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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 JULY 28, 2017**

APPELLANT'S REPLY BRIEF

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PRELIMINARY STATEMENT

As is evidenced by the trial court's questioning whether the regulatory approval that Gilead received had value (despite Gilead's own internal documents celebrating that approval), the court apparently believed it would be unfair to award SRS and the former Calistoga shareholders a $50 million milestone payment. This, however, is not a case about fairness. It is a case about contract interpretation. Parties, including highly sophisticated parties such as Gilead, are free to enter into contracts they may later regret. Absent a claim for reformation (and Gilead asserts none), the court's decision must turn on the language to which the parties actually agreed.

Gilead urges this Court to affirm the trial court's decision based upon interpreting "indication" as a synonym for "disease." Gilead's interpretation renders the word "indication" entirely superfluous in nearly two dozen places it is used in the Merger Agreement. When "indication" is read in the context in which it was used in the Agreement, it is clear that the word refers to a regulatory agency's approved use of the drug to treat a defined group of patients with a disease. SRS' interpretation gives "indication" an independent meaning in the agreement and is consistent with standard English forms of that word, "to indicate" and "indication," from which the meaning in the regulatory context is based. In

other words, an "indication" is not simply a disease; an "indication" is the specific approval that describes the disease and any other characteristics of the disease sufferers that "indicate" the propriety of using the drug in question to treat them. It is the drug label in common parlance. This is the very definition given not only by SRS' witnesses, but also by the Gilead executive in charge of the negotiations, Dr. Mansuri, whom Gilead elected not to call at trial and whose testimony on this subject is, somewhat strikingly, never mentioned in the Opinion.

In order to deny SRS the milestone payment, the court imposed a *further* requirement that the regulatory approval in question be for all patients with the disease. Inasmuch as the court did not purport to locate that requirement in the actual language of the Merger Agreement, but instead based it upon extrinsic evidence, the holding that a "disease-level" approval was required also cannot stand. Gilead's brief similarly does not purport to analyze what words in the Third Milestone purportedly gave rise to a "disease-level" requirement. Instead, Gilead spends pages arguing a fact not in dispute—that the indication in question did not permit CAL-101 to be used to treat all Chronic Lymphocytic Leukemia ("CLL") sufferers. Because nothing in the Agreement requires that an approval be for all patients with CLL, that fact is of no moment.

SRS respectfully submits that the decision of the trial court should be reversed.

ARGUMENT

I. GILEAD FAILS TO MEANINGFULLY ADDRESS SRS' CONTRACT ARGUMENTS

When Delaware courts interpret contracts, they begin by examining the language of the contract itself. Remarkably, Gilead begins its analysis not by looking at the words on the page, but by looking at the extrinsic evidence. AB at 19-25. This extrinsic evidence consists primarily of testimony acknowledging that a disease can be used as shorthand for the "indication" that is the subject of regulatory approval. This analysis is out of order. As part of its *de novo* review, this Court must look first to the language on the page to assess its plain meaning, not to extrinsic evidence as Gilead proposes. Accordingly, in addition to failing to counter SRS' substantive interpretive arguments, Gilead's "textual" arguments are legally deficient and can largely be ignored.

a. *The Court of Chancery Erred by Failing to Acknowledge the Meaning of "Indication"*

The only reasonable interpretation of the term "indication" as used in the Agreement is the regulator's approved use of a drug. OB at 23-25. Although the disease being treated is a necessary component of an "indication" approved by regulators, "disease" and "indication" are not synonyms (and Gilead does not cite a single dictionary definition of the word "indication" that suggests otherwise). Regulators do not approve diseases, and all of the milestone provisions are

premised on obtaining regulatory approvals. Thus, the court committed legal error by failing to take that context into account. *See Pharm. Prod. Dev., Inc. v. TVM Life Sci. Ventures VI, L.P.*, 2011 WL 549163, at *4 n.24 (Del. Ch. Feb. 16, 2011) (noting courts should not be blind to the context of agreements and rather "*must* take cognizance of the existence of…general meanings in determining whether a contract has only one plausible meaning" (emphasis added)).[1]

"Indication" as it is used in the regulatory context is consistent with the plain meaning of the word "indication," and its root-word "to indicate," as reflected in the dictionary definitions SRS cited in its Opening Brief. OB at 23-24. These dictionary definitions reinforce the basic concept of pointing to or demonstrating the advisability of *something*. In the regulatory context, the

[1] Gilead's only response to this fundamental proposition—that words in contracts must be interpreted in the context in which they are used—is on page 28 of its Answering Brief. First, Gilead contends that this reasoning is "entirely circular" without explanation. Gilead then offers the *non-sequitur* that SRS "admits" that regulators may approve drugs for entire populations of disease sufferers. While true, regulatory agencies also commonly approve drugs for subpopulations of patients defined by factors such as age or genetic mutations. Neither fact has anything to do with the meaning of the term "indication" as used in the regulatory context or in the milestone provisions. Gilead then resorts (yet again) to extrinsic evidence reflecting the uncontroverted fact that the parties referred to diseases during certain due diligence presentations when discussing indications that are the subject of regulatory approval (while ignoring the evidence reflecting the parties use of "indication" to mean the approved use of a drug). *Id*. Gilead's refusal to engage on this fundamental interpretive point—that context determines meaning—is fatal to its arguments.

presence of particular symptoms or factors "indicates" the propriety of a particular drug to treat *a disease*.[2]

Gilead nonetheless asserts that the numerous dictionary definitions supporting SRS' reading should be ignored because SRS did not present all of those definitions below. AB at 27. However, the citations to medical dictionary definitions of "indication" that Gilead takes issue with (TABER'S and OXFORD CONCISE) are in addition to the definitions cited to the trial court. B246-47 n.9. SRS does not rely on these additional definitions to make a foundational point, but rather to demonstrate the uncontradicted authority in SRS' favor. Moreover, this Court is free to take judicial notice of dictionary definitions. D.R.E. 201.

Gilead likewise fails to respond meaningfully to SRS' surplusage argument—namely, that Gilead's reading renders the critical term "indication" redundant (e.g., "hematologic cancer [~~indication~~ disease]") while SRS' reading gives all terms meaning. OB at 25-28. It is a fundamental principle of Delaware

[2] Seeking to distract from how its own position changed over the course of the litigation, (OB at 15-16), Gilead incorrectly accuses SRS of the same, (AB at 21). But SRS has always maintained 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. Although the concept can be expressed with different words, the meaning is the same: the factors describing sufferers of a disease "indicate" what treatment should be started or what drug should be used. Nor is it "irreconcilable" for SRS to refer to CLL as an "indication." SRS has consistently argued that CLL is the disease that is the subject of regulatory approval or "indicated" to be treated by CAL-101.

law that a contract should be construed so *all* the words have meaning. *Bank of N.Y. Mellon v. Commerzbank Capital Funding Trust II*, 65 A.3d 539, 548-51 (Del. 2013). Indeed, the court recognized that SRS' appeal to this fundamental principle had "some appeal to a law-trained judge," (Op. 49), but nevertheless disregarded it even though the agreement was not drafted by laypersons, but by lawyers.

In response, Gilead makes a new argument—not advanced below—that the words "cancer" and "indication" (standing in for "disease") were necessary to denote that the milestone contemplated regulatory approvals to treat cancers and to exclude non-cancerous blood diseases such as hemophilia. AB at 25-26.[3] But even if one accepts that the parties started with the phrase "hematologic indication" and then added in the word "cancer" to clarify that not all hematologic "diseases" would trigger milestones (which is counterfactual because Calistoga initially proposed the phrase "hematologic cancer indication," (OB at 10)), the word "indication" (disease) remains surplusage as soon as the word "cancer" is inserted.

If, as the trial court found, the parties intended Schedule 1.1 of the Merger Agreement to be merely a list of diseases, the parties could have simply called the schedule "hematologic cancers" and deleted the word "indication" each of the

[3] When Gilead's own expert discussed the meaning of "hematologic cancer indication" at trial, she did not say "cancer disease" or "hematologic cancer disease," but rather presented a demonstrative equating the three-word phrase to "blood cancer." A675-76 (717:23-720:6) (discussing demonstrative stating "Hematologic Cancer Indication=blood cancer").

twenty times that word is used in conjunction with "cancer" or "tumor" in the agreement. Gilead has no response.[4] Adding "indication" would only inject ambiguity given its recognized meaning in the regulatory context as the approved use of a drug. "Indication" only has meaning in the agreement under SRS' construction, referring to regulatory "indications" for treatment of hematologic cancers.

Gilead also has no response to the inconsistency its interpretation creates with Part 2 of Section 1.1 of the Company Disclosure Schedule. A156-57. Gilead appears to concede the "disease within disease" point, (OB at 28), as its only retort is to note that *some* of the diseases listed have diseases within them, (AB at 27-28). That is, Gilead's only defense to this defect is that its interpretation works *some* of

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[4] Gilead argues it is plausible (again without evidence) that the parties arrived at and agreed to phraseology meaning "cancer diseases" because examples of "cancer disease" exist in scientific literature. AB at 26. But if the net is cast wide enough, especially with modern search tools such as Google, it is possible to find practically any phraseology in some published source to make a point. *See Am. Legacy Found. v. Lorillard Tobacco Co.*, 886 A.2d 1, 27 (Del. Ch. 2005), *aff'd*, 903 A.2d 728 (Del. 2006). It does not alter the fact that the phrase is not commonly used and redundant.

More to the point, nouns almost always belong to broader categories. For example, all horses are animals. Animals are a broad category of being that includes horses. Saying "Jane owns a horse" communicates that Jane owns a horse that is an animal, because saying "horse" logically implies that Jane owns an animal. For that reason, the sentence "I am going to buy a horse animal" is nonsense. For the same reason "Bill has cancer disease" makes no sense, because "Bill has cancer" conveys that Bill has a disease. All cancers are diseases just like all horses are animals.

the time. But Gilead does not point to any inconsistencies that SRS' interpretation creates.

Rather, Gilead draws a caricature of SRS' interpretation based on the definition of "indication" used in the regulatory context by saying that SRS' interpretation does not work within the language of the Third Milestone—"Regulatory Approval…as a first-line drug treatment…for a Hematologic Cancer Indication"—because "[o]ne does not 'treat[]' 'the approved use of a drug.' 'One 'treat[s]' a 'disease.'" AB at 23. There is no inconsistency there. Regulatory agencies approve drugs as "treatments" for certain patients with a disease. The particular approval identifying the disease and the patient population who can use the drug is the "indication." Indeed, the label issued here by the EMA contains nearly identical phraseology to that used in the Third Milestone: "[CAL-101] is indicated in combination with rituximab *for the treatment of adult patients with [CLL]…as first line treatment in the presence of 17p deletion or TP53 mutation* in patients unsuitable for chemo-immunotherapy." AR41 (emphasis added). Thus, SRS' interpretation harmonizes all the language in the agreement.[5]

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[5] The trial court was also swayed by the fact that "Specified Hematologic Cancer Indication" refers to the "indications" listed on Part 2 of Schedule 1.1, which in turn is a list of specific diseases. Op. 51. Again, if the parties meant "hematologic cancer indication" to be synonymous with the diseases listed on the schedule, they would have called the schedule "Hematologic Cancers." The purpose of the list of diseases in Part 2 of Schedule 1.1 was to provide a more limited list of "major" diseases within the broader

b. *The Court of Chancery Compounded Its Initial Error by Imputing a "Disease-level" Limitation*

Even if this Court were to accept the trial court's determination that the word "indication" is ambiguous—*and* defer to the court's reliance on extrinsic evidence to conclude the parties intended the word "indication" to be synonymous with "a disease"—SRS is still entitled to judgment in its favor. Perhaps recognizing this, the trial court concluded that the Third Milestone also *required* a "disease-level" approval (i.e., only approvals to treat every person with that disease). That conclusion was an interpretive leap that has no basis in the language of the agreement and, therefore, constituted legal error. OB at 29-31.

Gilead too never explains what contractual language purportedly required "disease-level" approvals. Instead, Gilead misleadingly suggests that reading "indication" to mean "a disease" resolves the dispute in its favor, claiming that the court determined "as a matter of fact" that the "European Commission Did Not Approve CAL-101 as a First-Line Drug Treatment for the Disease CLL." AB at 30 (quoting Op. 75-78). But in the section of the Opinion Gilead cites, the court had already (erroneously) "determined that the required form of regulatory

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categories of Part 1 for purposes of the Second Milestone (which was limited to an approval in the broader list in a second jurisdiction or in the more limited list of diseases within the same jurisdiction). Moreover, it is of course not possible to list every potential regulatory indication that could be obtained. OB at 37.

[approval] must be a first-line *disease-level* approval." Op. 75. The court's discussion of the evidence in that section of the Opinion (and Gilead's parallel arguments in Section II of its brief) all stand for the fact that the regulatory approval at issue here was not for *all* patients with CLL, which SRS never disputed.

But it is also undisputed that the EMA approved CAL-101 as a first line treatment for a significant population of CLL patients.[6] Neither the trial court nor Gilead ever grapple with the basic interpretive question of whether that approval satisfies the plain language of the Agreement (if the word "indication" refers to "a disease")—i.e., does the approval of CAL-101 to treat less than all patients with CLL constitute "Regulatory Approval…as a first-line drug treatment…for a Hematologic Cancer [Disease]"? What word or words in the contract *require* that "Regulatory Approval" be for *all* patients with that particular disease? Gilead points to none.

Stated differently, it is undisputed that regulators sometimes approve drugs at the "disease-level" to treat all patients with a particular disease. But it is also undisputed that regulators frequently approve drugs to treat less than all patients

[6] Gilead cannot credibly argue to the contrary since (i) Gilead's expert acknowledged that fact (A672 (703:21-24)); (ii), the medical establishment recognized it (A355); and (iii) Gilead's own internal documents reflect the approval was a first-line treatment for CLL patients (*e.g.*, AR38, A345).

with a disease, i.e., subpopulations defined, for example, by age, co-morbidities, genetic mutations, or other factors.[7] In a world where regulatory approvals for subpopulations are not only possible, but standard, there is nothing in the language of the Third Milestone that addresses the possibility of subpopulations or expressly excludes regulatory approvals that do not treat all disease sufferers. There are no limiting words or qualifiers whatsoever (other than that the approval be first-line). The Court must enforce the words on the page. *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1196 (Del. 1992).

This is precisely the error addressed in *BLGH Holdings LLC v. enXco LFG Holding, LLC*, 41 A.3d 410 (Del. 2012), discussed in SRS' Opening Brief but ignored by Gilead. OB at 30-31. To reiterate, this Court reversed the trial court's decision for reading a "materiality" qualifier into contract language specifying the type of transaction that would trigger a bonus payment without any basis in the relevant contract language for doing so. *BLGH*, 41 A.3d at 414-16. Gilead's failure to even acknowledge this authority betrays the fundamental weakness of its position as a matter of law.

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[7] In fact, four other major drug companies received approvals to treat this subpopulation of CLL patients (perhaps explaining why Gilead refused the milestone). OB at 14-15. And there are numerous examples of regulatory approvals for subpopulations of patients with particular blood cancers in the record. Indications limited to "adult" patients are particularly commonplace. *E.g.*, AR24-30.

The only reasonable interpretation of the relevant language is that any regulatory approval to treat one of the listed hematologic cancers qualifies. That the approval at issue here was to use CAL-101 to treat a subpopulation of patients with the disease CLL, rather than all patients with CLL, did not alter that the approval was as a treatment for CLL. The disease that CAL-101 treats did not *cease* to be CLL because the approval was for a subpopulation of disease sufferers. Thus, the approval at issue here constituted "Regulatory Approval…as a first-line drug treatment…for a Hematologic Cancer Indication," i.e., "CLL," and, therefore, satisfies the Third Milestone.

Moreover, the court backed into its conclusion—only *after* relying on extrinsic evidence to impute a "disease-level" qualifier—based on the "[s]tructure and [o]peration of the [m]ilestone [p]rovisions." Op. 67-71. But the court's interpretive "analysis" did not support reading in a materiality qualifier. Instead, the Court relied on an absurd hypothetical, (Op. 68-69 n.244), and discounted the contractual provisions that gave Gilead the freedom to pursue (or not pursue) whatever regulatory approvals it wanted, (*see* OB at 31-32), to conclude SRS' interpretation was "contrary to reasonable business expectations." Gilead merely echoes this flawed reasoning. AB at 37.[8]

[8] The trial court also appears to have been persuaded by Gilead's assertions that this approval did not provide equivalent value to the other triggers in the

Gilead tries to rehabilitate the court's absurd hypothetical by citing *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010), for the proposition that "[a]n interpretation of a term that creates absurd results is highly disfavored." AB at 36. Interpretations that produce absurd results may be disfavored, but *Osborn* does not stand for the proposition that the court may re-write the plain terms of a contract. 991 A.2d at 1160 (explaining what would make an interpretation absurd for purposes of determining if an agreement was ambiguous); *see Great-W. Inv'rs LP v. Thomas H. Lee Partners, L.P.*, 2011 WL 284992, at *8 (Del. Ch. Jan. 14, 2011) ("The Court's role is not 'to rewrite the contract between sophisticated market participants….'"). Although Calistoga would not have agreed, the parties *could* have negotiated for language providing that only approvals for *all* patients with a hematologic cancer would trigger the milestone. It would have been a simple matter to require "Regulatory Approval…as a first-line drug treatment…for ~~a~~ [*all patients with a*] Hematologic Cancer ~~Indication~~." That they did not, and the

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Third Milestone for solid tumor indications or $1 billion in sales even though (i) Gilead presented *no* evidence at trial to support that conclusion, and (ii) the court cited none in its Opinion. The court instead put the burden on SRS to counter Gilead's interpretive argument, observing the record was "devoid of any hard evidence" such approvals would yield significant value, (Op. 70), despite Gallagher testifying about the "halo effect" from first-line approvals for subpopulations, (A542-43 (188:12-189:8)), and Gilead's internal documents touting the value of the approval here (OB at 15 n.1).

court nevertheless read in such a limitation and reformed a contract between sophisticated parties, was error and demands reversal.

II. THE TRIAL COURT'S CONCLUSIONS WERE NOT SUPPORTED BY THE AVAILABLE EXTRINSIC EVIDENCE

It is undisputed that the parties never discussed, much less agreed, that (i) the meaning of the term "indication" as it is used in the Merger Agreement would depart from its standard usage in the regulatory context,[9] or (ii) that only "disease-level" regulatory approvals would trigger milestones. OB at 37. The trial court nevertheless concluded based on the extrinsic evidence that the parties agreed that the word "indication" meant "disease" and that the milestones were limited to "disease-level" approvals. The court's conclusions are undermined by the evidence in the record and, therefore, were not "the product of an orderly or logical deductive reasoning process." *Motorola Inc. v. Amkor Tech., Inc.*, 958 A.2d 852, 859 (Del. 2008); OB at 37-41.

The court's interpretation of "indication" to mean "disease" and indeed, its assertion that there was no "textual anchor from which to import into the word 'indication' the concept of a regulatory label," (OB at 25), was expressly repudiated by a key Gilead witness. Dr. Mansuri, Gilead's Senior Vice President

[9] Gilead's claims to the contrary, (AB at 32-33), are based on nothing more than instances where the parties used the disease as shorthand for the regulatory indication for patients with that disease, OB at 37-40. Gilead's witnesses all admitted that the parties never expressly discussed that term during negotiations. *See* A698 (810:6-17); A728 (926:20-927:6); AR37 (61:4-63:15).

in charge of the negotiations on behalf of Gilead,[10] testified that "indication" was a "broad term" and, in the context of regulatory approval as used in the Merger Agreement, that it referred to the "label approval":

> Q: And the language we've been talking about in the third milestone says "receipt of regulatory approval of CAL-101…" and then I'm leaving some out, but "…as a first-line drug treatment…" and then it goes on, "…for a hematologic cancer indication." Do you see that?
>
> A: I do.
>
> Q: Yeah. And is there, to your knowledge, any kind of commonly understood meaning of the term "indication" when used in the context of regulatory approval of a drug?
>
> A: ***We tend to think – I tend to think in terms of the label***. So, you know, ***I assume that indication is a broad term.*** It can be used in different meanings in different contexts. ***So I assume by this it means the label approval or something. That's how I think about it.***
>
> Q: Okay. So your understanding, in the context of regulatory approval of an indication is that it refers to the label approval. Is that right?
>
> A: ***Yes.***

A387 (50:1-24) (objection omitted; emphasis added).

Mansuri's uncontroverted testimony, which expressly equates the term "indication" to a drug's label describing its approved use, is entirely consistent

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[10] Although Gilead now claims O'Connell was the "lead negotiator," (AB at 33), in a declaration Gilead submitted in February 2016, Mansuri stated under oath that he "was the senior Gilead executive directly managing the negotiation with Calistoga," (AR32).

with the testimony of SRS' witnesses. Dr. Gallagher testified that "indication" referred to "the label you would receive from a regulatory body about the specific patient population that you would treat with the hematologic cancer." A536 (161:11-22). Dr. Arbuck, an expert in the development of oncology drugs, similarly testified without contradiction that the commonly understood meaning of the term "indication" in milestone agreements is "regulatory approval of a drug for a particular indication" which is found in the label. A590; A593-94 (380:15-22, 391:22-393:17).

Given that both executives who negotiated the agreement—Mansuri and Gallagher—agree on the meaning of the word "indication," concluding that both parties were mistaken in precisely the same way should have required strong evidence. And even then, such a conclusion would sound in reformation, not to resolve an ambiguity. Nevertheless, the court ignored Mansuri's uncontroverted testimony and concluded that the parties understood "indication" was synonymous with "disease."[11] Gilead's Answering Brief similarly makes no effort to explain Mansuri's interpretation of the word "indication" as a "label approval."

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[11] Mansuri also undermines the trial court's conclusion that the parties *sub silentio* incorporated the WHO classification to list potential "indications" and therefore equated "indication" with "disease." Op. 17. When asked whether the WHO classification was a list of indications, Mansuri testified unequivocally that "it's a list of tumor types. *It's not a list of indications, no*." AR37 (62:6-8).

Likewise, although the court asserted that Gallagher was shown "presentation after presentation" in which diseases were described as "indications" (which is entirely inconclusive given that a disease is part of a regulatory "indication"), the trial court conceded on the very next page of the Opinion that those same presentations used the word "indication" as it is normally used in the regulatory context to mean the approved use of a drug. OB at 39-40; AR1-8; A580 (337:2-340:5). Notably, that usage—found in the very same presentations relied upon by the court—cannot be reconciled with treating "indication" and "disease" as the same word. For example, discussing regulatory approvals, the presentations reference "expanding indications," which could not mean "expanding [diseases]," but, instead, expanding the regulator's approved use of a drug. *See* A581 (342:1-343:6); B19; AR3; *see also* A719 (889:24-891:24) (O'Connell conceding same).[12]

[12] Gilead initially proposed a milestone that used "indication" as it is understood in the regulatory context: basing a milestone on initiating a Phase II Trial "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). Gilead discounts the significance by adopting the trial court's reasoning that the language still works if you substitute "disease" for "indication." AB at 38. This reading, with its circular and needless references to "disease or diseases" in "patients with a disease or condition," is nonsensical. "Indication or indications" plainly refers to a different concept than "disease or condition" and the court's decision to explain away this evidence was not reasonable. Gilead alternatively invents evidence that a drafting error omitted the plural "s" in "disease[s] or condition[s]." *Id.* Even assuming Gilead made a glaring drafting error, the phrase remains needlessly circular and nonsensical.

Moreover, as explained *supra* Section I.B., even if the parties meant "indication" to mean "disease," SRS still prevails under any reasonable reading of the Third Milestone. Therefore, the trial court had to essentially reform the contract by imputing a "disease-level" limitation. But there is no evidence the parties ever discussed, much less agreed, to such a limitation. OB at 40-41.[13] Indeed, Gilead's own witnesses refuted this, freely admitting that *some* subpopulations *would* satisfy the milestones. As SRS explained, when the FDA approved CAL-101, one of the indications was for use in relapsed CLL in a narrow subpopulation of "patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities," i.e., with other diseases that make them appropriate for another specific treatment, rituximab. A212. Dr. Bischofberger, Gilead's Chief Scientific Officer, confirmed that indications for a subpopulation would have qualified as a "Hematologic Cancer Indication" under the agreement. OB at 42.

Gilead's Hawkins emphatically agreed at trial. *Id.* He testified that *any* approval for a subpopulation of patients defined by "personal characteristics" would qualify. *Id.* Gilead cannot credibly suggest that a subpopulation defined by

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[13] Indeed, when Dr. Hawkins was asked at trial what language the parties could use to "*include* subpopulations…in the agreement," his immediate response in a moment of clarity was "'*any indication within the following tumor types*'"—the exact language used in Schedule 1.1. OB at 40 n.10 (emphasis added) (citing A695).

17p/*TP53* is distinct from one defined by other "personal characteristics." Indeed, Dr. Dearden, Gilead's expert, stated in a sworn declaration that "CLL in the presence of 17p deletion and *TP53* mutation describes *personal* characteristics of certain patients" and equated 17p/*TP53* to other "personal characteristics" including "age" and "co-morbidities." AR20-21.[14] Thus, the court ignored this evidence and Gilead's argument in response to this is made-up.

Finally, Gilead claims that "course of dealing" evidence supported the court's decision; namely emails reflecting that (i) Calistoga executives failed to recognize in summer 2014 the possibility that CAL-101 could receive a front-line indication, and (ii) following the September 2014 approval, it took the executives a few hours to recognize that the milestone had been met. *See* AR9-12. As an initial matter, emails among Calistoga executives years after the negotiation of the relevant language are not "course of dealing" evidence, which refers to the conduct and communications *between* the parties. RESTATEMENT (SECOND) OF CONTRACTS § 223. In any event, as Gilead's authority confirms, such evidence cannot

[14] At trial, Dearden broke down and could not answer whether an approval for a population defined by "adults" sufferers of a disease would be a "Hematologic Cancer Indication." A677-79 (723:19-732:19). Dearden's hesitation was understandable and highlights the absurdity of Gilead's interpretation since regulatory indications are frequently limited to "adult" patients. Gilead's only response is that the parties were "focused on" diseases that occurred exclusively in adults. AB at 41. This is not true. There are scores of diseases included within the tumor types listed in the Merger Agreement that occur in adults and children.

overcome the plain meaning of the agreement. *RCA v. Phila. Storage Battery Co.*, 6 A.2d 329, 340 (Del. 1939) ("If the meaning of a contract is plain, the acts of the parties cannot prove an interpretation contrary to its plain meaning."). Finally, as SRS previously explained, while the court cited to Calistoga's initial reactions, it ignored the evidence that Gilead itself initially recognized that the milestone might be due and at no point in time contemporaneous with the approval claimed that "indication" meant "disease" or that a "disease-level" approval was required. OB at 44 n.12.

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

The Merger Agreement contained an express conflict waiver permitting WSGR to represent the former Calistoga shareholders in disputes arising from the agreement. A151. Nevertheless, at Gilead's urging, the court prevented SRS, its attorneys at WSGR, and the former Calistoga directors/shareholders from accessing privileged communications between Calistoga and its deal counsel at WSGR bearing directly on, among other things, the drafting of the "any indication within" language in Schedule 1.1. Indeed, trial counsel was forbidden from speaking with deal counsel.

As SRS explained, the court's decision was premised on a faulty reading of the decision in *Great Hill Equity Partners IV, LP v. SIG Growth Equity Fund I, LLLP*, 80 A.3d 155 (Del. Ch. 2013). OB at 46-47. Moreover, despite the court's assurance that the "case would focus solely on the objective meaning of the contract" if Gilead elected to withdraw its reformation counterclaims, the court relied heavily on the *subjective* understanding of the witnesses,[15] as well as cherry-

[15] Gilead's claim that the court's conclusion was not based on the parties' subjective intent is contradicted by numerous statements in the Opinion. *E.g.*, Op. 15 (referring to O'Connell's explanation of his intent in compiling Schedule 1.1), 52 ("[T]he parties mutually understood when they entered into the Merger Agreement that the term 'indication' meant 'a disease.'"), 61 (same), 64 ("[B]oth parties understood that the milestones could only be triggered by a disease-level regulatory approval.").

picked privileged communications Gilead selectively produced. This plainly prejudiced SRS.[16]

Gilead does not address *Great Hill*. Instead, Gilead mischaracterizes SRS' arguments as an appeal from an untimely motion *in limine*, when they are nothing of the sort, and incorrectly claims that the draft lists created for the *specific purpose of assisting counsel* were not privileged. Gilead alternatively argues that there was more than sufficient evidence to support the court's ruling even if Gilead did selectively use privileged materials. But that is *precisely* the problem—the record was incomplete, and the court prevented SRS from presenting potentially highly probative evidence that would have corroborated Calistoga's intent (as Gallagher and Miller testified) in drafting the language at issue. This was reversible error.

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[16] Gilead's only response on the prejudice point is to note that SRS could have deposed its deal counsel at WSGR. That ignores that Gilead demanded that WSGR turn over its deal files and claimed wholesale privilege over them (i.e., Gilead did not produce the deal files in response to discovery requests although they were in their possession and clearly responsive) and there is no reason to believe (particularly following Gilead's motion to protect the privilege) that it would have permitted SRS to question WSGR deal counsel about its efforts in drafting the key language. Moreover, that ignores the broader point that SRS and Calistoga's stockholders were prejudiced by not being able to work with deal counsel at WSGR, the entire purpose of the waiver provision.

CONCLUSION

For these reasons, and those in its Opening Brief, SRS respectfully submits the Court of Chancery's Opinion should be REVERSED.

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