IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

SHAREHOLDER REPRESENTATIVE SERVICES LLC solely in its capacity as representative of the Securityholders,	)	
Plaintiff,	)	
v.	)	C.A. No. 2020-1069-MTZ
ALEXION PHARMACEUTICALS, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

Date Submitted: January 12, 2024
Date Decided: September 5, 2024

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ZURN, Vice Chancellor.

This case is about the acquisition, development, and eventual termination of research into a monoclonal antibody known first as SYNT001, and then ALXN1830. Nonparty Syntimmune, Inc. began developing SYNT001 in 2013. Defendant Alexion Pharmaceuticals, Inc. ("Alexion") acquired Syntimmune in November 2018, optimistic about SYNT001's therapeutic and commercial success. The merger agreement designated plaintiff Shareholder Representative Services, LLC ("SRS") as the former Syntimmune stockholders' representative.

The merger agreement provided for a purchase price of $1.2 billion. Of that amount, $400 million was to be paid upfront, and $800 million would be paid in installments upon the completion of each of eight milestones.[1] Milestone 1, at issue in this case, provided for a $130 million payment upon the completion of a successful Phase 1 Clinical Study, as defined by the agreement. The agreement required Alexion to use commercially reasonable efforts to achieve each milestone for seven years after closing. The agreement defined those efforts with an outward-facing metric, as Alexion's efforts would be measured by what a similarly situated company would do.

As of closing, Alexion intended to pursue treatments for three conditions, known as indications. At least four competitors were developing therapies similar

[1] For simplicity, I refer to individual milestones in the form "Milestone #."

to ALXN1830 during the relevant period. Alexion believed it could distinguish ALXN1830 by being first to treat a specified indication through intravenous administration. Alexion hoped to develop a subcutaneous means of administration, which patients would prefer over intravenous administration. Alexion also hoped clinical testing would reveal that ALXN1830 could be differentiated from its competitors.

But the ALXN1830 program began hitting hurdle after hurdle. First, by early 2020 it was clear that the bulk of Alexion's clinical drug supply was contaminated and could not be used. And it would be some time before Alexion could create more. With only a limited supply left, Alexion paused two ongoing Phase 1 trials and allocated its supply to two trials ongoing in the United Kingdom.

The same month, the first cases of the COVID-19 virus emerged in the UK. The third party administering the studies halted dosing, and Alexion could do nothing about it. For a time, Alexion pushed forward with its plans to conduct a Phase 2 clinical trial in patients in the United States. But the pandemic worsened, and Alexion determined it was not safe to proceed. Alexion decided to pause the study. At this point, Alexion had no ongoing clinical trials. Its competitors were able to continue with trials.

In April 2020, Alexion prioritized programs that were part of an initiative it referred to as "10 by 2023"—an externally announced goal of launching ten products

by 2023 to demonstrate value to investors. In doing so, Alexion reallocated a significant portion of the ALXN1830 program's funds to other programs. Though funding was not completely removed, the deprioritization meant that when Alexion had the clinical supply and willingness to resume studies in September 2020, it was not prepared to do so. The ALXN1830 program continued to fall further behind its competitors.

Alexion was unfazed by its lack of progress relative to its competitors and remained resolute that ALXN1830's development would continue. It began dosing in a Phase 1 trial in healthy volunteers called HV-108, which is at the heart of this case. It planned Phase 2 studies in two indications, even though it was clear ALXN1830 would be the fifth drug of its type to treat one of them and the third to treat the other—Alexion's hopes of being first to market in those indications had disappeared. Alexion's only hope was to differentiate ALXN1830, and it was optimistic it could do just that. It even identified two new indications to start pursuing.

But in July 2021, Alexion was acquired by AstraZeneca plc, a much larger pharmaceutical company. AstraZeneca promised $500 million in recurring synergies in connection with the acquisition, and it was Alexion's job to deliver. Every program at Alexion fell under review, including ALXN1830. From that moment, the company's tone on the ALXN1830 program changed. Within three

weeks, it paused one of the Phase 2 studies, which was on track to dose its first patient the following week.

In August 2021, the HV-108 study was paused due to a COVID outbreak. In mid-September, Alexon received preliminary HV-108 data. That data would take on great importance in assessing the ALXN1830 program, and its interpretation was a bellwether for perspectives on the program within Alexion. While the data reflected attributes typical of drugs like ALXN1830 and which had appeared in ALXN1830 data previously, Alexion began characterizing that data as new and unexpected. ALXN1830's safety and commercial viability began to be questioned, and the remaining ALXN1830 indications were at risk of termination. Despite those doubts, a safety committee gave the green light to resume dosing in HV-108.

Less than a week after the safety committee's green light, data suggested that the death of a primate in an ongoing ALXN1830 toxicology study could reflect that ALXN1830 was unsafe in humans. HV-108 was again paused. An AstraZeneca immunology expert and an external expert both opined that the HV-108 data did not reflect any safety concerns, and it was confirmed the primate death did not reflect that ALXN1830 might be unsafe.

But Alexion had made up its mind. In December, it officially terminated the program. It cited the HV-108 data and its implications as the primary driver.

SRS filed this action asserting claims for breach of the merger agreement. Its first claim asserts the HV-108 data reflected that Milestone 1 was satisfied, but Alexion failed to pay. Achievement of Milestone 1 is determined by the satisfaction of five criteria,[2] two of which are in dispute. After resolving disputes over the interpretation of those criteria and whether the HV-108 data reflect they were met, I conclude SRS met its burden and award damages in the amount of $130 million.

SRS's second claim asserts Alexion failed to use commercially reasonable efforts to achieve the remaining milestones. Under the merger agreement's outward-facing metric, the parties offered evidence of ALXN1830's commercial viability, informed by considerations including safety, efficacy, and likelihood of regulatory approval, which in turn are informed by the HV-108 data. I conclude Alexion breached the merger agreement's requirement to use commercially reasonable efforts by terminating the ALXN1830 program in December.

The damages for Alexion's breach will be addressed in a second opinion to follow. So will Alexion's counterclaim based on the problems with the drug supply it received from Syntimmune.

[2] Again for simplicity, I refer to the criteria in the form "Criterion #."

I. BACKGROUND[3]

This decision follows a seven day-trial. SRS bore the burden of proving its claims by a preponderance of the evidence.[4] The following constitute my findings of fact. I begin with primers on autoimmune therapies and drug development, followed by a note on the treatment of fact witness testimony based on the witness's specialized knowledge of those subjects.

A. Overview of Autoimmune Therapies

The human body produces antibodies when exposed to pathogens to block the pathogens and prevent disease.[5] The most common type of efficacious antibody is IgG.[6] FcRn is a protein that keeps IgG antibodies in the bloodstream for longer,

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[3] The trial record includes over 3,400 exhibits. As is typical, the parties elicited testimony on a subset of those exhibits. At times in this decision, I cite to exhibits that were not discussed at trial, and in some cases, not cited in post-trial briefing. Where I do so, I give appropriate weight to such exhibits keeping in mind the possible lack of complete context.

Citations in the form "[last name] Tr. –" refer to trial testimony of the referenced witness, available at docket item ("D.I.") 348, D.I. 349, D.I. 350, D.I. 351, D.I. 352, D.I. 353, and D.I. 354. Citations in the form "SRS Op. Br." refer to SRS's post-trial opening brief, available at D.I. 364. Citations in the form "ALXN Op. Br." refer to Alexion's amended opening post-trial brief, available at D.I. 369. Citations in the form "SRS Ans. Br." refer to SRS's post-trial answering brief, available at D.I. 370. Citations in the form "ALXN Ans. Br." refer to Alexion's post-trial answering brief, available at D.I. 371.

[4] *Zimmerman v. Crothall*, 62 A.3d 676, 691 (Del. Ch. 2013) ("As the party seeking enforcement of his interpretation of the [operating agreement], [the plaintiff] bears the burden to prove his breach of contract claim by a preponderance of the evidence.").

[5] *See* Kinch Tr. 226; JX 2498 ¶ 30 ("The primary function of antibodies is to elicit immunity by binding to foreign antigens, kill invading pathogens, and prevent infections from spreading to other parts of the body.").

[6] JX 2498 ¶ 31; *see also* Kinch Tr. 227 (explaining IgG "tends to be particularly efficacious in blocking . . . pathogens that might be considered threats by the body").

resulting in higher total numbers of IgG antibodies.[7] Higher levels of FcRn help the human body to fight pathogens more effectively.[8]

Some people develop autoimmune diseases.[9] In the case of an IgG autoimmune disease, IgG "goes from friend to foe" and attacks healthy cells.[10] Such conditions are rare, but can range from life-altering to fatal.[11] For those with IgG autoimmune disorders, the resulting higher IgG levels are harmful.[12]

One class of therapies for IgG autoimmune diseases is known as anti-FcRn treatments, which include humanized monoclonal antibodies.[13] These monoclonal antibodies bind with FcRn, making it unavailable to bind with, and extend the half-life of, IgG.[14] This reduces the amount of IgG in circulation, lessening the damage to healthy cells.[15] Anti-FcRns are increasingly being explored as a way to treat IgG autoimmune conditions.[16]

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[7] *See* JX 2498 ¶¶ 36–37; Kinch Tr. 228.

[8] *See* Kinch Tr. 227–28.

[9] *Id.* at 227.

[10] *Id.*

[11] D.I. 319 ¶ 30; *see* Hall Tr. 14.

[12] JX 2498 ¶ 41.

[13] *Id.* at ¶¶ 11, 43.

[14] *Id.* at ¶¶ 41, 43–44.

[15] *Id.* at ¶ 43.

[16] *Id.* at ¶ 44.

The autoimmune conditions targeted by anti-FcRn therapies include warm autoimmune hemolytic anemia ("WAIHA"), pemphigus vulgaris ("PV"), and generalized myasthenia gravis ("gMG").[17] These conditions and others targeted by anti-FcRns are rare[18] and chronic.[19] For example, as of 2018, about 19,000 people in the United States had a PV diagnosis.[20] Many of these conditions feature a high unmet need for effective therapies.[21]

Anti-FcRn therapies are potentially very lucrative, and, as early as 2014, the emerging anti-FcRn drug class was expected to generate substantial revenue.[22] Expectations only grew with time, with one analyst noting in 2018 that an estimated $20 billion market for anti-FcRns "could be conservative."[23]

[17] *Id.* at ¶ 42. It is my understanding there are different ways of writing many of the acronyms used in this decision. For example, WAIHA is sometimes written "wAIHA." *E.g.*, *id.* Where the parties embrace the same spelling, I have adopted their convention. Where the parties employ different spellings, I have chosen one, perhaps arbitrarily.

[18] Hall Tr. 12–13.

[19] Sarin Tr. 939.

[20] JX 2923 at 23.

[21] *See, e.g.*, Russell Tr. 689–90.

[22] JX 76 at 9 (explaining anti-FcRn drugs "are expected to generate $1.5-2.2 billion in 2018 combined sales").

[23] *See, e.g.*, JX 655 at 1.

B. Overview Of Drug Development

Bringing a drug to market is an expensive and lengthy process. Generally, it occurs over four phases.[24] First is the discovery and research phase, which culminates in the "selection of [a] candidate antibody for clinical testing."[25] Syntimmune completed this phase by selecting the molecule that would become ALXN1830.

Second is the development phase.[26] This phase comprises two stages: a preclinical stage and a clinical stage.[27] The preclinical stage entails the development of the drug formulation that will be used during the clinical stage.[28] "Formulation" refers to the method of delivery, and can include delivery "intravenously (i.e., into a vein), intramuscularly (i.e., into a muscle), or subcutaneously (i.e., under the skin)."[29] The intravenous and subcutaneous formulations receive extensive focus throughout this decision, and I refer to them as "IV" and "SC," respectively. The preclinical stage can also involve testing the drug *in vitro* (in a laboratory setting, for

[24] JX 2498 ¶ 46.

[25] *Id.* at ¶ 46(i).

[26] *Id.* at ¶ 46(ii).

[27] *Id.*; JX 2507 ¶ 50.

[28] JX 2498 ¶ 50.

[29] *Id.*

instance, examining cells in a test tube) and *in vivo* (in animals).[30] One goal of *in vivo* testing is to obtain toxicology data.[31]

The clinical phase involves administering a chosen formulation to humans "to test for both efficacy and safety."[32] Efficacy refers to the ability of the drug to accomplish its purpose—here, by lowering IgG.[33] Safety refers to the possibility that the drug will cause adverse health effects.

In clinical trials, safety is determined in part by the occurrence of negative side effects called adverse events.[34] There are five grades of adverse events.[35] Grades 1 or 2 adverse events are mild or moderate and can include headaches and rashes.[36] They can generally be treated with over-the-counter medication.[37] For purposes of this decision, Grade 1 and 2 adverse events will not influence the progression of an anti-FcRn clinical trial or the development of a therapy. Grade 3 to 5 adverse events are severe and denote conditions that require hospitalization or,

[30] *Id.* at ¶¶ 72–73.

[31] JX 2498 ¶¶ 72, 74(iii).

[32] *Id.* at ¶ 46(ii).

[33] *See id.* at ¶ 45 (identifying ALXN1830 as a humanized IgG antibody).

[34] Kinch Tr. 242–43.

[35] *Id.* at 243.

[36] Ledwith Tr. 1037.

[37] Kinch Tr. 271; Harvey Tr. 1713; *see also* Ledwith Tr. 1037; Hall Tr. 42.

in the case of a Grade 5 event, include death.[38] An adverse event is a "serious adverse event" ("SAE") if it is Grade 3 or higher.[39] The occurrence of an SAE is noteworthy.

Safety and efficacy can also be informed by data. Clinical investigators can see signs of potential safety problems before the occurrence of an adverse event. They monitor pharmacokinetics ("PK"), or the way the drug moves into, through, and out of the body.[40] Clinical investigators also look at pharmacodynamics ("PD"), which is the effect the drug has on the body.[41] Here, PK is measured by the drug's concentration in the body, and PD is measured by IgG lowering.[42]

When a drug is administered, the human body works to remove it.[43] There has to be a minimum level of the drug in the patient's body for it to be effective.[44] In the case of ALXN1830, the minimum effective concentration is established through the observation of IgG lowering.[45]

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[38] Kinch Tr. 243–44; *see also* Ledwith Tr. 1037; Hall Tr. 43.

[39] Kinch Tr. 243–44.

[40] *Id.* at 429; JX 2498 ¶ 71.

[41] *See* Kinch Tr. 429–30.

[42] *Id.* at 430.

[43] *See id.* at 258–59 (describing clearance rate).

[44] *Id.*; Robbins Tr. 552.

[45] *See* Kinch Tr. 259.

But if the level of drug gets too high, it can cause adverse health consequences.[46] One sign of a potential safety problem is unexplained drug accumulation.[47] Drug accumulation is the phenomenon of a drug building up (i.e., PK increasing) in the human body.[48] The range between the minimum effective level of drug concentration and the point at which the level of drug becomes toxic is known as the therapeutic window.[49] The therapeutic window cannot be known until it is established through clinical trials.[50] The minimum toxic concentration is established by the observation of adverse events.[51] An SAE indicates that the concentration is approaching the minimum toxic concentration.[52] Ideally, the drug will reach a concentration that remains stable over time, known as a steady state.[53]

For anti-FcRns, investigators look for signs that the body is mounting an immune response against the drug itself, particularly one that neutralizes or binds the drug. Immunogenicity "is the likelihood that a study drug will elicit an antibody

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[46] *Id.* at 258–60.

[47] *Id.* at 260 ("Q. Is it hypothetically possible for drug accumulation to lead to safety concerns? A. Oh, absolutely.").

[48] *Id.* at 253.

[49] *Id.* at 258–59; Jagannathan Tr. 1277.

[50] Kinch Tr. 260; *see also* Jagannathan Tr. 1290.

[51] Kinch Tr. 260.

[52] *Id.*

[53] Jagannathan Tr. 1280; Robbins Tr. 553, 2068.

response by the person being injected" through the creation of antidrug antibodies ("ADAs").[54] Because "ADAs, in certain cases, can limit the efficacy of a therapeutic product or trigger adverse events following the administration of the drug, pre-clinical and clinical studies monitor the incidence of ADA response rates throughout treatments."[55] All or nearly all monoclonal antibodies generate an ADA response.[56] The presence of ADAs does not present a safety concern per se.[57] Neutralizing antibodies ("nAbs") "are a subset of ADAs."[58] nAbs "block the pharmacological function and profile" of the drug, which can "reduce the therapeutic effect of the drug, leading to the need for increased dosing."[59]

Investigators look for nAbs because they can contribute to drug accumulation. A drug can accumulate in three forms: free drug, meaning the drug is still capable of binding with FcRn; partially bound, which means the drug's ability to bind with FcRn is reduced; and bound, which means the drug is incapable of binding with

[54] Kinch Tr. 248–49 (noting immunogenicity is also "a general term to indicate the likelihood that a particular molecule will be recognized by the immune system"); *see also* JX 2543 ¶ 39 ("Immunogenicity is frequently presented in the form of anti-drug antibodies, or ADAs. ADAs are antibodies that are produced by the human body in response to the introduction of a drug.").

[55] JX 2498 ¶ 71(ii) (footnote omitted).

[56] *See* Kinch Tr. 249.

[57] *Id.*

[58] JX 2543 ¶ 40.

[59] *Id.*

FcRn.[60] A drug becomes partially or fully bound when one or more nAbs bind with it.[61]

The clinical stage of development plays an outsized role in this case. Typically, a drug progresses through three phases of clinical trials.[62]

1. Phase 1 Clinical Trials

Phase 1 clinical trials are typically the first time the drug is administered to humans.[63] These trials are generally conducted with healthy volunteers.[64] The primary goal of a Phase 1 trial is to determine whether the drug is safe.[65] Safety is determined in part based on the occurrence of adverse events.[66] When possible, companies also look for evidence of efficacy in Phase 1 studies.[67]

Not all subjects in a clinical study receive the same dose of a drug. Rather, the pool of subjects is divided into cohorts, and each cohort receives a different dose.[68] Relevant here, there are two models of dosing cohorts. The first is a single

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[60] Jagannathan Tr. 1300–01.

[61] JX 2543 ¶ 40.

[62] JX 2498 ¶ 51. There are exceptions, which are discussed below.

[63] Kinch Tr. 242.

[64] JX 2498 ¶ 53.

[65] Kinch Tr. 242.

[66] *Id.* at 242–43.

[67] *Id.* at 244.

[68] *Cf. id.* at 275–77 (describing dosing levels of cohorts in a study of ALXN1830).

ascending dose, or "SAD" model. Under this model, the first cohort will receive the lowest dose in the study.[69] If there are no adverse safety signals, the next cohort will be dosed, and so on.[70] Subjects in a Phase 1 study are dosed once.[71]

The second is a multiple ascending dose, or "MAD" model. A MAD cohort will receive multiple doses of the same volume of a drug over a period of time.[72] Here, that is typically over a number of weeks.

2. Phase 2 Clinical Trials

Phase 2 studies are generally larger than Phase 1 studies and enroll patients with a specified condition as opposed to healthy volunteers.[73] From this point on, the clinical development process must focus on a specific indication.[74] Syntimmune first targeted PV; later development efforts would center on gMG, WAIHA, and others.

Like Phase 1 trials, Phase 2 trials focus primarily on safety.[75] In addition, the investigator in charge of the study seeks "evidence that the drug is efficacious,"

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[69] *See* JX 2498 ¶ 54; JX 0194 at 3 (describing methodology of a particular SAD trial).

[70] *See* JX 0194 at 3.

[71] *See* JX 2498 ¶ 54.

[72] *See id.*; JX 1142 at 2 (describing methodology of a particular MAD trial).

[73] JX 2498 ¶¶ 58–59.

[74] *Id.* at ¶ 59.

[75] Kinch Tr. 245.

meaning it is having its intended effect in that patient population.[76] Another goal of Phase 2 trials is to determine the dosage that will be used at the Phase 3 trial.[77]

3. Phase 3 Trials, Approval, And Marketing

The final clinical trial is a Phase 3 trial. The goal of a Phase 3 trial "is generally to generate sufficient information that the regulator will be convinced that U.S. marketing should be allowed."[78] After a Phase 3 trial concludes, the company submits the drug to the relevant regulatory body for approval.[79] If the drug is approved, it can be manufactured, marketed, and sold.[80]

Regulatory approval does not guarantee commercial success: the drug has to be competitive in the marketplace. One way to compete is being first to market in an indication.[81] If a drug is first to an indication, physicians have the opportunity to gain experience and comfort prescribing it, which helps give the drug some staying power.[82]

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[76] *Id.*

[77] *Id.* at 245–46.

[78] *Id.* at 246–47.

[79] *Id.* at 247; JX 2498 ¶ 46(iii).

[80] JX 2498 ¶ 46(iv).

[81] *See* Russell Tr. 733; Jagannathan Tr. 1329–30; Bahl Tr. 1743–45; *see also* Sarin Tr. 936.

[82] *See* Jagannathan Tr. 1329; JX 2501 ¶ 105–06 (explaining that first entrants retain a disproportionate market share due to a variety of factors).

4. Commercial Viability

Another way to compete is through differentiation.[83] Differentiation refers to having positive features that distinguish the drug from competitors to capture market share. When new therapies come to market, physicians "compare the relative benefits to the relative" downsides and "determine whether it's worth replacing [the] existing therapeutic."[84] At a high level, physicians look at three factors: efficacy, safety, and patient preference.[85]

Patient preference denotes exactly that: the therapy the patient prefers.[86] For example, patients generally prefer SC administration to IV administration.[87] IV administration requires a patient to drive to an infusion center, prepare to receive the infusion, and receive the infusion, which alone can take forty-five to ninety minutes.[88] By contrast, an SC dose can be self-administered at home.[89]

There are different ways to administer an SC dose that can make it more appealing to patients and therefore increase the drug's competitiveness. There are a

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[83] *See* JX 2501 ¶ 107 (explaining that companies can turn late-mover status into an opportunity through differentiation); *see also* Bahl Tr. 1730.

[84] Jagannathan Tr. 1329.

[85] *Id.* at 1330–32.

[86] *Id.* at 1331–32.

[87] *Id.*

[88] Borboroglu Tr. 1412–13.

[89] *See* Sarin Tr. 939–40; Borboroglu Tr. 1412; Jagannathan Tr. 1331.

few forms of SC delivery, including a syringe, auto injector, an SC pump, and an on-body device.[90] The syringe and auto injector could deliver only a relatively small dose volume, and so they were never a viable option for ALXN1830.[91] Alexion was focused on the SC pump and an on-body device.[92] An SC pump is "a pretty large" tabletop system.[93] The patient must sit still while the drug is administered, for a period of anywhere from ten to forty-five minutes.[94] Alexion found that preparation to deliver the dose through the pump was "too complex" for patients, making it less desirable.[95]

The second option Alexion considered was an on-body device.[96] The device would be "about the size of an iPhone or maybe a little bit bigger."[97] It adheres to the patient's skin, allowing them to move around while the drug is being administered.[98]

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[90] *See* Jagannathan Tr. 1331–32; Borboroglu Tr. 1411–12.

[91] Borboroglu Tr. 1410; Jagannathan Tr. 1331–32.

[92] *See* Borboroglu Tr. 1412; *see also* JX 2507 at 14.

[93] Borboroglu Tr. 1413.

[94] *Id.*; *see* JX 1745 at 8.

[95] JX 1745 at 9.

[96] *Id.*

[97] Borboroglu Tr. 1411–12.

[98] *Id.* at 1412.

Another factor that affects competitiveness is the product's label. The FDA provides a label to each drug it approves, which "is guidance to the physician who is thinking of prescribing the drug."[99] The information appearing on the label can include the ADA rate[100] and the occurrence of drug accumulation in a clinical trial.[101] To be sure, the FDA provides "guidance to clinicians . . . to consider that ADA rates are not directly comparable across labels."[102]

C. Fact Witness Opinion Testimony Based On Specialized Knowledge

With the aid of those primers, I will proceed to set forth my findings of fact. But first I must address some thorny evidentiary issues presented, perhaps predictably, by the specialized knowledge set forth in those primers and the lay witnesses called to testify about ALXN1830's progress and prognosis.

Under Delaware Rule of Evidence 701, a lay witness may offer opinion testimony that is "rationally based on the witness's perception," but "not based on scientific, technical, or other specialized knowledge within the scope of Rule 702."[103] That requirement was added in 2000 to "ensure[] that evidence qualifying

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[99] *See* Kinch Tr. 311–12; Robbins Tr. 612 ("Physicians utilize drug labels in determining which products they would like to use for their patients.").

[100] *See, e.g.*, Robbins Tr. 627.

[101] Harvey Tr. 1690.

[102] Jagannathan Tr. 1367–68.

[103] D.R.E. 701.

as expert testimony under Rule 702 will not evade the reliability scrutiny mandated by the Supreme Court's *Daubert* decision and the 2000 amendment to Rule 7."[104] Of course, a lay witness can offer factual descriptions of his personal observations.[105] From there, a lay witness can offer his opinion as long as a foundation is laid "that the witness'[s] testimony is rationally based on his own perception of and personal experience with the substance and not on scientific, technical or other specialized knowledge."[106] The witness's knowledge must be "accessible to ordinary persons"[107] or within "the realm of common experience."[108]

Alexion frequently cites and relies on the opinion testimony of lay witnesses to support its arguments as to topics including the proper interpretation of clinical data, the potential causes of drug accumulation observed during clinical trials,

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[104] 4 Weinstein's Federal Evidence § 701.03[4][b] at 701-39 (2d ed. Nov. 2022); *see also* D.R.E. 701 cmt. ("D.R.E. 701 tracks F.R.E. 701 in effect on December 31, 2000.").

[105] *Lamere v. N.Y. State Off. for the Aging*, 2004 WL 1592669, at *2 (N.D.N.Y. July 14, 2004); *Lundgren v. Matrixx Initiatives, Inc*., 2013 WL 3087726, at *2 n.3 (D. Utah June 18, 2013); *Pete v. Youngblood*, 2006 UT App 303, ¶¶ 13–14, 141 P.3d 629.

[106] *Campbell v. State*, 974 A.2d 156, 168–69 (Del. 2009); *accord Wright v. State*, 953 A.2d 188, 194–95 (Del. 2008) (concluding a lay witness "with familiarity and experience with the drug in question" could testify "he had bagged what he believed was cocaine based on its appearance, smell, and his two years of experience as a cocaine dealer"); *Norman v. State*, 968 A.2d 27, 31 (Del. 2009) (explaining that lay opinions on the identity of drugs can be offered so long as the opinion is not based on "training and [] specialized experience").

[107] *United States v. Jones*, 739 F.3d 364, 369 (7th Cir. 2014).

[108] *Montoya v. Sheldon*, 286 F.R.D. 602, 619–20 (D.N.M. 2012); *accord In re Appraisal of Dole Food Co., Inc.*, 114 A.3d 541, 553 (Del. Ch. 2014) (contrasting "rare disciplines" against "common skill").

immunogenicity, and the likelihood a monoclonal antibody will obtain FDA approval based on clinical data. As a general matter, those topics fall within the exclusive province of Rule 702.[109] And for much of the opinion testimony at issue, Alexion elicited no testimony establishing those witnesses have or could have any personal knowledge of the matter in question.

I will offer a couple discrete examples. Alexion elicited testimony from two lay employees, Brian Ledwith (Alexion's global medicine team lead for ALXN1830)[110] and Gialuca Pirozzi (Alexion's head of development, regulatory, and safety),[111] that immunogenicity data based on a multidose cohort was meaningfully more reliable or offered meaningfully more information than data from earlier single-dose studies.[112] This is opinion testimony that should be given exclusively by experts. Neither Ledwith nor Pirozzi was qualified as an expert. I could consider their testimony to the extent it credibly reflects the witness's contemporaneous views on the matter. Ledwith did not take part in the events relevant to this issue, so his

[109] 3 Christopher B. Mueller & Laird C. Kirkpatrick, Federal Evidence § 7:6 (4th ed. 2023) ("When testimony reflects expertise, whether based formally on something that everyone would call 'science' (such as chemistry) or based instead on something that few would term 'science' (such as the experience of a perfume tester), such testimony must satisfy the standards of Rule 702 and *Daubert*."); *Dole Food*, 114 A.3d at 553 (describing "rare disciplines like nuclear physics, brain surgery, or accident reconstruction").

[110] Ledwith Tr. 1035.

[111] Pirozzi Tr. 1434.

[112] ALXN Ans. Br. 23–24 (citing Pirozzi Tr. 1470–71; Ledwith Tr. 1092).

testimony cannot express any such contemporaneous views. While Pirozzi was directly involved, his testimony speaks in general terms, not to his personal and contemporaneous understanding of the data.[113] And as opinion evidence, it was also too vague to be helpful. He testified that one has to look at multiple dose data if "you truly want to understand immunogenicity," and that single dose data is "less meaningful."[114] But Pirozzi did not say he thought the single dose data was inaccurate, and he stopped far short of testifying that the single dose immunogenicity data was not at all informative on that question.[115]

As another example, Dr. Martine Zimmermann, Alexion's global head of regulatory affairs, R&D, and commercial quality,[116] gave her opinion as to the likelihood ALXN1830 would be approved by regulators.[117] But the record does not establish that Zimmermann, a fact witness, would have personal and unspecialized knowledge supporting her prediction. The trial transcript speaks generally to Zimmermann's credentials: she is a "doctor in pharmacy"; she "worked as a lab scientist" after receiving her doctorate; she eventually stopped working as a lab

[113] *See* Pirozzi Tr. 1470 ("[I]f you want to understand immunogenicity, you need to look at multiple doses over time, especially for a drug which is meant to be given chronically.").

[114] *Id.* at 1471.

[115] *See id.* at 1501.

[116] Zimmermann Tr. 1232.

[117] *Id.* at 1243.

scientist at an unknown time; as her next job after leaving her position as a lab scientist she "did regulatory affairs" at "a company called Aventis Pharmaceuticals"; she eventually left Aventis but "continued working in regulatory affairs"; she joined Alexion in 2009, where she remained through 2023; her "role at Alexion was regulatory affairs"; her job title was "global head of regulatory affairs, R&D, and commercial quality"; in that role she "overs[aw] the regulatory strategy of the entire Alexion portfolio," approximately 180 people reported to her, and she has "overseen" "programs" in her career; and she was involved with ALXN1830 from the time of the Syntimmune acquisition through 2021.[118] But the record is silent on Zimmermann's actual role in terminating ALXN1830 or determining its likelihood of regulatory approval. It is reasonable to infer from her involvement in "regulatory affairs" and her title at Alexion that she has some knowledge of the regulatory process, and I make that inference here. But there is no basis from which I can deduce the extent of her knowledge on the relevant topics.

As is typical in Chancery practice, I afford lay opinion testimony the weight it deserves rather than excluding it.[119] Rules 701 and 702 serve as helpful guideposts in deciding how much weight to give. Where the testimony plausibly refers to either

[118] *Id.* at 1231–33.

[119] *Murphy Marine Servs. of Del., Inc. v. GT USA Wilm., LLC*, 2022 WL 4296495, at *21 n.221 (Del. Ch. Sept. 19, 2022) (declining to exclude testimony that was improper under the Delaware Rules of Evidence and instead "giv[ing] it the appropriate weight").

the witness's personal perception or contemporaneous thoughts on the matter at issue, as opposed to opinion testimony, I considered it as a statement of personal knowledge.

D. SYNT001's Early Clinical Data

Our story starts in 2013, when Syntimmune was founded.[120] Since its inception, it was developing SYNT001, a humanized monoclonal antibody[121] and anti-FcRn. At least four other companies would try their hand at developing anti-FcRn therapies, including Argenx, Immunovant, Momenta, and UCB.

In August of 2016, Syntimmune opened its first clinical trial of SYNT001, called "SYNT-101."[122] It was a Phase 1 study of the IV formulation in healthy volunteers.[123] The study concluded in April of 2017.[124] The results were promising: the dose of SYNT001 was "well tolerated" and the data showed that "[p]roof-of-concept for SYNT001 was demonstrated for the lowering of levels of total IgG."[125] Syntimmune pushed forward with development.

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[120] D.I. 155 ¶ 22.

[121] *Id.* at ¶ 3.

[122] JX 194 at 1. The formal nomenclature for SYNT001 studies Syntimmune initiated is "SYNT001-###." The parties and witnesses referred to the studies as SYNT-###. With the understanding that all relevant studies were of the SYNT001 molecule, I adopt the shorter nomenclature.

[123] *Id.* at 2.

[124] *Id.* at 1.

[125] *Id.* at 80.

By early 2018, Syntimmune had opened two more trials: SYNT-102 and SYNT-103.[126] SYNT-102 studied the IV formulation in patients with WAIHA, and SYNT-103 studied the IV formulation in patients with PV.[127] Both were Phase 1B/2A studies.[128] Phase 1B/2A studies are a hybrid of Phase 1 and Phase 2 studies: they seek to establish proof of concept in patients while testing the safety of dosing through a MAD protocol.[129] But unlike Phase 2 studies, they generally do not establish the dose that would be used during a Phase 3 clinical trial.[130]

E. Alexion Expresses Interest In Acquiring Syntimmune.

Alexion was a large, publicly traded pharmaceutical company.[131] It concentrated on the "metabolic and complement space," with a focus on rare diseases.[132] It became interested in developing treatments for autoimmune diseases, leading it to take interest in the momentum anti-FcRn drugs were building.[133] In

[126] JX 1229 at 1; JX 1424 at 1.

[127] JX 1229 at 1–2; JX 1424 at 1–2.

[128] JX 1229 at 1; JX 1424 at 1.

[129] *See* JX 1229 at 29.

[130] *See* Harvey Tr. 1683.

[131] D.I. 308 ¶ 28.

[132] Sarin Tr. 933 (noting that the term "complement" pertains to "pathways in the body . . . relating to the immune system").

[133] *Id.* at 934.

May 2018, Alexion reached out to Syntimmune to discuss a potential acquisition.[134] By the end of the month the parties proceeded with due diligence.[135]

Alexion knew several companies were ahead of Syntimmune and that SYNT001 would not be the first anti-FcRn drug to market.[136] At the time, at least three other companies were developing anti-FcRn drugs: Argenx, Momenta, and UCB.[137] Argenx was in Phase 2 trials for an IV formulation and was also developing an SC formulation.[138] Momenta was testing an IV formulation, but Alexion did not know the indications Momenta was pursuing at the time.[139] UCB was testing an IV formulation and an SC formulation.[140] Alexion believed Argenx and UCB were ahead of Syntimmune at the time of the acquisition and that Syntimmune could be the third anti-FcRn drug to market.[141]

Alexion saw SYNT001's order of entry as a challenge to bringing a commercially successful product to market.[142] To be successful, Alexion believed

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[134] Hall Tr. 53; JX 302.

[135] *See* JX 348 at 73.

[136] Sarin Tr. 935.

[137] JX 2923 at 15.

[138] *Id.*; Sarin Tr. 935–36.

[139] JX 2923 at 15.

[140] *Id.*

[141] Sarin Tr. 939.

[142] *E.g.*, JX 437 at 2–3.

the drug had to get to market quickly and be differentiated from its competitors.[143] It saw its best opportunity to do so as being first to an indication with a low volume SC formulation that patients could administer on their own, for instance, through an on-body device.[144] Syntimmune agreed as to the importance of an SC formulation and had itself intended to eventually develop one.[145] At the time, Syntimmune had done no work on an SC formulation or on a device to deliver that formulation.[146]

Alexion initially saw potential in multiple indications, including WAIHA and gMG.[147] It viewed SYNT001 as having a "reasonable probability" of "regulatory success," and believed it could "expedite development of SYNT001 and launch in [a] first indication in 2022."[148] Its primary focus was in WAIHA, where it believed it could be the first anti-FcRn to market.[149] It also thought that it could be third to market in gMG.[150]

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[143] *E.g.*, *id.*

[144] Sarin Tr. 936, 940–41.

[145] *Id.* at 940–1.

[146] *Id.* at 938.

[147] JX 609 at 2.

[148] *Id.*

[149] *Id.* at 12; JX 697 at 1.

[150] JX 609 at 12.

F. Merger Negotiations

Alexion sent its first offer to acquire Syntimmune on July 27, 2018.[151] The offer letter noted that "FcRn has quickly become a highly competitive space" and that "[t]iming to market and the competitive profile . . . for [SC] administration remain open questions."[152] Alexion proposed acquiring Syntimmune for $900 million, $600 million of which was tied to milestone payments.[153] It proposed three milestones: (1) $100 million upon "the successful completion of Phase 1 trials" of the SC formulation, in which the drug is dosed once every two weeks; (2) $100 million upon "completion for each of the next two Phase 2 trials, regardless of indication"; and (3) $150 million upon "FDA approval for each of the next two indications, regardless of indication."[154]

Upon receipt of Alexion's offer, Syntimmune suggested internally that the first milestone pay $150 million for a subcutaneous dose every other week, and began crafting a bespoke definition of a successful Phase 1 trial.[155] Syntimmune acknowledged internally that at the time, their data supporting dosing every other week was in IV, and they had "no current evidence" that they could achieve dosing

[151] JX 437 at 1.

[152] *Id.* at 2.

[153] *Id.* at 3.

[154] *Id.*

[155] JX 447; JX 485.

every other week for SC; this was "a potential problem with [Alexion's] deal."[156] Syntimmune's CEO recommended they "push back for weekly (or even better for no mention of the regimen),"[157] and responded with an approach omitting any milestone based on dosing regimen.[158] Syntimmune made a $1.5 billion counteroffer, $1.1 billion of which would come from milestone payments.[159] It proposed the first milestone be paid out "for the initiation/(first patient dosing) of any Phase III trials (regardless of indication)," and the second "for achieving SC formulation."[160]

Alexion still wanted a milestone keyed to a dosing regimen.[161] The parties' negotiators spent time together, and Aradhana Sarin (Alexion's lead merger negotiator, and later chief financial officer ("CFO"))[162] recapped a discussion about what would be required to achieve once-weekly dosing; on this point, she concluded, "I am sure this will be a point of negotiation."[163]

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[156] JX 485 at 1.

[157] *Id.*

[158] *See* JX 486 at 2; JX 489.

[159] JX 497 at 2.

[160] *Id.*

[161] *See id.* at 1 (suggesting "every 2 weeks" as a definition of success for the SC formulation).

[162] Sarin Tr. 936. Sarin became Alexion's CFO in February 2019. She became AstraZeneca's CFO when AstraZeneca later acquired Alexion. *Id.*

[163] JX 515 at 1.

Alexion sent Syntimmune a proposal on August 3.[164] It emphasized that to be competitive, SYNT-001 would need earlier proof that SC could be dosed every week or less frequently.[165] Alexion explained:

> To have commercial viability in the current landscape for anti-FcRn drugs, we believe SYNT-001 will need to achieve a favorable low-volume, high-concentration subcutaneous formulation that meets the following benchmarks:
>
> (1) a volume of 3.5mL or lower per dose;
>
> (2) a concentration of 150mg/mL or higher;
>
> (3) dosing of once every week or less frequent;
>
> (4) comparable half-life, pharmacodynamics, and tolerability to the IV formulation;
>
> (5) provide sufficient exposure to maintain IgG suppression at steady state IgG reduction levels;
>
> (6) have favorable bioavailability; and
>
> (7) have no immunogenicity concerns or meaningful anti-drug antibody signals that would negatively impact efficacy.[166]

Alexion proposed those seven criteria would define the successful completion of a Phase 1 trial that would trigger the first milestone payment.[167] Syntimmune

[164] JX 508 at 1.

[165] *Id.* at 2–3.

[166] *Id.*

[167] *Id.* at 3.

discussed internally the risks and means of achieving dosing every other week,[168] and every week.[169]

On August 4, Alexion sent a revised counteroffer removing a limitation that the Phase 3 approvals in later milestones be in SC.[170] The parties agreed from that point on that the first milestone payment would be $130 million, and that it would be pegged to the "successful completion" of a Phase 1 study with weekly or less frequent dosing.[171] But the parties would continue to negotiate over the meaning of successful completion.[172]

Syntimmune discussed the criteria with its advisors, seeking simpler criteria that still included a requirement of dosing every week or less frequent.[173] On August 8, Alexion sent its "best and final" proposal, which provided that a Phase 1 trial would be considered successful upon:

> (a) completion of a clinical trial of the SC formulation in healthy volunteers as demonstrated by achievement of measures to be agreed by the parties in the definitive agreement and (b) any submission of any protocol for a Phase 2 or Phase 3 clinical trial containing a weekly or less frequent SC dosing arm.[174]

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[168] JX 509.

[169] JX 520.

[170] *Compare* JX 524.02, *with* JX 508.

[171] JX 524.02 at 2.

[172] *See, e.g.*, JX 534 at 3.

[173] JX 531 at 6.

[174] JX 534 at 3.

Syntimmune accepted these terms as a term sheet.[175]

Syntimmune and Alexion began exchanging merger agreement drafts. An August 24 draft paid the first milestone "upon the submission to the FDA of a clinical protocol for a Pivotal Clinical Trial containing a once-weekly or less frequent dosing regimen for the SC Formulation."[176] Alexion wanted to avoid "burdensome negotiation" on the definition of completion of a Phase 1 trial, and preferred language based on the submission of such a protocol.[177] For its part, Syntimmune agreed the protocol submission definition was "easier and more objective," but did not want to leave to Alexion the decision to submit such a protocol, even if the Phase 1 trial was successful.[178]

Syntimmune sent Alexion a draft on September 1.[179] It reinserted a bespoke definition for successful completion of Phase 1 for purposes of the first milestone by reference to an exhibit listing four criteria:

> 1) Weekly or less frequent injections
>
> 2) SC Formulation concentration >1=150 mg/ml
>
> 3) 50% average reduction in total IgG at steady state with no meaningful changes in IgA, IgM, or albumin

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[175] *Id.* at 4.

[176] JX 593.02 at 30.

[177] JX 594 at 1; *see* JX 637 at 1–2.

[178] JX 597 at 1.

[179] JX 610 at 1.

> 4) Safety and tolerability results permit continued dosing of cohorts in additional SC Formulation studies.[180]

Alexion representatives discussed how to respond.[181] In the first email on a September 5 chain, an Alexion employee related a revised list of internally agreed-upon criteria:

> 1. an observed PK/PD profile that supports weekly or less frequent SC administration in long term safety and efficacy studies
>
> 2. A SC formulation that supports commercially feasible dose volumes (<10 mL as a flat therapeutic dose for treated patients)
>
> 3. SC formulation that achieves a concentration ≥150 mg/mL
>
> 4. achieves ≥50% average reduction in total IgG at steady state throughout the dosing interval with no meaningful changes in IgA, IgM, or albumin
>
> 5. safety and tolerability profile that results permit continued dosing of cohorts in additional SC formulation studies
>
> 6. anti-drug antibody profile that does not have meaningful impact on PK/PD, including total IgG reduction.[182]

In response to those criteria, Sarin wanted to add language including regulatory input, keying the milestone to Alexion's ability to move on to Phase 2 or 3 after showing Phase 1 data to regulators.[183] She wanted such language because "it would delay at least slightly post Phase 1 completion and give [Alexion] a little more

[180] *Id.* at 42–43, 120; *see* JX 637.

[181] JX 617; JX 621.

[182] JX 617 at 2.

[183] *Id.* at 1.

certainty."[184] Another Alexion employee suggested accomplishing that goal via an addition to the third criterion making the SC formulation's concentration "sufficient for use in Ph[ase] 2 or Ph[ase] 3 clinical studies," to which Sarin responded, "Add it."[185]

By September 7, Alexion's internal proposal did not contain any such explicit regulatory benchmark.[186] On September 7, Alexion sent a revised merger agreement.[187] The draft changed the defined term in the merger agreement from "Phase I Clinical Trial" to "Phase Ib Clinical Trial."[188] That revised definition provided a "Phase Ib Clinical Trial" would be

> intended to . . . (b) determine the further safety and pharmacology of the SC Formulation in healthy human subjects . . . and (c) establish sufficient data to be included in regulatory filings for a Phase II Clinical Trial or a Pivotal Clinical Trial with the FDA or its foreign counterpart.[189]

The draft revised the criteria used to define completion of a Phase 1 (now Phase 1B) study for purposes of the first milestone:

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[184] *Id.* at 2.

[185] *Id.* at 1; *see* JX 621.

[186] JX 627.

[187] JX 633.01; JX 633.02; JX 633.03.

[188] JX 633.02 at 23. This at least appears to be what Alexion intended, as it deleted the defined term "Phase I Clinical Trial" from the agreement and replaced it with "Phase Ib Clinical Trial," though it did not replace the term "Phase I Clinical Trial" in the first milestone's language. *See id.* § 3.8(a)(i) at 40.

[189] JX 633.02 at 23.

> 1) An observed PK/PD profile that supports weekly or less frequent subcutaneous administration in long term safety and efficacy studies.
>
> 2) Commercially feasible dose volumes (≤7 mL as a flat therapeutic dose for treated patients).
>
> 3) A concentration >150 mg/mL that achieves minimum of nine (9) months stability at intended storage conditions for both drug supply and drug product.
>
> 4) >50% average reduction in total IgG at steady state throughout the dosing interval with no meaningful changes in IgA, IgM, or albumin.
>
> 5) Safety and tolerability profile that permits continued dosing of cohorts in additional subcutaneous formulation clinical studies.
>
> 6) Anti-drug antibody profile that does not have meaningful impact on PK/PD, including total IgG reduction.[190]

Syntimmune discussed internally, including the "expected dose range for subQ"[191] and the addition of a Phase 1B clinical trial.[192] Syntimmune employees thought the terms "look[] like a lawyer trying to define something that he does not understand," and that "[t]he entire nomenclature around phases is confused."[193] A Syntimmune employee wondered whether Alexion intended to define the Phase 1 study, or to describe a pivotal bridging study.[194] He concluded:

> By using the first clinical efficacy study in patients, this clearly describes that the milestone will be achieved . . . if they believe the SC

[190] *Id.* at 118; *see* JX 630; JX 637.

[191] JX 634; *see also* JX 630; JX 637 (tracking the negotiation history).

[192] JX 638 at 1–2.

[193] *Id.* at 2.

[194] *Id.*

> formulation is adequate to progress into development based on the phase 1 SC study.[195]

Syntimmune rejected Alexion's attempt to add a definition of "Phase Ib Clinical Trial."[196]

Syntimmune responded to Alexion's draft merger agreement with the following criteria:

> 1) An observed PK/PD profile that supports weekly or less frequent subcutaneous administration in long term safety and efficacy studies.
> 2) A concentration ≥150 mg/mL that achieves minimum of nine (9) months stability at intended storage conditions for both 150 mg/mL drug substance and 150 mg/mL drug product in vials.
> 3) ≥50% average reduction in total IgG at steady state with no meaningful changes in IgA, IgM, or albumin.
> 4) Safety and tolerability profile that permits continued dosing of cohorts in additional subcutaneous formulation clinical studies.
> 5) Anti-drug antibody profile that does not have meaningful impact on PK/PD as evidenced by total IgG reduction.[197]

Alexion found these criteria acceptable, and negotiation on those points ended.[198]

The parties also negotiated an efforts clause defining Alexion's obligation to try to achieve each of the milestones. On September 2, Alexion proposed one that required it to use "such efforts and resources . . . as are used by [Alexion] . . . for the development and commercialization of similar products at similar development

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[195] *Id.*

[196] JX 657 at 23.

[197] JX 659 at 41, 222.

[198] JX 653 at 11.

stages."[199] Syntimmune rejected this proposal and required a "customary objective CRE standard where the efforts are measured by comparable companies in the industry."[200] The parties agreed on an outward facing definition of commercially reasonable efforts.[201]

G. Alexion And Syntimmune Enter A Merger Agreement.

On September 28, the parties entered a merger agreement (the "Merger Agreement").[202] The agreement provided for an upfront payment of $400 million.[203] It also provided for milestone payments totaling $800 million if eight milestones were satisfied.[204] This dispute centers on Milestone 1, which reads:

> i. a one-time payment of One Hundred Thirty Million Dollars ($130,000,000) upon the earlier of (A) the successful completion of a Phase I Clinical Trial of the SC Formulation as demonstrated by achievement of the criteria set forth on Exhibit I or (B) submission to the FDA of a protocol for a Pivotal Clinical Trial for any subcutaneous formulation.[205]

Specifically, the parties dispute whether the criteria in Exhibit I were satisfied. They are:

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[199] JX 631 at 13.

[200] JX 649 at 9; *compare* JX 631 at 13, *with* JX 1 at 9 [hereinafter "Merger Agr."].

[201] JX 649 at 9; JX 653 at 12–13; *e.g.*, JX 657 at 11.

[202] Merger Agr.

[203] *Id.* § 3.6.

[204] *Id.* § 3.8(b).

[205] *Id.* § 3.8(a)(i).

> 1) An observed PK/PD profile that supports weekly or less frequent subcutaneous administration in long term safety and efficacy studies.
>
> 2) A concentration 150 mg/mL that achieves minimum of nine 9 months stability at intended storage conditions for both 150 mg/mL drug substance and 150 mg/mL drug product in vials.
>
> 3) 50% average reduction in total IgG at steady state with no meaningful changes in IgA IgM or albumin.
>
> 4) Safety and tolerability profile that permits continued dosing of cohorts in additional subcutaneous formulation clinical studies.
>
> 5) Anti-drug antibody profile that does not have meaningful impact on PK/PD as evidenced by total IgG reduction.[206]

The Merger Agreement required Alexion to use "Commercially Reasonable Efforts," as defined by the agreement, to satisfy each of the milestones for seven years (the "CRE Obligation").[207] That definition established an outward-facing standard, defining Commercially Reasonable Efforts as follows:

> [U]sing such efforts and resources typically used by biopharmaceutical companies similar in size and scope to [Alexion] for the development and commercialization of similar products at similar development stages taking into account, as applicable, [SYNT001's] advantages and disadvantages, efficacy, safety, regulatory authority-approved labeling and pricing, the competitiveness in the marketplace, the status as an orphan product, the patent coverage and proprietary position of [SYNT001], the likelihood of development success or Regulatory Approval, the regulatory structure involved the anticipated profitability of [SYNT001], and other relevant scientific technical and commercial factors typically considered by biopharmaceutical companies similar in size and scope to [Alexion] in connection with such similar products. The obligation to use such efforts and resources, however, does not

[206] *Id.* Ex. I.

[207] *Id.* § 3.8(f).

> require that [Alexion] or its Affiliates act in a manner which would otherwise be contrary to prudent business judgment and, furthermore, the fact that the objective is not actually accomplished is not dispositive evidence that [Alexion] or any of its Affiliates did not in fact utilize its Commercially Reasonable Efforts in attempting to accomplish the objective.[208]

The Merger Agreement also contained a clause granting Alexion sole discretion over business operations:

> Notwithstanding anything in this Agreement to the contrary, subsequent to the Closing, [Alexion] shall have sole discretion with regard to all matters relating to the operation of the Company, its Subsidiaries and their respective businesses and shall have no obligation, or liability as a result of the failure, to achieve any of the events described in Section 3.8(a) that would give rise to an Earn-Out Payment.[209]

And so, Alexion had sole discretion over ALXN1830, but its discretion was cabined by its promise to use commercially reasonable efforts to develop ALXN1830 into an approved anti-FcRn treatment.

The Merger Agreement designated SRS as the Syntimmune stockholders' representative in connection with the transaction.[210] The merger closed on November 2, 2018.[211] After closing, Alexion began referring to SYNT001 as ALXN1830.

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[208] *Id.* at 9.

[209] *Id.* § 3.8(j).

[210] *Id.* § 9.1(a).

[211] JX 765.

H. ALXN1830's Competitive Position Post-Closing

As of closing, Syntimmune had completed only the SYNT-101 study. SYNT-102, which tested the IV formulation in patients with WAIHA, and SYNT-103, which tested the IV formulation in patients with PV, were ongoing at the time.[212] SYNT-104, a Phase 1 study of the IV formulation in healthy volunteers, was planned.[213] The SC formulation had not yet been tested in humans, and Syntimmune had not identified a device by which to administer the SC formulation.[214] Though Alexion was primarily interested in bringing an SC formulation to market, it continued to pursue the IV formulation because it was expected to be approved almost two years before an SC formulation.[215] Because of that lead time, it made commercial sense to pursue both formulations simultaneously.[216]

Alexion was fairly far behind Argenx and UCB, but it was somewhat in line with Immunovant and Momenta. By November 2018, Argenx's anti-FcRn asset had completed Phase 1 and 2 trials and was being studied in a Phase 3 trial in gMG

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[212] Hall Tr. 140.

[213] *Id.* at 144; JX 713 at 14.

[214] Hall Tr. 149.

[215] *See* Ledwith Tr. 1079; Sarin Tr. 1018; JX 1407 at 2, 14 (showing development timeline as of March 2020).

[216] Bahl Tr. 1752–55; *see also* Ledwith Tr. 1084–85.

patients.[217] UCB's anti-FcRn asset completed a Phase 2 trial in gMG and was being studied in another ongoing Phase 2 trial.[218] Momenta's anti-FcRn asset had completed a Phase 1 trial.[219] Immunovant's anti-FcRn asset had completed a Phase 1 trial.[220]

I. Infusion Related Reactions Halt SYNT-104.

After the merger closed, Alexion removed some of its drug supply from its clinical studies due to contamination.[221] This forced it to prioritize its remaining supply and pause SYNT-103.[222]

The first subject was enrolled in SYNT-104 shortly after closing.[223] In early 2019, multiple study subjects experienced infusion related reactions ("IRRs").[224] The IRRs were generally thought to be caused by impurities in the drug substance used to make ALXN1830.[225] They led to Grade 1 and 2 adverse events, which were

[217] JX 2870 at 4.

[218] JX 758; JX 2873 at 2.

[219] JX 2876 at 1.

[220] JX 690 at 53; JX 2875 at 1.

[221] Ledwith Tr. 1029–30.

[222] *Id.* at 1030–31.

[223] JX 1158 at 1.

[224] *See id.* at 5; JX 883.02 at 1; *see also* JX 923 at 64.

[225] Robbins Tr. 518.

treated with over-the-counter medication.[226] The clinical investigator had to stop administering the drug each time they arose.[227] The SYNT-102 and SYNT-104 studies were paused in February pending an investigation into the drug supply.[228] Alexion officially terminated SYNT-104 in March 2019 and SYNT-102 later that year.[229]

The clinical study report ("CSR") for SYNT-102 concluded ALXN1830 was "well tolerated in patients with WAIHA."[230] Two SAEs were observed, but both "were assessed as not related to ALXN1830."[231] Two of eight patients developed treatment-emergent ADAs, but "the presence of ADAs did not appear to have a significant impact on the PK or PD of ALXN1830."[232] The CSR for SYNT-103 concluded ALXN1830 "was well tolerated in subjects with [PV]," and that there

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[226] JX 1171 at 21; Ledwith Tr. 1037. To be sure, a presentation states that one of the adverse reactions was a grade 3. JX 923 at 64. But Ledwith, who prepared the relevant table, testified that the grade 3 notation was a typo. Ledwith Tr. 1037.

[227] Ledwith Tr. 1036.

[228] *See* JX 923 at 39; Ledwith Tr. 1038; JX 1139.04 at 25.

[229] JX 1158 at 1; JX 1393 at 102; Ledwith Tr. 1036. The parties dispute whether Alexion knew of the drug substance problem before closing. Because I will be addressing Alexion's breach of contract claim in a separate decision, and because I resolve Alexion's unclean hands defense on other grounds, this decision makes no findings of fact as to whether Alexion had such knowledge or whether the manufacturing issues resulted in a breach of contract.

[230] JX 1393 at 6.

[231] *Id.*

[232] *Id.*

were no serious adverse events related to the administration of ALXN1830.[233] ALXN1830 resulted in an average IgG level reduction of 57.3%.[234] ADAs were detected in seven of the eight subjects, though the ADAs caused "[n]o apparent impact on the IgG lowering effect of ALXN1830."[235] SYNT-103 was terminated early because the study's objectives had been met.[236] Although the results were partial, SYNT-104 produced promising data. One of the groups showed IgG lowering of 64%.[237] ADAs were detected in at least eleven of the fifteen subjects.[238] No SAEs were reported.[239]

J. The FDA Rejects Alexion's Phase 2/3 Trial Request.

After the manufacturing issues were resolved in April 2019, Alexion sought to conduct what is known as a seamless Phase 2/3 study of the IV formulation in WAIHA. Typically, a drug candidate would receive approval for a Phase 2 study, and after that study was complete, the sponsor would meet with the FDA and receive approval for a Phase 3 study. The seamless Phase 2/3 study would allow Alexion to

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[233] JX 1229 at 5.

[234] *Id.* at 6.

[235] *Id.* at 5.

[236] JX 1114 at 67–68 (noting SYNT-103 was a "study of the safety, tolerability, PK, PD, efficacy, and immunogenicity of ALXN1830 in subjects with [PV] and pemphigus foliaceus").

[237] JX 1158 at 6.

[238] *Id.*

[239] *Id.*

convert the Phase 2 study into a Phase 3 study without that meeting.[240] Alexion sought approval for the seamless study because it would be faster than the normal process.[241] Approval for such studies is "rare."[242]

In support of its request, Alexion submitted the preliminary data from SYNT-101, SYNT-102,[243] SYNT-103,[244] and SYNT-104.[245] The materials conveyed ALXN1830 was "well tolerated" in study subjects, and did not raise any safety concerns.[246] But the FDA rejected the request to skip the pre-Phase 3 meeting, noting uncertainty around whether Alexion gathered sufficient data of "dose-response, efficacy and safety."[247] Notably, the FDA did not raise any concerns over whether the data presented safety concerns.

K. Alexion Begins Work On WAI-201, HV-105, and HV-106.

Later in 2019, Alexion opened three new studies: WAI-201, HV-105, and HV-106. WAI-201 was a Phase 2 study primarily designed to test the efficacy of

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[240] *See* Kinch Tr. 246.

[241] Ledwith Tr. 1058.

[242] Harvey Tr. 1716.

[243] JX 1114 at 63 (showing data through May 10, 2019).

[244] *Id.* at 67–68.

[245] *Id.* at 73–77.

[246] *Id.* at 23, 36, 61.

[247] JX 1143 at 5.

the IV formulation in WAIHA patients, to be conducted in the United States.[248] Alexion received approval for it in October 2019.[249]

In November of 2019, Alexion began dosing in HV-106, a Phase 1 SAD and MAD study in healthy volunteers primarily designed to assess the safety and tolerability of the IV formulation of ALXN1830.[250] HV-106 would be conducted in the United Kingdom.[251]

In December 2019, Alexion began dosing in HV-105.[252] HV-105 was a Phase 1 SAD and MAD trial of the SC formulation in healthy volunteers.[253] Significantly, HV-105 was the first time the SC formulation had been tested in humans.[254] HV-105 would also be conducted in the United Kingdom.[255]

L. The Trinity Consulting Report

In December 2019, Alexion received a presentation from an outside consultant regarding "opportunities for FcRn differentiation and strategic

[248] JX 2299 at 8; JX 1181.02 at 33.

[249] JX 1181.02.

[250] JX 1221.02 at 26.

[251] Ledwith Tr. 1063.

[252] JX 1259 at 1.

[253] JX 1139.04 at 25.

[254] *See id.* (explaining the HV-105 trial was testing the SC formulation).

[255] Ledwith Tr. 1063.

considerations for a novel product."[256] The report identified a lack of albumin lowering as a potential differentiator.[257] Albumin "is a serum protein."[258] The report explained this trait could appeal to certain subpopulations like the elderly and those with kidney problems by lowering the risk of hypoalbuminemia.[259] Importantly, the report identified that Immunovant's, Momenta's, and UCB's anti-FcRns all caused albumin lowering.[260] Argenx's anti-FcRn was the only competitor that shared ALXN1830's lack of albumin lowering.[261]

M. COVID-19 Causes A Pause Of All Alexion's Ongoing Trials.

On Friday, January 31, 2020, Alexion's clinical research organization in the UK, Richmond Pharmaceuticals ("RPL"), paused dosing of HV-105 and HV-106 in response to two people in the UK contracting the coronavirus.[262] Ledwith believed RPL was "being overly conservative" and "felt like [Alexion] could conduct [the] study safely."[263] He received Pirozzi's approval to fly to the UK to meet with RPL

[256] JX 1230 at 2.

[257] *Id.* at 25.

[258] Jagannathan Tr. 1304.

[259] Bahl Tr. 1766–77; JX 1230 at 25.

[260] JX 1230 at 25.

[261] *Id.*

[262] JX 1333 at 3; JX 1337; Ledwith Tr. 1063.

[263] Ledwith Tr. 1064.

the following Monday and Tuesday.[264] Over the weekend, Ledwith had the ALXN1830 development team put together a comprehensive risk assessment touching on the risk of infection, steps that could be taken to mitigate the risk of infection, and the like.[265] That assessment concluded that there was "[n]o increased risk of infection in previous anti-FcRn studies" and that any potential risks to study participants could be adequately mitigated.[266] In Ledwith's view, this was because HV-105 and HV-106 dosed subjects for a "relatively short" duration, the longest of which was twelve weeks.[267]

Ledwith flew to the UK to meet with RPL the following week.[268] He charted a path forward, agreeing to "pause dosing for a few weeks at RPL's request to allow the [COVID-19] exposure in the UK to be better understood."[269] During the pause, the ALXN1830 team would modify the study protocol and take other "preventative measures to minimize the risk of infection."[270] If the pandemic did not worsen

[264] *Id.*

[265] JX 1337; Ledwith Tr. 1064.

[266] JX 1334 at 51.

[267] Ledwith Tr. 1141; JX 2229 at 4 (noting cohort 5 would receive one dose a week for twelve weeks).

[268] Ledwith Tr. 1064.

[269] JX 1337.

[270] *Id.*

during that time, dosing could resume.[271] He expected the pause to last for four weeks.[272]

But the pandemic intensified and COVID cases in the UK spiked, prompting RPL to put an indefinite hold on the studies.[273] ALXN1830's clinical lead began pushing to halt the study, and Ledwith conducted "a very systematic risk assessment."[274]

In March, Ledwith, on behalf of the ALXN1830 development team, presented that assessment to the research and development leadership team and recommended they endorse pausing WAI-201.[275] His reasons included the fact that COVID-19 could "increase the number of infections (& SAEs) associated with ALXN1830," that the IRRs could "require[] access to hospitals, ICUs, & ventilators which [were] projected to be in shortages in [the] coming weeks and months," and that the trial population, which comprised WAIHA patients, is "[m]ore vulnerable to COVID-19" than the general population, among other things.[276]

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[271] Ledwith Tr. 1065.

[272] JX 1337; *see also* JX 1333 at 2 ("There has been a decision to shift ALXN1830 HV dosing by 1 month to assess whether coronavirus is contained in the UK.").

[273] Ledwith Tr. 1065.

[274] *Id.* at 1067–68.

[275] JX 1397 at 2.

[276] *Id.*

Between February and March, Ledwith did not change his conclusion that the administration of ALXN1830 posed no health risk to healthy subjects when administered for up to twelve weeks. Rather, his March recommendation for WAI-201 took into account the trial population (WAIHA patients as compared to healthy subjects in HV-105 and HV-106), the presence of IRRs, and the increase in the number of COVID cases.

Ledwith's presentation noted the possibility that pausing the WAI-201 IV study could shorten the lead that IV had over SC, in which case the study's value would be "diminished" such that it "may not restart."[277] The leadership team accepted the recommendation to pause the study.[278] SRS does not dispute that this decision to pause WAI-201 was reasonable.[279] It likewise does not contend that Alexion had the power to resume HV-105 and HV-106 in the UK.[280]

Alexion's competitors continued to advance further ahead, including in both gMG and WAIHA. At the time, Argenx had three ongoing IV Phase 3 studies, two

[277] *Id.*

[278] Ledwith Tr. 1070.

[279] Robbins Tr. 585–86.

[280] SRS points to one document in which Ledwith explains "off the record" that RPL's decision to pause the two UK studies was not just because of COVID, but also because it was seeking re-accreditation from the UK's health authority. JX 1353 at 1. Even if this is true, it does not change the fact Alexion could not override RPL's decision.

of which were in gMG.[281] It also had an ongoing IV Phase 2 study in PV.[282] UCB had two SC Phase 2 studies ongoing, both of which were in an indication Alexion did not pursue.[283] UCB also had three ongoing SC Phase 3 studies, two of which were in gMG.[284] And UCB had an ongoing Phase 1 study.[285] Momenta had three ongoing IV Phase 2 studies, two of which were in gMG.[286] It also had an ongoing IV Phase 2/3 study in WAIHA.[287] Immunovant had three ongoing Phase 2 studies, one of which was in gMG.[288] In contrast, Alexion had only limited data from a Phase 1A/2B study, and had yet to dose a patient in a Phase 2 study.

N. COVID Portfolio Rebalancing And The "10 By 2023" Initiative

By April, Alexion had no active ALXN1830 clinical trials. In late April, John Orloff, Alexion's head of R&D,[289] announced a "[r]ebalancing" of Alexion's "R&D [p]riorities."[290] He explained the company was doing so because the pandemic

[281] JX 2296; JX 2359; JX 2486.

[282] JX 1659.

[283] JX 2349; JX 2415.

[284] JX 2569; JX 2388; JX 2451.

[285] JX 1994.

[286] JX 2583; JX 2302; JX 2745.

[287] JX 2570.

[288] JX 2791; JX 2272.

[289] Orloff Tr. 870.

[290] JX 1451 at 2–4.

created a situation in which Alexion had to "find savings across the company."[291] To that end, Orloff explained that Alexion had to "ensure that we are prioritizing the most important work, while best positioning Alexion for future growth."[292] He also explained that Alexion had to "remain[] focused on advancing our priority programs towards 10 launches by 2023."[293] The mention of "10 launches by 2023" referred to an initiative started years earlier intended to demonstrate value to Alexion's investors.[294] I interpret Orloff's email, together with his testimony, to convey that COVID created a need to reallocate funds across the company, while prioritizing programs that could fulfill the promise of ten launches by 2023. His email noted ALXN1830 was among the programs that would be "paused and revisited during our 2021 prioritization this summer."[295]

ALXN1830's funding was "reduced significantly."[296] The deprioritization moved funding away from ALXN1830's clinical activities, including preparing trial

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[291] Orloff Tr. 862.

[292] JX 1451 at 3.

[293] JX 1456 at 2.

[294] *See* Orloff Tr. 859 ("[The 10 by 2023 program] was a way to characterize the breadth and depth of our pipeline to external people, investors, and comprised of all the assets that we did bring into the pipeline. So there was a definite focus to -- to demonstrate that we had a robust pipeline that we built from -- nearly from scratch and that we could execute on development progress because of our development prowess.").

[295] JX 1456 at 2.

[296] Orloff Tr. 862.

protocols.[297] But the program was not completely defunded, and some work continued, including manufacturing, device development, investigating potential new indications, and planning what would become the HV-108 study.[298]

In July, Orloff requested funding for ALXN1830 and Sarin authorized it.[299] Still, when SC clinical supply necessary to conduct the new study became available in September, Alexion was not prepared to move forward with HV-108.[300] Sarin lamented the delay and the "need to wait another several months because nobody ha[d] done any work on writing the protocol."[301]

O. Alexion Abandons The IV Formulation.

Early spring 2020 also saw Alexion move away from developing an IV formulation of ALXN1830 and shift its focus exclusively to the SC formulation. Though an IV formulation and SC formulation could both be commercially viable, an SC formulation is far more desirable from a patient standpoint.[302] The IV program

[297] JX 1613 at 3 ("We expect the pause to be for a minimum of 3 months, possibly longer. Pencils down on protocol prep, . . . new reg submissions, etc."); JX 1529 at 2 ("We are not authorized at present to work on the [HV-108] protocol."); *see also* JX 1613 at 2–3 (listing other activities that were paused).

[298] Ledwith Tr. 1071–88; *see also* Orloff Tr. 867.

[299] JX 1529 at 1.

[300] *See* JX 1597 at 2.

[301] *Id.*

[302] Borboroglu Tr. 1412–14.

was initially nearly two years ahead of the SC program in WAIHA.[303] So, since closing, Alexion had continued to pursue an IV formulation as a means to get its "foot in the door."[304] But after Alexion paused the WAI-201 trial because of COVID, the IV and SC development timelines began "coalescing."[305]

The ALXN1830 team proposed focusing exclusively on the SC formulation, with a plan to reduce the amount of time it would take to get SC to market.[306] Originally, Alexion planned to submit the SC on-body device for approval in the fourth quarter of 2026 and obtain approval in the fourth quarter of 2027.[307] Under the revised plan, Alexion would use an SC pump to allow ALXN1830 to reach the market sooner.[308] It planned on submitting the SC pump for approval early in the first quarter of 2026 and obtain approval in the first quarter of 2027.[309] It would then receive approval for the SC on-body device in the first quarter of 2028.[310] The revised plan meant that any formulation for WAIHA would reach the market over a

[303] JX 1407 at 2, 9, 14.

[304] Ledwith Tr. 1079.

[305] *Id.*

[306] JX 1407 at 14.

[307] *Id.*

[308] *Id.*

[309] *Id.*

[310] *Id.*

year later, and the SC device would reach the market about three months later than initially planned.[311]

P. Alexion Starts HV-108 With Optimism.

In March of 2020, the ALXN1830 team began thinking about conducting another SC SAD and MAD study in healthy volunteers "basically to pick up where 105 left off."[312] Such a study was needed to gather PK, PD, immunogenicity, and safety data.[313] While HV-105 was on hold, it made sense to pursue another SC study as that data was "critical to [the] program" in light of the move "away from IV for both MG and WAIHA."[314] Ledwith and his team arranged the HV-108 trial in New Zealand.[315]

The first HV-108 subject was enrolled in February 2021,[316] and dosing began in March.[317] The design of HV-108 was substantially similar to that of HV-105.[318] It called for dosing six cohorts with eight subjects each.[319] Six subjects in each

[311] *Id.*

[312] Ledwith Tr. 1087. It does not appear HV-105 ever resumed. JX 1699 at 4.

[313] JX 1606.02 at 58.

[314] Ledwith Tr. 1087–88.

[315] *See* Pirozzi Tr. 1459–60.

[316] JX 2367 at 1.

[317] Pirozzi Tr. 1460.

[318] *Compare* JX 2254.02 at 4, *with* JX 2367 at 3.

[319] JX 2367 at 2.

cohort would receive an SC dose of ALXN1830, and the other two would receive a placebo.[320] Cohorts 1 and 2 would receive a single dose; Cohort 3 would receive twelve doses over twelve weeks; and Cohorts 4, 5, and 6 would receive four doses over four weeks.[321] Cohort 3 is at the heart of this decision.

In February 2021, with HV-108 up and running, Alexion was optimistic about ALXN1830 even though the COVID pauses, supply issues, and delays getting off the ground again meant Alexion continued to slip further behind its competitors.[322] Preliminary modeling suggested that weekly dosing might be effective.[323] It intended to pursue two Phase 2 studies later in the year to evaluate dose schedules.[324] Alexion adjusted its projections and believed it would be fifth to market in gMG, down from third.[325] Nevertheless, it believed it could capture about 7% of the gMG market, with anti-FcRn treatments having a total of 61%.[326] This was despite Argenx, Immunovant, Momenta, and UCB all developing SC anti-FcRns for the

[320] *Id.* at 3.

[321] *Id.*

[322] JX 1699 at 4.

[323] *See id.* at 2 (noting that weekly dosing "may have the potential to provide >70% IgG lowering").

[324] *Id.* at 2, 4.

[325] *Id.* at 7; JX 609 at 12.

[326] JX 1699 at 7.

indication.[327] Alexion saw differentiation in dosing frequency and route of administration.[328]

Alexion expected to be third to market in WAIHA.[329] At the time, Alexion believed that WAIHA presented a "[h]igher probability of success and lower competitive headwinds than other FcRn indications."[330] Alexion saw the potential to differentiate within WAIHA through efficacy and safety.[331] It also noted another potential differentiator: lack of albumin lowering.[332] This trait meant ALXN1830 could appeal to certain subpopulations like the elderly and those with kidney problems.[333]

In the summer of 2021, Alexion resumed Phase 2 trials. In July, it was working on MG-201, a Phase 2 trial of the SC formulation in gMG patients.[334] It was also working on WAI-202, a Phase 2 trial of the SC formulation in WAIHA patients.[335]

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[327] *Id.*

[328] *Id.* at 5–7.

[329] *Id.* at 9.

[330] *Id.*

[331] *Id.*

[332] *Id.*

[333] Bahl Tr. 1766–77; JX 1230 at 25.

[334] JX 2298 at 1–2, 8.

[335] JX 2299 at 1–2, 8.

In June 2021, Alexion received data on a competitor's study that suggested anti-FcRns "that do not effect [sic] albumin levels (i.e., efgartigimod, ALXN1830) may have both an efficacy and safety advantage."[336] Orloff sent an email to Dana Washburn (ALXN1830's global medicine team leader),[337] Pirozzi, and others explaining "[t]his would appear to be good news for the 1830 program," and it "represents a distinct advantage for 1830, and a reason why we should continue moving forward aggressively."[338] Washburn wrote that the ALXN1830 team "completely agree[s] that this is potentially good news for 1830" and that they were "collecting . . . albumin data in [their] ongoing Study 108."[339] He continued, "[s]o far our albumin data (available from IV and SC administrations) are very encouraging, but we have not reached our maximal IgG lowering yet."[340]

Q. AstraZeneca Acquires Alexion.

In July 2021, Alexion was acquired by AstraZeneca plc.[341] In connection with that acquisition, AstraZeneca promised $500 million in recurring synergies.[342] The task of delivering on that promise fell to Alexion under the leadership of Marc

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[336] JX 1802 at 2.

[337] Washburn Tr. 638.

[338] JX 1802 at 1.

[339] *Id.*

[340] *Id.*

[341] JX 1865 at 3.

[342] *See* JX 1946 at 3.

Dunoyer, the CEO AstraZeneca installed after closing.[343] In furtherance of its mission, Alexion launched a full portfolio review of all ongoing Alexion drug programs and indications.[344]

The gMG program quickly found itself in the crosshairs, and by August 9 Alexion paused screening of a study participant in MG-201 scheduled for that same week.[345] In an email, Pirozzi explained that the decision was made to avoid a situation in which Alexion recruited a patient, started dosing, and then terminated the program due to budget cuts.[346] Alexion also announced the ALXN1830 program would pursue two additional indications: thyroid eye disease ("TED") and chronic antibody mediated rejection ("cAMR").[347] No decision was made as to WAIHA, and HV-108 was to proceed as planned.[348]

But on August 17, COVID cases spiked and New Zealand instituted a lockdown.[349] The lockdown was scheduled to last until August 24, but was subject

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[343] *See id.*

[344] *See generally* JX 1946; JX 1933; *see also* Washburn Tr. 638 ("[T]here was a reassessment of the portfolio strategies after AstraZeneca acquired Alexion. And in the process of reevaluating the overall pipeline of all activities, there was a decision made to pause gMG at that time.").

[345] JX 1928.

[346] JX 1933 at 1; Lee Tr. 445; *see also* JX 1948.

[347] JX 1928; Russell Tr. 732.

[348] JX 1928.

[349] JX 1972.02.

to possible extensions.[350] At the time, HV-108's Cohorts 3 and 4 completed dosing, Cohort 5 had been partially dosed, and Cohort 6 had not yet begun dosing.[351] The record is not clear as to whether the lockdown forced a pause, but the ALXN1830 team decided to pause dosing.[352]

R. The September HV-108 Data

Alexion received partial data from HV-108 by September 16 (the "September Data").[353] In an email, Pirozzi highlighted that two cohorts, including Cohort 3, showed ADA rates of 67%.[354] He referred to the 67% rate as "noteworthy given the high competitive environment of the class."[355] He conveyed that additional information on the ADAs and whether nAbs were present was forthcoming.[356] As of the following day, the belief was that the two Cohort 3 subjects who did not test positive for ADAs were members of the placebo group, bringing Cohort 3's ADA rate to 100%.[357]

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[350] *Id.*

[351] *See id.*; JX 2367 at 3.

[352] JX 1972.02.

[353] JX 1990 at 2.

[354] *Id.*

[355] *Id.*

[356] *Id.*

[357] *Id.* at 1–2.

Notably, the immunogenicity rates in the September Data were not news to Alexion. Pirozzi's email discussed data appearing in an earlier presentation. That presentation explained that ALXN1830 had "historically[] high ADA (63% to 91%) and Nab (44% to 65%) rates . . . in healthy volunteers and in two small patient studies."[358] Multiple contemporaneous documents confirm that the information on ADAs and nAbs was not news to Alexion, and that it had been aware of this information for some time.[359]

The next day, Lukasz Jarzyna, a vice president and head of global value, access, and pricing at Alexion,[360] talked with Dunoyer and Simone Lauchart,

[358] JX 1987 at 3. In post-trial briefing, Alexion attempts to distinguish the earlier immunogenicity findings on the basis that those were based on single dose administrations of ALXN1830. As support, it cites only the testimony of Ledwith and Pirozzi, which, as explained, I have given little weight because it is lay opinion testimony based on their specialized knowledge rather than personal knowledge. ALXN Ans. Br. 23–24 (citing Pirozzi Tr. 1470–71; Ledwith Tr. 1092); *see supra* Section I(C).

[359] JX 2006 at 1 ("Anti-Fcrn class has high level of immunogenicity (based on public data on Ph 1 or PH 2 studies) . . . Aware that 1830 is immunogenic, so this is not a new finding."); JX 2038 (October 5, 2021 email discussing a letter Alexion will send to the FDA, conveying that "[t]here is no new information to share as this is not a new finding. Immunogenicity and ADAs have always been present and we have been transparent that it is a potential risk."); JX 2094 at 1 (email summarizing October 23, 2021 GPT meeting, which notes "ADA rates are known with 1830"); *see also* JX 2042 (October 6, 2021 email from Washburn noting "if a decision is made to stop WAIHA 202 it will not be based on immunogenicity findings from 108," and "there have been no findings in 108 to date to indicate any adverse safety events or findings").

[360] Pirozzi Tr. 1602.

Alexion's head of finance.[361] Following those conversations, Jazyna updated Pirozzi and others:

> Based on yesterday's news, the current view is that development of 1830 is going to be stopped; while we don't have data from the additional dose cohort, the decision should be taken before the end of Q3 to include it with other costs that will be included as part of the Q3 earnings.[362]

Jarzyna left open the possibility that further data would "alter [the] current view."[363]

On September 17, the ALXN1830 global medicines team met.[364] Erica Lee, who was in charge of regulatory strategy for ALXN1830, sent an email with an "update" from that meeting, which explained the team was "[a]ware that 1830 is immunogenic, so this is not a new finding."[365] It noted there were no SAEs or safety concerns reflected in the September Data, and that the data showed ALXN1830 lowered IgG "at the expected level."[366] High ADAs were observed in all dosed subjects; "neutralizing effects" were not observed during the twelve weeks of dosing, though Lee's update noted the ADAs' long term effect was unclear.[367]

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[361] *Id.* at 1607.

[362] JX 1990 at 1.

[363] *Id.*

[364] *See* JX 2006 at 1.

[365] *Id.*

[366] *Id.*

[367] *Id.*

At some point in September, Pirozzi communicated to others working on the ALXN1830 program that the WAIHA study needed to be "paused."[368] After Lauchart suggested issuing a broader communication about the AstraZeneca prioritization exercise, Pirrozi wrote that the WAIHA pause "is not about prioritization," and that "for reasons [Lauchart] know[s], we should not say that WAIHA will be stopped because of prioritization."[369]

Since receiving the September Data, both Alexion's leadership and the ALXN1830 team maintained the HV-108 data showed no signs that ALXN1830 was unsafe, the ADAs observed did not affect the drug's efficacy, and that Alexion was awaiting further HV-108 data to determine whether nAbs were present, which was

[368] JX 2015 at 1.

[369] *Id.*

forthcoming at the end of October or beginning of November.[370] Lee and others consistently noted that the presence of ADAs was not a new finding.[371]

By the end of September, Pirozzi circulated a decision tree for ALXN1830 once additional immunogenicity data was received.[372] The decision tree provided that if the HV-108 data revealed ALXN1830 had an acceptable immunogenic profile, Alexion would proceed to "[a]ssess ADA/Nab with longer treatment (6-12 mos) in patients" and confirm stable efficacy data over a longer dosing period.[373] With the additional ADA and nAb data expected by November,[374] Pirozzi expected Alexion's leadership would provide a "Go/NoGo" decision on the ALXN1830 program by early November.[375]

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[370] JX 2019 at 4; JX 2032 at 8; JX 2065 at 1 ("[T]here has been emerging and prelim data coming from HV-108, in which there is a high occurrence of ADAs. There have been no safety signs, no adverse impact on efficacy (related to IgG level), and the Safety Review Committee for HV-108 has reviewed data and has approved escalation to the next cohort. No safety issues related to 1830 have been identified at this time. Additional data is expected from now until the end of October/Nov."); JX 2094 at 1 ("No SAE or safety signals"; "IRRs reported[,] but not related to ADA [sic]. They are mild and resolved with little to no assistance"; "ADAs. [E]ven at high frequency—no associated impact to lgG lowering and safety; no PK effect"; "ADA rates are known with 1830"; "End of Nov will have a better idea on which indications to move ahead.").

[371] *E.g.*, JX 2038 at 1 ("There is no new information to share as this is not a new finding. Immunogenicity and ADAs have always been present and we have been transparent that it is a potential risk.").

[372] JX 2025 at 1.

[373] *Id.*

[374] *Id.* at 2.

[375] *Id.* at 1.

Even with a path forward under the decision tree, the program remained under pressure. The termination of the gMG indication remained a forgone conclusion.[376] The ALXN1830 team also positioned itself to carry out the termination of the WAIHA indication if leadership decided to end the program.[377]

At some point in September, Alexion leadership "deprioritized" the WAIHA indication as well.[378] That did not stop all work on the program, but certain functions were stopped.[379] The record is not clear as to what work stopped.

By October 8, a "[s]afety [r]eview [c]ommittee for HV-108 . . . approved escalation to the next cohort."[380] Following that decision, the ALXN1830 global project team met to discuss the September Data.[381] It agreed with the safety review committee's determination that dosing could resume.[382] Dosing was scheduled to resume on October 22.[383]

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[376] *See* JX 1928; JX 1933 at 1.

[377] *See, e.g.*, JX 2042 at 1 ("Following our discussion last week, I've put together a draft Notification Plan for Termination for your review. As agreed, this is just pre-planning.").

[378] JX 2021 at 1; JX 2065 at 1; Lee Tr. 457.

[379] *See* Lee Tr. 457–58.

[380] JX 2065 at 1; Lee Tr. 459.

[381] JX 2070 at 1.

[382] *Id.* at 2; JX 2095 at 1; Pirozzi Tr. 1362–63.

[383] JX 2095 at 1.

But another setback came almost immediately. On October 5, a cynomolgus monkey died as part of an *in vivo* study of ALXN1830.[384] Initially, Alexion did not believe the death was caused by the administration of ALXN1830.[385] But on October 15—two days after the global project team's vote to resume dosing in HV-108—Alexion received additional data suggesting ALXN1830 may have contributed to the death.[386] A conclusive determination required more data, which was not expected for at least a few weeks.[387] In the meantime, the group working on the toxicology study believed the news had to be reported to health authorities in the countries where Alexion was testing ALXN1830.[388] The monkey death, with the backdrop of the forthcoming HV-108 immunogenicity data, caused Alexion to pause HV-108 once again.[389]

In late October, at Pirozzi's direction, Alexion consulted with AstraZeneca immunology expert Catherine Betts concerning the September Data.[390] After reviewing the available data, Betts conveyed her "initial thoughts [were] that the immunogenicity levels are not of too much concern given they are not actually

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[384] *Id.* at 2–3.

[385] *Id.*

[386] *Id.* at 1–2.

[387] *See id.*.

[388] *Id.* at 2.

[389] JX 2100 at 3; JX 2104 at 1.

[390] *See* Pradhan Tr. 887–88.

causing any observed adverse events, as far as we can tell."[391] Betts did not provide any follow up and Alexion asked for none.[392]

On October 27, Pirozzi, Rajendra Pradhan (Alexion's executive director of clinical pharmacology and drug metabolism and pharmacokinetics),[393] and others met to discuss the ALXN1830 immunogenicity data.[394] In advance of the meeting, Washburn circulated a decision tree similar to that used in September.[395] This version of the tree had two branches.[396] One concerned the monkey death and concluded Alexion would stop development of the ALXN1830 program if the analysis of the death suggested "[p]ossible direct toxicity."[397] The other branch provided that if an assessment of the HV-108 ADA and nAb data showed an "[i]mpact on efficacy/safety," Alexion would "likely" terminate the ALXN1830 program.[398] On the other hand, if there was "[n]o impact on efficacy/safety,"

[391] JX 2122; Pradhan Tr. 887–88.

[392] Pradhan Tr. 888–89.

[393] *Id.* at 872–73.

[394] *See* JX 2109; JX 2118 at 2.

[395] JX 2109 at 25.

[396] *Id.*

[397] *Id.*

[398] *Id.*

Alexion would continue the program, resume dosing in the HV-108 study, and "[p]ursue new indications."[399]

S. The November Data

In November, Alexion received additional data from the HV-108 study (the "November Data"), which the ALXN1830 team assessed on November 8.[400] At this point, the focus was almost exclusively on Cohort 3. There were eight subjects in the cohort, two of which received a placebo.[401] The new data showed that six of the eight subjects tested positive for the presence of ADAs, with the two testing negative being members of the placebo group.[402] All six who tested positive for ADAs also tested positive for the presence of nAbs.[403] The data showed that the ADAs began

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[399] *Id.*

[400] JX 2140; Pirozzi Tr. 1467.

[401] JX 2367 at 3.

[402] JX 2140 at 11–12; Pirozzi Tr. 1469.

[403] JX 2140 at 11–12; Pirozzi Tr. 1469. SRS contends that the immunogenicity rates were not reliable because 67% of the placebo group tested positive for ADAs and 22% tested positive for nAbs. SRS Ans. Br. 30. SRS is correct about the false positive rate. JX 1976 at 10; JX 2367 at 9. And Alexion had this information at the time. JX 1976 at 10. SRS's expert, Mark Robbins, testified that he took this to mean the HV-108 data was not "highly reliable." Robbins Tr. 544.

Alexion's expert, Dr. Prasanna Jagannathan, credibly and reliably testified that the false positive rate was of no concern. Jagannathan Tr. 1293–95. He explained there are three steps for immunogenicity testing during clinical trials: (1) a screening assay; (2) a confirmatory test, which quantifies the levels of ADAs; and (3) a neutralizing assay, which assesses whether the ADAs have a neutralizing quality. *Id.* at 1293–94. Jagannathan's testimony is supported by HV-108's protocol. JX 2206.02 at 68. It is further supported by the FDA guidance Robbins cites in his report. *Immunogenicity Testing of Therapeutic*

appearing in six subjects after the fourth dose.[404] A figure further depicted that the PK for each of these subjects began increasing after the fourth dose, reflecting drug accumulation.[405] At that point, the cause of the drug accumulation was not known.[406] At the same time, PD, measured by IgG levels, began decreasing less dramatically than it had after the first three doses.[407] Dosing stopped at day eighty-four.[408] At that time, the drug accumulation decreased and each subject's IgG levels began increasing.[409] That figure, which is at the heart of this dispute, appears below.[410]

Protein Products — Developing and Validating Assays for Anti-Drug Antibody Detection, FDA at 3 (Jan. 2019), https://www.fda.gov/media/119788/download. Jagannathan also testified that the titer levels were sufficiently low in the placebo group such that he interpreted the screening assay to have produced a true false positive. Jagannathan Tr. 1294–95. Based on Jagannathan's testimony, I find that the false positive rate in HV-108 does not render the data unreliable.

[404] *See* JX 2140 at -9068(12); Kinch Tr. 335.

[405] *See* JX 2140 at 12; Jagannathan Tr. 1368.

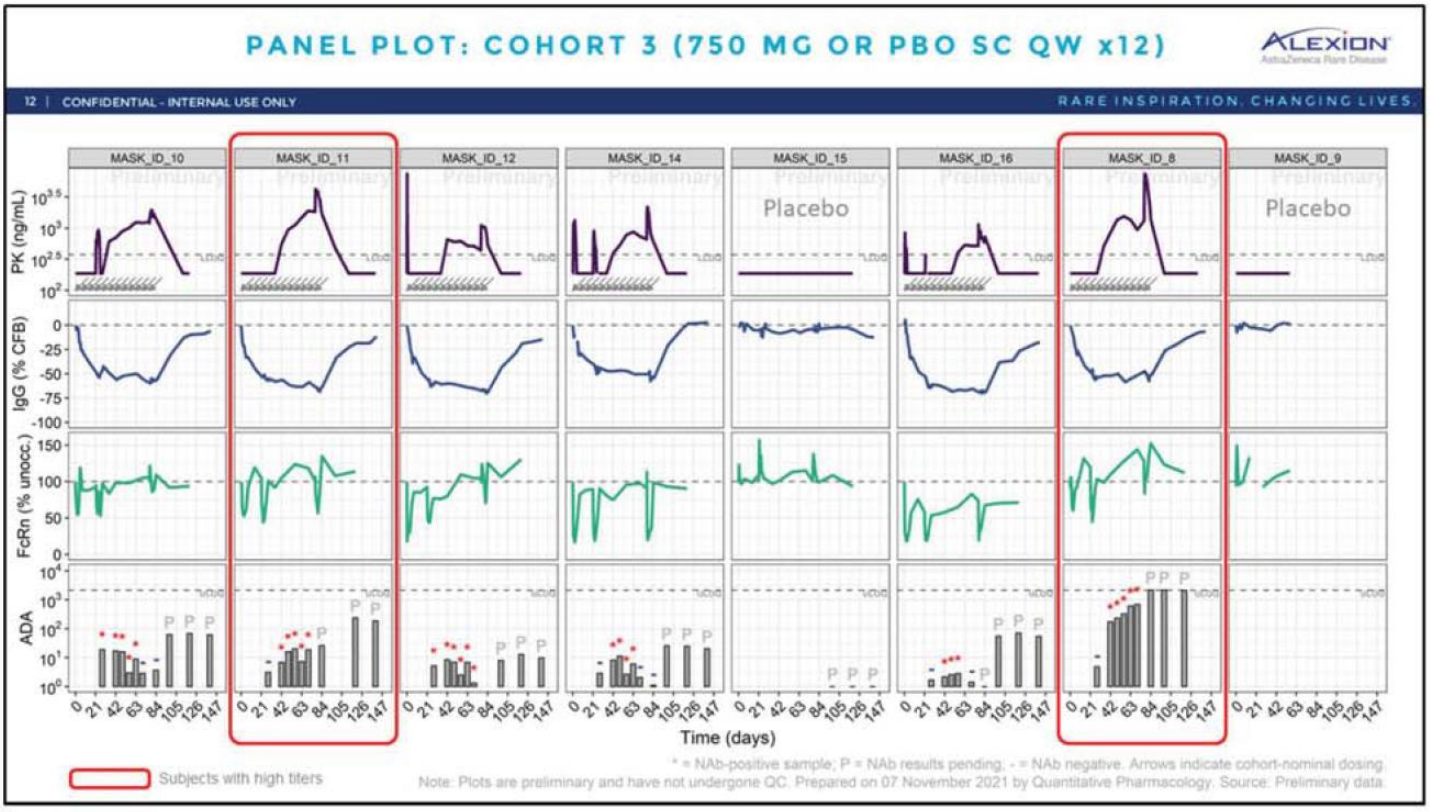
[406] *See* Pirozzi Tr. 1482–83; *see also* Jagannathan Tr. 1373 ("Q. And there's also no data showing 1830 binds to ADAs; right? A. That's correct.").

[407] JX 2140 at 12; Kinch Tr. 335–36.

[408] *See* JX 2140 at 12.

[409] *See id.*; *see also* Pirozzi Tr. 1474 (testifying that the drug accumulation began decreasing after the drug stopped being administered); Kinch Tr. 315 (testifying that patient IgG levels rose after cessation of treatment).

[410] JX 2140 at 12.



T. The Chamberlain Report

Pirozzi suggested that Alexion engage an external consultant to evaluate the HV-108 data and to "give advice on additional clinical work [Alexion] might want to take in order to clearly define the clinical significance of the ADA[s] [it] was seeing."[411] The hope was that the consultant would provide "an independent position or commentary" on the matter.[412] After consulting with an AstraZeneca employee on the best expert to hire, Alexion decided to retain Dr. Paul Chamberlain,[413] "an

[411] JX 2031; Pirozzi Tr. 1613 (testifying it was his idea to retain Chamberlain).

[412] Pradhan Tr. 889–90.

[413] JX 2031; *see generally* JX 2190.

expert in immunology."[414] Alexion met with Chamberlain on November 1 and formally retained him later that month.[415]

On November 17, Alexion received data showing that the monkey death did not reflect safety concerns with ALXN1830.[416] At that point, Alexion considered the matter resolved.[417] But dosing did not resume in HV-108, now because of the November Data.[418] Pirozzi testified that "[t]he general internal assessment was" that dosing could safely resume, but that he wanted AstraZeneca and Chamberlain to confirm that belief first.[419]

Chamberlain produced his analysis on November 23.[420] His analysis squarely took on the question posed by the September decision tree: whether ALXN1830 was "associated with an unacceptable immunogenicity profile."[421] He answered that question: "Based on results for SC administration in study HV-108, detected ADA response does not appear to compromise overall benefit vs. risk. There is an

[414] Zimmermann Tr. 1260–61.

[415] Pradhan Tr. 889; JX 2121; JX 2186.01 at 2.

[416] JX 2167; Pirozzi Tr. 1483–84.

[417] Pirozzi Tr. 1484.

[418] *Id.*

[419] *Id.* at 1485.

[420] JX 2189; JX 2186.01; JX 2186.02.

[421] JX 2189 at 5.

adequate weight of evidence to resume study HV-108 and to progress to next stage of clinical development, e.g. clinical study in subjects with [gMG].”[422]

He further concluded:

- “Subcutaneous route of administration reduces risk of immune complex mediated hypersensitivity reactions compared to intravenous administration”;[423]
- The dosing regimen used in Cohort 3 “was adequate to sustain FcRn saturation & reduction in serum total IgG”;[424]
- “PD responses IgG and FcRn saturation are maintained though 12 weeks of SC dosing, even in subjects with highest ADA levels”[425];
- “No serious reports of hypersensitivity, anaphylaxis, or other ADA-associated SAEs or AESIs”;[426]
- “ADA response did not compromise tolerability or PD response in [Cohort 3] . . . .”;[427]
- “Immunogenicity does not represent a ‘show-stopper’ for progression of ALXN-1830 to the next stage of clinical development”;[428]
- “Cannot exclude possible enhancement of immunogenicity in autoimmune populations, but risks can be monitored & mitigated”;[429] and

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[422] *Id.* at 26 (emphasis omitted).

[423] *Id.* at 19.

[424] *Id.*

[425] *Id.* at 20.

[426] *Id.* at 24.

[427] *See id.* at 27.

[428] *Id.*

[429] *Id.*

- The "SC route of adminsitration [sic] appears to reduce risk associated with immune complex formation."[430]

Despite this report, dosing did not resume. Alexion did not consult with any experts other than Betts and Chamberlain.

U. The November 30 Rare Disease Development Review Committee Meeting

Notwithstanding Betts' and Chamberlain's conclusions, Alexion's leadership increasingly favored terminating the ALXN1830 program. In November, the ALXN1830 team asked Alexion's Rare Disease Development Review Committee (the "rDRC") for input on the program's next steps.[431] The rDRC is "a committee within the R&D [group]" where employees discuss and "review programs."[432] The committee met on November 30.[433]

The rDRC considered "two important findings": the immunogenicity rates seen in HV-108, which had "no apparent impact on IgG lowering (PD)"; and "[d]rug accumulation[,] the cause of which is not entirely understood."[434] Its discussion "focused on what has changed since the last governance interaction and the impact

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[430] *Id.*

[431] JX 2195 at 2.

[432] Zimmermann Tr. 1234.

[433] JX 2187 at 1; JX 2195 at 1.

[434] JX 2195 at 2.

of recent findings on the development plan."[435] The minutes note that the ADA rate did not "appear to have an impact on safety, PK or PD" and that Chamberlain advised that the "immunogenicity data (alone) d[id] not warrant termination of the program."[436]

One attendee observed that "if the presence of ADA does not have an impact on clinical efficacy then nothing has changed since [Alexion's] preparation of the TPP,"[437] referring to the target product profile setting forth the features and characteristics a company expects a drug product to have.[438] It was noted that Alexion had "already taken action to mitigate the commercial disadvantage of being on the later order of entry for FcRn inhibitors by selecting 2 indications in which [its] competitors are not currently engaged."[439] Zimmermann stated "the immunogenicity data will complicate development from a regulatory perspective" due to the need for "constant monitoring" and "updates to health authorities throughout development and marketing," and that those burdens would "not

[435] *Id.*

[436] *Id.* at 3.

[437] *Id.*

[438] Bahl Tr. 1741.

[439] JX 2195 at 3.

dissipate over time."[440] Another attendee expressed the "need to understand the actual impact [of the ADAs] on PD and efficacy."[441]

The minutes reflect that Alexion was "close to achieving the desired level of IgG reduction," though the full implications of longer-term drug accumulation remain unknown.[442] The committee believed the accumulation was "likely related to ADA[s]."[443]

The minutes explain that moving forward with the program would require a Phase 1B/2A study, which would "address the uncertainty around immunogenicity with continued dosing and impact on the pharmacodynamic and safety profile."[444] But they note that in conducting the Phase 1B/2A study, Alexion would not "have the capacity to do enough patients necessary to dismiss the risk completely, [it] can only quantitate it"—with the capacity restriction inferably due to AstraZeneca's budget cuts.[445]

The committee reserved decision for a future meeting. It concluded: "Ultimately the decision will be whether the risk is worth carrying forward,

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[440] *Id.*

[441] *Id.*

[442] *Id.*

[443] *Id.*

[444] *Id.*

[445] *Id.* at 4.

particularly if our selected indications are not unique, or if other portfolio investments prove more favorable."[446]

V. The PTRS

The rDRC also considered a metric known as the probability of technical and regulatory success, or "PTRS."[447] Alexion uses PTRS "as a guide" when conducting program assessments.[448] Trial witnesses did not know and did not agree on how PTRS was calculated; trial revealed it to be an amalgamation of the subjective input of multiple ALXN1830 development team members.[449] As the name suggests, PTRS

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[446] *Id.*

[447] *Id.* at 3–4.

[448] Lee Tr. 476.

[449] *Id.* at 482 ("The PTRS is generally done by -- by the team, and we do evaluate based on the specific situation of the different program."); Washburn Tr. 645–46 ("Q. Do you know how the PTRS is calculated? A. It is done by the team using a set of inputs that I can't remember exactly what they are. But it is a way to assess at different stages of a development program what the probability is that you will be successful in getting a regulatory approval as well as a compound or drug that can be manufactured and delivered."); *id.* at 652–53 ("I would answer that by saying that we had relooked at the PTRS in light of all the new findings that we had, and the PTRS had decreased from approximately 30 percent, my recollection, 30 percent, to 11 percent. So when we were reviewing this, and a PTRS -- with senior leadership, and a PTRS of 11 percent raises very large doubts about whether a program could be successful going forward. . . . I can't remember the exact changes within the -- within the calculation of that, but the -- a component is safety. And since we didn't know if that drug accumulation could present a significant safety problem, I think we -- I can't remember the details. So I guess I will leave it at that."); Pradhan Tr. 898–99 ("Q. But do you know how PTRS is calculated? A. I am not the expert on calculating PTRS. Q. Who would be the expert? A. This would be somebody from portfolio prioritization group, SPPM group."). At times, the witnesses contradicted one another. *Compare* Washburn Tr. 646 ("We would rely on our commercial colleague to help with the assessment of the potential for a launch."), *with* Borborogulu Tr. 1403 ("Q. What is it? And how does it factor into your work? A. So it's the probability

is made up of "a technical portion and a regulatory portion."[450] The regulatory component is broken out as "the probability of regulatory success," or "PRS."[451] The PRS score was based on the subjective judgment of "the regulatory person that's on that particular program."[452] Trial did not identify the "regulatory person" responsible for setting the PRS before the rDRC meeting. It was equally unclear how the technical portion was calculated.

The rDRC minutes note the PTRS dropped from 30% to 11% for TED "based on emerging data from HV-108."[453] Lee circulated an email explaining the committee questioned whether the PTRS was too high.[454] Washburn directed Lee to "re-assess the prob[ability] of success for [TED] specifically."[455] Lee reduced the likelihood of proceeding to Phase 2 and 3 by 23% and 15%, respectfully, based on

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of technical and regulatory success. Technical success assigned by our clinical teams; regulatory success assigned by our regulatory teams. You multiply the two. That's PTRS. Commercial has no input on that. But what commercial will have is we'll take the PTRS and that essentially -- when I talked about risk times net present value equaling expected net present value, the PTRS is the risk."), *and* Lee Tr. 475 ("And one thing that a PTRS assessment looks at is the likelihood of a program being approved; right? A. That's just one portion of it. There's a technical portion and a regulatory portion.").

[450] Lee Tr. 475.

[451] *Id.* at 476–77.

[452] *Id.* at 483. Lee was in charge of regulatory strategy for ALXN1830. Lee Tr. 441–42.

[453] JX 2195 at 4. The minutes and accompanying presentation do not mention the PTRS for any other indication, including cAMR.

[454] JX 2199 at 1.

[455] *Id.*

the HV-108 immunogenicity data.[456] This further reduced the PTRS from 11% to 10%.[457]

W. The rESPC Meeting

Alexion's Rare Disease Early Stage Protocol Review Committee (the "rESPC") was scheduled to meet on December 14. The rESPC meetings are attended by "the CEO and the head of the functions in the company."[458]

The night before the meeting, Washburn emailed himself notes for the meeting.[459] One read: "The team believes in the science and in the program and wants to continue development. Consultant Paul Chamberlain also stated that there was no scientific reason to abandon the program at this time."[460] He continued, "the team does not have the full understanding of all factors affecting portfolio prioritization so is not able to make a final recommendation."[461]

The rESPC met the next day.[462] Pirozzi, Zimmerman, Lauchart, and others were in attendance.[463] The rESPC noted two paths forward. One was to continue

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[456] JX 2608 at 4.

[457] *Id.*

[458] Zimmermann Tr. 1254.

[459] JX 2221.

[460] *Id.* at 3.

[461] *Id.*

[462] JX 2225; JX 2226.

[463] JX 2195 at 1.

developing ALXN1830, including completing the HV-108 study to "better understand dose for patient studies" and "[e]valuat[ing] potential of a late neutralizing effect and POC in a longer duration Phase 1B/2A study in TED or cAMR."[464] The other was to stop developing ALXN1830.[465]

The meeting presentation acknowledges there was no evidence that the ADAs and nAbs had an "impact on IgG lowering."[466] It mentions the possibility that the nAbs may demonstrate a neutralizing effect (i.e., begin decreasing the IgG lowering) after twelve weeks.[467] Alexion would have to conduct an additional Phase 1B/2A study to get that data.[468] If the program was not terminated, HV-108 dosing would not resume until February 2022.[469] The presentation notes that immunogenicity data on the drug's label could impact its competitive strength.[470]

The meeting minutes note that that the committee did not know the cause of the drug accumulation, and that it would have to develop a new assay to "elucidate

[464] JX 2930 at 3.

[465] *Id.*

[466] *Id.* at 4.

[467] *Id.*

[468] *Id.*

[469] *Id.* at 10.

[470] *Id.* at 4.

the mechanism of" the accumulation.[471] They also note that there were still no competitors developing anti-FcRn treatments for TED and cAMR.[472]

The rESPC decided to terminate the ALXN1830 program.[473] The minutes provide that it considered:

- "The risk of immunogenicity having a potential impact on PD/efficacy would be carried throughout development and even into post marketing."[474]
- "ALXN1830 has a far greater incidence of immunogenicity, and IgG reduction was comparable or slightly less than competitors."[475]
- ALXN1830 would be the fifth FcRn to market.[476]
- "COVID and [the monkey death] which required a study pause for safety exacerbated the situation."[477]
- "Immunogenicity, drug accumulation, and high volume for the device all disadvantage this development program without advantages to balance the risks."[478]
- The lack of albumin lowering, which the committee viewed as a positive indication.[479]

[471] JX 2226 at 2.

[472] *Id.*

[473] *Id.*

[474] *Id.* at 1.

[475] *Id.*

[476] *Id.*

[477] *Id.*

[478] *Id.* at 1–2.

[479] *Id.* at 3.

The presentation notes other factors favoring continuing the program, including the lack of any adverse safety signals and the fact the HV-108 data was "[e]xpected to achieve IgG lowering threshold required for efficacy."[480]

SRS was notified of the program's termination in January 2022 via letter from Alexion.[481] Alexion's letter included the following non-exhaustive list of disadvantages that it said contributed to its decision to terminate the program: "ALXN1830's PK limitations, large required dosing volume and delivery challenges, less favorable immunogenicity profile, and unexplained immunogenicity and drug accumulation issues that would extend development timelines and would likely carry forward to post-marketing monitoring of the product."[482]

X. The HV-108 CSR

The HV-108 CSR was issued in August 2022.[483] The CSR was consistent with many contemporaneous documents from the fall and winter of 2021, noting: "Overall, across dose groups, irrespective of the presence of ADA, NAbs or high ADA titers, no impact on the drug concentrations (PK profile) or IgG (PD marker) levels were observed."[484] This phrase mirrored the merger agreement's Criterion 5

[480] JX 2220 at 16.

[481] JX 2261.

[482] *Id.* at 1.

[483] JX 2367 at 1.

[484] *Id.* at 10.

of Milestone 1, which requires that the Phase 1 data show an "[a]nti-drug antibody profile that does not have meaningful impact on PK/PD as evidenced by total IgG reduction."[485]

In May 2023, after this suit was filed, Alexion released a revised CSR for the HV-108 study, changing only that phrase.[486] It was revised to read: "Overall, across dose groups, irrespective of the presence of ADA, NAbs or high ADA titers, no reduction on the drug concentrations (PK profile) or IgG (PD marker) levels were observed."[487]

Y. Procedural History

SRS filed its complaint in this action on December 17, 2020, days after AstraZeneca announced it was acquiring Alexion, asserting claims for breach of the Merger Agreement's CRE Obligation to progress ALXN1830 towards achieving the milestones.[488] SRS also sought a declaratory judgment as to Alexion's request for indemnification based on contaminated drug supply. On February 12, 2021, Alexion answered the second count, counterclaimed for breach of SRS's indemnification obligations, and moved to dismiss SRS's breach of contract claim on the grounds

[485] Merger Agr. Ex. I.

[486] JX 2582 at 10.

[487] The revision replaces the word "impact" with "reduction." *Id.*

[488] D.I. 1; D.I. 71 ¶ J.

that it was unripe because the CRE Obligation continued for another five years.[489] I denied Alexion's motion to dismiss on September 1, explaining the CRE Obligation spoke to Alexion's efforts, not its results, and that it "requires persistent efforts for the entire contractual seven-year period, as distinct from long-term results."[490]

After Alexion terminated the ALXN1830 program, SRS filed an amended complaint in March 2022.[491] It added, among other things, a claim for breach of the Merger Agreement for failure to pay $130 million upon completion of Milestone 1. SRS's operative complaint presents Count I for failure to exercise commercially reasonable efforts to achieve Milestones 1-3; Count II for failure to exercise commercially reasonable efforts to achieve Milestones 4-8; Count III for failure to pay for achievement of Milestone 1; Count IV for taking or omitting actions to avoid achievement of milestone events; and Count V for a declaratory judgment on Alexion's indemnification claim.[492]

Alexion responded by amending its counterclaims, adding reciprocal causes of action for a declaratory judgment that it used commercially reasonable efforts,

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[489] D.I. 24; D.I. 26.

[490] D.I. 71 ¶ 2; *S'holder Representative Servs. LLC v. Alexion Pharms., Inc.*, 2021 WL 3925937, at *6 (Del. Ch. Sept. 1, 2021).

[491] D.I. 155.

[492] *Id.*

and another that it did not meet Milestone 1.[493] Alexion also presented a counterclaim for breach of Section 4.13(a) of the Merger Agreement, a representation that Syntimmune's product candidates were created and handled in compliance with regulations and good practices.[494]

The parties marched through extensive discovery and discovery motion practice. SRS brought several motions to preclude expert testimony. Before trial, I granted its motion to strike testimony based on an untimely expert report by Yogesh Bahl.[495] The parties proceeded to a seven-day trial from July 10 to July 18.[496] After trial, with the benefit of hearing the disputed testimony subject to SRS's objections, I denied SRS's motions to preclude testimony from Brian Harvey and rebuttal testimony by Bahl.[497] I granted in part its motion to exclude some testimony by Prasanna Jagannathan as outside his still formidable expertise, and as to some testimony outside the scope of permissible rebuttal testimony.[498]

Post-trial argument was held on January 12, 2024.[499] This opinion addresses the merits of the parties' claims concerning whether Alexion met Milestone 1 and

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[493] D.I. 158.

[494] *Id.*

[495] D.I. 272.

[496] D.I. 341.

[497] D.I. 359 at 4–5.

[498] *Id.* at 6–10.

[499] D.I. 379 at 1.

whether it used commercially reasonable efforts. Damages and Alexion's claim for indemnification will be addressed in a subsequent opinion.

II. ANALYSIS

SRS advances a claim for breach of the Merger Agreement for failure to pay $130 million following the successful completion of Milestone 1. It concedes Milestones 2 through 8 were not satisfied, but contends they would have been if Alexion had complied with the CRE Obligation. Alexion raises the affirmative defense of unclean hands to SRS's breach of the CRE Obligation claim. Alexion seeks judgment in its favor on SRS's claims as well as its own reciprocal declaratory judgment claims.

A. Alexion Satisfied Milestone 1.

Alexion and Syntimmune agreed that satisfaction of five criteria would demonstrate "successful completion of a Phase I Clinical Trial of the SC Formulation," thereby triggering Milestone 1.[500] Criterion 1 reads: "1) An observed PK/PD profile that supports weekly or less frequent subcutaneous administration in long term safety and efficacy studies."[501] Criterion 2 addresses storage stability, and Criterion 3 addresses reduction in total IgG without certain other effects. Criterion 4 requires the Phase 1 study data show a "[s]afety and tolerability profile that permits

[500] Merger Agr. § 3.8(a)(i), Ex. I.

[501] *Id.* Ex. I.

continued dosing of cohorts in additional subcutaneous formulation clinical studies."[502] And Criterion 5 addresses the anti-drug antibody profile. Alexion concedes Criteria 2, 3, and 4 have been satisfied.[503] The parties dispute the interpretation and satisfaction of Criteria 1 and 5.

"Delaware adheres to the 'objective' theory of contracts, i.e. a contract's construction should be that which would be understood by an objective, reasonable third party."[504] The Court reads the "contract as a whole and we will give each provision and term effect, so as not to render any part of the contract mere surplusage."[505] "When interpreting a contract, the Court will give priority to the parties' intentions as reflected in the four corners of the agreement."[506] "If a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity."[507]

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[502] *Id.* Ex. I(4).

[503] ALXN Ans. Br. 3 n.1 ("Alexion does not dispute that Criteria 2–4 were met . . . .").

[504] *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (internal quotation marks omitted) (quoting *NBC Universal v. Paxson Commc'ns*, 2005 WL 1038997, at *5 (Del. Ch. Apr. 29, 2005)).

[505] *Id.* (internal quotation marks omitted) (quoting *Kuhn Construction, Inc. v. Diamond State Port Corp.*, 2010 WL 779992, *2 (Del. Mar. 8, 2010)).

[506] *GMG Cap. Invs., LLC v. Athenian Venture P'rs I, L.P.*, 36 A.3d 776, 779 (Del. 2012).

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

1. Criterion 1

The parties disagree over the correct interpretation of Criterion 1 and whether Criterion 1 was satisfied. Both parties' briefing assumes, without seriously arguing, that the Merger Agreement's plain language supports their proposed interpretation. Neither party takes on the other's textual interpretation. Left to my own devices, I conclude Criterion 1's language is ambiguous. I then conclude the extrinsic evidence supports SRS's interpretation.

a. Criterion 1's Plain Language

I start with the Merger Agreement's plain language.[508] Criterion 1 requires that Phase 1 data show "[a]n observed PK/PD profile that supports weekly or less frequent subcutaneous administration in long term safety and efficacy studies."[509] The parties agree PK is measured by the concentration of ALXN1830 in the subject's blood.[510] They also agree PD is measured by IgG lowering.[511]

SRS argues Criterion 1 is keyed to dosing frequency. Under SRS's interpretation, Criterion 1 is satisfied if a Phase 1 trial produces PK/PD data supporting the concept that ALXN1830 would not have to be dosed more than once

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[508] *Symbiont.io, Inc. v. Ipreo Hldgs., LLC*, 2021 WL 3575709, at *29 (Del. Ch. Aug. 13, 2021) ("Contractual interpretation begins with plain language.").

[509] Merger Agr. Ex. I(1).

[510] ALXN Op. Br. 79; *see* SRS Op. Br. 47.

[511] ALXN Op. Br. 79; SRS Op. Br. 47.

per week in the event Alexion were to proceed to a long term safety and efficacy study.[512] SRS contends it prevails under this reading because the HV-108 data supported a weekly or less frequent dosing regimen for the duration of a long term study. SRS's reading comports with the plain meaning and gives every word meaning. It is reasonable.

Alexion agrees with SRS that Criterion 1 demands the Phase 1 data require dosing no more than once a week.[513] But Alexion contends Criterion 1 includes a second requirement: that the Phase 1 data show a PD/PK profile supporting the administration of ALXN1830 in a long term safety and efficacy study.[514] Put differently, under Alexion's interpretation, the language could read: "An observed PK/PD profile that supports administration in long term safety and efficacy studies, and the data must also support weekly or less frequent subcutaneous administration in the long term safety and efficacy study." Alexion argues that it prevails under this interpretation because the unexplained drug accumulation from HV-108 required further study before a long term safety and efficacy study could be conducted: the data did not support actually administering such a study.[515] The concept that data supporting weekly dosing would have to support dosing at all is

[512] SRS Op. Br. 49.

[513] ALXN Ans. Br. 3.

[514] *Id.*

[515] *Id.* at 6–8.

also consistent with the plain meaning and gives meaning to every word in the criterion. Alexion's reading is also reasonable.

SRS argued that each of the five Exhibit I criteria addresses a separate issue, and that because Criterion 4 speaks to safety, Alexion is trying to "create a double assessment of safety" through its interpretation of Criterion 1.[516] As an initial matter, SRS is incorrect that only one of the criteria speaks to safety. Criterion 5 addresses the presence of ADAs and whether those ADAs affect PK/PD, and the parties agree drug accumulation unaccompanied by IgG lowering can reflect a safety concern. And in any event, even if Criteria 1 and 4 overlap on the issue of drug accumulation, they do not overlap on all issues. Criterion 4, as measured by IgG lowering, is not superfluous of Criterion 1's dosing metric. SRS has offered no reason why the two criteria cannot speak to safety in different ways.

Left with two reasonable interpretations, I look next to the entire Merger Agreement for context. "When interpreting a contract, this Court 'will give priority to the parties' intentions as reflected in the four corners of the agreement,' construing the agreement as a whole and giving effect to all its provisions."[517] I see nothing in the Merger Agreement that makes either interpretation unreasonable. I first tried

[516] D.I. 379 at 12.

[517] *Salamone v. Gorman*, 106 A.3d 354, 368 (Del. 2014) (quoting *GMG Capital*, 36 A.3d at 779).

going down a rabbit hole of nested definitions in Milestone 1. Milestone 1 makes clear that the purpose of the criteria, including Criterion 1, are to demonstrate "the successful completion of a Phase 1 Clinical Trial."[518] The agreement defines "Phase 1 Clinical Trial" to mean "a Clinical Trial that is intended to satisfy the requirements of 21 C.F.R. § 312.21(a)."[519] That section of the CFR adds further context, explaining Phase 1 trials "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness" and that "sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies."[520] But the reference to Phase 1 Clinical Trials is of little interpretative value. The point of Exhibit I was to create a bespoke definition of success in a Phase 1 clinical trial.

I next looked to the purpose of Milestone 1 and its criteria. The purpose is to benchmark progress that warrants compensating Syntimmune stockholders. On the one hand, the parties agreed Alexion's efforts could take into account competitive and commercial considerations. This purpose emphasizes ALXN1830's attributes

[518] Merger Agr. § 3.8(a)(i)(A).

[519] *Id.* at 20. The agreement defines "Clinical Trial" as "a clinical study of a pharmaceutical product conducted on human subjects." *Id.* at 9.

[520] 21 C.F.R. § 312.21(a)(1).

that differentiate the drug in the marketplace, such as less frequent dosing; this tends to support SRS's interpretation. But the milestones also show an intention to compensate Syntimmune stockholders when regulatory approval is obtained, which would tend to support Alexion's interpretation.

The parties have pointed to nothing in the Merger Agreement that sheds any light on the parties' intended meaning of Criterion 1. I conclude Criterion 1 is ambiguous because it is fairly susceptible to both parties' reasonable interpretations.[521]

b. Extrinsic Evidence

Because I conclude Criterion 1 is ambiguous, I may consider extrinsic evidence to determine the parties' intent.[522] SRS bears the burden of proof of supporting its interpretation through extrinsic evidence.[523] When interpreting an

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[521] *Eagle Indus.*, 702 A.2d at 1232 ("When the provisions in controversy are fairly susceptible of different interpretations or may have two or more different meanings, there is ambiguity.").

I am not alone in finding the criteria ambiguous. As negotiations began, a Syntimmune employee wrote of the milestones, "I don't like these as written since they are quite vague." JX 509 at 1. Towards the end, Syntimmune employees observed, "[T]his looks like a lawyer trying to define something that he does not understand," and struggled to divine Alexion's intent. JX 638 at 2.

[522] *Eagle Indus.*, 702 A.2d at 1232 ("[W]hen there is uncertainty in the meaning and application of contract language, the reviewing court must consider the evidence offered in order to arrive at a proper interpretation of contractual terms.").

[523] *Lillis v. AT & T Corp.*, 2008 WL 2811153, at *4 (Del. Ch. July 21, 2008) ("As the party seeking judicial enforcement of their interpretation of an ambiguous contract, the plaintiffs bear the burden of proof in this action."), *aff'd sub nom. AT&T Corp. v. Lillis*, 970 A.2d

ambiguous contract provision through extrinsic evidence, "interpretation of the language becomes a question of fact."[524] The parties' negotiation history is extrinsic evidence.[525] Here, the extrinsic evidence shows the parties intended to compensate achievement of a dosing regimen based on Phase 1 data, not on readiness to move to Phase 2 or Phase 3.

First, the extrinsic evidence reveals an early and persistent emphasis on awarding prompt achievement of an infrequent dosing regimen. Alexion went into the merger negotiations emphasizing the significance of quickly establishing weekly or less frequent dosing for the SC formulation. It opened discussions with a benchmark of dosing every two weeks.[526] Syntimmune understood the importance of this benchmark, wondering if its data at the time supported a belief that benchmark could be met, and responded by removing a dosing regimen milestone.[527] Alexion

166 (Del. 2009); *Bell Atl. Meridian Sys. v. Octel Commc'ns Corp.*, 1995 WL 707916, at *6 (Del. Ch. Nov. 28, 1995) ("Under this analysis, then, it becomes incumbent upon the party seeking judicial enforcement of their interpretation of the ambiguous language to show by a preponderance of the evidence that the other party knew or had reason to know of the meaning they attached to the language.").

[524] *Motorola, Inc. v. Amkor Tech., Inc.*, 849 A.2d 931, 936 (Del. 2004).

[525] *See Emerging Eur. Growth Fund, L.P. v. Figlus*, 2018 WL 6446467, at *5 (Del. Ch. Dec. 10, 2018) (stating "the history of negotiations" is extrinsic evidence).

[526] JX 437 at 3.

[527] JX 485 at 1; JX 486 at 2; JX 489 at 2.

continued to emphasize a weekly or less frequent dosing regimen.[528] Alexion's August 3 offer described its dosing requirement as "critical" to the commercial viability of ALXN1830.[529] Alexion wrote that "dosing of once every week or less frequent" was necessary "[t]o have commercial viability in the current landscape."[530] The same letter proposed the first version of Milestone 1, which included dosing less than once a week as one of seven criteria.[531] Syntimmune understood Alexion's focus on dosing and weighed the risk that the criterion would not be met, but agreed that the first milestone would be based on successful completion of a Phase 1 study with weekly or less frequent dosing.[532] From there, that dosing requirement would remain constant.[533]

Second, Alexion consistently pushed for a milestone based on a demonstrable ability to move to a Phase 2 or Phase 3 study, while Syntimmune consistently pulled for one based on what the Phase 1 data revealed. This push-pull manifested within the definition of Milestone 1 itself. Alexion wanted to define a successful Phase 1

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[528] JX 489 at 1 (suggesting "every 2 weeks" as a definition of success for the SC formulation); JX 515 at 1.

[529] JX 524.02 at 2.

[530] *Id.*

[531] *Id.*

[532] JX 509; *see* JX 520.

[533] JX 610 at 42–43, 120; JX 617 at 2; JX 633.02 at 118; JX 649 at 8–9; *see* JX 630; JX 637.

trial as submission of a Phase 2 or Phase 3 protocol.[534] Syntimmune wanted to define a successful Phase 1 trial with bespoke criteria based on that trial's data.[535] Syntimmune's approach prevailed. This extrinsic evidence reveals that the Merger Agreement's definition of Phase 1 success was intended to benchmark Milestone 1 on Phase 1 data, not on readiness to move to Phase 2 or Phase 3.

Alexion would then try to incorporate readiness to move to Phase 2 or Phase 3 into those criteria. Crucially, this effort reveals that Alexion's lead negotiator did not believe that readiness was captured by Criterion 1's current language. On a September 5 email chain, an Alexion employee offered Sarin and others the current version of Criterion 1.[536] Sarin responded that it was important to add a regulatory demonstration that ALXN1830 was prepared for a Phase 2 or Phase 3 trial.[537] The solution at the time was to incorporate readiness for such a trial into an earlier version of Criterion 2, which addresses drug concentration.[538] This reveals Sarin did not believe Criterion 1 required that readiness.[539] And as negotiations unfolded, Syntimmune puzzled over Alexion's proposed criteria and whether they were based

[534] JX 534 at 3; JX 593.02 at 30; JX 594 at 1; *see* JX 637.

[535] JX 567 at 1; JX 610 at 42–43, 120; *see* JX 637.

[536] JX 617 at 2.

[537] *Id.* at 1–2.

[538] *Id.* at 1.

[539] This contemporaneous evidence carries far more weight than Sarin's conclusory testimony at trial, which I did not find credible. *See* Sarin Tr. 1006–07.

on Phase 1 data, or on progressing to a pivotal bridging study.[540] Syntimmune concluded:

> By using the first clinical efficacy study in patients, this clearly describes that the milestone will be achieved . . . if they believe the SC formulation is adequate to progress into development based on the phase 1 SC study.[541]

The push-pull between what Phase 1 data showed, and readiness to move on to Phase 2 or Phase 3, also manifested in other terms that Syntimmune rejected. Alexion attempted to add language to the concentration criterion providing that the data must "support[] storage conditions for drug supply and drug product suitable for use in Phase 2/Phase 3 clinical studies."[542] Syntimmune rejected that language.[543] Alexion also attempted to require readiness to move to Phase 2 or Phase 3 by revising the definition of Phase 1 Clinical Trial, changing the term to "Phase 1b Clinical Trial."[544] Under the revised definition, the clinical trial would be "intended to . . . establish sufficient data to be included in regulatory filings for a Phase II Clinical

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[540] JX 638 at 2.

[541] *Id.*

[542] JX 621.

[543] *See id.* (reflecting conversation between Sarin and Syntimmune representatives regarding the proposed criteria); JX 633 at 118.

[544] JX 633.02 at 23.

Trial or a Pivotal Clinical Trial with the FDA or its foreign counterpart."[545] Syntimmune rejected this proposed addition as well.

This extrinsic evidence supports SRS's interpretation that Criterion 1 was intended to emphasize the ability to dose weekly or less frequently. It shows the phrase was not intended to award readiness to dose a patient in a long term study. Alexion's internal communications reveal that it did not read the current version of Criterion 1 as imposing such a requirement. Alexion attempted to include similar requirements elsewhere, but Syntimmune rejected that language. As to Syntimmune, there is no evidence it ever intended Criterion 1 to require data supporting a long term safety and efficacy study: Syntimmune explicitly and persistently wanted language that would reward Phase 1 data, not readiness to move on to Phase 2 or 3.

The parties also hotly dispute the meaning of "long term safety and efficacy study." Alexion argues that "for chronically-administered drugs, like ALXN1830, [long term] is 'generally 12 months or longer' and therefore is typically a 'phase 3,' or 'pivotal' or 'registrational' study."[546] SRS disagrees, contending the meaning of "long term" varies by disease, and that a long term study in WAIHA "would last six-

[545] *Id.*

[546] ALXN Op. Br. 83–84 (citing Sarin Tr. 949–50; Robbins Tr. 619–21; Harvey Tr. 1683).

months."[547] As explained below, there is no evidence that ALXN1830 would have to be dosed more than once a week in a trial of any duration, and so I do not resolve that dispute.

c. Criterion 1 Was Satisfied.

SRS proved at trial that Criterion 1 was satisfied. The parties focus exclusively on the HV-108 Cohort 3 data. Cohort 3 was dosed once a week for twelve weeks.[548] That dosing resulted in sustained IgG lowering for the duration of the trial.[549] Dr. Michael Kinch (SRS's expert on antibody development),[550] Washburn, and Dr. Prasanna Jagannathan (Alexion's expert on immunology) all testified that the level of IgG lowering supported dosing in future trials at the same frequency, regardless of trial length.[551]

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[547] SRS Ans. Br. 12.

[548] JX 2367 at 3.

[549] Jagannathan Tr. 1355; JX 2032 at 8 (analyzing the September Data, noting "[r]obust and sustained IgG lowering" despite a "[h]igh ADA rate" and "[n]o potential impact of ADA on PK/PD"); JX 2367 at 11; JX 2180 at 22.

[550] Kinch Tr. 218.

[551] *Id.* at 314 ("Q. Do you see any evidence here that, in your view, would caution against weekly or less frequent subcutaneous administration in long-term safety and efficacy studies? A. Well, it's not just in this data. It's also the fact that when you see these levels of antibody, you're not detecting any adverse events that rise above a Grade 2, with, again, a majority being grade 1. So, no, there's nothing that would prevent weekly dosing."); Jagannathan Tr. 1354 ("[Y]ou are not aware of any data to support the rationale that 1830 would need to be given more frequently than once per week. Right? A. I'm not aware of any data that ALXN1830 would need to be given more frequently than once per week."); *id.* at 1358–59 (testifying that the Cohort 3 data supported "weekly dosing in future long-term trials" for purposes of achieving IgG lowering of at least 50%); Washburn Tr. 656

Alexion makes two arguments. First, it argues that unexplained drug accumulation reflected potential safety problems that precluded actual dosing at any frequency in a long term study. Alexion argues those potential problems required gathering additional data on the cause of the drug accumulation (whether it was bound or free drug, and whether it would continue to rise to a level where it would cause an SAE) before any such dosing could occur. That may be so; Alexion might have more work to do before proceeding to that study. But under Criterion 1 as I have interpreted it, that additional work is irrelevant to Criterion 1 so long as it does not threaten dosing more than once a week. The preponderance of the evidence demonstrates that HV-108 established that any future long term study would feature weekly or less frequent dosing.

Alexion also argues the Cohort 3 data reflect that ALXN1830 did not achieve a steady state, rendering the dose amount uncertain. This argument assumes that if the dose amount is uncertain, then the dosing frequency is necessarily also uncertain, and if the frequency is uncertain, both increasing and decreasing the frequency are possible solutions. The only support for the view that more frequent dosing was

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("Q. Did the data from HV-108 suggest that 1830 needed to be administered more frequently than once weekly? A. I don't believe so."); *see also* Pradhan Tr. 898 (testifying that as of the December 2021 rESPC meeting, Alexion was considering an initial once a week dose and then dosing "less frequently to maintain efficacy"); JX 2180 at 22 ("750 mg or PBO SC QW x12 dose regimen was adequate to sustain FcRn saturation & reduction in serum total IgG.").

even a possible response to the drug accumulation seen in Cohort 3 is the somewhat equivocal opinion testimony of Pradhan, a nonexpert.[552]

SRS established that Criterion 1 was satisfied.

2. Was Criterion 5 Satisfied?

SRS also established the HV-108 data satisfied Criterion 5. As with Criterion 1, the parties dispute both the interpretation of the criterion and whether it was satisfied.

a. Interpretation Of Criterion 5

Criterion 5 requires that the trial data show an "[a]nti-drug antibody profile that does not have meaningful impact on PK/PD as evidenced by total IgG reduction."[553] The parties dispute the metric by which Criterion 5 must be satisfied. SRS reads it to require an evaluation of only total IgG lowering, notwithstanding any other indications that ADAs may be affecting PK and PD. Alexion argues that the proper reading is broader, and that the Court should look to other markers of PK

[552] Pradhan Tr. 909 ("Q. Why would drug accumulation and ADA response necessitate more frequent dosing than once per week? A. The simple-minded way to look at this is if we cross some kind of threshold in this accumulation where there is sufficient ADA circulating that is capable of consuming or sucking up the drug that is being given once a week, that once-a-week administration will be insufficient to maintain the required efficacy or IgG lowering, and that's why the concern is we may have to give more frequent dosing.").

[553] Merger Agr. Ex. I.

and PD, including data reflecting safety generally and drug accumulation in particular.

The plain language of Criterion 5 demonstrates the parties intended it to ask whether ADAs meaningfully affected PK or PD. It unambiguously provides for one metric by which to measure this: IgG lowering. The parties included no other metrics, suggesting IgG lowering was intended as the sole metric.

Alexion argues this interpretation cannot be correct because the parties' experts agree PK is measured not by IgG lowering, "but rather by blood serum concentration."[554] I agree the record does not explain how IgG lowering would be a direct metric for whether ADAs affect PK.[555] But "[p]arties have a right to enter into good and bad contracts, the law enforces both."[556] The parties to the Merger Agreement were highly sophisticated. The language at issue was highly negotiated—and for good reason, as it is one of five criteria used to determine when Alexion would owe SRS a $130 million milestone payment. While IgG lowering may not be the most useful or direct metric for whether ADAs affect PK, it is the

[554] ALXN Ans. Br. 13 (citing Kinch Tr. 429–30; Jagannathan Tr. 1320–21).

[555] There is at least some connection between PK and IgG lowering. SRS's expert, Michael Kinch, testified that drug accumulation (measured by PK) is "an indication that you have got a reservoir that drug can be drawn from so that if you dip below that [therapeutic] window, it can draw the drug from that particular reservoir." Kinch Tr. 259–60. For ALXN1830, the therapeutic window begins where IgG lowering can be observed.

[556] *Nemec v. Shrader*, 991 A.2d 1120, 1126 (Del. 2010).

one the parties chose. It is not for the Court to alter the unambiguous language the parties agreed to.[557] Indeed, "it is not the job of a court to relieve sophisticated parties of the burdens of contracts they wish they had drafted differently but in fact did not."[558] I agree with SRS that Criterion 5 measures any effect on PK and PD solely by IgG lowering.

Though I resolved this issue solely based on the Merger Agreement's plain language, the extrinsic evidence supports this reading as well. The Court may resort to extrinsic evidence to discern the contracting parties' intent only when the agreement is ambiguous.[559] Extrinsic evidence includes the parties' negotiation

[557] *W. Willow-Bay Ct., LLC v. Robino-Bay Ct. Plaza, LLC*, 2007 WL 3317551, at *9 (Del. Ch. Nov. 2, 2007) ("The presumption that the parties are bound by the language of the agreement they negotiated applies with even greater force when the parties are sophisticated entities that have engaged in arms-length negotiations."), *aff'd*, 985 A.2d 391 (Del. 2009).

[558] *DeLucca v. KKAT Mgmt., L.L.C.*, 2006 WL 224058, at *2 (Del. Ch. Jan. 23, 2006).

[559] *Sunline Com. Carriers, Inc. v. CITGO Petroleum Corp.*, 206 A.3d 836, 847 (Del. 2019); *cf. Eagle Indus.*, 702 A.2d at 1232 ("If a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity.").

history.[560] Such evidence cannot be used to alter the plain meaning of the agreement.[561]

On September 7, 2018, Alexion's attorneys circulated a draft merger agreement with language mirroring the interpretation Alexion now advances: "Anti-drug antibody profile that does not have meaningful impact on PK/PD, *including total IgG reduction*."[562] The introduction of the IgG reduction metric through the use of "including" conveys that IgG reduction would be one of several

[560] *See SI Mgmt. L.P. v. Wininger*, 707 A.2d 37, 43 (Del. 1998) ("[I]t is proper to consider extrinsic evidence of bilateral negotiations when there is an ambiguous contract that was the product of those negotiations."); *see also Eagle Indus.*, 702 A.2d at 1233 ("In construing an ambiguous contractual provision, a court may consider evidence of prior agreements and communications of the parties as well as trade usage or course of dealing.").

[561] *IMO Ronald J. Mount 2012 Irrevocable Dynasty Tr. U/A/D Dec. 5, 2012*, 2017 WL 4082886, at *5 n.19 (Del. Ch. Sept. 7, 2017) ("[E]xtrinsic evidence cannot alter the plain language within the four corners of [a contract]." (citing *Eagle Indus.*, 702 A.2d at 1232–33)).

[562] JX 633.02 at 118 (emphasis added); JX 633.01 (transmitting draft of merger agreement); *see also* JX 617 at 2 (discussing framing used in the September 7 draft); JX 621 (same).

factors to consider.[563] SRS rejected that phrasing.[564] Instead, the parties settled on the "as evinced by" language seen in the final version of the Merger Agreement. The rejection of this language in favor of the language used in the final version of Criterion 5—which I have interpreted to unambiguously provide IgG lowering as the sole metric—demonstrates the parties did not intend for IgG lowering to be only one of several metrics used to assess whether the criterion was satisfied.[565]

b. The Levels Of IgG Lowering Shown In The HV-108 Trial Demonstrate Criterion 5 Was Satisfied.

I now turn to whether Criterion 5 was satisfied, i.e. whether the levels of IgG lowering in HV-108 reflect an effect from ADAs.

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[563] *Include*, Black's Law Dictionary (12th ed. 2024) (defining include to mean "[t]o contain as a part of something"); Kenneth A. Adams, *A Manual of Style for Contract Drafting* § 13.354 (4th ed. 2017) ("In interpreting contracts and statutes, courts have routinely held that *including* or *includes* introduces an illustrative list."); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 132 (2012) (explaining the use of the word "*include* does not ordinarily introduce an exhaustive list"); *see also Pauls v. State*, 554 A.2d 1125, at *2 (Del. 1989) ("As mentioned above, 11 *Del. C.* § 222(5) merely provides an *illustrative* list of the instruments which qualify as deadly weapons, as is made clear by its use of the word "includes" before giving the list containing examples of proscribed weapons.").

[564] Hall Tr. 87 (testifying SRS rejected the framing of the Milestone 1 criteria set forth in the September 7 draft). *Compare* Merger Agr. Ex. I ¶ 5 ("Anti-drug antibody profile that does not have meaningful impact on PK/PD *as evidenced by total IgG reduction*." (emphasis added)), *with* JX 633.02 at 118 ("Anti-drug antibody profile that does not have meaningful impact on PK/PD, *including total IgG reduction*." (emphasis added)).

[565] *See GRT, Inc. v. Marathon GTF Tech., Ltd.*, 2012 WL 2356489, at *7 (Del. Ch. June 21, 2012) ("Under basic principles of Delaware contract law, and consistent with Delaware's pro-contractarian policy, a party may not come to court to enforce a contractual right that it did not obtain for itself at the negotiating table.").

Myriad contemporaneous documents drafted by Alexion employees conclude the presence of ADAs did not have an impact on IgG lowering.[566] Experts for both parties testified the HV-108 data do not reflect that the presence of ADAs had any effect on IgG lowering, let alone a meaningful one.[567] Further, Pradhan testified Alexion did not observe an increase in PK at the time.[568] And notably, the August 2022 CSR for the HV-108 study concluded: "Overall, across dose groups, irrespective of the presence of ADA, NAbs or high ADA titers, no impact on the drug concentrations (PK profile) or IgG (PD marker) levels were observed."[569] That

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[566] JX 2032 at 8 (presentation analyzing the September Data, which notes "[r]obust and sustained IgG lowering" despite a "[h]igh ADA rate" and "[n]o potential impact of ADA on PK/PD."); JX 2094 at 1 (October 13, 2021 email from Lee giving an update from a GPT meeting, and explaining that "ADAs, even at high frequency — no associated impact to IgG lowering and safety; no PK effect"); JX 2109 at 5 (slides for October 26, 2021 meeting of ALXN1830 leadership team, reading, "Irrespective of the titer levels, no impact on % change of IgG."); *see also* JX 1998 at 2 (September 17, 2021 email containing slides stating "[n]o observed association between ADA status and PD response").

[567] Kinch Tr. 335–36; Jagannathan Tr. 1308 ("So in the context of HV-108, you see the development of neutralizing antibodies. You also see that IgG lowering has -- you have actually significant IgG lowering. You don't see loss of that lowering, meaning that you don't see IgG levels going back to normal, despite repeated administration. And so within the context of HV-108, you don't see loss of efficacy yet, at least within the context of the neutralizing antibodies that are there thus far.").

[568] Pradhan Tr. 881–82.

[569] JX 2367 at 10. In May of 2023—nine months after the HV-108 CSR was released and less than two months before trial was set to begin in this litigation—Alexion issued a second version of the CSR. JX 2582. It read: "Overall, across dose groups, irrespective of the presence of ADA, NAbs or high ADA titers, *no reduction* on the drug concentrations (PK profile) or IgG (PD marker) levels were observed." JX 2582 at 10 (emphasis added). The only change of which the Court is aware is that Alexion replaced the word "impact" with "reduction," so that the language no longer mirrored that of Criterion 5. *Compare* JX 2367 at 10, *with* JX 2582 at 10. I give the revised CSR no weight.

language was drafted by Alexion's head of immunogenicity.[570] No contemporaneous documents in the record even suggest that anyone at Alexion believed the HV-108 data showed ADAs affected IgG lowering through August of 2022.

Alexion argues that the IgG lowering in the Cohort 3 data was "incremental at best" following the fourth dose.[571] As support, it cites Pirozzi's trial testimony that at the time the data came in, he believed the PD chart showed IgG lowering "stayed pretty much flat" after the fourth or fifth dose.[572] Alexion's expert Jagannathan testified that no additional IgG lowering occurred after the fourth dose, but conceded that he "wasn't provided the actual numbers for IgG lowering."[573] Instead, he just looked at the graph, and "it appeared that the IgG lowering had reached a plateau."[574] By contrast, Kinch reviewed the data actually underlying the chart and testified that after the six subjects in Cohort 3 received their fourth dose,

[570] Pirozzi Tr. 1626–27.

[571] ALXN Ans. Br. 15.

[572] Pirozzi Tr. 1476. Alexion also cites to the testimony of Pradhan, but Pradhan does not testify that IgG lowering was incremental following the fourth dose. *See* ALXN Ans. Br. 15.

[573] Jagannathan Tr. 1368.

[574] *Id.*

IgG lowering continued, and "the lowest levels were detected just until the studied drug was discontinued."[575]

Having established that IgG lowering continued after the fourth dose, Kinch also testified that IgG lowering occurred after the appearance of ADAs. He testified that ADAs appeared on Day 23, and that IgG lowering reached its most significant levels thereafter.[576] With Alexion's contemporaneous views of the HV-108 data, the original HV-108 CSR, Chamberlain's opinion, and Kinch's opinion, SRS demonstrated Criterion 5 was satisfied.

B. Did Alexion Use Commercially Reasonable Efforts?

I now turn to whether SRS proved Alexion failed to use commercially reasonable efforts to achieve Milestones 2 through 8. SRS identifies three breaches of the CRE Obligation. First, it contends Alexion's decision to deprioritize ALXN1830 in April 2020 constituted a breach. Second, it argues that Alexion breached this obligation in connection with its pivot away from the IV formulation to pursue the SC formulation exclusively, which was then terminated. Third, it

[575] Kinch Tr. 335–36. Kinch explained that the rate of IgG lowering slowed because of saturation, not because of ADAs. *Id.* at 314–15. While Alexion points out that previous trials reached higher levels of target saturation, ALXN Ans. Br. 15, that argument does not dislodge Kinch's testimony that IgG lowering slowed as saturation was reached, rather than due to ADAs. And Alexion waived this argument by failing to present it in its opening brief. *Wimbledon Fund LP-Absolute Return Fund Series v. SV Special Situations Fund LP*, 2011 WL 6820362, at *3 (Del. Ch. Dec. 22, 2011).

[576] Kinch Tr. 335–36.

argues Alexion's decision to terminate ALXN1830 in December 2021 was a breach. I conclude SRS has met its burden as to the third.

The Merger Agreement affords Alexion discretion over ALXN1830's development and specifies that Alexion "shall have no obligation . . . to achieve any [milestone] events . . . that would give rise to an Earn-Out Payment."[577] The Merger Agreement cabins Alexion's discretion by requiring Alexion to use "Commercially Reasonable Efforts" to achieve each milestone.[578] The agreement defines Commercially Reasonable Efforts as follows:

[577] Merger Agr. § 3.8(j).

[578] *Id.* § 3.8(f).

> [U]sing such efforts and resources typically used by biopharmaceutical companies similar in size and scope to [Alexion] for the development and commercialization of similar products at similar developmental stages taking into account, as applicable, the Product's advantages and disadvantages, efficacy, safety, regulatory authority-approved labeling and pricing, the competitiveness in the marketplace, the status as an orphan product, the patent coverage and proprietary position of the Product, the likelihood of development success or Regulatory Approval, the regulatory structure involved, the anticipated profitability of the Product, and other relevant scientific, technical and commercial factors typically considered by biopharmaceutical companies similar in size and scope to [Alexion] in connection with such similar products. The obligation to use such efforts and resources, however, does not require that [Alexion] or its Affiliates act in a manner which would otherwise be contrary to prudent business judgment and, furthermore, the fact that the objective is not actually accomplished is not dispositive evidence that [Alexion] or any of its Affiliates did not in fact utilize its Commercially Reasonable Efforts in attempting to accomplish the objective.[579]

Commercially reasonable efforts clauses "define the level of effort that the party must deploy to attempt to achieve the outcome."[580] The provision is outward facing, meaning it imposes an objective standard.[581] With an outward facing provision, Alexion's "subjective intent or state of mind" does not determine whether it complied with its obligations.[582] When the parties do not agree on their own

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[579] *Id.* at 4.

[580] *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *86 (Del. Ch. Oct. 1, 2018), *aff'd*, 198 A.3d 724 (Del. 2018).

[581] *Neurvana Med., LLC v. Balt USA, LLC*, 2020 WL 949917, at *16 (Del. Ch. Feb. 27, 2020) (interpreting a similar provision).

[582] *Id.* ("These provisions are viewed as seller-friendly, as they allow the seller, when attempting to plead or prove that the buyer has breached its obligations, to point to an

definition of commercially reasonable efforts, the party must "take all reasonable steps" to achieve the outcome.[583] Here, the parties contractually defined commercially reasonable efforts. They defined them as the efforts and resources typically used by companies like Alexion, developing a product like ALXN1830, taking into account factors typically considered by such companies.

This Court considered similar provisions in *Himawan v. Cephalon, Inc.*[584] There, the buyer had complete discretion over drug development, subject to the requirement that the buyer use "commercially reasonable efforts to develop and commercialize . . . [the drug] so as to achieve" milestone events, which would trigger earnout payments.[585] The parties defined commercially reasonable efforts as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [the buyer], with due regard to the nature of efforts and cost required for the undertaking."[586] The Court concluded the parties intended "to impose the CRE requirement on the buyer, as it found itself

objective metric—comparable industry standards—rather than the buyer's subjective intent or state of mind.").

[583] *Akorn, Inc.*, 2018 WL 4719347, at *88 (citing *Williams Cos. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 272 (Del. 2017)).

[584] 2024 WL 1885560, at *4 (Del. Ch. Apr. 30, 2024).

[585] *Id.*

[586] *Id.*

situated, but that the requirement went beyond [the] buyer's subjective good faith"[587] in imposing an objective standard. Cabining the buyer's discretion in this way simply meant the buyer "may not avoid the earnouts in . . . a way that is commercially unreasonable."[588]

The *Himawan* clause permitted the buyer to give "due regard to the nature of efforts and costs," which meant it could "eschew development where the circumstances reasonably indicate[d], as a business decision, that they not go forward. This include[d] all the costs and risks involved, including the milestone payments and the opportunity costs faced by Defendants."[589] That provision "disallow[ed] actions of the buyer that would be against the buyer's self-interest."[590]

Here, the Merger Agreement's definition of Commercially Reasonable Efforts also cabins Alexion's exercise of discretion with an objective standard. That standard is more outward facing than the one in *Himawan*.[591] It calls for the efforts and resources "typically used by biopharmaceutical companies" like Alexion for the development of a product like ALXN1830 at its stage of development, taking into

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[587] *Id.* at *11.

[588] *Id.*

[589] *Id.*

[590] *Id.* at *12.

[591] The parties did not engage at all with the provision's verbiage. They offered no view on its interpretation.

account factors typically considered by those typical companies, including certain enumerated factors. While the *Himawan* provision explicitly allowed the buyer to consider its own efforts and cost required for the undertaking, Alexion's does not: Alexion's obligation permits it to consider anticipated profitability, but only insofar as typical companies might typically consider it. Alexion's efforts obligation is pegged to typical factors considered by typical companies—not Alexion's own self-interest. Rather than considering its self-interest in determining what is commercially reasonable, Alexion can consider its self-interest only in drawing the upper bound of its commercially reasonable efforts: Alexion's obligation "does not require that [it] act in a manner which would otherwise be contrary to prudent business judgment."[592]

In *Himawan*, the Court puzzled over what the parties intended the objective standard to be. At the pleading stage, Vice Chancellor Glasscock considered two possible "way[s] to give meaning to the unusual language of the CRE Clause": (1) a "yardstick approach," defining commercially reasonable efforts in comparison to "the efforts of similarly-situated pharmaceutical companies and their actions in the real world"; and (2) a "hypothetical company approach," defining commercially reasonable efforts as those efforts a similarly situated company "would expend under

[592] Merger Agr. at 9.

the circumstances at hand."[593] After trial, the Vice Chancellor determined the yardstick approach was unworkable because "no exemplar companies operate[d] under the actual conditions of [the buyer]."[594] Instead, the Court determined a hypothetical company standard was the best interpretation of the contract.[595]

Here, as in *Himawan*, the provision's reference to "biopharmaceutical companies" could refer to actual existing companies and the efforts and resources they actually used in developing similar products at similar stages. But its reference to the efforts and resources the companies "typically used," and the "scientific, technical and commercial factors" they "typically considered," calls for a more abstract and aggregated industry standard. And as in *Himawan*, trial has revealed the yardstick approach is unworkable. There are no adequate exemplar companies, as none of Alexion's competitors operated under the same conditions as Alexion. The competitors that the parties have referenced in this litigation even differ in their

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[593] *Himawan*, 2024 WL 1885560, at *11, *12 n.173; *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *8 (Del. Ch. Dec. 28, 2018); *see also Neurvana*, 2020 WL 949917, at *16 (contemplating a similar provision can apply an industry-wide standard or look to other actual participants in the industry and what they have done or would do).

Himawan rejected the plaintiffs' analogy to cases involving best efforts clauses aimed at closing a merger. The Court pointed out those clauses require "that a party pursue the contractual outcome *unless* it would be unreasonable to do so. . . . Here, the provisions are reversed; the buyer has complete discretion over development, cabined only by CRE." *Himawan*, 2024 WL 1885560, at *12 n.173.

[594] *Himawan*, 2024 WL 1885560, at *11.

[595] *Id.* at *11, *12 n.173.

circumstances as between themselves. Like *Himawan*, the realities of applying the provision call for a hypothetical company approach.

Thus, Alexion promised to use the efforts and resources that would be used by a hypothetical typical company of Alexion's size, working on a molecule like ALXN1830 at a similar stage of development, considering the factors such a company would typically consider, up until the point of being contrary to prudent business judgment. This provision is intended to adjust to Alexion's capitalization, progress on ALXN1830, and the molecule's developing attributes. It is not static. Identifying the benchmark at any moment in Alexion's journey with ALXN1830 requires factfinding to circumscribe that hypothetical company. The benchmark cannot be discerned from the plain text of the provision alone.

Both sides have offered a three-pronged approach to set the benchmark for Alexion's efforts. First, the parties identified four Alexion competitors, and compared and contrasted Alexion's progress to their progress, and Alexion's product to their product. The parties focused on Argenx, Immunovant, Momenta, and UCB. Each was a biopharmaceutical company developing anti-FcRn therapies.[596] At the

[596] Russell Tr. 675. To be sure, some competitors, like Argenx, already received approval for their anti-FcRns for at least one indication. And, at times, some of the competitors' therapies were at different clinical stages of development (at least as to some indications) than ALXN1830. I nevertheless consider some of their actions generally, and with regard to therapies in clinical development, as probative of what a similarly situated company would do.

time, none of the competitors were significantly larger than Alexion, and none had materially greater resources.[597] Under a similar hypothetical company approach, the actions of such companies remain useful in benchmarking the efforts and resources typically used. Second, the parties relied on experts to opine on conclusions to be drawn from Alexion's circumstances. And third, the parties focused on the efforts and resources Alexion used, and factors Alexion considered, before the 2020 deprioritization and before it terminated ALXN1830. In assessing this evidence, Alexion is not bound by what it has done in the past. That would only be appropriate if the Merger Agreement had defined commercially reasonable efforts as past practices. Here, Alexion's view of the ALXN1830 program is relevant insofar as it sheds light on what efforts and resources a similar hypothetical company would use under Alexion's circumstances at the time of the alleged breach, taking into account typical factors.

1. The April 2020 "Deprioritization"

SRS focuses on Alexion's shifting funding away from the ALXN1830 program "because it wanted to develop other drugs."[598] The ALXN1830 program's funding was "reduced significantly" as part of an R&D rebalancing program

[597] *Id.* at 675–76.

[598] SRS Ans. Br. 43. SRS does not contend the initial pause of HV-105 and HV-106 at the start of COVID was unreasonable. Nor does it charge Alexion with restarting those trials after RPL paused them. And it does not specifically challenge the initial decision to pause WAI-201.

initiated in response to COVID.[599] Orloff's April 27 email explained Alexion was rebalancing its portfolio to try to fulfill its promise to stockholders of ten launches by 2023.[600] Funding was moved so that Alexion could ensure the "10 by 2023" promise was not thwarted by the pandemic. ALXN1830 was not one of the programs set to be one of ten launches in 2023, so most of its funding was cut.[601]

To be sure, certain activities continued.[602] But moving those funds away prevented certain work from continuing, including preparing protocols for upcoming clinical trials: because funding was reduced, Alexion was not prepared to move forward when SC drug supply became available in September.[603]

SRS has proven Alexion's 2020 deprioritization of ALXN1830 fell short of the commercially reasonable efforts it agreed to use. A hypothetical company similar to Alexion, taking into account factors typically considered by such companies, would not have drastically reduced funding for a product like

[599] Orloff Tr. 862; JX 1456 at 2.

[600] JX 1451 at 3.

[601] *See* JX 1460 at 7.

[602] Ledwith Tr. 1071–88; *see also* Orloff Tr. 867 ("I should say that in the meantime, we did instruct the 1830 team to continue with their formulation, manufacturing, CMC, and device development work. In parallel, none of that activity was touched because of this reprioritization exercise.").

[603] JX 1613 at 3 ("We expect the pause to be for a minimum of 3 months, possibly longer. Pencils down on protocol prep, . . . new reg submissions, etc."); JX 1529 at 2 ("We are not authorized to present work on the [HV-108] protocol."); *see also* JX 1613 at 2–3 (listing other activities that were paused).

ALXN1830. Alexion cut funding for ALXN1830 because it could not be launched quickly enough to be part of "10 by 2023." But "10 by 2023" was not a typical factor. It was an idiosyncratic corporate initiative. A reduction in drug development efforts to accommodate such a unique program cannot satisfy an outward-facing efforts clause based on the typical efforts of similar companies. Alexion does not pretend otherwise.[604]

The evidence provided shows that Alexion's competitors were all moving forward with similar products in 2020.[605] John Russell (SRS's expert on the evaluation of pharmaceutical competitive landscape, market opportunities, and commercial potential and pricing and reimbursement)[606] testified that "[a]ll of the competitors made some sort of progress in the clinical development of their particular molecule during" the year.[607] Alexion itself had viewed the ALXN1830 program as a "high priority" and a "Key Strategic Interest."[608] Alexion believed

[604] Alexion has not suggested that the decision could be protected by the carveout for decisions that would be "contrary to prudent business judgment." Merger Agr. at 9. Rather, Alexion contends that there "was no 'deprioritization.'" ALXN Op. Br. 52.

[605] Russell Tr. 715; *see* JX 2870 (showing Argenx's open trials in 2020, including a Phase 1 trial in healthy volunteers); JX 2873 (same for UCB); JX 2876 (showing open trials in 2020); *see also* Robbins Tr. 534 (testifying Immunovant did not announce any pauses related to Covid); Russell Tr. 746 ("The key point here is all these companies are continuing to develop their products . . . in gMG.").

[606] Russell Tr. 669.

[607] *Id.* at 715.

[608] JX 1460 at 7. Alexion advances this position in this case. ALXN Ans. Br. 52.

ALXN1830 had commercial potential if it was brought to market on the heels of competitors poised to enter the marketplace first.[609] When ALXN1830 was deprioritized, all of Alexion's competitors had Phase 2 or Phase 3 trials ongoing in gMG, and Momenta had an ongoing Phase 2/3 trial in WAIHA.[610] gMG and WAIHA were the two indications Alexion was pursuing at the time. Alexion itself thought ALXN1830's development needed to be accelerated, not slowed.[611] The evidence at trial shows cutting ALXN1830's funding in April 2020 to support products that could be launched by 2023 fell short of commercially reasonable efforts.

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[609] ALXN Op. Br. 10 ("But Alexion believed that ALXN1830 had commercial potential if its development could be ***accelerated*** and it could be ***differentiated*** from other anti-FcRn drug candidates. Alexion hoped to accomplish this by developing a convenient, low volume SC means of delivery and by being the first anti-FcRn to market in an orphan indication, with speed to market critical for both objectives." (emphasis in original)); Sarin Tr. 936 ("But we felt that there was potential that we could be first in one indication, you know, if we -- if we moved the molecule fast enough. And we also thought that there was opportunity to differentiate, if we were able to get a sub-Q formulation."); *id.* at 939 ("[I]t was really important because of the order of entry. And, you know, time is of the essence, right? So we had Argenx that was ahead in terms of competition. We had UCB that was ahead. They were actually developing a subcutaneous formulation, but it was a large-volume subcutaneous formulation. So if you were third to market, for example, but you have a differentiated product because it's not IV and it's a small-volume sub-Q. So that's why the sub-Q was so important."); JX 518 at 2.

[610] JX 2296; JX 2359; JX 2569; JX 2388; JX 2302; JX 2067; JX 2570.

[611] Pirozzi Tr. 1534; *see also* JX 609 at 9.

But that does not end the inquiry. A claim for breach of contract requires proof that the breach caused the plaintiff to suffer harm.[612] SRS points to several delays in ALXN1830's development: after RPL's January 2020 pause of HV-105 and HV-106, Alexion did not open another Phase 1 trial for over a year, and after WAI-201 was paused, it took Alexion sixteen months to open a Phase 2 gMG trial and eighteen months to open a Phase 2 WAIHA trial.[613] But SRS fails to account for numerous confounding events during those periods, including any reasonable duration of the COVID pauses; for HV-105 and HV-106, the amount of time it would have taken to move the studies to a new country; and Alexion's need to wait for drug supply. SRS failed to account for the amount of time that it would take to prepare and launch new studies. SRS has not met its burden to show Alexion's failure to use commercially reasonable efforts caused those delays.

Even affording SRS a guess that the 2020 deprioritization caused a delay of several months,[614] SRS falters on proving it was harmed by that delay. The only harm SRS identifies is Alexion's failure to achieve Milestones 2 through 8. SRS has offered no evidence that delays from the 2020 deprioritization contributed to

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[612] *Trifecta Multimedia Hldgs. Inc. v. WCG Clinical Servs. LLC*, 318 A.3d 450, 470 (Del. Ch. 2024) ("The elements of a claim for breach of contract are (i) a contractual obligation, (ii) a breach of that obligation by the defendant, and (iii) a causally related injury that warrants a remedy, such as damages or in an appropriate case, specific performance.").

[613] SRS Op. Br. 24.

[614] JX 1597 at 2.

Alexion's failure to achieve the milestones, at all or independently from Alexion's termination of ALXN1830.[615] SRS failed to substantiate any role the 2020 deprioritization played in Alexion's failure to achieve the milestones. SRS has not proven the 2020 deprioritization harmed SRS as it must to obtain a judgment on its breach of contract claim.

2. The Decision To Terminate The IV Formulation In WAIHA

The second decision SRS challenges as a breach of the CRE Obligation is Alexion's pivot away from the IV formulation for the WAIHA indication.[616] Since the acquisition, Alexion was focused on developing an SC formulation. It believed it needed that formulation to be competitive in the increasingly crowded anti-FcRn market. It always viewed the SC formulation as the better product, but continued

[615] SRS Op. Br. 71 ("SRS also established that its damages 'flowed' from Alexion's breaches—Alexion's failure to obtain Milestones 2 to 8 was the 'foreseeable' consequence of its decision to abandon ALXN1830's development. Indeed, Alexion's decision to kill ALXN1830 made achieving these Milestones impossible.").

[616] In its answering brief, SRS argues that Alexion misconstrued its argument by focusing solely on WAIHA, while ignoring the effect the decision had on other indications. SRS Ans. Br. 46 ("As a preliminary matter, SRS's IV CRE claim is not limited to 'switch[ing] from IV to SC in WAIHA.' Rather, SRS argues that Alexion breached CRE by terminating IV ALXN1830's development to supposedly pursue the SC formulation, and then immediately abandoning clinical development of SC ALXN1830." (alteration in original)). SRS's opening brief does not address abandoning the IV formulation as to other indications. In fact, it addresses the pivot away from that formulation only in the background. To the extent this argument applies to other indications, SRS waived it by failing to raise the issue in its opening brief. *See Wimbledon Fund*, 2011 WL 6820362, at *3.

pursuing the IV formulation because it would get ALXN1830 to market just under two years earlier.[617]

Alexion presented credible testimony that the pause in early 2020 caused the development timelines for the IV and SC formulations to begin converging.[618] From there, Alexion's expert established it did not make sense to continue pursuing both methods of administration simultaneously.[619] Neither the record nor logic offers any reason to doubt that a hypothetical company in Alexion's situation would consider this factor in deciding whether to terminate a drug formulation. SRS failed to demonstrate by a preponderance of the evidence that the decision to terminate the ALXN1830 IV program for WAIHA was a breach of the CRE Obligation.

3. Terminating The ALXN1830 Program

SRS proved by a preponderance of the evidence that Alexion's 2021 termination of the ALXN1830 program breached the CRE Obligation.[620] The

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[617] *See* JX 1407 at 14.

[618] *See* Ledwith Tr. 1079–80; *see also* JX 1407 at 14.

[619] Bahl Tr. 1752–54.

[620] SRS also argued that Alexion breached Section 3.8(f) of the Merger Agreement because it decided to terminate ALXN1830 in September 2021, then created a paper trail to make it appear as though it really made the decision in December 2021 for facially legitimate reasons. This argument is based on a handful of joint exhibits. Many of SRS's citations are to Alexion's privilege log. SRS may not rely on inferences drawn from Alexion's privilege log. D.R.E. 512(a); *see DLO Enters., Inc. v. Innovative Chem. Prods. Grp., LLC*, 2021 WL 2258752 (Del. Ch. June 2, 2021) (ORDER).

definition of Commercially Reasonable Efforts calls for typical efforts based on at least eleven potential typical factors.[621] For ease of analysis, and in light of the parties' approach to this issue, I group those considerations into the following categories: safety, efficacy, order of entry, the likelihood of regulatory approval, and other advantages and disadvantages.

I do not read the remaining documents SRS cites to establish such a conspiracy. *See generally* SRS Op. Br. 68–70. First, a September 16, 2021 email in which Lukasz Jarzyna (an Alexion employee who did not testify at trial) conveys "the current view . . . that development of 1830 is going to be stopped." JX 1990 at 1. But the email goes on to explain that Alexion is awaiting further data, and nothing in the email suggests that a final decision had been made. The second document is an email on the same chain that discusses next steps Jarzyna identifies. JX 2214. Those next steps were in furtherance of being prepared in case Alexion decided to terminate ALXN1830, and they do not establish or even suggest that Alexion had already made that decision. The third is a presentation circulated on September 19, which lists the WAIHA and gMG ALXN1830 programs as "De-Prioritized." JX 2005 at 156. SRS elicited no testimony at trial about this document and has provided no context for it. It is not clear who drafted it, including who listed the WAIHA and gMG indications as deprioritized; what it means for an indication to be deprioritized in this context; and whether the presentation was suggesting the WAIHA and gMG indications should be deprioritized or whether they had already been deprioritized. Against that backdrop, this presentation carries little weight. Fourth, SRS argues Alexion "closed" MG-201 and WAI-202. JX 2015; JX 1928 ("slowing down" the gMG study); JX 1991 (pausing WAI-202 study); *see also* JX 2015 at 1 (indicating the WAI-202 study was paused). Lee testified credibly at trial that the decision was a pause, as opposed to closing the studies, and that it was possible for patients to be enrolled in the future. Lee Tr. 445–46. Documents in the record corroborate her testimony. JX 1932 at 2; JX 1933 at 1; *see also* JX 1948 at 1. The final piece of evidence on which SRS relies is an email concerning the WAI-202 pause, in which Pirozzi wrote to Lauchart that "for reasons you know we should not say that WAIHA will be stopped because of prioritization." JX 2015 at 1. Though it is plausible to read this email as suggesting Alexion had a pretext for terminating the ALXN1830 program, it does not alone establish that fact by a preponderance of the evidence.

[621] Merger Agr. at 9.

a. Safety

Safety is an important consideration for a company similar to Alexion bringing an anti-FcRn to market. If a drug is unsafe, it is less likely—and perhaps even unlikely or unable—to receive regulatory approval.[622] Without regulatory approval, the drug will never reach the market, making further development pointless. Even if approval is obtained, physicians consider safety in prescribing therapies to patients.[623] A doctor may be less willing to prescribe a therapy that is less safe than comparable alternatives, meaning safety can be an important differentiator within an indication.[624] To that end, a hypothetical company similarly situated to Alexion would consider any signals that a drug was unsafe during clinical development. If such signals were observed, the company would consider them in deciding whether to continue development. As explained, safety signals can manifest through the occurrence of SAEs, which suggest that the drug concentration is reaching the top of the therapeutic window.

SRS contends Alexion's decision to terminate ALXN1830 was not, as Alexion stated at the time and in this litigation, fairly based on safety concerns that would support termination by a hypothetical similar company. The parties spar over

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[622] *See* Harvey Tr. 1675 (testifying that the "overarching principle at FDA is patient protection, patient safety").

[623] Jagannathan Tr. 1330–31.

[624] Bahl Tr. 1765; *see also* Russell Tr. 666.

whether HV-108's Cohort 3 data, reflecting a 100% immunogenicity rate and the unexplained drug accumulation after the fourth dose,[625] supported termination.

The HV-108 trial did not record any SAEs.[626] This indicates the concentration of ALXN1830 accumulating in patients did not reach the top of the therapeutic window.[627] Dr. Mark Robbins (SRS's expert on clinical and regulatory development of biopharmaceuticals)[628] testified credibly and reliably that levels of total drug accumulation did not approach the top of the therapeutic window.[629] He explained that much higher concentrations were seen in SYNT-104 participants and HV-108's Cohort 1, without causing an SAE.[630] Additionally, numerous contemporaneous documents indicate Alexion believed ALXN1830 was safe and well tolerated in the HV-108 study, which also tends to show that the level of drug in the Cohort 3 subjects did not approach the top of the therapeutic window.[631]

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[625] Kinch Tr. 283, 432; Jagannathan Tr. 1285.

[626] Kinch Tr. 264, 268, 270; Robbins Tr. 549 (testifying no SAEs were reported in the HV-108 trial and that there is no basis to believe that "continued clinical study of ALXN1830 would present a serious risk to patients"). Even the December rESPC presentation pointed to ALXN1830's safety as a factor favoring continued development. JX 2220 at 16.

[627] JX 2367 at 35; Kinch Tr. 244, 260.

[628] Robbins Tr. 512.

[629] *Id.* at 552–57.

[630] *Id.* at 553–57.

[631] Kinch Tr. 260, 283, 298–99.

Alexion argues that the drug accumulation seen in Cohort 3 presented a possible safety issue because Alexion did not know the cause of the accumulation, and it could have been caused by bound drug instead of free drug. ALXN1830 did not reach a steady state during HV-108's twelve weeks of dosing.[632] Drug levels rose over the duration of the trial, and no expert could determine when they would have leveled off.[633] The experts agreed that it was possible the drug accumulation could have an effect on efficacy and safety.[634] The cause of the drug accumulation was unknown.[635]

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[632] *Id.* at 432; Jagannathan Tr. 1281.

[633] Kinch Tr. 432; Jagannathan Tr. 1281; *see also* Harvey Tr. 1664, 1671 ("[G]iven the data, you don't know whether [the drug concentration] was going to continue up, stay the same, or go down. So it was an incomplete story.").

[634] Kinch Tr. 260 ("Q. Is it hypothetically possible for drug accumulation to lead to safety concerns? A. Oh, absolutely.").

[635] Jagannathan Tr. 1289 ("We don't know why the drug is accumulating."); *see also* Kinch Tr. 317 (hypothesizing that drug accumulation could be due to the drug's sticking to albumin); Jagannathan Tr. 1305 (hypothesizing drug accumulation may be due to ADAs and nAbs).

Alexion cites Pradhan's testimony that at the time of receiving the relevant data, he and others believed it was clear that the drug accumulation was the product of bound drug. Pradhan Tr. 893. He disagreed that he could not "be certain that" ADAs were not binding to ALXN1830 and causing the accumulation, and "the observed data was clearly demonstrating that the drug accumulated, and we did not see a corresponding improvement in efficacy or [PD] effect." *Id.* at 894. Pradhan was directly contradicted by Pirozzi, who testified that at the time the data came in, Alexion did not understand what was causing the accumulation, and that the only way they could do so would be to do "additional testing." Pirozzi Tr. 1482–83. Pirozzi's testimony is corroborated by the December rESPC meeting minutes. JX 2226 at 2. And Jagannathan testified that there is "no data showing [ALXN]1830 binds to ADAs." Jagannathan Tr. 1373. Alexion also points to a February 2022 presentation as support for its 2021 hypothesis that the drug accumulation was caused

SRS has demonstrated drug accumulation posed only a hypothetical risk. There was no evidence that it caused any safety issue in the twelve weeks Cohort 3 was dosed. A hypothetical company using commercially reasonable efforts would respond by gathering further data, as Alexion's September and October decision trees provided—not by terminating the program.

b. Efficacy

A hypothetical similarly situated company would also consider the anti-FcRn's efficacy. Efficacy is an important differentiator, as it speaks to how well the anti-FcRn addresses the relevant indication.[636] Drugs with greater efficacy will typically have greater commercial success. ALXN1830's efficacy is measured by IgG lowering.

Sustained IgG lowering was observed in Cohort 3, indicating the drug had a beneficial effect.[637] The December rESPC presentation noted ALXN1830 demonstrated IgG lowering of 66%.[638] The HV-108 data reflected IgG lowering in

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by bound drug. JX 2292. I do not consider this exhibit in my analysis, as Alexion did not have this information at the time it made the decision to terminate the ALXN1830 program. The evidence shows that at the time of termination, it was possible, but far from certain, that the accumulation was caused by bound drug.

[636] Bahl Tr. 1765 (testifying that efficacy is the most important differentiator); *see also* Russell Tr. 702 (testifying physicians may cycle through different treatments due to "side effects or lack of efficacy").

[637] Jagannathan Tr. 1355; JX 2032 at 8; JX 2367 at 11; JX 2180 at 22.

[638] JX 2220 at 11.

excess of Alexion's targeted levels.[639] Still, that degree of lowering was less than that of Argenx's and Momenta's therapies, marginally better than UCB's, and at the low end of the range demonstrated by Immunovant's.[640] ALXN1830 would struggle to compete solely on the basis of efficacy, at least in indications in which Argenx and Momenta were present.[641]

Alexion further attacks ALXN1830's efficacy. It argues the presence of ADAs and nAbs, as observed in Cohort 3, threatened to diminish ALXN1830's efficacy in future trials.[642] But the nAbs observed did not affect IgG lowering for the duration of the HV-108 study.[643] A longer-term study might reveal such an effect, but trial showed that to be speculative.[644] I give no weight to Alexion's additional concerns over ADAs and nAbs decreasing ALXN1830's observed efficacy.

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[639] Pradhan Tr. 897 ("Q. Do you agree that 1830 showed expected IgG reduction in the HV-108 trial? A. Yes."); JX 2006 at 1 ("The IgG lowering effect has been consistent and is at the expected level . . . .").

[640] JX 2220 at 11.

[641] Bahl Tr. 1765 ("[I]f you have better efficacy, you're the likely winner in a majority of diseases, meaning that efficacy is very important. It's one of the primary differentiators.").

[642] ALXN Op. Br. 86.

[643] Kinch Tr. 283 ("[T]here was no impact [from ADAs] on the efficacy of the drug nor the safety that I was able to identify through my independent evaluation."); JX2094 at 1 ("ADAs. even at high frequency — no associated impact to lgG lowering and safety; no PK effect."); Jagannathan Tr. 1308.

[644] Robbins Tr. 596 ("Q. And the neutralizing antibodies seen with 1830 had the potential to impact efficacy. Correct? A. Yes, they had the potential.").

c. Likelihood Of Regulatory Approval

Likelihood of regulatory approval is an important factor because a drug cannot be marketed without that approval. Alexion itself, Alexion's expert, and SRS's expert each peered into different crystal balls to predict regulatory approval. None of those crystal balls offers me an answer that I afford any weight.

As described, Alexion, on the precipice of termination, downgraded ALXN1830's PRS based on the HV-108 immunogenicity and drug accumulation data.[645] As explained, I have afforded that reduction little weight. The PTRS percentage and its PRS component, at least for ALXN1830, was a subjective black box calculation.[646] And the reduction was based entirely on "immunogenicity observed from HV-108," unexplained drug accumulation, and the consequences of immunogenicity on labeling.[647] That subjective change is inconsistent with the objective trial record, which shows Alexion appreciated ALXN1830's immunogenicity before it received the HV-108 data. I give the trial record more weight than Alexion's PTRS number.

SRS offers Kinch's opinion; he calculated industry averages of approvals of similar molecules from his own open-source database tracking regulatory

[645] JX 2608; JX 2227 at 3.

[646] *See supra* note 452.

[647] JX 2608 at 2–3.

decisions.[648] He estimated a Phase 2 monoclonal antibody like ALXN1830 had a 39.8% chance of obtaining regulatory approval, then adjusted that probability upward based on his review of ALXN1830's clinical trial data, given its proof of concept in diseased patients.[649] But Kinch's opinion was offered to calculate damages if Alexion breached, and he specifically disclaimed any opinion on whether Alexion breached.[650] SRS offers no other evidence of how to consider the likelihood of regulatory approval in determining whether Alexion breached its CRE Obligation.

Alexion's expert Brian Harvey (expert in regulatory strategy and affairs) testified he believes ALXN1830 was unlikely to be approved in the US.[651] His conclusion was based on HV-108's data and what he referred to as "uncontrolled, unpredictable drug accumulation."[652] I afford this testimony little weight. Harvey was told by Alexion's lawyers that HV-108 showed immunogenicity and drug accumulation.[653] He then looked at the HV-108 Cohort 3 chart, observed that the "numbers" went from "about 35, around 50, and then well over 1,000," and

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[648] SRS Op. Br. 66 (citing Kinch Tr. 364–65); Kinch Tr. 207–09.

[649] Kinch Tr. 349–50, 356, 358.

[650] *Id.* at 369.

[651] Harvey Tr. 1691. Zimmermann also gave her opinion as to the likelihood ALXN1830 would be approved by regulators. As explained, I gave this opinion testimony almost no weight.

[652] Harvey Tr. 1691.

[653] *Id.* at 1662, 1698.

concluded on that basis that drug accumulation was "profound," and that the data left open the question of whether it was going to increase, decrease, or stay the same.[654] This statement was rebutted by Robbins, who compared HV-108's maximum concentration against previous studies and noted it was much lower.[655]

As explained, the contemporaneous record evidence supports at most speculation that future studies would reveal actual safety concerns or a concerning reason for drug accumulation. The drug accumulation seen in Cohort 3 did not reflect a safety problem and never reached the top of the therapeutic window. And as explained, that bound drug was causing the increase was speculation at the time. HV-108 offered no basis to conclude ALXN1830 had reached the top of the therapeutic window. ALXN1830's drug accumulation would be investigated in the normal course in the Phase 1B/2A trial. The record evidence on which Harvey relied did not itself substantiate any concerns stemming from drug accumulation.

And Harvey's opinion offers nothing more than speculation that the data might indicate a safety concern.[656] He agreed he did not go so far as to opine that HV-108 showed ALXN1830 was unsafe.[657] Instead, he opined the data left open the

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[654] *Id.* 1664; *see also id.* at 1716–18 (clarifying that Harvey had not performed any calculations using Cohort 3 data, nor seen written documents suggesting drug accumulation impacted IgG lowering, but rather he "just see[s] it in the graphs").

[655] Robbins Tr. 2069–70.

[656] Harvey Tr. 1664.

[657] *Id.* at 1703.

question of the direction drug accumulation would go.[658] Harvey's opinion that ALXN1830 would not receive regulatory approval because the HV-108 data presented unpredictable drug accumulation carries little weight.

Neither SRS nor Alexion has offered any credible evidence of the likelihood of ALXN1830's approval for purposes of determining whether Alexion breached its CRE Obligation. I draw no conclusions based on this factor.

d. Order Of Entry

Order of entry to an indication or multiple indications is important, especially here where Alexion was entering a relatively crowded field.[659] Physicians are typically more comfortable prescribing therapies that they have more experience with.[660]

In early 2019, Alexion believed that it could be first and third in WAIHA and gMG, respectively.[661] By June 2021, its expected order of entry into those

[658] *Id.* at 1664; *see also id.* at 1716–17 ("Q. Okay. Now, I want to ask you about drug accumulation, which you said was profound, in your view; right? A. Correct. Q. But you don't do numbers; right? A. I don't do numbers.").

[659] *See* Sarin Tr. 939.

[660] Jagannathan Tr. 1329–30.

[661] *See* Russell Tr. 741–42; JX 609 at 12.

indications had slipped to third and fifth, respectively.[662] gMG development was paused in August 2021[663] and WAIHA was paused in September.[664]

At the time of termination, Alexion was pursuing cAMR and TED.[665] The December rESPC presentation showed that Alexion predicted the Phase 1B/2A study would push back development by six months.[666] Still, Alexion believed it could be first in those indications, as it did not know of any other competitors developing therapies in those indications at the time.[667]

e. Other Advantages And Disadvantages

ALXN1830 had an important advantage in that it did not lower albumin.[668] The lack of albumin lowering meant ALXN1830 could appeal to certain subpopulations like the elderly and those with kidney problems.[669] This gave ALXN1830 a slight advantage over all competitors other than Argenx.[670]

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[662] Russell Tr. 741–42.

[663] JX 1928.

[664] JX 1991 at 2.

[665] *See* JX 2220 at 6.

[666] JX 2226 at 2; JX 2220 at 14–15.

[667] Russell Tr. 772; JX 1955 at 7.

[668] Russell Tr. 740–43; *see* JX 1802 at 2.

[669] Bahl Tr. 1766–77; JX 1230 at 25.

[670] Russell Tr. 740–41; s*ee also* Bahl Tr. 1766–69.

Labeling is another typical factor. ALXN1830's drug accumulation and immunogenicity rates would not meaningfully affect its label such that it would be less competitive. Alexion correctly points out that the FDA would require the immunogenicity rates and drug accumulation to be disclosed.[671] But Jagannathan testified that the FDA cautions against the utility of comparing ADA rates across products, and that the guidance provides "ADA rates are not directly comparable across labels."[672] The record contains no evidence that a hypothetical similarly situated company would think that ALXN1830's predicted labeling would support termination.

SRS points out that ALXN1830 also successfully obtained orphan drug designation in PV and that Alexion intended to seek the same in WAIHA.[673] As to WAIHA, whether Alexion sought to obtain orphan drug status has no bearing on the likelihood it would be obtained. And the indications in Alexion's pipeline at the

[671] *See* Robbins Tr. 627; Jagannathan Tr. 1332; Harvey Tr. 1690 ("[T]he product label is intended to inform the practitioner how -- the safe and effective use of a product and to then help select those patients where the benefits outweigh the risks."); Harvey Tr. 1690; *see also* Borboroglu Tr. 1429 ("So all biologics will have a section within their labeling that refers to immunogenicity that may or may not be observed. Regardless of wherever this would land, there would be a section within the ALXN1830 that would show ADA rates.").

[672] Jagannathan Tr. 1367–68.

[673] JX 2513 at 106; JX 2975 at 1, 2; JX 2011 at 1.

time of termination were cAMR and TED. SRS has not explained how orphan drug status would translate across indications. I draw no conclusions based on this factor.

SRS also points out ALXN1830 had strong patent protection until 2036, after its competitors' would have expired.[674] This factor inspired Alexion's acquisition of Syntimmune in the first place.[675]

* * *

Considering these typical factors, I conclude termination of ALXN1830 fell short of the typical efforts a hypothetical company similarly situated to Alexion would have devoted to the program. My holistic assessment of the above factors reveals ALXN1830 was not the strongest anti-FcRn that would come to market. It would not have the highest efficacy. It would be fifth to market overall, and at the time of termination, Alexion believed it could be first to market in TED and cAMR. More work in the form of a Phase 1A/2B study was needed; progress was slowing. But that did not mean ALXN1830 could not compete. It did not present concrete safety concerns or outsized risk due to immunogenicity, and its lack of albumin lowering gave it an advantage.

Alexion's own view of the efforts the program deserved just before termination supports this conclusion. In 2021, Alexion believed it could capture

[674] Tr. Bahl 1776; JX 690 at 231.

[675] JX 690 at 231.

about 7% of the gMG market[676] and saw the potential to differentiate within WAIHA through efficacy, safety, and lack of albumin lowering.[677] Alexion was pressing ahead with Phase 2 trials in gMG and WAIHA in the summer of 2021.[678] Alexion was still identifying new indications by exploring pursuing cAMR and TED by July 2021.[679] With the exception of the delay from a Phase 1B/2A study, there were no significant changes in any factor considered above between June 2021 and December 2021.[680] The parties have not identified, and the Court is not aware of, any information suggesting Alexion was hesitant about the program before June 2021 or believed that it was too far behind to make development worthwhile.

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[676] JX 1699 at 7.

[677] *Id.* at 9.

[678] JX 2298 at 1; JX 2299.

[679] JX 1955.

[680] The December 2021 rESPC presentation includes a slide listing information learned after August 2021. JX 2220 at 7. That slide listed: potential toxicity from the monkey death, immunogenicity, the need to assess the long-term effect of nAbs on PD, drug accumulation, and device development uncertainty. JX 2220 at 7. The parties agree that the monkey death did not provide new information. As to device development, the evidence shows that the delay in developing an on-body device is commensurate with the delay in conducting an additional clinical study of ALXN1830, such that considering the delay would be to double count the effect of conducting a Phase 1B/2A trial. Further, the slide states that the impact of the uncertainty in device development was that Alexion would have to use an SC pump at launch until it could complete development of the on-body device. But this had been Alexion's plan since early 2020 when it abandoned the IV formulation. *See* JX 1407 at 14. The other items in the list have been addressed elsewhere in this decision.

The six-month delay for a Phase 1B/2A study does not appear to have changed much. ALXN1830 was already going to be the fifth anti-FcRn to market, which Alexion describes as being "last."[681] There is no indication that Alexion believed it would no longer be first in TED or cAMR because of the delay. In fact, the rESPC meeting minutes confirm no competitors had entered those indications at the time of termination.[682] And though getting to market six months earlier would still have some benefit, Alexion did not seem worried: that delay received only passing mention in its termination discussions.[683]

As for competitors, they continued to move forward with development despite Argenx's advantages in being first to market generally, having a 31% immunogenicity rate, and not lowering albumin.[684]

C. Why?

All of this naturally gives rise to the question of why Alexion would terminate a program that it once believed in and that was supported under the factors defining Commercially Reasonable Efforts. Based on the trial record, the answer is in the AstraZeneca acquisition.

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[681] ALXN Op. Br. 61.

[682] JX 2226 at 2.

[683] JX 2227 at 3.

[684] *See* JX 2220 at 11.

When AstraZeneca acquired Alexion on July 21, 2021, AstraZeneca promised $500 million in recurring synergies.[685] In furtherance of delivering on that promise, Alexion launched a full portfolio review of all ongoing Alexion drug programs and indications.[686] Less than three weeks after the merger closed, Lee notified the ALXN1830 team that the gMG study would be slowed down following a "portfolio level review," with the cited rationale being competition within the indication and timing to market—both of which were known before the acquisition closed.[687]

The initial HV-108 data came in on September 15.[688] By the next day, "the current view [at Alexion was] that development of 1830 [was] going to be stopped," though a final decision was not yet made.[689] The stated rationale was the high rate of ADAs; both nAb rates (the nAb data would not arrive until later) and drug accumulation went unmentioned.[690]

By the end of September, Alexion developed a decision tree establishing it would continue development of ALXN1830 if the "[c]umulative ADA data from

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[685] *See* JX 1946 at 3.

[686] *See id.* at 7–9; JX 1933 at 1; JX 1997; Washburn Tr. 638 ("[T]here was a reassessment of the portfolio strategies after AstraZeneca acquired Alexion. And in the process of reevaluating the overall pipeline of all activities, there was a decision made to pause gMG at that time.").

[687] JX 1928 at 1.

[688] JX 1989.02; JX 1990 at 1.

[689] JX 1990 at 1.

[690] *See id.* at 1–2.

HV-108," which included the ADA positivity rate and the data on nAbs, was "[a]cceptable."[691] By the end of October, that decision tree was more refined: if the immunogenicity observed in HV-108 had "[n]o impact on efficacy/safety," then Alexion would continue development and even "[p]ursue new indications."[692] In early November, Alexion had the drug accumulation data at the center of this case and had already developed the often-discussed Cohort 3 charts.[693] By November 17, Alexion thought the ADAs and nAbs had "no impact on IgG lowering" and "[n]o safety events" were observed.[694] This was confirmed by the August 2022 CSR, which reported that despite the presence of ADAs and nAbs, Alexion observed "no impact on the drug concentrations (PK profile) or IgG (PD marker) levels."[695] Alexion retained Chamberlain to evaluate immunogenicity, and he likewise concluded that HV-108 presented no safety concerns and that the study saw sustained IgG lowering.[696] Further, the development team did not appear moved by the data that came in.[697]

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[691] JX 2025 at 1.

[692] JX 2109 at 24.

[693] JX 2161 at 8.

[694] JX 2163 at 2.

[695] JX 2367 at 10.

[696] JX 2186.02 at 18.

[697] *See* JX 2221 at 3 (showing notes Washburn emailed himself for the December rESPC presentation, which explain "[t]he team believes in the science and in the program and

Against this backdrop, the rESPC faced the decision of whether to continue development of ALXN1830 through completion of HV-108 and a longer duration Phase 1B/2A study or terminate ALXN1830's development.[698] The rESPC decided to terminate, citing immunogenicity, order of entry to market, and developmental issues caused by COVID and the monkey death.[699] The trial record simply does not support those reasons for termination. The preponderance of the evidence supports the conclusion that the decision was influenced, motivated by, or driven by AstraZeneca's pursuit of merger synergies.

D. Unclean Hands

Alexion asserts unclean hands as a defense to SRS's claim for breach of the CRE Requirement. Under that doctrine, the Court will refuse equitable relief "in circumstances where the litigant's own acts offend the very sense of equity to which he appeals."[700] SRS's claim sounds in contract and is therefore a legal claim. The

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wants to continue development. Consultant Paul Chamberlain also stated that there was no scientific reason to abandon the program at this time. However, the team does not have the full understanding of all factors affecting portfolio prioritization so is not able to make a final recommendation."); Washburn Tr. 658–60 (testifying that the development team "believed in the science" and that they "wanted to support the program").

[698] JX 2220 at 16.

[699] JX 2226 at 1.

[700] *Wagamon v. Dolan*, 2013 WL 1023884, at *2 n.19 (Del. Ch. Mar. 15, 2013) (quoting *Nakahara v. NS 1991 Am. Tr.*, 718 A.2d 518, 522 (Del. Ch. 1998)).

defense of unclean hands is unavailable where the plaintiff asserts a legal claim seeking monetary relief.[701] The defense of unclean hands is unavailable to Alexion.

E. A Note On What Remains

This opinion does not address damages for Alexion's breach of its CRE Obligation. I ask the parties to submit supplemental briefing on the proper damages model, including causation and the propriety of SRS's two proposed approaches.[702] Damages will be addressed in an opinion to come.

This opinion does not address whether Alexion breached Section 3.8(f) of the Merger Agreement by taking actions with the primary purpose of avoiding the achievement of any milestone. I ask the parties to advise if SRS's Count IV carries with it any additional potential for damages or practical ramifications, given what it has taken to get this far.

This opinion does not address the merits of the parties' dispute over the drug supply Alexion inherited from Syntimmune, presented in SRS's Count V requesting a declaratory judgment as to indemnification, and Alexion's third counterclaim for

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[701] *NASDI Hldgs., LLC v. N. Am. Leasing, Inc.*, 2019 WL 1515153, at *6 (Del. Ch. Apr. 8, 2019), *aff'd*, 276 A.3d 463 (Del. 2022).

[702] As the post-trial briefing page count already left me without the benefit of the parties' development of these important issues, I reject SRS's argument that Alexion waived any opposition to SRS's damages argument, on which SRS bears the burden, by not presenting it in its opening post-trial brief. SRS Ans. Br. 47 (citing *Gener8, LLC* v. *Castanon*, 2023 WL 6381635, at *19 n.262 (Del. Ch. Sept. 29, 2023) (addressing waiver of a factual point the plaintiff omitted from its opening brief). Alexion presented its opposition in its answering brief. ALXN Ans. Br. 47–56.

breach of Section 4.13(a) of the Merger Agreement. Those counts will be addressed in an opinion to come.

III. CONCLUSION

Alexion is liable for breach of Section 3.9(a) of the Merger Agreement by failing to pay SRS $130 million upon the successful completion of a Phase 1 Clinical Trial, as defined by the Merger Agreement. SRS is awarded damages in that amount. Judgment will be entered for SRS on its Count III and Alexion's Counterclaim II.

Alexion is liable for breaching Section 3.9(f) of the Merger Agreement through its termination of the ALXN1830 program. I ask the parties to confer on mapping this finding of breach onto SRS's counts I and II as presented in its amended complaint. Judgment will be entered for SRS on Alexion's counterclaim I.