IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

FORTIS ADVISORS LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	**C.A. No. 12147-VCS**
	:	
SHIRE US HOLDINGS, INC.,	:	
	:	
Defendant.	:	

MEMORANDUM OPINION

Date Submitted: June 2, 2017
Date Decided: August 9, 2017

Joel Friedlander, Esquire and Christopher Quinn, Esquire of Friedlander & Gorris, P.A., Wilmington, Delaware and William S. Ohlemeyer, Esquire, Robin A. Henry, Esquire and Jack Wilson, Esquire of Boies, Schiller & Flexner LLP, Armonk, New York, Attorneys for Plaintiff.

Stephen C. Norman, Esquire and Jaclyn Levy, Esquire of Potter, Anderson & Corroon LLP, Wilmington, Delaware; John D. Donovan, Jr., Esquire of Ropes & Gray LLP, Boston, Massachusetts; and David B. Hennes, Esquire and Adam M. Harris, Esquire of Ropes & Gray LLP, New York, New York, Attorneys for Defendant.

SLIGHTS, Vice Chancellor

Parties to a merger agreement dispute the right of the seller's representative to receive certain contingent post-closing payments. Plaintiff, Fortis Advisors LLC ("Fortis"), in its capacity as Stockholders' Agent for the former stockholders of SARcode Bioscience Inc. ("SARcode"), alleges that Defendant, Shire US Holdings, Inc. ("Shire"), has breached the provisions of the parties' agreement by refusing to pay so-called milestone payments that Fortis alleges are past due.

Shire acquired SARcode pursuant to an Agreement and Plan of Merger by and among Shire, Owl Merger Sub, Inc., SARcode Bioscience Inc., and Fortis Advisors LLC, as Stockholders' Agent Dated as of March 23, 2013 (the "Merger Agreement"). At the time the parties entered into the Merger Agreement, SARcode was in the process of developing and seeking regulatory approval for a drug, Lifitegrast, that showed promise to treat the signs and symptoms of dry eye disease. The Merger Agreement set forth a structure whereby the parties agreed to share the risks and rewards of developing Lifitegrast by allocating merger consideration between fixed up front payments and subsequent contingent payments that depended on Shire's ability to shepherd the drug through clinical trials and regulatory approvals. This arrangement allowed SARcode to monetize its at-risk investment in Lifitegrast while securing the promise of financial rewards if the drug continued to be developed successfully and ultimately was commercialized. For Shire, the milestone payments allowed it to hedge against future risks inherent in the drug's

development and commercialization by allocating the price it would ultimately pay for SARcode between an initial upfront payment and subsequent payments that would become due only if the defined milestones were reached per the agreed upon schedule.

In its Verified First Amended and Supplemental Complaint (the "Complaint"), Fortis alleges that two of the designated milestones have been achieved. This, in turn, has triggered Shire's obligation to make $425 million in milestone payments to former SARcode stockholders. Shire denies that the two milestones have been met and has refused Fortis' demands to make the milestone payments. The Complaint asserts a single Count for breach of contract. Shire has moved to dismiss the Complaint under Court of Chancery Rule 12(b)(6) on the ground that Fortis' claim of breach is premised on a construction of the Merger Agreement that cannot be reconciled with its clear and unambiguous terms.

After carefully considering the parties' arguments, I conclude that Shire's proffered construction of the relevant provisions of the Merger Agreement is the only reasonable construction. Because Fortis has failed to proffer a competing reasonable construction of the operative language, it has failed to state a claim for breach of contract. Accordingly, the motion to dismiss must be GRANTED.

I. FACTUAL BACKGROUND

The facts are drawn from allegations in the Complaint, documents integral to the Complaint and matters of which the Court may take judicial notice.[1] As it must at this stage of the proceedings, the Court assumes all well-pled facts in the Complaint are true.[2]

A. The Parties

Prior to the Merger Agreement, SARcode was a privately-held biopharmaceutical company based in Brisbane, California. By the terms of the Merger Agreement, Fortis serves post-merger as the "sole agent and attorney-in-fact" for and on behalf of the former SARcode stockholders.

Shire is a Delaware corporation and subsidiary of Shire PLC, a global biopharmaceutical company, whose United States headquarters is located in Lexington, Massachusetts. Shire acquired SARcode in March 2013.

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[1] *In re Crimson Exploration Inc. S'holder Litig.*, 2014 WL 5449419, at *8 (Del. Ch. Oct. 24, 2014); *In re Gardner Denver, Inc.*, 2014 WL 715705, at *2 (Del. Ch. Feb. 21, 2014). *See also Reiter v. Fairbank*, 2016 WL 6081823, at *5 (Del. Ch. Oct 18, 2016) ("where a complaint quotes or characterizes some parts of a document but omits other parts of the same document, the Court may apply the incorporation-by-reference doctrine to guard against the cherry-picking of words in the document out of context.").

[2] *Crimson*, 2014 WL 5449419, at *8.

B. SARcode's Development of Lifitegrast

Prior to the Shire acquisition, SARcode developed Lifitegrast as a treatment for dry eye disease. Dry eye disease is diagnosed by an eye care professional based on tests for objective signs of the disease, such as staining or tear break-up time (signs), and subjective symptoms reported by patients, such as eye dryness or discomfort (symptoms).

SARcode developed Lifitegrast to Phase III clinical trials. Phase III clinical trials are performed to test both efficacy and safety of drugs using larger patient populations than are involved in Phase I and Phase II trials. Prior to the Merger Agreement, SARcode had conducted a Phase II clinical trial and a Phase III clinical trial (OPUS-1) that had successfully established the efficacy and safety of Lifitegrast in reducing the signs of dry eye disease. These clinical trials demonstrated the commercial potential of Lifitegrast and their results attracted the interest of several pharmaceutical companies that sought to acquire development rights for the drug.

A second Phase III clinical trial (OPUS-2) was designed and initiated in late 2012 to evaluate the efficacy, safety and tolerability of Lifitegrast. The OPUS-2 Study had two co-primary efficacy endpoints that were specified in the OPUS-2 Study Protocol. One efficacy endpoint, the co-primary sign endpoint, was designed to evaluate Lifitegrast's effectiveness in treating the signs of dry eye disease while the other efficacy endpoint, the co-primary symptom endpoint, would evaluate the

drug's effectiveness in treating the symptoms of dry eye disease. The OPUS-2 Study was underway when Shire approached SARcode with an interest in acquiring the company and, by extension, Lifitegrast. Shire and SARcode began negotiating the Merger Agreement in early 2013.

C. The Merger Agreement

At the time SARcode and Shire entered into the Merger Agreement, the OPUS-2 Study was ongoing and Lifitegrast was many steps away from commercialization. To share the risks and rewards of further development of the drug, the parties included in the Merger Agreement a number of additional payments to SARcode stockholders that were contingent upon the drug successfully achieving certain defined milestones. These milestones are divided into several categories, described in § 9.1 of the Merger Agreement, only one of which is relevant to the current dispute. That category of milestone payments, the "Base Case Milestones," is triggered by the occurrence of the OPUS-2 Study Endpoint Achievement Date (the "Achievement Date"). When the Achievement Date is reached, former SARcode stockholders are entitled to receive $175 million for the OPUS-2 Successful Completion Milestone.

Following achievement of the OPUS-2 Successful Completion Milestone and regulatory approval of the drug, Shire is required to make an additional $250 million payment for the Base Case Approval Milestone. If certain revenue targets are met

following commercialization, former SARcode stockholders would be eligible for another $100 million for the Base Case Revenue Milestone. Fortis alleges that it is currently due the OPUS-2 Successful Completion Milestone Payment and the Base Case Approval Milestone Payment.

As noted, all of the Base Case Milestones are contingent upon the occurrence of the Achievement Date. That term is defined in the Merger Agreement as follows:

> "OPUS-2 Study Endpoint Achievement Date" shall be deemed to occur upon receipt by or on behalf of Parent, or one of its Affiliates, Licensees, or other transferees, of audited final tables, figures and listings from the OPUS-2 Study (x) that demonstrate that both components of the co-primary efficacy endpoints of the OPUS-2 Study as specified in the OPUS-2 Study Protocol have been achieved and (y) which do not, in a significant and clinically meaningful respect, result in a materially less favorable safety/tolerability profile (*e.g.*, treatment emergent adverse events, Serious Adverse Effects, *etc.*), taken as a whole, for the Product than for corresponding data generated for the Product in the OPUS-1 Study, which less favorable safety/tolerability profile would reasonably be expected to significantly reduce anticipated Product Sales (it being understood that such determination pursuant to this clause (y) shall be made in accordance with Section 9.3).[3]

If the Achievement Date is reached, the former SARcode stockholders are eligible to receive the Base Case Milestones payments at various designated intervals defined, in relevant part, as:

[3] Opening Br. of Shire US Hldgs., Inc. in Supp. of its Mot. to Dismiss the Verified First Am. and Supplemental Compl. ("Opening Br."), Ex. 1 ("Merger Agreement") §1.1.

(a) Base Case Milestones. If the OPUS-2 Study Endpoint Achievement Date shall have occurred:

(i) OPUS-2 Success. Within ten (10) business days following the OPUS-2 Study Endpoint Achievement Date (the "OPUS-2 Successful Completion Milestone"), Parent shall notify the Stockholders' Agent that the OPUS-2 Successful Completion Milestone has been satisfied and shall, within twenty (20) business days following the date of achievement of the OPUS-2 Successful Completion Milestone, pay or cause to be paid in accordance with Section 9.2(b), $175,000,000 (such amount, the "OPUS-2 Successful Completion Milestone Payment");

(ii) Base Case Regulatory Approval. Within ten (10) business days following receipt by or under the authority of Parent (or any of its Affiliates, Licensees or other transferee) of the first Regulatory Approval in the United States for a Product for the Covered Indication with the co-primary Sign and Symptom specified in the OPUS-2 Study Protocol included in the "Indications and Usage" section of the label of the Product (the "Base Case Approval Milestone"), Parent shall notify the Stockholders' Agent that the Base Case Approval Milestone has been satisfied and shall, within twenty (20) business days following the date of achievement of the Base Case Approval Milestone, pay or cause to be paid in accordance with Section 9.2(b), $250,000,000 (such amount, the "Base Case Approval Milestone Payment") . . . .

(iii) Base Case Revenue Milestone. If the Base Case Approval Milestone has been achieved, then within sixty (60) days following the first time on which Product Sales within any four consecutive calendar quarters exceed $750,000,000 (the "Base Case Revenue Milestone"), Parent shall notify the Stockholders' Agent that the Base Case Revenue Milestone has been satisfied and shall, within five (5) business days after such notification, pay or cause to be paid in accordance with Section 9.2(b), $100,000,000 (such amount, "Base Case Revenue Milestone Payment").[4]

[4] Merger Agreement § 9.1(a)(i)–(iii).

The Merger Agreement defines several other terms that appear in the definition of Achievement Date and are relevant to the determination of whether the Achievement Date has occurred. The term "OPUS-2 Study" is defined as:

> "OPUS-2 Study" means the Phase III clinical trial for Lifitegrast to be conducted in accordance with the OPUS-2 Study Protocol, as further described on Schedule C.[5]

The OPUS-2 Study Protocol is defined as:

> "OPUS-2 Study Protocol" means the Company's Protocol Number 1118-Dry-300, dated November 6, 2012, as amended from time to time in accordance with this Agreement.[6]

Importantly, the Merger Agreement separately defines the prior Phase III clinical trial, the OPUS-1 Study, as:

> "OPUS-1 Study" means the Phase III clinical trial for Lifitegrast conducted by or on behalf of the Company in accordance with the Company Protocol Number 1118-KCS-200, dated May 27, 2011, as amended August 5, 2011.[7]

Both parties were represented by sophisticated counsel in connection with the negotiation, drafting and execution of the Merger Agreement. As noted, the Merger Agreement was finalized on March 23, 2013.

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[5] Merger Agreement § 1.1

[6] *Id.*

[7] *Id.*

D. Regulatory Approval of Lifitegrast

Following the Merger Agreement, and at the completion of the OPUS-2 Study in November 2013, Shire informed Fortis that the OPUS-2 Study had achieved the co-primary symptom endpoint but had failed to achieve the co-primary sign endpoint. In a December 5, 2013 press release, Shire publicly reported that "Lifitegrast did not meet the pre-specified co-primary endpoint for the sign of inferior corneal staining score (change from baseline to Week 12) using fluorescein staining compared with placebo (p-value = 0.6186)."[8]

Shire designed and initiated an additional Phase III clinical trial called the OPUS-3 Study in November 2014. In early 2015, Shire filed a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") for Lifitegrast. The data Shire submitted to the FDA included evidence from the OPUS-2 Study, the OPUS-1 Study and other previous trials. In October 2015, the FDA issued a complete response letter in which it declined to approve Lifitegrast based on the data submitted in the NDA and requested additional data demonstrating the efficacy of the drug to treat the symptoms of dry eye disease.

On October 16, 2015, apparently believing that the Achievement Date had occurred, Fortis wrote to Shire to inquire whether it intended to make the

[8] Pl. Fortis Advisor LLC's Verified First Am. and Supplemental Compl. ("Compl.") ¶ 21.

$175 million OPUS-2 Successful Completion Milestone Payment. Later that month, on October 27, 2015, Shire announced that the OPUS-3 Study had been completed and the data from that clinical trial showed that Lifitegrast had achieved the symptom endpoint, data which would be provided to the FDA in a refiled NDA. Shire responded to Fortis' inquiry regarding the OPUS-2 Successful Completion Milestone Payment on November 12, 2015, stating that none of the Base Case Milestones had been met (or ever would be met) because the Achievement Date had not occurred given that the OPUS-2 Study had failed to meet the sign co-primary endpoint.

In February 2016, Shire refiled its NDA with the FDA and included the OPUS-3 Study data in its application. With this data in hand, on July 11, 2016, the FDA approved Lifitegrast, under the brand name Xiidra, to treat the signs and symptoms of dry eye disease. The FDA also approved the language and content of the Xiidra label that had been proposed by Shire. On July 12, 2016, the label appeared on the Shire website and showed graphical representations of the results from the clinical trials submitted to the FDA. Following approval by the FDA of Lifitegrast under the brand name Xiidra, Fortis alleged that the former SARcode stockholders were now due the Base Case Approval Milestone Payment in addition to the previously earned OPUS-2 Successful Completion Milestone Payment.

E. Procedural History

On March 29, 2016, Fortis filed its Verified Complaint alleging a breach of the Merger Agreement. Shire moved to dismiss the complaint on April 19, 2016. On July 29, 2016, with briefing on the motion to dismiss complete, Fortis moved to amend the complaint to update its allegations with facts relating to the FDA approval of Lifitegrast and the approval of the Xiidra label, which Fortis alleged entitled the former SARcode stockholders to the Base Case Approval Milestone Payment. Fortis opposed the motion. After a hearing on the motion to amend, the Court granted Fortis leave to file its amended complaint which it did on November 8, 2016.

The Complaint sets forth a single count of breach of contract. Shire moved to dismiss on December 9, 2016, arguing that Fortis' reliance upon an unreasonable interpretation of the plain and unambiguous language of the Merger Agreement as the basis for its breach of contract claim warranted dismissal under Court of Chancery Rule 12(b)(6) for failure to state a claim.

II. ANALYSIS

While the parties agree that the language of the Merger Agreement is clear and unambiguous, they disagree on how that language should be interpreted. Shire's motion to dismiss can be granted at this procedural stage only if its proffered interpretation stands apart as the lone reasonable construction of the Merger Agreement. After carefully considering both parties' proffered constructions of the

relevant provisions of the Merger Agreement, for the reasons that follow, I conclude that Shire's construction is reasonable and that Fortis' construction is unreasonable.

A. Motion to Dismiss Standard

The standards governing this motion to dismiss for failure to state a claim under Rule 12(b)(6) are now well settled:

> (i) all well-pleaded factual allegations are accepted as true; (ii) even vague allegations are 'well-pleaded' if they give the opposing party notice of the claim; (iii) the Court must draw all reasonable inferences in favor of the non-moving party; and (iv) dismissal is inappropriate unless the 'plaintiff would not be entitled to recover under any reasonably conceivable set of circumstances susceptible of proof.'[9]

Questions involving contract interpretation can be answered as a matter of law on a motion to dismiss "[w]hen the language of a contract is plain and unambiguous."[10] Dismissal of a contract dispute under Rule 12(b)(6) is proper, however, "only if the defendants' interpretation is the only reasonable construction as a matter of law."[11] If the Plaintiff has offered a reasonable construction of the contract, and that construction supports the claims asserted in the complaint, then

[9] *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896–97 (Del. 2002) (citations omitted).

[10] *Capital Corp. v. GC Sun Hldgs., L.P.*, 910 A.2d 1020, 1030 (Del. Ch. 2006).

[11] *VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 615 (Del. 2003).

the Court must deny the motion to dismiss even if the defendant's construction is also reasonable.[12]

B. The Parties' Competing Constructions of the Operative Language

By the clear terms of the Merger Agreement, the Base Case Milestone payments are not due unless the Achievement Date has occurred.[13] Under Fortis' interpretation of the Merger Agreement, the clinical data that may be considered when determining whether both co-primary efficacy endpoints have been achieved for purposes of assessing whether the Achievement Date has occurred is not limited to the OPUS-2 Study, but can incorporate data from prior clinical trials as well. As Fortis points out, the sign endpoint was achieved in the OPUS-1 Study. The symptom endpoint was achieved in the OPUS-2 clinical trial. Therefore, according to Fortis, the Achievement Date has occurred. Once that occurred, Fortis argues it was due the OPUS-2 Successful Completion Milestone Payment. And because Lifitegrast has now received regulatory approval following the Achievement Date, Fortis claims that Shire must also make the Base Case Approval Milestone Payment.

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[12] *See Vanderbilt Income and Growth Assocs., L.L.C. v. Arvida/JMB Managers, Inc.*, 691 A.2d 609, 613 (Del. 1996) ("On a motion to dismiss for failure to state a claim, a trial court cannot choose between two differing reasonable interpretations of ambiguous documents.").

[13] Merger Agreement § 9.1(a).

Shire, on the other hand, argues that the Achievement Date has not occurred, which forecloses Fortis from claiming that either the OPUS-2 Successful Completion Milestone Payment or the Base Case Approval Milestone Payment are due.[14] Under Shire's construction of the definition of Achievement Date, the clinical data must demonstrate that both sign and symptom co-primary efficacy endpoints were achieved in a specific clinical trial, the OPUS-2 Study. Because the OPUS-2 Study did not establish the sign efficacy endpoint, Shire contends that the Achievement Date did not and never will occur.

C. Shire's Construction of the Merger Agreement is Reasonable

In support of its construction, Shire begins by pointing to the definition of Achievement Date which occurs "upon receipt . . .of audited final tables, figures and listings from the OPUS-2 Study (x) that demonstrate that both components of the co-primary efficacy endpoints of the OPUS-2 Study as specified in the OPUS-2 Study Protocol have been achieved . . ."[15] Shire notes that this definition explicitly requires that the data triggering the occurrence of the Achievement Date come "from

[14] Although not directly at issue in this action, Shire's construction would also forever preclude payment of the Base Case Revenue Milestone Payment regardless of Shire's ability to hit the defined revenue targets. This is because, under Shire's construction, the Achievement Date has not occurred and will never occur. As noted, the occurrence of the Achievement Date is a precondition to all of the Base Case Milestones payments, including the Base Case Revenue Milestone.

[15] Merger Agreement § 1.1.

the OPUS-2 Study." The OPUS-2 Study, in turn, is defined as "the Phase III clinical trial for Lifitegrast to be conducted in accordance with the OPUS-2 Study Protocol, as further described on Schedule C."[16] The parties separately defined the OPUS-1 Study to mean "the Phase III clinical trial for Lifitegrast conducted by or on behalf of the Company in accordance with the Company Protocol Number 1118-KCS-200, dated May 27, 2011, as amended August 5, 2011."[17]

According to Shire, by separately defining the OPUS-1 and OPUS-2 studies, the Merger Agreement makes clear that the studies and the data from each study are distinct. And by expressly linking the Achievement Date to the receipt of data "from the OPUS-2 Study," and no other study, Shire argues that the only reasonable construction of the definition of Achievement Date is that the OPUS-2 Study data is the exclusive data relevant to determining whether the Achievement Date has occurred.

Moreover, Shire contends that any results reached in the OPUS-2 Study must be statistically significant in order to "achieve" the co-primary endpoints. In this regard, Shire points to the OPUS-2 Study Protocol which specifies that "[s]tatistical significance is required for both the sign and the symptom for treatment success."[18]

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[16] *Id.*

[17] *Id.*

[18] Opening Br., Ex. 2 ("OPUS-2 Study Protocol") at 73.

As Shire highlights, the OPUS-2 Study Protocol goes on to provide that statistical significance for the co-primary sign and symptom endpoints was a "p-value" of less than or equal to 0.05.[19]

If the Merger Agreement is construed to require that the determination of whether the Achievement Date has occurred be assessed by reference to OPUS-2 Study data only, and that the OPUS-2 Study data must reach statistical significance in order to "achieve" the co-primary endpoints, Fortis' demand for payment of the Successful Completion Milestone Payment and the Base Case Approval Milestone Payment fizzles. This is because the Merger Agreement clearly provides that to reach the Achievement Date, "*both* components of the co-primary efficacy endpoints of the OPUS-2 Study as specified in the OPUS-2 Study Protocol [must] have been achieved . . ."[20] With this construction in mind, Shire maintains that the payments Fortis has demanded in this litigation are not due and will never become due.

Shire's interpretation of the Merger Agreement is reasonable. By its clear terms, the definition of the Achievement Date requires that data "from the OPUS-2 Study" demonstrate that the sign and symptom co-primary efficacy endpoints have

[19] *Id.* at 71, 73. As explained in the Complaint, a "p-value is the probability of obtaining a result at least as extreme as the result that was actually observed when the then null hypothesis (in this case, that there is no relationship between Lifitegrast and the observed symptom or sign) is true." Compl. ¶ 21.

[20] Merger Agreement § 1.1 (emphasis supplied).

been achieved. No other data is referenced in the definition and no other provision of the Merger Agreement suggests that the parties intended other data to be relevant to the determination of whether the Achievement Date has occurred. Shire's construction harmonizes and gives meaning to all of the provisions in the Merger Agreement, including those that identify and define the OPUS-1 Study as separate and distinct from the OPUS-2 Study. It is also reasonable to construe the definition of Achievement Date as requiring that results from the OPUS-2 Study be statistically significant given that the OPUS-2 Study Protocol, which lays out how the OPUS-2 study is to be conducted, requires statistically significant results.[21]

Having determined that Shire's proffered construction is reasonable, however, does not end the inquiry. Shire's construction cannot prevail on a motion to dismiss if Fortis' construction of the same provisions is also reasonable.

D. Fortis' Construction is Unreasonable

Fortis maintains that the Merger Agreement makes clear that data from clinical trials other than the OPUS-2 Study can be considered when determining whether the Achievement Date has occurred. This construction rests on three principal arguments. *First,* Fortis contends that the absence of any language expressly excluding data from clinical trials other than the OPUS-2 Study in the

[21] OPUS-2 Study Protocol at 73 ("Statistical significance is required for both the sign and the symptom for treatment success.").

definition of Achievement Date reflects the parties' intent that such data could and should be considered when determining whether the Achievement Date has occurred. Indeed, according to Fortis, in order for Shire's construction of the operative language to make sense, the Court would have to insert additional language into the definition of Achievement Date. Specifically, Fortis argues that the following bracketed and bold language would need to be added:

> "OPUS-2 Study Endpoint Achievement Date" shall be deemed to occur upon receipt . . . of audited final tables, figures and listings from the OPUS-2 Study (x) that demonstrate that both components of the co-primary efficacy endpoints of the OPUS-2 Study as specified in the OPUS-2 Study Protocol have been achieved **[in the OPUS-2 clinical trial relying only on audited final tables, figures and listings from the OPUS-2 clinical trial and without reliance on any data from any other trial or study]** . . .

Fortis contends that "without the addition of this language not contained in the actual text of the Merger Agreement, the OPUS-2 Study Endpoint Achievement Date simply does not have the limitation that Shire seeks to impose."[22]

Second, Fortis argues that not only does the definition of Achievement Date not explicitly exclude data from prior studies, it makes clear that the parties did, in fact, contemplate that data from other clinical trials would be included. Specifically, Fortis points to the definition of OPUS-2 Study, a term incorporated in the definition

[22] Pl. Fortis Advisors LLC's Mem. in Opp'n to Shire's Mot. to Dismiss the Verified First Am. and Supplemental Compl. ("Answering Br.") 34.

of Achievement Date, and argues that while the OPUS-2 Study Protocol is defined separately from the OPUS-1 Study Protocol, the contractual language makes clear that a Phase III clinical trial need only be conducted "in accordance with" the OPUS-2 Study Protocol in order to constitute part of the OPUS-2 Study as referenced in the Achievement Date definition.[23] According to Fortis, in order "to be in accordance with" the OPUS-2 Study Protocol, the clinical trial need not be identical to the OPUS-2 Study, but rather need only be conducted in "a way that agrees with or follows" the OPUS-2 Study Protocol.[24] Furthermore, Fortis argues that while Shire highlights the use of the definite article "the" in the definition of OPUS-2 Study,[25] as in "*the* Phase III clinical trial,"[26] the Merger Agreement itself indicates that, when

[23] Merger Agreement § 1.1 (defining OPUS-2 Study).

[24] Answering Br. 20 n 7 (citing Merriam-Webster's Dictionary Online, https://www.merriam webster.com/dictionary/in%20 accordance%20with.).

[25] Specifically, Shire argues that "[t]he use of the definite article—'the'—means that the term that follows (*i.e.*, 'Phase III clinical trial') is a 'unique or a particular member of its class.'") Opening Br. 32 (citing to Merriam-Webster Dictionary Online, http://www.merriamwebster.com/dictionary/the). In this way, Shire contends that "[t]he word 'the' makes clear that the parties were referring to one *particular* clinical trial of Lifitegrast." *id.* (emphasis in original).

[26] Merger Agreement §1.1 ("OPUS-2 Study" means the Phase III clinical trial for Lifitegrast to be conducted in accordance with the OPUS-2 Study Protocol, as further described on Schedule C.)

construing its provisions, "the singular . . . shall include the plural . . ."[27] Thus, Fortis would read that provision as stating "the Phase III clinical *trials*."[28]

Third, Fortis argues that once the Xiidra label was approved by the FDA and publicly made available on Shire's website, Fortis was able to confirm that, contrary to Shire's representations, the OPUS-2 Study had, in fact, achieved both co-primary efficacy endpoints. Indeed, according to Fortis, the FDA approval and the contents of the Xiidra label confirm that the former SARcode stockholders are entitled to an additional Base Case Milestone Payment as well as providing further evidence that both co-primary efficacy endpoints have in fact been achieved for purposes of determining whether the previously earned milestone payments are due.[29]

Fortis' construction of the Merger Agreement is unreasonable. As for its first argument—that the parties' intent to allow data from the OPUS-1 Study to be considered in the definition of Achievement Date can be gleaned from the absence of any express exclusion of such data from the definition—Fortis' proffered

[27] Merger Agreement § 11.9(b).

[28] The definition of "OPUS-2 Study" would then read: "OPUS-2 Study" means the Phase III clinical trials for Lifitegrast to be conducted in accordance with the OPUS-2 Study Protocol, as further described on Schedule C.

[29] Fortis argues that when the Xiidra product label was released by Shire it "contain[ed] data sufficient to show that the OPUS-2 clinical trial produced data demonstrating the efficacy of the sign and symptom endpoints such that the [Achievement Date] occurred" because "[i]t notes that a 'larger reduction . . . favoring Xiidra was observed in three of the four studies.'" Answering Br. 22.

construction turns a "four corners" construction of the definition inside out. The canon of construction *expresio unius est exclusio alterius*—to express or include one thing implies the exclusion of the other—seems particularly apt here.[30] The fact that the parties decided separately to define the OPUS-1 and OPUS-2 studies as different Phase III clinical trials, and then designated the data "from the OPUS-2 Study" as relevant to the determination of whether the Achievement Date had occurred, clearly and unambiguously reflects an intent that only that data should be considered when assessing whether both the sign and symptom co-primary efficacy endpoints had been achieved. Indeed, as Shire points out, only Fortis' proffered construction requires the insertion of language not present in the Merger Agreement in order for the contract to get Fortis where it wants to go. Specifically, the Court would have to insert the bold and bracketed text in order for Fortis' construction to be reasonable:

> upon receipt . . . of audited final tables, figures and listings from the OPUS-2 Study **[or the OPUS-1 Study]** (x) that demonstrate that both components of the co-primary efficacy endpoints of the OPUS-2 Study as specified in the OPUS-2 Study Protocol have been achieved

[30] *Shintom Co., Ltd. V. Audiovox Corp.*, 888 A.2d 225, 230 (Del. 2005). To require that parties to a contract expressly exclude all that they intend to exclude, when the relevant contact language is expressly inclusive, would present a challenge to scriveners that would be extraordinarily difficult, if not impossible, to meet. Here, the express reference to the OPUS-2 Study data within the definition of Achievement Date would have been unnecessary and, indeed, confusing if the parties had intended for the definition to include other, unspecified data as well.

Of course, this new language that Fortis would have the Court blue-pencil into the Merger Agreement ignores that the Merger Agreement both defines the OPUS-2 Study as a separate Phase III clinical trial from the OPUS-1 Study and requires that the "audited final tables, figures and listings" that demonstrate both co-primary efficacy endpoints have been achieved come "from the OPUS-2 Study."[31] By ignoring these provisions, Fortis' proffered construction requires the Court to render them superfluous—something Delaware courts do not do when engaging in contact construction.[32]

Fortis' second argument—that the definition of OPUS-2 Study clearly and unambiguously allows for data from other clinical trials to be used to satisfy the Achievement Date—is likewise unpersuasive. To support this contention, Fortis

[31] Merger Agreement § 1.1.

[32] *See O'Brien v. Progressive Northern Ins. Co.*, 785 A.2d 281, 287 (Del. 2001). For the first time at oral argument, Fortis raised a new argument that the phrase "from the OPUS-2 Study" is merely a "temporal trigger" that identifies the time at which the determination of whether the OPUS-2 Endpoint Achievement Date has occurred is to be made. Oral Arg. on Def.'s Mot. to Dismiss the Verified First Am. and Supplemental Compl. ("Oral Arg. Tr.") 37–38. This argument was not previously raised in Fortis' briefing and is therefore waived. *See Emerald P'rs v. Berlin*, 2003 WL 21003437, at *43 (Del. Ch. Apr. 28, 2003) ("It is settled Delaware law that a party waives an argument by not including it in its brief."). Even if the argument were not waived, however, I would reject it in any event. The unambiguous language of the Merger Agreement clearly states that the "audited final tables, figures, and listings from the OPUS-2 Study" must "demonstrate that both components of the co-primary efficacy endpoints of the OPUS-2 Study as specified in the OPUS-2 Study Protocol have been achieved . . ." Nothing in this language suggests that the parties intended it to mean that the receipt of OPUS-2 Study data would act simply as a "temporal trigger" after which data from any and all other Phase III clinical trials will be evaluated to determine whether both endpoints had been achieved.

argues that, while the OPUS-2 Study is defined as "the Phase III clinical trial for Lifitegrast to be conducted in accordance with the OPUS-2 Study Protocol . . .," the Merger Agreement makes clear that "the singular . . . shall include the plural" and, therefore, it is reasonable to include other unspecified Phase III clinical trials within that definition.[33] Fortis correctly quotes Section 11.9(b) but shoots well wide of the mark in arguing that it somehow supports its construction of Shire's milestone payment obligations.

Even when one changes singular terms to plural within the definition of OPUS-2 Study, the language from that definition still does not support the notion that data from multiple clinical trials should be considered when assessing whether both co-primary efficacy endpoints have been achieved as contemplated in the definition of Achievement Date. The OPUS-2 Study is clearly defined as a clinical trial that is "to be conducted."[34] Applying the Merger Agreement's rule of construction to change the singular terms to plural, the definition of OPUS-2 Study would read "the Phase III clinical trials for Lifitegrast *to be conducted* in accordance with the OPUS-2 Study Protocol . . ."[35] The OPUS-1 Study, however, had already been conducted by the time the Merger Agreement was executed. That fact is

[33] Merger Agreement § 11.9(b).

[34] Merger Agreement § 1.1.

[35] *Id.* (emphasis added).

evident from the definition of OPUS-1 Study, which is "the Phase III clinical trial for Lifitegrast *conducted* by or on behalf of the Company in accordance with the Company Protocol Number 1118-KCS-200 . . ."[36] The Merger Agreement, therefore, clearly and unambiguously differentiates between the OPUS-1 Study that *had been conducted* and the OPUS-2 Study (and perhaps other Phase III trials) that were *to be conducted*. Adding plural terms to the definition of OPUS-2 Study does nothing to change this temporal reality.[37]

Fortis engages in even more strained interpretive gymnastics when it argues that any data from any clinical trial conducted "in accordance with" the OPUS-2 Study Protocol can be considered when determining whether the Achievement Date has occurred. This construction just outright ignores that the OPUS-1 and OPUS-2 studies were conducted pursuant to separately defined protocols. Moreover, even if the OPUS-1 Study was conducted "in accordance with" the OPUS-2 Study Protocol, a point Shire disputes at full throat, Fortis simply cannot explain how that clinical trial could fit within the definition of Achievement Date when that term is defined

[36] *Id.* (emphasis added).

[37] This, of course, assumes that the context here requires singular terms to be converted to plural. The rule of construction upon which Fortis relies within § 11.9(b) applies only "wherever the context requires." Given that the OPUS-1 and OPUS-2 studies were both separately defined in the Merger Agreement, and the provisions at issue here are clear and unambiguous as drafted, it is difficult to discern anything about this "context" that "requires" a conversion of terms from singular to plural.

to include only clinical trials "to be conducted" in accordance with the OPUS-2 Study Protocol. To reiterate, the OPUS-1 Study had already been conducted at the time of the Merger Agreement, a fact that is undisputed and is, in any event, clear from the definition of the OPUS-1 Study in the Merger Agreement. For these reasons, it is unreasonable to construe the definition of OPUS-2 Study as encompassing data from multiple clinical trials in addition to the OPUS-2 Study.[38]

As for Fortis' third and final basis to argue that the Achievement Date has occurred—that the Xiidra label provides irrefutable evidence the OPUS-2 Study did achieve both co-primary efficacy endpoints—the argument ignores that the Merger Agreement clearly and unambiguously requires that the study data achieve statistical significance. And it glosses over the fact that Fortis has not pled that the Xiidra label showed a statistically significant result for the OPUS-2 Study. To get around the reference to statistical significance in the OPUS-2 Study Protocol, Fortis contends that the reference to the OPUS-2 Study Protocol within the definition of the Achievement Date is simply intended to identify the co-primary efficacy endpoints

[38] I note that the Complaint is devoid of any well-pled allegations that would allow the Court reasonably to infer that the OPUS-1 Study, which was conducted in accordance with Company Protocol Number 1118-KCS-200, dated May 27, 2011, as amended August 5, 2011, was conducted "in accordance with" the OPUS-2 Study Protocol, a separately defined protocol designed well after the OPUS-1 Study. The Complaint makes no effort to compare the two protocols factually, scientifically or otherwise. Fortis' "in accordance with" construction, therefore, appears to be of post-pleading vintage. In any event, the construction cannot be squared with the clear and unambiguous terms of the contract and must be rejected for that reason alone.

as defined in the OPUS-2 Study Protocol; it does not, however, reflect an intent to incorporate all aspects of the OPUS-2 Study Protocol, including the requirement of statistical significance, within the Achievement Date definition. To characterize this construction as fanciful would be charitable.

In advancing its proffered construction, Fortis would have the Court ignore that the OPUS-2 Study Protocol, in its entirety, is an attached schedule to the Merger Agreement and is thereby expressly incorporated as part of the entire agreement.[39] By incorporating the entire OPUS-2 Study Protocol into their agreement without conditions or limitations, the parties unambiguously reflected their intent that all aspects of the protocol, including its detailed specifications for statistical significance, would become elements of their contract, equally as essential as any other element.[40] Fortis' attempt to read out of the OPUS-2 Study Protocol the

[39] *See* Merger Agreement, Schedule C. At § 11.4 of the Merger Agreement, the parties agreed that the schedules to the Merger Agreement were incorporated as part of the parties' entire agreement. *See* Merger Agreement § 11.4(a)(i) ("This Agreement and the documents and instruments delivered pursuant hereto, including the exhibits hereto, the Company Disclosure Schedule and the other schedules hereto, and the Escrow Agreement: (i) together constitute the entire agreement among the parties with respect to the subject matter hereof . . .").

[40] *See Realty Growth Inv. Council of Unit Owners of Pilot Pointe*, 453 A.2d 450, 454 (Del. 1982) (holding that documents incorporated by reference into a contract must be considered by the court when discerning the parties' intent); *Green Plains Renewable Energy, Inc. v. Ethanol Hldg. Co., LLC*, 2015 WL 590493, at *6 (Del. Super. Ct. Feb. 9, 2015) (holding that the operative contract's express "identification of all schedules to the [contract] as being part of the 'entire agreement' is sufficient to satisfy the incorporation by reference standard."); *accord Kerly v. Battaglia*, 1990 WL 199507, at *4 (Del. Super. Ct. Nov. 21, 1990) (noting that parties may limit the incorporation by reference of other

provisions that undermine its construction of the Achievement Date definition cannot be countenanced.

Moreover, as noted, Fortis has not attempted to plead that the Xiidra label shows that the co-primary efficacy endpoints were achieved in a statistically significant manner. Rather, it construes the data on the label as revealing only that the OPUS-2 Study demonstrated that the reduction for the sign endpoint was favorable for Lifitegrast as compared to the placebo.[41] Fortis contends that this means that the sign endpoint was "achieved" in the OPUS-2 Study if one construes the term "achieved," an undefined term, in accordance with its ordinary dictionary meaning. According to Fortis, as used in the operative language, "achieve" means "to reach or attain"; it does not mean or require that the study produce statistically

agreements by designating "only certain provisions" of the other agreement to be incorporated into the contract at issue).

[41] Fortis argues that Shire has denied it access to the actual data from the OPUS-2 Study even though it is contractually entitled to this data. According to Fortis, the actual data would allow it to determine if the results in the OPUS-2 Study were, in fact, statistically significant. Yet this is not the breach of contract claim Fortis brought in this action. If Fortis believes that it has been denied access to information that it is entitled, by contract, to receive, it may bring that claim and Shire may raise its defenses. The fact that the information has not been produced thus far, however, does not and cannot alter the fact that the clear and unambiguous terms of the Merger Agreement do not support the breach of contract claim that Fortis *has* asserted. As an aside, I cannot help but observe that it would be remarkable if the OPUS-2 Study actually did achieve statistically significant results when Shire reported to the FDA in a NDA, against its interest, that the study did *not* meet the co-primary Sign endpoint with statistical significance. *See* Transmittal Aff. of Jaclyn C. Levy, Ex. A at 37 (the NDA was incorporated by reference in the Complaint).

significant results. This construction, of course, ignores the details of the OPUS-2 Study Protocol where the parameters of the study are set forth in detail, including the population of patients to be tested, the number of study participants and how they would be sourced and screened, the methodology by which participants would be assigned to the Lifitegrast or placebo cohorts, the mechanics for the testing procedures and, importantly, the manner by which the outcomes would be evaluated for statistical significance. Under these circumstances, there is simply no room to embed a general dictionary definition for "achieve" within the definition of Achievement Date when the detailed ingredients of the OPUS-2 Study Protocol fully occupy the space.[42]

III. CONCLUSION

To state a claim for breach of contract, Fortis must proffer a reasonable construction of the operative terms of the Merger Agreement that would support its claim of breach. It has not done so. On the other hand, Shire's construction is

[42] *See Brinckerhoff v. Enbridge Energy Co., Inc.*, 159 A.3d 242, 254 (Del. 2017) (observing that "settled rules of contract interpretation requir[e] that the court prefer specific provisions over more general ones."). Although the Court is bound to a four corners analysis of the Merger Agreement unless the contractual language is ambiguous, I pause to note that it makes eminent sense that these two parties would require statistical significance as the measure for "achievement" in this context when seeking an objective means by which to determine whether milestones have been reached. While Fortis' interpretation would leave the trigger point for the milestone payments as something more fluid and open to debate, I cannot fathom that two sophisticated parties with hundreds of millions of dollars on the line would have been so cavalier.

entirely reasonable. Because Shire's construction reveals that it has not breached the Merger Agreement, Shire's motion to dismiss the Complaint must be GRANTED.

IT IS SO ORDERED.