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Case Number 226,2024

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

APPELLEES' ANSWERING BRIEF

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NATURE OF PROCEEDINGS

Following a five-day bench trial, Vice Chancellor Glasscock concluded that Defendants Cephalon and Teva fully satisfied their contractual obligation to use "commercially reasonable efforts" in pursuing the development of reslizumab ("RSZ"), a monoclonal antibody that Plaintiffs and Defendants had all hoped would be a successful treatment for two diseases, eosinophilic asthma ("EA") and eosinophilic esophagitis ("EoE"). The Vice Chancellor's determination properly recognizes what is obvious and what the evidence at trial overwhelmingly proved: having paid Plaintiffs hundreds of millions of dollars to acquire RSZ, Defendants had more incentive than anyone to develop RSZ into a productive, profit-generating asset, but that goal was not possible—not due to any action taken or not taken by Defendants, but because RSZ is a highly challenged product, both clinically and commercially. Standing to gain another $200 million payment, Plaintiffs' continued efforts to avoid this reality are perhaps not irrational, but as the Vice Chancellor correctly ruled, they are wholly without merit.

The record evidence firmly established that Defendants acted "commercially reasonably"—under the CRE provision here and any definition of that standard—when it came to RSZ in all respects. Defendants succeeded in gaining FDA and European Union approval to market and sell RSZ for EA—an undertaking that cost more than $1 billion, and resulted in Defendants promptly paying Plaintiffs $200

million in milestone payments. But RSZ for EA proved to be an abject failure in the marketplace, and Defendants will never come close to recouping the money they poured into developing RSZ for EA.

Unlike with EA, Defendants were unable to achieve the milestones for EoE, but not because they suddenly decided to act commercially unreasonably with respect to that indication. Extensive fact and expert evidence at trial proved that RSZ had no realistic prospect for regulatory and commercial success. There was and is no viable path to FDA approval for EoE, notwithstanding the years and millions of dollars Defendants spent trying to identify such a path. On top of that insurmountable regulatory hurdle, the evidence at trial proved that the commercial prospects for RSZ for EoE were and are particularly grim, even if FDA approval were somehow possible. So Defendants made the same decision as numerous other companies that had also attempted to develop therapies like RSZ to treat EoE: Defendants cut their losses and stopped development.

Plaintiffs' theory of the case appears to be that Defendants should have continued throwing good money after bad so that Plaintiffs could have a chance at an even greater windfall. At trial—as detailed in the Vice Chancellor's detailed factual findings—Plaintiffs did nothing to prove that a viable path to FDA approval exists, and they did nothing to prove that RSZ would have any hope of generating a profit even if it was approved for EoE. Nor did Plaintiffs prove that Defendants

failed to take *any* action that similarly situated companies took in comparable circumstances. Plaintiffs do not (and cannot) challenge any of those factual findings on appeal.

Given those failures of proof and the mountain of evidence pointing the other way, the Vice Chancellor correctly concluded that Defendants were under no obligation to continue investing in RSZ solely to try and enrich Plaintiffs further, and had done everything the CRE provision here required. *No* objectively reasonable pharmaceutical company would have behaved differently under the circumstances, the Vice Chancellor found as a matter of unchallenged fact. Accordingly, the Vice Chancellor held that Plaintiffs had not proven Defendants breached the Merger Agreement's CRE provision.

Plaintiffs' attempt to overturn that decision rests on a misreading of the Vice Chancellor's contractual interpretation and a fanciful retelling of the facts. Plaintiffs say the Vice Chancellor reduced the CRE obligation to a bare requirement that Defendants act in subjective good faith, ignored the CRE provision's reference to an external benchmark, and handed Defendants unfettered discretion about whether to exercise commercially reasonable efforts in the first place. None of that is true; a fair reading of the decision below makes short work of those charges. The Vice Chancellor's interpretation of the CRE provision is entirely correct: faithful to the text of the provision and to Delaware law. As to the facts, although Plaintiffs have

not challenged any of the Vice Chancellor's factual findings, their brief is littered with assertions that were thoroughly refuted at trial and fly in the face of the Vice Chancellor's detailed, carefully crafted findings. This effort is not persuasive. The decision below should be affirmed.

SUMMARY OF ARGUMENT

1. Denied. The Vice Chancellor correctly interpreted the CRE provision. Under the Vice Chancellor's reading, the CRE provision imposed an objective standard that required Cephalon and Teva to do more than act in subjective good faith, and required them to pursue development of RSZ for EoE by taking whatever actions companies facing similar circumstances would reasonably have taken in their own self-interests. (Op. 28-34.) That interpretation reflects the only permissible reading of the text of the CRE provision, and aligns with Delaware cases interpreting efforts clauses. Plaintiffs' asserted "missteps" depend on gross distortions of the Vice Chancellor's decision, and factual assertions that repeatedly contradict the Vice Chancellor's thoroughly supported—and unchallenged—factual findings.

2. Denied. The Vice Chancellor did not err in declining to give dispositive weight to the interpretation of efforts clauses in merger-consummation cases. Those cases arose in different contexts and did not involve the same contractual language at issue here. Regardless, there is no substantive daylight between the decision below and the merger-consummation cases Plaintiffs cite. (Op. 29-34.)

3. Denied. The implied covenant of good faith and fair dealing has no room to operate here because the Merger Agreement expressly establishes a comprehensive standard to evaluate Defendants' pursuit of RSZ. Plaintiffs' only

option was to prove that Defendants violated the CRE provision; failing that, Plaintiffs have no recourse for disagreements with Defendants' decision-making.

COUNTERSTATEMENT OF FACTS

Plaintiffs' Statement of Facts—and the factual assertions throughout their brief—read as though the parties never conducted a trial and the Vice Chancellor never made factual findings. That is improper, particularly because Plaintiffs chose not to appeal any of the Vice Chancellor's factual findings. (*See* Pl. Br. 23, 41 ("Scope of Review" sections limited to "[q]uestions of contract interpretation" and "[t]he trial court's 'formulation and application of legal principles'").) As this Court recently explained, when "the argument on appeal, and therefore [this Court's] analysis, is constrained to contract interpretation, [this Court] do[es] not review the court's post-trial factual findings and accept[s] them as accurate." *Exit Strategy, LLC v. Festival Retail Fund BH, L.P.*, --- A.3d ---, 2024 WL 3532886, at *6 (Del. July 25, 2024). In all events, factual findings following a bench trial "must be affirmed if they are supported by substantial evidence on the record and are the product of an orderly and logically deductive process." *Baker v. Long*, 981 A.2d 1152, 1156 (Del. 2009); *Coster v. UIP Cos., Inc.*, 300 A.3d 656, 663-64 (Del. 2023). Here, the Vice Chancellor's factual findings are not only unchallenged—they are unassailable, because they are amply supported by the record and the product of an orderly, logical process.

A. Background On Ception And Reslizumab

Plaintiffs are stockholder representatives of Ception Therapeutics, Inc., a start-up biopharmaceutical company. Ception sought to develop RSZ as a treatment for two indications in particular: EA and EoE. (Op. 4.) EA is a type of asthma caused by elevated eosinophil levels in the lungs, and EoE is a chronic digestive system disorder "in which large numbers of eosinophils are present in the esophagus." (Op. 5.) "Eosinophils" are a type of white blood cell that can be harmful when too many of them are present. (Op. 5.) RSZ is known as an "anti-IL5" because it targets interleukin 5 ("IL5"), a type of cytokine that is associated with eosinophils. (*See* Op. 5.) RSZ is intended to "control[]" the "overproduction of eosinophils" by "preventing [IL5] from binding to its receptor." (Op. 5.)

To commercialize RSZ for sale in the United States, Ception needed to convince FDA that RSZ is safe and effective for treating EA and EoE. Ception designed two clinical trials: one for EA (the "EA Study"), which began in November 2007, and one for EoE (Res-5-0002, or the "EoE Study"), which began in March 2008. (Op. 6-7.)

The EoE Study involved 228 subjects aged 5 to 18. (Op. 7.) Some were given RSZ, and some received a placebo. (Op. 7.) The EoE Study sought to measure improvement in two co-primary endpoints: (a) a decrease in the number of

eosinophils in patients' esophagus, and (b) improvements in patients' EoE symptoms. (Op. 6.) To be successful, the study needed to meet both endpoints.

The EoE Study concluded in October 2009. (Op. 7.) It was a "failed study." (Op. 34.) Although the EoE Study met its first endpoint (measuring reductions in patients' eosinophil levels), it "failed to meet" its second endpoint—the endpoint that assessed RSZ's efficacy at treating EoE—because symptom improvement associated with RSZ "did not have statistical significance" compared to placebo. (Op. 8.) After the EoE Study concluded, patients were allowed to enroll in a separate Open-Label Study, a long-term study that would generate additional safety data while allowing patients to continue receiving RSZ. (Op. 7.)

Plaintiffs say "[t]he results of the EoE Study were promising" (Pl. Br. 8), but that notion blinks reality. The results were devastating. One Ception shareholder testified that she "was very upset about the results," and that people at the company were "[c]rying" when the results came back. (A01676/121:8-13 (Rainville).) Not only did the EoE Study suggest RSZ might never be approved for EoE, but it also threatened to derail Ception's potential acquisition by Cephalon. Indeed, a year before the EoE Study concluded, Cephalon negotiated an option to purchase Ception for $250 million, but expressly carved out a right to abandon the acquisition if "the co-primary endpoints" of the EoE Study "have not been achieved." (B00013)

Rather than walk away after the EoE Study failed, Cephalon decided to wait for the results of the EA Study. (Op. 8.) That data ultimately "demonstrated that RSZ was likely effective in treating EA." (Op. 8.) Cephalon promptly issued an enthusiastic press release, celebrating the EA Study for showing "a strong treatment signal" and "meaningful treatment effect." (Op. 8.)

B. The Merger Agreement

Thanks to the encouraging results of the EA Study, Cephalon exercised its option to acquire Ception for $250 million in March 2010. (Op. 8-9; A00227.) The Merger Agreement also provided the possibility of an additional $400 million in milestone payments: $200 million if FDA and the European Commission approved RSZ for EoE, and $200 million if FDA and the European Commission approved RSZ for EA. (Op. 9; A00262, §3.4(a).) The Merger Agreement obligated Defendants "to use … commercially reasonable efforts to develop and commercialize" RSZ. (A00262, §3.4(a)(iii).) The CRE provision 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 [Defendants], with due regard to the nature of efforts and cost required for the undertaking at stake." (A00262, §3.4(a)(iii).)

The Merger Agreement also contained a provision that (i) granted Defendants "complete discretion with respect to all decisions related to … the research,

development, manufacture, marketing, pricing and distribution" of RSZ, (ii) stated that Plaintiffs "shall have no right to object to the manner in which" Defendants exercise that discretion, and (iii) affirmed that Defendants had "no obligation to … take any action to protect, attain or maximize any payment to be received by" Plaintiffs. (A00264, §3.4(c).) The Discretion provision specifically provided that Defendants had no "obligation to (i) conduct clinical trials; (ii) pursue regulatory approvals; (iii) maximize payment to Ception stockholders; (iv) follow Ception's business plan; or (v) consult with Ception stockholders with respect to the business." (Op. 9-10.) The Discretion provision acknowledged one limitation: Defendants' otherwise unbounded discretion was "[s]ubject to" the CRE provision. (A00264, §3.4(c).)

C. Cephalon Expends Significant Efforts Developing RSZ For EoE, But Those Efforts Fail.

Plaintiffs repeatedly assert that after the acquisition, Cephalon took no meaningful steps to develop RSZ for EoE. (*E.g.*, Pl. Br. 13.) The Vice Chancellor found otherwise, in detailed factual findings that Plaintiffs ignore. (Op. 10-13, 34-37.)

First, in April 2010, Cephalon met with two former high-ranking Ception officials—Dr. Tim Henkel, Ception's Head of Research and Development, and Dr. Jeff Wilkins, another Ception EoE project lead—to discuss "potential remedies to the failed EoE Study" and to explore a "protocol amendment to the Open-Label

Study," with the goal of charting a path to FDA approval. (Op. 10.) Cephalon went on to retain those two former Ception officials as paid consultants to progress EoE development. And, if anyone was motivated to find a regulatory path forward, it was Dr. Henkel and Dr. Wilkins, both of whom were Ception stockholders and stood to benefit from any EoE milestone payments. (A04606/94:2-96:13 (Tullman).)

Together with Dr. Henkel and Dr. Wilkins, "Cephalon created a plan to attempt to secure FDA approval for the EoE program." (Op. 10-11.) As part of this effort, "Cephalon spent months creating an alternative plan for FDA approval which drew from participant data in the Open-Label Study," and conducted numerous "meetings to explore the clinical development of EoE to ameliorate data that the FDA had concerns with." (Op. 11.) In September 2010—after months spent working closely with Dr. Henkel and Dr. Wilkins—Cephalon requested a meeting with FDA to present its EoE proposals. (Op. 11.) The meeting took place in December 2010. (Op. 11.) Cephalon invited Dr. Henkel and Dr. Wilkins "to help present the proposal to the FDA." (Op. 11.)

First, Cephalon tried to qualify for an FDA program for accelerated approval, and—to remedy the shortcomings of the EoE Study—Cephalon tried to persuade FDA to accept a "surrogate endpoint as proof of RSZ's efficacy." (Op. 12.) Instead of assessing symptom improvement directly, Cephalon advocated that FDA "should accept reduced eosinophil levels coupled with 'the reintroduction of previously

restricted foods' as 'reasonably likely to predict clinical benefit'" of RSZ for EoE. (Op. 11-12.) Second, Cephalon proposed to demonstrate RSZ's efficacy by amending the Open-Label Study, such that patients treated with RSZ would "reintroduc[e] foods into [their] diets … that had not been previously tolerated," and then Cephalon would "analyz[e] the percentage of patients able to successfully adjust to their diet." (Op. 12.)

FDA rejected both proposals. (Op. 11-12.) 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,'" and it rejected the second proposal because the results would not have had a close enough link "to a clinical improvement in symptoms among patients." (Op. 12.) FDA made clear that it would not approve RSZ for EoE unless Cephalon could "actually demonstrate symptom improvement in patients with a validated PRO tool." (Op. 12-13.) A "PRO tool" is a "patient reported outcome questionnaire," which is a way to measure symptom relief in a clinical trial; it must be "validated to ensure accurate measurement." (Op. 13 n.63.)

The December 2010 FDA meeting was unsuccessful, but Cephalon still pushed forward. "Despite the FDA's rejection of Cephalon's proposals," Cephalon spent months continuing to work with Dr. Henkel and Dr. Wilkins to search for a path to regulatory approval. (Op. 13.) Cephalon next attempted to demonstrate

RSZ's efficacy for EoE by designing "an enriched enrollment, randomized withdrawal ('EERW') study," which would "indicate symptom improvement by analyzing patient results that were removed from treatment in a randomized fashion compared to patients who continued to use RSZ." (Op. 13.) This was Cephalon's third attempt to devise a way to prove RSZ's efficacy—but FDA rejected it as well. In May 2011, "FDA rejected the plan to implement the EERW study, finding that it was unclear if the new approach would accurately depict symptom improvement." (Op. 13.)

Still, Cephalon pressed on. After the May 2011 meeting, FDA "provided general recommendations" on how Cephalon might use data from the EoE Study and the Open-Label Study to identify a path forward. (Op. 13.) Cephalon followed FDA's recommendations and, over the next six months, "conducted the requested analysis," but these efforts proved to be another dead end, because FDA's suggested analyses "could not 'identify a clinical benefit to treatment in a specific subpopulation with a predominant symptom of EoE.'" (Op. 14.)

Around five months later, having struck out yet again, Cephalon concluded that there was no viable way to convince FDA that RSZ was effective at treating EoE—particularly because no validated PRO existed "to measure clinical benefit," which FDA had said was necessary for approval back in December 2010. (Op. 14.) In light of that roadblock, Cephalon informed FDA in November 2011 "that it was

discontinuing developing RSZ for EoE since it was not feasible to study the existing patient population to support regulatory approval." (Op. 14.)

All told, "Cephalon spent in excess of $7.5 million in its efforts to develop RSZ for EoE." (Op. 35.) As described in more detail above, the Vice Chancellor's factual findings establish that Cephalon "created a plan to develop RSZ for EoE regulatory approval—with the assistance of Ception's former employees," and "proposed three separate plans to the FDA." (Op. 35.) Even Dr. Wilkins praised Cephalon for its diligent efforts to develop RSZ for EoE. Dr. Wilkins testified that Cephalon "work[ed] hard to find a pathway for [RSZ] for EoE," that he "respected the people [he] worked with at Cephalon," he "believed they were qualified to do their jobs" and "were experienced in clinical development," he believed they acted in good faith, and he "never saw anyone act in a manner … that [he] thought was not intended to obtain FDA approval for EoE." (A04704/370:9-371:8 (Wilkins).)

Furthermore, the Vice Chancellor found, as a matter of fact, that Cephalon's decisions were supported by "the actions of pharmaceutical companies that faced similar circumstances to Cephalon." (Op. 36.) The Vice Chancellor pointed to two companies in particular: Oxygen and Allakos. Both companies sought to develop treatments for EoE, but both companies terminated their programs after clinical trials failed to demonstrate efficacy, just as Cephalon did. (Op. 36.) Although Plaintiffs sought to compare Cephalon to several other companies that Plaintiffs claimed were

similarly situated (Op. 25-26), the Vice Chancellor rejected those comparisons, finding instead that only Oxygen and Allakos "faced similar circumstances to Cephalon." (Op. 36.) Extensive evidence in the record supported the Vice Chancellor's decision to reject Plaintiffs' comparisons. (*See, e.g.*, A05075-05081/1439:15-1469:3 (Selck) (defense expert demonstrating that Plaintiffs' comparator companies had vastly more resources, experience, and expertise than Cephalon across a range of relevant metrics, and that other companies were better comparators).)

In view of all the evidence—including that Cephalon expended significant efforts trying to develop RSZ for EoE, that "RSZ for EoE was not likely to receive regulatory approval," and that "pharmaceutical companies that faced similar circumstances to Cephalon" terminated their EoE programs—the Vice Chancellor concluded that "Cephalon's actions were commercially reasonable." (Op. 34, 36.)

D. Teva Acquires Cephalon And Successfully Commercializes RSZ For EA—But RSZ Is A Commercial Failure.

Teva acquired Cephalon in October 2011. (Op. 14.) By then, "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." (Op. 38.) Nevertheless, Teva met with Ception's former owners "to discuss RSZ, including the EoE indication." (Op. 14-15.) Given that Cephalon had terminated the EoE program, but that EA had shown clinical and commercial potential, Teva decided to focus its efforts on EA for

the time being. (Op. 15, 39.) The Vice Chancellor concluded that Teva's "prioritization" of EA over EoE was "objectively commercially reasonable," because it made good commercial sense "to prioritize a more promising indication to achieve marketable success." (Op. 39.) Prioritizing EA over EoE was also consistent with other pharmaceutical companies that were pursuing treatments for both indications, including several companies Plaintiffs held out as comparators. (*See, e.g.*, A04862/870:5-8 (MacFarlane) (Plaintiffs' expert conceding that Sanofi-Regeneron, GSK, and AstraZeneca "pursued regulatory approval … for EA before EoE").)

Teva devoted very substantial efforts developing RSZ for EA, spending "an estimated one billion [dollars]," including hundreds of millions of dollars building a new RSZ manufacturing facility in Germany, and $400 million in additional research, marketing, and developmental costs. (Op. 15.)

Those efforts paid off—for Plaintiffs, at least. In 2016, Teva received FDA and European Commission approval to market RSZ for EA, and having achieved those contractual milestones, promptly paid Plaintiffs $200 million. (Op. 15-16.) But RSZ for EA was a commercial failure, for two reasons—both of which destroyed the commercial prospects of RSZ for EoE as well, as discussed in more detail below. Plaintiffs' brief mentions neither of these reasons.

First, FDA required Teva to include a "black box warning" on RSZ's label—the most serious warning mandated by FDA—warning doctors that RSZ could cause severe, potentially fatal anaphylaxis. (Op. 16.) As the Vice Chancellor explained, "[t]his designation affected RSZ's commercial prospects, as there are many other treatments for EA on the market that did not include such designation." (Op. 16.) Second, and perhaps even more importantly, RSZ was "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." (Op. 16.) By contrast, other therapies could be administered subcutaneously, meaning patients could administer the treatment themselves outside of a medical facility, like insulin. (Op. 16.)

These circumstances destroyed the commercial potential of RSZ for EA. The failure to obtain approval for subcutaneous administration alone "eliminated … 90 percent of the whole business case" for RSZ as a treatment for EA. (A05053/1352:18-1353:5 (Dethlefs).) In a good year, RSZ for EA barely produces an operating profit, and "will never return the money that [Teva] invested" in it. (A05054/1357:20-1358:2 (Dethlefs).) And, as discussed below, the Vice Chancellor found that it was "likely" that these same "restrictions," *i.e.*, "black box warning and infusion [IV] administration," would apply to EoE as well, and "made EoE unlikely

to be a commercial success," even in the unlikely event it could secure FDA approval. (Op. 39.)

E. Teva Devotes Significant Resources To EoE, But Hits A Dead End.

As with Cephalon, Plaintiffs repeatedly assert that Teva did nothing and expended no efforts to develop RSZ for EoE. (*E.g.*, Pl. Br. 2, 16-18, 34.) But as with Cephalon, the Vice Chancellor found otherwise, with detailed factual findings Plaintiffs ignore.

For starters, Plaintiffs are wrong when they assert that "Defendants made ***no effort and committed no resources*** to develop RSZ for EoE between 2012 and 2016." (Pl. Br. 2 (emphasis in original).) The Vice Chancellor found that from 2011 onward, "Teva kept in contact with physicians that shared their thoughts on RSZ treating other disorders and considered the viability of EoE," but concluded that "EoE was not worth pursuing because there was not a successful path to secure FDA approval, since a PRO tool … did not demonstrate symptom improvement." (Op. 17; *see also* Op. 18 ("During its development of RSZ for EA, however, Teva monitored the regulatory landscape of EoE.").) Furthermore, evidence at trial showed that Plaintiffs *agreed* with Teva's decision to pursue approval for EA before devoting substantial efforts to EoE. (*See, e.g.*, A05065-05066/1402:23-1403:7 (Dethlefs) ("Ception … agreed that it ma[de] a whole lot of sense to first develop

the EA indication … and then move on from there."); A04598/62:14-20 (Tullman).) As discussed above, other companies made the same prioritization.

Teva's efforts with respect to EoE picked up steam in 2016, after FDA approved RSZ for EA. (Op. 18.) Contrary to Plaintiffs' assertions, it was not "[o]nly after Plaintiffs reminded Defendants of their CRE obligation" that Teva re-assessed EoE. (Pl. Br. 3.) Rather, as the Vice Chancellor found, "Teva began to assess the entire RSZ brand, including considering moving into the EoE indication," in February 2016—eight months before Plaintiffs purportedly "reminded" Teva of its CRE obligations in October 2016. (Op. 18.)

To ensure a comprehensive review with fresh eyes, Teva enlisted RxC, "a third-party biopharma strategy consulting firm that specializes in pharmaceutical life cycle planning and new product commercialization." (Op. 19.) Teva retained RxC "to conduct an opportunity assessment of RSZ for EoE," focusing on EoE's "clinical and regulatory viability." (Op. 19.) But as the Vice Chancellor summarized, RxC concluded that "regulatory approval was unlikely," owing to "difficulties in creating a successful clinical trial framework and RSZ's failure to show improvement in patients with EoE." (Op. 19-20.) Those conclusions were bolstered by RxC's investigation of other companies' lack of progress in developing treatments for EoE. Not only did RxC find that "no other company obtained FDA approval for treating EoE"—RxC also found that other companies "had made little progress" in even

identifying a potential path toward approval. (Op. 19-20.) Plaintiffs denigrate RxC's review as "not independent," and even manipulated by "Defendants and their lawyers" (Pl. Br. 18), but the Vice Chancellor rejected these characterizations, finding that RxC conducted an "independent evaluation." (Op. 20.)

The evidence at trial showed that Teva would have needed to invest at least an additional $200 million running clinical trials just to be in a position to submit an FDA application for EoE, assuming the clinical trials were successful. (A04914/954:4-23 (Shah).) But the evidence at trial overwhelmingly corroborated RxC's conclusion that additional clinical trials were *not* likely to be successful, and FDA approval was *not* likely to be obtained. As the Vice Chancellor found—as a matter of unchallenged fact—"RSZ for EoE was not likely to receive regulatory approval," RSZ had a "low probability of achieving approval of an EoE treatment," and Plaintiffs presented no credible evidence "that the FDA actually believed that there was a clear path for regulatory approval for RSZ for EoE." (Op. 32, 34, 37.)

It is easy to see why the Vice Chancellor found that FDA approval was so unlikely. Beyond RxC's independent review, the Vice Chancellor heard extensive testimony from Defendants' expert Dr. Brian Harvey, FDA's former Division Director in gastroenterology products—the division that would have been responsible for approving RSZ for EoE. (A04978/1208:22-1209:24 (Harvey).) Dr. Harvey provided a detailed scientific explanation of the clinical data bearing on

RSZ's efficacy as a treatment for EoE. (*See, e.g.*, A04980-A04981/1219:17-1223:9 (Harvey).) "[B]ased upon my evaluation of the available scientific data," Dr. Harvey testified, "it was unlikely that RSZ was going to be effective for EoE, and thus unlikely RSZ would ever gain FDA approval for an EoE indication." (A04980/1216:8-12 (Harvey).) Dr. Harvey testified that, in his view, the odds of FDA approval were "lower than 10 percent." (A05027/1247:17 (Harvey).) That prognosis is borne out by the fact that to this day, *no* clinical trial has shown an anti-IL5 to be effective in treating EoE. (A04927/1004:6-9 (Shah).)

The overwhelming evidence on the lack of a viable clinical and regulatory pathway would have more than justified Teva in declining to restart EoE development. But Teva went beyond a clinical and regulatory assessment, and independently "considered the commercial profile of RSZ" to determine whether restarting development would make sense *even assuming* a regulatory path existed. (Op. 20.) This commercial assessment was greatly influenced by two clinical trials that Teva conducted in an attempt to persuade FDA to allow RSZ to be administered subcutaneously. Teva spent $160 million conducting those trials. (A04914/953:22-954:3 (Shah).) But they failed for EA in 2018—confirming that RSZ would have to be administered intravenously—and the results were equally applicable for EoE. (Op. 20; *see also, e.g.*, A05034/1277:17-1278:23 (Harvey); A05035/1279:23-1280:2 (Harvey); A04536-A04541 (Harvey Expert Report).)

This subcutaneous setback was an independent dealbreaker for EoE from a commercial perspective, especially when coupled with RSZ's black box warning. As Dr. Tushar Shah, Teva's former Global Head of Respiratory R&D, testified about EoE: "Once we saw our label and we saw the competition and their labels, it changed the dynamic, because when you have a product that's an IV and everybody is sub-Q and that's what everybody wants to use, it doesn't make sense to invest more in developing this drug for any indication." (A04919/973:7-14 (Shah).) Following the failure of Teva's subcutaneous clinical trials in 2018, it "made no sense commercially" to continue developing RSZ for EoE, because Teva would never "get a return on that investment." (A04918/970:13-24 (Shah).) Underscoring that it would have been objectively unreasonable to continue pursuing EoE, evidence at trial showed that Teva worked with Plaintiffs to find third parties to assist with funding EoE development, but investors were not interested because "they didn't see the potential of this drug," particularly without "the subcutaneous formulation." (A05058/1371:17-1372:10 (Dethlefs).)

Plaintiffs' brief does not mention the subcutaneous and "black box" obstacles even once. But as the Vice Chancellor found, "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"—and "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." (Op. 20 & n.109.)

All of these circumstances made it a no-brainer for Teva to decline restarting the EoE program. Contrary to Plaintiffs' assertion that Teva "did not pursue RSZ for EoE solely because of the milestone payments" (Pl. Br. 18), the Vice Chancellor found that "*[b]ased on these conclusions*"—*i.e.*, that RSZ for EoE had no viable path to FDA approval, would not qualify for subcutaneous administration, and would require a black box warning—"Teva made the decision to not restart development." (Op. 20 (emphasis added).) The Vice Chancellor held that "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." (Op. 39.)

And as with Cephalon's decision to terminate EoE development, the Vice Chancellor concluded that Teva's decision not to restart development was supported by decisions of other companies. For example, GSK and AstraZeneca—two companies that had *more* resources and relevant expertise than Teva—also worked on anti-IL5 therapies, but they both abandoned their EoE programs, which Teva viewed as "validating" its decision that EoE was "too risky" to pursue. (A04917/964:11-965:1 (Shah); *see also* A05064-A05065/1398:21-1399:9

(Dethlefs).) To this day, no anti-IL5 therapy has been approved for EoE. (A04783/508:18-20 (Liacouras).) Plaintiffs mention Dupixent (Pl. Br. 37-38), which is the only FDA-approved treatment for EoE, but the evidence at trial showed that Dupixent is vastly different from RSZ—it uses a different mechanism of action (it is not an anti-IL5) and had much better clinical trial results—meaning Dupixent's approval says nothing about RSZ's prospects. (*E.g.*, A04917-A04918/965:2-968:9 (Shah); A04981/1222:24-1223:9 (Harvey); A04982/1226:12-1227:1 (Harvey); A05030-A05031/1262:11-1265:1 (Harvey)).

Once again, the Vice Chancellor acknowledged Plaintiffs' argument that Teva expended less effort than other companies that Plaintiffs contended were similarly situated, but the Vice Chancellor rejected these comparisons, which Defendants' experts showed were baseless. (Op. 25-26; A05075-05081/1439:15-1469:3 (Selck).) Instead, the Vice Chancellor found, as a matter of fact, that "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." (Op. 32.)

ARGUMENT

I. THE VICE CHANCELLOR CORRECTLY INTERPRETED THE MERGER AGREEMENT'S CRE PROVISION.

A. Question Presented

Whether the Vice Chancellor correctly interpreted the CRE provision to impose an objective standard that required Defendants to pursue development of RSZ for EoE by taking whatever actions reasonable companies facing similar circumstances would have taken in their own self-interests. (Op. 28-34.)

B. Scope of Review

This Court reviews questions of contract interpretation *de novo*. *Sunline Com. Carriers, Inc. v. CITGO Petroleum Corp.*, 206 A.3d 836, 845 (Del. 2019). Because Plaintiffs have not challenged the Vice Chancellor's factual findings (*see* Pl. Br. 23), this Court will "not review" them and will "accept them as accurate." *Exit Strategy*, 2024 WL 3532886, at *6. If Plaintiffs had challenged them, they "must be affirmed if they are supported by substantial evidence on the record and are the product of an orderly and logically deductive process." *Baker*, 981 A.2d at 1156. In addition, where a trial court applies the wrong legal standard, affirmance is warranted if the court's factual findings demonstrate that the appellee would be entitled to prevail even under the correct standard. *Exit Strategy*, 2024 WL 3532886, at *7; *Hoffecker v. Lexus of Wilmington*, 36 A.3d 349, 2012 WL 341714, at *2-3 (Del. 2012) (TABLE); *Lewis v. State*, 977 A.2d 898, 2009 WL 2469254, at *3 (Del. 2009) (TABLE).

C. Merits of Argument

Under the Vice Chancellor's interpretation, the CRE provision had significant bite. The Vice Chancellor held that the CRE provision embodies an objective standard that limited Cephalon and Teva's discretion with respect to developing RSZ for EoE, compelling them to do more than act in good faith—it required them to take whatever actions a company facing similar circumstances would reasonably have taken in its own self-interest. As the Vice Chancellor put it, the CRE provision means 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. 30-31 (emphasis altered).) In other words, "[t]he question is, … 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." (Op. 28-29.) And on the flipside, if Plaintiffs had proven that the answer was *no*—that Defendants did *not* take the steps that an objectively reasonable company would have taken to pursue RSZ for EoE—then there would have been a breach, even if Defendants had acted in the utmost good faith.

The Vice Chancellor's interpretation of the CRE provision is correct from start to finish. Although Plaintiffs offer several criticisms, none is remotely persuasive.

1. The Vice Chancellor correctly applied an objective standard that required Defendants to do more than act in subjective good faith.

Plaintiffs repeatedly assert that the Vice Chancellor equated the CRE provision with a requirement that Defendants merely act in subjective good faith. (*E.g.*, Pl. Br. 4-5, 22, 26-29.) This argument is baseless. The Vice Chancellor *agreed* with Plaintiffs that the CRE provision embodies an objective standard that required Defendants to do more than act in subjective good faith. As the Vice Chancellor put it: "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*." (Op. 29 (emphasis added); *see also*, *e.g.*, Op. 23 ("Plaintiffs assert, correctly, that the CRE Clause puts forth an 'objective standard.'"); Op. 33 (holding that the CRE provision requires "objective commercial reasonableness").)

And to be clear, the Vice Chancellor did not merely articulate an objective standard; the Vice Chancellor applied an objective standard as well. As the Vice Chancellor explained, Defendants "argue[d] that their efforts were in fact objectively commercially reasonable." (Op. 26.) The Vice Chancellor agreed, based on the unchallenged factual findings detailed above. As the Vice Chancellor summarized: "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." (Op. 32.) That factual finding means Defendants did far more than act in subjective good faith; it means they behaved in a manner that was objectively commercially reasonable, as required by the legal standard articulated by the Vice Chancellor. Plaintiffs cannot overcome that conclusion by pretending the Vice Chancellor applied a different standard than the one the court repeatedly embraced.[1]

Plaintiffs miss the mark by criticizing the Vice Chancellor's discussion of *ev3, Inc. v. Lesh*, 114 A.3d 527, 533 (Del. 2014). The Vice Chancellor explained that his analysis "adopt[s] … the reasoning of *ev3*, with the caveat that the provision in question there required subjective good faith, *as opposed, here, to objectively reasonable efforts*." (Op. 32 (emphasis added).) The Vice Chancellor explained that modifying *ev3* to fit an objective standard meant Defendants could "refuse … to proceed" with RSZ development efforts if those efforts were "not expected to yield … a commercially reasonable profit," considered objectively—meaning backed by objective evidence, like the RxC report, expert scientific, financial, and regulatory testimony, the decisions of potential third-party investors, and evidence of how other companies behaved in similar circumstances. (Op. 31.) And as

[1] Oddly, Plaintiffs appear to embrace a subjective standard, as they criticize Defendants for supposedly being unfamiliar with the CRE provision. (*E.g.*, Pl. Br. 16.) That assertion is false (*see, e.g.*, A04619/145:5-146:8 (Fosbury)), and it is irrelevant in light of the objective nature of the CRE provision.

discussed at length above, that body of objective evidence is exactly what the Vice Chancellor relied on in concluding that Defendants' behavior *was* objectively commercially reasonable. If the Vice Chancellor had been secretly applying a subjective good-faith standard, the court's analysis could have begun and ended by citing credible testimony from Defendants' fact witnesses that they sincerely believed developing RSZ was not in their economic self-interests. But that is not what the Vice Chancellor did. Instead, as explained, the court found—as a matter of unchallenged fact—that *no* reasonable pharmaceutical company, "even [one] with Teva's resources … would find it in its economic interests to go forward to approval and commercialization of RSZ for EoE," considering the extensive, objective evidence demonstrating "the low probability of achieving approval of an EoE treatment, the costs thereof, and the low probability of profitable commercialization." (Op. 32.)

For the same reasons, Plaintiffs are wrong to criticize the decision below for holding that the CRE provision did not require Cephalon and Teva "to take actions not in [their] self-interest, measured objectively." (Op. 33; *e.g.*, Pl. Br. 24 (asserting the Vice Chancellor's reference to Defendants' "'own self-interest' … turned the CRE Clause … on its head"); *id.* 29-30.) Anchoring the analysis in Defendants' "self-interest, measured objectively," did not magically transform the analysis into a subjective good-faith test. (Op. 33.) Again, if it had, the Vice Chancellor could

have shortened his opinion (and the trial) substantially by simply citing credible testimony that Defendants' fact witnesses honestly believed further RSZ development was not in their economic self-interest, rather than relying on the extensive record of objective evidence proving that *no* reasonable, similarly situated company would have believed further development efforts were economically justified. That is why the Vice Chancellor read the CRE provision to mean 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. 30-31 (emphasis altered).)

Furthermore, the text of the CRE provision expressly ensures that Defendants would not be forced to act to their economic detriment—which is why the CRE provision clarifies that it must be understood and applied "with due regard to the nature of efforts and cost required for the undertaking at stake." (A00262, §3.4(a)(iii).) "Regard" means "[a]ttention, care, or consideration," and "due" means what is "[j]ust, proper, regular, and reasonable." *Black's Law Dictionary* (12th ed. 2024). In this context—involving for-profit commercial enterprises like Cephalon and Teva—the "just, proper, regular, and reasonable" "consideration" they give to the "costs" and "efforts" of a potential project, is that such costs and efforts should not swamp the expected return on investment, or compare so unfavorably to other opportunities that it would be against the firm's self-interests to proceed. (*See, e.g.*,

A05073/1433:19-1434:22 (Selck) (expert testimony on how pharmaceutical companies consider costs and efforts when making investment decisions).) Hence, as the Vice Chancellor held, Defendants were "not required to take actions not in [their] self-interest, measured objectively." (Op. 33.)

Surely a provision requiring *commercially reasonable* efforts could not require a firm to act against its own economic self-interests. Indeed, "[d]eal practitioners" typically understand "[c]ommercially reasonable efforts" as "not requiring a party to take any action that would be commercially detrimental." *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *87 (Del. Ch. Oct. 1, 2018), *aff'd*, 198 A.3d 724 (Del. 2018). Regardless of whether that principle would otherwise go without saying, the parties here said so explicitly, by agreeing to the "due regard" proviso, and thereby protected Defendants from claims that they were required to pursue development of RSZ at all costs, or subordinate their own interests to those of Ception's former owners. Had the parties intended to obligate Defendants to pursue RSZ even against their own economic self-interests, the CRE provision would have required development *without regard* to costs; instead, the parties agreed that the CRE provision must be understood with *due regard* to costs, and thus ensured that Defendants would never be required to take actions that a reasonable party would consider to be against its economic self-interest. Given the plain text of the "due regard" proviso, no other reading is permissible.

2. The Vice Chancellor correctly recognized that Defendants' discretion was subject to the CRE provision.

Plaintiffs repeatedly assert that the Vice Chancellor erroneously allowed Cephalon and Teva to exercise unfettered discretion without regard to the CRE provision. (*E.g.*, Pl. Br. 31-32.) This argument fails because it ignores the Vice Chancellor's repeated explanation that he *agreed* with Plaintiffs that Defendants' discretion was subordinated to the CRE provision. The Vice Chancellor was explicit that "Plaintiffs assert, correctly, that the CRE Clause … afford[s] Defendants 'discretion to decide how to proceed with RSZ,' *subject to and 'cabined by the objective standard.'*" (Op. 23 (emphasis added); *see also*, *e.g.*, Op. 10 ("The Discretion Clause, however, was subjected to a 'commercially reasonable efforts' clause."); Op. 28 (same).)

The Vice Chancellor applied that standard by finding—as a matter of fact—that it would not have been commercially reasonable to continue developing RSZ for EoE, because *no* reasonable pharmaceutical company "would find it in its economic interests to go forward to approval and commercialization of RSZ for EoE," in light of "the low probability of achieving approval of an EoE treatment, the costs thereof, and the low probability of profitable commercialization." (Op. 32.) Because the court's factual findings compelled a conclusion that further development was not mandated by the CRE provision, pursuing development (or not) was left to Defendants' discretion. That is how the CRE provision and the

Discretion provision interact—if an activity is required by the CRE provision, Defendants have no discretion to forgo it, but if an activity is *not* required by the CRE provision, Defendants can pursue it or not as they see fit.

Plaintiffs continue attacking a strawman when they criticize the Vice Chancellor for holding that Defendants had discretion about "***whether*** to undertake CRE to develop RSZ for EoE," and when they insist that "Defendants ***did not have discretion*** to eschew development of RSZ for EoE because Defendants were required to use CRE to develop RSZ for EoE." (Pl. Br. 25, 32 (emphasis in original); *id.* at 11, 31-33.) This argument is fundamentally confused. The Vice Chancellor never held that Defendants could choose *not* to exercise commercially reasonable efforts; rather, he held (correctly) that *if* further development was not commercially reasonable, *then* Defendants could choose not to engage in further development—but if further development *were* commercially reasonable, Defendants would be "contractually obligated to" pursue it. (Op. 30-31.)

Plaintiffs halfheartedly assert that Defendants did not, as a matter of fact, exercise all of the efforts that were required under the CRE provision, because "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." (Pl. Br. 34 (emphasis in original).) This argument fails, first and foremost, because Plaintiffs did not appeal the Vice Chancellor's contrary

factual findings. In any event, as detailed above, the Vice Chancellor's contrary findings have overwhelming support in the record, far more support than necessary to withstand appellate review.

3. The Vice Chancellor did not ignore the CRE provision's continuing force.

Plaintiffs next assert that the "trial court erred when it effectively imposed a time limit on Defendants' obligation to use CRE to develop RSZ for EoE." (Pl. Br. 35.) Not so. The Vice Chancellor held that *if* there comes a point beyond which it is no longer reasonable to pursue development, then Defendants need not do so. That is what the Vice Chancellor meant in holding that "Defendants may eschew development where the circumstances reasonably indicate, as a business decision, that they not go forward." (Op. 30.) In other words, the obligation to pursue development has no time-based expiration date—but if and when the facts establish that additional efforts would be contrary to Defendants' objective interests, Defendants need not undertake them. (Op. 30-31.) Here, as discussed at length above, the evidence at trial proved that *no* reasonable company in Defendants' position would have continued pursuing development, and many companies in fact terminated their EoE programs. (*See, e.g.*, *supra* pp. 15-16, 19-25.) Given these unchallenged facts, the Vice Chancellor correctly held that Defendants were not obligated to continue banging their heads against the wall.

4. The Vice Chancellor properly evaluated Defendants' conduct against evidence of other companies' efforts.

Finally, Plaintiffs assert that the Vice Chancellor erred by failing to compare Defendants' efforts against an external benchmark informed by the conduct of other companies. According to Plaintiffs, the Vice Chancellor "eliminat[ed] the external benchmark from the CRE Clause" and merely "compared [Defendants] against themselves." (Pl. Br. 26; *see also, e.g.*, *id.* 39.)

This argument is wrong. The Vice Chancellor did measure the efforts of Cephalon and Teva against an external benchmark, informed by the conduct of other companies. First, the Vice Chancellor was explicit that the CRE provision required such a comparison. As the court explained, "[t]he question is, then, have Defendants taken those steps *that a reasonable decision-maker would make* under the facts pertaining to the development of RSZ for EoE? … That is, *if a reasonable actor with 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. 28-29, 30-31 (emphasis altered).) The Vice Chancellor then explained that he was adopting a "hypothetical company approach," according to which the Merger Agreement "would define the CRE Clause as those efforts 'a company with substantially the same resources and expertise as [Defendants]' *would expend under the circumstances at hand.*" (Op. 33 n.173 (emphasis in original).) The Vice Chancellor applied that external benchmark, concluding—based on extensive, unchallenged

factual findings—that Cephalon's decisions were supported by "the actions of pharmaceutical companies that faced similar circumstances to Cephalon," and that Teva made the same decisions that would have been made by any objectively reasonable "company … with Teva's resources." (Op. 32, 36.)

Plaintiffs' argument is especially bizarre because the Vice Chancellor's "hypothetical company approach" is the same approach Plaintiffs argue he should have applied. According to Plaintiffs, the proper approach "requir[es] CRE as measured against what other companies with substantially similar resources and expertise *would do* to develop RSZ for EoE." (Pl. Br. 22 (emphasis added).) The hypothetical question posed by Plaintiffs is exactly the same as the hypothetical question posed by the Vice Chancellor. And to be clear, the Vice Chancellor never held that applying an external benchmark was "unworkable"; the Vice Chancellor concluded it would be "unworkable" to follow a more restrictive approach—called the "yardstick standard"—that would limit the comparison to actually existing "exemplar companies" and "their actions in the real world," as opposed to using existing companies' actions as evidence to inform the hypothetical approach. (Op. 29, 33 n.173.) And to be equally clear, Plaintiffs agree with the Vice Chancellor's decision to reject the yardstick method—as Plaintiffs say in their brief, the CRE provision is "not a requirement that Plaintiffs point to ***actual*** efforts of ***actual*** companies to show Defendants failed to use CRE to develop RSZ for EoE." (Pl. Br.

26 (emphasis in original).) Everyone therefore agrees that the hypothetical company approach is the correct test.

Nevertheless, Plaintiffs complain that the Vice Chancellor "interpreted the Agreement 'to impose the CRE requirement on the buyer, ***as it found itself situated***,'" which supposedly meant that Defendants were not being held up to an external standard, but were merely being "compared against themselves." (Pl. Br. 26; *see also, e.g.*, *id.* at 39.) This argument makes no sense. The Vice Chancellor did not compare Defendants "against themselves"; rather, by taking into account how Defendants "found [themselves] situated," the Vice Chancellor tailored his "hypothetical company" analysis to the facts and circumstances established at trial—*i.e.*, the extensive evidence showing that RSZ had a "low probability of achieving approval" for EoE, that "the costs" of pursuing development would be substantial, and that even if approved, RSZ for EoE had a "low probability of profitable commercialization." (Op. 32.) Those circumstances are how Defendants found themselves situated: with a product that was highly unlikely to be approved, and highly likely to be a commercial failure even if approved. Plaintiffs' argument suggests that the Vice Chancellor should have ignored those circumstances when asking how a reasonable pharmaceutical company would have behaved. Proceeding in that fashion would have defied reason and constituted reversible error.

Finally, Plaintiffs complain that the Vice Chancellor was not persuaded by the evidence they put forward about other companies that Plaintiffs argued were similarly situated to Defendants. (Pl. Br. 26, 38.) But the Vice Chancellor considered extensive evidence concerning other companies that both sides put forward, and then rejected Plaintiffs' arguments, finding instead that the exemplar companies *Defendants* identified were more similar to Defendants, and supported the conclusion that Defendants' behavior was commercially reasonable. (Op. 29, 32, 36.) Those are factual findings that had ample support in the record. (*See, e.g.*, *supra* pp. 15-16, 24-25.) Plaintiffs have not challenged them, and they would not survive challenge in any event.

* * *

The Vice Chancellor correctly interpreted and applied the Merger Agreement's CRE provision, and Plaintiffs' criticisms are meritless. To the extent this Court would interpret the CRE provision differently, however, the decision below should still be affirmed because any resulting "error" was undoubtedly harmless. Given the Vice Chancellor's unchallenged, thoroughly supported factual findings—particularly that RSZ for EoE faced an exceedingly low likelihood of regulatory approval, as well as an exceedingly low likelihood of commercial success, and that numerous other companies have terminated EoE development in the face of similar circumstances—there is *no* conceivable interpretation of

"commercially reasonable efforts" that could have required Defendants to continue investing time and money into RSZ for EoE. *See, e.g.*, *Exit Strategy*, 2024 WL 3532886, at *7 ("Although we agree with Exit that the trial court misinterpreted Subsection (f)'s formula, we conclude that the error was harmless because the application of the correct formula yields the same result."); *Hoffecker*, 36 A.3d 349, 2012 WL 341714, at *2-3 (holding trial court's application of wrong legal standard was harmless where factual findings entitled appellee to prevail under correct legal standard); *Lewis*, 977 A.2d 898, 2009 WL 2469254, at *3 (holding that "[e]ven if the trial judge applied the wrong legal standard, any error was at most harmless," because "the factual conclusions reached by the trial judge" showed that appellant would have lost even under an alternative standard).

II. THE VICE CHANCELLOR DID NOT ERR IN HIS TREATMENT OF VARIOUS MERGER-CONSUMMATION CASES.

A. Question Presented

Whether the Vice Chancellor committed reversible error in describing various merger-consummation cases as "not … particularly helpful," but nevertheless interpreted the CRE provision here as imposing obligations that are materially indistinguishable from the obligations recognized in those cases. (Op. 29-34.)

B. Scope of Review

"The Court will affirm the trial court's legal rulings unless they represent an 'error in formulating or applying legal principles.'" *Zirn v. VLI Corp.*, 681 A.2d 1050, 1055 (Del. 1996) (brackets omitted).

C. Merits of Argument

In the trial court, Plaintiffs cited various merger-consummation cases involving efforts clauses, which the Vice Chancellor characterized as "not … particularly helpful, because the full language of the Merger Agreement here stresses the complete discretion of the buyer to develop, or not, the assets purchased," unlike the contracts in the cases Plaintiffs cited. (Op. 28-29.) Plaintiffs say this was reversible error, but this argument fails for at least two reasons.

First, the Vice Chancellor correctly privileged "the full language of the Merger Agreement" over standards of commercial reasonableness that have been articulated in other cases—including merger-consummation cases—because here,

the Merger Agreement supplied a definition of "commercially reasonable efforts" that trumps whatever might have been said in other cases. (A00262, §3.4(a)(iii).) The very cases Plaintiffs cite make clear that where "the parties agreed to a definition of Commercially Reasonable Efforts," their contractual language takes precedence over any "default meanings" established by the caselaw. *Neurvana Med., LLC v. Balt USA, LLC*, 2020 WL 949917, at *15-16 (Del. Ch. Feb 27, 2020); *see also, e.g.*, *Chordia v. Lee*, 2024 WL 49850, at *24 (Del. Ch. Jan 4, 2024). In *Menn v. ConMed Corp.*, 2022 WL 2387802, at *34 (Del. Ch. June 30, 2022)—one of the decisions Plaintiffs cite—the court even described the motion-to-dismiss decision *in this case* as "of little help," because "unlike [in *Menn*], the agreement [in *Himawan*] contained a contractual definition … by which the court was to measure 'commercially reasonable' efforts." The Vice Chancellor hardly erred by declining to put dispositive weight on cases that arose in a different context and involved different contractual language—particularly when those very cases already distinguished themselves from this one on those same grounds.

In all events, Plaintiffs cannot show any substantive daylight between the CRE test embraced by the Vice Chancellor, and the tests articulated in merger-consummation cases. The crux of Plaintiffs' argument is that merger-consummation cases "interpret a CRE or similar efforts clauses as imposing ***affirmative obligations to act***," supposedly unlike the decision below. (Pl. Br. 42 (emphasis in original).)

But that distinction is chimerical. The Vice Chancellor interpreted the CRE provision to mean 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. 30-31 (emphasis altered).) Thus, contrary to Plaintiffs' argument, the Vice Chancellor *did* interpret the CRE provision here as imposing affirmative obligations to act.

To the extent some merger-consummation cases could be read to suggest a party must do "essentially everything in its power" to consummate a transaction, perhaps without regard to costs, *see Akorn*, 2018 WL 4719347 at *86, such language would be inapplicable here because of the CRE provision's "due regard" proviso discussed above. Properly understood, however, there is no meaningful difference between the decision below and the merger-consummation cases. For instance, *Williams* held that the CRE provision in that case "placed an affirmative obligation on the parties to take all reasonable steps to … complete the transaction." *Williams Cos., Inc. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 273 (Del. 2017). That standard readily maps onto the Vice Chancellor's decision here, because any RSZ development activities that would qualify as "reasonable steps" under *Williams*, would also qualify as steps that "a reasonable actor" would pursue under the decision below, thus triggering an affirmative obligation to act under both formulations. Tellingly, Plaintiffs have not identified any actions that would be required under

Williams, but not under the decision below. Under either standard, therefore, the outcome would be the same, and the decision below should be affirmed. *Exit Strategy*, 2024 WL 3532886, at *7; *Hoffecker*, 36 A.3d 349, 2012 WL 341714, at *2-3; *Lewis*, 977 A.2d 898, 2009 WL 2469254, at *3.

III. THE VICE CHANCELLOR CORRECTLY DISMISSED PLAINTIFFS' IMPLIED COVENANT CLAIM.

A. Question Presented

Whether the Vice Chancellor erred in dismissing Plaintiffs' claim that Defendants breached an implied covenant of good faith and fair dealing, when the Merger Agreement expressly set forth a comprehensive standard to evaluate Defendants' decision-making with respect to RSZ. (MTD Op. at 22-25.)

B. Scope of Review

Decisions granting motions to dismiss are reviewed *de novo*. *Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Holdings LLC*, 27 A.3d 531, 535 (Del. 2011).

C. Merits of Argument

The implied covenant of good faith and fair dealing "is 'a limited and extraordinary legal remedy' and 'not an equitable remedy for rebalancing economic interests that could have been anticipated.' It cannot be invoked 'when the contract addresses the conduct at issue.'" *Glaxo Grp. Ltd. v. DRIT LP*, 248 A.3d 911, 920 (Del. 2021). Plaintiffs' implied-covenant claim asserts 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." (Pl. Br. 49.) This argument fails.

First, the implied covenant has no room to operate here because the CRE provision and the Discretion provision together supplied a comprehensive standard

to judge whether Defendants properly pursued RSZ. The Discretion provision granted Defendants "*complete discretion* with respect to all decisions related to … the research" and "development" of RSZ, expressly stated that Plaintiffs "shall have *no right to object* to the manner in which" Defendants exercised that discretion, and expressly affirmed that Defendants had "*no obligation* to … take any action to protect, attain or maximize any payment to be received by" Plaintiffs. (A00264, §3.4(c) (emphasis added).) The Discretion provision then provided that the *only* limitation on that unbounded discretion was the CRE provision. (A00264, §3.4(c) (providing that the Discretion provision was "[s]ubject to" the CRE provision, but nothing else).) In other words, the Discretion provision expressly establishes that the CRE provision sets the only boundary on Defendants' otherwise limitless discretion with respect to RSZ.

Taken together, the Discretion provision and the CRE provision "addressed the full range of discretionary conduct relevant to the earn-out calculation, leaving no room for the implied covenant to operate at all." *Lazard Tech. Partners, LLC v. Qinetiq N. Am. Operations LLC*, 114 A.3d 193, 196 n.13 (Del. 2015). In other words, "the Merger Agreement sets a contractual standard by which to evaluate if [Defendants'] failure to achieve and pay the earn-out payments … was improper." *Fortis Advisors LLC v. Dialog Semiconductor PLC*, 2015 WL 401371, at *5 (Del. Ch. Jan. 30, 2015); *Menn*, 2022 WL 2387802, at *39 ("Plaintiff's arguments for

breach of the implied covenant … duplicate its claims … for breach of express contractual provisions to … use commercially best efforts. The implied covenant cannot be used to override express contractual provisions."). There is no gap here—based on the clear language of the Discretion provision, Plaintiffs must prove that Defendants breached the CRE provision, or else they have no recourse. And, plainly, "that [Defendants] might act voluntarily to end [RSZ development] was not an event outside the contemplation of the parties…. The time to demand restrictions on an express contractual right was during negotiations—not years later through the implied covenant." *Glaxo Grp.*, 248 A.3d at 920.

Second, and in any event, Plaintiffs' implied-covenant argument is premised on the factual assertion that "Defendants refused to put forth any effort into developing RSZ for EoE, … solely because of the fact that the milestone payment would be due to Plaintiffs if Defendants were successful." (Pl. Br. 50.) That assertion is meritless. It was thoroughly aired and refuted at trial, and is foreclosed by the Vice Chancellor's detailed factual findings that Plaintiffs have not challenged. (Op. 20; *see supra* pp. 19-25.)

CONCLUSION

The decision below should be affirmed.

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