IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

DAVID KABAKOFF, PH.D. and ARNOLD ORONSKY, PH.D., in their capacity, collectively, as Stockholders' Agent,	)	
Plaintiffs,	)	
v.	)	**C.A. No. 2017-0459-JRS**
ZENECA, INC., a Delaware corporation, and MEDIMMUNE, LLC, a Delaware limited liability company,	)	
Defendants.	)	

MEMORANDUM OPINION

Date Submitted: August 5, 2020
Date Decided: November 18, 2020

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SLIGHTS, Vice Chancellor

In the realm of commercial pharmacology, the fight against cancer is as competitive as it is promising. An area of particular promise is the development of so-called PD-1 and PD-L1 inhibitors as anti-cancer therapies. These therapies do not directly attack cancer cells, like traditional chemotherapies (with all the attendant, frequently severe side-effects), but instead enable the body's own immune system more effectively to interfere with the mechanisms that allow cancer cells to grow and spread within the body. This new class of immuno-oncology therapies has the potential to revolutionize cancer treatment, spurring intense competition among pharmaceutical companies.

By the spring of 2013, Defendant, MedImmune, LLC, had established a competitive presence in certain areas of cancer pharmacology but was eager to accelerate its development of an anti-PD-1 therapy. With this goal in mind, MedImmune began to search for acquisition targets that already had a PD-1 drug in development. This search led it to Amplimmune, Inc., a company founded by physicians and scientists and funded by venture capital firms to study and develop cutting edge cancer therapies. Amplimmune had several molecules in development when it was approached by MedImmune, but its PD-1 inhibitor, AMP-514, was among the most promising. Eager to add AMP-514 to its pipeline, MedImmune began negotiating with senior executives of Amplimmune regarding a possible acquisition.

Negotiations moved quickly, culminating in the execution of an Agreement and Plan of Merger ("Merger Agreement") whereby MedImmune's parent company, Defendant, Zeneca Inc., agreed to acquire Amplimmune (the "Acquisition") for an upfront purchase price of $225 million, followed by three *contingent* milestone payments: (1) $100 million for the "Successful Completion of a Phase 1 Study" of AMP-514 as a monotherapy (the "Monotherapy Milestone"); (2) $50 million for the "Successful Completion of a Phase 1 Study" of AMP-514 in combination with any MedImmune molecule (the "Combination Therapy Milestone"); and (3) $50 million for the "Successful Completion of a Phase 1 Study" of AMP-514 in combination with a second MedImmune molecule.[1]

The Acquisition closed on October, 4, 2013.[2] As frequently occurs in acquisition agreements containing so-called "earn-out" provisions, the parties now dispute whether (and when) several of the Merger Agreement's milestones were achieved.

"Successful Completion" is defined in the Merger Agreement as the occurrence of three prongs, all of which must be satisfied before a milestone

[1] Joint Pre-Trial Stipulation ("PTO") ¶¶ 40–42. I cite to the Joint Pre-Trial Stipulation and Order as "PTO ¶ __," the joint trial exhibits as "JX__," the trial transcript as "Tr.__ (witness name)"; and depositions lodged as evidence as "(Name) Dep. __."

[2] PTO ¶ 46.

payment is owed. Two of those prongs are at issue in this case.[3] For the Monotherapy Milestone, the parties dispute whether there was a regulatory filing for "additional clinical development" of AMP-514 as a monotherapy (the "Monotherapy") under the third prong. For the Combination Therapy Milestone, the disagreement centers on when a "study report" for the Phase 1 study of the first Combination therapy (the "Combination") was completed under the second prong.

Plaintiffs, David Kabakoff, Ph.D, and Arnold Oronsky, Ph.D., acting as representatives of Amplimmune's former stockholders as designated by the Merger Agreement, brought this suit in 2017 claiming the Monotherapy Milestone and Combination Therapy Milestone were both met in early 2016. Plaintiffs also maintain that the Merger Agreement's acceleration clause (the "Acceleration Clause") requires Defendants to make *all* milestone payments related to AMP-514 if the Court determines that Defendants breached their obligations as to any one milestone payment. Because they allege Defendants failed to make two milestone payments in breach of the Merger Agreement, Plaintiffs seek an order compelling Defendants to make *all* milestone payments, totaling $200 million, plus interest.

[3] Plaintiffs voluntarily dismissed before trial claims for unpaid milestone payments related to a separate Amplimmune molecule acquired by MedImmune in the Acquisition. D.I. 111.

Defendants respond that the Monotherapy Milestone has not been, and never will be, achieved because there was no regulatory filing seeking to advance the Monotherapy for additional clinical development. According to Defendants, the Monotherapy performed poorly in clinical trials and all parties appreciated that there was no purpose to be served by pursuing further development after the Phase 1 trial. As for the Combination, Defendants maintain the Combination Therapy Milestone was accomplished only upon the filing with the Food and Drug Administration ("FDA") of a Clinical Study Report ("CSR") in the spring of 2020, at which time they promptly made the Combination Therapy Milestone payment in compliance with the Merger Agreement. Finally, Defendants argue that Plaintiffs misread the Merger Agreement's Acceleration Clause and, even if their reading is correct, the clause cannot be enforced under Plaintiffs' construction because to do so would impose an unenforceable penalty.

In this post-trial opinion, I find that Plaintiffs have not met their burden of proving the Monotherapy Milestone has been met. I also find that Plaintiffs have not met their burden of proving the Combination Therapy Milestone was owed before that milestone payment was actually made earlier this year. Because I find in favor of Defendants on both of these claims of breach, I need not construe the Acceleration Clause. Judgment will be entered in favor of Defendants on all remaining claims.

I. BACKGROUND

The Court held a five-day trial between February 14–20, 2020. The following facts were proven by a preponderance of the competent evidence.

A. The Parties and Relevant Non-Parties

Plaintiffs, David Kabakoff, Ph.D, and Arnold Oronsky, Ph.D., bring this action in their capacity as agents for the former stockholders of Amplimmune.[4]

Defendant, Medimmune, is a Delaware limited liability company. At the time the Merger Agreement was executed, MedImmune was the global biologics research and development arm of AstraZeneca plc, a multinational pharmaceutical company.[5]

Defendant, Zeneca, is a privately held Delaware corporation that operates as a subsidiary of AstraZeneca.[6]

Prior to the Acquisition, Amplimmune was a privately-held Delaware corporation.[7] Its primary focus was on the development of immuno-oncology therapies.[8]

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[4] PTO ¶ 23.

[5] *Id.* ¶¶ 24–26.

[6] *Id.* ¶ 25.

[7] *Id.* ¶ 24.

[8] *Id.*

B. The Mechanics of PD-1 and PD-L1 Immuno-Oncology Therapies

The body's immune system has natural tools for identifying and fighting cancer cells.[9] Relevant here, white blood cells known as lymphocytes are able to make contact with a cancer cell, identify it as such and kill the cancer cell by injecting it with antibodies.[10] This system, when functioning correctly, can be highly effective at combatting cancer, but it can also be extremely dangerous.[11] Uncontrolled lymphocytes will attack healthy cells as well as cancer cells, posing a potentially lethal threat to the body. This threat can be moderated by genetic mechanisms acting either to disable lymphocytes or make them difficult to activate.[12]

One of these genetic mechanisms is known as the PD-1 pathway.[13] This pathway can be conceptualized as a "key-hole" on the surface of an immune cell.[14] Molecules known as "ligands," which form as protein on the cell surface, can bond

[9] Tr. 548:8–550:16 (Bradley).

[10] *Id.* at 548:10–15 (Bradley).

[11] An uncontrolled immune response will lead to chronic, sometimes fatal "autoimmune diseases." *See generally Autoimmune Diseases*, U.S. Nat'l Libr. of Medicine, https://medlineplus.gov/autoimmunediseases.html (last visited October 30, 2020).

[12] Tr. 548:15–19 (Bradley).

[13] *Id.* at 548:20–21 (Bradley).

[14] *Id.* at 548:20–549:2 (Bradley).

with these pathways and thereby render the cell inactive.[15] In other words, the ligands act as keys that insert themselves into a cell's keyhole and "lock" the immune cell, permanently disabling it. PD-L1 is the ligand that functions as the key to lock the PD-1 pathway.[16]

While these system shutoffs are essential for protecting the body from an overactive immune system, cancer cells have developed mechanisms to hijack these functions for their own benefit.[17] Specifically, cancer cells "learn" to express the PD-L1 ligand on their surface in order to lock immune cells and weaken the body's immune response.[18] Anti-PD-1 therapies seek to counteract this process by blocking a lymphocyte's PD-1 pathway so the lymphocyte remains activated to attack cancer cells.[19] Similarly, an anti-PD-L1 therapy seeks to block the ligand expressed on cancer cells to prevent those cells from deactivating lymphocytes with unblocked PD-1 pathways.[20]

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[15] *Id.* at 549:1–2 (Bradley).

[16] *Id.* at 549:3–4 (Bradley).

[17] *Id.* at 549:3–14 (Bradley).

[18] *Id.* at 549:7–14 (Bradley).

[19] *Id.* at 549:18–22 (Bradley).

[20] *Id.* at 550:11–16 (Bradley).

Because a cancer cell "locking" a lymphocyte renders that immune cell perpetually incapable of killing cancer cells—and cancer cells far outnumber lymphocytes—even a drug that achieves 95%–99% blockage is inadequate.[21] Instead, something close to a 100% blockade is required for these drugs to have a significant anti-cancer effect.[22] Although anti-PD-1 and anti-PD-L1 drugs often struggle to achieve this "complete pathway blockade," MedImmune's scientists theorized that combining the two could operate "belt and suspenders" to achieve a near 100% blockade.[23]

C. MedImmune Acquires Amplimmune

In 2013, MedImmune was in advanced development of an anti-PD-L1 molecule, known as durvalumab, but lacked an anti-PD-1 molecule in its pipeline.[24] While the FDA had yet to approve an anti-PD-1 drug, Bristol-Myers Squibb Co. ("BMS") and Merck & Co. ("Merck") were both nearing FDA approval of their

[21] *Id.* at 550:1–10 (Bradley).

[22] *Id.*

[23] *Id.* at 550:1–16 (Bradley).

[24] *Id.* at 552:10–18 (Bradley).

respective PD-1 inhibitors.[25] To catch up, MedImmune sought to acquire a company with an anti-PD-1 therapy already in development.[26]

By 2013, Amplimmune's anti-PD-1, AMP-514,[27] had shown promising results in preclinical trials, suggesting the drug would be "fully active" at "extraordinarily low doses," and Amplimmune was actively preparing the drug for Phase 1 clinical trials.[28] Given the risk and expense of clinical trials, however, Amplimmune was also exploring a possible partnership with a larger pharmaceutical company, including preliminary discussions regarding a partnership with Celgene Corporation which would have allowed Amplimmune to remain an independent company.[29] MedImmune, by contrast, was interested in acquiring anti-PD-1

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[25] PTO ¶¶ 49–50. BMS's drug, nivolumab, was approved for patients with some melanomas in the United States in December 2014, and Merck's drug, pembrolizumab, was approved for these same class of patients in September 2014. *Id.*

[26] Tr. 552:10–553:18 (Bradley); *id.* at 226:6–227:6 (Richman); PTO ¶¶ 29, 31.

[27] The molecule would become known as Medi0680 after the Acquisition, and is frequently referred to as such in internal documents. For clarity and consistency, as the parties did in their papers, I will refer to it exclusively as AMP-514.

[28] Tr. 246:14–24 (Richman); *id.* at 545:17–547:10 (Bradley); *id.* at 550:1–553:18 (Bradley); PTO ¶ 48. Drug trials in the United States are generally separated into Phase 1, Phase 2 and Phase 3 trials. *See* 21 C.F.R. § 312:21. Phase 1 trials typically focus on determining a drug's safety at various doses, but also attempt "to gain early evidence of effectiveness." 21 C.F.R. § 321.21(a). Phase 2 trials involve "controlled clinical studies conducted to evaluate the effectiveness of the drug . . . ." 21 C.F.R. § 321.21(b). Phase 3 trials are large-scale efficacy trials. 21 C.F.R. § 312.21(c).

[29] PTO ¶ 30; Tr. 226:6–227:12 (Richman); *id.* at 414:16–415:10 (Kabakoff).

capabilities through a traditional acquisition. In pursuit of this goal, AstraZeneca's CEO, Pascal Soriot, approached Amplimmune in the summer of 2013 to gauge its interest in a sale.[30]

D. The Merger Agreement

Once Amplimmune expressed interest, negotiations moved quickly, culminating in the signing of the Merger Agreement on August 25, 2013.[31] The parties agreed that consideration for the Acquisition would take two forms. First, Amplimmune's stockholders received $225 million in up-front cash.[32] Second, the parties negotiated five contingent milestone payments, three of which (totaling $200 million) were tied to the development of AMP-514.[33] Specifically, the Monotherapy Milestone payment of $100 million would be owed upon "Successful Completion of a Phase 1 Study" of AMP-514 as a monotherapy;[34] the Combination Therapy Milestone payment of another $50 million would be owed upon "Successful Completion of a Phase 1 Study" for a combination of AMP-514 and durvalumab;[35]

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[30] Tr. 226:15–22 (Richman); PTO ¶ 31.

[31] JX 21 ("Merger Agreement").

[32] PTO ¶ 39.

[33] *Id.*

[34] Merger Agreement § 9.1(a); PTO ¶ 40.

[35] *Id.* § 9.1(b); PTO ¶ 41.

and another $50 million would be owed upon "Successful Completion of a Phase 1 Study" for a combination of AMP-514 and a second MedImmune proprietary molecule.[36]

Successful Completion is a defined term in the Merger Agreement, requiring satisfaction of three conditions (or "prongs"):[37] (1) "completion of [a] Phase 1 Study . . . in a manner sufficient to support a regulatory filing for additional clinical development" (the "first prong");[38] (2) "completion of a study report for such Phase 1 Study" (the "second prong")[39] and (3) "a regulatory filing . . . submitting the protocol for additional clinical development" of the Monotherapy or Combination (the "third prong").[40] The parties dispute *whether* the third prong has been met for the Monotherapy Milestone and *when* the second prong was met for the Combination Therapy Milestone.[41]

[36] *Id.* § 9.1(c); PTO ¶ 42. Plaintiffs admit this last milestone has not been met, but argue the $50 million payment is owed nonetheless by operation of the Merger Agreement's Acceleration Clause. PTO ¶ 42. I address the Acceleration Clause below.

[37] Merger Agreement § 1.1 at 15.

[38] *Id.*; PTO ¶ 43.

[39] Merger Agreement § 1.1 at 15.

[40] *Id.*; PTO ¶ 44.

[41] PTO ¶¶ 81–82.

The Merger Agreement's Acceleration Clause states, in relevant part:

> Any Milestone Payments with respect to an (A) AMP-514 Mono Product or AMP-514 Other Combination Product, (B) AMP-514 First Combination, (C) AMP-[514] Second Combination or (D) B7 Molecule, as applicable, that have not been paid shall be immediately due and payable in full if Parent shall have materially breached any of its material obligations under this ARTICLE IX with respect to such Product . . . *provided, however*, for purposes of sentence, if Parent can demonstrate that the actual damages resulting from any such material breach or breaches are less than such Milestone Payments payable in accordance with the terms of ARTICLE IX not yet earned, then Parent shall be required to pay such lesser amount in lieu of paying such unpaid Milestone Payments calculated as of the date of such material breach. For clarity, in no event shall a material breach with respect to one Product cause a Milestone Payment with respect to any other Product to be due pursuant to the preceding sentence.[42]

Plaintiffs argue this clause requires payment of *each* AMP-514 milestone payment if they can prove a breach with respect to *any* AMP-514 milestone payment.[43] Defendants respond that the clause only accelerates payment of a specifically breached milestone payment.[44]

The Merger Agreement also contains a requirement that MedImmune use "Commercially Reasonable Efforts" in developing the Monotherapy or Combination.[45] Relatedly, the Merger Agreement appears to contemplate that

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[42] Merger Agreement § 9.2(b)(iv).

[43] PTO ¶ 79.

[44] D.I. 195, Defs.' Post-Trial Br. at 62–65.

[45] Merger Agreement § 9.2(b)(ii).

MedImmune alone, without input or assistance from Plaintiffs, would be responsible for AMP-514's development.[46]

E. Development of AMP-514

After the Acquisition, MedImmune quickly began Phase 1 trials of both the Monotherapy and the Combination. Recognizing that their development of AMP-514 lagged far behind the development of other companies' PD-1 inhibitors, Dr. Edward Bradley, who oversaw development of MedImmune's oncology portfolio, recommended a focus on Combination trials, noting "[i]f [] AMP-514 is not differentiated from [nivolumab] [BMS's drug] or lambro [Merck's drug], we should probably not do mono trials but would focus only on combo trials."[47] The first patient was dosed with the Monotherapy in December 2013, and the first patient was dosed with the Combination in May 2014.[48] I discuss each trial in turn.

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[46] *See, e.g.*, JX 95 (Kabakoff acknowledging that MedImmune has the authority to discontinue unilaterally the development of AMP-514); Tr. 227:10–12 (Richman) (stating MedImmune's acquisition of Amplimmune would "entail relinquishing, you know, full control of the organization and our ongoing programs regarding further development.").

[47] JX 13. Indeed, while Plaintiffs trumpet that MedImmune was enthusiastic about AMP-514's potential as a monotherapy, the evidence shows that MedImmune's primary focus was always on AMP-514's use in combination therapies. *See* Tr. 239:22–241:4 (Richman); *id.* at 526:3–9 (Pardoll); JX 17 at 5 (minutes from an August 2013 meeting noting that while MedImmune believed AMP-514 had potential as a monotherapy, "the real value in this approach is thought to be in combination therapies, of which there are several to explore."); JX 30 at 3 (a post-merger internal report noting MedImmune's advisors "recommended spending limited time in monotherapy development, and instead were more in favor of advancing a PD1 + PDL1 antibody combination therapy option.").

[48] PTO ¶¶ 54, 59.

1. The Phase 1 Monotherapy Trial

Although MedImmune was focused on the potential of AMP-514 in combination with other MedImmune molecules, it was hopeful that AMP-514 as a monotherapy would prove substantially superior to its monotherapy competitors. Accordingly, Dr. Bradley recognized that if MedImmune "got lucky and saw that [AMP-514] was twice as good as [nivolumab] or Lambro—or some big degree of superiority—we would then take a different and additional development route to go head to head with [nivolumab] and knock them out cold."[49] With this in mind, MedImmune began Phase 1 trials with not only the primary goal of determining a safe dose of AMP-514, but also looking for preliminary indications of the drug's efficacy as a Monotherapy.[50]

MedImmune submitted the required Investigator's Brochure ("IB") to the FDA on October 10, 2013, detailing the planned Monotherapy trial.[51] The IB

[49] JX 24 at 1.

[50] JX 20 at 1; Tr. 679:2–680:20 (Bradley); *id.* at 492:21–493:4 (Pardoll) (noting that clinical trials are "always looking for a signal of efficacy."); JX 27 at 2 (noting secondary objective of the Phase 1 monotherapy trial was to "assess preliminary antitumor activity of AMP-514"); 21 C.F.R. § 321.21(a) (FDA regulations stating that Phase 1 trials should try to "gain early evidence on effectiveness.").

[51] JX 27. An Investigator's Brochure is continually updated during clinical trials. Tr. 158:24–161:2, 164:20–165:13 (Spector).

described a Phase 1 trial where patients would be treated once every three weeks with doses of the Monotherapy ranging from 0.1 mg/kg to 10 mg/kg.[52]

The early results at low doses were not encouraging. While results showed AMP-514 was safe and well-tolerated by patients, there was no evidence of preliminary anti-tumor activity.[53] Perhaps even more discouraging, AMP-514 was not achieving the level of "receptor occupancy"—a measurement of the rate at which lymphocytes had their PD-1 pathway blocked—that the preclinical data had predicted would be achieved.[54] These preliminary results stood in contrast to nivolumab's results at low doses in its clinical trials.[55]

Concerned with these data, MedImmune conducted a new test intended to demonstrate AMP-514's affinity—a key measure of the number of molecules needed to bind to the cell's receptors.[56] This test also yielded disappointing results—an affinity level of 29.1 nM, about ten times worse than what was previously thought and fifteen times worse than the result nivolumab had achieved in a similar test.[57]

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[52] *Id.* at 4.

[53] JX 116 at 60; JX 39 at 1; Tr. 582:14–583:10 (Bradley).

[54] Tr. 583:11–18 (Bradley); JX 42 at 2 (noting a receptor occupancy of only 60%).

[55] Tr. 500:1–12 (Pardoll); *id.* at 206:3–6 (Spector); *see also* JX 3; JX 5; JX 61.

[56] Tr. 583:19–584:2 (Bradley).

[57] JX 46 at 1. Plaintiffs dispute the value of this finding. D.I. 193, Pls.' Opening Post-Trial Br. at 15–17; 52–53. They note that a subsequent affinity test, using a different methodology, found an affinity level roughly similar to what nivolumab had achieved.

In other words, "to get the same effect as [nivolumab] you will need to give fifteen times more [AMP-]514."[58] From MedImmune's perspective, AMP-514's performance as a Monotherapy was "a disaster."[59]

Seeing no positive response at low dosages, MedImmune dramatically increased the AMP-514 doses patients received. This revealed one of the molecule's positive attributes: it was well-tolerated by patients at extremely high doses—up to 20 mg/kg administered every two weeks.[60] And, after increasing the dose, patients receiving AMP-514 saw a stronger anti-tumor response—with similar tumor shrinkage in renal cell carcinoma to results nivolumab had shown at a similar stage in trials—with the best results occurring at the highest dosages.[61]

JX 115 at 12 (noting an affinity of 3.25 ± .90 nM); JX 138 ("Morse Dep.") 203:5–18; Tr. 714:2–716:4 (Coats). Regardless of which measure better reflects AMP-514's affinity, the drug was either roughly as good or nearly twice as bad as nivolumab. Neither outcome is the kind of blockbuster result evidently required to shift MedImmune's focus from Combination therapy to Monotherapy development. *See* JX 24 at 1; JX 17 at 5; JX 30 at 3.

[58] Tr. 585:10–12 (Bradley).

[59] *Id.* at 664:22 (Bradley).

[60] JX 116 at 60. By comparison, nivolumab was effective at a 3 mg/kg dose. Tr. 519:2–7 (Pardoll).

[61] JX 116 at 60; JX 163 at 8, 10; JX 62 (noting "while the suspicion is that [AMP-514] monotherapy is less potent than pembro or nivo, it nevertheless is active and the response rates are not statistically different from the others given the large error bars. The safety is fine."); Tr. 845:1–846:12 (Morse).

While encouraging, MedImmune's team still needed to decide whether this new batch of preliminary results justified a dose expansion trial for the Monotherapy given how far AMP-514's development was behind nivolumab and pembrolizumab and how much more AMP-514 was required to be dosed in order to achieve comparable results.[62] In June 2015, Dr. Bradley thought it best to "complete [dose] escalation, declare victory ('active and well tolerated') and stop monotherapy activity."[63] This recommendation was accepted by all levels of the MedImmune team, and the decision was then made to complete the Monotherapy Phase 1 trial and focus on development of the Combination.[64] Kabakoff appeared to acknowledge this decision, noting in an email to James Pedicano, Senior Director of Biologics Project Management at MedImmune, that "it appears that Medimmune does not plan to continue the development of [AMP-514] as a single agent or in combination with any agents other than [durvalumab]."[65]

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[62] Tr. 284:3–285:9 (Richman).

[63] JX 62.

[64] *Id.*; Tr. 593:4–594:10 (Bradley); JX 66A at 12 (September 2015 pipeline report noting "no plans for expansion" of the Monotherapy Study); Tr. 363:11–365:2 (Pedicano). Given the small sample sizes involved in these trials, it was still possible that the AMP-514 Monotherapy could end up being superior to the Combination therapy. Tr. 757:8–14 (Coats); *see* JX 116 at 60 (noting a total of 58 patients dosed in the Monotherapy trial). Accordingly, that hypothesis still had to be tested before MedImmune could definitively determine its next steps with AMP-514.

[65] JX 95.

2. Additional Clinical Development of the Combination Therapy

Despite some disappointment that AMP-514 was not "twice as good" as the competition, the identification of a safe and effective dose of AMP-514 meant the molecule might still fulfill its potential in combination with durvalumab.[66] That is, "complete pathway blockade" was still viewed as viable, and the MedImmune team got to work on designing a dose expansion trial to test that hypothesis.[67]

The Phase 1 Combination Therapy trial had been a single-arm study, whereby patients were only dosed with the Combination, and those patients' results were compared to data from other trials.[68] Dr. Bradley initially considered also conducting a single-arm study for the dose expansion.[69] MedImmune, however, eventually decided to conduct a two-armed trial whereby patients were chosen randomly to be dosed with either the Combination or another drug as a comparison arm.[70]

The question, then, was what treatment to use in the comparison arm of the study. Numerous options were considered. MedImmune initially proposed using

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[66] JX 24 at 1; Tr. 626:8–10 (Bradley).

[67] This trial was to be focused on treating patients with renal cell carcinoma. JX 82 at 2.

[68] JX 34 at 2; Tr. 547:11–18 (Bradley); *id.* at 595:20–597:9 (Bradley); JX 65 at 1.

[69] JX 65 at 1; Tr. 547:11–18, 594:11–597:9 (Bradley).

[70] Tr. 596:6–597:23 (Bradley); JX 65 at 1.

nivolumab, but that drug was not yet approved for treating kidney cancer in all the jurisdictions in which the study was to occur, making it an unattractive option.[71] MedImmune next considered shifting the study's focus to lung cancer and using durvalumab as the comparison arm, but that option was rejected after it was suggested that there would be enrollment delays caused by "compet[ition] for patients."[72] After much deliberation, in December 2015, it was decided that AMP-514 would be used as the monotherapy comparator in a study of patients with renal cell carcinoma.[73]

MedImmune filed a Protocol Amendment with the FDA in February 2016, describing "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 in Subjects with Select Advanced Malignancies."[74] The parties' disagreement regarding the purpose of this trial is the principal driver of their dispute regarding whether the Monotherapy Milestone payment is owed. While the parties agree that this trial constituted "additional clinical development" of the Combination, satisfying the third prong of Successful Completion for the

[71] JX 70 at 23; Tr. 602:5–15 (Bradley); JX 67 at 1.

[72] JX 71 at 20; JX 72 at 1; Tr. 604:9–606:9 (Bradley); JX 75 at 1; JX 102 at 1.

[73] JX 77 at 2; Tr. 606:11–608:2 (Bradley).

[74] JX 82.

Combination, they disagree whether this trial also constituted "additional clinical development" of the Monotherapy.[75]

The Phase 1/2 study protocol submitted to the FDA listed as the trial's primary hypothesis that "[AMP-514] in combination with [durvalumab] will have a higher response rate than [AMP-514] monotherapy in subjects with advanced or metastatic clear cell renal cell carcinoma."[76] It described the trial's primary objective as "evaluat[ing] the antitumor activity of [AMP-514] monotherapy and in combination with [durvalumab]" in patients with kidney cancer.[77]

The study used a single-tailed design, which allowed statistically significant conclusions about whether the Combination was superior to the Monotherapy, but not statistically significant conclusions in the other direction.[78] This lack of symmetry is a product of design; single-tail studies "test[] for the possibility of the relationship in one direction and completely disregard the possibility of a relationship in the other direction."[79] Practically, this meant if the data (unexpectedly) suggested the Monotherapy was more effective than the

[75] Pls.' Opening Post-Trial Br. at 37–53.

[76] JX 82 at 2.

[77] *Id.*

[78] *Id.* at 6; JX 201; Tr. 822:14–824:7 (Morse).

[79] JX 201 at 2; Tr. 197:11–18 (Spector).

Combination, MedImmune would have to regroup and shift the focus of future studies in order to test that hypothesis further.[80]

The Phase 1/2 trial involved testing up to 60 patients with the Combination and up to 60 patients with the Monotherapy.[81] The patient consent forms related to the study disclosed that the purpose of the study was to "evaluate [AMP-514] in combination with [durvalumab] and [AMP-514] monotherapy in treating clear-cell Renal Cell Carcinoma."[82] Because the study also involved dosing patients outside of the United States, MedImmune was required to submit an Investigational Medicinal Product Dossier to the foreign regulatory authorities.[83] This document similarly described MedImmune's development of AMP-514 as both a monotherapy and in combination with durvalumab.[84] Plaintiffs point to this document, in addition to the amended study protocol submitted to the FDA and the patient consent forms, as evidence that MedImmune was proceeding with clinical trials of both the Monotherapy and Combination.

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[80] Tr. 373:17–374:20 (Pedicano); *id.* at 65:7–66:5 (Spector).

[81] JX 82 at 33.

[82] JX 85 at 3.

[83] JX 144 at 2.

[84] JX 91 at 4.

The Phase 1/2 trial began in the spring of 2016, but MedImmune quickly encountered difficulties enrolling patients into the trial.[85] This was because nivolumab had been approved in 2015 for treating renal cell cancer, leading many patients to opt for treatment with the standard of care rather than with an experimental drug.[86] Indeed, the first patient did not enroll in the Phase 1/2 trial until August 2016, six months after the protocol amendment was filed with the FDA.[87] In the face of this challenge, in March 2017, the decision was made to replace the Monotherapy as the comparator arm with nivolumab in an effort to attract patients—a change requiring a budget increase of $7.2 million.[88] This shift was described in Amendment 5 to the Combination Trial protocol, which laid out other changes in the study's design, including dosing twice as many patients with the combination therapy than with nivolumab as a monotherapy.[89]

Between 2016 and 2019, MedImmune submitted three IBs to the FDA.[90] An IB tracks the development of a molecule and, accordingly, under FDA regulations,

[85] JX 105 at 2; Tr. 734:2–24 (Coats); *id.* at 766:5–17 (Coats).

[86] Tr. 734:2–16 (Coats).

[87] PTO ¶ 65.

[88] JX 109 at 5; JX 112 at 1; JX 111 at 2.

[89] JX 112 at 37.

[90] JX 81; JX 113; JX 115.

an IB must be updated with current data and results from any ongoing clinical trials involving the molecule.[91] True to their purpose, the IBs for AMP-514 presented the results for the Combination trials as MedImmune was receiving the data.[92] These interim results were disappointing, with the Combination arm producing no better outcomes than nivolumab alone.[93] With this data in hand, MedImmune made the decision to terminate the Combination trial, and the last patient was treated with the Combination in March 2020.[94]

MedImmune completed a CSR—a formal summary of a clinical trial—and submitted it to the FDA upon completion of the study. After submitting the CSR, MedImmune determined the Combination Therapy Milestone had been achieved, and it made the required $50 million earn-out payment in April 2020.

F. Procedural History

Plaintiffs filed their Complaint in June 2017, and the operative Amended Complaint was filed in September 2017.[95] The Amended Complaint asserts one

[91] 21 C.F.R. §§ 312.23(5), 312.55; Tr. 83:21–84:5 (Spector).

[92] JX 81; JX 113; JX 115.

[93] Tr. 745:24–746:9 (Coats).

[94] *Id.* 746:10–5 (Coats).

[95] D.I. 1; D.I. 25 (the "Amended Complaint").

Count of Breach of Contract.[96] After voluntarily dismissing certain claims, Plaintiffs sought relief for the following alleged breaches: (1) failure to pay the $100 million Monotherapy Milestone payment; (2) failure to pay the $50 million Combination Therapy Milestone payment when it was allegedly triggered in 2016; (3) failure to exercise commercially reasonable efforts in developing AMP-514; and (4) failure to comply with the Merger Agreement's reporting requirements.[97] As noted, Plaintiffs separately claim that a finding of breach with respect to any single milestone payment related to AMP-514 triggers the Acceleration Clause, thereby making all milestone payments due and owing.[98]

The parties cross-moved for summary judgment in August 2019.[99] Plaintiffs' Motion for Summary Judgment argued there was no genuine dispute of material fact that the Monotherapy and Combination Therapy Milestone payments were owed because the Phase 1/2 trial indisputably constituted "additional clinical development" of the Monotherapy, and numerous documents prepared by

[96] Amended Complaint ¶¶ 106–112.

[97] *Id.* Other claims asserted in the Complaint were voluntarily dismissed. D.I. 111.

[98] Amended Complaint ¶ 112(d).

[99] D.I. 112; D.I. 118.

MedImmune indisputably could be classified as a "study report."[100] Plaintiffs' motion further argued that the Acceleration Clause, as a matter of law, required all milestone payments related to AMP-514 be paid if the Court found a breach with regard to either the Monotherapy or Combination Therapy Milestone.[101]

In opposition to Plaintiffs' motion, Defendants maintained that Plaintiffs' construction of the third prong of Successful Completion was not the only reasonable construction because that provision could reasonably be read to require not only clinical testing but also some movement towards commercialization of the Monotherapy before the milestone payment was triggered.[102] Additionally, they argued Plaintiffs had not proven as a matter of undisputed fact and law that there had been a "study report" completed for the Combination (per the second prong) because a reasonable construction of that milestone would require submission of a Clinical Study Report, a term of art, which indisputably had not been completed, much less submitted to the FDA, at the time the motions were argued.[103]

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[100] D.I. 175 *Kabakoff v. Zeneca, Inc.*, C.A. No. 0459, at 6–7 (Del. Ch. Jan. 17, 2020) (TRANSCRIPT) ("Summary Judgment Op.").

[101] *Id.* at 8.

[102] *Id.* at 11.

[103] *Id.* at 13.

Defendants' Cross-Motion for Partial Summary Judgment argued there was no dispute of material fact that Defendants had exercised commercially reasonable efforts in developing AMP-514.[104] It further argued the only reasonable construction of the Acceleration Clause was that it required an accelerated payment of only a specifically breached milestone payment.[105] Finally, Defendants argued Plaintiffs could not prove any damages arising from a breach of the Merger Agreement's reporting requirements, requiring dismissal of that claim.[106]

In a Bench Ruling on the motions,[107] I found the phrase "additional clinical development" in the definition of "Successful Completion" was unambiguous, and Defendants had offered the only reasonable construction of that phrase.[108] Under that construction, Plaintiffs are required to show there was some "movement towards commercialization" of the Monotherapy in order to trigger the milestone payment.[109] Finding there was an open question of fact as to whether the Phase 1/2 trial was intended to move the Monotherapy towards commercialization, I denied Plaintiffs'

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[104] *Id.* at 8.

[105] *Id.*

[106] Plaintiffs agreed to dismiss this claim before the Court ruled. D.I. 152.

[107] Summary Judgment Op. at 6–7.

[108] *Id.* at 11.

[109] *Id.* at 12.

motion.[110] I further found both sides had proffered reasonable constructions of the term "study report," and therefore that term was ambiguous.[111] Accordingly, I denied Plaintiffs' motion as to the Combination Therapy Milestone payment.[112] Next, I found both sides had proffered reasonable constructions of the Acceleration Clause, requiring denial of both motions for summary judgment with respect to that clause.[113] Last, I found there was no genuine dispute of material fact that Defendants had exercised commercially reasonable efforts in developing AMP-514, and granted Defendants' motion as to that claim.[114]

Having narrowed the issues, the Court convened a five-day trial from February 14, 2020 through February 20, 2020. Trial focused on three questions: (1) whether the Phase 1/2 trial was intended as a continuation of the Monotherapy Trial such that it would constitute "additional clinical development" of the Monotherapy, or was instead intended only to advance the Combination towards commercialization; (2) what the extrinsic evidence demonstrated to be the proper construction of "study report" in the Merger Agreement; and (3) what the extrinsic

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[110] *Id.*

[111] *Id.* at 13–14.

[112] *Id.* at 14.

[113] *Id.* at 16.

[114] *Id.* at 18.

evidence demonstrated to be the proper construction of the Acceleration Clause. Post-trial closing arguments were presented on August 5, 2020, and the matter was submitted for decision that day.[115]

II. ANALYSIS

The Merger Agreement obligates Defendants to pay Plaintiffs upon "Successful Completion" of a Phase 1 study for AMP-514 as either a Monotherapy or Combination. As noted, Section 1.1 of the Merger Agreement defines "Successful Completion" as the satisfaction of three independent requirements:

> (1) "completion of such Phase 1 Study, in accordance with the protocol, in a manner sufficient to support 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" of the Monotherapy or of the Combination.[116]

Where, as here, contractual obligations are contingent on the achievement of certain conditions, Delaware courts place on the party seeking enforcement of the contract the burden to prove that the conditions have been satisfied.[117] That element of proof is layered on top of the traditional elements for proving breach of contract:

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[115] D.I. 208 Post-Trial Oral Arg. ("Oral Arg. Tr.").

[116] Merger Agreement at § 1.1 (formatting added).

[117] *See S'holder Representative Servs. LLC v. Shire US Hldgs. Inc.*, 2020 WL 6018738, at *49 (Del. Ch. Oct. 12, 2020) (citing *Ewell v. Those Certain Underwriters of Lloyd's, London*, 2010 WL 3447570, at *3 (Del. Super. Aug. 27, 2010)).

(1) the existence of a contract; (2) the breach of an obligation that contract imposes; and (3) resulting damages.[118] Because neither party disputes the existence of a valid agreement, my analysis focuses on whether Plaintiffs have satisfactorily proven the remaining elements of breach by a preponderance of the competent evidence.

I first address the Monotherapy Milestone. My analysis focuses on the factual issue of whether MedImmune satisfied the third prong of "Successful Completion," namely that MedImmune made "a regulatory filing . . . submitting the protocol for additional clinical development." For reasons I explain below, I have determined that Defendants did not breach their obligation to pay the Monotherapy Milestone because the preponderance of the evidence does not support Plaintiffs contention that a regulatory filing was submitted for additional clinical development of the Monotherapy.[119]

I next address the Combination Milestone. Here, the analysis centers on the meaning of the ambiguous term "study report" in the second prong of "Successful Completion." Because I find Defendants offer the more reasonable construction of "study report" based on the preponderance of the extrinsic evidence, I have

[118] *Zayo Gp., LLC v. Latisys Hldgs., LLC*, 2018 WL 6177174, at *10 (Del. Ch. Nov. 26, 2018).

[119] PTO ¶¶ 81, 82; Tr. 647:4–17 (Bradley).

determined that their Milestone payment for the Combination was timely made after the submission of a Clinical Study Report.

My determination that Defendants did not breach their obligation to pay either the Monotherapy or the Combination Milestones obviates the need to take up Plaintiffs' claim under the Acceleration Clause.

A. Plaintiffs Have Not Proven Breach of the Monotherapy Milestone

Plaintiffs contend the February 2016 Protocol Amendment ("Amendment 3") for the Phase 1/2 trial—laying out a two-armed trial dosing patients with AMP-514 as either the Combination or the Monotherapy—satisfies the third prong's requirement for "additional clinical development."[120] Defendants counter that the Phase 1/2 trial was purposed solely to test the Combination Therapy, and that the Monotherapy was selected only as a last-resort control arm after MedImmune considered three other experimental design options that ultimately proved untenable.[121]

Resolution of this dispute requires both a construction of the third prong's phrase "additional clinical development" as well as a factual inquiry into whether Defendants' actions satisfied that definition. While I previously provided a

[120] Pls.' Opening Post-Trial Br. at 38.

[121] Defs.' Post-Trial Br. at 48 (citing JX 66 at 41; JX 77 at 2; JX 99 at 1).

construction of the third prong on summary judgment,[122] the parties continued to spar at trial over the evidence required to satisfy that standard. I therefore return to the issue of contract construction before turning to the factual issues contested at trial.

1. The Unambiguous Contractual Language

On summary judgment, I held that "additional clinical development" required "movement towards commercialization."[123] Having fixed on that construction, I advised the parties that the factual dispute to be resolved at trial would center on "what the Phase 1/2 trial actually intended to accomplish."[124] If the Phase 1/2 Trial was a "continuation of the monotherapy Phase 1 trial," then the Phase 1/2 Trial would satisfy the third prong of "Successful Completion."[125] If the Phase 1/2 Trial was "only meant as a continuation of the combination therapy trial," however, then Amendment 3 would not reflect "additional clinical development" of the Monotherapy under the Merger Agreement.[126]

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[122] *See generally* Summary Judgment Op.

[123] *Id.* at 11–12 ("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. . . . [T]he definition of "Development Plan" in Section 1.1 . . . is used to describe movement towards commercialization.")

[124] *Id.* at 12.

[125] *Id.*

[126] *Id.*

Notwithstanding that pretrial ruling, the parties continue in their post-trial briefs to joust over what precisely must be shown to prove "movement towards" commercialization. Defendants contend Plaintiffs must show that the purpose and design of the regulatory filing was to move the product towards commercialization. Plaintiffs protest that Defendants' proposed standard of proof saddles them with an impossible burden, forcing Plaintiffs to produce evidence that individuals at MedImmune had the subjective intent to commercialize the Monotherapy by believing that it would, at the Phase 1 stage, differentiate itself from other PD-1s then on the market. Plaintiffs instead propose that the submission of a protocol calling for testing and evaluation of both the Monotherapy and Combination in a Phase 2 dose expansion trial should, on its own, suffice to demonstrate "additional clinical development" under the Merger Agreement.

To be clear, in order to prove "movement towards" commercialization, Plaintiffs must prove by a preponderance of the evidence that the relevant regulatory filing or protocol was made for the purpose of advancing the Monotherapy towards commercialization. Mere inclusion of the Monotherapy within a trial does not conclusively establish "additional clinical development." Information incidentally gathered on a drug included in a study as a control arm, for example, does not

advance that control towards commercialization.[127] The subjective intent of individuals within MedImmune may be probative of MedImmune's purpose, but it is by no means dispositive. Most important in this determination are MedImmune's "objective acts (words, acts and context) . . . ."[128]

While "Successful Completion" must be proven with objective markers, unfortunately, those markers are not expressly identified in the contract. Even so, Plaintiffs can prove (and could have proven) "additional clinical development" in a variety of ways, such as through the stated goals and methods of relevant regulatory filings or internal documents relating to the clinical trial at issue. A clinical study can have multiple purposes; and a study might test multiple hypotheses. If Plaintiffs had proven that one of the goals in making the relevant regulatory filing or protocol was to develop AMP-514 as a Monotherapy for commercialization, Plaintiffs would

[127] Plaintiffs argue that any use of data from the Monotherapy's Phase 1 trial to inform the Phase 1/2 trial represents a "continuation" of the Monotherapy's development and should suffice to show "additional clinical development." Pls.' Opening Post-Trial Br. at 37–38. But mere inclusion of the Monotherapy in the Phase 1/2 trial (and the gathering of data related to the molecule from that trial) is not tantamount to "additional clinical development" that would justify the payment of significant additional merger consideration. *See* Summary Judgment Op. at 12.

[128] *Sterling Prop. Hldgs. v. New Castle Cty.*, 2013 WL 1821594, at *6 (Del. Ch. Apr. 30, 2013); *see also Haft v. Haft*, 671 A.2d 413, 417 (Del. Ch. 1995) (explaining that, in ascertaining the purpose of a contract, "courts do not look for and give legal force to a private subjective state of mind (intent) but to objective acts (words, acts and context).").

have proven that the Monotherapy Milestone was triggered. As explained below, however, the preponderance of the evidence says otherwise.

2. Plaintiffs Did Not Prove "Additional Clinical Development" of the Monotherapy

To prove "additional clinical development" of the Monotherapy, Plaintiffs rely on two categories of evidence, both of which relate to Amendment 3 and the Phase 1/2 trial. First, they argue that Amendment 3 was designed to generate data to support picking the Monotherapy as a "winner" in the trial, to distinguish the Monotherapy from other similar therapies and to pursue further development of the Monotherapy for use in treating other diseases. Second, Plaintiffs point to regulatory documents filed by MedImmune that, by Plaintiffs' lights, confirm the Phase 1/2 trial constituted "additional clinical development" of the Monotherapy. I disagree on both fronts.

a. The Phase 1/2 Trial Was Designed and Intended to Test Only the Combination Therapy

On February 11, 2016, MedImmune submitted a protocol (Amendment 3) calling for the testing and evaluation of both the Monotherapy and Combination in up to sixty new cancer patients each.[129] As noted, the protocol is titled "A Phase 1/2, Open-label Study to Evaluate the Safety and Antitumor Activity of MEDI0680

[129] JX 82.

[AMP-514] in Combination with MEDI4736 [Durvalumab] *and MEDI0680 [AMP-514] Monotherapy* in Subjects with Selected Advanced Malignancies."[130] Amendment 3's hypothesis dealt exclusively with the Combination, but it stated as its "primary objective" the evaluation of antitumor activity of both the Monotherapy and Combination.[131] It also noted among its "secondary objectives" a plan to characterize the Monotherapy.[132] Patient consent forms disclosed the study would "evaluate . . . the effect both MEDI4736 [durvalumab] in combination with MEDI0680 [AMP-514] or MEDI0680 [AMP-514] alone have on your cancer."[133]

Plaintiffs place great weight on this protocol and its objectives in particular. They point out that even Defendants' expert conceded at trial that "the objectives" of the protocol (in addition to the hypothesis) provide evidence of its purpose.[134] And Defendants do not contest the dictionary definitions cited by Plaintiffs demonstrating that the word "objective" is synonymous with "intent" and "purpose." According to Plaintiffs, Amendment 3's stated objectives alone suffice to show the Phase 1/2 trial was formulated to test the Monotherapy in addition to the

[130] *Id.* at 1 (emphasis added).

[131] *Id.* at 2.

[132] *Id.*

[133] JX 85 at 4.

[134] Tr. 820:3–7 (Morse).

Combination, thereby "mov[ing the Monotherapy] towards commercialization" in satisfaction of the third prong of "Successful Completion."

The problem with Plaintiffs' theory is that these objectives, while probative, do not exist in a vacuum, and the preponderance of the evidence places Plaintiffs' proffered proofs in context and ultimately contradicts their characterization of the Phase 1/2 trial. More specifically, the Phase 1/2 trial's design, the governance record relating to the Monotherapy and the commercial context within which the Monotherapy was being developed collectively demonstrate that the Phase 1/2 trial was not undertaken to move the Monotherapy towards commercialization. Rather, the Phase 1/2 trial was intended to test the complete pathway blockade hypothesis, using the Monotherapy solely "to compare" how "it look[s] if you are blocking only one agent not two."[135]

i. The Design of Amendment 3

Plaintiffs' expert stipulated at trial that the sole hypothesis of Amendment 3 shows MedImmune "believed the combination was better" than the Monotherapy.[136] In credible expert testimony, Dr. Michael Morse, a clinical oncologist called by Defendants who specializes in immnunotherapies, including anti-PD-1 and anti-PD-

[135] (Jallal) Dep. 147:10–148:2, 160:7–162:7.

[136] Tr .181:15–18, 182:22–183:9 (Spector); JX 82 at 2.

L1,[137] explained that if MedImmune intended to advance the Monotherapy's development, one would expect Amendment 3 to offer hypotheses regarding the efficacy of the Monotherapy.[138] No such hypothesis is stated. This corroborates Defendants' position that MedImmune was interested solely in testing the dual-blockade hypothesis (which is stated), and included the Monotherapy in the study design only to discover whether the dual-blockade treatment would outperform a single-blockade treatment.[139]

While a failure to hypothesize about the Monotherapy's efficacy does not, on its own, prove that the Phase 1/2 trial was not advancing the Monotherapy towards commercialization, the absence of a Monotherapy hypothesis coupled with the study's statistical design amounts to persuasive evidence that MedImmune was not interested in the Monotherapy's Phase 1/2 results for the sake of subjecting the Monotherapy to "additional clinical development." The study used one-sided

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[137] JX 131.

[138] Tr. 828:9–18 (Morse).

[139] Plaintiffs argue the dual blockade hypothesis pertains both to the Monotherapy as well as the Combination, as it is connected to the efficacy of both the Monotherapy and the Combination. *See* D.I. 199, Pls.' Reply Post-Trial Br. at 9. But the evidence showed the dual blockade hypothesis deals with combining anti-PD-1 and anti-PD-L1 drugs to achieve a complete pathway blockade, using the Monotherapy only to compare the Combination's relative efficacy. *See, e.g.*, JX 77 (IMed leadership team minutes describing the development plan of a study to be "[d]ifferentiating complete vs single blockade."); Tr. 608:3–16 (Bradley) ("[T]he purpose of the trial was to see whether the combo was better than the mono.").

significance for its statistical power, allowing MedImmune to draw statistically significant conclusions only about whether the Combination was better than the Monotherapy, but not the other way around.[140] Like the single hypothesis, a one-tailed design suggests the Monotherapy was included only as a single-blockade molecule to test a dual-blockade hypothesis. If MedImmune intended to move the Monotherapy toward commercialization, or was even agnostic to the results (as it would be in a "pick-the-winner" trial),[141] one would expect a two-tailed statistical analysis where the Monotherapy could be evaluated on its own merits.[142]

Plaintiffs argue that the statistical design of the trial is a red herring. They say the statistical analysis in Amendment 3 was employed only for selecting the study's sample size; nothing prevented MedImmune from running a two-tailed statistical

[140] JX 82, at 6; JX 201; Tr. 822:14–824:7 (Morse); *id.* at 197:11–18 (Spector) (admitting that a "one-tailed test, you are testing for the possibility of the relationship in one direction and completely disregarding the possibility of a relationship in the other direction.").

[141] A "pick-the-winner" trial is an adaptive trial design whereby the study sponsor compares the results of molecules in a trial's different arms and advances the molecule that performs best. *See* Pls.' Opening Post-Trial Br. at 42–43; *see also* JX 201 (explaining the differences between one- and two-tailed tests).

[142] *See* Tr. 829:2–9 (Morse) (noting that the Phase 1/2 Trial's statistical analysis plan's one-tailed design was set up to "only ask one question"—"whether the combination is better than the monotherapy."). *See* Pls.' Reply Post-Trial Br. at 21 (recognizing implicitly that a two-tailed analysis would be typical in a pick-the-winner trial by arguing that a two-tailed analysis could have been done at the end of trial.).

inquiry at the end of the trial.[143] Further, the statistical design was irrelevant to the study, according to Plaintiffs, not only because the statistical power was too low to generate a statistically meaningful result but also because the FDA does not require statistical significance in smaller Phase 2 studies.[144] Because the data collected for the Combination is identical to the Monotherapy (i.e., each treatment was administered to the same number of patients), Plaintiffs believe MedImmune was agnostic to the trial's outcome and willing to proceed with either treatment based on the Phase 1/2 trial's results.

These arguments miss the point. Plaintiffs bear the burden to prove by a preponderance of the evidence that MedImmune, through the purpose and design of Amendment 3, was subjecting the Monotherapy to additional clinical *development*. While the statistical design may be changed at the study's conclusion, that is not the relevant question. Instead, the relevant question is why MedImmune would not, in its protocol, provide for a two-tailed statistical design in the first place if the study was designed to advance the Monotherapy towards commercialization. Indeed, the Court received credible testimony that a sponsor typically uses "the same type of

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[143] Pls.' Opening Post-Trial Br. at 22; Tr. 193:17–194:8 (Spector); *id.* at 484:21–485:20 (Pardoll).

[144] Tr. 193:21–194:8 (Spector) (testifying that "[y]ou don't consider something statistically significant unless the P value is .05 or less," and the P value for the study here was .10.); *id.* at 763:8–14 (Coats) (confirming that the FDA does not require statistical significance in these smaller Phase 2 studies).

statistical analysis at the end of the study" that was used to pick the original sample size.[145] Moreover, the fact that a study is insufficiently powered does not mean the study's results are ignored. Indeed, the credible evidence is that "in oncology . . . a good drug declares itself early"[146] and the Monotherapy would have to be significantly better than its more mature competition to justify additional clinical development.[147] While not dispositive, Amendment 3's one-tailed design further supports Defendants' characterization of the Monotherapy as a "comparator" or "control" in the Phase 1/2 trial, included purely "to compare" how "it look[s] if you are blocking only one agent not two."[148]

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[145] Tr. 825:20–827:7 (Morse).

[146] *Id.* at 680:7–20 (Bradley).

[147] *See, e.g.*, JX 13 (2013 MedImmune email explaining that AMP-514 would need to be "differentiated" or else they would "focus only on combo trials"); Tr. 642:1–644:9 (Bradley).

[148] (Jallal) Dep. 157:10–148:2, 160:7–162:7. Plaintiffs make much of the semantic difference between "control" and "comparator," arguing the protocol did not explicitly describe the Monotherapy as a "control" and that "comparators" are not treated the same as "controls" because this prejudges the result. Tr. 508:14–509:5 (Pardoll). Regardless of the semantic differences between the two terms, the Monotherapy's role is implied in the study's design, and MedImmune characterized the Monotherapy interchangeably as both a "comparator" or "control" in numerous internal and external documents predating the litigation. *See, e.g.*, JX 92 at 2 (describing the Monotherapy arm as a "comparator"); JX 100 at 6 (describing the Monotherapy arm as a "control arm"); JX 77 at 2 (describing the monotherapy arm as a "control arm"). This corroborates Defendants' witness testimony that the "principal distinction" between a "control" and "comparator" is largely one of "nomenclature." *See* Tr. 508:7–14 (Pardoll); *accord, e.g.*, (Jallal) Dep. 183:4–184:24; JX 159; JX 160. Consistent with this understanding, I refer to the Monotherapy as a "comparator" in the Phase 1/2 trial because it was not a standard of care.

Plaintiffs argue the Monotherapy could not possibly serve as a control by which to measure the Combination's efficacy because the Monotherapy was not the standard of care,[149] but Defendants produced credible testimony that the difference is irrelevant to determine whether the Monotherapy was included in the Phase 1/2 trial for purposes of commercial development. Dr. Morse testified that, to understand how the Monotherapy stacks up to its competition, it would have to be compared with "another drug in the class or another proxy for other drugs in the class if you were really interested in how MEDI0680 [the Monotherapy] performed compared to what's available out in the real world."[150] Amendment 3 provided for no such comparator.[151]

Later Amendments support Defendants' contention that Amendment 3 was not intended to clinically develop the Monotherapy. In Amendment 5, for example, MedImmune switched from AMP-514 to nivolumab—the standard of care. This study was indisputably not a "pick-the-winner" trial seeking to develop

[149] The argument, more specifically, is that sponsors of a clinical study may not use an unapproved drug in the control arm of the study. *See* Pls.' Reply Post-Trial Br. at 19–20.

[150] Indeed, Michael Richman, a former MedImmune employee who testified on behalf of Plaintiffs, admitted that the biotech company he currently works for also uses anti-PD-1 agents "as a comparator or control" to "compare how a given candidate will perform against a known benchmark." Tr. 236:13–237:18 (Richman).

[151] *Id.* at 828:19–829:1 (Morse) (testifying that using the Combination as a comparator "doesn't make sense").

nivolumab.[152] And yet, Amendment 5 and Amendment 3 remained similar in meaningful ways. The protocols stated the same hypothesis, collected and evaluated similar data in both arms, had objectives and endpoints involving the comparator arm and employed the same statistical design.[153] While the Amendments differed in some respects, such as the randomization ratio and certain objectives and endpoints, Defendants presented credible evidence that explain these differences. Most importantly, because the Monotherapy, unlike nivolumab, had not already been characterized and had no historical data available to compare it against the Combination, MedImmune had to gather more information on the Monotherapy to make a meaningful comparison.[154]

Overall, an evaluation of the Phase 1/2 trial's design yields powerful evidence that MedImmune included the Monotherapy in the Phase 1/2 study only to test whether the Combination could outperform a single blockade molecule.

ii. The Governance Documents

The incompatibility of the study design with additional clinical development of the Monotherapy comports with statements about the Phase 1/2 trial in the

[152] *Id.* at 69:16–19, 200:19–24 (Spector).

[153] *Compare* JX 82 at 6, *with* JX 112 at 2–4, 6.

[154] Tr. 779:12–780:11 (Coats); *id.* at 736:20–737:17, 745:9–16 (Coats) (explaining that the different randomization ratios were used to accelerate enrollment).

mountain of governance documents related to Amendment 3. Decisions regarding trial design and strategy are made according to an established governance process.[155] Within MedImmune, the AMP-514 Product Development Team ("PDT") reported to the IMed Committee, which in turn reported to the Early Stage Product Committee.[156] This internal reporting process produced a contemporaneous record documenting MedImmune's purpose and goals in conducting the Phase 1/2 trial. If MedImmune had a secondary developmental purpose for the Monotherapy during the Phase 1/2 trial, that intent would likely be documented by the trial's governance committee in some form, whether through meeting minutes, governance memos or presentations.[157]

MedImmune initially contemplated a single-arm study of the Combination,[158] and pursued a two-arm trial only after its parent, AstraZeneca, requested a "more robust control" in the study by introducing a "real control arm and do[ing] a

[155] *See, e.g.*, (Jallal) Dep. 43:23–45:6; (Gallagher) Dep. 9:15–20.

[156] Tr. 352:5–354:24 (Pedicano).

[157] Tr. 781:1–11 (Coats) (credibly testifying, as AMP-514 PDT's leader, that if MedImmune had further plans to develop the Monotherapy, "it absolutely would have been reflected" in the PDT meeting minutes or in a governance interaction); *see also id.* at 736:6–11 (Coats) (noting that, as the AMP-514 PDT leader, he never saw "any documents or any information that suggested that while [the Monotherapy] was serving as the benchmark, that there were any other purposes for having the [Monotherapy] arm of the study" during the Phase 1/2 trial).

[158] JX 65 at 1; Tr. 547:11–18, 594:11–597:9 (Bradley).

prospective randomized trial of the single agent versus a double agent."[159] The Monotherapy was chosen only after two other single-blockade inhibitors were rejected for logistical reasons.[160] In December 2015, MedImmune's IMed Committee settled on using the AMP-514 Monotherapy as the "control arm" in a study of patients with kidney cancer.[161] The meeting minutes stated, "[d]ifferentiating complete versus single blockade is the goal of this study."[162] This singular purpose was corroborated by a 2016 Scientific Advisory Board presentation, and by Dr. Bradley, leader of the oncology group and then-member of the IMed Committee, who attended the December 2015 IMed meeting where the initial Phase 2 trial design was approved.[163]

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[159] Tr. 596:6–597:23 (Bradley); JX 65 at 1 (September 2015 email suggesting as a comparator "durva alone, nivo, or a separate arm for both.").

[160] As noted, Nivolumab was first considered but ultimately rejected because it had not yet been approved for the indication to be studied (kidney cancer). JX 70 at 23; Tr. 598:15–601:23 (Bradley); *id.* at 602:5–15 (Bradley); JX 67 at 1; (Jallal) Dep. 66:7–22, 167:8–169:2. Durvalumab was next considered but rejected due to unacceptable risk of enrollment delays. JX 71 at 20; JX 72 at 1; Tr. 602:9–606:9 (Bradley); *id.* at 744:4–12 (Coats); JX 75 at 1; JX 102 at 1, 8.

[161] JX 77 at 1; Tr. 606:11–608:2 (Bradley).

[162] JX 77 at 1; Tr. 608:3–13 (Bradley) (corroborating the meeting minutes as consistent with his independent understanding).

[163] *See, e.g.*, JX 65; JX 70; JX 72; JX 75; JX 77; Tr. 594:11–602:15, 606:10–21, 612:23–613:5 (Bradley). Richman testified that Dr. Bradley "would know for a fact whether the company had decided to further clinically develop the monotherapy or not." *Id.* at 288:1–23 (Richman).

Amendment 3 was subsequently filed to implement that plan. Every witness with first-hand knowledge of the Phase 1/2 trial laid out in Amendment 3 credibly testified that it was intended only to develop the Combination and not the Monotherapy.[164] Despite extensive discovery, Plaintiffs found no governance documents to controvert the facts that the Phase 1/2 trial was motivated to "[d]ifferentiat[e] complete versus single blockade," that the Monotherapy was included only as the "control arm" of the study, and that there was "[n]o expansion planned" for the Monotherapy.[165]

Plaintiffs argue that some internal documents contradict Defendants' narrative of institutional consensus. For example, they cite April 2015 meeting minutes showing the Clinical team contemplated expansion of the Monotherapy even as the Commercial team projected that the "monotherapy will not be a registration option."[166] They also cite an internal pipeline tracker from September 2015 detailing plans to escalate the Monotherapy in certain patients to "evaluate efficacy to support continuation of trial to expansion phase," despite the fact that the pipeline tracker stated on the same page that there are "[n]o plans for expansion [of the Monotherapy]

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[164] Tr. 608:14–23 (Bradley); *id.* at 625:11–17 (Bradley) ("At that time, there was no development plan, no intention of developing monotherapy, period."); JX 129 207:9–23; Tr. 375:3–13 (Pedicano); *id.* at 722:1–5 (Coats); *id.* at 736:6–11 (Coats).

[165] JX 77 at 2; JX 66 at 41; JX 99 at 1.

[166] JX 207 at 2.

at this time."[167] Finally, they cite Dr. Drew Pardoll's testimony that Dr. Ashok Gupta, MedImmune's Vice President for Clinical Development in Oncology, had expressed "enthusiasm" and that he "advocated, successfully . . . in his leadership role" to move AMP-514 forward to the randomized Phase 2 trials.[168] Notwithstanding the weight of the governance record, the plan for discontinuing commercial advancement of the Monotherapy must have changed, Plaintiffs believe, before Amendment 3 was filed.

But some documented confusion among MedImmune's ranks in discrete, isolated parts of a voluminous set of governance records does not detract from the overwhelming evidence that the Monotherapy was not considered by the relevant governance committees to be worth pursuing. While the Clinical team may have disagreed with the Commercial team about the Monotherapy's commercial prospects in early 2015, an updated report on the Monotherapy in November of that year indicated MedImmune was "not doing any additional studies in

[167] JX 66 at 41.

[168] Tr. 518:6–22, 521:1–8 (Pardoll). Plaintiffs make the same argument with regard to Mr. Pedicano because he predicted that AMP-514 would be a "critical molecule in the next three years." JX 83. It is unclear, however, whether Pedicano was referring to the molecule as a Monotherapy or as part of the Combination, as the update to which Pedicano was responding concerned *both*. In other words, this fact, without more, does not suggest Pedicano believed the Monotherapy alone would be a viable commercial option.

monotherapy."[169] Indeed, Dr. Kabakoff acknowledged in his response to the report that "MedImmune does not plan to continue the development of MEDI0680 [AMP-514] as a single agent."[170] As for Dr. Gupta, it is unclear from Dr. Pardoll's testimony whether Dr. Gupta's enthusiasm was for the Monotherapy or the Combination.[171] A single pipeline tracker with ostensibly contradictory entries regarding the Monotherapy cannot detract from the overwhelming evidence that the Monotherapy was included in the Phase 1/2 trial as a last-choice comparator based more on necessity than any commercial interest.

iii. The Commercial Reality of the Monotherapy

Before attempting to discern the parties' shared intent with respect to particular provisions of a contract, the "basic business relationship between parties must be understood" and the contract must be "read in full and situated in the commercial context between the parties."[172] There is some evidence that the Monotherapy outperformed the Combination in clinical trials.[173] And yet,

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[169] Tr. 363:11–365:2 (Pedicano); JX 73 at 20.

[170] JX 95; *see also* Tr. 369:10–21 (Pedicano).

[171] Indeed, Dr. Bradley similarly expressed optimism that AMP-514 was sufficiently active to allow further development of the Combination, and there is no question Dr. Bradley did not see a commercial future for the Monotherapy. *See* Tr. 622:18–623:3 (Bradley).

[172] *Chi. Bridge & Iron Co. v. Westinghouse Elec. Co.*, 166 A.3d 912, 927 (Del. 2017).

[173] Tr. 69:23–71:7, 71:11–15 (Spector); JX 82 at 26; Pls.' Opening Post-Trial Br. at 13.

MedImmune evidently discontinued development of the Monotherapy.[174] While MedImmune's decision to abandon development of what appeared to be an effective drug may at first seem confusing, it makes sense when viewed in the context of drug development at major pharmaceutical companies.

MedImmune's interest in AMP-514 was born of a need to develop an anti-PD-1 molecule to complement its existing anti-PD-L1 portfolio.[175] MedImmune acquired Amplimmune and its anti-PD-1 molecule, AMP-514, at a time when the industry began focusing on the potential of combining multiple immunotherapies.[176]

AMP-514's competitive potential as a monotherapy was encumbered by the fact that its development lagged well behind its competitors. Two rival companies were already in late-stage clinical trials with anti-PD-1 monotherapies in the race to market by the time MedImmune began developing AMP-514.[177] Thus, MedImmune's "core strategy" in acquiring Amplimmune was always to test its complete pathway blockade hypothesis[178] in order to achieve a "breakthrough[]" that

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[174] *See* JX 207 at 2.

[175] *See* Tr. 547:6–10, 561:2–14 (Bradley).

[176] *Id.* at 237:23–238:6 (Richman).

[177] PTO ¶¶ 49–50.

[178] *See* Tr. 239:22–240:4, 241:4–13, 242:2–5, 242:24–243:2, 249:19–250:5 (Richman); *see also, e.g.*, JX 17 at 5 (August 2013 meeting minutes of Science Committee stating that the "real value in this approach is thought to be in combination therapies" and explaining that the acquisition would "place MedImmune in a unique position to develop optimal

would "leapfrog" the competition.[179] While MedImmune "would certainly have considered developing [AMP-514] as a monotherapy, in addition to the combination therapy,"[180] it would only do so if it "got lucky" and AMP-514 proved superior to its competitors.[181] If AMP-514 were only "a little better" than its competition, MedImmune would not "try to take that possible small advantage and go head to head with" the two more mature monotherapies.[182] Because MedImmune needed the Monotherapy to demonstrate a "large" degree of superiority to be commercially viable, the Phase 1 trial was expected to suffice for assessing its competitive potential despite the fact that Phase 1 trials are only secondarily aimed at assessing a drug's efficacy.[183]

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proprietary combination regimens"); *see also, e.g.*, JX 30 at 3 (2013 report reflecting the external advisors "recommended spending limited time in monotherapy development, and instead were more in favor of advancing a PD1/PDL1 antibody combination therapy option").

[179] Tr. 547:6–10, 561:2–14, 567:2–7 (Bradley).

[180] Tr. 555:15–556:7 (Bradley); *see also* (Jallal) Dep. 80:11–23.

[181] JX 24 at 1.

[182] JX 20 at 1; *see also, e.g.*, JX 13 (2013 Bradley email explaining that if AMP-514 was not "differentiated," they would "focus only on combo trials"); Tr. 642:1–644:9 (Bradley).

[183] Tr. 679:2–680:6 (Bradley); JX 20 at 1; *see also* Tr. 680:7–20 (Bradley) (explaining that "in oncology . . . a good drug declares itself early" and citing durvalumab as an example); 21 C.F.R. § 321.21(a) (FDA regulations stating that Phase 1 trials should also seek to "gain early evidence on effectiveness.").

MedImmune's hopes for the Monotherapy's superiority were dashed when its Phase 1 trial revealed the Monotherapy compared unfavorably to its competitors. Unlike competing drugs,[184] none of the patients dosed with AMP-514 experienced any tumor shrinkage in the first six months of Phase 1 trials.[185] Concerned with early patient data, MedImmune then conducted new testing of AMP-514's affinity and found the molecule's affinity level to be roughly fifteen times *worse* than its top competitor.[186] Dr. Bradley credibly testified that "any hope that [AMP-514] would be even as good, not to mention better than the other competitors, kind of went out the window. . . . But there was still the hope that we could at least test the hypothesis that two is better than one."[187]

This commercial reality—that early testing of the Monotherapy revealed it would not perform as well as, much less outperform, more developed drugs with which it would compete—provides color to the protocol and the governance record relating to Amendment 3. The Monotherapy was the fourth-choice comparator in

[184] The earliest cohorts treated with nivolumab showed anti-tumor responses at dosages as low as 0.1 mg/kg in the same types of tumors tested in the Amp-514 trials. Tr. 496:6–501:17 (Pardoll); JX 3; JX 5; JX 61; Tr. 206:3–6 (Spector).

[185] JX 116 at 66; JX 39 at 1; Tr. 582:14–583:10 (Bradley).

[186] JX 42 at 2; *see also, e.g.*, Tr. 583:11–584:2 (Bradley); JX 45; JX 46 at 1. This affinity level meant that, in effect, "to have the same effect as nivo, you [would] need to give 15 times more [AMP-]514." Tr. 585:10–12 (Bradley).

[187] Tr. 585:15–586:11 (Bradley).

Amendment 3 because it did not earlier demonstrate superiority over other molecules, and so was not viewed as a viable competitor to the rival anti-PD-1s. The governance record overwhelmingly shows that MedImmune was not interested in commercially developing the Monotherapy because, again, its equal-at-best performance vis-à-vis competitors did not warrant the expense. While it remained possible MedImmune might abruptly change course between December 2015 (when it evaluated the Monotherapy's performance)[188] and February 2016 (when Amendment 3 was filed), Plaintiffs have not presented any credible evidence that a change of course was ever seriously contemplated much less implemented.

b. Other Regulatory Filings Do Not Evidence the Monotherapy's "Additional Commercial Development"

MedImmune filed various documents with regulatory authorities that discussed MedImmune's commercial development plans regarding the Phase 2 trial. Plaintiffs highlight representations made to two different regulators in those documents as evidence of MedImmune's intent to move the Monotherapy towards commercial development.[189]

[188] JX 77.

[189] There is no dispute MedImmune's statements in regulatory filings are accurate. Tr. 345:22–346:22, 337:12–339:19 (Pedicano) (affirming that MedImmune "stand[s] by" what it submits to the FDA).

First, Plaintiffs point again to Amendment 3. Specifically, MedImmune represented to the FDA through Amendment 3's "Benefit-risk evaluation" section that "[e]merging data" for the AMP-514 Monotherapy demonstrated "encouraging clinical activity with a manageable safety profile."[190]

Second, in April 2016 and April 2017, MedImmune filed with European Union regulators an Investigational Medicinal Product Dossier (IMPD) to support the expansion phase of their AMP-514 study outside the United States.[191] The IMPD is a "clinical trial application" submitted to the European Medicines Agency (EMA) ("like the European FDA"[192]) that allows investigators to decide whether to allow participation in the trial.[193] It is the European counterpart to the IB, describing what is known about the drug and why the study sponsor believes the potential benefits outweigh the potential risks for patients taking part in the clinical trial.[194] Dr. Gupta, the "senior clinician" working on the AMP-514 program who was "responsible for" the Phase 1/2 trial,[195] signed the IMPD.[196] Section 2.3 of the IMPD states

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[190] JX 82 at 26.

[191] JX 91; JX 168; JX 144.

[192] Tr. 720:6–721:1, 730:22–731:2 (Coats).

[193] *Id.*

[194] *Id.* at 720:6–721:1 (Coats).

[195] *Id.* at 344:16–345:1 (Pedicano); *see also id.* at 659:12–18 (Bradley).

[196] JX 91 at 9.

"MEDI0680 [AMP-514] is being developed as a potential anticancer therapy in both a monotherapy and combination therapy setting for patients with advanced malignancies."[197] It goes on to say:

> MEDI0680 [AMP-514] in monotherapy or combination settings may provide meaningful clinical benefit with a manageable safety and tolerability profile by generating durable and improved rate of clinical responses. . . . . Based on available data, the sponsor [MedImmune] believes that MEDI0680 [AMP-514] continues to demonstrate an overall benefit-risk balance to support its further clinical evaluation in cancer patients.[198]

Contrary to Plaintiffs' characterizations, these regulatory filings are hardly "smoking guns." The FDA filing, for its part, adds nothing to the analysis. To repeat, the competitive dynamics of the anti-PD-1 market makes clear that merely "encouraging clinical activity with a manageable safety profile" alone would not warrant the Monotherapy's "additional clinical development."

Nor is the European IMPD persuasive evidence that MedImmune was advancing clinical development of the Monotherapy. The "Benefit-Risk Conclusion" in the April 2016 IMPD reflects that MedImmune believed it was ethical (i.e., the potential benefits outweighed the possible risks) to dose patients

[197] *Id.* at 4.

[198] *Id.* at 8.

with either the Monotherapy or the Combination;[199] it does not speak directly to whether the Monotherapy was being moved towards commercialization. And the April 2017 IMPD does not proffer any conclusions about the Monotherapy in its benefit-risk analysis because the Monotherapy was not included in that trial.

Further, the 2016 IMPD's statement that the Monotherapy was "being developed" does not mean there was "additional clinical development" underway as contemplated by the Merger Agreement. Indeed, in the April 2016 IMPD—submitted when AMP-514 was no longer used in the comparator arm—the introductory language cited by Plaintiffs remains unchanged.[200] MedImmune did not change this language because the Monotherapy's Phase 1 trial was ongoing at the time of both cited versions of the IMPD.[201] That trial's purpose and design was indisputably to move the Monotherapy towards commercialization. Thus, MedImmune's representation in the IMPD that AMP-514 was "being developed" as a Monotherapy could reasonably be understood as a reference to its Phase 1 trial (not at issue here), as opposed to its role as comparator in the Phase 1/2 trial. While MedImmune determined to stop developing the Monotherapy during the Phase 1 trial, the purpose of that trial did not retroactively change because of, or following,

[199] Tr. 722:6–723:5 (Coats).

[200] *See* JX 168 at 3.

[201] *See id.* at 3–4; Tr. 725:8–13 (Coats).

that determination.[202] Accordingly, the related regulatory filings cited by Plaintiffs provide no persuasive evidence that the Phase 1/2 trial constituted "additional clinical development" of the Monotherapy.

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Because Plaintiffs have not carried their burden to prove that MedImmune submitted a regulatory filing to subject the Monotherapy to "additional clinical development," Defendants owe no obligation to make the $100 million Milestone payment for the Monotherapy under Section 9.1(a) of the Merger Agreement.

B. Plaintiffs Have Not Proven Breach of the Combination Therapy Milestone

Both parties agree the Combination Therapy Milestone has been triggered, but dispute *when* it was triggered.[203] Plaintiffs argue the Milestone payment was owed in February 2016, upon the filing of Amendment 3 to the Combination Trial protocol. Defendants agree the filing of Amendment 3 satisfied the third prong of "Successful Completion,"[204] but maintain that the Milestone's second prong—

[202] Tr. 778:1–13 (Coats).

[203] For context, as noted, the Milestone's date of completion implicates the Agreement's Acceleration Clause. If Plaintiffs are correct that Defendants breached their Agreement by delaying payment on the Combination Milestone, then the Acceleration Clause arguably makes due all money owed on *every* Milestone. Because I ultimately determine that the Defendants timely paid the Milestone, I do not reach that question.

[204] Defs.' Post-Trial Br. at 61; *see also, e.g.*, JX 106 at 10.

requiring "completion of a study report for such Phase 1 Study"—was not satisfied until Defendants submitted a CSR on the Combination's Phase 1 trial in March 2020.

With these battle lines drawn, the parties' dispute centers on the meaning of "study report," a term left undefined in the Merger Agreement. Plaintiffs argue a "study report" is "any summary of findings and data from Phase 1 that would enable MedImmune to proceed with further development."[205] Under their definition, MedImmune "complet[ed]" a study report upon filing its 2016, 2017, and 2019 IBs, as well as its 2015 Annual Report. Defendants argue a "study report" was intended to reference the industry-specific CSR (case study report)—a comprehensive document describing the conduct and results of a clinical trial in a prescribed regulatory format.[206] On summary judgment, I determined that the undefined term "study report" was ambiguous.[207] Because "reasonable minds could differ as to the contract's meaning," the Court must "consider admissible extrinsic evidence."[208]

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[205] Pls.' Opening Post-Trial Br. at 53.

[206] Defs.' Post-Trial Br. at 34–36.

[207] *See* Summary Judgment Op. at 12–14. Of course, by declaring the term ambiguous, the Court did not pass on which of the two proffered "reasonable constructions" was *most* reasonable. *See Bank of New York Mellon v. Commerzbank Capital Funding Tr. II*, 65 A.3d 539, 550 (Del. 2013) ("Even a 'less natural' reading of a contract term may be 'reasonable' for purposes of an ambiguity inquiry.").

[208] *GMG Capital Invs., LLC v. Athenian Venture P'rs I, L.P.*, 36 A.3d 776, 783 (Del. 2012) (citing Lawrence M. Solan, *Pernicious Ambiguity in Contracts and Statutes*, 79 Chi-Kent L. Rev. 859, 862 (2004) ("If a contract is clear, then resorting to extrinsic evidence that might undermine the plain language of the agreement is barred by the parol evidence rule.

Having declared an ambiguity, the analysis from here proceeds in two sequential steps. First, I must determine the superior construction of the disputed contract language as informed by the competent extrinsic evidence. Second, I must interpret the implications of my chosen construction on the parties' obligations. I take up each inquiry in turn.

1. "Study Report" Refers to a Clinical Study Report

Despite both parties' shared intent to use "objective," "clear," "black and white" metrics by which to measure "Successful Completion,"[209] the Merger Agreement's drafters inexplicably chose to leave the term "study report" undefined.[210] As noted, this choice has left the Court to discern the intended meaning of the term from the preponderance of the extrinsic evidence.[211] "Such extrinsic evidence may include overt statements and acts of the parties, the business context, prior dealings between the parties, [and] business custom and usage in the industry."[212] Extrinsic evidence disambiguates contractual language when it reveals

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When, in contrast, contractual texts are deemed ambiguous, the resolution of the ambiguity becomes a trial issue for the jury. Thus, a court acts as a gatekeeper in making its initial inquiry into whether an ambiguity exists.")).

[209] Tr. 268:20–270:8 (Richman); *id.* at 569:16-570:9, 573:7–574:6 (Bradley).

[210] *See* Summary Judgment Op. at 12–14.

[211] *Eagle Indus. v. DeVilbiss Health Care*, 702 A.2d 1228, 1232 (Del. 1997).

[212] *United Rentals, Inc. v. RAM Hldgs. Inc.*, 937 A.2d 810, 834–35 (Del. Ch. 2007) (alteration in original) (internal quotation marks omitted).

what an "(objectively) reasonable party in the position of either bargainer would have understood the nature of the contractual rights and duties to be."[213]

To begin, both parties agree that Defendants' proposed definition for "study report"—a CSR—satisfies the second prong.[214] The question more narrowly focused, then, is whether Plaintiffs' proffered study reports—IBs and Annual Reports—also qualify. Contracts can, of course, include a "broad, flexible" term that "may encompass a spectrum of events" without sacrificing clarity.[215] But the burden is on the Plaintiffs to prove, by a preponderance of the evidence, that the parties intended MedImmune's obligation to pay tens of millions of dollars in milestone payments would be triggered upon MedImmune's completion of any one of an undefined "spectrum" of documents regarding the Combination Therapy.

Plaintiffs do not import their definition of "study report" from a regulatory authority or published source. Indeed, neither Plaintiffs nor any of their witnesses could identify a regulatory or other published document characterizing an IB or an Annual Report as a "study report," despite the fact that clinical trials, not

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[213] *U.S. West, Inc. v. Time Warner, Inc.*, 1996 WL 307445, at *10 (Del. Ch. June 6, 1996).

[214] *See* Pls.' Reply Post-Trial Br. at 30.

[215] *E.I. Du Pont de Nemours & Co. v. Admiral Ins. Cor.*, 711 A.2d 45, 63–64 (Del. Super. Ct. 1995).

surprisingly, are highly regulated.[216] Rather, Plaintiffs' proposed definition purportedly derives from the contemporaneous understanding of three trial witnesses who negotiated the Merger Agreement on Amplimmune's behalf: Mr. Richman, Dr. Spector and Dr. Kabakoff. Plaintiffs urge the Court to disregard Defendants' witnesses, who steadfastly maintained throughout trial that a study report was intended to reference only a CSR,[217] because none of Defendants' witnesses actually participated in the Merger Agreement's negotiations.

While Plaintiffs' strategy of presenting negotiators makes perfect sense, the execution of the strategy requires consistency among the witnesses in order to deliver the desired result. That did not happen at trial. The inconsistencies were particularly conspicuous against the backdrop of the parties' stated goal of crafting "black and white" Milestone objectives that were beyond dispute.[218] Mr. Richman testified that he understood "study report" to mean *any* written document (an email, a memo, an article abstract) so long as it included "some data" from the clinical trial—even if that data concerned only one patient.[219] Dr. Spector—Amplimmune's

[216] *See* Tr. 148:23–150:18, 152:2–11 (Spector).

[217] *Id.* at 359:2–5 (Pedicano); *id.* at 574:18–576:2 (Bradley).

[218] *Id.* at 268:20–270:8 (Richman); *id.* at 569:16–570:9, 573:7–574:6 (Bradley).

[219] *Id.* at 274:15–275:15 (Richman).

lead negotiator—disagreed, identifying IBs as the only viable study reports.[220] Dr. Kabakoff's interpretation of "study report" landed somewhere between the two. His definition encompassed not only an IB but also any "report that presents the result of the study" and "that would contain sufficient data that it could be summarized in a report and it could go into a regulatory filing to FDA or a foreign regulatory body that would support additional clinical development."[221] The inconsistencies were not subtle and their impact was to diminish the credibility of each witness on the point.

Beyond their witnesses' inconsistent descriptions of the parties' intent, Plaintiffs offered evidence of drafting history and emails among MedImmune employees to support their broad construction of "study report."[222] Specifically, Plaintiffs point to the following:

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[220] *Id.* at 153:11–155:17 (Spector) (stating that "a memo describing the results" of a study would not qualify as a study report and replying "[y]es" when asked if he could not identify any study reports outside the 2016, 2017 and 2019 IBs).

[221] *Id.* at 398:2–23 (Kabakoff). Plaintiffs argue that the "fine distinctions" between their witnesses' testimony "misses the forest for the trees" because the witnesses testified to the same basic understanding of "study report." Pls.' Reply Post-Trial Br. at 24 n.4. I disagree. Mr. Richman's idea of a study report was clearly more expansive than the others. And Dr. Spector's ability to identify only IBs as study reports conflicts with Plaintiffs' argument that annual reports also meet that standard. When parties purportedly negotiate for "black and white" metrics by which to measure multi-million dollar earnout provisions, "fine distinctions" matter.

[222] *See* Pls.' Opening Post-Trial Br. at 53–60.

- The term "study report" is preceded by "a" not "the", evidencing the drafters' intent that "study report" would encompass multiple documents;[223]

- Past iterations of the Merger Agreement saw the drafters remove the qualifier "final" previously placed before "study report,"[224] signaling the parties' intent to allow other documents presenting trial data, such as IBs and Annual Reports, to satisfy the second prong's requirements;

- An email chain where two MedImmune employees refer to an Annual Report as a "study report";[225] and

- Prongs (i) and (iii) of the Milestone triggers both refer expressly to actions taken to support "additional" development.[226] Thus, "Successful Completion of a Phase 1 Study" concerns what is necessary to advance from Phase 1 to Phase 2. With this in mind, a "study report" should be understood to call for documentation of a drug's development from the beginning to support the additional clinical development referenced in the other prongs; IBs and annual reports do exactly that.

In response, Defendants argue that "study report" must be understood to mean CSR when one considers industry practice and usage as well as the context in which the term is used. In this regard, they note that the chosen determiner preceding "study report" ("a" vs. "the") is irrelevant because there can be more than one

[223] Pls.' Reply Post-Trial Br. at 29.

[224] JX 16.

[225] *See* JX 148; Tr. 853:17–854:18 (Morse).

[226] Merger Agreement § 1.1 at 15.

CSR.[227] And removal of the word "final" in the Merger Agreement's drafting history is likewise irrelevant given that the "final" CSR need not be submitted until after Phase 3 trials are completed, but the industry's (and MedImmune's internal) practice, both when the Merger Agreement was drafted and now, is to prepare a CSR upon the completion of each trial.[228] Thus, the drafters' removal of the word "final" merely reflects an intent to clarify that the second prong is satisfied by the completion of a CSR upon the conclusion of the Phase 1 study.

Although Plaintiffs note the drafters could have written "clinical study report" or "CSR" explicitly into the Merger Agreement, MedImmune's witnesses maintained that "study report" and "CSR" are "interchangeable terms."[229] As Dr. Pedicano explained, while the second prong "doesn't say 'clinical' in front of study report, . . . I can't think of anything else it would refer to."[230] Emails sent by MedImmune employees both before and after the contract's signing refer to a CSR when discussing the second prong's Milestone trigger, evidencing MedImmune's understanding that the second prong's "study report" means CSR.[231] Even

[227] Defs.' Post-Trial Br. at 34–36.

[228] Tr. 729:9–730:16 (Coats); JX 155 at 61–62.

[229] *Id.* at 304:4–10 (Pedicano).

[230] *Id.*

[231] JX 12 at 2 (internal MedImmune email from August 2013 discussing the milestone trigger as "completion of a final CSR"); JX 87 at 1–2 (internal MedImmune email from

Plaintiffs' expert, Dr. Spector, agreed "CSR" is a "study report" and that is "a widely understood term in the clinical industry . . . . [a]nd there's almost no one you could find anywhere that would think it was not a study report."[232]

Plaintiffs proffer another MedImmune email chain, where two MedImmune employees appear to use "study report" to refer to Annual Reports, as evidence supporting their construction.[233] Defendants respond that, at the time the emails were written, the MedImmune employees were preparing an AMP-514 IND annual report for the FDA, which concerns a molecule rather than an individual study.[234] Indeed, the subject of both IBs and Annual Reports generally is the specific molecule of interest, encompassing any studies where the molecule is being tested.[235] Defendants maintain that JX 148 does not relate to a "study report for such Phase 1 Study" because the second prong's language contemplates a report that addresses

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March 2016 inquiring about the date the "CSRs might be completed" in reference to milestone discussions). Plaintiffs claim that the former email in 2013 merely evidences that MedImmune negotiated down from "CSR" to "study report," but the latter email shows that MedImmune's equation of a CSR with study report persisted after the Merger Agreement was executed.

[232] Tr. 162:7–15 (Spector); *see also, e.g.*, *id.* at 169:8–9 (Spector); *id.* at 362:24–363:3 (Pedicano).

[233] *See* JX 148; Tr. 853:17–854:18 (Morse).

[234] Tr. 855:5–856:17 (Morse).

[235] *Id.* at 359:6–20 (Pedicano) (testifying that an IB's purpose is "not at all" the same as a CSR because an IB offers "information about the molecule"—not the study—and in fact is "a distillation of a lot of different research that's done.").

the study itself.[236] In other words, a "study report" is different than a report on a molecule under study.

After carefully considering all of the extrinsic evidence presented at trial, it is clear the overwhelming weight of that evidence reveals that no industry participant or deal party would reasonably understand the term "study report" to refer to an IB or annual report, much less an email or informal document describing a study. Dr. Bradley credibly testified that study reports and IBs are "totally different thing[s]."[237] Mr. Pedicano testified that industry participants do not refer to an IB as a "study report."[238] Even Dr. Spector—who testified (incredibly) that the negotiators intended study report to include an IB—could not recall ever having heard of an IB being referred to as a study report.[239] A single email chain among two employees referring to an annual report as a study report does not counter the substantial weight of extrinsic evidence speaking to the contrary collective understanding held by industry participants and deal parties.

Without sufficient evidence of industry usage or credible testimony as to the parties' contemporaneous understanding of the term, Plaintiffs are left to rely upon

[236] Defs.' Post-Trial Br. at 35 n.8.

[237] *Id.* at 574:18–576:2 (Bradley).

[238] *Id.* at 360:2–5 (Pedicano).

[239] *Id.* at 147:21–148:7 (Spector).

their structural argument that the prongs of "Successful Completion," read together, convey an intent to trigger Milestone payments once the Phase 1 study is functionally completed—that is, when the tested molecule progresses from Phase 1 to Phase 2. To be sure, if all prongs in fact were concerned only with functional completion, then that would lend some logical support for the contention that IBs and Annual Reports, which are drafted throughout a study's lifecycle, fall within the scope of the second prong.

While Plaintiffs' concept of functional completion finds no support in any FDA guidance or regulatory documents,[240] the text of the other two prongs does lend some superficial credence to their construction. The third prong is clearly concerned with functional advancement, as the parties agree it was satisfied when the Combination advanced from Phase 1 to Phase 1/2 upon the filing of Amendment 3.

Plaintiffs argue the first prong is likewise focused on completion as expressly stated in that provision.[241] But that is not all the first prong says. The express language 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."[242] Defendants argue the dependent clause "in accordance with the

[240] *See id.* at 116:10–118:2 (Spector).

[241] Pls.' Reply Post-Trial Br. at 26–28.

[242] Merger Agreement § 1.1 at 15 (emphasis added).

protocol" refers back to the preceding half of the sentence, which deals with the study's "completion," thereby incorporating by reference the Phase 1 Study protocol's definition of "study completion." The protocol in both the Monotherapy and Combination defines "study completion" as "the last protocol-specified visit/assessment (including telephone contact)."[243] Thus, Defendants argue, the second prong's "completion of a study report" corresponds to the "completion of such Phase 1 Study," which occurs upon the last patient's last visit.[244] The CSR is the only report completed at the end of the Phase 1 study.[245]

Plaintiffs' construction of the first prong cannot be reconciled with the clause "in accordance with the protocol." Under Plaintiffs' reading, the first prong is satisfied once the Phase 1 Study is completed "in a manner sufficient to support a regulatory filing." But that reading renders superfluous the clause "in accordance with the protocol," contrary to basic canons of contract construction.[246] If the "manner sufficient" language relates to the time at which the first prong is satisfied, as Plaintiffs claim, there would be no need to reference the protocol because "a

[243] JX 27 at 85; JX 34 at 104.

[244] Defs.' Post-Trial Br. at 29–30.

[245] Tr. 169:22–170:3 (Spector); *see also id.* at 163:11–170:4 (Spector); JX 155 at 61–62; Tr. 303:10–23 (Pedicano); *id.* at 574:7–17 (Bradley).

[246] *See NAMA Hldgs., LLC v. World Mkt. Ctr. Venture, LLC*, 948 A.2d 411, 419 (Del. Ch. 2007), *aff'd*, 945 A.2d 594 (Del. 2008).

manner sufficient to support a regulatory filing" necessarily implies compliance with the regulated protocol.

Defendants' construction, by contrast, imports a critical and unique meaning into the latter half of the first prong's sentence. When the first prong speaks to the "manner" in which the study is to be performed, it constrains the way in which the Phase 1 trial is to be conducted, not (as Plaintiffs suggest) the time at which the study is to be completed. In other words, the latter half of the first prong is conduct-oriented, ensuring that the Phase 1 study complies with regulatory requirements and best practices such that the Phase 1 results can inform the Combination's later stages of development. By giving effect to all parts of the first prong's language, Defendants offer the more reasonable construction of the first prong, which was satisfied "in accordance with the protocol."

Plaintiffs nonetheless maintain there is no basis to incorporate the study's protocol when attempting to discern the parties' broader intent.[247] First, they argue that Defendants' reading improperly elevates a definition in another document that postdated the Merger Agreement over the language of the contract.[248] Second, they argue that the vague reference to "the protocol" could address any aspect of the

[247] Pls.' Reply Post-Trial Br. at 27–28.

[248] *See Town of Cheswold v. Cent. Del. Bus. Park*, 188 A.3d 810, 819 (Del. 2018) ("To incorporate one document into another, an explicit manifestation of intent is required.").

protocol affecting how the study is completed, from dosing to data analysis.[249] The more specific language, they say, must therefore control.[250]

Neither argument is persuasive. As conditions precedent, all three prongs of "Successful Completion" contemplate actions and documents yet to be completed; those documents may nevertheless be incorporated by reference into a contract.[251] Moreover, a reasonable person would not understand the first prong's reference to the protocol to be vague. While the first prong of "Successful Completion" (like all the other prongs) could have been written more clearly, neither party disputes that "the protocol" references the Phase 1 trial's protocol. The dependent clause "in accordance with the protocol" immediately follows "completion of such Phase 1 Study." Thus, the text makes clear enough that the parties explicitly invoked the

[249] I note that Plaintiffs do not dispute whether the Agreement's reference to "the protocol" is vague as to the actual instrument; both parties agree that "the protocol" references the study's protocol. *See* Pls.' Reply Post-Trial Br. at 27–28.

[250] *See DCV Hldgs., Inc. v. Conagra, Inc.*, 889 A.2d 954, 961 (Del. 2005) (stating the "well-settled rule of contract construction" that "specific language in a contract controls over general language").

[251] 11 *Williston on Contracts* § 30:25 ("As long as the contract makes clear reference to the document and describes it in such terms that its identity may be ascertained beyond doubt, the *parties to a contract may incorporate contractual terms by reference to a separate, noncontemporaneous document*, including a separate agreement to which they are not parties, and including a separate document which is unsigned. It is not necessary to refer to or incorporate the entire document; if the parties so desire, they may incorporate a portion of the document.") (emphasis added).

protocol to define "completion" of that "Phase 1 Study." The protocol expressly defines "study completion" as, in effect, last patient/last visit.[252]

Moreover, Defendants' interpretation comports with the parties' stated intent to define "black and white" metrics by which to measure each prong's achievement.[253] The last patient's last visit is a definite date tracked for regulatory reporting purposes.[254] Witnesses and relevant regulatory filings stated the Combination's Phase 1 trial was "ongoing" until the last patient's last visit, contrary to Plaintiffs' contention that the first prong's "completion of Such Phase 1 Study" allowed for an earlier ending.[255] Indeed, Plaintiffs' construction leaves uncertain the final end date of the first prong. Dr. Spector acquiesced at trial that he could not "venture a guess as to when" the date of completion might occur under his definition.[256]

The persuasive evidence reveals that, consistent with the parties' intent to remove doubt regarding when the milestone payments were due, and when they were

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[252] JX 27 at 85; JX 34 at 104; Tr. 271:24–272:5 (Richman) (testifying that protocols would typically define "study completion" as last patient, last visit).

[253] Tr. 268:20–270:8 (Spector); Tr. at 568:4–570:9 (Bradley).

[254] *See, e.g.*, JX 164 at 5 (citing a regulation that defines "study completion date" as the date of the "last subject's last visit").

[255] *See* Tr. 717:14–20, 746:19–24 (Coats); (Gallagher) Dep. 102:23–104:6; JX 82 at 22–23; JX 110 at 12–13; JX 112 at 22–23; Tr. 113:14–116:2, 136:15–137:6 (Spector).

[256] Tr. 118:3–13 (Spector); *see also id.* 111:13–19 (Spector).

not due, Defendants' construction of "study report" is the only one that comports with that intent.[257] A CSR is a known quantity, and it is a document all parties knew would have to be "completed" with respect to the Phase 1 study.[258] On the other hand, pegging the obligation to pay a substantial milestone payment to the completion of any number of documents that fit within a litigation-driven construct of "reporting on the study" is hardly "black and white."[259]

Indeed, understanding a "study report" to mean CSR makes sense in view of the commercial relationship between the parties and the "real-world" context of drug development by pharmaceutical companies more broadly.[260] An early-stage molecule's successful development is uncertain. Pharmaceutical acquisitions often account for this uncertainty through milestone payments, which reward target companies as their acquired assets progress toward commercialization.[261] The

[257] Tr. 268:20–270:8 (Spector); *id.* at 568:4–570:9 (Bradley).

[258] Tr. 169:22–170:3 (Spector) (acknowledging that a CSR is "required to be prepared after a clinical trial is completed or terminated."); *id.* at 361:8–362:12 (Pedicano).

[259] Tr. 268:20–270:8 (Spector); *id.* at 568:4–570:9 (Bradley).

[260] *Chi. Bridge & Iron Co.*, 166 A.3d at 926–27.

[261] *See* Brian J.M. Quinn, *Putting Your Money Where Your Mouth Is: The Performance of Earnouts in Corporate Acquisitions*, 81 U. Cin. L. Rev. 127, 160–61 (2012) (observing that earnouts are likely more prevalent in industries such as the pharmaceutical industry where the value of the assets are not yet credibly conveyed to an acquirer.).

Merger Agreement effectuated that intent in the second prong by identifying as a milestone the completion of a definite and objective document: the CSR.[262]

After considering all of the credible evidence, I cannot conclude that Plaintiffs carried their burden of proving the Combination milestone payment was due prior to MedImmune's completion of the Phase 1 CSR. To review: No regulatory documents or definitions support Plaintiffs' equation of an IB, Annual Report or more informal documents to a study report. Plaintiffs' negotiator witnesses impugned each other's credibility by offering different understandings of what constituted a "study report" under the second prong, contrary to their stated goal of setting out clear metrics by which to measure each prong's achievement. Plaintiffs' structural argument fails because the first prong concerned itself not with functional completion (i.e., when the Combination could proceed from Phase 1 to Phase 2), but with study completion. Plaintiffs' only evidence that MedImmune understood a study report to mean an annual report was a single isolated and vague email chain among two employees. And, most important, Plaintiffs' interpretation of "study report" as a moving target is directly contrary to the parties' intent to effectuate precision in the determination of when milestone consideration was due.

[262] Tr. 729:9–730:16 (Coats); JX 155 at 61–62.

This holding does not, as Plaintiffs suggest, contravene a "basic canon of contract interpretation" that contract terms should not be interpreted in such a manner "that would lead to an absurd result."[263] Contrary to Plaintiffs' expostulation, Defendants could not unreasonably delay their completion of a CSR in order to delay payment of the Combination milestone without exposing themselves to liability for breach of the Merger Agreement's "Commercially Reasonable Efforts" provision.[264] That provision works hand in glove with the milestone provisions to ensure that MedImmune does not unreasonably frustrate Plaintiffs' rights to milestone consideration.[265]

2. Plaintiffs Did Not Prove a Breach of the Combination Milestone

The preponderance of the evidence reveals that the three prongs of "Successful Completion" were satisfied on the following dates:

- The first prong of "Successful Completion" for the Combination was achieved in March 2019 after the last patient's last visit for the Combination's Phase 1 trial.[266]

[263] *Kan-Di-Ki, LLC v. Suer*, 2015 WL 4503210, at *24, n.251 (Del. Ch. July 22, 2015).

[264] *See* Merger Agreement at § 9.2(b)(ii).

[265] Of course, Plaintiffs did not claim or present any credible evidence that MedImmune had unreasonably delayed in the preparation of the CSR.

[266] Tr. 746:19–24 (Coats).

- The second prong of "Successful Completion" for the Combination was achieved on March 31, 2020, upon submission of the CSR for the Combination Trial.[267]

- The third prong of "Successful Completion" for the Combination was achieved in February 2016 with the filing of Amendment 3 to the Combination Trial protocol.[268]

Because the Merger Agreement requires all three prongs of "Successful Completion" to be met before a Milestone Payment is due, the First Combination Milestone Payment was not due until March 31, 2020. Defendants timely made that Milestone Payment.

III. CONCLUSION

For the reasons stated above, judgment will be entered for Defendants on all claims. Defendants shall present a form of final judgment, on notice to Plaintiffs, within ten (10) days.

[267] Defendants presented unrebutted testimony establishing that Defendants' policy is to prepare a CSR within twelve months of a study's completion. *See* Tr. 729:9–21 (Coats).

[268] *See, e.g.*, JX 106 at 10.