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IN THE SUPREME COURT OF THE STATE OF DELAWARE

JEFF HIMAWAN, JOSH TARGOFF and STEPHEN TULLMAN, as the duly-appointed Representatives of the former stockholders of CEPTION THERAPEUTICS, INC., Plaintiffs-Below, Appellants, v. CEPHALON, INC. and TEVA PHARMACEUTICALS USA, INC., Defendants-Below, Appellees.	No. 226, 2024 Case Below: Court of Chancery of the State of Delaware, C.A. No. 2018-0075

APPELLANTS' OPENING BRIEF

Dated: July 25, 2024.

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NATURE OF PROCEEDINGS

This is an appeal from a post-trial, final judgment of the Court of Chancery (Glasscock, V.C.), by Memorandum Opinion dated April 30, 2024 ("Op." or "Opinion"),[1] denying Plaintiffs' claim for breach of contract against Defendants Cephalon and Teva.[2] Plaintiffs, stockholder representatives of Ception, alleged that Defendants failed to make the contractually-required commercially reasonable efforts to develop and commercialize a pharmaceutical product so as to achieve for Plaintiffs certain promised milestone payments. In its Opinion, the trial court disagreed based on, among other things, a misinterpretation of the relevant contractual provision. The Opinion was the result of legal error that, if not corrected by this Court, will reduce commonly-used "commercially reasonable efforts" clauses to mere subjective, good faith efforts clauses.

Ception and Cephalon entered into a merger agreement ("Agreement") by which Ception agreed, in part, to accept certain deferred consideration in the form of milestone payments worth hundreds of millions of dollars. Ception would only receive these additional payments if Cephalon achieved approval by regulatory

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[1] The trial court revised the Opinion on May 17, 2024, fixing typographical errors.

[2] Cephalon became a wholly-owned subsidiary of Teva in 2011. (Op. at 4, 14; A00628-33.) Thus, "Defendants" refers to Teva and Cephalon post-merger. Each defendant is referred to as "Cephalon" and "Teva" pre-merger.

agencies for the commercialization of reslizumab ("RSZ") to treat eosinophilic esophagitis ("EoE") and/or eosinophilic asthma ("EA"). Critically, Cephalon agreed to use commercially reasonable efforts ("CRE") to develop RSZ so as to achieve those milestones. The Agreement defined CRE as "***such efforts and commitment of such resources by a company with substantially the same resources and expertise as Parent, with due regard to the nature of efforts and cost required for the undertaking at stake***"[3] ("CRE Clause"). Thus, the CRE Clause afforded Cephalon no discretion in ***whether*** it undertook resources and efforts to develop RSZ for EoE because it was contractually required to use such efforts and commit such resources of a company "with substantially the same resources and expertise."

Only eighteen months after the Cephalon-Ception merger (and the Agreement to undertake CRE) and after just two meetings with the FDA, Cephalon abandoned development of RSZ for EoE. In late 2011, after the death of Cephalon's CEO, another large pharmaceutical company, Teva, acquired Cephalon and assumed Cephalon's obligations under the Agreement.

Defendants made ***no effort and committed no resources*** to develop RSZ for EoE between 2012 and 2016, despite Plaintiffs continuously pushing Defendants to do so. In 2016, Plaintiffs asked Defendants for an update on their development

[3] Emphasis added throughout unless otherwise stated.

efforts only to learn that Defendants mistakenly believed they had complete discretion regarding any development of RSZ for EoE. Defendants, for the first time, told Plaintiffs that they had terminated development of RSZ for EoE. Only after Plaintiffs reminded Defendants of their CRE obligation did Defendants conduct a *post hoc* assessment of the commercial likelihood of developing RSZ for EoE in a belated effort to justify why they had abandoned development after only eighteen months.

Plaintiffs filed suit against Defendants on February 1, 2018, for breach of contract, breach of the implied covenant of good faith and fair dealing, and tortious interference with contract. Defendants moved to dismiss. On December 28, 2018, by Memorandum Opinion ("MTD Op."), the trial court dismissed Plaintiffs' good faith and fair dealing and tortious interference claims, but denied dismissal with respect to Plaintiffs' breach of contract claim.

A five-day trial was held from September 19-23, 2022, on the breach of contract claim. On November 13, 2023, the trial court heard post-trial oral argument.[4] On April 30, 2024, the trial court issued its Opinion, in which it, among other things, misinterpreted the CRE Clause. Instead of protecting sellers' expectations of real efforts being exerted to achieve the milestone payments, the

[4] Post-trial argument was originally scheduled for February 15, 2023, but was rescheduled multiple times, and occurred in November 2023.

Opinion required no more "effort" than protecting the seller against actions of the buyer that would be against the buyer's self-interest. This was legal error. On June 6, 2024, Plaintiffs appealed to this Court.

The Court should reverse the decision of the trial court and remand for new proceedings with instructions to consider the evidence in light of the objective, seller-friendly CRE Clause that Plaintiffs' bargained for, not the subjective, good faith clause that the trial court interpreted the clause to be.

SUMMARY OF ARGUMENT

1. The trial court erred in its interpretation of the Agreement by holding the CRE Clause to only require Defendants to use their subjective, good faith in determining whether or not to pursue the development of RSZ for EoE. In a series of missteps, the trial court turned a seller-friendly CRE Clause into a clause that vested near-complete discretion in Defendants as to whether they would undertake any efforts to achieve the relevant milestones, so long as they did not act against their own "self-interest." (Op. at 30-31.)

2. The trial court erred in rejecting Delaware law stemming from merger consummation cases on the unsupported basis that earn-out cases, like this one, are different and, thus, Defendants, in this case, had "complete discretion" to achieve the milestones (or not), while the defendant-buyers in merger consummation cases purportedly lack such discretion. (Op. at 29-30, n.166.) Had the trial court properly applied binding Delaware precedent concerning satisfaction of contractual CRE obligations, it would have concluded that the factual record supports a finding that Defendants breached the CRE Clause.

3. In the alternative, the trial court erred by dismissing Plaintiffs' claim for breach of the implied covenant of good faith and fair dealing because of the court's reasoning that no "gap" existed in the Agreement, but the trial court improperly ignored that Defendants' arbitrary and unreasonable exercise of

discretion under the CRE Clause resulted in a breach of the implied covenant of good faith and fair dealing. (MTD Op. at 22-25.)

STATEMENT OF FACTS

A. Plaintiffs' Development of RSZ Garners Interest from Cephalon.

In May 2004, Plaintiff Tullman and others formed Ception and acquired the rights to RSZ. (Op. at 4.) Ception invested more than $100 million to research and develop RSZ to treat EoE and EA and to develop a regulatory plan toward commercialization. (Op. at 4; A05148-49; A04586/14:24-15:3 (Tullman), A04586-87/16:20-17:13 (Tullman); A04645/251:2-52:17 (Wilkins); A04647/260:13-61:11 (Wilkins).) Eosinophils typically help fight off infections, unless the body overproduces them. (Op. at 5.) EoE and EA are disorders caused by the overproduction of eosinophils in the esophagus and lungs, respectively. (*Id*.) RSZ works by inhibiting the growth of eosinophils. (*Id*.) When Ception began development of RSZ to treat EoE, EoE was considered a rare disease. (*Id*. at 5-6; A05150.)

Ception's efforts culminated in clinical trials of RSZ for the treatment of EoE and EA. (Op. at 6-7.) Ception's clinical trial for EA began in November 2007 ("EA Study"), and its clinical trial for EoE ("EoE Study"), which was the first of its kind, began in March 2008. (Op. at 7; A05135; A05149; A04698/347:5-7 (Wilkins).) However, before the studies were completed, and in order to continue development and bring RSZ to market, Ception needed additional funding. (Op. at 7; A04587/18:15-22, 20:23-21:12 (Tullman).)

On January 13, 2009, Cephalon paid Ception $100 million for the *option* to later acquire Ception pending results from the ongoing EoE and EA trials. (Op. at 7.) Under that option agreement, the form merger agreement provided for an upfront payment to Plaintiffs of $250 million with hundreds of millions in additional developmental milestone payments. (Op. at 7, 9; A05151-52.) Cephalon also agreed to use CRE to achieve those milestones, and without any time limitation. (Op. at 7, 10, 23.)

Ception completed the EoE Study on October 20, 2009. (Op. at 7.) The results of the EoE Study were promising despite one of two endpoints not being achieved (A05153-54; A04649/265:14-21 (Wilkins); A04652/277:22-78:5 (Wilkins).) Indeed, 199 of 226 EoE Study patients opted to continue treatment with RSZ through an Open Label Extension Study (Op. at 7), the results of which would allow the sponsoring company to get additional data on safety and efficacy for FDA approval efforts. (Op. at 6-7; A05153; A04651-52/276:20-77:6 (Wilkins); A04595/49:16-50:1 (Tullman).)

Before Cephalon exercised its option, Ception and Cephalon jointly announced on November 23, 2009, the results of Ception's EoE Study (Op. at 7-8; A05154), noting they would "continue to review the data from this study and from our ongoing open-label study to find the best path forward for [RSZ] for the treatment of [EoE]." (A00211.)

After the EoE Study results announcement, Ception extended Cephalon's option period until after the EA Study was completed. (Op. at 8.) Although the parties agreed to extend the option period to see the EA Study results, no changes to the EoE milestone or CRE Clause in the Agreement were made or even requested by Cephalon. (A05155; A04593-94/44:24-45:22 (Tullman).) On February 23, 2010, Ception and Cephalon jointly announced not only the results of Ception's EA Study, but also that Cephalon was acquiring Ception to continue work on developing RSZ for ***both*** indications. (Op. at 8; A05154; A00215-19; A00220-26.)

B. Cephalon Acquires Ception and Is Bound to Use CRE to Develop and Commercialize RSZ for EoE and EA so as to Achieve the Milestones.

On March 10, 2010, Ception and Cephalon executed the Agreement. (Op. at 8-9.) Cephalon paid $250 million in cash to Ception and agreed to pay developmental milestones, i.e., earn-out payments, based on certain future approvals relating to RSZ. (Op. at 9.) These milestones totaled 550 million dollars, as follows:

> (A) Upon FDA Approval of [RSZ] for the treatment of eosinophilic esophagitis, a cash payment of $150,000,000 (one-hundred fifty million dollars);
>
> (B) Upon marketing authorization of [RSZ] for the treatment of eosinophilic esophagitis being granted by the European Commission in accordance with Regulation (EC) No. 726/2004, a cash payment of $50,000,000 (fifty million dollars) minus the aggregate amount of any Excluded Third Party IP Fees paid prior to the date on which such Development Milestone Payment is made;
>
> . . .

> (D) Upon FDA approval of [RSZ] for any asthma indication, a cash payment of $150,000,000 (one-hundred fifty million dollars);
>
> (E) Upon marketing authorization of [RSZ] for the treatment of any asthma indication being granted by the European Commission in accordance with Regulation (EC) No. 726/2004, a cash payment of $50,000,000 (fifty million dollars); and
>
> (F) Upon FDA approval of an Oral Anti-TNF Product, a cash payment of $100,000,000.

(Op. at 9; A00261-62 § 3.4(a)(A)-(F).) Cephalon also agreed to use CRE to develop and commercialize RSZ, including, as was at issue here, commercialization for EoE:

> From and after the Closing, Parent hereby agrees to use, or to cause its Affiliates to use, ***commercially reasonable efforts to develop and commercialize (or cause the development and commercialization of) [RSZ] so as to achieve the Developmental Milestones*** set forth in clauses (A) through (E) above.

(A00262 § 3.4(a)(iii); Op. at 10.) The only milestone for which Cephalon was ***not*** contractually obligated to use CRE was for the Oral Anti-TNF Product. (A00262 §§ 3.4(a)(F), 3.4(a)(iii).) Because the future development of the Oral Anti-TNF Product was not governed by the CRE Clause, such development was contractually left to Cephalon's discretion and there was no obligation on Cephalon's part to undertake CRE to achieve for Ception's benefit that developmental milestone. (A00264 § 3.4(c).) Yet, for the development of RSZ for EoE, Cephalon was under such a contractual obligation. (A00261-26 §§ 3.4(a)(A)-(B), 3.4(a)(iii); A00264 § 3.4(c).)

"Commercially reasonable efforts" is defined in the Agreement:

> For purposes of this Section 3.4 only, the phrase "commercially reasonable efforts" means the exercise of such efforts and commitments of such resources by a company with substantially the same resources and expertise as Parent, with due regard to the nature of efforts and cost required for the undertaking at stake.

(A00262 § 3.4(a)(iii) (emphasis in original).)

Although, ***elsewhere*** in the Agreement, Cephalon retained "discretion with respect to all decisions related to the business of the Surviving Corporation[,]" (A00264 § 3.4(c)) this discretion was specifically "subject to" the CRE Clause in Section 3.4(a)(iii). (Op. at 9-10.) This meant that although Cephalon might have had some discretion as to the specifics of the CRE it would need to make to achieve the developmental milestones, Cephalon did not have discretion as to ***whether*** to extend such efforts.

Cephalon's promised future undertakings pursuant to the CRE Clause were of critical importance to Plaintiffs as the future earn-out payments constituted the ***majority*** of consideration that would be paid to the Ception shareholders for the business. (A04591/36:7-14 (Tullman); A04875/921:15-20 (Shah); Op. at 9.) Therefore, Ception negotiated for the Agreement to provide that Cephalon's discretion for future development of RSZ was "subject to" the CRE requirement so as to trigger the earn-out payments. (Op. at 9-10; A00262 § 3.4(a)(iii).) Indeed, Ception turned down a competitive option offer from Wyeth specifically because it

did ***not*** contain any commitment by Wyeth to use CRE to achieve the contemplated $325 million in milestone payments and because Wyeth intended to impose a deadline of January 1, 2018, to achieve those milestones. (A05151; A04587/19:20-20:9 (Tullman); A00092; A00104-05.)

The Ception-Cephalon merger closed on April 5, 2010. (Op. at 10.)

C. Cephalon Terminates Development of RSZ for EoE.

From April 2010 to October 2011, Cephalon controlled development of RSZ for EoE. (Op. at 10, 14.) Cephalon's efforts—such as they were—were to meet only twice with the FDA to discuss development of RSZ for EoE. (Op. at 11, 13; A05157-60; A00328; A00344-400; A00408-16; A00401-15; A00598; A00613-23.)

First, Cephalon requested a meeting with the FDA to attempt to get accelerated approval based on the existing EoE Study. (A05157; Op. at 10-11; A04653/282:18-83:2, 283:5-17 (Wilkins); A00355; A00328-43.) Although it was unlikely that the FDA would grant Cephalon's request for accelerated approval based on the FDA's preliminary comments to Cephalon's meeting request (A00401-07), Cephalon and the FDA met in person on December 14, 2010, for the FDA to provide guidance on a regulatory pathway for EoE. (Op. at 11-13; A05157-58; A04654/287:22-88:17 (Wilkins); A00408-15.)

At the meeting, the FDA provided such guidance, instructing Cephalon it would need to demonstrate a reduction in eosinophils that was concurrent with a statistically significant improvement in patient symptoms, i.e., a clinical endpoint. (A05157; A00402; A00411.) The FDA encouraged Cephalon to conduct a study in older adolescents and adults (as opposed to pediatric patients) and explained that it should choose the clinical endpoint before the initiation of any future Phase 3 study. (A05157-58; A00411.) The FDA also told Cephalon that it remained eager to work

together on further development. (Op. at 13; A05158; A00408-16; A04688/306:8-07:4 (Wilkins); A04924-25/993:9-99:18 (Shah).) Cephalon understood that the FDA meeting was ultimately a positive indicator of the potential regulatory approval of RSZ for EoE. (A05158; A04688/308:19-09:8 (Wilkins); A00417.) But two days after that meeting, Cephalon's CEO, Frank Baldino, who was the driver of the Cephalon-Ception merger, died. (A00462; A05158-59.) Cephalon became an acquisition target. (A04689-91/310:12-20, 317:3-18 (Wilkins); A05158-59.)

On May 4, 2011, Cephalon and the FDA met a second time, this time by telephone (A00613-23), and Cephalon proposed, again, that the same EoE Study population be used for approval. (Op. at 13, A05159-60; A00598.) Cephalon sought to withdraw randomly some patients from the Open Label Extension Study by putting those patients on placebo and seeing if their symptoms worsened. (A05159; A00598.) The FDA rejected this proposal, again encouraging Cephalon to study a more homogenous patient population where all the study participants had a predominant symptom, such as difficulty swallowing, and to use of a different clinical endpoint for symptom improvement. (A005159; Op. at 13; A00617-19; A04690-91/315:20-24, 318:2-17 (Wilkins).) The FDA again outlined a path towards approval, giving Cephalon an "action item" to submit a proposal by analyzing the EoE Study data to better characterize the patient population. (Op. at 13; A05159-60; A00617-18, A00622.) The FDA retained high interest in continuing the

development dialogue with Cephalon. (A05160; A04691/320:19-23 (Wilkins); A04693/325:10-28:22 (Wilkins); A04702/361:8-10 (Wilkins); A00609-10.)

Despite that encouraging FDA meeting, Cephalon suddenly stopped its efforts to obtain regulatory approval of RSZ for EoE. (A05160; A00611-12; A00602-08; A01520-54.) Cephalon never submitted its analysis or its assessment of the potential path forward to the FDA. (A05161; Op. at 14; A00625; A00627.) Cephalon—proceeding toward consummating its forthcoming merger with Teva (A00602-08)—instead documented its developmental progress and a potential path forward but left it to Teva to figure out next steps for RSZ for EoE. (A05159; A00611-12.)

In September 2011, Cephalon told the FDA that it had made an internal business decision to discontinue its "current" development efforts. (A05161; Op. at 14; A00611-12.) As Vice Chancellor Glasscock found, before the Teva-Cephalon merger was consummated "Cephalon had ended the EoE program." (Op. at 15.[5]) On October 14, 2011, Teva acquired Cephalon. (Op. at 14; POPTB at 18; JX_0091; JX_0120.)

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[5] Plaintiffs presented evidence that post-merger, Teva employees believed RSZ for EoE remained a potential opportunity for development. (A05162; A00676-78; A01830/275:2-13 (Rainville); A02804/82:2-10 (Del Ricc); A02845/123:21-24:24 (Del Ricci); A02940/218:16-23 (Del Ricci); A02174/25:7-26:19 (Hayen); A02216-17/67:21-68:5 (Hayen); A02225/76:1-76:11 (Hayen); A02311/162:8-20 (Hayen).) In any event, Plaintiffs were not informed until 2016 that Teva had officially terminated development of RSZ for EoE. (A00720.)

D. Defendants Take No Action to Develop RSZ for EoE Post-Merger and Paper Over Their Inaction.

Remarkably, Defendants had no idea of their post-merger obligation to use CRE to develop RSZ for EoE, despite Cephalon having agreed to the CRE Clause and Teva having assumed the obligation. (A05163, A05176-78; A04631/194:13-95:21 (Fosbury); A04634/208:10-17 (Fosbury); A04922/987:21-88:17 (Shah); A01917/54:1-2 (Shah); A01933-34/70:21-71:3 (Shah); A02221/72:11-14 (Hayen); A02616/58:3-11 (Slusky); A03485/94:4-9 (Holcomb).) Teva's Dr. Tushar Shah, whose group was responsible for RSZ development, admitted that he was not aware of the CRE obligation (A04920/979:5-15 (Shah)) and that he did not understand the CRE Clause. (A04875/921:22-22:5 (Shah); A04920/979:16-80:5 (Shah).) Teva's current CEO and President of North America, Sven Dethlefs, who at the relevant time was Teva's Vice President of Respiratory Global, admitted he had never read the Agreement, and that he believed that Teva had "complete discretion" with respect to RSZ for EoE. (A05177-78; A05068-69/1411:15-1415:20 (Dethlefs).)

Defendants never even analyzed development of RSZ for EoE from the date of the Cephalon-Teva merger until 2017. (Op. at 14-18; A05163-69; A04631/194:13-95:21 (Fosbury); A04634/208:10-17 (Fosbury).) Defendants did not perform a cost-benefit analysis, conduct a regulatory review, or assess whether terminating development was in line with their CRE obligation—including because, as the testimonies of Dr. Shah and Mr. Dethlefs show, they were not even aware the

obligation existed. (A05163-69; A04920/979:5-15 (Shah), A04921/981:1-11 (Shah); A04922/986:16-87:5 (Shah); A05068-69/1411:15-415:20 (Dethlefs).) No budget for the development of RSZ for EoE was established, nor did Defendants expend funds post-Cephalon-Teva merger on a clinical program for development of RSZ for EoE or testing of any clinical endpoints or patient reported outcomes ("PROs"). (A04922/984:14-22 (Shah); A04632-33/198:12-22, 203:19-23 (Fosbury); A01520-1554; A02230, A02332/81:6-81:17, 183:20-84:5 (Hayen).) This remained true despite that, in 2015, Dr. Kurt Brown—a Children's Hospital of Philadelphia-trained pediatric gastroenterologist and Teva executive—concluded that "EoE is now a viable indication to pursue[.]" (A05173-74; A00707; A04638/224:10-25:6 (Wilkins).) Dr. Brown shared his conclusion regarding the viability of RSZ for EoE with another high-ranking Teva executive, Francine Del Ricci, but noted, based on conversations with Dr. Shah, that "a potential $200M EoE milestone payment may be the 'killer' for an EoE program[,]" another conclusion with which Ms. Del Ricci agreed. (A05173-74; A00707; A00708-10; A00711-15; A0744-746; A02899/177:3-8 (Del Ricci).)

In 2016, given promising developments in the market, Plaintiffs asked Defendants about their development of RSZ for EoE. (Op. at 18; A05178-79; A00716-19.) On November 3, 2016, Defendants (through Ms. Del Ricci), for the first time, informed Plaintiff Himawan that they had terminated development of RSZ

for EoE because, consistent with their mistaken view that they had complete discretion, they instead committed their resources elsewhere and not to the development of RSZ for EoE. (Op. at 18-19; A00720.) Indeed, internal emails demonstrated that Defendants did not pursue RSZ for EoE solely because of the milestone payments. (A00707; A00711-15; A05174-76.) In response, Plaintiffs objected and pointed Defendants to their ongoing CRE obligations under the Agreement. (A00737-38.)

After Plaintiffs directed Defendants to the CRE Clause, Defendants engaged a third-party consultant, RxC International ("RxC"), to analyze the feasibility of development of RSZ for EoE. (Op. at 19; A05180; A00722; A00724-25; A00726-32; A02256/107:14-17 (Hayen).) RxC's review was not independent, as highlighted by Defendants directing RxC to meet with Defendants' lawyers before reaching any conclusions. (A05181-82; A00747-64; A00765-70; A03256/105:17-19 (Jayanthi); A03304-08/153:1-57:1 (Jayanthi); A03314-15/163:18-64:1 (Jayanthi); A03318/167:3-69:17 (Jayanthi).) Unsurprisingly, after receiving instructions from Defendants and their lawyers, RxC found no further development of RSZ for EoE was warranted in 2017. (Op. at 19-20; A00778-807; A003323-24/172:25-73:7 (Jayanthi). *But see* A03968-76; A04766, A04800-17/618:9-90:22 (MacFarlane).)

This was despite the fact that Teva had begun to develop a separate biologic, befittingly named "Reslizumab 2," during the same time frame. (A05173-74;

A00634-75.) Reslizumab 2 was the functional equivalent of RSZ, an anti–IL-5, but, unlike RSZ, its future development would have occurred without any associated milestone payments owed to Plaintiffs. (A05173-74; A00634-75.) Moreover, as part of a separate "pipeline analysis" project for Defendants in 2017, RxC ranked RSZ for EoE in an initial draft presentation as one of the highest scoring products for future development. (A05182-83; A00817; A03221/70:3-16 (Jayanthi); A03328/177:1-6 (Jayanthi); A03332/181:16-19, (Jayanthi); A03334-35/183:23-84:8 (Jayanthi).) In a later version of the presentation, Defendants had RxC remove the score and note that anti–IL-5 for EoE was being analyzed as "part of a separate work stream." (A005172; A00818.)

E. Defendants Did Not Expend Efforts and Commitments of a Company with Substantially Similar Resources and Expertise.

At trial, Plaintiffs presented expert evidence through Dr. MacFarlane, a pharmaceutical industry expert, that Defendants did not conduct any of the typical and basic development efforts for RSZ for EoE beyond 2011, including meeting with opinion leaders, creating a target product profile, developing a clinical development plan, conducting market research, analyzing the competitive landscape, conducting a pricing analysis, or developing a regulatory strategy. (A05201; A03949 (Table 8).) Yet, Defendants clearly understood the importance of such activities, given that they had undertaken them for RSZ for ***EA***, but never undertook such activities for

EoE despite the independent contractual obligation with respect to EoE. (A05201; A03946-47 at n.148-53, 156-161; A04750-51/556:12-57:21 (MacFarlane).)

Defendants' failure to put forth ***any*** development effort is underscored by the fact that other companies forged ahead with typical development efforts for drugs for the treatment of EoE, despite the initial challenges with finding an acceptable clinical endpoint for EoE studies. (A05185-86; A02093/230:2-13 (Shah); A03659/46:8-12 (Van Markus).) Defendants were repeatedly updated of efforts other companies were undertaking for EoE products. (A05169-70; A04595/52:1-7 (Tullman); A04633/202:11-03:5 (Fosbury); A00688; A00733-36; A00740; A00771-73.)

Even after RxC's purportedly unfavorable evaluation of RSZ for EoE in 2017, multiple Teva employees themselves recognized that Defendants might pursue development of RSZ for EoE in light of regulatory developments and new data from the study of long-term RSZ use by EoE patients after nine years. (A05183-84; A00886-906; A00907-08; *see also* A04928 /1008:24-11:21 (Shah).) Meritage (now Takeda), Celgene (now Bristol Myers Squibb), GSK, and AstraZeneca all continued to develop EoE products, even though their respective drug candidates missed clinical endpoints. (A05185-86; A05210-237; A05261-63; A05238-59; A05310-20; A05336-46; A05347-58; A03909-4048.) Sanofi-Regeneron tested at least four different clinical endpoints between 2010 and 2014, and its biologic targeting EoE,

Dupixent, was approved by the FDA in May 2022. (A05184-85; A04049-50; A04573-82; A02093/230:2-13 (Shah).); A03659 /46:8-12 (Van Markus).) And yet, Defendants did nothing to develop RSZ for EoE after 2011. (A04928/1008:24-11:21 (Shah).)

The development efforts of those other companies constitute additional evidence contradicting any purported claim by Defendants (and the findings of the trial court) that efforts to develop RSZ for EoE were somehow impossible or unworkable. Further, while every other company pursed ***multiple*** indications for their product simultaneously—i.e., as a potential treatment for both EoE and EA—Defendants pursued only one indication, EA. (A04474 Fig. 6.) This evidence directly relates to the CRE Clause's requirement that Defendants use "such efforts and commitment of such resources [by Defendants] of a company with substantially the same resources and expertise." (A00262 § 3.4(a)(iii).) Defendants would have been obligated to undertake such efforts even in the absence of any comparable companies doing so. But the fact that such other companies ***did undertake such efforts*** only serves to underscore Defendants' breach of the Agreement.

ARGUMENT

I. THE TRIAL COURT ERRED WHEN IT MISCONSTRUED THE CRE CLAUSE TO PROTECT THE SELLER ONLY AGAINST "ACTIONS OF THE BUYER THAT WOULD BE AGAINST THE BUYER'S SELF-INTEREST."

A. Question Presented.

Did the trial court err when it misinterpreted multiple aspects of the Agreement to lower the level of effort required by the CRE Clause, from requiring CRE as measured against what other companies with substantially similar resources and expertise would do to develop RSZ for EOE, to only require a subjective, good faith showing by Defendants? (Op. at 29-39.)

B. Scope of Review.

Questions of contract interpretation are reviewed *de novo*. *Sunline Comm. Carriers, Inc. v. CITGO Petrol. Corp.*, 206 A.3d 836, 845 (Del. 2019).

C. Merits of Argument.

Section 3.4(a)(iii) of the Agreement required that Defendants use CRE "to develop and commercialize (or cause the development and commercialization of) [RSZ] so as to achieve the Developmental Milestones." (A00262.) CRE is defined therein by reference to an objective benchmark. Defendants were contractually required to "exercise . . . such efforts and commit[] . . . such resources" of "a company with substantially the same resources and expertise" as Defendants. (*Id.*)

Plaintiffs bargained for the protection of the CRE Clause to ensure that Defendants would expend time, effort, and resources so Plaintiffs would receive the benefit of substantial milestone payments that were part of their deferred compensation. Plaintiffs-sellers did not leave the question of development of RSZ for EoE to the discretion of Defendants-buyers.

The Opinion made four legal errors in its interpretation of the Agreement that transformed this seller-friendly, objective CRE Clause, to a buyer-friendly, subjective good-faith clause. The trial court's conclusion was contrary to the language of the Agreement.

First, the trial court transformed Section 3.4(a)(iii) from a CRE Clause to only require a showing that "a reasonable actor faced with the same restraints and risks would go forward ***in its own self-interest***." (Op. at 30-31.) This turned the CRE

Clause, which was how Plaintiffs-sellers ensured real efforts would be undertaken to achieve the milestones, on its head.

Second, the trial court relied on unrelated references in the Agreement to Defendants' "discretion" as justification for Defendants to "eschew development" of RSZ. (Op. at 30.) Although the Agreement stated that Defendants "shall have complete discretion with respect to all decisions related to the business of the Surviving Corporation and its subsidiaries, including decisions relating to the research, development, manufacture, marketing, pricing and distribution of [RSZ] . . ." that discretion was "[s]ubject to" the CRE Clause. (A00264 § 3.4(c).) Thus, Defendants ***did not have discretion*** to eschew development of RSZ for EoE because Defendants were required to use CRE to develop RSZ for EoE. Defendants had discretion as to ***how*** they must go about developing RSZ for EoE, subject to the requirement to use CRE, not ***whether*** they must pursue development.

Third, the trial court misconstrued the Agreement by finding that Cephalon acted reasonably when it terminated development of the drug at issue after only eighteen months from the execution of the Agreement, and without any meaningful efforts having been undertaken. (Op. at 38.) But, under the terms of the Agreement, Defendants' CRE obligations had no expiration date. The evidence showed that Defendants did nothing for more than six years.

Fourth, the trial court erred when it found the CRE Clause "unworkable" because "no exemplar companies operate under the actual conditions of Defendants." (Op. at 29.) The trial court provided no reason why it should disregard the plain meaning of the Agreement because it found the CRE Clause "unworkable."

The reference in the Agreement to "other companies" simply further defined the types of efforts Defendants were contractually required to undertake by requiring those efforts to be made given the expertise and resources of similar companies. It was not a requirement that Plaintiffs point to ***actual*** efforts of ***actual*** companies to show Defendants failed to use CRE to develop RSZ for EoE. Even so, Plaintiffs did present expert testimony explaining what companies with substantially similar resources and expertise typically do to develop a pharmaceutical product. As if that evidence were not enough, Plaintiffs identified other, similarly-sized companies that sought to develop and commercialize a biologic to treat EoE, and that evidence showed that Defendants' efforts paled in comparison. The trial court, instead, interpreted the Agreement "to impose the CRE requirement on the buyer, ***as it found itself situated***," thus eliminating the external benchmark from the CRE Clause. (Op. at 29.) Defendants, when compared against themselves, did everything they expected to do regarding RSZ for EoE—nothing.

These errors transformed a seller-friendly CRE requirement into a buyer-friendly, good-faith efforts clause. The trial court erred when it held Defendants'

conduct to that standard; if held to the actual contractual terms, Defendants' efforts fell far short of any objective benchmark.

1. The trial court transformed the CRE Clause into a subjective good faith requirement.

The CRE Clause required Defendants to use CRE, which means "the exercise of such efforts and commitments of such resources by a company with substantially the same resources and expertise . . . with due regard to the nature of efforts and cost required for the undertaking at stake." (A00262 § 3.4(a)(iii).)

Such a CRE provision has been understood by courts and commentators to impose an "objective standard" to determine whether the buyer used commercially reasonable efforts in its pursuit of development and commercialization. *See, e.g.*, *Neurvana Med., LLC v. Balt USA, LLC*, 2020 WL 949917, at *16 (Del. Ch. Feb. 27, 2020) ("These provisions are viewed as seller-friendly, as they allow the seller, when attempting to plead or prove that the buyer has breached its obligations, to point to an objective metric—comparable industry standards—rather than the buyer's subjective intent or state of mind."); *Menn v. ConMed Corp.*, 2022 WL 2387802, at *34 (Del. Ch. June 30, 2022) ("Often, transactional designers will define benchmarks for the [CRE] standard relevant to the efforts clause within the governing agreement."); Charles Thau, *Is This Really The Best We Can Do? American Courts' Irrational Efforts Clause Jurisprudence and How We Can Start to Fix It*, 109 Geo. L.J. 665, 701, n.223 (2021) ("[I]t may be particularly important

for a party who wishes to use a "[CRE]" provision to anchor its commitment to objective guidelines."). The "objective" benchmark is created by referencing "prevailing trade practice among reputable and responsible business and commercial enterprises engaged in the same or similar businesses." *Menn*, 2022 WL 2387802, at *29 (quoting *Hicklin v. Onyx Acceptance Corp.*, 970 A.2d 244, 250 (Del. 2009)).

The trial court had initially recognized the "objective" nature of this provision in denying Defendants' motion to dismiss. (MTD Op. at 23.) Instead of concluding that the development of RSZ for EoE was a matter solely left to Defendants' discretion, it found that "'[c]ommercially reasonable efforts,' as defined by the Agreement, is an objective standard . . . . The Agreement set a ***contractual standard*** by which to evaluate whether Cephalon's failure to achieve and pay these Milestone payments was improper." (*Id*.)

However, the trial court, post-trial, improperly interpreted the Agreement to require from Defendants nothing more than good faith, citing extensively to this Court's decision in *ev3, Inc. v. Lesh*, 114 A.3d 527 (Del. 2014). However, unlike here, *Lesh* involved only a ***subjective, good faith*** clause. In *Lesh*, the Court interpreted an agreement that provided, "***Notwithstanding any other provision in the Agreement to the contrary***, from and after the closing, [ev3's] obligation to provide funding for the Surviving Corporation, ***including without limitation funding to pursue achievement of any of the Milestones***, shall be at [ev3's] ***sole***

discretion, to be exercised in good faith." *Id.* at 533 (emphasis in original). Based on ***entirely different language***, the Court concluded that "it could be bad faith if the expected profits to ev3 were commercially reasonable and ev3 nonetheless acted to delay accomplishment of the milestones so as to shift additional profits its way at the expense of the former Appriva shareholders." *Id.* at 541.

The trial court improperly "adopt[ed] . . . the reasoning of [*Lesh*], with the caveat that the provision in question there required subjective good faith, as opposed, [to] here, [] objectively reasonable efforts." (Op. at 32.) But that "caveat" left a massive gulf in logic that the trial court never bridged. Instead, the trial court simply used *Lesh* to transform Section 3.4(a)(iii), which required CRE to be measured objectively (as the trial court itself recognized), into a mere good faith clause by only requiring that "if a reasonable actor . . . faced with the same restraints and risks would go forward ***in its own self-interest***, the buyer is contractually obligated to do the same." (Op. at 30-31.) It then effectively doubled-down on this interpretation when it rejected Plaintiffs' argument that such an interpretation "gives sellers little protection, since it is invoked only to disallow actions of the buyer that would be against the buyer's self-interest." Instead, the trial court concluded that its reading of the CRE Clause gives Plaintiffs "***all that the sellers bargained for***." (Op. at 33.)

However, this Court's precedent makes clear the significant difference between a good faith clause and a CRE provision, which requires, in addition, "an

affirmative obligation . . . to take all reasonable steps" pursuant to the terms of the Agreement. *Williams Co., Inc. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 273 (Del. 2017); *see also Hicklin*, 970 A.2d at 252 ("A secured party's failure to act in good faith may evidence a lack of commercial reasonableness, but the converse is not necessarily true. That is, a showing of good faith . . . without more, cannot establish . . . commercial reasonableness . . . ."). Defendants' failure to take "all [such] reasonable steps" was manifest here but ignored by the trial court because it applied the wrong legal standard to Defendants' obligations.

Based on the lesser, subjective good faith standard, the trial court concluded that Defendants met the requirements of Section 3.4(a)(iii). (Op. at 34-40.) Because the trial court misinterpreted the terms of the Agreement, and applied a different and less seller-friendly standard than called for in the Agreement, this Court should remand with instructions to review the evidence under the appropriate, objective CRE standard.

2. The trial court gave Defendants broad discretion to "eschew development" of RSZ, to which Defendants were not entitled to under Section 3.4(a)(iii).

The trial court also minimized Defendants' contractual burden to develop and commercialize RSZ by misinterpreting two portions of the Agreement as granting Defendants additional "discretion" to "eschew development" of RSZ for EoE. (Op. at 30.)

First, the trial court cited Section 3.4(c) of the Agreement, which granted Defendants "complete discretion with respect to all decisions related to the business of the Surviving Corporation and its subsidiaries, including decisions relating to the research development, manufacture, marketing, pricing and distribution of [RSZ] . . ." (A00264.) The trial court mistakenly determined:

> [T]he full language of the [ ] Agreement here stresses the complete discretion of the buyer ***to develop, or not***, the assets purchased. Limiting that discretion to require objective commercial reasonableness, given the facts as they exist, only means, in my view, that Defendants may not avoid the earn-outs in in a way that is commercially unreasonable.

(Op. at 30.) It further concluded that Defendants "ha[ve] complete discretion over development, cabined only by CRE." (*Id.* at 30, n.166.)

But the trial court misinterpreted this provision of the Agreement. By its terms, Section 3.4(c)'s grant of "complete discretion" was "subject to" Section 3.4(a)(iii), i.e., the CRE Clause. (*Id*.) When one provision of an agreement is

"subject to" another provision, the latter provision trumps the former. (A00262 § 3.4(a)(iii).) *See, e.g.*, *Penn Mut. Life Ins. Co. v. Oglesby*, 695 A.2d 1146, 1150 (Del. 1997) ("But this general coverage provision is expressly made 'subject to all provisions of this policy.' Therefore, any other provision of the policy that may be inconsistent with this 'first manifest' provision can sublimate-or 'trump'-the first manifest provision."); *United Rentals, Inc. v. RAM Holdings, Inc.*, 937 A.2d 810, 833 (Del. Ch. 2007) ("[T]he contracting parties here chose terms, such as 'subject to,' that impose a hierarchy among provisions.").

Because Section 3.4(c) was "subject to" Section 3.4(a)(iii), Defendants had ***no discretion*** when it came to the decision of ***whether*** to undertake CRE to develop RSZ for EoE (that is "to develop, or not"). (A00262 § 3.4(a)(iii); A00264 § 3.4(c).) Instead, they were ***required*** to use "[CRE] to develop and commercialize (or cause the development and commercialization of) [RSZ] so as to achieve the Developmental Milestones," as defined by Section 3.4(a)(iii). (A00262 § 3.4(a)(iii).) Their discretion was strictly limited to the specific ***means*** by which to do that, i.e., ***how*** such "commercially reasonable efforts" would be undertaken. But even that discretion was restricted, with those "efforts" being measured against the efforts companies with "substantially the same resources and expertise" as Defendants might themselves have undertaken.

Second, the trial court misemphasized the final clause in Section 3.4(a)(iii), which permits consideration of Defendants' CRE "with due regard to the nature of efforts and cost required for the undertaking at stake." (A00262 § 3.4(a)(iii).) The trial court incorrectly determined that "'[d]ue regard' for the 'efforts and costs' meant that Defendants could simply fail to undertake efforts to develop RSZ for EoE where the circumstances reasonably indicate, as a business decision," other "compan[ies] with substantially the same resources and expertise" "would not go forward." (Op. at 30.) This was a wholesale re-writing of the CRE Clause. The trial court excused Defendants from exercising CRE if another company—including one not under a contractual obligation to exercise CRE—could reasonably choose not to go forward.

Specifically, the fact that Defendants could pay "due regard" to "efforts and costs" in their development and commercialization of RSZ, could not serve as a license for Defendants not to use CRE ***at all***, as was the case here. (A00262 § 3.4(a)(iii).) But this would write the CRE requirement out of the Agreement. Instead, "due regard to efforts and costs" simply modifies the extent of "efforts" and the extent of "commitment" of resources Defendants must undertake, as measured against "a company with substantially the same resources and expertise." (A00262 § 3.4(a)(iii).) It does not allow Defendants to refuse to take those efforts and commitments ***at all***.

Here, the evidence showed that they did not make ***any*** efforts, commit any resources, and never paid "due regard" to the efforts and costs that may be involved in developing and commercializing RSZ. (*Supra*, Facts, Section D.) Other than two meetings with the FDA, one of which was a telephone call, and with promising communications from the FDA about the possible development of RSZ for EoE, Cephalon simply made no further effort to pursue RSZ for EoE. (*Supra*, Facts, Section C-D.) Similarly, Defendants did not initiate any clinical trials for the purpose of obtaining FDA approval of RSZ for EoE, nor did they even design any additional clinical trials. (A01529-30, A01541-42; *supra*, Facts, Section D.).) Defendants never had a clinical development program for RSZ for EoE, never attempted to test any PROs, and never budgeted for the clinical development of RSZ for EoE. (A04632/198:12-22 (Fosbury); A04633/203:19-23 (Fosbury); *supra*, Facts, Section D.) The trial court afforded Defendants far more discretion than they were entitled to and permitted them to "eschew development" a mere eighteen months after the Agreement was executed, and to spend virtually no time or money on development of RSZ for six years. This Court should remand with instructions to review the evidence in light of the fact that Defendants were contractually required to exercise efforts and to commit resources, and could not simply "eschew development" at their discretion.

3. The trial court allowed Defendants to terminate development of RSZ despite a continuing contractual obligation to exercise CRE.

The trial court erred when it effectively imposed a time limit on Defendants' obligation to use CRE to develop RSZ for EoE. Here, the CRE Clause was not time-limited. By its terms, the Agreement did not permit Defendants to cease developing RSZ for EoE upon the occurrence of a defined event or date certain. Thus, under Delaware law, the Agreement required Defendants to put forth "persistent efforts for the entire . . . contractual period." *S'holder Representative Servs., LLC v. Alexion Pharm., Inc.*, 2021 WL 3925937, at *6 (Del. Ch. Sep. 1, 2021). Defendants did not—as Vice Chancellor Glascock found, "Cephalon had ended the EoE program," eighteen months after it acquired RSZ. (Op. at 15.)

In *Alexion*, the defendant argued that a breach of contract claim for failure to use CRE was not ripe because there was still sufficient time for defendant to achieve the milestones at issue. *Alexion*, 2021 WL 3925937, at *6 ("[Defendant] argues that it can catch up and achieve the Milestone Events despite any lapse in its efforts."). In rejecting this argument, the Court of Chancery distinguished defendant's "obligations to pay upon certain results" from "its obligations to pursue those results with a certain amount of diligence" for the contractual period (seven years under the applicable contract). *Id.* The Court of Chancery held that "[w]hen [defendant] failed to put forward those [persistent] efforts, it breached" the CRE provision. *Id.*

Here, the trial court effectively let Defendants "off the hook," despite having found that "termination [of development] occurred before Teva acquired Cephalon" and that "Teva did not restart the program." (Op. at 38, n.183.) Moreover, it recognized that Defendants failed to take any action for six years, from 2011 through 2017:

> Defendants failed to (1) conduct a 'rigorous or analytical review'; (2) continue or restart development; (3) budget for or expend any funds on development; (4) monitor developments or activities of competitors; (5) regularly assess viability of all potential indications annually; and (6) consider Ception stockholders' and experts' inquiries. But the burden is on Plaintiffs to demonstrate that these failures are commercially unreasonable; otherwise, such inaction was within Defendants' complete discretion with respect to RSZ.

(Op. at 39-40.)

By permitting Defendants to not act in the face of a contractual obligation requiring specific action, the Court undercut the CRE obligation as a ***continuing*** obligation.

4. The trial court failed to measure Defendants' efforts and commitments against a company with substantially similar resources and expertise.

The CRE Clause imposed upon Defendants an obligation to undertake the same type of "efforts and commitments" to develop RSZ for EoE that a company with "substantially the same resources and expertise" would make to achieve the milestones. (A00262 § 3.4(a)(iii).) This was an objective metric requiring that the Court compare Defendants' "efforts" against "prevailing trade practice" among companies engaged in similar business, *Menn*, 2022 WL 2387802, at *29, and to "comparable industry standards." *Nuervana*, 2020 WL 949917, at *16.

Defendants' lack of efforts fell well below that benchmark. Plaintiffs' expert Dr. MacFarlane testified that Defendants did not conduct any of the basic development efforts common in the pharmaceutical industry for RSZ for EoE beyond 2011. (A05201; A03949, Table 8).)

Above and beyond that, the trial court was presented here with actual evidence regarding the conduct of Defendants' competitors "with substantially the same resources and expertise", who surged ahead and devoted resources to the development of EoE treatments and progression of their clinical programs, while Defendants sat on their hands. (A03948-51; *supra*, Facts, Sections D-E.)

For example, Plaintiffs presented evidence that Sanofi-Regeneron developed and commercialized Dupixent, a biologic for treating EoE. Dupixent, like RSZ,

received mixed results in its initial Phase 2 study for EoE. (A05264-309; A05205; *supra*, Facts, Section D.) However, unlike Defendants, Sanofi-Regeneron then conducted a three-part Phase 3 trial in adult and adolescent EoE patients. (A05321-35; A05205; *supra*, Facts, Section D.) Sanofi-Regeneron's design of this study followed the same advice that the FDA provided to Defendants ***back in 2010 and 2011***. (A03956-66; A05205; *compare supra*, Facts, Section D *with* Section C.) Sanofi-Regeneron's experience demonstrates how other pharmaceutical companies react to setbacks. Not only should Defendants have followed the path identified by the FDA, but they were contractually required to do so.

The trial court failed to assess the evidence presented at trial and did not attempt to determine whether Defendants made such efforts and committed such resources as a company with substantially similar resources and expertise would have. Instead, the trial court

> [Foun]d this method unworkable; no exemplar companies operate under the actual conditions of Defendants, who, I note, are also different from one another as to their circumstances. I find that the best interpretation of the contract is that the parties meant to impose the CRE requirement on the buyer, as it found itself situated, but that the requirement went beyond buyer's subjective good faith.

(Op. at 29.)

The trial court's interpretation was contrary to the Agreement, which required it to measure Defendants' efforts against what a similar company "with substantially

the same resources and expertise" as Defendants would be capable of doing or, as here, what such companies ***were doing***. (A00262 § 3.4(a)(iii).) By referring to how Defendants found ***themselves*** situated, the trial court wrote the objective requirement out of the Agreement. It did so on the mistaken belief that it had to find "***exemplar*** companies" that "operate under the ***actual*** conditions" of Defendants. (Op. at 29.) That is wrong. The trial court needed only to identify the basic development efforts and activities similar companies undertake when developing a pharmaceutical product. Here, Defendants did ***none of them***. (*Supra*, Facts, Section D.)

Moreover, as if the evidence of what steps companies typically undertake were not enough, in this case Plaintiffs presented evidence of what companies ***did*** to pursue a treatment for EOE. (*Supra*, Facts, Section E.) Defendants, by contrast, essentially undertook ***no*** efforts, believing themselves to have, incorrectly, complete discretion over whether they would develop RSZ for EoE, with ample testimony that Defendants may not have even been aware of—much less complied with—the CRE Clause. (*Supra*, Facts, Section D.)

II. THE TRIAL COURT ERRED BY IGNORING THIS COURT'S PRECEDENT IN MERGER CONSUMMATION CASES THAT INVOLVE EFFORTS CLAUSES.

A. Question Presented.

Did the trial court err when it sought to make a distinction between the meaning of CRE in the merger consummation context from its meaning in the earn-out context, and thereby failed to apply binding precedent relating to efforts clauses under Delaware law to the provision at issue in this case? (Op. at 23, 29-31 & n.166.)

B. Scope of Review.

The trial court's "formulation and application of legal principles" is reviewed *de novo*. *Gannett Co., Inc. v. Bd. of Managers of the Del. Crim. Justice Info. Sys.*, 840 A.2d 1232, 1239 (Del. 2003).

C. Merits of Argument.

When a party commits to a CRE provision subject to Delaware law,[6] that party undertakes an "***affirmative obligation***" to act. *Williams*, 159 A.3d at 267. This "affirmative obligation" ***requires*** the promising party "***to take all reasonable steps to solve problems***" encountered when fulfilling the associated promise ***and to*** "***consummate***" ***the contractual promise***. *Id.* at 272. Delaware courts have applied these principles in all sorts of commercial cases in which the parties have agreed to a CRE provision. *Williams* involved an efforts provision to consummate a merger, while others such as *Menn*, as here, arose in the context of earn-out payments for development milestones. Decisions authored by this Court and the trial court—except the Vice Chancellor's decision here—interpret a CRE or similar efforts clauses as imposing ***affirmative obligations to act***. (A05189.)

Here, the trial court erred by refusing to apply *Williams* and its progeny to interpret the CRE Clause. (Op. at 29, n.166.[7]) Instead, the trial court embarked upon a novel detour by concluding, without foundation, that the legal principles found in

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[6] Plaintiffs also argued that Delaware courts generally interpret the various types of efforts clauses—such as "best efforts," "reasonable best efforts," and "commercially reasonable efforts" to mean the same thing. (A05188.) Defendants did not dispute this point of law below nor did the trial court hold otherwise in its Opinion.

[7] Notably, the Opinion inexplicably gives short shrift to *Menn*, which applies Delaware's "affirmative obligation" and "all reasonable steps" standard to an efforts clause in the earn-out context.

merger consummation cases were not "particularly helpful" in an earn-out case simply because consummating a merger concerns one's non-discretionary contractual obligation to close a deal rather than one's apparently "discretionary" obligation to satisfy any other type of contractual promise. (Op. at 29-30.) Effectively, the trial court relied on a distinction that represented no real difference in law or logic. The Opinion fails to offer any rigorous analysis or legal support for turning Delaware efforts law on its head.

Significantly, in *Williams*, this Court addressed a CRE clause that "required the parties to use '[CRE] to obtain a 721 opinion" and "'reasonable efforts' to consummate" a merger. 159 A.3d at 267. When one party, ETE, failed to live up to its contractual obligations, the other party, Williams, sued. *Id.* The Court of Chancery in *Williams* imposed "only a negative duty not to thwart or obstruct performance of the [a]greement, rather than an affirmative duty to help ensure performance." *Id.* at 272. This Court disagreed. It held that the language of the agreement "not only prohibited the parties from preventing the merger, but ***obligated the parties to take all reasonable actions to complete the merger***" and "***placed an affirmative obligation on the parties to take all reasonable steps*** to obtain the 721 opinion and ***otherwise complete the transaction***." *Id.* at 273.

Delaware Courts have relied upon *Williams* in their interpretation of CRE clauses, in a variety of different contexts, ***including the earn-out context***. In *Menn*, for example, the Court of Chancery held that:

> The "commercially best efforts" provision is what is known as an "efforts" clause. Efforts clauses generally replace "the rule of strict liability for contractual non-performance that otherwise governs" with "***obligations to take all reasonable steps to solve problems and consummate the*** " ***contractual promise***. Efforts clauses "define the level of effort that the party must deploy to attempt to achieve the outcome."

2022 WL 2387802, at *34 (internal citations omitted). Throughout *Menn*, the Court of Chancery cited to and relied upon both merger consummation and non–merger consummation cases in defining the level of effort necessary to satisfy a CRE provision. *See S'holder Representative Servs. LLV v. Shire US Hldgs., Inc.*, 2020 WL 6018738 (Del. Ch. Oct. 12, 2020) (non–merger consummation case cited in *Menn* at n. 329, 331); *Channel MedSystems, Inc. v. Bos. Sci. Corp.*, 2019 WL 6896462 (Del. Ch. Dec. 18, 2019) (merger consummation case cited at n.331); *Hicklin*, 970 A.2d at 250 (non–merger consummation context cited at n.375); *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347 (Del. Ch. Oct. 1, 2018) (merger consummation case cited at n.375); *Williams*, 159 A.3d at 272. Other Delaware courts have done the same. *See Neurvana*, 2020 WL 949917, at *15, n.123-28 (earn-out case relying upon, *inter alia*, *Williams* and *Akorn*); *Zenith Energy Terminals Joliet Holdings, LLC v. CenterPoint Props. Trust*, 2023 WL 615997, at *11 (Del.

Super. Jan. 23, 2023) (quoting *Williams* and *AB Stable VIII LLC v. Maps Hotels & Resorts One LLC*, 2020 WL 7024929, at *91 (Del. Ch. Nov. 30, 2020)).

Recently, Vice Chancellor Cook in *Chordia v. Lee* explained that Delaware courts read the various types of efforts clauses as all "having the same general meaning[,]" and interpret them to impose upon the promising party an "affirmative obligation" to "'take all reasonable steps to solve problems and consummate the' contractual promise." 2024 WL 49850, at *24 (Del. Ch. Jan. 4, 2024) (quoting *Menn*, 2022 WL 2387802, at *34 (an earn-out CRE case) and citing *Akorn*, 2018 WL 4719347, at *86–87 (a merger-consummation "reasonable efforts" case).) In footnotes 280-286 of the *Chordia* decision, Vice Chancellor Cook cites a litany of Delaware law, both ***merger consummation*** and, importantly, ***earn-out cases*** alike, and secondary sources to support the proper interpretation of Delaware efforts law that the trial court ignored here, all of which impose an affirmative obligation to take all reasonable steps to make good on a promise so that parties may "enjoy the benefits" of what was negotiated for in the contract. *Chordia*, 2024 WL 49850, at *24-25 & n.280-85.

Here, the trial court provided no compelling explanation for its departure from this well-established precedent. Nor did it explain why an efforts clause in the merger consummation context should be seen as imposing real and objective obligations but an efforts clause, as here, in the earn-out context, should be

interpreted as imposing no real obligation. At best, the trial court hypothesized in a footnote that the policy of "discretion" in the merger consummation context is different than the discretion afforded to Defendants under the Agreement here. (Op. at n.166.) However, as discussed *supra* I.C.2, Defendants ***had no discretion*** when it came to the decision whether to undertake CRE to develop and commercialize RSZ for EoE, as their efforts were subject to the CRE Clause and not the general discretion clause (Section 3.4(c)) which, at most, applied to the ***manner*** as to which such efforts might be undertaken. Even so, the reason parties enter into CRE clauses ***in any context*** is the same: To ***limit*** a party's discretion to act in its own self-interest.

For these reasons, this Court should remand the case with instructions to analyze Defendants' conduct related to its CRE obligation under Delaware's "affirmative obligation" and "all reasonable steps" standard, not a standard in which a party is only required to not act against its own self-interest.

III. THE TRIAL COURT ERRED IN DISMISSING PLAINTIFFS' BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING CLAIM.

A. Question Presented.

Did the trial court err when, at the motion to dismiss stage, it dismissed Plaintiffs' claim for breach of the implied covenant of good faith and fair dealing because there was no gap identified in the Agreement and ignored that Defendants' arbitrary and unreasonable exercise of their limited discretion under the CRE Clause could nevertheless result in a breach of the implied covenant of good faith and fair dealing? (MTD Op. at 22-25.)

B. Scope of Review.

The grant of a motion to dismiss is reviewed *de novo*. *Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Holdings LLC*, 27 A.3d 531, 535 (Del. 2011).

C. Merits of Argument.

"To sufficiently plead a breach of the implied covenant of good faith and fair dealing, a complaint must allege a specific implied contractual obligation, a breach of that obligation by the defendant, and resulting damage to the plaintiff." *Baldwin v. New Wood Res. LLC*, 283 A.3d 1099, 1117-18 (Del. 2022) (citation and internal quotations omitted). Plaintiffs alleged a specific implied contractual obligation that Defendants could not refuse to develop and commercialize RSZ for EoE in an unreasonable and arbitrary manner designed to purposely and intentionally avoid making the milestone payments to Plaintiffs. (A00944 ¶ 130; A01181.) The trial court nevertheless dismissed Plaintiffs' claim, finding the CRE Clause governed Defendants' conduct and thus there was no gap in the agreement to be filled by the implied covenant. (MTD Op. at 23.) But this was an error of law.

Under Delaware law, "the implied covenant is implicated when a party 'is given discretion to act as to a certain subject and it is argued that the discretion has been used in a way that is impliedly proscribed by the contract's express terms.'" *Osios LLC v. Tiptree, Inc.*, 2024 WL 2947854, at *5 (Del. Ch. June 12, 2024). A party may not engage in "arbitrary or unreasonable conduct which has the effect of preventing the other party from receiving the fruits of its bargain." *Gerber v. Enter. Prod. Holdings, LLC*, 67 A.3d 400, 419 (Del. 2013), *overruled on other grounds by Winshall v. Viacom Int'l, Inc.,* 76 A.3d 808 (Del. 2013). Even where a "contract

may identify factors that the decision-maker can consider, and it may provide a contractual standard for evaluating the decision[,]" the implied covenant can still be implicated if a party exercises discretion under that contractual standard unreasonably. *Id.* The relevant test to invoke the implied covenant "is whether it is clear ***from what was expressly agreed upon*** that the parties meant to prohibit the conduct at issue." *Allied Cap. Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1033 n.24 (Del. Ch. 2006) (emphasis in original).

Here, the CRE Clause was a contractual standard that limited Defendants' discretion with respect to development of RSZ for EoE. Defendants were afforded discretion as to ***how*** to exercise CRE—not whether to exercise CRE—and the implied covenant mandates that Defendants' discretion under that contractual standard must be exercised in a non-arbitrary, reasonable manner.

Plaintiffs adequately pled a claim for breach of the implied covenant by alleging in their complaint that Defendants did not exercise efforts to develop RSZ for EoE at all because of, and to avoid paying, the milestone payment to Plaintiffs, i.e., the fruit of Plaintiffs' bargain. (A00944 ¶ 130.) Moreover, at trial, Plaintiffs presented evidence that Defendants refused to put forth any effort into developing RSZ for EoE, even after determining that the indication was scientifically viable, solely because of the fact that the milestone payment would be due to Plaintiffs if Defendants were successful in their development efforts. (*Supra*, Facts, Section D;

A0707; A00711-15.) Defendants argued in response that they were permitted to consider "cost" of the development undertaking in assessing CRE. But Defendants never conducted a cost analysis, formulated a budget, or considered any cost, other than the amount of the milestone payment, in refusing to develop RSZ for EoE. (*Supra*, Facts, Section D.)

However, the Agreement's express terms impliedly proscribed Defendants' use of the milestone payment as justification for not exerting efforts at all to achieve the milestones because the Agreement stated that Defendants must use CRE "so as to achieve the milestones." (A00262 § 3.4(a)(iii).) To allow Defendants to not exert efforts ***at all*** to achieve the milestones, claiming the amount of the very milestone payments as the sole justification, would completely frustrate Plaintiffs' fruits of the bargain. (*Supra*, Facts, Section D; A00707.) Plaintiffs, at the time of contracting, would never have agreed to allow Defendants to point later solely to the amount of the milestone payments as a reason to ***not*** undertake CRE at all to achieve the milestones. Indeed, the bargain Plaintiffs struck with Cephalon was to defer a portion of up-front compensation in favor of "earn-outs" hopefully to be achieved based on Defendants agreement to exercise CRE to do so. (*Supra*, Facts, Section B.) Therefore, in no event could Defendants have relied on the amount of the milestone payments as a reason not to develop RSZ for EoE.

The trial court erred by dismissing Plaintiffs' implied covenant claim when it should have been used to protect the reasonable expectations of the parties with respect to Defendants' exercise of discretion under the CRE Clause. *Baldwin*, 283 A.3d at 1116. The trial court's error is further highlighted by the fact that, post-trial, Vice Chancellor Glasscock found the CRE Clause to be "unworkable." (Op. at 29.) This Court should reverse the trial court's dismissal of the implied covenant claim and remand for further proceedings.

CONCLUSION

Plaintiffs respectfully request the Court reverse the trial court's decision and enter judgment in favor of Plaintiffs or, in the alternative, remand with instructions to review the evidence presented pursuant to the objective, CRE Clause, which required Defendants to take "all reasonable steps necessary" to commercialize and develop RSZ, as compared to companies with substantially similar resources and expertise. In addition, Plaintiffs respectfully request a new trial as to its implied covenant of good faith and fair dealing claim.

Dated: July 25, 2024.

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/s/ Richard L. Renck

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EXHIBIT A

EFiled: Dec 28 2018 10:36AM EST
Transaction ID 62804493
Case No. 2018-0075-SG

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

JEFF HIMAWAN, JOSH TARGOFF and STEPHEN TULLMAN, as the duly-appointed Representatives of the former stockholders of CEPTION THERAPEUTICS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 2018-0075-SG
CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS USA, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION

Date Submitted: September 21, 2018
Date Decided: December 28, 2018

Richard L. Renck and Oderah C. Nwaeze, of DUANE MORRIS LLP, Wilmington, Delaware; OF COUNSEL: John J. Soroko, Wayne A. Mack, Jessica Priselac, and Joseph J. Pangaro, of DUANE MORRIS LLP, Philadelphia, Pennsylvania, *Attorneys for the Plaintiffs*.

Kevin Shannon and J. Matthew Belger, of POTTER ANDERSON & CORROON LLP, Wilmington, Delaware; OF COUNSEL: Jay P. Lefkowitz, Matthew Solum, Shireen A. Barday, Amanda B. Elbogen, and Z. Payvand Ahdout, of KIRKLAND & ELLIS LLP, New York, New York, *Attorneys for the Defendants*.

GLASSCOCK, Vice Chancellor

An antibody is a protein that allows an organism's immune system to overcome disease-causing pathogens. Science has identified numerous antibodies that are or may be useful in fighting human diseases. As with new drugs, the process of bringing antibodies to market, it appears, is long, arduous, and risky. Rigorous governmental oversight for risk and efficacy, in both the United States and in Europe, requires a significant investment of time and effort on the part of an entity seeking to monetize potentially beneficial antibodies. The Plaintiffs here are representatives of former stockholders of a company, Ception, that owned rights to such an antibody. It was purchased by another entity, Cephalon; like Ception, a Delaware corporation. The parties to that sale attempted to allocate the risk of the development of the antibody among the parties. The resulting merger agreement provided an initial sales price, together with earn-outs to be paid to the sellers by the buyer. Those earn-outs were payable upon the meeting of certain milestones in the approval of the antibody to treat two different conditions, in both Europe and the United States. The buyer agreed to use commercially reasonable efforts to develop the antibody and achieve the milestones.

This matter involves the sellers' contention that the buyer's efforts, which have been abandoned with respect to development of the antibody to treat one of the medical conditions upon which earn-outs depend, were not commercially reasonable. The sellers argue that this breached the merger agreement, and seek

damages from the buyer and its affiliates. This Memorandum Opinion concerns the Defendants' Motions to Dismiss for failure to state a claim. In short, the Defendants argue that the Complaint is inadequate, because, per the Defendants, it is entirely conclusory as to their failure to use commercially reasonable efforts.

Ultimately, the Plaintiffs here face a difficult matter of proof. The merger agreement leaves discretion on how to pursue development of the antibody with the buyer. It is, perhaps, unlikely that the buyer failed to use commercially reasonable efforts to develop the antibody, given the buyer's financial interest in monetizing the antibody. However, here the parties have defined "commercially reasonable efforts" as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [the buyer], with due regard to the nature of efforts and cost required for the undertaking at stake."[1] This rather inartful draftsmanship appears to create a standard based on the effort that companies similarly situated in the market employ, or would employ. The Plaintiffs, in the Complaint, point to other companies and their efforts to develop similar medical treatments, as exemplars against which the Defendants efforts fall short. In briefing, the Defendants point to dissimilarities between the buyer and its products, and the exemplars and their products. These dissimilarities, according the Defendants, render the Plaintiffs' exemplars contractually irrelevant. That may ultimately prove

[1] Compl. ¶ 74.

true. At the pleadings stage, however, I must employ plaintiff-friendly inferences, consonant with which I find that the Defendants have only identified factual issues that may be resolved when a record is created. The Plaintiffs have stated a claim for breach of contract, and the Motion to Dismiss that claim is denied. However, other ancillary claims must be dismissed. My reasoning follows.

I. BACKGROUND

The Plaintiffs, Jeff Himawan, Josh Targoff, and Stephen Tullman, are appointed representatives of the former stockholders of Ception Therapeutics, Inc. ("Ception").[2] Ception was acquired by Defendant Cephalon, Inc. ("Cephalon") in February 2010.[3] Both companies were organized under Delaware law.[4] The merger agreement governing that acquisition forms the basis of this litigation. Later, in October 2011, Cephalon itself was acquired by Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), an Israeli company that lists its principal place of business in Petah Tikva,[5] Israel.[6] Teva Ltd. has filed a Motion to Dismiss for lack of personal jurisdiction under Court of Chancery Rule 12(b)(2) and for failure to state a claim under Rule 12(b)(6).[7] Cephalon and Defendant Teva Pharmaceuticals

[2] *Id.* ¶¶ 20–23.
[3] *Id.* ¶ 71.
[4] *Id.* ¶¶ 19, 24.
[5] And not Beit Hatikva, Israel, which, I note, is spelled with a "B."
[6] Compl. ¶¶ 26, 77.
[7] *See* Def. Teva Ltd. Mot. to Dismiss.

USA, Inc. ("Teva USA"), a Delaware corporation and a wholly owned subsidiary of Teva Ltd.,[8] have also filed a Motion to Dismiss under Rule 12(b)(6).[9]

On a Rule 12(b)(6) motion to dismiss, the Court must assume as true all well-pleaded allegations of fact in the complaint, and accept as true all inferences that can be reasonably drawn in favor of the plaintiff from those well-pleaded allegations of fact.[10] The Court does not normally consider documents extrinsic to the complaint, with the exception of "documents[s] integral to a plaintiff's claim and incorporated into the complaint."[11] As a result, the factual background that follows relies only on the Plaintiffs' Complaint, which this Court accepts as true for purposes of the motions before it.

A. Ception Acquires the Rights to "RSZ" and Pursues a Sale

In 2004, Plaintiff Stephen Tullman and others formed Ception,[12] and through Ception they licensed the rights to Rezlizumab ("RSZ"), an antibody.[13] Ception sought to develop and commercialize RSZ as a treatment for eosinophilic asthma ("EA") and for eosinophilic esophagitis[14] ("EoE").[15] Ception took such steps as

[8] Compl. ¶¶ 9, 24, 27.
[9] *See* Defs. Cephalon and Teva USA Mot. to Dismiss.
[10] *LeCrenier v. Cent. Oil Asphalt Corp.*, 2010 WL 5449838, at *3 (Del. Ch. Dec. 22, 2010).
[11] *Orman v. Cullman*, 794 A.2d 5, 15–16 (Del. Ch. 2002).
[12] Compl. ¶ 19.
[13] To be precise, RSZ is an "anti-interleukin 5 monoclonal antibody." *Id.* ¶ 3.
[14] "EoE is a chronic disorder of the digestive system in which large numbers of a particular type of white blood cells called eosinophils are present in the esophagus." *Id.*
[15] *Id.* ¶ 42.

qualifying RZA for certain Food and Drug Administration ("FDA") development programs,[16] submitting data to the FDA,[17] and gaining FDA approval for clinical trials of RZA.[18] Ception designed three clinical trials, two trials for the treatment of EoE and one trial for the treatment of EA.[19] The EA clinical trial and one EoE clinical trial were designed to measure improvements in defined endpoints (an "endpoint study").[20] The other EoE clinical trial was an "open label extension study" and was designed to measure long term safety and efficacy of RSZ,[21] whereby, after the completion of the EoE endpoint study, its participants would be invited to continue receiving RZA.[22]

In 2008, after the FDA had approved the clinical trials, but before Ception began conducting them, Ception was approached separately by Wyeth Pharmaceuticals, Inc. and Cephalon to conduct a sale.[23] In January 2009, Ception entered into an option agreement with Cephalon (the "Option Agreement").[24] Under the Option Agreement, Cephalon paid $100 million for the option to acquire Ception

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[16] Such as the Orphan Drug Designation Program, which provided incentives to develop drugs for rare diseases. *See id.* ¶¶ 43–46.
[17] *Id.* ¶ 48.
[18] *Id.*
[19] *Id.* ¶ 47.
[20] The EA endpoint study had one endpoint, improvement in the participant's responses to an asthma questionnaire. *Id.* ¶ 51. The EoE endpoint study had two endpoints, changes in the participant's esophageal eosinophil levels and changes in physicians' assessments of the participants. *Id.* ¶ 49.
[21] *Id.* ¶¶ 49–51.
[22] *Id.* ¶ 86.
[23] *Id.* ¶ 52.
[24] *Id.* ¶ 57.

for a further $250 million.[25] The prospective acquisition would be made pursuant to a pre-agreed form of merger agreement, which included potential milestone payments to Ception stockholders totaling $550 million; the milestone payments, in large part, related to the development and commercialization of RZA by Cephalon.[26] As part of the Option Agreement, Cephalon also loaned Ception $25 million to help conduct the clinical trials.[27] The exercise period for Cephalon's option to purchase Ception was tied to the completion of the EoE endpoint study.[28]

B. The Merger of Ception and Cephalon

The EoE endpoint study was completed in October 2009; the study met one of its two endpoints.[29] The completion of the study triggered the exercise period for Cephalon's option to acquire Ception.[30] However, Ception agreed to extend the exercise period until after the EA endpoint study was also concluded.[31] The EA endpoint study was completed in February 2010; the study missed its only endpoint.[32] With knowledge of both studies, Cephalon decided to exercise its option

[25] *Id.* ¶ 58.
[26] *Id.* ¶¶ 59, 60.
[27] *Id.* ¶ 62.
[28] *Id.* ¶ 58. According to the Option Agreement, Cephalon had fifteen days to exercise its option to purchase Ception after being notified that the EoE endpoint study had met its endpoints, or thirty days if the endpoints had not been met. *Id.*
[29] *Id.* ¶¶ 64–66.
[30] Under the option agreement, as the EoE endpoint study had not met both its endpoints, Cephalon had thirty days after the conclusion of the EoE endpoint study to decide whether to exercise the option. *Id.* ¶ 68.
[31] *Id.*
[32] *Id.* ¶ 69.

to acquire Ception, pursuant to an amended version of the form of merger agreement (the "Merger Agreement").[33]

Under the Merger Agreement, Cephalon would pay Ception stockholders $250 million at closing.[34] Following closing, Cephalon would pay up to $550 million in milestone payments to the now-former stockholders of Ception.[35] The milestone payments (the "Milestones") were: (A) $150 million for FDA approval of RSZ as treatment for EoE, (B) $50 million for the European Commission's grant of marketing authorization of RSZ for the treatment of EoE, (C) $50 million for the completion of the EA endpoint study,[36] (D) $150 million for FDA approval of any asthma indication for RSZ, (E) $50 million for the European Commission's grant of marketing authorization of RSZ for the treatment of any asthma indication, and (F) $100 million for FDA approval of an Oral Anti-TNF Product.[37]

The development and monetization of new medical treatments involves substantial risk, risk the parties attempted to allocate by their agreement. As laid out

[33] *Id.* ¶¶ 71, 72.
[34] *Id.* ¶ 73.
[35] *Id.*
[36] The only notable difference between the form of merger agreement in the Option Agreement and the Merger Agreement was a change in the definition of the milestone payment related to the EA endpoint study. As discussed, the exercise period for the option was extended to allow Ception to complete the EA endpoint study, and the study was thus completed before the Merger Agreement. The change in definition effectively eliminated the $50 million milestone payment envisioned in the form of merger agreement for completion of the EA endpoint study. *Id.* ¶¶ 72, 73.
[37] *Id.* ¶ 73. The "Oral Anti-TNF Product" is unrelated to RSZ, and is otherwise not defined in the record. *Id.* ¶ 60.

above, the initial payment to Ception stockholders was relatively modest, while a large part of the purchase price was contingent on the success of RSZ. To recapitulate, RSZ was seen as a potential treatment for two conditions, a type of asthma, EA, and an inflammation of the esophagus, EoE. In the Merger Agreement, Cephalon agreed if certain Milestones related to RSZ as a treatment for those two conditions were reached, it would pay former stockholders of Ception additional lump sums. If RSZ was approved as a treatment *for EoE* by both the FDA and the European Commission, then Cephalon would pay former stockholders of Ception a total of $200 million, according to Milestones (A) and (B). If RSZ was approved as a treatment *for EA* by both the FDA and the European Commission, then Cephalon would pay former stockholders of Ception a total of $200 million, according to Milestones (D) and (E).

According to Section 3.4(a)(iii) of the Merger Agreement, Cephalon was required to use "commercially reasonable efforts to develop and commercialize (or cause the development and commercialization of) [RSZ] so as to achieve the Developmental Milestones set forth in clauses (A) through (E);" these are Milestones (A)-(E) referenced above.[38] "Commercially reasonable efforts" was defined "for purposes of . . . Section 3.4" as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources

[38] *Id.* ¶ 74.

and expertise as Parent, with due regard to the nature of efforts and cost required for the undertaking at stake."[39]

Under Section 3.4(c) of the Merger Agreement, "(i) . . . control of the Surviving Corporation . . . shall rest with Parent . . . and the [former stockholders] shall have no right object to the manner in which business of the Surviving Corporation is conducted . . . and (ii) Parent shall have complete discretion with respect to all decisions related to the business of the Surviving Corporation . . . ."[40] The Merger Agreement was signed on March 10, 2010.[41]

C. Cephalon's Post-Merger Efforts and the Acquisition of Cephalon by Teva Ltd.

In May 2011, Teva Ltd. announced it was acquiring Cephalon at an enterprise value of $6.8 billion.[42] Teva Ltd. completed its acquisition of Cephalon in October 2011, and Cephalon became a wholly owned subsidiary of Teva Ltd.[43] After the acquisition, Tullman met with Teva leadership[44] more than a dozen times between 2012 and 2016 to discuss the development and commercialization of RSZ,[45]

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[39] *Id.*
[40] *Id.* ¶ 75.
[41] The Complaint does not actually provide the date the merger was closed, only that Cephalon decided to exercise its option to buy Ception in February 2010. *Id.* ¶ 71. However, the Merger Agreement, which is dated March 10, 2010, was incorporated into the Complaint. *Id.* at Ex. A.
[42] *Id.* ¶ 77.
[43] *Id.*
[44] The Complaint does not distinguish between Defendants Teva Ltd. and Teva USA in this regard; presumably, then, the Plaintiffs refer to leadership of both entities. *See id.* ¶ 99.
[45] *Id.*

including for the treatment of EoE.[46] In 2015, Teva Ltd. acquired Allergan Generics in a transaction valued at $40.5 billion; Teva Ltd. announced that as a result of the transaction it "planned for 1,500 generic launches globally in 2017."[47]

Cephalon and Teva[48] continued to develop and commercialize RZA for EA;[49] in March 2016, Teva Ltd. announced FDA approval for RZA as a treatment for EA;[50] and in August 2016, Teva Ltd. received approval from the European Commission to market RSZ as an EA treatment.[51] These were Milestones (D) and (E) of the Merger Agreement. Teva USA made the related Milestone payments to the former stockholders of Ception,[52] totaling $200 million.

When Teva Ltd. acquired Cephalon, the EoE open label extension study was ongoing.[53] Data collection for the study was substantially completed in January 2012, but Cephalon did not immediately submit the results to the FDA.[54] In 2012, Congress passed the Food and Drug Safety and Innovation Act ("FDSIA"), which created new development programs for certain types of drugs; Cephalon did not

[46] *Id.* ¶ 100.
[47] *Id.* ¶¶ 104, 105.
[48] The Complaint again does not distinguish between Defendants Teva Ltd. and Teva USA in this regard; presumably, then, both entities worked to develop and commercialize RZA for EA. *See id.* ¶ 78.
[49] *Id.*
[50] *Id.* ¶ 81.
[51] *Id.* ¶ 82.
[52] *Id.* ¶ 84.
[53] *Id.* ¶¶ 50, 63, 85.
[54] *Id.* ¶ 92.

attempt to designate RSZ as a treatment for EoE under any of these new programs.[55] One of the researchers who helped conduct the EoE open label extension study continued to use RSZ to treat patients with EoE; and in February and March 2016 the researcher independently published and presented positive results for RSZ as a treatment for EoE.[56] In March 2016, Cephalon and Teva Ltd. submitted the results of the EoE open label extension study to the FDA, although not all the data collected was submitted.[57]

On October 10, 2016, Plaintiff Himawan wrote to Francine Del Ricci, then a Senior Vice President at Teva USA,[58] and specifically asked about Cephalon's and Teva Ltd.'s efforts to commercialize and develop RSZ as a treatment for EoE.[59] Del Ricci replied on November 3, 2016.[60] Del Ricci wrote, in pertinent part:

> Cephalon has the obligation under its March 10, 2010 Merger Agreement with Ception to use commercially reasonable efforts to develop and commercialize [RSZ]. However, the Merger Agreement goes on to provide that Cephalon will have "complete discretion with respect to all decisions relating to the research, development, manufacture, marketing, pricing and distribution of [RSZ] . . . and shall have no obligation to conduct clinical trials related to, or otherwise pursue regulatory approvals of, any indication for [RSZ] . . . or otherwise take any action to protect, attain or maximize any payment

[55] *Id.* ¶¶ 111, 112.
[56] *Id.* ¶¶ 96–98.
[57] *Id.* ¶¶ 92–94.
[58] Tullman had previously corresponded with Del Ricci in 2013 about RSZ. Del Ricci's position at that time was Vice President of Corporate Alliance Management & Pipeline Governance at Teva USA. *Id.* ¶ 102.
[59] *Id.* ¶ 106.
[60] *Id.* ¶ 106; *id.* at Ex. C.

> to be received by the holders of Stock Certificates and Stock Agreements pursuant to this Section 3.4."
>
> In any event, it would not be commercially reasonable for Cephalon to develop [RSZ] for [EoE] for numerous reasons, including the need to commit substantial resources that such an undertaking would require in light of other ongoing development and portfolio-building initiatives of the company.[61]

In other words, Del Ricci revealed that Cephalon had abandoned its efforts to develop and commercialize RSZ as a treatment for EoE.[62] Pharmaceutical companies Shire,[63] Sanofi and Regeneron,[64] Celgene,[65] and GlaxoSmithKline,[66] have substantially similar resources and expertise to Cephalon and are currently pursuing products for treatment of EoE.[67]

D. Procedural History

The Plaintiffs filed the Complaint in this action on February 1, 2018. Cephalon and Teva USA filed a Motion to Dismiss on February 28, 2018. Teva Ltd.

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[61] Rather than reproduce the segments of Del Ricci's response provided in the Complaint, I have reproduced a fuller response, which was incorporated into the Complaint. *Id.* at Ex. C; *see id.* ¶¶ 106, 107.
[62] *Id.* ¶ 17.
[63] Shire has received FDA Breakthrough Therapy designation for its EoE treatment, which is currently in a Phase III clinical trial. *Id.* ¶ 109a.
[64] Sanofi and Regeneron are planning Phase III trials for their EoE treatment in 2018. *Id.* ¶ 109b.
[65] Celgene has completed a Phase II trial for its EoE treatment and is currently conducting an open label extension study. *Id.* ¶ 109c.
[66] GlaxoSmithKline has received FDA approval for "Nucala" to "treat eosinophilic granulomatosis with polyangiitis" and is now seeking FDA "approval of Nucala as an add on treatment for patients who have COPD with an eosiniphilic phenotype." *Id.* ¶ 109d.
[67] *Id.* ¶ 109.

filed a Motion to Dismiss on April 10, 2018. I heard oral argument on both Motions to Dismiss on September 21, 2018.

II. LEGAL ANALYSIS

The Plaintiffs bring a breach of contract claim against Defendant Cephalon, alleging that by abandoning efforts to develop and commercialize RSZ as a treatment for EoE, Cephalon breached the Merger Agreement. The Plaintiffs also bring a claim for breach of implied covenant of good faith and fair dealing against Cephalon, to the extent Cephalon's conduct is not covered by the Merger Agreement. Finally, the Plaintiffs bring a tortious interference with contract claim against Defendants Teva USA and Teva Ltd., arguing that they intentionally interfered with Cephalon's ability to meet its obligations under the Merger Agreement. The Plaintiffs seek, among other things, monetary relief in the amount of the Milestone payments related to EoE and a grant of the rights to RSZ.[68]

In response, the Defendants have filed Motions to Dismiss all of the claims brought by the Plaintiffs. Cephalon argues, pursuant to Rule 12(b)(6), that the Plaintiffs failed to state a claim that Cephalon breached the Merger Agreement; specifically, that the Plaintiffs did not sufficiently plead that Cephalon failed to use "commercially reasonable efforts." Cephalon also argues, under Rule 12(b)(6), that the Plaintiffs failed to state a claim for breach of implied covenant of good faith and

[68] *Id.* ¶¶ 38–39.

fair dealing because there was no room in the Merger Agreement for such an implied covenant and, in any event, there was no bad faith. Teva Ltd. argues, pursuant to Rule 12(b)(2), that it should be dismissed from this action because Teva Ltd., an Israeli company, is not subject to personal jurisdiction in Delaware. Teva USA and Teva Ltd. argue, pursuant to Rule 12(b)(6), that the Plaintiffs made only conclusory allegations that Teva USA and Teva Ltd. "direct[ed] Cephalon to abandon . . . RSZ for EoE," and that therefore the Plaintiffs failed to state a claim for tortious interference with contract.[69] Finally the Defendants together argue that all claims against them should be dismissed because the Plaintiffs acquiesced and the Defendants relied on the Plaintiffs' apparent consent to their efforts to develop RSZ. I begin with Cephalon's Motion to Dismiss.

A. Cephalon's Rule 12(b)(6) Motion to Dismiss the Counts of Breach of Contract and Breach of Implied Covenant of Good Faith and Fair Dealing

1. Legal Standard

Defendant Cephalon has moved to dismiss the counts of breach of contract and breach of implied covenant of good faith and fair dealing. Cephalon does so pursuant to Rule 12(b)(6). A motion to dismiss for failure to state a claim must be denied "unless the plaintiff could not recover under any reasonably conceivable set

[69] *Id.* ¶ 138.

of circumstances susceptible of proof."[70] During this inquiry, the Court accepts all well-pleaded allegations in the complaint as true and draws all reasonable inferences in favor of the Plaintiff.[71] However, "[c]onclusory allegations unsupported by specific factual allegations will not be accepted as true."[72] A claim for breach of contract requires: "(1) a contractual obligation; (2) a breach of that obligation by the defendant; and (3) a resulting damage to the plaintiff."[73] A claim for breach of implied covenant of good faith and fair dealing requires a similar showing, except that the obligation is a "specific *implied* contractual obligation."[74]

2. The Plaintiffs Stated a Claim for Breach of Contract

Cephalon argues that the Plaintiffs failed to state a claim for breach of contract because the Plaintiffs failed to plead facts sufficient to establish that Cephalon did not use "commercially reasonable efforts" to develop and commercialize RSZ for EoE, as was their contractual obligation per the Merger Agreement. Furthermore, Cephalon argues that the Complaint shows Cephalon actually used commercially reasonable efforts as it developed and commercialized RSZ as a treatment for EA.

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[70] *Cent. Mortg. Co. v. Morgan Stanley Mortg. Capital Holdings LLC*, 27 A.3d 531, 536 (Del. 2011).
[71] *Id.*
[72] *LeCrenier v. Cent. Oil Asphalt Corp.*, 2010 WL 5449838, at *3 (Del. Ch. Dec. 22, 2010).
[73] *Cedarview Opportunities Master Fund v. Spanish Broad., Inc.*, 2018 WL 4057012, at *6 (Del. Ch. Aug. 27, 2018) (internal quotations omitted).
[74] The elements for breach of implied covenant of good faith and fair dealing are "a specific implied contractual obligation, a breach of that obligation by the defendant, and resulting damage to the plaintiff." *NAMA Holdings, LLC v. Related WMC LLC*, 2014 WL 6436647, at *16 (Del. Ch. Nov. 17, 2014) (internal quotations omitted).

In response, the Plaintiffs point to allegations in their Complaint that studies showed positive results for RSZ as a treatment for EoE[75] and that Cephalon could have submitted RSZ for certain FDA development programs; and that despite the promise of and opportunities for RSZ, Cephalon chose to abandon efforts to commercialize and develop RSZ for EoE. Additionally, the Plaintiffs point out that the Merger Agreement required Cephalon to use commercially reasonable efforts to achieve the Milestones related to RSZ for EoE, and not just for RSZ for EA. To determine whether the Plaintiffs sufficiently pled that Cephalon breached their contractual obligation, I turn first to the contractual obligation.

"Commercially reasonable efforts" is defined in the Merger Agreement as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon], with due regard to the nature of efforts and cost required for the undertaking at stake."[76] There is no dispute that this is an objective standard. Furthermore, it is undisputed that other provisions in the Merger Agreement gave Cephalon sole discretion to decide how to proceed with RSZ. That discretion, however, was cabined by the objective standard. Thus the question remains what was required from Cephalon under this standard.

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[75] Cephalon suggests that results of the EoE endpoint study result were not positive because the study missed one of its two endpoints. However, the EA endpoint study missed its only endpoint and yet Cephalon was still able to commercialize and develop RZA for EA. As a result, and given the pleadings stage of this action, I will assume that the studies showed positive support for RSZ as a treatment for EoE.

[76] Compl. ¶ 74.

Contract interpretation "is a question of law and thus suitable for determination on a motion to dismiss."[77] "If the contractual language is 'clear and unambiguous,' the ordinary meaning of the language generally will establish the parties' intent."[78] However, where there is ambiguity, "[o]n a motion to dismiss, a trial court cannot choose between two different reasonable interpretations of an ambiguous document."[79] The Plaintiffs argue that Cephalon was obligated to pursue the development and commercialization of RSZ as a treatment for EoE under all circumstances.[80] The Merger Agreement is clear and unambiguous in this regard: Cephalon was obligated to use only "commercially reasonable efforts," as defined, and was not obligated to pursue RSZ as a treatment for EoE to all ends. However, it is not clear and unambiguous, at this stage in the pleadings, what additional obligation "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon]" imposes on Cephalon. This contractual language presumptively has meaning.[81] If I were faced with two reasonable interpretations of ambiguous contractual language

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[77] *Narrowstep, Inc. v. Onstream Media Corp.*, 2010 WL 5422405, at *7 (Del. Ch. Dec. 22, 2010)
[78] *Id.*
[79] *Id.*
[80] At Oral Argument, counsel for the Plaintiffs stated that "[t]he reference to similarly situated companies is to talk about a resource, that resources must be expended in an absolute affirmative effort to advance RSZ for EoE. It must occur." Transcript of Oral Argument at 34:22–35:2.
[81] "We will not read a contract to render a provision or term 'meaningless or illusory.'" *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (quoting *Sonitrol Holding Co. v. Marceau Investissements*, 607 A.2d 1177, 1183 (Del. 1992)).

on a motion to dismiss, I would have to deny that motion. Here, as of yet, neither side has convincingly suggested a reasonable interpretation of this language,[82] a fact which similarly supports denial of a motion to dismiss. One reasonable interpretation, I suspect, is to treat the language as intending to define "commercially reasonable efforts" as those efforts "a company with substantially the same resources and expertise as [Cephalon]" *would expend under the circumstances at hand*; such a definition, again supports denial of the Defendants' Motion to Dismiss. Before denying the Motion, however, I analyze whether that language is implicated in the alleged breach of contract.

On many occasions, this Court has dealt—indeed wrestled—with contractual obligations in merger agreements made subject to varying "efforts clauses" imposed

[82] *See* Transcript of Oral Argument at 32:23–40:3, 50:8–52:7.

on the acquiring party.[83] While some cases required factual inquiry and even trial,[84] others could be (and were) resolved at the pleadings stage.[85] Cephalon explained to the Plaintiffs in its November 3, 2016 letter that "it would not be commercially reasonable for Cephalon to develop [RSZ] for [EoE] for numerous reasons, including the need to commit substantial resources that such an undertaking would require in light of other ongoing development and portfolio-building initiatives of

[83] For example, in *Alliance Data Systems Corp. v. Blackstone Capital Partners V L.P.*, there was an obligation to use "reasonable best efforts," which "[a]lthough it does not have a specific meaning . . . is, at least, clearly understood by transactional lawyers to be less than an unconditional commitment. 963 A.2d 746, 763 n.60 (Del. Ch. 2009). In *Ev3, Inc. v. Lesh* there was an obligation to act in "good faith," and the Delaware Supreme Court found that it would not "constitute bad faith . . . to refuse to proceed . . . if the pursuit, after taking into account the milestones and development costs, was not expected to yield . . . a commercially reasonable profit . . . ." 114 A.3d 527, 541 (Del. 2014). In *Williams Companies, Inc. v. Energy Transfer Equity L.P.* the Delaware Supreme Court found that provisions that obligated "reasonable best efforts" and "commercially reasonable efforts" together "placed an affirmative obligation on the parties to take all reasonable steps." 159 A.3d 264, 273 (Del. 2017). For a description of the various standards of "efforts clauses" as defined by certain practitioners and a description of the Delaware Supreme Court's ruling in *Williams* on "commercially reasonable efforts," *see Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *86–88 (Del. Ch. Oct. 1, 2018). What these various obligations or "efforts clauses" require also depend on the context of the obligation. In *Williams*, for example, the context was obligations in a merger agreement to expend efforts to achieve necessary pre-requisites for closing, specifically "an affirmative obligation on the parties to take all reasonable steps to obtain [a tax] opinion and otherwise complete the transaction." *Williams*, 159 A.3d at 273. By contrast, here, the obligation in the merger agreement is to expend efforts *post-merger* and is directed at the discretionary business decisions of the merged corporation.

[84] As the Plaintiffs highlight in their briefing, several notable cases on "efforts clauses" went to trial. *See e.g., Williams Cos., Inc. v. Energy Transfer Equity, L.P.*, 2016 WL 3576682 (Del. Ch. June 24, 2016), *aff'd*, 159 A.3d 264 (Del. 2017); *WaveDivision Holdings, LLC v. Millennium Dig. Media Sys. L.L.C.*, 2010 WL 3706624 (Del. Ch. Sept. 17, 2010); *Hexion Specialty Chems., Inc. v. Huntsman Corp.*, 965 A.2d 715 (Del. Ch. 2008).

[85] *See, e.g., Alliance Data Sys. Corp.*, 963 A.2d 746 (granting a motion to dismiss a breach of contract claim where there was an obligation to use "reasonable best efforts"); *Sparton Corp. v. O'Neil*, 2017 WL 3421076 (Del. Ch. Aug. 9, 2017) (granting a motion to dismiss a breach of contract claim where there was an obligation to use "commercially reasonable efforts").

the company."[86] The Plaintiffs allege that there was promise and opportunity in RSZ as a treatment for EoE. However, as Cephalon points out, the Plaintiffs have not made any allegations that pursuing such promise and opportunity was commercially reasonable "with due regard to the nature of efforts and cost required for the undertaking at stake."[87] That is, the Plaintiffs have not alleged any facts that controvert Cephalon's stated economic rationale for abandoning RSZ as a treatment for EoE.

If taking into account the "nature of efforts and cost" was all that was required of Cephalon, it might be appropriate and consistent with this Court's prior rulings to grant a motion to dismiss for failure to state a claim in this instance, as the Plaintiffs did not allege facts from which to reasonably infer that the "nature of efforts and cost" supported continued efforts. However, Cephalon was also obligated to "exercise . . . such efforts and commit[] . . . such resources [as] a company with substantially the same resources and expertise as [Cephalon]."[88] In their Complaint, the Plaintiffs alleged that several companies with substantially the same resources and expertise as Cephalon are currently working to develop treatments for EoE. I assume that one reasonable reading of the contractual language here is that the actions of other similarly situated companies are a relevant yardstick to decide at this

[86] Compl. ¶¶ 106, 107; *id.* at Ex. C.
[87] *Id.* ¶ 74.
[88] *Id.*

stage in the pleadings whether Cephalon itself used "commercially reasonable efforts." At Oral Argument, the Defendants argued that, even so, the exemplars in the Complaint are not similar to the Defendant entities, and are not pursuing approval of the same antibody. The Defendants conclude that the actions of these companies are ultimately irrelevant to the reasonableness inquiry here. Perhaps so. However, at the pleading stage, I find that the allegation that similarly situated companies are pursuing treatments for EoE reasonably supports the inference that Cephalon, in doing otherwise, did not meet its contractual responsibility here.

In light of the absence of reasonable interpretations of the contractual obligation to "exercise [ ] such efforts and commit[ ] such resources by a company with substantially the same resources and expertise as Parent, with due regard to the nature of efforts and cost required for the undertaking at stake," the relative novelty of this contractual obligation, and the Plaintiffs' allegations that companies with similar resources and expertise as Cephalon are currently developing treatments for EoE, I cannot say that the Plaintiffs cannot recover under any reasonably conceivable set of circumstances susceptible of proof. As a result, the Motion to Dismiss as it relates to the breach of contract claim brought against Cephalon must be denied.

3. The Plaintiffs Failed to State a Claim for Breach of Implied Covenant of Good Faith and Fair Dealing

Defendant Cephalon moved to dismiss the claim of breach of implied covenant of good faith and fair dealing. "When presented with an implied covenant claim, a court first must engage in the process of contract construction to determine whether there is a gap that needs to be filled."[89] That is, "because the implied covenant is, by definition, implied, and because it protects the spirit of the agreement rather than the form, it cannot be invoked where the contract itself expressly covers the subject at issue."[90]

Here, the subject at issue is Cephalon's efforts (or lack thereof) to commercialize and develop RSZ for EoE. Cephalon argues that the parties to the Merger Agreement expressly chose an objective standard, "commercially reasonable efforts," as defined in the Agreement, to measure Cephalon's efforts, and that this standard leaves no "gap" for an implied term. The Plaintiffs, in turn, argue that they "reasonably expect[ed] that Cephalon would take affirmative steps to develop and commercialize RSZ for EoE" and "Cephalon's refusal to develop and commercialize RSZ for EoE is unreasonable and arbitrary, and intentionally designed to avoid achieving [the Milestones in the Merger Agreement and making the associated

[89] *Allen v. El Paso Pipeline GP Co., L.L.C.*, 2014 WL 2819005, at *10 (Del. Ch. June 20, 2014).
[90] *Id.* (quoting *Fisk Ventures, LLC v. Segal*, 2008 WL 1961156, at *10 (Del. Ch. May 7, 2008)).

payments] . . . ."[91] The Plaintiffs contend that there is no language in the Merger Agreement to address such behavior.

The Plaintiffs have not, however, identified a gap in the Merger Agreement, and there is therefore no role for the implied covenant of good faith and fair dealing. Cephalon and the Plaintiffs contracted for a series of Milestones and related payments, and Cephalon agreed to use "commercially reasonable efforts" to achieve those Milestones. "Commercially reasonable efforts," as defined by the Agreement, is an objective standard. Cephalon did not meet the Milestones related to RSZ as a treatment for EoE and the Plaintiffs cried foul. The Agreement set a contractual standard by which to evaluate whether Cephalon's failure to achieve and pay these Milestone payments was improper.[92] The standard (once adequately construed) is applicable and relevant, even if Cephalon's failure to achieve the Milestones was based on complete inaction or if it was based on Cephalon's opinion that the Milestone payments would make the endeavor uneconomical. As such, in the light most favorable to the Plaintiffs, there is nevertheless no gap.

Through their claim of breach of an implied covenant of good faith and fair dealing, the Plaintiffs seek to impose an alternative standard with which to review

[91] Compl. ¶¶ 129, 130.

[92] Here, I paraphrase Chancellor Bouchard in *Fortis Advisors LLC v. Dialog Semiconductor PLC*. 2015 WL 401371, at *5 (Del. Ch. Jan. 30, 2015) ("Thus, the Merger Agreement sets a contractual standard by which to evaluate if Dialog's failure to achieve and pay the earn-out payments in its operation of the Power Conversion Business Group was improper.").

Cephalon's efforts. To the extent I understand the Plaintiffs' view, this alternative standard prohibits Cephalon from abandoning efforts to develop and commercialize RSZ for EoE because that abandonment could never be "commercially reasonable" in light of the associated Milestone payments.[93] But this contradicts the express understanding of the parties.

The Plaintiffs, having agreed to the Milestones being *contingent* on Cephalon's "commercially reasonable efforts," cannot now contend that they did not actually expect any contingency. "The implied covenant of good faith and fair dealing . . . serves a gap-filling function by creating obligations *only where the parties to the contract did not anticipate some contingency*, and had they thought of it, the parties would have agreed at the time of contracting to create that obligation."[94]

Ception and Cephalon negotiated over the Milestones in the Merger Agreement, and the bargained-for language requires Cephalon to use "commercially

[93] The Plaintiffs cite the Delaware Supreme Court for the proposition that "[s]ophisticated parties in competitive negotiations 'do not include obvious and provocative conditions' in their agreements." Pls. Br. in Opp'n to Defs.' Mot. to Dismiss at 38 (quoting *Dieckman v. Regency GP LP*, 155 A.3d 358, 368 (Del. 2017)). Plaintiffs then claim that an "obvious and provocative" condition in this case would be "Cephalon will not act in an unreasonable and arbitrary manner to intentionally avoid achieving Development Milestones in order to avoid making Development Milestone Payments." *Id.* The Plaintiffs define their own position to be "that Cephalon deliberately thwarted the clinical approval process in order to avoid making contractually mandated payments to the former stockholders." *Id.*

[94] *Am. Capital Acquisition Partners, LLC v. LPL Holdings*, 2014 WL 354496, at *5 (Del. Ch. Feb. 3, 2014).

reasonable efforts" to achieve those Milestones. I have found that a claim for breach of contract based on that "commercially reasonable efforts" standard survives the Defendants' Motion to Dismiss and may proceed past the pleadings stage. However, no gap exists within which to employ implication, and the implied covenant claim must be dismissed.[95]

B. Teva Ltd. and Teva USA's Rule 12(b)(6) Motion to Dismiss the Count of Tortious Interference with Contract

1. Legal Standard

Defendants Teva Ltd. and Teva USA argue that the tortious interference with contract claim against them should be dismissed for failure to state a claim, pursuant to Rule 12(b)(6). I have already reviewed the applicable legal standard for Rule 12(b)(6) above. A claim for tortious interference with contract requires a showing that: "(1) there was a contract, (2) about which the particular defendant knew, (3) an intentional act that was a significant factor in causing the breach of contract, (4) the act was without justification, and (5) it caused injury."[96]

Teva Ltd. is an Israeli company. Its principal place of business is Petah Tikva, Israel.[97] In addition to moving to dismiss under Rule 12(b)(6), Teva Ltd. also moved to dismiss on the ground of lack of personal jurisdiction under Rule 12(b)(2).

[95] "[T]he implied covenant is not a license to rewrite contractual language just because the plaintiff failed to negotiate for protections that, in hindsight, would have made the contract a better deal." *Winshall v. Viacom Intern., Inc.*, 55 A.3d 629, 637 (Del. Ch. 2011).
[96] *WaveDivision Holdings, LLC v. Highland Capital Mgmt., L.P.*, 49 A.3d 1168, 1174 (Del. 2012).
[97] "Such a city, everybody loves it." *See* David Yazbek, *The Band's Visit* (Broadway 2017).

Logically, this defense should be examined first, as absent jurisdiction any resolution of the Rule 12(b)(6) motion with respect to Teva Ltd. would be moot. In this case, however, the jurisdictional issues, involving Teva Ltd.'s business-related actions within this jurisdiction and its alleged contractual waiver of jurisdictional defenses, are complex. Moreover, the Rule 12(b)(6) defense mounted by Teva Ltd. is practically indistinguishable from that raised by Teva USA, jurisdiction over which is unquestioned; in other words, the Rule 12(b)(6) defense must be engaged whether or not Teva Ltd. remains in the case. Because I find that I must dismiss the claims against both Teva entities under Rule 12(b)(6), I need not reach the jurisdictional defense.

Returning to the Rule 12(b)(6) Motions to Dismiss, Teva Ltd. and Teva USA are affiliates of Cephalon. "The gist of a well-pleaded complaint for interference by a corporation of a contract of its affiliate is a claim that the 'interfering' party was not pursuing in good faith the legitimate profit seeking activities of the affiliated enterprises."[98] The other side of the same coin would be that the "affiliate sought not to achieve permissible financial goals but sought maliciously or in bad faith to injure the plaintiff."[99] In the parent-subsidiary context, "the test for holding a parent corporation liable for tortious interference ha[s] to be high or every-day consultation

[98] *Shearin v. E.F. Hutton Grp., Inc.*, 652 A.2d 578, 591 (Del. Ch. 1994).
[99] *Id.*

or direction between parent corporations and subsidiaries about contractual implementation would lead parents to be always brought into breach of contract cases."[100] With that guidance in mind, I evaluate the Motions to Dismiss.

2. The Plaintiffs Failed to State a Claim of Tortious Interference Against Teva Ltd. and Teva USA

In support of their Motions to Dismiss, Teva Ltd. and Teva USA argue that the Plaintiffs made only conclusory allegations of bad faith in their Complaint and thus failed to adequately plead bad faith on the part of Teva Ltd. or Teva USA. They further argue that the Plaintiffs failed to plead any actual acts taken by either Teva Ltd. or Teva USA in regard to the alleged breach of contract.[101] The Plaintiffs did allege in their Complaint that Teva Ltd. and Teva USA "did not pursue the profit-seeking objectives of Cephalon, but instead acted in bad faith to injure Plaintiffs,"[102] and also alleged that "Teva Ltd. and/or Teva USA control the actions of Cephalon."[103] The Plaintiffs disagree that their allegations are merely conclusory and argue that their claim is a fact-intensive one that should survive a motion to dismiss.

[100] *Allied Capital Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1039 (Del. Ch. 2006).
[101] Teva USA and Teva Ltd. also argue that the Plaintiffs failed to adequately plead an underlying breach of contract, which is a necessary element of a claim of tortious interference with contract. As discussed above, I find that the Plaintiffs have, given this early stage in the pleadings, alleged sufficient facts to defeat a motion to dismiss on the breach of contract claim.
[102] Compl. ¶ 138.
[103] *Id.* ¶ 28.

The Plaintiffs argue that they have alleged, or that it can be reasonably inferred from their allegations, that Teva Ltd. and Teva USA have taken intentional acts that were significant factors in causing a breach of contract and did so for reasons other than legitimate profit-seeking activities of the affiliated enterprise. In their Complaint, the Plaintiffs aver that Teva Ltd. acquired Allergan Generics, and as a result, Teva Ltd. planned to launch thousands of generic products. However, this allegation says nothing of the effect of the Allergan acquisition on Cephalon and on the Merger Agreement. The Plaintiffs ask that I infer—based on the fact that Teva Ltd. acquired Allergan—that Teva Ltd. instructed Cephalon, an existing subsidiary, to breach its contract with the Plaintiffs, presumably in order to focus on Teva Ltd.'s plan for Allergan. However, I do not find it is reasonable to infer from *only* the fact that a parent company acquired another subsidiary that the parent then directed a different subsidiary to abandon its contractual obligations. Such an inference is unreasonable, without further factual allegations linking the parent's plans for its new subsidiary to the parent's plans for its existing subsidiaries. For example, there is no allegation in the Complaint that Allergan and Cephalon are competitors, such that it may be reasonable to infer that Teva Ltd. may prefer one to the detriment of the other. Nor do the Plaintiffs posit in their Complaint that Teva Ltd. has insufficient resources, such that it may be reasonable to infer that Teva Ltd.'s acquisition and plan for Allergan would necessarily involve removing resources

from Teva Ltd.'s other subsidiaries. The pleading, in this regard, is simply conclusory.

In their Complaint, the Plaintiffs also alleged that the FDA launched new development programs and that *Cephalon* did not pursue a designation in these programs for RZA as a treatment for EoE. This allegation makes no mention of either Teva Ltd. or Teva USA. I do not find it reasonable to infer from the fact Cephalon, a subsidiary of Teva Ltd., made a decision not to seek designation in this program, that the decision was actually made by Teva Ltd., its parent, or Teva USA, its affiliate, let alone that the decision was taken for reasons other than the legitimate pursuit of their business.

Finally, the Plaintiffs alleged in their Complaint that an independent study, performed by a former researcher of the EoE open label extension study, produced positive results. The Plaintiffs do not allege in their Complaint that those result were ignored by Cephalon, much less by Teva Ltd. or Teva USA. I do not find it reasonable to infer, from a mere description of a study done independent of Cephalon that Teva Ltd. or Teva USA took action—or; more accurately here, inaction. The allegations that the Plaintiffs cite, even with all reasonable inferences drawn in their favor, do not support the allegation that Teva Ltd. or Teva USA intentionally acted to interfere with the Merger Agreement, much less that they did so in bad faith. The allegation is therefore conclusory.

The Plaintiffs also allude to their correspondence with an employee of Teva USA about Cephalon's efforts related to RSZ. It was this employee who told the Plaintiffs that Cephalon would no longer pursue RSZ for EoE, effectively ending Cephalon's obligations in the Merger Agreement. However, it is not reasonable to infer from those facts alone that Teva Ltd. or Teva USA, as affiliates of Cephalon, acted with an improper purpose. The sole act of ending efforts to develop the antibody, which Cephalon was permitted to do if development is not commercially reasonable, cannot by itself be inferred to be improper conduct on behalf of Teva Ltd. or Teva USA. In the parent-subsidiary or affiliate context, this Court has held that a high standard applies; otherwise, a parent and a subsidiary would be unable to discuss the subsidiary's contractual obligations without pulling the parent into a breach of contract suit. As a result, Rule 12(b)(6) requires that the tortious interference with contract claim against Teva Ltd. and Teva USA be dismissed.

C. The Defendants Motion to Dismiss Based on the Plaintiffs' Acquiescence

The Defendants argue that each of the Plaintiffs' claims should be deemed forfeited under the acquiescence doctrine. As explained above, only the Plaintiffs' claim of breach of contract against Cephalon remains; the rest of the Plaintiffs' claims have been dismissed. With respect to the remaining claim, dismissal based on acquiescence is premature at this pleadings stage. "To prevail on a defense of acquiescence, a defendant must show: "(1) the plaintiff remained silent (2) with

knowledge of her rights (3) and with the knowledge or expectation that the defendant would likely rely on her silence, (4) the defendant knew of the plaintiff's silence, and (5) the defendant in fact relied to her detriment on the plaintiff's silence."[104]

The Plaintiffs' Complaint does not support an argument for acquiescence. The acquiescence doctrine is particularly fact intensive, and the facts supporting acquiescence are not in the record. As a result, I deny the Defendants' Motion to Dismiss based on acquiescence.

III. CONCLUSION

The count of tortious interference with contract brought against Defendants Teva Ltd. and Teva USA is dismissed for failure to state a claim pursuant to Rule 12(b)(6). As a result, Teva Ltd.'s Motion to Dismiss for lack of personal jurisdiction pursuant to Rule 12(b)(2) is moot. The count of breach of implied covenant of good faith and fair dealing brought against Defendant Cephalon is also dismissed for failure to state claim under Rule 12(b)(6). However, the count of breach of contract brought against Cephalon survives the Defendants' Motion to Dismiss. As a result, the Defendants' Motions to Dismiss are granted in part and denied in part. The parties should provide an appropriate form of order.

[104] *Cedarview Opportunities Master Fund, L.P. v. Spanish Broad. Sys., Inc.*, 2018 WL 4057012, at *13 (Del. Ch. Aug. 27, 2018) (internal quotations omitted).

EXHIBIT B

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

JEFF HIMAWAN, JOSH TARGOFF and STEPHEN TULLMAN, as the duly-appointed Representatives of the former stockholders of CEPTION THERAPEUTICS, INC., Plaintiffs, v. CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS USA, INC., Defendants.	C.A. No. 2018-0075-SG

[PROPOSED] ORDER DENYING IN PART AND GRANTING IN PART DEFENDANTS' MOTIONS TO DISMISS

THIS MATTER having been opened to the Court by counsel for Defendants Cephalon, Inc., Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc., by motions for entry of an Order dismissing Plaintiffs' Verified Complaint (Trans. ID 61637319) (the "Complaint");

AND the Court having read and considered the pleadings herein, and any opposition papers filed in connection with the aforesaid application, and having heard oral argument of the parties;

AND the Court having issued, on December 28, 2018, a Memorandum Opinion denying in part and granting in part Defendants' Motions to Dismiss (the "Memorandum Opinion");

IT IS on this _____ day of _____, 2019 **ORDERED**, for the reasons set forth in the Memorandum Opinion, that:

1. Defendants' Motion to Dismiss Plaintiffs' claim of breach of contract against Defendant Cephalon, Inc. is **DENIED**;
2. Defendants' Motion to Dismiss Plaintiffs' claim of breach of the implied covenant of good faith and fair dealing against Defendant Cephalon, Inc. is **GRANTED**;
3. Defendants' Motion to Dismiss Plaintiffs' claim of tortious interference with contract against Defendants Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. is **GRANTED**;
4. Counts II and III of the Complaint are hereby dismissed with prejudice for failure to state a claim pursuant to Court of Chancery Rule 12(b)(6);
5. Teva Pharmaceutical Industries Ltd.'s Motion to Dismiss for lack of personal jurisdiction pursuant to Court of Chancery Rule 12(b)(2) is moot;
6. Cephalon, Inc. shall file its answer with respect to Count I of the Complaint within 20 days of the entry of this Order.

_____
Sam Glasscock III, Vice Chancellor

This document constitutes a ruling of the court and should be treated as such.

Court: DE Court of Chancery Civil Action

Judge: Sam Glasscock

File & Serve Transaction ID: 62822520

Current Date: Jan 08, 2019

Case Number: 2018-0075-SG

/s/ Judge Glasscock, Sam

EXHIBIT C

EFiled: May 17 2024 03:37PM EDT
Transaction ID 73098063
Case No. 2018-0075-SG

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

JEFF HIMAWAN, JOSH TARGOFF and STEPHEN TULLMAN, as the duly-appointed Representatives of the former stockholders of CEPTION THERAPEUTICS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 2018-0075-SG
CEPHALON, INC. and TEVA PHARMACEUTICALS USA, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION

Date Submitted: November 16, 2023
Date Decided: April 30, 2024

Richard L. Renck, Mackenzie M. Wrobel, and Michael B. Gonen, DUANE MORRIS LLP, Wilmington, Delaware; OF COUNSEL: John Soroko, Wayne A. Mack, Michael J. Rinaldi, and Jessica Priselac, DUANE MORRIS LLP, Philadelphia, Pennsylvania, *Attorneys for Plaintiffs*.

J. Matthew Belger and Kevin R. Shannon, POTTER ANDERSON & CORROON LLP, Wilmington, Delaware; OF COUNSEL: Jay P. Lefkowitz, P.C., Devora Allon, P.C., John P. Del Monaco, and Alexandra I. Russell, KIRKLAND & ELLIS LLP, New York, New York, *Attorneys for Defendants*.

GLASSCOCK, Vice Chancellor

In 2010, Defendant Cephalon Inc. purchased another Delaware corporation, Ception Therapeutics, Inc. Plaintiffs are stockholders' representatives of Ception. Ception at the time had, essentially, a single asset, an antibody called Reslizumb ("RSZ") which showed some promise in treating a type of inflammation in the lungs ("EA") and esophagus ("EoE"). To oversimplify, white blood cells are part of the body's defense against infection. When the body overproduces certain types of these cells, however, they can cause inflammation and harm. RSZ was, the parties hoped, a way to limit overproduction of the cells. The parties' intent was the commercialization of RSZ to treat EA and EoE. This, in turn, would require extensive development and FDA approval.

As described below, for the next year-and-a-half after the acquisition, Cephalon continued Ception's attempts to obtain FDA approval for sale of RSZ. To oversimplify again, testing of RSZ for EA, while not entirely successful, showed more promise than testing for EoE. In November of 2012, Cephalon told the FDA that it was halting its attempts to commercialize RSZ for EoE.

In October of 2012, Cephalon was acquired by Teva Pharmaceutical Industries Ltd. Teva adopted Cephalon's opinion that RSZ for EoE was a failed product, and pursued the commercialization of RSZ for EA, which was ultimately approved by the FDA.

The Merger Agreement by which Cephalon acquired Ception provided for payment of $250 million upfront to Ceptions' stockholders. Also accruing to the stockholders were "milestone" payments based on FDA and European approval of RSZ for EA and EoE. The milestones, realized, could result in up to $200 million for approval and commercialization for EA, and $200 million for EoE. The development of RSZ, per the Merger Agreement, was entirely at the discretion of Cephalon, subject to the obligation to use commercially reasonable efforts to reach the milestones. This obligation was assumed by Teva when it acquired Cephalon. The EA milestones were achieved, and Ception stockholders were paid the full milestone payments, $200 million. The EoE milestones have not been reached.

Plaintiff stockholder representatives allege that Cephalon and Teva have failed to use commercially reasonable efforts to commercialize the EoE function, measured objectively as called for in the Merger Agreement, and that the stockholders have been damaged as a result. They brought this action, which was bifurcated as to liability and damages; what follows is my post-trial opinion on whether Cephalon and Teva have breached the Merger Agreement requirement of commercially reasonable efforts ("CRE").

The parties largely agree as to the facts. They interpret the contractual language differently. Plaintiffs see the CRE obligation as akin to a best efforts obligation, under which Defendants must pursue commercialization, through the

milestones, at least, unless it would be unreasonable to do so. Defendants believe the CRE clause only obligates them to act in good faith. Below, I assess Defendants' actions in light of the language of the Merger Agreement, to see if they have breached the CRE clause. I find they have not. My reasoning follows a statement of the facts.

I. BACKGROUND[1]

A. The Parties

Plaintiff Ception was a corporation organized and existing under the laws of the State of Delaware.[2]

Plaintiff Stephen Tullman is an appointed representative of the former stockholders of Ception.[3]

Plaintiff Jeff Himawan is an appointed representative of the former stockholders of Ception.[4]

[1] Citations to the parties' joint trial exhibits are referred to by the numbers provided by the parties and cited as "JX __". *See* Ex. A to Joint Pre-Trial Stipulation and [Proposed] Order, Dkt. No. 161. Citations to the parties' stipulated pre-trial order are cited as "PTO ¶ __". Granted (Joint Pre-Trial Stipulation and [Proposed] Order), Dkt. No. 172. References to the trial transcripts are cited as "Tr. (WITNESS NAME) __:__". Tr. of 9-19-2022 Trial — Volume I, Dkt. No. 186; Tr. of 9-20-2022 Trial — Volume II, Dkt. No. 187; Tr. of 9-21-2022 Trial — Volume III, Dkt. No. 188; Tr. of 9-22-2022 Trial — Volume IV, Dkt. No. 189; Tr. of 9-23-2022 Trial — Volume V, Dkt. No. 190.
[2] PTO ¶ 1.
[3] *Id.* ¶ 2.
[4] *Id.* ¶ 3.

Plaintiff Josh Targoff is an appointed representative of the former stockholders of Ception.[5]

Defendant Cephalon was a corporation and effective June 30, 2022, is a limited liability company organized and existing under the laws of the state of Delaware.[6] Cephalon is an indirect wholly-owned subsidiary of non-party Teva Pharmaceutical Industries Ltd. ("Teva Ltd." or "Teva") and has been since October 14, 2011.[7]

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware.[8] Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.[9]

B. Ception Develops RSZ through License Rights

In 2004, Tullman and others formed Ception Therapeutics, Inc. ("Old Ception"), which licensed from Schering Corporation and Celltech R&D Limited the rights to Rezlizumab ("RSZ").[10] The company sought to develop and commercialize RSZ as a treatment for eosinophilic asthma ("EA") and for eosinophilic esophagitis ("EoE").[11]

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[5] *Id.* ¶ 4.
[6] *Id.* ¶ 6.
[7] *Id.* ¶ 7.
[8] *Id.* ¶ 8.
[9] *Id.* ¶ 9.
[10] *Id.* ¶ 15.
[11] Trial Tr. (Tullman) 16:11–14; JX830 at 4–6.

Eosinophils help the body fight off certain types of infections when functioning properly.[12] But, when above-average amounts of eosinophils appear in the blood or certain parts of the body, they can cause inflammation and are associated with a variety of disorders.[13] EoE is a chronic disorder of the digestive system in which large numbers of eosinophils are present in the esophagus.[14] EA is a type of asthma that is caused by high levels of eosinophils in the airways of the lungs.[15] RSZ is a humanized monoclonal antibody that targets interleukin 5 ("IL5") and inhibits the growth of eosinophils by neutralizing circulating IL5 and preventing it from binding to its receptor.[16] To oversimplify, if the body's defense mechanisms, eosinophils, overpopulate, they are themselves harmful; in theory, RSZ controls this overproduction of eosinophils.

Old Ception merged with Fulcrum Pharmaceuticals, Inc. on December 20, 2005, and as a result Old Ception and Fulcrum became wholly-owned subsidiaries of "new" Ception.[17] In 2007, RSZ was designated by the U.S. Food and Drug Administration ("FDA") as an orphan drug under the Orphan Drug Act, 21 U.S.C. § 360aa et seq., which provides incentives to companies to work to develop cures for

[12] *Id.* ¶ 12.
[13] *Id.*
[14] *Id.* ¶ 13.
[15] Pls.' Verified Am. Compl. ¶ 36, Dkt. No. 137 ("Am. Compl.").
[16] PTO ¶ 14.
[17] *Id.* ¶ 16.

rare diseases, including market exclusivity for seven years and various developmental tax credits.[18]

As a biological product, RSZ would potentially qualify for a twelve-year period of exclusivity under the Public Health Services Act, 42 U.S.C. § 262.[19] To obtain FDA approval to market RSZ, Ception designed three clinical trials to establish the efficacy and safety of RSZ for treating EoE (two of the trials) and EA (one of the trials).[20] Clinical Trial Res-5-0002 was a Phase IIb/III clinical trial of RSZ as a treatment for pediatric EoE (the "EoE Study"), which sought to measure improvement in two co-primary endpoints: (a) changes in esophageal eosinophil levels and (b) changes in physicians' assessments based upon the participant's reporting of symptoms, weight, dietary status, and overall well-being.[21] Clinical Trial Res-5-0004 was an open label extension study of RSZ in the pediatric subjects who had participated in the EoE Study (the "Open Label Extension Study").[22] The Open Label Extension Study was designed to measure the long-term safety and efficacy of RSZ in treating EoE.[23]

[18] *Id.* ¶ 17.
[19] *Id.* ¶ 18.
[20] *Id.* ¶ 19.
[21] *Id.* ¶ 20.
[22] *Id.* ¶ 21.
[23] *Id.*

In November 2007, Ception initiated its EA Study.[24] The following year on March 24, 2008, Ception began its EoE Study.[25] Prior to the study, Ception needed additional funding to carry on with its clinical trials in order to bring RSZ to the market.[26] On January 13, 2009, Ception and Cephalon entered into an option agreement ("Option Agreement") whereby Cephalon paid $100 million for an option to acquire all of the outstanding stock of Ception for a purchase price of $250 million.[27] The Option Agreement included a pre-agreed form of merger agreement (the "Form Agreement") pursuant to which the acquisition of Ception was to be made, without any further negotiation, if the option were exercised.[28] The Option Agreement also allowed Cephalon to observe the results from the ongoing trials.[29]

On October 20, 2009, Ception completed its EoE Study, which involved 228 children and adolescents, between the ages of 5 and 18.[30] Some received RSZ, and some a placebo, and the results of these populations were compared.[31] After the study ended, participants were given the option to move to the Open Label Extension Study, which allowed them to continue receiving RSZ but not the placebo.[32] A

[24] JX18 at 6; JX12 at 18.
[25] JX42; JX1094 at 3.
[26] Trial Tr. (Tullman) 20:23–21:12.
[27] PTO ¶ 24.
[28] JX24.
[29] *Id*.
[30] PTO ¶ 26.
[31] JX42.
[32] PTO ¶ 38.

month later, on November 23, 2009, Ception and Cephalon jointly announced Ception's EoE Study failed to meet its co-primary endpoint.[33] The study demonstrated that the system improvement endpoint did not have statistical significance because all patients, even those treated with a placebo, reported symptom improvement.[34] Although Ception had missed one of its co-primary endpoints, Ception agreed to extend Cephalon's option period until after the EA Study was completed.[35]

C. Cephalon Acquires Ception

The EA Study concluded in February 2010 and demonstrated that RSZ was likely effective in treating EA.[36] After the results of the EA Study, on February 23, 2010, Dr. Lesley Russell, Chief Medical Officer at Cephalon, issued a press related stating:

> "This study showed a strong treatment signal and compelling internal consistency on the effect of [RSZ] on measurements of asthma and lung function" and advising that "[t]hese data provide confidence that [RSZ] shows a meaningful treatment effect in this patient population. We look forward to advancing [RSZ] into Phase Three clinical trials."[37]

Consequently, Cephalon exercised its option to acquire Ception and the parties executed a merger agreement on March 10, 2010 (the "Merger

[33] PTO ¶ 27; JX36.
[34] JX42.
[35] Trial Tr. (Tullman) 41:5–43:18.
[36] JX108 at 1.
[37] Am. Compl. ¶ 71; Ans. ¶ 71; JX43, Feb. 2010 Press Release.

Agreement").[38] Cephalon paid $250 million to Ception stockholders in consideration of the Merger Agreement.[39] Under Section 3.4(a) of the Merger Agreement, Cephalon agreed to pay milestones tied to approval by regulatory authorities of RSZ:

> (i) FDA approval of RSZ for the treatment of EoE ($150 million);
> (ii) the European Commission's grant of marketing authorization of RSZ for the treatment of EoE ($50 million);
> (iii) FDA approval of RSZ for any asthma indication, including EA ($150 million); and
> (iv) the European Commission's grant of marketing authorization of RSZ for the treatment of any asthma indication, including EA ($50 million) (the "Developmental Milestones").[40]

Under Section 3.4(c) of the Merger Agreement, "(i) . . . control of the Surviving Corporation . . . shall rest with Parent . . . and the [former stockholders] shall have no right object to the manner in which business of the Surviving Corporation is conducted . . . and (ii) Parent shall have complete discretion with respect to all decisions related to the business of the Surviving Corporation . . . ." (the "Discretion Clause").[41] The Discretion Clause further outlined Cephalon's obligations to Ception, as it provided that Cephalon did not have an obligation to (i) conduct clinical trials; (ii) pursue regulatory approvals; (iii) maximize payment to

[38] JX46.
[39] *Id.*
[40] *Id.* at § 3.4(a)(A)-(B), (D)-(E).
[41] *Id.* at § 3.4(c).

Ception stockholders; (iv) follow Ception's business plan; or (v) consult with Ception stockholders with respect to the business.[42]

The Discretion Clause, however, was subjected to a "commercially reasonable efforts" clause ("CRE" or the "CRE Clause") which required Cephalon to use "commercially reasonable efforts to develop and commercialize . . . [RSZ] so as to achieve the Developmental Milestones."[43] "Commercially reasonable efforts" was defined as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon], with due regard to the nature of efforts and cost required for the undertaking at stake."[44] The parties consummated the Merger on April 5, 2010.[45]

D. Cephalon Undertakes RSZ for EoE

After the acquisition, Cephalon took actions to develop RSZ for EoE.[46] Cephalon met with Dr. Tim Henkel, Ception's Head of Research and Development, to discuss the EoE program on April 7, 2010.[47] At that meeting, Cephalon discussed potential remedies to the failed EoE Study, as well as a protocol amendment to the Open-Label Study.[48] Cephalon created a plan to attempt to secure FDA approval

[42] *Id.*
[43] *Id.* at 36.
[44] *Id.* at § 3.4(a)(iii).
[45] JX74 at 104.
[46] JX874 at 2–3.
[47] *Id.* at 2.
[48] *Id.*

for the EoE program with input from Drs. Henkel and Jeff Wilkins, both former Ception employees.[49] Cephalon spent months creating an alternative plan for FDA approval which drew from participant data in the Open-Label Study[50] and conducting meetings to explore the clinical development of EoE to ameliorate data that the FDA had concerns with.[51] On September 2, 2010, Cephalon requested a pre-Biologics License Application meeting ("BLA") regarding EoE with the FDA to present its plan.[52]

Cephalon and the FDA held the BLA meeting on December 14, 2010.[53] Drs. Henkel and Wilkins attended the meeting to help present the proposal to the FDA.[54] Cephalon submitted proposals to gain FDA approval for EoE for RSZ all of which were rejected.[55] Cephalon first proposed to submit a pre-Biologics License Application for RSZ under an FDA program for accelerated approval of biological products.[56] As part of that proposal, Cephalon sought to convince the FDA that it should accept reduced eosinophil levels coupled with "the reintroduction of previously restricted foods" as "reasonably likely to predict clinical benefit of [RSZ]

[49] *Id.*; Trial Tr. (Wilkins) 357:19–358:4. Dr. Jeff Wilkins was also a former employee of Ception. Trial Tr. (Wilkins) 247:16–17.
[50] JX217; JX50.
[51] JX50.
[52] JX71 at 3.
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*

in the treatment of children with [EoE] as a surrogate endpoint as proof of RSZ's efficacy.[57] The FDA rejected this proposal because "there was insufficient evidence to support histological changes in eosinophils alone as a surrogate endpoint reasonably likely to predict clinical benefit."[58]

Cephalon also proposed to amend the Open-Label Study to convert it into an efficacy study, by (i) reintroducing foods into diets of patients treated with RSZ that had not been previously tolerated and (ii) analyzing the percentage of patients able to successfully adjust to their diet.[59] The FDA also rejected this proposal since the results would be considered exploratory in nature and would not be linked to a clinical improvement in symptoms among patients.[60] However, the FDA did note that "*post hoc* efficacy endpoints in an on-going open label study may provide important information that may aid in the design and planning of future studies."[61] Ultimately, the BLA meeting was unsuccessful,[62] as the FDA made clear that Cephalon must actually demonstrate symptom improvement in patients with a

[57] *Id.* at 3–4.
[58] *Id.*
[59] *Id.* at 5.
[60] *Id.*
[61] *Id.*
[62] There was significant disappointment coming out of the meeting. Trial Tr. (Wilkins) 308:17-309:8.

validated PRO tool[63] in order to receive approval, which Cephalon had not demonstrated.[64]

Despite the FDA's rejection of Cephalon's proposals for RSZ for EoE, Cephalon prepared a proposal for an enriched enrollment, randomized withdrawal ("EERW") study, which would include individuals who began in the original EoE study and continued in the Open-Label Study.[65] The goal of this study was to indicate symptom improvement by analyzing patient results that were removed from treatment in a randomized fashion compared to patients who continued to use RSZ.[66] On May 4, 2011, the FDA rejected the plan to implement the EERW study, finding that it was unclear if the new approach would accurately depict symptom improvement.[67] Notwithstanding this rejection, the FDA was encouraging, and stated it "remain[ed] eager to work with [Cephalon] on further development of" RSZ for EoE.[68]

The FDA provided general recommendations for Cephalon to gain FDA approval and requested additional data from the EoE Study and Open-Label Study.[69]

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[63] Measuring symptom relief in a clinical trial is often done through a patient reported outcome questionnaire, or a "PRO." Trial Tr. (MacFarlane) 587:12–88:8. A PRO can be validated to ensure accurate measurement. *Id.*
[64] JX71 at 4.
[65] Trial Tr. (Wilkins) 309:12–311:18.
[66] JX100 at 2–3.
[67] *Id.* at 1. The meeting originally was supposed to be in person, but a day before the meeting was scheduled, Cephalon requested that the meeting take place over the phone. JX97.
[68] JX71; Trial Tr. (Wilkins) 306:8–07:4.
[69] JX71 at 2–4; JX112 at 6.

Cephalon conducted the requested analysis but could not "identify a clinical benefit to treatment in a specific subpopulation with a predominant symptom of EoE" and concluded that the "[l]ack of validated endpoint tool to measure clinical benefit (PRO) limit[ed] further development."[70]

Ultimately, on November 8, 2011, Cephalon notified the FDA that it was discontinuing developing RSZ for EoE since it was not feasible to study the existing patient population to support regulatory approval.[71] The November 2011 letter to FDA relayed Cephalon's conclusions from its September 2011 analyses, including that "defining a patient population using a single predominant symptom approach will not result in a sample size that is large enough to re-randomize into a Phase 3 study."[72] The EoE Open Label Extension Study concluded in January 2012.[73]

E. Cephalon is Acquired by Teva

In the meantime, in October 2011, Teva acquired Cephalon, which became a wholly-owned subsidiary of Teva.[74] Consequently, Teva assumed all of Cephalon's contractual obligations under the Merger Agreement, becoming the decisionmaker for programs undertaken from Ception.[75] Immediately after the merger, Teva representatives met with Dr. Tullman and others to discuss RSZ, including the EoE

[70] JX112 at 8.
[71] JX912 at 1.
[72] JX118.
[73] PTO ¶ 38.
[74] JX120.
[75] Dep. Rainville 275:2–13.

indication.[76] Teva decided to focus on the development and commercialization of RSZ for EA, because that use of RSZ had demonstrated positive clinical and commercial results[77] as compared to RSZ for EoE,[78] and in view of the fact that Cephalon had ended the EoE program.[79] In support of this decision, Teva built a manufacturing facility dedicated to the manufacture of RSZ in Ulm, Germany.[80] Teva also invested almost $400 million in research, marketing, and developmental costs on RSZ for EA.[81] In sum, Teva spent an estimated one billion to bring RSZ for EA to the market.[82]

In March 2016, Teva received FDA approval for RSZ for EA under the brand name "CINQAIR," and a few months later paid Ception stockholders $150 million due as a milestone payment.[83] Five months later, the European Commission granted

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[76] Trial Tr. (Tullman) 48:17–49:12.

[77] Internal Teva forecasts demonstrate that Teva thought the commercial viability of the EA indication estimated roughly $1.345 billion in revenue per year at its peak (assuming that Teva could obtain approval of a subcutaneous form of RSZ). *See* JX180 at 22; see also Trial Tr. (Fosbury) 160:16–161:6.

[78] *See* JX108 at 1 (Castro, Mario et al., "Reslizumab for Poorly Controlled, Eosinophilic Asthma: A Randomized, Placebo-controlled Study").

[79] Trial Tr. (Shah) 912:9–18 (testifying Teva's clinical team was asked to focus on asthma); Trial Tr. (Shah) 953:14–21 (testifying Teva invested almost $400 million in research and development on asthma); Trial Tr. (Dethlefs) 1356:23–1357:6 (testifying that Teva built a manufacturing facility dedicated to the manufacture of RSZ); *id.* at 1357:7–19 (testifying that Teva spent $400 million in marketing, sales, and development costs for EA); *id.* (testifying that Teva spent an estimated one billion dollars to bring RSZ for EA to market).

[80] Trial Tr. (Dethlefs) 1356:23–1357:6 (testifying that Teva built a manufacturing facility dedicated to the manufacture of RSZ).

[81] Trial Tr. (Shah) 953:14–21 (testifying Teva invested almost $400 million in research and development on asthma); Trial Tr. (Dethlefs) at 1357:7–19 (testifying that Teva spent $400 million in marketing, sales, and development costs for EA).

[82] *Id.*

[83] PTO ¶¶ 42–44.

marketing authorization to RSZ for EA, and Teva paid Ception stockholders another $50 million.[84] Having successfully secured approval and marketing authorization for RSZ as a treatment for EA, the asthma-related Developmental Milestone payments, $200 million in total, were paid to former Ception stockholders.[85]

As a part of its approval, the FDA required that Teva include a "black box" warning on the label for RSZ, which warned that CINQAIR may cause anaphylaxis, a potentially deadly condition.[86] This designation affected RSZ's commercial prospects, as there are many other treatments for EA on the market that did not include such designation.[87] CINQAIR/RSZ was also only approved to be administered in its intravenous form, which required patients to receive the drug at medical facilities through a catheter at appointments that could last up to 20-50 minutes.[88] Other competing drugs in the market did not require intravenous administration, and patients could take the drug by intramuscular injection, without the assistance of a supervised medical facility.[89] Ultimately, CINQAIR proved to

[84] *Id.*
[85] *Id.*
[86] JX996 at 1.
[87] Trial Tr. (Fosbury) 170:15–171:23; Trial Tr. (MacFarlane) 790:14–16.
[88] Trial Tr. (MacFarlane) 788:7–10.
[89] *Id.* at 858:24–859:3.

be a commercial failure, as it did not significantly compete well with other products for EA on the market.[90]

F. Teva's Efforts for EoE after Acquiring Cephalon

Shortly after acquiring Cephalon in 2011, Teva kept in contact with physicians that shared their thoughts on RSZ treating other disorders and considered the viability of EoE.[91] Teva ultimately concluded that there was no path forward for EoE from a regulatory perspective.[92] Through 2015, Teva continued to believed that EoE was not worth pursuing because there was not a successful path to secure FDA approval, since a PRO tool, a patient reported outcome questionnaire used to measure symptom relief, did not demonstrate symptom improvement.[93]

Teva also determined the pursuit of EoE impractical in light of related milestone payments. For instance, Dr. Kurt Brown, a Clinical Program Leader at Teva, emailed Francine Del Ricci, a former high-ranking Cephalon executive who transitioned to Teva and became the manager of the Teva's relationship with the former Ception stockholders, about RSZ for EoE writing "scientifically we agreed EoE is now a viable indication to pursue; but . . . I am assuming that a potential $200

[90] JX884 (Morgan Stanley, "Specialist Prescribing Dynamics: Focus on Severe Asthma," June 19, 2019, 6); JX883 (Morgan Stanley, "Specialist Prescribing Dynamics: Focus on Severe Asthma," December 4, 2019, 6); JX837 (Morgan Stanley, "Specialist Prescribing Dynamics: Focus on Severe Asthma," May 30, 2022, 7-8); JX846 (Expert Report of Frederic Selck at Figure 3).
[91] JX165.
[92] JX144.
[93] Trial Tr. (Shah) 924:8–19, 922:20–923:12.

[million] EoE milestone payment may be the 'killer' for an EoE program?"[94] In addition, in a conversation between Ms. Del Ricci and Dr. Tushar Shah, former Global Head of Respiratory of Cephalon, Dr. Shah expressed that Teva's obligation to pay EoE related milestones was detrimental to the EoE program.[95]

During its development of RSZ for EA, however, Teva monitored the regulatory landscape of EoE.[96] After receiving regulatory approval for EA, in February 2016, Teva began to assess the entire RSZ brand, including considering moving into the EoE indication.[97] In the meantime, on October 14, 2016, Himawan wrote Teva about his concerns on the lack of development of EoE.[98] Ms. Del Ricci wrote to Himawan, in pertinent part:

> Cephalon has the obligation under its March 10, 2010 Merger Agreement with Ception to use commercially reasonable efforts to develop and commercialize [RSZ]. However, the Merger Agreement goes on to provide that Cephalon will have "complete discretion with respect to all decisions relating to the research, development, manufacture, marketing, pricing and distribution of [RSZ] . . . and shall have no obligation to conduct clinical trials related to, or otherwise pursue regulatory approvals of, any indication for [RSZ] . . . or otherwise take any action to protect, attain or maximize any payment to be received by the holders of Stock Certificates and Stock Agreements pursuant to this Section 3.4."

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[94] JX236.
[95] Del Ricci Dep. at 177:3–8.
[96] Trial Tr. (Shah) 943:12-944:14; *see also* Trial Tr. (Harvey) 1303:2-23 (recapping Teva's efforts to monitor EoE indication).
[97] *See generally* JX895 (Reslizumab Brand Overview); see also Trial Tr. (Fosbury) 163:2-169:11 (testimony regarding pipeline assessment).
[98] JX323 at 3.

> In any event, it would not be commercially reasonable for Cephalon to develop [RSZ] for [EoE] for numerous reasons, including the need to commit substantial resources that such an undertaking would require in light of other ongoing development and portfolio-building initiatives of the company.[99]

In December 2016, Teva hired RxC, a third-party biopharma strategy consulting firm that specializes in pharmaceutical life cycle planning and new product commercialization, to conduct an opportunity assessment of RSZ for EoE.[100] The purpose of the opportunity assessment was to "assess the clinical and regulatory viability of anti-IL5 therapy to treat Eosinophilic Esophagitis (EoE) patients."[101]

On April 26, 2017, RxC reported its findings to Teva.[102] RxC concluded that the probability of starting a successful new trial of RSZ for EoE was low because of difficulties in creating a successful clinical trial framework and RSZ's failure to show improvement in patients with EoE.[103] RxC also found that the commercial viability of RSZ for EoE provided limited upside.[104] In evaluating other companies' development of treatment for EoE, RxC found that those companies had made little progress.[105] For instance, at the time of its analysis no other company obtained FDA

[99] JX326
[100] *See* Trial Tr. (Fosbury) 177:9–17; *see also* Trial Tr. (Jayanthi) 1117:2–5.
[101] *See* JX700 at 7.
[102] *Id.*
[103] *Id.* at 23.
[104] *Id.* at 20.
[105] *Id.* at 24–29.

approval for treating EoE.[106] In sum, RxC reported that successfully developing RSZ for EoE for regulatory approval was unlikely.

Teva also considered the commercial profile of RSZ in determining whether to restart development in the EoE indication. Teva determined that the fact that RSZ required administration by infusion, and the requirement that it display a black box warning label, made RSZ a highly challenged commercial product in any indication.[107] In Teva's view, it was not commercially reasonable to continue further RSZ development, including in EoE, if Teva could not obtain a viable subcutaneous route of administration for RSZ.[108] Eventually, in 2018 Teva learned that its clinical trials of the subcutaneous form of RSZ had failed to demonstrate clinical efficacy in patients with EA.[109] Based on these conclusions, as well as RxC's independent evaluation, Teva made the decision to not restart development of RSZ for EoE.

G. Procedural Background

Plaintiffs initiated this action against Cephalon, Teva Ltd., and Teva USA on February 1, 2018, for (i) breach of contract against Cephalon; (ii) breach of implied covenant of good faith and fair dealing against Cephalon; and (iii) tortious

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[106] *Id.*
[107] Trial Tr. (Dethlefs) 1398:4–20.
[108] *Id.*
[109] *See* Trial Tr. (Dethlefs) 1402:23–1403:12. As Dr. Dethlefs explained, the subcutaneous formulation was so important to the commercial success of the product, that Teva would never have moved forward with the EoE indication without first securing the subcutaneous formulation. *Id.* at 1387:23–1388:11 (describing subcutaneous approval as a "prerequisite" to EoE development); *id.* at 1402:23–1403:12.

interference with contract against Teva Ltd. and Teva USA.[110] Defendants filed their Motion to Dismiss on February 28, 2018.[111] I heard oral arguments on the Motion to Dismiss on September 21, 2018,[112] and granted it in part, but denied Defendants' Motion to Dismiss the breach of contract claim against Cephalon.[113]

Thereafter, on November 30, 2021, Plaintiffs sought leave file to file an Amended Complaint to include a breach of contract claim against Teva Ltd. and Teva USA under a theory of successor liability.[114] On June 6, 2022, Teva USA and Plaintiffs executed a Guarantee Agreement, where Teva USA agreed to guarantee any judgment entered against Cephalon in this action.[115] Plaintiffs also agreed not to name Teva Ltd. in the Amended Complaint.[116] Plaintiffs filed the Amended Complaint on July 11, 2022.[117] On August 25, 2022, Defendants filed their Answer to the Amended Complaint.[118] Defendants filed a Motion in Limine to Exclude Testimony of Kathryn MacFarlane Regarding Likelihood of Regulatory Approval

[110] PTO ¶¶ 4–5.
[111] Mot. to Dismiss Verified Compl., Dkt. No. 17.
[112] Judicial Action Form for Oral Arg. held 09.21.18, Dkt No. 38.
[113] *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *1 (Del. Ch. Dec. 28, 2018) ("Mem. Op.").
[114] Pls.' Mot. for Leave to File Verified Am. Compl., Dkt. No. 104.
[115] Granted (Stipulation and [Proposed] Order Resolving Pls.' Mot. for Leave to File Verified Am. Compl.), Dkt. No. 139.
[116] *Id.*
[117] Pls.' Verified Am. Compl., Dkt. No. 137.
[118] Defs.' Answer to Am. Verified Compl., Dkt. 154.

on September 12, 2022,[119] and Plaintiffs filed their opposition on September 16, 2022.[120]

I held a trial in this action on September 19, 2022 through September 23, 2022.[121] The parties stipulated to bifurcating post-trial briefing into two phases, with Phase I determining commercially reasonable efforts and whether there was a breach and Phase II determining the consequences of that breach.[122] I heard post-trial oral argument on November 16, 2013.[123] This opinion addresses the briefing and evidence presented at trial concerning Phase I, that is, whether Defendants breached the CRE Clause.

II. ANALYSIS

The issue before me is whether Defendants used commercially reasonable efforts, as defined and cabined by the Merger Agreement, to develop RSZ for EoE. Plaintiffs seek monetary relief in the amount of the Developmental Milestone payments related to EoE and a reversionary grant of rights to RSZ, among other

[119] Defs.' Mot. in Limine to Exclude Testimony of Kathryn MacFarlane Regarding Likelihood of Regulatory Approval, Dkt. No. 165.
[120] Pls.' Opp'n to Defs.' Mot. In Limine, Dkt. No. 174. I reserved ruling on the Motion in Limine at trial. I decline to rule on the Motion in Limine, as I did not rely on the expert report in making my decision.
[121] Trial before Vice Chancellor Sam Glasscock dated Sept. 19, 2022 through Sept. 23, 2022, Dkt. No. 183.
[122] Granted (Defs.' [Proposed] Order Governing Post-Trial Submissions and Briefing), Dkt. No. 185.
[123] Post Trial Oral Arg. before Vice Chancellor Sam Glasscock, Dkt. No. 222.

requests.[124] Plaintiffs have the burden of proving that it is more likely than not that Defendants breached the CRE Clause by not exercising commercially reasonable efforts.[125]

A. Defendants Utilized Commercially Reasonable Efforts to Develop RSZ for EoE

Plaintiffs assert, correctly, that the CRE Clause puts forth an "objective standard" while affording Defendants "discretion to decide how to proceed with RSZ," subject to and "cabined by the objective standard."[126] Plaintiffs also point out that the CRE Clause did not impose a time limit or terminate upon the happening of a specific event.[127]

Plaintiffs construe these strictures in the Merger Agreement to impose an obligation on Defendants through the CRE Clause "to take all reasonable steps to solve problems" encountered when fulfilling the associate promise, and to "consummate" the promise to obtain regulatory approval for RSZ for EoE.[128] Plaintiffs contend that the indication for EoE was viable and that there was a path

[124] Am. Compl. ¶ 42.
[125] *Physiotherapy Corp. v. Moncure*, 2018 WL 1256492, at *3 (Del. Ch. Mar. 12, 2018).
[126] Pls. Opening Post-Trial Br., Dkt. No. 194 (citing *Himawan*, 2018 WL 6822708, at *6) ("PL PT OB").
[127] Post Trial Oral Arg. 53:16–54:5.
[128] PL PT OB 43 (quoting *Williams Cos. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 272 (Del. 2017); *Menn v. ConMed Corp.*, 2022 WL 2387802, at *34–35 (Del. Ch. June 30, 2022); *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *87, 91 (Del. Ch. Oct. 1, 2018), *aff'd*, 198 A.3d 724 (Del. 2018)).

forward to secure regulatory approval for RSZ for EoE.[129] As such, Plaintiffs argue that Defendants' abandonment of RSZ for EoE is a breach of the Merger Agreement.[130] Plaintiffs point to non-action of Defendants to support its assertion.[131] For instance, Plaintiffs point out that Teva did not continue developing RSZ for EoE after it acquired Cephalon,[132] but waited six years after acquisition to assess its viability, to Ception stockholders' detriment.[133] Plaintiffs contend that Defendants did not do the following for RSZ for EoE within this six-year period: (1) conduct a "rigorous or analytical review;"[134] (2) continue or restart development;[135] (3) budget for or expend any funds on development;[136] (4) monitor developments or activities of competitors;[137] (5) regularly assess viability of all potential indications annually;[138] and (6) consider Ception stockholders' inquiries.[139]

Regarding the Discretion Clause, which gave Defendants sole discretion over Ception's former affairs, Plaintiffs contend that the CRE Clause imposes an outward restraint on Defendants' ability to exercise their discretion.[140] Put another way,

[129] PL PT OB 3–4.
[130] *Id.* at 49–57.
[131] *Id.* at 20–35.
[132] *Id.* at 28.
[133] *Id.* at 37–40.
[134] *Id.* at 20.
[135] *Id.* at 20–22.
[136] *Id.* at 22–23.
[137] *Id.* at 23–24.
[138] *Id.* at 24–25.
[139] *Id.* at 26–27.
[140] *Id.* at 47–49.

Plaintiffs argue that "the future development of RSZ for EoE was ***not*** a matter left solely to Defendants' discretion or business judgment."[141]

In addition to pointing out the arguable lethargy of Defendants, Plaintiffs also seek to compare Defendants efforts to pharmaceutical companies that have developed and commercialized pharmaceutical products, which include: (i) Amgen Inc.; (ii) AstraZeneca Pharmaceuticals LP; (iii) Bristol-Myers Squibb Company; (iv) GlaxoSmithKline; (v) Sanofi-Regeneron; and (vi) Takeda, some of the largest pharmaceutical companies in the world.[142] Plaintiffs put forth Teva's purported status as a major pharmaceutical enterprise[143] together with the amount it spends on research and development[144] to support this comparison.[145] According to Plaintiffs, while Defendants' efforts for RSZ for EoE was stagnant, these competitors "surged ahead and devoted resources to the development of EoE treatments and progression of their clinical programs."[146] For example, Plaintiffs point to Sanofi-Regeneron's development and commercialization of Dupixent, a biologic for the treatment of EoE, even after receiving mixed results in its initial Phase 2 study for EoE.[147]

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[141] *Id.* at 47.
[142] *Id.* at 60; JX832 at 35; Trial Tr. (MacFarlane) 706:22–707:1.
[143] JX1222 (stating Teva has "significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products"); JX1223 ("Today, Teva is among the top 15 global pharmaceutical companies–a world leader in generic and specialty medicines"); Tr. (Dethleds) 1338:22–24 (stating that Teva is the largest customer of the FDA).
[144] JX832 at 44–45.
[145] PL PT OB 61.
[146] *Id.* at 61–64.
[147] *Id.* at 62.

Sanofi-Regenerson achieved this result after following the FDA's recommendations,[148] which Plaintiffs argue indicates that Defendants could have achieved the same result if it followed through with their obligations.[149]

Defendants in turn argue that their efforts were in fact objectively commercially reasonable.[150] Regarding Cephalon's efforts, Defendants state that Cephalon fulfilled its obligation by hiring former Ception employees, developing plans to salvage the EoE program, and meeting with the FDA three times.[151] Concerning Teva's efforts, Defendants state that Teva acted reasonably by prioritizing the EA indication over the EoE indication.[152] Defendants also argue it was justifiable for Cephalon to terminate the development of EoE because of clinical study failures.[153]

Defendants likewise contend that it was commercially reasonable for Teva to decline to restart the development of EoE since the assessment by their advisor, RxC, determined that RSZ for EoE was not viable and the indication for EA with RSZ was a commercial failure.[154] Defendants further point out that the Merger Agreement gives them sole discretion to develop, cabined only by an objective

[148] JX832 at Section 4.2.
[149] PL PT OB 62.
[150] Defs.' Opening Post-Trial Br. 25–28; 31–32, Dkt. No. 195 ("DEF PT OB").
[151] *Id.* at 26–28.
[152] *Id.* at 31–32.
[153] *Id.* at 28–30.
[154] *Id.* at 32–38.

reasonableness standard that allows them to consider all business factors and circumstances,[155] and that, if the parties desired the buyer to use best efforts to commercialize RSZ for EoE, they could have so agreed.[156]

Defendants argue that Plaintiffs' "similarly situated companies" are not valid comparators to Defendants' efforts.[157] Defendants assert that resources such as revenue and research and development budgets of the Plaintiffs' purpored "similarly situated companies" were significantly higher than Cephalon in 2010[158] and Teva in 2017.[159] Nevertheless, Defendants contend that their efforts were commercially reasonable compared to those non-comparable "similarly situated companies" since the companies' EoE therapies did not include anti-IL5 antibodies, and many of Plaintiffs' comparators acted the same way Defendants did in rejecting development of that form of treatment.[160] Further, in regard to "similarly situated companies" that did in fact develop a monoclonal antibody that targets IL5, Defendants assert that they did so after successfully prioritizing developing the treatment for EA, similar

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[155] *Id.* at 30 (quoting *Himawan*, 2018 WL 6822708, at *7).
[156] Post Trial Oral Arg. 76:6–77:19.
[157] DEF PT OB 39–45.
[158] *Id.* at 41; *see* Trial Tr. (MacFarlane) 716:20–720:2; *see also* JX999 at 2 (2009 *Pharmaceutical Executive* top-50 list) (demonstrating that Cephalon's revenue in 2010 was $2.2 billion as compared to "similarly situated companies" whose revenue ranged from $48.322 billion to $14.2 billion).
[159] DEF PT OB 42; JX769 at 13, 16–19 (2018 Pharmaceutical Executive top-50 list) (demonstrating that demonstrating that Teva's budget for research and development in 2017 was $1.778 billion as compared to "similarly situated companies" whose budgets ranged from $9.017 billion to $3.067 billion).
[160] DEF PT OB 45–50.

to Teva.[161] Defendants also state their actions were commercially reasonable as compared to other companies that Plaintiffs did not include in their comparison because those companies stopped EoE development after it failed to show symptom improvement in clinical trials.[162]

To prevail on a claim for breach of contract, the plaintiff must establish by a preponderance of the evidence that: (1) a contract existed between the parties; (2) the defendant breached his obligation imposed by the contract, and (3) plaintiff suffered damages as a result of the defendant's breach.[163] "When the contract is clear and unambiguous, [Delaware courts] will give effect to the plain-meaning of the contract's terms and provisions."[164]

The contractual language here gives the Defendants "complete" discretion over the development of the RSZ assets they acquired via the merger. That discretion is cabined, however, by the commercially reasonable efforts clause, which is a defined term in the Merger Agreement. Commercially reasonable efforts are "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon], with due regard to the nature of efforts and cost required for the undertaking at stake."[165] The question is,

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[161] *Id.* at 51–53.
[162] DEF PT OB 53–56.
[163] *See VLIW Tech., LLC v. Hewlett–Packard, Co.*, 840 A.2d 606, 612 (Del. 2003).
[164] *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159–60 (Del. 2010).
[165] JX46 at § 3.4(a)(iii).

then, have Defendants taken those steps that a reasonable decision-maker would make under the facts pertaining to the development of RSZ for EoE? If yes, there is no breach.

I note that in my decision rejecting the Defendants' motion to dismiss in this matter, I suggested that one way to give meaning to the unusual language of the CRE Clause was to compare the efforts of similarly-situated pharmaceutical companies and their actions in the real world. After trial, I find this method unworkable; no exemplar companies operate under the actual conditions of Defendants, who, I note, are also different from one another as to their circumstances. I find that the best interpretation of the contract is that the parties meant to impose the CRE requirement on the buyer, as it found itself situated, but that the requirement went beyond buyer's subjective good faith. It imposed an objective standard—this is the meaning of the imposition of a requirement to "exercise . . . such efforts and commitment of such resources [as] a company with substantially the same resources and expertise as" the buyer.

Plaintiffs point to cases where the subject of a reasonable-efforts or best-efforts clause is aimed at completing the steps necessary to a merger that is the subject of the agreement.[166] I do not find those cases particularly helpful, because

[166] Plaintiffs cite various decisions, which in their view provide the objective standard to cabin Defendants' actions. PL PT OB 43 (citing *Williams Cos. v. Energy Transfer Equity, L.P.*, 159

the full language of the Merger Agreement here stresses the complete discretion of the buyer to develop, or not, the assets purchased. Limiting that discretion to require objective commercial reasonableness, given the facts as they exist, only means, in my view, that Defendants may not avoid the earn-outs in in a way that is commercially unreasonable. "Due regard" for the "efforts and costs" means that Defendants may eschew development where the circumstances reasonably indicate, as a business decision, that they not go forward. This includes all the costs and risks involved, including the milestone payments and the opportunity costs faced by Defendants, as evidenced by the provision that the reasonableness be measured against the actions expected of a company with "substantially the same resources and expertise" as the buyer. That is, if a reasonable actor with faced with the same

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A.3d 264, 272 (Del. 2017); *Menn v. ConMed Corp.*, 2022 WL 2387802, at *34–35 (Del. Ch. June 30, 2022); *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *87, 91 (Del. Ch. Oct. 1, 2018), *aff'd*, 198 A.3d 724 (Del. 2018)). These sorts of cases, however, involve efforts clauses in the pre-merger context, where business considerations are within a different context compared to post-merger circumstances.

In these contexts, commercially reasonable efforts clauses mandate that a party must pursue the contractual outcome *unless* it would be commercially unreasonable to do so, as the clause relates contractual closing itself, and promotes deal certainty. For example, in *Williams Companies, Inc. v. Energy Transfer Equity, L.P.*, a merger agreement set forth two milestones to be achieved after signing a merger agreement but before the merger was to be consummated. The merger agreement contained provisions that required the parties to use "commercially reasonable efforts" to obtain one of the milestones and to use "reasonable best efforts" to consummate the transaction. Plaintiffs brought suit after one milestone failed to occur as a result of the market taking a downturn, resulting in the acquiring company refusing to complete the merger. The court interpreted the provision contained in the merger agreement, "[the parties] shall cooperate and each use its commercially reasonable efforts to cause (i) the Merger to qualify for [tax free treatment under Section 721]," placed an affirmative obligation on the acquiring company to take all reasonable steps to complete the milestone and complete the merger. Here, the provisions are reversed; the buyer has complete discretion over development, cabined only by CRE.

restraints and risks would go forward *in its own self-interest*, the buyer is contractually obligated to do the same.

This approach is typified in *ev3, Inc. v. Lesh*, where a merger agreement provided for payments to a target company's stockholders, upon achievement of regulatory milestones, FDA approval and marketability, of a medical device at the acquiring company's sole discretion, which was cabined by exercising such discretion in good faith.[167] After it became apparent that the milestones were not going to be achieved, the target company's stockholders brought a breach of contract action against the buyer for failure to fund and pursue the regulatory milestones.[168] The acquiring company asserted that the development costs for the medical device to secure regulatory approval were astronomical, and concluded further investment required to secure FDA approval and efforts to bring it to the market was not worthwhile.[169]

The Court held that it would not "constitute bad faith . . . to refuse . . . to proceed . . . if the pursuit, after taking into account the milestones and development costs, was not expected to yield . . . a commercially reasonable profit . . . ."[170] The court, however, held that it would constitute bad faith if the expected profit to the

[167] 114 A.3d 527, 533 (Del. 2014).
[168] *Id.* at 528.
[169] *Id.* at 533.
[170] *Id.* at 541.

medical device at issue were in fact commercially reasonable and the company *delayed* development in order to avoid payment to former stockholders of the target company.[171]

I adopt here the reasoning of *eV3*, with the caveat that the provision in question there required subjective good faith, as opposed, here, to objectively reasonable efforts.

The parties disagree whether a similarly-situated hypothetical company used to measure CRE means a smaller company like Cephalon, the buyer, or a medium-sized company like Teva, which assumed the CRE obligations. I need not resolve that question, because the record fails to demonstrate that a company even with Teva's resources—taking into account the low probability of achieving approval of an EoE treatment, the costs thereof, and the low probability of profitable commercialization—would find it in its economic interests to go forward to approval and commercialization of RSZ for EoE.

It is notable that Defendants did undertake approval of RSZ for EA, where the preliminary test results were more favorable than for EoE,[172] that they were

[171] *Id.* at 541 (emphasis added).
[172] *Compare* JX108 (demonstrating that RSZ was likely effective in treating EA); JX43, Feb. 2010 Press Release (advising that "[t]hese data provide confidence that [RSZ] shows a meaningful treatment effect in this patient population), *with* JX36 (stating that RSZ for EoE failed to meet its second co-primary endpoint).

successful in doing so, and the milestone payment were made to Plaintiffs. The different circumstances regarding EoE led to a different result.

Plaintiffs point out that my reading of the CRE Clause[173] gives sellers little protection, since it is invoked only to disallow actions of the buyer that would be against the buyer's self-interest.[174] But this reading gives the Plaintiffs *all that the sellers bargained for.* Cephalon purchased an option to buy Ception to acquire its rights to RSZ. The initial test of RSZ for EoE was not successful, but the subsequent test for EA, also not fully a success, showed more promise. Cephalon then exercised its option. It purchased Ception and RSZ for a cash payment, with the discretion to develop RSZ as it saw fit, cabined only by objective commercial reasonableness. If it proved commercially reasonable to undertake the commercialization, and if Cephalon were successful in such an undertaking, the sellers would be entitled to milestone payments. But Cephalon was not required to take actions not in its self-interest, measured objectively. Ception was free to have bargained for more, but

[173] At the motion to dismiss stage, I held that the CRE Clause could be subject to two reasonable interpretations, (1) a hypothetical company and (2) yardstick standard. Mem. Op., 2018 WL 6822708, at * 8. Under the hypothetical company approach, the language would define the CRE Clause as those efforts "a company with substantially the same resources and expertise as [Cephalon]" *would expend under the circumstances at hand*. *Id.* In contrast, a yardstick approach would define the CRE Clause as those efforts compared to actions of other similarly situated companies. *Id.* For the reasons given, I have analyzed Defendants' actions under the former standard.

[174] Unlike in *eV3,* there is no endpoint after which commercialization would not trigger the milestone payments.

this was the bargain the parties actually struck. I now turn to the facts demonstrated at trial that support my finding that the Defendants did not breach.

1. Defendants Exercised Reasonable Commercial Efforts

a. Cephalon's Actions and Subsequent Decision to Terminate Developing RSZ for EoE was Commercially Reasonable

I find that Cephalon's actions were commercially reasonable since RSZ for EoE was not likely to receive regulatory approval. After Cephalon acquired Ception in 2010, it took actions to develop RSZ for EoE. In response to the initial failed study, Cephalon met with a former Ception employee to discuss potential remedies. Afterward, Cephalon hired two former Ception employees, and used their input to identify and execute a path to achieve regulatory approval. Over months, Cephalon created an alternative plan for FDA approval which drew from the continued Open-Label Study and conducted meetings to ameliorate data that the FDA had concerns with.

At the end of creating its plan, Cephalon requested a BLA meeting to present the plan. At this meeting, Cephalon proposed to (i) designate a surrogate endpoint as proof of RSZ's efficacy and (ii) to amend the Open-Label Study to convert it into an efficacy study. The FDA rejected the first proposal because "there was insufficient evidence to support histological changes in eosinophils alone as a surrogate endpoint reasonably likely to predict clinical benefit." In a similar vein, the FDA rejected the second proposal because such a conversion would be

exploratory in nature. Most importantly, the FDA made clear that Cephalon was unable to receive regulatory approval since Cephalon had not actually demonstrated symptom improvement in patients pursuant to a validated PRO tool.

Cephalon then prepared a proposal for an enriched enrollment, randomized withdrawal study, which would analyze actual users and non-users of RSZ in a randomized fashion. Cephalon met with the FDA on May 4, 2011, to present its proposal. The FDA once again rejected Cephalon's proposal, because it was unclear if the new approach would accurately depict symptom improvement. Cephalon attempted to implement the FDA's recommendations provided at the second meeting but concluded that the lack of a validated endpoint tool limited further development. Ultimately, Cephalon decided that it was not feasible to continue the study and terminated it. In total, Cephalon spent in excess of $7.5 million in its efforts to develop RSZ for EoE.

The evidence demonstrates that Cephalon took actions which were commercially reasonable to pursue development of RSZ for EoE. Cephalon created a plan to develop RSZ for EoE regulatory approval–with the assistance of Ception's former employees–that failed. It proposed three separate plans to the FDA, all were rejected. At this point in time, Cephalon had paid Ception stockholders $250 million in stockholder consideration. It had an incentive to develop and market RSZ for EoE, if commercially viable. Taking into consideration the failed FDA meetings–

even those before Cephalon acquired Ception–I find it commercially reasonable for Cephalon to have discontinued development for EoE at the time it did so.

I find that the actions of pharmaceutical companies that faced similar circumstances to Cephalon tend to support Cephalon's decision to terminate development of RSZ for EoE.[175] For example, Oxygen, a pharmaceutical company, conducted a clinical study of a drug for treatment of EoE in 2011.[176] The study failed because patient-reported outcomes did not differ significantly between the treatment and placebo groups, which is similar to circumstances that Cephalon faced.[177] As such, Oxygen is no longer developing its compound for EoE in the United States or European Union.[178] Similarly, another pharmaceutical, Allakos, launched a clinical trial of its anti-Siglet-8 therapy, lirentelimab, for the treatment of EoE, but the treatment failed to show symptom improvement.[179] Allakos also terminated development for EoE after the failure of its trial.[180]

[175] As Plaintiffs point out, these exemplar companies are not precise analogs of the Defendants, which is the mirror image of the *Defendants'* dissatisfaction with *Plaintiffs'* comparable companies. I cite these examples only to bolster my finding of commercial reasonableness, not as determinative of themselves.
[176] Trial Tr. (MacFarlane) 873:20–874:4.
[177] *Id.* at 873:20–875:23; JX1115 at 9.
[178] *Id*. at 875:21–876:2.
[179] Trial Tr. (Harvey) 1266:12–1267:2; JX823 (Doomsday for Allakos Article) ("Yesterday Allakos was worth $4.4[billion]. Today its valuation is a minute fraction of that after the catastrophic failure of Lirentelimab.").
[180] *Id.*

Plaintiffs argue that the FDA's recommendations and guidelines to secure a path to regulatory approval suggest a commercially reasonable path to commercialization existed. Although the FDA gave recommendations and guidelines, each time RSZ for EoE was up for approval it was rejected. The FDA's language, in the minutes of its meeting with Cephalon on developing RSZ for EoE, indicated that it looked forward to working together with Cephalon; this does not in my mind change the CRE analysis.[181] This anodyne encouragement does not support a finding that the FDA actually believed that there was a clear path for regulatory approval for RSZ for EoE. As the record evidences, the FDA does not have the authority to completely reject BLA submissions by companies, and thus must "present some path forward, even if that path forward isn't really viable or really isn't a realistic path forward."[182]

More fundamentally, the fact that the FDA was willing to work with Cephalon, like the fact that there were undoubtably more actions Cephalon could have undertaken and more resources it could have expended, is not the measure of CRE here. Under the Merger Agreement, Cephalon was not obligated to move the Earth to securing regulatory approval of RSZ for EoE. It only had to employ those effort as were commercially reasonable.

[181] *See* Trial Tr. (Wilkins) 308:19–309:8; Trial Tr. (Shah) 993:9–999:18.
[182] Trial Tr. (Harvey) 1243:10-20.

b. Teva's Actions to Prioritize RSZ for EA and its Decision to Decline to Restart Development of RSZ for EoE was Commercially Reasonable

When Teva acquired Cephalon, it took on the CRE obligation of the Merger Agreement. At that time, the decision to terminate had been taken by Cephalon, thus Teva did not acquire Cephalon with an on-going RSZ-for-EoE program in development.[183] Teva did not restart the program. From 2011 to 2017, however, Defendants prioritized and expended substantial resources to develop RSZ for EA, under the brand name CINQAIR, securing two milestones, which resulted in a $200 million Development Milestone payment to Ception stockholders. The FDA's approval, however, came with two caveats, (i) CINQAIR was to be administered intravenously while other competitors provided dosages available in a more convenient form, and (ii) a "black box" warning had to be affixed on every bottle of RSZ. These caveats, in turn, affected the commercial success of CINQAIR. After the commercialization of RSZ for EA proved to be unsuccessful, Teva turned its attention to RSZ for EoE. But, after conducting a third-party review and assessing the commercial profile of RSZ from the EA indication, Teva declined to restart developing RSZ for EoE.

[183] The parties are in dispute on when termination occurred, but I find that termination occurred before Teva acquired Cephalon. JX118 (stating the EoE program was terminated not put on hold); JX90 at 55 (stating that Teva did not have the right to be involved in decisions before closing); Trial Tr. (Shah) 912:9–18 (stating due diligence was performed on RSZ for EA because EoE had been discontinued).

I find that this prioritization objectively commercially reasonable because the record evinces that the EA indication was promising clinically and commercially. These facts, in comparison to the situation with EoE, which at the time had not secured regulatory approval and for which there was no clear path for regulatory approval, support Teva's decision to prioritize a more promising indication to achieve marketable success. I also find that the success of the first indication supports a finding that Teva's decision to decline to restart development was objectively commercially reasonable. In these particular circumstances, it was commercially reasonable for Teva to decline to invest substantial resources developing an indication like EoE, given the regulatory hurdles facing that indication and the likely restrictions—black box warning and infusion administration—that made EoE unlikely to be a commercial success. Since pursuit of the development of the EoE indication was not commercially reasonable, Teva's actions fell within its "complete" discretion over development of RSZ.[184]

Finally, Plaintiffs argue that Teva's inaction, for six years, to pursue or even evaluate development of RSZ for EoE, is itself commercially unreasonable. Plaintiffs argue that Defendants failed to (1) conduct a "rigorous or analytical review (2) continue or restart development; (3) budget for or expend any funds on development; (4) monitor developments or activities of competitors; (5) regularly

[184] *See ev3,* 114 A.3d 541.

assess viability of all potential indications annually; and (6) consider Ception stockholders' and experts' inquiries. But the burden is on Plaintiffs to demonstrate that these failures are commercially unreasonable; otherwise, such inaction was within Defendants' complete discretion with respect to RSZ. Given the facts as set out above, I find that Plaintiffs have not met that burden.

III. CONCLUSION

For the foregoing reasons, I find that Defendants used commercially reasonable efforts to develop RSZ for EoE. The parties should submit a form of order consistent with this Memorandum Opinion.

EXHIBIT D

GRANTED

THE COURT OF CHANCERY OF THE STATE OF DELAWARE

JEFF HIMAWAN, JOSH TARGOFF and STEPHEN TULLMAN, as the duly-appointed Representatives of the former stockholders of CEPTION THERAPEUTICS, INC., Plaintiffs, v. CEPHALON, INC. and TEVA PHARMACEUTICALS USA, INC. Defendants.	C.A. No. 2018-0075-SG

[PROPOSED] FINAL ORDER AND JUDGMENT

WHEREAS, on February 1, 2018, Jeff Himawan, Josh Targoff, and Stephen Tullman ("Plaintiffs") filed a Verified Complaint (Trans. ID 61637319) against Cephalon, Inc. ("Cephalon"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), and Teva Pharmaceuticals USA, Inc. ("Teva USA") for (i) breach of contract against Cephalon (Count I), (ii) breach of the implied covenant of good faith and fair dealing against Cephalon (Count II), and (iii) tortious interference with contract against Teva Ltd. and Teva USA (Count III);

WHEREAS, Defendants filed a Motion to Dismiss (Trans. ID 61736544) on February 28, 2018, and the Court heard oral argument on that motion (Trans. ID 62540145) on September 21, 2018;

WHEREAS, on December 28, 2018, the Court issued a Memorandum Opinion (Trans. ID 62804493) that granted in part and denied in part the Motion to Dismiss;

WHEREAS, on January 8, 2019, the Court entered an Order Denying in Part and Granting in Part Defendants' Motions to Dismiss (Trans. ID 62835782), (i) denying the Motion to Dismiss Plaintiffs' claim of breach of contract against Cephalon (Count I), and (ii) dismissing with prejudice Plaintiffs' claim of breach of the implied covenant of good faith and fair dealing against Cephalon (Count II) and Plaintiffs' claim of tortious interference with contract against Teva Ltd. and Teva USA (Count III);

WHEREAS, on January 28, 2019, Cephalon filed an Answer to Verified Complaint (Trans. ID 62859850);

WHEREAS, on July 11, 2022, Plaintiffs filed a Verified Amended Complaint (the "Amended Complaint") (Trans. ID 67810562) for breach of contract against Cephalon and Teva USA ("Defendants");

WHEREAS, on August 25, 2022, Defendants filed their Answer to the Amended Complaint (Trans. ID 67974370);

WHEREAS, the Court held a trial in this action on September 19-23, 2022;

WHEREAS, the parties stipulated to bifurcating post-trial briefing into two phases, with Phase I determining commercially reasonable efforts and whether there

was a breach and Phase II determining the consequences of that breach (Trans. ID 68197243; 68203388);

WHEREAS, the Court heard post-trial oral argument on November 16, 2023 (Trans. ID 71688363); and

WHEREAS, on April 30, 2024, the Court issued its Memorandum Opinion (the "Post-Trial Memorandum Opinion") (Trans. ID 72863274);

NOW, THEREFORE, it is hereby ORDERED this ___ day of May, 2024, that:

1. For the reasons set forth in the Post-Trial Memorandum Opinion, final judgment is entered in favor of Defendants and against Plaintiffs with respect to all counts in the Amended Complaint.

2. Plaintiffs shall pay Defendants' costs of $10,315.60 pursuant to Court of Chancery Rule 54(d), and the parties shall otherwise bear their own fees and expenses.

3. This Final Order and Judgment may be entered by the Prothonotary of the Superior Court in the same manner and form and in the same books and indices as judgments and orders in the Superior Court in accordance with 10 *Del. C.* § 4734.

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Dated: May 10, 2024

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IT IS SO ORDERED this _____ day of _____, 2024.

Vice Chancellor Sam Glasscock III

This document constitutes a ruling of the court and should be treated as such.

Court: DE Court of Chancery Civil Action

Judge: Sam Glasscock

Current Date: May 13, 2024

Case Number: 2018-0075-SG

/s/ Judge Sam Glasscock