IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

FORTIS ADVISORS LLC, in its capacity as the Shareholders' Representative for the former stockholders of Oculeve, Inc.,	)	
Plaintiff,	)	
v.	)	C.A. No. 2019-0159-MTZ
ALLERGAN W.C. HOLDING INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

Date Submitted: July 9, 2019
Date Decided: October 30, 2019

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ZURN, Vice Chancellor.

The parties to a merger dispute the seller's entitlement to post-closing milestone payment consideration. For the seller to earn the milestone payment, the new company had to achieve a specifically defined enhanced treatment authorization from the Federal Drug Administration. After the Federal Drug Administration gave its authorization, the company declined to pay the seller the milestone payment.

The seller stockholders' representative asserts the buyer breached the merger agreement by refusing to pay the milestone payment and by failing to exercise commercially reasonable efforts in pursuit of the authorization. The buyer moved to dismiss, contending the enhanced treatment authorization did not trigger the milestone payment, and that the buyer failed to allege sufficient facts in support of its commercially reasonable efforts claim. This decision concludes that the seller adequately alleged a breach of contract claim based on the plain meaning of the contract and the authorization, and that the seller alleged sufficient facts to support its commercially reasonable efforts claim. Accordingly, I deny the buyer's motion to dismiss.

I. BACKGROUND

I draw the facts from the seller's Verified First Amended Complaint (the "Amended Complaint") and the documents incorporated by reference therein.[1] I

[1] *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 860 A.2d 312, 320 (Del. 2004). All citations to the Amended Complaint are to the Verified First Amended Complaint. Docket Item

must accept as true the Amended Complaint's well-pled factual allegations and draw all reasonable inferences from those allegations in plaintiff's favor.[2]

A. The Merger Agreement

In July 2015, an affiliate of defendant Allergan W.C. Holding Inc. ("Allergan") acquired Oculeve, Inc. ("Oculeve"). At issue in this case is Oculeve's primary product in development at the time: a medical device for insertion in the nostrils that causes a person's eyes to tear by way of a small electric charge (the "Product").

The parties executed an Agreement and Plan of Merger (the "Merger Agreement") on July 5, 2015, and the merger closed on August 10. The Merger Agreement designated Fortis Advisors LLC ("Fortis") as the seller stockholders' representative.

Under the Merger Agreement, Allergan's affiliate paid the sellers $125 million at closing and contracted for future payments of up to $300 million upon achievement of specific post-closing milestones. The first two milestones compensate the sellers for the Product's regulatory achievements, namely Federal

("D.I.") 10 [hereinafter "Am. Compl."]. I address the parties' dispute as to what documents I should consider in Section II(A), *infra*.

[2] *In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 168 (Del. 2006).

Drug Administration ("FDA") authorization, while the remaining milestones track the Product's sales.

The first milestone is triggered by "achievement of U.S. Launch,"[3] defined as the first sale of the Product "following written receipt from the FDA of FDA Authorization for the Product with an 'indication for use' for Increased Tear Production associated with dry eye disease."[4] The Merger Agreement defines "Increased Tear Production" as "the temporary increase in tear production in the study population in response to administration of electrical stimulation as measured by [the] Schirmer score."[5] Allergan received FDA approval of the Product on April 24, 2017, with an indication for use that "[the Product] provides a temporary increase in tear production during neurostimulation in adult patients."[6] Allergan then made the first milestone payment of $100 million.

The second milestone is triggered by "achievement of Enhanced Product Labeling,"[7] which "means the receipt by a Milestone Party of written notice of FDA Authorization of the Product that includes an 'indication for use' for Increased Tear

[3] Am. Compl. Ex. A § 2.11(b)(i) [hereinafter "Merger Agreement"].

[4] *Id.* §§ 1.1, 2.11(b)(i).

[5] *Id.* § 1.1.

[6] D.I. 27, Ex. 5.

[7] Merger Agreement § 2(b)(ii).

Production and for the treatment of at least one Dry Eye Disease Symptom" (the "Enhanced Product Labeling Milestone").[8] The Merger Agreement provides varying payments based on the date the FDA authorized the Enhanced Product Labeling Milestone: a $100 million payment if authorized by March 31, 2018; a $75 million payment if authorized by June 30, 2018; or a $50 million payment if authorized by September 30, 2019.

Section 2.11(i) of the Merger Agreement requires that Allergan use "Commercially Reasonable Efforts," as defined therein, when pursuing the Enhanced Product Labeling Milestone.[9]

On May 2, 2017, Allergan began its pursuit of the enhanced product labeling by submitting a premarket notification to the FDA to obtain enhanced product labeling (the "510(k) Application").[10] The 510(k) Application sought an indication authorizing that "[t]he [Product] provides a temporary increase in tear production during neurostimulation and a temporary improvement in dry eye symptoms following neurostimulation in adult patients."[11]

[8] *Id.* § 1.1.

[9] *Id.* § 2.11(i).

[10] Am. Compl. ¶ 22; D.I. 27, Ex. 6.

[11] D.I. 27, Ex. 6.

In June, the FDA informed Allergan that the new indication required a "de novo application"[12] because the

> predicate device is indicated "to increase tear production"; however, you propose to indicate your device for "temporary improvement in dry eye symptoms." Because your new indication now includes a specific patient population along with an intended treatment/therapeutic effect (e.g., your new indication includes mitigation of a disease), there are new safety and effectiveness concerns that were not included as risks in the review of the predicate device in the [initial] De Novo classification request.[13]

On October 20, Allergan submitted its de novo application (the "De Novo Application") seeking approval of the following indication for use: "The [Product] provides a temporary increase in tear production during neurostimulation resulting in an improvement in dry eye symptoms in adult patients with dry eye disease."[14] Allergan based its De Novo Application on a clinical study that asked patients to self-assess their symptoms five minutes after using the Product.

On December 22, the FDA responded with a deficiency letter asking for additional metrics supporting a benefit assessment for the Product's proposed indication for use. The FDA requested "outcomes among subpopulations" and "the

[12] Am. Compl. ¶ 22; D.I. 27, Ex. 8.

[13] D.I. 27, Ex. 8.

[14] Am. Compl. ¶ 23; D.I. 27, Ex. 11.

persistence of symptom relief after the application of the [Product]."[15] As for the clinical study assessing symptoms five minutes after using the Product, the FDA requested measurement of the "change of symptom severity over time after the treatment in the [controlled adverse environment] to evaluate the persistence of the treatment effect."[16]

Allergan responded to the deficiency letter two months later, on February 15, 2018. In the letter, Allergan focused on validating the study methodologies; stratifying the results among patient populations, including mild, moderate, and severe dry eye disease; and identifying the duration of symptom relief.

About three months later, on May 17, the FDA notified Allergan that it had approved the following indication for the Product's use (the "Second Authorization"): "[the Product] provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms."[17]

Upon receiving this FDA authorization, Allergan refused to pay the Enhanced Product Labeling Milestone. Allergan told the seller that the Second Authorization

[15] D.I. 27, Ex. 13.

[16] *Id.*

[17] Am. Compl. ¶ 27.

did not meet the Enhanced Product Labeling Milestone because it "does not include 'treatment' or 'disease'[; and] increase is 'temporary.'"[18]

On February 26, 2019, Fortis commenced this litigation.[19] Fortis filed the Amended Complaint one month later, on March 26.[20] Fortis claims Allergan materially breached its obligations under the Merger Agreement by failing to make the Enhanced Product Labeling Milestone payment, and by failing to use commercially reasonable and good faith efforts to achieve the Enhanced Product Labeling Milestone before March 31, 2018. Allergan moved to dismiss the Amended Complaint on April 24.[21] The parties finished briefing on June 21,[22] and the Court held oral argument on July 9.[23]

II. ANALYSIS

Allergan has moved to dismiss Fortis' Amended Complaint pursuant to Court of Chancery Rule 12(b)(6). When reviewing a motion to dismiss, the Court must

> accept all well-pleaded factual allegations in the Complaint as true, accept even vague allegations in the Complaint as 'well-pleaded' if they provide the defendant notice of the claim, draw all reasonable inferences in favor

[18] *Id.* ¶¶ 31–32.

[19] D.I. 1.

[20] D.I. 10.

[21] D.I. 22.

[22] D.I. 27, 30, 32.

[23] D.I. 37–38.

> of the plaintiff, and deny the motion unless the plaintiff could not recover under any reasonably conceivable set of circumstances susceptible of proof.[24]

A. The Court Considers Extrinsic Documents Integral To The Amended Complaint, And Those Subject To Judicial Notice.

As an initial matter, Allergan asserts that the Court should consider twenty-five exhibits filed in support of Allergan's motion to dismiss.[25] Allergan contends that all of its exhibits are integral to the complaint or constitute judicially noticeable facts. Allergan cites the Amended Complaint's "liberal[] discuss[ion]" of the regulatory record as justification for including that entire record.[26]

"On a motion to dismiss, the Court may consider documents that are 'integral' to the complaint, but documents outside the pleadings may be considered only in 'particular instances and for carefully limited purposes.'"[27] "Whether a document is integral to a claim and incorporated into a complaint is largely a facts-and-circumstances inquiry."[28] Generally, "a document is integral to the claim if it is the

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[24] *Cent. Mortg. Co. v. Morgan Stanley Mortg. Capital Hldgs. LLC*, 27 A.3d 531, 536 (Del. 2011) (quoting *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896–97 (Del. 2002)).

[25] *See* D.I. 27 Exs. 1–23; D.I. 32 Exs. 24–25.

[26] D.I. 32 at 3.

[27] *Wal-Mart Stores, Inc.*, 860 A.2d at 320 (quoting *In re Santa Fe Pac. Corp. S'holder Litig.*, 669 A.2d 59, 69 (Del. 1995)); *see also CelestialRX Invs., LLC v. Krivulka*, 2019 WL 1396764, at *1 (Del. Ch. Mar. 27, 2019) ("In a Rule 12(b)(6) motion to dismiss, the Court does not consider documents extrinsic to the complaint, except for documents that are integral to a plaintiff's claim and are incorporated into the complaint.").

[28] *In re Gardner Denver, Inc.*, 2014 WL 715705, at *3 (Del. Ch. Feb. 21, 2014).

'source for the . . . facts as pled in the complaint.'"[29] Fortis concedes that it referenced some of Allergan's exhibits in its Amended Complaint, but contends that those documents are not integral to its breach of contract claim.[30] I find that Fortis uses these referenced documents to form the factual foundation for its claim, and therefore that they are integral to the claim. I conclude that only those Allergan exhibits that Fortis cited are properly considered as integral to Fortis' complaint. I will consider Allergan's Exhibits 1, 6, 8, 11, 12, 13, 14, and 18.

Allergan also claims that the Court should take judicial notice of Exhibits 2 through 19, comprising FDA approvals and nonpublic communications between Allergan and the FDA, because the FDA regulatory record contains facts that are "not subject to reasonable dispute."[31] Under Delaware Rule of Evidence 201, a Court may take judicial notice of adjudicative facts.[32] A judicially noticed fact "is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."[33] "Applying Rule 201,

[29] *Id.* (quoting *Orman v. Cullman*, 794 A.2d 5, 16 (Del. Ch. 2002)).

[30] D.I. 30 at 14.

[31] D.I. 32 at 6 (citing D.R.E. 201).

[32] D.R.E. 201.

[33] *Id.* 201(b).

Delaware courts have taken judicial notice of publicly available documents that 'are required by law to be filed, and are actually filed, with federal or state officials.'"[34]

Delaware courts frequently take judicial notice of public filings with the Securities and Exchange Commission ("SEC").[35] Allergan analogizes the FDA to the SEC, and invites this Court to extend judicial notice to the FDA's final approvals submitted as Exhibits 5 and 19. Exhibit 5 is the FDA final report that triggered the Product's first milestone payment. Exhibit 19 is the final FDA approval of another, unrelated device. Allergan cites two cases in support of judicial notice for these Exhibits. In *Funk v. Stryker Corp.*, the United States Court of Appeals for the Fifth Circuit affirmed the lower court's decision to take judicial notice of "publicly-available documents and transcripts produced by the FDA, which were matters of public record directly relevant to the issue at hand."[36] In *Eidson v. Medtronic, Inc.*, the United States District Court for the Northern District of California took judicial notice of "all of the documents at issue [that] appear on the FDA's public website."[37]

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[34] *In re Rural Metro Corp. S'holders Litig.*, 2013 WL 6634009, at *7 (Del. Ch. Dec. 17, 2013) (quoting *In re Tyson Foods, Inc. Consol. S'holder Litig.*, 919 A.2d 563, 584 (Del. Ch. 2007)).

[35] *Wal-Mart Stores, Inc.*, 860 A.2d at 320 n.28.

[36] 631 F.3d 777, 783 (5th Cir. 2011).

[37] 981 F. Supp. 2d 868, 879 (N.D. Cal. 2013).

Like in *Funk*, Allergan asks this Court to take judicial notice of FDA pre-market approval letters. Allergan has represented that these Exhibits are publicly available documents produced by the FDA, similar to those documents at issue in *Eidson*.[38] Fortis has not refuted that representation. Accordingly, I am persuaded by *Funk* and *Eidson* to take judicial notice of Allergan's Exhibits 5 and 19.

Exhibits 2 through 4, and 6 through 18, are Allergan's nonpublic correspondence with the FDA.[39] Allergan's communications with the FDA are not publicly available, and their contents cannot be reasonably described as "generally known." While the existence of the communications may be readily determined, the accuracy of the facts contained therein cannot.[40] The same is true for Exhibit 25, which is correspondence between the FDA and a nonparty. I decline to extend Rule 201 to these communications, which are being offered to prove the facts asserted therein.

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[38] *See* D.I. 38 at 28:23–30:7.

[39] *Id.*

[40] *See Rural Metro*, 2013 WL 6634009, at *7–8 (citing *Santa Fe Pac. Corp.*, 669 A.2d at 69-70) (noting that a document may be subject to judicial notice for the purpose of determining what statements had been disclosed publicly, but not for the truth of those statements).

I will take judicial notice of Allergan's Exhibits 1, 5, 6, 8, 11, 12, 13, 14, 18, and 19. The remainder of Allergan's Exhibits are not properly considered on Allergan's motion to dismiss.[41]

B. Allergan Has Not Shown That The Plain Meaning Of The Merger Agreement Forecloses The Enhanced Product Labeling Milestone.

Having circumscribed the pleadings and documents integral thereto, I consider whether Fortis has stated a claim. Allergan claims Fortis' breach of contract claim must be dismissed because the Second Authorization plainly fails to satisfy the Enhanced Product Labeling Milestone.

"[T]o 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."[42] "[A] claim may be dismissed if allegations in the complaint or in the exhibits incorporated into the complaint

[41] In briefing, Allergan did not specifically advocate for consideration of Exhibits 20 through 24. To clarify the record upon which I make my decision, I will also examine these Exhibits. Exhibits 20 through 23 comprise academic research papers and a book chapter. These exhibits are not integral to Fortis' Amended Complaint, and the accuracy of their contents cannot be readily determined. Exhibit 24 is an email chain between counsel that is not integral to the Amended Complaint and not subject to judicial notice. I do not consider any of these documents here.

[42] *VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 612 (Del. 2003). Allergan moves for dismissal on breach alone, arguing that Fortis has not alleged a breach because it cannot "show that [the Enhanced Product Labeling Milestone] has been achieved[.]" D.I. 27 at 33.

effectively negate the claim as a matter of law."[43] Otherwise, "[t]he court may grant a motion to dismiss based on contractual language . . . only if the contractual language is unambiguous—meaning, the language is susceptible of only one reasonable interpretation."[44]

To determine the obligations imposed by a contract, "Delaware courts start with the text."[45] "When the contract is clear and unambiguous," Delaware courts "will give effect to the plain-meaning of the contract's terms and provisions."[46] "[A] term is not ambiguous simply because it is not defined[.]"[47] "Delaware courts look to dictionaries for assistance in determining the plain meaning of terms which are not defined in a contract."[48] "If a contract is unambiguous, extrinsic evidence may

[43] *VLIW Tech*, 840 A.2d at 614–15 (quoting *Malpiede v. Townson*, 780 A.2d 1075, 1083 (Del. 2001)).

[44] *Fortis Advisors LLC v. Stora Enso AB*, 2018 WL 3814929, at *3 (Del. Ch. Aug. 10, 2018).

[45] *Sunline Comm. Carriers, Inc. v. CITGO Pet. Corp.*, 206 A.3d 836, 846 (Del. 2019).

[46] *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159–60 (Del. 2010).

[47] *ClubCorp, Inc. v. Pinehurst, LLC*, 2011 WL 5554944, at *12 (Del. Ch. Nov. 15, 2011) (alteration in original) (quoting *Sassano v. CIBC World Mkts. Corp.*, 948 A.2d 453, 468 n.86 (Del. Ch. 2008)).

[48] *Horton v. Organogenesis Inc.*, 2019 WL 3284737, at *4 (Del. Ch. July 22, 2019) (quoting *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 738 (Del. 2006)).

not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity."[49]

Allergan's motion to dismiss hinges on whether the FDA's indication for use "*to improve* dry eye *symptoms*" is equivalent to the Enhanced Product Labeling Milestone's requirement of "*treatment* of dry eye *disease* symptoms." As a prefatory matter, I consider whether the indication, limited to symptoms, falls short of any contractual requirement to treat the underlying disease. The FDA approved the following indication for use: "The [Product] provides a temporary increase in tear production during neurostimulation *to improve* dry eye symptoms in adult patients with severe dry eye symptoms."[50] The FDA explained, "[t]he [Product] is limited only to the improvement in dry eye symptoms as the safety and effectiveness in the treatment of dry eye disease has not been established."[51] Thus, the Second Authorization explicitly distinguished the treatment of dry eye *disease*, and is cabined to *symptoms*.

Similarly, the Merger Agreement only contemplated the treatment of dry eye disease symptoms. Under the Merger Agreement, the Enhanced Product Labeling

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[49] *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997); *see e.g.*, *Citadel Hldg. Corp. v. Roven*, 603 A.2d 818, 822 (Del. 1992) ("Only when there are ambiguities may a court look to collateral circumstances.").

[50] Am. Compl. ¶ 27 (emphasis added).

[51] D.I. 27, Ex. 18 at 2.

Milestone required the "receipt by a Milestone Party of written notice of FDA Authorization of the Product that includes an 'indication for use' for Increased Tear Production and for the *treatment* of at least one Dry Eye Disease Symptom."[52] "Dry Eye Disease Symptoms" are defined as just that: symptoms.[53] The Merger Agreement does not hinge milestone payments on treatment of the underlying disease. So, the Second Authorization's exclusion of the treatment of disease does not foreclose the satisfaction of the Enhanced Product Labeling Milestone.

I now turn to Allergan's specific arguments as to why the Second Authorization did not satisfy the Enhanced Product Labeling Milestone. Allergan reads the Enhanced Product Labeling Milestone as imposing three requirements—causation, duration, and the entire patient population—and concludes the Second Authorization failed to satisfy all three. I conclude Fortis pled a breach of the Merger Agreement over each of Allergan's arguments.

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[52] Merger Agreement § 1.1.

[53] "'Dry Eye Disease Symptom' means any of the following ***subjective patient reported conditions*** associated with dry eye disease, including dry eye ***symptoms*** measured in total score on the Ocular Surface Disease Index ("OSDI"), individual ***symptoms*** of painful or sore eyes, eyes that feel gritty, blurred vision, poor vision as measured on OSDI coupled with a sign endpoint, ocular discomfort measured by the Ora Calibra Ocular Discomfort Scale, ocular discomfort, burning, dryness, grittiness, or stinging as measured by the Ora Calibra Ocular Discomfort and 4-Symptom Questionnaire, or individual ***symptoms*** of ocular discomfort, dryness, burning, stinging, eye pain, foreign body sensation, or perception of blurred or poor vision measured by a validated individual dry eye questionnaire." *Id.* (emphasis added).

First, Allergan contends that the Merger Agreement's use of the word "treatment" requires "a causal relationship" not present in the Second Authorization's use of the term "to improve."[54] The Merger Agreement does not define "treatment," and Allergan has provided no other definition. Dictionary definitions for treatment include "a particular method or type of medical care";[55] "to care for or deal with medically or surgically";[56] and "management in the application of medicines, surgery, etc."[57] Delaware courts have also defined treatment as "[t]he management of illness, by the use of drugs, dieting, or other means designed to bring relief or effect a cure."[58] I accept these definitions as the plain meaning of

[54] D.I. 27 at 36.

[55] *Treatment*, MacMillan Online Dictionary, https://www.macmillandictionary.com/us/dictionary/american/treatment (last visited Oct. 27, 2019).

[56] *Treat*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/treat (last visited Oct. 29, 2019). *Compare* "treat" *with Treatment*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/treatment (last visited Oct. 29, 2019). Merriam-Webster defines treatment as "the act or manner or an instance of treating someone or something"; "the techniques or actions customarily applied in a specified situation"; "a substance or technique used in treating"; "an experimental condition." Thus, the noun form of treatment is defined in terms of the verb "treat." The definition of "treat" informs my understanding of the plain meaning of "treatment."

[57] *Treatment*, Dictionary.com, https://www.dictionary.com/browse/treatment (last visited Oct. 27, 2019).

[58] *Collis v. Topper's Salon & Health Spa, Inc.*, 2012 WL 1408884, at *4 (Del. Super. Ct. Mar. 29, 2012) (citing 2 *Webster Dictionary* 1337 (Int'l ed. 1998)).

"treatment," an unambiguous term. The definitions also support Allergan's view that "treatment" implies causation. The phrases "bring relief or effect a cure," to "care for," and to "manage[]" an illness, suggest causation.

According to Fortis, the indication's use of the term "to improve" satisfies this element of causation. The FDA issued the Second Authorization with an accompanying guide. That guide states "[t]he [Product] is limited only to the improvement in dry eye symptoms . . . ."[59] "An improvement in" symptoms suggests the Product "bring[s] relief" or "care[s] for" dry eye symptoms, synonymously with "treatment." This interpretation is consistent with the federal statute that hinges FDA approval on a "reasonable assurance of safety and effectiveness"[60] of the Product. The authorization is therefore based on the Product's effectiveness in improving dry eye symptoms.[61] Thus, I conclude that both "to improve" and

[59] D.I. 27, Ex. 18 at 2. Allergan attempted to introduce Exhibit 17, detailing the course of communications with the FDA, to inform the Second Authorization's scope. Because Fortis did not reference Exhibit 17 in the Amended Complaint, I do not consider it for the purpose of this motion. *See supra* Section (II)(A). Further, because "treatment" and "to improve" are not ambiguous, "extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity." *See Eagle Indus., Inc.*, 702 A.2d at 1232. For this reason, I do not consider Fortis' allegations of the parties' conduct during the approval process (*e.g.*, celebrations upon obtaining the Second Authorization) in interpreting the unambiguous Merger Agreement and Second Authorization. *See* D.I. 30 at 16–17.

[60] 21 U.S.C. § 360e(d)(1)(A) (2019) (effective Aug. 18, 2017).

[61] Allergan highlights that a portion of patients with severe dry eye symptoms experienced worsening symptoms after application of the Product, as set forth in the FDA disclosure. *See* D.I. 27, Ex. 18 at 22. The FDA further stated that "[t]here were more subjects with

"treatment" contemplate causation. Allergan has not shown the Second Authorization cannot meet the Enhanced Product Labeling Milestone's causation requirement.

Second, Allergan contends the Merger Agreement imposes a duration requirement that the Second Authorization failed to satisfy. Allergan contends that the Enhanced Product Labeling Milestone requires "a long-term improvement—*i.e.*, that the device actually results in long-term reduction or elimination of a Dry Eye Disease Symptom."[62]

The plain meaning of "treatment" does not differentiate between short-term and long-term improvement. Short-term relief is consistent with the definition of treatment that contemplates "management . . . designed to bring relief."[63] Allergan has not offered an alternative definition that requires long-term improvement.

As the term "treatment" is used in the Enhanced Product Labeling Milestone, Allergan sees an interplay between the two requirements of a) Increased Tear Production, and b) the treatment of at least one Dry Eye Disease Symptom.

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severe dry eye symptoms that had a meaningful improvement in symptoms from baseline as measured with the OSDI than the number with meaningful worsening of symptoms . . . ." *Id.* Although this result does not demonstrate unanimous improvement, the FDA's authorization shows meaningful improvement among certain patients, supporting causation.

[62] D.I. 27 at 36.

[63] *Collis*, 2012 WL 1408884 at *4 (citing 2 *Webster Dictionary* 1337 (Int'l ed. 1998)).

"Increased Tear Production," is defined as a "*temporary* increase in tear production."[64] Allergan points out that the word "temporary," present in the Increased Tear Production requirement, is absent from the treatment requirement, and concludes that "treatment" must be longer-term.

I draw a different conclusion. In my view, an "increase in tear production" is specified to be "temporary" to make clear that the patient's eyes should not produce tears at that increased rate at all times, forever. I do not construe the unmodified term "treatment" to preclude short-term relief.

More fundamentally, Allergan has yet to show that the Second Authorization was limited to temporary symptom relief. Allergan points to a FDA deficiency letter dated December 22, 2017, in which the FDA requested support for "the persistence of symptom relief after the application of the [Product]" beyond the five minute measurement to evaluate the benefits and risks for the proposed indication.[65] According to Allergan, this letter shows the Second Authorization did not contemplate persistent relief.

But after that letter, and additional advocacy by Allergan, the FDA issued the Second Authorization with the guide that detailed the FDA's evaluation of symptom

[64] Merger Agreement § 1.1 (emphasis added).

[65] D.I. 27, Ex. 13 at 3.

improvement at days seven and thirty.[66] This guide explained "[t]he proportion of subjects with a clinically important change in [Ocular Surface Disease Index] at the follow-up days 7 and 30 for all available subjects [were] stratified by dry eye severity subgroup . . . ." [67] And "[o]f the 97 subjects that were enrolled, 77 had severe dry eye symptoms at the start of the study and were seen following treatment. Of these subjects, between 18 (23%) and 33 (43%) were shown to have a clinically meaningful improvement in their symptoms."[68] In my view, on the available record, the Second Authorization guide shows that Allergan remedied the FDA's concerns expressed in the December 2017 deficiency letter. In relying on the December 2017 deficiency letter, Allergan falls short of demonstrating that the Second Authorization was for only temporary improvement.

Finally, Allergan contends that the Second Authorization fell short of an Enhanced Product Labeling Milestone requirement to improve dry eye symptoms for the entire patient population. The Second Authorization states, "[the Product] provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in *adult patients with severe dry eye symptoms*."[69] Allergan

[66] D.I. 27, Ex. 18 at 22.

[67] *Id.*

[68] *Id.*

[69] Am. Compl. ¶ 27 (emphasis added).

contends "[t]he parties agreed to an Enhanced Product Labeling Milestone payment if the device could be marketed as a treatment for dry eye disease symptoms generally, *implicitly but clearly to the total patient population*."[70] Allergan notes the truism that the Product's commercial success is dependent on the population eligible to use it to Allergan; complains that the Second Authorization's limited patient population has dramatically undercut the Product's commercial success; and concludes the parties could not have contracted for less than the entire patient population. Because the Second Authorization is limited to patients suffering from severe dry eye symptoms, Allergan contends it falls short of the Enhanced Product Labeling Milestone.

Allergan correctly notes that any requirement that the Second Authorization apply to the entire patient population would be implicit. On its face, the Enhanced Product Labeling Milestone does not specify any patient population. Allergan fails to show an ambiguity in the text that would allow the Court to import an implicit reading that is not otherwise evident. Even if Allergan now views the resulting limitation to patients with "severe" symptoms as "a patent commercial failure,"[71] Allergan's *post hoc* disappointment does not support an otherwise unsupported requirement that the Second Authorization be available to the entire population.

[70] D.I. 27 at 40 (emphasis added).

[71] *Id.* at 41.

Allergan has failed to demonstrate that the Second Authorization's limitation on "severe" symptoms could not have satisfied the Enhanced Product Labeling Milestone.

In sum, Allergan has failed to establish that the Second Authorization fell short of the Enhanced Product Labeling Milestone in any of the three ways advanced in Allergan's motion to dismiss. Fortis has sufficiently alleged a breach, and so Allergan's motion to dismiss on these grounds is denied.

C. Fortis Has Pled A Breach Of The Commercially Reasonable Efforts Provision.

Allergan contends that Fortis failed to plead that Allergan breached the Merger Agreement by failing to use commercially reasonable efforts to obtain the Second Authorization.[72] Allergan first asserts that this claim is moot because Fortis cannot plead that the Enhanced Product Labeling Milestone requirement was satisfied.[73] Having concluded otherwise, I turn to Allergan's second argument that Fortis has not adequately alleged that Allergan failed to use "Commercially Reasonable Efforts" as defined in the Merger Agreement.[74]

[72] *Id.* at 44.

[73] *Id.*

[74] *Id.* at 45–46.

Under the Merger Agreement, Commercially Reasonable Efforts means:

> [W]ith respect to the performance of development, regulatory or commercialization activities with respect to the Product, the carrying out of such activities using commercially reasonable, diligent and good faith efforts ***and expending resources that Buyer would typically devote to, and with respect to, products of similar market potential at a similar stage in development or product life***, considering the following: conditions then prevailing and taking into account, without limitation, issues of safety and efficacy, expected and actual cost and time to develop, expected and actual profitability, expected and actual competitiveness of alternative products in the marketplace, the nature and extent of the expected and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected and actual reimbursability and pricing, the expected and actual amounts of marketing and promotional expenditures required, product profile (including the expected and actual labeling), anticipated timing of commercial entry, the regulatory environment and status of the product (including the likelihood of regulatory approval), and all other relevant legal, medical, scientific, technical and commercial factors.[75]

Fortis alleges that Allergan waited for two years to apply for the Enhanced Product Labeling Milestone;[76] filed a procedurally deficient 510(k) Application;[77]

[75] Am. Compl., Ex. A § 1.1.

[76] Am. Compl. ¶ 40.

[77] *Id.* ¶¶ 40–41.

waited another four months to submit the De Novo Application;[78] and prolonged that delay by waiting two months to respond to the FDA's deficiency letter.[79]

Allergan contends that Fortis fails to allege any facts about Allergan's comparable commercial efforts, which serves as the metric for Commercially Reasonable Efforts under the Merger Agreement.[80] Allergan stops short of demonstrating what it must: that Fortis failed to give notice of its claim, or that Fortis alleged no facts that, if true, could support a breach of the Merger Agreement's Commercially Reasonable Efforts provision.[81] Drawing all reasonable inferences in favor of Fortis, as I must at this stage,[82] I find that Fortis has alleged substantial delay during multiple phases. These allegations support an inference that Allergan's efforts fell short of its comparable efforts for other similar products. From the facts alleged, and with the aid of discovery into Allergan's comparable efforts, Fortis may prevail on its breach of contract claim. Fortis' claim survives Allergan's motion to dismiss.

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[78] *Id.* ¶ 42.

[79] *Id.* ¶ 43.

[80] D.I. 27 at 45.

[81] *VLIW Tech.*, 840 A.2d at 615 ("A trial court must not dismiss any claim pursuant to Rule 12(b)(6) unless it appears with reasonable certainty that the plaintiff cannot prevail on any set of facts which might be proven to support the allegations in the complaint.").

[82] *Cent. Mortg. Co.*, 27 A.3d at 536.

III. CONCLUSION

Fortis has stated a claim for breach of the Merger Agreement based on Allergan's refusal to make the Enhanced Product Labeling Milestone payment. Fortis has also pled facts that, if proven, would support a breach of the Commercially Reasonable Efforts provision. For these reasons, Allergan's motion to dismiss is DENIED.