

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INSTITUTE FOR ENVIRONMENTAL  
HEALTH, INC.,

Plaintiff,

v.

NATIONAL BEEF PACKING COMPANY,  
LLC,

Defendant.

CIVIL ACTION  
NO. 23-826

**OPINION**

Slomsky, J.

December 16, 2024

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## I. INTRODUCTION

This case arises out of Defendant National Beef Packing Company, LLC's ("Defendant") alleged infringement of four patents owned by Plaintiff Institute for Environmental Health ("Plaintiff" or "IEH"): (1) U.S. Patent No. 7,534,584 (the "'584 Patent"), (2) U.S. Patent No. 8,822,143 (the "'143 Patent"), (3) U.S. Patent No. 9,637,771 (the "'771 Patent"), and (4) U.S. Patent No. 9,845,486 (the "'486 Patent") (collectively, the "Asserted Patents"). (Doc. No. 40 at 15 ¶ 13.) In its Complaint, Plaintiff alleges Defendant, a beef processing company, infringes on the Asserted Patents by performing microbiological testing on its beef through a method allegedly covered by these patents. (Doc. No. 1 at ¶¶ 35-47.) In the Amended Answer, Defendant asserts multiple affirmative defenses and counterclaims against Plaintiff, including the eighth affirmative defense and third counterclaim which were both asserted for the first time in the Amended Answer.<sup>1</sup> (See Doc. No. 40.) In the eighth affirmative defense, Defendant asserts the defense of inequitable conduct and in Count III of the Amended Counterclaim, it seeks a declaration of unenforceability of the '143 and '771 Patents based on inequitable conduct. (See *id.* at 13, 19-21.)

In response to the Amended Answer, Plaintiff filed a Motion to Dismiss Count III of Defendant's Amended Counterclaims and a Motion to Strike Defendant's Eighth Affirmative Defense ("Plaintiff's Motion"). (Doc. No. 43.) Defendant then filed an Answering Brief in Opposition to Plaintiff's Motion in which it requested leave to amend the Amended Answer if the Court grants Plaintiff's Motion. (Doc. No. 47 at 5, 17-19.) For reasons that follow, Plaintiff's Motion to Dismiss Count III of Defendant's Amended Counterclaims and Motion to Strike Defendant's Eighth Affirmative Defense (Doc. No. 43) will be granted and Defendant's request for leave to amend the Amended Answer will be granted.

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<sup>1</sup> The Amended Answer is the operative Answer in this case. (See Doc. No. 40.)

## II. BACKGROUND

### A. Factual Background

As noted, Plaintiff alleges that the microbiological testing process Defendant uses to test its beef for contamination infringes on four patents owned by Plaintiff: (1) the ‘584 Patent, (2) the ‘143 Patent, (3) the ‘771 Patent, and (4) the ‘486 Patent. (Doc. No. 40 at 15 ¶ 13, 7 ¶¶ 35-36.) Also relevant for the purposes of Plaintiff’s Motion is U.S. Patent No. 8,389,233 (the “‘233 Patent”). (Doc. No. 47 at 6.)

#### 1. The ‘584 Patent

The ‘584 Patent, titled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents,” originally issued on May 19, 2009. (*Id.* at 2-3 ¶ 9.) On January 13, 2010, a company named bioMérieux, Inc. filed an inter partes reexamination proceeding against the ‘584 Patent, requesting the United States Patent and Trademark Office (“PTO” or “USPTO”) to reexamine the patentability of the ‘584 Patent’s claims (the “‘584 Reexamination”). (Doc. No. 47 at 5.) The ‘584 Reexamination took place over nine (9) years, consisting of two prosecution phases and two appeals. (Doc. No. 47 at 5.) Defendant summarizes the nine-year reexamination process as follows:

During the first prosecution phase, on December 17, 2010, the [PTO’s] Central Reexamination Unit (“CRU”) concluded that all of the claims of the ‘584 Patent application were not patentable. On March 5, 2012, IEH filed a notice of appeal. Thereafter, in a decision dated January 20, 2015, the Patent Trial and Appeal Board (“PTAB”) agreed with the CRU and concluded that the claims of the ‘584 Patent were not patentable. IEH requested reopening of prosecution and, during this second prosecution phase, narrowed the claims. Despite this narrowing of claims, the CRU still maintained the rejections and determined the claims were unpatentable. After another appeal, in a decision dated December 22, 2016, the PTAB reversed the Examiner at the CRU and allowed the amended claims. The Patent Office issued a Notice of Intent to Issue Inter Partes Reexamination Certification on January 24, 2019.

(*Id.* at 5-6.) A timeline outlining the ‘584 Patent’s reexamination process is as follows:

| <b>Date</b>       | <b>Event</b>                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| January 13, 2010  | Reexamination commenced                                                                                                                                                                                                                                                                                                                                                                                   |
| May 26, 2010      | (CRU) All claims found to be not patentable over the prior art                                                                                                                                                                                                                                                                                                                                            |
| July 26, 2010     | IEH amends and narrows the claims to get over the prior art                                                                                                                                                                                                                                                                                                                                               |
| December 17, 2010 | (CRU) All claims found to be not patentable over the prior art                                                                                                                                                                                                                                                                                                                                            |
| January 31, 2011  | IEH again amends and narrows the claims to get over the prior art                                                                                                                                                                                                                                                                                                                                         |
| February 8, 2012  | (CRU) All claims found [to] be not patentable over the prior art                                                                                                                                                                                                                                                                                                                                          |
| March 5, 2012     | IEH appeals to [PTAB]                                                                                                                                                                                                                                                                                                                                                                                     |
| March 5, 2013     | IEH [Information Disclosure Statement] in which “IEH makes known to Reexam that the ‘233 Patent was recently issued. The ‘233 patent is deemed by IEH as “highly material”; misrepresents that the Examiner “reviewed the entire reexamination and appeal record . . . and in view of said review, both the Examiner and his Supervisory Examiner deemed that the claims of [‘233 Patent] were allowable” |
| January 20, 2015  | Appeal board determines claims are not patentable; remands                                                                                                                                                                                                                                                                                                                                                |
| February 20, 2015 | IEH again amends and narrows claims (reopens prosecution)                                                                                                                                                                                                                                                                                                                                                 |
| July 20, 2015     | (CRU) All claims deemed not patentable                                                                                                                                                                                                                                                                                                                                                                    |
| December 23, 2016 | Patent Board Decision – Examiner reversed                                                                                                                                                                                                                                                                                                                                                                 |
| January 23, 2017  | Request for Rehearing after Board Decision                                                                                                                                                                                                                                                                                                                                                                |
| April 18, 2018    | Decision on Reconsideration                                                                                                                                                                                                                                                                                                                                                                               |
| January 24, 2019  | Notice of Intent to issue Reexamination certificate                                                                                                                                                                                                                                                                                                                                                       |
| March 6, 2019     | Reexamination certificate issues                                                                                                                                                                                                                                                                                                                                                                          |

As noted on the above timeline, on March 6, 2019, the PTO issued the ‘584 Patent’s Reexamination Certificate. (Doc. No. 40 at 15 ¶ 15.) The Reexamination Certificate contained claims that had been amended during the reexamination process and was missing claims from the original ‘584 Patent that had been canceled on reexamination. (Id.)

## **2. The ‘143, ‘771, and ‘486 Patents**

During the ‘584 Reexamination, IEH filed continuation applications for the ‘584 Patent that later issued as the ‘143 and ‘771 Patents. (Id. at 15 ¶ 16.) This means that the ‘584 Patent is the parent patent of the ‘143 and ‘771 Patents. In other words, it is the patent that was filed first between the ‘584, ‘143, and ‘771 Patents and each of these patents share the same specification and claim similar inventions. (See id.) On March 4, 2013, IEH filed an application for the ‘143 Patent. (Doc. No. 1-1 at 15.) The ‘143 Patent is also titled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents,” and eventually issued on September 2, 2014. (Doc. No. 40 at 3 ¶ 10.) On August 28, 2014, IEH filed an application for the ‘771 Patent. (Doc. No. 1-1 at 28.) The ‘771 Patent also shares the same title as the ‘584 and ‘143 Patents and was issued on May 2, 2017. (Doc. No. 40 at 3 ¶ 11.) The ‘486 Patent does not belong to the same patent family as the ‘584, ‘143, and ‘771 Patents. It is titled “Enrichment Methods for the Detection of Pathogens and Other Microbes” and issued on December 19, 2017. (Id. at 4 ¶ 12.)

## **3. The ‘233 Patent**

While not at issue in this action, the ‘233 Patent is also a continuation patent of the ‘584 Patent, meaning it belongs to the same patent family as the ‘584, ‘143, and ‘771 Patents. (Id.) The ‘233 Patent application was filed on January 27, 2009 and eventually issued on March 5, 2013. (Id. at 6-7.) Importantly here, the ‘233 Patent’s prosecution overlapped with the ‘584 Reexamination, which began in January 2010. (See id. at 5.) Throughout the ‘233 Patent’s prosecution, Plaintiff filed with the PTO several Information Disclosure Statements in which it submitted references to the ‘584 Reexamination record and created a “record of notification” to the PTO of the ongoing ‘584 Reexamination proceeding. (Id. at 6-7.) However, Plaintiff’s Information Disclosure Statements did not include any specific documents from the ‘584

Reexamination, “including those from the Patent Office (e.g. office actions, decisions, orders, etc.), bioMérieux (e.g., requests, comments, etc.), or IEH (e.g., responses, etc.) . . . .” (Id. at 7.)

## **B. Procedural Background**

On August 1, 2023, Plaintiff filed a Complaint against Defendant. (Doc. No. 1.) On May 30, 2024, Defendant filed an Answer to the Complaint.<sup>2</sup> (Doc. No. 29.) On June 20, 2024, Plaintiff filed a Motion to Dismiss Defendant’s Counterclaims and Motion to Strike Defendant’s Seventh and Eighth Affirmative Defenses. (Doc. No. 32.) On July 10, 2024, in lieu of responding to this Motion, Defendant filed an Amended Answer. (Doc. No. 40.) In the Amended Answer, Defendant revised its eighth affirmative defense and added a third counterclaim. (See id.) In the eighth affirmative defense, Defendant alleges as follows:

Any additional defenses revealed through discovery, such as inequitable conduct. For example and without limitation, U.S. Patent Nos. 8,822,143 and 9,637,771 are unenforceable due to IEH’s inequitable conduct before the USPTO as is more fully set forth in National Beef’s counterclaims, infra, which are incorporated herein.

(Id. at 13.) Similarly, in the third counterclaim, Defendant requests “the issuance of a declaratory judgment of unenforceability of the ‘143 and ‘771 Patents” due to IEH’s inequitable conduct while prosecuting these patents. (See id. at 19 ¶ 37.) The entirety of the allegations supporting Defendant’s inequitable conduct counterclaim are set out in the following paragraphs:

17. During the prosecution of the ‘143 and ‘771 Patents, IEH failed to abide by its duty of disclosure owed to the USPTO by failing to fully apprise the examiner with relevant information from the ‘584 Reexamination that was material to the patentability of the claims of the ‘143 and ‘771 Patents.

18. IEH withheld and failed to disclose material information to the examiner which would impact the patentability of the claims of the ‘143 and ‘771 Patents.

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<sup>2</sup> Defendant initially responded to the Complaint by filing a Motion to Dismiss for Improper Venue. (Doc. No. 11.) This Court denied the Motion on May 16, 2024. (Doc. No. 27.) Thereafter, Defendant filed its initial Answer, which was later amended. (Doc. No. 29.)

37. As a result of the acts described herein, there exists a substantial controversy of sufficient immediacy between National Beef and IEH to warrant the issuance of a declaratory judgment of unenforceability of the '143 and '771 Patents.

38. During the prosecution of the '143 Patent, IEH failed to disclose relevant and material documents, such as office actions, responses, and third-party comments from the '584 Reexamination proceeding that would have impacted the patentability of the '143 Patent's claims. Also, the interview summaries from three interviews conducted do not indicate that any documents or references from the '584 Reexamination were considered during the prosecution of the '143 Patent. When the issue fee was paid for the '143 Patent, claims of the '584 Patent—that were found not patentably distinct from those that issued in the '143 Patent—had been deemed not patentable on multiple occasions by the Central Reexamination Unit ("CRU") involved in the '584 Reexamination. These rulings by the CRU were not provided to the examiner of the '143 Patent.

39. During the prosecution of the '771 Patent, IEH failed to disclose relevant and material documents, such as office actions, responses, and third-party comments from the '584 Reexamination proceeding that would have impacted the patentability '771 Patent claims. Also, the interview summary from an interview does not indicate that any documents from the '584 Reexamination were considered during the prosecution of the '771 Patent. When the issue fee was paid for the '771 Patent, the '584 Reexamination had issued its first decision concluding that the claims of the '584 Patent were not patentable and a CRU examiner had reached the same conclusion. The examiner of the '771 Patent was not informed about these adverse findings regarding claims that he considered to be not patentably distinct from the claims of the '584 Patent.

40. The same attorneys that were conducting the '584 Reexamination were also prosecut[ing] the applications that became the '143 and '771 Patents. As such, at least IEH's attorneys had knowledge of the adverse rulings and other material documents in the '584 Reexamination proceedings and that the examiner for the '143 and '771 Patents had determined that the proposed claims for those patents were patentably indistinct from the claims in the '584 Reexamination. IEH and its attorneys had a duty to disclose these documents and findings in the '143 and '771 Patent prosecution proceedings. They did not do so in violation of their duty of candor under 37 CFR § 1.56. This failure of disclosure constitutes inequitable conduct.

41. A judicial declaration is necessary and appropriate so that National Beef may ascertain its rights regarding the enforceability of the '143 and '771 Patents.

42. National Beef is entitled to a declaratory judgment that the '143 and '771 Patents are unenforceable due to inequitable conduct before the USPTO as described with particularity in the foregoing paragraphs.

(Id. at 15-16 ¶¶ 17-18, 19-20 ¶¶ 37-42.)<sup>3</sup>

On July 24, 2024, Plaintiff again filed a Motion to Dismiss Count III of Defendant’s Amended Counterclaims and Motion to Strike Defendant’s Eighth Affirmative Defense along with an Opening Brief in support of its Motion. (Doc. Nos. 43, 44.) On August 7, 2024, Defendant filed its Answering Brief in Opposition to Plaintiff’s Motion. (Doc. No. 47.) On August 14, 2024, Plaintiff filed a Reply. (Doc. No. 49.) On November 20, 2024, the Court held a hearing on the Motion. (See Doc. No. 71.) Plaintiff’s Motion is now ripe for disposition.

### III. STANDARD OF REVIEW

#### A. Motion to Dismiss a Counterclaim Under Federal Rule of Civil Procedure 12(b)(6)

“Courts evaluate a motion to dismiss a counterclaim under the same standard as a motion to dismiss a complaint.” Mr. Sandless Franchise, LLC v. Karen Cesaroni LLC, 498 F. Supp. 3d 725, 732 (E.D. Pa. 2020). Therefore, in analyzing a motion to dismiss a counterclaim, the Court must “accept all factual allegations as true, construe the [counterclaim] in the light most favorable to the [defendant], and determine whether, under any reasonable reading of the [counterclaim], the [defendant] may be entitled to relief.” NTP Marble, Inc. v. AAA Hellenic Marble, Inc., 799 F. Supp. 2d 446, 450 (E.D. Pa. 2011) (citations omitted) (alterations in original).

The motion to dismiss standard under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim is set forth in Ashcroft v. Iqbal, 556 U.S. 662 (2009). After Iqbal it is clear that “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory

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<sup>3</sup> As explained by counsel at the November 20, 2024 hearing on Plaintiff’s Motion, “office actions” are intermediate decisions by the PTO regarding whether a patent’s claims are patentable. (Doc. No. 71 at 7:24-25, 8:1-23.) “Responses” are the patent applicant’s response to these office actions. (Id.) And “third-party comments” are a third party’s analysis of the patent applicant’s evidence regarding whether their invention is patentable. (Id.)

statements, do not suffice” to defeat a Rule 12(b)(6) motion to dismiss. Id. at 678; see also Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). Therefore, “[t]o survive dismissal, a [counterclaim] must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” Tatis v. Allied Interstate, LLC, 882 F.3d 422, 426 (3d Cir. 2018) (quoting Iqbal, 556 U.S. at 678) (internal quotations omitted). Facial plausibility is “more than a sheer possibility that a [Plaintiff] has acted unlawfully.” Id. (quoting Iqbal, 556 U.S. at 678). Instead, “[a] claim has facial plausibility when the [defendant] pleads factual content that allows the court to draw the reasonable inference that the [plaintiff] is liable for the misconduct alleged.” Id. (quoting Iqbal, 556 U.S. at 678).

“Under the plausibility pleading standard, this Circuit uses a three-step process to evaluate a motion to dismiss [a counterclaim] for failure to state a claim for relief.” Lutz v. Portfolio Recovery Assocs., LLC, 49 F.4th 323 (3d Cir. 2022). These three steps are as follows:

The first step in that process requires an articulation of the elements of the claim. The second step involves reviewing the [counterclaim] and disregarding any “‘formulaic recitation of the elements of a ... claim’ or other legal conclusion,” as well as allegations that are “so threadbare or speculative that they fail to cross the line between the conclusory and the factual.” The third step evaluates the plausibility of the remaining allegations. That involves assuming their veracity, construing them in the light most favorable to the [defendant], and drawing all reasonable inferences in the [defendant]’s favor.

Id. at 327-28 (internal citations omitted). The inquiry is normally broken into three parts: “(1) identifying the elements of the [counter]claim, (2) reviewing the [counterclaims] to strike conclusory allegations, and then (3) looking at the well-pleaded components of the [counterclaim] and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged.” Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011).

A counterclaim must do more than allege a defendant’s entitlement to relief, rather it must “show” such an entitlement with its facts. Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d

Cir. 2009) (citing Phillips v. County of Allegheny, 515 F.3d 224, 234-35 (3d Cir. 2008)). “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the [counterclaim] has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” Iqbal, 556 U.S. at 679 (alteration in original) (citation omitted). The “plausibility” determination is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” Id.

**B. Motion to Strike an Affirmative Defense Under Federal Rule of Civil Procedure 12(f)**

Federal Rule of Civil Procedure 12(f) provides in pertinent part that “[t]he court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). At times, “motions to strike ‘serve a useful purpose by eliminating insufficient defenses and saving the time and expense which would otherwise be spent in litigating issues which would not affect the outcome of the case.’” White v. PNC Fin. Servs. Grp., Inc., No. 11-7928, 2017 WL 3675311, at \*2 (E.D. Pa. Aug. 24, 2017) (quoting Mifflinburg Telegraph, Inc. v. Criswell, 80 F. Supp. 3d 566, 573 (M.D. Pa. 2015)) (citations omitted). But “[t]he striking of a pleading is a drastic remedy to be used sparingly because of the difficulty of deciding a case without a factual record.” Id. (internal quotations and citations omitted). Therefore, “[m]otions to strike are generally disfavored.” Id.

**IV. ANALYSIS**

**A. Defendant’s Inequitable Conduct Allegations Fail to Meet Federal Rule of Civil Procedure 9(b)’s Particularity Requirement**

Because Defendant fails to plead with particularity its inequitable conduct counterclaim and affirmative defense, for reasons described in more detail below, it does not meet Federal Rule of Civil Procedure 9(b)’s heightened pleading requirement. In its eighth affirmative defense,

Defendant alleges Plaintiff's '143 and '771 Patents "are unenforceable due to [Plaintiff's] inequitable conduct before the USPTO." (Doc. No. 40 at 13.) Similarly, in its third counterclaim, Defendant requests the Court declare unenforceable the '143 and '771 Patents due to Plaintiff's inequitable conduct during the prosecution of these patents. (See id. at 19-20 ¶¶ 36-42.) Because Defendant's eighth affirmative defense and third counterclaim are both based on inequitable conduct allegations, the parties agree they "rise and fall together." (See Doc. No. 44 at 11; Doc. No. 47 at 11; Doc. No. 49 at 4.)

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." <sup>4</sup> Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011). To prove inequitable conduct, the asserting party "must present evidence that the [patent] applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the Patent and Trademark Office (PTO)." Star Sci., Inc., v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008). Because "[a] claim for patent unenforceability premised upon inequitable conduct is a claim sounding in fraud," inequitable conduct counterclaims must meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). Senju Pharm. Co., Ltd. v. Apotex, Inc., 921 F. Supp. 2d 297, 306 (D. Del. 2013); Therasense, 649 F.3d at 1304-05. Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

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<sup>4</sup> Federal Circuit law, rather than "the law of the regional circuit," is applied "to the question of whether inequitable conduct has been plead with particularity under Rule 9(b)." Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009).

“[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, and how of the material misrepresentation or omission committed before the PTO.” Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328 (Fed. Cir. 2009). The Federal Circuit has held that “the materiality required to establish inequitable conduct is but-for materiality.” Therasense, 649 F.3d at 1291. In other words, to prove the allegedly omitted information is material, the party asserting inequitable conduct must allege that but-for the omitted information, the PTO would not have issued the patent. Id. “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 information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” Id. at 1328-29.

Here, because Defendant fails to plead the specific “who,” “where,” and “how” of its inequitable conduct claim, and also fails to demonstrate the materiality of the allegedly omitted information, its allegations do not satisfy Rule 9(b)’s particularity requirement.<sup>5</sup> The Court will address each requirement in turn.

### **1. Defendant Fails to Identify “Who” Committed the Material Omission Before the Patent and Trademark Office**

To satisfy the “who” requirement, “[t]he Federal Circuit has held that a pleading must name a specific individual associated with the patent application.” Telebrands Corp. v. 1byOne Products, Inc., No. 17-997, 2018 WL 3696558, at \*2 (D. Del. Aug. 3, 2018) (citing Exergen, 575 F.3d at 1328) (emphasis added). “This ruling is consistent with cases in this district finding

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<sup>5</sup> As described in more detail below, Defendant does sufficiently allege the “what” and “when” of the material omission committed before the PTO.

adequate identification of the ‘who’ when the pleading specifically identifies individuals by name who were associated with the patent application.” Id. Moreover, identifying a corporation, rather than an individual, as the “who” is not enough to satisfy this requirement. See Exergen, 575 F.3d at 1329 (explaining that the duty of candor and good faith in dealing with the PTO, the duty upon which inequitable conduct claims are based, applies exclusively to individuals and not to organizations).

Here, because Defendant only vaguely alleges that “IEH failed to disclose relevant and material documents,” it fails to satisfy the “who” requirement under Rule 9(b). (Doc. No. 40 at 19-20 ¶¶ 38-39 (emphasis added).) Defendant’s use of “IEH” is short for Plaintiff’s full organizational name, the Institute for Environmental Health. As such, Defendant is attempting to identify an entire corporation as the “who” that allegedly failed to disclose material information. But courts have held that identifying a corporation rather than an individual is not enough to satisfy Rule 9(b)’s particularity requirement. See Int’l Business Machines Corp. v. Priceline Group Inc., No. 15-137, 2017 WL 1349175, at \*8 (D. Del. Apr. 10, 2017) (“[T]o the extent Defendants’ allegations are directed against the corporate entities ‘IBM’ and ‘Trintex,’ they cannot serve as the basis for an inequitable conduct counterclaim.”), report & recommendation adopted, 2017 WL 11549735 (D. Del. May 10, 2017); Senju, 921 F. Supp. 2d at 307 (concluding the defendant’s “inclusion of general entities . . . in the pleadings does not permit the court to reasonably infer that any specific individual was responsible”).

Moreover, to the extent that Defendant alleges “IEH’s attorneys” omitted material information, this is similarly insufficient to satisfy the “who” requirement. (See Doc. No. 40 at 20 ¶ 40 (“[A]t least IEH’s attorneys had knowledge of the adverse rulings and other material documents . . .”)); see also Exergen, 575 F.3d at 1329 (holding that because the pleadings merely

referred “generally to ‘Exergen, its agents and/or attorneys,’ but fail[ed] to name the specific individual associated with the filing or prosecution of the application” of the patent, this did not satisfy the “who” requirement); Senju, 921 F. Supp. 2d at 307 (finding the defendant’s allegation that “Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf made the alleged misrepresentations and omissions before the PTO” is insufficient with respect to the “who” requirement because the defendant’s “vague allegations could implicate all or none of the individuals who had dealings with the PTO during the reexamination”).

Defendant argues that because “only one individual could have been responsible for the omission on behalf of IEH during prosecution of the ‘143 and ‘771 Patents,” and this individual’s name is reflected on the publicly available PTO proceeding records, it satisfies the “who” requirement. (Doc. No. 47 at 12.) But because Defendant elected to identify “IEH” or its attorneys generally in its Amended Answer rather than the one individual it claims is responsible for the omission on behalf of IEH, this language is not specific enough to satisfy the “who” requirement.

For example, in Int’l Business Machines Corp. v. Priceline Group Inc., the court acknowledged that the defendant’s pleading identifying “‘named inventors’ and ‘prosecuting attorneys’ . . . could be specific enough to meet the ‘who’ requirement,” but only “to the extent that [these identifications] could be understood to accuse each of the members of a known, clearly ascertainable group.” Priceline, 2017 WL 1349175, at \*9 (emphasis in original). Here, Defendant’s use of “IEH” cannot be understood as an accusation of inequitable conduct against every member of IEH. And to the extent that Defendant alleges “IEH’s attorneys” omitted material information, this allegation is also not specific enough to satisfy the “who” requirement because, as Defendant admits, it is only accusing one attorney of inequitable conduct rather than every IEH attorney as the allegation’s language implies. (See Doc. No. 47 at 12.)

Accordingly, because Defendant failed to identify a specific individual associated with the ‘143 and ‘771 Patents’ applications and instead vaguely identified an entire corporation and its attorneys, its allegations in the Amended Answer are not pled with the requisite particularity to satisfy the “who” requirement under Rule 9(b).<sup>6</sup>

## **2. Defendant Sufficiently Identifies “What” the Material Omission Before the Patent and Trademark Office Consists Of**

To sufficiently allege “what,” the pleading must identify specific claims and claim limitations to establish the materiality of the omitted information or documents to the patents-in-suit. Exergen, 575 F.3d at 1329. Here, as above, Defendant alleges that “IEH failed to disclose relevant and material documents, such as office actions, responses, and third-party comments from the ‘584 Reexamination proceeding,” and that these omitted documents are relevant because certain claims of the ‘143 and ‘771 Patents were found not patentably distinct from claims of the ‘548 Patent that the ‘584 Reexamination deemed not patentable. (Doc. No. 40 at 19-20 ¶¶ 38-39.) While Defendant does not specify which of the ‘143 and ‘771 Patents’ claims were not patentably distinct from the ‘584 Patent’s claims, this information is discoverable through the PTO’s publicly

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<sup>6</sup> While the Court considers, *infra*, the PTO’s public record when concluding that Defendant met the requirements for “what” and “when,” the fact that the specific “who” responsible for the ‘143 and ‘771 Patents’ prosecution is discoverable through the PTO’s public records does not make Defendant’s vague allegations that “IEH failed to disclose” and “IEH’s attorneys had knowledge” sufficient to satisfy the “who” requirement. (Doc. No. 40 at 19-20 ¶¶ 38-40.) Courts have repeatedly considered similarly vague allegations and have consistently concluded that the pleadings must name the specific individual accused of inequitable conduct despite the fact the names of the individuals responsible for the patent prosecutions are available in the PTO’s public record. *See Exergen*, 575 F.3d at 1329 (concluding the defendant’s allegation that “Exergen, its agents and/or attorneys” did not satisfy the “who” requirement because it “fail[ed] to name the specific individual associated with the filing or prosecution of the application”); *Senju*, 921 F. Supp. 2d at 307 (concluding the defendant’s allegation that “Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf” did not satisfy the “who” requirement); *Telebrands*, 2018 WL 3696558, at \*2 (concluding the defendant’s “generic reference [in its pleading] to the ‘named inventors’ [on a patent] is insufficient to satisfy the ‘who’ component of the pleading standard”).

available proceeding records. See Senju, 921 F. Supp. 2d at 306 (explaining that, when reviewing a motion to dismiss filed under Rule 12(b)(6), “[a] court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference”). As such, because Defendant alleged that the omitted documents are relevant to the claims of the ‘143 and ‘771 Patents that were deemed not patentably distinct from the ‘584 Patent’s claims and the exact claims found not patentably distinct are discoverable through the PTO’s public records, Defendant has pled “what” with the requisite particularity under Rule 9(b).

### **3. Defendant Sufficiently Identifies “When” the Material Omission Was Committed Before the Patent and Trademark Office**

To sufficiently allege “when,” the pleading should indicate when the party accused of inequitable conduct allegedly submitted a filing to the PTO that should have identified the omitted information or documents. Telebrands Corp. v. 1byOne Products, Inc., No. 17-997, 2018 WL 3696558, at \*3 (D. Del. Aug. 3, 2018). Here, Defendant alleges that “[d]uring the prosecution of the ‘143 [and ‘771] Patent[s], IEH failed to disclose relevant and material documents . . . .” (Doc. No. 40 at 19-20 ¶¶ 38-39 (emphasis added).) Because Defendant specified the relevant period was during the ‘143 and ‘771 Patents’ prosecution, and the specific dates of this period are a matter of public record, this allegation is pled with sufficient particularity to satisfy the “when” requirement under Rule 9(b).

### **4. Defendant Fails to Identify “Where” the Material Omission Was Committed Before the Patent and Trademark Office**

To adequately allege “where,” the pleading must point to where in the allegedly omitted documents the material information is found. Exergen, 575 F.3d at 1329. Here, as above, Defendant argues it satisfied the “where” requirement by alleging that Plaintiff “failed to disclose [during prosecution of the ‘143 and ‘771 Patents] relevant and material documents, such as office

actions, responses, and third-party comments from the ‘584 Reexamination proceeding.” (Doc. No. 40 at 19-20 ¶¶ 38-39.) In other words, Defendant contends it satisfied the “where” requirement by pleading “that the materials were omitted in submissions to the Patent Office during prosecution” of the ‘143 and ‘771 Patents. (Doc. No. 47 at 15.) But the “where” requirement does not ask the asserting party to plead where the material documents are omitted from but rather where in the omitted documents material information is found.

Defendant relies on Senju Pharm. Co., Ltd. v. Apotex, Inc. to support its argument that the “where” requirement can be satisfied by indicating where the material documents are omitted from. 921 F. Supp. 2d 297 (D. Del. 2013). In Senju, the court found the “where” requirement was satisfied because the defendant’s pleading described “materials omitted in submissions to the PTO and teachings of the written description.” Id. at 306-07 (emphasis added). Although the Senju defendant did not point to exactly where in the omitted documents the material information was located, it did describe with specificity the information contained in the omitted documents that it alleged to be material. Id. at 300-01, 305. Through these descriptions, an individual reading the omitted documents could locate the allegedly material information within the documents.

Here, Defendant does not describe in its Amended Answer the specific information contained in the omitted documents that it alleges to be material. (See generally Doc. No. 40.) Instead, as discussed supra, it merely alleges that Plaintiff “failed to disclose relevant material documents, such as office actions, responses, and third-party comments from the ‘584 Reexamination proceeding” and implies that these documents are relevant because certain claims in the ‘584 Patent “deemed not patentable on multiple occasions” throughout the ‘584 Reexamination were found not patentably distinct from claims in the ‘143 and ‘771 Patents. (Id. at 19-20 ¶¶ 38-39.) But unlike the information provided in the Senju defendant’s pleading, the

statement in Defendant’s Amended Answer that three broad categories of documents are relevant would not allow a reader to locate within those documents the specific information that Defendant claims to be material. As such, Defendant’s reliance on Senju is misplaced, and therefore its Amended Answer fails to plead with particularity where in the allegedly omitted documents material information is found.

**5. Defendant Fails to Identify “How” the Material Omission Was Committed Before the Patent and Trademark Office**

To adequately allege “how,” the pleading must identify how an examiner would have used the allegedly omitted “information in assessing the patentability of the claims.” Exergen, 575 F.3d at 1329-30. Here, Defendant alleges IEH failed to disclose material documents from the ‘584 Reexamination that “would have impacted the patentability” of both patents. (Doc. No. 40 at 15-16 ¶¶ 17-18, 19-20 ¶¶ 38-39.) But these allegations do not explain how the examiner of the ‘143 and ‘771 Patents would have used the allegedly omitted information in assessing the patentability of the claims. Without specific allegations providing this explanation, Defendant’s vague assertion that the omitted information “would have impacted the patentability” of the ‘143 and ‘771 Patents does not satisfy the “how” requirement. See Telebrands, 2018 WL 3696558, at \*3 (“The pleading also fails to address the ‘how’ factor, offering no explanation as to how a reasonable examiner would use the omitted prior art references in determining the patentability of the Asserted Patents.”); Priceline, 2017 WL 1349175, at \*11 (“Although Defendants assert that the Trintex NEXIS Articles are material to patentability, and that the ‘967 patent ‘would not have properly issued [if the articles were disclosed] because the Trintex NEXIS Articles anticipated the claimed subject matter or rendered the claimed subject matter obvious[,]’ they do not offer any specific reasoning as to how what was in the articles show that this is the case.”)

**6. Defendant's Allegations Do Not Support a Reasonable Inference of But-For Materiality**

As described above, a party asserting an inequitable conduct claim must allege the omitted information is material through Therasense's but-for test, pleading that the PTO would not have issued the patent-in-suit but-for the omission. See Therasense, 649 F.3d at 1291. Here, Defendant alleges the omitted information is material because it "would have impacted the patentability" of the '143 and '771 Patents. (Doc. No. 40 at 16 ¶ 18, 19-20 ¶¶ 38-39.) But alleging omitted information would have *impacted* the patentability is not the same as alleging that it would have *prevented* the patents from issuing. Under Therasense's but-for test, merely alleging an impact on patentability is not enough without further providing the underlying reasoning on how the impact would have prevented issuance of the patent.

At best, Defendant's allegations state generally that the allegedly omitted documents would be relevant to and would have an impact on the '143 and '771 Patents' prosecution. Defendant alleges the '143 and '771 Patents contained claims that were deemed patently indistinct from claims in the '584 Patent that, on reexamination, were determined to be not patentable. (See id. at 20 ¶¶ 38-40.) But merely saying that omitted information would be relevant does not rise to the level necessary to establish but-for materiality. The fact that a general category of information is relevant to the prosecution of a patent does not allow a court to draw the inference that but-for the disclosure of this relevant information, the patent would not have issued. See XpertUniverse, Inc. v. Cisco Systems, Inc., 868 F. Supp. 2d 376, 383 (D. Del. 2012) ("Cisco alleges only that [a third party] identified prior art that was 'relevant' to potentially patentable inventions; there is no allegation . . . that the prior art [the third party] identified would have prevented a patent examiner from issuing the patents but for the alleged omission. . . . The Court cannot reasonably draw the inference that the patents would not have issued but for the alleged omission of the generally

‘relevant’ references [the third party] identified.”) As such, Defendant fails to demonstrate the but-for materiality of the allegedly omitted information. Accordingly, accepting Defendant’s allegations as true and construing all facts in the light most favorable to it, Defendant’s inequitable conduct allegations do not meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b).<sup>7</sup>

**B. Defendant’s Request for Leave to Amend Its Amended Answer Will Be Granted**

“After amending once or after an answer has been filed, [a party] may amend only with leave of court or the written consent of the opposing party, but ‘leave shall be freely given when justice so requires.’” Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000) (quoting Fed. R. Civ. P. 15(a)). Whether to grant or deny leave to amend is within the discretion of the District Court. Id. “Among the grounds that could justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice, and futility.” In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997).

Plaintiff argues Defendant’s request for leave to amend should be denied because amendment would be futile. (Doc. No. 44 at 14.) Denying leave to amend based on futility “means that the complaint, as amended, would fail to state a claim upon which relief could be granted.” Shane, 213 F.3d at 115. “In assessing ‘futility,’ the District Court applies the same standard of legal sufficiency as [it] applies under Rule 12(b)(6). Accordingly, if a claim is vulnerable to

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<sup>7</sup> Plaintiff further argues that Defendant fails to adequately allege inequitable conduct because its Amended Answer contains no “allegations sufficient [for the Court] to reasonably infer that IEH’s representatives intended to deceive the PTO.” (Doc. No. 44 at 13.) But because Defendant’s failure to satisfy Rule 9(b)’s heightened pleading requirement is fatal to its inequitable conduct counterclaim and affirmative defense, the Court need not consider whether Defendant alleged the requisite intent.

dismissal under Rule 12(b)(6), but the [party] moves to amend, leave to amend generally must be granted unless the amendment would not cure the deficiency.” Id.

Here, because Defendant has demonstrated through its arguments in its Opposition Brief and by counsel at the November 20, 2024 hearing that it can amend its pleading to better satisfy Rule 9(b)’s particularity standard, amendment would not be futile.<sup>8</sup> (See Doc. Nos. 47, 71.) For example, when arguing in its Opposition Brief that it sufficiently alleged “who” omitted the material information from the ‘143 and ‘771 Patents’ prosecution, Defendant specifies that Dr. Barry L. Davison was “the sole attorney who appears on behalf of IEH in all of the prosecution and Reexamination proceedings.” (Doc. No. 47 at 12.) With this information, Defendant can satisfy the “who” requirement that the pleading “name a specific individual associated with the patent application.” Telebrands, 2018 WL 3696558, at \*2 (emphasis added).

Moreover, at the November 20, 2024 hearing, Defendant explained that among the “office actions, responses, and third-party comments from the ‘584 Reexamination proceeding” were decisions from the PTO Central Reexamination Unit (“CRU”) in which the CRU found all claims of the ‘584 Patent to be not patentable. Defendant presented a timeline, reproduced in part above, indicating that the CRU had reached this conclusion three times over a two-year period spanning from May 2010 to February 2012. The timeline also indicated that after the CRU’s final decision in February 2012, Plaintiff appealed these CRU decisions and that, in January 2015, the Appeal Board issued a decision also determining that the ‘584 Patent’s claims were not patentable. After

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<sup>8</sup> Defendant cannot save its eighth affirmative defense and third counterclaim from dismissal by raising facts and arguments in its Opposition Brief and at the November 20, 2024 hearing that were not pled in its Amended Answer. See Equil IP Holdings LLC v. Akamai Techs., Inc., 722 F. Supp. 3d 450, 455 (D. Del. 2024) (declining to consider arguments raised for the first time in the defendant’s opposition brief on a motion to strike); M2M Sols. LLC v. Telit Commc’ns PLC, No. 14-1103, 2015 WL 4640400, at \*3 (D. Del. Aug. 5, 2015) (declining to consider new facts and theories from the plaintiff’s opposition brief on a motion to dismiss).

this decision, the timeline reflects that Plaintiff attempted to amend and narrow the ‘584 Patent’s claims but that, in July 2015, the CRU again issued a decision finding the claims not patentable. If Defendant were to include this information in its inequitable conduct counterclaim and affirmative defense, specifically the decisions made by the CRU and Appeal Board deeming the ‘584 Patent’s claims not patentable, this would better satisfy the “where” requirement. See Senju, 921 F. Supp. 2d at 306-07 (holding the defendant’s pleading satisfied the “where” requirement because it contained descriptions of the specific information contained within the omitted documents that the defendant alleged to be material).

Defendant also demonstrated it can better satisfy the “how” and but-for materiality requirements. As discussed above, Defendant attempts to satisfy these requirements by merely alleging that the omitted information “would have impacted the patentability” of the ‘143 and ‘771 Patents. (Doc. No. 40 at 15-16 ¶¶ 17-18, 19-20 ¶¶ 38-39.) But if Defendant were to further elaborate, as its counsel did during the hearing, that the omitted information included decisions from the ‘584 Reexamination concluding the ‘584 Patent’s claims were not patentable and that the unpatentable claims are similar to the claims of the ‘143 and ‘771 Patents, this would better explain how an examiner would have used these decisions in assessing the patentability of the ‘143 and ‘771 Patents’ claims. Furthermore, if Defendant drew on these allegations for the “how” requirement and simply changed its allegation from “would have *impacted* the patentability” to “would have *prevented* the patentability,” this would better satisfy the but-for materiality requirement that Defendant allege the PTO would not have issued the ‘143 and ‘771 Patents but-

for the omitted information. Accordingly, Defendant's request for leave to amend its Amended Answer will be granted.<sup>9</sup>

## **V. CONCLUSION**

For the foregoing reasons, Plaintiff's Motion to Dismiss Defendant's Third Counterclaim and Motion to Strike Defendant's Eighth Affirmative Defense (Doc. No. 44) will be granted and Defendant's request for leave to amend its Amended Answer will be granted. An appropriate Order follows.

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<sup>9</sup> Although the Court highlights readily available information that may overcome deficiencies in the Amended Answer, Defendant may wish to include more allegations to satisfy the pleading standard and the but-for materiality standard.