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Case Number 170,2021

IN THE SUPREME COURT FOR THE STATE OF DELAWARE

SHIRE US HOLDINGS, INC. and SHIRE PHARMACEUTICALS LLC,	)	
Defendants Below-Appellants,	)	No. 170, 2021
v.	)	Court Below: Court of Chancery of the State of Delaware,
SHAREHOLDER REPRESENTATIVE SERVICES LLC, in its capacity as the Equityholders' Representative for the former stockholders of FerroKin BioSciences, Inc.,	)	C.A. No. 2017-0863-KSJM
Plaintiff Below-Appellee.	)	

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Nature of Proceedings

This case involves the interpretation of a pharmaceutical merger agreement (the "Merger Agreement") under which Defendant Shire Pharmaceuticals LLC ("Shire") purchased an experimental drug candidate, deferitazole, from FerroKin BioSciences, Inc. ("FerroKin"). The Court of Chancery construed the Agreement to require Shire to make a $45 million milestone payment to FerroKin after deferitazole had already failed. That result cannot be reconciled with the Agreement's text and operation—in particular, the parties' allocation of the risk that deferitazole would fail—and it hands FerroKin a $45 million windfall that it never bargained for when it negotiated the agreement.

As is common in the pharmaceutical industry, the Merger Agreement allocated the risk of drug failure between the parties by providing for deferred compensation: FerroKin would receive an upfront payment, plus a series of deferred contingent milestone payments that would come due upon deferitazole's achievement of specified development targets. The milestone payment at issue here was due upon initiation of a Phase III clinical trial. That target would be "deemed" achieved—whether or not a Phase III trial had actually begun—on December 31, 2015 (the "deeming date"), unless the failure to begin trials was "as a result of a Fundamental Circumstance." A492. A Fundamental Circumstance is a material safety or efficacy concern that reasonably would make continued development of

deferitazole impracticable—that is, a concern equating to deferitazole's failure as a drug.

Over the course of non-clinical and clinical studies, deferitazole was plagued by both safety and efficacy concerns. In February 2014, almost two years before the deeming date of December 31, 2015, a carcinogenicity study (initiated by FerroKin) indicated that the drug caused cancer in rats, and the FDA promptly issued a clinical hold prohibiting further human trials. After significant evaluation, Shire concluded that a Fundamental Circumstance had occurred, terminated further development, and did not make the Phase III milestone payment. Deferitazole was a failure for Shire, despite Shire's investment of many millions of dollars in acquisition and development costs.

In 2017, Plaintiff Shareholder Representative Services ("SRS"), representing FerroKin's equityholders, brought this breach of contract action, alleging that Shire was obligated to make the $45 million milestone payment even though deferitazole had failed well before the deeming date. The Court of Chancery held that Shire had breached the Merger Agreement by failing to make the milestone payment. In the court's view, a Fundamental Circumstance had to be the *sole, but-for* cause for the failure to initiate Phase III trials by the deeming date. Because—as the court concluded—Shire had earlier made drug-development decisions in response to other safety and efficacy concerns that had delayed the projected timeline for the Phase III

trial, the court concluded that it was irrelevant that a Fundamental Circumstance had occurred before the deeming date, even though the Fundamental Circumstance precluded further clinical testing of the drug. That construction overrides the parties' allocation of the risk of drug failure and creates absurd results that no reasonable parties to a pharmaceutical merger agreement would ever agree to. This Court should vacate the Court of Chancery's decision and remand for further proceedings.

Summary of Argument

1. The Court of Chancery erred in construing Section 2.9(f) of the Merger Agreement's Phase III milestone as achieved unless a Fundamental Circumstance was the sole but-for cause of the failure to begin Phase III trials before December 31, 2015. Delaware law requires that Section 2.9(f) be construed in light of "[t]he basic business relationship between [the] parties," and in a manner "informed by its function in the overall . . . [a]greement." *Chicago Bridge & Iron Co. N.V. v. Westinghouse Elec. Co. LLC*, 166 A.3d 912, 927-28 (Del. 2017), *as revised* (June 28, 2017). Given Section 2.9(f)'s role in allocating the risk of drug-development failure, the operation of Section 2.9 as a whole, and the absurd results occasioned by the Court of Chancery's construction, reasonable persons in the parties' positions would have understood that Section 2.9(f) provides that the failure to achieve the Phase III milestone is "as a result of a Fundamental Circumstance" when a Fundamental Circumstance has occurred, thereby preventing Phase III trials, before the deeming date. A Fundamental Circumstance is necessarily a superseding cause when it *entirely* prevents Phase III trials from occurring because it renders any other pre-existing delays irrelevant. Shire therefore had no obligation to make the milestone payment if a Fundamental Circumstance occurred before the deeming date and prevented Phase III trials. At the very least, Section 2.9(f) is ambiguous as to how it should apply when ordinary drug-development delays precede the occurrence

of a Fundamental Circumstance before the deeming date, and the extrinsic evidence uniformly supports Shire's construction.

2. The Court of Chancery also erred in assigning the burden of proof to Shire. Under the correct construction of Section 2.9(f), Shire's obligation to make the Phase III milestone payment turns on whether the safety and efficacy concerns that arose before the deeming date constituted a Fundamental Circumstance. The Court of Chancery assumed without deciding that the answer to that question was "yes." On remand, SRS should bear the burden of proving that the safety and efficacy issues were *not* a Fundamental Circumstance. The Court of Chancery held, however, that Shire bore the burden of proof because, in its view, Section 2.9(f) establishes a condition subsequent. That is incorrect. Section 2.9(a) establishes a condition precedent by providing that the milestone payment comes due "upon the occurrence" of a Phase III trial. It is therefore contingent. Section 2.9(f) likewise provides that Shire's payment obligation depends on the occurrence of a condition precedent, i.e., Shire's failure to start clinical trials in the absence of a Fundamental Circumstance. SRS accordingly bears the burden of proving that the condition was satisfied.

Statement of Facts

A. Negotiation of the Merger Agreement

This case concerns the proper interpretation of the Merger Agreement under which Shire acquired FerroKin and the experimental drug deferitazole. Ex. A (Mem. Op.) at 1; *see* A466. Deferitazole was intended for therapeutic use as an iron chelator (a drug that absorbs excess iron in patients). Ex. A at 2; A117. Shire identified deferitazole as a "[h]igh risk / high reward opportunity" given the drug's commercial and clinical development risks. Ex. A at 5-6; A120; A294.

The parties' negotiations accordingly focused on allocating the risk of deferitazole's failure (and the benefits if it succeeded) between the parties. Given the significant uncertainty inherent in developing any drug, pharmaceutical purchase agreements ordinarily allocate the risk of drug failure by providing for a partial upfront payment—which the seller receives regardless of the drug's success—and contingent milestone payments that come due if and when the drug progresses toward regulatory approval and commercialization. Accordingly, the parties' "negotiations centered on two issues: the structure of the milestone payments and the degree to which Shire would be obligated to pursue development of deferitazole." Ex. A at 11; *see* A346-A347; A333-A334. Like most sellers, FerroKin sought to maximize the upfront payments and to ensure that Shire would pursue deferitazole's development so long as the drug remained viable from a safety

and efficacy standpoint. Ex. A at 11-12; A168. FerroKin therefore initially proposed a provision obligating Shire to make "[c]ommercially [r]easonable [e]fforts" toward deferitazole's development. Ex. A at 12. It also proposed a compensation structure that included a large upfront payment, a subsequent automatic payment, additional milestone payments contingent on certain targets, and a provision obligating Shire to pay outstanding milestone payments if, before December 31, 2020, it "substantially abandoned" development "*other than as a result of the occurrence of a Fundamental Circumstance*." Ex. A at 11-12 (emphasis added); A411-A413.

FerroKin defined a "Fundamental Circumstance" as "the existence of material safety or efficacy concerns . . . that would reasonably be expected to make the production and sale of such Covered Product [deferitazole], or receipt of applicable Regulatory Approvals . . . impracticable without substantially altering such Covered Product." A476; Ex. A at 14-15. Put more simply, a "Fundamental Circumstance" occurs if deferitazole was reasonably understood to have failed as a drug candidate. Thus, although FerroKin sought to build in incentives for Shire to pursue deferitazole's development, FerroKin also understood that if Shire concluded that deferitazole was no longer viable, it should have no further obligation to pursue the drug, or to make further milestone payments. Indeed, in subsequent negotiations, Dr. Hugh Rienhoff—FerroKin's founder and lead negotiator—explained 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*." Ex. A at 13 (emphasis added); A463-A464.

Ultimately, Shire rejected FerroKin's proposed "commercially reasonable efforts" clause and the parties agreed that Shire would have "sole and absolute discretion" to develop deferitazole. A493. The parties also agreed to an upfront payment and a series of contingent milestone payments that incorporated the Fundamental Circumstance definition that FerroKin had proposed.

B. The Merger Agreement

The parties executed the Merger Agreement in March 2012. Shire paid $95 million in an up-front payment to purchase FerroKin, and it agreed to pay up to $225 million in additional contingent milestone payments if deferitazole achieved various development and commercialization targets. Ex. A at 15; A121.

Section 2.9 of the Merger Agreement sets forth the milestone payments. Section 2.9(a) establishes the triggering events and amounts of each milestone payment. The first milestone—at issue here—is defined as the initiation of the Phase III clinical trials for the "Covered Product" (deferitazole). Upon that event, Shire would have to make a $45 million milestone payment. A489-A490.

Section 2.9(b) addresses the scenario in which a Fundamental Circumstance occurs, rendering deferitazole's development impracticable, but Shire nevertheless decides to "substantially alter[]" deferitazole's composition and develop an "alternative covered product."[1] A476. Shire would then be obligated to pay only *half* of the amount specified in Section 2.9(a) for achievement of each successive milestone. A490. Taken together, 2.9(a) and (b) obligate Shire to make the full milestone payment of $45 million if it initiated a Phase III clinical trial for deferitazole, but only half that amount if, after a Fundamental Circumstance occurred, it decided to develop an alternative drug and initiate Phase III trials on that drug.

Section 2.9(f) elaborates on the achievement of the Phase III milestone, stating:

> Notwithstanding anything else in this Agreement to the contrary, in the event that the Company 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. In other words, the Phase III milestone payment would be triggered upon initiation of Phase III trials, or deemed achieved as of the deeming date—unless the failure to initiate Phase III trials by that date was "as a result of a Fundamental Circumstance."

[1] An "alternative covered product" is another "isomeric form" of deferitazole. A472.

Finally, Section 2.9(g) provides that Shire had the "sole and absolute discretion" to "control the development" of deferitazole, and had no "obligation, duty or expectation to test, develop, pursue . . . or otherwise advance" deferitazole's development. A493.

C. Deferitazole Exhibits Multiple Severe Efficacy and Safety Issues

By the time Shire acquired FerroKin, FerroKin had already initiated the development process that would be necessary to obtain FDA approval. The clinical development process for new drugs "comprises three 'phases' that can 'take anywhere from five to fifteen years.'" Ex. A at 3; A189. Research from clinical trials in humans at each development phase successively generates more information about the drug's efficacy and safety. Additional data is generated through non-clinical studies of animals. Ex. A at 3; A189; A182; A202. In deferitazole's case, each successive study revealed significant safety or efficacy concerns. Particularly troubling, deferitazole appeared to require high doses to be effective, but those higher doses caused significant nerve damage in humans.

Before the merger, FerroKin had initiated a Phase II clinical trial to test deferitazole's efficacy at certain doses, and a non-clinical two-year study testing deferitazole in rats for signs of cancer (the "RatCarc Study"). After the merger, Shire conducted two other Phase II clinical trials (Study 202 and Study 203). Shire

intended to initiate a fourth Phase II trial, Study 204, to compare deferitazole's safety and efficacy against Exjade, the primary iron chelator on the market. Ex. A at 18.

In February 2013, after the initial Phase II trials showed that higher doses were necessary to lower cardiac iron (a critical capability in an iron chelator), Shire doubled the dosage administered to patients in Study 203. In April 2013, however, Shire observed a "high incidence" of peripheral neuropathies among Study 203 patients. Ex. A at 21, 26-27; A555; A635.[2] Thereafter, Shire convened a group of external neurologists (the Peripheral Neuropathy Advisory Committee) to assess the issue.

In November 2013, Shire's Pipeline Committee met to discuss the "[n]eed to define the Therapeutic Window" for the drug—that is, the appropriate dose that would lower iron in patients without causing peripheral neuropathy. Ex. A at 28-29; A681. The Committee acknowledged that Shire's "[e]fficacy [and] safety targets" for the drug had not yet been met, which could result in potential "[d]elays for clinical trials." A692. The Committee also recognized that delays could hinder deferitazole's commercial success, as the generic version of Exjade was soon to be released, and deferitazole needed to gain a footing in the market before then. Ex. A at 29. Despite the commercial downside, the Committee decided it needed to wait

[2] Peripheral neuropathy is damage to the peripheral nervous system and can be a serious safety issue. A183.

for the Study 203 results before initiating further clinical studies, including Study 204, as the results would "inform the decision whether [the] program is viable." *Id.*; A760; A711.

In January 2014, the external Peripheral Neuropathy Committee identified peripheral neuropathy as a "dose limiting toxicity" and recommended lowering the doses administered in the clinical trials. Ex. A at 29-30; A129-A130. Shire agreed with this expert advice and proceeded with a lower dose in the ongoing 203 Study.

In February 2014, the RatCarc Study results revealed that rats receiving deferitazole had developed malignant kidney tumors. Ex. A at 17, 31; A131-A132; A764. That was a "very big deal" to Shire because Shire could not ethically continue human trials without being confident that the carcinogenicity finding in rats did not translate to humans. Ex. A at 32; A185. Shire thus decided to stop dosing human patients in clinical trials. Ex. A at 33-35; A844. In March 2014, after Shire informed the FDA of its decision to halt clinical trials, Ex. A at 35-36; A768, the FDA "fully agree[d] with Shire's approach," found that humans "would be exposed to an unreasonable and significant risk of illness or injury" from deferitazole, and imposed a full clinical hold, Ex. A at 36; A781; A775. Shire therefore could not reinitiate clinical trials without the FDA's approval. A775.

In February 2015, Shire decided to cease all commercialization activities for deferitazole's possible approval and launch.[3] Shire also sent SRS a "Notice of Fundamental Circumstance." Ex. A at 43; A839-A843. The Notice highlighted the rat carcinogenicity findings, the clinical hold, and also the other safety and efficacy concerns, including peripheral neuropathies. Shire concluded that the Phase III milestone "shall not be deemed to have been achieved on December 31, 2015," A843, and it did not make the Phase III milestone payment. For almost three years, SRS raised no objection or claim that the milestone payment was owed.

D. Procedural History

In December 2017, Plaintiff SRS, representing FerroKin's former equityholders, brought this action in the Court of Chancery, seeking to recover the $45 million milestone payment plus interest and attorneys' fees. Chancery Dkt. 1; Ex. A at 2. In October 2019, the case was tried before the court. *Id.* at 46.

1. SRS argued that under Section 2.9(f), the Phase III milestone should have been "deemed to have been achieved" on December 31, 2015—even though Shire did not initiate Phase III trials after multiple safety and efficacy concerns arose—because the failure to initiate trials was not "as a result of a Fundamental Circumstance." A51. SRS's primary contention was that—despite the cancer risk,

[3] Deferitazole's Investigational New Drug Application remained open past 2015, for the sole purpose of observing patients who had received deferitazole to ensure they did not develop cancer.

FDA clinical hold, and cardiac-iron and peripheral neuropathy concerns—no Fundamental Circumstance had occurred. A52. SRS also argued that even if a Fundamental Circumstance had occurred before the deeming date, the subsequent failure to initiate Phase III trials was not "as a result of" the Fundamental Circumstance, but was instead "as a result of" delays caused by decisions Shire made in response to the cardiac-iron and peripheral neuropathy concerns. A53. In other words, SRS took the position that Section 2.9(f) required Shire to pay SRS $45 million even if deferitazole had already failed as a drug candidate before the deeming date, so long as other events would have delayed the start of Phase III trials past December 2015 anyway.

2. At trial, however, FerroKin's CEO and chief negotiator, Dr. Rienhoff, testified to a different understanding of Section 2.9(f). Dr. Rienhoff repeatedly described a Fundamental Circumstance as an "out" that would relieve Shire of any obligation to make the milestone payment. *See, e.g.*, A169; A173 (Shire wanted "an out; and the fundamental circumstance was the out."). His "understanding" was "[t]hat there would be automatic payments . . . unless there was a fundamental circumstance." A169. He further explained that if there were a "material safety or efficacy issue . . . it would be a fundamental circumstance which would relieve Shire of the obligation to meet that first milestone." A171; *see also* A179 (explaining his understanding that Shire would pay despite not starting the Phase III study "unless

there was a fatal flaw that would not allow approval of the drug"). That is consistent with his view during negotiations that if Shire undertook an obligation to use reasonable efforts to develop deferitazole, that obligation would only apply "assuming the product is safe and effective." Ex. A at 13 (emphasis added); A463-A464.

Dr. Rienhoff's understanding was shared by every single witness who testified about the Merger Agreement, and it was also reflected in contemporaneous correspondence. For example, Armand Girard, Shire's Senior Director of Business Development, explained: "Section 2.9 and this concept of fundamental circumstance was a provision in the merger agreement to deal with that unknown risk. To give Shire an out, quite honestly. . . . If one of these material events occurs, safety, efficacy, timing, there needs to be outs. And that was the point of that [Section 2.9(f)] provision." *See* A195. That testimony was consistent with "[i]nternal Shire post-closing communications," which reflected Shire's understanding that "the only scenario in which the Initiation of Phase III Clinical Trial Milestone payment would not be made was for a Fundamental Circumstance." Ex. A at 16-17 (internal quotation marks and alterations omitted); A552.

3. After trial, the Court of Chancery requested supplemental briefing on the "contractual causation analysis" required by the phrase "as a result of a Fundamental Circumstance." Ex. B.

4. In July 2020, the Court of Chancery issued its decision holding that Shire had breached the Merger Agreement by failing to make the $45 million milestone payment.

The court first held that even though Shire is the defendant in this breach of contract action, Shire bore the burden of proving that it was not obligated to make the Phase III milestone payment because Phase III trials were not initiated "as a result of a Fundamental Circumstance." Ex. A at 48-54.[4] The court reasoned that even though Section 2.9(a) provided that the payment obligation would arise only "upon the first occurrence" of the milestone event, the Phase III milestone represented a non-contingent "mandatory obligation" that could be excused only by the Fundamental Circumstance clause. *Id.* at 52.

The court next held that Shire had not proven that its failure to initiate Phase III trials was "as a result of a Fundamental Circumstance." *Id.* at 54-75. The court assumed without deciding that the RatCarc study and ensuing FDA clinical hold constituted a Fundamental Circumstance. *Id.* at 54. Nonetheless, the court held that the failure to begin Phase III trials was not "as a result of" that Fundamental Circumstance. Relying on the dictionary definition of "as a result of"—"because of something"—and decisions allocating responsibility in the tort and criminal

[4] The court had declined to address the burden issue before or during trial, even though Shire had raised the parties' dispute on that question. *See* A145-A150.

contexts, the court held that Section 2.9(f) deemed the Phase III milestone to have been achieved unless a Fundamental Circumstance was the sole *but-for cause* of the failure to initiate trials. *Id.* at 69-70 & n.357.

The court then engaged in a chronological, step-by-step review of Shire's decisions in responding to the safety and efficacy concerns that arose during clinical studies. The court identified Shire's decisions by January 2014—to reduce the Study 203 dosage and delay starting Study 204—as having the effect of pushing the projected start date for the Phase III trials past the December 31, 2015 deeming date. *Id.* at 64. Although those safety- and efficacy-related decisions took place almost two years before the deeming date, and although the RatCarc study results—a Fundamental Circumstance—were issued just a month later, in February 2014, the court concluded that Shire's earlier decisions were the sole but-for cause of the failure to begin trials. The court therefore held that Shire was obligated to pay SRS $45 million even though deferitazole had failed well before the deeming date.

Argument

I. Under Section 2.9(f), the Phase III milestone is not deemed achieved when a Fundamental Circumstance prevents the initiation of Phase III clinical trials

A. Question Presented

Whether the failure to initiate Phase III clinical trials was "as a result of a Fundamental Circumstance" under Section 2.9(f) of the Merger Agreement, where a Fundamental Circumstance occurred before the deeming date of December 31, 2015, and prevented Phase III trials from beginning. A870-A883.

B. Standard of Review

This Court reviews questions of contract interpretation de novo. *GMG Cap. Invs., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 779 (Del. 2012).

C. Merits of Argument

The Court of Chancery construed Section 2.9(f) to provide that the Phase III milestone would be deemed achieved, and Shire would be obligated to pay $45 million, unless a Fundamental Circumstance was the *but-for cause* of the failure to begin Phase III trials by December 31, 2015. That construction perversely obligated Shire to make the $45 million Phase III milestone payment *even though deferitazole had already failed*, solely because Shire had previously made routine drug-development decisions (related to safety and efficacy) that contemplated delaying Phase III trials past the deeming date. That cannot be right. Section 2.9(f) must be construed in light of the Merger Agreement's milestone payment framework, which

allocates the risk of drug failure between the parties by providing for deferred milestone payments that are conditioned on the continued success of the drug-development process. The Court of Chancery's but-for construction overrode the parties' allocation of risk and handed SRS a $45 million windfall for which it did not bargain.

The court's counterintuitive construction cannot be reconciled with well-established contract-interpretation principles. This Court construes a contractual provision by "determining what a reasonable person in the position of the parties would have thought the language of the contract means." *See Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006). In undertaking that analysis, the Court will take into account the parties' respective commercial positions and the risks that the contract seeks to allocate: "[t]he basic business relationship between parties must be understood to give sensible life to any contract." *Chicago Bridge & Iron Co. N.V.*, 166 A.3d at 927. And, this Court will reject an interpretation that produces a result "that no reasonable person would have accepted when entering the contract." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010); *see also ITG Brands, LLC v. Reynolds Am., Inc.*, 2017 WL 5903355, at *12 (Del. Ch. Nov. 30, 2017).

Those principles require that Section 2.9(f) be construed in a manner that is "informed by its function in the overall . . . [a]greement." *Chicago Bridge*, 166 A.3d

at 928. In providing that the Phase III milestone would be deemed achieved unless failure to achieve the milestone was "as a result of a Fundamental Circumstance," Section 2.9(f) protects Shire against the risk of drug-development failure, and FerroKin against certain delays in beginning Phase III trials. Reasonable persons in the parties' positions would have understood that the occurrence of a Fundamental Circumstance (against which Shire was protected) that would prevent Phase III trials renders other delays in initiating those trials (against which SRS may have been protected) irrelevant. In other words, regardless of any pre-existing delays in the timetable for Phase III trials, the occurrence of a Fundamental Circumstance ensures that deferitazole will not be developed as contemplated on *any* timetable.[5] The failure to achieve the Phase III milestone therefore is "as a result of a Fundamental Circumstance" when a Fundamental Circumstance has occurred, thereby preventing Phase III trials before the deeming date.

[5] In that event, Section 2.9(b) anticipated that Shire might choose to develop an Alternative Covered Product after the occurrence of a Fundamental Circumstance—but that would not be developing deferitazole as initially contemplated. *See* p.32-33, *infra*.

1. Under Section 2.9(f), failure to achieve the Phase III milestone is "as a result of a Fundamental Circumstance" if a Fundamental Circumstance prevents Phase III trials before the deeming date.

a) The phrase "as a result of a Fundamental Circumstance" must be construed to effectuate the parties' allocation of the risk that further drug development would become impracticable.

Section 2.9(f) provides that if Shire "has not achieved" the Phase III milestone "on or before December 31, 2015, other than as a result of a Fundamental Circumstance," then the milestone "shall be deemed to have been achieved on such date." A492. The Court of Chancery construed the phrase "as a result of a Fundamental Circumstance" to require that the Fundamental Circumstance must be the but-for cause of the failure to timely initiate Phase III trials. The court based that conclusion solely on the dictionary definition of "result of"—which the court understood to mean "because of," Ex. A at 69—and the fact that the phrase "as a result of" generally has been construed to mean but-for causation in the tort and criminal contexts, *id.* at 70 & n.357.

That was error. Although the phrase "as a result of" is often understood to require a factual inquiry into "a causal connection" in statutory or common law settings, *Brown v. Gardner*, 513 U.S. 115, 119 (1994), those contexts—and all of the decisions on which the Court of Chancery relied—involve allocating *responsibility* for a particular result or injury. Ex. A at 70 (citing formulations that

allocate fault for another's death or for workplace injury). But that is not the purpose of Section 2.9(f). Milestone payments allocate risk, not fault.

The Court of Chancery committed legal error when it failed to construe the phrase "as a result of a Fundamental Circumstance" in the context of the Merger Agreement as a whole and the commercial relationship between parties to a pharmaceutical merger, and instead divorced the phrase "as a result of" from its contractual context and function. Reasonable persons in the parties' positions would have understood that, when a Fundamental Circumstance sufficient to prevent Phase III trials occurred, the failure to achieve the Phase III milestone necessarily would be "as a result of a Fundamental Circumstance." *See Lorillard*, 903 A.2d at 739. That follows from the parties' overall risk allocation, Section 2.9(f)'s text and operation, and surrounding provisions in Section 2.9.

i. The Merger Agreement's milestone provisions must be understood against the backdrop of how parties to a pharmaceutical merger agreement allocate risk. Because the process of developing a new drug is lengthy and extremely risky, "[p]harmaceutical acquisitions often account for th[e] uncertainty [of a drug's successful development] through milestone payments, which reward target companies as their acquired assets progress toward commercialization." *Kabakoff v. Zeneca, Inc.*, 2020 WL 6781240, at *25 (Del. Ch. Nov. 18, 2020), *judgment entered*, (Del. Ch. 2020). Such agreements allocate the risk of drug failure between

the parties: the overall purchase price is divided into an initial upfront payment (which protects the seller by guaranteeing some compensation regardless of the drug's success or failure) and subsequent milestone payments that come due only so long as the drug proceeds toward regulatory approval and commercialization (which protects the buyer by lessening its payment obligation if the drug fails). *See, e.g.*, *Fortis Advisors LLC v. Shire US Holdings, Inc*., 2017 WL 3420751, at *1 (Del. Ch. Aug. 9, 2017) ("[T]he parties agreed to share the risks and rewards of developing [the drug] by allocating merger consideration between fixed up front payments and subsequent contingent payments that depended on Shire's ability to shepherd the drug through clinical trials and regulatory approvals.").

Critically, because the very purpose of milestone payments is to protect the buyer against the risk of drug failure, it would make no sense for the buyer to agree to make milestone payments even *after* events have made clear that the drug has failed. *See id*. ("the milestone payments allowed [buyer] to hedge against future risks" through "subsequent payments that would become due *only if* the defined milestones were reached") (emphasis added); *Himawan v. Cephalon, Inc*., 2018 WL 6822708, at *3 (Del. Ch. Dec. 28, 2018) (given "substantial risk" in treatment development, agreement involved "modest" initial payment, "while a large part of the purchase price was contingent on the success of" the drug); *Callinan v. Lexicon Pharms., Inc*., 2020 WL 4740487 (S.D. Tex. Aug. 14, 2020) (similar).

The Merger Agreement reflects those commercial realities. *Chicago Bridge*, 166 A.3d at 927. When negotiations began, Shire's diligence team presented deferitazole as a "high risk / high reward" opportunity. Ex. A at 5-6. Shire, as the buyer, was thus well aware that deferitazole posed a high risk of failure, and the parties structured the transaction to allocate that risk. Section 2.9 of the Merger Agreement provided for a $95 million upfront payment, which protected FerroKin's equityholders from the risk of drug failure by ensuring substantial compensation even if deferitazole subsequently failed. The Merger Agreement also provided for up to $225 million in additional contingent milestone payments that would be made only upon achievement of specified development and marketing milestones. A489. The evident purpose of the parties' agreement to base 70% of the deal consideration on contingent, future milestone payments was to protect Shire against the high risk that deferitazole would fail in drug development.

ii. Section 2.9(f)'s deeming provision operates within the framework of the parties' overall allocation of risk and must be construed accordingly. *Chicago Bridge*, 166 A.3d at 926–27 (provision must be construed in light of entire agreement, "read in full and situated in the commercial context between the parties"). That risk allocation provided a measure of security to both parties. It protected FerroKin against delays in the initiation of Phase III trials by requiring that the milestone would "be deemed to have been achieved" on December 31, 2015,

regardless of whether trials had actually begun, absent, of course, a "Fundamental Circumstance." In turn, the "Fundamental Circumstance" language afforded protection to Shire by eliminating its obligation to make further payments when material issues related to safety or efficacy made approval and commercialization of deferitazole "impracticable." The question presented here therefore is whether Section 2.9(f) protects FerroKin from delays in initiating Phase III trials notwithstanding that a Fundamental Circumstance had occurred before December 31, 2015, such that it was clear in advance of—indeed almost two years in advance of—the deeming date that deferitazole was no longer viable.

The answer to that question must be no. It strains credulity to think that a reasonable party in Shire's position would have agreed to make the Phase III milestone payment when the drug had *already* failed. That would defeat the very purpose of structuring the transaction as a series of milestone payments. Once it was clear that deferitazole was not viable, a reasonable party in Shire's position would not expect to have to make future contingent milestone payments, and a reasonable party in FerroKin's position would not expect to receive future milestone payments. *See ITG Brands*, 2017 WL 5903355, at *12. Conversely, requiring Shire to make the milestone payment would give FerroKin a windfall that no reasonable party would expect: in addition to the $95 million upfront payment to which it was entitled regardless of deferitazole's success or failure, FerroKin would receive a $45 million

contingent milestone payment even though the drug could not be further developed—simply because Shire had made safety- and efficacy-related decisions that resulted in other projected delays to the timeline.

To effectuate the parties' risk allocation, the "as a result of a Fundamental Circumstance" clause must be construed to protect FerroKin from delay only so long as the drug was still viable and could "progress toward commercialization." *Kabakoff*, 2020 WL 6781240, at *25. Specifically, 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. In other words, the milestone is not an absolute guarantee for FerroKin's equityholders. It cannot be deemed achieved if it has become clear before the deeming date that the contemplated development of deferitazole was not practicable. *See Chicago Bridge*, 166 A.3d at 930 ("Thus, this interpretation of the [provision at issue] maintains the underlying economics of the parties' bargain."). Section 2.9(f) thus does not contemplate a factual inquiry into whether *other* factors might also have resulted in the failure to initiate Phase III trials by December 2015. When a Fundamental Circumstance—which, by definition, is an event that renders further drug development *impracticable*—prevents such development, the Fundamental Circumstance is the superseding and legal cause of the failure to further pursue drug development.

That construction follows not only from the parties' risk allocation, but from the definition of a Fundamental Circumstance and the backward-looking nature of the contractual deeming inquiry. The occurrence of a Fundamental Circumstance means that attempting to develop deferitazole in its current form would be futile or at least unreasonably difficult. Reasonable parties therefore would expect that the occurrence of a Fundamental Circumstance would cause—in some cases, compel—Shire to halt development, including Phase III trials. Evaluating events from the perspective of December 31, 2015—as Shire was entitled to do, given that the parties chose that date as the date on which Shire's payment obligation would be determined—the Fundamental Circumstance constituted an intervening event that ensured that, no matter what else had occurred, Phase III trials could not begin by December 31, 2015. The occurrence of a Fundamental Circumstance sufficient to prevent Phase III trials therefore is a superseding cause that renders other delays both factually and legally irrelevant. At that point, the contemplated development of deferitazole could not occur. The failure to achieve the milestone is therefore "as a result of a Fundamental Circumstance."

That is the only sensible reading of the contract: the milestone framework, of which Section 2.9(f) is a part, 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.

Indeed, the Court of Chancery's search for the but-for cause of the failure to initiate Phase III trials, notwithstanding the occurrence of a Fundamental Circumstance, cannot be reconciled with Section 2.9(f)'s requirement that the deeming analysis must be conducted from the perspective of December 31, 2015. As of that date, the Fundamental Circumstance had occurred and Phase III trials could not take place. The inquiry into but-for cause was therefore counterfactual, asking whether, *if the Fundamental Circumstance had not occurred and Phase III trials could have proceeded*, those trials would have been delayed for reasons attributable to Shire. That inquiry cannot be sensibly undertaken, as the Fundamental Circumstance prevented Shire from completing—and learning the results of—the *Phase II* trials, which might have revealed other reasons why the development of deferitzole was impracticable. There is no sound reason that the parties would have required a counterfactual inquest into events that no longer mattered once deferitazole had failed, when the whole purpose of Section 2.9(f) is to allocate the risk of failure.

The Court of Chancery's attempt to perform that counterfactual analysis proves the point: the court's conclusion that Shire was liable for the milestone payment because of projected delays in January 2014—just before the Fundamental Circumstance occurred—effectively (and irrebuttably) presumed that deferitazole would have enjoyed clinical success in the pre-Phase III trials had the Fundamental Circumstance not occurred. But there is no way to know what the discontinued

studies would have revealed. The safety and efficacy concerns that led Shire to redesign its study plans in January 2014 could well have developed into Fundamental Circumstances themselves. There was no assurance, for example, that the lowered dose of deferitazole necessary to reduce safety risks would be sufficiently effective to secure FDA approval. Thus, under the court's counterfactual inquiry, the occurrence of the Fundamental Circumstance in February 2014 left Shire in a *worse* position than if no Fundamental Circumstance had occurred. Effectively, the court treated January 2014, not December 2015, as the contractual deeming date for the milestone payment.

Indeed, the only evident reason to answer the theoretical question whether Shire's actions would have caused delays in Phase III trials, when a Fundamental Circumstance had occurred and precluded trials entirely, would be to allocate *fault* to Shire. To hold, as the Court of Chancery did, that SRS should receive the milestone payment despite deferitazole's failure, solely because Shire made decisions that delayed the initiation of a Phase III trial, is to impose liability on the basis of fault—that is, to treat Shire as though it breached a duty to proceed expeditiously. The Court of Chancery seemed to approach the issue in just that way. The court engaged in a painstaking, chronological examination of Shire's drug-development decisions, emphasizing whether those decisions were driven by commercial as well as safety or efficacy considerations. And having found

(incorrectly) that Shire was responsible for the delay, the court ordered Shire to pay damages in the amount of the milestone payment, even though the Fundamental Circumstance would have prevented the development of deferitazole in any event. *Contra, e.g.*, *Errico v. Stryker Corp.*, 281 F.R.D. 182, 186 (S.D.N.Y. 2012) (damages equal to milestone payment as remedy for breach of reasonable-efforts clause).

But Section 2.9(f) is not a "commercially reasonable efforts" clause, and the parties expressly declined to include such a requirement in their agreement. Although FerroKin sought to obligate Shire to make reasonable efforts, at least "assuming the product is safe and effective," A463-A464, Shire rejected that proposal, and the parties agreed that Shire would have sole discretion over deferitazole's development. A493. The protection against delay that Section 2.9(f)'s deeming provision accords FerroKin therefore must be understood in light of Shire's sole discretion over the development process. Given that Shire had no obligation to begin Phase III trials by December 31, 2015, or to proceed at any particular speed, the parties could not have understood Section 2.9(f) to require the very inquiry into Shire's development decisions that the parties elected *not* to mandate through a reasonable-efforts clause. Put differently, Shire had the right to pursue the clinical development of deferitazole at whatever pace it deemed appropriate. Shire cannot be faulted for exercising a right the contract granted to it.

Reasonable actors in the parties' position also would have avoided a but-for inquiry into Shire's decisions because parties to pharmaceutical agreements endeavor to draft milestone provisions so as to "remove doubt regarding when the milestone payments [will be] due." *Kabakoff*, 2020 WL 6781240, at *25. Construing Section 2.9(f) to require only an inquiry into whether a Fundamental Circumstance occurred provides as much predictability as possible, consistent with the parties' allocation of risk. Reasonable parties would not have intended that even if a Fundamental Circumstance had already occurred, Shire (or a reviewing court) would then have to analyze whether *other* events were nonetheless the but-for cause of the delay. That open-ended, subjective (and, indeed, unworkable, *see* p.33-36, *infra*) inquiry would inject substantial uncertainty as to whether Shire would be obligated to make the payment. Commercial counterparties do not needlessly inject unpredictability into provisions as critical as milestone payments. *See Kabakoff*, 2020 WL 6781240, at *25 (although term in milestone provision could have multiple meanings, court rejected instruction that was "directly contrary to the parties' intent to effectuate precision in the determination of when milestone consideration was due").

b) Section 2.9(b) provides further support for Shire's construction.

Section 2.9(b) reinforces the conclusion that Section 2.9(f) does not obligate Shire to make the milestone payment when a Fundamental Circumstance prevents

Phase III trials. *See Kuhn Const., Inc. v. Diamond State Port Corp.*, 990 A.2d 393, 396-97 (Del. 2010) (Court "read[s] a contract as a whole" to determine "what a reasonable person in the position of the parties would have thought the contract meant").

The milestone provisions of Section 2.9 work together to allocate the risk of drug failure under various circumstances. Section 2.9(a) provides that Shire would pay $45 million upon the initiation of the Phase III clinical trials. A489-A490. Section 2.9(b) provides that "in the event that there occurs a Fundamental Circumstance," but Shire "pursues an Alternative Covered Product"—i.e., a "substantially altered" but related product—"then any remaining Milestone Payments that first become due and payable following the occurrence of such Fundamental Circumstance shall be *one-half*" what they otherwise would be. A490 (emphasis added). Together, 2.9(a) and (b) 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.

That risk-allocation structure makes clear that the parties calibrated the payment amounts based on whether Shire was able to develop deferitazole or was instead forced to develop a less-desirable alternative. The plain implication of subsection (b) is that if a Fundamental Circumstance occurs and Shire cannot salvage

any alternative form of the drug, FerroKin should receive *less* than half of the milestone payment. Indeed, in that circumstance (which is presented here) deferitazole would have proven entirely nonviable, so it follows that Shire should not have to make any subsequent milestone payments. Under Shire's reading of Section 2.9(f), that is exactly what would happen: as long as the Fundamental Circumstance occurred before December 31, 2015, preventing Phase III trials, FerroKin would not receive the full Phase III milestone payment.

Under the Court of Chancery's interpretation, however, FerroKin receives the full $45 million milestone payment even if deferitazole fails entirely and Shire does not develop any Alternative Covered Product, so long as there were other causes for the failure to initiate Phase III trials by December 31, 2015. Ex. A at 74-75 (asserting that if events other than a Fundamental Circumstance were the but-for cause of a delay in Phase III trials, Shire would pay half of $45 million if it developed an alternative product and the full $45 million if it did not develop *any* product). That construction turns the parties' economic bargain on its head by entitling FerroKin to *more* money in a situation in which deferitazole is *less* viable. That is a nonsensical interpretation of the contract. *See Chicago Bridge*, 166 A.3d at 928-33.

c) The Court of Chancery's but-for interpretation leads to unworkable and unreasonable results.

The Court of Chancery's but-for construction of Section 2.9(f) should also be rejected because it requires a causation inquiry that would be unworkable and

unreasonable given the reality of how a Fundamental Circumstance would arise. *See Osborn*, 991 A.2d at 1160 (interpretations that produce absurd or unworkable results should be rejected).

By definition, a Fundamental Circumstance often will be the culmination of, and intertwined with, significant drug-development delays. Material safety or efficacy concerns do not arise without warning; rather, they are ordinarily preceded by increasing evidence of problems, followed by attempts to address those concerns. This case is illustrative. Assume, for instance, that the RatCarc study and related clinical hold had not occurred, and the cardiac iron and neurological damage concerns eventually ripened into a Fundamental Circumstance—but only after Shire made decisions, in an effort to investigate and address those concerns, that pushed the projected start of Phase III trials past December 31, 2015. Under the Court of Chancery's reasoning, Shire's decisions, not the Fundamental Circumstance, would be the but-for cause of the failure to begin trials by December 2015, because those decisions would have delayed the projected start of Phase III trials before Shire had enough evidence to conclude that a Fundamental Circumstance had occurred. In that circumstance, Shire would be required to pay FerroKin $45 million for a drug afflicted with dispositive safety or efficacy concerns because of Shire's own efforts to treat those concerns with the seriousness they deserved. No reasonable party in Shire's position would have agreed to such a self-defeating milestone term.

The but-for inquiry is no more sensible in the situation presented here, in which deferitazole suffered from multiple significant safety and efficacy concerns that Shire had to address in tandem. The carcinogenicity results—a Fundamental Circumstance—were released in February 2014, and ultimately ensured that Phase III trials could not occur by the deeming date. But one month earlier, in January 2014, Shire had responded to the *other* serious safety and efficacy concerns by making decisions that delayed the projected start of Phase III clinical trials beyond December 2015. The Court of Chancery thus deemed Shire obligated to pay the $45 million because of temporal happenstance: had the RatCarc results and clinical hold happened a month earlier, those events would have qualified as the but-for cause under the Court's approach. No parties to a pharmaceutical merger agreement would make a multimillion dollar milestone payment turn on such fortuity.

That outcome is all the more perverse because the Fundamental Circumstance forced Shire to discontinue its investigation of the significant safety and efficacy concerns that had already arisen. The cardiac-iron and peripheral-neuropathy investigations could well have revealed that deferitazole was not safe or effective at *any* dose (or at least at any FDA-approvable dose)—which would have been a Fundamental Circumstance in itself. But the Court of Chancery's approach effectively used the occurrence of a Fundamental Circumstance in February 2014 to *cement* Shire's obligation to make the milestone payment almost two years before

the deeming date, even though the already-known, serious safety and efficacy concerns could have developed into their own Fundamental Circumstance. That is irreconcilable with the parties' negotiated choice of December 31, 2015 as the date on which events would be evaluated.

Construing Section 2.9(f) to provide that failure to achieve the milestone is "as a result of a Fundamental Circumstance" when a Fundamental Circumstance prevents further development before the deeming date avoids those incongruities. That construction focuses the inquiry on the consideration that was actually critical to the parties—whether the contemplated development of deferitazole was impracticable—rather than on an unworkable inquiry into whether Shire's decisions were responsible for delaying the projected start of Phase III trials before the Fundamental Circumstance occurred.

2. If the Court concludes that Section 2.9(f) is ambiguous, extrinsic evidence establishes that Shire's payment obligation does not arise if a Fundamental Circumstance occurs before the Phase III milestone date.

As discussed above, Section 2.9(f) unambiguously provides that the Phase III milestone will not be deemed to have been achieved if a Fundamental Circumstance has prevented Phase III trials before the milestone date. But at the very least, the provision is ambiguous as to what should happen when a Fundamental Circumstance prevents the trials after other decisions have delayed their projected start. When a contract is ambiguous, "[c]ourts consider extrinsic evidence to interpret the

agreement." *Nw. Nat. Ins. Co. v. Esmark, Inc.*, 672 A.2d 41, 43 (Del. 1996); *see also S'holder Representative Servs. LLC v. Gilead Scis., Inc.*, 2017 WL 1015621, at *19-22 (Del. Ch. Mar. 15, 2017), *aff'd*, 177 A.3d 610 (Del. 2017). Here, the extrinsic evidence confirms that the parties contemplated that Shire would not be obligated to make the milestone payment if a Fundamental Circumstance had occurred.

Every trial witness involved in negotiating and drafting the Merger Agreement understood that the Phase III milestone would not be deemed achieved if a Fundamental Circumstance arose and prevented the initiation of Phase III trials before the deeming date. During negotiations, FerroKin did not even *seek* the sort of extraordinary protection that the Court of Chancery viewed Section 2.9(f) as providing: FerroKin's founder, Dr. Rienhoff, asserted only 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*." Ex. A at 13 (emphasis added); A463-A464. Even FerroKin's negotiating position, then, did not contemplate receiving a windfall milestone payment if Shire delays preceded deferitazole's failure.

At trial, both parties' negotiators explained that Shire would not be obligated to make the milestone payment if a Fundamental Circumstance occurred. Dr. Rienhoff repeatedly described a Fundamental Circumstance as an "out" that would

relieve Shire of any obligation to make the milestone payment. *See, e.g.*, A169; A173. He also made clear his understanding "[t]hat there would be automatic payments . . . unless there was a fundamental circumstance." A169; *see also* A171 ("[I]f that were the case, it would be a fundamental circumstance which would relieve Shire of the obligation to meet that first milestone."); A179 (explaining his understanding that Shire would effectively pay a penalty for not starting Phase III "unless there was a fatal flaw that would not allow approval of the drug"). Shire's negotiators made the same point. *See* A195 (testimony of Armand Girard, Shire's Senior Director of Business Development, that "Section 2.9 and this concept of fundamental circumstance was a provision in the merger agreement to deal with that unknown risk. To give Shire an out, quite honestly. . . . If one of these material events occurs, safety, efficacy, timing, there needs to be outs. And that was the point of that [Section 2.9(f)] provision.").

The parties' course of performance after the Merger Agreement was executed reinforces the conclusion. *See Sun-Times Media Grp., Inc. v. Black*, 954 A.2d 380, 398 (Del. Ch. 2008) ("When the terms of an agreement are ambiguous, 'any course of performance accepted or acquiesced in without objection is given great weight in the interpretation of the agreement.'" (citing Restatement (Second) of Contracts § 202)); *In re Viking Pump, Inc.*, 148 A.3d 633, 649 (Del. 2016). In early 2014, an SRS representative reported to FerroKin shareholders that Phase III trials had been

delayed beyond December 31, 2015, noting that the milestone "is deemed achieved on December 31, 2015 *unless there has been a Fundamental Circumstance* (essentially a determination that the product has material safety or efficacy concerns that make going forward impracticable)." A766-A767 (emphasis added). SRS did not suggest that Shire's delays meant that shareholders would receive the Section 2.9(f) milestone payment regardless of any Fundamental Circumstance that later arose. In addition, as the Court of Chancery found, "[i]nternal Shire post-closing communications reflect that Shire understood that the only scenario in which the Initiation of Phase III Clinical Trial Milestone payment would not be made was for a Fundamental Circumstance." Ex. A at 16-17 (internal quotation marks and alterations omitted); A552. No one on either side of the bargaining table ever imagined that Section 2.9(f) would require Shire to pay SRS a $45 million windfall, despite the occurrence of a Fundamental Circumstance prior to the deeming date, solely because Shire's decisions delayed the projected start of Phase III trials first.[6]

[6] That shared understanding is underscored by SRS's nearly three-year delay after the Notice of Fundamental Circumstance before it claimed that Shire owed it the milestone payment. And during that time, SRS's theory was that Shire owed the payment because no Fundamental Circumstance had occurred. *See* A864 (FerroKin equityholder director recommending in 2016 "to advise Shire that we do not believe that a Fundamental Circumstance arose and that they therefore owe us the Ph 3 initiation milestone"); A862 (SRS director agreeing, and merely clarifying Fundamental Circumstance definition).

II. On remand, SRS bears the burden of proving that a Fundamental Circumstance was not an independently sufficient cause of the failure to initiate Phase III trials by December 31, 2015.

Under the correct construction of Section 2.9(f), Shire's obligation to make the Phase III milestone payment turns on whether the RatCarc study and FDA clinical hold, which occurred before the deeming date of December 31, 2015, constituted a Fundamental Circumstance. The Court of Chancery assumed without deciding that the answer to that question was "yes." A remand therefore is appropriate to permit the Court of Chancery to address that issue, which entails factual determinations, in the first instance. On remand, SRS—as the party seeking to establish the occurrence of a condition precedent to Shire's obligation to make the milestone payment—should bear the burden of proving that the cancer finding and the ensuing clinical hold were not a Fundamental Circumstance.

The Court of Chancery, however, held that Shire bore the burden of proving that it was *not* obligated to make the Phase III milestone payment. In its view, Section 2.9(f) establishes a condition subsequent—that is, an event that terminates a pre-existing, non-contingent duty to make the milestone payment—such that Shire must prove that it was released from that duty by the occurrence of a Fundamental Circumstance. Ex. A at 49-50; 16 Williston on Contracts § 49:87 (4th ed.) ("[T]he burden of proof with respect to conditions subsequent is on the defendant[.]"). That conclusion rests on an erroneous construction of Section 2.9.

A. Question Presented

Whether the Court of Chancery erred in concluding that Shire bears the burden of proof, based on its characterization of Section 2.9(f) as setting out a condition subsequent—that is, an event that terminates a pre-existing duty to pay—rather than a condition precedent to Shire's obligation to make the milestone payment. A872-A874; A267-A270.

B. Standard of Review

"The proper allocation of the burden of proof is a question of law" that this Court reviews de novo. *State Farm Mut. Auto. Ins. Co. v. Spine Care Del., LLC*, 238 A.3d 850, 857 (Del. 2020).

C. Merits of Argument

Under the Merger Agreement, SRS, not Shire, bears the burden of proving that Shire is obligated to make the Phase III milestone payment. Properly understood, that obligation depended on the occurrence of a condition precedent: the initiation of Phase III trials, a condition that would be deemed to have occurred on the deeming date unless the failure to start clinical trials was due to a Fundamental Circumstance. *See* 13 *Williston on Contracts* § 38:26 (4th ed.) ("[T]he ultimate burden of proof with regard to conditions precedent . . . remains on the plaintiff.").

As an initial matter, Section 2.9(f) must be understood in the context of Section 2.9(a), which provides that any milestone payments come due only upon the occurrence of a condition precedent: "[u]pon the first occurrence of any of the events

set forth in the table below under 'Milestone Trigger Event' (each a 'Milestone'), [Shire] shall" make the specified payment. A489; *Himawan*, 2018 WL 6822708, at *3 (milestone payments "contingent" upon drug's success); *see* 13 *Williston on Contracts* § 38:16 ("[T]he words 'if' or 'provided,' as well as the phrases 'provided that,' 'on condition that,' '*in the event that*,' and other terms that purport to condition performance on another act or event, usually connote an intent for a condition rather than a promise.") (emphasis added).

Section 2.9(f) does not transform Section 2.9(a)'s contingent obligation to make the milestone payment *if* Phase III trials begin into a non-contingent, pre-existing duty to pay *unless* a Fundamental Circumstance occurs and terminates that duty. Rather, the provision simply instructs how to determine whether the condition precedent—initiation of Phase III trials—has occurred. Specifically, if the initiation of trials has not occurred by December 31, 2015, that condition precedent "shall be deemed to have been achieved on such date," unless a Fundamental Circumstance has prevented the trials' initiation.

That understanding is confirmed by the operative language of Section 2.9(f):

> [I]n the event that the Company 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.

Restated more simply, *if* Shire had not started a Phase III clinical trial on or before December 31, 2015 other than because of a Fundamental Circumstance (the condition), *then* (the contractual obligation) the milestone is deemed achieved. That language does not alter the contingent nature of the milestone obligation as set forth in Section 2.9(a). Rather, it reaffirms the conditional nature of Shire's payment obligation: it arises only if Shire has not started a Phase III clinical trial by the deeming date, other than as a result of a Fundamental Circumstance. *See* 13 *Williston on Contracts* § 38:16. The inquiry into whether the failure was as a result of a Fundamental Circumstance is thus an inquiry into whether the condition precedent should be deemed to have occurred.[7] The overarching obligation to make the milestone payment always remains conditioned upon the initiation of a Phase III trial (whether that initiation actually occurs or is deemed to have occurred).

The Court of Chancery's contrary reading was based on its conclusion that Section 2.9(f) "*automatically* deems the Initiation of Phase III Clinical Trial Milestone to have occurred on December 31, 2015." Ex. A at 52 (emphasis added). Under that view, the milestone obligation would become non-contingent on December 31, 2015, and that duty would be terminated only by a Fundamental Circumstance. That construction is inconsistent with the milestone structure, the

[7] That evaluating whether the condition occurred involves asking whether a Fundamental Circumstance has *not* occurred does not change the fact that it remains a condition precedent. *See* Restatement (Second) of Contracts § 224 cmt. b.

purpose of which is to allocate risk by conditioning payments on the continued success of the drug, not on the mere passage of time. And if the parties had wanted to provide that the Phase III milestone obligation was non-contingent beginning on December 31, 2015, they would not have used the convoluted method of providing that the condition (initiation of Phase III trials) would be deemed to have occurred in some but not all circumstances.

Under the correct construction of Section 2.9(f), SRS has the burden of demonstrating that Shire's timely notice of a Fundamental Circumstance was inoperative because there was no Fundamental Circumstance sufficient to delay the initiation of Phase III trials beyond December 31, 2015. The evidence at trial overwhelmingly demonstrated that both the RatCarc study and FDA clinical hold constituted a Fundamental Circumstance. But because the Court of Chancery erred in placing the burden of proving those issues on Shire, and Section 2.9(f)'s condition-precedent framework will govern the analysis on remand, this Court should make clear that SRS bears the burden of demonstrating that Section 2.9(f)'s conditions have been met.

CONCLUSION

For the foregoing reasons, this Court should vacate the Court of Chancery's judgment and remand for further proceedings.

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Dated: July 13, 2021.

CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2021, a true and correct copy of the foregoing was served as follows:

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EXHIBIT A

EXHIBIT B

EXHIBIT C

EXHIBIT D

EXHIBIT E