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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.	No. 430, 2020 On appeal from the Court of Chancery, C.A. No. 2017-0459-JRS **PUBLIC VERSION Dated: February 24, 2021**

APPELLANT'S OPENING BRIEF

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NATURE OF PROCEEDINGS

This appeal arises from defendants' refusal to make the Milestone Payments they owed to stockholders of Amplimmune, Inc. ("Amplimmune") under the plain language of the Agreement and Plan of Merger ("Agreement").

Delaware courts must interpret unambiguous contracts according to what a reasonable person would understand the plain language to mean. But the Court of Chancery did the opposite here. First, it held that the phrase "additional clinical development" does not mean treatment and study of additional patients—as the words "clinical development" indicate—but rather and instead, ***commercial*** development. Second, it held that the phrase "a study report for such Phase 1 Study" refers not to a written summary of the Phase 1 results and data—as the words themselves suggest—but instead and ***exclusively*** to one particular document, a "Clinical Study Report" (CSR), which defendants chose to submit four years ***after*** they decided to advance the drug past Phase 1. Both interpretations violate the plain language of the Agreement, produce absurd results, and conflict with dictionary definitions, contextual evidence in the rest of the Agreement, interpretive canons, and the parties' unambiguous intent.

Defendants Zeneca, Inc. and Medimmune, LLC purchased Amplimmune because they hoped to develop a promising Amplimmune anti-cancer molecule

called AMP-514 as both a standalone "monotherapy" and a "combination therapy" with one or more of defendants' existing drugs. The parties' bargain was that defendants and Amplimmune would share risk and reward for AMP-514's success only up to Phase 1, the earliest stage of clinical development, but thereafter defendants would bear all risk and reap all reward. This allocation of risk was an important part of the Agreement; Amplimmune forwent deals with other potential suitors for more money that were tied to success at later stages of clinical development.

The parties allocated this risk via Phase 1 Milestones. As relevant to this dispute, the Agreement obligated defendants to pay $100 million for "Successful Completion of a Phase 1 Study" using Amplimmune's molecule as a Monotherapy (the "Monotherapy Milestone"), and $50 million for "Successful Completion of a Phase 1 Study" of Amplimmune's molecule in combination with one of defendants' molecules (the "Combination Milestone"). Defendants breached the Agreement by failing to make these Milestone Payments on the required dates.

"Successful Completion" is a defined term in the Agreement, which requires three prongs be met:

(1) "completion of a Phase 1 Study, in accordance with the protocol, in a manner sufficient to support a regulatory filing for additional clinical development";

(2) "completion of a study report for such Phase 1 Study"; and

(3) "a regulatory filing . . . submitting the protocol for additional clinical development".

Everyone agrees that the first prong was met for both Milestones—a Phase 1 Study *was* completed in a manner sufficient to support a regulatory filing. Defendants withheld payment on the Monotherapy Milestone and delayed payment on the Combination Milestone for purported deficiencies with prongs three and two, respectively:

Requirement	**Monotherapy** Milestone Completion	**Combination** Milestone Completion
(1) Completion of a Phase 1 Study in a manner sufficient to support a regulatory filing for additional clinical development.	*Uncontested*	*Uncontested*
(2) Completion of **a study report** for such Phase 1 Study.	*Uncontested*	**Contested**
(3) A regulatory filing submitting the protocol for **additional clinical development**.	**Contested**	*Uncontested*

Defendants also disputed ***when*** the first two prongs for the Monotherapy Milestone and the first prong for the Combination Milestone had been accomplished. The

Court of Chancery did not reach the issue whether the earlier dates identified by plaintiff or the later dates identified by defendants were correct.[1]

Defendants refused to honor the Monotherapy Milestone because they claimed that the phrase "additional clinical development" in the third prong ***actually*** required some "movement toward commercialization," a condition not found in the Milestone language. Although defendants admitted they submitted a regulatory filing with a protocol for additional clinical development that would administer the Monotherapy to new patients—satisfying the first prong—defendants insisted that study was only intended to ***commercially*** advance the Combination Therapy and thus, under their reading, there was no regulatory filing for additional clinical (commercial) development of the Monotherapy under prong three.

Additionally, defendants delayed payment of the Combination Therapy Milestone by claiming that "completion of a study report for such Phase 1 Study" could ***only*** refer to a document called a CSR, which the FDA requires to be filed by the end of Phase 3 (if the drug advances that far). Defendants argued that a "study report for such Phase 1 Study" could not possibly refer to an updated Investigator's

[1] The payment timing is relevant because the Agreement includes a provision that accelerates all Milestone Payments in the event of a breach. (A215-A216.) While Plaintiff argued below that defendants' breach triggered the acceleration provision, the court did not reach that issue. (Final Op. 25, 30.)

Brochure, a report that defendants filed with the FDA in 2016 detailing data and results from the Phase 1 Study. On that basis, defendants claimed the second prong was not satisfied as to the Combination Milestone until last year, four years after defendants made the decision to proceed past a Phase 1 study.

Due to the nonpayment, plaintiff Dr. David Kabakoff brought this action for breach of contract in his capacity as stockholders' agent for Amplimmune.[2] The Court of Chancery issued a bench ruling on summary judgment on January 24, 2020, and a post-trial memorandum opinion on November 18, 2020. Plaintiff challenges parts of each. The disputes before this Court are entirely those of contract interpretation: what the phrases "a study report" and "additional clinical development" mean.

In its bench ruling, the court decided that the simple phrase "additional clinical development" unambiguously (yet silently) also required "movement towards commercialization." (Summ. J. Order 11.) Despite the fact that the lowercase word "development" appears 41 times in the Agreement (never synonymously with "commercialization"), the court instead analyzed the definition of the separate, capitalized term "Development Plan," which the court decided was dispositive. (*Id.*

[2] Dr. Kabakoff's co-plaintiff, Dr. Arnold Oronsky, passed away after judgment. This brief refers to "plaintiff" in the singular.

12.) But the Development Plan definition says nothing at all about ***either*** "clinical development" or "commercialization." (A148.) The court also rejected plaintiff's definition of "additional clinical development" (as requiring treatment and study of additional patients) because the court decided that plaintiff's definition was "largely synonymous with 'research,' a separate term in the agreement." (Summ. J. Order 12.) In doing so, the court chose to ignore that the word "commercialization" is ***actually*** used elsewhere in the Agreement and is even distinguished from "development" in multiple places. (*See, e.g.*, A146 (referring to "a similarly situated Person engaged in the research, development, manufacturing, ***or*** commercialization of biologic or pharmaceutical products") (emphasis added); A176 (referring to the right to use "all Company Intellectual Property . . . for the development, manufacture ***and*** commercialization of the Products") (emphasis added).) The Court of Chancery offered no other basis for its conclusion that "clinical" unambiguously meant "commercial." The court's rationale, which this Court reviews *de novo*, is self-evidently deficient, and the court erred by ignoring the plain language, the contextual evidence, the absurd result of its interpretation, and the parties' intent.

In the same bench ruling, the Court of Chancery improperly relied on extrinsic evidence of purported trade usage to conclude that the phrase "a study report" was ambiguous. The court acknowledged that plaintiff's arguments were well-taken,

most specifically plaintiff's contention that the phrase "a study report" does not have a specialized meaning because it was uncapitalized and undefined and because the parties easily could have used the term "Clinical Study Report" but chose not to. (Summ. J. Order 13-14.) However, the court also observed that defendants offered "some record support" for the proposition that plaintiff's definition was overbroad and that "no one in the industry understands 'study report' to refer to anything but the CSR." (*Id*. 14.) The court violated the parol evidence rule because it used extrinsic evidence to create ambiguity, a decision which is also subject to *de novo* review.

At trial, the court found that defendants' view that "a study report" exclusively means the CSR was most reasonable. In so doing, it inappropriately privileged defendants' ***post***-negotiation evidence over plaintiff's evidence from the negotiations themselves. The court rejected the testimony of the ***only*** witnesses with direct knowledge of the negotiations—plaintiff's—citing perceived (minor) inconsistencies between them and with a third person, an expert witness ***who the court misidentified as a negotiator***. Although defendants chose not to offer witnesses involved in the negotiations (presumably because such testimony would have been unhelpful to them), the court credited defendants' witnesses' after-the-fact testimony about what the Agreement meant. The court also ignored other

evidence of the parties' intent from within the Agreement and outside of it, including the drafting history and the fact that the parties could have used the term CSR if that was what they had meant.

The Court of Chancery misapplied the settled law of contract interpretation and misread the plain text of the Agreement. Accordingly, this Court should vacate the judgment with respect to the Monotherapy Milestone; reverse the judgment with respect to the Combination Milestone; and remand for application of the correct interpretation of the phrase "additional clinical development" and further proceedings regarding (1) the date on which the payments became due and (2) the acceleration clause.

SUMMARY OF ARGUMENT

1. When the Court of Chancery concluded that the contractual phrase "additional clinical development" required "movement towards commercialization," it violated "the well-established general principle that . . . it is not the proper role of a court to rewrite or supply omitted provisions to a written agreement." *Cincinnati SMSA Ltd. P'ship* v. *Cincinnati Bell Cellular Sys. Co.*, 708 A.2d 989, 992 (Del. 1998) (citation omitted). The phrase "additional clinical development" unambiguously refers to treatment and study of additional patients, as demonstrated by several pieces of evidence. ***First,*** dictionary definitions distinguish "clinical," which refers to "observation of a patient," from "commercialize," which refers to "apply[ing] methods of business to [something] for profit." *American Heritage Dictionary of the English Language* 347, 371 (5th ed. 2016). ***Second,*** other provisions of the Agreement confirm this interpretation by, for example, repeatedly distinguishing "commercialization" from "development," and by including explicitly non-commercial tasks as part of "clinical development." ***Third,*** plaintiff's reading is not redundant with "research," because research can occur in settings without patients. ***Fourth,*** the court's reliance on the definition of the separate capitalized phrase "Development Plan" is unavailing because the definition doesn't actually refer to commercialization (or even clinical development). Moreover, the

actual Development Plan, attached as an Annex to the Agreement and incorporated therein, explicitly includes steps that are not tethered or related to commercialization, including one that takes place before a drug can even be tested on humans. ***Fifth,*** the court's definition necessarily implies that the Phase 1 study constituted commercialization—subsequent commercial development being "additional" thereto—whereas the goal of a Phase 1 study is typically the treatment and study of patients. ***Sixth*** and finally, the parties chose to allocate risk for everything after Phase 1, including additional clinical development and ***all*** commercialization, to defendants exclusively; tethering Milestones to progress towards commercialization that typically happens only ***after*** Phase 1 makes no sense. Accordingly, this Court should vacate the judgment on the Monotherapy Milestone and remand for application of the correct interpretation.

2. Alternatively, if this Court instead concludes that the phrase "additional clinical development" is ambiguous, it should vacate and remand for the Court of Chancery to develop a factual record on the extrinsic evidence of its meaning.

3. The Court of Chancery also erred when it concluded that "a study report for such Phase 1 Study" was ambiguous on summary judgment for purposes of the Combination Milestone. It further erred when it ruled that the phrase "a study report" referred exclusively to the CSR, a specific document that only has to be filed

after a Phase 3 study if trials proceed that far. ***First,*** dictionaries define a "report" as a statement or account, which includes more than one type of document. ***Second,*** the Agreement elsewhere refers to "clinical, pre-clinical, and non-clinical study reports," fatally undermining the argument that the term "study report" can only refer to the CSR. The Court of Chancery's interpretation would mean that this other provision was referring to a "non-clinical [Clinical Study Report]." ***Third,*** the Agreement uses the nonspecific, indefinite article "a" before "study report," showing that there could be multiple qualifying reports. ***Fourth,*** the fact that the term "study report" is uncapitalized confirms that no specific form of document was contemplated; if the parties intended to tether the Milestone only to the CSR, they would have used that term instead. ***Fifth,*** in the Agreement's Annex A, an incorporated portion of the Agreement describing the "Development Plan" (the definition of which the Court of Chancery relied on to interpret the meaning of the phrase "additional clinical development"), the parties observed that "***All study reports*** are being finalized and on track to be completed in time for an October 2013 IND filing" (A288 (emphasis added)), referring to safety and efficacy reports that are ***not*** CSRs. ***Sixth*** and finally, because a CSR need only be filed after the conclusion of Phase 3 if trials proceed that far, the Court of Chancery's interpretation is contrary to the parties' bargain that they would share risk and reward only through

Phase 1. The court's interpretation could lead to the absurd result here—that defendants could delay payment for ***years*** by not preparing a CSR. Any such result would also be contrary to the plain meaning of a "milestone" as a point along the way in a project, and would subvert the Agreement's deliberate use of "Phase 1" to describe the Milestones.

4. The Court of Chancery's conclusion that the phrase "a study report" was ambiguous rested heavily on extrinsic evidence of industry usage, but the parol evidence rule prevents the use of extrinsic evidence to manufacture ambiguity. Accordingly, the Court should hold that the phrase "a study report" unambiguously means a statement or account of a study. Under that definition, the updated Investigator's Brochure containing a detailed summary of the investigation that defendants submitted to the FDA in 2016 is a study report, and defendants impermissibly delayed paying the Combination Milestone.

5. If this Court instead concludes the term is ambiguous, it should still reverse the Court of Chancery's decision on the Combination Milestone. The best evidence of the term's meaning comes from the negotiations that led to the Agreement. The only two witnesses with direct knowledge of the negotiations both testified that the phrase "a study report" meant more than just the CSR and offered definitions broad enough to include the updated Investigator's Brochure from

February 2016. The drafting history of the Agreement also reveals that a prior draft referred to "a final study report" before "final" was struck, which belies defendants' arguments that there is only one kind of study report, that the phrase "a study report" is a specific term, and that the report must include all Phase 1 data from every trial participant. The Court of Chancery unreasonably focused on minor differences in the witnesses' testimony and compounded the error by treating one of plaintiff's experts as "Amplimmune's lead negotiator." It also misunderstood the purpose of the Agreement and relied on testimony from witnesses who admitted playing no direct role in the negotiations. The inferences that the Court of Chancery drew are thus unreasonable.

STATEMENT OF FACTS

A. Background on AMP-514

Immunotherapy, which harnesses the body's own immune system to fight cancer, is a cutting-edge technique that is widely anticipated to revolutionize cancer treatment. Ordinarily, and without immunotherapy, cancer cells try to disable our white blood cells to prevent them from attacking the cancer. (Final Op. 6.) Immuno-oncological therapies can try to prevent this from happening in one of two ways: either by protecting the white blood cell's pathways or by targeting the cancer molecule sent to disable the white blood cell. (*Id.* 6-7.)

In 2013, defendant MedImmune, LLC, and its parent, defendant Zeneca, Inc., were developing a therapy to target the disabling molecule, while several of its competitors were developing therapies to protect the white blood cell pathway. (*Id.* 8-9.) To improve their competitive position, defendants sought to purchase a pathway-protecting molecule from another company. Defendants eventually entered negotiations with Amplimmune, a company developing a pathway-protecting molecule known as AMP-514. (*Id.* 9.) For its part, Amplimmune sought a relationship with a large pharmaceutical company to run the gauntlet of clinical trials. (*Id.*)

B. The Merger

In August 2013, the parties signed an Agreement and Plan of Merger. (*Id.* 10.) In the Agreement, defendants agreed to acquire Amplimmune for $225 million and as much as $275 million in contingent Milestones linked to the development of AMP-514. (*Id.*; A213.) Significantly, the parties agreed that all Milestones would be tethered to Phase 1.

This allocation of risk and compensation was a critical part of the parties' bargain, and was attractive to Amplimmune. As the Court of Chancery explained, "Drug trials in the United States are generally separated into Phase 1, Phase 2 and Phase 3 trials." (Final Op. 9 n.28.) "Phase 1 trials typically focus on determining a drug's safety at various doses, but also attempt 'to gain early evidence of effectiveness.'" (*Id.* (quoting 21 C.F.R. §321.21(a)).) Approximately 70% of drugs successfully complete Phase 1, according to the FDA. *Step 3: Clinical Research*, FDA (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research. "Phase 2 trials involve 'controlled clinical studies conducted to evaluate the effectiveness of the drug . . . .'" (*Id.* 9 n.28 (quoting 21 C.F.R. §321.21(b)).) "Phase 3 trials are large-scale efficacy trials." (*Id.*) Here, the Milestones in the Agreement were tied to Phase 1 studies, rather than Phase 2 or 3 studies or FDA approvals. (A1108-1109.) Although everyone hoped that AMP-514

would be among the approximately 5% of oncology drugs to reach Phase 2 and Phase 3 clinical trials, FDA market approval, and commercialization, only defendants bore ***any*** of that risk under the terms of the Agreement.

Two of the Milestones are at issue in this appeal. The first is for $100 million upon "Successful Completion of a Phase 1 Study" of AMP-514 as a Monotherapy—that is, a therapy consisting only of AMP-514. (Final Op. 10.) The second is for $50 million upon "Successful Completion of a Phase 1 Study" of AMP-514 in combination with one of MedImmune's molecules, known as a Combination Therapy. (*Id.*) The Agreement also contained other Milestones not at issue in this appeal, as well as an acceleration clause that made ***all*** Milestones "immediately due and payable in full" in the event of a material breach by defendants. (A215-A216.)

The Agreement defines "Successful Completion" in three parts. First, there must be "completion of such Phase 1 Study, in accordance with the protocol, in a manner sufficient to support a regulatory filing for additional clinical development" of the Monotherapy (for the Monotherapy Milestone) or the Combination Therapy (for the Combination Milestone). (A156.) Second, there must be "completion of a study report for such Phase 1 Study." (*Id.*) Third, there must be "a regulatory filing . . . submitting the protocol for additional clinical development" of the Monotherapy

(for the Monotherapy Milestone) or the Combination Therapy (for the Combination Milestone). (*Id.*)

For each Milestone, the parties dispute one of the prongs on appeal. For the Monotherapy Milestone, the parties agree that the first two prongs were satisfied. Their only disagreement is about the third prong and the meaning of the phrase "additional clinical development." For the Combination Milestone, the parties agree that the first and third prongs were satisfied. Their only disagreement is about the second prong and the meaning of "a study report."

The Agreement contains certain exhibits and annexes, which the parties attached to the document and expressly incorporated within it. Among those is a "Development Plan," defined as "the plan and timeline for the further development of AMP-514 to support Regulatory Approval thereof in the United States attached to this Agreement as Annex A, as such plan and timeline may be amended from time to time in accordance with this Agreement." (A148.) That Development Plan is 14 pages long, and contains a written summary of development efforts, including planned filings and studies. With respect to AMP-514, and the first Development Plan objective, which was IND (Investigational New Drug) authorization to ultimately test the molecule on humans, the Development Plan observes: "***All study reports*** are being finalized and on track to be completed in time for an October 2013

IND filing." (A288.) Such "study reports" related to molecule safety and efficacy and are indisputably ***not*** CSRs.

A section of the Development Plan referred to as "Supporting Clinical Development" obligates Amplimmune to assist in "conducting the [first-in-human] clinical trial for AMP-514" and "provid[ing] critical services to support the FIH clinical trial and enable future trials." (A293.) Amplimmune was tasked to "develop, validate, and execute [pharmacokinetics], immunogenicity, and [pharmacodynamic] assays," as well as "additional pharmacology studies" such as "cell signaling studies." (*Id.*) None of these tasks are related to commercialization.

Finally, the Development Plan also included a schematic called the "AMP-514 Development Timeline" which included boxes for studies prior to Phase 1, a Phase 1a study, and twelve Phase 1b studies. (A295.) Nothing beyond Phase 1 is listed on the "AMP-514 Development Timeline." There is also no mention of commercialization on the timeline.

C. The Development of AMP-514

Following the merger, MedImmune began Phase 1 studies for both the Monotherapy and the Combination Therapy. The Phase 1 study for the Monotherapy began in December 2013. (Final Op. 13.) It initially had discouraging results. (*Id.* 15.) But after MedImmune increased the dose, it found a stronger

immune response and good toleration by patients. (*Id.* 16.) The Phase 1 study for the Combination Milestone began in May 2014. (*Id.* 13.)

MedImmune did not wait for the last patient visit in the Phase 1 studies before proceeding with a Phase 1/2 trial for the Monotherapy and Combination Therapy. A Phase 1/2 trial is a hybrid patient study bridging Phases 1 and 2, which is intended to test safety, side effects, and dosing. In February 2016, MedImmune filed a Protocol Amendment with the FDA for a study comparing the Monotherapy with a Combination Therapy using durvalumab, one of MedImmune's molecules. The amendment described "A Phase 1/2 Open-label Study to Evaluate the Safety and Antitumor Activity of [AMP-514] in Combination with [durvalumab] and [AMP-514] Monotherapy." (*Id.* 19 (alterations in original).) The protocol anticipated that up to 60 new cancer patients would get the Monotherapy, and an equal number would receive the Combination Therapy. (A550.)

The protocol had several primary objectives and hypotheses relating specifically to the Monotherapy, including determining whether AMP-514 "in combination with [durvalumab] will have a higher response rate than [AMP-514] ***monotherapy***" and "evaluat[ing] the antitumor activity of [AMP-514] ***monotherapy***." (A547 (emphasis added).) The protocol also had several secondary objectives and hypotheses, including determining whether the AMP-514

"***monotherapy*** . . . will be adequately tolerated," "describ[ing] the safety and tolerability of [AMP-514] ***monotherapy***," "describ[ing] the pharmacokinetics (PK) of [AMP-514] ***monotherapy***," and "determin[ing] the immunogenicity of [AMP-514] ***monotherapy***." (*Id.* (emphasis added).) The protocol had further objectives pertaining to biomarkers, gene expression, and the pharmacodynamic activity of the AMP-514 ***Monotherapy***. (A548.) And the filing reported that "[e]merging data with . . . [AMP-514] in a ***monotherapy*** setting [from the Phase 1 study] across a range of tumor types demonstrate encouraging clinical activity with a manageable safety profile." (A571.)

Other documents related to this Phase 1/2 trial also indicated that MedImmune was developing the Monotherapy alongside the Combination Therapy. The consent forms advised patients that defendants sought to "evaluate AMP-514 in combination with durvalumab and AMP-514 ***monotherapy*** in treating clear-cell Renal Cell Carcinoma." (Final Op. 21 (alterations adopted and emphasis added).) An Investigational Medicinal Product Dossier submitted to foreign governments likewise characterized MedImmune's purpose as developing ***both*** a Monotherapy and a Combination Therapy. (*Id.*)

The same month that it filed the protocol amendment, February 2016, MedImmune also filed an updated Investigator's Brochure with reports on the

Phase 1 studies of both therapies and information about the Phase 1/2 study. (*Id.* 22; A434.) MedImmune's February 2016 Investigator's Brochure complied with FDA's regulations, 21 C.F.R. §312.23(a)(5), and provided over 100 pages of detail, including a data summary with Phase 1 results. (A434-A545.) It served as an update to "keep each participating investigator informed of new observations." 21 C.F.R. §312.55(b).

But MedImmune did not pay either Milestone after the submission of the updated Investigator's Brochure and Third Protocol in 2016. Instead, it delayed the $50 million Milestone for the Combination Therapy until 2020, after it finally submitted the CSR. It never made the $100 million payment at all for the Monotherapy Milestone because, it contended, the Phase 1/2 study did not constitute "additional clinical development" of the Monotherapy.

	Monotherapy	**Combination Therapy**
Phase 1 Milestone "Successfully Completed"	February 2016	February 2016
CSR for Phase 1 Study	March 2019	March 2020
Milestone Payment Paid	N/A	April 2020

D. Procedural History

Plaintiff filed this action for breach of contract in June 2017 in his capacity as stockholders' agent. Among other claims, the complaint sought relief for

MedImmune's failure to make the $100 million Monotherapy Milestone and its decision to withhold the $50 million Combination Milestone until 2020 instead of paying it when due in 2016.

On August 23, 2019, plaintiff and defendants cross-moved for summary judgment. Plaintiff sought summary judgment on the Monotherapy Milestone by arguing that the third prong, which requires a filing for "additional clinical development," was satisfied by the February 2016 Protocol Amendment outlining the Phase 1/2 study. He also sought summary judgment on the Combination Milestone by arguing that the second prong, which requires a "study report," was satisfied by the February 2016 updated Investigator's Brochure, which analyzed the results of the Phase 1 studies and detailed the transition to a Phase 1/2 study.

The Court of Chancery denied summary judgment on the Monotherapy Milestone, relying on its interpretation that "additional clinical development" unambiguously required movement towards commercialization. In a bench ruling, it explained its decision as follows:

> After reviewing the provision at issue, I am satisfied that defendants have proffered the superior construction and, in this instance, the only reasonable construction.
>
> When a word is used in different parts of a contract, that word is presumed to have the same meaning throughout. . . .

> "Development" is used elsewhere in the agreement. And in those sections, specifically the definition of "Development Plan" in Section 1.1, it is used to describe movement towards commercialization. Additionally, plaintiffs' proffered definition is largely synonymous with "research," a separate term in the agreement, and is overly broad. I find it to be unreasonable.

(Summ. J. Order 11-12.) The Summary Judgment Order does not mention: the many other references to "development" throughout the Agreement, which are entirely unrelated to commercialization; the ***actual*** Development Plan, which includes a timeline of events that are indisputably unrelated to commercialization; or the multiple references to "commercialization" in the Agreement, which are distinguished from "development" therein.

The court denied summary judgment on the Combination Milestone as well. In favor of plaintiff's interpretation, it noted that "'study report' is not a capitalized term in the agreement, [and] not defined, suggesting it does not have a specialized meaning." (*Id.* 13-14.) The court also noted that "the parties easily could have used the term 'clinical study report' instead of just 'study report,' and their failure to do so might suggest that the specialized meaning is not what was bargained for." (*Id.* 14.) In defendants' favor, the court looked beyond the Agreement and concluded there was "some record support" for the proposition that plaintiff's "definition is overbroad" and that "no one in the industry understands 'study report' to refer to anything but the CSR." (*Id.*)

The Court of Chancery held a five-day bench trial. The parties presented extrinsic evidence about the meaning of the phrase "a study report" to address the perceived ambiguity in the term. Among other evidence, plaintiff and a former MedImmune employee both testified based on their experience with the merger negotiations that the phrase "a study report" refers to more than just the CSR, and is broad enough to include the 2016 updated Investigator's Brochure. (A950, A994, A1117.) Plaintiff also introduced emails between MedImmune employees that referred to a document other than the CSR as a study report. (Final Op. 61 (citing A430-A433).) Defendants produced emails of their own indicating that the CSR would satisfy the requirement, along with testimony from witnesses who had no direct knowledge of the negotiations but who testified that they understood the phrase "a study report" to mean the CSR. (*Id.* 62-64.)

In a post-trial decision dated November 18, 2020, the Court of Chancery ruled for defendants on both issues. Because it had already decided on summary judgment that the phrase "additional clinical development" required "movement towards commercialization," the court attempted to determine at trial whether "the relevant regulatory filing or protocol was made for the purpose of advancing the Monotherapy towards commercialization." (*Id.* 32.) The court decided that the Phase 1/2 trial, although designed to treat equal numbers of patients with the

Monotherapy and the Combination Therapy, "was not undertaken to move the Monotherapy towards commercialization." (*Id.* 29, 36.)

With respect to the Combination Milestone, the court entertained extrinsic evidence of the meaning of the phrase "a study report" and concluded the phrase could refer only to the CSR. In so doing, the court rejected the testimony of the only witnesses with direct knowledge of the negotiations because of purported inconsistencies between their testimony and that of an expert witness ***who the court misidentified as a negotiator***. (*Id*. 59-60.) It also found defendants' witnesses, who testified that the phrase "a study report" meant the CSR, persuasive even though none had direct involvement in the negotiations. (*Id.* 64.) The court came to the conclusion that plaintiff's interpretation failed to give independent meaning to "in accordance with the protocol" in the first prong (*id.* 66), and "most important[ly]" that a broad definition of the phrase "a study report" was contrary to the parties' desire for clear metrics (*id.* 69-71). Because the Milestone was paid in 2020 when defendants finished the CSR, the court denied relief. The Court of Chancery entered final judgment for defendants on November 25, 2020. (Final Order.)

ARGUMENT

I. DEFENDANTS BREACHED THEIR OBLIGATION TO PAY THE MONOTHERAPY MILESTONE.

A. Question Presented

Whether the Court of Chancery erred by concluding that the phrase "additional clinical development" required additional "movement towards commercialization," in contravention of the plain language, the contractual context, and the parties' intent. (Summ. J. Order 7-12.)

B. Standard of Review

This Court reviews the "grant of summary judgment *de novo* to determine whether, viewing the facts in the light most favorable to the nonmoving party, the moving party has demonstrated that there are no material issues of fact in dispute and that the moving party is entitled to judgment as a matter of law." *GMG Capital Invs., LLC* v. *Athenian Venture Partners I, L.P.*, 36 A.3d 776, 779 (Del. 2012) (internal quotation marks and citation omitted).

This Court likewise shall "review questions of contract interpretation *de novo*." *Id.*

C. Merits of the Argument

"Delaware adheres to the objective theory of contracts, i.e. a contract's construction should be that which would be understood by an objective, reasonable

third party." *Osborn ex rel. Osborn* v. *Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (internal quotation marks and citation omitted). "Contract terms themselves will be controlling when they establish the parties' common meaning so that a reasonable person in the position of either party would have no expectations inconsistent with the contract language." *Eagle Indus., Inc.* v. *DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997) (citation omitted). Only if the contractual language is ambiguous will a court "look beyond the language of the contract to ascertain the parties' intentions.'" *Id.* (citations omitted). But a "contract is ***not*** rendered ambiguous simply because the parties do not agree upon its proper construction." *GMG Capital*, 36 A.3d at 780 (emphasis added) (internal quotation marks and citation omitted). Nor does ambiguity exist "where a court can determine the meaning of a contract without any other guide than a knowledge of the simple facts on which, from the nature of language in general, its meaning depends." *AT&T Corp.* v. *Lillis*, 953 A.2d 241, 252 (Del. 2008) (internal quotation marks and citation omitted).

The Court of Chancery erred by interpreting the undefined phrase "additional clinical development" in the definition of successful completion to include a further, unwritten requirement of "movement towards commercialization." The plain meaning of the phrase "additional clinical development" is treatment and study of

additional patients. The court improperly rewrote the Agreement and denied stockholders the benefit of Amplimmune's bargain. The case should be remanded for further proceedings using the correct interpretation. If this Court were to conclude the term is ambiguous, plaintiff has at least offered a reasonable interpretation and the case should be remanded for the Court of Chancery to develop a record on extrinsic evidence.

1. "Additional Clinical Development" Unambiguously Means Treatment and Study of Additional Patients.

It "is axiomatic that courts cannot rewrite contracts," *Murfey* v. *WHC Ventures, LLC*, 236 A.3d 337, 355 (Del. 2020), but that is exactly what the Court of Chancery did by redefining "clinical development" as "commercial development."

a. Plain Dictionary Meaning

Dictionaries (and common sense) confirm that "clinical development" has a very different meaning from "commercialization." "This Court often looks to dictionaries to ascertain a term's plain meaning." *In re Solera Ins. Coverage Appeals*, 240 A.3d 1121, 1132 (Del. 2020) (citations omitted). Here, dictionaries establish that the phrase "additional clinical development" refers to treatment and study of additional patients. First, the noun "development" refers generally to the "application of techniques or technology to the production of new goods or services." *American Heritage Dictionary*, *supra*, at 496; *see also id.* at 495 (defining

"develop" as "To bring from latency to or toward fulfillment"). The adjective "clinical" describes something "Of, relating to, or connected with a clinic" or "Involving or based on direct observation of a patient." *Id.* at 347; *see also Merriam-Webster's Collegiate Dictionary* 232 (11th ed. 2012) ("of, relating to, or conducted in or as if in a clinic . . . involving direct observation of the patient").

The meaning of the word "commercialize" is very different from "clinical." Dictionaries define "commercialize" to mean to "apply methods of business to for profit" or to "do, exploit, or make chiefly for financial gain." *American Heritage Dictionary*, *supra*, at 371.

b. Surplusage Canon

The Court of Chancery ignored the way in which the words "development" and "commercialization" were used—and ***distinguished***—within the Agreement. Courts "interpret contracts 'as a whole and . . . give each provision and term effect, so as not to render any part of the contract mere surplusage.'" *In re Shorenstein Hays-Nederlander Theatres LLC Appeals*, 213 A.3d 39, 56 (Del. 2019) (quoting *Osborn*, 991 A.2d at 1159). In so doing, courts "giv[e] each . . . term an independent meaning." *Norton* v. *K-Sea Transp. Partners L.P.*, 67 A.3d 354, 365 (Del. 2013) (citation omitted). Here, the Agreement uses "development" and "commercialization" as separate terms multiple times. (A146 ("research,

development, manufacturing, ***or*** commercialization") (emphasis added); A176 ("development, manufacture, ***and*** commercialization") (emphasis added).) Reading "clinical" to mean "commercial" would create surplusage and leave the words with no independent meaning. Additionally, the Agreement separately refers to "development" throughout, entirely untethered to commercialization. It even distinguishes "development" from "importing or exporting, licensing, . . . distributing or marketing" (A150), and from "sale[s]" and "marketing" (A174)—all inherently commercial concepts.

c. Contextual Evidence

The Agreement supports the plain meaning of "clinical development" in other ways too, and "courts must read the specific provisions of the contract in light of the entire contract." *Chi. Bridge & Iron Co. N.V.* v. *Westinghouse Elec. Co.*, 166 A.3d 912, 913-914 (Del. 2017). The Agreement uses the very same phrase in the definition of "Same Indication" to require that "such ***additional clinical development*** [be] 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 (emphasis added).) This clause relates entirely to the specifics of treating and studying patients.

Moreover, the "Development Plan" expressly incorporated into the Agreement as Annex A defines Amplimmune's duties in "Supporting ***Clinical Development***" to include "conducting the [first-in-human] clinical trial for AMP-514" and "provid[ing] critical services to support the FIH clinical trial and enable future trials." (A293 (emphasis added).) Specifically, Amplimmune was tasked to "develop, validate, and execute [pharmacokinetics], immunogenicity, and [pharmacodynamic] assays," as well as "additional pharmacology studies" such as "cell signaling studies." (*Id.*) ***All*** of these duties involve treatment and study of patients, but ***none*** can fairly be said to involve "movement towards commercialization." Many of these obligations arise during Phase 1. Additionally the Development Plan's "AMP-514 Development Timeline" through 2017 only included events prior to or during Phase 1 and did not include any events relating to commercialization.

While the court below professed to rely on contextual evidence of meaning, it focused on a word that does not even appear in the definition of Successful Completion. Instead of examining the Agreement's usage of "clinical" (or "commercialization"), the court chose to focus on the irrelevant term "research" because it decided that plaintiff's definition of clinical as relating to treating and studying patients was "largely synonymous" with research. (Summ. J. Order 12.)

Of course it is true that treating and studying patients involves research. But research is not conterminous with clinical development because some research takes place without patients; prior to Phase 1, ***none*** of the research conducted on AMP-514 was on patients.

Similarly, instead of examining the Agreement's use of the word "development," the Court of Chancery relied on the definition of the entirely separate defined concept of the "Development Plan," which nowhere uses "clinical" to modify development and does not require commercialization. As described above, the Development Plan ***actually*** invokes the term "Clinical Development" to describe non-commercial steps and obligations.

d. Unreasonable Result

Plaintiff's interpretation is unambiguously correct for another reason as well: the Court of Chancery's interpretation "leads to unreasonable results." *Axis Reinsurance Co.* v. *HLTH Corp.*, 993 A.2d 1057, 1063 (Del. 2010) (citation omitted). "***Additional*** clinical development" after a Phase 1 study presupposes that clinical development has occurred in the Phase 1 study. But it is unreasonable to refer to a Phase 1 study as movement towards commercialization. According to FDA regulations, "Phase 1 includes the initial introduction of an investigational new drug into humans." 21 C.F.R. §312.21(a)(1). "These studies are designed to

determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." *Id.* Because a Phase 1 study is plainly not "movement towards commercialization," the Court of Chancery's requirement that the phrase "additional clinical development" include progress towards commercialization is unreasonable.

e. Parties' Intent

The parties' deal was clear: they would split risk and reward through Phase 1 and thereafter defendants would go it alone. The parties structured the deal consideration, and specifically the Milestones, accordingly. The Agreement refers to the Milestones as "Phase 1" Milestones. (A212-A213.) Yet commercialization happens after Phase 1. So the court's interpretation that payment is contingent on movement towards commercialization would necessarily drag the risk-sharing beyond what the parties negotiated, improperly depriving the stockholders of the benefit of Amplimmune's bargain.

For the foregoing reasons, the plain and unambiguous meaning of the phrase "additional clinical development" is treatment and study of additional patients, not "movement toward commercialization." The judgment should be vacated and the case remanded accordingly.

2. In the Alternative, Plaintiff's Interpretation Is At Least Reasonable.

At the very least, the foregoing reasons demonstrate the reasonableness of plaintiff's interpretation. If both interpretations are reasonable, the phrase "additional clinical development" is ambiguous and the court must consider extrinsic evidence, including "evidence of prior agreements and communications of the parties as well as trade usage or course of dealing." *Eagle Indus.*, 702 A.2d at 1233 (footnote omitted). This would create "an unresolved issue of material fact that renders summary judgment inappropriate." *GMG Capital*, 36 A.3d at 784. Because the Court of Chancery ruled that its interpretation was unambiguous, it did not develop such a record. If this Court determines the Agreement is ambiguous, it should thus remand for fact-finding on extrinsic evidence of meaning.

II. DEFENDANTS BREACHED THEIR OBLIGATION TO PAY THE COMBINATION MILESTONE.

A. Question Presented

Whether the Court of Chancery erred by concluding that the phrase "a study report" in the Agreement refers specifically and exclusively to a "Clinical Study Report" and not to any other study reports including an updated Investigator's Brochure. (Summ. J. Order 12-14; Final Op. 55-73.)

B. Standard of Review

Contract interpretation is a "question of law that this Court reviews *de novo* for legal error." *AT&T*, 953 A.2d at 251-252 (internal quotation marks and citation omitted). Because the court incorrectly determined at the summary judgment phase that the Agreement was ambiguous, that decision is subject to *de novo* review.

To the extent the Court of Chancery's determination at trial that the phrase "a study report" refers exclusively to the CSR "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." *Id.* (internal quotation marks and citation omitted).

C. Merits of the Argument

The phrase "a study report" unambiguously refers to any statement or account about a study, not just the CSR. Most relevant here, the phrase encompasses the February 2016 updated Investigator's Brochure submitted by defendants. This interpretation is apparent from dictionary definitions; the use of "pre-clinical . . . study report," "non-clinical . . . study report," and "clinical . . . study report" elsewhere in the Agreement; and other contextual indications of the phrase's generality. The Court of Chancery impermissibly relied on extrinsic evidence to manufacture ambiguity in the Agreement, contrary to binding precedent. The Court should thus reverse the judgment on the Combination Milestone and hold that the phrase "a study report" unambiguously includes the February 2016 updated Investigator's Brochure.

Even if this Court finds the term ambiguous, it should still reverse. As Delaware courts have recognized, evidence from negotiations is "especially revealing." *Zayo Grp., LLC* v. *Latisys Holdings, LLC*, 2018 WL 6177174, at *12 (Del. Ch. Nov. 26, 2018). The only witnesses with direct knowledge of the negotiations, Michael Richman and Dr. Kabakoff, agreed that the phrase "a study report" meant more than just the CSR, including at least an updated Investigator's Brochure. The drafters' initial inclusion of "final study report" and subsequent

deletion of "final" confirms this meaning. In rejecting this evidence, the Court of Chancery misidentified an expert witness as "Amplimmune's lead negotiator," focused on irrelevant details of key testimony and evidence, misunderstood the intent behind the Agreement, and relied on witnesses with no direct knowledge of the negotiations. The construction that the court reached—that the phrase "a study report" refers only to the specific document known as the "Clinical Study Report"—was unreasonable.

1. "A Study Report" Unambiguously Means a Statement or Account About a Study.

Because the phrase "a study report" is not defined in the Agreement or any applicable regulations, the Court must interpret that term in accordance with its ordinary meaning.

a. Plain Dictionary Meaning

Once again, dictionaries are a standard guide to plain meaning. *In re Solera Ins. Coverage Appeals*, 240 A.3d at 1132. Definitions of "study" and "report" all denote a statement or account about a methodical examination. A report is a "detailed account or statement," *Merriam-Webster's Collegiate Dictionary*, *supra*, at 1056, or a "spoken or written account of an event, usually presented in detail," *American Heritage Dictionary*, *supra*, at 1490. And a "study" is an "Attentive examination or analysis." *Id.* at 1732. There is nothing in these definitions that

requires there to be only one "study report" for a Phase 1 study and certainly nothing that equates the phrase "a study report" with the CSR.

b. Surplusage Canon

Beyond dictionary definitions, there are several indicia in the Agreement that the phrase "a study report" includes multiple kinds of study reports. Courts must "interpret contracts 'as a whole and . . . give each provision and term effect, so as not to render any part of the contract mere surplusage.'" *In re Shorenstein Hays-Nederlander Theatres LLC Appeals*, 213 A.3d at 56 (quoting *Osborn*, 991 A.2d at 1159). Here, Section 3.19 refers to "clinical, pre-clinical and non-clinical study reports." (A190.) It makes no sense to refer to a "pre-clinical . . . [Clinical Study Report]" or a "non-clinical [Clinical Study Report]." It likewise makes no sense to refer to a "clinical . . . [Clinical Study Report]" because courts do not interpret contracts "in a way that renders some terms repetitive." *In re IAC/InterActive Corp.*, 948 A.2d 471, 497 (Del. Ch. 2008) (internal quotation marks and citation omitted). Because the Court of Chancery's narrow definition of a study report is nonsensical in Section 3.19, it is also inappropriate in the definition of "Successful Completion"—evidence that the Court of Chancery completely ignored.

c. Contextual Evidence

There is other contextual evidence that cuts against the court's decision as well.

First, as the Court of Chancery conceded in its summary judgment ruling, "Clinical Study Report" is a term that two sophisticated parties would have used if that was what they meant. (Summ. J. Order 14.)

Second, the clause uses the indefinite article "a" rather than the definite article "the," giving the clause an "indefinite or generalizing force" rather than a "specifying or particularizing effect." *Patricca* v. *Zoning Bd. of Adjustment of Pittsburgh*, 590 A.2d 744, 751 (Pa. 1991) (internal quotation marks and citation omitted); *see also Emmons* v. *Hartford Underwriters Ins. Co.*, 697 A.2d 742, 746 (Del. 1997) (drawing the same distinction). The rejoinder that there can be a different CSR for Phase 1, Phase 2, and Phase 3 is unavailing because the entire purpose of the Phase 1 Milestones, as evidenced by their explicit context and names, is tethered to Phase 1.

Third, the term "study report" is lowercase, not capitalized as one would expect if it referred to a specific document. (Summ. J. Order 13.) In contrast, no fewer than eleven terms are capitalized in the definition of "Successful Completion," alone. (*See* A156.) And ***185 terms*** are defined in the agreement. (*See* A143-A157.)

Fourth, the Development Plan, incorporated as Annex A to the Agreement, observes that "***All study reports*** are being finalized and on track to be completed in time for an October 2013 IND filing." (A288 (emphasis added).) The referenced "study reports" related to molecule safety and efficacy and are indisputably *not* CSRs. Although these are not Phase 1 study reports, this language makes it untenable to equate all "study reports" with the CSR.

d. Unreasonable Result

The Court of Chancery's interpretation also produces the absurd result that a Phase 1 study might not be successfully completed—and a Phase 1 Milestone might not be paid—until the end of a Phase 3 study. The FDA does not require filing of the CSR "until after Phase 3 trials are completed," if trials progress that far. (Final Op. 62.) This would give defendants discretion to delay writing the CSR and thereby making payment for successful completion of Phase 1 until after a Phase 3 trial, if there had been one. Such an interpretation leads to "unreasonable results," which courts seek to avoid. *Axis Reinsurance Co.*, 993 A.2d at 1063. It is also at odds with the plain meaning of a "milestone" as a "stage to be reached (in a project, etc.)," not the end of the project. "Milestone," *Oxford English Dictionary* (online ed.) (accessed Feb. 17, 2021). And it is at odds with the use of "Phase 1" in the name of the Milestone. (A212.)

The Court of Chancery speculated that defendants would not so delay because they were separately required to take commercially reasonable efforts and the CSR is sometimes submitted after each phase. (Final Op. 72.) But nothing in the general reasonable-efforts clause guaranteed that defendants would not delay in writing the CSR until it was due to the FDA and paying a Milestone. All defendants agreed to was "the expenditure of efforts and resources . . . consistent with the efforts and resources that a similarly situated Person engaged in the research, development, manufacturing, or commercialization of biologic or pharmaceutical products, would typically devote to the development of compounds of similar market potential at a similar stage in development." (A146.) Defendants offered no specific assurances that they always produce a CSR after Phase 1. A general obligation to take best efforts says nothing about Milestones and certainly does not close the gaping loophole that the court created.

e. Parties' Intent

Finally, because the CSR is only required after the conclusion of Phase 3 (if trials proceed that far), tethering the Milestones to it would necessarily violate the parties' intent that Amplimmune share risk and reward only through Phase 1. The parties could have created Phase 3 or regulatory approval milestones, but they instead created ***Phase 1*** Milestones.

2. The 2016 Investigator's Brochure Is "A Study Report."

The February 2016 updated Investigator's Brochure submitted by defendants to the FDA is a study report under the correct interpretation of that term. As the Court of Chancery explained, an Investigator's Brochure "tracks the development of a molecule and, accordingly, under FDA regulations, an [Investigator's Brochure] must be updated with current data and results from any ongoing clinical trials involving the molecule. True to their purpose, the [Investigator's Brochures] for AMP-514 presented the results for the Combination trials as MedImmune was receiving the data." (Final Op. 22-23.) Specifically, and as required by FDA regulations, the February 2016 updated Investigator's Brochure presented a "description of the drug substance and the formulation," a "summary of the pharmacological and toxicological effects of the drug," a "summary of the pharmacokinetics and biological disposition of the drug," a "summary of information relating to safety and effectiveness in humans obtained from prior clinical studies," and a "description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and of precautions or special monitoring to be done as part of the investigational use of the drug." 21 C.F.R. §312.23(a)(5); (*see* A434.) This updated

Investigator's Brochure was over one hundred pages long and included a summary of Phase 1 data. (A434-A545.)

Because there is no dispute about the facts surrounding the 2016 updated Investigator's Brochure, this Court should reverse the judgment on the Combination Milestone and remand with instructions to treat February 2016 as the date that the second prong was satisfied.

3. The Court of Chancery Erred by Using Extrinsic Evidence to Manufacture Ambiguity.

The court's justifications for deciding the phrase was ambiguous were that plaintiff's interpretation was "overbroad" and that "no one in the industry understands 'study report' to refer to anything but the CSR." (Summ. J. Order 14.) For the reasons given above, plaintiff's reading is not overbroad. (*Supra*, pp. 37-41.) The court's reliance on industry usage is also a reversible error. "[P]arol evidence such as industry usage" cannot "be used to create ambiguity." *Sassano* v. *CIBC World Mkts. Corp.*, 948 A.2d 453, 468 n.86 (Del. Ch. 2008); *see also S'holder Representative Servs. LLC* v. *Gilead Sciences, Inc.*, 2017 WL 1015621, at *16 (Del. Ch. Mar. 15, 2017), *aff'd*, 177 A.3d 610 (Del. 2017) (TABLE); *Del. Express Shuttle, Inc.* v. *Older*, 2002 WL 31458243, at *7 (Del. Ch. Oct. 23, 2002); *In re Explorer Pipeline Co.*, 781 A.2d 705, 713-714 (Del. Ch. 2001). The Court of Chancery impermissibly used a purported industry term ("Clinical Study Report") to

manufacture ambiguity in a contractual phrase ("study report") where there was none.

4. If "A Study Report" Is Ambiguous, Plaintiff's Interpretation Is the Most Reasonable One.

Even assuming that the phrase "a study report" is ambiguous, plaintiff's reading is the most reasonable one. When language is ambiguous, courts in Delaware give great weight to drafting history and other evidence from negotiations. *See, e.g.*, *DCV Holdings, Inc.* v. *ConAgra, Inc.*, 889 A.2d 954, 960-961 (Del. 2005); *Zayo Grp.*, 2018 WL 6177174, at *12. Here, the testimony of the only witnesses with direct knowledge of the negotiations and an earlier draft of the Agreement both strongly indicate that the phrase "a study report" had a broader meaning than merely the CSR. The Court of Chancery's concern about inconsistent testimony appears to rest chiefly on an expert witness who it misidentified as a participant in the negotiations. Its interpretation also relies on defendants' witnesses—none of whom had direct involvement in the negotiations—and its own misunderstanding of the intent and operation of the Agreement. In light of the overwhelming evidence presented by plaintiff and defendants' lack of evidence from the negotiations, it was unreasonable for the Court of Chancery to infer that the phrase "a study report" means only the CSR. *See AT&T*, 953 A.2d at 252.

The evidence of negotiations unequivocally "establishes the contracting parties' intent." *DCV Holdings*, 889 A.2d at 960-961; *see also In re IBP, Inc. S'holders Litig.*, 789 A.2d 14, 55, 60 (Del. Ch. 2001) (relying on extrinsic evidence from negotiations). As the Court of Chancery acknowledged, "presenting negotiators [as witnesses] makes perfect sense." (Final Op. 59.) Only two witnesses with direct knowledge of the negotiations testified at trial. They both agreed that the phrase "a study report" referred to more than the CSR and defined it broadly enough to encompass the 2016 updated Investigator's Brochure. (A950, A993-A994, A1117.)

The Court of Chancery's finding that the witnesses with direct knowledge gave inconsistent testimony is clearly erroneous. As an initial matter, the Court of Chancery seems to have focused principally on discrepancies in the testimony of Dr. Thomas Spector, one of plaintiff's experts who the court erroneously referred to as "Amplimmune's lead negotiator." (*Compare* Final Op. 59-60 (lead negotiator) *with id.* 63 (expert).) Dr. Spector's testimony should hardly "diminish the credibility" of Richman and Dr. Kabakoff. In any event, the Court of Chancery vastly overstated Dr. Spector's uncertainty about the scope of the term "study report." And when one excludes Dr. Spector, who had no role in negotiations, there was no meaningful disagreement.

Even if the Court of Chancery were correct that Richman and Dr. Kabakoff disagreed at trial, that fact would be irrelevant. The Court need not give comprehensive content to the term "study report;" it need only resolve this particular dispute. Plaintiff's primary argument is that the 2016 updated Investigator's Brochure qualifies as a "study report," and Richman, Spector, and Dr. Kabakoff ***all*** defined the phrase "a study report" broadly enough to cover that Investigator's Brochure. There is no need to reach the alternative argument that the 2015 Annual Report also qualifies as a study report. For these reasons, the Court of Chancery's discounting of Richman and Dr. Kabakoff's testimony is unreasonable.

Richman and Dr. Kabakoff's testimony is amplified by the drafting history, which is "especially revealing of the process by which the parties reached a meeting of the minds and the ground on which that meeting occurred." *Zayo Grp.*, 2018 WL 6177174, at *12 (citations omitted). During the drafting of the Agreement, the parties originally used "final" before "study report." (Final Op. 61 (quoting A61).)

The use of "final" to modify "study report" in an earlier draft indicates that there are other "study reports" besides "final study reports" (i.e., CSRs). While the Court of Chancery conjectured that "final" could distinguish the CSR after Phase 3 from a CSR after Phase 1 (Final Op. 62), none of the record evidence cited by the court drew that distinction. "Evidence of what was deleted from the original draft

sheds light on the intended meaning of" the final Agreement. *DCV Holdings, Inc.* v. *ConAgra, Inc.*, 2005 WL 698133, at *10 (Del. Super. Ct. Mar. 24, 2005), *aff'd*, 889 A.2d 954 (Del. 2005). Moreover, the parties' deletion of "final" further supports plaintiff's argument that the 2016 updated Investigator's Brochure constituted a "study report" even though additional Phase 1 patient data was forthcoming.

Despite this evidence, the Court of Chancery found it "most important" that the parties intended to be precise about the Milestones. (Final Op. 71.) But the fact that a term "may encompass a spectrum of events of notable breadth does not make it less understandable or clear." *E.I. du Pont de Nemours & Co.* v. *Admiral Ins. Co.*, 711 A.2d 45, 64 (Del. Super. Ct. 1995). In any event, the Court of Chancery's argument is logically backwards. The commercial reality it described, in which "target companies" seek "reward . . . as their acquired assets progress toward commercialization," weighs in favor of a broader meaning for "study report," not a narrower one. (Final Op. 70.)

The Court of Chancery further erred by concluding that only its interpretation gave meaning to all of the language in the first prong of "Successful Completion," which requires "completion of such Phase 1 Study, in accordance with the protocol, in a manner sufficient to support a regulatory filing for additional clinical development." (*Id.* 65 (emphasis omitted).) The Court of Chancery adopted the

view that "in accordance with the protocol" in the first prong would do no work if a study report for the Phase 1 study could be prepared before the Phase 1 study was finished. (*Id.* 65-66.) But plaintiff's reading makes sense of the entire first prong by assuming that the requirement that the Phase 1 study must be "in accordance with the protocol," means what it says: the study must conform to the protocol. Plaintiff's reading also makes sense in light of the parties' decision to strike "final" from the phrase "a study report" in the second prong.

Moreover, the most obvious reading of the first prong is that it exists independently from the subsequent prongs for a reason. The court's reading impermissibly adds "completion of such Phase 1 Study" as a requirement in the second prong. Mere reference to "the protocol" in both does not override the clause's plain language because "a mere reference in one agreement to another [document], without more, does not incorporate the latter [document] into the former by reference." *Town of Cheswold* v. *Cent. Del. Bus. Park*, 188 A.3d 810, 819 (Del. 2018) (alteration adopted and citation omitted). The necessary "explicit manifestation of intent," *id.* (citations omitted), is absent, not least because the protocol did not exist at the time of the Agreement.

In light of the full record, it was not "the product of an orderly or logical deductive reasoning process," *AT&T*, 953 A.2d at 252 (citation omitted), to find that the extrinsic evidence favors defendants' interpretation.

CONCLUSION

The judgment of the Court of Chancery should be vacated as to the Monotherapy Milestone; reversed as to the Combination Milestone; and remanded for application of the correct interpretation of the phrase "additional clinical development" and further proceedings regarding (1) the date on which the payments became due and (2) the acceleration clause.

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