IN THE COURT OF CHANCERY 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, v. GILEAD SCIENCES, INC. and GILEAD BIOPHARMACEUTICS IRELAND CORPORATION, Defendants.	)	C.A. No. 10537-CB
GILEAD SCIENCES, INC. and GILEAD BIOPHARMACEUTICS IRELAND UC, Counterclaimants, v. SHAREHOLDER REPRESENTATIVE SERVICES LLC, in its capacity as the Stockholders' Agent for the former securityholders of Calistoga Pharmaceuticals, Inc., Counterclaim-Defendant.	)	

MEMORANDUM OPINION

Date Submitted: January 10, 2017
Date Decided: March 15, 2017

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BOUCHARD, C.

This post-trial decision holds that Gilead Sciences, Inc. is not required to pay a $50 million milestone payment under the terms of a merger agreement pursuant to which Gilead acquired Calistoga Pharmaceuticals, Inc. in 2011. The core of the dispute boils down to the meaning of essentially one word—"indication"—as used in an 84-page merger agreement.

As part of the merger consideration, Gilead agreed to make three payments to the former securityholders of Calistoga if its main compound at the time—CAL-101—achieved certain milestones. In August 2014, Gilead paid $175 million in satisfaction of the first two milestones after receiving certain regulatory approvals for CAL-101 from the United States Food and Drug Administration.

In September 2014, the European Commission approved CAL-101, in combination with another drug, as a first-line treatment for patients with chronic lymphocytic leukemia in the presence of genetic abnormality known as 17p deletion or *TP53* mutation who are unsuitable for chemo-immunotherapy. The question before the Court is whether that approval satisfies the third milestone, one of the triggers for which is "the receipt of Regulatory Approval of CAL-101 in the United States or the European Union, whichever occurs first, as a first-line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer ***Indication***."

The parties agree that the term "indication" has multiple meanings in the oncology industry that are context specific. Plaintiff Shareholder Representative Services LLC contends that, as used in the merger agreement, "indication" means "the approved use of a drug in a population of patients with a particular disease" and thus that the milestone at issue can be triggered by a regulatory approval of CAL-101 as a first-line therapy for a subpopulation of people suffering from a disease, such as CLL patients with 17p deletion or *TP53* mutation. Gilead, by contrast, contends that "indication" means "disease" and thus that the milestone at issue can be triggered only by a disease-level regulatory approval of CAL-101.

For the reasons explained below, after finding that the word "indication" is ambiguous when construed within the four corners of the merger agreement, I find that the overwhelming weight of extrinsic evidence supports the conclusion that the shared intention of the parties at the time of contracting was that the word "indication" means "disease" and that the milestone at issue could only be triggered by a disease-level regulatory approval. Finally, I find that the European Commission's approval of CAL-101 was not a disease-level approval and thus that the milestone in question is not due.

I. Background

The facts recited in this opinion are my findings based on the testimony and documentary evidence of record from a four-day trial held in September 2016 during

which four fact and two expert witnesses testified. Plaintiff's expert was Dr. Susan G. Arbuck, a consultant who provides strategic research and development services for drug development. Gilead's expert was Dr. Claire Dearden, the Clinical Director of the Haemato-Oncology Department and the Specialist Haematological Malignancy Diagnostic Service at the Royal Marsden Hospital & Biomedical Research Center in London, United Kingdom. I accord the evidence the weight and credibility I find it deserves.

A. The Parties

Before the merger, Calistoga Pharmaceuticals, Inc. ("Calistoga") was a privately-held biotechnology company that developed and held a portfolio of proprietary compounds for the treatment of inflammatory and autoimmune diseases and hematologic cancers.

Defendant Gilead Sciences, Inc., a Delaware corporation with its principal place of business in California, is a biopharmaceutical company that develops and commercializes drugs for the treatment of life-threatening diseases and illnesses. Defendant Gilead Biopharmaceutics Ireland Corporation, a company formed under the laws of Ireland, was a wholly-owned subsidiary of Gilead Sciences, Inc.[1] In this

[1] On September 22, 2014, Gilead Biopharmaceutics Ireland Corporation was renamed Gilead Biopharmaceutics Ireland UC. JX702-004.

opinion, I refer to Gilead Sciences, Inc. and Gilead Biopharmaceutics Ireland Corporation together as "Gilead."

On February 21, 2011, Gilead and Calistoga executed an Agreement and Plan of Merger (the "Merger Agreement") pursuant to which Gilead acquired Calistoga. Under Section 9.3(a) of the Merger Agreement, plaintiff Shareholder Representative Services LLC ("SRS"), a Colorado limited liability company, was appointed as the agent for the former securityholders of Calistoga for the purpose of, among other things, enforcing the terms of the Merger Agreement.

B. Calistoga Initiates a Sale Process

In the fall of 2010, Calistoga began considering various potential strategic alternatives, including licensing the commercial rights of its drugs, an initial public offering, and a sale of the company.[2] By the fourth quarter of 2010, Calistoga decided to run a sale process.[3] Around that time, it retained J.P. Morgan Securities LLP ("JP Morgan") to assist it in the sale process.[4] Carol Gallagher, Calistoga's Chief Executive Officer, oversaw the sale process with assistance from Cliff Stocks, Calistoga's Chief Business Officer.[5]

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[2] Tr. 140-41 (Gallagher).

[3] Tr. 190 (Gallagher).

[4] Tr. 142-43 (Gallagher).

[5] Tr. 155 (Gallagher); Tr. 43 (Miller).

By December 7, 2010, Calistoga had received offers from a number of pharmaceutical companies including: AstraZeneca, Human Genome Sciences, Bristol-Myers Squibb, Daiichi Sankyo, and GlaxoSmithKline.[6] Later that month, Gilead expressed interest in acquiring Calistoga.[7] Gilead's team was led by Dr. Muzammil Mansuri, Executive Vice President of Strategy, Business Development, and Licensing; and Sean O'Connell, Senior Director of Corporate Development.[8]

C. Calistoga Makes Due Diligence Presentations to Gilead

At the time of the sale process, Calistoga held a portfolio of compounds.[9] Only two compounds (CAL-101 and CAL-263) had been tested on human beings, and only one (CAL-101) had demonstrated initial efficacy in humans.[10]

CAL-101 had shown promise in early trials to treat blood cancers, including two types of incurable B-cell malignancies known as chronic lymphocytic leukemia (CLL) and indolent Non-Hodgkin's Lymphoma (iNHL).[11] CAL-101 also showed potential as a treatment in solid tumors and inflammatory ailments.[12] CAL-101 was

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[6] JX057-004; Tr. 144 (Gallagher).

[7] Tr. 144-45 (Gallagher); Tr. 831-32 (O'Connell); Mansuri Dep. 66-67; JX066.

[8] Tr. 884 (O'Connell); JX712-005.

[9] JX371-007.

[10] Tr. 192-93 (Gallagher).

[11] JX068-002; JX068-013; Tr. 15-16 (Miller).

[12] JX068-065; Tr. 217 (Gallagher).

later given the generic name idelalisib, and is now sold by Gilead under the trade name Zydelig.[13] In this opinion, I use the terms "CAL-101," "idelalisib," and "Zydelig" interchangeably.

During due diligence, Calistoga provided Gilead with information about CAL-101's potential for treating hematologic cancers, with a particular focus on CLL and iNHL.[14] Calistoga also explained to Gilead the clinical trials it was conducting and planned to conduct for CAL-101 in support of regulatory approvals of the drug.[15] For example, in two January 2011 presentations, Calistoga outlined its plans to obtain an accelerated approval of CAL-101 "for the treatment of patients with iNHL refractory to rituximab and alkylating agents" by 2013; and to obtain full approvals "for use in combination for the treatment of patients with previously treated CLL" by 2015, and "for use in combination for the treatment of patients with previously treated iNHL" by 2016.[16]

In the United States, the term "accelerated approval," which is known as "conditional approval" in Europe, is a special process that allows a drug to be approved more rapidly when there is a high unmet medical need.[17] After one obtains

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[13] *See* Tr. 5 (Miller), Stephens Dep. 17-18.

[14] Tr. 15-16 (Miller); Tr. 768-69 (Hawkins); *see* Tr. 13-14 (Miller); JX068.

[15] Tr. 24-28 (Miller); *see e.g.*, JX068-017 (summarizing studies).

[16] JX068-050; JX084-004-05.

[17] Tr. 23 (Miller); Tr. 151-52 (Gallagher); Tr. 401-02 (Arbuck); Tr. 907-08 (O'Connell).

an accelerated approval, additional studies still must be conducted to secure a full and unconditional approval from the relevant regulatory authority.[18]

The term "refractory" or "previously treated" refers to "the time of treatment of the drug relative to previous therapies."[19] The cancers that are the subject of this case typically are incurable and will return.[20] After the first therapy of a patient—known as the "first-line" or "frontline" treatment—a patient who relapses becomes "refractory."[21] The next line of therapy for a refractory patient is known as a "second-line" treatment, which can progress to a third-line treatment and so on.[22]

Early data for CAL-101 that Calistoga presented to Gilead suggested that the drug was effective in all patients with CLL.[23] The presentation highlighted the drug's efficacy in one particular subgroup—CLL patients with genetic abnormalities known as "17p deletion/*TP53* mutation."[24] Patients with 17p deletion do not have

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[18] Tr. 24 (Miller).

[19] Tr. 250 (Gallagher).

[20] Tr. 249 (Gallagher).

[21] Tr. 381 (Arbuck).

[22] Tr. 76 (Miller); Tr. 775 (Hawkins).

[23] JX068-027; JX068-029; Tr. 771 (Hawkins).

[24] JX068-027; Tr. 31-33 (Miller); Tr. 257 (Gallagher); *see* Milligan Dep. 68-69.

the short arm of chromosome 17, on which the *TP53* gene resides.[25] Even if a patient has the *TP53* gene, the *TP53* gene may have mutated and still not function.[26]

The oncology community widely recognized that patients with the 17p deletion or the *TP53* mutation had tumors that were particularly resistant to then-existing forms of treatment, such as chemotherapy and certain types of immunotherapy.[27] As a result, those patients were commonly considered to have the worst prognosis among all CLL patients.[28] Approximately 10% of newly diagnosed CLL patients and 50% of relapsed/refractory CLL patients have 17p deletion or *TP53* mutation.[29] Calistoga's initial data for CAL-101 suggested that, unlike some traditional regimens, CAL-101 circumvented the treatment-resistant characteristics of the 17p deletion or *TP53* mutation genetic abnormality.[30]

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[25] Tr. 579-80 (Dearden).

[26] Tr. 580 (Dearden).

[27] Tr. 412-13 (Arbuck); Tr. 673 (Dearden); Milligan Dep. 68.

[28] Tr. 412-13 (Arbuck); JX1000-003; JX1002-003.

[29] *See* Tr. 428-29 (Arbuck) (testifying that around 10% of newly diagnosed CLL patients have 17p deletion or *TP53* mutation, and the number rises to 40-50% among relapsed and refractory CLL patients); JX785-006 (Gilead marketing presentation stating that around 7-13% of frontline CLL patients and 48-53% of relapsed/refractory CLL patients have 17p deletion or *TP53* mutation); Tr. 114 (Miller) ("about 5 to 8 percent of CLL patients will exhibit 17p deletion or TP53 mutation if tested at the time of their first treatment"); Tr. 659-60 (Dearden) (acknowledging studies that found around 10-15% of CLL patients have a defect in the *TP53* gene at the time of diagnosis and that as high as 40-50% of refractory CLL patients have this genetic abnormality).

[30] Tr. 32 (Miller); Tr. 771-72 (Hawkins).

D. Gilead and Calistoga Exchange Drafts of the Merger Agreement

On January 28, 2011, Gilead provided JP Morgan with a preliminary and non-binding expression of interest to acquire Calistoga.[31] Gilead's preliminary offer consisted of a cash payment of $310 million at closing and additional contingent payments totaling $275 million based on the achievement of three milestones:

a) One time payment of $100M payable after receipt of the first accelerated approval (i.e., "Subpart H" in US or "Conditional" in EU) of CAL-101 for indolent Non-Hodgkin's Lymphoma (iNHL) or Chronic Lymphocytic Leukemia (CLL) provided such accelerated approval is obtained <u>no later than December 31, 2013</u>. For clarity, no such milestone payment will be payable if such accelerated approval is obtained after December 31, 2013.

b) One time payment of $75 million upon dosing of first patient in a Phase III study of CAL-101 for first line treatment of patients with iNHL or CLL.

c) One time payment of $100M payable upon obtaining first full regulatory approval of CAL-101 in US or EU for iNHL or CLL (in either relapsed/refractory or first line setting).[32]

After Gilead made its preliminary offer, the parties began an exchange of drafts of a merger agreement,[33] and occasionally engaged in conversations.

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[31] Tr. 148 (Gallagher); JX160.

[32] JX160-003.

[33] The dates of the drafts discussed in this opinion refer to the dates they were exchanged, which varies for some drafts by one day from the date that appears on the document.

1. The February 1 Calistoga Draft

On February 1, 2011, Calistoga sent Gilead a first draft of a merger agreement, which contemplated an up-front payment of at least $300 million and four different milestones totaling at least $300 million:[34]

- $100 million within "10 business days following the receipt of the first Regulatory Approval in the United States or an EU Country, whichever occurs first, of CAL-101 for a hematologic cancer indication."[35]
- $75 million within "10 business days following the receipt of the second Regulatory Approval in the United States or an EU Country, whichever occurs first, of CAL-101 for a hematologic cancer indication."[36]
- $50 million within "10 business days following the receipt of the first Regulatory Approval in the United States or an EU Country, whichever occurs first, of a P110 Delta Product, for an indication other than a hematologic cancer indication."[37]
- $75 million within "10 business days following the Initiation of a Registration Study involving CAL-101 as a first line treatment for an oncology indication."[38]

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[34] JX175-016; Tr. 154 (Gallagher).

[35] JX175-053 § 9(bk)(i). If the first Regulatory Approval is obtained on or before June 30, 2014, then the first milestone payment shall be increased to $150 million. *Id.*

[36] JX175-053 § 9(bk)(ii).

[37] JX175-053-054 § 9(bk)(iii). "P110 Delta Product" was defined as "a pharmaceutical product (i) the manufacture, use, importation or sale of which is covered by a Valid Claim or (ii) is a P13K-delta inhibitor for which clinical trials for an oncology indication are conducted prior to the fifth anniversary of the Closing Date." JX175-013.

[38] JX175-054 § 9(bk)(iv). "Initiation of a Registration Study" was defined as "first dosing of the first patient in such Registration Study." JX175-012. "Registration Study" was defined as a "human clinical trial of a P110 Delta Product on patients, which trial is

The first two of these milestones were each triggered by a "Regulatory Approval" of CAL-101 for a "hematologic cancer indication,"[39] which term was not defined.[40] The draft defined "Regulatory Approval" as "all approvals, licenses, registrations or authorizations by any Regulatory Authority necessary to market a P110 Delta Product in such country or jurisdiction. For clarity, an Accelerated Approval shall constitute a Regulatory Approval."[41] "Accelerated Approval" in turn was defined as "a Regulatory Approval in the United States or an EU Country, based on the results of a single Registration Study (such as Study 101-09), i.e., without a second Registration Study being required to be completed prior to the receipt of such Regulatory Approval."[42]

The February 1 draft of the merger agreement required Gilead to use "Commercially Reasonable Efforts" to achieve all of the milestones "in a prompt and expeditious manner."[43] The term "Commercially Reasonable Efforts" was defined to mean "the expenditure of efforts and resources, consistent with the usual

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designed to establish substantial evidence of the efficacy and/or safety of the P110 Delta Product to support Regulatory Approval of such P110 Delta Product . . . ." JX175-014.

[39] JX175-053-054.

[40] *See generally* JX175; Tr. 161 (Gallagher); Tr. 840 (O'Connell).

[41] JX175-015.

[42] JX175-007.

[43] JX175-056 § 9(bl)(iii)(B).

practice of [Gilead], with respect to development and/or commercialization of its other important pharmaceutical products with significant market potential being actively and diligently pursued by [Gilead]."[44]

After receiving Calistoga's February 1 draft, Sean O'Connell, the lead negotiator for Gilead,[45] prepared a summary of Calistoga's proposed milestones for himself, which stated in relevant part as follows:

> (a) $100M upon first regulatory approval of CAL-101 in US or EU country (whichever occurs first) for hematological cancer
>
> . . .
>
> (c) $75M upon first patient dosing in registrational [*sic*] study for CAL-101 for first line treatment
>
> (d) $75M upon second regulatory approval of CAL-101 in US or EU country (whichever occurs first) for hematological cancer
>
> (e) $50M upon first regulatory approval of a P110 Delta Product for an indication other than hematological cancer (e.g., CAL-101 for solid tumors or back-up compound for any non-hematological cancer indication)[46]

On February 4, 2011, O'Connell sought clarification from Cliff Stocks, Calistoga's lead negotiator,[47] concerning the operation of the first two milestones. Stocks responded in an email the same day, explaining that each of the proposed milestones would have "significant commercial value:"

> As one potential example, iNHL approval in the US and then in an EU Country would trigger the First and Second milestones, respectively.

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[44] JX175-009.

[45] Tr. 829 (O'Connell).

[46] JX185-002 (emphasis in original); Tr. 841-42 (O'Connell).

[47] Tr. 73 (Miller); Tr. 829 (O'Connell).

> As a second potential example, iNHL approval in the US and then CLL approval in an EU Country also would trigger the First and Second milestones, respectively. As a third potential, iNHL approval in the US and then CLL approval in the US also would trigger the first and second milestones, respectively. . . . We believe in any of these cases . . . the event would result in significant commercial value and therefore worthy of the milestone defined.[48]

2. The February 8 Gilead Draft

Later on February 4, O'Connell wrote an email to another member of Gilead's deal team, asking for help to generate "a list of hematological cancers in order of size (either patient number or size of market)," so he could "qualify the . . . milestone payment obligations as only applying to the first or second approval for a 'major' hematological cancer so [Gilead is not] paying a big milestone for a tiny hemonc indication."[49] "Hemonc" was O'Connell's shorthand for "hematological."[50]

On February 6, a consultant from the Boston Consulting Group, which was assisting Gilead, sent O'Connell an email attaching some slides summarizing "estimated size of patient populations for all hematological cancers."[51] The first slide in the attachment listed certain blood cancers in descending order based on the estimated incidence for each cancer in the United States in 2010.[52] O'Connell drew

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[48] JX196-001; Tr. 847-48 (O'Connell).

[49] JX192-001.

[50] *See* Tr. 854 (O'Connell).

[51] JX197-001; Tr. 851 (O'Connell).

[52] JX197-002.

a line on the slide under "Chronic Myeloid Leukemia," which was the last blood cancer on the list with an incidence in the United States exceeding 4,000 in 2010, and placed check marks next to nine of the blood cancers listed above the line.[53]

The nine blood cancers O'Connell selected became Schedule 1.1 in a revised draft of the merger agreement that Gilead sent to Calistoga on February 8, 2011.[54] In this draft, which included an upfront payment of $310 million, Gilead replaced the undefined term "hematologic cancer indication" in the milestone provisions of the February 1 draft with the defined term "Specified Hematologic Cancer Indication," which referred to "any hematologic cancer indication specifically listed on Schedule 1.1."[55] Schedule 1.1 in turn stated as follows:[56]

SPECIFIED HEMATOLOGIC CANCER INDICATIONS

Diffuse Large B-cell lymphoma
Multiple Myeloma
Chronic Lymphocytic Leukemia/Lymphoma
Acute Myeloid Leukemia
Indolent or Follicular Non-Hodgkin's Lymphoma
Hodgkin's Lymphoma
Marginal Zone Lymphoma
Acute Lymphocytic Leukemia
Chronic Myeloid Leukemia

[53] *See* JX197-002; Tr. 852-53 (O'Connell).

[54] JX206-102; Tr. 852-53 (O'Connell).

[55] JX207-021 & 075-076 § 9.1; JX207-019.

[56] JX 207-100.

O'Connell explained that his intent in compiling the Schedule 1.1 was to make sure the milestones were triggered by "significant commercial events for Gilead."[57]

In its February 8 draft, Gilead proposed several other changes to the milestone provisions contained in Calistoga's February 1 draft, three of which are relevant here. First, Gilead revised the definition of "Regulatory Approval" to exclude accelerated approvals so that they would not trigger any of the milestones.[58] Second, Gilead further narrowed the scope of milestone-eligible regulatory approvals by requiring the regulatory approval to come from the United States or a "Major Market Country," which was defined to include only "France, Germany, Spain, Italy and the U.K."[59] Calistoga previously had proposed that the required regulatory approval could come from the United States or any "country that is a member state of the European Union."[60] Third, Gilead removed the obligation to use Commercially Reasonable Efforts to achieve the third milestone once CAL-101 was approved for a Specified Hematologic Cancer Indication in both the United States and a Major Market Country.[61]

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[57] Tr. 852 (O'Connell); *see also* Tr. 913 (O'Connell).

[58] JX207-019; *see also* Tr. 912 (O'Connell).

[59] JX207-014; JX207-075-076.

[60] JX175-011; JX175-053.

[61] JX207-079 § 9.1(b)(iii)(B).

3. The February 12 Calistoga Draft

On February 12, Calistoga sent Gilead a revised draft of the merger agreement that pushed back against Gilead's revisions to the milestone provisions in three ways. First, Calistoga introduced a new Schedule 1.1, set forth below,[62] which defined "Specified Hematologic Cancer Indication" as "[a]ny indication within the following tumor types," and thereafter listed eleven types of tumors. It is undisputed that tumors are "cancers."[63]

SCHEDULE 1.1

SPECIFIED HEMATOLOGIC CANCER INDICATIONS

[Any indication within the following tumor types:

1. B-cell neoplasms
2. T-cell and putative NK-cell neoplasms
3. Hodgkin lymphoma
4. Myeloproliferative neoplasms (MPN)
5. Myeloid and lymphoid neoplasms associated with eosinophilia and abnormalities of *PDGFRA*, *PDGFRB*, or *FGFR1*
6. Myelodysplastic/myeloproliferative neoplasms (MDS/MPN)
7. Myelodysplastic syndrome (MDS)
8. Acute myeloid leukemia
9. Acute leukemias of ambiguous lineage
10. B lymphoblastic leukemia/lymphoma
11. T lymphoblastic leukemia/lymphoma][6]

[62] JX223-017 & 089.

[63] Tr. Oral Arg. 26, 103 (Jan. 10, 2017).

Second, Calistoga again revised the definition of Regulatory Approval to include accelerated approvals.[64] Third, Calistoga reinstated Gilead's obligation to use Commercially Reasonable Efforts to achieve all milestones and added that Gilead shall "refrain from taking any action the primary purpose of which is to avoid the satisfaction of any Milestone."[65]

Significant to this case, when it revised Schedule 1.1 in its February 12 draft, Calistoga relied on the WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues (the "WHO Classification") to establish what "indications" would trigger the regulatory milestones.[66] The WHO Classification, which is compiled by the World Health Organization, is considered the authoritative source of hematologic tumor classifications.[67] Thus, although the subject was a matter of considerable dispute before trial, the evidence at trial clearly establishes that Calistoga effectively incorporated the framework of the WHO Classification into Schedule 1.1 for purposes of defining when the regulatory milestone payments would be due.[68]

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[64] JX224-018.

[65] JX224-079 § 9.1(b)(iii)(B).

[66] *See e.g.*, Tr. 262, 264, 273-74 (Gallagher); Tr. 55, 64 (Miller).

[67] Tr. 389-90, 537 (Arbuck); Tr. 569-70, 574 (Dearden).

[68] There are slight differences in wording between Schedule 1.1 and the top-level tumor types in the WHO Classification, which Dr. Dearden credibly testified are likely the result of the use of different versions of the WHO Classification. Tr. 597-99 (Dearden).

Specifically, in connection with preparing the February 12 draft to send to Gilead, Dr. Gallagher asked Dr. Langdon Miller, Calistoga's Executive Vice President of Research and Development, to prepare "a list of possible indications or possible diseases in which [CAL-101] might be used" that "would be used as part of the definition of the milestone."[69] Dr. Miller was assisted by Dr. Albert Yu, Calistoga's Vice President of Clinical Affairs and Chief Medical Officer.

On February 11, 2011, Dr. Yu emailed Dr. Miller, attaching a document entitled "REAL WHO Classification Lymphoma."[70] The next day, on February 12, Dr. Miller emailed back to Dr. Yu, stating: "Just FYI. Here's the final list sent to Carol [Gallagher]. Myeloid list comes from an update published in Blood in 2009. Thanks for the collective help on this."[71] The 2009 *Blood* article Dr. Miller referred to in his email was an article entitled "The 2008 revision of the World Health Organization (WHO) classification of myeloid neoplasms and acute leukemia: rationale and important changes."[72] Table 2 of the article "lists the major subgroups of myeloid neoplasms and acute leukemia in the WHO classification, and the specific entities of which they are composed."[73]

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[69] Tr. 54 (Miller).

[70] JX217-001.

[71] JX226-001; Tr. 56-57 (Miller).

[72] Tr. 61 (Miller); *see* JX028.

[73] JX028-003; Tr. 62 (Miller).

Dr. Miller testified at trial that the final list he sent to Dr. Gallagher was a combination of the list Dr. Yu had sent him and the list he took from the 2009 *Blood* article.[74] Dr. Miller also testified that the "List of Hematological Malignancies" he prepared is "a list of diseases within hematologic cancer tumor types," which did not include any "subpopulations of patients," "any type of patient risk stratification factors," or any "genetic aberrations in CLL cells."[75]

On February 12, at 12:43 a.m., Dr. Gallagher emailed Calistoga's legal and financial advisors, attaching the "List of Hematological Malignancies" that Dr. Miller had prepared.[76] The email read: "Langdon went to the WHO listing which is attached for a definition of hematological malignancies."[77] The Schedule 1.1 in Calistoga's revision of the merger agreement, which was sent to Gilead at 11:15 a.m. on February 12, tracks the top-level headers in Dr. Miller's list, such as "B-cell neoplasms" and "T-cell and putative NK-cell neoplasms."[78] It does not contain the more specific diseases listed under the top-level headers, but instead uses the phrase

[74] Tr. 47-48, 64 (Miller).

[75] Tr. 57-58, 60 (Miller).

[76] JX227.

[77] JX227-001.

[78] JX223-001.

"Any indication within the following tumor types" before the list of top-level headers to capture the more specific diseases.[79]

4. The February 16 Gilead Draft

After receiving Calistoga's February 12 draft of the merger agreement, O'Connell recognized that the new Schedule 1.1 reflected "the WHO accepted classification system of hematological cancer diseases."[80] O'Connell initially thought it "looked familiar" based on his work in the field and then consulted with Dr. Michael Hawkins, Gilead's Senior Director of Oncology and the clinical advisor on Gilead's deal team, who "confirmed that it was the accepted list of hematological diseases."[81]

Dr. Hawkins corroborated O'Connell's testimony. He explained that, at some point during the merger negotiations, someone on Gilead's team provided him with Calistoga's proposed schedule and asked where it came from.[82] Dr. Hawkins recognized that the list came from the WHO Classification because of the nomenclature, and then went online and confirmed that there was a one-to-one

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[79] *Compare* JX227-002-004 *with* JX223-089.

[80] Tr. 855-56 (O'Connell).

[81] Tr. 856 (O'Connell). Dr. Mansuri testified similarly in deposition. *See* Mansuri Dep. 42-43. Dr. Claire Dearden, Gilead's expert, also testified that Part 1 of Schedule 1.1 was "immediately recognizable" as tumor types defined within the WHO Classification. Tr. 595-98 (Dearden).

[82] Tr. 789 (Hawkins).

correlation between the terms in Calistoga's list and the terms in the WHO Classification.[83] Dr. Hawkins reported back that, "This looks to me like the WHO classification."[84]

Recognizing that Calistoga had "[e]xpanded the definition of 'Specified Hematologic Cancer Indication' to include all hematologic cancer indications" by using the WHO Classification, O'Connell considered making a counter-proposal to limit the hematologic cancer indications that could trigger the milestones to only "those that satisfy a minimum number of annual cases."[85] Gilead prepared an internal draft reflecting this approach, but did not sent it to Calistoga.[86] Gilead instead took a different approach.[87]

Specifically, in a February 16 draft it sent to Calistoga, Gilead introduced a new term—Hematologic Cancer Indication—which was defined as "any hematologic cancer indication specifically identified in Part 1 of Schedule 1.1."[88] Gilead then divided Schedule 1.1 into two parts. Part 1 was identical to the Schedule

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[83] Tr. 789-90 (Hawkins).

[84] Tr. 790 (Hawkins).

[85] JX385-003 (original phrase was in all caps); Tr. 858-59 (O'Connell).

[86] *See* JX247-276 § 9.1(a)(i) & (ii).

[87] JX240.

[88] JX241-012.

1.1 that Calistoga proposed in its February 12 draft.[89] Part 2 was identical to the Schedule 1.1 Gilead proposed in its February 8 draft.[90] Gilead also revised the definition for Specified Hematologic Cancer Indication, which now meant "any hematologic cancer indication specifically identified in Part 2 of Schedule 1.1."[91]

The February 16 draft included an up-front payment of $310 million and up to $300 million in five milestone payments.[92] The first and second milestones of $100 million and $50 million, respectively, would be triggered by the first and second Regulatory Approvals in the United States or in a Major Market Country of CAL-101 for a Hematologic Cancer Indication,[93] unless both approvals were in the same location (*i.e.*, both in the United States or in a Major Market Country), in which case one of the two approvals must be for a ***Specified*** Hematologic Cancer Indication to trigger the second milestone.[94] Once again, Gilead removed accelerated approvals from the definition of Regulatory Approval.[95]

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[89] *Compare* JX241-095 *with* JX223-089.

[90] *Compare* JX241-095-096 *with* JX207-100.

[91] JX241-018.

[92] JX241-019; JX241-072-073 § 9.1(a).

[93] JX241-072-073 § 9.1(a)(i) & (ii).

[94] JX241-072-073 § 9.1(a)(ii). The remaining three milestones in this draft were dropped from the later draft and are irrelevant to the analysis in this opinion.

[95] JX241-017.

Shortly before sending the February 16 draft to Calistoga, O'Connell sent Stocks an email giving him "a heads up on the draft" and summarizing the proposed second milestone as follows:

> $50M 2nd approval in any hematological indication but if it is for a second indication in the same territory as the 1st, 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 hemonc cancers, as we tentatively agreed yesterday in Foster City)[96]

As O'Connell's email to Stocks reflects, the intent of creating the term "Specified Hematologic Cancer Indication" was to create a "narrower list" of "cancers" to trigger the milestone when that term applied rather than the boarder term "Hematologic Cancer Indication."

5. The February 18 Calistoga Draft

On February 18, 2011, the day after Gilead's board of directors authorized the purchase of Calistoga for up to $750 million in total consideration,[97] Calistoga sent Gilead a further revision of the merger agreement. The February 18 draft increased the up-front payment from $310 million to $375 million and contained a new set of three milestones totaling $225 million—down from $300 million in the prior draft.[98] O'Connell summarized the terms of the milestones in an email to Stocks, stating that

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[96] JX256-001.

[97] JX274-007. *See also* Milligan Dep. 84; Mansuri Dep. 111-12.

[98] JX277-018; JX277-072-073 § 9.1(a).

if his summary was correct, "we are in agreement with the economic terms of the agreement:"[99]

> (1) $100M upon first approval of CAL-101 in [the] US or EMA (centralized approval) for any hematologic indication (CRE[100] APPLIES)
> (2) NO EARLY APPROVAL MILESTONE[101]
> (3) $75M upon second approval of CAL-101 in [the] US or EMA, provided that if the second approval is in the same territory as the first, one of the approvals must be for a "specified" hematologic indication (CRE APPLIES)
> (4) $50M for the first to occur of the following: (i) approval of CAL-101 for solid tumors, (ii) approval of CAL-101 as a first-line treatment for any hematologic indication, OR (iii) if annual net sales of CAL-101 exceed $1B (NO CREs)[102]

Calistoga made several other changes to the milestone provisions. First, it revised the definition of Hematologic Cancer Indication in Part 1 of Schedule 1.1 to add a twelfth category to the previous list of eleven tumor types, namely: "Any Specified Hematologic Cancer Indication listed in Part 2 of this Schedule 1.1."[103] Second, it again defined Regulatory Approval to include an accelerated approval,

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[99] JX304-001.

[100] "CRE" and "CREs" are acronyms for "Commercially Reasonable Efforts." *See* Tr. 184 (Gallagher); Mansuri Dep. 120.

[101] In some of the earlier drafts of the merger agreement, the first milestone payment could be increased to $150 million if the first Regulatory Approval was obtained on or before June 30, 2014. *See* JX175-053; JX207-075; JX223-068; JX241-072.

[102] JX304-001.

[103] JX277-096.

which term was not separately defined.[104] Third, it changed the geographical limitation in the milestone provisions from "in the United States or in a Major Market Country" back to "in the United States or in the European Union"—what it proposed in its initial February 1 draft.[105] Finally, it agreed to limit Gilead's obligation to use Commercially Reasonable Efforts to the first two milestones, although it still required Gilead to "refrain from taking any action the primary purpose of which is to avoid the satisfaction of any Milestone."[106]

E. The Parties Finalize and Execute the Merger Agreement

On the evening of February 18, Calistoga informed Gilead that its "Board supports management's recommendation to move forward expeditiously with Gilead to get to a deal announcement by Monday [February 21] night."[107] On February 21, the parties executed the Merger Agreement.

The milestone provisions in the final Merger Agreement differed from Calistoga's February 18 draft in one significant respect: the requirement that Gilead refrain from taking any action for the primary purpose of avoiding the third

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[104] JX277-016-017.

[105] JX277-072-073 § 9.1(a).

[106] JX277-075-076 § 9.1(b)(iii)(B).

[107] JX307-001; Mansuri Dep. 114-16.

milestone payment was removed.[108] The final Schedule 1.1, which was renamed "Section 1.1" in the Company Disclosure Schedule, reads as follows:[109]

Section 1.1 Hematologic Cancer Indications.

PART 1 - HEMATOLOGIC CANCER INDICATIONS:

Any indication within the following tumor types:

- B-cell neoplasms
- T-cell and putative NK-cell neoplasms
- Hodgkin lymphoma
- Myeloproliferative neoplasms (MPN)
- Myeloid and lymphoid neoplasms associated with eosinophilia and abnormalities of PDGFRA, PDGFRB, or FGFR1
- Myelodysplastic/myeloproliferative neoplasms (MDS/MPN)
- Myelodysplastic syndrome (MDS)
- Acute myeloid leukemia
- Acute leukemias of ambiguous lineage
- B lymphoblastic leukemia/lymphoma
- T lymphoblastic leukemia/lymphoma
- Any Specified Hematologic Cancer Indication listed in Part 2 of this Schedule 1.1

PART 2 – SPECIFIED HEMATOLOGIC CANCER INDICATIONS:

- Diffuse Large B-cell lymphoma
- Multiple Myeloma
- Chronic Lymphocytic Leukemia/Lymphoma
- Acute Myeloid Leukemia
- Indolent or Follicular Non-Hodgkin's Lymphoma
- Hodgkin's Lymphoma
- Marginal Zone Lymphoma
- Acute Lymphocytic Leukemia
- Chronic Myeloid Leukemia

[108] JX351-070-071 § 9.1(b)(iii)(B).

[109] JX350-002-003.

Hereafter, I refer at times to the two parts of Section 1.1 of the Company Disclosure Schedule as "Part 1" and "Part 2."

Under Section 9.1(a)(i) of the Merger Agreement, the first milestone payment of $100 million (the "First Milestone") became due fifteen business days after the receipt of "the first Regulatory Approval in the United States or in the European Union, whichever occurs first . . . of CAL-101 for a Hematologic Cancer Indication." Under Section 9.1(a)(ii) of the Merger Agreement, the second milestone payment of $75 million (the "Second Milestone") became due fifteen business days after the receipt of the second "Regulatory Approval of CAL-101 in the United States or in the European Union, whichever occurs first, for a Hematologic Cancer Indication," but if the second approval was obtained in the same location as the first approval, and the First Milestone was "achieved for an indication other than a Specified Hematologic Cancer Indication, then the [Second Milestone] shall not be satisfied unless such second Regulatory Approval is received for a Specified Hematologic Cancer Indication."

Under Section 9.1(a)(iii) of the Merger Agreement, the third milestone of $50 million (the "Third Milestone") became due fifteen business days after the earliest to occur of:

> (A) the receipt of Regulatory Approval of CAL-101 in the United States or the European Union, whichever occurs first, for a solid tumor indication, (B) the receipt of Regulatory Approval of CAL-101 in the United States or the European Union, whichever occurs first, as a first-

> line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer Indication, or (C) Annual Net Sales of CAL-101 achieving at least $1 Billion, so long as such Annual Net Sales are achieved on or before the first day of the first calendar quarter beginning after the Outside Date [*i.e.*, the tenth (10th) anniversary of the Closing Date[110]].

The Merger Agreement further provides that, if the First Milestone has been met but the Second Milestone has not when CAL-101 achieves annual net sales of at least $1 billion, then the Second Milestone shall be deemed to have been met.[111] In other words, the achievement of annual net sales of at least $1 billion for CAL-101 potentially could trigger both the Second and Third Milestones, provided that they have not already been paid and the First Milestone has been met.

In a presentation to Calistoga dated February 21, 2011, the day the Merger Agreement was executed, JP Morgan estimated that there was a 63% chance that the Third Milestone could be triggered by 2019.[112]

On March 8, 2011, after the parties executed the Merger Agreement but before the merger closed, representatives from Calistoga and Gilead met to discuss their

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[110] JX351-068 § 9.1(a)(iv)(A).

[111] JX351-069 § 9.1(a)(iv)(C).

[112] JX345-004. In a footnote, JP Morgan suggested that it believed it was more likely for Calistoga to trigger the third milestone by meeting the $1 billion annual sales requirement than by obtaining a Regulatory Approval of CAL-101 for a solid tumor indication or as a first-line treatment for a Hematologic Cancer Indication.

strategic plans after the merger.[113] A slide deck for the meeting identified a "comprehensive" development program for CAL-101 that Calistoga was generating, which included three registration studies.[114]

F. Gilead's Development of CAL-101 after the Merger

According to a Gilead internal document dated May 3, 2013, Gilead's project review committee had "previously approved two Phase 3 . . . trials [of idelalisib] in previously untreated CLL patients,"[115] and Gilead's idelalisib project team was "requesting approval for a companion single arm Phase 2 study, in order to address the del(17p) patient population which is unlikely to participate in the Phase 3 trials due to concerns of lack of efficacy on either of the control arms."[116] Dr. Hawkins explained the rationale for taking this approach, as follows:

> [The] concern was that if you only had the two Phase 3 studies and you didn't have very many 17p patients in it, that the regulators might come back to you and say[:] "Well, you haven't studied enough 17p patients. And so you can't include them in your label," even though you knew that the drug worked in that population. So to get around that, you create a Phase 2 study, a single-arm study, where all the patients get CAL-101.[117]

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[113] JX371-001; Tr. 778-79 (Hawkins).

[114] JX371-032.

[115] JX434-022.

[116] JX434-001; JX434-022.

[117] Tr. 798 (Hawkins).

The same internal document showed that the idelalisib project team planned to meet with the FDA "to discuss the proposed development plan in untreated CLL (two Phase 3 studies plus this proposed Phase 2 study). Included in this meeting will be a discussion of whether data from the proposed Phase 2 study could support accelerated approval in patients with untreated CLL with 17p deletion."[118]

On September 5, 2013, representatives of Gilead met with FDA officials "to discuss Idelalisib for the treatment of previously untreated chronic lymphocytic leukemia."[119] When requesting this meeting, Gilead stated that the "Proposed Indication" was "[f]or the treatment of previously untreated chronic lymphocytic leukemia (CLL)."[120]

According to the minutes of the September 5 meeting, Gilead asked if the FDA had "any comments on whether [the Phase 2 study in subjects with previously untreated CLL with 17p del and/or *TP53* mutation] meets the requirements for regular approval in patients with previously untreated CLL with 17p del and/or *TP53* mutation."[121] The FDA officials responded that they "do not agree that the proposed study design would be adequate for regulatory submission because it does not isolate

[118] JX434-023.

[119] JX457-001.

[120] JX443-003.

[121] JX457-008.

the effect of idelalisib."[122] Gilead also asked whether the FDA "agree[d] that with demonstration of efficacy of IDELA in the 3 proposed CLL registration studies, a companion diagnostic for 17p del and/or *TP53* mutation will not be required in the post-approval setting."[123] The FDA referred Gilead to the previous response and added that it was "unclear at this time whether a companion diagnostic [would] be required for the indications described in this submission."[124]

G. Gilead Receives Approval from the FDA and Pays the First and Second Milestones

On July 23, 2014, Gilead announced that the FDA had granted approval for CAL-101 under the trade name Zydelig.[125] The FDA-approved label (the "FDA Label") states as follows:

> **----------INDICATIONS AND USAGE----------**
> Zydelig is a kinase inhibitor indicated for the treatment of patients with:
> - Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. (1.1)
> - Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies. (1.2)
> - Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies. (1.3)
>
> Accelerated approval was granted for FL and SLL based on overall response rate. Improvement in patient survival or disease related

[122] JX457-008.

[123] JX457-009.

[124] JX457-009.

[125] PTO ¶ II.19; JX643 ¶ 5.

> symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.[126]

It is undisputed that CLL, FL, and SLL are all B-cell blood cancers, and that CLL and FL are both Specified Hematologic Cancer Indications under Part 2 of Schedule 1.1 of the Merger Agreement.[127]

On July 24, 2014, the day after receiving the FDA Label, Gilead sent Calistoga a notice that the First and Second Milestones had been satisfied, but the notice did not specify which of the three approvals had triggered either the First or Second Milestone.[128] In August 2014, Gilead paid $175 million to the former Calistoga securityholders in satisfaction of those milestone obligations.[129]

H. Gilead Receives Approval from the European Commission

When Gilead sought regulatory approval of idelalisib in the United States, it also sought regulatory approval in the Europe. On October 29, 2013, Gilead submitted a "Marketing Authorization Application" for idelalisib to the European Medicines Agency ("EMA").[130] The application stated that the "proposed

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[126] JX510-001.

[127] JX702 ¶ 5.

[128] *See* JX540.

[129] JX643 ¶ 28; JX702 ¶ 28.

[130] JX455.

indications are treatment of refractory indolent non-Hodgkin lymphoma and, alone or in combination, treatment of relapsed chronic lymphocytic leukaemia."[131]

On June 26, 2014, the Committee for Medicinal Products for Human Use ("CHMP"), the scientific committee of the EMA, provided its preliminary review of Gilead's application. The CHMP noted the exceptional result of idelalisib among patients with either 17p deletion or *TP53* mutation, and asked Gilead "to discuss a potential (explicit) inclusion of these patient groups in the indication for idelalisib, ie as first line treatment."[132]

On June 28, 2014, Gilead responded to the CHMP's preliminary review, noting that:

> The development program for IDELA in CLL has to date reported on clinical outcomes from 153 subjects with either 17p deletion or TP53 mutation; an additional 216 subjects are currently enrolled in the ongoing, randomized studies. Both treatment-naïve and relapsed, refractory subjects with these and other adverse genetic features have been successfully treated with IDELA monotherapy or with IDELA in combination with chemoimmunotherapy.[133]

Gilead also discussed four clinical studies in its response, based on which it proposed "that the data summarized herein are sufficient to support the following proposed indication statement:"

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[131] JX455-002.

[132] JX505-049.

[133] JX508-005.

> *Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):*
> - *who have received at least one prior therapy, or*
> - *as first line treatment in the presence of high-risk features, such as a 17p deletion or TP53 mutation.*[134]

On July 14, 2014, the Rapporteurs (*i.e.*, reporters) for the CHMP issued an assessment report in which they recommended following modified approval for Zydelig:

> Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
> -who have received at least one prior therapy, or
> -as first line treatment in the presence of 17p deletion or *TP53* mutation in patients unsuitable for chemo-immunotherapy.[135]

On July 25, 2014, the CHMP recommended that the European Commission approve Zydelig as a first-line treatment in combination with rituximab for CLL patients in the presence of 17p deletion or *TP53* mutation who are unsuitable for chemo-immunotherapy.[136]

An internal Gilead presentation in this timeframe noted that "17p deletion is an important segment," "[f]rontline is a smaller population," and "[t]he fact that Zydelig is 'EVEN' indicated for frontline (difficult patients) suggests that it should be an excellent option for second/third."[137] Another internal Gilead presentation,

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[134] JX508-006 (emphasis in original).

[135] JX518-004.

[136] *See* JX536; JX537.

[137] JX549-210.

dated August 15, 2014, similarly noted that "[t]he first line indication in the hardest-to-treat patients will have a positive halo effect on the attractiveness of Zydelig," and that going forward, "CLL relapse forecast should assume . . . [s]trong competitive advantage for both Zydelig and irutinib in patients with 17pDel/TP53 which account for 31% of the whole relapse population: expect maximum penetration in this segment at peak."[138]

On September 19, 2014, Gilead announced that it had received approval of Zydelig from the European Commission.[139] The "Summary of Product Characteristics" the European Commission issued in connection with its approval states in relevant part:

> **4.1 Therapeutic indications**
> Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
> - who have received at least one prior therapy, or
> - as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.
>
> Zydelig is indicated as monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.[140]

[138] JX556-077-078.

[139] JX591; JX702 ¶ 29.

[140] JX796-002.

The part of this label authorizing the use of Zydelig "as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy" is referred to hereafter as the "17p/*TP53* Label."

I. Disputes over the Third Milestone Payment Arise

On July 15, 2014, Pat Kilgannon, a former Calistoga employee now working at Gilead, asked Robert Christian, a member of Gilead's Alliance Management team tasked with interacting with Calistoga's former securityholders, whether the potential approval of Zydelig as a "first line treatment in the presence of high-risk features, such as a 17p deletion or *TP53* mutation in patients unsuitable for chemo-immunotherapy" would trigger the Third Milestone.[141] Later that day, Christian forwarded the inquiry to O'Connell.[142]

On July 28, 2014, Chris Letang, a managing director at SRS responsible for monitoring the progress on achieving the milestones, emailed Dr. Topper, Calistoga's founder and Chairman, and Dr. Gallagher, both of whom are members of the committee controlling this litigation on behalf of Calistoga's former securityholders. In his email, Letang recapped the terms of the Third Milestone, stating that one of the triggers for the Third Milestone was "approval as a first-line

[141] JX520; Tr. 947 (O'Connell).

[142] JX520.

drug treatment."[143] The next day, Dr. Gallagher sent an email to her husband containing a link to a Gilead press release announcing that the CHMP had recommended the approval of the 17p/*TP53* Label.[144] The text of the email stated: "Approval in EU as well!"[145]

The Merger Agreement obligates Gilead to provide status reports to SRS periodically concerning the progress of its development and regulatory activities.[146] On August 18, 2014, Christian emailed Dr. Mansuri a draft of such a report, noting in the text of his email that "[t]he Shareholder agent sent me an e-mail last week, asking about the third milestone and its status."[147] Dr. Mansuri replied on August 25: "With regard [to] the final payment, can we not simply say we are looking at this. I still have not had a chance to discuss with John Milligan and Norbert."[148] Milligan was Gilead's President and Chief Executive Officer, and Norbert Bischofberger was its Executive Vice President of Research and Development and Chief Scientific Officer.

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[143] JX567-003; Tr. 312-13 (Gallagher).

[144] JX544; JX536; Tr. 319 (Gallagher).

[145] JX544.

[146] *See* JX351-072 § 9.1(b)(iii)(F).

[147] JX564-002.

[148] JX564-002.

On August 27, 2014, Letang emailed Drs. Topper and Gallagher again, attaching an update report from Gilead.[149] Page 3 of the update report stated that: "Plans for registration trials in patients with previously untreated CLL are being implemented and include two phase 3 studies and one phase 2 study (described below). As of 31 July 2014, 2 studies were open for enrollment."[150] Page 5 of the update report noted the most recent positive opinion from the CHMP concerning Zydelig:

- CHMP Positive Opinion on 24 July 2014—proposed label text below
  The approved indication is:
  - Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): who have received at least one prior therapy, or as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.[151]

The same day, Dr. Topper forwarded Letang's email, including the attached update report, to another partner in his venture capital firm, noting: "Phase 3 upfront trials are enrolling[.] That is one of the triggers for the rest of the milestones[.]"[152]

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[149] JX567-001; JX567-007-013.

[150] JX567-009.

[151] JX567-011.

[152] JX567-001.

On September 19, 2014, the day the European Commission approved the 17p/*TP53* Label, Dr. Topper sent an email to the partners in his venture capital firm entitled "zydelig was approved in EU today." The text of the email stated: "*No milestone*, but good progress to next one."[153]

Also on September 19, Dr. Topper sent an email to some of Calistoga's former executives announcing that "Zydelig was just approved in the EU today."[154] Dr. Roger Ulrich, Calistoga's Chief Development Officer, emailed back, asking what the Third Milestone conditions were.[155] In reply, Dr. Topper wrote: "One of three[:] 1B in sales[;] Approval in an upfront indication for heme malig[;] Approval of a non hem onc indication (solid tumors e.g.)[.] I think first two are likely to happen, given it is phase III in upfront now[.]"[156]

Still on September 19, Kamal Puri, a former Calistoga employee now working at Gilead, asked several former Calistoga executives in an email whether the 17p/*TP53* Label would trigger the Third Milestone.[157] At 2:44 p.m., Dr. Gallagher replied: "The last milestone will most likely be achieved by a sales goal so a few

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[153] JX589 (emphasis added).

[154] JX585-001.

[155] JX585-001.

[156] JX585-001.

[157] JX587.

years away perhaps."[158] At 3:24 p.m., Dr. Yu informed Dr. Gallagher that he had "[j]ust got a message from Leanne that Gilead is indicating the frontline label in subset of CLL patients does not meet milestone" and asked Dr. Gallagher for her thoughts on the subject.[159] At 3:35 p.m., Dr. Gallagher replied to Puri's email again, stating: "I forgot about the front-line path for the milestone. I haven't heard through the official channels yet."[160]

Later on September 19, Dr. Gallagher emailed Letang, stating that since the 17p/*TP53* Label "is a front-line label in a heme malignancy, it seems that this approval could trigger the third milestone."[161] Letang agreed to "take a closer look" and to get back to Dr. Gallagher.[162] On September 20, Dr. Topper also emailed Letang, stating: "With the approval of Zydelig in the EU, for in part, the up front treatment of 17p negative or p53 mutant patients with heme malignancy, it would seem pretty clear that milestone 3 has been satisfied. . . . My suggestion is that we notify Gilead that we believe the milestone has been triggered."[163]

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[158] JX587; Tr. 321-22 (Gallagher).

[159] JX854.

[160] JX586.

[161] JX583-002.

[162] JX583-001.

[163] JX592-001.

On September 24, 2014, Letang emailed Cryn Nutt, corporate counsel at Gilead, stating Calistoga's belief that "the new approvals [in Europe] . . . would appear to trigger the third ($50M) milestone." Letang further stated that he "was hoping to connect with [Nutt] or someone at Gilead to confirm that this milestone was achieved and begin to work through the mechanics for the distribution of the milestone payment."[164]

On October 7, 2014, Christian notified Letang that Gilead did not believe the Third Milestone had been triggered because "the intent of the agreement was that the approval needed to be for a broad indication, not a smaller subset of an indication, for it to trigger the milestone."[165] To date, Gilead has not made the Third Milestone payment.

II. Procedural Posture

On January 14, 2015, SRS filed a complaint against Gilead asserting a single claim for breach of the Merger Agreement for failure to pay the Third Milestone as a result of the European Commission's approval of the 17p/*TP53* Label.

On February 27, 2015, Gilead filed an answer and three counterclaims, which it later amended. The first counterclaim seeks a declaration that the European Commission's approval of the 17p/*TP53* Label did not trigger the Third Milestone.

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[164] JX607-004.

[165] JX609-001; *see also* Letang Dep. 134-35.

The second and third counterclaims, which were asserted in the alternative to the first counterclaim, sought reformation of the Merger Agreement on the grounds of mutual and unilateral mistake. On December 11, 2015, Gilead notified the Court that it had dropped its two reformation counterclaims and associated affirmative defenses.

On January 13, 2016, SRS filed a motion for judgment on the pleadings on its claim for breach of the Merger Agreement and Gilead's remaining counterclaim for declaratory relief. On May 25, 2016, after briefing and argument, I deferred resolution of the motion for judgment on the pleadings until after trial because the scientific and technical nature of the subject matter at issue in this case prevented me from being able to resolve the matter on the pleadings.

III. Analysis

A. Legal Standard

To succeed at trial, "Plaintiffs, as well as Counterclaim-Plaintiffs, have the burden of proving each element, including damages, of each of their causes of action against each Defendant or Counterclaim-Defendant, as the case may be, by a preponderance of the evidence."[166] "Proof by a preponderance of the evidence

[166] *inTEAM Associates, LLC v. Heartland Payment Systems, Inc.*, 2016 WL 5660282, at *13 (Del. Ch. Sept. 30, 2016).

means proof that something is more likely than not."[167] This standard applies to both SRS's claim for breach of the Merger Agreement for failure to pay the Third Milestone, and Gilead's counterclaim for a declaration that the Third Milestone was not triggered by the European Commission's approval of the 17p/*TP53* Label.[168]

"A contract's express terms provide the starting point in approaching a contract dispute."[169] If, on its face, the "contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity."[170] If a contract is ambiguous, however, the Court may consider extrinsic evidence, including "evidence of prior agreements and communications of the parties as well as trade usage or course of dealing."[171]

Under Delaware's objective theory of contracts, "a contract is not rendered ambiguous simply because the parties do not agree upon its proper construction. Rather, a contract is ambiguous only when the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more

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[167] *Id.*

[168] *See Medicalgorithmics S.A. v. AMI Monitoring, Inc.*, 2016 WL 4401038, at *17 (Del. Ch. Aug. 18, 2016).

[169] *Ostroff v. Quality Servs. Labs., Inc.*, 2007 WL 121404, at *11 (Del. Ch. Jan. 5, 2007).

[170] *GMG Capital Inv., LLC v. Athenian Venture P'rs I, L.P.*, 36 A.3d 776, 783-84 (Del. 2012) (quoting *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997)).

[171] *Eagle Indus.*, 702 A.2d at 1233.

different meanings."[172] In considering extrinsic evidence, the Court should uphold, "to the extent possible, the reasonable shared expectations of the parties at the time of contracting."[173] "In giving effect to the parties' intentions, it is generally accepted that the parties' conduct before any controversy has arisen is given 'great weight.'"[174]

Importantly, ascertaining the shared intent of the parties does not mandate slavish adherence to every principle of contract interpretation. As this Court recently stated: "Contract principles that guide the Court—such as the tenet that all provisions of an agreement should be given meaning—do not necessarily drive the outcome. Sometimes apparently conflicting provisions can be reconciled, but in order to prevail on a contract claim, a party is not always required to persuade the

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[172] *Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1196 (Del. 1992).

[173] *Comrie v. Enterasys Networks, Inc.*, 837 A.2d 1, 13 (Del. Ch. 2003).

[174] *Ostroff*, 2007 WL 121404, at *11; *see also Radio Corp. of Am. v. Philadelphia Storage Battery Co.*, 6 A.2d 329, 340 (Del. 1939) ("It is a familiar rule that when a contract is ambiguous, a construction given to it by the acts and conduct of the parties with knowledge of its terms, before any controversy has arisen as to its meaning, is entitled to great weight, and will, when reasonable, be adopted and enforced by the courts. The reason underlying the rule is that it is the duty of the court to give effect to the intention of the parties where it is not wholly at variance with the correct legal interpretation of the terms of the contract, and a practical construction placed by the parties upon the instrument is the best evidence of their intention.").

Court that its position is supported by every provision or collection of words in the agreement."[175]

B. The Term "Indication" is Ambiguous as used in the Merger Agreement

The provision of the Merger Agreement at the center of this dispute is the Third Milestone, which states that:

> Within fifteen (15) Business Days following . . . (B) the receipt of Regulatory Approval of CAL-101 in the United States or the European Union, whichever occurs first, as a first-line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer Indication . . ., [Gilead] shall notify [SRS] that the [Third Milestone] has been satisfied and pay or cause to be paid to the Company Securityholders in accordance with Section 9.1(b) Fifty Million Dollars ($50,000,000), as such amount may be adjusted pursuant to Section 9.1(b).[176]

It is undisputed that the 17p/*TP53* Label constituted a "Regulatory Approval of CAL-101 in the European Union," but it is heavily disputed whether CAL-101 was approved "as a first-line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer Indication," and in particular, what the word "indication" means as used in this term.

"Hematologic Cancer Indication" is defined in the Merger Agreement to mean "any hematologic cancer indication specifically identified in Part 1 of Section 1.1 of

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[175] *Cyber Hldg. LLC v. CyberCore Hldg., Inc.*, 2016 WL 791069, at *7 (Del. Ch. Feb. 26, 2016).

[176] JX351-068 § 9.1(a)(iii)(B).

the Company Disclosure Schedule."[177] Part 1 of Section 1.1 of the Company Disclosure Schedule in turn states that "Hematologic Cancer Indications" means "[a]ny indication within the following tumor types," the first of which is "B-cell neoplasms," and the last of which is "[a]ny *Specified* Hematologic Cancer Indication listed in Part 2 of this Schedule 1.1."[178]

"Specified Hematologic Cancer Indication" is defined in the Merger Agreement as "any hematologic cancer indication specifically identified in Part 2 of Section 1.1 of the Company Disclosure Schedule."[179] Part 2 of Section 1.1 lists nine specific diseases, including "Chronic Lymphocytic Leukemia," or CLL.[180]

The definitions in the Merger Agreement are only the starting point, rather than the end, of the parties' dispute. As witnesses for both SRS and Gilead testified, in the oncology industry, the meaning of the term "indication" is context specific.[181] Depending on the context, for example, it could refer to a "disease," a "tumor," "an indication for starting treatment in a patient," or "a regulatory approval."[182]

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[177] JX351-011.

[178] JX350-002 (emphasis added).

[179] JX351-016.

[180] JX350-002.

[181] *See, e.g.*, Tr. 88 (Miller); Tr. 336 (Gallagher); Tr. 386; 502 (Arbuck); Tr. 613 (Dearden); Tr. 889 (O'Connell).

[182] *See, e.g.*, Tr. 88 (Miller); Tr. 386-87, 502 (Arbuck); Tr. 889 (O'Connell).

Gilead contends that in the context of the Merger Agreement the only reasonable interpretation of the word "indication" is that it means a "disease."[183] By contrast, SRS contends that the only reasonable interpretation of the word is "the approved use of a drug in a population of patients with a particular disease."[184] Thus, according to SRS, the term "indication" does not describe a disease but instead "refers to the label or indication statement that Gilead receives from a regulatory authority such as the EMA or FDA," which describes "the particular patient population with that disease that a drug can be used to treat."[185] Despite their sharp disagreement, SRS and Gilead both argue that the Merger Agreement is unambiguous and that the plain language of the contract supports their respective interpretations.

"Indication" appears five times in Schedule 1.1, and the parties agree that it has the same meaning in all five places.[186] The parties also agree that Part 2 of Schedule 1.1 (set forth below) is a list of blood cancers or diseases.[187]

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[183] Answering Post-Trial Br. 45.

[184] Opening Post-Trial Br. 1.

[185] Opening Post-Trial Br. 44; *see also* Reply Post-Trial Br. 2.

[186] Tr. Oral Arg. 16; Answering Post-Trial Br. 46-47; *see also* Tr. 523-24 (Arbuck); Tr. 601-02 (Dearden).

[187] Tr. 166; 273 (Gallagher); Tr. 602 (Dearden); *see also* Answering Post-Trial Br. 45; Reply Post-Trial Br. 7.

PART 2 – SPECIFIED HEMATOLOGIC CANCER INDICATIONS:

- Diffuse Large B-cell lymphoma
- Multiple Myeloma
- Chronic Lymphocytic Leukemia/Lymphoma
- Acute Myeloid Leukemia
- Indolent or Follicular Non-Hodgkin's Lymphoma
- Hodgkin's Lymphoma
- Marginal Zone Lymphoma
- Acute Lymphocytic Leukemia
- Chronic Myeloid Leukemia

Building on this point of agreement, Gilead argues that, since "Specified Hematologic Cancer Indications" is defined as "any hematologic cancer indication specifically identified in Part 2" and since Part 2 consists of a list of diseases, it logically follows that the term "Hematologic Cancer Indications" as used in Part 1 also must refer to diseases.

SRS advances two arguments in response to Gilead's plain meaning argument. First, SRS argues that to interpret "indication" to mean "disease" would render the very same word superfluous as used in the phrase "Hematologic Cancer Indications," contrary to the principle of contract construction that each word in a contract must be given meaning and effect. It is undisputed that a "hematologic cancer" is a "blood cancer," which is a disease.[188] Therefore, according to SRS, if "indication" also means "disease," it adds nothing to the phrase "Hematologic

[188] Tr. 718 (Dearden).

Cancer Indication." In essence, SRS argues that people in the oncology industry do not use the phrase "hematologic cancer disease" or "cancer disease" because that would be repetitive.

Although this argument has some appeal to a law-trained judge accustomed to applying interpretative principles to construe a contract, the reality of life is that human language is not perfect.[189] In this case, for example, O'Connell, Gilead's lead negotiator, used the term "hematologic cancer diseases" at least ten times in a natural, unforced manner when responding to questions at trial.[190] As reflected in numerous publications, moreover, people in the oncology industry in fact do use the phrase "cancer diseases" or "hematologic cancer diseases," including in peer-reviewed journals, to describe the disease of cancer or blood cancer.[191] Thus, I am

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[189] *See Atlantic Northern Airlines v. Schwimmer*, 96 A.2d 652, 656 (N.J. Supr. 1953) ("Language is only too often an imperfect and uncertain means of communicating ideas and concepts.").

[190] *See e.g.*, Tr. 846; 852; 859-60; 864; 919; 920; 956 (O'Connell). O'Connell also used "hematological cancer" and "hematologic cancer indication" interchangeably in Gilead's internal documents concerning the milestones. *See, e.g.*, JX185-002.

[191] Gilead's Objs. to New Reply Evid. 2-3 (citing nine different publications). Although Gilead submitted these publications after the close of the evidence, I take judicial notice of them in the interests of fairness because they were submitted in response to certain dictionary definitions SRS relied on for the first time in its post-trial reply brief and because the contents of these publications are not subject to reasonable dispute. *Khanna v. McMinn*, 2006 WL 1388744, at *30 (Del. Ch. May 9, 2006) ("[T]he Court may take judicial notice 'of matters that are not subject to reasonable dispute.'").

not persuaded that it would be unreasonable to construe "indication" to mean "disease" based on SRS's surplusage argument.[192]

SRS next argues that Gilead's interpretation of "indication" to mean "disease" makes no sense when the initial clause of Part 1 is read together with the last bullet point in Part 1. More specifically, according to SRS, it would be nonsensical "to read the reference in the disclosure schedule to '[a]ny indication within . . . any Specified Hematologic Cancer Indication listed in Part 2 of this Schedule 1.1' as meaning '[a]ny [disease or blood cancer] within . . . any Specified Hematologic Cancer Indication'" because "Part 2 of the Company Disclosure Schedule lists only 'diseases' such as CLL" but "there are no diseases '***within***' CLL."[193] Although a highly technical point, this discrepancy illustrates an apparent inconsistency when Gilead's proffered interpretation is applied to all uses of the word "indication" found in Schedule 1.1.

SRS's plain meaning argument, on the other hand, suffers from more profound problems. To start, there is no obvious textual anchor in the Merger Agreement from which to import into the word "indication" the concept of a regulatory label reflecting an "approved use of a drug in a population of patients

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[192] *See Cyber Hldg. LLC*, 2016 WL 791069, at *7 ("in order to prevail on a contract claim, a party is not always required to persuade the Court that its position is supported by every provision or collection of words in the agreement.").

[193] Opening Post-Trial Br. 53 (emphasis added) (citation omitted).

with a particular disease," as SRS advocates. Additionally, it is difficult to see how such a construction can be reconciled with the fact that Part 2 of Schedule 1.1 concededly defines "Specified Hematologic Cancer Indications" to mean a specified list of diseases.

SRS counters that it is consistent for Part 2 to be a list of blood cancers and for "indication" to mean an approved label or an indication statement, since a label normally would identify both the type of disease and the population of disease sufferers the drug is approved to treat.[194] This contention is unconvincing. It is true that a drug label would identify the specific disease the drug is approved to treat, but that does not turn the label into a disease. The definition of Specified Hematologic Cancer Indication in the Merger Agreement is clear in my view. It is "any hematologic cancer indication specifically identified in Part 2 of Section 1.1 of the Company Disclosure Schedule." What is identified in Part 2 is a list of diseases, not labels that describe diseases.

For the reasons discussed above, I find the word "indication" to be ambiguous when considered within the four corners of the Merger Agreement. This result is hardly surprising given the shifting positions both parties have taken in this litigation. In its motion for judgment on the pleadings, for example, SRS advanced

[194] Reply Post-Trial Br. 7-8.

a seemingly different interpretation, arguing that the term Hematologic Cancer Indication meant "[t]he basis for initiation of a treatment or of a diagnostic test."[195] For its part, Gilead did not display much confidence in the plain meaning of the term at the outset of this case when it asserted, albeit in the alternative, that the Merger Agreement should be reformed because of a mutual or unilateral mistake—claims it has since abandoned.[196] Given the ambiguity, I turn to extrinsic evidence to interpret the term.

C. The Parties' Negotiation History Demonstrates that "Indication" Means "Disease" in the Merger Agreement

When the extrinsic evidence in the record is considered, in particular the negotiation history concerning the Merger Agreement, the overwhelming weight of the evidence demonstrates in my opinion that the parties mutually understood when they entered into the Merger Agreement that the term "indication" meant "a disease." I begin by recapping the evolution of the terms "Hematologic Cancer Indication" and "Specified Hematologic Cancer Indication" as the parties negotiated the milestone structure in the Merger Agreement.

On January 28, 2011, Gilead made its preliminary offer to Calistoga, proposing three milestones, two of which were based on regulatory approvals of

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[195] JX729-027-028 n.9.

[196] JX702-037-040.

CAL-101 for one of two specific blood cancers, *i.e.*, indolent Non-Hodgkin's Lymphoma (iNHL) or Chronic Lymphocytic Leukemia (CLL).[197] On February 1, Calistoga sent Gilead the first draft of the merger agreement, introducing a new set of four milestones, the first two of which would be triggered by regulatory approvals for a "hematologic cancer indication," which term was not defined.[198]

On February 8, Gilead responded with a revised draft of the merger agreement in which it replaced the undefined term "hematologic cancer indication" with a defined term "Specified Hematologic Cancer Indication," which referred to "any hematologic cancer indication specifically listed on Schedule 1.1."[199] Gilead's proposed "Schedule 1.1" was a list of nine blood cancers O'Connell had compiled with the assistance of the Boston Consulting Group for the purpose of limiting the milestone payments to "major" blood cancers.[200]

On February 12, Calistoga sent Gilead another draft of the merger agreement, replacing Schedule 1.1 in Gilead's last draft with a new list of eleven tumor types that came under the heading "Specified Hematologic Cancer Indications."[201] Significantly, as discussed above, the trial record clearly establishes that Calistoga

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[197] JX160-003 (emphasis added).

[198] JX175-053-054 § 9(bk)(i)&(ii).

[199] JX207-075-076 § 9.1(a); JX207-019.

[200] JX206-102; Tr. 852 (O'Connell).

[201] JX223-089.

derived its list of eleven tumor types from the top level categories of diseases in the WHO Classification, which lists numerous other diseases under these eleven categories. These subcategories of diseases were not listed by name in Calistoga's February 12 revision of Schedule 1.1, but to ensure that the disease subcategories would trigger a milestone payment, Calistoga inserted a clause before the list of eleven tumor types stating: "Any indication within the following [eleven] tumor types." Dr. Gallagher, the person who oversaw Calistoga's sale process, confirmed at trial that the "within the following tumor types" language "was intended to sweep in the subcategories of diseases."[202]

When Gilead received Calistoga's February 12 draft, it recognized that Calistoga's revision of Schedule 1.1 tracked the WHO Classification and thus that Calistoga was seeking to expand Gilead's prior list of nine blood cancers "to include all hematologic cancer indications" in the WHO Classification.[203] On February 16, Gilead went back with a compromise in order to narrow the triggers for the second milestone that was under discussion.

Specifically, in its February 16 draft, Gilead divided Schedule 1.1 into two parts, Part 1 being the last schedule Calistoga had proposed on February 12, and Part

[202] Tr. 271 (Gallagher); *see also* Tr. 67-68 (Miller).

[203] JX385-003.

2 being the nine blood cancers Gilead had proposed on February 8.[204] The draft introduced a new defined term "Hematologic Cancer Indication," meaning "any hematologic cancer indication specifically identified in Part 1 of Schedule 1.1," and changed the definition of "Specified Hematologic Cancer Indication" to mean "any hematologic cancer indication specifically identified in Part 2 of Schedule 1.1."[205] Under the February 16 draft, if both the first and the second regulatory approvals were in the same location (*i.e.*, the United States or a Major Market Country), then in order for the second milestone to be triggered, one of the two approvals had to be for a Specified Hematologic Cancer Indication.[206]

On February 18, Calistoga sent another draft to Gilead, proposing a new set of three milestones and adding what became the twelfth and final bullet to the definition of Hematologic Cancer Indication in Part 1 of Schedule 1.1, namely to include "[a]ny Specified Hematologic Cancer Indication listed in Part 2 of this Schedule 1.1."[207] Although the record provides no definitive evidence of the reason for this late change to Schedule 1.1, the timing of its addition—coming two drafts after Calistoga already had introduced into Part 1 of the schedule the "within the

[204] JX241-095-096.

[205] JX241-012; JX241-018.

[206] JX241-072-073 § 9.1(a)(ii).

[207] JX277-096.

following tumor types" language to pick up the subcategories of diseases for the first eleven bullets—suggests to me, and I so find, as Dr. Gallagher testified,[208] that it was added simply to make clear (for the avoidance of any doubt) that the Specified Hematologic Cancer Indications "listed in Part 2" also were included in Part 1. The final Merger Agreement maintained the milestone structure and Schedule 1.1 from the February 18 draft.[209]

In sum, the drafting history of the Merger Agreement shows that the parties always were talking about regulatory approval of CAL-101 ***for a disease*** when they were negotiating over the milestone payments. By contrast, the drafting history does not reflect that the parties were discussing regulatory labels when negotiating the triggers for the milestone payments. Indeed, to find that "indication" means "label" or "label approval" would contradict Dr. Gallagher's testimony that "the 'within the following tumor type' language was not intended to depart from the scientifically recognized definition of diseases," that "no one at Calistoga evinced, in words or deeds, to Gilead that the purpose of Section 1.1 was to depart from the scientifically recognized definition of diseases," that she "never told anyone at Gilead that the purpose of the 'any hematologic indication' language in Schedule 1.1 was to sweep

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[208] Tr. 273 ("Q. And the purpose of the last bullet point in part 1 is to confirm that it also sweeps in the specific blood cancers listed in part 2, correct? A. Yes."); *see also* Arbuck Dep. 81.

[209] JX350-002-003; JX351-067-068 § 9.1(a).

in any patient with any genetic mutation that may also have a blood cancer," and that it "was not the intent of Calistoga to depart from the scientific[ally] accepted definition of 'tumors' when it prepared Schedule 1.1."[210]

In addition to the merger agreement drafts, other contemporaneous communications between SRS and Gilead show that both parties used "indication" as synonymous for "disease" during their negotiations. For example, when O'Connell sought clarification from Stocks concerning the operation of the milestones in the first draft of the merger agreement that Calistoga had prepared, Stocks focused on approvals for diseases (*e.g.*, iNHL and CLL) as the triggers for the first two milestones:

> As one potential example, *iNHL approval* in the US and then in an EU Country would trigger the First and Second milestones, respectively. As a second potential example, *iNHL approval* in the US and then *CLL approval* in an EU Country also would trigger the First and Second milestones, respectively. As a third potential, *iNHL approval* in the US and then *CLL approval* in the US also would trigger the first and second milestones, respectively.[211]

As another example, in a February 16 email to Stocks to give him "a heads up" on Gilead's forthcoming revisions to the merger agreement, O'Connell characterized the trigger for second milestone as an approval for a blood cancer:

> $50M 2nd approval in any hematological indication but if it is for a second indication in the same territory as the 1st, one of the two

[210] Tr. 271-72 (Gallagher).

[211] JX196-001 (emphasis added).

> indications would need to be in the narrower list of *Specified Hematological Indication (i.e., CLL, iNHL and the other major hemonc cancers, as we tentatively agreed yesterday in Foster City)*[212]

Calistoga also used "indication" to refer to "diseases" in some of the presentations and regulatory materials it sent to Gilead during the negotiations.[213] In fact, Dr. Gallagher expressed no surprise to the prospect of being shown "presentation after presentation in which 'indication' was used as synonymous with 'blood cancer' at Calistoga,"[214] and testified that when using the word "indication" in a presentation to refer to blood cancers, Calistoga was "trying to use it in the way that folks generally in the industry use it."[215]

In contrast to the abundance of evidence supporting Gilead's position, SRS could point to little concrete evidence in its favor. Gilead's February 16 draft of the merger agreement defined the term "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."[216] Pointing to this definition, SRS argues that Gilead "specifically used the

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[212] JX256-001 (emphasis added).

[213] *See, e.g.*, JX123-018; JX874-009 § 2.2; JX377-007 § 2.2; JX086-011 § 3; JX086-046 § 10.1.7 ("in the indications indolent B-cell NHL, MCL and CLL"); JX086-152 § 4; Stocks Dep. 25-26; Tr. 507-11 (Arbuck).

[214] Tr. 245 (Gallagher).

[215] Tr. 240-43 (Gallagher) (discussing JX183-014).

[216] JX241-016.

term ‘particular indication or indications’ to describe the use of a drug in a patient population with a disease.”[217] This definition, however, actually makes as much, if not more, sense if “indication” means “disease” than if it means “label,” because people normally talk about the “effectiveness of a drug for a particular [disease] or [diseases],” as opposed to the “effectiveness of a drug for a particular [label] or [labels].”

SRS next points to some slide presentations during the parties’ negotiations where the term “indication” was used to refer to “the approved use of a drug” in the context of regulatory approval.[218] But as discussed above, the parties also used “indication” to refer to “disease” in those presentations as well as in regulatory materials Calistoga shared with Gilead.[219] Thus, this evidence is non-conclusive and just highlights a point on which both parties agree—that use of the term “indication” in the oncology industry is context specific.

The fact that SRS failed to identify any better evidence to support its interpretation is hardly surprising, considering Dr. Gallagher’s admission that she could not recall any time during the negotiations when Calistoga told Gilead that “indication” meant “a label that you would receive for the specific patient population

[217] Opening Post-Trial Br. 56.

[218] Opening Post-Trial Br. 56-60.

[219] *See supra* note 213.

that you would treat with the hematologic cancer."[220] Nor could she recall any time during the negotiation when Calistoga used the term "indication" to refer to any genetic subpopulations.[221]

In an attempt to make up for a scarcity of helpful evidence from the negotiation history, SRS argues that the Court should construe the milestone provisions in the context of regulatory approval of a drug, and cites to parts of the record where people testified that in the regulatory approval context, "indication" could mean the indication statement in a drug label. Putting aside that SRS used "indication" to refer to "disease" in some of its own regulatory materials that it shared with Gilead during the negotiations, as discussed above,[222] this argument misses the mark. The milestone at issue here is triggered by a regulatory approval, but the appropriate context in which the contract provision should be construed is the context in which the Merger Agreement was negotiated, which is evinced, first and foremost, by the parties' contemporaneous communications, such as their exchange of drafts of the merger agreement.[223]

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[220] Tr. 233 (Gallagher).

[221] Tr. 256-57 (Gallagher).

[222] *See* JX086-011 § 3; JX086-046 § 10.1.7 ("in the indications indolent B-cell NHL, MCL and CLL"); JX086-152 § 4.

[223] *See* Tr. 246 (Gallagher).

For all the reasons discussed above, the overwhelming weight of the extrinsic evidence demonstrates in my opinion that the parties mutually understood when they entered into the Merger Agreement that the term "indication" meant "a disease."

D. The Third Milestone Can Only Be Triggered by a Disease-Level Approval

SRS next argues that even if the word "indication" means a blood cancer or disease, the Third Milestone was still triggered because the Merger Agreement does not specify that a Regulatory Approval must cover an entire population of disease sufferers to qualify for the milestone. More specifically, SRS argues that even though the 17p/*TP53* Label limited the patient population to those with "17p deletion or *TP53* mutation [who are] unsuitable for chemo-immunotherapy," Zydelig still was approved as a first-line treatment for CLL.[224] The parties do not dispute that CLL is a blood cancer within the tumor type B-cell neoplasms listed in Part 1 of Schedule 1.1 as well as a Specified Hematologic Cancer Indication listed in Part 2 of Schedule 1.1.[225] Thus, according to SRS, the 17p/*TP53* Label triggered the Third Milestone under both Parts 1 and 2.

I disagree with SRS's position for two basic reasons. First, the negotiation history of the milestone provisions, the subsequent conduct of SRS's own witnesses,

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[224] Opening Post-Trial Br. 61.

[225] JX702 ¶ 5.

and the structure and operation of the milestone provisions all support the conclusion that the form of regulatory approval necessary to trigger a milestone payment must be a disease-level approval. Second, the 17p/*TP53* Label does not satisfy the disease-level approval requirement in the Third Milestone.

1. The Parties' Negotiation History Demonstrates, and Their Subsequent Conduct Confirms, that only a Disease-Level Regulatory Approval Could Trigger the Third Milestone

Simplifying its second line of argument to its essence, SRS contends that the "key is . . . are the people being treated with this drug for diseases [that are] listed" in Schedule 1.1.[226] In other words, under SRS's logic, as long as Zydelig was approved to treat a subpopulation of CLL patients, no matter how small that subpopulation may be, the Third Milestone payment would be due. Fatal to SRS's position, however, is that this argument finds no support in the parties' negotiation history.

As discussed in detail above, the extrinsic evidence demonstrates that the parties were discussing ***disease-level*** regulatory approvals throughout their negotiations over the milestones.[227] No evidence was presented suggesting that they discussed approvals for subpopulations of disease sufferers when negotiating the milestones. As Dr. Hawkins testified, that subject "never came up" during the

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[226] Tr. Oral Arg. 49.

[227] *See supra* Section III.C.

negotiations.[228] Rather, the consistent focus of the parties' discussions was on ***which diseases*** would trigger the milestones. Indeed, by incorporating the WHO Classification—an authoritative list of hematologic tumors—into Part 1 of the Schedule 1.1, and by agreeing to a specific list of diseases in Part 2, the parties effectively excluded subpopulation approvals as a trigger for a regulatory milestone. In short, for the same reasons I have concluded that the term "indication" means "disease" in the Merger Agreement, the form of regulatory approval required to trigger a milestone payment under the Merger Agreement logically must be a disease-level approval.

SRS points to evidence that Calistoga "repeatedly rejected Gilead's efforts to limit the application of the milestones as (a) applying only to major hematological cancers; (b) as applying only to approvals in 'Major Market Countries;' and (c) as not including accelerated or conditional approvals."[229] This evidence is beside the point. The fact that SRS was successful in expanding the list of blood cancers that could trigger a milestone (from the two initial diseases Gilead proposed (iNHL and CLL) to all of the blood cancers in the WHO Classification), and in broadening the scope of the necessary Regulatory Approval (to include more countries and accelerated approvals), may have enlarged the number of opportunities to trigger a

[228] *See* Tr. 795 (Hawkins).

[229] Opening Post-Trial Br. 62 n.26; *see also* Reply Post-Trial Br. 18-19.

milestone payment in certain respects, but that does not change the fact that the necessary approval had to occur at the disease level.

The conduct of Calistoga's principals before the dispute in this action arose confirms my finding that both parties understood that the milestones could only be triggered by a disease-level regulatory approval. Dr. Gallagher (who oversaw the merger negotiations) and Dr. Topper (Calistoga's founder and Chairman at the time of the merger) both worked with SRS to oversee this litigation on behalf of Calistoga's former securityholders.[230] Significantly, for the two-month period from July 29, 2014, when the CHMP publicly recommended the 17p/*TP53* Label, until September 19, 2014, when Gilead publicly announced the European Commission's approval of the 17p/*TP53* Label, they both believed that the Third Milestone was not due.[231] Indeed, neither of them concluded that the Third Milestone had been triggered even after first learning about the European Commission's approval of the 17p/*TP53* Label.

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[230] Tr. 315 (Gallagher).

[231] Dr. Gallagher admitted that she did not inform anyone between July 29, 2014 and August 27, 2014 that she believed the Third Milestone was triggered. Tr. 319-20 (Gallagher). Dr. Topper similarly admitted that, on August 27, 2014, after reading a Gilead update report disclosing both CHMP's positive opinion on Zydelig and the fact that Gilead was conducting two phase 3 studies and one phase 2 study in patients with previously untreated CLL, he looked to the phase 3 trials, rather than the 17p/*TP53* Label, as the potential trigger for the Third Milestone. JX567; Topper Dep. 25-26.

On September 19, 2014, upon learning about the European Commission's approval, Dr. Topper specifically said in an email entitled "zydelig was approved in EU today" that "*No milestone*, but good progress to next one."[232] Later that day, in emails responding to two separate inquiries from former Calistoga employees as to whether the 17p/*TP53* Label triggered the Third Milestone, both Drs. Topper and Gallagher, who had been reminded about the terms of the Third Milestone in an email from SRS as recently as July 28, 2014,[233] took the same position.

At 2:38 p.m., Dr. Topper, after summarizing the three triggers in the Third Milestone in his email, did not say that the milestone had been triggered because of the 17p/*TP53* Label, but that it was "likely" the milestone would be satisfied in the future because of the pending Phase III study: "I think first two [triggers] are *likely* to happen, given it is phase III in upfront now."[234] At 2:44 p.m., Dr. Gallagher also did not say that the milestone had been triggered because of the 17p/*TP53* Label, but that it "most likely" would be triggered under the $1 billion sales subpart of the milestone: "The last milestone will most likely be achieved by a sales goal so a few years away perhaps."[235]

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[232] JX589 (emphasis added).

[233] JX567-003.

[234] JX585-001 (emphasis added).

[235] JX587; Tr. 321-22 (Gallagher).

Dr. Gallagher attempted to minimize this evidence at trial, testifying emphatically that shortly after sending her 2:44 p.m. email she pulled out a copy of the Merger Agreement at her home office and reviewed the milestone provisions, which prompted her to send out another email at 3:35 p.m. saying she "forgot about the front-line path for the milestone."[236] Putting aside that the meaning of the 3:35 p.m. email is inconclusive, Dr. Gallagher's explanation for why she sent it strains credibility given her previous testimony that she had not read the Merger Agreement on September 19, 2014, and that she was out of town that day and thus could not have reviewed it then at her home as she claimed so confidently at trial.[237]

Noting that the reactions of Drs. Topper and Gallagher discussed above occurred several years after the Merger Agreement was signed, SRS argues that this evidence is not useful to the interpretation of the Merger Agreement. Although contemporaneous evidence is far more probative of the shared expectations of contracting parties as a general matter, that does not mean that a party's subsequent conduct has no probative value. Indeed, this Court has stated that, "[i]n giving effect to the parties' intentions, it is generally accepted that the parties' conduct before any controversy has arisen is given 'great weight.'"[238] That proposition rings

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[236] JX586, Tr. 353-58 (Gallagher).

[237] Tr. 363-64 (Gallagher).

[238] *Ostroff*, 2007 WL 121404, at *11. In support of its position, SRS relies on *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228 (Del. 1997). There, the Supreme Court

particularly true here, where the party whose conduct is at issue acts in a manner directly contrary to their personal financial interests.

In any event, even if I were to completely disregard this evidence, it would make no difference. The extensive evidence concerning the negotiation of the milestone provisions is more than sufficient by itself in my opinion to support the conclusion that the parties both understood that a disease-level approval was necessary to trigger the Third Milestone. The Topper/Gallagher admissions are merely corroborative. Also corroborative are reasonable inferences concerning the commercial logic of the Third Milestone that can be drawn from its structure and operation, which I address next.

2. The Structure and Operation of the Milestone Provisions Further Corroborates that the Regulatory Approval Must Be at the Disease Level

SRS argues that the Third Milestone "was a great deal for Gilead" even if it could be triggered by a regulatory approval in a subpopulation of disease sufferers as evidenced by the fact that Gilead was not obligated to use "Commercially Reasonable Efforts" to meet the Third Milestone and was not even prevented from taking any action for the primary purpose of avoiding the Third Milestone.[239] In

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did not proscribe reliance on all subsequent conduct evidence, but commented only that "backward-looking evidence gathered after the time of contracting is *not usually helpful*." *Eagle Indus.*, 702 A.2d at 1233 n.11 (emphasis added).

[239] *See* JX351-070 § 9.1(b)(iii)(B).

SRS's words, Gilead "had the liberty under the contract to actually [step] in front of the train and stop the third milestone from happening."[240]

The problem with this reasoning is that if the Third Milestone could be triggered by a subpopulation approval, then the First and Second Milestones logically also could be triggered by subpopulation approvals, since they similarly were conditioned upon a regulatory approval of CAL-101 for a Hematologic Cancer Indication.[241] But Gilead was obligated to use Commercially Reasonable Efforts to achieve the first two milestones and to refrain from taking any action the primary purpose of which was to avoid the satisfaction of the first two milestones.[242]

There are genetic mutations within CLL that are present in only 0.44% of CLL patients.[243] Thus, under SRS's reasoning, Gilead negotiated a Merger Agreement that potentially obligated it to pay $175 million if it received regulatory approvals for the treatment of patients who have CLL and a mutation present in 0.44% of CLL.[244] Not only is this interpretation contrary to reasonable business expectations,

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[240] Tr. Oral Arg. 42; Opening Post-Trial Br. 66.

[241] JX351-067-068 § 9.1(a)(i)-(ii).

[242] JX351-070 § 9.1(b)(iii)(B).

[243] JX705-023.

[244] SRS contends that Gilead "had no obligation to pursue a milestone that it did not believe would result in [significant commercial gain]" because Commercially Reasonable Efforts was defined as efforts "consistent with the usual practice of [Gilead], with respect to development and/or commercialization of its other important pharmaceutical products with significant market potential being actively and diligently pursued by [Gilead]." Reply

it contradicts the express language of the Merger Agreement, which states that "[t]he parties acknowledge and agree that [Gilead's] achievement of the Milestones are material factors in determining the valuation of [Calistoga by Gilead]."[245]

The structure of the Third Milestone itself suggests that the parties did not contemplate it would be triggered by a frontline approval for treatment of a subpopulation of disease sufferers. As set forth below, the Third Milestone could be triggered by the earliest to occur of three events:

> (A) the receipt of Regulatory Approval of CAL-101 in the United States or the European Union, whichever occurs first, for a solid tumor indication, (B) the receipt of Regulatory Approval of CAL-101 in the United States or the European Union, whichever occurs first, as a first-line drug treatment (i.e., a treatment for patients that have not previously undergone systemic drug therapy therefor) for a Hematologic Cancer Indication, or (C) Annual Net Sales of CAL-101 achieving at least $1 Billion, so long as such Annual Net Sales are achieved on or before the first day of the first calendar quarter beginning after the Outside Date [*i.e.*, the tenth (10th) anniversary of the Closing Date].[246]

Post-Trial Br. 17. But this would not necessarily shield Gilead from the risk of milestone payments for approvals in a tiny population. If, for example, Gilead pursued a disease-level approval, but the Regulatory Authority only granted an approval for treatment of a small subpopulation of the disease sufferers because of weakness in its data or for some other reason, Gilead could be required as a practical matter to make the milestone payments under SRS's theory even if the approval was not commercially valuable. *See* Arbuck Dep. 88, 190 ("[I]f the European Union asked you to do something, you'd do what they ask you to do. . . . [A]nd for sure if they asked us to submit language to get an indication, we would do that.").

[245] JX351-072 § 9.1(b)(iii)(E).

[246] JX351-068 § 9.1(a)(iii).

As Calistoga's lead negotiator Stocks testified, each of the three subparts were "intended to recognize value inflections that could lead to significant commercial reward."[247] Obtaining an approval for a solid tumor in satisfaction of the first subpart would be highly valuable because it would expand the drug's use "to a completely different class and universe of cancers."[248] The commercial value of achieving annual net sales of at least $1 billion in satisfaction of the third subpart is self-evident.[249] Given Stocks' testimony, which accords with common sense and which I credit, one reasonably would expect that satisfaction of the second subpart—Regulatory Approval of CAL-101 as a first-line drug treatment for a Hematologic Cancer Indication—also was intended to reward an event of significant commercial success. Yet the record is devoid of any hard evidence that a first-line regulatory approval for a small subpopulation of disease sufferers would yield such a result.

SRS's best evidence on this point is Dr. Gallagher's testimony that "having any first-line approval gives a halo effect to the drug, to be able to then continue to broaden the use" because even though the drug "may be indicated for this small

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[247] Stocks Dep. 52.

[248] Yu Dep. 70; Tr. 872 (O'Connell) ("[S]olid tumors is very large diseases, much larger than hematological diseases in terms of patient numbers. So it meant a significant commercial gain, really an upside for Gilead that we hadn't even anticipated."); Tr. 803-04 (Hawkins).

[249] Yu Dep. 70.

patient population . . . it tells physicians that there's a positive risk/benefit profile that would then have them think about using it in other first-line indications."[250] Dr. Gallagher also acknowledged, however, that the parties put in the "$1 billion annual sales" trigger of the Third Milestone as a "backstop" or "schmuck insurance" for protection for "a small approval."[251] Although not dispositive, the existence of such a backstop cuts against the notion that the second subpart of the Third Milestone was intended to trigger an immediate payment for a sub-disease level approval (*i.e.*, before a meaningful amount of sales is achieved), particularly if, as Stocks testified, each of the three subparts was intended to capture events that one reasonably would expect to lead to a significant commercial reward.

3. SRS's Other Subpopulation Arguments Also Fail

I next address two remaining arguments SRS advances in support of its subpopulation approval argument. First, SRS contends that the FDA Label that triggered the First and Second Milestones was itself a subpopulation approval.[252] The FDA Label approved Zydelig for the treatment of patients with:

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[250] Tr. 188-89 (Gallagher).

[251] Tr. 210-12, 359-60 (Gallagher); *See also* Tr. 873-76 (O'Connell). Indeed, under Section 9.1(a)(iv)(C) of the Merger Agreement, if the First Milestone has been met but the Second Milestone has not been met when CAL-101 achieves annual net sales of at least $1 billion, then Gilead would be obligated to make both the Second and Third Milestone payments.

[252] Tr. Oral Arg. 57.

- Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. (1.1)
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies. (1.2)
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies. (1.3)[253]

In other words, the FDA Label contained three approvals. The first approval was for the treatment of relapsed CLL patients with certain co-morbidities; the second approval was for the treatment of FL patients who were receiving third-line or later therapies; and the third approval was for the treatment of SLL patients who were receiving third-line or later therapies.

SRS asserts that the concept of "relapse" or "third-line" denotes "subpopulation" in the same sense as genetic mutations such as 17p deletion or *TP53* mutation.[254] This argument is disproved by both the language of the Merger Agreement and trial testimony.

The Third Milestone expressly separates the concepts of "lines of therapy" and "Hematologic Cancer Indication" by requiring "receipt of Regulatory Approval of CAL-101 . . . as *a first-line drug treatment* . . . for a *Hematologic Cancer Indication*."[255] As Dr. Gallagher admitted, when "the parties were thinking about

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[253] JX510-001.

[254] *See* Opening Post-Trial Br. 62.

[255] JX351-068 § 9.1(a)(iii)(B) (emphasis added). *See also* Tr. 617-18 (Dearden).

hematologic cancer indication, whatever it meant, it was defined separately from the line of treatment."[256]

Gilead's lead negotiator O'Connell explained that he understood lines of therapy to be a description of usage rather than a subpopulation of patients because at each stage of therapy, the same patient is being treated.[257] Drs. Hawkins and Dearden concurred.[258] SRS's witnesses also do not seriously dispute the point. Dr. Miller expressly agreed that the same patient could receive different lines of treatment,[259] and Dr. Arbuck agreed that first line, second line and later lines are "usage descriptors."[260] Therefore, even though the second and third approvals under the FDA Label were for patients who were receiving third-line or later treatments, these two approvals were still at the disease level.

The first approval under the FDA Label, on the other hand, was limited to relapsed CLL patients "for whom rituximab alone would be considered appropriate therapy due to other co-morbidities" and thus might be considered a subpopulation approval. But as SRS itself acknowledged, it did not know whether the first approval

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[256] Tr. 250-51 (Gallagher). *See also* Stocks Dep. 40-41 (line of therapy "doesn't have anything to do with tumor type").

[257] Tr. 835-36 (O'Connell).

[258] Tr. 774-75 (Hawkins); 633 (Dearden).

[259] Tr. 76 (Miller).

[260] Tr. 493-94 (Arbuck).

was a basis for triggering either of the first two milestones because the notice Gilead sent out announcing satisfaction of the first two milestones did not specify which of the three approvals in the FDA Label triggered them.[261]

Second, SRS contends that the parties' inclusion of "accelerated approval or conditional approval" in the definition of "Regulatory Approval" shows that Gilead contemplated paying milestones for a subpopulation of disease sufferers.[262] SRS acknowledges, however, that "accelerated or conditional approval is granted upon a showing of unmet medical need."[263] It has no direct correlation with whether the approval sought is for a disease or a subpopulation.[264] Indeed, in the FDA Label that Gilead received, the FDA granted disease-level accelerated approvals of Zydelig for third-line treatment of two diseases: follicular B-cell non-Hodgkin lymphoma (FL) and small lymphocytic lymphoma (SLL).[265]

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[261] Tr. Oral Arg. 58; *see* JX540.

[262] Opening Post-Trial Br. 63.

[263] Opening Post-Trial Br. 63 (emphasis added); *see also* Tr. 23 (Miller); Tr. 151-52 (Gallagher); Tr. 401-02 (Arbuck); Tr. 907-08 (O'Connell).

[264] Tr. 784 (Hawkins).

[265] JX510-001. Another example is that the drug Imbruvica recently received accelerated approval as a second-line treatment for "Mantle cell lymphoma (MCL)," a blood cancer. JX841-001.

In view of the extrinsic evidence as well as the structure and operation of the milestone provisions discussed above, I conclude that to trigger the second subpart of the Third Milestone, the required regulatory approval must be at the disease level.

4. The European Commission Did Not Approve CAL-101 as a First-Line Drug Treatment for the Disease CLL

Having determined that the required form of regulatory must be a first-line disease-level approval, the final issue is whether the17p/*TP53* Label constitutes such an approval. SRS contends that the European Commission's approval "unquestionably" was for a "first line treatment for the disease CLL."[266] The record, however, is replete with evidence to the contrary.

In a March 18, 2016 report concerning certain safety issues related to idelalisib, the EMA's Pharmacovigilance Risk Assessment Committee observed that "[p]reviously untreated CLL" is "[n]ot an authorized indication for CLL."[267] Reviewing this report, SRS's expert, Dr. Arbuck, agreed that the EMA was observing that "Idelalisib in Europe was not previously approved as front line or for previously untreated CLL patients."[268] Dr. Miller testified similarly, stating

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[266] Opening Post-Trial Br. 61.

[267] JX723-005.

[268] Tr. 460. Dr. Arbuck re-characterized her testimony at trial to suggest that the report meant that idelalisib had not been approved for "all" persons with CLL. *Id.* 466-67. Even if true, it would not matter because, as discussed above, only a disease-level approval could trigger the second subpart of the Third Milestone.

explicitly that "Zydelig has not been approved in Europe *for the disease of CLL*."[269] Both witnesses also admitted that there is no disease recognized as "within" CLL.[270]

Both sides agree that a first-line approval is "the culmination of a complex regulatory program proceeding through trials that appropriately demonstrate safety and efficacy as treatment for the disease" and makes the drug a "gold standard."[271] Gilead received the 17p/*TP53* Label, however, in a situation very different from the typical first-line drug approval process. For example, although Zydelig had demonstrated effectiveness in CLL patients, including those with 17p deletion or *TP53* mutation, Gilead had not even completed the "pivotal" phase 3 studies in previously untreated CLL patients when the 17p/*TP53* Label was approved.[272] As the CHMP's Rapporteurs noted in their July 14, 2014 assessment report, "the front-line experience for idelalisib in del17p / TP53 is limited to 9 patients" and the follow-up period was only 6 to 12 months.[273] In other words, as expert witnesses from both sides testified, the efficacy and safety data for Zydelig was insufficient to support a regulatory approval as a first-line treatment for the disease CLL.[274]

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[269] Tr. 114 (Miller) (emphasis added). *See also* Tr. 112 (Miller).

[270] Tr. 67 (Miller); 527-29 (Arbuck).

[271] Tr. 79-80 (Miller), 804 (Hawkins), Tr. 649 (Dearden); *see also* JX372-031.

[272] *See* JX567-001, JX567-009, Bischofberger Dep. 78-79; Tr. 624 (Dearden) (describing "Phase 3 randomized trials" as being "pivotal").

[273] JX518-003; *see also* Tr. 626-27 (Dearden).

[274] *See* Tr. 624-25, 633-34, 637 (Dearden); Tr. 482, 478-79 (Arbuck).

The European Commission nevertheless granted the 17p/*TP53* Label not as a first-line treatment for the disease of CLL, but to address the dire needs of a specific subpopulation of patients with CLL. As Gilead's expert Dr. Dearden credibly explained, the EMA was,

> making an exceptional circumstance for an exceptional population of patients who not only have this genetic abnormality, but also were unable to receive other treatments, that they don't have options. That couldn't be more different from the situation of a regular CLL patient, who has in the first-line a number of excellent options for treatment that have been well defined through pivotal registration Phase 3 randomized trials.[275]

In sum, when Gilead submitted its application to the EMA on October 29, 2013, it sought approval of CAL-101 for treatment of "*relapsed* chronic lymphocytic leukaemia."[276] Gilead did not seek approval of CAL-101 as a first-line treatment for the disease CLL, and the record shows that it did not receive such an approval.

IV. Conclusion

For the reasons explained above, SRS has failed to prove by a preponderance of evidence that the 17p/*TP53* Label triggered the Third Milestone under the Merger Agreement, and Gilead has proven by a preponderance of evidence that it did not. Accordingly, SRS's motion for judgment on the pleadings is DENIED. Gilead is entitled to judgment in its favor on its counterclaim for declaratory judgment and on

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[275] Tr. 624 (Dearden).

[276] JX455-002 (emphasis added).

SRS's claim for breach of contract. The parties are directed to submit an implementing form of final order and judgment within five business days.

IT IS SO ORDERED.