EFiled: Apr 20 2021 04:00PM EDT
Filing ID 66531539
Case Number 430,2020

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: April 20, 2021**

APPELLANT'S REPLY BRIEF

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

INTRODUCTION[1]

As demonstrated in plaintiff's opening brief, the Court of Chancery disregarded the unambiguous meaning of two phrases in the parties' Agreement and Plan of Merger: "additional clinical development" and "a study report." The first term means treatment and study of additional patients, a requirement that was satisfied for the Monotherapy when defendants Zeneca, Inc. and MedImmune, LLC advanced it to a Phase 1/2 study. The second term means a written summary of results and data, a requirement that was satisfied for the Combination Therapy when defendants completed an updated Investigator's Brochure with data from the Phase 1 study. Rather than following the indicia of meaning provided by dictionaries, the rest of the Agreement, and canons of interpretation, the court below rewrote the contract. Because the court below misinterpreted both unambiguous phrases, and defendants offer no convincing response to plaintiff's opening brief, this Court should vacate the judgment regarding the Monotherapy, reverse the judgment regarding the Combination Therapy, and remand.

First, the court below incorrectly concluded that the phrase "additional clinical development," as used in the Monotherapy Milestone, unambiguously meant

[1] Unless otherwise stated, capitalized terms have the meanings set forth in Plaintiff's Opening Brief (D.I. 26, "PB").

"movement towards commercialization." Defendants argue that, because they no longer intended to commercially develop AMP-514 when they administered it to patients for additional clinical development as a Monotherapy, they were not required to make the Monotherapy Payment. But the truism that there is an overarching commercial context to the entire pharmaceutical enterprise—including clinical drug trials—does not mean that the parties intended to incorporate a subjective drive towards downstream commercialization into the Phase 1 Milestone conditions, particularly when the Agreement says no such thing. Although Phase 1 leads to Phase 2 and Phase 3 (just like animal trials lead to human trials), the focus of Phase 1 is ***not*** commercialization. Defendants concede as much when they observe that commercialization typically occurs ***after*** Phase 2 or 3. (Defendants' Br. (D.I. 28, "DB") 20.) Moreover, in defendants' telling, whether a particular trial constitutes "additional clinical development" depends on what is in the investigators' hearts—if the investigators think the drug could eventually be sold, then testing that drug constitutes "additional clinical development"; if the investigators' expectations change, then testing that drug is no longer "additional clinical development." Such a subjective definition that depends on their own unspoken intentions at any given moment is at odds with the parties' intent to devise "objective and 'black and white'" Milestones. (DB 9.)

Nor do defendants explain how "clinical development," as a purported term of art, means "movement towards commercialization." As pointed out in plaintiff's opening brief, "clinical" and "commercialization" have different dictionary definitions. Defendants do not dispute this, nor do they cite any dictionaries or scholarly sources defining "clinical development" this way. The lone support for their argument is a website, PharmaIQ, which is ***not*** a dictionary or a scholarly source, but rather a mash-up of LinkedIn, a newsletter, and an events bulletin board.

As plaintiff explained in his opening brief, both the canons of interpretation and evidence from the rest of the Agreement further prove that "additional clinical development" means treatment and study of additional patients. Defendants do nothing to avoid the absurd implication of the Court of Chancery's interpretation: If commercialization concededly occurs *after* Phase 2 or 3 (DB 20), why would a "Phase 1" Milestone turn on commercialization at all, let alone "***additional***" movement towards commercialization? And defendants have no persuasive response to the use of "clinical development" elsewhere in the Agreement to refer to tasks that have nothing to do with commercialization.

Second, the court below erred by using extrinsic evidence to find the phrase "a study report" ambiguous and by weighing the extrinsic evidence at trial to limit this general phrase to one particular kind of document known as the Clinical Study

Report ("CSR"), which defendants submitted ***four years*** after the Combination Therapy advanced beyond Phase 1. Defendants insist that the parties sought to have objective Milestones; if the parties ***only*** intended payment upon completion of the Clinical Study Report, they would have said so.

Defendants contend that this phrase, too, is a term of art, but they again cannot muster any dictionary definitions or scholarly support. Defendants argue plaintiff's reading is overly broad and vague, but dictionary definitions, the use of "a" rather than "the," and the failure to define or capitalize "study report" all indicate that the parties did not refer to only the CSR. Nor do defendants convincingly respond to the absurdity that, under the Court of Chancery's interpretation, they could delay a Phase 1 Milestone Payment until well after the study has proceeded beyond Phase 1, as they did here. The Court of Chancery's interpretation is inconsistent with the parties' intent as expressed by the unambiguous words that they chose.

The court erred in finding ambiguity where none exists and further erred by concluding that the extrinsic evidence supported defendants' interpretation. The court below based its decision on purported inconsistencies between the witnesses. In so doing, it ***misidentified*** an expert witness as Amplimmune's lead negotiator—which defendants concede—and fixated on irrelevant variations in the testimony of the only two witnesses who did have direct knowledge of the negotiations.

Defendants cannot dismiss this mistake as insignificant when it was the reason that the court below discounted the evidence from the negotiations. Defendants do not (and cannot) dispute that evidence from the negotiations itself is illuminating, and both of the witnesses with direct knowledge of the negotiations agreed that the updated Investigator's Brochure is a study report, and only disagreed about what other documents might theoretically also be considered "a study report." The relevant question is whether the completion of the Investigator's Brochure satisfied the "study report" prong of the Phase 1 Milestone—it is irrelevant whether some other report could have achieved the same. And while defendants rely on extrinsic evidence that the CSR is ***one*** kind of study report (which plaintiff has never disputed), that fails to disprove that there are study reports ***besides*** the CSR.

ARGUMENT

I. "ADDITIONAL CLINICAL DEVELOPMENT" UNAMBIGUOUSLY MEANS TREATMENT AND STUDY OF ADDITIONAL PATIENTS.

As demonstrated in plaintiff's opening brief, the meaning of "additional clinical development" in the third requirement for the Monotherapy Milestone is unambiguous: treatment and study of additional patients. (PB 26-33.) This requirement was satisfied when defendants filed a protocol to administer the Monotherapy to real cancer patients in 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***." (Final Op. 19 (emphasis added).) In their answering brief, defendants claim that because they subjectively did not intend to commercially develop the Monotherapy, the Phase 1/2 study was not "additional clinical development." But defendants fail to identify any ambiguity, let alone prove that the phrase unambiguously requires "movement towards commercialization," which is a different concept.

First, only plaintiff's interpretation is consistent with the structure of the Agreement, in which the parties split risk and pre-negotiated reward only through Phase 1. Defendants cannot shoehorn the later task of commercialization into this earlier, non-commercial phase of development. Nor can they condition whether a trial is "additional clinical development" on the subjective intentions of the

investigators. ***Second,*** defendants never explain how clinical development can mean commercialization when dictionaries define the terms differently and the Agreement differentiates between these concepts. Defendants treat "clinical development" as a term of art, but one would expect a term of art to have a dictionary definition, and defendants do not offer a single one. ***Third,*** plaintiff's interpretation leads to no absurd results, whereas defendants' reading would mean that Phase 1 was so inherently and specifically focused on commercialization that the phrase "additional clinical development" (which presupposes "clinical development" in Phase 1) can only mean "movement towards commercialization" (and not additional patient testing). ***Fourth,*** references to commercialization in other parts of the "Development Plan" do not change the fact that the plan's list of "***Clinical*** Development" tasks—the "term of art" that defendants claim can ***only*** imply commercialization—are ***non***-commercial.

In the alternative, defendants argue that this Court should affirm even if it adopts plaintiff's interpretation because they say the Phase 1/2 Trial—in which, to be clear, defendants chose to treat cancer patients with the Monotherapy—was somehow not a study of the Monotherapy, only the Combination Therapy. Defendants thus suggest they submitted a protocol to get regulatory approval to administer the Monotherapy to cancer patients without intending that the

Monotherapy be a treatment or a subject of study. Even if this (ethically dubious) scenario were true, it would not change the fact that defendants submitted a protocol to treat cancer patients with the Monotherapy and study the results. The Court should vacate and remand for further proceedings on that basis.

A. The Meaning of "Additional Clinical Development" Is Unambiguous.

1. Plaintiff's Interpretation Reflects the Parties' Intent.

Commercialization was not a component of the ***Phase 1*** Milestones because, as conceded by defendants and acknowledged by the court below, commercialization typically occurs ***after*** Phase 1. As the court below explained, it is only in Phase 3 that efficacy trials are conducted on a large scale to provide data for seeking regulatory approval. (Final Op. 9 n.28.) Phase 1 is about assessing safety and, if feasible, effectiveness. (*Id*.) Phase 1 does not even lead directly to Phase 3; a drug must first undergo "controlled clinical studies conducted to evaluate the effectiveness" in Phase 2. (*Id.* (quoting 21 C.F.R. §312.21(b).) If defendants were right that anything that eventually could lead to regulatory approval is "movement towards commercialization," no matter how many steps removed, then a study with laboratory animals would be "movement towards commercialization." And if defendants were right that Phase 1 is about commercialization, then it would

follow that a Phase 1/2 study is about commercialization, thus satisfying the "additional clinical development" prong, anyway.

The proper inference to draw from the fact that the pharmaceutical industry is closely regulated and complex is not that the parties would never agree to Phase 1 Milestones, but in fact the opposite. (DB 19.) It is precisely because complex regulations prevent the vast majority of drugs from successfully completing Phase 3 that Amplimmune declined to pursue a competing offer premised on later-phase success and accepted defendants' bid with fixed "Phase 1" Milestones. (A212-A213.) By design, these Milestones offered payment only for success in Phase 1, not success ***beyond*** Phase 1.

The deal was that Amplimmune would be rewarded as soon as a Milestone was accomplished. Defendants mischaracterize the entire basis of the bargain when they state "[t]here is no 'reward' to 'share' unless the Milestone is compensating for … forward progress toward the point where MedImmune could realize a profit on its investment." (DB 20.) To the contrary, the parties agreed that Amplimmune would sell to defendants all of the future rewards of commercialization—potentially billions of dollars—and all control over how and whether to even pursue commercialization, in exchange for being compensated more quickly and with more certainty.

Much of defendants' argument relies on the fact that AMP-514 did not "demonstrate[] the requisite superiority over competitors necessary for MedImmune to continue developing it as a Monotherapy." (*Id.* 12.) But this was never the basis for payment—and if it had been, the parties would have said so in the Agreement. Moreover, defendants themselves represented, ***in a filing for the Phase 1/2 study***, that the Monotherapy was "encouraging." (A571.) If subsequent study revealed that AMP-514 turned out to be less promising than defendants had hoped—though no less promising than the 67% of drugs that do not advance beyond Phase 2—such disappointment does not permit defendants to rewrite the Agreement.

Although defendants emphasize the parties' intention to set "objective" Milestones, their interpretation would inject un-administrable subjectivity to the question of whether Amplimmune was paid. (DB 1, 6, 9, 41.) On defendants' reading, if investigators believe that a drug could achieve commercial success, then additional trials are additional clinical development. If investigators administer the same drug to the same patients with no expectation of commercial success, then the trials are not. This shifting, subjective scheme is at odds with the concept of Milestones as objective triggers.

2. Plaintiff's Interpretation Is Consistent with the Plain Meaning of "Additional Clinical Development."

Defendants identify no meaningful disagreement about the definition of "develop." The difference between "to create or produce especially by deliberate effort over time" (*id.* 21); "to lead or conduct (something) through a succession of states or changes each of which is preparatory for the next" (*id.*); the "application of techniques or technology to the production of new goods or services," *American Heritage Dictionary of the English Language* 496 (5th ed. 2016); and moving "from latency to fulfillment," *id.* at 495, is insignificant. In the pharmaceutical context, all of these definitions suggest "creation," "production," or "preparation" of a treatment. What they do not suggest, particularly when modified by the adjective "clinical," is commercialization.

The only definition that defendants offer to suggest that "clinical development" has anything to do with "commercialization" is from PharmaIQ, a website that lacks the reliability of a dictionary. (DB 21.) "Because dictionaries are routine reference sources that reasonable persons use to determine the ordinary meaning of words," this Court will "often rely on them." *Angstadt* v. *Red Clay Consol. Sch. Dist.*, 4 A.3d 382, 390 (Del. 2010). The same is not true of PharmaIQ, which is a website offering "newsletters," "[i]nvitations to attend … events and webinars," and "[n]etworking." *About PharmaIQ*, https://www.pharma-

iq.com/about-us (last visited Apr. 5, 2021). There is no indication that PharmaIQ has the same scholarly, lexicographical approach as the dictionaries that this Court relies upon.

Defendants further assert that "clinical development" is a single term that is different from the sum of its parts, but their brief is devoid of any definitions of "clinical development" as a single term of art. (DB 23.) The example that defendants use is "hat trick," which is commonly defined in dictionaries. *See, e.g.*, *American Heritage*, *supra*, at 805; *Merriam-Webster's Collegiate Dictionary* 571 (11th ed. 2012). If "clinical development" were similarly a term of art, one would expect defendants to cite at least a few dictionary definitions of it.

Defendants' cases about phrases are irrelevant. In *FCC* v. *AT&T Inc.*, the Court rejected AT&T's argument that, because a corporation is a legal "person," the adjective "personal" encompassed corporations. 562 U.S. 397, 406 (2011). As the Court noted, AT&T did not "cite a single instance in which this Court or any other … expressly referred to a corporation's 'personal privacy.'" *Id.* Nor did the company cite any dictionary definitions of "personal" that encompassed corporations. Furthermore, in *Helvering* v. *Gregory*, the Second Circuit explained, in the statutory construction context, that it would disregard the meaning of the text because it thought Congress could not have "meant to cover" the transaction at issue.

69 F.2d 809, 810 (2d Cir. 1934), *aff'd*, 293 U.S. 465 (1935). That approach departs from the general rule, including in Delaware, that courts interpreting contracts give "clear and unambiguous terms … their ordinary meaning." *GMG Cap. Invs., LLC* v. *Athenian Venture Partners I, L.P.*, 36 A.3d 776, 780 (Del. 2012).

Defendants ultimately fail to explain how ***clinical*** development can mean ***commercialization***, as a matter of plain text. They do not dispute that "clinical" means having to do with patients. *American Heritage, supra*, at 347. Nor do they dispute that "commercialization" means "apply[ing] methods of business to for profit." *Id.* at 371. In rewriting the agreement to avoid the plain meaning of "clinical development," the Court erred.

3. Defendants' Interpretation, Not Plaintiff's, Produces Unreasonable Results.

Plaintiff's theory creates none of the absurd results feared by defendants. Defendants, on the other hand, have no response to the absurd consequences of their own interpretation.

First, contrary to defendants' accusations, it is hardly absurd that "expand[ing] the trial to test higher and more frequent doses" constitutes additional clinical development. (DB 24.) An expansion of the study because of the possibility—borne out in this case—that a higher dose might produce a stronger response is ***exactly*** what ordinary English speakers would call "additional clinical

development." Regardless, increased dosing was tested during Phase 1; plaintiff's position is that the subsequent Phase 1/2 study, not clinical development ***during*** Phase 1, constituted "***completion of a Phase 1 study*** … in a manner sufficient to support a regulatory filing for additional clinical development." (A156 (emphasis added).)

Second, defendants' argument that the eventual use of nivolumab (a competitor) in the Phase 1/2 study would constitute additional clinical development under plaintiff's definition ignores the rest of the operative sentence (and the Agreement). The Monotherapy Milestone is triggered only by "additional clinical development ***of the AMP-514 Mono[therapy]***."

Third, defendants have no convincing response to the unreasonable result produced by their own interpretation. The Court of Chancery's misconstruction would require "***additional***" "movement towards commercialization" after Phase 1, thus necessitating ***prior*** movement towards commercialization ***within*** Phase 1—which makes no sense given defendants' concession that commercialization happens ***after*** Phase 2 or 3. This is the kind of "unreasonable result[]" that a court should avoid. *Axis Reinsurance Co.* v. *HLTH Corp.*, 993 A.2d 1057, 1063 (Del. 2010). Plaintiff's reading makes far more sense because Phase 1, which according to federal regulations involves "the initial introduction of an investigational new drug into

humans," 21 C.F.R. §312.21(a)(1), plainly entails the treatment and study of patients: paradigmatic "clinical" activity.[2]

4. The Contextual Evidence and Canons of Construction Support Plaintiff's Reading.

Furthermore, plaintiff's interpretation makes sense of the whole agreement by giving the words "clinical development" a consistent meaning and avoiding surplusage. Defendants' interpretation does not.

First, plaintiff's interpretation is supported by the Development Plan attached to the Agreement. Although the Development Plan as a whole aims at "Regulatory Approval" (A148), when the Development Plan uses the precise phrase "Clinical Development" in a subheading, it lists tasks that have to do with treatment and study of patients, ***not*** commercialization:

- "conducting the [first-in-human] clinical trial for AMP-514";
- provide "critical services to support the FIH clinical trial and enable future trials";

[2] Plaintiff did not "misconstrue[]" the Court of Chancery's statement that "plaintiffs' proffered definition is largely synonymous with 'research.'" (DB 24 n.1 (quoting Summ. J. Order 12).) Contrary to defendants' claim, the Court was referring to plaintiff's definition of "clinical development," not just "development." Plaintiff's definition of "clinical development" is not synonymous with "research," which can occur without patients. (*See* PB 32.)

- "develop, validate, and execute [pharmacokinetics], immunogenicity, and [pharmacodynamic] assays"; and
- conduct "additional pharmacology studies," including "cell signaling studies."

(A293.) Defendants' only response is once again that these measures are "part of the overall effort to move the product to commercialization." (DB 26.) The Court should reject this argument for the reasons discussed above. *See* pp. 8-10, *supra*.

Second, the Agreement's definition of "Same Indication" only supports plaintiff's interpretation, not defendants'. To satisfy the second prong of the Combination Milestone, a regulatory filing must be "for the Same Indication," which it defines as "additional clinical development … in substantially the same ***patient population*** as [the] Phase 1 Study or in a ***patient population*** that is a subset of the ***patient population*** of [the] Phase 1 Study." (A155 (emphasis added).) Defendants argue that this definition excludes follow-up studies that do not move towards "registration" (DB 27), but they do not and cannot explain which words do so. The definition merely requires continuity of patient population, which can occur without movement towards commercialization. And the emphasis on "patients" only makes sense if "additional clinical development" refers to treatment and study of additional

patients, as plaintiff contends. The entirety of the Agreement thus supports plaintiff's reading.

B. This Court Should Vacate and Remand.

The Court should remand for application of the correct interpretation. Defendants do not deny that they filed a protocol amendment to treat patients with the AMP-514 Monotherapy and study its effects. (Final Op. 19.) Nor do they deny that the study was titled "Phase 1/2 Open-label Study to Evaluate the Safety and Antitumor Activity of [AMP-514] in Combination with [durvalumab] ***and [AMP-514] Monotherapy***" (Final Op. 19 (emphasis added)) or that the protocol called for the same number of patients to receive the Monotherapy and the Combination Therapy. (A550.) This filing for treatment and study of additional patients with the Monotherapy is all that is required for vacatur and further proceedings on the Monotherapy Milestone.

Defendants' factual arguments for affirmance are irrelevant. ***First,*** they argue that other companies use molecules similar to AMP-514 as controls. But that does not change the fact that defendants chose to use AMP-514 as a Monotherapy and studied its effects in cancer patients.

Second, the fact that defendants ***could*** have used a two-tailed statistical analysis to study the effects of the AMP-514 Monotherapy is irrelevant. Defendants

never deny that the single-tailed statistical analysis they used ***did*** capture the effectiveness of the AMP-514 Monotherapy, nor that: the protocol treated the therapies equally (including number of patients receiving each); the consent forms informed patients that the study would "evaluate … the effect" of AMP-514 "alone" (AR4); and foreign regulatory filings explicitly stated that the Monotherapy was "being developed." (AR37; PB 19-20.)

Third, defendants argue that they were not "interested in 'developing'" the Monotherapy.[3] (DB 30.) But this argument implies that they planned to administer the Monotherapy to patients in a trial without any expectation that it was a viable treatment or any intention of studying it. This is implausible, concerning if true, and irrelevant. Defendants gave real people with real cancer AMP-514 to see how they would respond to the drug. Unless defendants lied to patients, the FDA, and foreign governments, they were studying the Monotherapy, not just using it as a control.[4]

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[3] Defendants try to turn the objective question of what they said and did into a subjective question of their unspoken intentions, thus violating their own view of the Milestones as objective triggers. (*See* DB 1, 6, 9, 41.)

[4] Controls must be the standard of care, not unapproved, experimental therapies like the Monotherapy.

II. "A STUDY REPORT" DOES NOT EXCLUSIVELY MEAN THE "CLINICAL STUDY REPORT."

As shown in plaintiff's opening brief, the court below made two fundamental errors in concluding that "a study report" refers only to the CSR. ***First,*** it used extrinsic evidence to create ambiguity, which is impermissible under this Court's precedents. When the proper tools of statutory interpretation are used to assess ambiguity, the meaning of "a study report" as a written summary of data and results is clear. ***Second,*** the court below misidentified an expert witness as Amplimmune's lead negotiator (Final Op. 59-60) and then used the expert's testimony as proof that the witnesses with direct knowledge of negotiations disagreed. Contrary to defendants' arguments, the extrinsic evidence supports plaintiff's interpretation.

A. "A Study Report" Unambiguously Means a Written Summary of Study Data and Results.

1. The Updated Investigator's Brochure Is Clearly "A Study Report."

Defendants have failed to identify any ambiguity in the meaning of "a study report."

First, defendants' contention that "study report" is a term of art fails because they offer no dictionary definitions or scholarly support for that assertion. *See* pp. 11-12, *supra*. And even if it were correct, it would only underscore that "Clinical Study Report" is a term that two sophisticated parties in the industry would have

used if that was what they had meant—particularly if they "intended the milestone triggers to be black-and-white." (DB 36.)

Second, plaintiff's reading is not overly broad. It is consistent with dictionary definitions, the use of the indefinite article "a" before "study report," and the fact that "study report" is lowercase, unlike 185 other terms in the Agreement. (PB 37-38, 39-40.) Defendants respond that the definition can only refer to the CSR because the Agreement "requires 'a study report *for such Phase 1 study*.'" (DB 34.) But if any summary document contains results and data for Phase 1, it is "a study report for [a] Phase 1 study."

Plaintiff's reading is neither vague nor difficult to apply. The February 2016 updated Investigator's Brochure plainly contains a summary of data and results from the Phase 1 study of the Combination Therapy. (A434-A545.) Defendants counter that "an IB is about an individual molecule" rather than a study (DB 41), but that means that an updated IB for AMP-514 would encompass all studies for that molecule, including Phase 1 studies.

Third, plaintiff's interpretation is consistent with the Agreement as a whole. The Agreement's representations and warranties about regulatory compliance contain no superfluities—merely inelegant phrasing. The provision states that Amplimmune must provide "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.) It is obvious that the drafters meant to place the "(i)" after "copies of." The actual surplusage to be avoided is defendants' reading of the last clause to refer to "clinical, pre-clinical and non-clinical Clinical Study Reports."

Defendants concede that plaintiff identified two instances in the Agreement where "study report" refers to reports that are ***not*** CSRs. (DB 42.) That itself is dispositive. Defendants' response that these are not study reports for Phase 1 misses the point. (DB 43.) Although they are not study reports for Phase 1 studies, they prove that the CSR is not the only "study report."

Fourth, defendants have no meaningful response to the absurdity produced by their interpretation. Under their reading, they could delay preparing the CSR until after Phase 2 or Phase 3, thereby unilaterally delaying payment of a ***Phase 1*** Milestone Payment for years. Defendants counter that they have a "practice" of preparing the CSR sooner (DB 44), but (1) that is irrelevant, particularly since there is no indication plaintiff knew or was thus persuaded to accept this risk of delay; and (2) this case belies that reassurance. The Combination Therapy successfully proceeded to Phase 1/2 in February 2016, but defendants did not begin the CSR until

2019 and did not finish it until March 2020—over four years later. (Final Op. 72-73.) The Court should reject defendants' unreasonable interpretation.

Fifth, and relatedly, defendants' interpretation makes a mockery of the parties' intent to condition the Milestone Payments on Phase 1. Because, as defendants concede, the CSR is not *required* until after the end of Phase 3 (if the study advances that far), limiting the meaning of "a study report" to the CSR would violate this intent.

Sixth, defendants' invocation of the "forthright negotiator principle" is misplaced because it applies only after a court has already determined that the contract is ambiguous. *United Rentals, Inc.* v. *RAM Holdings, Inc.*, 937 A.2d 810, 834-35 (Del. Ch. 2007).

2. Defendants Impermissibly Use Extrinsic Evidence to Manufacture Ambiguity.

Like the court below, defendants impermissibly weigh extrinsic evidence before establishing that the Agreement is ambiguous. "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). Only if the contractual language is ambiguous will a court "look beyond the language of the contract to ascertain the

parties' intentions.'" *Eagle Indus., Inc.* v. *DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997).

None of defendants' cases cast any doubt on that bright-line rule. In the first case, *FleetBoston Fin. Corp.* v. *Advanta Corp.*, neither party appears to have argued that the contract was unambiguous and the court below did not use extrinsic evidence to find ambiguity. 2003 WL 240885, at *21 & n.79 (Del. Ch. Jan. 22, 2003). The second case is a 1986 decision of the Court of Chancery (where the parties conceded ambiguity), stating only that a term may have "some special or technical meaning," not that extrinsic evidence can create ambiguity. *See Garrett* v. *Brown*, 1986 WL 6708, at *5 (Del. Ch. June 13, 1986), *aff'd*, 511 A.2d 1044 (Del. 1986). The third case is a 1938 Superior Court decision that does not appear to have been cited by a Delaware court since 1948 and that, to the extent it permits extrinsic evidence before ambiguity is established, is inconsistent with—and thus superseded by—this Court's more recent precedents. *See Colvocoresses* v. *W.S. Wasserman Co.*, 196 A. 181, 183-84 (Del. Super. Ct. 1938).

Modern precedent makes clear that "parol evidence such as industry usage" may not "be used to create ambiguity." *See, e.g., Sassano* v. *CIBC World Mkts. Corp.*, 948 A.2d 453, 468 n.86 (Del. Ch. 2008). At most, industry usage is relevant when "the same word can have more than one general meaning," *Pharm. Prod. Dev.*,

Inc. v. *TVM Life Sci. Ventures VI, L.P.*, 2011 WL 549163, at *4 n.24 (Del. Ch. Feb. 16, 2011), such as distinguishing between a river bank and a financial bank by considering the context of the contract. That is not what defendants seek to do here.

B. Defendants' Extrinsic Evidence Is Unpersuasive.

Even if the Agreement were ambiguous, plaintiff's interpretation is the most reasonable one. The most persuasive extrinsic evidence of meaning comes from the two witnesses with direct knowledge of the negotiations, as well as an earlier draft of the Agreement that referred to a "final" study report. (Final Op. 61; A61.) Defendants do not dispute that courts give great weight to evidence from negotiations. *See, e.g.*, *DCV Holdings, Inc.* v. *ConAgra, Inc.*, 889 A.2d 954, 960-61 (Del. 2005). They instead contend that the witnesses disagreed about the meaning of the phrase, but they fail to identify any relevant disagreement.

As an initial matter, defendants concede that the court below misidentified plaintiff's expert, Dr. Spector, as Amplimmune's "lead negotiator." (Final Op. 59-60.) They try to downplay the error as "a molehill" (DB 39 n.2), but they forfeited that argument by relegating it to a footnote. *Borealis Power Holdings Inc.* v. *Hunt Strategic Util. Inv., L.L.C.*, 233 A.3d 1, 10 n.28 (Del. 2020). Regardless, the error is not a molehill because the court's sole basis for discrediting the testimony of the witnesses with direct knowledge of the negotiations was that those witnesses

purportedly disagreed. Misidentifying who had direct knowledge of negotiations was thus a significant error and was "not supported by the record." *AT&T Corp.* v. *Lillis*, 953 A.2d 241, 252 (Del. 2008).

Furthermore, defendants' effort to find significant disagreement between the two witnesses who did have direct knowledge of the negotiations is no more convincing than the Court of Chancery's. Defendants never identify any disagreement between these two witnesses about whether the February 2016 updated Investigator's Brochure qualified as a Phase 1 study report, which is the only dispositive question. Nor do defendants explain why disagreement about what else might hypothetically constitute a "study report" undermines the witnesses' agreement about the only relevant document. The "simple fact of disagreement" at the margins (DB 38) is not enough to discount this probative evidence—particularly because none of defendants' witnesses had direct knowledge of the negotiations.

None of defendants' extrinsic evidence overcomes the evidence from the actual negotiations. ***First,*** that the CSR is one kind of study report does not establish that the CSR is the only kind of study report. ***Second,*** that the CSR is the only study report ***required*** to be prepared after a clinical trial does not mean that it is the only study report that ***can*** be prepared. ***Third,*** the testimony of one witness with no direct knowledge of negotiations should not outweigh the testimony of two witnesses with

direct knowledge. ***Fourth,*** defendants concede that "Clinical Study Report" is "the more formal terminology" (DB 40), but they never explain why sophisticated parties seeking contractual specificity failed to use the more precise term.

Finally, the forthright negotiator principle—on which the court below did not rely—provides no help for defendants. Under this principle, "a court may consider the subjective understanding of one party that has been objectively manifested and is known or should be known by the other party." *United*, 937 A.2d at 835. Here, the extrinsic evidence supports plaintiff's reading.[5] But even if it did not, defendants identify ***no*** evidence that they "objectively manifested" ***to Amplimmune*** an understanding that "a study report" only means the CSR in a way that was "known or should [have] be[en] known" by Amplimmune. *Id.* Internal MedImmune emails do not suffice. (DB 44.) For all of these reasons, the Court should reverse the judgment on the Combination Milestone.

[5] If anything, the best objective manifestation of intent is an earlier draft of the Agreement that used "final" before "study report" (A61), demonstrating that there are study reports besides the CSR. Defendants' argument that non-final study reports are all interim versions of the CSR lacks any support in the record. (DB 44.)

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.

Dated: April 5, 2021

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