IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC., Plaintiff, v. EXELA PHARMA SCIENCES, LLC, Defendant.	C.A. No. 22-1233-GBW

MEMORANDUM ORDER

Pending before the Court is Defendant Exela Pharma Sciences, LLC's ("Exela") Motion to Dismiss Plaintiff Nexus Pharmaceuticals, Inc.'s ("Nexus") First Amended Complaint for Failure to State a Claim (D.I. 7, the "Motion"). The Motion has been fully briefed and the Court has considered the parties' briefing. D.I. 8; D.I. 13; D.I. 15. Exela requests that the Court dismiss all counts in Nexus' First Amended Complaint (D.I. 5) because Nexus has failed to plausibly allege infringement by Exela. There are two counts in the First Amended Complaint. D.I. 5. Count I alleges that Exela's AKOVAZ prefilled syringe ("PFS") product infringes U.S. Patent No. 11,426,369 ("the '369 patent"), and Count II alleges that Exela's AKOVAZ PFS product infringes U.S. Patent No. 11,464,752 ("the '752 patent"). *Id.* ¶¶ 29-50. For the reasons set forth below, the Court GRANTS Exela's Motion without prejudice.

I. LEGAL STANDARDS

To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief . . . ." FED. R. CIV. P. 8(a)(2). Such a claim must plausibly suggest "facts sufficient to 'draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d

Cir. 2022) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "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.'" *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). But the Court will "'disregard legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements.'" *Princeton Univ.*, 30 F.4th at 342 (quoting *Davis v. Wells Fargo*, 824 F.3d 333, 341 (3d Cir. 2016)). Under Rule 12(b)(6), the Court must accept as true all factual allegations in the Complaint and view those facts in the light most favorable to the plaintiff. *See Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 351 (3d Cir. 2020).

II. DISCUSSION

For the reasons explained below, Nexus has failed to satisfy the *Iqbal/Twombly* pleading standard because its allegations are conclusory.[1] Nexus "needs to have pleaded facts that plausibly indicate that Defendant['s] accused products practice each of the limitations asserted in the relevant claims." *DIFF Scale Operation Rsch., LLC v. MaxLinear, Inc.*, C.A. No. 19-2109-LPS-CJB, 2020 WL 2220031, at *1 (D. Del. May 7, 2020), report and recommendation adopted, C.A. No. 19-2109-LPS-CJB, 2020 WL 6867103 (D. Del. Nov. 23, 2020) (citing *Modern Telecom Sys., LLC v. TCL Corp.*, C.A. No. 17-583-LPS-CJB, 2017 WL 6524526, at *2 (D. Del. Dec. 21, 2017); *Raindance Techs., Inc. v. 10x Genomics, Inc.*, C.A. No. 15-152-RGA, 2016 WL 927143, at *2-3 (D. Del. Mar. 4, 2016)). "After all, if after reading a complaint, the Court cannot conclude that it

[1] "It is now well established that both direct and indirect infringement claims are subject to the *Twombly/Iqbal* standard." *Shire ViroPharma Inc. v. CSL Behring LLC*, C.A. No. 17-414-MSG, 2019 WL 3546692, at *3 (D. Del. Aug. 5, 2019) (citing *IP Commc'n Sols., LLC v. Viber Media (USA) Inc.*, C.A. No. 16-134-GMS, 2017 WL 1312942, at *2 (D. Del. Apr. 5, 2017); *RAH Color Techs LLC v. Ricoh USA Inc.*, 194 F. Supp. 3d 346, 350-51 (E.D. Pa. 2016)).

is plausible that the accused infringer's product reads on a limitation of an asserted claim of a patent-in-suit, then it cannot be plausible that the accused infringer actually infringes that patent claim." *Id.* (citation omitted).

Nexus contends that Exela infringes "at least claim 1 of the '369 patent." D.I. 5 ¶ 32. Claim 1 of the '369 patent recites:

> 1. A method of making a shelf-stable, ready-to-use ephedrine sulfate composition, the method comprising:
>
> combining ephedrine sulfate, sodium chloride or dextrose, and water to form a batch solution comprising an initial ephedrine sulfate level of 5 mg/mL, 9 mg/mL sodium chloride or 5% dextrose, and no preservative;
>
> optionally contacting the batch solution with an acid or a base to obtain an initial pH level of the solution of 4.5 to 7;
>
> filtering the batch solution through a membrane filter to obtain a filtered batch solution;
>
> sanitizing one or more containers;
>
> placing not more than 20 mL of the filtered batch solution into one of the one or more sanitized containers to obtain one or more filled containers;
>
> sealing each filled container to obtain sealed containers including a shelf-stable, ready-to-use ephedrine sulfate composition; and
>
> maintaining a pH level of the shelf-stable, ready-to-use ephedrine sulfate composition in the sealed containers that is within 0.5 pH units of the initial pH level during storage at 25° C. and 60% relative humidity for at least 12 months or during storage at 40° C. and 75% relative humidity for at least 6 months.

'369 patent, claim 1. With respect to the '369 patent infringement allegations, the First Amended Complaint merely states the following:

> 21. Exela filed a supplemental New Drug Application sNDA No. 208289/S-006 on or about November 10, 2020, seeking FDA approval to market a shelf stable, ready to use prefilled syringe (PFS) composition of ephedrine sulfate with a 5 mg/mL concentration that requires no dilution prior to administration ("Exela's Akovaz PFS Product").

. . .

> 25. The Akovaz PFS Product is a shelf-stable, ready-to-use ephedrine sulfate composition that meets each and every limitation of at least one claim of the '369 patent, either literally or under the doctrine of equivalents.

D.I. 5 ¶¶ 21, 25. The First Amended Complaint "does little more than parrot back the language" of the preamble of claim 1 of the '369 patent and then, in a conclusory manner, states Exela's accused product infringes. *N. Star Innovations, Inc. v. Micron Tech., Inc.*, C.A. No. 17-506-LPS-CJB, 2017 WL 5501489, at *2 (D. Del. Nov. 16, 2017), report and recommendation adopted, C.A. No. 17-506-LPS-CJB, 2018 WL 11182741 (D. Del. Jan. 3, 2018). To plead direct infringement, Nexus must allege facts "that plausibly indicate that the accused products contain each of the limitations found in the claim." *TMI Sols. LLC v. Bath & Body Works Direct, Inc.*, C.A. Nos. 17-965-LPS-CJB, 17-966-LPS-CJB, 17-967-LPS-CJB, 17-968-LPS-CJB, 17-969-LPS-CJB, 2018 WL 4660370, at *9 (D. Del. Sept. 28, 2018) (citations omitted). While Nexus "need not prove its case at the pleading stage," the First Amended Complaint must "place the potential infringer on notice of what activity is being accused of infringement." *Nalco Co. v. Chem–Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (internal quotation marks and citation omitted) (cleaned up). Nexus has failed to provide such notice. As Exela argues, the First Amended Complaint is silent "as to any of the steps that Exela performs in the process of making AKOVAZ® PFS, including whether the product is filtered through a membrane, whether one of more containers are sanitized, whether not more than 20 mL of the filtered batch solution is placed into sanitized containers, whether the containers are sealed, and whether a pH level within 0.5 pH units of the initial pH level is maintained 'during storage at 25° C and 60% relative humidity for at least 12 months or during storage at 40° C and 75% relative humidity for at least 6 months.'" D.I. 8 at 6. "In the Court's view, a patentee cannot meet its obligation to assert a plausible claim of infringement under the

Twombly/Iqbal standard by merely copying the language of a claim element, and then baldly stating (without more) that an accused product has such an element," as Nexus has done here. *N. Star*, 2017 WL 5501489, at *2.

Nexus' infringement allegations with respect to the '752 patent also parrots back portions of the asserted claims. Nexus contends that Exela infringes "at least claims 1 and 12 of the '752 patent." D.I. 5 ¶ 43. Claim 1 of the '752 patent recites:

> 1. A pharmaceutical product comprising:
>
> a packaged syringe containing a sterilized ready-to-use ephedrine composition comprising:
>
> a packaged concentration of ephedrine sulfate of 5 mg/mL,
>
> 9 mg/mL sodium chloride,
>
> no preservative,
>
> water, and
>
> an initial pH level of about 4.5 to about 7; and
>
> having, after storage in the syringe at 25° C. and 60% relative humidity for 12 months or after storage at 40° C. and 75% relative humidity for 6 months:
>
> a pH level within 0.5 pH units of the initial pH level,
>
> an ephedrine sulfate concentration of at least 95% of the packaged concentration, and
>
> a bacterial endotoxin level not more than 7 EU/mg.

'752 patent, claim 1. Claim 12 in the '752 patent depends from claim 10. Claims 10 and 12 recite, respectively:

> 10. A pharmaceutical product comprising:
>
> a packaged ready-to-use single-use container comprising a shelf-stable sterilized pharmaceutical composition comprising:

a packaged concentration of ephedrine sulfate of 5 mg/mL;

9 mg/mL sodium chloride;

water;

no preservative;

an initial pH level of about 4.5 to about 7; and

having, after storage in the single-use container at 25° C. and 60% relative humidity for 12 months or after storage at 40° C. and 75% relative humidity for 6 months:

an ephedrine sulfate concentration of at least 95% of the packaged concentration, and

a pH level within 0.5 pH units of an initial pH level.

12. The pharmaceutical product of claim 10, wherein the pharmaceutical composition is sterilized by terminally sterilizing the pharmaceutical composition in the single-use container.

'752 patent, claims 10 & 12. Again, Nexus' allegations are conclusory. Nexus' First Amended Complaint merely states:

> 26. The Akovaz PFS Product is a pharmaceutical product including a packaged syringe containing shelf-stable, sterilized ready to use ephedrine compositions that meets each and every limitation of at least one claim of the '752 patent, either literally or under the doctrine of equivalents.

D.I. 5 ¶ 26. As Exela correctly notes, the First Amended Complaint "is entirely silent as to AKOVAZ® PFS's initial pH level, whether it contains sodium chloride or dextrose, the concentration of sodium chloride or dextrose, and whether it contains a preservative, as well as whether, after storage at '25° C and 60% relative humidity for at least 12 months' or storage at '40° C and 75% relative humidity for at least 6 months,' AKOVAZ® PFS would maintain 'a pH level within 0.5 pH units of the initial pH level,' 'an ephedrine sulfate concentration of at least 95% of the packaged concentration,' or 'a bacterial endotoxin level not more than 7 EU/mg.'" D.I.

8 at 5-6. Accordingly, Nexus has not met its obligation to assert a plausible claim of infringement for either patent under the *Twombly/Iqbal* standard. "There needs to be *some* facts alleged that articulate *why it is plausible* that the other party's product infringes that patent claim—not just the patentee asserting, in conclusory fashion, that it is so." *N. Star*, 2017 WL 5501489, at *2 (emphasis in original) (citation omitted).[2]

In its Answering Brief, Nexus requests that, if the Court grants Exela's Motion, the "dismissal should be without prejudice and the Court should grant Nexus leave to cure any identified deficiencies in its [First Amended Complaint]." D.I. 13 at 13. Although the operative complaint before the Court is an amended complaint, the original complaint did not have claims dismissed under Rule 12(b)(6). The original complaint was filed on September 21, 2022, and only included allegations regarding the '369 patent. D.I. 1. The '752 patent issued on October 11, 2022, and, on that same day, Nexus filed an Amended Complaint alleging that Exela infringes both the '369 and '752 patents. D.I. 5. Leave to file an amended complaint should be freely granted "when justice so requires." FED. R. CIV. P. 15(a)(2). Because this is the first instance that this Court has found Nexus' allegations deficient, this Court will grant Nexus leave to file a second amended complaint.

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[2] In its brief, Nexus relies heavily on *Disc Disease Solutions Inc. v. VGH Solutions, Inc.*, 888 F.3d 1256 (Fed. Cir. 2018) to support is argument that its First Amended Complaint (D.I. 5) sufficiently meets the pleading standard. *See* D.I. 13 at 7-8, 9-11. In *Disc*, the Federal Circuit provided guidance regarding the pleading standards for "simple technology." *Id.* at 1260. The Court held the complaint at issue met "the plausibility standard of *Iqbal/Twombly*" because the complaint identified the accused product, attached photos of the product packaging as exhibits, and alleged that the accused products meet each and every element of at least one claim of the asserted patents. *Id.* The Court concluded that these disclosures and allegations were sufficient to provide the defendant "fair notice of infringement of the asserted patents." *Id.* The facts here are distinguishable. The asserted patents do not encompass simple technology, Nexus did not attach photos to its First Amended Complaint, and, as discussed above, the disclosures and allegations in the First Amended Complaint do not provide Exela fair notice of infringement of the asserted patents.

III. CONCLUSION

For the foregoing reasons, Exela's Motion is granted without prejudice.

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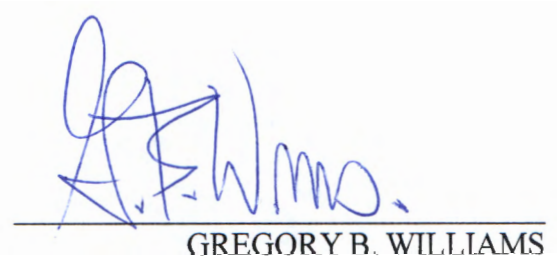
WHEREFORE, at Wilmington this 13th day of June, 2023, **IT IS HEREBY ORDERED** that:

1. Exela's Motion to Dismiss Plaintiff Nexus' First Amended Complaint for Failure to State a Claim (D.I. 7) is **GRANTED** without prejudice.
2. Nexus shall have twenty-one (21) days to file a second amended complaint to cure the deficiencies set forth in this Memorandum Order.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE