

IN THE SUPREME COURT OF THE STATE OF DELAWARE

SHAREHOLDER REPRESENTATIVE	§	
SERVICES LLC, in its capacity as the	§	
Stockholders' Agent for the former	§	No. 162, 2017
securityholders of Calistoga	§	
Pharmaceuticals, Inc.,	§	
	§	
Plaintiff Below-Appellant,	§	Court Below: Court of
	§	Chancery of the State of
v.	§	Delaware
	§	
GILEAD SCIENCES, INC. and GILEAD	§	C.A. No. 10537-CB
BIOPHARMACEUTICS IRELAND	§	
CORPORATION,	§	
	§	
Defendants Below-Appellees.	§	
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GILEAD SCIENCES, INC. and GILEAD	§	
BIOPHARMACEUTICS IRELAND UC,	§	
	§	
Counterclaimants	§	
Below-Appellees,	§	
	§	
v.	§	
	§	
SHAREHOLDER REPRESENTATIVE	§	
SERVICES LLC, in its capacity as the	§	
Stockholders' Agent for the former	§	
securityholders of Calistoga	§	
Pharmaceuticals, Inc.,	§	
	§	
Counterclaim-Defendant	§	
Below-Appellant.	§	
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Submitted: November 1, 2017
Decided: December 12, 2017

Before **STRINE**, Chief Justice; **VALIHURA**, **VAUGHN**, **SEITZ**, and **TRAYNOR**, Justices, constituting the Court *en Banc*.

ORDER

In this appeal, the parties differ on the meaning of contractual language critical to whether a milestone payment is due to a corporation that sold itself to another corporation. In a thorough decision, the Court of Chancery concluded that certain key language in the acquisition agreement, “Hematologic Cancer Indication,” was ambiguous, considered the parol evidence, and concluded that the term meant one of the diseases listed in Schedule 1.1 to the Merger Agreement.¹ The milestone payment that is at issue was only due upon “receipt of Regulatory Approval of CAL-101 . . . 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.”²

Based on his determination that Hematologic Cancer Indication meant disease, that the relevant disease in Schedule 1.1 for which regulatory approval was sought was Chronic Lymphocytic Leukemia (“CLL”), that first-line approval was not granted for the treatment of CLL, but only for a sub-population of patients with one of two genetic defects that constituted about one-tenth of the overall CLL

¹ *Shareholder Rep. Servs. LLC v. Gilead Sciences, Inc.*, 2017 WL 1015621, at *1 (Del. Ch. Mar. 15, 2017).

² App. to Opening Br. at 131 (Merger Agreement art. IX, § 9.1(a)(iii)).

population, the Chancellor held that no milestone payment was due.³ Although there was evidence on the other side of the question, the Court of Chancery's decision was supported by sufficient record evidence, and resolved the contractual ambiguity in a commercially sensible manner. In this situation, it is our duty to defer to a trial judge's properly supported fact findings and we thus affirm. We note in this regard that the record evidence was that the parties hoped that first-line treatment approval would be granted for CLL as an entire disease class and that approval of that type was not obtained. The milestone payment of \$50 million is not a trifle. This provides commercial context supporting the Chancellor's determination that the approval necessary to trigger the payment was of the disease the parties sought, not of a small subset (around 10%) of the patients suffering from the disease for which approval was received.⁴ This, along with other evidence, such as the text of Schedule

³ *Shareholder Rep. Servs. LLC*, 2017 WL 1015621, at *3, 28–29.

⁴ Transcript of Oral Argument on Plaintiff's Motion For Judgment On The Pleadings at 74–75, *Shareholder Rep. Servs. LLC v. Gilead Sciences, Inc.*, 2017 WL 1015621 (Del. Ch. Mar. 15, 2017) (“Here’s what’s undisputed in the pleadings. CLL, that population is over 17,000 patients in Europe. That’s who could have been addressed if we would have received an indication within the tumor type. What we received is something that allows us to address less than 200 patients, a miniscule number. No rational human being could ever make back, much less the investment in first-line, not putting aside the 50 million or 75 million or 100 million, if milestones were based on rare genetic mutations, you would never make the money back. You might as well have just burned it.”); *Shareholder Rep. Servs. LLC*, 2017 WL 1015621, at *3 n.29 (citing record evidence estimating the percentage of patients subject to the approval received as five to fifteen percent of what was sought); Deposition Testimony of Dr. Derrell Porter (“[T]he number of patients that the 17p deletion/TP53 approval language applies to is less than a thousand; and even our expectations for the number of patients that Zydelig would be treating, the number of these patients that would use Zydelig and be treated with Zydelig was less than 200. . . . I mean, the likelihood that Gilead will capture any benefits financially from that approval language for 17p/TP53 patients is almost with certainty zero.”).

1.1 that refers to a list of diseases including CLL, supports the resolution of the ambiguity in the manner chosen by the Chancellor.

With this context in mind, we therefore AFFIRM the Court of Chancery's March 24, 2017 Final Judgment and Order on the basis of its detailed March 15, 2017 decision.

FOR THE MAJORITY:

/s/ *Leo E. Strine, Jr.*

Chief Justice

SEITZ, Justice, dissenting, with **TRAYNOR**, Justice, joining:

Because we write only for the parties to this contractual dispute, we will not repeat in detail the analysis ably conducted by the Chancellor in his post-trial opinion. The Court of Chancery thoughtfully considered the language of the Purchase Agreement, found the parties’ use of the words “Hematologic Cancer Indication” ambiguous, weighed the parol evidence, and decided that Hematologic Cancer Indication referred to a “disease” listed in Schedule 1.1 to the Purchase Agreement.⁵ As the Majority notes, we defer to that finding on appeal.

Where we part company is the second step of the court’s analysis—that “disease” also meant “disease-level approval” when it came to the third milestone payment. Under the Purchase Agreement, the third milestone payment is due when three conditions are met: (1) “receipt of Regulatory Approval of CAL-101”; (2) as a “first-line drug treatment”; and (3) “for a Hematologic Cancer Indication.”⁶ The first two conditions were not seriously in dispute. CAL-101, the Gilead drug, received regulatory approval in Europe as a first-line treatment. Also not in dispute were the patients covered by the regulatory approval—“adult patients with chronic

⁵ *Shareholder Rep. Servs. LLC v. Gilead Sciences, Inc.*, 2017 WL 1015621, at *19 (Del. Ch. Mar. 15, 2017).

⁶ App. to Opening Br. at 131 (Merger Agreement art. IX, § 9.1(a)(iii)).

lymphocytic leukaemia (CLL) . . . in the presence of 17p deletion or *TP53* mutation in patients unsuitable for chemo-immunotherapy.”⁷

In our opinion, the analysis should have ended there. Gilead received regulatory approval for its drug from the European Union as a first-line treatment for patients with CLL—a disease listed in Schedule 1.1. That they also had a genetic abnormality is irrelevant. Under the plain language of the Purchase Agreement, and in particular Schedule 1.1, the third milestone payment was due.

Instead of applying the unambiguous meaning of the word disease by reference to the diseases listed in Schedule 1.1, however, Gilead persuaded the court to embark on a search for ambiguity where there was none, and added a “disease-level” approval requirement to trigger the third milestone payment. The court’s interpretation of “disease,” however, “burdens that term with far more precision than it can reasonably bear.”⁸ Neither the Purchase Agreement nor Schedule 1.1 contained such a condition. We would apply the plain meaning of “disease” with reference to Schedule 1.1, and find that the European Union’s approval for patients

⁷ App. to Answering Br. at 136 (EUROPEAN MEDS. AGENCY, PRAC ASSESSMENT REPORT ON PROVISIONAL MEASURES 4 § 2.1 (Mar. 18, 2016)).

⁸ *BLGH Holdings LLC v. enXco LFG Holding, LLC*, 41 A.3d 410, 415 (Del. 2012). The Majority points to the commercial reality that CLL patients with the genetic abnormality make up about 10% of CLL patients. The parties did not, however, define the trigger for the third milestone payment in economic terms. Whether the trigger the parties chose made financial sense was irrelevant when no ambiguity existed about the meaning of the term “disease.” See *Nemec v. Shrader*, 991 A.2d 1120, 1126 (Del. 2010) (“Parties have a right to enter into good and bad contracts, the law enforces both.”).

with CLL satisfied the conditions for the third milestone payment. We respectfully dissent.