IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BAXTER HEALTHCARE CORP.,
BAXTER INTERNATIONAL INC.,
BAXTER HEALTHCARE S.A.,
GAMBRO LUNDIA AB, and
GAMBRO UF SOLUTIONS, INC.,

Plaintiffs,

v.

B. BRAUN MEDICAL INC., and
B. BRAUN AVITUM AG.

Defendants.

CIVIL ACTION
No. 20-5659

MEMORANDUM OPINION

SCHMEHL, J. /s/ JLS **September 12, 2022**

Plaintiffs plead that defendants fraudulently induced them into a settlement agreement, and therefore, that settlement agreement should be nullified and the fraud adjudicated. Plaintiffs also plead separate patent infringement claims through entities who are not parties to the settlement agreement. Presently, defendants move to dismiss by arguing that the settlement agreement's non-reliance clause precludes any claims of fraud as extra-contractual statements, the alleged fraud does not relate to any specific contractual representation, and plaintiffs fail to plead standing for the separate patent infringement claims. The Court grants defendants' Motions to Dismiss and plaintiffs' case is dismissed with leave to amend as specified below.

I. Background

In 2018, Baxter Healthcare Corporation and Gambro Lundia AB filed suit against B.Braun Medical Incorporated and B.Braun Avitum AG for patent infringement. (ECF Case Number 18-cv-163 (E.D. Pa. 2018)). That lawsuit was "predicated upon the notion that a single

imported device was the extent of any potential infringement." (ECF #40, Plaintiffs' Opposition, at 1.) During that case, through "pleadings, discovery, and other communications" defendants "perpetuated that the infringing activity" was the sole importation and display of an alleged infringing device at a trade show in the United States. Defendants do not dispute that the first lawsuit was predicated and settled on that notion.

Unbeknownst to plaintiffs during the first lawsuit, defendants were also allegedly manufacturing component(s) of the infringing device in the United States. In light of this newly discovered commercial activity, plaintiffs now plead that the following "pleadings, discovery and communications" from defendants in the first case constitute fraud:

> In a declaration included with [B. Braun US]'s motion to dismiss the 2018 litigation, Rebecca Stolarick ("and"), Corporate Vice President of Regulatory Affairs at [B. Braun US] wrote: "because the FDA market clearance process can take up to nine (9) months or longer, and additional time would be required to manufacture, test and ship product from Germany, [B. Braun US] does not anticipate being able to commercialize an OMNI device for the United States marketplace under at least April of 2021" ([Complaint] at ¶41);
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> In the 2018 Motion to Dismiss, [B. Braun US] stated that that "[b]ecause the regulatory process can take up to nine (9) months or longer, and additional time would be required to manufacture, test and ship the device from Germany, [B. Braun US] estimates that it will not be able to commercialize an OMNI device in the United States prior to April of 2021 - i.e., at least three (3) years from now" (*Id.* at ¶42);
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> In the 2018 Motion to Dismiss, [B. Braun US] stated that "the import of a single OMNI device for display at an international trade show where no offer for sale was or even could have been made (let alone 'intended'), because the device had not received FDA market clearance for commercial use or sale in the United States, is insufficient basis upon which to state a claim for an allegedly infringing importation or use under 35 U.S.C. § 271(a)" (*Id.* at ¶43);
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> In the 2018 Motion to Dismiss, [B. Braun US] stated that the court "should dismiss under Rule 12(b)(1) because the Complaint amounts to an improper request for an advisory infringement opinion and therefore fails to give rise to an immediate, real case or controversy under Article III of the Constitution" (*Id.* at ¶32);

> In the 2018 Motion to Dismiss, [B. Braun US] stated that the alleged infringement was directed to "uncertain future activities that may or may not occur" (*Id.* at ¶33);
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> In the 2018 Motion to Dismiss, [B. Braun US] stated that the court "should dismiss under Rule 12(b)(6) because no claims may lie where, as here, there have been no commercial sales or offers for sale for the allegedly infringing device" (*Id.* at ¶34);
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> In the 2018 Motion to Dismiss, [B. Braun US] stated that "[t]he Complaint also alleges no case or controversy because it is unclear when, if ever, an OMNI device will actually be cleared by the FDA for commercial use and sale in the United States, and what the final form of the device will be" (*Id.* at ¶35);
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> In the 2018 Motion to Dismiss, [B. Braun US] stated that the court should dismiss the action "because absent sales or offers for sale, the mere importation and display/demonstration of an allegedly infringing product at a trade show does not constitute an infringing 'use' or 'importation' under 35 U.S.C. § 271(a)" (*Id.* at ¶36);
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> In a reply brief in further support of the 2018 Motion to Dismiss, [B. Braun US] stated that Plaintiffs' suit should be dismissed, "to be re-commenced only if there ever comes a time that a genuine case or controversy arises" (*Id.* at ¶47); and
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> In [B. Braun US]'s Responses to Plaintiff's First Set of Interrogatories in the 2018 litigation, [B. Braun US] stated that: '(1) the OMNI device has not received FDA market clearance for marketing and sale in the United States []; (2) the single displayed-device has been shipped out of the United States to Germany []; (3) [B. Braun US] is no longer in possession of an OMNI device in the United States []; (4) an OMNI device has not been and cannot be marketed or sold in this country until a 510(k) application for FDA market clearance is filed and approved[]; (5) [B. Braun US] will not import, display or demonstrate an OMNI device in the United States prior to filing for FDA market clearance . . .

(ECF #40, Plaintiffs' Opposition, at 6-7.) (citing defendants' Motions to Dismiss, at 7-9.) Plaintiffs argue that these statements amount to actionable fraud given that defendants "perpetuated" the "notion that a single imported device was the extent of any potential infringement" while defendants were also allegedly manufacturing a component in the United States. (ECF #40, Plaintiffs' Opposition, at 1.)

The Court accepts these pleadings as true, but need not determine whether fraud was adequately plead. While defendants argue that the statements are not fraud, false, nor omissions,

defendants also argue that the settlement agreement precludes plaintiffs from complaining of any alleged fraud given the agreement's non-reliance clause. According to defendants, the non-reliance clause precludes plaintiffs from complaining that any extra-contractual statement induced them into the agreement, fraudulent or not. The alleged fraud also does not relate to any specific contractual representation to circumvent the non-reliance clause. Lastly, given that the settlement agreement precludes certain plaintiffs from filing suit, the remaining plaintiffs lack standing for the separate patent infringement claims. More specifically, the remaining patent infringement claims are not brought by the patent holders nor licensees who are endowed with "all substantial patent rights," thus, they do not have standing.

The issues before the Court then are, under Delaware law, whether the non-reliance clause precludes plaintiffs from alleging fraud, or alternatively, whether the alleged fraud directly relates to any specific contractual representation to circumvent the non-reliance clause. Lastly, whether the plaintiffs outside of the settlement agreement have standing to sue for patent infringement without joining the patent holders. The Court finds in favor of defendants on all issues.

II. Standard of Review

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim satisfies the plausibility standard when the facts alleged "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Burtch v. Millberg Factors, Inc.*, 662 F.3d 212, 220-21 (3d Cir. 2011) (citing *Iqbal*, 556 U.S. at 678). While the plausibility standard is not "akin to a 'probability requirement,'" there nevertheless must be more than a

"sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

The Court of Appeals requires us to apply a three-step analysis under a 12(b)(6) motion: (1) "it must 'tak[e] note of the elements [the] plaintiff must plead to state a claim;'" (2) "it should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth;'" and, (3) "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Connelly v. Lane Construction Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Iqbal*, 556 U.S. at 675, 679); *see also Burtch*, 662 F.3d at 221.

In our analysis of a motion to dismiss, the Court of Appeals allows us to also consider documents "attached to or submitted with the complaint, and any 'matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case.'" *Buck v. Hampton Tp. School Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (quoting 5B Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 1357 (3d ed. 2004)).

III. Analysis

I. Delaware Law Applies to the Interpretation of the Settlement Agreement.

As a Federal Court sitting in Pennsylvania, we apply Pennsylvania's choice of law rules to determine which state's law applies to the agreement at issue. *Nova Ribbon Prod., Inc. v. Lincoln Ribbon, Inc.*, 1992 WL 393614, at *1 (E.D. Pa. Dec. 14, 1992). Pennsylvania's choice of law rules asks whether the parties "explicitly or implicitly chose which law to apply" within the

agreement, and "'Pennsylvania courts give effect to choice of law provisions of a contract.'" *Medlar v. Regence Grp.*, 2005 WL 1241881, at *4 (E.D. Pa. May 23, 2005) (citing *Miller v. Allstate Ins. Co.*, 763 A.2d 401, 403 (Pa. Super. Ct. 2001); *see also Stone St. Servs. Inc. v. Daniels*, 2000 WL 1909373, at *4 (E.D. Pa. Dec. 29, 2000). The parties explicitly contracted that Delaware law applies to the interpretation of the settlement agreement. (ECF #1, Ex. S, *Settlement Agreement*, 6. Governing Law.).

II. Under Delaware Law, Non-Reliance Clauses Preclude Extra-Contractual Claims of Fraud Unless the Alleged Fraud Relates to a Specific Contractual Provision, Which It Does Not Here.

Under Delaware law, "sophisticated parties may not reasonably rely upon representations that are inconsistent with a negotiated contract, when that contract contains a provision explicitly disclaiming reliance upon such outside representations." *Progressive Int'l Corp. v. E.I. Du Pont de Nemours & Co.*, 2002 WL 1558382, at *7 (Del. Ch. July 9, 2002). "Delaware courts routinely enforce these anti-reliance provisions as long as the contractual language, when read as a whole, can be said to add up to a clear anti-reliance clause by which the plaintiff has contractually promised that it did not rely upon statements outside the contract's four corners in deciding to sign the contract." *Infomedia Group, Inc. v. Orange Health Solutions, Inc.*, 2020 WL 4384087, at *5 (Del. Super. Ct. July 31, 2020) (quotation omitted).

The parties contracted that their settlement agreement:

> "constitutes the entire agreement between the Parties . . . . No Promises or oral or written statements have been made by or to either Party other than those in this Agreement. Neither Party is relying on any promise or oral or written statement by or to either Party in executing this Agreement, other than the representations set forth in this Agreement . . . ."

(ECF #1, Ex. S, Settlement Agreement, 14. Entire Agreement.) Plaintiffs argue that their allegations of fraud "frustrate the very purpose and nature" of the Settlement Agreement, run

"contrary to the premise of the Settlement Agreement," and B.Braun's perpetuated "misimpression" is the very reason why the Settlement Agreement's prohibited activities fail to prohibit B.Braun from manufacturing an allegedly infringing device in the United States. (ECF #40, Plaintiff's Opposition, 5-8.)

The non-reliance clause is an unambiguous bargained for term, and under Delaware law, the clause precludes the parties from alleging that extra-contractual statements, misrepresentations, fraud, or omissions induced them into the agreement. *See MidCap Funding X Trust v. Graebel Companies, Inc.*, 2020 WL 2095899, at *2 (Del Ch. Apr. 30, 2020) ("Because the plaintiffs failed to secure such contractual protections, they regretfully reflect upon the deal the company agreed to and ask this Court to fashion a remedy when they agreed that none would be afforded to them. Accepting the plaintiffs' allegations as true, their retrospective angst is understandable. But the plain language of the agreement governs.")

Plaintiffs may still use "external sources of information to plead that a contractually identified fact was false or misleading." *Prairie Capital III, L.P. v. Double E Holding Corp.*, 132 A.3d 35, 52 (Del. Ch. 2015). Thus, for plaintiffs to succeed they must point to a specific contractual representation within the agreement that the alleged fraud relates to, and plaintiffs relied upon. *Id.* ("For arms' length counterparties, therefore, contractual provisions that identify the representations on which a party exclusively relied define the universe of information that is in play for purposes of a fraud claim.").

For example, in the main case that plaintiffs cite, *Overdrive*, the Delaware Court of Chancery denied a Partial Motion to Dismiss where plaintiff alleged, in part, that defendant made misrepresentations relating to provisions within the parties' agreement. *Overdrive, Inc. v. Baker & Taylor, Inc.*, 2011 WL 2448209, at *1, 5, 10 (Del. Ch. June 17, 2011). That court held that

"plaintiff's fraud claim would not be barred by the anti-reliance clause in the Agreement" because the alleged misrepresentations "relate directly to [the Agreement]" as defendant allegedly told plaintiff that a provision was "nothing to worry about and assured [plaintiff] that" defendant's relationship with another entity in the Agreement's "preexisting agreement" list "was limited" and "would never be expanded . . . ." *Id.* at 3, 6. *But see MidCap*, 2020 WL 2095899, *20 n. 156 (distinguishing *Overdrive*, where the "Court noted that the representations and omissions relate directly to specific provisions, and, indeed, go to the very core of the agreement," to allegations where the "misrepresentations are not within the Agreement, and do not relate directly to any specific provisions."); *see also Universal Am. Corp. v. Partners Healthcare Solutions Holdings, L.P.*, 61 F.Supp.3d 391, 400 (D.Del. 2014); *see generally Prairie Capital*, 132 A.3d at 54-56.

Here, plaintiffs argue in their Opposition to defendants' Motions to Dismiss that the alleged fraud relates to two specific 'whereas clause' provisions: "Whereas, the parties wish to fully and finally settle the Litigation upon the terms and subject to the conditions set forth below" and "Whereas, settlement of the Litigation will permit the Parties to avoid the substantial costs, uncertainty, and risk of prolonged patent infringement litigation, trial, and appeal." (ECF #1, Ex. S, Settlement Agreement, at 1.) Although plaintiffs failed to plead this in their Complaint, the Court will still accept these arguments to fully adjudicate the Motions to Dismiss.

The alleged fraud does not relate to the two aforementioned contractual representations. The alleged fraud relates to where the alleged infringing device was manufactured, where it was tested, where it could be shipped from, the timing of regulatory approval and commercial use, the circumstances of the importation and trade show, future activities of the device, and other similar matters. (*See* ECF #40, Plaintiffs' Opposition, at 6-7.) While interpreting contractual

representations, we must accept and apply representations as written. The alleged fraud simply does not relate to whether the parties intended to "fully and finally settle the Litigation" nor does it relate to avoiding typical litigation considerations. More extensive discovery in the prior lawsuit, or a contractual representation of the essence that the lawsuit was "predicated upon the notion that a single imported device was the extent of any potential infringement" would very likely have permitted plaintiffs to pursue the alleged fraud under a contractually identified representation.

Therefore, the alleged fraud is barred by the settlement agreement's non-reliance clause, and as it clearly does not relate to any contractual representations, Plaintiffs' fraud claims in this action must be dismissed. The patents infringement claims for the patents listed within the settlement agreement are also dismissed, and plaintiffs Baxter Healthcare Corporation and Gambro Lundia AB are dismissed as they may not bring suit for patent infringement until "after B.Braun receives FDA approval . . . ." (ECF #1, Ex. S, Settlement Agreement, at 1.)

III. The Remaining Plaintiffs Fail to Plead Standing for the Patent Infringement Claims.

A patent holder, a successor in title to the patent holder, or an exclusive licensee who shows that he possesses "all substantial rights" may bring an action for patent infringement. *Fieldturf, Inc. v. Southwest Recreational Industries, Inc.*, 357 F.3d 1266, 1268 (Fed. Cir. 2004); *International Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1276 (Fed. Cir. 2007). "A purported exclusive licensee must show that he possesses 'all substantial rights in the patent,'" and if he does not, then he may only bring suit as a co-plaintiff with the patent holder or successor in title. *Fieldturf*, 357 F.3d at 1268 (citations omitted); 35 U.S.C. §§ 100(d) 261, 281. The party claiming "all substantial rights" has the burden of "provid[ing] evidence endowing it" as such. *Id.*

Plaintiffs plead that the plaintiffs who are not implicated in the settlement agreement are "lawful owners by assignment" and "[c]ollectively, [all plaintiffs] holds all right, title and interest . . . ." (*see generally* ECF #1, Complaint.) Plaintiffs also argue that a motion at this stage of the proceedings is "not the proper mechanism for sorting out this dispute." (ECF #40, Plaintiffs' Opposition, at 16.)

Given that the apparent patent owners, Baxter Healthcare and Gambro Lundia AB are dismissed from this suit because of the settlement agreement and the Court's aforementioned ruling, the remaining plaintiffs must be endowed with "all substantial rights." Plaintiffs do not plead that those plaintiffs retain "all substantial rights"; plaintiffs only generally plead that they were assigned patent rights. Accordingly, the remaining claims are dismissed for a lack of standing, and plaintiffs may file an Amended Complaint if there is evidence showing that the remaining plaintiffs are endowed with "all substantial rights" to the relevant remaining patent infringement claims.

IV. Conclusion

For all of these reasons, defendants' Motions to Dismiss are granted, the case is dismissed, and plaintiffs may file an Amended Complaint in accordance with this Memorandum Opinion within sixty days.