IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

APOTEX INC. and APOTEX CORP.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. N20C-07-055 MMJ CCLD
	)	
MYLAN SPECIALTY LP and MEDA PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

Submitted: January 7, 2021
Decided: February 16, 2021

On Defendant's Motion to Dismiss
GRANTED

OPINION

David E. Ross, Esq., S. Michael Sirkin, Esq., Ross Aronstam & Moritz LLP, Wilmington, Delaware, Jay P. Lefkowitz, Esq., Devora W. Allon, Esq. (Argued), Vera C. Esses, Esq., Kirkland & Ellis LLP, New York, New York, *Attorneys for Plaintiffs.*

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JOHNSTON, J.

FACTUAL AND PROCEDURAL CONTEXT

Parties

This dispute follows the launch of an Authorized Generic pharmaceutical product. Plaintiff Apotex Inc. is a Canadian corporation with its principal place of business in Toronto, Ontario, Canada.[1] Plaintiff Apotex Corp. is a Delaware corporation with its principal place of business in Weston, Florida.[2] Plaintiffs collectively will be referred to as "Apotex." Defendant Meda Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Somerset, New Jersey.[3] Defendant Mylan Specialty LP is a Delaware limited partnership with its principal place of business in Basking Ridge, New Jersey.[4] Defendants collectively will be referred to as "Mylan."

Dymista® Patent Litigation

Mylan and Meda have marketed Dymista®, a medicated nasal spray which relieves symptoms of seasonal allergies in some patients, since 2012.[5] In 2014, Apotex sought FDA approval to market a generic version of Dymista® by filing an Abbreviated New Drug Application ("ANDA").[6] In October 2014, Apotex

[1] Compl. ¶ 5.
[2] *Id.* ¶ 6.
[3] *Id.* ¶ 7.
[4] *Id.* ¶ 8.
[5] *Id.* ¶ 11.
[6] *Id.* ¶ 12.

notified Meda and Cipla Limited (Cipla) of its attempt to secure FDA approval.[7] In response, Meda and Cipla sued Apotex on December 2, 2014 in the United States District Court for the District of Delaware. The suit alleged that Apotex was infringing on patents owned by Cipla and licensed exclusively to Meda.[8] Meda was acquired by Mylan in 2016.[9]

The Parties Enter into a Settlement Agreement

To resolve the patent litigation, Apotex, Meda, and Cipla entered into a Settlement Agreement on May 9, 2017.[10] The Settlement Agreement granted Apotex a non-exclusive license "to make, use, import, market, offer for sale, and sell" an ANDA version of Dymista®.[11] Two sections of the Settlement Agreement form the basis of this suit.

Section 4 of the Settlement Agreement defines when Apotex's license became effective. Under this section, Apotex's License Effective Date is earliest of: (1) March 1, 2020; (2) September 1, 2019, if Mylan provides notice of its intent to distribute an Authorized Generic version of Dymista® as required in Section 7(e); (3) the License Effective Date provided to a third party; (4) the date of a mandate following a court decision; (5) upon an at-risk launch triggering event; or

[7] *Id.* ¶ 13. Cipla Limited is not a party to this litigation.
[8] *Id.* ¶ 14.
[9] *Id.*
[10] Compl., Ex. 1.
[11] *Id.* § 3(a).

(6) ten calendar days after the end of any consecutive six month period where prescriptions for Dymista® fell below proscribed levels.[12]

Section 7(e) of the Settlement Agreement states:

> Meda and Cipla have retained the right itself or though [sic] Affiliates or Third Parties to Market Authorized Generics at any time, provided that (i) they provide Apotex with at least two hundred seventy (270) days' notice before the first commercial sale of an Authorized Generic (with such notice being waived if Apotex launches its Apotex ANDA Product during this notice period), and (ii) only for the period from Apotex's Launch Date until one hundred eighty (180) consecutive calendar days thereafter, [Meda and Cipla] shall not launch more than one Authorized Generic (for the avoidance of doubt, this Agreement does not otherwise restrict [Meda and Cipla's] ability to launch an Authorized Generic commensurate with Apotex's launch of the Apotex ANDA Product according to Section 4)[.][13]

The Parties Launch Their Products

On February 25, 2020, Mylan notified Apotex of Mylan's intent to market an Authorized Generic version of Dymista®.[14] On March 2, 2020, Apotex began marketing its ANDA product.[15] In April 2020, Mylan launched its Authorized Generic product.[16]

[12] *Id.* § 4(a)-(f).
[13] *Id.* § 7(e).
[14] Compl. ¶ 23.
[15] *Id.* ¶ 26.
[16] *Id.*

Procedural History

Apotex filed suit in this Court on July 13, 2020. Apotex asserts claims for breach of contract and, in the alternative, breach of the implied covenant of good faith and fair dealing. On October 5, 2020, Mylan filed the Motion to Dismiss at issue in this Opinion.

STANDARD OF REVIEW

Failure to State a Claim Upon Which Relief Can be Granted

In a Rule 12(b)(6) Motion to Dismiss, the Court must determine whether the claimant "may recover under any reasonably conceivable set of circumstances susceptible of proof."[17] The Court must accept as true all well-pleaded allegations.[18] Every reasonable factual inference will be drawn in the non-moving party's favor.[19] "To survive a motion to dismiss for failure to state a breach of contract claim, a plaintiff must allege (1) the existence of a contract; (2) the breach of an obligation imposed by that contract; and (3) resulting damages."[20] If the claimant may recover under that standard of review, the Court must deny the Motion to Dismiss.[21]

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[17] *Spence v. Funk*, 396 A.2d 967, 968 (Del. 1978).
[18] *Id.*
[19] *Wilmington Sav. Fund. Soc., F.S.B. v. Anderson*, 2009 WL 597268, at *2 (Del. Super.) (citing *Doe v. Cahill*, 884 A.2d 451, 458 (Del. 2005)).
[20] *Equity Trust Co. v. Interactive Brokers LLC*, 2018 WL 1216082, at *3 (Del. Super.), aff'd, 196 A.3d 885 (Del. 2018).
[21] *Spence*, 396 A.2d at 968.

ANALYSIS

Defendants' Contentions

Mylan argues that the Complaint must be dismissed because Apotex failed to state a claim for relief. Mylan asserts that it was not required to provide notice prior to September 1, 2019. Additionally, Apotex was not entitled to 180 days of market exclusivity. Apotex is attempting to insert additional language into the Settlement Agreement to alter its interpretation. Apotex's attempt to apply the implied covenant of good faith and fair dealing fails because the Settlement Agreement expressly covers all notice requirements. Mylan maintains that the April 2020 release of its Authorized Generic version of Dymista® fully comported with all requirements under the Settlement Agreement.

Plaintiffs' Contentions

Apotex argues in response that the language found in Section 7(e)—that Mylan may launch its own product "at any time" and "commensurate with" Apotex's product launch—is ambiguous. Apotex conceded during oral argument that there is no 180-day exclusivity period explicitly set out in the Settlement Agreement. Nevertheless, Apotex asserts that it was statutorily entitled to such a period. Finally, Apotex contends that Mylan's failure to provide notice of its intent to market an Authorized Generic version before September 1, 2019 deprived Apotex of a benefit of the bargain.

Mylan was Not Required to Provide Notice Prior to September 1, 2019

Delaware law provides well-settled guidance on interpreting contracts. Contracts must be construed as a whole.[22] A court must give contractual language the ordinary and usual meaning.[23] If a contract is unambiguous, no extrinsic evidence will be considered.[24] It is especially appropriate to rely only on the contractual language where, as here, the parties are sophisticated and the contract was heavily negotiated at arms-length.[25]

The Settlement Agreement Unambiguously Sets Out the Launch Procedures

Sections 4 and 7, quoted above, set out how and when the parties may launch their respective products. Apotex could not launch its ANDA product until March 1, 2020, unless Mylan provided 270 days' notice of its intent to market an Authorized Generic product. If Mylan provided such notice, Apotex was free to launch its product at any time after September 1, 2019. But, if Apotex launched its product within the 270-day window between the time Mylan provided notice and the time of Mylan's launch, this notice period would be waived. Mylan would then be able to launch its Authorized Generic product at any time—provided that Mylan launch only one Authorized Generic version of Dymista® in the 180-day

[22] *Northwestern Nat. Ins. Co. v. Esmark, Inc.*, 672 A.2d 41, 43 (Del. 1996).
[23] *Id.*
[24] *Eagle Industries, Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997).
[25] *JFE Steel Corp. v. ICI Ams., Inc.*, 797 F. Supp. 2d 452, 469 (D. Del. 2011); *W. Willow-Bay Ct., LLC v. Robino-Bay Ct. Plaza, LLC*, 2007 WL 3317551, at *9 (Del. Ch.).

period following the launch of Apotex's ANDA product. The Court finds that the launch procedures set forth in the Settlement Agreement are clear and unambiguous.[26]

The Settlement Agreement was signed on May 19, 2017. On February 21, 2020, Mylan provided 270 days' notice pursuant Section 7(e). On March 2, 2020, Apotex launched its ANDA product, thereby waiving the notice period. In April 2020, Mylan launched its Authorized Generic product. The Court finds that the facts of this case comply with the unambiguous terms of the Settlement Agreement.

The Notice Requirement Relates Only to Mylan's First Commercial Sale

In arguing that Mylan was required to provide notice of its intent to launch an Authorized Generic product prior to September 1, 2019, Apotex attempts to equate "first commercial sale" with "License Effective Date." However, the Settlement Agreement cannot reasonably be interpreted as Apotex suggests because the terms refer to different things. Section 7(e) states that Mylan is required to provide "at least 270 days' notice before the first commercial sale of an

[26] There is some ambiguity in the "for avoidance of doubt" language at the end of Section 7(e). It is not entirely clear what "commensurate" means in this context or how Sections 4 and 7 apply to each other. However, this does not affect the Court's interpretation of the launch procedures for the purposes of the issues subject to this Motion. The final clause obviously and clearly is intended to ensure that Mylan's ability to launch is not restricted. It expands, not limits, Mylan's contractual rights. Therefore, regardless of the meaning of this clause, it does not otherwise restrict Mylan's ability to launch under the facts presented in this case.

Authorized Generic." Here, "first commercial sale" must be given its ordinary and usual meaning. The required notice only relates to the date that Mylan would first market its Authorized Generic. In contrast, the "License Effective Date" is a term expressly defined in Section 4.

Apotex and Mylan are sophisticated parties well-versed in how the pharmaceutical industry works. The Settlement Agreement was no doubt heavily negotiated. If Apotex wanted to include a requirement that Mylan provide notice prior to the accelerated License Effective Date—in this case, September 1, 2019—then that requirement should have been expressly included in the Settlement Agreement. Giving the terms of the Settlement Agreement their ordinary and usual meanings, the unambiguous notice requirement is measured only in relation to Mylan's first commercial sale. The Court finds that there is nothing in the Settlement Agreement that required Mylan to provide notice prior to the accelerated License Effective Date.

Apotex was Not Entitled to 180 Days of Market Exclusivity

Apotex's position is that it was statutorily entitled to 180 days of market exclusivity. Apotex further argues that if Mylan decided to market an Authorized Generic product within 180 days of the release of Apotex's ANDA product, Apotex would be entitled to the accelerated License Effective Date as bargained

for in the Settlement Agreement. However, these arguments are not supported by law.

The 180-Day Exclusivity Period Does Not Apply to Mylan

Under the Hatch-Waxman Act, the first generic company that files an abbreviated application for a new drug is entitled to 180 days of market exclusivity.[27] However, such exclusivity only prevents other generic companies from producing ANDA products. The Act "says nothing about how the holder of an approved NDA may market its drug; rather, [it] grants 'exclusivity' to the first to file an ANDA . . . by delaying the effective date upon which the FDA may approve any subsequent ANDA . . . certification with respect to the same drug."[28] The Act "clearly does not prohibit the holder of an approved NDA from marketing, during the 180-day exclusivity period, its own 'brand-generic' version of its drug."[29] Mylan did not attempt to market an ANDA product. Rather, Mylan is the holder of an approved NDA that released an Authorized Generic of its own product. Therefore, the Court finds that the statutory 180-day exclusivity period does not apply to Mylan.

[27] 21 U.S.C. § 355 (j)(5)(B)(iv).
[28] *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 53 (D.C. Cir. 2005).
[29] *Id.* at 55.

Apotex Did Not "Bargain For" an Accelerated License Effective Date

Apotex contends that "the Settlement Agreement gave Mylan the option to launch an Authorized Generic version of Dymista® during Apotex's statutory 180-day exclusivity period *in exchange for* accelerating Apotex's generic launch by six months."[30] However, it is a fundamental rule of contract formation that consideration is required for any promise to be binding. Consideration is the exchange of legal value.[31] "'Consideration' means not so much that one party is profiting as that the other abandons some legal right in the present, or limits his legal freedom of action in the future, as an inducement for the promise of the first."[32]

Because nothing in the Act prohibited Mylan from marketing an Authorized Generic version of Dymista® at any time, the accelerated License Effective Date cannot constitute a bargained-for exchange. Apotex had no legal right to prevent Mylan from releasing an Authorized Generic for 180 days following the release of Apotex's ANDA product and therefore gave nothing up "in exchange for" an accelerated License Effective Date. Therefore, the Court finds that Apotex's narrow argument that it bargained for an accelerated License Effective Date fails for lack of consideration.

[30] Resp. Br. at 1 (emphasis added).
[31] *Harmon v. State of Del.*, 2010 WL 8250826, at *2 (Del. Super.).
[32] *Hamer v. Sidway*, 27 N.E. 256, 257 (N.Y. App. 2d Div. 1891) (internal citation omitted).

The Court Cannot Not Infer a 180-Day Exclusivity Period from the Settlement Agreement

As a final matter, the Settlement Agreement also cannot reasonably be interpreted to infer a 180-day exclusivity period. Section 7(e) states that Mylan agrees to not launch more than one Authorized Generic version of Dymista® for 180 days following Apotex's Launch Date—in this case, March 2, 2020. This clause cannot be read as implying exclusivity in the market. While the contractual language unambiguously limits Mylan's ability to launch products between March and September 2020, it is not a complete bar. By saying that Mylan could not launch "*more than* one Authorized Generic product," it is clear that Mylan was indeed permitted to launch the *one* Authorized Generic product at issue. The Court finds that Mylan was in no way precluded from launching its Authorized Generic product on the basis of Apotex's alleged right to market exclusivity.

Implied Covenant

Count II of the Complaint argues, in the alternative, that Mylan breached the implied covenant of good faith and fair dealing. Apotex asserts that even if the Settlement Agreement did not expressly require Mylan to provide Apotex with notice of Mylan's intent to market an Authorized Generic version of Dymista®

prior to September 1, 2019, such notice still would be required under the implied covenant.[33]

Under Delaware law, an implied covenant of good faith and fair dealing attaches to every contract.[34] However, where a contract controls the parties' actions, the implied covenant cannot be used to circumvent the contractual terms.[35] An "implied covenant analysis will only be applied when the contract is truly silent with respect to the matter at hand, and only when the court finds that the expectations of the parties were so fundamental that it is clear that they did not feel a need to negotiate about them."[36]

In this case, the contract governing the parties' actions expressly addresses the procedures and requirements surrounding Mylan's ability to release an Authorized Generic version of Dymista®. The Court finds that the Settlement Agreement covers the subject matter at issue in this litigation. Therefore, the Court need not imply a covenant of good faith and fair dealing.

CONCLSION

The Settlement Agreement forming the basis of Apotex's lawsuit can only reasonably be interpreted one way. The contractual terms, which were heavily

[33] Compl. ¶ 44.
[34] *Dunlap v. State Farm Fire & Cas. Co.*, 878 A.2d 434, 441 (Del. 2005).
[35] *Id.*
[36] *Allied Capital Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1032-33 (Del. 2006).

negotiated by sophisticated parties, unambiguously define what notice must be given prior to Mylan's launch of an Authorized Generic version of Dymista®. The contract additionally discusses Mylan's ability to launch one Authorized Generic product in the 180-day period following the launch of Apotex's ANDA product. As the Settlement Agreement covers the subject matter at issue in this litigation, there is no need to analyze the claim under any implied covenants. For the reasons set forth in this Opinion, Mylan's April 2020 launch complied with the terms of the Settlement Agreement.

Apotex has failed to state a claim pursuant to Rule 12(b)(6). **THEREFORE,** Mylan's Motion to Dismiss is hereby **GRANTED**.

IT IS SO ORDERED.

/s/ Mary M. Johnston
The Honorable Mary M. Johnston