IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIVAGEN PHARMACEUTICALS, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS of NEW YORK, LLC, AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS PVT LTD., and AMNEAL EU, LTD.,

Defendants.

C.A. No. 24-846-GBW

JURY TRIAL DEMANDED

[redacted]

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DEFENDANTS' ANSWERING BRIEF TO PLAINTIFF'S MOTION TO DISMISS AMNEAL PHARMACEUTICALS LLC'S COUNTERCLAIMS V AND VI, AND STRIKE DEFENDANTS' SECOND, THIRD, AND SEVENTEENTH AFFIRMATIVE DEFENSES

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Defendants Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals LLC ("APLLC"), Amneal Pharmaceuticals Pvt. Ltd., and Amneal EU, Ltd.'s (collectively, "Amneal") oppose Plaintiff Nivagen Pharmaceuticals, Inc.'s ("Nivagen") motion to dismiss APLLC's inequitable conduct and wrongful enjoinment counterclaims and to strike Amneal's inequitable conduct, unclean hands, and patent misuse affirmative defenses. ("Motion," D.I. 95.)

I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Nivagen fails to satisfy the high hurdle it must overcome. Amneal has presented in its more than 70-page Answer and Counterclaims over 30 pages of detailed factual allegations supporting APLLC's Counterclaims and Amneal's affirmative defenses. Those allegations more than satisfy *Twombly* and Rule 9(b) where required.[1] Nivagen's scattershot and superficial arguments fail to negate Amneal's well-pled allegations of Nivagen's pattern of misrepresentations to the USPTO to obtain the Asserted Patents and this Court to obtain a TRO/PI. Nivagen's Motion should be denied.

APLLC's inequitable conduct allegations show that each of the named inventors (Brijeshkumar B. Pandya, Govind R. Jagadale, Dasaradhi Lakkaraju, Bala Tripura Sundari Chodavarapu, Anand Shukla, and Jwalant Shukla (the "Named Inventors")) and Nivagen's prosecuting attorneys systematically withheld material information from the United States Patent and Trademark Office ("USPTO") during the prosecution of the Asserted Patents—U.S. Patent Nos. 11,813,291 (the "'291 Patent") and 11,925,661 (the "'661 Patent"). (D.I. 91, ¶ 15[2], Fifth Counterclaim.) Attempting to avoid the consequences of these actions, Nivagen improperly

[1] Amneal's affirmative defenses that are not entirely based on fraud are not entirely subject to a heightened pleading standard.
[2] The cited paragraph numbers in D.I. 91 refer to the paragraphs in APLLC's Counterclaims.

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dissects APLLC's inequitable conduct allegations and presents them piecemeal. In doing so, Nivagen fails to examine the allegations as a whole, as required by governing law. Nivagen's isolated attacks ignore allegations, rely on disputed facts, and improperly demand that APLLC fully prove its case at the pleading stage. Indeed, Nivagen's Motion seeks to preclude APLLC from alleging inequitable conduct altogether based on the Court's preliminary findings during the temporary restraining order ("TRO")/preliminary injunction ("PI") proceedings last year. Nivagen provides no support for such an extraordinary request and Supreme Court precedent forbids it. Amneal has alleged sufficient facts to meet the pleading requirements of Rule 9(b).

Nivagen's arguments as to APLLC's wrongful enjoinment counterclaim also fail. APLLC's detailed allegations support the premise that Nivagen knowingly made false and misleading statements in bad faith to secure the TRO/PI to delay Amneal's product launch. (D.I. 91, Sixth Counterclaim, ¶¶ 121-137.) During the TRO/PI proceedings, Nivagen's arguments for a low bond amount directly contradicted its arguments that it would suffer substantial irreparable harm. (*See* D.I. 68, Exhibit A (providing a table of Nivagen's contradictory representations during the TRO/PI proceedings).) APLLC's detailed pleadings, when accepted as true at this stage, meet the heightened pleading standard.

Nivagen's Motion should be denied.

II. STATEMENT OF FACTS AND WELL-PLED ALLEGATIONS

A. Nivagen Merely Owns the Asserted Patents and Has No Ability to Market and Sell Potassium Phosphates Products in the United States

Nivagen is a company in California that relies on partners to obtain FDA approval of pharmaceutical products which it distributes. *See* https://nivagen.com/our-products/ (identifying its approximately ten generic drug products). In this case, Nivagen alleges that it is the owner of

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the Asserted Patents—both titled "Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions." (D.I. 88, ¶ 23.)

Nivagen does not own a new drug application ("NDA") for a ready-to-use ("RTU") potassium phosphates product. (D.I. 91 (Answer), ¶¶ 27, 30, 123.) Instead of filing its own NDA, Nivagen allegedly entered into a business arrangement with the leader in the potassium phosphates injectable market, Fresenius Kabi ("FK"), who filed an NDA [redacted].[3] (*See* D.I. 91, ¶¶ 27, 28, 132.) Notably, there is no evidence that Nivagen has the practical ability or legal authority [redacted] which would be in direct competition with FK's market leading injectable product, [redacted]. (*See id.* ¶ 130.) Indeed, after the Court ordered Nivagen to post a $30,000,000 bond, [redacted] (*See id.* ¶ 51-55.)

B. Nivagen Concealed the FK PI from the USPTO

APLLC's Counterclaim pleads textbook inequitable conduct—withholding material prior art (the 2019 Fresenius Kabi Package Insert ("FK PI")) during prosecution of the Asserted Patents with the intent to deceive the USPTO. The Counterclaim provides the names of the individuals that violated their duty of disclosure to the USPTO, the evidence of their knowledge, the details of the material prior art that was concealed from the USPTO, and how and why that information was material to patentability. (*See* D.I. 91 ¶¶ 9-26, 88-120.) The Counterclaim states that the

[3] In its TRO/PI application, Nivagen claimed that its potassium phosphates products would be FDA approved [redacted] After the TRO/PI was dissolved due to Nivagen's inability to post a bond, it amended its Complaint, [redacted]. (D.I. 91, ¶ 56.) Nivagen has not explained the reasons for this change in circumstances, including when it knew [redacted]

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Named Inventors knew about the FK PI because, among other things, it was the starting point for the alleged development of the potassium phosphates products claimed in the Asserted Patents and was the standard of care potassium phosphates product described in the FK PI. (*Id.* ¶¶ 93-96.) The Named Inventors even included references to the FK PI in the U.S. Provisional Application the Asserted Patents claim priority to ("Provisional Application"). (*Id.* ¶ 97.) The Counterclaim also alleges that Martin Fessenmaier, Mei Tsang, Ryan Dean, and Darian McMillan ("Prosecutors") knew of the FK PI because they were involved in the drafting and filing of the Provisional Application. (*Id.* ¶¶ 25, 92-93, 97.)

The Counterclaim goes on to allege that the Named Inventors and the Prosecutors knew about the FK PI during prosecution of the Asserted Patents, but knowingly concealed that information from the USPTO by (1) withholding the FK PI from the USPTO and (2) specifically removing any reference of the FK PI from the non-provisional application that ultimately issued as the '291 Patent to hide its existence during prosecution. (*Id.* ¶¶ 92, 107, 114.) In other words, Nivagen's intentional and fraudulent deception is exemplified by its active concealment of its own understanding of the FK PI's disclosures and further evidences the Named Inventors' and Prosecutors' knowledge and intent to deceive. (*Id.* ¶¶ 118-120.)

The Counterclaim also explains the materiality of the FK PI. For example, the Counterclaim steps through some of the key disclosures in the FK PI (*id.* ¶¶ 99-110) and details how it anticipates at least one claim of the Asserted Patents. (*Id.* ¶¶ 111-120.) Accordingly, had the Named Inventors and Prosecutors "disclosed the FK PI to the Examiner in accordance with their duty of candor in an information disclosure statement, the [Asserted Patents] would not have issued." (*Id.* ¶¶ 112-113; 115-118.) Thus, the Counterclaim plausibly pleads that the Named Inventors and Prosecutors (i) had a duty of candor that required them to submit the FK PI to the

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USPTO; (ii) believed that the USPTO would not have allowed claims of the Asserted Patent if it had known of the FK PI; and (iii) as a result deliberately withheld that FK PI from the USPTO to deceive the examiner during prosecution of the Asserted Patents.

C. Nivagen's Misrepresentations to the Court Resulted in Wrongful Enjoinment

APLLC's wrongful enjoinment counterclaim has also been properly pled. (D.I. 91, Sixth Counterclaim.) During the TRO/PI proceedings, Nivagen repeatedly made statements to the Court about the status of FK's NDA file, the sales Nivagen expected to make as the first mover, and how low the sales would be if Amneal launched its FDA-approved RTU product first. (D.I. 91, Sixth Counterclaim; D.I. 68, Exhibit A.) These contradictory positions were designed to secure the TRO and PI by arguing that Nivagen would be substantially damaged for purposes of irreparable harm, but conversely that Amneal would make almost no sales and experience little to no damage for purposes of securing a low bond. (D.I. 68, Exhibit A.) The Court relied on Nivagen's statements for irreparable harm when granting the TRO/PI as Nivagen "assured" the Court of its expected approval of the FK RTU NDA in 2024 (D.I. 91, ¶ 40) and the alleged damage that would occur if Amneal launched first. Despite Nivagen's assurances, the FK RTU NDA did not receive FDA approval when Nivagen "expected" it to in 2024 and such approval [redacted] (D.I. 91, ¶ 56.) The Court also agreed with Amneal and found that "many of Plaintiff's arguments in support of a lower bond amount contradict Plaintiff's earlier claims of irreparable harm." (D.I. 70 (Memorandum Order) citing D.I. 68 at 1 ("Nivagen cannot have it both ways—total destruction when arguing for irreparable harm and near zero impact when arguing for a lower bond.").) As pleaded in APLLC's Answer (and incorporated by reference into Defendants' affirmative defenses), Nivagen's statements were knowingly false and made in bad faith to delay Amneal's launch and delay fair competition. (D.I. 91, Sixth Counterclaim.)

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III. LEGAL STANDARDS

A. Motion to Dismiss

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 (cleaned up).

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). "The court's determination is not whether the non-moving party 'will ultimately prevail' but whether that party is 'entitled to offer evidence to support the claims.'" *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, No. 14-1482, 2015 WL 4477700, at *2 (D. Del. July 22, 2015) (quoting *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011)). The *Twombly* standard "does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips*, 515 F.3d at 234 (internal citations and quotation marks omitted).

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B. Inequitable Conduct Pleading Standard[4]

Inequitable conduct must be pleaded with particularity in compliance with Rule 9(b), which requires that "a party must state with particularity the circumstances constituting fraud" while "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). "The standard for proving inequitable conduct is a more rigorous one than the standard for pleading inequitable conduct." *Courtesy Prods L.L.C. v. Hamilton Beach Brands, Inc.*, No. 13-2012, 2015 WL 6159113, at *5 (D. Del. Oct. 20, 2015). To meet the materiality element, the pleader must "identify the specific 'who, what, when, where, and how' of the material misrepresentation or omission committed before the PTO." *Evonik Degussa GMBH v. Materia Inc.*, No. 09-636, 2012 WL 4503771, at *4 (D. Del. Oct. 1, 2012); *see also Delano Farms Co. v. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011). "At the pleading stage, the court does not decide the merits of the claim, only whether materiality has been alleged with sufficient particularity." *Quest*, 2015 WL 4477700, at *4 (citing *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000)); *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 382 (D. Del. 2012) (finding materiality properly pleaded where defendant "specifically identified the alleged patent application and its date of publication, and alleged that it constitutes a printed publication sufficient to trigger the printed publication bar" and, therefore, the court "can reasonably infer that but for the alleged omission of this published patent application, the Examiner would not have issued the patents in suit").

[4] In its Legal Standard section and throughout its Motion, Nivagen conflates the evidentiary analysis in *Therasense* with the pleading standard in *Exergen*, to impose an unreasonable pleading bar for allegations of inequitable conduct. *Therasense* addresses ***proving*** intent at trial, it did not disturb the pleading standard or require a party satisfy that burden of proof at the pleading stage. *See Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09–955–LPS–CJB, 2012 WL 600715, at *5 (D. Del. Feb. 3, 2012).

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"[K]nowledge" and "intent" may be alleged generally, although a pleading of inequitable conduct must include sufficient facts from which a court can "reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO." *Delano Farms*, 655 F.3d at 1350.

C. Wrongful Enjoinment Pleading Standard

"[T]he party who obtained the injunction in bad faith . . . should not be entitled to enjoy the benefits of a ceiling on damages . . . ." *Don Post Studios, Inc. v. Cinema Secrets*, Inc., 148 F. Supp. 2d 572, 575 (E.D. Pa. 2001). "To allege a breach of a contractual duty to act in good faith, a complaint need only allege 'facts related to the alleged act taken in bad faith, and a plausible motivation for it.'" *Clean Harbors, Inc. v. Safety-Kleen, Inc.*, No. 6117-VCP, 2011 WL 6793718, at *7 (Del. Ch. Dec. 9, 2011).

D. Affirmative Defenses Pleading Standard

"The pleading standard for an affirmative defense is less demanding than that of a claim or counterclaim." *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, 636 F. Supp. 3d 483, 489–90 (D. Del. 2022) (citation omitted) (noting that affirmative defenses "need not be plausible to survive" under Rule 8(c)). Fed. R. Civ. P. 8 is the appropriate standard unless the allegation is based on fraud. *See id.* at 488 (denying a motion to strike and holding that Rule 8 was the correct standard when unclean hands was pled based on litigation misconduct and not fraud); *see also Bayer CropScience AG v. Dow AgroSciences LLC*, No. 10-1045, 2011 WL 6934557, at *4 (D. Del. Dec. 9, 2011) (denying a motion to strike and holding that Rule 8 applied when patent misuse was based on the patentee's knowledge the patent was invalid, not infringed, or unenforceable, and not based on fraud).

IV. ARGUMENT

A. APLLC Has Adequately Stated a Claim for Inequitable Conduct

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Nivagen argues that APLLC's inequitable conduct Counterclaim should be dismissed based two grounds: *First*, Nivagen argues that APLLC's inequitable conduct counterclaim is precluded by the Court's preliminary findings during TRO/PI proceedings. (D.I. 95 at 5-10.) *Second*, Nivagen argues that Amneal does not adequately plead the "who," "what," and "why" under *Exergen*. (D.I. 95 at 11-15.) Nivagen is wrong on both counts. Longstanding Supreme Court precedent contradicts Nivagen's first argument. Nor does this case present any of the "rare" or narrow exceptions to the general principle that findings during TRO/PI proceedings are not final determinations. Second, contrary to Nivagen's assertions, APLLC's Counterclaim provides more than sufficient factual basis to place Nivagen on notice of the "precise misconduct with which [it is] charged." *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 502 (3d Cir. 2017); *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 249 (3d Cir. 2017).

1. The Court's Preliminary Findings During TRO/PI Proceedings Do Not Preclude APLLC's Inequitable Conduct Counterclaim

Nivagen provides no support for its extraordinary request for the Court to give preclusive effect to its TRO/PI decision, particularly when the Court's TRO/PI opinion states that its findings were preliminary and "subject to change upon the ultimate trial on the merits." (D.I. 61 at 4.) Nivagen's Motion thus invites this Court to do something it has **already** declined to do—make a final determination based on an underdeveloped record and absent any fact discovery. The Court should decline this invitation again as it violates established precedent that "any findings of fact and conclusions of law made at the preliminary stage are of no binding effect whatsoever." *Clark v. K-Mart Corp.*, 979 F.2d 965, 969 (3d Cir. 1992) (citing *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395–96 (1981)); *see also Experior Glob. Warehousing, LLC v. BTC III Hamilton DC LLC*, No. 23-8472, 2024 WL 3409828, at *7 (D.N.J. July 15, 2024) ("the Court is not bound by the factual findings or legal conclusions underpinning its prior decision."). This applies even more so

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here because the Court explicitly noted in the TRO/PI opinion that its findings were "subject to change upon the ultimate trial on the merits." (D.I. 61 at 4.)

Nivagen's reliance on *Trs. of the Gen. Assembly of the Lord Jesus Christ of the Apostolic Faith, Inc. v. Patterson*, No. 21-634, 2024 WL 1096527, at *1 (E.D. Pa. 2024) and *Astrazeneca AB v. Dr. Reddy's Lab'ys, Inc*., 209 F. Supp. 3d 744, 753 (D. Del. 2016) to argue that "findings made in granting or denying preliminary injunction have preclusive effect" is misplaced. *Trs. of Gen. Assembly of Lord Jesus Christ of the Apostolic Faith* and *Astrazeneca* only give preclusive effect to ***legal*** determinations, and do not extend this narrow exception to factfinding. For example, the *Astrazeneca* court explicitly noted that preclusion is a "rare case[]" limited to issues of ***law*** not fact. *Astrazeneca*, 209 F. Supp. 3d at 753 ("While findings from a preliminary injunction typically are not considered for a motion to dismiss, there are rare cases where it is appropriate in the interest of judicial resources."). In so holding, *Astrazeneca* relied on *McTernan v. City of York, Penn.* which gave preclusive effect to a court's finding on an issue of ***law*** rather than fact—whether a ramp was a public or nonpublic forum. *Id.* at 531. Indeed, district courts in the Third Circuit have declined to extend the limited exception to the general rule against preclusion after *McTernan*. *See Revzip, LLC v. McDonnell*, No. 3:19-cv-191, 2020 WL 1929523, at *8 (W.D. Pa. Apr. 21, 2020) ("Accordingly, the *McTernan* exception is particularly well suited to legal questions, rather than factual ones."). Thus, Nivagen's motion to dismiss should also be denied because, unlike the claims in *Trs. of Gen. Assembly of Lord Jesus Christ of the Apostolic Faith* and *Astrazeneca*, inequitable conduct is an intensely factual issue that requires extensive fact discovery. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003) (In the context of inequitable conduct "[b]oth materiality and intent to mislead are questions of fact

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reviewed for clear error.") (citation omitted).[5] The Court's TRO/PI findings should not preclude APLLC's inequitable conduct counterclaim.

2. APLLC Has Sufficiently Pleaded the "Who," "What," and "Why" of the Material Omissions Committed before the USPTO

Nivagen contends that APLLC's inequitable conduct Counterclaim should be denied because it fails to allege the "who," "what," and "why." (D.I. 95 at 2, 11.) The Counterclaim satisfies each of these inquiries. For example, the Counterclaim identifies by name the individuals that violated their duty of disclosure to the USPTO, the evidence of their knowledge, the details of the material prior art that was concealed from the USPTO, and how and why that information was material to patentability. (*See supra* Section II.B.; D.I. 91 ¶¶ 9-25, 88-120.) Rather than addressing the Counterclaim's detailed factual averments, Nivagen largely takes issue with what is **not** alleged in the Counterclaim. But Nivagen's arguments are irrelevant at the pleading stage. Taking APLLC's allegations as true, its Counterclaim sufficiently pleads the "who," "what," and "why" underlying Amneal's inequitable conduct claim.

Materiality – the "Why"

To distract from APLLC's well-pled inequitable conduct Counterclaim, Nivagen first identifies three alleged "omissions" it argues show that APLLC failed to allege that the FK PI is material. (D.I. 95 at 11.) Each of these purported "omissions" is addressed in APLLC Counterclaim.

First, Nivagen claims that "there is not a single factual allegation against the earlier '291 patent in Counterclaim V." (*Id.*) Nivagen is wrong. APLLC alleges that inequitable conduct

[5] Nivagen also tries to fault APLLC for presenting the "same documentary evidence" in its Counterclaim as Amneal did during TRO/PI proceedings. (D.I. 95 at 6.) But discovery has not even started in this case, so there are no new facts to allege. Nor is APLLC attempting to "re-litigate" its claims. *Id.* The inequitable conduct claims have not been decided in a final decision on the merits, so there is nothing to re-litigate.

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occurred during prosecution of **both** Asserted Patents, and specifically identifies the '291 Patent throughout its Counterclaim (¶¶ 107, 112, 116, 117) or together with the '661 Patent as one of the Asserted Patents (¶¶ 89-90, 92- 94, 96, 111, 114-115, 120).

Second, contrary to Nivagen's claim, APLLC's Counterclaim also addresses how the FK PI is material to the '291 and '661 Patents. (D.I. 95 at 11.) "In the context of inequitable conduct, this Court has evaluated '[m]ateriality . . . by what a reasonable examiner would have considered important in deciding whether to allow a patent application.'" *CMC Materials, Inc. v. DuPont De Nemours, Inc.*, No. 20-738-GBW, D.I. 218 at 12-14 (D. Del. Nov. 13, 2023) (citing *Innogenetics, N.V. v. Abbott Lab'ys*, 512 F.3d 1363, 1378 (Fed. Cir. 2008)) (Williams, J.) (Exhibit A). Here, APLLC has alleged sufficient facts to support its claim that an examiner would have considered the FK PI to be important to a determination of patentability. As Nivagen admits, the Counterclaim alleges that the FK PI anticipates (i.e., discloses each limitation) in the '291 and '661 Patents. (D.I. 95 at 12.) Indeed, the Counterclaim provides exemplary disclosures of where in the FK PI each element claimed by the '291 and '661 Patents is present, including providing a claim chart that identifies where the FK PI discloses the "sterility" limitation Nivagen claims the Counterclaim does not address. (*See* D.I. 91 ¶¶ 99-111 (alleging that the FK PI discloses "aseptic technique").) Armed with these disclosures, the Counterclaim alleges that "FK PI discloses the subject matter of at least one claim of the Asserted Patents" and "[h]ad the Named Inventors and Prosecutors disclosed the FK PI, at least [one claim of each of the Asserted Patents] would not have issued." (*Id.* ¶¶ 111-113; 116-117.) Amneal's allegations satisfy the materiality prong. *CMC*, D.I. 211 at 12-14.

Third, Nivagen argues that APLLC's Counterclaim failed to address the prosecution history of the Asserted Patents or explain how the disclosures of the FK PI were not cumulative of

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a prior art reference cited during prosecution. (*See* D.I. 95 at 12.) But *Exergen* does not require the detail Nivagen seeks. As another court in this District found in *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 23-239-KAJ, 2024 WL 2804703, at *3 (D. Del. May 31, 2024), "[a]t the pleading stage, the claimant does not have to demonstrate that the claim limitations are non-cumulative (i.e., absent from the examiner's references), it needs to only identify the claim limitations that it believes are 'supposedly' absent from the record." In *Abbott*, the court found the following allegations sufficient to meet the materiality standard:

> The STS system, its User's Guide, the STS-7 system, and the G4 system are material to the patentability of the '528 Patent because each renders obvious claims of the '528 Patent, either alone or in combination with other prior art including DexCom's own the '549 Patent and related patents and applications, as exemplified in the claim charts attached as Exhibits C through F. Had the USPTO been aware of the STS system, the STS-7 system, the G4 system, and the STS User's Guide, either alone or in combination with other prior art including DexCom's own the '549 Patent and related patents and applications, the USPTO would not have issued the '528 Patent claims.

Id. APLLC's Counterclaim are even more detailed than those found sufficient in *Abbott.* On top of identifying that every element claimed in the Asserted Patent is disclosed in the FK PI and was not before the Examiner, APLLC also alleges that the "FK PI discloses the subject matter of at least one claim of the Asserted Patents" and "[h]ad the Named Inventors and Prosecutors disclosed the FK PI, at least [one claim of each of the Asserted Patents] would not have issued." (D.I. 91 ¶¶ 111-113; 116-117.) Indeed, when as here, the pleading alleges that the patentee failed to disclose an anticipatory reference to the examiner and explains how the reference anticipates at least one claim of the Asserted Patents, "it has adequately alleged why the withheld reference is material and not cumulative." *See Nat'l Prods. Inc. v. Gambler-Johnson LLC*, No. 20-cv-1108-WMC, 2022 WL 2176335, at *4 (W.D. Wisc. June 16, 2022); *Pres. Techs LLC v. Mindgeek USA Inc.*, No. 17-8906-DOC (JPRx), 2019 WL 8137707, at *4 (C.D. Cal. Nov. 27, 2019) (finding the allegation that a reference "discloses each and every element of Claim 1 of the [Asserted Patent and] [t]he

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USPTO Examiner would not have allowed [the] Claim but for the non-disclosure" was sufficient under *Exergen*).

Even though not required, APLLC's Counterclaim also alleges that the FK PI was "not cumulative of any of the prior art that was of record during prosecution of the Asserted Patents because none of the prior art that was before the examiner disclosed a ready-to-use potassium phosphates product" and because "it discloses a more complete combination of relevant features." (D.I. 91 ¶ 115.) APLLC's Counterclaim thus meets the materiality requirement and Nivagen's argument at best improperly contradicts the factual allegations in APLLC's Counterclaim.

The "Who"

APLLC's Counterclaim satisfies *Exergen*'s "who" requirement. In *Exergen,* the Federal Circuit held that a pleading referring generally to "Exergen, its agents and/or attorneys" failed to meet the "who" requirement since "[e]ach *individual* associated with the filing and prosecution of a patent application has a duty of candor and good faith," and that ''the duty applies only to individuals, not to organizations." 575 F.3d at 1329 (quoting 37 C.F.R. § 1.56(a); Manual of Patent Examining Procedure ("MPEP") § 2001.81 (8th ed., rev. 2, May 2004)) (emphasis in original). Amneal does not merely allege that a corporate entity committed inequitable conduct. Rather, APLLC identifies specific individuals—the six inventors listed on the face of the Asserted Patents—Brijeshkumar B. Pandya, Govind R. Jagadale, Dasaradhi Lakkaraju, Bala Tripura Sundari Chodavarapu, Anand Shukla, and Jwalant Shukla—and the four prosecuting attorneys. (D.I. 91 at ¶¶ 13, 15.) Each of these individuals has an independent duty of candor to the USPTO: (i) the inventors named on the face of the Patents-in-Suit and (ii) the attorneys or agents preparing or prosecuting the Patents-in-Suit. (*Id.* ¶ 15.) Indeed, these individuals match the PTO's regulations defining the persons who owe the PTO a duty of candor: (i) "[e]ach inventor named in the [patent]

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application" and (ii) "[each attorney or agent who prepares or prosecutes the application." 37 C.F.R. § 1.56(c)(l)-(2).

Nivagen cannot credibly claim that APLLC was "impermissibly vague" or that it is not aware of "who" committed inequitable conduct (D.I. 95 at 13) when the Counterclaim specifically names the ten people it alleges withheld material prior art during prosecution of the Asserted Patents with the specific intent to deceive the USPTO. (D.I. 91 at ¶¶ 15, 25, 92-94, 97-98, 107, 112-114, 116, 118-120.) The specific identification of these individuals and their deceptive conduct satisfies the "who" requirement under *Exergen.* For example, this Court has found allegations sufficient when, as here, "[d]efendants list[ed] a group of inventors by name and allege[d] that each one of the group of individuals engaged in inequitable conduct." *W.R. Grace & Co.-Conn. v. Elysium Health, Inc.*, No. 20-1098-GBW, D.I. 225, at (D. Del. Feb. 10, 2023) (citing *Diebold Nixdorf Inc. v. Hyosung Tns, Inc.*, No. 19-1695-LPS, 2021 WL 861734, at *3 (D. Del. Mar. 4, 2021)) (Williams, J.) (Exhibit B). Nor is it improper to refer to these individuals collectively. Indeed, the Court has found that allegations of "each of the members of a known, clearly ascertainable group" were "specific enough to meet the 'who' requirement . . . ." *Int'l Bus. Machs. Corp. v. Priceline Grp. Inc.*, No. 15-137, 2017 WL 1349175, at *9 (D. Del. Apr. 10, 2017) (citation omitted). Accordingly, Amneal's Counterclaim satisfies the "who" requirement.

The "What"

Finally, Nivagen argues that APLLC's Counterclaim failed to identify—(1) what the material information was concealed; and (2) what concealed information each named individual was aware of. (D.I. 95 at 14-15.) Each of these arguments miss the mark.

First, APLLC's Counterclaim identifies that the Named Inventors and Prosecutors each knew of the FK PI and failed to disclose that anticipatory reference to the USPTO. (*See* D.I. 91 ¶¶

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9-25, 88-120.) The Counterclaim alleges that the Named Inventors and the Prosecutors knew about the FK PI during prosecution of the Asserted Patents, but knowingly concealed that information from the USPTO by withholding the FK PI from the USPTO and specifically removing any reference of the FK PI from the non-provisional application that issued as the '291 Patent to keep hiding it during prosecution. (*Id.* ¶¶ 92, 107, 114.)

Nivagen tries to dispute these well-pleaded allegations in the Counterclaim by claiming that the '661 Patent includes some of the information disclosed in the FK PI or that some of the information is not in the FK PI. (D.I. 95 at 14.) But Nivagen is incorrect. None of the Asserted Patents identify the FK PI. Indeed, Nivagen cites to only a vague reference in the '661 Patent to "a commercially available product" to support this argument. Nivagen's claim that the FK PI does not disclose the molar ratio, aluminum content, and pH range as alleged in the Counterclaim also ignores that most of that information was based on the Named Inventors and Prosecutors ***own calculations*** of the FK PI, which they intentionally removed from their patent application before examination. (*See* D.I. 91 at ¶ 107.) Regardless, these types of factual disputes are improper on a motion to dismiss and are more appropriately addressed at summary judgment or trial. *Pennsylvania State Univ. v. Parshall*, No. 4:19-CV-01299, 2020 WL 2217279, at *4 (M.D. Pa. May 7, 2020) ("Factual disputes must be resolved through discovery, summary judgment motions, or a trial.").

Second, Nivagen argues that the Counterclaim fails to adequately allege that the individuals accused of inequitable conduct knew about the concealed information. (D.I. 95 at 15.) But the Counterclaim alleges that the Named Inventors and Prosecutors knew about the FK PI, its anticipating disclosures, and withheld it because, among other things, it was the starting point for the alleged development of the potassium phosphates products claimed in the Asserted Patents.

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(D.I. 91, ¶¶ 25, 92-97.) Indeed, the Named Inventors and Prosecutors included references to the FK PI in the Provisional Application and then removed them from their application just before examination to hide the FK PI's anticipatory disclosure from the USPTO. (*Id.* ¶¶ 107, 111-114.)

APLLC thus has identified the "what" under *Exergen.*

B. Amneal's Second, Third, and Seventeenth Affirmative Defenses Are Well-Pled

Amneal's affirmative defenses for patent misuse and unclean hands are properly pled and should not be dismissed. Unless based in fraud, affirmative defenses "need not be plausible to survive" under Rule 8(c). *Allergan USA Inc.*, 636 F. Supp. 3d at 489–90. Here, the patent misuse and unclean hands affirmative defenses meet the Rule 8 standard for non-fraud conduct (*e.g.*, knowingly asserting a not infringed patent or misleading the court as pleaded with wrongful enjoinment). *See id.* at 488; *see also Bayer*, 2011 WL 6934557, at *4.

Nivagen's motion to strike Amneal's inequitable conduct affirmative defense mirrors its motion to dismiss APLLC's inequitable conduct counterclaim. (D.I. 95 at 16.) Thus, Amneal's inequitable conduct affirmative defense also meets the pleading standard under Fed. R. Civ. P. 9(b) for the reasons set forth in Section IV.A., above. Amneal's misuse and unclean hands defenses, as they relate to inequitable conduct, also meet this standard for the same reasons.

C. APLLC Has Properly Pled a "Wrongful Enjoinment" In Counterclaim VI

1. Wrongful Enjoinment Is a Proper Cause of Action

Contrary to Nivagen's contentions, APLLC's Sixth Counterclaim pleads a proper cause of action. The Third Circuit has long recognized that while the general rule is that damages are capped at the amount of the bond, in certain cases a wrongfully enjoined party can recover damages in excess of the bond. *Don Post Studios, Inc. v. Cinema Secrets, Inc.*, 148 F. Supp. 2d 572, 575-76 (E.D. Pa. 2001) (citing *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 804 (3d Cir. 1989)). In *Don Post Studios*, the court found persuasive case law in the Seventh and Tenth Circuits

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which permits recovery in excess of the bond where the party seeking injunctive relief acted in bad faith. *Id.* at 575 (citing *Coyne-Delany Co., Inc. v. Capital Development Board*, 717 F.2d 385, 393 (7th Cir. 1983) ("The bond is the limit of the damages the defendant can obtain for a wrongful injunction, even from the plaintiff, provided the plaintiff was acting in good faith."); *Adolph Coors Co. v. A & S Wholesalers, Inc.*, 561 F.2d 807, 813 (10th Cir. 1977) ("Absent proof of malice in obtaining injunctive relief, a party cannot be liable in damages resulting from a wrongfully or erroneously granted injunction beyond the limits or maximum amount of the bond or bonds."). The *Don Post Studios* court held that the plaintiffs acted in bad faith by filing an objectively unreasonably lawsuit and sought an injunction, as here, to gain a marketplace advantage over a competitor. *See id.* at 575-6. Thus, the plaintiffs were not entitled to a cap on their damages to the extent of the posted bond. *Id.* at 576.

More recently, a court in this District, citing *Don Post Studios*, held that when a party's liability may exceed the bond amount, including when the situations involving bad faith or fraud in seeking the injunction. *See Takeda Pharms., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-1268-RGA, 2018 WL 6529289, at *3 (D. Del. 2018) (citing *Don Post Studios*, 148 F. Supp. 2d at 575). Accordingly, Third Circuit case law supports that damages are recoverable for wrongful enjoinment at least in situations involving bad faith, which Nivagen acknowledges has been pled in Counterclaim VI. (*See* D.I. 95, at 17 ("Amneal therefore alleged 'false and misleading statements' and 'bad faith' in Counterclaim VI seemingly attempting to trigger (without actually stating so) a 'wrongful injunction common law remedy' to recover in excess of the bond.").)

2. Nivagen's Reliance on *Globus Med. v. Vortex Spine* Is Inapposite

As the Court is aware, Nivagen moved for and obtained a TRO and PI. (D.I. 62.) Nivagen would now like the Court ignore the PI so that it can argue APLLC cannot seek damages for wrongful enjoinment because "this common law remedy is **not applicable to TROs**." (D.I. 95, at

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17 (citing *Globus Med., Inc. v. Vortex Spine, LLC*, No. 14-3105, 2016 WL 5724453, at *1 n. 3 (E.D. Pa. 2016) (emphasis added).) But Nivagen sought and obtained a TRO **and** a PI. *Globus*, relied on by Nivagen, is therefore inapposite, because in *Globus*, the court based its ruling on a PI having never issued. *Globus*, 2016 WL 5724453, at *1 n.3. Indeed, the court expressly acknowledged that PIs did not accompany the TROs: "The Court never issued a preliminary injunction order for either TRO. Vortex failed to cite any case showing that the wrongful injunction common law remedy was applicable to temporary restraining orders. No preliminary injunction was issued in this case." *Id.* at *1, n.3.

But here the Court ordered that "Plaintiff Nivagen Pharmaceuticals, Inc.'s Motion for a Temporary Restraining Order and for a Preliminary Injunction (D.I. 12) is **GRANTED**." (D.I. 62.) There can be no reasonable dispute that the Court granted a PI, and not only a TRO. Accordingly, *Globus*, as relied on by Nivagen, is inapplicable here because the Court ordered a PI and a TRO.

3. Nivagen's False Statements And Misrepresentations Directly Relate to the Wrongful Enjoinment

Finally, to avoid a wrongful enjoinment counterclaim, Nivagen tries to parse out its false and misleading statements and argues that the Court never actually relied on its misrepresentations when finding "irreparable harm." (D.I. 95, at 19.) According to Nivagen, the Court credited "the loss of first mover advantage" as the sole basis for "irreparable harm" and that first-mover advantage is based on "long-lasting relationships with early customers," and "reputation [as an innovator]." (D.I. 95, at 19.) But contrary to Nivagen's position, the Court did not ignore Nivagen's false and misleading statements that would allow it to take advantage of the first mover situation. (*See* D.I. 68, 68-1.) To take advantage of a first mover advantage, Nivagen would need an approvable RTU NDA and an expectation of sales. Nivagen tried to mislead the Court by arguing that it had both when in reality, it had neither. APLLC has properly alleged that Nivagen's

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statements regarding its file approvability, backing from the actual owner of the RTU NDA, and its inflated expected sales as a first mover were false and misleading. (D.I. 91 ¶¶ 123-133.) APLLC expects to prove these allegations at trial and to show that the PI was sought in bad faith through arguments that were knowingly false and misleading to delay fair competition. It is now February 2025 and the FK RTU NDA (which Nivagen calls the "Nivagen Product") [redacted]

V. IN THE ALTERNATIVE, AMNEAL SHOULD BE GRANTED LEAVE TO AMEND TO CURE THE ALLEGED DEFICIENCIES

The Third Circuit has "instructed that if a [counterclaim] is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 236 (3d Cir. 2008). Indeed, the cases that Nivagen cites in support of dismissal have permitted amendment of inequitable conduct counterclaims. *See, e.g.*, *Finjan Inc. v. ESET, LLC*, No. 17-cv-00183-CAB-BGS, 2017 WL 3149642, at *7 (S.D. Cal. July 24, 2017) (dismissing inequitable conduct defense and counterclaim with leave to amend). Accordingly, if the Court grants Nivagen's Motion, it should do so without prejudice and permit APLLC the opportunity to amend its inequitable conduct and wrongful enjoinment counterclaims and for Amneal to amend its affirmative defenses to plead more specific facts, to the extent the Court finds they are currently missing.

VI. CONCLUSION

For these reasons, Amneal respectfully requests that the Court deny Nivagen's Motion.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on February 4, 2025, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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