

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	:	
PURDUE PHARMACEUTICA-	:	
LS L.P., and THE P.F. LABOR-	:	
ATORIES, INC.,	:	
	:	
Plaintiffs.	:	
v.	:	Civil Action No. 18-226-CFC
	:	
	:	
COLLEGIUM NF, LLC and	:	
COLLEGIUM PHARMACEU-	:	
TICAL, INC.,	:	
	:	
	:	
Defendants.:	:	

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Counsel for Defendants

MEMORANDUM OPINION

June 19, 2019
Wilmington, Delaware


COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. (collectively “Purdue”) initiated this action with the filing of a three-count complaint against Defendants Collegium NF, LLC and Collegium Pharmaceutical, Inc. (collectively “Collegium”) for patent infringement of U.S. Patent No. 9,861,583 (“#583 patent”), U.S. Patent No. 9,867,784 (“#784 patent”), and U.S. Patent No. 9,872,836 (“#836 patent”). On December 10, 2018, at the request of all the parties, I stayed the case “with the exception of briefing on and resolution of Defendants’ anticipated motion for judgment on the pleadings and any discovery related to that motion.” D.I. 39 at 2. Later that day, Collegium filed a Motion for Judgment on the Pleadings pursuant to Federal Rule of Civil Procedure 12(c), asking that I dismiss the complaint and enter judgment in Collegium’s favor. D.I. 42. For the following reasons, I will deny the motion.

I. BACKGROUND¹

Purdue alleges in its complaint that “[s]ince at least January 10, 2018,” Collegium has infringed the asserted patents “by using, offering for sale, selling,

¹ As I am assessing the merits of Collegium’s Rule 12(c) motion for judgment on the pleadings, I accept as true all factual allegations in the pleadings of Purdue and view those facts in the light most favorable to Purdue. *See Zimmerman v. Corbett*, 873 F.3d 414, 417–18 (3d Cir. 2017) (citations omitted).

and/or distributing” certain Nucynta® and Nucynta® ER tablets (collectively, “the Nucynta Products”). D.I. 1 at ¶¶ 46, 59, 72. Purdue further alleges that Collegium induced Assertio Therapeutics, Inc. to infringe the asserted patents.² Assertio is the holder of the New Drug Applications (NDAs) approved by the FDA for the manufacturing, marketing, and sale of the Nucynta Products. *Id.* at ¶¶ 16–17, 20–21. Collegium sold the Nucynta Products pursuant to a Commercialization Agreement it had with Assertio.

When Collegium and Assertio signed the Commercialization Agreement in December 2017, section 3.2(c)(viii) of the agreement provided in relevant part:

(c) Supply by [Assertio]. [Assertio] has obtained and will continue to use commercially reasonable efforts to obtain supply of the [Nucynta] Products for Commercialization in the [United States] pursuant to one or more CMO Supply Agreements, and from and after the Closing Date shall supply the [Nucynta] Products in finished goods form to Collegium on a pass-through basis, under the terms and conditions applicable to the supply of the [Nucynta] Products, as applicable, to [Assertio] under the applicable CMO Supply Agreements. Collegium and its Affiliates and any other Sublicensees shall purchase all of their [Nucynta] Product requirements for Commercialization in the [United States] from [Assertio] in accordance with the terms and conditions of the applicable CMO Supply Agreements, unless otherwise agreed to by Collegium and [Assertio]. . . .

² At the time Assertio filed the NDAs and this lawsuit was filed, Assertio did business under the name Depomed, Inc. *See* D.I. 1 at ¶¶ 16, 20. For ease of reference and consistent with the parties’ practice in their briefing, I refer only to Assertio in this Memorandum Opinion.

(viii) To the extent permitted under the applicable CMO Supply Agreement, title to the [Nucynta] Products ordered hereunder by or on behalf of Collegium shall transfer to Collegium . . . upon fulfillment of the applicable CMO’s delivery obligation pursuant to the applicable CMO Supply Agreement . . . *and at no time shall title to such [Nucynta] Products transfer to [Assertio].*

D.I. 44–1, Ex. A at 0055578, 0055580 (emphasis added).

On August 28, 2018—six months after Purdue filed this lawsuit—Purdue and Assertio entered into a Settlement Agreement to settle their “disputes relating to” a patent case they had been litigating in the District of New Jersey since 2013. *See id.*, Ex. C. Three sections of the Settlement Agreement are relevant to the pending motion.

First, in section 6 of the Settlement Agreement, Purdue granted Assertio a covenant not to sue Assertio and certain related entities. The covenant not to sue expressly carved out Collegium. It reads in relevant part:

Purdue Covenant Not to Sue. The Purdue Entities[] . . . hereby covenant that neither the Purdue Entities nor any of their Associated Companies will sue, assert or purport to assert any claim or counterclaim against or otherwise assist, encourage, facilitate or participate in any action or proceeding in the [United States] against Assertio or its Associated Companies or their direct or indirect customers, users, licensees, agents, service providers, distributors, retailers, or their direct or indirect manufacturers or suppliers (excluding Collegium) claiming or otherwise asserting that any of the making, having made, using, marketing, selling, offering for sale,

importing and/or other distributing of any Assertio Product [including the Nucynta Products] in the [United States] infringes any Purdue Patents, or other patent rights that are or have been owned or controlled (including any right of enforcement) by any of the Purdue Entities or any of their Associated Companies, including any patent rights that are owned or controlled by the Purdue Entities or any of their Associated Companies in the future. . . . The covenant contained in this Section 6 shall also not apply to Collegium.

Id. at 00251341 (bolded and underscored typeface in original).

Second, in section 7 of the Settlement Agreement, Purdue agreed to release Assertio and certain related entities from infringement claims related to the Nucynta Products. The release expressly carved out Collegium. It reads in relevant part:

Purdue Release. The Purdue Entities, on behalf of themselves and each of their Associated Companies, hereby release and forever discharge Assertio, each of its Associated Companies (as of Signing Date), and their respective current and former directors, officers, employees, attorneys, other representatives or their direct or indirect customers, users, licensees, service providers, distributors, retailers, or their direct and indirect manufacturers or suppliers (excluding Collegium) (collectively the “Assertio Releasees”) from any and all actions, causes of action, suits, claims and liabilities whatsoever, in law, admiralty or equity against the Assertio Releasees relating to (i) any claim of infringement of the Purdue Patents . . . arising from the making, having made, using, marketing, selling, offering for sale, importing and/or other distributing of any Assertio Product [including the Nucynta Products] in or for the [United States], on or prior to the Signing Date, (ii) any claims in the [United States] that were made or

could have been made against the Assertio Releasees in the Civil Action or the Related *Inter Partes* Review Proceedings, including in each case, any claim for attorneys' fees or costs, and (iii) any other claims or counterclaims related to the Purdue Patents or other patent rights that are or have been owned or controlled (including any right of enforcement) by the Purdue Entities or their Associated Companies (as of the Signing Date) that could have been brought in the [United States] on or prior to the Signing Date with respect to the Assertio Products [including the Nucynta Products]. For the avoidance of ambiguity, the release provided by this Section 7 will not apply to any action to enforce any provision of this Agreement. The release contained in this Section 7 will also not apply to Collegium.

Id. at 00251342 (bolded and underscored typeface in original).

Third, in section 15 of the Settlement Agreement, Purdue and Assertio agreed to the following:

No Exhaustion of Rights as to Collegium. Any activity by Collegium (and solely with respect to Collegium and not any Third Party engaging in such activity), including the making, having made by any Third Party other than by or on behalf of Assertio or its Associated Companies, using, offering to sell, selling, shipping, distributing or importing in or outside the [United States] of NUCYNTA® or NUCYNTA® ER shall not be authorized and no determination that any of the Purdue Patents or any other patent rights or other intellectual property owned or controlled by any of the Purdue Entities or any of their Associated Companies have been terminated or exhausted as to Collegium shall be based upon any provision of this Agreement. For the sake of clarity, none of the activities described above with respect to NUCYNTA® or NUCYNTA® ER by Collegium is authorized by any of the Purdue Entities or any of their Associated Companies and no release or

covenant not to sue given by any of the Purdue Entities or any of their Associated Companies shall be applicable to Collegium. Neither Assertio nor any of its Associated Companies shall assert, in any context, alone or in cooperation with Collegium or any other Third Party, that any of the Purdue Patents or any other patent rights or other intellectual property owned or controlled by any of the Purdue Entities or any of their Associated Companies have been exhausted with respect to Collegium by any of its activities relating to NUCYNTA® or NUCYNTA® ER. For greater clarity, it shall not be a violation of the covenant not to sue contained in Section 6 for any of the Purdue Entities or any of their Associated Companies to assert any direct or indirect infringement claims against Collegium, including but not limited to Civil Action No. 18-cv-226-[CFC] pending in the District Court for the District of Delaware.

Id. at 00251350 (bolded typeface in original).

On August 29, 2018—the day after Assertio and Purdue executed the Settlement Agreement—Assertio and Collegium executed Amendment No. 2 to Commercialization Agreement. Amendment No. 2 “amended and restated” section 3.2(c)(viii) of the Commercialization Agreement to read in relevant part:

To the extent permitted under the applicable CMO Supply Agreement, title to the [Nucynta] Products ordered hereunder by or on behalf of Collegium shall transfer as follows:

- (A) *Title shall transfer from the applicable CMO to [Assertio] at such time as the [Nucynta] Products are loaded onto a carrier vehicle arranged for and managed by [Assertio] for shipment at the shipping point; and*

- (B) *Title shall transfer from [Assertio] to Collegium upon delivery of the [Nucynta] Products to the loading dock of Collegium’s third-party logistics provider.*

D.I. 44–1, Ex. A at 0055659 (emphasis added).

II. LEGAL STANDARDS

“The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference.” *Int’l Bus. Machines Corp. v. Groupon, Inc.*, 289 F. Supp. 3d 596, 600 (D. Del. 2017) (citations omitted). “A motion for judgment on the pleadings should be granted if the movant establishes that there are no material issues of fact, and [the movant] is entitled to judgment as a matter of law.” *Zimmerman*, 873 F.3d at 417 (internal quotation marks and citations omitted). “In considering a motion for judgment on the pleadings, a court must accept all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw all reasonable inferences in favor of the non-moving party.” *Id.* at 417–18 (citations omitted).

“A motion for judgment on the pleadings . . . is analyzed under the same standards that apply to a Rule 12(b)(6) motion.” *Revell v. Port Auth. of NY, NJ*, 598 F.3d 128, 134 (3d Cir. 2010). To state a claim upon 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). Detailed

factual allegations are not required, but 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). A claim is facially plausible when the factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

III. DISCUSSION

Collegium argues that the covenant not to sue and release in the Settlement Agreement “authorize all Assertio sales of the Nucynta Products, thereby terminating Purdue’s patent rights to those products.” D.I. 43 at 3. In Collegium’s words, “[b]ecause [it] takes title to the Nucynta Products from Assertio, it cannot infringe the Patents-in-Suit[]” under the doctrine of patent exhaustion and therefore is entitled to judgment on the pleadings. D.I. 43 at 2–3. Purdue responds with two main arguments: (1) Collegium’s motion is “procedurally improper” because Purdue has not been afforded a reasonable opportunity to take discovery concerning the factual bases for Collegium’s patent exhaustion defense, D.I. 54 at 8; and (2) Collegium’s patent exhaustion defense fails as a matter of law because “[s]ales of Nucynta to Collegium are not authorized by the [] Settlement Agreement[,]” *id.* at 12.

A. Patent Exhaustion

“When a patentee sells one of its products . . . the patentee can no longer control that item through the patent laws—its patent rights are said to ‘exhaust.’” *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523, 1531 (2017). “A patentee is free to set the price and negotiate contracts with purchasers, but may not, *by virtue of his patent*, control the use or disposition of the product after ownership passes to the purchaser.” *Id.* (emphasis in original; internal quotation marks and citation omitted). Thus, under the “longstanding doctrine of patent exhaustion[,] . . . the initial authorized sale of a patented item terminates all patent rights to that item.” *Quanta Comput., Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008).

The Supreme Court emphasized in *Quanta* that “[e]xhaustion is triggered *only* by a sale *authorized* by the patent holder.” *Id.* at 636 (emphasis added; citation omitted). Thus, “if a patentee has not given authority for a licensee to make a sale, that sale cannot exhaust the patentee’s rights.” *Lexmark*, 137 S. Ct. at 1535.

Sales made pursuant to a patent holder’s “unconditional covenant not to sue” are “authorize[d] sales by the covenantee for purposes of patent exhaustion.” *TransCore, LP v. Elec. Transaction Consultants Corps.*, 563 F.3d 1271, 1274 (Fed.

Cir. 2009). Whether a covenant not to sue or a release can retroactively authorize sales for the purposes of patent exhaustion, however, is “not free from doubt.” *Sunoco Partners Mktg. & Terminals L.P. v. U.S. Venture, Inc.*, 2017 WL 4283946, at *8 (N.D. Ill. Sep. 27, 2017). Neither the Supreme Court nor the Federal Circuit has addressed that question, and there is a split among the district courts that have addressed the question. *Compare id.* (holding that covenant not to sue cannot retroactively authorize sales for purposes of patent exhaustion), *and Cascades Comput. Innovation, LLC v. Samsung Elecs. Co.*, 70 F. Supp. 3d 863, 869–71 (N.D. Ill. 2014) (holding that release and covenant not to sue cannot retroactively authorize sales for purposes of patent exhaustion), *with PSN Illinois LLC v. Abbott Labs.*, 2011 WL 4442825, at *10 (N.D. Ill. Sep. 20, 2011) (holding that release can retroactively authorize sales for purposes of patent exhaustion).

B. Analysis

1. Purdue’s Covenant Not to Sue Authorizes Sales of the Nucynta Products to Any and All Purchasers

Pursuant to section 6 of the Settlement Agreement, Purdue covenanted that it would not sue Assertio and certain entities associated with Assertio (the “Associated Entities”)—but not Collegium—for infringement based on the “selling” of the Nucynta Products. This covenant not to sue unconditionally authorized Assertio and the Associated Entities to sell the Nucynta Products.

Citing sections 6, 7, and 15 of the Settlement Agreement, Purdue argues that “[t]he Settlement Agreement expressly excludes sales to Collegium from the scope of Purdue’s covenant not to sue and release.” D.I. 54 at 12. But none of these sections nor any other provision in the Settlement Agreement precludes or restricts in any way Assertio or the Associated Entities from selling the Nucynta Products to *any* particular purchaser. In section 6, Purdue “exclude[ed] Collegium” from the list of the Associated Entities it was covenanting not to sue. In section 7, Purdue “exclud[ed] Collegium” from the list of releasees covered by the release Purdue gave. Purdue did not, however, exclude sales of the Nucynta Products by Assertio or the Associated Entities to Collegium from the scope of either its covenant not to sue or its release.

Although titled “No Exhaustion of Rights as to Collegium,” section 15 does not change the fact that Purdue unconditionally authorized Assertio and the Associated Entities to sell the Nucynta Products to anyone, including Collegium.

That section reads in relevant part:

[a]ny activity by Collegium (and solely with respect to Collegium and not any Third Party engaging in such activity), including the making, having made by any Third Party other than by or on behalf of Assertio or its Associated Companies, using, offering to sell, selling, shipping, distributing or importing in or outside the [United States] of NUCYNTA® or NUCYNTA® ER shall not be authorized

D.I. 44–1, Ex. C at 00251350 (emphasis added). Thus, section 15 recites merely that Purdue was not authorizing sales made *by Collegium* or other potentially infringing activity performed *by Collegium* (and by third parties *other than Assertio or its Associated Companies* to make the Nucynta Products). There is irony here. Purdue relies on section 15 as proof that the Settlement Agreement did not authorize Assertio’s sales of the Nucynta Products to Collegium and therefore did not exhaust Purdue’s patent rights with respect to Collegium, when in fact section 15 explicitly carves out Assertio from Purdue’s putative “non-authorization” of Nucynta Product sales.

Because Purdue’s covenant not to sue unconditionally authorized Assertio and the Associated Entities to sell the Nucynta Products, judgment in Collegium’s favor is warranted under the doctrine of patent exhaustion to the extent Collegium’s alleged infringing activities resulted from sales that fall within the scope of that covenant.

2. The Temporal Scope of The Covenant Not to Sue

Collegium argues that Purdue’s covenant not to sue “is unlimited in time” and “authorizes all past, present, and future Assertio sales of the Nucynta Products.” D.I. 43 at 12. It argues further that the release in section 7 of the Settlement Agreement independently authorizes Assertio’s past sales.

I have doubts that the language of the covenant not to sue in section 6 covers past sales. Collegium points to the fact that section 6 refers to “selling” with “[n]o temporal limitation.” D.I. 59 at 12. But the clause in question in section 6 refers to “making, *having made*, using, marketing, selling, offering for sale, importing and/or distributing[.]” D.I. 44–1, Ex. C at 00251341. The fact that the clause uses both “making” and “having made” suggests that past activities for everything listed except “making” are *not* covered by the covenant.

But in any event, I need not decide whether the covenant applies to past sales. Nor is it necessary for me to decide whether the release in section 7 of the Settlement Agreement authorized past sales. Assuming *arguendo* that the Settlement Agreement authorized past sales, the record before me does not establish as a factual matter that Collegium’s alleged infringing activities resulted from sales covered by the Settlement Agreement.

3. Factual Issues Exist About Whether Collegium’s Alleged Infringing Acts Resulted from Sales Authorized by Purdue’s Covenant Not to Sue

In its opening brief, Collegium framed the question of whether its purchases of the Nucynta Products are authorized under the Settlement Agreement as turning on whether “Collegium takes title to the Nucynta Products *from Assertio*[.]” See D.I. 43 at 2–3 (emphasis added). But in its reply brief, Collegium took the position that, before it signed Amendment No. 2 to Commercialization Agreement, it

“received title to the Nucynta Products *from Assertio’s CMOs*, and after that date, it received title *from Assertio*.” D.I. 59 at 14 (emphasis added). Collegium relied exclusively on section 3.2(c)(viii) of the Commercialization Agreement and Amendment No. 2 as proof of both of these positions. *See* D.I. 43 at 4, 9; D.I. 59 at 14.³ Neither the Commercialization Agreement nor Amendment No. 2, however, establish definitively (1) that title of the Nucynta Products was or is transferred to Collegium; or (2) if title was or is transferred, what entity transferred or transfers it.

As originally written, section 3.2(c)(viii) provided that

To the extent permitted under the applicable CMO Supply Agreement, title to the [Nucynta] Products ordered hereunder by or on behalf of Collegium shall transfer to Collegium or its designated recipient upon fulfillment of the applicable CMO’s delivery obligation pursuant to the applicable CMO Supply Agreement (which delivery is directed to Collegium or its designated recipient) and at no time shall title to such [Nucynta] Products transfer to [Assertio].

D.I. 44–1, Ex. A at 0055580 (emphasis and underscoring added). By its terms, section 3.2(c)(viii) addresses the issue of *to which party* title shall be transferred under the Commercialization Agreement; the section does not address or make

³ Although Purdue argued that Collegium “provide[d] no support for its argument [] that it is procedurally proper for the Court to consider documents referenced in a defendant’s answer and counterclaims[.]” D.I. 54 at 9, it did not object in its briefing to my consideration of the agreements.

clear *from which party* title is to be transferred. Moreover, the language “at no time shall title . . . transfer to [Assertio]” suggests that Assertio was never in the chain of title for the Nucynta Products. But the language of section 3.2(c)(viii) that is dispositive for purposes of the pending motion is found in the section’s prefatory clause: “to the extent permitted by the applicable CMO Supply Agreement.”

Because of that language, without knowing the terms of the applicable CMO Supply Agreements, it is impossible to determine whether title of the Nucynta Products was transferred to Collegium, let alone by what entity. None of the CMO Supply Agreements, however, are part of the record before me. For that reason alone, judgment on the pleadings is inappropriate.

Amendment No. 2 similarly conditions the transfer of title to Collegium on the terms of the applicable CMO Supply Agreement:

To the extent permitted under the applicable CMO Supply Agreement, title to the [Nucynta] Products ordered hereunder by or on behalf of Collegium shall transfer as follows:

- (A) *Title shall transfer from the applicable CMO to [Assertio] at such time as the [Nucynta] Products are loaded onto a carrier vehicle arranged for and managed by [Assertio] for shipment at the shipping point; and*
- (B) *Title shall transfer from [Assertio] to Collegium upon delivery of the [Nucynta] Products to the loading dock of Collegium’s third-party logistics provider.*

Id. at 0055659 (emphasis added). Accordingly, without knowing the terms of the applicable CMO Supply Agreement, there is a material issue of fact about whether title of the Nucynta Products transfers from Assertio to Collegium under Amendment No. 2.

IV. CONCLUSION

The premise of Collegium's patent exhaustion defense is that Assertio or one of its Associated Entities transferred title of Nucynta Products to Collegium pursuant to the Commercialization Agreement both as originally drafted and as revised by Amendment No. 2. There are, however, material issues of fact concerning that premise. Accordingly, Collegium is not entitled to judgment on the pleadings.

The Court will enter an order consistent with this Memorandum Opinion.