IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CONFLUENT SURGICAL, INC., INTEGRA LIFESCIENCES CORPORATION AND INTEGRA LIFESCIENCES SALES LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 17-688-LPS-CJB
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Pending before the Court in this patent case is a motion filed pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6) and 12(f) by Plaintiffs/Counterclaim-Defendants Confluent Surgical, Inc. ("Confluent"), Integra Lifesciences Corporation and Integra Lifesciences Sales LLC (collectively, "Plaintiffs"), seeking an order dismissing and/or striking portions of Defendant/Counterclaim-Plaintiff HyperBranch Medical Technology, Inc.'s ("Defendant" or "HyperBranch") Amended Answer and Counterclaims (the "Motion"). (D.I. 148) For the reasons that follow, the Court recommends that the Motion be DENIED.

I. BACKGROUND

This is a patent case arising from Plaintiffs' allegations that Defendant infringes seven of Plaintiffs' patents. Those patents are United States Patent Nos. 9,517,478 (the "'478 patent"), 8,210,453 (the "'453 patent"), 8,876,021 (the "'021 patent"), 8,033,483 (the "'483 patent"), 8,616,468 (the "'468 patent"), 9,101,946 (the "'946 patent"), and 9,700,290 (the "'290 patent") (collectively, "the asserted patents" or "the patents-in-suit").

These seven asserted patents can be separated into two "families." The "Family 1 Patents" consist of two patents—the '483 patent and the '021 patent; these patents' disclosures

are similar and the patents are both entitled "Silicone Spray Tip." (D.I. 40, exs. C-D) The '483 patent was filed on April 22, 2009 and is the grandparent of the '021 patent, filed on February 4, 2013. (*Id.*) Both Family 1 Patents claim priority to U.S. Provisional Patent Application No. 61/047,826, filed on April 25, 2008, and both Family 1 Patents list Jason Fortier ("Fortier"), Les Hull ("Hull"), and Arthur Driscoll ("Driscoll") as the inventors (collectively, the "inventors"). (*Id.*) The "Family 2 Patents" consist of five patents—the '453 patent, the '468 patent, the '946 patent, the '478 patent, and the '290 patent; these patents are all entitled "Spray Applicator" and their specification disclosures are essentially identical. (*Id.*, exs. A-B, E-F, Q) All Family 2 Patents claim priority to U.S. Provisional Patent Application No. 61/096,345, filed on September 12, 2008. (*Id.*) All Family 2 Patents list Hull and Fortier as the inventors. (*Id.*) The '453 patent is the eldest of the Family 2 Patents and was filed on September 8, 2009. (*Id.*, ex. B) The '468 patent was filed on June 11, 2012 and is a child of the '453 patent. (*Id.*, ex. E) The '946 patent was filed on December 30, 2013 and is a child of the '468 patent. (*Id.*, ex. F) The '478 patent was filed on July 27, 2015 and is a child of the '946 patent. (*Id.*, ex. A) The '290 patent was filed on December 9, 2016 and is a child of the '478 patent. (*Id.*, ex. Q) Thus the path of ancestry goes: (oldest) '453 → '468 → '946 → '478 → '290 (newest).

Plaintiffs filed the instant case on June 6, 2017. (D.I. 1) Chief Judge Leonard P. Stark thereafter referred the case to the Court to hear and resolve all pretrial matters, up to and including case-dispositive motions. (D.I. 8)

Plaintiffs filed the currently-operative Second Amended Complaint ("SAC") on November 20, 2017. (D.I. 40) In the SAC, Plaintiffs are alleging that Defendant's Adherus AutoSpray Dural Sealant product and Adherus AutoSpray Extended Tip (ET) Dural Sealant product (the "accused products") infringe claims of the seven patents-in-suit. (*Id.*) The patents-

in-suit relate to applicator assemblies for mixing components of, for example, a polymer or synthetic material for use in internal and external wound closure, and for dispensing the resulting mixture of components for application, for example as a bioadhesive or tissue sealant. (*Id.* at ¶ 22)

Defendant's Amended Answer and Counterclaims, at issue here, was filed on January 11, 2019. (D.I. 137) In that pleading, Defendant asserts counterclaims seeking a declaratory judgment of non-infringement of each of the asserted patents (Counts I-VII), a declaratory judgment of invalidity of the asserted patents (Counts VIII-XIV), and a declaratory judgment of unenforceability of the asserted patents due to inequitable conduct (Counts XV-XXI). (*Id.* at ¶¶ 55-278) Defendant's counterclaims include, *inter alia*, allegations of non-infringement of two different configurations of the Adherus AutoSpray Extended Tip (ET) Dural Sealant product—the so-called "ET Baffle-1 Configuration" and the "ET Baffle-2 Configuration." (D.I. 137 at ¶¶ 56, 59, 62, 65, 68, 71, 74; *see also id.* at ¶¶ 13-29)[1]

Plaintiffs filed the instant Motion on January 28, 2019. (D.I. 149) With their Motion, Plaintiffs seek the following forms of relief:

- Dismissal of Defendant's inequitable conduct counterclaims (Counts XV-XXI) as insufficiently pleaded, pursuant to Rule 9(b) and 12(b)(6), and, relatedly, the striking of Defendant's Seventh Affirmative Defense of unenforceability due to inequitable conduct, pursuant to Rule 12(f);

- Striking of certain allegedly immaterial, impertinent and scandalous material from the Amended Answer and Counterclaims, pursuant to Rule 12(f); and

[1] Defendant's Amended Answer and Counterclaims is divided into two sets of sequentially-numbered paragraphs. (D.I. 137 at 1-12 (Answer and Affirmative Defenses), 13-87 (Counterclaims)) Unless otherwise specified, reference to "D.I. 137 at ¶¶ ##" refers to the paragraphs of the "Counterclaims" beginning on page 13.

- Dismissal of Defendant's non-infringement counterclaims relating to the ET Baffle-2 Configuration, pursuant to Rule 12(b)(1).

(D.I. 149 at 1-2) Briefing on the Motion was complete as of February 19, 2019. (D.I. 164)

II. STANDARD OF REVIEW

A. Motion to Dismiss Under Rule 12(b)(1)

A motion under Rule 12(b)(1) is a motion to dismiss for "lack of subject-matter jurisdiction[.]" Fed. R. Civ. P. 12(b)(1). Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *Kuhn Constr. Co. v. Diamond State Port Corp.*, Civ. No. 10-637-SLR, 2011 WL 1576691, at *2 (D. Del. Apr. 26, 2011). "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). "In reviewing a factual attack, the court may consider evidence outside the pleadings." *Id.*

The Declaratory Judgment Act requires that a "case of actual controversy" exist between the parties before a federal court may exercise jurisdiction. 28 U.S.C. § 2201(a). In *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the Supreme Court of the United States has held that jurisdiction over a declaratory judgment action requires a dispute that is:

> definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admi[t] of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. . . . Basically, the question in each case is *whether the facts alleged, under all the circumstances*, show that there is a substantial controversy, between parties having adverse legal interests, *of sufficient immediacy and reality* to warrant the issuance of a declaratory judgment.

549 U.S. at 127 (emphasis added, internal quotation marks and citations omitted) (noting that the Declaratory Judgment Act's requirement that a "'case of actual controversy'" exist is a reference to the types of cases and controversies that are justiciable under Article III); *see also Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1334 (Fed. Cir. 2008). A case or controversy thus must be "based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco, LLC*, 537 F.3d at 1339 (emphasis in original).

A decision as to whether an actual controversy exists in the context of a patent declaratory judgment claim "will necessarily be fact specific and must be made in consideration of all the relevant circumstances." *W.L. Gore & Assocs., Inc. v. AGA Med. Corp.*, Civil No. 11-539 (JBS-KMW), 2012 WL 924978, at *4 (D. Del. Mar. 19, 2012) (citing *MedImmune, Inc.*, 549 U.S. at 127). The burden is on the party asserting declaratory judgment jurisdiction (here, Defendant) to establish that an Article III case or controversy existed at the time that the claim for declaratory relief was filed and that it has continued since. *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1329 (Fed. Cir. 2014); *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, Civ. No. 12-1301-SLR, 2013 WL 1856308, at *2 (D. Del. May 2, 2013). Under the Declaratory Judgment Act, the Court is permitted, but not required, to hear a claim for declaratory relief. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997).

B. Motion to Dismiss Under Rule 12(b)(6)

When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11.

Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In assessing the plausibility of a claim, the court must "construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). As such, a well-pleaded complaint may not be dismissed simply because "it strikes a savvy judge that actual proof of [the alleged] facts is improbable, and that a recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (internal quotation marks and citation omitted). Determining whether a claim is plausible is "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679).

C. Motion to Strike Under Rule 12(f)

Defendant has asserted inequitable conduct here in two substantively identical but procedurally distinct forms—as both an affirmative defense and as a counterclaim. Rule 12(b)(6) does not offer a mechanism for dismissing an affirmative defense, and instead refers only to "claim[s]." Fed. R. Civ. P. 12(b)(6). However, pursuant to Rule 12(f), the Court "may strike from a pleading an insufficient defense[.]" Fed. R. Civ. P. 12(f). When ruling on a motion to strike, the court must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient under law. *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 301 (D. Del. 2013). Further, a court should not grant a motion to strike a defense unless the

insufficiency of the defense is clearly apparent. *Id.* (citing *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009)).

Rule 12(f) also provides that "[t]he court may strike from a pleading . . . immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "Immaterial matter is that which has no essential or important relationship to the claim for relief or the defenses being pleaded." *Delaware Health Care, Inc. v. MCD Holding Co.*, 893 F. Supp. 1279, 1291-92 (D. Del. 1995) (internal quotation marks and citation omitted). "Impertinent matter consists of statements that do not pertain, and are not necessary to the issues in question." *Id.* (internal quotation marks and citation omitted). Scandalous matter has been defined as "'that which improperly casts a derogatory light on someone, most typically on a party to the action.'" *Aoki v. Benihana, Inc.*, 839 F. Supp. 2d 759, 764 (D. Del. 2012) (quoting *Carone v. Whalen*, 121 F.R.D. 231, 233 (M.D. Pa. 1988)).

Motions to strike serve "to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." *The Penn Mut. Life Ins. Co. v. Norma Espinosa 2007–1 Ins. Tr.*, C.A. No. 09-300-LPS, 2011 WL 710970, at *4 (D. Del. Feb. 22, 2011) (internal quotation marks and citations omitted). And district courts are afforded "'considerable discretion'" when addressing such motions. *Yellow Book Sales & Distrib. Co. v. White*, Civil Action No. 10-3062, 2011 WL 830520, at *4 (E.D. Pa. Mar. 10, 2011) (citation omitted). However, granting a motion to strike is generally disfavored and considered to be "a drastic remedy to be resorted to only when required for the interests of justice." *Penn Mut. Life Ins.*, 2011 WL 710970, at *4 (internal quotation marks and citation omitted). When ruling on a motion to strike, the court must construe all facts in favor of the nonmoving party. *Juniper Networks, Inc. v. Palo Alto Networks, Inc.*, 881 F. Supp. 2d 603, 605 (D. Del. 2012).

D. Pleading Inequitable Conduct Under Rule 9(b)

An individual associated with the filing and prosecution of a patent application commits inequitable conduct when he or she (1) makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO; (2) with the specific intent to deceive the PTO. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008); *Micron Tech., Inc. v. Rambus Inc.*, 917 F. Supp. 2d 300, 321-22 (D. Del. 2013). If both of these elements—materiality and intent—are proven by clear and convincing evidence, this equitable defense bars enforcement of a patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011); *Micron Tech.*, 917 F. Supp. 2d at 322-23.

A claim of patent unenforceability premised upon inequitable conduct is a claim sounding in fraud. *Senju*, 921 F. Supp. 2d at 306. Under Federal Rule of Civil Procedure 9(b), fraud is a clear exception to the otherwise broad notice-pleading standards. *Id.* A party alleging unenforceability, therefore, must plead with particularity those facts which support the claim that the patent holder acted fraudulently before the PTO. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009); *Senju*, 921 F. Supp. 2d at 306. Just as a claim for inequitable conduct must meet the heightened pleading requirements of Rule 9(b), a defendant is also required to plead this affirmative defense with particularity under Rule 9(b). *Senju*, 921 F. Supp. 2d at 306. As a result, Defendant's counterclaim and affirmative defense for inequitable conduct rise and fall together. *Id.* (citing cases).

In *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009), the United States Court of Appeals for the Federal Circuit established the standard for evaluating the sufficiency of inequitable conduct allegations. *Exergen* held that:

> [T]o plead the "circumstances" of inequitable conduct with the requisite "particularity" under Rule 9(b), the pleading must identify the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO. Moreover, although "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

575 F.3d at 1328-29.

Roughly 18 months after the Federal Circuit's decision in *Exergen*, an *en banc* Federal Circuit altered and clarified the elements for *proving* inequitable conduct in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011). Unlike *Exergen*, which specifically outlined the requirements for *pleading* inequitable conduct, *Therasense* involved the review of a district court decision as to inequitable conduct made after a bench trial. *Id.* at 1285. In *Therasense*, the Federal Circuit retained the two-pronged construct requiring a showing of both materiality and intent to deceive. However, in various ways, it elected to "tighten[] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." *Id.* at 1290.

For example, the *Therasense* Court overruled a separate series of decisions that placed the materiality and intent prongs on a "sliding scale," in which a weak showing of intent could be found sufficient based on a strong showing of materiality, or vice versa. *Id.* at 1288, 1290. In addition, as to the first prong regarding materiality, *Therasense* held that absent evidence of "affirmative egregious misconduct," this prong requires a "but-for" showing. *Id.* at 1291-92. In other words, the party making an inequitable conduct claim must show that but for an omission

or misrepresentation by the patent applicant, the PTO would not have allowed a patent claim to issue. *Id.*

As for the intent prong, *Therasense* expressly overruled a series of decisions holding that if a misrepresentation or omission at issue amounted to gross negligence or mere negligence, this would be sufficient to satisfy the intent prong; instead, a deliberate decision to make the misrepresentation or omission would be required. *Id.* at 1287-90. Lastly, the Federal Circuit re-emphasized its prior holding that although "a district court may infer intent from indirect and circumstantial evidence . . . ., to meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference and able to be drawn from the evidence.'" *Id.* at 1290 (quoting *Star Scientific*, 537 F.3d at 1366). At the pleading stage of the case, however, "the claimant need only allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the PTO." *Wyeth Holdings Corp. v. Sandoz, Inc.*, Civ. Action No. 09-955-LPS-CJB, 2012 WL 600715, at *7 (D. Del. Feb. 3, 2012) (emphasis in original); *see also Exergen*, 575 F.3d at 1328-29. "A reasonable inference is one that is plausible and that flows logically from the facts alleged." *Exergen*, 575 F.3d at 1329 n.5.

III. DISCUSSION

The Court will address the various aspects of Plaintiffs' Motion in the order Plaintiffs present those arguments in their briefing. First, the Court will address whether Defendant's counterclaims of inequitable conduct have been pleaded with sufficient particularity under Rule 9(b). Second, the Court will consider whether certain material in the Amended Answer and Counterclaims should be stricken pursuant to Rule 12(f) as immaterial, impertinent or scandalous. And third, the Court will consider whether it has subject matter jurisdiction over

Defendant's counterclaims of non-infringement of the asserted patents as they relate to the so-called "ET Baffle-2 Configuration."

A. Inequitable Conduct Allegations

As noted above, Defendant raises inequitable conduct allegations for each of the asserted patents as both an affirmative defense and as individual counterclaims. (D.I. 137 at 12, at ¶ 64 (Affirmative Defense); *id.* at ¶¶ 230-78 (Counterclaims))[2] Defendant alleges therein that two prior art systems were manufactured and sold by third-party Micromedics, Inc. ("Micromedics") before the critical dates of the asserted patents, and that these systems render the asserted patents invalid. (*Id.* at ¶¶ 120-69) Below, the Court will first summarize the relevant factual allegations regarding the inequitable conduct counterclaims and then will discuss whether those counterclaims have been sufficiently pleaded.

1. Factual Background

Defendant alleges that the Micromedics FibriJet Blending Connector with Spray Tip (Product No. SA-3674) ("Fibrijet System (Blending Connector)") is exemplary of the first allegedly-invalidating prior art system. (*Id.* at ¶¶ 122-23) Defendant also asserts that certain Micromedics FibriJet Gas-Assisted Endoscopic Applicators (Product Nos. SA-3653 to SA-3658) were used in combination with a gas regulator to form a second allegedly-invalidating prior art system ("FibriJet System (Gas-Assisted Endoscopic)" and, together with the "Fibrijet System (Blending Connector)" the "Micromedics FibriJet System" or "Micromedics prior art systems").

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[2] Defendant's Seventh Affirmative Defense for unenforceability due to inequitable conduct incorporates by reference the factual allegations in Defendants' counterclaims relating to inequitable conduct. (D.I. 137 at 12, at ¶ 64) For this reason, to the extent that the Court below refers to Defendant's "inequitable conduct counterclaims," that should also be understood as a reference to the Seventh Affirmative Defense.

(*Id.* at ¶¶ 132-39) Defendant alleges that both of these systems were sold as early as 2006, (*id.* at ¶¶ 124, 133), which is more than a year prior to the filing of either provisional application to which the asserted patents claim benefit (April 25, 2008 and September 12, 2008). Thus, Defendant alleges that the systems were sold more than a year before the earliest possible effective filing dates of the asserted patents.

Defendant also provides specific allegations and claim charts mapping the elements of the prior art Micromedics systems (either alone or in view of other prior art) to at least one of the asserted claims for each of the asserted patents. In this way, Defendant alleges that the Micromedics prior art systems were material to the patentability of the asserted patents. (*Id.* at ¶¶ 152-69; *see also id.*, exs. 11-23 (claim charts)) As alleged in Defendant's inequitable conduct counterclaims (and claim charts), both systems are relevant to the Family 1 Patents, (*id.* at ¶¶ 232-34, 240-42), but only the FibriJet System (Gas-Assisted Endoscopic) is relevant to the Family 2 patents, (*id.* at ¶¶ 247-49, 254-56, 261-63, 268-70, 275-77).

It is undisputed that neither Micromedics system was disclosed to the United States Patent and Trademark Office ("Patent Office") by the inventors during the prosecution of the asserted patents. Defendant alleges that the inventors deliberately did not disclose these systems to the Patent Office and, in doing so, had the intention to deceive the Patent Office. (*Id.* at ¶¶ 170-229 (section entitled "The Inventors Deliberately Withheld Material Prior Art From the Patent Office")) As a basis for this allegation, Defendant pleaded facts indicating that: (1) the inventors knew of the Micromedics prior art systems; (2) they conducted "extensive testing" of those systems; (3) they therefore had intimate knowledgeable of the details of those systems and knew that those systems were material to the patentability of the patents-in-suit; (4) they discussed the Micromedics systems in relation to Plaintiffs' intellectual property mere weeks

before filing the Family 1 provisional application; (5) they deliberately failed to disclose either system to the Patent Office during the duration of the prosecution of the patents-in-suit, despite their awareness of their obligation to do so; (6) the patents-in-suit would not have issued had the inventors disclosed their knowledge of the systems to the Patent Office. (*Id.*; *see also id.*, exs. 24-38, 46)

Thus, Defendant asserts that because this material prior art was deliberately withheld with the specific intent to deceive the Patent Office, the asserted patents are therefore unenforceable due to inequitable conduct.

2. Discussion

In their Motion, Plaintiffs challenge the sufficiency of Defendant's inequitable conduct allegations on two grounds: (1) that Defendant failed to plead facts showing that any of the inventors had a specific intent to deceive; and (2) that Defendant failed to plead that a specific intent to deceive is the "single most reasonable inference" to be drawn from the pleaded facts. (D.I. 149 at 2-8) The Court will address both arguments in turn.

a. Specific Intent to Deceive

With regard to Plaintiffs' first line of argument, they assert that Defendant has "fail[ed] to recite a single fact from which it is reasonable to infer that either Messrs. Driscoll, Fortier, or Hull failed to disclose the Micromedics Fibrijet System with a specific intent to deceive." (D.I. 149 at 3 (emphasis omitted)) In more specifically explaining the nature of their argument here, Plaintiffs go on to assert that even if Defendant has pleaded facts alleging that the inventors (1) knew of the Micromedics Fibrijet System during prosecution of the asserted patents; (2) knew that it was prior art to the asserted patents; (3) knew that it was material to the patentability of the asserted patents; (4) stood to benefit from the issuance of the asserted patents; and (5)

deliberately withheld the system from the Examiner, Defendant "*must allege something more in order to show that there was a deliberate decision to withhold the Micromedics Fibrijet System with a specific intent to deceive*[.]" (*Id.* at 4 (emphasis added)) And in then explaining why Defendant has not sufficiently pleaded this "something more," Plaintiffs: (1) note that Defendant alleges that the inventors deliberately failed to disclose the Micromedics Fibrijet System "to secure issuance of the patents[,]" (*id.* (quoting D.I. 137 at ¶ 170); *see also* D.I. 137 at ¶¶ 221, 228); and then (2) argue that such allegations must fail, because Defendant "pleads no *reason* for the alleged deliberate withholding, *other than* generally stating that each of [the inventors] 'deliberately withheld this knowledge with deceptive intent *to secure issuance of the patents*[,]'" (D.I. 149 at 4 (quoting D.I. 137 at ¶ 170) (emphasis added)).

The Court is aware of no authority supporting Plaintiffs' position (i.e., that if a party pleading inequitable conduct alleges that the only reason why an inventor withheld material prior art was due to a desire to obtain issuance of a patent, that necessarily dooms the allegations). In the body of their opening brief, Plaintiffs cite only two cases in support of that position: *Exergen* and *Kranos IP Corp. v. Riddell, Inc.*, 334 F. Supp. 3d 907 (N.D. Ill. 2018). (D.I. 149 at 4-5) Neither citation persuades the Court of the merit of Plaintiffs' position.

In *Exergen*, the reason why the Federal Circuit found that the pleading in question did not disclose the "level of deceptive intent required to support an allegation of inequitable conduct" was that the pleading did "not contain specific factual allegations to show that the individual who had previously cited the [non-disclosed prior art] knew of the specific information that is alleged to be material to the [patent-in-suit] and then decided to deliberately withhold it from the

relevant examiner." 575 F.3d at 1331.[3] Moreover, in *Exergen*, the Federal Circuit nowhere concluded that even if the pleading party had sufficiently alleged materiality and deliberate withholding, the pleading party would still have needed to discern and plead some extra "reason" why the individual at fault had done these things (separate and apart from a desire to get the patents issued).

In *Kranos*, the district court found that the defendant had not sufficiently alleged that four named individuals (three inventors and the plaintiff's CEO) committed inequitable conduct by failing to bring to the Patent Office's attention a prior art football helmet (the "Revolution helmet") while prosecuting a patent on a particular type of helmet. 334 F. Supp. 3d at 910-11. Much of the *Kranos* Court's decision was centered on its finding that the defendant had not pleaded sufficient facts to show that these four individuals were aware of the Revolution helmet's materiality at the time of prosecution. *Id.* at 914-15. Now, to be sure, the *Kranos* Court did also conclude that the defendant had failed to allege "facts from which one reasonably could infer that the [four individuals] made deliberate decisions to withhold the information from" the Patent Office; to that end, the Court noted that "beyond legal conclusions" the "*only facts* that [defendant] alleges on this point are that each of the four named individuals 'stood to benefit' from the issuance of the patent." *Id.* at 915 (emphasis added). The *Kranos* Court then concluded that the "counterclaim [at issue] entirely fails to 'explain why these ordinary economic circumstances would plausibly induce fraud on the PTO.'" *Id.* at 915-16 (citation omitted). However, unlike in *Kranos*, here the fact that the inventors stood to benefit from the issuance of

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[3] The *Exergen* Court held that the "mere fact" that the applicant had disclosed certain prior art during prosecution of another patent application, but did not disclose it during prosecution of the patent application at issue, was insufficient to meet the threshold for pleading deceptive intent. *Id.*

the patents is not the "only fact" that Defendant has alleged regarding the inventors' alleged deliberate decision to withhold the prior art from the Patent Office.[4] Moreover, the Court does not read *Kranos* as standing for a bright-line proposition like the one Plaintiffs suggest here: that if the only reason the pleader cites as to why a party committed inequitable conduct is the party's desire to benefit from the patent's issuance, that necessarily renders the pleader's allegations as to specific intent insufficient. Indeed, such a rule would make little sense, as securing issuance of a patent is presumably the main (and often the only) reason motivating most of those persons who are alleged to be guilty of inequitable conduct. *See Int'l Bus. Machs. Corp. v. Priceline Grp. Inc.*, Civil Action No. 15-137-LPS-CJB, 2017 WL 1349175, at *3, *18 (D. Del. Apr. 10, 2017) (finding that defendants had pleaded sufficient facts to satisfy the intent prong of an inequitable conduct claim, where defendants alleged that by hiding the co-pending patent applications from the respective Examiners, a prosecuting attorney acted with "the intent of deceptively avoiding a double patenting rejection and extending [patent owner's] monopoly power over the same invention for years longer than permitted by statute"); *see also Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 995 (Fed. Cir. 1995) ("[I]ntent as an essential

[4] Defendant pleaded many facts that can support the reasonable inference that the inventors deliberately withheld reference to the Micromedics prior art systems with an intent to deceive the Patent Office. Among these are facts indicating that: (1) the inventors evaluated several Micromedics applicators, including the Micromedics Fibrijet System, prior to filing the provisional patent applications for the Family 1 and Family 2 patents; (2) the inventors then recognized that Micromedics made "similar applicators" to Plaintiffs' applicators for which Plaintiffs were seeking patent protection; and (3) just days before filing the first of these provisional patent applications, the inventors scheduled a meeting in which they discussed their "findings of the Micromedics offerings vs our IP." (D.I. 137 at ¶¶ 170-229 (internal quotation marks, citations and emphasis omitted)) It is reasonable to infer that the inventors did not disclose the existence of these "similar" products, which the inventors had been closely studying right up to the submission of the applications at issue, to the Patent Office because they had the deliberate intent to deceive the Patent Office.

predicate to patent unenforceability does not mean that the inventor intended to do what he did in patent prosecution; it means that the inventor intended to deceive or mislead the examiner *into granting the patent*.") (emphasis added).

For these reasons, Plaintiffs' first line of argument is not persuasive.

b. "Single Most Reasonable Inference"

With their second line of argument, Plaintiffs assert that the inequitable conduct allegations fail because Defendant never alleges that the "single most reasonable inference" to be drawn from the pleaded facts is that the inventors had the specific intent to deceive. (D.I. 149 at 5-8 ("Because HyperBranch cannot establish that 'an inference of deceptive intent [is] the single most reasonable inference' to be drawn from the evidence, the Court[] should dismiss HyperBranch's inequitable conduct counterclaims.")) But as Defendant notes, (D.I. 161 at 5-6), the Court has previously concluded in *Wyeth Holdings Corp. v. Sandoz, Inc.*, Civ. Action No. 09-955-LPS-CJB, 2012 WL 600715 (D. Del. Feb. 3, 2012), that at the pleading stage, no such allegation is required. Instead, in *Wyeth*, the Court explained that in pleading inequitable conduct, "the claimant need only allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the PTO." *Wyeth*, 2012 WL 600715, at *7 (emphasis in original); *see also Finjan, Inc. v. Bitdefender Inc.*, Case No.17-cv-04790-HSG, 2018 WL 1811979, at *2 n.3 (N.D. Cal. Apr. 17, 2018); *Kranos*, 334 F. Supp. 3d at 914-15.[5] Indeed, by the time of the filing of their reply brief, Plaintiffs seemed to acknowledge that

[5] In arguing in its opening brief that the "single most reasonable inference" standard applied at the pleading stage, Plaintiffs cited three district court opinions, each of which were discussed in the Court's decision in *Wyeth*. (D.I. 149 at 7-8); *see also Wyeth*, 2012 WL 600715, at *7. Yet Plaintiffs did not mention the *Wyeth* decision (or other subsequent decisions that come to the same conclusion) in their opening brief. (D.I. 149)

this portion of their Motion was premised on an inaccurate reading of inequitable conduct pleading standards. (D.I. 164 at 2 (Plaintiffs now acknowledging that the pleadings need only include sufficient allegations "from which a court may *reasonably infer* that a specific individual . . . withheld or mispresented this information with *a specific intent to deceive the PTO*") (emphasis in original))

Because the initial arguments in this portion of Plaintiffs' Motion were entirely premised on an incorrect proposition of law, (D.I. 161 at 6), they also cannot support grant of the Motion.[6]

c. Conclusion

For the reasons set out above, the Court recommends that the District Court deny Plaintiffs' Motion to the extent it: (1) seeks dismissal of Defendant's counterclaims of inequitable conduct; and (2) seeks to strike Defendant's inequitable conduct affirmative defense.

B. Motion to Strike Content as Immaterial, Impertinent and Scandalous

Next, Plaintiffs move to strike particular statements in Defendant's Amended Answer and Counterclaims as "impertinent, immaterial, and scandalous[.]" (D.I. 149 at 8-10; *see also* D.I. 164 at 8)[7] This portion of the Motion relates to parts of paragraphs 38, 50, 53 and 54 in Defendant's counterclaims. In those paragraphs, Defendant asserted that: (1) Plaintiffs had

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[6] As Defendant notes, (D.I. 161 at 7), when Plaintiffs acknowledged in their opening brief that "multiple reasonable inferences can be drawn from the evidence" pleaded regarding inequitable conduct, (D.I. 149 at 6), Plaintiffs therein seemed to be making the "tacit admission that one reasonable inference to be drawn from the evidence is that the inventors *did* possess the specific intent to deceive the [Patent Office, which] is fatal to [Plaintiffs'] Motion[,]" (D.I. 161 at 7 (emphasis in original)).

[7] By the time of Plaintiffs' reply brief, Plaintiffs seem to have limited their argument to the contention that the material should be stricken because it is "scandalous" (and thus no longer appeared to be asserting that the challenged material was "immaterial" or "impertinent"). (D.I. 164 at 8) But because Plaintiffs raised immateriality and impertinence in their opening brief, the Court will briefly discuss those issues here too.

"engaged in a campaign of patent litigation" against Defendant[8] in order to "stifle HyperBranch's legitimate and non-infringing commercial activities"; (2) statements by Plaintiffs' CEO about the instant case show that Plaintiffs' litigation efforts were "a competitive response to" Defendant's sale of accused products or were driven by "competition" from Defendant; and (3) Plaintiffs' filing of patent litigation against Defendant was "unrestrained[.]" (D.I. 149 at 9 (quoting D.I. 137 at ¶¶ 38, 50, 53-54)) However, for the following reasons, Plaintiffs have not met their burden to show that the drastic and disfavored remedy of striking this material is warranted.

First, the allegations at issue are not "immaterial" or "impertinent." To the contrary, they are relevant to the issues in this case because, *inter alia*, in its Amended Answer and Counterclaims Defendant is seeking a declaratory judgment of non-infringement with regard to a newly-identified product (the ET Baffle-2 Configuration). (D.I. 161 at 14-16) As Defendant has argued, (*id.* at 14-15), in those declaratory judgment counterclaims, it was required to explain why a justiciable controversy exists regarding this product (e.g., why it fears that Plaintiffs would soon have accused it of infringement regarding the product had Defendant not filed the counterclaims). And here, Defendant has pleaded that it believes such a suit was imminent in part because Plaintiffs have previously aggressively initiated litigation against Defendant as to similar products (in what Defendant views as an "unrestrained" manner meant to stifle Defendant's competing products). *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (noting that "related litigation involving the same technology

[8] In addition to the instant case, here Defendant is also referring to *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, Civil Action No. 15-819-LPS-CJB, a heavily-litigated matter in which certain of Plaintiffs accused Defendant's products of infringing six patents. (D.I. 137 at ¶ 39)

and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on other related patents"). Plaintiffs did not respond to this relevance-based argument in their reply brief, (D.I. 164 at 8), and the Court finds Defendant's argument to be a winning one. *See Delaware Health Care, Inc.*, 893 F. Supp. at 1292 ("When faced with allegations that could possibly serve to achieve a better understanding of plaintiff's claims or perform any useful purpose in promoting the just disposition of the litigation, courts generally deny such motions to strike.").[9]

Second, Plaintiffs have not met their burden to show that the material at issue is "scandalous" (that is, that it "improperly" casts a "derogatory light" on Plaintiffs). *Aoki*, 839 F. Supp. 2d at 764. Defendant's words—especially those suggesting that Plaintiffs' claims are not meritorious and are simply a "competitive response" to Defendant's efforts in the market—are tough ones, to be sure. And they may not be flattering. But as noted above, they are not irrelevant to the case as they shed light on Defendant's mindset about why an imminent controversy exists between the parties. In light of that, and in light of the high bar that Plaintiffs must meet to strike the material, the Court is unconvinced that these allegations "improperly" cast Plaintiffs in a derogatory light.[10] *Cf. Karpov v. Karpov*, 307 F.R.D. 345, 349 (D. Del. 2015); *Gateway Bottling, Inc. v. Dad's Rootbeer Co.*, 53 F.R.D. 585, 588 (W.D. Pa. 1971).

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[9] Defendants argued in their answering brief that the identified statements are also relevant to Defendant's request that it be awarded its "attorneys' fees, and expenses" pursuant to 35 U.S.C. § 285. (D.I. 137 at 87; *see also* D.I. 161 at 15-16) The Court need not address this alternative argument in light of its conclusion set out above.

[10] The Court pauses here to underscore that nothing about the denial of this portion of Plaintiffs' Motion suggests that the Court has determined or believes that the challenged assertions are *true*; they are simply *allegations*. But yet-unproven, relevant allegations are the stuff of claims and counterclaims.

Thus, the Court recommends that this portion of Plaintiffs' Motion also be denied.

C. Defendant's Counterclaims Relating to Non-Infringement of the "ET Baffle-2 Configuration"

With the last portion of its Motion, Plaintiffs argue that the Court should dismiss Defendant's declaratory judgment counterclaims of non-infringement with respect to the ET Baffle-2 Configuration. (D.I. 149 at 10-13; *see also* D.I. 137 at ¶¶ 55-75) It asserts that this is so because the Court does not possess subject matter jurisdiction over such claims.

With regard to the relevant allegations, Defendant's Amended Answer and Counterclaims explain that the accused Adherus AutoSpray Extended Tip (ET) Dural Sealant product includes a "mixing baffle" as part of its spray tip. (D.I. 137 at ¶ 7) Defendant alleges that since Defendant began selling the product in the United States in November 2016, all of the product applicators have used the same mixing baffle ("Baffle-1"), which is manufactured by third party [redacted]. (*Id.* at ¶ 8) Defendant's pleading explains, however, that [redacted] Defendant has recently begun the process to add a second manufacturer source ([redacted]) for an alternative mixing baffle—"Baffle-2." (*Id.* at ¶¶ 10-16)

Defendant notes that it would need approval from the United States Food and Drug Administration ("FDA") to actually use the ET Baffle-2 Configuration in the United States as part of a final applicator. (*Id.* at ¶ 17) In Defendant's pleading and in a declaration that Defendant submitted along with its response to the Motion from Michael Carnahan, Ph.D. ("Carnahan declaration"),[11] Defendant states that it has already taken many steps necessary to

[11] The Court considers Plaintiffs' challenge to subject matter jurisdiction to be a factual challenge, in that: (1) in its opening brief, Plaintiffs cited FDA regulations not referenced in the pleading at issue, (D.I. 149 at 10, 12); and (2) when Defendant submitted the Carnahan declaration along with its answering brief and relied upon it to counter Plaintiffs' Motion,

confirm for the FDA that the Baffle-2 is a suitable replacement for the Baffle-1. These steps include: (1) Defendant has now entered into a supply contract with [redacted]; (2) Defendant has purchased over [redacted] of the Baffle-2 units; (3) it has used the Baffle-2 to build ET applicators; and (4) it has performed extensive testing on those applicators, which demonstrated that the "Baffle-2 functioned equivalently to the Baffle-1 configuration." (*Id.* at ¶¶ 17-24; D.I. 162 at ¶ 11) Defendant explains that its plan was to soon submit a "PMA [or "Premarket Approval"] Supplement" to the FDA, in order to formally seek the necessary FDA approval; it notes that the PMA Supplement process is a "less intensive process" than other means of obtaining FDA approval, one requiring only a 30-day notice period prior to approval. (D.I. 162 at ¶ 14) Defendant expected that approval would be quickly granted thereafter, in part because: (1) [redacted] has already been using the same Baffle-2 in its products, which have been cleared by the FDA for marketing in the United States; and (2) in 2017, Defendant successfully and quickly obtained a PMA Supplement for a "secondary supplier" for the "plastic caps" used on the Accused Products, a circumstance similar to its efforts to add [redacted] as a secondary plastic baffle supplier here. (*Id.* at ¶¶ 8, 16) As of the time of the filing of the Amended Answer and Counterclaims, Defendant estimated that it would secure approval for the configuration from the FDA "by or near the end of April 2019,[12] [and stated that it] intends to sell [the

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Plaintiffs did not object in their reply brief to Defendant's use of the declaration, (D.I. 164 at 8-10). *Cf. TSMC Tech., Inc. v. Zond, LLC*, Civil Action No. 14-721-LPS-CJB, 2015 WL 661364, at *3 (D. Del. Feb. 13, 2015) (citing cases). In light of this, the Court may consider the content of the Carnahan declaration in resolving this portion of the Motion. *See MedImmune*, 549 U.S. at 121 (considering both the facts alleged in the complaint and "unopposed declarations that petitioner submitted in response to the motion to dismiss").

[12] In the intervening time between when the Motion was filed and the date of this Report and Recommendation, the Court has not been advised that the FDA has, in fact, approved the ET Baffle-2 Configuration.

configuration] as soon as possible (*i.e.*, within weeks)" thereafter. (D.I. 137 at ¶ 27; D.I. 162 at ¶ 12) Lastly, Defendant stated that when FDA approval is received, it intends to then have the ET Baffle-2 Configuration "available to fulfill sales in the United States immediately[.]" (D.I. 162 at ¶ 18)

Defendant also pleads other facts in an effort to establish a controversy of sufficient reality and immediacy. For example, in explaining how it knows that Plaintiffs would immediately accuse the ET Baffle-2 Configuration of infringement upon FDA approval, Defendant states that: (1) the ET Baffle-2 Configuration is "identical to" the ET Baffle-1 Configuration that Plaintiffs have already accused of infringement, with the "sole exception of the differences between the [redacted] Baffle-1 and [redacted] Baffle-2"; and (2) certain of Plaintiffs' infringement contentions include pictures of the Baffle-2 (utilized by another of Defendant's products) and those contentions assert that this baffle reads on the claim limitations of an asserted patent. (D.I. 137 at ¶¶ 45-48; D.I. 162 at ¶ 10; *see also* D.I. 161 at 13) Moreover, (as was noted in the prior subsection) Defendant also pleads facts relating to Plaintiffs' prior history of accusing Defendant of patent infringement. (D.I. 137 at ¶¶ 37-42, 49-54) If Plaintiffs have often sued it before for patent infringement as to similar products, Defendant suggests it is likely that Plaintiffs would sue again when the use of the ET Baffle-2 Configuration is approved by the FDA.

In response, Plaintiffs do not challenge the accuracy of Defendant's above-referenced factual allegations regarding Defendant's use of the Baffle-2 or its plans for the ET Baffle-2 Configuration. (*See* D.I. 149 at 10-13; D.I. 164 at 8-9) Nor do Plaintiffs seriously contest Defendant's claim that if the ET Baffle-2 Configuration *does* receive FDA approval, Plaintiffs would soon file patent infringement allegations relating to that product. Instead, Plaintiffs

challenge the asserted fact that FDA approval will soon be forthcoming. Indeed, the core of Plaintiffs' argument is that because the ET Baffle-2 Configuration "*has not received* approval from the FDA, and thus cannot be marketed or sold" in this country, and because "[t]here is no guarantee that the FDA *will ever approve* [Defendant's] device" or approve it in its current form, there can be no actionable case or controversy. (D.I. 149 at 10 (emphasis added), 12 (emphasis added); D.I. 164 at 9)[13]

The case on which Plaintiffs most significantly rely is *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992). (D.I. 149 at 11-12) However, that case is readily distinguishable from our facts here. In *Telectronics*, the plaintiff/patentee filed a declaratory judgment claim for patent infringement, wherein the accused device (an implantable defibrillator) had only recently begun clinical trials and was "years away" from potential FDA approval. 982 F.2d at 1527. There was also real reason to doubt whether the specific accused defibrillator product (i.e., the device that had begun clinical trials) would be the same device by the time of FDA approval—a concern seemingly heightened by the fact that the defendant did in fact modify the device during the clinical trials. *Id.* In light of these realities, the *Telectronics* Court upheld the district court's decision that the declaratory judgment count lacked sufficient immediacy and reality to meet the actual controversy requirement. *Id.*

Here, in contrast, the record indicates that FDA approval (if it is to be earned) will not be "years away"; instead, a decision as to such approval is expected to come in the very near term.

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[13] Plaintiffs assert (and Defendant does not here contest) that because Defendant's "previous use or testing of the 'ET Baffle-2 Configuration' is exempt [from infringement liability] under 35 U.S.C. § 271(e)(1)[,]" Defendant's only need for a declaration of non-infringement would relate to conduct that would occur after FDA approval of the relevant configuration. (D.I. 149 at 11)

The record also suggests that, in the meantime, Defendant is not likely to change the current configuration of the ET Baffle-2 Configuration on its own accord (in light of the resources that Defendant has put into the project already and the fact that the Baffle-2 is an off-the-shelf product). (D.I. 162 at ¶¶ 18-20); *see also Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 882 (Fed. Cir. 2008) (distinguishing *Teletronics* as a case involving technology that was "fluid and in an early stage of development" and finding subject matter jurisdiction where the defendant did not expect to make substantial modifications to its designs at issue in the future). Moreover, the facts provide reason to think that the FDA is actually likely to approve the configuration at issue (in that it has previously approved the Baffle-2 for use in other [redacted] products). (D.I. 162 at ¶ 8)

As a result, the facts here are more consistent with those at play in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). In *Glaxo*, the plaintiff/patentee filed a declaratory judgment claim of patent infringement with regard to defendant's ranitidine hydrochloride ("RHCl") product; the plaintiff asserted that the defendant would infringe plaintiff's patent if and when the defendant imported the RHCl product, following FDA approval of defendant's Abbreviated New Drug Application ("ANDA") for the drug. *Id.* at 1564. Although defendant had not yet obtained FDA approval for the product, in a June 1994 letter it told the plaintiff that it: (1) intended to market the product as soon as December 1995 and (2) had "submitted an ANDA accompanied by data sufficient to make FDA approval imminent." *Id.* at 1571. The *Glaxo* Court distinguished the case from the circumstances in *Teletronics*, explaining that unlike in that case, "the threat of [the defendant] entering the U.S. market was not 'years away' nor was there doubt that [defendant] wished to sell some form of RHCl." *Id.* Thus, because the claimant had pleaded facts indicating "imminent FDA approval and actual threats of

future infringement [thereafter,]" the Federal Circuit upheld the district court's determination that there was subject matter jurisdiction for the claim. *Id.* Here, like in *Glaxo*, Defendant has put forward a sufficient record to support standing based on "imminent FDA approval and actual threats of future infringement." (*See* D.I. 137 at ¶¶ 6-54); *see also Wyeth & Cordis Corp. v. Abbott Labs.*, Civil Action No. 08-0230 (JAP), 2008 WL 2036805, at *5 (D.N.J. May 8, 2008) (exercising jurisdiction where, *inter alia*, the accused infringer had "clearly made preparation for launch of [the accused products]" post-FDA approval and had announced a particular timeframe in which it expected PMA application approval—"in the first half of 2008," when the complaint was filed in January 2008).

Here then, the "'facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant' [relief]." *MedImmune*, 549 U.S. at 127 (internal quotation marks and citation omitted). And Plaintiffs have not provided a "sound basis for refusing[, in the Court's discretion,] to adjudicate [this] actual controversy." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007).[14] Thus, the Court has subject matter jurisdiction over Defendant's counterclaims of non-infringement of the ET Baffle-2 Configuration and recommends that this portion of Plaintiffs' Motion also be denied.

[14] The Amended Answer and Counterclaims were filed on January 11, 2019, months before the close of the May 8, 2019 fact discovery deadline effective at the time of the briefing for the present motion. (D.I. 164 at 2 n.1) The Court also notes that the fact discovery cutoff has since been extended by stipulation to August 30, 2019. (D.I. 188) Under these circumstances, the Court disagrees with Plaintiffs that adding the product to this case is "neither prudent nor fair" to Plaintiffs. (D.I. 164 at 2)

IV. CONCLUSION

For the foregoing reasons, the Court recommends that Plaintiffs' Motion be DENIED.[15]

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **July 15, 2019**, for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: July 10, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

[15] Defendant's request for oral argument, (D.I. 167), is DENIED.