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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.	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.	**PUBLIC VERSION FILED ON JUNE 19, 2017**

APPELLANT'S OPENING BRIEF

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NATURE OF PROCEEDINGS

This case arises from the February 2011 acquisition of Calistoga Pharmaceuticals ("Calistoga") by Gilead Sciences, Inc. ("Gilead"). Shareholder Representative Services ("SRS"), representing the former securityholders of Calistoga, appeals the decision of the Court of Chancery concluding that a September 2014 regulatory approval of Calistoga's principal hematologic (or blood) cancer drug, CAL-101, did not trigger a $50 million milestone payment (the "Third Milestone") under the parties' Merger Agreement. A64-154. SRS' entitlement to the milestone rises and falls on the language of the parties' agreement. The agreement provides that the Third Milestone is triggered if Gilead receives "Regulatory Approval of CAL-101…as a first-line drug treatment [i.e., for patients who were not previously treated]…for a Hematologic Cancer Indication." A131. That is precisely what Gilead received: first-line approval of CAL-101 to treat patients with chronic lymphocytic leukemia ("CLL") who have a common genetic mutation (17p deletion or TP53 mutation) that makes them less responsive to other drugs.

The trial court concluded, however, that the term "indication," as used in the milestone and the merger agreement, was ambiguous. The parties advanced different interpretations: SRS asserted that "indication" meant the approved use of a drug, whereas Gilead asserted that "indication" meant merely a disease. But

resort to extrinsic evidence is proper only where two or more *reasonable* interpretations are advanced. SRS' definition recognized that each milestone, including the one at issue, was triggered by receipt of regulatory approval for an "indication." When regulators approve drugs, they approve "indications" for the use of a drug, and there is no dispute that such "indications," including the one Gilead received here, identify not merely a disease, but the target patient population for the drug. In contrast, treating the word "indication" as synonymous with "disease," ignores the context in which it is used, and leaves the word "indication" with no meaning distinct from "cancer" in the phrase "hematologic cancer indication" used in multiple places in the agreement. The court even acknowledged this "surplusage" argument has "some appeal to a law-trained judge accustomed to applying interpretive principles to construe a contract" but dismissed it because "the reality of life is that human language is not perfect."

But the court did not stop after interpreting "indication" to mean "disease." If it had, it would still have been compelled to rule in SRS' favor. The milestone would then have been triggered by "Regulatory Approval of CAL-101…as a first-line drug treatment…for a Hematologic Cancer ~~Indication~~ [Disease]." That is what Gilead received: an approval of CAL-101 as a first-line drug treatment for CLL, a hematologic cancer. The disease in question did not cease to be CLL because the approval was for a subpopulation of CLL sufferers.

Indeed, the trial court implicitly acknowledged this by inserting a further requirement into the agreement; namely, that only "disease-level" approvals would trigger milestones—i.e., that the regulators must approve the drug for use in all patients with a disease. But the court had no basis to interpret the word "indication" to mean "disease-level" and no witness even suggested that as a meaning. Nor did the court explain what *other* word or phrase in the agreement was ambiguous or that it read as requiring "disease-level" approvals. In effect, the court reformed the contract to insert a "disease-level" qualifier even though Gilead had affirmatively withdrawn its reformation claim to avoid waiving privilege.

Moreover, the court purported to base this conclusion upon the limited extrinsic evidence from the parties' negotiations, even though there is no evidence that the parties ever discussed, much less agreed, to limit the milestones to "disease-level" approvals and Gilead's own witnesses acknowledged that regulatory approvals for *some* subpopulations *would* trigger the milestones. The court buttressed its conclusion by asserting that it would be "contrary to reasonable business expectations" if a small approval (which Gilead never proved this was) could trigger a $50 million milestone payment.

Parties are free to make bad contracts. The trial court apparently felt that the first-line indication Gilead received for CAL-101 was not worth awarding $50 million to SRS. Yet the perceived unfairness of this result was not a basis for

rewriting an agreement drafted by highly sophisticated parties. This is a contract case and the language of the contract unambiguously provides that SRS is entitled to judgment in its favor.

SUMMARY OF ARGUMENT

1) The Court of Chancery erred when it ignored fundamental principles of contract law in refusing to enforce the unambiguous terms of the Third Milestone provision. First, the court found ambiguity where none existed by choosing to ignore the plain meaning of the operative term "indication" in the context in which it was used in the Merger Agreement, i.e., in the context of regulatory approval. The court erroneously credited Gilead's proffered interpretation that "indication," meant "disease," even though (1) the word "indication" has a meaning separate from "disease," (2) it rendered the term "indication" surplusage in the phrase "Hematologic Cancer Indications," and (3) it created discrepancies elsewhere in the Agreement. Then, the court compounded the error by improperly imputing a "disease-level" limitation onto its (erroneous) interpretation of "indication" as meaning "disease" without any basis in the agreement for doing so.

2) The trial court's findings based on the extrinsic evidence were clearly erroneous because there was no basis whatsoever to impute a "disease-level" limitation into the Third Milestone provision. There was no evidence that the parties ever discussed the meaning of "indication," much less that they contemplated limiting the milestone to regulatory approval for the entire population of patients with the particular disease. Indeed, the extrinsic

evidence cited in support of this limitation is inconclusive at best and is rendered hollow by the court's omission of critical evidence that proves SRS' reading is correct.

3) The trial court erred by permitting Gilead to assert attorney-client privilege over legal advice of *Calistoga's* deal counsel (despite having also waived privilege by putting those communications "at issue") thereby preventing SRS from developing a record with respect to key language in the agreement.

STATEMENT OF FACTS

A. Background

Calistoga was a small, privately-held biotechnology company. Calistoga's clinical development efforts were focused on CAL-101, a first-in-class drug that showed promise. A159. CAL-101 was subsequently given the generic name idelalisib, and is sold by Gilead under the trade name Zydelig. A497 (5:17-19).

In 2010, Calistoga began considering strategic alternatives, including a sale of the company. A530-31 (140:24-141:20). Dr. Carol Gallagher, Pharm.D., Calistoga's CEO, oversaw that process. A534 (155:4-12); A506 (43:9-44:6). She was assisted by Cliff Stocks, Calistoga's Chief Business Officer, Dr. Langdon Miller, EVP of Research and Development, and outside counsel at Wilson Sonsini Goodrich and Rosati ("WSGR"). *Id.*

Gilead expressed interest in acquiring Calistoga in late December 2010. A531-32 (144:7-145:6). Gilead's team was led by Dr. Muzammil Mansuri, Gilead's then-EVP of Strategy, Business Development and Licensing, and his subordinate, Sean O'Connell, Gilead's Senior Director of Corporate Development. A718 (884:6-15). Mansuri and O'Connell reported to then-COO (and current CEO) John Milligan and Chief Scientific Officer Norbert Bischofberger. A385 (12:4-12); A388 (102:15-104:20).

In early January 2011, Calistoga provided an initial commercial presentation to Gilead. *See* A158. The presentation emphasized that trials of CAL-101 had produced promising data suggesting CAL-101's potential to treat subpopulations of disease sufferers with CLL and the group of cancers known as indolent non-Hodgkin's leukemia ("iNHL") with unmet medical need. *See, e.g.*, A498-99 (11:4-24,15:20-16:1); A501-03 (24:13-29); A160-61. Accelerated approvals to treat populations with unmet medical need allow drugmakers to reach the market quickly and later expand the scope of the regulatory approval. A536 (162:14-19).

In particular, Calistoga's presentation stated a labeling objective to pursue a "rapid approval" indication for a subpopulation of refractory iNHL patients that were no longer responding to rituximab, an immunotherapeutic drug, and alkylating agents, which are a particular class of chemotherapy drugs. A164; A502-03 (27:22-29:5). In CLL, Calistoga highlighted that it had initiated a study of CAL-101 in combination with rituximab to treat CLL in elderly patients (A162), and was considering pursuing an indication to treat relapsed patients with CLL in combination with some other undetermined therapy. A164. Calistoga's presentation also noted CAL-101's efficacy in a subpopulation of CLL patients whose tumor cells expressed the 17p/*TP53* defects, the precise population at issue here. A503-04 (30:7-33:16); A527 (127:10-22); A560 (257:6-9); A391 (68:17-69:3).

The 17p deletion occurs when a sufficient number of the CLL patient's malignant cells express deletions of the short arm of the seventeenth chromosome, where the *TP53* gene is located. A598 (411:5-13). The *TP53* mutation occurs when the *TP53* gene itself is mutated and, therefore, does not function properly. *Id.* (410:24-411:4). CLL patients with 17p deleted or *TP53* mutated tumors—who constitute 10% or more of first-line CLL patients and 50% or more of previously treated patients—were long known to be resistant to chemotherapy and have the worst prognosis of CLL patients. A602-03 (428:20-429:16). In fact, in 2008, Gilead's expert, Dr. Dearden, wrote that novel CLL treatments were being targeted to "subtypes" of CLL patients, including "patients with 17p" deletions, and predicted that "[t]he *indication* for which [another cancer drug] may become accepted as standard front-line therapy for CLL is in the high risk cytogenetic group exhibiting *TP53* deletion." A366-67 (emphasis added).

By 2010, initial trial data for CAL-101 suggested it circumvented the treatment-resistant characteristics of the 17p/*TP53* defects—a result that was "virtually a miracle at the time." A503 (31:23-32:2). Accordingly, Calistoga devoted a slide in its commercial presentation to a chart summarizing data evincing CAL-101 efficacy in patients with CLL, including the subpopulation with 17p deletions (A163) and another slide that highlighted the interest in studying of

CAL-101 for "front-line use" in "patients with del (17p) mutations." A165; *see also* A504 (34:6-36:3).

B. Negotiation of the Merger Agreement

On January 28, 2011, two potential acquirers [redacted] and Gilead—submitted initial, non-binding expressions of interest, both of which contemplated upfront payments and milestone payments based on obtaining regulatory approvals. Based on the initial offers, Calistoga instructed WSGR to prepare a draft agreement to provide to each party. A166; A535 (160:9-22).

Calistoga's initial draft, sent on February 1, 2011, proposed two milestone payments to be triggered by the first and second "Regulatory Approvals" received for CAL-101 for "hematologic cancer indications"—a phrase that was not defined. A167-68; A535-36 (160:23-161:8). At trial, Gallagher testified that each of the words in this phrase had a meaning:

> So, first, "hematologic" typically would refer to something to do with blood cells or lymph cells. "Cancer," we know, is a malignancy. And "indication" is the label that you would receive from a regulatory body about the specific patient population that you would treat with the hematologic cancer.

A536 (161:16-22). Gilead's lead negotiator, Mansuri, agreed, testifying that the "commonly understood meaning of the term 'indication', when used in the context of regulatory approval" is the "label approval." A387 (50:1-24).

On February 8, 2011, Gilead responded with a revised draft that inserted a new term, "Specified Hematologic Cancer Indications," defined as "any hematologic cancer indication specifically identified on Schedule 1.1." A173. Schedule 1.1 listed nine of the most incident hematologic cancers. *See* A174. O'Connell testified that the purpose of this revision was to limit the regulatory approvals that would trigger the milestones from all hematologic cancers to "significant commercial events, meaning approvals of the major hematologic diseases." A725 (913:11-15). However, O'Connell did not recall either discussing Gilead's proposal with anyone at Calistoga, or saying that Gilead was not going to pay a "big milestone for a small indication." A725-26 (913:19-918:1).

On February 12, Calistoga responded to Gilead's February 8 draft agreement with a revised draft that, *inter alia*, rejected Gilead's proposed Schedule 1.1 entirely. Calistoga's counsel at WSGR expanded the definition of "Specified Hematologic Cancer Indication" by including the lead-in language "[a]ny indication within the following tumor types" followed by a list of eleven broad tumor types. *See* A179; A525 (117:14-16); A538 (172:10-15). As Gallagher explained, the intent was to ensure that Calistoga would be compensated for any regulatory indication that Gilead achieved within the broad set of listed tumors. *See* A539 (173:6-24).

On February 16, Gilead provided a revised draft agreement containing new defined terms, "Hematologic Cancer Indications" and "Specified Hematologic Cancer Indications." A189-91. Part 1 of the proposed Schedule 1.1, titled "Hematologic Cancer Indications," was the list of tumors that Calistoga proposed in its February 12 draft, which Gilead accepted without change, including the lead-in language of "[a]ny indication within the following tumor types." A193; *see* A713 (864:1-6). Part 2 of the revised Schedule 1.1 was Gilead's list of "Specified Hematologic Cancer Indications" from its prior draft. A193-94; A540 (177:22-178:10).

Gilead's draft agreement also contained a new milestone triggered by the "first dosing of the first patient in a Phase II Trial…as treatment for any indication." A192. Gilead defined "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 patients with the *disease* or condition under study." A190 (emphasis added). Thus, Gilead's definition of "Phase II Trial" makes clear that Gilead understood "indication" to have a separate meaning from "disease" at the time.

On February 18, Calistoga circulated a new draft of the agreement containing the final substantive changes to the structure of the milestone provisions. Of note, Calistoga added a bullet to the end of Part 1 of Schedule 1.1 to

specifically incorporate indications within any of the diseases listed in Part 2 into Part 1, i.e., "[a]ny indication within…[a]ny Specified Hematologic Cancer Indication listed in Part 2 of this Schedule 1.1." A200. Calistoga also insisted that accelerated approvals would trigger milestones. *See* A198-99; A540 (177:12-15); A728 (924:2-925:7). O'Connell acknowledged that accelerated approvals could be given for subpopulations of patients suffering from a disease. A724 (908:16-21).

After Calistoga's February 18 draft, the parties continued to negotiate Gilead's obligation to use commercially reasonable efforts to achieve the milestones. Ultimately, while Calistoga's February 18 draft prohibited Gilead from taking actions to avoid any milestone payment, the final Merger Agreement gave Gilead complete discretion to pursue (or avoid) the achievement of the Third Milestone. A133-34; A542 (185:11-186:9); A731 (938:3-939:9).

At trial, no witness testified to any communication between the parties regarding the meaning of the word "indication" during the course of negotiations, nor was there any discussion that only "disease-level" approvals would trigger the milestones (indeed, neither Gilead nor its witnesses ever used that phrase until post-trial briefing).

C. FDA Approval of CAL-101 Triggers the First Two Milestones

On July 23, 2014, Gilead announced FDA approved of CAL-101 for three specific "indications" to treat populations of disease sufferers. The "Indications

and Usage" section of the label identified the uses for which CAL-101 was approved:

- Relapsed [CLL], in combination with rituximab, in patients for whom rituximab alone would not be considered appropriate therapy due to other co-morbidities.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

See A212. Gilead's subsequent press release used "indication" five times, yet never to mean "disease." A220. The FDA approval satisfied the First and Second Milestones and Gilead paid out $175 million. A269.

D. EMA Approval of CAL-101

On September 23, 2014, Gilead announced that the EMA had approved CAL-101 for first-line treatment of CLL. A237 ("In the EU, [CAL-101] is *indicated* in combination with rituximab for the treatment of adult patients with 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." (emphasis added)). The Summary of Product Characteristics (the EMA equivalent of a label) for CAL-101 similarly stated that the "Therapeutic *indications*" for CAL-101 were "for the treatment of adult patients with chronic lymphocytic leukaemia (CLL)…as first line treatment in the presence of 17p

deletion or *TP53* mutation in patients unsuitable for chemo-immunotherapy." A350 (emphasis added). Internally, Gilead expressed elation at this approval. Indeed, Roger Dansey, Gilead's Vice President of Clinical Oncology Research, observed internally that [redacted] A213.[1] Gilead also issued marketing materials touting the first-line approval. *See, e.g.*, A345-46; A347 (CAL-101 [redacted]) (emphasis added). Other major pharmaceutical companies pursued approvals in the 17p/*TP53* subpopulation of CLL patients. *See* A596 (402:14-20); A602 (427:24); A224 (Imbruvica, developed by Pharmacyclics and Janssen, approved for "CLL with 17p deletion"); A342-43 (Venetoclax, developed by Abbvie and Genentech, approved for an indication in relapsed CLL patients with 17p-deletions).

E. Procedural History

On January 14, 2015, SRS filed its Verified Complaint on behalf of the former securityholders of Calistoga asserting breach of contract. A252-54. On

[1] Other internal Gilead documents noted the first-line indication [redacted] A235; *see also* A232 ("The first line *indication* in the hardest-to-treat patients will have a positive halo effect on the attractiveness of [CAL-101]."); A230 ("The fact that [CAL-101] is 'EVEN' *indicated* for frontline (difficult patients) suggests that it should be an excellent option for second/third [lines of treatment]" (emphasis added)).

February 27, 2015, Gilead filed an Answer and Verified Counterclaims ("Answer"), including a counterclaim for reformation of the merger agreement based on unilateral and mutual mistake premised on its allegation that the parties "understood and intended" that the Third Milestone would be triggered "only if Gilead completed a pivotal trial for CAL-101 as a first-line treatment, if the trial was successful, and, if thereafter, Gilead asked for and received regulatory approval for the use of CAL-101 as a first-line treatment for a Hematologic Cancer Indication." *See* A279.

On October 14, 2015, Gilead filed an Amended Answer and Amended Verified Counterclaims (the "Amended Answer"). *See* A297. The Amended Answer added an affirmative defense based on commercial frustration and reasserted its counterclaims. A320; A333-36. Neither Gilead's Answer nor Amended Answer claimed that "indication" as used in the agreement meant "disease," much less that only "disease-level approvals" would trigger the milestones. Gilead's written discovery responses, verified by O'Connell, similarly lacked any reference to these concepts. A340; A341.[2]

[2] While Gilead's position regarding the meaning of "indication" shifted drastically during the litigation, SRS always took the position that "the term 'indication' has its usual and customary meaning, defined generally as the basis for initiation of treatment for a disease and, in the context of the Merger Agreement, as any Regulatory Authority's approved use of a drug." A296.

Meanwhile, on September 25, 2015, Gilead filed a "Motion to Protect Privileged and Confidential Information" (the "Privilege Motion") that argued that control over Calistoga's privileged communications passed to Gilead under *Great Hill Equity Partners IV, LP v. SIG Growth Equity Fund I, LLLP*, 80 A.3d 155 (Del. Ch. 2013). In response, SRS argued, *inter alia*, that any possible privilege had been waived because, *inter alia*, Gilead put the communications "at issue" by pleading reformation. Ultimately, the court held that Gilead could avoid waiver of privilege if it chose to withdraw its reformation counterclaims. *See* A481-82 (7:10-8:19). The court explained that if the reformation claim were dropped, "much of the dispute over this information [the former employees' understanding of the Merger Agreement] would be moot, as the case would focus solely on the objective meaning of the contract." A482 (8:24-9:3). Gilead dropped its reformation claims and pivoted to an argument based on the "plain language" of the Merger Agreement. A492.

Once Gilead conceded that the milestone provision was unambiguous, SRS moved for judgment on the pleadings. On May 25, 2016, the court deferred resolution of the motion for judgment on the pleadings until trial because of the "scientific and technical nature" of the subject matter. A494.

Trial took place over four days in September 2016. On March 15, 2017, the court issued its Memorandum Opinion denying SRS' motion for judgment on the

pleadings and entering judgment in favor of Gilead on its counterclaim for declaratory judgment and SRS' claim for breach of contract.

ARGUMENT

I. THE TRIAL COURT ERRED BY FAILING TO ENFORCE THE UNAMBIGUOUS TERMS OF THE THIRD MILESTONE

A. Question Presented

Whether the Court of Chancery erred by determining that the term "indication" as used in the Merger Agreement was ambiguous even though Gilead's proffered interpretation would, among other things, read out the term "indication" in the phrase "hematologic cancer indication." Moreover, once the court determined that "indication" meant "disease," whether it erred again by failing to enforce the plain meaning and instead improperly resorting to extrinsic evidence to read in a "disease-level" limitation. A793-810.

B. Standard of Review

Matters of contract interpretation, including whether a contractual provision is ambiguous, are questions of law that this Court reviews *de novo*. *BLGH Holdings LLC v. enXco LFG Holding, LLC*, 41 A.3d 410, 414 (Del. 2012).

C. Merits of the Argument

1. The Trial Court Erred By Determining the Word "Indication" in the Term "Hematologic Cancer Indication" Was Ambiguous

Delaware law requires that courts enforce contracts according to the plain meaning of the terms the parties agreed to. *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1195 (Del. 1992). An exception to this

rule exists for contracts that are truly ambiguous—that is, contracts where "the provisions in controversy are fairly susceptible of different interpretations or may have two or more different meanings." *GMG Capital Invs., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 780 (Del. 2012) (citation omitted).

At trial, Gilead proffered a competing interpretation of the term "indication" as used in the Merger Agreement, i.e., that "indication" meant "disease" rather than, as SRS contended, the approved use of a drug. While there is no doubt that "indication" is sometimes used to signify a "disease," in the context of the Merger Agreement where the word appears, receipt of regulatory approval for "indications" is what triggers milestones. In that context, the only *reasonable* interpretation of "indication" is exactly as it is always used when regulators approve "indications," i.e., to refer to the approved use of a drug to treat a population of patients with a particular disease. Although the court examined extrinsic evidence to conclude otherwise, not a single Gilead fact witness testified that, in the context of regulatory approval, an "indication" means a "disease." SRS' interpretation also harmonizes the language of the agreement and gives effect to all of its terms. Conversely, Gilead's interpretation not only requires the Court to assume the parties departed from the normal meaning of "indication" in the regulatory context (and indeed from the manner Gilead used the term both publicly and privately, *see*

supra 14-15), but would also require the Court to read the word "indication" out of the defined term "Hematologic Cancer Indication."

a) *SRS' reading of the word "indication" is the only reasonable interpretation*

The milestones in the Merger Agreement are triggered by "Regulatory Approval," defined as "all approvals, licenses, registrations or authorizations by any Regulatory Authority [i.e., the FDA or EMA] necessary to market a Company Product in such country or jurisdiction." A78. The first and second milestones are triggered by receipt of "Regulatory Approval" of CAL-101 "for a Hematologic Cancer Indication." The Third Milestone, the milestone in dispute, is triggered by "the receipt of Regulatory Approval of CAL-101…as a first-line drug treatment…for a Hematologic Cancer Indication." A131. It is not disputed that Gilead received Regulatory Approval for CAL-101 as a first-line drug treatment. Op. 1, 45, 70. Thus, the central question in this case is what the parties meant by "for a Hematologic Cancer Indication."

A "hematologic cancer" is a blood cancer. In the context of drug approvals—the context in which the term is used in the agreement—"indication" refers to the approved use of a drug. This interpretation is confirmed by the undisputed fact contained in the parties' pleadings that Gilead's September 19 press release announcing the approval at issue here stated that CAL-101 was

"indicated" as a first-line treatment of CLL for patients with the 17p deletion or TP53 mutation. A237. In other words, the "indication" describes the patient population that is approved to use the drug, here, patients who have CLL with the 17p deletion or TP53 mutation.

Section 1.1 of the Disclosure Schedule defines the Hematologic Cancer Indications that can trigger the milestones. Part 1 of Section 1.1 defines Hematologic Cancer Indications as "[a]ny indication within the following tumor types," followed by a bulleted list of categories of hematologic cancers and a final bullet incorporating "[a]ny Specified Hematologic Cancer Indication listed in Part 2." A156. Part 2 lists several hematologic cancers. A156-57.

In other words, a Hematologic Cancer Indication is *any* indication *within* one of the enumerated tumor types or one of the specific diseases listed in Part 2. The approval of CAL-101 to treat CLL patients with 17p /*TP53* was an indication within both the broader category of "B-cell neoplasms" listed on Part 1 of Schedule 1.1 and within "Chronic Lymphocytic Leukemia/Lymphoma," which is listed on Part 2, because it was an *indication*—i.e., an approved use of CAL-101 to treat particular patients with a disease—that is *within* the broad category of a tumor types listed in Part 1 and a disease specifically identified in Part 2.

b) *Indication as used in the Agreement has its normal technical meaning and cannot mean "disease"*

"When interpreting contractual terms, Delaware law is to the effect that technical words or terms used are to be interpreted as usually understood by persons in the trade, unless it is clear they are used in a different sense." *Andersen v. State, Dep't of Admin. Servs.*, 1992 WL 183080, at *3 (Del. July 7, 1992). Although the Agreement contains the defined terms "Hematologic Cancer Indication" and "Specified Hematologic Cancer Indication," each of those defined terms—and the phrase "any indication within the following tumor types" contained in Schedule 1.1—use the lower-case term "indication," which is not otherwise defined in the agreement. A156.

The plain meaning of the term "indication" is distinct from the concept of a "disease," which may be the subject of an "indication" but is not the indication itself. The Merriam-Webster Medical Dictionary defines "indication" as "a symptom or particular circumstance that indicates the advisability or necessity of a specific medical treatment or procedure." *Indication*, MERRIAM-WEBSTER'S MEDICAL DICTIONARY (2006). This definition of "indication" is thus a logical derivation of the standard, non-technical definition of "to indicate," meaning "to point out or point to" something or "to demonstrate or suggest the necessity or advisability of" something. *Indicate*, MERRIAM-WEBSTER'S COLLEGIATE

DICTIONARY (10th ed. 2001). Thus, the term "indication" necessarily incorporates the concept of pointing to or demonstrating the advisability of *something*. In medicine, the presence of particular symptoms or factors "indicate" the propriety of a particular treatment *for a disease*. "Indication," as it is used in the Merger Agreement and in medicine generally, refers to this process—factors indicate a treatment for individuals with a disease. Although the disease being treated is a necessary component of an "indication," the concept of "indication" is distinct from the disease itself.

Critically, other medical dictionary definitions reinforce this meaning and confirm that "indication" does not mean solely a "disease," but rather captures the concept of an approved use of a drug to treat a disease for a defined patient population. *E.g.*, *Indication*, TABER'S CYCLOPEDIC MEDICAL DICTIONARY (23rd ed. 2017) ("An approved use for any therapeutic intervention or drug, e.g., in the U.S., a use that has met the standards set by the [FDA]. SYN: *SEE*: *labeled use.*"); *Indication*, OXFORD CONCISE MEDICAL DICTIONARY (9th ed. 2015) ("[A]ny of the conditions for which a particular drug treatment may be prescribed, as defined by its license." "License" is: "a document that allows a pharmaceutical company to market a particular drug…A drug is licensed only for defined uses (indications), which the health-care professional prescribing it should adhere to."). These definitions demonstrate that an "indication" is not synonymous with a disease itself.

With this definition in mind, the only reasonable meaning of the operative provision is clear. The Third Milestone payment is triggered by first-line approval of CAL-101 for any "indication," that is, for any approval of CAL-101 as a treatment for the diseases listed in Section 1.1 in whatever form that approval might take, i.e., for a defined population of patients with that disease. The court's contention that there was "no obvious textual anchor…from which to import into the word 'indication' the concept of a regulatory label" does not follow. Op. 50. That *is* what "indication" means in the context of regulatory approval (and not a single witness suggested otherwise). Because each of the milestones in the Merger Agreement is triggered by a "Regulatory Approval" for an "indication" it is clear that the types of "indications" that the agreement is referring to are those that occur in the context of regulatory approval and not some other context. Therefore, when a triggering approval occurred, it was necessarily going to come in the form of a regulatory label defining the approved use of the drug by a particular patient population. No "anchor" is required.

c) *The trial court ignored well-established principles of contract construction to find ambiguity*

Critically, the court's finding of ambiguity was erroneous because it ignored two important principles of contract construction. First, the court ignored the canon of construction against surplusage, which mandates agreements be read so

as to give meaning and effect to all terms. *Bank of N.Y. Mellon v. Commerzbank Capital Funding Trust II*, 65 A.3d 539, 548-51 (Del. 2013); *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010). This Court has made clear that it "will read a contract as a whole and…give each provision and term effect, so as not to render any part of the contract mere surplusage." *Kuhn Constr., Inc. v. Diamond State Port Corp.*, 990 A.2d 393, 396-97 (Del. 2010). Second, the court ignored the principle that a contract is not rendered ambiguous merely because the parties proffer competing interpretations. *E.g.*, *Rhone-Poulenc*, 616 A.2d at 1196 ("Courts will not torture contractual terms to impart ambiguity.").

Despite acknowledging these principles, the court cited *Cyber Holding LLC v. CyberCore Holding, Inc.*, 2016 WL 791069 (Del. Ch. Feb. 26, 2016), for the proposition that "ascertaining the shared intent of the parties does not mandate slavish adherence to every principle of contract interpretation." Op. 44. It then cited a passage from *Cyber Holding* which discussed the principle that courts sometimes must discern the meaning of contractual provisions without reconciling every conflicting provision. But *Cyber Holding* dealt with conflicting provisions that the court did not need to reconcile to determine the parties' intent with respect to the disputed provision. Thus, the uncontroversial admonition against "slavish adherence" to contract principles does not mean the court can (i) read out one *word*

in a three-word defined term by rendering it surplusage, or (ii) adopt an interpretation that would inject inconsistencies into the language at issue.

But Gilead's proffered interpretation, which the trial court ultimately adopted, does both. First, it renders the critical word "indication" surplusage in the term "hematologic cancer indication" used in multiple places. A "hematologic cancer" is a "blood cancer." "Cancer" is a collective term for a broad category of diseases, and in standard English usage is not accompanied by the word "disease." Accordingly, if "indication" meant "disease," then "hematologic cancer indication" would mean "hematologic cancer disease," which is redundant.

Indeed, the court acknowledged this tension and the logic of SRS' surplusage argument, observing that it has "some appeal to a law-trained judge accustomed to applying interpretive principles to construe a contract." Op. 49. The court's only retort was to make the platitudinous observation that "the reality of life is that human language is not perfect"[3] and to observe that (i) a prepared Gilead witness was able to use the phrase "hematologic cancer diseases" in an "unforced manner" at trial, and (ii) Gilead was able to point to a handful of

[3] For this proposition, the court cited *Atlantic Northern Airlines, Inc. v. Schwimmer*, 96 A.2d 652 (N.J. 1953), a case about tortious conversion of an airplane in 1948 by an instrumentality of the nascent State of Israel. It does not sanction ignoring established principles of contract construction.

medical journals containing the phrase "cancer diseases."[4] That is simply not enough to overcome the plain meaning of the word "indication" as distinct from the word "disease" described above or the more natural reading of the phrase "hematologic cancer" without the redundant use of the word "disease."

Second, the trial court acknowledged that reading "indication" to mean "disease" resulted in a further "discrepancy" in Section 1.1. Replacing "indication" with "disease" makes no sense in the context of the last bullet point in Part 1 of Section 1.1, which incorporates the specific diseases in Part 2. Gilead is unable to explain how, if "indication" means "disease," there can be a "[disease] within" the disease CLL or any of the other diseases listed in Part 2. *Id.* The court again acknowledged but disregarded this "discrepancy" in Gilead's interpretation. Op. 50.

For the reasons stated above, SRS presented the only reasonable interpretation of the word "indication" that harmonizes the language of the

[4] In post-trial briefing, Gilead scoured medical journals to find nine instances in highly technical sources and non-native English speaking journals—such as the Iranian Journal of Child Neurology—of the phrase "cancer diseases." A820. Apart from the fact that those journals were not defining the term "indication," much less in a regulatory context, the ability to locate a non-standard usage of a term does not alter the fact that in standard usage it continues to be awkward surplusage. *Cf. Am. Legacy Found. v. Lorillard Tobacco Co.*, 886 A.2d 1, 27 (Del. Ch. 2005) (noting that "examples can be found indicating that vilification [the term whose definition was at issue] is commonplace" but recognizing that nevertheless "the overwhelming majority of references to vilification are directed at much more serious topics, such as violations of human dignity" and thus that this more serious definition controlled), *aff'd*, 903 A.2d 728 (Del. 2006).

Agreement. The court erred by not enforcing the unambiguous meaning of the term "indication" to mean the approved use of a drug.

2. After Interpreting "Indication" to Mean "Disease," the Court Again Failed to Enforce the Plain Meaning of the Third Milestone

The trial court compounded its error by imputing a meaning that burdened the term "disease" with more precision than that term reasonably supported. That is, if "indication" meant "disease," that would resolve the ambiguity *in favor of SRS*. The regulatory approval at issue was a "Regulatory Approval…as a first-line drug treatment…for a [disease]," i.e., CLL. A131. The fact that the approval was to use CAL-101 to treat a population of disease sufferers with CLL, rather than *all* sufferers from the disease, did not alter the fact that the approval was, on its face, for CAL-101 as a treatment for CLL.[5] Stated differently, the disease that CAL-101 treats did not cease to be CLL because the approval was for a subpopulation of CLL sufferers. Having thus resolved the ambiguity in a manner that supported judgment *in favor of SRS*, the court improperly resorted to extrinsic evidence to insert a "disease-level" qualifier into the Third Milestone—that regulatory approval "for a [disease]" meant that the approval had to be for all patients with that disease.

[5] As is recognized by European guidelines for treating CLL (*see* A355) and Gilead's expert. A663 (677:11-14).

Critically, the trial court did not explain what word or phrase in the contract it was purporting to interpret when it used extrinsic evidence to examine whether the parties intended that only "disease-level" approvals would trigger the milestone in question. It could not be the word "indication" because the court had already resolved that "indication" meant "disease," not "all sufferers with a disease." Nor could the court properly resort to extrinsic evidence for purposes of reforming the contract. Setting aside the fact that there was no legal basis for reformation, Gilead had expressly withdrawn its reformation claim in order to avoid waiving attorney-client privilege. *Supra* 17.

Thus, the court erred as a matter of law by failing to interpret the entire provision on its face and, instead, reading in the "disease-level" qualifier out of thin air. This Court found similar error in *BLGH*, reversing after finding that the trial court, without any basis in the relevant contractual language, read in a "materiality" qualifier into contract language specifying the type of transaction that would trigger a bonus payment. 41 A.3d at 414-15. The issue was whether a provision that said the consummation of a transaction "outlined" elsewhere would trigger the bonus payment implied that the transaction had to be "'substantially along the lines' of, or 'materially similar to'" th[e] terms set out in that other section of the agreement. *Id.* at 414. This Court held that the meaning ascribed to the disputed contract language "burden[ed] the term ["outlined"] with far more

precision than it [could] reasonably bear when read in context." *Id.* at 415; *see also Nationwide Emerging Managers, LLC v. Northpointe Holdings, LLC*, 112 A.3d 878, 893-94 (Del. 2015) (reversing after the trial court read-in a qualifier to a contractual term with no articulated basis and that rendered another important provision surplusage). Likewise here, the court's insertion of a "disease-level" qualifier had no basis in any contractual language, and burdened the term "disease" in the phrase "for a [disease]" with more precision than it reasonably could support.

The only interpretative "analysis" the trial court performed to support imputing a "disease-level" qualifier was its discussion—*after* relying on extrinsic evidence—of the "[s]tructure and [o]peration of the [m]ilestone [p]rovisions" to support limiting the milestone to all patients with the disease. Op. 67-71. But this merely served to back into the court's previous determination based on extrinsic evidence that the parties had somehow agreed to a "disease-level" limitation even though no such limitation could be found in the words of the contract itself. Specifically, even though Gilead was not obligated in any way to pursue regulatory approvals that would trigger the Third Milestone—and its obligation to use the defined "Commercially Reasonable Efforts" (A70) with respect to the First and Second Milestones provided Gilead leeway to pursue whatever regulatory approvals it wanted—the Court speculated that Gilead might nonetheless get stuck with an approval for a small population and have to pay the milestone "even

if the approval was not commercially valuable." Op. 25-26, 69 n.244. As a result, the Court concluded that that result is "contrary to reasonable business expectations." Op. 68-69.[6]

But that logic suffers for two reasons. First, it assumes that regulatory approvals for subpopulations result in limited commercial value. Indeed, the Court seemingly credited Gilead's conclusory assertion to that effect even though Gilead introduced *zero* evidence to support that fact at trial and despite the significant testimony and contemporaneous evidence SRS introduced that Gilead (and the four other major drug companies pursuing it simultaneously) in fact thought the approval was highly valuable, *supra* 14-15. Instead, although Gilead advanced this argument as a *post-hoc* rationalization for limiting the scope of the milestones, the court appeared to place the burden *on SRS* when it observed that "the record is devoid of any hard evidence that a first-line regulatory approval for a small population of disease sufferers would yield [significant commercial success]" and

[6] The court buttressed this conclusion by mistakenly relying on Section 9.1(b)(iii)(E) in the Agreement providing that the achievement of the milestones are "material factors" in Gilead's valuation of Calistoga and that [redacted] A135. But that language was never intended to graft a "materiality" qualifier onto the milestones. By its terms it simply prevents stockholders from claiming damages for the full value of the milestones before they were achieved. *See* Frederic L. Smith Jr. et al., *M&A Jurisprudence Subcommittee: Binding Non-Signatory Stockholders Under Merger Agreements*, 2016 M&A JURIS. SUBCOMM. OF THE M&A COMM. OF THE BUS. LAW SEC. OF THE A.B.A. 1, 35 (recognizing the need to draft agreements to prevent such claims).

thereby disregarded Gallagher's testimony that seeking approvals for key subpopulations with a disease was a common regulatory strategy to obtain further indications and that drug companies expect a "halo effect" associated with receiving such approvals. Op. 70; A377a-b (188:12-189:8).[7]

Second, and more to the point, "[t]he Court's role is not 'to rewrite the contract between sophisticated market participants, allocating the risk of an agreement after the fact, to suit the court's sense of equity or fairness.'" *Great-W. Inv'rs LP v. Thomas H. Lee Partners, L.P.*, 2011 WL 284992, at *8 (Del. Ch. Jan. 14, 2011) (citation omitted); *see also Fritz v. Nationwide Mut. Ins. Co.*, 1990 WL 186448, at *5 (Del. Ch. Nov. 26, 1990) ("[P]arties are free to make bad bargains."). Gilead, an exceedingly sophisticated party, could have negotiated for express language to exclude subpopulations. Indeed, it would have been a simple matter for Gilead to have required that the milestone be triggered by "the receipt of Regulatory Approval of CAL-101…as a first-line drug treatment…for ~~a~~ [*all patients with a*] Hematologic Cancer ~~Indication.~~" It did not. Instead, it

[7] The court also did not consider the opposite (and more absurd) result that *any* limitation on the scope of an approval to less than the entire population of disease sufferers, no matter how trivial the limitation, or how valuable the approval, would prevent SRS from receiving a milestone payment under the court's interpretation.

successfully negotiated away any obligation to pursue an unattractive first-line indication. The Court should enforce the plain meaning of the Third Milestone.[8]

[8] The court also erroneously cited a March 2016 EMA safety report as somehow confirming that CAL-101 was not approved "for the disease." Op. 75-76. First, under the Merger Agreement, payment of the milestone was due in October 2014. It is not clear how a report that was issued 18 months after the milestone was due is relevant to whether at the time Gilead received regulatory approval it was to treat the disease CLL. Second, the report says nothing to that effect. That report merely reflects in a footnote the undisputed fact that CAL-101 has not been approved for *all* patients with CLL.

II. THE TRIAL COURT IMPROPERLY WEIGHED THE AVAILABLE EXTRINSIC EVIDENCE.

A. Question Presented

Whether the court, having resorted to extrinsic evidence, erred in concluding that the parties agreed that only "disease-level" approvals would trigger a milestone. A798-810.

B. Standard of Review

To the extent the court's contract interpretation is based on extrinsic evidence, this Court "defer[s] to the trial court's findings, unless those 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. All other questions concerning contract interpretation are questions of law and are reviewed *de novo*." *Motorola Inc. v. Amkor Tech., Inc.*, 958 A.2d 852, 859 (Del. 2008).

C. Merits of Argument

To the extent "indication" had more than one reasonable interpretation—and it did not for the reasons discussed above—the trial could properly consider extrinsic evidence regarding its meaning. Notably, not a single Gilead witness testified that the parties ever discussed, much less agreed, that the word "indication" as used in the Merger Agreement meant "disease." Indeed, the *only* evidence of what "indication" meant in the context of regulatory approval—i.e., in the context it was used in the Merger Agreement—was that it meant the approved use

of a drug. This was confirmed by Gilead's own witness, Mansuri, who was ultimately responsible for negotiating the Merger Agreement on Gilead's behalf. *Supra* 10. The court never mentioned, much less grappled with, Mansuri's testimony in its Opinion.

But the trial court did not stop at examining the extrinsic evidence to determine whether the parties decided to adopt an idiosyncratic interpretation of "indication" in the regulatory context as meaning a "disease." This, as noted, would still have triggered the Third Milestone. Instead, the court looked at the extrinsic evidence to come up with its own additional requirement, that only "disease-level" approvals triggered the milestones because, according to the court, the parties were "discussing ***disease-level*** regulatory approvals throughout their negotiations" and thus "effectively excluded subpopulation approvals as a trigger for a regulatory milestone." Op. 62-63. But that assertion is not supported by the limited extrinsic evidence. None of Gilead's own witnesses testified that the parties even discussed, let alone agreed, to limit approvals to every disease sufferer with that particular disease. Instead, all but one could not rule out that *some* subpopulations *would* trigger a milestone. Thus, the court's determination, effectively reforming the agreement to read in that limitation, was not "the product of an orderly or logical deductive reasoning process." *Motorola*, 958 A.2d at 859.

1. The Limited Extrinsic Evidence the Trial Court Cited Is Not Dispositive

As a critical first step, the trial court recognized that (1) the parties never discussed the meaning of the term "indication," and (2) there was "no evidence" the parties ever discussed whether regulatory approvals for less than all disease sufferers would trigger the milestones. Op. 52-59, 62. Yet the court nonetheless concluded that the "drafting history" shows that the parties "always were talking about regulatory approval of CAL-101 ***for a disease*** when they were negotiating over the milestone payments." Op. 56. But it goes without saying that the parties were discussing regulatory approvals for diseases. Regulatory approvals are by definition approvals to treat *a disease*. The fact that the parties exchanged drafts of Schedule 1.1 containing lists of diseases to identify the universe of potential malignancies that could serve as the basis for regulatory approval is neither surprising nor dispositive. Indeed, it is not possible to prospectively list all potential regulatory approved uses of a drug that might be obtained given the variables that could define the patients approved to use the drug. Thus, the court drew meaning from the exchange of drafts of Schedule 1.1 where there was none.

Beyond that, the court relied upon the thinnest of reeds, consisting of (1) a few stray references in two emails; and (2) presentations shared during due diligence, well in advance of the parties' negotiations of the relevant language in

the agreement, none of which was dispositive on the meaning of the term "indication," but, more importantly, did not suggest that "indication" meant "disease-level" as opposed to "disease."

The court relied on a February 16 email from Gilead's O'Connell which characterized the trigger for the second milestone in Gilead's forthcoming draft merger agreement by noting "one of the two *indications* would need to be in the narrower list of Specified Hematological Indication (i.e., CLL, iNHL and the other major hemoc cancers.)." A195. This email is not dispositive of whether "indication" as it was used in the Merger Agreement meant "disease" for several reasons. First of all, O'Connell used the terms "indication" and "hemoc cancers" (i.e., a disease) separately in the same sentence, yet the court found these terms were synonymous. Indeed, the reference to the indications needing to be "in" a list of diseases, such as "in" CLL, is consistent with SRS' interpretation that the approved use needed to be for patients with one of the listed "hemoc cancers."

More importantly, O'Connell went on to describe in that same email (not excerpted in the Opinion) another contemplated milestone that Gilead intended to propose that O'Connell described as "$25M for start of Phase II in any indication"—again using "indication," not the term "hemoc cancer" used elsewhere in the same email—which was a reference to a new defined term in the draft circulated later that evening. That draft defined "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 patients with the *disease* or condition under study." A190 (emphasis added). That definition *only* makes sense if one understands the term "indication" to refer to the approved use of a drug for certain patients with the disease. Contrary to the court's suggestion, one cannot replace the term "indication" with "disease"—i.e., "the effectiveness of a drug for a particular [disease] or [diseases] in patients with *the* disease." *Id.* What is the singular "the disease" referring to if three words prior the word that supposedly means disease is plural? In contrast, there are multiple approved uses of a drug for the same disease based on the patient population being treated.[9]

The court also purported to rely on the fact that Gallagher was shown "presentation after presentation" shared during due diligence that used the term "indication" more generally to reference diseases that were the subject of Calistoga's regulatory efforts. Op. 58 & n.213. Putting aside the fact that this does not suggest that "indication" ever meant "disease-level" to anyone, the court

[9] The February 4 email from Calistoga's Stocks also cited in the Opinion did not use "indication" synonymously with "disease" either. A171. Instead, the court placed emphasis on references to the receipt of "CLL approval" or "iNHL approval" as suggesting Stocks was "focused on approvals for diseases." Op. 57. This a non-sequitor—as noted above, all regulatory approvals are necessarily to treat a disease. Referring to something as a "CLL approval" is simply not dispositive. Regulatory approval for a subpopulation of CLL sufferers is still a "CLL approval" in common vernacular. Indeed, when Gilead hailed the very indication at issue here, it noted that "[redacted]" A213.

acknowledged on the next page that those same presentations *also* used the term indication to refer to "approved use of a drug" and, thus, at a minimum, the evidence was in equipoise. Op. 59; *see also supra* 8-10.

2. The Trial Court's Decision to Insert a "Disease-Level" Qualifier is not Supported by the Extrinsic Evidence

Finally, the trial court appears to have read the *broad* lead-in language "any indication within the following tumor types" in Part 1 of Schedule 1.1 as somehow *limiting* approvals that would trigger the milestone to "disease-level" approvals. In particular, the court cites to Gallagher as confirming that language was intended to "sweep in" subcategories of diseases, Op. 54, and not to "depart from the scientifically recognized definition of diseases," Op. 56. But this testimony is entirely consistent with Gallagher's testimony elsewhere that an "indication" in the regulatory context means the approved use of a drug. A536 (161:16-22). There is, for example, no testimony from Gallagher (or anyone else) that the language "any indication within" was intended *solely* to sweep in subcategories of diseases but *exclude* subpopulations of disease sufferers.[10]

[10] To the contrary, Gilead's Hawkins was asked on direct specifically what "language that Calistoga could have used if they wanted to include subpopulations of diseases in the agreement" and his immediate response in a moment of clarity was that "they could have said 'any indication within the following tumor types'"—the *precise* language used in the agreement. A695 (795:8-15). Yet the court did not cite this testimony in its Opinion either.

The court's observation that Gallagher confirmed she "never told anyone at Gilead that the purpose of [that language] was to sweep in any patient with any genetic mutation that may also have a blood cancer" likewise does not support the court's conclusion that only "disease-level" approvals trigger the milestones. Op. 56-57 (citation omitted). First, it is noteworthy that the court relied on Gilead's characterization of the approval as being one for "any patient with a genetic mutation that may also have a blood cancer." *Id.* The approval in question was for "adult patients with [CLL]…as first line treatment in the presence of 17p deletion or *TP53* mutation." A350. On its face, the approval was to treat a subpopulation of CLL sufferers, not an approval to treat a "genetic mutation" for people who might also have CLL. Gilead's own witnesses admitted as much. A665 (678:10-14).

Second, nothing in Gallagher's testimony suggests that either "indication" or the "any indication within" language meant "disease-level." Therefore, the "failure" of Gallagher to share her view of what the phrase means could, at best, be relevant to a claim for reformation based on unilateral mistake. Setting aside that Gilead withdrew its reformation claim, Gallagher's testimony shows only that the parties never discussed the issue. But the court relied on this testimony as "evidence" that the parties *agreed* to the opposite—that only disease-level approvals qualify. Op. 56-57.

What is perhaps most surprising about the court's decision to read-in a "disease-level" limitation that "effectively excluded subpopulations" is that it was directly contrary to the testimony of Gilead's *own* witnesses. Indeed, none of Gilead's witnesses could agree on how the "disease-level" limitation would work and all but one could not rule out that *some* subpopulations would trigger a milestone. Bischofberger, testified that the first-line approval here did not trigger the milestone because the "spirit" of the agreement did not mandate payment where regulatory approval was received for a "very small population." A379 (51:20-52:8); A382 (78:25-79:5); A383 (123:4-7). But he agreed that subpopulation approvals *could* trigger a milestone. In particular, Bischofberger confirmed that the FDA's indication for CLL satisfied the language of the Merger Agreement even though it was an approval for a narrow subpopulation of CLL patients. A380-81 (56:12-58:2).

At trial, Hawkins initially testified on direct that all subpopulation approvals were excluded (A695 (795:8-22); A699 (811:1-5)) and then when pressed with Bischofberger's testimony reversed course. On cross examination, Hawkins conceded that certain subpopulations based on "personal characteristics"—as opposed to "disease characteristics" such as the genetic mutation at issue here—*would* trigger a milestone. A699-700 (813:12-818:21). Hawkins testified that subpopulations of CLL sufferers defined by co-morbidities or other characteristics

that "don't have anything to do with the disease itself" would qualify. *Id.* Likewise, Gilead's expert, Dearden, when asked at trial how the "disease-level" limitation would work, broke down on the witness stand and could not answer whether a regulatory approval for a population defined by adult sufferers of a disease would trigger the milestone. A677-79 (723:19-732:19).[11]

The only Gilead witness who adopted the interpretation the trial court ultimately arrived at was Gilead's lead negotiator, O'Connell, who, contrary to all other Gilead witnesses, testified that subpopulations defined by "personal characteristics" would not trigger the milestones. A731-32 (939-941). But O'Connell acknowledged that the parties did not specifically discuss a "disease-level" limitation or that approvals for less than every disease sufferer would not qualify. A728-29 (927:24-928:6). Instead, O'Connell was careful to repeat that his subjective "understanding" based on the language of the contract was that only indications for the entire population of people with the disease qualified. A713 (866:9-22); *see also* A707 (840:8-18); A708 (845:2-7). Ultimately, even if this were O'Connell's understanding, he did not claim the parties discussed much less

[11] Dearden was confident that a subpopulation defined by "genetic characteristics" such as the 17P/*TP53* defects was not an "indication." But, notably, that is directly contrary to a 2008 article—not cited in the Opinion—in which she referred to the *exact same* patient population as an "indication."

agreed that the term "indication" meant "disease-level" and thus his purported understanding has no relevance.[12]

[12] Finally, the court relied on the initial reactions of Calistoga's former executives in the few hours immediately after receiving word of the approval (although the court subsequently concluded that it would "make no difference" if it disregarded such evidence). Op. 64-67. But the court gave no weight to Gilead's reactions to the news of the regulatory approval that cut the other direction, most notably that no one at Gilead claimed at the time that the milestone required a "disease-level" approval. *See* A382 (78:25-79:5); A383 (123:4-7) (claiming that the "spirit" of the Merger Agreement did not mandate payment where a Phase 3 study had not been completed and approval was for a "very small population."); *see also* A284-85 (claiming the Third Milestone was contingent on, *inter alia*, completion of a "pivotal trial"). To the contrary, Gilead recognized the issue of milestone liability immediately. A379 (51:15-52:6).

III. THE TRIAL COURT ERRED BY ALLOWING GILEAD TO SHIELD CALISTOGA'S PRIVILEGED COMMUNICATIONS

A. Question Presented:

Whether the trial court erred by permitting Gilead to assert the attorney-client privilege to shield highly probative evidence from Calistoga's deal counsel concerning the drafting of the Merger Agreement. A464-474.

B. Standard of Review:

"Appellate review of a trial court's ruling limiting discovery is based on an abuse of discretion standard but [this Court] exercise[s] *de novo* authority to review the application of the attorney-client privilege." *Zirn v. VLI Corp.*, 621 A.2d 773, 780 (Del. 1993).

C. Merits of Argument:

Gilead's Privilege Motion argued that Calistoga's former securityholders' "understanding of the contract language is likely to be inextricably bound up with, and is probably entirely derived from, privileged legal advice about that very subject" and requested that the court order WSGR litigation counsel to cease any communications with former Calistoga employees and with the WSGR lawyers who negotiated the agreement on behalf of Calistoga. *Supra* 17. Ultimately, the court agreed that Gilead could block access to Calistoga's privileged communications regarding the negotiation, and to WSGR deal counsel, reasoning

that if the reformation counterclaims were dropped, "the case would focus solely on the objective meaning of the contract." A483 (9:1-3); A486-87 (12:9-13:22).[13]

Instead, the trial court's Opinion ultimately relied heavily upon the parties' *subjective* understanding regarding the meaning of the key terms in the agreement. Yet SRS' attorneys were not permitted to (a) speak to the attorneys who drafted those key terms in the agreement, including the "any indication within" language in Schedule 1.1, or (b) review any of Calistoga's privileged communications with deal counsel, all of which would have confirmed the testimony of SRS' witnesses. A372-73 (45:9-49:16,52:4-15); A375-76 (111:18-112:5,115:6-116:1) (describing counsel's role in drafting the "any indication within" language).[14]

The trial court misapplied *Great Hill*: that decision rejected a selling shareholders' effort to shield privileged communications belonging to the pre-closing surviving entity from the buyer, who, by virtue of the acquisition, acquired

[13] While the court permitted Gilead to avoid the consequences of "inadvertent" waiver by withdrawing its reformation counterclaims, Gilead's waiver was hardly "inadvertent": it twice asserted counterclaims for reformation and verified discovery responses asserting mistake. *See Fitzgerald v. Cantor*, 1999 WL 64480, *3 (Del. Ch. Jan. 28, 1999) (finding waiver based reformation claims).

[14] When it became clear Gilead intended to introduce cherry-picked communications with Calistoga's deal counsel at trial, SRS objected and asked the court to prohibit Gilead from selectively introducing privileged communications or require Gilead produce all communications involving Calistoga's deal counsel related to the drafting of the agreement. At the pre-trial conference, the court denied SRS' request as untimely, expressly reserving judgment on whether the selected communications at issue were privileged. A969-71.

the target entity's privileges. 80 A.3d at 162. It does not support the proposition that the buyer (Gilead) can assert the privilege of the acquired corporation (Calistoga) to shield privileged communications that occurred when the buyer and selling shareholders were across the negotiation table, particularly when Gilead explicitly agreed that Calistoga's deal attorneys could represent the former securityholders in any dispute arising from the merger agreement. A151.[15]

If the trial court concluded it was appropriate to reverse course and rule based on witnesses' purported subjective understanding of the agreement, it prevented SRS from accessing and developing a record of evidence that was clearly "at issue." *E.g.*, *Tackett v. State Farm Fire & Cas. Ins. Co.*, 653 A.2d 254, 262-63 (Del. 1995). For its part, Gilead's successful efforts to prevent Calistoga's shareholders from reviewing even their own attorneys' files strongly suggests that such evidence would have been material to the disposition of the case.

[15] *Great Hill* certainly does not support prohibiting Gallagher, a director of Calistoga during the negotiation of the merger agreement, from accessing Calistoga's privileged communications regarding the negotiation. As a former director, privilege could not be asserted against Gallagher. *E.g.*, *Kirby v. Kirby*, 1987 WL 14862, at *7 (Del. Ch. July 29, 1987).

CONCLUSION

For the foregoing reasons, SRS respectfully submits that the trial court's Opinion should be REVERSED.

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