IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CILAG GMBH INTERNATIONAL, a Swiss corporation; and JANSSEN BIOTECH, INC., a Pennsylvania corporation,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 22-589-RGA-SRF
HOSPIRA WORLDWIDE, LLC, a Delaware corporation f/k/a Hospira Worldwide Inc.; and HOSPIRA, INC., a Delaware corporation,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Presently before the court in this diversity action alleging breach of a supply contract is a partial motion to dismiss Count II of the amended complaint for lack of standing and failure to state a claim under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), respectively, which was filed by defendants Hospira Worldwide, LLC ("Hospira") and Hospira, Inc. (collectively, "Defendants"). (D.I. 26)[1] For the following reasons, I recommend that the court GRANT Defendants' partial motion to dismiss.

I. BACKGROUND

Plaintiffs Cilag GmbH International ("Cilag") and Janssen Biotech, Inc. ("Janssen Biotech;" collectively, "Plaintiffs"), both subsidiaries of Johnson & Johnson ("J&J"), filed this action in the Superior Court for the State of Delaware on April 28, 2022, and it was removed to this court on May 2, 2022. (D.I. 1 & Ex. B; D.I. 23 at ¶¶ 9-10) The original complaint asserted

[1] The briefing associated with the pending motions is found at D.I. 27, D.I. 28, and D.I. 31.

four causes of action based on alleged breaches of a 2006 Development and Supply Agreement ("DSA") executed between Cilag and Hospira, and a 2017 Quality Technical Agreement ("QTA") executed between Hospira, Inc. and non-party Janssen Pharmaceuticals. (D.I. 1, Ex. B at ¶¶ 1, 7) Defendants moved to dismiss Counts II, III, and IV of the complaint, as well as Plaintiffs' claim for damages for lost profits on sales to third parties. (D.I. 14 at 1) A Report and Recommendation was issued on December 6, 2022, recommending dismissal of Counts II, III, and IV of the complaint without prejudice. (D.I. 21) No objections were filed, and the Report and Recommendation was adopted. (D.I. 22)

Plaintiffs filed their amended complaint on December 30, 2022. (D.I. 23) Count I of the amended complaint asserts a cause of action for breach of contract by Cilag against Defendants. (*Id.* at ¶¶ 103-07) Count II of the amended complaint asserts a cause of action for breach of contract by Janssen Biotech against Defendants. (*Id.* at ¶¶ 108-19) Pending before the court is Defendants' motion to dismiss Count II of the amended complaint. (D.I. 26) Defendants do not seek dismissal of Count I.

The facts alleged in the amended complaint are consistent with those in the original complaint, and the court refers to its prior Report and Recommendation for a more detailed account of the facts. (D.I. 21 at 1-4) A brief summary of those facts suffices here, with a focus on allegations unique to the amended complaint.

ReoPro is a cardiac drug that was first developed by Centocor, Inc. ("Centocor") in the early 1990s. (D.I. 23 at ¶¶ 17-18) Pursuant to a 1992 agreement, Centocor manufactured and sold ReoPro to Eli Lilly, and Eli Lilly marketed and sold ReoPro worldwide. (*Id.* at ¶ 19) In 1999, J&J acquired Centocor. (*Id.* at ¶ 18) Centocor continued meeting its obligation to supply

ReoPro to Eli Lilly until 2016, when Centocor's successor, Janssen Biotech, assumed responsibility for selling ReoPro. (*Id.* at ¶¶ 20-21)

Under the terms of the DSA, Cilag agreed to supply Hospira with the active biologic ingredient for ReoPro. (D.I. 23 at ¶¶ 1, 39) In exchange, Hospira agreed to exclusively manufacture and supply ReoPro to Cilag for a contractually agreed-upon per-vial price to satisfy the worldwide ReoPro requirements of Cilag and its affiliates. (*Id.* at ¶¶ 1, 23-25) The amended complaint alleges that Hospira was aware of Centocor's obligations to supply ReoPro to Eli Lilly when Hospira executed the DSA in 2006. (*Id.* at ¶ 29)

Between October 2017 and April 2018, Hospira experienced quality issues and shut down production of ReoPro after four of five fills of ReoPro were rejected for quality failures. (*Id.* at ¶¶ 79-81) In June of 2018, Hospira notified Cilag that it was terminating the DSA effective as of December 31, 2020, but it represented that it would continue to manufacture ReoPro until the termination date. (*Id.* at ¶ 82) The amended complaint alleges that Hospira "continually failed" to satisfy its obligation to supply ReoPro between 2018 and 2020. (*Id.* at ¶ 7) As a result, Plaintiffs discontinued and delisted ReoPro due to their inability to meet their worldwide requirements of the drug. (*Id.* at ¶¶ 82, 84)

II. LEGAL STANDARDS

A. Rule 12(b)(1)

"Standing is a jurisdictional matter and thus a motion to dismiss for want of standing is also properly brought pursuant to Rule 12(b)(1)." *Yeransian v. Markel Corp.*, C.A. No. 20-762-MN, 2021 WL 979604, at *3 (D. Del. Mar. 16, 2021) (internal citations and quotation marks omitted). A challenge to standing under Rule 12(b)(1) may be "either a facial or a factual attack." *Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). In this case, Defendants

present a facial challenge to Janssen Biotech's standing and do not challenge the validity of the factual claims made in the amended complaint. (D.I. 27 at 8-9) In reviewing a facial challenge to standing, the court must apply the same standard used in reviewing a motion to dismiss for failure to state a claim under Rule 12(b)(6). *See In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017) (citing *Petruska v. Gannon Univ.*, 462 F.3d 294, 299 n.1 (3d Cir. 2006)).

B. Rule 12(b)(6)

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff. *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 790-91 (3d Cir. 2016).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), 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). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

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." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal citations and quotation marks

omitted). This "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 v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64.

III. DISCUSSION

There is no dispute that Janssen Biotech is not a signatory to the DSA and is not expressly named as a third-party beneficiary in the DSA. Consequently, Defendants argue that the court should dismiss Count II of the amended complaint for breach of contract against Janssen Biotech for lack of standing. (D.I. 27 at 9-10)

Plaintiffs allege that a reasonable person could interpret the DSA in a manner that confers third-party beneficiary status on Janssen Biotech. (D.I. 28 at 10-11) But the court previously considered and rejected such an interpretation of the DSA in the Report and Recommendation issued on December 6, 2022. (D.I. 21 at 8-11) Plaintiffs did not file objections, and the Report and Recommendation was subsequently adopted as "legally and factually correct." (D.I. 22)

The arguments raised by Plaintiffs in opposition to Defendants' motion to dismiss the amended complaint largely track those raised in connection with the original complaint. (*Compare* D.I. 16 at 15-19, *with* D.I. 28 at 12-15) New arguments about the language of the DSA are limited to two provisions addressing the drug substance specifications and the notice provision. (D.I. 23, Ex. A at §§ 1.8, 12.2) Plaintiffs also emphasize the importance of the circumstances surrounding the execution of the DSA in determining whether Cilag and Hospira intended to confer third-party beneficiary status on Janssen Biotech. (D.I. 28 at 11-12) Plaintiffs

argue that these new arguments, considered in view of the DSA provisions previously addressed by the court, establish Janssen Biotech's status as a "unique" Affiliate. (*Id.* at 8-10)

I recommend that the court grant Defendants' motion to dismiss Count II of the complaint. To determine whether an entity is a third-party beneficiary under a contract, the court must consider the intent of the parties who entered into the contract, i.e., "(a) the contracting parties must have intended that the third party beneficiary benefit from the contract, (b) the benefit must have been intended as a gift or in satisfaction of a pre-existing obligation to that person, and (c) the intent to benefit the third party must be a material part of the parties' purpose in entering into the contract." *In re Stone & Webster, Inc.*, 558 F.3d 234, 241 (3d Cir. 2009). Plaintiffs have not pled facts plausibly showing that both parties to the DSA intended Janssen Biotech to be a third-party beneficiary under the first prong of this conjunctive inquiry. *See Micro Focus (US), Inc. v. Ins. Servs. Office, Inc.*, C.A. No. 15-252-RGA, 2022 WL 1503918, at *2 (D. Del. May 12, 2022) (stating that the plaintiff "must show that both parties to the contract intended for [the alleged third-party beneficiary] to be a third-party beneficiary.").

The newly raised provisions of the DSA do not give rise to a reasonable inference that Hospira specifically intended to benefit Janssen Biotech. Section 1.8 defines the specification for the active biologic ingredient of ReoPro, requiring the inclusion of Centocor's lot number, part number, and quality assurance signature. (D.I. 23 at ¶ 39; Ex. A at § 1.8 & Ex. 1.8) According to Plaintiffs, this provision demonstrates Hospira's awareness that Centocor and Janssen Biotech supplied the active biologic ingredient for ReoPro. (*Id.* at ¶ 39) But § 1.8 does not establish a benefit conferred on Janssen Biotech under the DSA. Instead, it describes Cilag's obligation to satisfy the specified criteria.

Likewise, § 12.2 of the DSA does not establish an intent to benefit Janssen Biotech. This provision directs notices to be addressed to Global Biologics Supply Chain, LLC ("GBSC"), another affiliate of Cilag. (D.I. 23, Ex. A at §§ 8.1(f); 12.2) Plaintiffs stress that Hospira's termination letter was sent directly to Janssen Biotech, suggesting that Hospira viewed Janssen Biotech as having a "key and primary function under the DSA." (*Id.* at ¶ 48) But the subject line of the termination letter attached to the amended complaint identifies Cilag as the contracting party and then defines Cilag as "Janssen." (*Id.*, Ex. C) The termination letter is addressed to the Horsham, Pennsylvania address specified in § 12.2 of the DSA as belonging to GBSC. (*Id.*, Ex. A at § 12.2; Ex. C) In this regard, the facts and circumstances surrounding Hospira's termination letter confirm that Hospira provided notice to Cilag, as the contracting party, in accordance with the notice provision at § 12.2 of the DSA.

Plaintiffs' position that Janssen Biotech has a "unique" Affiliate status is not supported by the terms of the DSA or the surrounding circumstances. (D.I. 28 at 8-10) Nothing in the record suggests that Hospira has any direct rights or obligations with respect to Janssen Biotech's predecessor, Centocor, as an Affiliate of Cilag. *See Madison Realty Partners 7, LLC v. Ag ISA, LLC*, 2001 WL 406268, at *5-6 (Del. Ch. Apr. 17, 2001) (describing a comparable agreement as conferring incidental, as opposed to intended, beneficiary status). Section 8.1(f) expressly states that Cilag is responsible for the acts and omissions of its Affiliates, confirming that the DSA does not give Hospira and Centocor direct rights against each other. (D.I. 23, Ex. A at § 8.1(f)); *see Micro Focus*, 2022 WL 1503918, at *2 (finding that pleading contained no facts which could reasonably lead to the inference that MF UK was an intended third-party beneficiary). And § 5.1 provides that Cilag is responsible for purchasing and delivering ReoPro on behalf of its Affiliates. (D.I. 23, Ex. A at § 5.1) To the extent that Cilag assigned certain of its obligations to

an Affiliate in § 5.1, the DSA specifies that the Affiliate responsible for such obligations is GBSC, not Centocor. (*Id.*) Because the DSA does not articulate an intent to benefit Centocor or Janssen Biotech specifically, the integration clause precludes an inference that Hospira possessed any such intent by "supersed[ing] all written or oral prior agreements or understandings" regarding the DSA. (D.I. 23, Ex. A at § 12.6)

Sophisticated parties such as Cilag and Hospira could have expressly identified Janssen Biotech's predecessor, Centocor, as a third-party beneficiary in the DSA, and their failure to do suggests they did not intend to confer third-party beneficiary status. Therefore, the court need not reach the remaining two factors in the third-party beneficiary test pertaining to whether the benefit was in satisfaction of a pre-existing obligation or whether the intent to benefit Janssen Biotech was a material part of the parties' purpose in entering into the contract. *See Micro Focus*, 2022 WL 1503918, at *2 (finding lack of standing for non-signatory's breach of contract claims based on analysis of first prong of the third-party beneficiary test). Consequently, I recommend that the court dismiss with prejudice Count II of the amended complaint for Janssen Biotech's claim for breach of contract. Plaintiffs have already been given an opportunity to amend Count II, and those amendments implausibly characterized various provisions of the DSA. *See McCoy v. Favata*, C.A. No. 17-1046-MN, 2020 WL 1929040, at *19 (D. Del. Apr. 21, 2020) (dismissing with prejudice certain claims where plaintiff had been given an opportunity to cure substantive issues and had failed to do so). On this record, further amendment would be futile.

IV. CONCLUSION

For the foregoing reasons, I recommend that the court GRANT Defendants' partial motion to dismiss and dismiss Count II of the amended complaint with prejudice.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: May 2, 2023

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE