EFiled: Aug 12 2021 04:47PM EDT
Filing ID 66843055
Case Number 170,2021

IN THE

Supreme Court of the State of Delaware

SHIRE US HOLDINGS, INC. and SHIRE PHARMACEUTICALS LLC, Defendants Below-Appellants, v. SHAREHOLDER REPRESENTATIVE SERVICES LLC, in its capacity as the Equityholders' Representative for the former stockholders of FerroKin BioSciences, Inc., Plaintiff Below-Appellee.	**No. 170, 2021** COURT BELOW: COURT OF CHANCERY OF THE STATE OF DELAWARE, CONSOLIDATED C.A. No. 2017-0863-KSJM

APPELLEE'S ANSWERING BRIEF

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NATURE OF PROCEEDINGS

This appeal arises from a judgment of the Court of Chancery that Shire was bound by a contract to pay $45 million to the former stockholders of FerroKin BioSciences. That contract (the "Agreement," A466-551) concerned the drug deferitazole, which FerroKin initially developed and Shire bought to develop further. The core of the bargain concerned how to balance the discretion Shire wanted over deferitazole's development with the assurance FerroKin required that Shire would not abandon product development prematurely. The parties therefore agreed to structure several of Shire's payments to FerroKin around a sequence of milestones, the first of which is central to this appeal.

Specifically, they agreed that Shire would make a $45 million milestone payment ("Phase III Milestone Payment") when it began Phase III clinical trials for deferitazole. They further agreed that, even if those trials had not begun by December 31, 2015, Shire still had to make that payment, subject to a narrow exception. That exception applied only if Shire's failure to timely begin Phase III trials was "as a result of" a circumstance (known as "a Fundamental Circumstance") in which material safety or efficacy concerns made it impracticable for Shire to obtain regulatory approval for, or to produce and sell, deferitazole. A492 (§ 2.9(f)).

Shire neither initiated Phase III clinical trials nor made the payment on (or after) December 31, 2015. Instead, in February 2015, Shire notified Plaintiff

Shareholder Representative Services ("SRS"), the representative of the former FerroKin stockholders, that Shire was terminating the deferitazole program and declaring the occurrence of a Fundamental Circumstance. But the Court of Chancery held, and Shire now concedes, that Shire's own business decisions independently made it inevitable that Shire would not timely initiate Phase III trials. In a carefully reasoned opinion, the Court of Chancery held that, because Shire's failure to timely initiate Phase III clinical trials was not "*as a result of* a Fundamental Circumstance," Shire's duty to make the payment was not excused. This Court should affirm.

SUMMARY OF ARGUMENT

I. Denied. Under the Agreement, by default, the Phase III Milestone is "deemed to have been achieved" as of a date certain, and Shire must make the associated payment. The Agreement carves out just one exception ("other than"), which applies only if a specific causal relation is shown ("as a result of a Fundamental Circumstance"): it applies, that is, *only* if a Fundamental Circumstance not only occurs, but also *is the reason* that Shire then fails to timely achieve the Phase III Milestone. As Shire now concedes, its own prior business decisions guaranteed it would fail to timely initiate Phase III clinical trials. The Court of Chancery thus properly held that, even assuming a Fundamental Circumstance had later occurred, Shire's failure to timely initiate Phase III clinical trials did not arise "as a result of" such "a Fundamental Circumstance," and the sole exception to Shire's duty to pay does not apply.

Shire, for its part, reads "other than as a result of" out of the Agreement. It retreats to generalizations about "how parties to a pharmaceutical merger agreement allocate risk" (OB 22), "the very purpose of milestone payments" (OB 23), and what "a reasonable party" would have expected (OB 25). But Shire does not tether these abstractions to this case. Nor can it, as the record shows there is nothing "absurd" about the "results" (OB 3) that follow from § 2.9(f)'s causal inquiry. The parties sensibly allocated *ex ante* the burdens and benefits of

developing deferitazole: FerroKin surrendered control of its prized asset's development only in exchange for a deadline requiring Shire to initiate Phase III trials or to incur a cost, unless specified exceptional circumstances caused Shire to fail to do so. This Court should thus affirm, holding Shire to the bargain the parties struck.

II. Denied. The Court of Chancery also properly placed on Shire the burden to prove that the "as a result of a Fundamental Circumstance" exception is satisfied. That result follows from black-letter law because Shire is attempting to use that exception to avoid an existing obligation. Shire's contrary assertion would require SRS to prove a negative, in conflict with basic burden-assignment principles. Accordingly, even if the Court remands the case for additional proceedings, it should affirm the Court of Chancery's assignment of the burden.

STATEMENT OF FACTS

I. FACTUAL BACKGROUND

A. Citing Great Promise for Deferitazole, Shire Bids To Acquire FerroKin

FerroKin was founded by Dr. Hugh Rienhoff to develop a novel iron chelation drug called deferitazole. An iron chelator is a molecule with a "very high affinity for iron" that is used to absorb excess iron in transfusion-dependent patients with hematological diseases. Memorandum Opinion ("MO") 2; B31 (Rienhoff). FerroKin sought Food and Drug Administration ("FDA") permission to begin clinical trials in 2009, and the FDA gave that permission soon thereafter. B2215; B182.

By 2011, FerroKin had received promising results in early clinical trials and had raised $27 million from investors. B147-52; B510. But with costly Phase III trials looming,[1] FerroKin faced a choice between raising additional capital and selling itself to a larger company, like Shire, that would take over development. A167 (Rienhoff). Opting for the latter approach, FerroKin looked at companies with "drugs in similar stages of development, with similar potential market opportunities," and determined that a total sales price in the $300 to $500 million

[1] In "Phase III" clinical trials, "clinicians conduct studies negotiated and designed with the FDA with the goal of getting the drug approved by the FDA and placed on the market." MO 3.

range "would be a price that [it] would consider." B34 (Henner); *accord* MO 8; B342.

While FerroKin began exploring an acquisition, Shire had begun "build[ing] a hematology business unit," for which it identified deferitazole as a potential "corner stone" asset. B9 (Girard); A198 (Girard). From the outset, Shire recognized that deferitazole was a "[h]igh risk / high reward opportunity," but, given its "[p]otential superiority to [the] gold standard," A275, A277, Shire ultimately thought the deal was worth finalizing, B20 (Murdoch), "even if $ doesn't always add up," B185-86.

B. The Agreement Reflected Shire's Insistence on Developmental Autonomy and FerroKin's Need for a Commitment to Advancement

Although the parties quickly settled on a framework for a deal—an upfront payment and a series of milestone payments, together totaling hundreds of millions of dollars, B210—a key "disconnect" emerged, B40 (Girard). Whereas Shire wanted "the right, in [its] sole and absolute discretion, to direct and control the development" of the drug, B211, FerroKin wanted to "protect[ ] against events such as changes in corporate priorities within Shire" by "defin[ing] [the] efforts Shire must make to progress product development" and imposing "consequences for NOT making progress," B264; B260.

The parties' negotiations "centered" on these "two issues: the structure of the milestone payments and the degree to which Shire would be obligated to pursue development of deferitazole." MO 11. Shire's initial drafts called for several milestone payments, but left Shire without any obligation to achieve them. *E.g.*, A311-84; B266-340. FerroKin's draft, in contrast, included both milestone payments and commercially reasonable efforts provisions obligating Shire to develop deferitazole. *E.g.*, A385-461; B348-422.

In particular, because FerroKin wanted the agreement to contain "something that would compel [Shire] to go forward and not just can the program . . . at [its] whim," Rienhoff suggested inserting two time-based milestone payments into an early draft.[2] The first milestone would be tied to the initiation of a Phase III clinical trial and would be "deemed" "achieved" as of "545 days after the Closing Date" if not already satisfied. A413. The second would require Shire to pay all remaining milestones if it "substantially abandoned" the product before December 31, 2020, and the abandonment was "other than as a result of the occurrence of a Fundamental Circumstance." *Id.* Shire rejected all of FerroKin's proposed additions. B291-92.

[2] A168 (Rienhoff); *see* MO 11-12; *accord* A169, A170 (Rienhoff), A192 (Girard stating that Rienhoff sought assurance Shire would start Phase III), A198 (Girard agreeing that FerroKin "wanted some assurance that Shire would devote resources to the drug"); *see also* B12 (Girard).

But giving Shire "sole and absolute discretion" to develop the drug without any incentive to do so was a nonstarter for FerroKin. As Rienhoff explained to his Shire counterpart, "[g]iven that more than two-thirds of the total consideration to FerroKin is deferred well past closing . . . [and] given that FerroKin is not for sale for $100 or $150 million, FerroKin stakeholders need[ed] strong assurances that Shire w[ould] advance the program." B263. Rienhoff was therefore "very disappoint[ed]" in Shire's refusal to agree to any of FerroKin's suggestions, expressing that "a transaction so heavily dependent on the achievement of milestones . . . must be accompanied by Shire commitments to diligently pursue clinical development and commercialization assuming the product is safe and effective." A463-64; *see* MO 13.

The parties resolved their disagreement following a January 27, 2012 meeting. B39 (Girard); B344; B345-47. FerroKin accepted language (ultimately reflected in § 2.9(g) of the Agreement) giving Shire "sole and absolute discretion" to control development. B373. In return, Shire agreed to a time-based milestone payment (in § 2.9(f)) that was all but guaranteed: it would be due automatically on December 31, 2015, subject only to FerroKin's previously proposed exception for a "Fundamental Circumstance"—something akin to a fundamental failure of the drug. B427.

These provisions thus became the "heavily negotiated" resolution to the parties' "yin and yang" objectives concerning milestones and "control of the development program." B10, B12 (Girard); B36 (Henner). That is, they reflected a "tradeoff": § 2.9(g) would afford Shire "absolute discretion" as to how quickly and how far to pursue development of deferitazole, but § 2.9(f) would constrain Shire to make at least the Phase III Milestone Payment if it delayed development beyond the anticipated timeline or abandoned the project for any reason "other than as a result of a Fundamental Circumstance."[3] As § 2.9(f)'s text makes clear, it "provide[d] Shire with only a narrow escape" from its payment obligation, serving as "a FerroKin-friendly backstop" against Shire's control over development, MO 72:

> Notwithstanding anything else in this Agreement to the contrary, in the event that [Shire] has not achieved the Initiation of the Phase III Clinical Trial Milestone on or before December 31, 2015, other than as a result of a Fundamental Circumstance, then the Initiation of Phase III Clinical Trial Milestone shall be deemed to have been achieved on such date.

A492 (§ 2.9(f)).

The parties executed the Agreement on March 14, 2012, A470, and the transaction closed on April 2, 2012, A124-25 (¶ 37). Shortly thereafter, Shire internally acknowledged that § 2.9(f)'s payment obligation could be triggered purely by the "end of Expiration Period"—that is, the mere passage of time to December

[3] B12 (Girard); A173 (Rienhoff); *accord* B11, B13-14 (Girard).

31, 2015. B468. In Shire's words, "[a] delay would trigger the payment of the milestone based on timing." B918. Shire in fact estimated that there was a 19% chance it would have to pay the milestone as a result of delay—compared to just a 1% chance of avoiding payment. *Id.*; *see also* A552.

C. Commonplace Drug Development Challenges and Budgetary Considerations Delayed the Start of Phase III Trials Into 2016

Shire made business decisions that made it inevitable by November 2013 that Shire would not initiate Phase III trials before December 31, 2015. MO 54-65.

In April 2012, when it took control of deferitazole, Shire expected to begin Phase III trials in late 2013. MO 19; B440. Almost immediately, however, Shire's decisions made that goal unlikely. "The first decision that delayed deferitazole's overall development timeline was Shire's choice to switch to twice-daily dosing in Study 203." MO 55-56; *see* B2035. Further decisions—to shift focus from one patient population to another and to change the drug's formulation—injected additional uncertainty into the development program. *E.g.*, B1969. By April 2013, Shire had pushed Phase III trials into early 2015. B2153.

Thereafter, Shire delayed development again. By April 2013, Shire faced "[d]ownward changes in Shire revenue forecasts" that had "resulted in a 2017 projected revenue gap of $700[million]." B571. That month, Shire appointed a new CEO, Dr. Flemming Ornskov, with a mandate to focus Shire on "late stage development" and implement a "[n]ew operating model" with "a leaner footprint

and cost structure." B621. Ornskov learned on his first official day as CEO that deferitazole was the most expensive early-stage product in the 2013 budget. B524, B577-78.

Ornskov promptly launched steps slowing deferitazole's development. To address his goal of "selectively decreas[ing] investment in early stage programs," Ornskov established a Pipeline Committee charged with "adopt[ing] a more holistic approach to prioritize pipeline investment." B571; *see* MO 23-24. At the Pipeline Committee's inaugural meeting on May 15, 2013, deferitazole's costs were noted as part of Shire's 2013 and 2014 budgets. B915; *see also* B778-79; MO 24.

During late summer and fall 2013, the Pipeline Committee and Shire executives repeatedly discussed the deferitazole program's high development costs. MO 24-27, 60-63; B1156 (Pipeline Committee discussing deferitazole in August 2013 "due to its high 2014 cost"); B1234 (executive noting "from a budget perspective this is a very expensive program"); B1254 (same executive remarking "[o]ne of us can flag that this is the most expensive program in 2014!"). As the Court of Chancery summarized: "the Pipeline Committee was actively engaged in an effort to reduce the deferitazole program's budget." MO 63; *accord* B1256; B1259; B1261.

Cost concerns came to a head at a November 2013 Pipeline Committee meeting. The deferitazole development team entered that meeting trumpeting its

"[c]onfidence in the [drug's] ability to control liver iron concentration" and the drug's demonstration of a "[f]avourable renal and [gastrointestinal adverse event] profile" in studies to date. A715, A725. It also relayed feedback from clinical testing sites that deferitazole was "easy to take, well tolerated and liked by the patients." A725.

As would be expected with an early-stage drug, the presentation identified certain targets as "To Be Achieved." *Id*. Deferitazole's ability to control iron concentration in the heart, for instance, could not be fully assessed without more data. A721, A725. Likewise, some patients who were enrolled in Phase II studies were experiencing symptoms described under the broad rubric of "peripheral neuropathy." A722; B1245. But the emergence of such a side effect is common in drug development,[4] and investigators deemed the side effect "mainly as mild/moderate." B608. In early November 2013, Shire convened a group of independent experts as a Peripheral Neuropathy Adjudication Committee ("PNAC") to further investigate the data as the studies continued. A681. As the Court of Chancery found "striking," the PNAC had not yet reported its preliminary conclusions when the Pipeline Committee met in November 2013.[5] MO 58.

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[4] B27 (Siegel); B38 (MacFarlane).

[5] The PNAC ultimately recommended in December 2013 and January 2014 that Shire discontinue the highest dose that had been administered in clinical trials to reduce the risk of peripheral neuropathy, but that clinical trials continue at lower doses. B1265-313.

Despite the positive news from the development team, the Pipeline Committee abided its mandate to reduce costs and realign Shire's development program consistent with Ornskov's focus on later-stage candidates. Specifically, the Committee decided to "de-risk[]" the deferitazole program and "stagger[]" Shire's "investment" by delaying Study 204 (Shire's next study) until after Shire had received data from Study 203 (the twice-daily-dosing study). A760; B1262; *see also* B3 (Fasciocco). This decision delivered the savings Shire sought, single-handedly reducing deferitazole's 2014 budget by approximately $28.5 million. B1321. The decision also postponed the start of Phase III clinical trials to May 27, 2016, five months *after* the "deeming date" of December 31, 2015. MO 64; B1320.

Following the November 2013 Pipeline Committee meeting, the development team implemented the "desired delay." B1317. On February 3, 2014, Shire gave notice to SRS that initiation of Phase III was "currently planned [for] May 2016" but there was further "potential for delay." B1330. SRS in turn informed the FerroKin stockholders that the deemed-achieved provision in § 2.9(f) "is now implicated based on the current timelines." A766-67.

D. Shire Elected To Halt, Rather Than Merely Delay, Development After Receiving the Results of a Rat Carcinogenicity Study

On February 19, 2014, Shire was advised that preliminary findings from a two-year rat carcinogenicity study indicated an increased incidence of tumors in the kidneys of male rats. A764. But positive rat carcinogenicity findings are common

in drug development,[6] and many drugs have been marketed successfully following the emergence of similar issues. B37 (MacFarlane); *see also* B1963. Accordingly, "the usual course is to investigate [the finding] and determine whether or not it's relevant to humans, and then make a determination of what steps to take to go forward." B37 (MacFarlane).

Indeed, the Shire team developing deferitazole, supported by an independent expert pathologist, believed its clinical trials could continue while Shire simultaneously reported to the FDA and developed further information to support the hypothesis that the tumors were unique to male rats. MO 32-33; B1366. Paul Streck, the Group Vice President of Clinical Development overseeing the deferitazole program, agreed. B32.

Shire's executive team, however, elected an approach more closely aligned with its skepticism of the drug's future costs. On February 23, 2014, Philip Vickers, Shire's Global Head of Research and Development, wrote Ornskov: "We ha[d] already thought that this program was on the ropes and at the end of this coming week we may need to make a more drastic decision on the program." B1332. The Executive Committee opted to "[p]ause/suspend dosing," B1368, a decision Shire later characterized as a "voluntary clinical hold," B1408; *see also* B1334. Once

[6] B28-29 (Siegel); B1957, B1963; B42 (Popp).

Shire disclosed that decision to the FDA on March 4, 2014, A768-74, the agency imposed its own clinical hold, A781; *see* MO 35-36.

Shire did begin investigating the cause of the positive rat carcinogenicity study by convening a Pathology Working Group ("PWG") composed of recognized experts. B1463-597. But Shire also used the clinical hold to reevaluate its investment. In speaking to outside advisors on Shire's Scientific Advisory Board ("SAB") in late March 2014, executives pondered whether its continued development was "the best use of Shire's money." B1403. Even before the PWG began its work, the executives speaking to the SAB considered whether Shire should "fish versus cut bait," B1381, and Streck observed that "the [Pipeline Committee] does not have a whole lot of love for this asset," B1369.

E. After a Months-Long "Justification" Project, Shire Issued the Notice of Fundamental Circumstance

As Shire began to coalesce around the idea of abandoning deferitazole, Howard Mayer, Shire's Head of Global Clinical Development, warned Vickers in April 2014 that "[i]f there are any plans to announce discontinuation of SHP602 [deferitazole] . . . there is a significant milestone payment ($40M?) based on termination of the program in the absence of clear efficacy/safety reason and this could be an issue from the perspective of Hugh Rienhoff and other legacy Ferrokin investors." B1404; *see also* B1410; MO 40. The Pipeline Committee thus set its

sights on how to "cut bait," B1381, without triggering the "significant milestone payment," B1404; *see* MO 40.

A June 8, 2014 slide deck laid out for the Pipeline Committee the contractual definition of Fundamental Circumstance and Shire's analysis of the limited circumstances triggering the exception. MO 40-41. Shire acknowledged that the clinical hold and its associated delay did not, without more, suffice: only "[i]f FDA decline[d] to lift Clinical Hold after considering Shire's complete response" would there "likely be a Fundamental Circumstance," and even then it would "depend[ ] on FDA's actual response." B2196. Shire also recognized that "changes in Shire's business model or financial forecasts (in and of themselves) would not qualify as a Fundamental Circumstance." *Id.* As such, Shire suggested that it try to "consider[ ] together" various less significant issues it had encountered, though it was "not as clear cut" that doing so would "qualify as a Fundamental Circumstance." *Id.*

Shire's last hope for a "clear efficacy/safety" issue sufficient to constitute a Fundamental Circumstance faded when, on June 13, 2014, the PWG submitted an initial draft report concluding that the rat tumor "findings are unlikely to indicate a carcinogenic risk for humans." B1426. The PWG's final report, issued two weeks later, confirmed that conclusion. B1473-74. Richard Pfeifer, Shire's Head of Toxicology, reported that "the consensus findings by the PWG put us in a better position than anticipated," which was "good news" for deferitazole's further

development. B1412-13. That news, however, was inconsistent with Shire's efforts to justify avoiding the Phase III Milestone Payment.

Shire thus launched a months-long project to justify declaring a Fundamental Circumstance. MO 42. Streck created a document, named "602 Fundamental Circumstance Justification Outline.docx," B1450, which he told colleagues would "likely be used for discussions and legal proceedings with FerroKin," B1457.[7]

Shire ultimately issued the Notice of Fundamental Circumstance on February 25, 2015. That Notice generally tracked the justification outline. A839-43; B1601, B1607-12. It set forth a series of safety and efficacy concerns that Shire purported to have observed—including the rat carcinogenicity study results, peripheral neuropathies, undesirable drug-to-drug interactions, and the drug's ability to clear iron from both the heart and the liver—and it summarized Shire's skeptical position on deferitazole's prospects for regulatory approval and commercial viability. A783-843.

F. Shire Confirmed in 2016 That Rat Carcinogenicity Findings Posed Little to No Risk to Humans

As Shire wound down the deferitazole program in the wake of declaring a Fundamental Circumstance, it confirmed, consistent with the deferitazole

[7] Several Shire employees candidly disagreed with that document's assertions. *E.g.*, B1454-55; B1598; B23 (Pavillard).

development team's initial instinct and the PWG's preliminary report, that the rat carcinogenicity study results did not portend danger to humans.

Specifically, in early 2016, Shire received results from a follow-up study in mice concluding that the results "suggest[ ] the risk of kidney [tumors] in humans is low" as tumors were found "in only one species/sex (male rats only)." B1619. Shire then terminated a follow-up study of human patients previously dosed with deferitazole, B1778-86, informing investigators who had treated patients with it that "there is no evidence suggesting SHP602 [deferitazole] poses a carcinogenic risk to humans," B1775. In line with what Shire described internally as a "business decision" to discontinue development of deferitazole, B1650, Shire informed the FDA that "[t]he decision to discontinue further development of SHP602 [deferitazole] is ***based on portfolio prioritization***; this decision was ***not based on safety concerns***," B1783 (emphases added); *see also* B1948.

II. PROCEDURAL BACKGROUND

SRS filed suit on December 4, 2017. The Court of Chancery denied Shire's motion to dismiss, supervised extensive discovery, conducted a four-day trial, and received post-trial briefing and argument. The court also requested supplemental briefing on the causation analysis required by § 2.9(f)'s "other than as a result of a Fundamental Circumstance" language. OB, Ex. B.

The Court of Chancery held that Shire had breached the Agreement by failing to make the Phase III Milestone Payment. MO. The court assumed without deciding that either "the RatCarc Study results [or the] subsequent FDA clinical hold" might constitute a Fundamental Circumstance. MO 1. (By the time of post-trial briefing, Shire had abandoned all other justifications it had included in its Notice of Fundamental Circumstance. *See* A839-43.) The court concluded that "Shire's failure to initiate Phase III clinical trials by December 31, 2015 was not 'as a result of' any Fundamental Circumstance but, rather, was 'as a result of' a series of routine drug development delays and financially motivated business decisions." MO 54; *see also* MO 54-75.

ARGUMENT

I. THE COURT OF CHANCERY PROPERLY CONCLUDED THAT SHIRE FAILED TO INITIATE PHASE III CLINICAL TRIALS "OTHER THAN AS A RESULT OF A FUNDAMENTAL CIRCUMSTANCE"

A. Question Presented

Whether Shire failed to initiate Phase III clinical trials by December 31, 2015, for a reason "other than as a result of a Fundamental Circumstance" where its own business decisions—independently of any assumed Fundamental Circumstance—prevented it from timely initiating those trials. SRS argued this issue, among other places, in its post-trial briefing. B78-80; B125-36.

B. Standard of Review

"Appellate courts review a trial court's legal conclusions *de novo*." *Bank of N.Y. Mellon Tr. Co. v. Liberty Media Corp.*, 29 A.3d 225, 236 (Del. 2011).

C. Merits of the Argument

Because Shire failed to timely initiate Phase III clinical trials as a result of its own business decisions, its failure to initiate those trials was not "as a result of a Fundamental Circumstance." Shire thus was contractually bound to make the Phase III Milestone Payment. Shire's contrary position defies § 2.9(f)'s language, distorts § 2.9's structure, and invokes generalizations about industry contracting practices that conflict with these parties' bargained-for allocation of risk.

"When interpreting a contract, the role of a court is to effectuate the parties' intent." *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006). "If the contractual language at issue is 'clear and unambiguous,' the ordinary meaning of the language generally will establish the parties' intent." *Meso Scale Diagnostics, LLC v. Roche Diagnostics GMBH*, 2011 WL 1348438, at *8 (Del. Ch. Apr. 8, 2011). Further, the Court must read "'the specific provisions of the contract in light of the entire contract.'" *HUMC Holdco, LLC v. MPT of Hoboken TRS, LLC*, 2020 WL 3620220, at *6 (Del. Ch. July 2, 2020) (quoting *Chicago Bridge & Iron Co. v. Westinghouse Elec. Co.*, 166 A.3d 912, 913-14 (Del. 2017)).

1. The ordinary meaning of § 2.9(f)'s "other than as a result of" exception requires but-for causation

Section 2.9(f) provides:

> Notwithstanding anything else in this Agreement to the contrary, in the event that [Shire] has not achieved the Initiation of the Phase III Clinical Trial Milestone on or before December 31, 2015, other than as a result of a Fundamental Circumstance, then the Initiation of Phase III Clinical Trial Milestone shall be deemed to have been achieved on such date.

A492. The ordinary meaning of "other than as a result of" confirms that this exception applies only if but-for causation is shown. *See USA Cable v. World Wrestling Fed'n Ent., Inc.*, 766 A.2d 462, 474 (Del. 2000) (when a term's definition is not altered or has "no 'gloss' in the industry," it "should be construed in accordance with its ordinary dictionary meaning").

That follows from the ordinary meaning of "other than" and "as a result of." The phrase "other than" means "with the exception of" or "except for."[8] The court below correctly explained (MO 69) that § 2.9(f) thus creates an exception to a default rule. That exception depends on "as a result of," which in turn means "because of something"[9]—as "[a] consequence, effect, or conclusion" of something. *Result*, *Black's Law Dictionary* 1509 (10th ed. 2014). Read as a whole, § 2.9(f) therefore provides that the Milestone is deemed achieved except if Shire fails to start Phase III by December 31, 2015, *because of* a Fundamental Circumstance.

As the court below further held, the required causal relation is but-for causation, for two reasons. *First*, the provision's character as an exception supports this reading. "Because the clause is cast as an exception," the question the contract asks is straightforward: "Did Shire fail to initiate Phase III clinical trials on or before December 31, 2015 because of anything except for a Fundamental Circumstance?" MO 70; *see also id.* ("In other words, if the delay would have transpired notwithstanding the absence of the Fundamental Circumstance Shire claims to have occurred, Shire's payment obligation remains intact.").

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[8] *Other than*, *Merriam-Webster.com*, https://www.merriam-webster.com/dictionary/other%20than (last visited Aug. 7, 2021); *other than, Collins*, https://www.collinsdictionary.com/us/dictionary/english/other-than ("You use other than after a negative statement to say that the person, item, or thing that follows is the only exception to the statement.") (last visited Aug. 7, 2021).

[9] *As a result*, *Merriam-Webster.com*, https://www.merriam-webster.com/dictionary/as%20a%20result (last visited Aug. 7, 2021).

Second, but-for causation is the common legal meaning of "as a result of." "When established legal terminology is used in a legal instrument, a court will presume that the parties intended to use the established legal meaning of the terms." *Penton Bus. Media Holdings, LLC v. Informa PLC*, 252 A.3d 445, 461 (Del. Ch. 2018). As the Court of Chancery recognized (MO 70 n.357) and Shire silently concedes (OB 21), many courts have interpreted "as a result of" as requiring but-for causation. *See*, *e.g.*, *Finocchiaro v. D.P., Inc.*, 2006 WL 3873257, at *6 (Del. Super. Ct. Dec. 29, 2006) (interpreting "as a result of" in statutory language as requiring but-for causation).[10] The parties therefore incorporated but-for causation by using the term "as a result of" in § 2.9(f).

[10] *See also Burrage v. United States*, 571 U.S. 204, 214 (2014) ("[A] phrase such as 'results from' imposes a requirement of but-for causation."); *Fleming v. United States*, 224 A.3d 213, 223 (D.C.) (en banc) (finding jury instruction that used "as a result of" to describe but-for causation), *cert. denied*, 141 S. Ct. 123 (2020); *Kuhn v. Ret. Bd.*, 343 P.3d 316, 320 (Utah Ct. App. 2015) (affording the phrase "as a result of" its ordinary meaning of "consequently"—requiring but-for causation); *United States v. Sandlin*, 589 F.3d 749, 757 (5th Cir. 2009) ("as a result of" means "because of"); *Pentax Corp. v. Robison*, 125 F.3d 1457, 1463 (Fed. Cir. 1997) (interpreting "as a result of" in statute "as requiring nothing less than but-for causation"), *amended on reh'g on other grounds*, 135 F.3d 760 (Fed. Cir. 1998); *Black Hills Aviation, Inc. v. United States*, 34 F.3d 968, 975 (10th Cir. 1994) ("The use of the plain language—'as a result of'—is logically interpreted to mean 'caused by.'"); *Haesche v. Kissner*, 640 A.2d 89, 94 (Conn. 1994) (defining "as a result of" to mean "caused by"); *cf. United States v. Abdelbary*, 746 F.3d 570, 573 (4th Cir. 2014) (finding sentencing court had found but-for-causation where it concluded attorney's fees "were incurred as a result of the bankruptcy fraud").

2. The Agreement's structure supports reading "other than as a result of" as requiring but-for causation

Reading § 2.9(f) "in light of the entire contract," as the Court must, *HUMC*, 2020 WL 3620220, at *6, only reinforces this conclusion.

a. Sections 2.9(a) and 2.9(b) make clear the distinction between the mere occurrence of a Fundamental Circumstance and events that arise "as a result of a Fundamental Circumstance"

Two other provisions of § 2.9 confirm that the mere *occurrence* of a "Fundamental Circumstance" is insufficient to trigger § 2.9(f)'s "*as a result of*" exception. *See Dewey Beach Enters., Inc. v. Bd. of Adjustment of Dewey Beach*, 1 A.3d 305, 308 (Del. 2010) ("The use of a different term suggests a different meaning."). Section 2.9(a) provides that, "[u]pon the first occurrence of" a Milestone Trigger Event, Shire will (after a prescribed period of time) notify SRS and deposit the amount owed. A489-90. Section 2.9(b) provides that, "in the event there occurs a Fundamental Circumstance" but Shire pursues development of an "alternative" product, any future Milestone Payments are cut in half. A490. Both provisions hinge on whether a prescribed event *occurs*, confirming the parties understood how to condition a payment on the "occurrence" of an event. A489-90.[11]

[11] *See*, *e.g.*, *Fortis Advisors LLC v. Shire US Holdings, Inc.*, 2017 WL 3420751, at *2 (Del. Ch. Aug. 9, 2017) ("That category of milestone payments, the 'Base Case Milestones,' is triggered by the occurrence of the OPUS-2 Study Endpoint Achievement Date . . . .").

In the exception § 2.9(f) sets forth, however, SRS and Shire agreed to different language. They did not structure the payment provision to depend on the mere occurrence of a Fundamental Circumstance. They instead chose the "as a result of" proviso. A492. That difference in language implies a difference in meaning: the mere occurrence of a Fundamental Circumstance is insufficient to excuse Shire's obligation absent the causal relation that § 2.9(f) requires.

b. The structure of § 2.9 differentiates the Phase III Milestone Payment from other milestone payments, underscoring the narrowness of § 2.9(f)'s "as a result of" exception

Section 2.9 assigns the Phase III Milestone Payment a unique character that further supports the Court of Chancery's conclusion. The Agreement contemplates five milestone payments of between $30 and $50 million. Each is triggered by a different "Milestone Trigger Event": initiation of Phase III clinical trials, U.S. approval of the drug, E.U. approval, and increasing net sales. The parties agreed that most milestone payments would depend on the occurrence of a specific event: the U.S. Approval Milestone occurs when Shire receives "a written letter of approval by the FDA of a[ ] [new drug approval application]"; the E.U. Approval Milestone occurs when Shire receives "written approval by the [European Medicines Agency] to market and sell" the drug; and the First and Second Net Sales Milestones occur when aggregate worldwide net sales exceed $500 million and $1 billion, respectively. *See* A476, A478-84 (Definitions).

But § 2.9(f) made the Phase III Milestone unique. It alone is "*deemed* to have been achieved" by default, and the associated payment alone was therefore neither conditional nor contingent on a specific event. A492. It instead was *guaranteed* to occur by pure passage of time (absent the exception). The Court of Chancery thus correctly concluded that the "other than as a result of" exception should be read narrowly to require but-for causation. MO 70. Moreover, as explained next, this contractual feature effectuates the parties' *ex ante* intention to protect FerroKin if Shire failed to timely develop the drug through the Phase III Milestone because of anything other than a Fundamental Circumstance.

3. The causal quality of § 2.9(f)'s language sensibly allocates the risks and benefits of deferitazole's development

Reading § 2.9(f) as requiring but-for causation also best reflects "[t]he basic business relationship between [the] parties," in a manner "informed by [the provision's] function in the overall . . . [a]greement." *Chicago Bridge & Iron*, 166 A.3d at 927-28. Indeed, Shire's account of the "commercial context" of the Agreement ignores key facts about the parties' negotiations.

Shire concedes (OB 24) it entered the Agreement with FerroKin to capture a "high risk / high reward" opportunity. In negotiations, each party sought to manage its own risks and rewards. FerroKin sought to maximize payment—indeed, it rejected $100 million as too low a price, *see* B263—and to ensure that Shire would diligently develop the drug. *See* OB 24 (conceding § 2.9(f) "protected FerroKin

against delays in the initiation of Phase III trials"). Shire, for its part, wanted control over development while minimizing its downside risk.

The parties allocated these risks primarily through § 2.9(f) and § 2.9(g). Shire successfully bargained for complete control over development and regulatory approval. In exchange, FerroKin received a $95 million upfront payment and five potential payments, each keyed off of a different milestone and together worth up to an additional $225 million. Further, Shire agreed to treat the first milestone payment differently from the others: Shire would make that first payment on December 31, 2015, whether it actually reached that first milestone or not, unless a Fundamental Circumstance was the reason Shire failed to initiate Phase III clinical trials by that date.

This risk-and-benefit allocation was commercially sensible for both sides. FerroKin agreed to forgo any guarantee Shire would develop the drug (in the form of, *e.g.*, a "commercially reasonable efforts" clause), and therefore any guarantee it would receive more than half of its all-in potential compensation (*i.e.*, the remaining $180 million in milestones). But it did so only on the condition that Shire accepted a strong incentive to work through obstacles to reaching the Phase III Milestone. FerroKin therefore received a near-guarantee that its total compensation would exceed what it had made clear *ex ante* was a walk-away price. *See* B263; *supra* p. 8. Shire, in exchange, received total control of the drug's development, while leaving

more than half of the consideration it owed to FerroKin both deferred and contingent on other markers of advancement and its own business priorities.

Shire describes this understanding (OB 3) as "absurd." But, properly read, those provisions reflect a sensible commercial outcome in unambiguous language that the parties negotiated fiercely and then adopted.

4. Shire's contrary arguments conflict with § 2.9(f)'s text and the Agreement's structure

Shire's contrary position rests primarily on generalizations about business considerations in *other* pharmaceutical merger agreements. That ignores the Court's proper task—"giv[ing] effect to the plain-meaning of" this specific "contract's terms and provisions." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159-60 (Del. 2010). Moreover, it conflicts with the record of these parties' specific business considerations and the contractual text to which they agreed.

a. Shire's focus on atextual commercial matters is misplaced

Shire unpersuasively contends (OB 22) the Court of Chancery erred by failing to interpret § 2.9(f) in the context of "the commercial relationship between parties to a pharmaceutical merger." Shire asserts (OB 23) that pharmaceutical merger agreements generally allocate risk by dividing consideration into upfront payments and "subsequent milestone payments that come due only so long as the drug proceeds towards regulatory approval and commercialization." But even if

milestone payments in *other* agreements come due only when a drug *in fact* passes a certain development threshold, § 2.9(f) creates a different time-based obligation to make the first Milestone Payment, by "deem[ing] . . . achieved" the Phase III Milestone on December 31, 2015 (subject to a narrow exception). A492. It does so by carefully calibrating the risks each party would bear: Shire's risk the drug would fail *and* FerroKin's risk Shire would unilaterally delay or cease development.

Indeed, § 2.9(f)'s unique role as a counterbalance to § 2.9(g)'s grant of "sole and absolute discretion," A493, distinguishes the parties' Agreement from the other pharmaceutical merger contracts Shire cites (OB 22-23). Unlike the Agreement, each contract cited by Shire contained "commercially reasonable efforts" clauses to ensure the buyer continued to develop the drug toward meeting the defined milestones.[12] This Agreement instead gave Shire "sole and absolute discretion" over development, with FerroKin receiving no similar guarantee Shire would in fact

[12] *See Kabakoff v. Zeneca, Inc.*, 2020 WL 6781240, at *4 (Del. Ch. Nov. 18, 2020) ("The Merger Agreement also contains a requirement that MedImmune use 'Commercially Reasonable Efforts' in developing the Monotherapy or Combination."), *judgment entered*, 2020 WL 7059291 (Del. Ch. Nov. 25, 2020); *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *1 (Del. Ch. Dec. 28, 2018) ("The buyer agreed to use commercially reasonable efforts to develop the antibody and achieve the milestones."); B2994 (*Fortis*, C.A. No. 12147-VCS, Dkt. 11 at Ex. 1, p. 80 ("Parent and the Surviving Corporation shall use Commercially Reasonable Efforts to develop, obtain Regulatory Approval for, and to commercialize, at least one (1) Product for the Covered Indication and, subject to and without modifying such obligation, to satisfy the Milestones in a prompt and expeditious manner . . . .")).

develop the drug through all of the agreed milestones. Reading the exception in § 2.9(f) narrowly, so that the first milestone is different and near-guaranteed, therefore accords with the bargain these parties struck. Other merger structures the parties eschewed are relevant only by contrast.

b. Shire's reading of § 2.9(f) contradicts that provision's text

Shire next argues "the failure to achieve the milestone is 'as a result of a Fundamental Circumstance' when a Fundamental Circumstance *has occurred* before December 31, 2015, thereby preventing Phase III trials." OB 26 (emphasis added). That contention, however, contorts § 2.9(f)'s plain language and conflicts with Delaware law.

To start, Shire's reading of § 2.9(f) erases the distinction the Agreement draws between "as a result of" and "occurs," and it ignores "other than." Shire asserts (OB 27) that § 2.9(f) calls for what it labels a "backward-looking" analysis, under which "the [parties'] milestone framework . . . is concerned with deferitazole's success or failure, not with ascertaining the reason for other projected delays in beginning Phase III trials when those delays have been rendered irrelevant by the Fundamental Circumstance." This follows, Shire contends (*id.*), because "[t]he occurrence of a Fundamental Circumstance means that attempting to develop deferitazole in its current form would be futile or at least unreasonably difficult." Again, however, the Agreement distinguishes between the mere "occurrence of a Fundamental

Circumstance" and events that occur "as a result of" one: § 2.9(f)'s narrow exception incorporates the latter phrase, and its ordinary meaning requires proof of but-for causation.

Notably, Shire offers no plausible alternative reading. It instead brushes aside the many cases interpreting that phrase to require proof of but-for causation (OB 21-22) on the ground those cases involve allocating what it calls "*responsibility*" or "fault," rather than "risk." But Shire cites nothing drawing this novel distinction. Nor would it make a difference, in light of the established background rule that, if a contract incorporates terms with well-defined meanings, the parties presumptively intended to incorporate those meanings. By instead functionally reading "other than as a result of" out of the Agreement, Shire's reading violates fundamental contract law. *See Sonitrol Holding Co. v. Marceau Investissements*, 607 A.2d 1177, 1183 (Del. 1992) ("Under general principles of contract law, a contract should be interpreted in such a way as to not render any of its provisions illusory or meaningless.").

Contrary to Shire's claim (OB 33-35), this but-for causation standard does not require an "unworkable and unreasonable" inquiry or lead to a "perverse" result. Shire first asserts (OB 34) it may be possible for a Fundamental Circumstance to be intertwined with a lesser drug-development issue in ways that could complicate the causation inquiry. That may be so in theory, but not here: the Court of Chancery

found, and Shire now concedes, that Shire's business decisions were the first and an independently sufficient cause of its failure to timely initiate Phase III clinical trials.[13] *See infra* pp. 37-38. Shire also asserts (OB 35) this interpretation leads to a payment based on "temporal happenstance" or "fortuity." Yet Shire's own excuse is that the happenstance of a (benign) rat carcinogenicity finding excused all of its previous delays. And what Shire dismisses as "happenstance" or "fortuity" is in fact an entirely foreseeable result of the parties' calculated *ex ante* risk allocation: that the unique "deemed . . . achieved" character of the Phase III Milestone would give FerroKin some assurance that Shire would not abandon FerroKin's prized asset unilaterally and attempt to find an *ex post* Fundamental Circumstance to justify doing so.

c. Shire also misreads § 2.9(b)

Shire's third contention—that § 2.9(b) supports its reading of § 2.9(f) (OB 31-33)—misreads both provisions.

Section 2.9(b) provides in relevant part:

> [I]n the event that there occurs a Fundamental Circumstance, but [Shire] pursues development of an Alternative Covered Product that

[13] Shire cites nothing supporting its passing invocations of the doctrine of superseding causation (*e.g.*, OB 4, 26, 27), for good reason: As the RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM (2010) explains, where a later event (the Fundamental Circumstance) only *would have been* sufficient to cause an outcome that an earlier event (business decisions and ordinary development challenges) had already brought about, the later event is *not* considered the cause-in-fact. *See id.* §§ 26 cmt. k, 27 cmt. h.

> constitutes a Covered Product, then any remaining Milestone Payments that first become due and payable following the occurrence of such Fundamental Circumstance shall be one-half (1/2) the applicable amount . . . .

A490.

On Shire's account (OB 32-33), the Court of Chancery's reading of § 2.9(f) creates tension with § 2.9(a) and § 2.9(b) "together." Shire contends (OB 32) that the latter sections "provide that if no Fundamental Circumstance occurs, Shire must pay $45 million upon initiating Phase III trials, and if a Fundamental Circumstance occurs but Shire opts to develop a related (but presumably less valuable) product, it is obligated only to pay half of $45 million." Accordingly, Shire faults (OB 33) the Court of Chancery's interpretation of § 2.9(f) because it "entitl[es] FerroKin to *more* money in a situation in which deferitazole is *less* viable."

But Shire reaches this strained conclusion only by excising key language from § 2.9(f), which provides that, if Shire fails to initiate Phase III by December 31, 2015, "as a result of" a Fundamental Circumstance, Shire does not have to pay anything on that date, regardless of whether it develops an alternative product. Section 2.9(b), on the other hand, provides that if a Fundamental Circumstance "occurs"—regardless of whether it is the but-for cause of Shire's failure to achieve Phase III—*and* Shire develops an alternative product, Shire pays half the value of the Phase III Milestone Payment, and all subsequent milestone payments, whenever they become due. A490.

Accordingly, giving effect to the entire contract, no tension exists between § 2.9(b) and § 2.9(f). Section 2.9(f) determines *whether* the Phase III Milestone will be deemed achieved such that a payment is due December 31, 2015, whereas § 2.9(a) and § 2.9(b) together determine *how much* each milestone payment will be whenever it becomes due. Where the Phase III Milestone was deemed achieved under § 2.9(f) and no alternative product was being developed (as happened here), Shire owes $45 million. If Shire had developed an alternative product, however, only $22.5 million would have been due. That scenario creates no inconsistency. Shire would still make a payment for its delay in initiating Phase III for reasons other than the Fundamental Circumstance, but would owe only half to account for its additional development obligations and risk associated with developing an alternative product.

Moreover, even if tension existed between these provisions (and it does not), § 2.9(f) begins with a clause explaining that it applies "[n]otwithstanding anything else in this Agreement to the contrary." That clause "'clearly signals the [parties'] intention that the provisions of the "notwithstanding" section override conflicting provisions of any other section.'" *Medicis Pharm. Corp. v. Anacor Pharms., Inc.*, 2013 WL 4509652, at *8 n.46 (Del. Ch. Aug. 12, 2013) (quoting *Cisneros v. Alpine Ridge Grp.*, 508 U.S. 10, 18 (1993)).[14]

[14] *See also W. Willow-Bay Ct., LLC v. Robino-Bay Ct. Plaza, LLC*, 2007 WL 3317551, at *10 (Del. Ch. Nov. 2, 2007) ("Sentence 8 is given special prominence within Amended Section 11. Its introductory clause, '[a]nything to the contrary

d. The Court of Chancery's interpretation produced no windfall

Shire's suggestion (OB 30) that the Court of Chancery's interpretation gives SRS a windfall through an unwritten "commercially reasonable efforts" clause misconstrues § 2.9(f)'s function. Shire emphasizes the notion that pharmaceutical merger agreements allocate risk through milestone payments that allow the "buyer to hedge against future risks through subsequent payments that would become due *only if* the defined milestones were reached." OB 22-23 (brackets omitted). Again, however (*see supra* pp. 28-30), even if that is true of some agreements, this Agreement's treatment of the Phase III Milestone in particular differs in the ways already described: it gives a presumptive payment to FerroKin and implicitly imposes a development incentive on Shire, subject to a narrow exception. That far more surgical approach to this specific issue differs from the broader "commercially reasonable efforts" clause that FerroKin wanted and Shire rejected. Shire mistakenly contends that the Court of Chancery imported a rejected clause found in other agreements in the industry. Rather, the court below construed the contract by the plain terms the parties had negotiated at arms' length.

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notwithstanding,' allows Sentence 8 to trump any other provision that might conflict with it."), *aff'd*, 2009 WL 4154356 (Del. Nov. 24, 2009) (judgment noted at 985 A.2d 391 (table)).

e. Shire misuses extrinsic evidence

Shire's attempt to undermine the Agreement's unambiguous language with extrinsic evidence is legally improper and factually incorrect. At the outset, Shire's attempt to rely on "extrinsic evidence to contradict the plain terms of the Merger Agreement is not permitted by the contract law of this state." *Alliance Data Sys. Corp. v. Blackstone Cap. Partners V L.P.*, 963 A.2d 746, 769 (Del. Ch. 2009), *aff'd*, 2009 WL 1740171 (Del. June 18, 2009) (judgment noted at 976 A.2d 170 (table)). Further, Shire's one-sided retelling of the contract negotiations and course of performance ignores key facts revealing that Shire and FerroKin understood the Fundamental Circumstance clause to excuse Shire's first Milestone Payment under very narrow circumstances.

As explained above, § 2.9(f) and § 2.9(g) represented the "heavily negotiated" resolution to the parties' competing objectives concerning milestones and "control of the development program." B10, B12 (Girard); B36 (Henner). The parties determined that their business relationship required mitigating not only Shire's risk that the drug would fail, but also FerroKin's risk that Shire would choose to delay or abandon it for other reasons. Consequently, Shire wanted "absolute discretion" while FerroKin wanted the agreement to contain "something that would compel [Shire] to go forward and not just can the program . . . at [its] whim." MO 11 (alterations in original); *see also* B263-64; B260 (noting FerroKin's interest in

"defin[ing] [the] efforts Shire must make to progress product development" and imposing "consequences for NOT making progress"). Sections 2.9(f) and 2.9(g) thus reflected a "tradeoff" that "allowed Shire to abandon the project at [its] discretion"—even "whim"—but imposed "a penalty associated with" doing so. B12 (Girard); A173 (Rienhoff).

Shire wholly ignores that evidence. Accordingly, even if Shire's effort to evade the Agreement's plain text with extrinsic evidence were legally proper (and it is not), it is factually mistaken.

5. The Court of Chancery properly concluded, and Shire now concedes, that Shire failed to initiate Phase III trials because of its own independent business decisions

Under the correct standard, which the court below applied (MO 54-75), Shire cannot prevail because its failure to initiate Phase III trials "would have occurred without" the Fundamental Circumstance that the court assumed, for the sake of argument, had happened. *Culver v. Bennett*, 588 A.2d 1094, 1097 (Del. 1991) (explaining but-for causation). As it found, the evidence showed that Shire's own independent business decisions made it impossible for Shire to have initiated Phase III by December 31, 2015, regardless of whether a Fundamental Circumstance had occurred. Shire makes no effort to show that the court's findings in these respects were erroneous (much less clearly so, as they must be to warrant reversal, *see CDX Holdings, Inc. v. Fox*, 141 A.3d 1037, 1041 (Del. 2016)). Instead, Shire concededly

made its own "decisions" that "delayed the projected start of Phase III clinical trials beyond December 2015." OB 35; *see also*, *e.g.*, OB 2-3 (noting "Shire had earlier made drug-development decisions . . . that had delayed the projected timeline for the Phase III trial"), 29, 34, 39 (similar). The court's factual finding on this score therefore stands unchallenged.

Shire's suggestion (*e.g.*, OB 17) that deferitazole had "failed" was neither found by the Court of Chancery nor supported by the record. On the contrary, as shown above (*see supra* pp. 17-18), the rat carcinogenicity findings hardly sounded the death knell. Instead, as Shire told the FDA, its choice to discontinue the drug's development was "***based on portfolio prioritization***" not "***safety concerns***." B1783 (emphases added); *see also* B1948.

Even assuming Shire's contrary view, however, the Court of Chancery properly interpreted the "as a result of" exception in holding that Shire remains obligated to make the Phase III Milestone Payment. This Court need go no further to affirm the judgment.

II. THE COURT OF CHANCERY CORRECTLY HELD THAT SHIRE BEARS THE BURDEN OF PROVING THAT IT FAILED TO TIMELY INITIATE PHASE III CLINICAL TRIALS "AS A RESULT OF A FUNDAMENTAL CIRCUMSTANCE"

A. Question Presented

Whether the Court of Chancery correctly concluded that Shire bears the burden to show it failed to initiate Phase III clinical trials "as a result of a Fundamental Circumstance" to invoke that exception to its duty to make the Phase III Milestone Payment. SRS argued this issue in, among other places, its post-trial briefing. B76-78; B123-25.

B. Standard of Review

This Court reviews the placement of the burden of proof *de novo*. *See Yiannatsis v. Stephanis ex rel. Sterianou*, 653 A.2d 275, 279 (Del. 1995).

C. Merits of the Argument

If this Court deems it necessary to remand (which it should not), the Court should adopt the Court of Chancery's holding that Shire must prove facts satisfying the "as a result of a Fundamental Circumstance" exception.

1. Under Delaware contract law, Shire bears the burden to prove that § 2.9(f)'s exception excuses its obligation

Because Shire seeks to benefit from an "exception" to a "clear payment obligation," OB, Ex. C at 35, Delaware law "charge[s]" Shire "with the burden of proving facts necessary to come within the exception." *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *59 n.619 (Del. Ch. Oct. 1, 2018), *aff'd*, 2018 WL

6427137 (Del. Dec. 7, 2018) (judgment noted at 198 A.3d 724 (table)); *see generally Hollinger Int'l, Inc. v. Black*, 844 A.2d 1022, 1070 (Del. Ch. 2004) (defendant "bears the burden to establish that this contractual exception applies"), *aff'd*, 872 A.2d 559 (Del. 2005) (per curiam); *see also* 29 AM. JUR. 2D EVIDENCE § 173 (2019) ("A party seeking to take advantage of an exception to a contract is charged with the burden of proving facts necessary to come within the exception.").

As discussed above, the Agreement required Shire to pay as of the earlier of two events: the initiation of Phase III trials or December 31, 2015. *See* A489-90 (§ 2.9(a)) (Shire "shall promptly . . . deposit or cause to be deposited" the required payment at that point). Shire's obligation to pay would arise no later than a fact certain to occur—the arrival of a specified date. The Agreement is therefore most sensibly understood as imposing a duty to make the Phase III Milestone Payment, subject only to a defined exception. *See* MO 52.

This reading compels the conclusion that Shire bears the burden to prove that the "other than as a result of" exception applies. Many cases cited by the Court of Chancery (MO 52-53 n.283) and ignored by Shire confirm that the burden of proof is appropriately assigned to parties invoking conditions that relieve them of existing duties. *See*, *e.g.*, *AB Stable VIII LLC v. Maps Hotels & Resorts One LLC*, 2020 WL 7024929, at *48-49 (Del. Ch. Nov. 30, 2020). Because the Agreement imposes a

similar duty-exception structure, Shire bears the burden of showing the condition is satisfied.

2. Section 2.9(f)'s "as a result of" exception creates a condition subsequent as to which Shire bears the burden of proof

The Court of Chancery correctly characterized § 2.9(f)'s "as a result of" exception as a condition subsequent—a genre of provision that, as Shire nowhere disputes, places the burden of proof on the defendant.[15] That characterization follows from two principles.

First, an event is a condition subsequent if "an obligor's matured duty will be extinguished on the occurrence of [that] event." RESTATEMENT (SECOND) OF CONTRACTS § 230 cmt. a (1981). The Agreement provides that the Milestone is *deemed* achieved—it matures—on December 31, 2015. Only if Phase III was not reached "as a result of a Fundamental Circumstance" can that matured duty be extinguished.

Second, unlike conditions subsequent, most "conditions precedent are easily ascertainable objective facts." *Hexion Specialty Chems., Inc. v. Huntsman Corp.*, 965 A.2d 715, 739 (Del. Ch. Sept. 29, 2008). Sensibly so: because such a condition

[15] *See Ewell v. Those Certain Underwriters of Lloyd's, London*, 2010 WL 3447570, at *3 (Del. Super. Ct. Aug. 27, 2010) ("[T]he burden of proof and allegation of a condition subsequent is on the defendant."); 16 WILLISTON ON CONTRACTS § 49:87, at 748 (4th ed. 2014) ("the burden of proof with respect to conditions subsequent is on the defendant").

"must be performed or happen before a duty of immediate performance arises on the promise which the condition qualifies," 13 WILLISTON ON CONTRACTS § 38:7, at 435 (4th ed. 2013), contracting parties naturally tie such a condition to a fact they can readily determine has or has not occurred. The Court of Chancery correctly recognized (MO 53-34) that whether Shire's failure to reach the Milestone was "as a result of a Fundamental Circumstance" is not such a fact. This litigation proves the point: a central disputed question at trial was whether any of the events on which Shire relies constituted a "Fundamental Circumstance" in the first place. SRS believes that the weight of the evidence shows that no "Fundamental Circumstance" occurred, but the complexity of litigating the question—and Shire's pre-litigation justification project and internal disagreement—confirms that the provision is not sensibly understood as creating a condition precedent.

Shire's contrary view (OB 41-44) that the provision sets forth a condition precedent substitutes form for substance. Shire focuses (OB 41-43) on the conditional form of § 2.9(a)'s wording—that the duty to pay matures "[u]pon the first occurrence of" two specified events, *see* A492 (§ 2.9(f)). But although such phrases can connote the creation of a condition precedent in appropriate circumstances, that is not always true: as the court below explained, "the difference between a condition precedent and a condition subsequent 'is one of substance and not merely of the form in which the provision is stated.'" MO 51 (quoting

RESTATEMENT (SECOND) OF CONTRACTS § 230 cmt. a); *see also* MO 51 n.277 (pointing to Restatement's use of conditional language to illustrate a condition subsequent). Because the Agreement conditioned Shire's duty to pay on the arrival of a date certain, that provision cannot be meaningfully described as conditional.

Shire answers only (OB 43-44) that "the purpose of [the milestone structure] is to allocate risk by conditioning payments on the continued success of the drug, not on the mere passage of time." But Shire cites nothing to support the notion that this was "the purpose" of *this Agreement's* milestone structure, and the Agreement on its face shows otherwise. Again, although the parties tied a series of payments to a series of milestones, they conditioned most of those payments on the *actual* achievement of the respective milestones, but conditioned the Phase III Milestone Payment (and only that payment) on a milestone that would be *deemed achieved* absent an exception. The Agreement as a whole is thus sensibly read as setting forth a preexisting "mandatory obligation" to make payment by a date certain, which may be excused by "a condition subsequent that Shire must prove." MO 52.

3. Shire's contrary position defies settled principles of burden allocation

Finally, assigning the burden to SRS would require SRS to prove that Shire *did not* fail to initiate Phase III clinical trials as a result of a Fundamental Circumstance. But settled precedent disfavors requiring a party to prove a negative. *See Behrman v. Rowan Coll.*, 1997 WL 719080, at *2 (Del. Super. Ct. Aug. 29,

1997) (reallocating burden of proof to avoid requiring a party to prove a negative); *Wilmington Tr. Co. v. Culhane*, 129 A.2d 770, 773 (Del. Ch. 1957) (questioning allocation requiring a party to bear "the burden to prove a negative"). That is for good reason: "[I]t cannot be done. Thus, the affirmative of an issue has to be proved, and the party against whom the affirmative defense is asserted is not required to prove a negative." 29 AM. JUR. 2D EVIDENCE § 173 (footnote omitted).

Moreover, "it is fairer to place the burden of proof on" Shire because it "can more readily access [the] relevant evidence" for which this condition calls, *Policemen's Annuity & Benefit Fund of Chicago v. DV Realty Advisors LLC*, 2012 WL 3548206, at *11 (Del. Ch. Aug. 16, 2012), *aff'd*, 75 A.3d 101 (Del. 2013)—the reasons why Shire failed to timely achieve the Phase III Milestone. To assign the burden to SRS would unfairly force it to reconstruct decisions Shire can more easily address.

At any rate, "the real-world effect of the burden of proof is 'modest' and only outcome-determinative in 'very few cases' where the 'evidence is in equipoise.'" *AB Stable VIII*, 2020 WL 7024929, at *5 (quoting *Ams. Mining Corp. v. Theriault*, 51 A.3d 1213, 1242 (Del. 2012)). That is not this case. The evidence established deferitazole did not "fail[] as a drug"; instead, Shire abandoned the deferitazole program based on its own business decisions. Accordingly, remand would yield the

same conclusion: the bargain Shire struck requires it to make the Phase III Milestone Payment.

CONCLUSION

The Court of Chancery's judgment should be affirmed.

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August 12, 2021