can move relative to rows of black dots depending on the degree of expansion of the Plasma Formation Array.

Hologic alleges that Minerva infringes its patent in the use of the Minerva EAS. It alleges that use of the Minerva EAS, consistent with its instructions for use, practices each and every step of the method claims of the '183 Patent. It asserts that Minerva directly infringes these claims and induces and contributes to the infringement by its customers. It further alleges that Minerva infringes the apparatus claims of the '348 Patent by making, selling and/or offering to sell the Minerva EAS in the United States. Also, Hologic contends that Minerva's infringement of the Patents-in-Suit has been and continues to be willful.

Minerva denies that it infringes—directly or indirectly (under inducement or contributory infringement)—any of the asserted claims of the Patents-in-Suit and denies that infringement, if any, has been willful. In addition, Minerva asserts an invalidity defense to the asserted claims. With respect to the '183 patent, it argues that all the asserted claims of the Patents-in-Suit are invalid for lack of written description and lack of enablement under 35 U.S.C. § 112.

II. Minerva's Motion to Dismiss (D.I. 275)

A. Background

A threshold issue is Minerva's motion to dismiss. Minerva seeks dismissal of Hologic's claim for infringement of the '183 Patent under Federal Rule of Civil Procedure 12(b)(1) and 12(c). Minerva asserts that the '183 Patent claims "should be dismissed as moot" because "no viable cause of action" remains. Minerva's motion is based on a final written decision of the Patent and Trial Appeals Board ("PTAB") in an inter partes review under 35 U.S.C. § 318(a) of the '183 patent. Minerva contends the PTAB's decision extinguishes any cause of action Hologic may have had with respect to its asserted '183 patent. Hologic has appealed the Patent Office's decision on the '183 Patent to the Federal Circuit (D.I. 344, Hologic Brief at 9).

In response, Hologic asserts Minerva is estopped from contending the patent is invalid by the doctrine of assignor estoppel. It argues that Minerva profited from its assignment and subsequent sale of the intellectual property and cannot disclaim the patent's validity. Assignor estoppel is also the subject of one of Hologic's motions for summary judgment and will be discussed below.

B. Law

A party may move to dismiss for "lack of subject-matter jurisdiction" under Federal Rule of Civil Procedure 12(b)(1). The federal courts are courts of limited jurisdiction. Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994). The court's power to render judgment is circumscribed by the Article III requirement that a live case or controversy exist throughout all stages of litigation, including appellate review. United States v. Huff, 703 F.3d 609, 611 (3d Cir. 2013). This requirement is satisfied when the parties "continue to have a 'personal stake in the outcome' of the lawsuit." Id. "When the parties lose their personal stake in the outcome, the case becomes

moot and must be dismissed, even if it once was a live controversy at an earlier stage of the proceedings." *Id.* Courts lack subject matter jurisdiction over moot claims. *See Target Training Int'l, Ltd. v. Extended Disc N. Am., Inc.*, 645 F. App'x 1018, 1025 (Fed. Cir. 2016) ("a dismissal for mootness is a dismissal for lack of jurisdiction."). In patent cases, the existence of a case or controversy must be evaluated on a claim-by-claim basis. U.S.C.A. Const. art. III, § 2, cl. 1; *see Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1282 (Fed. Cir. 2012).

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter pleadings are closed—but early enough not to delay trial." When evaluating a motion for judgment on the pleadings, the court must consider factual allegations in a complaint in the light most favorable to the nonmoving party. Rosenau v. Unifund Corp., 539 F.3d 218, 221 (3d Cir. 2008). The court may consider matters of public record as well as authentic documents upon which the complaint is based if they are attached to the complaint or as an exhibit to the motion. Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994).

"When a [patent] claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot." Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1340 (Fed. Cir. 2013). Under 35 U.S.C. § 141(c), "[a] party to an inter partes review or a post-grant review who is dissatisfied with the final written decision of the Patent Trial and Appeal Board" has a right to appeal to the Federal Circuit. See Pers. Audio, LLC v. Elec. Frontier Found., 867 F.3d 1246, 1249 (Fed. Cir. 2017), cert. denied, — U.S. —, 138 S.Ct. 1989, 201 L.Ed.2d 249 (2018). The Patent Office

cannot cancel claims of patents until after appeal. 35 U.S.C. § 318(b) (for *inter partes* reviews, after "the time for appeal has expired or any appeal has terminated," the Director will "issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable"). The Federal Circuit has held that "a determination of patentability... occur[s] only after all appeals have terminated." *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 645 (Fed. Cir. 2011) (explaining that a certificate cancelling patent claims "only happens 'when the time for appeal has expired or any appeal proceeding has terminated").

C. Discussion

The court rejects Minerva's argument that the PTAB's final written order on *inter partes* review renders this action moot. The patent has not been cancelled. The PTAB finding is on appeal and does not have preclusive effect as to this action unless and until the appeal is resolved. Accordingly, the court finds Minerva's motion to dismiss should be denied.

In light of this disposition, the court need not address Hologic's assignor estoppel argument in connection with the motion to dismiss, but will address the doctrine in Hologic's motion for summary judgment. See infra.

III. The Parties' Motions to Preclude or to Strike (D.I. 290, 279 and 317)

A. Background

More preliminary issues are Hologic's motion to preclude consideration of certain evidence (D.I. 290), Minerva's motion to strike the expert testimony of Karl Leinsing and Christopher C. Barry (D.I. 279), and

Minerva's motion to strike the supplemental expert report of Karl Leinsing (D.I. 317).

Hologic contends the court should exclude the lay opinion of David Clapper, Minerva's current CEO and former CEO of NovaCept, on the issue of market value for endometrial ablation devices. Further, Hologic argues the court should exclude invalidity and infringement opinions of Robert Tucker, M.D. because they are not based on the court's claim constructions and are based on exceedingly narrow characterizations of what he understands the invention to be. It argues Dr. Tucker's reliance on an impermissible claim construction renders his opinions irrelevant and unreliable and not helpful to the finder of fact. Hologic also challenges Minerva's damages expert Blake Inglish's apportionment calculations because they are based entirely on Dr. Tucker's allegedly flawed opinions. Hologic next challenges Burt Magen's conclusion that several prototype Minerva EAS's handpieces would not infringe the claims of the '348 patent. Hologic argues that Magen's opinions are not relevant to any fact at issue since Magen's opinions relate to three proposed handpiece designs, none of which are the accused product. Hologic also argues that Magen failed to apply the court's construction of an "indicator mechanism." Last, Hologic states that the court should exclude Dr. Eugene Skalnyi from testifying regarding facts and opinions not disclosed to Hologic.

In response, Minerva contends Clapper's testimony does not relate to any scientific, technical, or other specialized knowledge that would fall under Federal Rule of Evidence 702 and is properly admissible under Rule 701. Minerva also controverts Hologic's conclusion that Dr. Tucker did not properly apply the court's claim construction. Minerva also contends the testimony of Mr. Inglish is proper and should be considered,

further arguing that Mr. Magen's testimony survives Hologic's challenge.

Minerva moves to preclude Leinsing's opinions on validity and infringement. It contends Leinsing improperly relied on claim construction legal standards to render opinions on invalidity for lack of a written description under § 112. Minerva contends Hologic fails to apply the relevant authority that rejects a patentee's attempt to argue that the specification does not limit the claims (which is a claim construction argument) in the context of § 112. See Rivera v. Int'l Trade Comm'n, 857 F.3d 1315, 1322 (Fed. Cir. 2017). Hologic, on the other hand, contends that Leinsing properly considered the claims as construed by the court and analyzed the disclosure of the Patents-in-Suit to conclude that the asserted claims of the Patents-in-Suit are described and enabled.

Next, Minerva argues Leinsing's opinions relying on unreliable and misleading documents should be excluded, arguing that unverified Internet data, with no connection to Minerva or its EAS, is not something an expert would reasonably rely upon to prove infringement. Minerva is challenging Dr. Leinsing's testimony about Bernoulli's principle, which was found on a website. In response, Hologic contends that Leinsing's opinions are valid because they rely on documents that confirm the existence of Bernoulli's principle and Minerva's own technical documents.

Last, Minerva challenges Leinsing's opinions regarding copying. Hologic argues that Leinsing never offered an opinion that Minerva's EAS copied NovaSure and that Leinsing is entitled to rebut Minerva's expert's opinions on the subject.

B. Law

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert witnesses. Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. District court judges are to perform a screening function with respect to expert testimony. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 597, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Daubert requires courts to conduct an inquiry into the reliability and relevance of the proposed expert testimony. Yazujian v. PetSmart, 729 Fed.Appx. 213, 214-16 (3d Cir. 2018). To be admissible, expert testimony must be connected to the inquiry at hand. Id.; see Daubert, 509 U.S. at 591–92, 113 S.Ct. 2786.

The Court of Appeals for the Third Circuit identifies the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *Elcock v. Kmart Corp.*, 233 F.3d 734, 745–46 (3d Cir. 2000). The expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). *Daubert* applies to the other expert matters described in Rule 702, even when the proposed expert is offering non-scientific, but specialized, testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

"The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595, 113 S.Ct. 2786. "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91, 131 S.Ct. 2238, 180 L.Ed.2d 131 (2011).

Under Rule 701, on the other hand,

If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:

- (a) rationally based on the witness's perception;
- (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and

(c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

Fed. R. Evid. 701; see Hirst v. Inverness Hotel Corp., 544 F.3d 221, 225 (3d Cir. 2008) ("The plain language of Rule 701 establishes that lay opinion testimony must satisfy the criteria set forth in subsections (a), (b), and (c) in order to be admissible.")

Some evidentiary submissions cannot be evaluated accurately or sufficiently by the trial judge in the context of a pretrial motion. Jonasson v. Lutheran Child and Family Servs., 115 F.3d 436, 440 (7th Cir. 1997). A pretrial motion or motion in limine is appropriate for "evidentiary submissions that clearly ought not be presented to the jury because they clearly would be inadmissible for any purpose." Id. In other instances, it is necessary to defer ruling until during trial, when the trial judge can better estimate the impact of the evidence on the jury. *Id.* To the extent that a party challenges the probative value of the evidence, an attack upon the probative sufficiency of evidence relates not to admissibility but to the weight of the evidence and is a matter for the trier of fact to resolve. United States v. Beasley, 102 F.3d 1440, 1451 (8th Cir. 1996).

Under 35 U.S.C. § 112, "the written description inquiry looks to 'the four corners of the specification' to discern the extent to which the inventor(s) had possession of the invention as broadly claimed." Rivera, 857 F.3d at 1322 (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); see also Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1571 (Fed. Cir. 1997) ("It is the disclosures of the applications that count."). The knowledge of ordinary artisans may be used to inform what is actually in the specification, but not to teach

limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification. *Lockwood*, 107 F.3d at 1571–72.

C. Discussion

The court is inclined to believe that Hologic's challenges go more to the weight than admissibility of the evidence. At any rate, the court need not rule on Hologic's motion at this juncture because the challenged evidence is not particularly relevant to the motions presently under consideration by the court. The court did not rely on the testimony of any of the challenged witnesses in making its determination on the pending motions. Some of the testimony relates solely to damages and will be addressed via a proper motion at trial or in limine.

For the most part, the court finds Minerva's challenges are similarly in the nature of objections or are the proper subjects of motions in limine. Minerva's arguments go more to the weight than to admissibility of the challenged evidence. The court disagrees with Minerva's characterization of Leinsing's testimony with respect to 35 U.S.C. § 112 issues. Leinsing's testimony merely relates to the content of the specifications, not to teaching limitations that are not in the specifications. Similarly, Minerva's challenge to testimony on the Bernoulli principle is similarly unavailing. There is no serious dispute that the principle is a widely accepted principle of physics and fluid dynamics that is verified in other testimony and exhibits. The motions to preclude will be denied at this time without prejudice to reassertion.

With respect to Minerva's motion to preclude opinions on copying and independent development, the court finds Minerva's position is misplaced. Minerva concedes that Leinsing never states that the Minerva EAS is a copy of the NovaSure system and Minerva's own technical expert expressed an opinion similar to that of Leinsing. (D.I. 292–2, Hologic Ex. 30, Rebuttal Declaration of Robert Tucker, M.D., ¶ 54.) ("Minerva's EAS is not identical to, substantially similar to, or a copy of the NovaSure, and in fact incorporates Minerva's own patentably-distinct technology.")

Again, the issue is moot for purposes of the present motion because the court did not consider the challenged information in connection with its determination. Accordingly, Minerva's motion will be denied, without prejudice to reassertion at trial to the extent that Leinsing's testimony remains relevant to issues in the trial.

Minerva also challenges Hologic's expert Christopher C. Barry's damages testimony. It contends he failed to apply the correct lost profits standards or the correct reasonable royalty standards.

The court is unable to evaluate the relevance of the challenged evidence in the context of a pretrial motion. Minerva's concerns may warrant a cautionary or limiting instruction, but the court cannot determine the ambit of such an instruction at this time. The court will admit the evidence at issue only on a showing that it is relevant to the issues in the case, is proper under the law, and only to the extent that the relevance of the evidence outweighs its potential to cause prejudice or confusion under Fed. R. Evid. 403. The court finds the motion can be adequately resolved at trial, either in a hearing immediately prior to commencement of the trial, as an objection with a sidebar, or with a review of the evidence outside the presence of the jury. Accordingly, the court finds that Minerva's motion to preclude expert opinions should be overruled at this time, without prejudice to its reassertion via timely objection to the admissibility of such evidence at trial.

Minerva's also moves to strike the supplemental expert declaration of Karl Leinsing. (D.I. 317.) Minerva contends the report is untimely and argues it has been prejudiced by having prepared and submitted its opening summary judgment and Daubert briefing in reliance on the timely Leinsing reports and deposition, only to be blindsided by new opinions based on new evidence raised for the first time in the Supplemental Leinsing Declaration. The court again finds the evidence is not particularly relevant and notes that Minerva had an opportunity to respond to any new information in its reply briefing. Further, the court notes that Minerva could have moved to reopen discovery in order to re-depose Leinsing, if necessary. The court is inclined to agree with Hologic that the allegedly new information merely elaborates on Leinsing's ultimate opinions. The court did not rely on the new information and finds the motion should be denied as most without prejudice to reassertion to the extent the opinions remain relevant to issues in the trial.

IV. Motions for Summary Judgment

A. Hologic's Motion for Summary Judgment on Assignor Estoppel (D.I. 289).

1. Background

In response to Minerva's motion to dismiss, and in support of its motion for summary judgment, Hologic argues that the court should find as a matter of law that Minerva's invalidity defenses and counterclaims are barred by assignor estoppel.

Undisputed evidence shows that Truckai founded Minerva. He used his expertise to research, develop, test, manufacture, and obtain regulatory approval for the Minerva EAS. It is undisputed that Truckai's job responsibilities as Minerva's President and CEO included bringing the accused product to market to directly compete with Hologic. Hologic contends the accused product incorporates the same patented technology that Truckai's company sold to Hologic. It is undisputed that Truckai, an inventor on each of the Patents-in-Suit, executed broad assignments of his inventions to NovaCept, which was then sold to Hologic's predecessor for \$325 million dollars.

Hologic contends that the balance of equities strongly favor a finding of privity and the application of assignor estoppel in light of Truckai's role as Minerva's founder, his efforts to invent, develop, test, and manufacture the accused device, and his broad executive leadership of Minerva. In essence, it argues that—more than 19 years after Mr. Truckai executed his initial patent assignment—Minerva and Truckai attempt to destroy the value of what Truckai sold to Hologic so that Minerva can directly compete with Hologic using the patented technology he already sold to Hologic.

1. Law

Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity. Diamond Sci. Co. v. Ambico, Inc., 848 F.2d 1220, 1224 (Fed. Cir. 1988) (recognizing "the implicit representation by the assignor that the patent rights that he is assigning (presumably for value) are not worthless.... To allow the assignor to make that representation at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee.") The doctrine of

assignor estoppel is applied "to prevent unfairness and injustice." *Id.* "[A]n assignor should not be permitted to sell something and later assert that what was sold is worthless, all to the detriment of the assignee." *Diamond*, 848 F.2d at 1224. "[A]ssignor estoppel prevents an assignor from asserting that its own patent, for which it may have received value upon assignment, is invalid and worthless." *Pandrol USA*, *LP v. Airboss Ry. Prod.*, *Inc.*, 424 F.3d 1161, 1167 (Fed. Cir. 2005). The Federal Circuit recently reaffirmed the "continued vitality of the doctrine of assignor estoppel." *Mentor Graphics Corp. v. EVE–USA*, *Inc.*, 851 F.3d 1275, 1283 (Fed. Cir. 2017) (citations omitted).

Assignor estoppel also operates to bar other parties in privity with the assignor, such as a corporation founded by the assignor. Diamond, 848 F.2d at 1224. "Privity, like the doctrine of assignor estoppel itself, is determined upon a balance of equities." Shamrock Techs. Inc. v. Med. Sterilization, Inc., 903 F.2d 789, 793 (Fed. Cir. 1990). "In other words, '[i]f an inventor assigns his invention to his employer company A and leaves to join company B, whether company B is in privity and thus bound by the doctrine will depend on the equities dictated by the relationship between the inventor and company B in light of the act of infringement." Juniper Networks, Inc. v. Palo Alto Networks, Inc., 15 F.Supp.3d 499, 509 (D. Del. 2014) (quoting Shamrock Techs., 903 F.2d at 793). "The closer that relationship, the more the equities will favor applying the doctrine to company B." *Id*.

Status as the founder of a company is generally "dispositive of the issue of privity." *Juniper Networks*, 15 F.Supp.3d at 508; see also Diamond, 848 F.2d at 1224; *Synopsis, Inc. v. Magma Design Automation, Inc.*, C-04-3923 MMC, 2005 WL 1562779, at *4-5 (N.D. Cal. July 1, 2005); *Vitronics Corp. v.*

Conceptronic, Inc., No. C-91-696-L, 1992 WL 515321, at *4-5 (D.N.H. July 20, 1992) ("no question that privity is established" for founder and executive officer); Nortel Networks Inc. v. Foundry Networks, Inc., No. 01-CV-10442-DPW, 2003 WL 26476584, at 8– 9 (D. Mass. March 24, 2003). Assignor estoppel was not designed to prevent companies from competing for talented employees; rather, it was intended to prevent the assignor (whether acting individually or through another entity) from "making [a] representation [of the patent's validity at the time of assignment (to his advantage) and later . . . repudiat[ing] it (again to his advantage)." Acushnet Co. v. Dunlop Maxfli Sports Corp., No. CIV. A. 98-717-SLR, 2000 WL 987979, at *3 (D. Del. June 29, 2000) (quoting *Diamond*, 848 F.2d at 1224).

Assignor estoppel generally arises in the context of an anticipation or obviousness defense. Diamond, 848 F.2d at 1224; see also Babcock v. Clarkson, 63 F. 607, 609 (1st Cir.1894) (stating "[T]he estoppel historically has applied to invalidity challenges based on 'novelty, utility, patentable invention, anticipatory matter, and the state of the art.") However, the doctrine has also been applied with reference to a § 112 defense. Pandrol USA, LP v. Airboss Ry. Prods., Inc., No. 99-0182-CV-W-SOW, 2003 WL 24272366, at *1 (W.D. Mo. Oct. 15, 2003), aff'd, 424 F.3d 1161 (Fed. Cir. 2005). Assignor estoppel does not limit an assignor's ability to defend a subsequent patent suit in ways other than challenging validity. *Mentor Graphics Corp.* Quickturn Design Sys., Inc., 150 F.3d 1374, 1379 (Fed. Cir. 1998). The assignor is permitted to introduce evidence of prior art to narrow the scope of the assigned patent's claims in an effort to show that the accused device falls outside the scope of the assigned patent, and assignor estoppel does not preclude the estopped party from arguing that the patentee is itself collaterally estopped from asserting a patent found invalid in a prior proceeding. *Id.* at 1380. An estopped party may also argue for a narrow claim construction, or that the accused devices are within the prior art and therefore cannot infringe. *Id.* at 1379–80.

3. Discussion

Considering the balance of equities and the relationship of Truckai to Minerva, the court first finds privity between Truckai and Minerva. It is clear that Truckai executed a broad assignment of his patent rights to NovaCept and later sold NovaCept to Hologic's predecessor for \$325 million dollars. Minerva does not seriously dispute those facts. It argues instead that the doctrine is not applicable to bar a § 112 defense. It relies on a balance-of-equities argument, contending Hologic attempts to assert overly broad claims and therefore keep Minerva's competing product out of the market.

The court finds Minerva's overly broad claims argument is effectively foreclosed by the court's adoption of Hologic's claim construction. Considering the balance of equities and the relationship of Minerva and Truckai, the evidence demonstrates that Truckai is in privity with Minerva, therefore, assignor estoppel applies to Minerva's defenses to Hologic's patent infringement claims.

B. Cross-motions for Summary Judgment on the Issue of Validity (D.I. 277 and 287)

1. Background

Minerva contends that all the asserted claims are invalid for failure to meet the written description and enablement requirements of 35 U.S.C. § 112. It raises the same or similar arguments that it raised in

connection with claim construction, again arguing the distinction between a flow sensor and a pressure sensor and comparing the Patents-in-Suit to its own patents for the accused EAS and, in particular, to its Uterine Integrity Test (UIT). Hologic contends it is entitled to a summary judgment of "no invalidity," arguing that Minerva is not applying the court's claim construction in its analysis.

2. Law

The burden is on the party challenging the validity of a patent to show invalidity by clear and convincing evidence. *Impax Labs., Inc. v. Aventis Pharma., Inc.,* 545 F.3d 1312, 1314 (Fed. Cir. 2008). A patent specification must contain an adequate written description. 35 U.S.C. § 112, ¶ 1. Under 35 U.S.C. § 112, the specification is required to "contain 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 make and use the same." 35 U.S.C. § 112.

The written description "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation and quotations omitted); see Streck, 665 F.3d at 1285. The test is whether the disclosure "conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Id. "This test requires an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." Id. (quoting Ariad, 598 F.3d at 1351. "Given this perspective, in some instances, a patentee can rely on information that is 'well-known in the art' to satisfy written description." Id.; see

Boston Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1366 (Fed. Cir. 2011).

"It is well-established that the 'hallmark of written description is disclosure.' "Streck, 665 F.3d at 1285 (quoting Ariad, 598 F.3d at 1351). "The level of detail required to satisfy the written description requirement depends, in large part, on the nature of the claims and the complexity of the technology." Id. "'Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party.' "Id. (quoting PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

The claims as filed are part of the specification, and may provide or contribute to compliance with § 112. *Id*. Minutiae of descriptions or procedures perfectly obvious to one of ordinary skill in the art, yet unfamiliar to laymen, need not be set forth. *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998). Missing subject matter in a description can be shown to be part of the prior art that would be understood as part of the description of the subject matter of the count. *Id*.

There is no requirement that a patent describe the unclaimed features of the infringing product. See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1333 (Fed. Cir. 2003). "[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003). "Not every claim must contain every limitation or achieve every disclosed purpose." ScriptPro LLC v. Innovation Assocs., Inc., 833 F.3d 1336, 1342 (Fed. Cir. 2016).

"Enablement 'is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention.' "Streck, 665 F.3d at 1288 (quoting Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) (citation omitted)). "To be enabling, a patent's specification must 'teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' "Id. (quoting ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) (citations omitted)). It is well-established, however, that a specification need not disclose what is well-known in the art. Id.; see Hybritech, 802 F.2d at 1384 ("[A] patent need not teach, and preferably omits, what is well known in the art.").

The asserted claims rather than the accused device must be "enabled" by the patent-in-suit. Edwards Lifesciences AG v. CoreValve, Inc., C.A. No. 08-91-GMS, 2011 WL 446203, at *6 (D. Del. Feb. 7, 2011); see Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306 (Fed. Cir. 2001)). The enablement requirement is met if any mode of making and using the invention is disclosed. See Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005).

"The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.' "Streck, 665 F.3d at 1288 (quoting In re Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988) (setting forth the following factors to consider when determining whether a disclosure requires undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims). "'[I]t is not necessary that a court review all the Wands factors to find a disclosure enabling. They are illustrative, not mandatory.'" *Id.* (quoting *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)).

3. Discussion

The court finds Minerva's invalidity defenses are barred by assignor estoppel. However, even if Minerva were not estopped from raising the defense, the court would find Minerva's motion for a summary judgment of invalidity lacks merit.

Minerva's argument that the Patents-in-Suit had to provide written description and enablement of the accused devices plasma formation feature is unavailing. The claims at issue herein do not recite a plasma formation feature. Minerva's emphasis on the accused device and its plasma formation feature reflects its misguided notion that the improvements over the claimed material (the plasma formation feature) would have to have been disclosed. That an accused product might include other, un-claimed features does not mean the accused product avoids infringement.

Similarly, the court rejects Minerva's argument that undue experimentation would be required to practice the invention. Minerva failed to produce evidence that the experimentation required to create surgical instruments and methods for use in endometrial ablation such as those described in the claims of the Patents-in-Suit would be unduly laborious for one of ordinary skill in the art. The evidence shows that any such experimentation would involve repetition of commonly known or used techniques and application of techniques well known in the art. Minerva's expert's

testimony on the subject does not controvert Hologic's testimony that a person of ordinary skill in the art would have known that a flow sensor could be used as a pressure sensor. Conclusory expert assertions do not give rise to a genuine issue of material fact.

The court already rejected Minerva's argument that exemplary embodiments define "the invention" and require a "moisture transport system" with a "permeable external array" during the claim construction phase. Minerva's other criticisms for the descriptions are also directed at exemplary embodiments and raise previously rejected arguments that would serve to improperly limit that claims.

The court finds Minerva's Section 112 arguments rest on a flawed definition of the claims that ignores the court's claim constructions. Minerva has not satisfied its burden of showing invalidity by clear and convincing evidence. No reasonable jury could find that Minerva has met its burden of proving by clear and convincing evidence that the claimed "applicator head," "indicator mechanism" and "one or more electrodes" are not properly described or enabled in the asserted claims of the Patents-in-Suit. Minerva's arguments with respect to undue experimentation focus on the amount of experimentation necessary to make Minerva's EAS, which is not the relevant enablement analysis.

Hologic, on the other hand has shown that the '183 and '348 Patent disclosures adequately describe the claims as construed by the court. The relevant enablement analysis is whether the specification teaches how to make and use a system that performs the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal. The patent

disclosure reasonably conveys to a person of ordinary skill in the art that the inventors had possession of "[a] distal end portion of an ablation device that applies energy to the uterine tissue" including "[o]ne or more electrical conductors" and "[a]n applicator of an ablation device that delivers energy to the uterine tissue."

The court finds no reasonable jury could find that Minerva can meet its clear and convincing evidence burden of showing that the claims of the Patents-in-Suit do not describe monitoring for the presence of a perforation in the uterus using a pressure sensor. Accordingly, the court finds Hologic's motion for a summary judgment of no invalidity should be granted and Minerva's corresponding motion should be denied.

C. Minerva's Motion for Summary Judgment on the Doctrine of Equivalents and Prosecution History Estoppel. (D.I. 278, Brief at 44–47)

1. Background

Minerva argues that prosecution history shows that the Patent Examiner rejected Hologic's pending claims as obvious under 35 U.S.C. § 103, and therefore invalid over prior art in August 2015. In response to the rejection Hologic, among other things, struck "a handle coupled to the proximal portion" from pending claim 19 (later issued as Claim of the '348 patent), and replaced it with more detail about the handle including: "wherein the handle comprises a proximal grip and a distal grip pivotally attached to one another at a pivot point." D.I. 278 at 45. Minerva contends that Hologic elected to narrow the scope of what issued

¹² Minerva raises a similar argument with respect to the '989 Patent, but that Patent is no longer at issue.

as independent claim 1 of the '348 Patent by adding the "pivot point" limitation in order to overcome the prior art rejection and secure the patent, and accordingly, prosecution history estoppel operates to foreclose Hologic from relying on the doctrine of equivalents to allege infringement.

Hologic contends that Minerva seeks an improper advisory opinion in connection with this argument. It argues that the device with Minerva's new pivot handle is not an accused product because it has not been commercialized.

2. Law

The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. Id. at 733, 122 S.Ct. 1831. "Estoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'" Id. (quoting Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 220–221, 312 U.S. 654, 61 S.Ct. 235, 85 L.Ed. 132 (1940)). The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes. Id. "When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." Id. "On the contrary, "[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,]... and [t]he difference which [the patentee] thus disclaimed must be regarded as material." *Id.* (quoting *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136–137, 62 S.Ct. 513, 86 L.Ed. 736 (1942)). The Supreme Court has "consistently applied prosecution history estoppel only where claims have been amended for a limited set of reasons,' such as 'to avoid the prior art, or otherwise to address a specific concern—such as obviousness—that arguably would have rendered the claimed subject matter unpatentable." *Id.* (quoting *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30–32, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope. Festo Corp., 535 U.S. at 736, 122 S.Ct. 1831. If a § 112 amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. Id. at 736–37, 122 S.Ct. 1831. On the other hand, if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply. Id. A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112. Id. at 737, 122 S.Ct. 1831. The patentee is regarded as "having conceded an inability to claim the broader subject matter or at least as having abandoned his right to appeal a rejection." Id.; see O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1366 (Fed. Cir. 2008) (finding that the "district court erred in allowing the jury to find infringement under the doctrine of equivalents" because PHE applied). "Such argument-based disavowals will be found, however,

only if they constitute clear and unmistakable surrenders of subject matter." *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008).

3. Discussion

Minerva's motion is directed at the pivot-point limitation of the '348 Patent. It argues that "[b]ecause Hologic elected to narrow the scope of what issued as independent claim 1 of each of the '348 and '989 by adding the 'pivot point' limitation in order to overcome the prior art rejection and secure the patent, PHE forecloses Hologic from now relying on the DOE in litigation to allege infringement." The court finds no clear and unmistakable surrender of all equivalents to the pivot point limitation. Further, the court is not convinced that the added detail is more than tangential to patentability. Notably, the limitation relates more to the '989 Patent, which is no longer at issued, than to the '348 Patent. Moreover, the court agrees with Hologic's position that a ruling on the purported handle redesign would be an improper advisory opinion since the product is not being marketed and is not alleged to be infringing Hologic's patent. The court need not address whether Minerva's "new" handle design would infringe Hologic's '348 Patent because that design is not at issue. Minerva has not shown it is entitled to summary judgment on the issue.

> D. Cross-Motions for Summary Judgment on the Issue of Infringement (D.I. 277 and 288)

1. Background

Hologic moves for summary judgment in the issue of infringement, contending that Minerva has failed to raise a genuine issue of fact to counter the court's finding that evidence submitted in preliminary injunction proceedings supports a prima facie showing of infringement. It argues that there is no genuine dispute that the Minerva EAS embodies apparatus claim 1 of the '348 Patent. Claim 1 comprises a preamble and five limitations. Hologic argues that only the fifth limitation, "an indicator mechanism configured to indicate a dimension of the uterus" is at issue and contends that the Minerva "PFA Width Indicator" is such an indicator mechanism that measures a dimension of the uterus. Further, it argues that it is undisputed that Minerva's EAS infringes the asserted claims of the '183 Patent in that it detects perforations using a pressure sensor.

Minerva contends that a summary judgment of no infringement is warranted because Hologic cannot show that Minerva's UIT meets the court's construction of "pressure sensor" for at least two reasons: (1) the flow sensor's "input" does not "detect[], directly or indirectly, a force per unit area"; and (2) its "output" is not "a corresponding electrical signal," as the court's construction requires. It also contends the UIT does not perform the monitoring step using a pressure sensor as the claim requires. Minerva's arguments are premised on its contention that Minerva's flow sensor detects a flow rate—not a pressure at its input.

In its earlier order, the court stated:

"Pressure sensor." The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/ signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over

a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." ('183 patent, 2:36–44) The pressure sensor "monitors pressure in the pressure signal line... and delivers the signal to the microprocessor." (*Id.* at 5:23–25) The specification explains that during testing "[w]hen the pressure at gauge 84 rises and remains above 50 mmHg for 4 seconds, the test has passed." (*Id.* at 6:44–46)

(D.I. 127, Memorandum Order at 13–14. The court went on to find:

Hologic has identified Minerva EAS' flow meter as meeting the "pressure sensor" limitation. Minerva argues that the flow meter does not measure pressure (differential or otherwise) to operate and its output is not a pressure measurement. (D.I. 86 at 8–11) Minerva EAS' operator manual describes a "uterine integrity test" aimed at detecting perforations. (D.I. 12, ex. 11 at 9, 33) Minerva's expert, Dr. Tucker, testified, "[a]s the pressure goes down, the flow rate goes up. As the pressure goes up, the flow rate goes down." (D.I. 115, ex. 2) at 64:17–20) The design documents for Minerva EAS state that "if the uterine cavity and the system is perforation free, gas used to insufflate the uterine cavity will stop flowing once the gas pressure in the uterine cavity matches the supply pressure." (D.I. 87, ex. 82 at 2337) The court concludes that the evidence supports a prima facia showing of infringement.

(Id. at 14) (footnotes omitted).

2. Law

The patentee has the burden of proving infringement by a preponderance of the evidence. *Centricut*, *LLC v. Esab Group*, *Inc.*, 390 F.3d 1361, 1367 (Fed.

Cir. 2004). Patent infringement and invalidity are two separate issues. See Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1583 (Fed. Cir. 1983) (stating that "[t]hough an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity.").

The determination of infringement is a two-step process: first, the court construes the asserted claims as a matter of law to determine their meaning, and second, the trier of fact compares the properly construed claims to the accused product to determine whether it contains each limitation of the claims, either literally or under the doctrine of equivalents. Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1338 (Fed. Cir. 2003). Application of the claim to the accused device is a question of fact. Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc., 246 F.3d 1336, 1345 (Fed. Cir. 2001). The infringement inquiry remains focused at all times on the claim language, as illuminated by the written description and the prosecution history. Id. at 1345-46. "[I]t is elementary patent law that a patent may issue on an improvement which infringes another's patent." Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 669 (Fed. Cir. 1988).

Although it has not stated a *per se* rule, the Federal Circuit has noted that "relevant expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential" to the infringement inquiry. *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1369–70 (Fed. Cir. 2004) (holding that a patentee could not withstand summary judgment on the issue of literal infringement in a case involving complex technology in the absence of expert testimony). "'[T]ypically expert testimony will be

necessary in cases involving complex technology." *Id.* at 1370.

3. Discussion

The court finds that Minerva's non-infringement arguments were essentially mooted when the court rejected Minerva's erroneous claim constructions. Minerva's arguments for non-infringement all depend on claim construction that is contrary to the court's construction. Applying the court's construction, Hologic has shown that Minerva's accused product infringes the asserted claims of the patents. Minerva's non-infringement arguments go to differences in or additions to its device that are not claimed in the patents, but are improvements.

The court's construction of the term "pressure sensor" in claim 9 of the '183 Patent as "[a] device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal" is determinative. Minerva contends the claim requires directly detecting a force per unit area. Nothing in the specification requires the pressure sensor to measure pressure directly or to convert to a unit of measure. The undisputed facts show that use of the Minerva EAS practices the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

Bernoulli's equation is a well-known principle of fluid dynamics that would have been known to persons of ordinary skill in the art at the time of the invention. Minerva's expert conceded that a person of ordinary skill in the art in 1998 would have known that it was "just a fundamental law of fluid dynamics" that there would have to be a pressure differential to generate

flow. The equation describes the physical relationship between pressure and flow rate and, therefore, it shows that Minerva's use of a flow meter involves "indirectly" detecting pressure. Minerva's flow sensor, in conjunction with the orifice, is a pressure sensor because it indirectly detects pressure via flow rate.

Minerva does not dispute that use of the Minerva EAS practices all of the remaining limitations of the asserted claims. No reasonable jury could find that the remaining steps in the method for ablating a uterus claimed in the patent—inserting an ablation device, flowing an inflation medium, and treating the disorder—are not performed when using the Minerva EAS. Also, Minerva does not dispute that use of the Minerva EAS prevents performance of the treating step until after the monitoring step has been carried out, as claimed in Claim 7 of the '183 Patent.

Claim 9 of the '183 Patent comprises a preamble and four limitations, only one of which is in serious dispute—"monitors for the presence of a perforation in the uterus using a pressure sensor." Minerva does not dispute that use of the Minerva EAS practices a method of detecting a perforation in a uterus or that use of the Minerva EAS practices the step of "passing an inflation medium into the uterus" or the steps of then permitting or preventing the ablation, depending on detection of a perforation. Minerva's argument with respect to monitoring with a pressure sensor is again precluded by the court's claim construction. Further, Minerva does not dispute that practicing the Minerva EAS includes activating a notification signal alerting the user to the presence of a perforation in the uterus included in claim 11 or introducing the inflation medium using the ablation device as recited in Claim 13 or using an RF ablation device as recited in Claim 14 of the '183 Patent.

Minerva's reliance on elements of its device—i.e., use of argon gas and plasma energy—to differentiate its device is unavailing. Those elements are not claimed by Hologic. Minerva's argument that Minerva EAS embodies Minerva's patent (U.S. Patent No. 8,343,078) is relevant but is not dispositive of the issue of infringement. National Presto Indus., Inc. v. West Bend Co., 76 F.3d 1185, 1192 (Fed. Cir. 1996) (stating "[t]he grant of a separate patent on the accused device does not automatically avoid infringement, either literal or by equivalency. Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may or may not avoid infringement of the prior patent."). That an infringer may patent improvements to an invention does not negate the fact of infringement.

The evidence shows that Minerva has directly infringed the asserted claims of the '183 and '348 Patents by having its paid consultants perform infringing endometrial ablations in its promotional videos. Further, it produces operating manuals, instructions for use, instructional videos, training materials, and on-site training on how to use the Minerva EAS that infringes the Patents. Also, Minerva clearly induces and contributes infringement by its customers. Minerva's customers infringe by using Minerva's included components for their intended purpose consistent with Minerva's instructions.

Consistent with the court's claim construction, the court finds that undisputed evidence in the record establishes that Minerva has infringed the asserted claims of Hologic's patents. Accordingly, the court finds that Hologic's motion for summary judgment on

the issue of infringement should be granted and Minerva's corresponding motion should be denied.

E. Minerva's Motion for Summary Judgment on Unfair Competition (D.I. 277)

1. Background

Minerva moves for summary judgment on Hologic's unfair competition claims. Minerva states that all four of Hologic's unfair competition claims hinge on the same theory—i.e., that Minerva's sales staff deceptively described Minerva's EAS as the "new NovaSure," "NovaSure 2.0" and/or is from "the makers of NovaSure." It asserts that Hologic's claims fail as a matter of law because Hologic has failed to produce or elicit any evidence supporting its allegations of deceptive statements, and cannot establish causation or harm. Minerva also argues that any allegedly disparaging comments were mere puffery.

Hologic contends the motion should be denied because Minerva has not addressed its claim relating to disparagement. It further argues that it has shown a likelihood of confusion as a result of Minerva's alleged conduct. It argues, at the least, a jury should resolve the issue of whether there is a likelihood of confusion.

¹³ In its amended complaint, in addition to its Lanham Act claim, Hologic asserted claims for deceptive trade practice under Delaware statutory and common law alleging Minerva "has engaged in and continues to engage in conduct that disparages the prior NovaSure systems" and was likely to cause confusion; unfair competition under Delaware common law, alleging the defendant wrongfully interfered with business relationships by targeting Plaintiffs' existing customers and disparaging the prior NovaSure systems and tortious interference with a business relationship under Delaware common law.

Hologic has presented evidence that Minerva's employees obtained Hologic's confidential and proprietary data and information and circulated it to the sales team. There is also evidence that Minerva employees made allegedly disparaging remarks about Hologic to potential customers, hired former NovaSure sales representatives, used misleading sales tactics and allegedly advised customers to break Hologic contracts.

2. Law

Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), prohibits false designations of origin, false descriptions, and dilution. The Act creates "two distinct bases of liability: false association . . . and false advertising." Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 134 S.Ct. 1377, 1384, 188 L.Ed.2d 392 (2014). Subsection (a)(1)(B) forbids "commercial advertising or promotion" that "misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities[.]" 15 U.S.C. $\S 1125(a)(1)(B)$. To prove a violation under the statute. a plaintiff must prove that it has a valid, protectable trademark; owns rights to the mark; the defendant used the mark in interstate commerce; without the consent of the defendant in a manner that is likely to cause confusion among ordinary purchasers as to the source of the product and the defendant's use of the mark caused an injury to the plaintiff's commercial interest in sales or business reputation. 15 U.S.C. § 1125(a)(1)(A); see Lexmark Int'l, Inc. 134 S.Ct. at 1384; Parks LLC v. Tyson Foods, Inc., 863 F.3d 220, 230 (3d Cir. 2017). The Lanham Act's "likelihood of confusion" standard is predominantly factual in nature, making summary judgment inappropriate when a jury could reasonable conclude that there is a likelihood of confusion. NTP Marble, Inc. v. AAA Hellenic Marble, Inc., No. 09-CV-05783, 2012 WL 607975, at *7 (E.D. Pa. Feb. 27, 2012) (same).

The Delaware Deceptive Trade Practices Act ("DTPA") prohibits "disparage[ment] of the goods, services or business of another by false or misleading representations of fact," committed "in the course of a business, vocation, or occupation or that generally "creates a likelihood of confusion or of misunderstanding." 6 Del. C. §§ 2532(a)(8) & (a)(12). "The DTPA has a lower burden of proof than the Lanham Act since 'a complainant need not prove competition between the parties or actual confusion or misunderstanding' to prevail in an action under the DTPA, 6 Del. C. § 2532(b)." Keurig, Inc. v. Strum Foods, Inc., 769 F.Supp.2d 699, 712 (D. Del. 2011). The Act is intended to address unfair or deceptive trade practices that interfere with the promotion and conduct of another's business. Wright v. Portfolio Recovery Affiliates, No. CIV.A. 09-612-GMS, 2011 WL 1226115, at *5 (D. Del. Mar. 30, 2011).

3. Discussion

The court's review of the materials submitted in support of and against Minerva's motion show that there are genuine issues of material fact on several issues essential to resolution of the deceptive trade practices claims and counterclaims. There are issues of fact on the nature and extent of alleged misrepresentations and/or disparagement, deception, and the likelihood of confusion. Resolution of those issues requires assessments of credibility. Accordingly, Minerva has not shown it is entitled to summary judgment on Hologic's deceptive trade practices claims. The court finds the motion should be denied.

F. Minerva's Motion for Summary Judgment on Willfulness (D.I. 277)

1. Background

Minerva contends there are no genuine issues of material fact on the issue of willful infringement. It contends the patents did not issue until after Minerva had developed the accused product and Hologic has not produced evidence of deliberate copying.

Hologic argues that it does not seek pre-issuance damages, but is relying on Minerva's pre-issuance conduct to support its showing of willful infringement. It also argues that there are genuine issues of fact on issues of copying, knowledge, investigation, and good faith.

2. Law

Enhanced damages under 35 U.S.C. § 284 "are not to be meted out in a typical infringement case, but are instead designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior." *Halo Elecs., Inc.* v. Pulse Elecs., Inc., — U.S. —, 136 S.Ct. 1923, 1932, 195 L.Ed.2d 278 (2016). The award of enhanced damages is limited to egregious cases of misconduct beyond typical infringement. Id. at 1935. "As with any exercise of discretion, courts should continue to take into account the particular circumstances of each case in deciding whether to award damages, and in what amount." Id. at 1933.

The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless. *Id.* at 1933; see WesternGeco L.L.C. v. ION Geophysical Corp., 837 F.3d 1358, 1362 (Fed. Cir. 2016) (stating "Halo emphasized that subjective willfulness alone—i.e., proof that the

defendant acted despite a risk of infringement that was 'either known or so obvious that it should have been known to the accused infringer,'—can support an award of enhanced damages" (quoting *Halo*, 136 S.Ct. at 1930)(internal citations omitted)).

"'[W]hether an act is 'willful' is by definition a question of the actor's intent, the answer to which must be inferred from all the circumstances." WCM Indus., Inc. v. IPS Corp., 721 F. App'x 959, 970 (Fed. Cir. 2018) (quoting Gustafson, Inc. v. Intersystems Indus. Products, Inc., 897 F.2d 508 (Fed. Cir. 1990)). There is no per se rule that a finding of willful infringement cannot stand whenever manufacture of an accused device begins prior to the issuance of a patent, instead courts must look to the totality of the circumstances presented in the case. Id.; see also ACCO Brands, Inc. v. ABA Locks Mfrs., 501 F.3d 1307, 1312 (Fed. Cir. 2007) (noting that the willfulness inquiry is one of fact and "is determined from the totality of the circumstances.").

3. Discussion

The court finds there are genuine issues of fact with respect to willfulness. There is evidence from which a jury could find Minerva acted despite a risk of infringement that was either actually known or was so obvious that it should have been known to Minerva. Resolution of the issue involves a determination of intent and credibility. These are issues for the fact-finder. Accordingly, the court finds Minerva's motion for summary judgment should be denied.

An appropriate order will issue this date.

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APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2019-2054, 2019-2081

Hologic, Inc., Cytyc Surgical Products, LLC,

Plaintiffs-Appellants,

v.

MINERVA SURGICAL, INC.,

Defendant-Cross-Appellant.

Appeals from the United States District Court for the District of Delaware in No. 1:15-cv-01031-JFB-SRF, Senior Judge Joseph F. Bataillon.

ON PETITIONS FOR PANEL REHEARING AND REHEARING EN BANC

NOTE: This order is nonprecedential.

Before Prost, *Chief Judge*, Newman, Lourie, Clevenger*, Dyk, Moore, O'Malley, Reyna, Wallach, Taranto, Chen, Hughes, and Stoll, *Circuit Judges*.

^{*} Circuit Judge Clevenger participated only in the decision on the petitions for panel rehearing.

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PER CURIAM.

ORDER

Cross-Appellant Minerva Surgical, Inc. filed a combined petition for panel rehearing and rehearing en banc. Appellants Hologic, Inc. and Cytyc Surgical Products, LLC separately filed a petition for rehearing en banc. Responses to both petitions were invited by the court and filed by the parties. The petitions were referred to the panel that heard the appeal, and thereafter the petitions for rehearing en banc were referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petitions for panel rehearing are denied.

The petitions for rehearing en banc are denied.

The mandate of the court will issue on July 29, 2020.

FOR THE COURT:

July 22, 2020 Date

/s/ Peter R. Marksteiner Peter R. Marksteiner Clerk of Court