

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

NIVAGEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-846-GBW
	)	
AMNEAL PHARMACEUTICALS, INC.,	)	JURY TRIAL DEMANDED
AMNEAL PHARMACEUTICALS of	)	
NEW YORK, LLC, AMNEAL	)	
PHARMACEUTICALS LLC, AMNEAL	)	
PHARMACEUTICALS PVT LTD., and	)	
AMNEAL EU, LTD.	)	
	)	
Defendants.	)	

**NIVAGEN PHARMACEUTICALS, INC.’S REPLY BRIEF IN SUPPORT OF
ITS MOTION TO DISMISS DEFENSES AND COUNTERCLAIMS**

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TABLE OF CONTENTS

**I. COUNTERCLAIM V IS PRECLUDED AND FAILS TO MEET THE
EXERGEN STANDARD 1**

A. The Preclusive Effect Applies to Both the Legal Conclusion and the
Factual Findings Made in the TRO/PI Proceedings 1

B. Defendants Cannot Articulate What New Evidence They Could Obtain to
Change the Court’s Legal Conclusion 3

C. Defendants Failed to Meet the “But-for” Materiality Pleading Standard.....3

D. “Group Liability” Pleading Has Never Been Sufficient Under *Exergen* to
Show the “Who” and Sustain an Inequitable Conduct Claim.....6

E. Counterclaim V Fails to Specify “What” Material Information Was
Knowingly and Intentionally Withheld 7

F. The Second, Third, and Seventeenth Affirmative Defenses Are Baseless 9

**II. DEFENDANTS CANNOT RECOVER FOR “WRONGFUL
ENJOINMENT” 9**

III. CONCLUSION 10

TABLE OF AUTHORITIES**CASES**

<i>Abbott Diabetes Care, Inc. v. Dexcom, Inc.</i> , C.A. No. 23-239-KAJ, 2024 WL 2804703 (D. Del. May 31, 2024)	5, 6
<i>Astrazeneca AB v. Dr Reddy's Labs., Inc.</i> , 209 F. Supp. 3d 744 (D. Del. 2016).....	2
<i>Baxalta Inc. v. Bayer Healthcare LLC</i> , C.A. No. 17-1316-RGA-SRF, D.I. 494 (Report and Recommendation) (D. Del. July 13, 2020)	6
<i>Clark v. K-Mart Corp.</i> , 979 F.2d 965 (3d Cir. 1992)	1
<i>CMC Materials, Inc. v. DuPont De Nemours, Inc.</i> , C.A. No. 20-738-GBW, D.I. 218 (D. Del. Nov. 13, 2023).....	4, 5
<i>Diebold Nixdorf Inc. v. Hyosung Tns, Inc.</i> , C.A. No. 19-1695-LPS, 2021 WL 861734 (D. Del. Mar. 4, 2021)	6
<i>Exergen Corp. v. Wal-Mart Stores, Inc.</i> , 575 F.3d 1312 (Fed. Cir. 2009)	8, 9
<i>Exterior Global Warehousing, LLC v. BTC III Hamilton DC LLC</i> , No. 23-8472 (RK) (JBD), 2024 WL 3409828 (D.N.J. July 15, 2024)	1
<i>Globus Medical, Inc. v. Vortex Spine, LLC</i> , No. 14-3105, 2016 WL 5724453 (E.D. Pa. Sept. 30, 2016).....	9
<i>Intl. Bus. Machines Corp. v. Priceline Group Inc.</i> , C.A. No. 15-137-LPS-CJB, 2017 WL 1349175 (D. Del. Apr. 10, 2017)	5, 6, 7
<i>Jazz Pharm. Ireland Ltd. v. Lupin Inc.</i> , No. 21-14271 (SRC), 2025 WL 517856 (D.N.J. Feb. 18, 2025).....	3, 4, 8
<i>McTernan v. City of York, PA</i> , 577 F.3d 521 (3d Cir. 2009)	2
<i>National Products. Inc. v. Gamber-Johnson LLC</i> , No. 20-cv-1108-WMC, 2022 WL 2176335 (W.D. Wis. June 16, 2022)	8
<i>Preservation Technologies LLC v. Mindgeek USA Inc.</i> , No. 17-8906-DOC, 2019 WL 8137707 (C.D. Cal. Nov. 27, 2019).....	4

Revzip, LLC v. McDonnell,
No. 19-cv-191, 2020 WL 1929523 (W.D. Pa. Apr. 21, 2020) 2

Therasense v. Becton, Dickinson & Co.,
649 F.3d 1276 (Fed. Cir. 2011) (en banc) 3, 4, 5

Trustees of the General Assembly of the Lord Jesus Christ of the Apostolic Faith, Inc. v. Patterson,
No. 21-634-KSM, 2024 WL 1096527 (E.D. Pa. Mar. 13, 2024) 1

W.R. Grace & Co. v. Elysium Health, Inc.
No. 20-1098-GBW, D.I. 225 (D. Del. Feb. 24, 2023) 4, 6

Wyeth Holdings Corp. v. Sandoz, Inc.,
C.A. No. 09-955-LPS-CJB, 2012 WL 600715 (D. Del. Feb. 3, 2012) 4, 6

XpertUniverse, Inc. v. Cisco Systems, Inc.,
868 F. Supp. 2d 376 (D. Del. 2012) 4, 7

RULES

Fed. R. Civ. P. 8..... 9

Fed. R. Civ. P. 65(c) 9

The Amneal Defendants misread the law and failed to find any support from the record of the case for their position on multiple key issues. Nivagen’s Motion should be granted.

I. COUNTERCLAIM V IS PRECLUDED AND FAILS TO MEET THE EXERGEN STANDARD

A. The Preclusive Effect Applies to Both the Legal Conclusion and the Factual Findings Made in the TRO/PI Proceedings

“[F]indings made [for] preliminary injunction have preclusive effect if the circumstances make it likely that the findings are sufficiently firm to persuade the court that there is no compelling reason for permitting them to be litigated again.” *Trustees of the General Assembly of the Lord Jesus Christ of the Apostolic Faith, Inc. v. Patterson*, 2024 WL 1096527, at *1 (E.D. Pa. Mar. 13, 2024). “Findings” include findings of *fact*. *Id.* at *2 (preclusion when a defendant “fails to identify an issue of fact that stands to be resolved, but rather continues to disagree with the legal conclusions”).

Defendants first argue that any findings and conclusions from a PI decision “are of no binding effect whatsoever.” (D.I. 100 at 9) (citing *Clark v. K-Mart Corp.*, 979 F.2d 965, 969 (3d Cir. 1992)). *Clark* dealt with factual disputes that remained to be resolved *at trial*. *Clark* does not prevent “sufficiently firm” factual findings to be preclusive so as to conserve judicial resources. Defendants then quote from *Experior*: “the Court is not bound by ... its prior decision.” (D.I. 100 at 9). The “prior decision” in *Experior* was an initial TRO decision, which was reversed after a preliminary injunction hearing during which “the parties have had extensive opportunities to present evidence and argue the relevant issues.” *Experior Global Warehousing, LLC v. BTC III Hamilton DC LLC*, 2024 WL 3409828, at *7 (D.N.J. July 15, 2024).

Defendants then pivot and argue that, even if the TRO/PI findings can be preclusive, such effect is limited to issues of law. (D.I. 100 at 10). That is incorrect. In *Trustees v. Patterson*, the preclusive effect was based on the district court’s “findings of fact” made in its “exhaustive 85-

page [PI] opinion,” where there was “no new evidence,” and where further “discovery is unnecessary.” 2024 WL 1096527, at *2. In *McTernan v. City of York, PA*, the district court relied on both the fact findings *and* legal conclusions made during the previous PI proceeding. 577 F.3d 521, 531 (3d Cir. 2009). The legal conclusion on whether the ramp was a public forum was made after “an evidentiary hearing” and predicated on the fact finding that “it was entirely reasonable for Officer Jay to instruct individuals not to stand or congregate on the ramp, because their static presence on the ramp necessarily conflicts with the ramp’s accessibility requirements.” *Id.* The Third Circuit applied the preclusive effect on both “[the] district court’s findings and conclusions on a PI motion,” because “the issues [in the PI motion and the later motion to dismiss] were exactly the same.” *Id.* Defendants also mischaracterize *Revzip, LLC v. McDonnell*. (D.I. 100 at 10). The *Revzip* court analyzed *McTernan*, noting that “the city produced evidence,” and that the Third Circuit “affirmed, holding that the district court did not err in relying on *its factual findings from the PI motion*.” 2020 WL 1929523, at *7-8 (W.D. Pa. Apr. 21, 2020) (emphasis added). *Trustees v. Patterson, McTernan*, and *Revzip* all stand for the proposition that both the legal conclusions *and the fact findings* made during PI proceedings can be preclusive.¹

The case law compels the conclusion here that the Court’s “no substantial question on ‘inequitable conduct’” legal conclusion and “FK PI was not material” fact finding are both proper bases for a preclusive effect. In fact, the “no substantial question” legal conclusion is *solely* based on the subsidiary and necessary fact finding of a lack of materiality. (D.I. 61, at 10 n. 3 (“it is likely that the ’661 patent would have issued even if the applicant disclosed more details about FK

¹ Defendants also cite *Astrazeneca AB v. Dr Reddy’s Labs., Inc.* for “only giv[ing] preclusive effect to **legal** determinations.” (D.I. 100 at 10). In *Astrazeneca*, the TRO decision was solely based on “plain language” contract interpretation, a legal issue. 209 F. Supp. 3d 744, 753-54 (D. Del. 2016). *Astrazeneca* does not address or prohibit any preclusive effect of factual findings.

PI to the examiner. Thus, Defendants have not demonstrated a substantial question that the '661 patent is unenforceable.”)). Both are “sufficiently firm” and should not be “permitt[ed] to be litigated again.” *Trustees v. Patterson*, 2024 WL 1096527, at *1.

B. Defendants Cannot Articulate What New Evidence They Could Obtain to Change the Court’s Legal Conclusion

Nivagen explained that Defendants could not obtain any new evidence to make FK PI “material.” (D.I. 95, at 9-10). Defendants have *no answer* on this point. Defendants simply re-argue the same documents, hoping to change the Court’s “no substantial question” legal conclusion. For example, Defendants argue that the “aseptic technique” in the FK PI reference amounts to a disclosure of the “sterility” claim limitation. (D.I. 100, at 12). Yet, the same “aseptic compounding” technique disclosure in the same FK PI reference had been thoroughly analyzed during the PI proceedings, and the Court found that the “sterility and RTU properties” of the patented invention were *not* disclosed. (D.I. 61, at 10). Defendants also fall back on the “discovery has not started” statement in a footnote, (D.I. 100 at 11 n. 5), but Defendants do not say anywhere in their brief what possible new discovery could reverse the Court’s legal conclusion of “no substantial question based on FK PI.”

This case presents the perfect circumstances for applying preclusive effect because the Court’s finding and conclusion regarding “inequitable conduct” are based on a thorough analysis of all relevant documentary evidence. The finding and conclusion on the materiality of the FK PI reference are sufficiently firm, and Counterclaim V should be dismissed with prejudice.

C. Defendants Failed to Meet the “But-for” Materiality Pleading Standard

“Pursuant to *Therasense*, the facts must make plausible the inference that, but for the omitted information the PTO would not have allowed the claims.” *Jazz Pharm. Ireland Ltd. v. Lupin Inc.*, 2025 WL 517856, at *3-4 (D.N.J. Feb. 18, 2025). Counterclaim V is based solely on

alleged acts of omission, which are insufficient without addressing “but-for materiality.” (D.I. 100, at 1 (“systematically withheld material information”), 3 (“withholding material prior art”), 4 (“withholding the FK PI” and “removing any reference of the FK PI”)). See *Jazz*, 2025 WL 517856, at *3-4 (finding allegations of “removal of ... data and misrepresentation of [the meaning of the data]” not “sufficient facts to make plausible the inference that the omitted information was material”). Defendants did not allege any “affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit,” and, therefore, Defendants must adequately plead FK PI’s “but-for” materiality. *Therasense v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291-92 (Fed. Cir. 2011) (en banc).

Therasense absolutely “disturb[ed] the pleading standard,” contrary to Defendants’ erroneous view. (D.I. 100, at 7 n. 4). Defendants cited cases that actually *confirm* that omission-based allegations must allege sufficient facts to make “but-for” materiality plausible in order to survive a motion to dismiss. See *Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, at *6 (D. Del. Feb. 3, 2012) (“Sandoz concedes that ..., in light of *Therasense*, it must allege facts allowing for the reasonable inference of ‘but-for’ materiality”); *XpertUniverse, Inc. v. Cisco Systems, Inc.*, 868 F. Supp. 2d 376, 382 (D. Del. 2012) (“Cisco alleges facts sufficient to allow for the reasonable inference that but for the alleged omission”); *Preservation Technologies LLC v. Mindgeek USA Inc.*, 2019 WL 8137707, at *4 (C.D. Cal. Nov. 27, 2019) (“5. But-For Standard” for pleading); *W.R. Grace & Co. v. Elysium Health, Inc.* No. 20-1098-GBW, D.I. 225, at 6 (D. Del. Feb. 24, 2023) (“the Court agrees that the facts alleged ... are sufficient to establish that, but-for omission of the alleged pre-priority date sales, the PTO would not have approved the Asserted Patents.”). Defendants also cited *CMC Materials, Inc. v. DuPont De Nemours, Inc.*, No. 20-738-GBW, D.I. 218 at 12-14 (D. Del. Nov. 13, 2023) for the proposition that materiality means “an

examiner would have considered important in deciding whether to allow a patent application.” (D.I. 100, at 12, Ex. A). *CMC* quoted from the 2008 *Innogenetics* Federal Circuit opinion, which used “examiner considered important” to mean the “but-for materiality” clarified by the 2011 *Therasense* opinion. *Id.*

Defendants studiously avoided discussing “but-for” materiality. (See D.I. 100, at 11-14). Defendants have no answer to Nivagen’s arguments regarding the Koneru reference. (D.I. 95, at 12). Defendants do not allege that the examiner would have credited FK PI more than Koneru, which disclosed less aluminum and lower nutrient concentration than FK PI. (D.I. 61, at 10 n. 3). In view of the examiner’s discussion of Koneru in the Reason for Allowance, Defendants must at least make sufficient allegations on what material information contained in FK PI was not in front of the examiner through Koneru (i.e. what claim element is missing from Koneru).

Instead, Defendants assert that “it needs to only identify the claim limitations that it believes are ‘supposedly’ absent from the record.” (D.I. 100, at 13) (quoting *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, 2024 WL 2804703, at *3 (D. Del. May 31, 2024)). *Abbott* does not address any comparison to a prior art reference that was expressly discussed in the Reason for Allowance. After the examiner put on the record the exact prior art over which the claims were allowed, pleading another reference’s “but-for” materiality necessarily requires some comparison of the two references to show they are not cumulative. See *Intl. Bus. Machines Corp. v. Priceline Group Inc.*, 2017 WL 1349175, at *11 (D. Del. Apr. 10, 2017) (after “the PTO considered some of the [prior art references],” a defendant is required to “sufficiently articulate how the omitted information is not cumulative of the information already on the record, by identifying the particular claim limitations that are absent from the record”). In fact, in *Abbott*, the court required that *Abbott* “tell[] DexCom which claim limitations it believes were supposedly absent from the

information of record.” *Abbott Diabetes Care, Inc.*, 2024 WL 2804703, at *4. Here, Amneal failed to do even that. Defendants still have not identified any “supposedly missing claim elements” from Koneru.

D. “Group Liability” Pleading Has Never Been Sufficient Under *Exergen* to Show the “Who” and Sustain an Inequitable Conduct Claim

Defendants cannot identify a single wrongful act attributable to a particular “who.” (D.I. 14-15). Their allegations state generally “Inventors” and “Prosecutors.” “This lack of connection between the allegations of knowledge by particular individuals and contentions regarding concealment directed broadly to the ‘Applicants’ is fatal to the claim.” *Baxalta Inc. v. Bayer Healthcare LLC*, C.A. No. 17-1316-RGA-SRF, D.I. 494 (Report and Recommendation), at 10 (D. Del. July 13, 2020). “Allegations styled in this matter do not allege that any *one* of those individuals necessarily committed the particular act and fail to plead any joint concert of action.” *Id.*

Defendants’ “somebody must have done something bad” approach cannot possibly be sufficient post-*Exergen*. For example, in *W.R. Grace*, Elysium alleged “that Reynolds told Peggy Smith not to continue investigating the prior sales,” and identified Carlson as the signatory on the withheld batch records. (D.I. 100 Ex. B, at 8-9). Based on such specific allegations, the Court in *W.R. Grace* found the pleading sufficient “with respect to Carlson and Reynolds,” but no one else. *Id.* at 9-10. The *W.R. Grace* opinion cited *Diebold Nixdorf Inc. v. Hyosung Tns, Inc.* (D.I. 100, at 15). In *Diebold*, “Defendants allege that one of the inventors, Douglas Kovacs, was aware of the 1064i ATM.” 2021 WL 861734, at *3 (D. Del. Mar. 4, 2021). Similarly, in *Wyeth*, a specific Wyeth employee who submitted a declaration to the PTO was named in the pleading, which was found to be sufficient. 2012 WL 600715, at *9. Defendants also cite *Intl. Bus. Machines*, 2017 WL 1349175 for support. (D.I. 100, at 15). However, in *IBM*, despite allegations against all

attorneys and inventors, the court held that the counterclaim “may only survive as it pertains to Mr. Scifo.” 2017 WL 1349175, at *8. “[T]here are not sufficient facts pleaded to establish ... that the ‘named inventors’ or ‘prosecuting attorneys’ (other than Mr. Scifo) actually had knowledge of the activities that they allegedly failed to disclose.” *Id.* at *9. The court held that it is the claimant’s duty to plead “actual facts” to “allow the inference that each of the named inventors (or, for that matter, each of the prosecuting attorneys other than Mr. Scifo) had knowledge of the relevant commercialization efforts.” *Id.*

Under the *Exergen* standard, naming specific individuals in the pleading is not by itself sufficient. In *XpertUniverse*, the court held that “[d]ropping Zelkin’s name in the scrum of ‘XU personnel including at least Abraham Zelkin or one or more of the other individuals listed as an inventor’ fails to meet the pleading standard for ‘who’ deceived the PTO.” 868 F. Supp. 2d at 381. Here, Defendants did not link any wrongdoing to any specific individual in Counterclaim V. The counterclaim is insufficient to plead “who” specifically deceived the PTO and should be dismissed.

E. Counterclaim V Fails to Specify “What” Material Information Was Knowingly and Intentionally Withheld

First, Defendants still cannot identify a single allegation to show FK PI’s materiality to the ’291 patent. Defendants pointed to general statements “throughout its Counterclaim,” but none of the cited paragraphs contain any comparison of FK PI to any claim of the ’291 patent. (D.I. 100, at 12). Defendants never made even the faintest attempt in comparing the allegedly “removed” information to any ’291 patent claims. (*Id.* at 12, 16). Defendants then relied on conclusory statements such as “FK PI discloses the subject matter of at least one claim of the Asserted Patents,” (*id.* at 12), but such statements are not sufficient under the case law, including those *Defendants* cited in their Opposition Brief. In *National Products*, the defendant “charted how the reference anticipates the asserted claims.” *National Products, Inc. v. Gamber-Johnson LLC*, 2022

WL 2176335, at *4 (W.D. Wis. June 16, 2022). In *IBM*, after the defendants alleged “that Agarwal is not cumulative,” they provided “detailed claim chart describ[ing], on a limitation-by-limitation basis, how fifteen of the ’967 patent’s claims are plausibly rendered invalid by Agarwal.” 2017 WL 1349175, at *12. Such analyses were sufficient. On the other hand, when a defendant offers “no facts that plausibly demonstrate [claim invalidity],” and, just like here, “the Court has no way of knowing *which* claims of the [asserted patent] are even alleged to be anticipated,” “the Court cannot reasonably infer that the failure to disclose certain [information] was ‘but-for’ material to the issuance of claims....” *Id.* at *11; *see also Jazz*, 2025 WL 517856, at *4 (“conclusory assertions of but-for materiality” not sufficient).

Second, while the law requires a claimant to allege with particularity “the specific material information contained in that reference,” Defendants subtly attempted to circumvent that requirement. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009) (underlining added). Defendants assert that a “duty of disclosure” is applicable to “the evidence of [some individuals’] knowledge.” (D.I. 100, at 3). Defendants cite to nothing to substantiate such a duty to disclose a mental state, understanding, or “knowledge.” Despite the lack of any legal underpinning of their position, Defendants then double down and state that “Nivagen’s intentional and fraudulent deception is exemplified by its active concealment of *its own understanding of the FK PI’s disclosures ...*” (*Id.* at 4) (emphasis added). Defendants then admit that the allegedly omitted “knowledge” and “understanding” actually refers to “the Named Inventors and Prosecutors **own calculations** of the FK PI [*sic*], which they intentionally removed from their patent application before examination.” (*Id.* at 16) (emphasis in the original). A sufficient allegation of “what” must go beyond what an individual “reasonably should be aware.” *Exergen*, 575 F.3d at 1330. Defendants’ admissions that the “withheld information” actually refers

to “evidence of knowledge,” “understanding” or “calculations,” none of which is “information contained in [the FK PI] reference,” provide ample grounds for dismissing Counterclaim V. *Id.*

F. The Second, Third, and Seventeenth Affirmative Defenses Are Baseless

Defendants argue that their “patent misuse” and “unclean hands” affirmative defenses could be based on “non-fraud conduct,” “e.g., knowingly asserting a not infringed patent or misleading the court as pleaded with wrongful enjoinder.” (D.I. 100, at 17). Defendants made no allegations in their pleading that Nivagen *knowingly asserted* a not-infringed patent. Fed. R. Civ. P. 8 requires some articulated basis in the pleading, so as to provide fair notice. Defendants cannot now belatedly add new allegations in a motion brief. As to “wrongful enjoinder” as a basis for “patent misuse” and “unclean hands,” the “wrongful enjoinder” Counterclaim VI should be dismissed, and with it these affirmative defenses.

II. DEFENDANTS CANNOT RECOVER FOR “WRONGFUL ENJOINMENT”

Defendants do not argue that Fed. R. Civ. P. 65(c) serves as the basis for Counterclaim VI. (D.I. 100, at 18). However, Defendants refuse to clarify whether they are asserting a common-law tort claim. (*Id.*). Assuming Counterclaim VI is a tort claim, Defendants failed to allege the necessary causative link. As Nivagen pointed out, and Defendants do not dispute, *no court* has created a tort-based “wrongful enjoinder” cause of action for damages caused by a TRO. *See Globus Medical, Inc. v. Vortex Spine, LLC*, 2016 WL 5724453, at *1 n. 3 (E.D. Pa. Sept. 30, 2016). In this case, the “wrongful enjoinder” allegedly lasted a maximum of 23 days. (D.I. 91, at ¶¶ 122, 128). This is close to a typical duration of a TRO. To allow a tort claim to proceed for such a short enjoinder would require creating a new cause of action. Otherwise, because Defendants made no allegation that the “wrongful PI” caused damages in addition to what “damages” the TRO might have caused, no relief is available.

Furthermore, Defendants still cannot link any of the alleged “misrepresentations” to the granting of the TRO/PI. Defendants argue in the Opposition Brief that Nivagen “would need an approvable RTU NDA and an expectation of sales” to enjoy a “first mover situation.” (D.I. 100, at 19). Defendants alleged nothing to show that Nivagen would *not* have an approvable RTU product to sell in the very near future. Variations in the FDA approval timeline (or even whether there would be approval at all) was discussed at the TRO/PI motion hearing, and noted by the Court. (D.I. 91 Ex. F, at 6:8-7:12; 8:1). Such variations do not change the fact that Amneal now has the first-mover advantage in this RTU market.

Defendants also did not link Nivagen’s “\$45-50 million in sales” expectation to the granting of the TRO/PI. (D.I. 100, at 19-20) (no discussion on how the sales number factored into the TRO/PI decision). The Court noted the “\$45-50 million” figure during the TRO/PI proceedings but concluded that any sales that could be “quantified or compensated with money damages” would not be “irreparable.” (D.I. 61, at 17-18). The Court also noted that some financial difficulty caused by a loss of sales still was “not enough to prove irreparable injury.” (*Id.* at 18). The actual basis for the TRO/PI, which is a loss of “first-mover advantage,” depends on who would get on the market first. (*Id.* at 20-24). The first-mover advantage is based on “long-lasting relationships with early customers,” and “reputation [as an innovator].” (*Id.* at 22-23). The Amneal Defendants have not alleged any misrepresentations by Nivagen on a first mover’s ability to gain customers or reputation as an innovator. There are no allegations of any misrepresentations that caused the “irreparable harm” conclusion and served as the basis of the TRO/PI in this case.

III. CONCLUSION

For the foregoing reasons and the reasons stated in Nivagen’s Opening Brief, D.I. 95, Nivagen respectfully requests that the Court grant its Motion (D.I. 94).

Respectfully submitted,

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