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IN THE SUPREME COURT OF THE STATE OF DELAWARE

SHAREHOLDER REPRESENTATIVE SERVICES LLC, in its capacity as the Stockholders' Agent for the former securityholders of Calistoga Pharmaceuticals, Inc., Plaintiff Below-Appellant v. GILEAD SCIENCES, INC. and GILEAD BIOPHARMACEUTICS IRELAND CORPORATION, Defendants Below-Appellees.	**PUBLIC VERSION** **DATE: July 17, 2017** No. 162, 2017 Court Below: Court of Chancery of the State of Delaware, C.A. No. 10537-CB
GILEAD SCIENCES, INC. and GILEAD BIOPHARMACEUTICS IRELAND UC, Counterclaimants Below-Appellees, v. SHAREHOLDER REPRESENTATIVE SERVICES LLC, in its capacity as the Stockholders' Agent for the former securityholders of Calistoga Pharmaceuticals, Inc. Counterclaim-Defendant Below-Appellant.	

APPELLEES' ANSWERING BRIEF

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NATURE OF PROCEEDINGS

After a four-day trial, the Court of Chancery issued a 78-page decision that found the term "indication" ambiguous, an unremarkable conclusion given that SRS admitted that the word has different meanings in the industry and itself advanced at least three different definitions throughout the proceedings. After weighing the evidence and credibility of witnesses, the trial court concluded that in the context of the Agreement "indication" means "disease." Finally, the trial court made the factual finding that the European approval did not satisfy the third milestone because it did not approve Zydelig as a first-line treatment for a disease. This finding was neither arbitrary nor lacking in evidentiary support, but instead tracked exactly a statement of the European Medicines Agency (EMA) and the admissions of SRS's expert. The trial court's decision should be affirmed.

SUMMARY OF ARGUMENT

1. Denied. The trial court did not err in concluding that a reasonable interpretation of the term "indication" in the Agreement is "disease." SRS concedes that the word "indication" has multiple meanings, including "disease." In this case, the Agreement expressly defines indications as diseases. For example, the Agreement defines "Specified Hematologic Cancer Indications" as "any hematologic cancer ***indication specifically identified***[1] in Part 2" of Section 1.1. SRS concedes that "the things listed" in Part 2 are recognized "***diseases***." A537 (166:11–23) (Gallagher). Indeed, far from being unreasonable, at various stages in the case SRS advocated that diseases, and specifically the blood cancer CLL, are "indications." SRS stated: "CLL itself is both an indication and a hematologic cancer indication as defined in the agreement," B322, and "a first-line treatment for a blood cancer would trigger the final milestone." B465. Finally, SRS's assertion that if "indication" means "disease" SRS should prevail contradicts the express factual findings of the trial court. After considering the testimony of both parties' experts, admissions of SRS's witnesses, and statements of the EMA, the trial court made the factual finding that "The European Commission Did Not Approve CAL-101 as a First-Line Drug Treatment for the Disease CLL." Op. 75.

[1] All emphasis is added unless otherwise noted.

This factual determination can be overturned only if arbitrary or lacking any evidentiary support. SRS does not even attempt to satisfy this standard.

2. Denied. SRS's contention that there is a distinction between a regulatory approval for treatment of a disease and a "disease-level" approval is a fiction. SRS's witnesses admitted that when regulatory agencies approve drugs for treatment of diseases, such as CLL, as opposed to a rare genetic subpopulation, this is called a "disease-level approval." *E.g.*, A515 (77:9–78:21) (Miller).

3. Denied. SRS conceded that deal counsel's privileged information was only relevant if Gilead pursued a claim for reformation: "if the reformation claim is out, this is just a nonissue." B188 (31:5–16). Gilead withdrew its reformation claim, and at no point during fact or expert discovery did SRS ever request discovery of deal counsel's privileged information. Six business days before trial, SRS for the first time requested privileged deal-counsel information. The trial court ruled this request waived as untimely. The trial court's decision was not an abuse of discretion.

STATEMENT OF FACTS

I. ZYDELIG WAS DESIGNED AND VALUED AS A DISEASE-LEVEL TREATMENT

Cancer drugs fall into two classes: (1) those designed to treat an entire type of cancer and (2) those designed to target specific genetic mutations. Zydelig falls into the first category. It was designed to treat blood cancers, not just patients with rare genetic mutations. B829 (168:16–19 (Arbuck)).

The disease at issue is Chronic Lymphocytic Leukemia (CLL), a type of blood cancer. There are at least 59 recognized genetic mutations that may be present in CLL cells. A641–42 (581:23–584:11) (Dearden). One example is 17p/*TP53*, which is present in approximately 5–8 percent of patients when first treated. A524 (114:12–15) (Miller).

As Dr. Miller, Calistoga's head of development, testified, at the time of negotiation multiple drugs were approved at the "disease level" for CLL.[2] Examples include Treanda, Chlorambucil, Campath, and Obinutuzumab (Gazyva). A515 (77:9–80:14). Dr. Miller testified that the "end goal for CAL-101" was such an approval—"at the disease level." *Id.* (80:8–14).

[2] SRS incorrectly states that the phrase "disease level" was never used until post-trial briefing. Appellant's Opening Brief ("OB") 13. Witnesses and counsel for both sides repeatedly explained at trial that regulatory approvals occur at the "disease-level." *E.g.*, A653 (630:16–24) (Dearden), A658 (648:23–650:8); A515 (80:8–14) (Miller), A525 (119:18–120:16).

The valuations of Calistoga prepared by both parties in connection with the negotiation reflect a shared understanding that CAL-101 was a disease-level drug. All valuations exclusively modeled CAL-101 approvals for recognized blood cancers, not genetic subpopulations. A547 (207:7–208:1) (Gallagher) ("There is no reference to valuation based on genetic subpopulations[.]"); B14; B20; B39. Additionally, the valuations exclusively modeled CAL-101 first receiving approval for later lines of therapy ("relapsed/refractory") and culminating in a first-line approval for the same disease. B14; B20; B39.[3]

Relapsed/Refractory (sometimes abbreviated as "Rel/Ref" or "R/R") and first-line (sometimes referred to as FL, 1st line, upfront, or frontline) refer to lines of therapy. CLL is considered incurable. The patient "relapses" or becomes "refractory" to the first-line therapy. The same patient then receives a second-line therapy. The cycle repeats with third-line therapy, and potential subsequent lines. A514 (76:13–22) (Miller); A558 (249:9–251:3) (Gallagher); A689–90 (774:23–775:17) (Hawkins); B426 at n.6 ("relapsed/refractory" are "additional lines of treatment").

[3] SRS has incorrectly suggested that "accelerated approvals" relate to rare genetic subpopulations. Accelerated approvals also occur for "disease-level" approvals. A692 (784:21–24) (Hawkins); *see, e.g.*, A212 (accelerated approval of Zydelig for FL and SLL); A571 (302:3–304:20) (Gallagher).

During the valuation process, Calistoga disclosed alternatives to regulatory approval for CLL. All were other recognized blood cancers, described interchangeably as "diseases" and "indications." B38 ("other indications including Mantle Cell lymphoma and Hodgkin's lymphoma"); B41 (referring to same entities as "diseases").

Calistoga had no plan to seek approval in genetic subpopulations and made that clear to Gilead during negotiations. Calistoga provided clinical plans to Gilead, all of which described approvals for blood cancers such as CLL. A689 (772:5–10) (Hawkins), A690 (778:2–19); A707 (840:5–18) (O'Connell); A516 (81:18–84:5) (Miller); B57; A583 (351:11–352:5) (Gallagher). Calistoga's FDA submissions that were provided to Gilead made no reference to 17p/*TP53* patients or any other genetic subpopulation. A514 (73:2–75:23) (Miller), A516 (81:18–82:1); *see also* A515–16 (80:15–82:1) (Miller) (discussing B61–62, JX384-002–03). In the "comprehensive CAL-101 development plan presented to Gilead, there was no mention whatsoever of seeking approval for any genetic subpopulation[.]" A521 (104:13–22) (Miller) (discussing B57, JX371-032); *see also* B26–30.[4]

The parties discussed performance in patients with genetic mutations such as 17p precisely because Calistoga's value proposition was that CAL-101 worked

[4] These documents refer to "stratification" based on factors such as 17p. This does not reflect an approval strategy for 17p. A640 (577:5–18) (Dearden); A516–17 (82:2–85:20) (Miller); B797 (201:3–15, 203:1–5 (Gallagher)).

across "All Evaluable Patients with CLL." A163; A688–89 (770:9–773:13) (Hawkins). Dr. Gallagher, Calistoga's CEO, admitted she had no recollection of ever discussing with Gilead CLL plus 17p as an "indication."[5] A559–60 (256:24–257:12). Consistent with Dr. Miller's testimony that the goal was "disease-level" approval, Gilead witnesses testified that failing to obtain a disease-level approval would have been seen as a failure. A694 (792:20–793:2, 794:6–24) (Hawkins); A713–14 (867:16–868:2) (O'Connell).

II. THE PARTIES NEGOTIATED MILESTONES BASED ON SPECIFIC DISEASES

The negotiation record reflects the parties' shared understanding that the term "indication" in the milestones refers to specific diseases—recognized blood cancers.

First, Calistoga's lead negotiator Cliff Stocks[6] testified that during negotiations the parties used "indication" to refer to recognized diseases within the World Health Organization (WHO) classification system. B802–04 (20:18–21:4, 22:2–23:8, 24:10–18, 25:21–26:4 (Stocks)) (discussing B43, JX183-014). Mr. Stocks testified that the parties' description of CLL, a WHO-recognized tumor, as

[5] SRS refers to outside interest in a potential study of 17p/*TP53* patients. OB 9–10. Calistoga chose not to implement the third party's suggestion in its clinical plan. A560 (258:5–260:11) (Gallagher); *see also* A583 (349:13–352:5) (Gallagher); B19.

[6] A514 (73:7–9) (Miller); A704 (829:5–14) (O'Connell).

an "indication" was intentional: "***tumors are indications***. So, yes, you can describe it as a tumor or an indication." B803–04 (24:10–18, 25:21–26:4 (Stocks)).

Dr. Miller confirmed that in negotiations Calistoga "use[d] 'indication' and 'disease' interchangeably." A518–19 (91:16–94:5); B36; B17; s*ee also* A519–20 (96:19–97:7).

Dr. Gallagher initially testified that indication means "a label that you would receive for the specific patient population that you would treat with the hematologic cancer indication." A554 (233:22–234:9). However, on cross-examination, she admitted that Calistoga neither shared that definition with Gilead nor included it in the Agreement. *Id.* (233:14–21, 235:9–17). Instead, in negotiation presentations to Gilead, Calistoga "was using [indication] as synonymous with disease," and did so because Calistoga "was trying to use it in the way that folks generally in the industry use it." A555–56 (239:5–242:24) (discussing B43, JX183-014); *see also* A557 (245:7–246:21); A519 (93:18–94:5) (Miller); B806 (45:12–46:1 (Stocks)) (Calistoga's discussion of "indications" in "pitch documents" are "definitions").

Second, Mr. Stocks sent Gilead a packet of regulatory materials, which repeatedly refer to recognized blood cancers as "indications." B24 ("PROPOSED INDICATION Indolent Non-Hodgkin Lymphoma (NHL); Mantle Cell Lymphoma

(MCL)"); B25 ("indications indolent B-cell NHL, MCL and CLL"); B142 ("Section 2.2 Indications"); A692–93 (785:13–787:23) (Hawkins). Dr. Arbuck, SRS's expert, admitted that in Calistoga's regulatory documents "folks are using the term 'indication' to mean disease" and "those folks are Calistoga." A622 (507:1–508:19) (discussing B59, JX377-007); *see also* A623 (509:12–511:4) (discussing B142, JX874-009).

Third, Calistoga supplied Gilead with regulatory materials that use the WHO classification to define the indications within B-cell indolent NHL. B144 ("B-cell indolent NHL of the following subtypes as defined by the WHO Lymphoma Classification"). Dr. Arbuck confirmed, "***Calistoga was using the WHO classification system to define the indications*** within B-cell indolent non-Hodgkin's lymphoma." A629 (534:2–15).

A. 2/1/2011 Calistoga Draft

Calistoga initially proposed milestones using the undefined term "hematologic cancer indication." A167–68. After receiving Calistoga's draft, Mr. O'Connell asked Mr. Stocks to explain the intended scope of the milestones. A171. In response, Mr. Stocks offered a number of scenarios in which approvals for a "hematologic cancer indication" would trigger milestones, all of which

involved approvals for recognized blood cancers: "iNHL[7] approval in the US and then in an EU country," "iNHL approval in the US and then CLL approval in an EU country" and "iNHL approval in the US and then CLL approval in the US." *Id*.

B. 2/7/2011 Gilead Draft

In the next draft, Gilead replaced the undefined term "hematologic cancer indication" with "Specified Hematologic Cancer Indication," expressly defined as "any ***hematologic cancer indication*** specifically identified in Schedule 1.1." A173. Schedule 1.1 recited a list of nine diseases, including CLL. A174. Dr. Gallagher admitted that Calistoga understood this list of "indications" to be a list of "diseases," and specifically a list of "blood cancer[s]." A537 (166:11–23); A564 (273:14–16).

C. 2/11/2011 Calistoga Draft

Calistoga accepted verbatim the definition of "Specified Hematologic Cancer Indication." B49–50. Calistoga, however, expanded the listing in Schedule 1.1 to include a larger list of recognized diseases encompassed by eleven categories of "tumor types." B48.

The trial established the following about Calistoga's version of Section 1.1:

[7] iNHL (indolent non-Hodgkin lymphoma) is a group of recognized blood cancers. A522 (105:2–7) (Miller); A556 (242:6–9) (Gallagher); A693 (788:4–11) (Hawkins).

First, Calistoga's source for the eleven "tumor types" was the WHO classification. A561 (262:2–20) (Gallagher); A511 (64:2–13) (Miller); B783 (31:14–22; 32:20–33:7 (Yu)).

Second, the listed "tumor types" are the top-level collections of blood cancers from the WHO classification. A564 (273:9–13) (Gallagher); A625 (519:3–6) (Arbuck). Indeed, there is a one-to-one correspondence between Calistoga's listing of "tumor types" and the top-level WHO tumor types. A511 (63:6–64:13) (Miller); B10; B52–54. Slight differences in wording are non-substantive and due to the fact that different versions of the WHO classification exist. A645–46 (597:16–599:10) (Dearden); B834.

Third, in the industry, what it means to be "within" a "tumor type" is well-understood: the recognized diseases that are classified within each tumor type. A640 (575:7–21) (Dearden), A645–46 (598:16–599:10); A624 (513:1–514:4) (Arbuck); B805 (30:19–31:4 (Stocks)).

Fourth, the blood cancers that are defined as within the WHO classification's tumor types are properly described as "indications." A627 (525:15–526:16) (Arbuck); B821-22 (38:9–14; 45:21–46:21 (Arbuck)); B805 (30:19–31:4 (Stocks)); B818 (18:17–19:2 (Kilgannon)).

Fifth, the "indications within the following tumor types" language refers to the recognized diseases defined as within the top-level WHO categories. In the

original version of the list drafted by Calistoga's Drs. Yu and Miller, below each top-level tumor type was a complete list of all WHO-recognized hematologic cancer diseases within them. *Compare* A185 (B-cell neoplasm) *with* A156 (B-cell neoplasms). Drs. Gallagher and Miller confirmed that the language "any indication within the following tumor type" in the final version sent to Gilead was shorthand to refer to these recognized diseases listed within each category:

> Q. The "within" language was intended to sweep in the subcategories that are described in Dr. Miller's list below B-cell neoplasms; correct?
>
> A. Yes.

A563 (271:4–7) (Gallagher); B794 (53:16–56:8 (Gallagher)) (purpose of "within" was to include recognized diseases like "mantle cell lymphoma); A512 (67:16–68:16) (Miller). This served a practical purpose because the list of recognized diseases evolves over time. B793 (51:24–52:6 (Gallagher)), B796 (114:8–12).

Dr. Gallagher admitted that the language "'within the following tumor type[s]' . . . was not intended to depart from the scientifically recognized definition of diseases" and "[it] was not the intent of Calistoga to depart from the scientific accepted definition of 'tumors' when it prepared Schedule 1.1." A563 (271:14–18, 272:18–21).

Dr. Gallagher admitted that "the place that Drs. Miller and Yu went to understand what was encompassed by the tumor types in Section 1.1 was the WHO

classification system." A564 (273:21–274:2) (Miller); A512 (68:10–16), A513 (71:2–72:4).

As Calistoga intended, Gilead understood that Calistoga's definition reflected the WHO classification and that "within the following tumor types" referred to the recognized diseases within the listed tumor types. A727 (920:9–16) (O'Connell), A728–29 (927:7–928:6); A693–94 (790:10–791:7) (Hawkins); B815 (42:8–43:2 (Mansuri)). Calistoga never communicated to Gilead "in words or deeds" that the "'within the following tumor type' language was to depart from the WHO classification standards for defining diseases" or "from the scientifically recognized definition of diseases." A563 (271:8–13, 271:19–272:5, 272:12–17) (Gallagher).

D. 2/15/2011 Gilead Draft

Gilead responded by creating two defined categories of hematologic cancer indications (Part 1 and Part 2), one tracking Gilead's original proposal limited to nine diseases, and the other tracking Calistoga's expressed desire to include all recognized diseases with the listed tumor types. A189, A191, A193–94; A710–11 (855:10–857:2) (O'Connell), A712 (860:2–861:2); B45; A693–94 (790:10–791:7) (Hawkins).

Significantly, Part 2, the list of diseases originally provided by Gilead on February 7, was expressly defined as "specifically identif[ying]" "hematologic

cancer indication[s]." A191. Dr. Gallagher admitted that Part 2 is a list of "diseases." A537 (166:11–23), A564 (273:14–16). Numerous former Gilead employees involved with the negotiation confirmed that Part 1 defined "hematologic cancer indications" the same way—to refer to recognized blood cancers. A693 (789:6–790:9) (Hawkins), A693–94 (790:10–791:7), A694 (791:23–792:5); A710–11 (855:18–857:2) (O'Connell), A727 (920:9–16), A728–29 (926:14–928:6), A729 (929:3–20), A711 (858:11–20); B815 (42:8–43:2 (Mansuri)). Dr. Hawkins explained that this "removed any kind of an open-ended element to the negotiation."[8] A693–94 (789:6–791:7).

Mr. O'Connell wrote to Mr. Stocks and specifically explained that, for the second regulatory approval milestone, "one of the two ***indications*** would need to be . . . ***CLL, iNHL and the other major hemonc cancers***." A195. The examples of "indications" that Mr. O'Connell provided are all recognized blood cancers. *Id.*; *see also* A714 (868:15–869:11) (O'Connell).

In the final Agreement, the term "Hematologic Cancer Indication" is used in defining all three milestones, including the one at issue, a $50 million payment triggered by: "Regulatory Approval of CAL-101 . . . as a first-line drug treatment . . . for a Hematologic Cancer Indication." A130–31.

[8] SRS's suggestion that Dr. Hawkins believed the "indications within the following tumor types" language refers to genetic subpopulations is incorrect. He testified to the opposite. A700 (817:15–818:6) (Hawkins).

The Agreement also provides alternative triggers for the milestone, including a provision providing for the $50 million milestone (and potentially other milestones as well) to be paid if $1 billion in annual sales occurs, A131–32, even if regulatory approval for a Hematologic Cancer Indication has not occurred. Dr. Gallagher testified that "the billion in sales [trigger] was ***to protect in case you got any approval, a small, small approval***, and then it had this halo effect which you talked about." A548 (210:7–211:5) (Gallagher); s*ee also id.* (211:22–212:11); A585 (359:5–20) (Gallagher); A715–16 (873:8–876:4) (O'Connell).

III. THE EMA DID NOT APPROVED ZYDELIG AS FIRST-LINE TREATMENT FOR A HEMATOLOGIC CANCER INDICATION

Gilead submitted to the EMA an application for Regulatory Approval. B65–73. As it related to CLL, Gilead requested that Zydelig be approved for: "treatment of ***relapsed*** [second-line or higher] chronic lymphocytic leukaemia." B66. The EMA, on its own initiative, requested data on, and then drafted language permitting access to Zydelig for, patients who have the 17p deletion and are not suited for chemo-immunotherapy. A614–15 (475:2–479:2) (Arbuck); A652 (623:24–624:21) (Dearden), A654 (633:21–634:24); B75–77; A350. The EU label states:

> Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
>
> - who have received at least one prior therapy, or

- as first line treatment in the presence of 17p deletion or *TP53* mutation in patients unsuitable for chemo-immunotherapy.

A350. The second bullet point, the subject of this case, was a narrow exception created by the EMA to allow patients with rare genetic mutations access to the drug when they had no other options (the "Exception"). A652 (623:24–624:21) (Dearden); A617 (486:17–21) (Arbuck).

In a safety document, the EMA discussed the nature of the Exception. The EMA expressly confirmed that "Previously untreated CLL"—*i.e.*, first-line CLL—is "[n]ot an authorised indication." B137. SRS's witnesses Drs. Miller and Arbuck agreed with the EMA that the approval is not a first-line approval for CLL, but rather a ***second-line*** approval for CLL with an exception for a unique genetic subpopulation. A524 (114:4–21) (Miller); B830 (251:9–16 (Arbuck)); *see also* A610–11 (459:4–461:1) (Arbuck); A655 (637:3–13) (Dearden).

IV. SRS REPEATEDLY ACKNOWLEDGED THAT THE MILESTONE WAS NOT MET

On multiple occasions before they brought suit, the Calistoga executives who control this litigation admitted that the milestone requires a disease-level approval and the Exception does not satisfy the milestone.

Between 2012 and 2014, Drs. Gallagher and Topper (Calistoga's Chairman), and Chris Letang (SRS's executive responsible for monitoring milestone progress) repeatedly discussed the milestones. *E.g.*, B63–64; A570 (298:22–299:10)

(Gallagher); B122; B83; A573–74 (310:3–313:1) (Gallagher). Mr. Letang identified "blood cancers" as Hematologic Cancer Indications, and Dr. Gallagher expressed no disagreement. A572 (308:6–24) (Gallagher), A573 (309:1–11); B123.

On July 28, 2014, Mr. Letang again briefed Drs. Topper and Gallagher on the milestone terms. B82–83; A573–74 (312:1–313:1) (Gallagher). The next day, Dr. Gallagher read Gilead's press report stating that the scientific body in the EMA responsible for drug review—the CHMP—had released the language of the approval for Zydelig, including the Exception. She announced, "Approval in EU." B80; B78–79; A574 (313:2–315:16) (Gallagher). Neither Dr. Gallagher nor anyone else at SRS stated that the Exception satisfied the milestone. *Id.*

A month later on August 25, 2014, Gilead provided an update to SRS. Gilead stated that it was conducting Phase III "registration trials in patients with previously untreated CLL." B96. Gilead also reported the CHMP's decision, expressly reciting the Exception's language: "first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy." B98; B788 (34:20–25 (Topper)). Dr. Gallagher received the report and again did not conclude that the milestone was triggered. A574–75 (315:17–320:12) (Gallagher).

After Dr. Topper read the CHMP's positive opinion, he similarly did not conclude that the milestone was due. Instead he expressed hope that the ongoing

"upfront" (first-line) clinical trials would ultimately lead to a milestone: "Nice read. Phase 3 upfront trials are enrolling. This is one of the targets for the rest of the milestones." B81.

Dr. Topper's opinion that the third milestone was not triggered by the EU approval remained the same a month later. On September 19, 2014, Dr. Topper provided an update to his partners in an email entitled "zydelig was approved in EU today." The update was a single sentence, explicitly acknowledging: "***No milestone,*** but good progress to next one[.]" B121. Dr. Topper also recited the milestone terms to Calistoga's Chief Development Officer, Dr. Ulrich, and again affirmed that the milestone was not triggered. B118–19; B787 (22:16–23:10 (Topper)).

On the day of the EU approval, Dr. Gallagher was asked by Kamal Puri, an ex-Calistoga employee and a shareholder then working at Gilead, whether it triggered the milestone. B120. In response, Dr. Gallagher again did not state that the milestone was triggered and instead identified the $1 billion backstop as the likely future trigger. A576–77 (321:23–325:16) (Gallagher).

ARGUMENT

I. THE TRIAL COURT DID NOT COMMIT LEGAL ERROR IN CONCLUDING THAT THAT THE CONTRACT WAS AMBIGUOUS

A. Question Presented

Is the term "indication" in the Agreement's definition of "Hematologic Cancer Indication" fairly susceptible to the meaning "disease"?

B. Scope Of Review

On appeal, this Court reviews "*de novo* for legal error" the conclusion that a provision is ambiguous. *AT&T Corp. v. Lillis*, 953 A.2d 241, 252 (Del. 2008).

C. Merits Of Argument

A term is ambiguous if it is "reasonably or fairly susceptible of different interpretations or may have two or more different meanings." *Phillips Home Builders, Inc. v. Travelers Ins. Co.*, 700 A.2d 127, 129 (Del. 1997). For an interpretation to be reasonable, it need not be a perfect fit with all elements of the contract. The fact that competing interpretations result in some surplusage or inconsistency does not make them unreasonable. *See id.* at 129–30.

In this case, the trial court was faced with at least three different interpretations of "indication" that SRS proposed and abandoned throughout the case. In contrast, Gilead has consistently advocated one interpretation—that in the Agreement indications are ***diseases***—and that Hematologic Cancer Indications

therefore are the recognized blood cancers defined by Section 1.1.[9] Gilead maintains that the final interpretation SRS settled upon is unreasonable. At a minimum, however, the trial court correctly concluded that there were alternative reasonable interpretations.

1. "Indication" Has Multiple Meanings and Is Used To Mean "Disease"

The trial court correctly found overwhelming evidence that "indication" has different meanings,[10] and is commonly used to mean "disease" in the bio-pharmaceutical industry. Op. 46; B790 (69:6–12 (Topper)); B791 (77:24–78:5 (Topper)) (indication and disease "commonly interchanged"); A556 (242:13–24) (Gallagher); A512 (67:16–68:9) (Miller); A517 (88:5–23) (Arbuck); A518 (92:13–17); A621 (503:19–23); A622–23 (507:1–511:4); A648–49 (610:10–612:5) (Dearden); A708 (845:11–23) (O'Connell), A714 (868:15–869:11). As SRS admits, "there is no doubt that 'indication' is sometimes used to signify a 'disease.'" OB 20.

[9] Indeed, the day the Exception was announced, Gilead stated that no milestone was due because it was only for a subpopulation with a rare genetic disorder, in response to an inquiry by a Calistoga shareholder. B140.

[10] A623 (510:23–24) (Arbuck); A517 (88:5–23) (Miller); B789 (68:1–5 (Topper)); A647–48 (606:18–607:4) (Dearden).

2. SRS Has Proposed Multiple Different Interpretations, Including The Interpretation Adopted By The Trial Court

As the trial court noted, SRS proposed and abandoned several different interpretations of the term indication. Op. 51–52. Notably, SRS has argued that indications are diseases. SRS represented to the trial court that "CLL is thus a 'Hematologic Cancer Indication' that is 'specifically identified in part 1 of Section 1.1' because it is an 'indication within' the tumor type 'B-Cell neoplasms'" and because "[t]he 'Specified Hematologic Cancer Indications' listed in Part 2 includes CLL." A445. CLL is not a label or regulatory approval—it is a blood cancer. SRS revived this argument in its pre-trial brief, stating that "the parties specifically agreed that any Regulatory Approval for Zydelig as a first-line treatment for a ***blood cancer*** would trigger the final milestone." B465; A517 (86:6–10) (Miller).

SRS offered another alternative interpretation in its Motion for Judgment on the Pleadings: "[t]he basis for initiation of a treatment for a disease or of a diagnostic test." B247 at n.9. SRS subsequently abandoned this interpretation after conceding that "all of the established guidelines recognize that the presence of the 17p deletion or *TP53* mutation in patients is ***not*** the basis for initiating treatment of CLL." B417; B784 (40:3–20 (Yu)); B832 (278:24–279:4 (Arbuck)).

SRS also offered a series of evolving interpretations that attempted to equate "indication" with "regulatory approval." At deposition, SRS expert Dr. Arbuck described "indication" as "***any regulatory approval of any indication that the***

regulatory authority approves." B820 (28:17–23 (Arbuck)); *accord* B795 (64:7–14 (Gallagher)); A590 (380:16–22) (Arbuck). SRS continued to advance variations of this interpretation in its post-trial brief: "the ***only*** reasonable interpretation of the word 'indication' as it is used in the Merger Agreement is that it refers to the label or indication statement that Gilead receives from a regulatory authority such as the EMA or FDA." B569. SRS maintains on appeal that the "only reasonable interpretation" is "the approved use of a drug." OB 1. SRS's interpretation is irreconcilable with the Agreement and its own admissions:

First, SRS repeatedly admitted that CLL, which is a ***disease***, is an "indication" within the meaning of the Agreement:

- "CLL itself is both an indication and a hematologic cancer indication as defined in the agreement." B322.
- "CLL is thus a 'Hematologic Cancer Indication' . . . because it is an 'indication within' the tumor type 'B-cell neoplasms.'" A445.

CLL is not a regulatory approval, it is not a label, and it is not a patient. It is a disease within a recognized hematologic cancer tumor type listed in Section 1.1, Part 1, and also a disease expressly listed in Part 2.

Second, the milestone uses the term "Regulatory Approval" separately from the term "Hematologic Cancer Indication," not as a synonym. A517 (86:11–19) (Miller); A558 (250:18–22) (Gallagher); A650 (617:1–618:10) (Dearden).

Third, the milestone describes a "Hematologic Cancer Indication" as something that is "treat[ed]": "a first-line drug ***treatment*** . . . ***for*** a Hematologic Cancer Indication." A131. SRS concedes this. B608 (11:20–23). One does not "treat[]" "the approved use of a drug." One "treat[s]" a "disease."

Fourth, Section 1.1, Part 1, references "indications within the following ***tumor types***." SRS's witnesses agree that "tumor types" are scientific categories of tumors, and that what is "within" tumor types are diseases—the recognized blood cancers. A522 (105:2–7) (Miller); A562 (265:10–15) (Gallagher); A626–27 (524:24–525:8) (Arbuck). It is nonsensical to speak about a regulatory approval—"the approved use of a drug to treat a population of patients with a particular disease"—as "within" a collection of blood cancers.

3. The Agreement's Plain Language Establishes That Gilead's Interpretation Is Reasonable

The trial court correctly concluded that interpreting "indication" to mean "disease" is, at the very least, reasonable. Op. 47–50. In the Agreement, "indication" appears in two related definitions. The definitions of "Hematologic Cancer Indication" and "Specified Hematologic Cancer Indication" refer to "any hematologic cancer indication ***specifically identified*** in" Part 1 or Part 2 of Section 1.1, respectively.

It is undisputed that the "hematologic cancer indication[s]" identified in Part 2 are ***diseases***—recognized blood cancers or collections of recognized blood cancers. Dr. Gallagher expressly admitted this:

> Q. ***And what are the things listed on that schedule***?
>
> A. ***Diseases***.

A537 (166:11–23); *see also* A564 (273:14–16) ("Q. And everything in part B [*sic*, Part 2] is a ***blood cancer***; correct? A. Yes.").

SRS's expert, Dr. Arbuck, conceded that "indication" means the same thing throughout Section 1.1. A626 (523:12–524:21). The indications listed in Part 2 are undisputedly diseases. "Indication" is properly interpreted in the same manner in Part 1.

Part 1 describes a Hematologic Cancer Indication as "any indication within the following tumor types," followed by a list of "tumor types." A156. Part 1 thus describes two entities: (1) "tumor types" and (2) "indications within" these tumor types. The parties' experts agreed there is a worldwide consensus on what entities are "within" the tumor types listed in Part 1—***blood cancers***. B823–24 (56:24–57:4, 58:9–13 (Arbuck)); A626–27 (524:24–525:8) (Arbuck); A645–46 (598:16–599:10) (Dearden), A639 (572:2–12), A639–40 (574:13–575:12). Dr. Arbuck testified, for example, that "CLL is an indication within B-cell neoplasms." B821–22 (38:8–14, 45:21–46:2 (Arbuck)). Drs. Dearden, Kilgannon, and Mr. Stocks also

testified that recognized blood cancers are indications within the tumor types listed in Part 1. A646 (599:3–10) (Dearden), A648 (608:19–609:8); B818 (18:17–19:2 (Kilgannon)); B805 (30:19–31:4 (Stocks)).

Dr. Dearden testified that Part 1 is immediately recognizable in the industry as the WHO classification system for defining blood cancers. A639 (574:5–12); A638 (569:20–570:1); A645 (595:24–596:21, 597:16–598:15); A646 (599:3–10). Calistoga is charged with what a reasonable person in the industry would have understood Part 1 to mean. *AT&T Corp.*, 953 A.2d at 252–53 ("what a reasonable person in the position of the parties would have thought it meant").

Dr. Gallagher ultimately admitted that, "when folks in the industry use the word 'indication,' they don't use it to mean 'any indication, any label that you receive for a specific patient population.' They use it to refer to blood cancers[.]" A564 (274:14–275:5) (Gallagher).

4. SRS's Textual Arguments Are Incorrect

The trial court considered SRS's textual arguments and properly rejected them. Op. 48–50. SRS's main argument is that interpreting "hematologic cancer indication" to mean "hematologic cancer disease" is redundant. This is incorrect as a matter of common sense and the trial record.

First, each word in the phrase "hematologic cancer indication" plays an independent role. "Hematologic" (blood) and "indication" (disease) make clear

that the subject of the milestone is blood diseases. But the milestone is not triggered by all blood diseases (*e.g.*, hemophilia, a hematologic indication but not a cancer). Instead, the milestone provision is limited to blood diseases which are cancers—hematologic cancer indications. Moreover, industry publications confirm that, far from being "absurd" or "redundant," the phrase "cancer disease" is commonly used. A818–919. SRS incorrectly argues that such usage is limited to "highly technical sources and non-native English speaking journals." OB 28. Notably, several examples in the record are from *Blood*—which is published in the United States, "[o]ne of the highest impact hematologic cancer journals," A522–23 (108:16–19, 110:14–21) (Miller), and the very publication Calistoga used to create the list defining Hematologic Cancer Indication, A509 (55:1–7) (Miller) & A180–83. The trial court's finding that the terms "hematologic cancer disease" and "cancer disease" are used in the "oncology industry" was reasonable. Op. 49–50. Moreover, SRS's assertion that what matters is the "standard English usage" is self-contradictory because SRS admitted that "indication" "is ***a term of art*** the parties understood." B607 (10:2–3).

Second, parsing individual words in the defined phrase "Hematologic Cancer Indication" clearly was not the intent of the parties. "Hematologic Cancer Indication" is a term with a special definition—the entities "specifically identified" in Section 1.1. Section 1.1 defines the diseases in Part 2 as "indications." And

Part 1 uses the phrase "any indication within the following tumor types." Defining indication as a disease results in no surplusage in Section 1.1.

Third, SRS points to dictionary definitions, principally relying on the second definitions in two dictionaries (Taber's and Oxford Concise) which SRS did not present below. OB 24. SRS provides no explanation for why these second definitions in these new dictionaries provide the only reasonable meaning, as opposed to, for example, the definitions it previously presented. B247 at n.9. Indeed, Dr. Arbuck admitted that the "Indication" section of an EU regulatory approval does ***not*** "define the meaning of indication in the merger document." B827–28 (156:15–17, 157:25–158:2, 160:10–12) (Arbuck) (discussing B12, JX030-007).

Fourth, SRS claims that the last bullet point in Part 1 should be read as "any indication within" "any Specified Hematologic Cancer Indication listed in Part 2," and that indication cannot mean disease because there are no diseases within CLL. OB 28. Not even SRS's witnesses support this argument. Dr. Gallagher admitted that the purpose of the bullet point is to confirm that the entities in Part 2 are also covered by Part 1. A564 (273:17–20) (Gallagher). Moreover, even if SRS's interpretation were correct, it does not support its argument. Many of the diseases listed in Part 2 also have recognized diseases within them, including Diffuse Large B-cell lymphoma, Acute Myeloid Leukemia, and Hodgkin's Lymphoma. B5–7. It

is undisputed, however, that there is no "disease or tumor ***within*** CLL." A512 (67:4–15) (Miller); A627–28 (527:6–529:4) (Arbuck).

Finally, SRS claims that the "context" in which "indication" is used in the Agreement is regulatory approval. B579. This is entirely circular. SRS admits that Regulatory Approval can occur at the "disease-level." A515 (77:9–80:14) (Miller). Further, as the trial court found, in the "regulatory context," SRS repeatedly used "indication" to mean "disease." Op. 58; *supra* pages 8–9. Most importantly, the context relevant to contract interpretation is not regulatory approval generally, but the Agreement. Dr. Gallagher admitted that, in "the context in which this agreement was negotiated," Calistoga used "'indication' to mean 'blood cancer'" and not a "regulatory approval" or "label." A556–57 (244:23–246:21) (Gallagher); *see also* A648–49 (608:19–611:8) (Dearden), A654 (632:13–16); A672 (706:15–20); A695 (795:1–7) (Hawkins).[11]

[11] Dr. Mansuri concurred that the Agreement was narrower than SRS's proffered definition of indication. B814 (37:6–17 (Mansuri)). Section 1.1 triggers milestones based on "broad tumor types," which is different from approvals based on "particular patients." B816 (55:19–56:4 (Mansuri)).

II. THE TRIAL COURT'S FINDINGS THAT THE EXCEPTION IS NOT REGULATORY APPROVAL AS FIRST LINE TREATMENT FOR CLL IS NOT ARBITRARY OR LACKING IN EVIDENTIARY SUPPORT

A. Question Presented

Was the trial court's factual finding that the Exception does not approve CAL-101 as first-line treatment for CLL arbitrary or lacking any evidentiary support?

B. Scope Of Review

The trial court weighed the evidence, including the credibility of witnesses and expert testimony from both SRS and Gilead, in rendering its factual finding that the Exception does not satisfy the milestone. These findings can be "overturned only if arbitrary or lacking any evidentiary support." *In re Walt Disney Co. Derivative Litig.*, 906 A.2d 27, 71 (Del. 2006).

C. Merits Of Argument

SRS argues that the trial court improperly added what it describes as a "disease-level" limitation to the Agreement. The crux of SRS's argument is that regulatory approval for a "disease" is different from "disease-level" approval. As discussed in Section III.C.2 below, this argument is factually incorrect. The industry uses "disease-level" to refer to a regulatory approval for treatment of a disease as opposed to a genetic subpopulation. But even if SRS's argument were correct, its appeal still fails. SRS claims that "if 'indication' meant 'disease,' that

would resolve the ambiguity ***in favor of SRS***" because the Exception is a first-line approval for the disease CLL. OB 29. The trial court, however, found as a matter of fact the exact opposite: "The European Commission ***Did Not*** Approve CAL-101 as a First-Line Drug Treatment for the Disease CLL." Op. 75–78. The trial court expressly rejected SRS's contention that the Exception "was for a 'first line treatment for the disease CLL,'" based on a record "replete with evidence to the contrary." *Id*. at 75. The trial court relied on the testimony of Drs. Arbuck, Dearden, and Miller, and the conclusions of the EMA in finding that "Gilead did not seek approval of CAL-101 as ***a first line treatment for the disease CLL***, and the record shows that ***it did not receive such an approval***." Op. 77.

The trial court's decision was not arbitrary or lacking evidentiary support. The EMA expressly stated that "Previously untreated CLL" is "[n]ot an authorised indication for CLL" under the EU Zydelig label. B137.[12] And SRS's own expert agreed that Zydelig was never approved as first-line treatment for CLL:

> Q. And so what the PRAC is at least observing here is that ***Idelalisib in Europe was not previously approved as front line or for previously untreated CLL patients***; correct?
>
> A. ***That's correct. It wasn't.***

B830 (251:9–13 (Arbuck)).

[12] Dr. Dearden explained that the EMA's observation did not alter the Exception; it simply confirmed the limited scope of the EMA's original approval. A656 (642:11–16) (Dearden).

SRS claims that the EMA simply concluded that the Exception is not a first-line treatment for "all" of CLL and that the Agreement does not say "all." At trial, however, Dr. Arbuck admitted that the EMA did not use the term "all" and instead made the definitive statement that "Zydelig is not approved for first-line or previously untreated CLL." A612 (467:3–468:2). Dr. Miller likewise conceded that the Exception is not for first-line treatment of CLL. A524 (114:4–21). Dr. Dearden agreed. A656 (641:18–642:16), A657–58 (646:22–647:4). These same witnesses testified that there is no disease recognized as "within" CLL. A512 (67:4–15) (Miller); A627–28 (527:6–529:4) (Arbuck). As a result, SRS's argument collapses into re-drafting the Agreement to read "[***any subpopulation*** of patients with] any indication within the following tumor types."

After first representing that "Zydelig [was] approved as a first-line treatment for CLL," A610 (458:4–8), Dr. Arbuck withdrew that testimony, *id.* (459:4–21), A612 (468:3–11). Ultimately, SRS's expert was unable to defend or explain the premise on which SRS's claim depends. *Compare* B131 (SRS contending that "the new approvals include use of idelalisib as a first-line treatment ***of CLL***") *with* A613 (472:5–24) (Arbuck) (unable to answer the question).

III. THE TRIAL COURT'S HOLDING THAT "INDICATION" MEANS "DISEASE" IS SUPPORTED BY THE RECORD AND THE RESULT OF AN ORDERLY AND LOGICAL DEDUCTIVE PROCESS

A. Question Presented

Did the trial court's finding that the parties intended "indication" to mean "disease" have evidentiary support and result from an orderly and logical deductive process?

B. Scope Of Review

"To the extent the trial court's interpretation of the contract rests upon findings extrinsic to the contract, or upon inferences drawn from those findings, our review requires us to defer to the trial court's findings, unless the findings are not supported by the record or unless the inferences drawn from those findings are not the product of an orderly or logical deductive reasoning process." *Honeywell Int'l Inc. v. Air Prod. & Chemicals, Inc.*, 872 A.2d 944, 950 (Del. 2005).

C. Merits Of Argument

The trial court's factual finding that "the parties mutually understood when they entered into the Agreement that the term 'indication' meant 'a disease'" was supported by the extrinsic record and the subject of an orderly and logical deductive process. Op. 52–61.

SRS represents that "not a single Gilead witness testified that the parties ever discussed, much less agreed, that the word 'indication . . . meant 'disease.'"

OB 35. This is not accurate, as the trial court expressly found. The parties consistently used "indication" to mean disease during their discussion of the milestones. Op. 57–58; *see also* A518–19 (91:16–94:5) (Miller); A557 (245:7–246:21) (Gallagher); B804 (25:21–26:4 (Stocks)). The trial court credited the testimony of Gilead witnesses and also noted the demeanor of SRS witness Dr. Gallagher, who "expressed no surprise to the prospect of being shown 'presentation after presentation in which "indication" was used as synonymous with "blood cancer" at Calistoga,' and testified that when using the word 'indication' in a presentation to refer to blood cancers, Calistoga was 'trying to use it in the way that folks generally in the industry use it.'" Op. 58. The trial court also noted exchanges between lead negotiators Stocks and O'Connell, repeatedly discussing "indications" as diseases, and that many materials Calistoga sent to Gilead used "indications" to refer to "diseases." Op. 57–58. Such contemporaneous negotiation discussions are among the most important classes of extrinsic evidence. *E.g.*, *Hartley v. Consol. Glass Holdings, Inc.*, 2015 WL 5774751, at *10 (Del. Ch. Sept. 30, 2015), *aff'd*, 137 A.3d 122 (Del. 2016) (relying on "evidence of the parties' overt acts, dealings, and correspondence").

SRS claims it is possible to interpret the negotiation correspondence differently. OB 37–38. But the trial court's analysis was clearly ordered and logical.

Additionally, the trial court appropriately placed significant weight on the admissions of Dr. Gallagher:

- "[S]he could not recall any time during the negotiations when Calistoga told Gilead that 'indication' meant 'a label that you would receive for the specific patient population that you would treat'" and did not recall ever using "'indication' to refer to any genetic subpopulations." Op. 59–60.
- She admitted that the Agreement's definition of indication "was not intended to depart from the scientifically recognized definition of diseases." Op. 56–57.

SRS claims that this testimony is not probative because it reflects her subjective unexpressed view. Not so. Dr. Gallagher admitted that a reasonable person in the industry would understand "indication" to mean a recognized blood cancer:

> Q. And in fact, when ***folks in the industry use the word 'indication,'*** they don't use it to mean 'any indication, any label that you receive for a specific patient population.' ***They use it to refer to blood cancers***; correct?
>
> A. Yes.

A564 (274:3–275:5). Calistoga never discussed an alternative definition in its negotiations. And SRS is charged with "what a reasonable person in the position of the parties would have thought it meant." *AT&T Corp.*, 953 A.2d at 252–53.

The trial court also discussed in detail the course of dealing of the parties before the dispute arose. Op. 64–67. The Calistoga executives who negotiated the Agreement and control this litigation repeatedly acknowledged that the Exception did not trigger a milestone payment. B81; B121; B118–19; B120. SRS essentially ignores this evidence and in particular refuses to engage with the trial court's conclusion that the testimony of its main witness, Dr. Gallagher, attempting to explain why SRS changed position was not credible. Op. 66. How parties operate under an agreement is a proper, and often uniquely informative, form of extrinsic evidence. *Radio Corp. of America v. Philadelphia Storage Battery Co.*, 6 A.2d. 329, 340 (Del. 1939) ("when a contract is ambiguous, a construction given to it by the acts and conduct of the parties with knowledge of its terms, before any controversy has arisen as to meaning, is entitled to great weight[.]").

Finally, the trial court discussed how the structure and operation of the Agreement's milestone provisions also support Gilead's interpretation. Op. 67–71. The $50 million milestone has three alternative triggers. Calistoga's lead negotiator Mr. Stocks explained that they each were intended as "value inflections that could lead to significant commercial reward." B807 (52:8–15 (Stocks)). One is regulatory approval in a solid tumor. A131 § 9.1(a)(iii)(A). Zydelig was developed to treat blood cancers. Approval in solid tumors would expand the drug's use "to a completely different class and universe of cancers[.]" B785

(70:7–17 (Yu)). Another is "Annual Net Sales of CAL-101 achieving at least $1 Billion," the value of which is self-evident. A131 § 9.1(a)(iii)(C).

Under Gilead's interpretation, the trigger at issue (*id.* § 9.1(a)(iii)(B)) is similarly commercially significant. First-line approval for treatment of a hematologic cancer disease is a major goal of drug development, considered the "gold standard." A515 (79:23–80:7) (Miller); A697 (804:5); A691 (780:13–781:8) (Hawkins).

In contrast, the trial court observed that "under SRS's reasoning, Gilead negotiated a Merger Agreement that potentially obligated it to pay $175 million if it received regulatory approvals for the treatment of patients who have CLL and a mutation present in 0.44% of CLL." Op. 68. An interpretation of a term that creates "absurd result[s]" is highly disfavored. *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010). The results become even more absurd because SRS claims this rare genetic subpopulation is not only a Hematologic Cancer Indication but also a Specified Hematologic Cancer Indication. A552 (225:21–226:19) (Gallagher), A553 (230:1–17), A553–54 (232:3–233:13). During negotiations, Mr. O'Connell and Mr. Stocks referred to the Specified Hematologic Cancer Indications list as the "***major hemonc cancers***" and give as an example "CLL." A195. SRS's interpretation of "indication" would equate an

extraordinarily rare genetic subpopulation to a "major hemonc cancer," which is irreconcilable with the language of the Agreement and the negotiation record.

SRS claims that the Exception was valuable, and therefore does not lead to an absurd result. This is a flawed argument. What matters is that SRS's ***interpretation*** can lead to absurd results, which is strong evidence that reasonable parties would not have understood "indication" as SRS advocates. And, although not necessary to the trial court's conclusion, there was compelling evidence in the record that the value of the Exception was extremely small and could never justify the windfall SRS sought. B809 (53:19–56:24 (Porter)).

1. SRS's Arguments That the Trial Court Should Have Weighed the Evidence Differently Are Legally Improper

SRS suggests that this Court should come to a different conclusion based on other extrinsic evidence that SRS proffered. As an initial matter, this is not the proper inquiry on appeal. The question is whether the trial court analyzed the evidence in a logical fashion, and whether there is evidentiary support for the trial court's conclusion, which SRS does not seriously dispute. Furthermore, the inferences that SRS suggests could have been drawn from its cited evidence are incorrect and contrary to the great weight of the evidence.

For example, the trial court expressly considered and rejected SRS's argument based on a draft milestone that did not appear in the final Agreement that defined a "Phase II Trial" as "a randomized controlled clinical human study

conducted to evaluate the effectiveness of a drug for a particular indication or indications in the patients with the disease or conditions under study." Op. 58–59. There was nothing disordered or illogical about the trial court's conclusion that this draft provision that was never adopted did not compel a finding in SRS's favor. The trial court noted that the more natural fit for the phrase "indication or indications" in the definition was disease or diseases. While the draft Phase II language makes sense under Gilead's interpretation ("effectiveness of a drug for a particular [disease] or [diseases]") it is incongruous with SRS's position, as one does not speak of drugs being effective for a "regulatory approval" or "label." SRS makes much of a contrast between the singular word "disease" at the end of the draft definition versus the plural "indication or indications." OB 39. However, there was no evidence in the record that the inadvertent omission of the plural "s" in the phrase "disease[s] or condition**s**" was intended to depart from the repeated use of indication to mean disease during the negotiation. Notably, in the final Agreement the word "disease" no longer appears, and in ***all*** instances in which diseases are referenced the term "indication" consistently is used instead.

The trial court also analyzed and rejected SRS's argument that Gilead understood it could have to pay the milestone for a rare genetic subpopulation because the parties contemplated approvals that would apply to only "relapsed" patients. As the trial court concluded, crediting the testimony of Gilead's lead

negotiator and admissions from SRS witnesses, this conflates two very different concepts—lines of therapy and Hematologic Cancer Indications. Op. 73. Milestone 3(b) expressly separates the concepts of approval, line of therapy, and Hematologic Cancer Indication, referring to "***Regulatory Approval*** . . . as a ***first-line*** drug treatment . . . for . . . any ***Hematologic Cancer Indication*** . . . ." A650 (617:1–618:10) (Dearden). Dr. Gallagher admitted that the parties treated line of therapy differently from Hematologic Cancer Indications. Op. 72–73; A558 (250:23–251:3). Drs. Arbuck and Miller conceded the same. A521 (101:21–102:3) (Miller); B826 (147:5–148:6 (Arbuck)). The parties contemplated a development program to obtain approvals for recognized blood cancers, starting with later lines and progressing to first-line, the "gold standard." A515 (79:23–80:14) (Miller); A697 (804:5–8) (Hawkins); B57.

For example, in the FDA approval for Zydelig, the first bullet point recites "[r]elapsed chronic lymphocytic leukemia (CLL) . . . in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities." A212. SRS's brief suggests that this represents a subpopulation but the witness testimony to which SRS cites correctly describes it as a line of therapy. After multiple lines of treatment, chemotherapy can no longer be used. The FDA label therefore is "a further refinement of the line of therapy concept." A690

(775:18–776:15) (Hawkins).[13] Dr. Bischofberger likewise describes the FDA language as for a "***subset of relapsed*** CLL," meaning a line of therapy beyond second-line. B812 (57:21–58:2 (Bischofberger)); *see also* A700 (815:23–816:3) (Hawkins) ("Yes, he says it's a subset of relapsed CLL . . . it's simply a . . . ***line of therapy***.").

SRS suggests there is an inconsistency between Gilead witnesses regarding the impact of what it describes as "personal characteristics" on whether an approval is for a recognized blood cancer. OB 42–44. There is no disagreement. SRS is simply attempting to take advantage of differing uses of the vague term "personal [or "patient"] characteristics" that SRS counsel inserted into its questions. Each of these witnesses testified that an approval limited to a genetic subpopulation such as 17p/*TP53* mutation is not for a recognized blood cancer, and does not satisfy the milestone. A700 (817:15–818:6) (Hawkins); A716 (876:11–22) (O'Connell); *see also* B811 (26:12–27:7 (Bischofberger)).

Dr. Hawkins used the term "disease characteristic" to refer to 17p/*TP53* mutation, which is present only in a genetic subpopulation. A700 (817:20–

[13] Likewise, SRS makes reference to a trial it proposed in "iNHL patients that were no longer responding to rituximab . . ." and suggests that this is equivalent to the 17p/*TP53* mutation. OB 8. But SRS's witnesses admit that the trial SRS is referring to is simply for "third line" iNHL—a line of therapy, which in the Agreement is distinct from indication. A571 (302:3–304:12) (Gallagher) (discussing A212, JX510); A620 (498:2–500:21) (Arbuck); A691–92 (782:19–783:10) (Hawkins).

818:19). In contrast, he refers to line of therapy as a "patient characteristic." *Id.* (818:11–14) (Hawkins). Like Dr. Hawkins, Mr. O'Connell was definitive that line of therapy is not a subpopulation; indeed, the same patient who receives second or third-line treatment will also have received first-line treatment. A705–06 (835:19–836:14), A716 (876:11–14). When Mr. O'Connell was asked about an approval for "personal characteristics," he did not recognize the term. A716 (876:15–22). When counsel reframed the question as "genetic mutations," Mr. O'Connell responded such an approval would not trigger the milestone. *Id.* (876:19–22).

SRS has asserted that the Agreement treats it unfairly because milestones are not triggered when an approval is limited by the term "adult." SRS, however, constructs a hypothetical that has no connection to the actual Agreement. First, the diseases that the parties focused on developing Zydelig to treat are exclusively diseases of adults. A732 (940:11–941:17) (O'Connell); A678 (728:4–10) (Dearden). Indeed, Dr. Gallagher admitted that in 2012 she concluded that an age-limited approval (elderly CLL) would not trigger a milestone. A570–71 (297:10–301:20). And second, as to the first two milestones, Gilead was obligated to use reasonable efforts to achieve disease-level approvals. A133 § 9.1(b)(iii). As to the third milestone, the $1 billion "backstop" protected Calistoga shareholders.

Finally, SRS cites a 2008 article from Dr. Dearden that discusses the drug Alemtuzumab. A366. This article merely confirms that "indication" can be used

in different ways. It clearly does not use "indication" to refer to Alemtuzumab's regulatory label, which is SRS's proffered definition. As the article states, Alemtuzumab was approved as a first-line treatment for CLL, a recognized disease, and not just for the genetic subpopulation. A361; B101.

2. SRS's Argument That The Trial Court Reformed The Agreement Is Inaccurate

SRS argues that the trial court ***reformed*** the Agreement by allegedly inserting the phrase "disease-level" into it. This argument is a caricature. The fact that the trial court's opinion sometimes refers to approvals of treatments for a Hematologic Cancer Indication as "disease-level approvals" simply tracks the language of the milestone as construed and the actual industry parlance used by both sides at trial. The trial record established that regulatory agencies can and often do approve drugs for the treatment of diseases, such as CLL, as opposed to just genetic subpopulations, and that this is called a "disease-level approval." A515 (77:9–80:14) (Miller); *see also* B831 (272:7–22 (Arbuck)); A689 (772:5–10) (Hawkins); A694 (792:11–793:2); A653 (630:16–24) (Dearden), A658 (648:23–650:17). The trial court never suggested that any qualifier was being written into the Agreement. And as discussed above in Section II.C, the conclusion that the EMA's Approval is not a first-line approval for CLL does not depend in any way on whether the phrase "disease-level" is used.

If the parties wanted to include in the milestones any genetic subpopulation of a disease, no matter how small, they would have written "a first-line drug treatment . . . for ~~a~~ [*any patient who has a*] Hematologic Cancer Indication." The trial court reviewed the extrinsic record, and reached a conclusion that was strongly supported by the record evidence.

IV. THE TRIAL COURT DID NOT ABUSE ITS DISCRETION IN HOLDING THAT SRS WAIVED ITS ARGUMENT THAT DEAL COUNSEL PRIVILEGED COMMUNICATIONS SHOULD BE PRODUCED

A. Question Presented

After SRS declined to seek any discovery of privileged information until after the close of discovery and on the eve of trial, did the trial court properly hold the argument waived?

B. Scope Of Review

"The standard of review with respect to pretrial discovery rulings is abuse of discretion." *Coleman v. PricewaterhouseCoopers, LLC*, 902 A.2d 1102, 1106 (Del. 2006).

C. Merits Of Argument

Early in this case, SRS represented that privileged communications between Calistoga and deal counsel were irrelevant to its claim. SRS's attempt to argue to the contrary on appeal is improper.

In its answer, Gilead denied that SRS was entitled to the third milestone under the terms of the contract. A304. It also presented counterclaims in the alternative for reformation. A333–36. Delaware rules expressly allow for claims in the alternative. Del. Ch. Ct. R. 8.

After Gilead's answer, SRS's counsel conceded that upon completion of the merger of Calistoga into Gilead, the privilege remained with Gilead: "WSGR

agrees, under *Great Hill*, that privileged communications between WSGR and Calistoga remains the property of Calistoga."[14] B145–51, Exs. F (B152–54) & H (B155–57) (SRS counsel agreeing not to access privileged deal counsel files).

Gilead brought a motion to clarify what role SRS's litigation counsel could play with regard to Calistoga witnesses that held privileged information. SRS conceded in response that if the reformation claims were not part of the case, privileged communications involving deal counsel were irrelevant. B183 (26:5–12) ("the only reason that privileged communications might even be relevant in this case is because Gilead . . . has asserted a claim for reformation . . . . Now, if they're going to withdraw that claim, I think that all goes away."); B188 (31:14–16) ("if the reformation claim is out, this is just a nonissue. This doesn't even exist.").

The trial court ruled that if Gilead withdrew its reformation counterclaims, SRS litigation counsel should refrain from having any more *ex parte* communications with deal counsel. A487–88 (13:10–13:22, 14:7–10). The trial court did not preclude SRS from deposing deal counsel. The trial court also placed no limits on the ability of SRS litigation counsel to represent Calistoga non-

[14] Pursuant to section 2.3 of the Agreement, "all property, rights, ***privileges***, powers" were expressly transferred to the wholly-owned subsidiary of Gilead. 8 *Del. C.* § 259; A82 § 2.3. And although Gilead provided a conflict waiver, that conflict waiver did not permit WSGR to access privileged records.

attorney witnesses. A484–85 (10:24–11:3). Gilead withdrew its reformation counterclaims.

At no point during discovery did SRS seek to depose deal counsel or request that SRS have access to any records withheld by Gilead as privileged.

On September 2, 2016, six business days before trial, SRS argued that if Gilead relied on two lists of WHO tumor types prepared by Calistoga's scientists Drs. Miller and Yu, SRS should be entitled to access deal counsel's privileged files. B493. In effect, SRS argued to the trial court that any consideration of internal Calistoga decision-making entitled it to all deal-counsel privileged information. This is the exact same argument on appeal. SRS's new argument was remarkable given that: the two lists were produced on September 17, 2015, B501; the authors of the documents were deposed extensively regarding them between January 8 and February 16, 2016, B782–83 (29:6–33:7 (Yu)); B799–800 (29:11–35:16 (Miller)), the documents and associated testimony were discussed in Gilead's February 29, 2016 opposition to SRS's motion for judgment on the pleadings, B269–72; the documents were discussed in Gilead's expert reports served on March 31, 2016 and May 10, 2016; and SRS itself listed the documents on its exhibit list on August 10, 2016, B502.

The trial court properly held that SRS waived its argument, for two reasons. First, SRS's motion was a motion *in limine* that violated the deadline set by the

scheduling order. A969 (48:5–13). Second, SRS waived the argument that the Yu/Miller Lists were privileged in light of their extensive use in the case over the past year. A969–71 (48:14–50:15). The trial court did not abuse its discretion. *Alaska Elec. Pension Fund v. Brown*, 988 A.2d 412, 419 (Del. 2010) ("application of the at-issue exception is a fact-specific inquiry" reviewed for "abuse of discretion"). Moreover, although the trial court did not need to reach the issue, the Yu/Miller Lists were clearly not privileged. They were scientific documents prepared by non-lawyers that neither ask nor answer a legal question. B510–15; *see In re Ciroc Corp*., 1998 WL 409166 at *5 (Del. Ch. 1998).

SRS's argument on appeal is an indirect way of challenging the trial court's decision not to release to SRS all of deal counsel's records on the eve of trial. This was the exact argument the trial court found waived. Moreover, to the extent SRS is suggesting that the trial court improperly considered the "subjective" intent of the parties, this is incorrect. The trial court determined what a reasonable person would understand from the contract language. Both Calistoga and Gilead witnesses testified that at the time of negotiation they understood Section 1.1, Part 1, to be a system for defining diseases within tumor types. *See* Section I.C.3 above. Finally, even without the Yu/Miller lists there was more than sufficient evidence to support the trial court's rulings. *See Canadian Indus. Alcohol Co. v.*

Nelson, 188 A. 39, 55–56 (Del. 1936) (harmless error where fact was independently established).

CONCLUSION

For the foregoing reasons, the trial court's decision should be affirmed.

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CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2017, the foregoing document was served electronically via *File & ServeXpress* on the following counsel of record:

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