

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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NATERA, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 20-1352
	:	
GENOSITY INC.,	:	
	:	
Defendant.	:	

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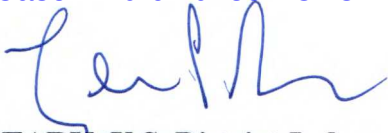
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**MEMORANDUM OPINION**

March 14, 2022  
Wilmington, Delaware



**STARK, U.S. District Judge:**

Pending before the Court is Plaintiff Natera, Inc.’s (“Plaintiff” or “Natera”) motion to dismiss and strike (D.I. 12), filed pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(f), directed to Defendant Genosity Inc.’s (“Defendant” or “Genosity”) counterclaim for a declaratory judgment of unenforceability due to inequitable conduct and the affirmative defenses of unclean hands, prosecution laches, and inequitable conduct, as set forth in the Answer and Counterclaims (D.I. 9). The Court has reviewed the parties’ briefs and other submissions. (*See, e.g.*, D.I. 13, 14, 17, 19) For the reasons explained below, the Court will deny Natera’s motion.

## **I. BACKGROUND**

Natera filed its complaint in this case on October 6, 2020, alleging that Genosity has infringed U.S. Patent No. 10,731,220 (the “’220 patent”).<sup>1</sup> (D.I. 1 ¶ 1) The ’220 patent claims “methods for simultaneously amplifying multiple nucleic acid regions of interest in a single reaction volume using universal primers, gene specific primers and molecular barcode.” (*Id.* ¶ 31) The complaint alleges that Genosity “does not have freedom to operate its AsTra products for minimal residual disease (‘MRD’) and personalized cancer monitoring” and that the accused products “use ArcherDX, Inc.’s (‘Archer’s’) ctDNA chemistry and region-specific primers, which infringe the ’220 patent.” (*Id.* ¶ 1)

Natera has also sued Archer in a separate patent infringement action in this Court. (*Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125) (the “*Archer* action”) In the *Archer* action, Natera asserts five patents, including the ’220 patent and U.S. Patent No. 10,538,814 (the “’814 patent”). (C.A. No. 20-125 D.I. 391 ¶ 1) The ’814 patent shares the same specification as

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<sup>1</sup> The Court believes that Natera’s reference to the patent-in-suit as “United States Patent No. 10,732,220” is a typographical error. (*See* D.I. 1 Ex. 1; D.I. 9 Answer ¶ 1 n.2)

the '220 patent. (D.I. 9 Answer ¶ 127, Counterclaims ¶ 41) In connection with a motion for judgment on the pleadings in the *Archer* action (C.A. No. 20-125 D.I. 23), Archer challenged the subject matter eligibility of the asserted patents under 35 U.S.C. § 101. The Court denied that motion, finding that “the claims here, as represented by claim 1 of the '814 [patent], . . . are method of preparation claims and therefore eligible for patenting.” (C.A. No. 20-125 D.I. 63 at 8) The *Archer* action remains pending in this Court.

On February 15, 2021, Genosity answered the complaint in this action and asserted 14 affirmative defenses and three counterclaims. (D.I. 9) At issue in the pending motion are the counterclaim for a declaratory judgment of unenforceability of the '220 patent due to inequitable conduct and the affirmative defenses of unclean hands, prosecution laches, and inequitable conduct. (*See id.* Answer ¶¶ 95-138, Counterclaims ¶¶ 33-52) Genosity alleges that Natera’s Executive Chairman, Dr. Rabinowitz, failed to disclose several litigation-related documents to the U.S. Patent and Trademark Office (“PTO”) during prosecution of the '220 patent. (*See id.* Answer ¶¶ 120-38, Counterclaims ¶¶ 33-52) The affirmative defenses also include allegations that Natera misused Archer’s confidential information and obtained claims to cover methods Natera did not invent (*see id.* Answer ¶¶ 95-117), and that Natera unreasonably delayed the prosecution of the claims of the '220 patent (*see id.* Answer ¶¶ 118, 119).

On March 8, 2021, Natera filed the pending motion to dismiss and strike. (D.I. 12)

## **II. LEGAL STANDARDS**

### **A. Motion to Dismiss**

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). “The issue is not whether a plaintiff will ultimately prevail but

whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted).

Thus, the Court may grant such a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, “[t]o survive a motion to dismiss, a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). At bottom, “[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim. *Wilkerson v. New Media Tech. Charter School Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true “bald assertions,” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), “unsupported conclusions and unwarranted inferences,” *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are “self-evidently false,” *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

**B. Motion to Strike**

“Rule 12(b)(6) does not offer a mechanism for dismissing an affirmative defense.” *Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, at \*4 (D. Del. Feb. 3, 2012). Instead, “pursuant to Rule 12(f), the Court may strike from a pleading any insufficient defense.” *Id.* (internal quotation marks omitted). A court should not strike a defense unless its insufficiency is “clearly apparent.” *Fesnak & Assocs., LLP v. U.S. Bank Nat’l Ass’n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010) (quoting *Cipollone v. Liggett Grp., Inc.*, 789 F.2d 181, 188 (3d Cir. 1986)). However, “a court is not required to accept affirmative defenses that are mere bare bones conclusory allegations, and may strike such inadequately pleaded defenses.” *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 408 (D. Del. 2009).

**III. DISCUSSION**

**A. Inequitable Conduct  
(Genosity’s Fourteenth Defense and Third Counterclaim)**

To prevail on the merits of an inequitable conduct defense, “the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). With respect to materiality, the accused infringer must show that but for an omission by the applicant, the PTO would not have issued the patent claim. *See id.* at 1291-92. Deceptive intent may be inferred from indirect and circumstantial evidence. *See id.* at 1290. On the merits, “to meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.” *Id.* (internal quotation marks omitted). At the pleading stage, however, proof by clear and convincing evidence is not required. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 n.5 (Fed. Cir. 2009). Nonetheless, inequitable

conduct must be pled with particularity, to satisfy the requirements of Federal Rule of Civil Procedure 9(b). *See id.* at 1328-29. Hence, a pleading of inequitable conduct must include “sufficient allegations of underlying facts from which a court may reasonably infer” both the knowledge of material information and the specific intent to deceive the PTO. *See id.*

In this case, Genosity alleges that Dr. Rabinowitz, the Executive Chairman of Natera, engaged in inequitable conduct during prosecution of the ’220 patent by failing to disclose several litigation-related documents to the PTO.<sup>2</sup> (*See* D.I. 9 Answer ¶¶ 120-38, Counterclaims ¶¶ 33-52) Natera contends that Genosity’s pleading is insufficient because it fails to plausibly allege: (1) the withheld documents are material to the patentability of the ’220 patent (*see* D.I. 13 at 8-13), and (2) Dr. Rabinowitz possessed the specific intent to deceive the PTO (*see id.* at 13-16). The Court disagrees, as explained below.

**1. Materiality**

**a. Materiality as related to 35 U.S.C. § 101**

Natera first contends that the *Archer* documents (including some *Illumina* documents and *CareDx* documents referenced therein) cannot be but-for material to the patentability of the ’220 patent under Section 101 because the Court had considered these documents and denied Archer’s

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<sup>2</sup> The allegedly withheld documents include: (a) from the *Archer* action: (1) Archer’s Answer (D.I. 14), (2) Archer’s Answer to the First Amended Complaint (D.I. 21), (3) Archer’s Opening Brief in Support of its Motion for Judgment on the Pleadings (D.I. 24), and (4) Archer’s Reply Brief in Support of its Motion for Judgment on the Pleadings (D.I. 36) (collectively, the “*Archer* documents”); (b) in *CareDX, Inc. v. Natera, Inc.*, C.A. No. 19-557 (D. Del.) (the “*CareDX* action”): (1) Natera’s Reply in Support of Motion to Dismiss (D.I. 19), (2) Natera’s Objections to Report and Recommendations (D.I. 63), (3) Natera’s Opening Brief in Support of Renewed Motion to Dismiss (D.I. 87), (4) Natera’s Opening Brief in Support of Summary Judgment of Invalidity (D.I. 101), and (5) Natera’s Statement re Motion for Summary Judgment of Invalidity (D.I. 102) (collectively, the “*CareDX* documents”); (c) in *Illumina, Inc. v. Natera, Inc.*, C.A. No. 18-1662 (N.D. Cal.) (the “*Illumina* action”): (1) Natera’s Motion to Dismiss (D.I. 24), and (2) Natera’s Reply in Support of Motion to Dismiss (D.I. 35) (collectively, the “*Illumina* documents”). (*See* D.I. 9 Answer ¶¶ 123, 128, 130, Counterclaims ¶¶ 37, 42, 44)

Rule 12(c) motion challenging the subject matter eligibility of the '814 patent, which claims methods “closely related” to the '220 patent.<sup>3</sup> (See D.I. 13 at 8-9; see also D.I. 9 Answer ¶¶ 124, 126, Counterclaims ¶¶ 38, 40) The Court’s denial of Archer’s Rule 12(c) motion, however, is not final and may be reviewed on appeal. See, e.g., *CardioNet, LLC v. InfoBionic, Inc.*, 2021 WL 5024388, at \*6-7 (Fed. Cir. Oct. 29, 2021) (finding that district court should have granted defendant’s Rule 12(c) motion as to unpatentability and remanding for entry of judgment of no liability). Hence, Natera’s conclusion that “this Court’s holdings of patentable subject matter . . . preclude but-for materiality of Archer’s failed Rule12(c) motion papers,” is premature.<sup>4</sup> (See D.I. 19 at 2)

**b. Materiality as related to 35 U.S.C. § 103**

Natera’s argument that the *Archer* documents cannot be relevant with respect to Section 103 is also unavailing. Natera contends that the *Archer* documents are not material to the patentability of the '220 patent because the prior art references, which Archer relied on for the invalidity theory disclosed in the *Archer* documents, had been cited to the PTO. (See D.I. 13 at 10-11) However, as Genosity points out, it is the *Archer* documents, “and not the individual prior art references, [that] form the basis for the ‘but-for material’ allegation.” (D.I. 17 at 7) The *Archer* documents “did not merely identify prior art references” but also “set forth that the prior

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<sup>3</sup> Natera requests that the Court take judicial notice of the “Excerpts of Oct. 2, 2020 Transcript, Judge’s Opinion on 9/30/2020 Section 101 Hearing in *Natera, Inc. v. ArcherDX, Inc.*, Case No. 1:20-CV-00125 (D. Del.)” (D.I. 14 at 1) Genosity does not address this request but relies on the same transcript in its brief. (See D.I. 17 at 6) The Court, thus, understands that Genosity does not object.

<sup>4</sup> The Court need not address the parties’ disputes concerning the potential impact of claim construction on the materiality of the withheld documents under Section 101. (See D.I. 17 at 6-7; D.I. 19 at 3-4)

art of Mir alone or Mir in a *specific* combination with Wang, Spertini, or Makarov, discloses all elements of the '814 patent claims.” (D.I. 17 at 7; *see also* D.I. 9 Counterclaims ¶ 40) The Court does not agree with Natera that the *Archer* documents contain “nothing more than a conclusory allegation” (D.I. 19 at 5); instead, at this stage of the proceedings, the Court is persuaded by Genosity that these documents may be found to plausibly provide an “invalidity roadmap” that is materially “different from a collection of thousands of references dumped on a patent examiner” (D.I. 17 at 8). Thus, Natera’s disclosure to the PTO of the individual references cited in the *Archer* documents does not preclude a finding (once this issue reaches the evidentiary stage) that the *Archer* documents are also material to patentability.

Natera’s reliance on *Fiskars, Inc. v. Hunt Manufacturing Co.*, 221 F.3d 1318 (Fed. Cir. 2000), is misplaced. In *Fiskars*, the patentee cited a brochure for a prior art device to the examiner, and the examiner did not consider it during prosecution. *See id.* at 1327. The defendant nonetheless contended that the patentee should have further explained to the examiner the relevance of the device itself. *See id.* The Federal Circuit rejected that contention, holding instead that “[a]n applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.” *Id.* *Fiskars* does not broadly hold, however, that once prior art references are cited to the examiner, patentability information involving the combination of those references can no longer be material. *See, e.g., Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000) (“A withheld reference may be highly material when it discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references.”). Thus, *Fiskars* does not compel a grant of Natera’s motion.



Natera also unpersuasively argues that the withheld documents are cumulative of the information that the PTO already had. (*See* D.I. 13 at 11-12; D.I. 19 at 5-6) The Court disagrees, for essentially the same reasons justifying the Court’s conclusion with respect to materiality. Additionally, the fact that “the examiner was aware of these other litigations and Natera had submitted documents from such litigations to the examiner” does not necessarily lead to the conclusion that the information disclosed in the specific documents at issue here is cumulative of the information included in the documents that had been provided to the PTO. (*See* D.I. 19 at 5)

**c. Materiality as related to 35 U.S.C. § 112**

Natera next contends that Genosity has failed to plead but-for materiality with respect to Section 112. (*See, e.g.*, D.I. 13 at 12) Genosity alleges that Dr. Rabinowitz failed to disclose the *Archer* documents, which set forth that the ’814 patent – a patent that shares a specification with, and claims subject matter closely related to, the ’220 patent (*see* D.I. 9 Answer ¶¶ 124, 127, Counterclaims ¶¶ 38, 41) – is invalid under Section 112.<sup>5</sup> Genosity further alleges that “[i]f the [PTO] had been made aware of these documents setting forth arguments for invalidity under [Section 112] . . . the ’220 patent would not have issued.” (*Id.* Answer ¶ 133, Counterclaims ¶ 47) Based on these factual allegations, at this stage of this case, Genosity has plausibly pled that the *Archer* documents are but-for material to the patentability of the ’220 patent under Section 112.

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<sup>5</sup> For example, Genosity alleges that the *Archer* documents explain how the specification of the ’814 patent “does not disclose (a) an embodiment corresponding to the claimed methods, (b) that the named inventors were in possession of the alleged invention, or (c) sufficient information to enable a person of ordinary skill in the art to practice the claims.” (D.I. 9 Answer ¶ 127, Counterclaims ¶ 41) Genosity also alleges that “the claims were not entitled to a priority date earlier than the filing date” because Natera’s earlier-filed applications do not comply with the requirements under Section 112. (*See id.* Answer ¶¶ 84, 127, Counterclaims ¶ 41)

## 2. Intent To Deceive

With respect to Genosity's allegations of deceptive intent, Natera argues that Genosity fails to plead "*specific factual allegations* showing that a specific individual with knowledge of the material information *decided to deliberately withhold it* from the relevant examiner." (D.I. 13 at 14) (internal quotation marks omitted) Contrary to Natera's suggestion, Genosity is not required at the pleading stage to allege facts satisfying the "high standard" that deceptive intent is the "single most reasonable inference." (*See id.* at 13) Instead, Genosity "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.

Genosity has met this obligation. It has plausibly alleged Dr. Rabinowitz's intent to deceive the PTO. For example, Genosity alleges that, "as a named inventor on the patent in dispute and the Executive Chairman of Natera and someone active in Natera's management," Dr. Rabinowitz was aware of Natera's ongoing litigations and knew of the arguments set forth in the withheld documents while the '220 patent was still in prosecution before the PTO. (*See* D.I. 9 Answer ¶¶ 123, 128, 130, Counterclaims ¶¶ 37, 42, 44) Genosity also alleges that Dr. Rabinowitz knew "he had a duty to disclose these documents to the [PTO]," because other documents in the *Illumina* action pertaining to Section 101 were disclosed to the PTO during prosecution of the '220 patent. (*See id.* Answer ¶ 137, Counterclaims ¶ 51) Genosity further alleges that Dr. Rabinowitz, despite understanding that the withheld documents were material and must be disclosed to the PTO, failed to fulfill his duty of disclosure. (*See id.*) These alleged facts are sufficient to support a reasonable inference that Dr. Rabinowitz intentionally withheld the litigation documents at issue from the PTO during prosecution of the '220 patent, knowing that they were material to the patentability.

For the foregoing reasons, Genosity has plausibly alleged both the materiality of the withheld documents and Dr. Rabinowitz's deceptive intent. Thus, the Court will deny Natera's motion to dismiss the counterclaim for a declaratory judgment of unenforceability due to inequitable conduct and to strike the affirmative defenses of inequitable conduct.

**B. Unclean Hands  
(Genosity's Twelfth Defense)**

“[A] determination of unclean hands may be reached when misconduct of a party seeking relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation.” *Gilead Scis., Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018) (internal quotation marks omitted). Thus, to establish an unclean hands defense, a defendant must show that “(1) a party seeking affirmative relief (2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith (3) directly related to the matter in issue (4) that injures the other party (5) and affects the balance of equities between the litigants.” *Sprint Commc'ns Co. L.P. v. Charter Commc'ns, Inc.*, 2021 WL 982726, at \*12 (D. Del. Mar. 16, 2021).

Genosity alleges that Natera never claimed ArcherDX's method during “protracted and convoluted prosecution at the [PTO] spanning more than a decade” and then drafted the claims of the '220 patent in an attempt to cover ArcherDX's method, doing so “only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's technology and then returned to Natera.” (D.I. 9 Answer ¶¶ 96, 114) A plausible inference can be drawn from these alleged facts that Natera misused ArcherDX's confidential information to obtain claims that it did not invent and then asserted these claims against Genosity.

Natera's contention that it is not inequitable to draft patent claims to cover a competitor's products (*see* D.I. 13 at 17; *see also Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863

F.2d 867, 874 (Fed. Cir. 1988)), is not dispositive here. Even assuming Natera's contention is correct, Genosity's unclean hands defense is not predicated simply on this allegation alone. Natera's remaining criticisms of Genosity's allegations, including that the unclean hands defense is based on merely "conclusory allegations around Section 101 and 103" (D.I. 13 at 18), do not provide a meritorious basis for granting Natera's motion, for reasons including those given above in connection with assessing Natera's attacks on the inequitable conduct claims.

**C. Prosecution Laches  
(Genosity's Thirteenth Defense)**

Prosecution laches "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances." *Cancer Rsch. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010) (internal quotation marks omitted). Natera contends that Genosity's affirmative defense of prosecution laches "simply pleads the legal conclusion of unreasonable delay or prejudice and does not plead any facts, other than simply citing the timeline of applications." (D.I. 13 at 19) The Court, however, agrees with Genosity that its allegations that Natera delayed its prosecution of the claims of the '220 patent, and "Natera has improperly sought to delay competition in the IVD market by pursuing patent claims it did not invent" (*see* D.I. 9 Answer ¶¶ 96, 111, 116), plausibly support an inference that Natera's prosecution delay is "unreasonable and unexplained." (D.I. 17 at 12-13) Accordingly, the Court will deny Natera's motion to strike the affirmative defense of prosecution laches.

**IV. CONCLUSION**

For the foregoing reasons, the Court will deny Plaintiff's motion to dismiss and strike (D.I. 12). An appropriate order follows.