**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 and Mackenzie M. Wrobel, DUANE MORRIS LLP, Wilmington, Delaware; OF COUNSEL: John Soroko, Wayne A. Mack, Michael J. Rinaldi, and Jessica Priselac, DUANE MORRIS, 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]

---

[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 for

[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.*

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]

---

[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

---

[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. (Dethelfs) 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. (Dethelfs) 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. (Dethelfs) 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."

---

[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

[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]

---

[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

[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,

---

[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

---

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.