IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UPSHER-SMITH LABORATORIES, LLC, Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD., Defendants.	Civil Action No. 21-1132-GBW REDACTED PUBLIC VERSION

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MEMORANDUM OPINION

[redacted]

October 11, 2022
Wilmington, Delaware

GREGORY B. WILLIAMS
U.S. DISTRICT JUDGE

Pending before the Court is Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.'s (collectively, "Zydus") Motion to Dismiss Plaintiff Upsher-Smith Laboratories, LLC's ("USL") Complaint Pursuant to Federal Rule of Civil Procedure 12(b)(6). D.I. 13. For the reasons below, the Court will grant-in-part and deny-in-part Zydus's Motion to Dismiss.

I. BACKGROUND[1]

In 2014, the FDA approved USL's New Drug Application ("NDA") No. 205122 for QUDEXY® XR (topiramate) extended-release capsules in 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg strengths. D.I. 2 at ¶ 28. The Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") lists QUDEXY® XR (topiramate) extended-release capsules as covered by one or more claims of USL's United States Patent Nos. 8,652,527, 8,889,190, 9,101,545, 9,555,005, and 10,363,224. *Id.* In 2016, Zydus filed its Abbreviated New Drug Application ("ANDA") No. 208949 seeking approval for a generic version of QUDEXY® XR. *Id.* at ¶ 29. Zydus's ANDA No. 208949 included a Paragraph IV certification that Zydus did not infringe any claims of the patents listed in FDA's Orange Book. *Id.* Because Zydus submitted the first ANDA to the FDA seeking approval of a generic version of QUDEXY® XR with a Paragraph IV certification, Zydus was the "first applicant" eligible for 180-day exclusivity under the Hatch Waxman Act. *Id.* Zydus,

[1] Under Federal Rule of Civil Procedure 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).

therefore, was entitled to 180 days of exclusivity against subsequent generic applicants. *Id.*; *see also FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013).[2]

Soon after Zydus filed ANDA No. 208949, USL filed a patent infringement action against Zydus in this District, alleging Zydus's generic version of QUDEXY® XR infringed certain patents listed in FDA's Orange Book. D.I. 2 at ¶ 4; *see generally Upsher-Smith Labs. v. Zydus Pharms. (USA), Inc.*, No. 16-248-SLR (D. Del.). The parties settled the patent litigation and entered into a settlement agreement dated January 12, 2017 (the "Settlement Agreement"). D.I. 2, Ex. A. The stated purposes of the Settlement Agreement are to: (1) "avoid the substantial costs, uncertainty and risk involved with prolonged patent-infringement litigation[;]" (2) "permit the management of the Parties to refocus on running their respective companies rather than devoting substantial time and resources to the Litigation[;]" (3) significantly benefit the public "from this procompetitive final settlement of the patent litigation[;]" and (4) to "permit Zydus to market Zydus Generic Products in the Territory prior to the expiration of the Asserted Patents" in 2033. *Id.* at 2. The Settlement Agreement included a non-exclusive license granting Zydus the right to import, make,

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[2] There are ways for a later ANDA filer than Zydus to bring its generic product to market:

> After the FDA has determined that the first ANDA filer is entitled to the 180-day Hatch-Waxman Exclusivity, there are limited ways for a later ANDA filer to enter the market:
>
> (1) the first ANDA filer can get approval and launch;
> (2) the first ANDA filer can relinquish its Hatch-Waxman Exclusivity;
> (3) the FDA can determine that the first ANDA filer has forfeited their right to the Hatch-Waxman Exclusivity Period; or
> (4) the NDA holder can grant the later ANDA filer rights to market an authorized generic of the brand drug (a generic product sold under the NDA).

D.I. 2 at ¶ 47 (citing 21 U.S.C. § 355(j)(5)(D)); *see also* D.I. 14 at 4-5.

have made, distribute, use, market, sell, and offer to sell its generic version of QUDEXY® XR prior to the 2033 expiration of USL's patents on the earliest to occur of the following dates: "(a) March 19, 2020; [redacted] *Id.* at 3, §3.1; *see also* D.I. 2 at ¶ 5. The Settlement Agreement also sets forth the period during which Zydus would have to pay USL royalties on Zydus's sales of its generic version of QUDEXY® XR:

[redacted]

D.I. 2, Ex. A at 5.

In 2017, Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark") filed an ANDA seeking FDA approval to market its generic topiramate extended-release capsules and included a Paragraph IV certification that Glenmark does not infringe any claims of the patents listed in FDA's Orange Book. D.I. 2 at ¶¶ 10, 46. Shortly thereafter, USL filed a patent infringement against Glenmark in this District. *Id.* at ¶ 46; *see also Upsher-Smith Labs., Inc. v. Glenmark Pharms. Ltd*, No. 17-649-CJB (D. Del.). In March 2018, the parties settled the patent litigation and entered into a settlement agreement. *Id.*

In January 2019, the FDA did not grant Glenmark's ANDA because:

> [p]rior to the submission of your [Glenmark's] ANDA, another applicant [Zydus] or applicants submitted a substantially complete ANDA providing for Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg, and containing a paragraph IV certification. Your ANDA will be eligible for final

> approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

Id. at ¶ 47.

Glenmark approached USL to request an earlier market entry date for its generic topiramate extended-release capsules. *Id.* at ¶ 48. USL refused. *Id.*

By November 17, 2020, Zydus relinquished its eligibility for Hatch-Waxman exclusivity with respect to its generic version of QUDEXY® XR. *Id.* at ¶ 50. Other generics, including Glenmark, could now obtain approval for their generic version of QUDEXY® XR. *Id.* The FDA approved Glenmark's ANDA to market its generic topiramate extended-release capsules in February 2021. *Id.* at ¶ 57.

On August 4, 2021, USL filed its Complaint in this action for damages and equitable relief against Zydus for breach of contract and breach of implied covenant of good faith and fair dealing. *See generally id.* USL alleges in its Complaint that Zydus relinquished its eligibility for Hatch-Waxman exclusivity

> in furtherance of an agreement Zydus entered into with Glenmark that would allow Glenmark the ability to be the first generic to enter the topiramate extended-release market [and] Zydus received and continues to receive monetary compensation from Glenmark in exchange for clearing a path for Glenmark to receive final approval from the FDA and enter the topiramate extended-release capsule market early.

Id. at ¶ 51.

USL argues that it was Zydus's agreement with Glenmark to relinquish its Hatch-Waxman exclusivity without regard to the benefits to accrue to USL from the Settlement Agreement, including the royalties to be paid by Zydus upon generic entry, that constitutes breach of the Settlement Agreement. In the alternative to the breach of contract claims, USL alleges that Zydus breached the implied covenant of good faith and fair dealing. *Id.* at ¶ 82. USL argues that "Zydus's

arbitrary and unreasonable conduct frustrated the overarching purpose of the [Settlement] Agreement and had the effect of preventing USL from receiving the full benefits of the [Settlement] Agreement." *Id.* at ¶ 92.

As of the date the Complaint was filed on August 4, 2021, Zydus had not received final FDA approval for its ANDA No. 208949 and Zydus has not entered the market for generic topiramate extended-release capsules. *Id.* at ¶¶ 60-61. On October 26, 2021, Zydus filed its Motion to Dismiss. D.I. 13.

II. LEGAL STANDARD

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 *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). "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)).

"'The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Pinnavaia v. Celotex Asbestos Settlement Tr.*, 271 F. Supp. 3d 705, 708 (D. Del. 2017) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)), *aff'd*, 2018 WL 11446482 (3d Cir. Apr. 6, 2018). Rule 12(b)(6)

requires the court to accept all factual allegations in the complaint as true and view them in the light most favorable to plaintiff. *AbbVie Inc*, 976 F.3d at 351. The court may consider matters of public record and documents attached to, "integral to[,] or explicitly relied upon in" the complaint. *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (cleaned up); *see also Spizzirri v. Zyla Life Scis.*, 802 F. App'x 738, 739 (3d Cir. 2020) (same). "A motion to dismiss 'may be granted only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.'" *McCrone v. Acme Markets*, 561 F. App'x 169, 172 (3d Cir. 2014) (quoting *Burlington Coat Factory*, 114 F.3d at 1420).

III. DISCUSSION

USL's breach of contract claim (Count I) sets out plausible fact-based allegations. Thus, the Court will deny Zydus's Motion to Dismiss as to the breach of contract allegation. The Court will grant Zydus's Motion to Dismiss as to USL's other claims: USL fails to state a claim for specific performance (Count II) by stating that it seeks compensatory damages. USL also fails to state a claim for violation of Delaware's implied covenant of good faith and fair dealing (Count III) because the implied covenant does not cover express contractual rights.

A. Breach of Contract (Count I)

Under Delaware law, "[i]n order to survive a motion to dismiss for failure to state a breach of contract claim, the plaintiff must demonstrate: first, the existence of the contract, whether express or implied; second, the breach of an obligation imposed by that contract; and third, the resultant damage to the plaintiff." *VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 612

(Del. 2003) (footnote and citations omitted); *see also Pharm. Corp. of Am. v. Askari*, No. 16-1123-RGA-MPT, 2018 WL 2108200, at *5 (D. Del. May 7, 2018).[3]

Zydus argues that USL failed to point to any provision of the Settlement Agreement that prohibits Zydus from relinquishing its Hatch-Waxman exclusivity or any provision that requires Zydus to maintain or attempt to obtain approval of its ANDA. D.I. 14 at 10. Zydus points out that when the Settlement Agreement imposes an express obligation on the parties it states so. *Id.* For example, Section 3.7(b) of the Settlement Agreement requires that USL [redacted]

[redacted]

D.I. 2, Ex. A at § 3.7(b).

Zydus also argues that USL's interpretation of the Settlement Agreement—"that Zydus be barred from relinquishing first-filer exclusivity where Zydus does not have FDA approval, allowing another generic to obtain FDA approval and begin selling low-cost generic drugs"—is contrary to the Hatch-Waxman Act and public policy. D.I. 14 at 12. Congress created the Hatch-Waxman 180-day exclusivity period to incentivize generic drug applicants to challenge the innovator's patents. *Actavis*, 570 U.S. at 143-44. Lastly, Zydus argues that it does not owe any

[3] The Settlement Agreement contains a provision establishing that "[t]his Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its conflict of laws principles. The Parties hereby consent to the exclusive jurisdiction of the federal courts located in Delaware, and expressly waive any objections or defenses based on lack of personal jurisdiction or venue in connection with any dispute arising out of or relating to this Agreement." D.I. 2, Ex. A at § 6.6. The parties agree that Delaware law applies to the Settlement Agreement. D.I. 14 at 9-10; D.I. 22 at 8.

royalties. The start date of the "Royalty Period" has not occurred because Zydus has not received FDA approval and it has not started selling its generic product. D.I. 14 at 12-13; *see also* D.I. 2, Ex. A at § 1.1 (defining "Royalty Period"). The end date of the Royalty Period, however, was triggered because [redacted] D.I. 14 at 13. For these reasons, Zydus argues that USL has alleged "no set of facts to establish that Zydus breached the Settlement Agreement." D.I. 24 at 9.

In the Court's view, however, USL's breach of contract claim sets out plausible fact-based allegations. The parties do not dispute the existence of the contract—the Settlement Agreement—in this action. The crux of Zydus's Motion to Dismiss is whether USL has demonstrated a breach of an obligation imposed by the Settlement Agreement. USL argues that Zydus breached Section 2.4(c) of the Settlement Agreement. Section 2.4(c) of the Settlement Agreement provides, in relevant part:

[redacted]

D.I. 2, Ex. A at § 2.4(c).

USL alleges that Zydus breached Section 2.4(c) by taking actions that allowed Glenmark to enter the topiramate extended-release capsular market as the first generic, [redacted] USL argues that Zydus's actions deprived USL of the full benefits contemplated by the Settlement Agreement. D.I. 2 at ¶¶ 67-70. USL also pleads in its

Complaint that, as a result of Zydus's breach, USL continues to be harmed in the loss of market exclusivity and the loss of royalty payments contemplated under the Settlement Agreement. *Id.* at ¶ 71. USL's Complaint thus alleges specific facts supporting a breach of contract claim.

For these reasons, the Court denies Zydus's Motion to Dismiss with respect to the breach of contract claims that USL seeks in Count I.

A. Specific Performance (Count II)

Zydus also argues that USL's Count II should be dismissed because "USL has failed to allege sufficient facts establishing that specific performance is warranted or that the Court is even in a position to grant the relief requested." D.I. 14 at 14. USL failed to address specific performance or address Zydus's arguments in its Answering Brief in Opposition to Zydus's Motion to Dismiss. *See generally* D.I. 22. In fact, in USL's Answering Brief it states, "Plaintiff USL's Complaint is simple: it asks for *compensatory* damages arising from Zydus's clear breach of Section 2.4(c) of the [Settlement] Agreement." *Id.* at 1 (emphasis added). "Specific performance is an equitable remedy available only when there is no adequate remedy at law . . . a legal remedy is inadequate if an assessment of monetary damages is impractical or too speculative." *Marker v. United States*, 646 F. Supp. 433 (D. Del. 1986).

For these reasons, the Court grants Zydus's Motion to Dismiss with respect to specific performance that USL seeks in Count II.

B. Breach of the Implied Covenant of Good Faith and Fair Dealing (Count III)

In the alternative to Count I and Count II, USL pleads that Zydus breach the implied duty of good faith and fair dealing. D.I. 2 at ¶ 82. USL argues that "Zydus breached Section 2.4(c) of the [Settlement] Agreement by taking actions that allowed Glenmark to enter to the topiramate extended-release capsular market as the first generic, thereby [redacted] and otherwise depriving USL of the full benefits of the [Settlement] Agreement,

and assisting Glenmark to materially alter the terms of the [Settlement] Agreement." *Id.* at ¶ 91. USL alleges that "Zydus's arbitrary and unreasonable conduct frustrated the overarching purpose of the [Settlement] Agreement and had the effect of preventing USL from receiving the full benefits of the [Settlement] Agreement." *Id.* at ¶ 92.

The implied covenant of good faith and dealing "is a limited and extraordinary remedy." *Oxbow Carbon & Mins. Holdings, Inc. v. Crestview-Oxbow Acquisition, LLC*, 202 A.3d 482, 507 (Del. 2019). The implied covenant "does not apply when the contract addresses the conduct at issue, but only when the contract is truly silent concerning the matter at hand." *Id.* (citations and quotations omitted). Even where a contract is silent, "[a]n interpreting court cannot use an implied covenant to re-write the agreement between the parties, and should be most chary about implying a contractual protection when the contract could easily have been drafted to expressly provide for it." *Id.* (citations and quotations omitted).

As noted by Zydus, the Settlement Agreement [redacted], which is exactly what occurred here." D.I. 14 at 16. "[O]ne generally cannot base a claim for breach of the implied covenant on conduct authorized by the agreement." *Nemec v. Shrader*, 991 A.2d 1120, 1125-26 (Del. 2010) (citations and quotations omitted). Tellingly, USL's claim for relief for Count I—the breach of contract claim—and Count III—the breach of the implied covenant of good faith and fair dealing claim—are nearly identical. *Compare* D.I. 2 at ¶¶ 63-71 *with id.* at ¶¶ 82-92. In both Count I and Count III, USL argues that Zydus breached Section 2.4(c) of the Settlement Agreement. The only contractual obligation USL invokes is an express obligation, not an implied obligation, and to invoke the implied covenant of good faith and dealing

USL must allege an implied obligation. Thus, the Settlement Agreement is not truly silent regarding the conduct at issue and the implied covenant of good faith and dealing does not apply.

For these reasons, the Court grants Zydus's Motion to Dismiss USL's claim for violation of Delaware's implied covenant of good faith and fair dealing that USL seeks in Count III.

IV. CONCLUSION

For the above reasons, the Court will deny Zydus's Motion to Dismiss as to USL's breach of contract claim. The Court will grant Zydus's Motion to Dismiss as to USL's claims for specific performance and violation of Delaware's implied covenant of good faith and fair dealing. Federal Rule of Civil Procedure 15(a)(2) requires the Court to "freely give leave [to amend] when justice so requires." But dismissal with prejudice for futility is appropriate when "'the complaint, as amended, would fail to state a claim upon which relief could be granted.'" *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 243 (3d Cir. 2010) (citation omitted). Here, USL stated that its Complaint "is simple: it asks for compensatory damages arising from Zydus's clear breach of Section 2.4(c) of the [Settlement] Agreement." D.I. 22 at 1. By asking for compensatory damages, USL pleads itself out of any right to specific performance. *See Marker*, 646 F. Supp. 433 at 438. USL's claim for violation of Delaware's implied covenant of good faith and fair dealing arises from the breach of an express contractual provision. D.I. 2 at ¶¶ 90-91. The implied covenant "does not apply when the contract addresses the conduct at issue, but only when the contract is truly silent concerning the matter at hand." *Oxbow Carbon & Mins. Holdings, Inc.*, 202 A.3d at 507. No additional factual allegations could make either claim one on which relief can be granted. Both claims should be dismissed with prejudice.

The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UPSHER-SMITH LABORATORIES, LLC, Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD., Defendants.	Civil Action No. 21-1132-GBW

ORDER

At Wilmington this 11th day of October 2022:

For the reasons set forth in the Memorandum Opinion issued this day, **IT IS HEREBY ORDERED** that Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.'s Motion to Dismiss Plaintiff Upsher-Smith Laboratories, LLC's ("USL") Complaint Pursuant to Federal Rule of Civil Procedure 12(b)(6) (D.I. 13) is **GRANTED-IN-PART** and **DENIED-IN-PART**:

1. The Motion is **DENIED** as to Count I;
2. The Motion is **GRANTED** as to Count II and as to Count III; and
3. Count II and Count III are dismissed with prejudice.

Because the Memorandum Opinion is filed under seal, the parties shall meet and confer and, no later than October 18, 2022, submit a joint proposed redacted version, accompanied by a supporting memorandum, detailing how, under applicable law, the Court may approve any

requested redactions. In the absence of a timely, compliant request, the Court will unseal the entire opinion.

GREGORY B. WILLIAMS
U.S. DISTRICT JUDGE