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IN THE SUPREME COURT OF THE STATE OF DELAWARE

DAVID KABAKOFF, PH.D., in his capacity as Stockholders' Agent,

Plaintiff Below,
Appellant

v.

ZENECA, INC., a Delaware Corporation, and MEDIMMUNE, LLC, a Delaware limited liability company,

Defendants Below,
Appellees

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FILED APRIL 5, 2021

No. 430, 2020.

On appeal from the
Court of Chancery,
C.A. No. 2017-0459-JRS

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Dated: March 19, 2021

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NATURE OF PROCEEDINGS

This appeal arises from the Court of Chancery's rejection of Plaintiff's demand for a $200 million windfall payday for a failed cancer therapy, despite a contract negotiated and structured to pay out for ***success*** in a Phase 1 clinical trial. Plaintiff's illogical interpretation of the contract turns two contingent milestones into mere installment payments, shorn of any connection to the outcome of the clinical trials at the heart of the original deal.

In 2013, MedImmune sought to expand its pipeline of innovative cancer treatments, so its parent company, AstraZeneca, purchased Amplimmune in order to acquire an anti-PD-1 immunotherapy molecule. (Mem. Op. 2.) AstraZeneca paid a hefty sum: $225 million in up-front cash, (*id.*), and up to five contingent milestone payments worth, in total, an additional $275 million, (A213). The $225 million payment fully compensated Amplimmune for handing over its immunotherapy portfolio, and a majority of the contingent $275 million was intended to share some of the potential reward that AstraZeneca and MedImmune might obtain ***if*** the lead molecule was as successful as Amplimmune touted. The two milestones at issue here require payment of $100 million and $50 million, respectively, following "Successful Completion" of a Phase 1 trial. (Mem. Op. 2.) The parties endeavored to define the milestone triggers objectively, to avoid questions about if or when hundreds of millions of dollars might be owed. "Successful Completion" was

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defined to require (1) "completion" of a Phase 1 study; (2) "completion of a study report for such Phase 1 study"; and (3) "a regulatory filing . . . submitting the protocol for additional clinical development." (*Id.* 11) Each of those three requirements has a straight-forward meaning to someone familiar with FDA-regulated clinical trials, and each aligns with the goal of tying payment of the contingent milestones to both completion of a Phase 1 trial and a successful outcome of that trial.

MedImmune conducted the two Phase 1 trials contemplated by the contract, using Amplimmune's molecule alone (i.e., as a "Monotherapy") and paired with another treatment (i.e., in "Combination"), but the Monotherapy results were disappointing. Despite the significant investment it had made, MedImmune decided the molecule could not compete with other drugs in the same class. It eventually cut its (enormous) losses, and ceased development of the Monotherapy. (*Id.* 17.) MedImmune carried out a Phase 2 trial for the Combination, after promising Phase 1 results, but that trial also ended in disappointment. (*Id.* 23.)

Not satisfied with receiving $225 million for a medicine that would never produce a penny of revenue, Plaintiff sued for more. He alleged that MedImmune had "Successfully Completed" both clinical trials, on the basis that it had conducted "additional clinical development" of the Monotherapy by using it as a control arm in a Phase 2 Trial of the Combination. (B16–29.) Despite MedImmune's

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acknowledgement that the Combination Phase 1 Trial had succeeded, by nature of having moved into Phase 2, and confirmation that it would pay the $50 million Combination milestone once the final element of the trial—a "study report"—was done, Plaintiff sued for that also, claiming the milestone was owed years before the trial was completed. (*Id.*)

On summary judgment, the Court of Chancery correctly determined that conducting "additional clinical development" in the context of completing a Phase 1 clinical trial requires taking steps that entail some "movement towards commercialization." (Summ. J. Order 10–12.) It also concluded that "study report" was ambiguous and its meaning would be resolved at trial. (*Id.* 12–14.)

The Court of Chancery held a five-day trial, (Mem. Op. 5), and concluded that MedImmune did not conduct "additional clinical development" of the Monotherapy, (*id.* 34–55). It found that the Phase 2 study Plaintiff claimed as continued development of the Monotherapy was in fact "Designed and Intended to Test Only the Combination Therapy." (*Id.* 34.) In line with the overwhelming majority of credible evidence, it also held that the contractual phrase "study report," in the context of completion of a Phase 1 clinical trial, refers exclusively to a Clinical Study Report. (*Id.* 57–72.)

Plaintiff now appeals on both issues. He contends first that "additional clinical development" "unambiguously refers to treatment and study of additional

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patients." But this strips away the "success" element of the contingent milestone and replaces it with a mere delayed payment. Second, he claims that a "study report" for a completed Phase 1 study "unambiguously" means *any* "statement or account of a study," such that a clinical trial could be deemed "completed" while patients are still in treatment and data is still being collected. (Opening Br. 9, 12.) The parties' clear intention—that Amplimmune would receive further payments beyond the initial $225 million if, and only if, the clinical trials continued to the point of being fully complete and were successful—would be nullified by Plaintiff's construction of the contract. The medicine at issue here was a failure. There is no further up-side reward available to MedImmune, and thus nothing to left to share with Plaintiff.

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SUMMARY OF ARGUMENT

1. Denied. The Court of Chancery correctly held that "additional clinical development" unambiguously requires "movement towards commercialization." ***First***, the Court of Chancery's holding recognizes the commercial purpose underlying the Agreement: to reward a successful outcome in Phase 1 trials. The resource-intensive clinical trial process exists *solely* to bring new therapies to market. Plaintiff's argument misleadingly frames Phase 1 as an academic exercise disconnected from the rest of the clinical trial process. ***Second***, the Court of Chancery's ruling is faithful to the plain language. To "develop" means "to create or produce especially by deliberate effort over time." (B662.) The concept of "development" requires movement towards a goal. In clinical trials, that goal is commercialization of a medicine. Plaintiff's argument uses an atypical dictionary definition, fails to grapple with the phrase as a whole, and effectively replaces "development" with "research." ***Third***, the parties' intent can also be discerned through their use of "development" elsewhere in the Agreement, where "Regulatory Approval" is identified as the goal of the "Development Plan." ***Fourth***, Plaintiff's irrational interpretation of "additional clinical development" would mean the Monotherapy milestone could have been triggered in the *middle of Phase 1*, when the study protocol was first amended, despite an overall requirement for "Successful Completion" of a Phase 1 trial.

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2. Denied. The phrase "additional clinical development" is not ambiguous, but if it were, the extrinsic evidence at trial amply supported the Court of Chancery's interpretation. Furthermore, even if Plaintiff's definition were correct, MedImmune *still* would not owe the Monotherapy milestone because use of the Monotherapy as a control was not development. The Court of Chancery correctly found that "The Phase 1/2 Trial Was Designed and Intended to Test Only the Combination Therapy." (Mem. Op. 34.) This factual conclusion is not clearly erroneous, and is fatal to Plaintiff's claim.

3. Denied. The Court of Chancery's ruling that the phrase "study report," as used in the Agreement, was ambiguous was justified by the conflicting definitions offered by Plaintiff's own witnesses. In any event, the plain language, the parties' intent as reflected in the context and structure of the contract, and MedImmune's pre-litigation conduct all confirm the post-trial ruling that the contract term "study report for such Phase 1 study" refers exclusively to a Clinical Study Report ("CSR"). ***First***, trial testimony established that "study report" and "CSR" are interchangeable in the context of a Phase 1 study. By contrast, Plaintiff was unable to marshal any evidence showing that an Investigator's Brochure had *ever* been referred to as a study report. ***Second***, construing the Agreement to refer to a CSR aligns with the parties' intent to have objective milestone triggers, and connects the "study report" requirement to the concept of study "completion." ***Third***, contemporaneous

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documents reflect that MedImmune understood "study report" to mean CSR at the time the contract was negotiated.

4. Denied. The Court of Chancery properly denied Plaintiff's motion on summary judgment because he offered an "overbroad" definition that is "contrary to common understanding." It did not use parol evidence to manufacture ambiguity that did not otherwise exist.

5. Denied. The Court of Chancery's ruling, based heavily on the conflicting testimony of two of Plaintiff's witnesses regarding the definition of "study report," as well as the quantum of evidence supporting MedImmune's interpretation, was correct—and certainly not clearly erroneous. Plaintiff's interpretation of the drafting history is incorrect. The parties deleted the word "final" from the Agreement in order to trigger the milestone payment upon the completion of any CSR, regardless of whether it was the "final" version ultimately submitted in support of regulatory approval.

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STATEMENT OF FACTS

A. MedImmune Wanted To Develop Combination Therapies.

In 2013, MedImmune was pursuing development of innovative cancer therapies in a burgeoning field known as immuno-oncology. MedImmune was in advanced development of an anti-PD-L1 antibody known as durvalumab, but wanted to test that medicine in combination with an anti-PD-1. (Mem. Op. 8.) The theory was that blocking both sides of the PD-1/PD-L1 pathway would be more effective at boosting the immune system than blocking just one side. (*Id.*)

The fastest path to accomplish that goal was to acquire Amplimmune, a biotech company with an anti-PD-1 known as AMP-514 that was nearly ready to begin clinical trials. (*Id.* 9.)

B. MedImmune Planned to Test the Monotherapy for Superiority.

Although MedImmune was focused primarily on combination therapies, Amplimmune suggested that AMP-514 would be worth developing alone (as a "monotherapy"), and MedImmune agreed to test whether AMP-514 might "prove substantially superior to its monotherapy competitors." (Mem. Op. 13–14.) If AMP-514 turned out not to be differentiated from its competitors, MedImmune would not pursue development of the Monotherapy and would focus only on the Combination. (Mem. Op. 13; A1361–63.)

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C. The Parties Agreed that Milestones Would be Contingent on Success.

Negotiations between AstraZeneca and Amplimmune moved rapidly—with the Merger Agreement ("Agreement") being signed on August 25, 2013. (Mem. Op. 10.) From the outset, the proposed deal was structured with an up-front payment and contingent milestone payments. (*Id.*) Amplimmune originally proposed tying the AMP-514 milestone payments to "Completion" of the Phase 1 clinical trials. AstraZeneca countered (successfully) that payment should instead be tied to "Successful Completion" of the trials. (B312; *see also, e.g.*, B317-18.)

The final Agreement provided for payment of $225 million in up-front cash, and up to five contingent milestones that might (or might not) be achieved, three of which depended on whether MedImmune decided to move forward with further development of AMP-514, beyond the initial Phase 1 trials. (Mem. Op. 10; A212–13.) The AMP-514 contingent milestones hinged on whether "Successful Completion of a Phase 1 Study" occurred, for either the Monotherapy or the Combination. For each, the parties defined "Successful Completion" as requiring: (1) "completion" of a Phase 1 study, (2) "completion of a study report for such Phase 1 Study," and (3) "a regulatory filing . . . submitting the protocol for additional clinical development." (Mem. Op. 11.) Both parties to the Agreement also sought milestone triggers that would be objective and "black and white" in order to avoid disputes about whether or when a milestone should be paid. (*Id.* 69.)

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The overall scheme was to share some of the (potential) up-side associated with AMP-514, if it performed well enough in Phase 1 studies to move forward with the next step in the lengthy drug development process. (*See* A212–217.) The Agreement also obligated AstraZeneca to use "commercially reasonable efforts" to try to achieve the milestones, while acknowledging that such efforts might nevertheless include a decision to abandon development. (A215.)

D. AMP-514 Did Not Live up to Expectations.

1. Clinical Trial Structure and Documentation.

Traditionally, clinical trials conducted as part of the drug approval process in the United States are classified as Phase 1, Phase 2, or Phase 3. In addition to studying safety and tolerability, FDA regulations state that Phase 1 trials should also try to "to gain early evidence on effectiveness." (Mem. Op. 9 n.28.)

The clinical trials for AMP-514 started by treating a few subjects at a low dose and were designed to add new cohorts at progressively increasing doses, until an appropriate dose was found. (*Id.* 14–15.) MedImmune prepared and submitted to FDA a clinical trial protocol for the Monotherapy, as well as an Investigator's Brochure ("IB") about AMP-514. (*Id.*; B325–426.) The protocol described how the trial would be conducted. The IB contained prescribed categories of information about the molecule and would be provided to doctors treating patients in the clinical study. (*See, e.g.*, B603.)

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After all data for a study has been collected, the sponsor can begin to prepare the CSR, a comprehensive document describing the conduct and results of a clinical trial. (A881, A1079, A1294.) Although a sponsor technically need not submit the final CSR to the FDA until it applies for marketing approval, MedImmune prepares a separate CSR upon completion of each individual study, consistent with industry best practice. (A1449; B646–47; *see also, e.g.*, B612–13.) The CSR may be updated or amended before final submission to the FDA. (A1080-81, A1294.)

2. Early Results for the Phase 1 Trials Were Poor.

Amplimmune's preclinical data suggested AMP-514 "would be 'fully active' at 'extraordinarily low doses.'" (Mem. Op. 9 (quoting A965).) Six months into the Monotherapy Trial, however, there was no sign that the treatment was effectively shrinking patients' tumors. (*Id.* 15.) By contrast, competitor treatments had shown anti-tumor responses in the earliest cohorts and lowest dosages. (A925, A1215; B266–306, B547–55.)

In response, MedImmune decided to conduct additional laboratory testing of AMP-514's "affinity," meaning how well it adhered to its target. (Mem. Op. 15.) The resulting affinity data was, in short, "a disaster." (*Id.* 16 (quoting A1383).) It revealed that a patient would need to receive a dose of AMP-514 fifteen times larger than the dose of a competitor treatment to obtain the same the effect. (*Id.*)

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3. AMP-514 Required a Higher and More Frequent Dose than the Competitors.

After debating whether to halt both trials mid-stream, MedImmune instead decided to amend the trial protocols. (Mem. Op. 16; *see also* A974–75; A1310–11.) The protocol amendments created additional cohorts of new patients, who would be receiving larger and more frequent dosages. (Mem. Op. 16; *see also* B427–544.) Ultimately, MedImmune did see anti-tumor responses at the higher dose levels, which were comparable to the results observed for competitor anti-PD-1s at lower doses. (Mem. Op. 16.)

The head of MedImmune's oncology research division, Dr. Ed Bradley, was "encouraged by the fact that [MedImmune] could find the dose where finally we could see antitumor response," demonstrate "reasonable safety," and "then [] use it in the combination trial." (A1341–42.) It was undeniable, though, that the Monotherapy had not lived up to the high expectations set by Amplimmune's preclinical data. (A978.) Nor had AMP-514 demonstrated the requisite superiority over competitors necessary for MedImmune to continue developing it as a Monotherapy. (Mem. Op. 17.)

E. MedImmune Decided Not to Pursue the Monotherapy, but Took the Combination into a Phase 2 Trial.

Two months later, MedImmune sent Plaintiff an update report indicating it was "not doing any additional studies in monotherapy" and that "the future was in

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combination." (A1082–84; B575.) Dr. Kabakoff responded, acknowledging that "MedImmune does not plan to continue the development of MEDI0680 as a single agent." (Mem. Op. 17 (quoting B585).) In June 2016, an internal memorandum sent to the MedImmune governance committee confirmed that there was "no expansion planned" for the Monotherapy. (B587.) Shortly thereafter, MedImmune sent the formal abandonment notice to Plaintiff. (B589–95.)

In contrast, the Combination Trial moved forward. Initially, plans contemplated a single-arm study in which the results would be compared against data from other trials. (B545; A1266, A1313–16.) AstraZeneca, however, asked for a "more robust control" arm. (A1315–16; B545.)

MedImmune's team then worked to design a two-armed trial. Dr. Bradley was "agnostic" regarding whether an anti-PD-1 or an anti-PD-L1 was used as the control. (A1316–17.) The first proposal was to use nivolumab, a competitor anti-PD-1, but it had not yet been approved for the indication to be studied (kidney cancer) and so it was not a viable choice. (Mem. Op. 18–19.) MedImmune then considered using its anti-PD-L1, durvalumab, as the comparator and running the study in lung cancer patients, but was concerned that competition for patients would lead to enrollment delays. (*Id.* 19.) As a last resort, MedImmune decided to use AMP-514 as the "control arm" in a study of kidney cancer patients. (*Id.*) The

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meeting minutes reflecting this decision reported that "[d]ifferentiating complete [versus] single blockade is the goal of this study." (B580; A1327.)

To implement this plan, MedImmune amended the Combination Trial protocol on February 11, 2016 ("Amendment 3"). (Mem. Op. 19.) The primary hypothesis was that "[AMP-514] in combination with [durvalumab] will have a higher response rate than [AMP-514] monotherapy in subjects with" kidney cancer. (Mem. Op. 20 (quoting A547).) The statistical analysis plan was designed to test the validity of that hypothesis—and only that hypothesis. (Mem. Op. 20, 37; *see also* A916.)

Amendment 3 reflected MedImmune's intent to continue developing the Combination and to use the Monotherapy only as a tool in aid of that purpose. Every witness with first-hand knowledge agreed that the trial was designed to develop the Combination and not the Monotherapy. (*See* B637–38, B660; A1094, A1327; *see also* A1060–63, A1441, A1455.)

The Phase 2 Combination Trial began in the spring of 2016, but encountered unacceptably slow enrollment. (Mem. Op. 22.) Accordingly, MedImmune amended the Combination Trial protocol ("Amendment 5") to replace AMP-514 with nivolumab in the control arm—despite requiring a budget increase of $7.2 million (and an overall program budget of $87.4 million). (*Id.*) After the interim results

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showed that the dual blockade approach was not superior, MedImmune elected not to proceed further. (*Id.* 23.)

MedImmune completed the CSR for the Combination Trial in March 2020, and paid the $50 million Combination Milestone one month later. (*Id.*)

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ARGUMENT

I. MedImmune Does Not Owe the Monotherapy Milestone for Using It as a Control Arm in the Combination Trial.

A. Question Presented

Whether the Court of Chancery erred by interpreting the phrase "additional clinical development" to require "movement towards commercialization," where the purpose of conducting FDA-regulated clinical trials is to bring a drug to market. (Summ. J. Order 10–12.) (Preserved B156.)

B. Standard of Review

This Court reviews the "grant of summary judgment *de novo*." *Sunline Com. Carriers, Inc. v. CITGO Petroleum Corp.*, 206 A.3d 836, 845 (Del. 2019) (internal quotation marks omitted). "A grant of summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Id.* (internal quotation marks omitted).

This Court reviews questions of contract interpretation *de novo*. *Id.* But it "will uphold the trial court's factual findings unless they are clearly erroneous." *Gatz Props., LLC v. Auriga Cap. Corp.*, 59 A.3d 1206, 1212 (Del. 2012) (en banc) (per curiam).

C. Merits of the Argument

Plaintiff's argument fails first because it contorts the contract from payment for a positive outcome to an installment plan, fundamentally destroying the purpose

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animating the Agreement and twisting the plain text into an incoherent knot. Second, Plaintiff cannot overcome the Court of Chancery's findings that the Phase 2 Trial was intended to test and study the Combination, not the Monotherapy. Under any definition, including Plaintiff's, that Phase 2 Trial was development of the Combination, and the Combination alone; the Monotherapy was used only as a control arm. Indeed, Mr. Richman (Amplimmune's chief negotiator for the Agreement) conceded that a control in a two-arm trial is merely a tool to develop the main product, and is not itself being developed. His testimony puts an end to this appeal.

1. The Court of Chancery Correctly Held That "Additional Clinical Development" Requires Movement Towards Commercialization.

The Court of Chancery's summary judgment ruling was correct because it adhered to the parties' intent that contingent milestones would be paid if the Phase 1 trial was successful. Plaintiff's contract interpretation was rejected, and should be rejected again, because it erases the core contingency in the contractual milestone, rendering the parties' Agreement irrational.

The first prong of this Court's analysis requires examining the broader purpose for which the contract was negotiated. Second, the plain language reflects and confirms that overriding intent of the contract. Third, the parties' use of the word "development" elsewhere in the Agreement bolsters the Court of Chancery's

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interpretation. Fourth, Plaintiff's proposed interpretation of "additional clinical development" would produce irrational and impossible results. These factors demonstrate that the Agreement mandates a milestone payment only when a therapy completes a Phase 1 trial *and* shows enough promise to take the next step towards commercialization.

a. The Parties Intended the Milestone to Be Tied to Moving Forward, Indicating Success.

The overarching goal in any contract dispute is vindicating the parties' shared purpose, and this Court's analysis begins there. *See, e.g.*, *Viking Pump, Inc. v. Century Indem. Co.*, 2 A.3d 76, 90 (Del. Ch. 2009). Thus, the "basic business relationship between parties must be understood" and the contract must be "read in full and situated in the commercial context between the parties." *Chi. Bridge & Iron Co. v. Westinghouse Elect. Co.*, 166 A.3d 912, 926–27 (Del. 2017); *see also Eames v. Quantlab Grp.*, 2018 WL 2041548, at *9 (Del. Ch. May 1, 2018).

The Agreement provides for AMP-514 milestone payments upon "Successful Completion" of a Phase 1 trial, and defines that term to require each of the following: (1) "completion" of a Phase 1 study, (2) "completion of a study report for such Phase 1 Study," and (3) "a regulatory filing . . . submitting the protocol for additional clinical development." (Mem. Op. 11.) This definition of "Successful Completion" has two components: finishing the trial (i.e., completion) *and* taking a step beyond

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the Phase 1 trial, which advances the drug in the clinical development process (i.e., success).

This Agreement was negotiated within the context of an industry governed by extensive regulations dictating when and how medicines—like the anti-cancer treatment at the core of this case—can be brought to market. Yet Plaintiff's argument portrays Phase 1 studies as entirely distinct from the process of moving a drug to market. Plaintiff asserts that the phrase "additional clinical development" "presupposes that clinical development has already occurred." (Opening Br. 32.) And, according to Plaintiff, "it is unreasonable to refer to a Phase 1 study as movement towards commercialization." (*Id.*) Thus, he claims, "additional clinical development" cannot require movement towards commercialization. (*Id.* 32–33.)

That logic is defective. A Phase 1 trial, compliant with all applicable FDA regulations, is conducted for only one reason: to determine whether a drug is safe enough (and, in some cases, effective enough) to continue with the long and expensive process of seeking marketing approval. The FDA itself confirms as much, when it describes clinical trials generally (including Phase 1) as "an integral part of new product discovery and development [that] are required by the [FDA] before a new product can be *brought to market*." *Conducting Clinical Trials*, Food and Drug Administration (June 30, 2020), https://www.fda.gov/drugs/development-approval-process-drugs/conducting-clinical-trials (emphasis added).

[redacted]

Nevertheless, Plaintiff argues that the parties sought to share risk only in Phase 1, and because "commercialization" is something that happens exclusively after Phase 1, it is irrelevant to the definition of "additional clinical development." (Opening Br. 2, 33.) It is of course true that commercialization *itself* typically (although not always) occurs after Phase 2 or 3. But a Phase 1 study, as with every other step in the clinical development process, is an integral part of *movement towards* commercialization.

Moreover, Plaintiff's description of the purpose animating the Milestones—sharing of risk and reward in Phase 1—only makes sense if the payment is tied to the success or failure of the Phase 1 trial. There is no "reward" to "share" unless the Milestone is compensating for success, reflected in the form of forward progress toward the point where MedImmune could realize a profit on its investment.

b. The Plain Language Reflects the Intent to Progress Toward Commercialization.

The Court of Chancery correctly held that the plain language selected by the parties ties the milestone payment to an affirmative step (i.e., a regulatory filing) taken to move the product closer to the end-goal of FDA approval (i.e., for additional clinical development). The phrase "additional clinical development" refers not to something that happens accidentally or coincidentally, as might occur with mere information-gathering—it refers to a concerted effort, over time, to demonstrate a

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molecule's safety and efficacy for the purpose of eventually obtaining approval to market it.

This commonsense understanding of the contract's plain text is supported by dictionary definitions. Delaware courts interpret "clear and unambiguous terms according to their ordinary meaning." *GMG Cap. Invs. v. Athenian Venture Partners I*, 36 A.3d 776, 779 (Del. 2012) (en banc). It is undisputed that "clinical" refers to observation or study of human patients. (Opening Br. 29.) And Merriam-Webster defines "develop" as "to create or produce especially by deliberate effort over time" and "to lead or conduct (something) through a succession of states or changes each of which is preparatory for the next." (B662.) Plaintiff's secondary definition of "development" as moving "from latency towards fulfillment" conveys a similar idea. (Opening Br. 29.) The concept of "development" inherently requires both intent and progression towards *something*, which, here, is approval to commercialize a medicine.

Industry publications further confirm this understanding of the phrase. For example, the website PharmaIQ, which serves as a "portal . . . for analysis, resources and tools for all aspects of the pharmaceutical field," provides a glossary that defines "clinical development" as "a blanket term used to define the entire process of bringing a new drug or device to the market." *Clinical Development*, PharmaIQ,

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https://www.pharma-iq.com/glossary/clinical-development (last visited March 18, 2021).

Notwithstanding all of this, Plaintiff contrives an artificial and unsupported definition of "additional clinical development," seeking to lower the milestone payment threshold. This effort begins with an ill-fitting definition of the word "development": the "application of techniques or technology to the production of new goods or services." (Opening Br. 28.) Plaintiff defines "clinical" as "involving or based on direct observation of a patient," and somehow asserts that those components produce the unduly broad definition of "additional clinical development" as any "treatment and study of additional patients." (*Id.* 27–29.) This results-oriented approach does not withstand even a modicum of scrutiny.

First, Plaintiff's disregard for the common and straight-forward meaning of "development" makes no sense. Plainly, in the context of the pharmaceutical drug testing process, the word "development" does not refer to "techniques" for the "production of new goods." Plaintiff offers no reason for adopting such an esoteric dictionary definition, and tellingly never mentions the definition again, after first citing it. (*See id.* 28.) Moreover, Plaintiff's definition of "development" is entirely disconnected from his definition of "additional clinical development," revealing the flimsy construction underlying his argument.

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Second, Plaintiffs' myopic approach violates a cardinal rule of legal interpretation: Phrases should be interpreted as a whole. *See e.g.*, *FCC v. AT&T Inc.*, 562 U.S. 397, 406 (2011) ("[T]wo words together may assume a more particular meaning than those words in isolation."); *Helvering v. Gregory*, 69 F.2d 809, 810–11 (2d Cir. 1934) (Hand, J.) ("[T]he meaning of a sentence may be more than that of the separate words, as a melody is more than the notes."), *aff'd*, 293 U.S. 465 (1935); William Eskridge Jr., *Interpreting Law: A Primer on How to Read Statutes and the Constitution* 62 (2016) (explaining that a phrase can refer to a "dramatically smaller category than either component term.").

This rule makes good sense, as phrases used in a specialized setting often mean something different from the sum of each part. Fans of hockey and soccer, for example, celebrate a "hat trick" when a player scores three goals in a game. But under Plaintiff's approach, a "hat trick" would be a "crafty procedure" related to a "covering for the head." *See Hat*, Merriam-Webster, https://www.merriam-webster.com/dictionary/hat; *Trick*, Merriam-Webster, https://www.merriam-webster.com/dictionary/trick. Here, "additional clinical development" is best understood as a single phrase, rather than three isolated words.

Third, Plaintiff's proposed definition of "additional clinical development" turns the word "development" into a synonym for "study" or "research." The Court of Chancery correctly rejected Plaintiff's arguments below precisely because the

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concepts of "clinical research" and "clinical development" are ordinarily understood as logically distinct.[1]

c. Plaintiff's Interpretation Leads to the Absurd Result of a "Success" Fee Incurred for a Failure.

Because Plaintiff's definition is artificially derived, it leads to an inherently absurd result. Plaintiff seeks to rewrite the contract terms, so that a milestone contingent on "success" will be owed for a mediocre molecule that failed to advance beyond Phase 1. That outcome would be quintessential absurdity.

The illogic of Plaintiff's contract interpretation also is apparent from the other protocol amendments that would qualify as "additional clinical development." First, after the initial cohorts in the AMP-514 Monotherapy Phase 1 trial showed little improvement, MedImmune expanded the trial to test higher and more frequent doses. (B629–32.) This protocol amendment necessarily entailed the "treatment and study of additional patients," seemingly satisfying Plaintiff's definition, although the amendment did not reflect either success *or* completion of the Phase 1 trial—indeed, it reflected the exact opposite.

[1] The Court of Chancery concluded on summary judgment that the "plaintiffs' proffered definition [of development] is largely synonymous with 'research.'" (Summ. J. Order 12.) Plaintiff misconstrues this finding as a "definition of clinical," and counters that "some research takes place without patients," but that "clinical development" must involve the study of patients. (Opening Br. 31–32.) This is a non-responsive (and misleading) response.

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Second, Amendment 5 to the Combination Trial protocol swapped nivolumab for AMP-514 as the control arm. Plaintiff's contract interpretation would mean that MedImmune therefore conducted "additional clinical development" of nivolumab, a drug owned by one of MedImmune's competitors—a result that Plaintiff agrees is impossible. (B77.)

These absurd results are strong evidence that Plaintiff's interpretation is not faithful to the parties' intent.

d. The Court of Chancery's Interpretation Was Faithful to Canons of Construction.

Two established canons of construction provide a further layer of support for the ruling below. First, the presumption of consistent usage supports the Court of Chancery's reading of the Agreement. *See, e.g.*, *Comerica Bank v. Glob. Payments Direct*, 2014 WL 3567610, at *11 (Del. Ch. July 21, 2014) ("Absent anything indicating a contrary intent, the same phrase should be given the same meaning when it is used in different places in the same contract."); 28 Richard A. Lord, *Williston on Contracts* § 32:6 (4th ed.) (same).

The parties used the word "development" elsewhere in the Agreement to describe the same general conduct described in the "Successful Completion" definition: planning and execution of Phase 1 clinical trials for AMP-514. The Merger Agreement defines "Development Plan," referring to a document annexed to the contract, as meaning "the plan and timeline for the further development of

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AMP-514 to support Regulatory Approval thereof in the United States." (A148.) Thus, the parties explicitly agreed that the clinical trials, including Phase 1, were intended to move AMP-514 closer to marketing approval by the FDA.

By contrast, Plaintiff's acrobatic efforts to account for the "Development Plan" defy common sense. He contends that this document describes various studies done in patients, and it therefore shows that "development" means "treatment and study of patients." (Opening Br. 31.) A cursory review of the Development Plan itself defeats Plaintiff's argument. First, Plaintiff is simply wrong when he asserts that the tasks described in the plan (such as pharmacokinetics, immunogenicity, pharmacodynamics assays, pharmacology studies and cell signaling studies) "involve treatment and study of patients, but none can fairly be said to involve 'movement towards commercialization.'" (*Id.*) Each of these steps is part of the overall effort to move the product to commercialization, although many involve pre-clinical or non-clinical testing—occurring in a laboratory or in animals. Second, the text of the document confirms that it was a roadmap for moving AMP-514 towards "Regulatory Approval," or commercialization by listing as one "[o]bjective" to "[s]upport[] [c]linical [d]evelopment," by "enabl[ing] future trials." (A293.) In other words, the "Development Plan" was not aimed at expanding the number of patients to be studied, but was intended to facilitate the subsequent trials that would be necessary to bring AMP-514 to market.

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Plaintiff also points to the Agreement's definition of "same indication," and claims it shows that "clinical development" must "relate[] entirely to the specifics of treating and studying patients." (Opening Br. 30.) This is misguided.

The Agreement defines "Same Indication" as

> "with respect to the conduct of additional clinical development following a Phase 1 Study for a given molecule or combination of molecules, that such additional clinical development is being conducted in substantially the same patient population as such Phase 1 Study or in a patient population that is a subset of the patient population of such Phase 1 Study." (A155.)

This term pertains to the Combination Milestone and serves to limit the regulatory filings that can reflect "additional clinical development," to those that build or expand upon the findings of the initial Phase 1 trial. Thus, if MedImmune did a Phase 1 Combination Trial in a specific cancer type, was unimpressed with the results, and decided to do another Phase 1 trial in a different cancer type, that second trial would not trigger the contingent milestone—because it would be moving sideways rather than forward. Thus, this definition underscores that "additional clinical development" must describe a second step that moves the medicine *toward* registration.

Second, Plaintiff claims that the surplusage canon requires reversal because the Agreement uses "development" to mean something distinct from "commercialization." (Opening Br. 29–30.) This straw-man argument badly

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misconstrues the Court of Chancery's reasoning, which did *not* treat "clinical" and "commercial" as interchangeable. It instead held that the phrase "additional clinical development" requires "movement towards commercialization." (Summ J. Order 11–12.) In other words, development and commercialization are related, but not synonymous. The surplusage canon has no role to play here.

* * *

Plaintiff's argument about the Monotherapy Milestone hinges on a definition of "additional clinical development" that is unmoored from the real-world context in which the contract was negotiated, unsupported by the dictionary definitions on which he purports to rely, and detached from the parties' intentions. Ultimately, Plaintiff's definition of "additional clinical development" is synonymous with "additional clinical research"—requiring only that further "study" in patients occur, regardless of the intent animating that study. The Court of Chancery rightly rejected this construction.

2. Even Under His Own Definition, Plaintiff Is Not Entitled to the Monotherapy Milestone.

Even under his gerrymandered definition, Plaintiff cannot obtain reversal. Supposing a milestone payment were triggered by any "treatment and study of additional patients," (Opening Br. 27–28), the Court of Chancery's factual findings at trial would render any legal error harmless and support upholding judgment for Defendants. *See, e.g.*, *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728,

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738–39 (Del. 2006) (en banc) ("Assuming, without deciding, that the Vice Chancellor erred in not using dictionaries in this case, we find that this error was of no moment, *i.e.* harmless, because the [alternate definition] still requires the entry of summary judgment.").

The Phase 2 Combination Trial was not "study of [AMP-514 in] additional patients." It focused exclusively on development and research of the Combination Therapy. The Monotherapy was included only as a "control," against which the Combination could be measured, and so was not itself the subject of study, even though Protocol Amendment 3 called for patients to receive AMP-514 and for data to be collected from those patients.

Mr. Richman, Amplimmune's founder and chief contract negotiator, testified that his current company uses anti-PD-1 molecules as a control in some of their clinical trials, and that this use is not "development." (A955.) He agreed that the control serves only "as a benchmark against which you're measuring the molecule you are hoping to develop." (A955–56.) Mr. Richman's testimony demonstrates that inclusion of a control in a trial is "not developing the comparator or control [product]," but rather "us[ing] it to develop something else." (A956.) This evidence was and is an insurmountable hurdle for Plaintiff.

After considering all of the evidence, including Mr. Richman's, the Court of Chancery made a number of relevant factual determinations that must be upheld

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"unless they are clearly erroneous"—which they are not. *See Gatz Props.*, 59 A.3d at 1212. Notably, it titled a section of its opinion "The Phase 1/2 Trial Was Designed and Intended to Test Only the Combination Therapy." (Mem. Op. 34.) The Court drew this conclusion after evaluating the study design and MedImmune's internal governance documents, and its weighing of this evidence is entitled to deference.

The Court of Chancery found the study design "powerful evidence that MedImmune included the Monotherapy in the Phase 1/2 study only to test whether the Combination could outperform a single blockade molecule." (*Id.* 42.) It highlighted that the "study used one-sided significance for its statistical power, allowing MedImmune to draw statistically significant conclusions only about whether the Combination was better than the Monotherapy, but not the other way around." (*Id.* 37–38.) If MedImmune were interested in "developing" the Monotherapy, it would have included a "two-tailed statistical analysis where the Monotherapy could be evaluated on its own merits," (*id.* 38), and "hypotheses regarding the efficacy of the Monotherapy," (*id.* 37). The Court of Chancery also analyzed governance documents summarizing MedImmune's "[d]ecisions regarding trial design and strategy." (*Id.* 43.) But "[d]espite extensive discovery, Plaintiffs found no governance documents to controvert the facts that the Phase 1/2 trial was motivated to differentiate complete versus single blockade, that Monotherapy was included only as the control arm of the study, and that there was no expansion

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planned for the Monotherapy." (*Id.* 45 (cleaned up).) Indeed, these conclusions were buttressed by the testimony of several witnesses with "first-hand knowledge of the Phase 1/2 trial," each of whom the Court found credible and each of whom testified that the purpose was "only to develop the Combination and not the Monotherapy." (*Id*.) Thus, the "singular purpose" of the Phase 2 Trial was to compare the effects of the Combination therapy with a "single blockade." (*Id.* 44.) The goal was *not* to "study [AMP-514 in] additional patients," much less to develop AMP-514 towards commercialization.

None of the Court of Chancery's factual findings about the purpose of Protocol Amendment 3 were wrong, let alone "clearly erroneous." *See Gatz Props.*, 59 A.3d at 1212. For that reason, even on its own terms, Plaintiff's argument withers. No reasonable interpretation of the contract phrase "additional clinical research" can plausibly encompass the Phase 2 Trial, the *sole purpose* of which was to test and evaluate the Combination therapy.

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II. MedImmune Timely Paid the Combination Therapy Milestone.

A. Question Presented

Whether the Court of Chancery erred by interpreting the phrase "a study report" as an ambiguous term which, in accordance with the uniform and credible evidence presented at trial, meant a "Clinical Study Report." (Mem. Op. 55–72.) (Preserved B231–238.)

B. Standard 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), and "will uphold the trial court's factual findings unless they are clearly erroneous," *Gatz Props.*, 59 A.3d at 1212. The denial of Plaintiff's summary judgment motion, on the grounds that Plaintiff did not proffer the only reasonable interpretation of the phrase "study report," is subject to *de novo* review. *Sunline Com. Carriers*, 206 A.3d at 845 (Del. 2019). This Court can reverse only if "there is no genuine issue as to any material fact." *Id.* (internal quotation marks omitted).

In appealing the post-trial ruling, Plaintiff thus bears the burden to prove that the parties intended the completion of "any one of an undefined 'spectrum' of documents regarding the Combination Therapy" to trigger a multi-million dollar milestone payment. (Mem. Op. 58.) *See also S'holder Representative Servs. v.*

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Shire US Holdings. Inc., 2020 WL 6018738, at *49 (Del. Ch. Oct 12, 2020). He cannot do so.

Moreover, the Court of Chancery's construction of the phrase "study report" based on the trial evidence is afforded deference. When a "trial court's interpretation of [a] contract rests upon findings extrinsic to the contract, or upon inferences drawn from those findings," this Court will "defer to the trial court's findings, unless the findings are not supported by the record or unless the inferences drawn from those findings are not the product of an orderly or logical deductive reasoning process." *Honeywell Int'l Inc. v. Air Prod. & Chems., Inc.*, 872 A.2d 944, 950 (Del. 2005). Here, the Court of Chancery's post-trial interpretation of "a study report" undoubtedly and appropriately "rest[ed] upon findings extrinsic to the contract" and "inferences drawn from those findings."

C. Merits of the Argument

1. The Court of Chancery Correctly Ruled that Plaintiff's Interpretation of "Study Report" Was Not the Only Reasonable Interpretation.

Plaintiff urges this Court to overturn the Court of Chancery's denial of summary judgment on the meaning of the phrase "study report," and to find instead that the term *unambiguously* refers to any "statement or account" about a clinical trial. Plaintiff's interpretation of "study report" is inconceivably broad and vague—far from the only reasonable interpretation of the contract language. Mr. Richman,

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for example, testified in his deposition that "any summary" of data from a trial would qualify as a "study report," including an informal internal discussion. (B624–25.) What is more, even today, Plaintiff's fact witnesses are unable to agree on a definition of the phrase, much less which documents do or do not qualify. On this record, it strains credulity to assert that "there is no genuine issue as to any material fact." *Sunline Com. Carriers*, 206 A.3d at 845 (Del. 2019) (internal quotation marks omitted).

At summary judgment, Plaintiff claimed that "'study report' is an umbrella term that may cover a variety of documents reporting on the objectives, progress, and results of the AMP-514 studies." (B104.) Under the "umbrella," Plaintiff included "Annual Reports, Investigator's Brochures, Safety Reports, and journal publications." (*Id.*) According to Plaintiff, a qualifying "study report" could be a "spoken . . . account," or even materials "prepared in support of the original IND in 2014"—before the clinical trial *started*. (*Id.*) This is an absurdly broad reading, given that Prong 2 requires "a study report *for such Phase 1 study*." (A156 (emphasis added).)

The Court of Chancery correctly denied summary judgment, because it concluded that Plaintiff's definition was "overbroad and contrary to common understanding." (Summ. J. Order 14.) Plaintiff contends that the Court committed reversible error because it also noted MedImmune's evidence that "no one in the

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industry understands 'study report' to refer to anything but the CSR." (Opening Br. 43 (quoting Summ. J. Order 14).) According to Plaintiff, this was impermissible use of parol evidence "to create ambiguity," where none otherwise existed. *Id.* (quoting *Sassano v. CIBC World Mkts. Corp.*, 948 A.2d 453, 468 n.86 (Del. Ch. 2008)). In fact, the Court denied Plaintiff's motion because it was premised on an "overbroad" definition that was "contrary to common understanding." This holding was correct, for the reasons explained below, and was not tainted by reliance on parol evidence.

2. The Evidence at Trial Established that the Term "Study Report for Such Phase 1 Study" Refers Exclusively to a "Clinical Study Report."

The plain language, the parties' intent as reflected in the context and structure of the contract, and MedImmune's pre-litigation conduct all confirm that the contract term "study report for such Phase 1 study" refers exclusively to a CSR. The Court of Chancery held that "the overwhelming weight of th[e] evidence reveals that no industry participant or deal party would reasonably understand the term 'study report' to refer to an IB or annual report, much less an email or informal document describing a study." (Mem. Op. 64.) Plaintiff reiterates the illogical argument he asserted at trial, claiming that "study report" "unambiguously refers to *any* statement or account about a study." (Opening Br. 36 (emphasis added).) That suggestion is precisely the sort of "absurd result" that Delaware law forbids. *See Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010). It also flies in the face of

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uncontroverted trial testimony that both parties intended the milestone triggers to be black-and-white, rather than mushy and subjective. At bottom, Plaintiff's argument fails because he cannot show that the Court of Chancery's evaluation of the extrinsic evidence at trial was so deficient that it was not "the product of an orderly or logical deductive reasoning process." *Honeywell Int'l*, 872 A.2d at950.

a. Within the Pharmaceutical Industry, the Plain Language of the Agreement Refers Exclusively to a CSR.

Delaware courts construe an undefined term to have its ordinary meaning, which is "the meaning commonly understood in the [relevant] industry, as established by the record." *FleetBoston Fin. Corp. v. Advanta Corp.*, 2003 WL 240885, at *21 & n.79 (Del. Ch. Jan. 22, 2003); *see also Garrett v. Brown*, 1986 WL 6708, at *5 (Del. Ch. June 13), *aff'd*, 511. A.2d 1044 (Del. 1986); *Colvocoresses v. W.S. Wasserman Co.*, 196 A. 181, 183 (Del. Super. Ct. 1938). Here, the plain language of the parties' Agreement and the applicable industry context both support the Court of Chancery's holding.

First, trial testimony confirmed that, in the pharmaceutical industry, the phrases "study report" and "CSR" are "interchangeable terms." (A1023.) Witnesses for both parties agreed that "there's almost no one you could find anywhere [in the industry] that would think [a CSR] is not a study report." (A881; *see also* A1081–82.) Moreover, a CSR is the only "study report" that is "required to be prepared

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after a clinical trial is completed or terminated." (A888–89; *see also* A1022, A1293; B612–613.) The CSR is therefore the logical and obvious document meant by the term "study report for such Phase 1 trial."

By contrast, there is no support for the suggestion that industry participants would understand "study report" to refer to an IB. The Court of Chancery credited Mr. Pedicano's testimony that "industry participants do not refer to an IB as a 'study report.'" (Mem. Op. 64.) Even Plaintiff's own expert—Dr. Spector—was unable to recall *ever* having heard an IB referred to as a study report. (A866–67.) What is more, the evidence included no basis in "regulatory authority or published source" to support Plaintiff's interpretation. (Mem. Op. 58.) Indeed, Plaintiff's witnesses could not identify a single published document "characterizing an IB . . . as a 'study report.'" (*Id.* 58–59; *see also* A867–69.)

The trial record, therefore, consistently demonstrated that professionals in the pharmaceutical industry use the term "study report" to describe a CSR, and do not use that same term to refer to an IB. On this basis alone, the Court's judgment was reasonable and supported.

Second, Plaintiff's proffered definition suffers from the same mistake he makes in interpreting "additional clinical development." Instead of reading the phrase "a study report for such Phase 1 study" as a whole, he turns to dictionary definitions of the words "study" and "report" to conclude that a "study report" is

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merely any "statement or account about a methodical examination." (Opening Br. 37.) But an industry-specific phrase is best understood as a whole, not as the sum of its individual components. *See supra*, Section I.C.1.b. Plaintiff's misguided approach misses the forest for the trees.

Third, Plaintiff's argument that the plain language of the contract means that a milestone payment could be triggered by any "statement or record" about the trial—of whatever format, and describing any aspect or result, preliminary or otherwise—is disproved by the simple fact of disagreement between the three witnesses called to testify by Plaintiff. If the words had a single, indisputable meaning, one would expect at least the witnesses who were involved in contract negotiations (and who had a financial stake in this litigation) to testify to that one meaning. That did not happen. Instead, throughout this litigation, Plaintiff has been unable to offer a single, coherent definition of "study report." Plaintiff claimed on summary judgment that a "study report" could even encompass oral statements regarding animal studies. Then at trial, Plaintiff's witnesses each offered a different reading of the term, none of which match the definition Plaintiff now offers to this Court.

Mr. Richman provided a boundless interpretation of "study report." In his view, it could include *any* written document that included *any* data from a clinical trial. (A993–94.) He thought that the milestone payment would be triggered even

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by, for example, an email reflecting data for just a single patient—a patently nonsensical interpretation for a sub-component of a definition based on "completion" of a clinical trial. (*Id.*)

Unsurprisingly, Dr. Kabakoff disagreed. Consistent with the litigation position he was advancing, he contended that a "study report" must "present[] the result of the study" and "contain sufficient data that it could be summarized in a report and it could go into a regulatory filing to the FDA or a foreign regulatory body that would support additional clinical development." (A1117.) Plaintiff's expert—Dr. Spector—declined to offer an understanding of what the phrase itself means, but was willing to testify that either a CSR or an IB, but no other documents, could qualify as a "study report." (A872–77, A881.)[2] Plaintiff's witnesses each offered their own opinions as to what might constitute a "study report" but failed to offer any basis for their views.

[2] Plaintiff makes much of the Court of Chancery's description of Dr. Spector as Plaintiffs' "lead negotiator." (*See, e.g.*, Opening Br. 45–46.) This is a molehill, not a mountain. Regardless of the Court of Chancery's inaccurate (but also immaterial) description of Dr. Spector, its reasoning was that the inconsistency between different witnesses diminished the credibility of each. As noted above, Mr. Richman and Dr. Kabakoff—the two witnesses who indisputably *did* participate (directly or indirectly) in negotiations—could not agree on what documents qualified as a "study report." This conflict provided a sufficient reason for the Court of Chancery to discount their testimony. (*See* Mem. Op. 59–60.) Despite Plaintiff's heavy focus, this minor detail provides no basis to reverse the lower court's findings.

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Fourth, Plaintiff criticizes the Court of Chancery for construing "study report" as equivalent to "Clinical Study Report," after purportedly "conced[ing]" that the latter "is a term that two sophisticated parties would have used if that was what they meant."[3] (Opening Br. 39.) He goes on to argue that, because the term "study report" is not capitalized, it cannot refer to a specific document. (*Id.*) Both claims miss the mark. In an industry where "study report" and "CSR" are interchangeable terms, it is immaterial that the parties here used the less formal rather than the more formal terminology to reflect their agreement. Dr. Spector's testimony that everyone in the industry would understand a CSR to be a "study report," and that he could not recall a single occasion on which anyone had used the phrase "study report" to refer to an Investigator's Brochure, is fatal to Plaintiff's argument.

b. As Shown by the Structure and Context of the Contract, the Parties Intended to Trigger Payment upon the Completion of a CSR.

"When interpreting a contract, this Court will give priority to the parties' intentions as reflected in the four corners of the agreement, construing the agreement as a whole and giving effect to all its provisions." *Salamone v. Gorman*, 106 A.3d

[3] The Court of Chancery obviously did not "concede" this point. If it had, it would have ruled for Plaintiffs. Instead, it merely noted that the parties' failure to explicitly use the term "Clinical Study Report" "*might suggest* that the specialized meaning is not what was bargained for." (Summ. J. Order 14 (emphasis added).) It ultimately rejected this argument, finding that "study report" and "CSR" are "interchangeable terms" in the context of a completed Phase 1 study. (Mem. Op. 62.)

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354, 368 (Del. 2014) (internal quotation marks omitted). The Court of Chancery made a factual determination that both parties sought "to use 'objective,' 'clear,' 'black and white' metrics by which to measure 'Successful Completion.'" (Mem. Op. 57.) Under Delaware law, Courts interpret each term in accordance with the parties' "clear purpose." *Viking Pump, Inc. v. Century Indem. Co.*, 2 A.3d 76, 90 (Del. Ch. 2009). MedImmune's interpretation vindicates this overriding intent: It is easy to determine, by reference to objective measures, what a CSR is and the date on which it is completed. (Mem. Op. 70.)

Not so with Plaintiff's expansive interpretation, which runs afoul of the parties' desire to use "black-and-white" metrics. (A987–89.) "[P]egging the obligation to pay a substantial milestone payment to the completion of any number of documents that fit within a litigation-driven construct of 'reporting on the study' is hardly 'black and white.'" (Mem. Op. 70.)

Understanding the contract to refer to a CSR also matches the parties' intent that the "study report" document triggering a milestone be one corresponding to the "Successful Completion" of a specific clinical trial. While a CSR details the final results of a particular study, an IB is about an individual molecule. (A1027–29, A1078.) The sponsor drafts an IB before the product is ever used in a clinical trial and periodically updates it throughout the clinical trial process, *but not* after the trial is complete (unless a second or different trial using that same molecule is expected).

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(*See* A883–84; *see also* B607, B613.) Plaintiff thus urges this Court to adopt an interpretation of "study report" that bears no relationship to study completion, or the parties' shared intent for the Agreement.

In an effort to overcome these features of a CSR that align with the parties' intent, Plaintiff points to two other provisions of the Agreement that refer to "study reports" and argues that these provisions reveal the breadth of the term. First, Plaintiff points to a portion of the Agreement that addresses "clinical, pre-clinical and non-clinical study reports." (Opening Br. 38.) And, because this phrase would be illogical and repetitive if "study reports" meant "Clinical Study Reports," Plaintiff concludes that "a study report for such Phase 1 study" cannot possibly refer to a CSR. (*Id.*) True enough, "words used in one sense in one part of the contract will ordinarily be considered to have been used in the same sense in another part of the same instrument." *Radio Corp. v. Phila. Storage Battery Co.*, 6 A.2d 329, 334 (Del. 1939). But only "*where the contrary is not indicated*." *Id.* (emphasis added). Here, the contract does indicate a contrary understanding.

Plaintiff focuses on the "Representations and Warranties" portion of the Agreement, which describes Amplimmune's obligation to provide to AstraZeneca "copies of the study reports of (i) all clinical studies and trials conducted, and (ii) all clinical, pre-clinical and non-clinical study reports submitted to a Regulatory Authority." (A190.) This provision already violates the surplusage canon, as it

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requires provision of "study reports of . . . study reports." It also describes documents that cannot possibly qualify as the "study report" referred to in the definition of Successful Completion: at the time of the Agreement, Amplimmune had not conducted any clinical trials for AMP-514 so its obligation to provide these study reports plainly related to the pre-clinical and non-clinical studies it had carried out, and not to any Phase 1 trial study report. Thus, this provision necessarily refers to different documents than the milestone provision.

Second, Plaintiff also points to the Agreement's use of the words "[a]ll study reports" in an Annexure to the Agreement, to refer to "molecule safety and efficacy [studies] [that] are indisputably *not* CSRs." (Opening Br. 40.) This argument fails for the same reason as the first: references to pre- or non-clinical reports do not offer any illumination as to the parties' intended meaning of "a study report for such Phase 1 study."

Plaintiff also contends that the Court of Chancery's interpretation contradicts the parties' intent because "[t]he FDA does not require filing of the CSR 'until after Phase 3 trials are completed,' if the trials progress that far." (*Id.*) According to Plaintiff, reading "study report" to mean CSR would permit MedImmune to delay payment of the milestone "until the end of a Phase 3 study," despite the fact that the parties' deal focused on Phase 1. (*Id.* 40–41.)

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This argument ignores industry's (and MedImmune's) practice to prepare a CSR upon the completion of each trial. (A1448–49; B612–13.) Here, MedImmune diligently started work on the CSR shortly after completing the Phase 1 study (in the spring of 2019) and completed it in March 2020. (*See* Mem Op. 72–73.) Moreover, the parties did *not* tie payment to the "filing" of the CSR, which is the event occurring after Phase 3. (Opening Br. 40.) Instead, they pegged it to "completion," which always occurs before the CSR is formally filed and typically occurs relatively soon after the study is completed. (A212–13.)

The Court of Chancery's interpretation also makes the parties' deletion of the word "final" from the draft Agreement understandable, as well as the use of the indefinite article "a" rather than the definite article "the." These changes were consistent with an intent to trigger payment of the milestone once a CSR was completed following the Phase 1 study, regardless of whether that was the "final" version filed as part of the registration process.

c. MedImmune's Contemporaneous Understanding Reflects the Parties' Intent.

The evidence at trial showed "MedImmune's understanding that the second prong's 'study report' means CSR." (Mem. Op. 62.) Specifically, the Court of Chancery pointed to emails sent by MedImmune employees "both before and after the contract's signing" that "refer to a CSR when discussing the second prong's Milestone trigger." (*Id.*)

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The forthright negotiator principle, which permits courts to consider "what one party *subjectively* believed the obligation to be, coupled with evidence that the other party knew or should have known," thus supports the Court of Chancery's conclusions. *See United Rentals v. RAM Holdings*, 937 A.2d 810, 835 (Del. Ch. 2007) (internal quotation marks omitted). Plaintiff should have understood that participants in the pharmaceutical industry use "study report" as a shorthand for CSR. His expert, Dr. Spector, did. (A881.) Plaintiff should have anticipated MedImmune's understanding of that term. But he introduced *no* evidence showing that MedImmune knew or should have known that Amplimmune's subjective understanding of the phrase of "study report" referred to a limitless array of documents and oral statements related in *any manner* to the Phase 1 study. In fact, when pressed on this issue, Dr. Kabakoff was unable to recall any contemporaneous conversations with MedImmune in which he or anyone else from Amplimmune conveyed their broad interpretation to MedImmune. (A1143, A1147.)

3. MedImmune Paid the Combination Milestone upon Completion of the CSR

Although MedImmune decided not to pursue commercialization of the Combination after disappointing Phase 2 results, MedImmune completed the Combination CSR in March 2020. (Mem. Op. 23.)

The first prong of "Successful Completion" for the Combination therapy was met in March 2019, the second prong was met on March 31, 2020, and the third

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prong was met in February 2016. (*Id.* 72–73.) Thus, the "Successful Completion" definition was satisfied on March 31, 2020. MedImmune then promptly paid Plaintiff, (*id*. 23), thereby timely complying with its obligations under the Agreement, even though MedImmune will never be able to bring the Combination to market.

CONCLUSION

For the foregoing reasons, the Court of Chancery's judgment should be affirmed.

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CERTIFICATE OF SERVICE

I hereby certify that on April 5, 2021, I caused a copy of the foregoing **Redacted – Public Version of Appellee's Answering Brief** to be served via File & Serve*XPress* on the following:

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