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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.	)	

APPELLANTS' REPLY BRIEF

Of Counsel:

Donald B. Verrilli, Jr.
Ginger D. Anders
Dahlia Mignouna
MUNGER, TOLLES & OLSON LLP
601 Massachusetts Ave. NW, Ste. 500E
Washington, D.C. 20001-5369
Telephone: (202) 220-1100
Facsimile: (202) 220-2300
Donald.verrilli@mto.com

Timothy W. Mungovan
Colin G. Cabral
Michael R. Hackett
James R. Anderson
PROSKAUER ROSE LLP
One International Place
Boston, MA 02110
(617) 526-9600

Dated: August 27, 2021

BAYARD, P.A.

Peter B. Ladig (#3513)
600 N. King Street, Suite 400
Wilmington, Delaware 19801
(302) 655-5000

Attorneys for Defendants Below-Appellants Shire US Holdings, Inc. and Shire Pharmaceuticals LLC

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INTRODUCTION

SRS asks this Court to construe the Merger Agreement to require Shire, as the purchaser of FerroKin's pharmaceutical drug candidate deferitazole, to make a $45 million milestone payment to FerroKin after deferitazole had already failed, purely as a penalty for delays caused by routine safety- and efficacy-related decisions that another provision of the Agreement, Section 2.9(g), gave Shire "sole and absolute discretion" to make. 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.

SRS effectively concedes that its construction gives rise to precisely the irrational results that Shire has identified. SRS agrees (Br. 29) that it seeks a $45 million payment even though deferitazole had already failed, and it characterizes that payment as a "payment for . . . delay" (Br. 34)—even though deferitazole's failure made any such "delay" irrelevant long before that $45 million payment would have come due. SRS even argues (Br. 32) that the delays caused by Shire's drug-development decisions should not be "excused" by deferitazole's failure, though it makes no effort to reconcile that argument with Shire's sole discretion over development and the parties' decision not to include any "commercially reasonable efforts" clause in the Agreement.

Instead, SRS asks this Court to blind itself to those perverse results on the ground that the phrase "as a result of" in Section 2.9(f) ordinarily connotes but-for causation in other (quite different) statutory and common-law contexts. But SRS's invitation to construe that phrase as though it were a stand-alone statute—without regard to the parties' allocation of risk in the rest of the agreement—violates fundamental principles of contract interpretation. Those principles compel that Section 2.9(f) must be construed to deem the Phase III milestone achieved on December 31, 2015, unless a Fundamental Circumstance prevented the initiation of Phase III clinical trials. That construction follows ineluctably from the definition of a Fundamental Circumstance as the existence of a material concern equating to drug failure—which by definition precludes further development—and it gives effect to all of the Agreement's relevant provisions and implements the parties' ex ante allocation of the risk of failure.

Because Shire's milestone obligation, properly understood, turns on whether the rat carcinogenicity findings and FDA clinical hold constituted a Fundamental Circumstance (as the Court of Chancery assumed for purposes of its decision), this Court should remand to permit the Court of Chancery to resolve that factual question. On remand, SRS must bear the burden of proving the carcinogenicity findings and clinical hold that shut down the development program was not a Fundamental Circumstance. SRS's arguments to the contrary are meritless. Under

Section 2.9(f), the Phase III milestone is not deemed achieved when a Fundamental Circumstance occurs, thereby preventing initiation of Phase III clinical trials.

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

A. SRS's construction of Section 2.9(f) ignores surrounding provisions of the Agreement and cannot be reconciled with the parties' ex ante allocation of the risk of drug failure.

As Shire demonstrated, reasonable persons in the parties' positions would have understood that, when a Fundamental Circumstance sufficient to prevent Phase III trials has arisen, the failure to achieve the Phase III milestone necessarily would be "as a result of a Fundamental Circumstance." Opening Br. 22, 26-27. That conclusion follows directly from the definition of "Fundamental Circumstance": "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. Because the occurrence of a Fundamental Circumstance means that attempting to develop deferitazole in its current form would be futile, reasonable parties would expect that the existence of a Fundamental Circumstance would halt progress toward commercialization and approval. Therefore, when a Fundamental Circumstance exists before initiation of Phase III trials, the failure to begin those trials is "as a result of" the Fundamental

Circumstance. Whatever else may be true, when a Fundamental Circumstance arises nearly two years in advance of the milestone date, precluding any further clinical testing of the drug, by definition, the failure to meet the milestone was "as a result of a Fundamental Circumstance." This reading of the contractual language is straightforward. It is consistent with the text of Section 2.9(f) and the only sensible way to effectuate the parties' allocation of risk: FerroKin was assured that it would receive the Phase III milestone by a date certain, but only so long as deferitazole had not already failed as a drug candidate by that date.

SRS's principal contention (Br. 21-23) is that the "ordinary meaning" of "as a result of" requires but-for causation, and therefore Section 2.9(f) deems the Phase III milestone achieved on December 31, 2015, unless a Fundamental Circumstance is the sole but-for cause of the failure to begin Phase III trials by December 31, 2015. Like the Court of Chancery, SRS focuses narrowly on the phrase "as a result of" in isolation from the rest of the Agreement. But "[c]omplex commercial contracts are best interpreted not by focusing on a single clause, but by considering the parties' language in the context of their entire agreement." *First Olefins L.P. v. Am. Olefins, Inc.*, 1996 WL 209719, at *7 (Del. Ch. Mar. 1, 1996). And in examining the entire Agreement, the Court must construe provisions to "give sensible life" to the parties' "basic business relationship," *Chicago Bridge & Iron Co. N.V. v. Westinghouse Elec. Co. LLC*, 166 A.3d 912, 927 (Del. 2017), and avoid constructions "that no

reasonable person would have accepted when entering the contract," *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010). SRS's rigid and myopic but-for construction does precisely what these fundamental interpretive principles forbid.

SRS's arguments only confirm that the Court of Chancery's "but-for" construction leads to irrational results to which reasonable commercial actors never would have agreed ex ante. SRS does not dispute that the upshot of its position is that Shire obligated itself to make a $45 million milestone payment *after deferitazole had already failed*, solely because Shire had previously made routine drug-development decisions (related to safety and efficacy) that might have delayed Phase III trials past the deeming date.[1] SRS is unable to proffer *any* explanation why a

[1] Perhaps realizing the counterintuitive nature of its argument that it is entitled to a $45 million windfall payment for a drug that had already failed, SRS goes on at length (Br. 13-18, 38) trying to create the impression that no Fundamental Circumstance arose. But the Court of Chancery assumed for purposes of its decision that the carcinogenicity findings and FDA clinical hold constituted a Fundamental Circumstance, and this Court must do the same.

In any event, SRS's account is deeply misleading. For instance, SRS claims (Br. 18) that a follow-up study of humans showed no cancer risk—but that study concluded only that there was no risk to humans who had previously received limited doses during trials and then stopped taking the drug. The study did not rule out cancer risk from continued long-term exposure—and deferitazole was to be marketed for chronic, long-term administration for adults and children. *See* AR6. Moreover, although SRS belittles the carcinogenicity findings as "benign" (Br. 32), it neglects to mention that the findings concerned both benign *and* malignant tumors. Those findings were concerning because there was no margin of safety for humans; to the contrary, the human dosages of deferitazole were 50 times greater, relatively speaking, than the doses that rats received. *See* AR3. Most significantly, the fact that the FDA forbade further testing puts the lie to SRS's efforts to minimize the significance of the carcinogenicity findings.

reasonable buyer in Shire's position would agree to such a thing. That is because no pharmaceutical purchaser would do so, and Shire certainly did not do so here. SRS's but-for construction is thus contrary to the risk allocation inherent in a milestone payment structure generally and in this Agreement; it is irreconcilable with other provisions of the Agreement; and it irrationally makes a significant financial obligation hinge entirely on temporal happenstance.

1. SRS does not dispute (Br. 25) that contingent milestone payments in a pharmaceutical merger agreement—including *this* Agreement—allocate the risk of drug failure between the parties. Instead, SRS argues (Br. 26-27), relying only on its own say-so, that Section 2.9(f) is an *atypical* provision that was intended to provide FerroKin with a "near-guarantee" of a Phase III milestone payment. But none of SRS's arguments come close to establishing that the parties agreed that FerroKin should be "guaranteed" a $45 million windfall for a drug that had already failed.

SRS's argument rests principally on the fact that Section 2.9(f) provides that the Phase III milestone will be "deemed" achieved on December 31, 2015, subject to the Fundamental Circumstance clause. Br. 26-27, 29. But that simply begs the question, which is the meaning of the Fundamental Circumstance provision.[2] Under

[2] For that reason, SRS emphasizing (Br. 22) that the phrase "*other than* as a result of" a Fundamental Circumstance connotes an "exception" to the deeming clause adds nothing to its argument. The Fundamental Circumstance clause's structure

both parties' constructions of the provision, the Phase III milestone would be deemed achieved on December 31, 2015, so long as deferitazole remained a viable drug candidate—that is, so long as no Fundamental Circumstance had occurred and deferitazole continued to be developed as contemplated. The question is whether the contract gave FerroKin *something more*—an entitlement to payment even if deferitazole had failed, in cases where Shire's earlier decisions could have delayed Phase III trials past December 2015. The deeming provision does not even suggest, much less compel, that counterintuitive result. Reasonable parties would provide such a "guarantee" of a milestone payment only so long as the drug remained viable—as Section 2.9(f), properly understood, does here. *See, e.g.*, *Fortis Advisors LLC v. Shire US Holdings, Inc.*, 2017 WL 3420751, at *1 (Del. Ch. Aug. 9, 2017).

SRS next argues (Br. 27, 29) that because the Agreement does not include a "commercially reasonable efforts" clause, Section 2.9(f) reflects the parties' "ex ante" agreement to protect FerroKin against the "risk [that] Shire would unilaterally" cease development by giving Shire "a strong incentive to work through obstacles to reaching the Phase III Milestone." That argument, too, cannot establish FerroKin's entitlement to a $45 million windfall. Under Shire's construction, Section 2.9(f) indisputably created an incentive to press forward on deferitazole: Shire would have

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does not suggest anything about its *scope*, which is the focus of the parties' disagreement.

to make the milestone payment unless a Fundamental Circumstance intervened. Thus, Shire had every "incentive to work through obstacles" that might emerge during clinical development, at least until a Fundamental Circumstance arose and made those efforts futile. However, SRS's but-for construction irrationally contorts those incentives. Under SRS's construction, Shire's only *additional* ex ante incentive would be to avoid making *any* decision to alter clinical development based on safety or efficacy data if that decision might delay Phase III trials past December 2015. If emerging data necessitated changing clinical development to address safety or efficacy concerns, and a Fundamental Circumstance thereafter emerged, then under SRS's view, Shire would have to pay $45 million for an already-failed drug. But creating incentives to avoid rigorous inquiry into safety-and-efficacy concerns is inconsistent with Section 2.9(g)'s grant to Shire of "sole and absolute discretion" over deferitazole's development—a grant that necessarily included discretion to respond appropriately to safety and efficacy concerns. Having given Shire "total control" over deferitazole's development—as SRS puts it (Br. 27)—the parties would not then have used the "as a result of a Fundamental Circumstance" clause as an elliptical means of constraining the very discretion conferred in Section 2.9(g).

Moreover, SRS's argument that its but-for construction compensates for the absence of a "commercially reasonable efforts" clause makes no sense. Shire rejected a "commercially reasonable efforts" clause, and successfully bargained for

the sole discretion conferred in Section 2.9(g). Opening Br. 30. But SRS's but-for construction would impose a *more* severe constraint on Shire's discretion over drug development than any "commercially reasonable efforts" clause. Under SRS's view, in the situation presented here, Shire must pay $45 million despite deferitazole's failure because of delays caused by Shire's earlier safety- and efficacy-related decisions—*no matter how commercially reasonable those decisions were*.

In sum, SRS cannot point to a single provision of the Agreement or aspect of the parties' risk allocation that provides even a sliver of support for SRS's position that it should receive $45 million for a failed drug.

2. In fact, SRS's but-for construction is irreconcilable with other provisions of the Agreement. SRS's attempts to defend its construction only confirm that conclusion.

First, as just mentioned, SRS's but-for construction conflicts with Section 2.9(g)'s grant of "sole" discretion over drug development. SRS *admits* (Br. 34) that under its but-for construction, Section 2.9(f)'s "as a result" language penalizes Shire for having earlier made decisions that delayed the start of Phase III trials past the deeming date, by requiring Shire to "make a payment *for its delay* in initiating Phase III for reasons other than the Fundamental Circumstance." (Emphasis added.) SRS thus concedes that under its construction, the function of the "as a result" language is to allocate *fault* to Shire by exacting a penalty for previous decisions resulting in

delay. That penalty for delay cannot be reconciled with Shire's sole discretion under Section 2.9(g).

Moreover, SRS cannot explain why any reasonable parties would agree that Shire should be penalized for its delaying decisions if deferitazole failed, but not if it remained viable and Shire continued to pursue development. Section 2.9(f)'s deeming clause preserves Shire's absolute discretion to proceed as deliberately as it saw fit (including by delaying Phase III trials in response to safety and efficacy concerns): although the milestone would be deemed achieved on December 31, 2015 even if trials had not yet begun (barring a Fundamental Circumstance), FerroKin had no right to challenge Shire's decisions to delay trials for any reason—no matter how vehemently FerroKin disagreed with those decisions. But SRS argues here that in situations in which a Fundamental Circumstance occurred and Shire has ceased development, Section 2.9(f) penalizes Shire for those very same delaying decisions. No reasonable parties would structure the Agreement to insulate Shire from challenges to those decisions so long as drug development is continuing—when delays could implicate FerroKin's interests in the commercialization timeline—but penalize Shire for the very same decisions in the event of drug failure—when FerroKin's interest in expeditious development has been rendered irrelevant.

Second, SRS's construction cannot be reconciled with the fact that—as SRS does not dispute (Br. 30)—under Section 2.9(f)'s plain text, Shire's obligation to make the Phase III milestone payment did not arise until December 31, 2015, the date on which the Phase III trials would be deemed to have been achieved. The deeming date was negotiated; SRS initially proposed that the Phase III trials be deemed to have been initiated by a date in 2013. Ex. A, at 12. Shire was thus entitled to have its obligation to make the milestone payment evaluated as of December 31, 2015. But instead, the Court of Chancery, evaluating Shire's decisions in chronological order, irrebuttably presumed that once Shire made decisions in January 2014 that delayed the projected start of Phase III trials, no subsequent Fundamental Circumstance could have occurred—even though the peripheral neuropathy and cardiac-iron concerns that prompted the delay could themselves have ripened into a Fundamental Circumstance before December 2015. Opening Br. 28-29. SRS's effort to contest (Br. 12-13) the severity of those concerns only underscores that point. Regardless of how severe SRS believes those risks were in *January 2014*, the parties agreed that the severity of all adverse events—that is, whether they rose to the level of a Fundamental Circumstance—would be assessed for purposes of determining whether the Phase III Milestone would be deemed achieved on December 31, 2015, not before.

Third, SRS's but-for construction renders the operation of Section 2.9(b) irrational. As Shire explained, Section 2.9(b) states that if a Fundamental Circumstance occurs and Shire subsequently modifies the drug and pursues a less valuable "Alternative Covered Product," then any remaining milestone payments are one-half what they otherwise would be. A490. Shire thus pays less if it is forced to develop a less valuable drug; common sense would then require that if a Fundamental Circumstance prevented Shire from developing any drug at all, it should pay even less than what it would pay for an Alternative Covered Product. That is what would happen under Shire's construction. But under SRS's but-for construction, if events other than a Fundamental Circumstance were a but-for cause of a delay in Phase III trials and the Phase III milestone were deemed achieved, Shire would pay $22.5 million if it developed an alternative product and the full $45 million if (as here) it did not develop *any* product.

SRS does not dispute that its construction produces that perverse result. Instead, it tries to recast it as a justifiable "payment for [Shire's] delay." That penalty for delay, according to SRS, is ordinarily $45 million, but if Shire develops an alternative product after making delaying decisions, the payment is discounted to $22.5 million to account for Shire's "additional development obligations and risk associated with developing an alternative product." Br. 34. Thus, the only way SRS can give the interaction of Section 2.9(f) and Section 2.9(b) any semblance of

rationality is by characterizing Section 2.9(f) as a freestanding penalty for Shire's decisions that delay the projected start of Phase III trials. But that understanding of Section 2.9(f) is indefensible, as explained above.

3. Finally, SRS concedes (Br. 32) that its but-for construction makes Shire's milestone obligation turn on temporal happenstance. As Shire has explained, if the carcinogenicity study and related clinical hold had occurred just one month earlier, the Fundamental Circumstance would have occurred *before* Shire made the safety- and efficacy-related decisions that delayed the projected start of Phase III trials, and even SRS agrees that Shire would not have to make the milestone payment. Opening Br. 35. But, if Shire's decisions delaying Phase III trials and the Fundamental Circumstance had both occurred on the same day (i.e., simultaneously), under SRS's construction, Shire *would* have to make the payment, because neither the Fundamental Circumstance nor Shire's decisions would be the sole but-for cause of the delay (each would have been independently sufficient causes). The problem for SRS is that neither of those scenarios is distinguishable from this case in any way that reasonable parties would think should matter—in both scenarios, deferitazole has failed well before the deeming date—and there is no evident reason that visible parties would agree that a $45 million milestone payment should turn on such fortuity.

SRS's only response (Br. 32) is that any "happenstance" is the "foreseeable result" of the parties' "ex ante" risk allocation. But that proves *Shire's* point: reasonable parties to a pharmaceutical merger agreement would never have agreed ex ante that the buyer's milestone obligation should turn on such accidents of timing. Moreover, the parties' ex ante consideration most likely would have focused on the most straightforward Fundamental Circumstance scenario: one in which escalating safety and efficacy concerns—like the cardiac iron and neurological concerns here—eventually ripened into a Fundamental Circumstance. It would have been obvious that Shire's efforts to address those very safety or efficacy concerns as they arose could have delayed the projected start of Phase III trials past December 2015 *before* the issues ripened into a Fundamental Circumstance. No reasonable party in Shire's position would agree to pay $45 million for a drug revealed to have dispositive safety or efficacy concerns *because of* Shire's own efforts to act responsibly by addressing those concerns. SRS's only response to that entirely foreseeable scenario—that it was not what happened here (Br. 31-32)—is no response at all.

4. Having failed to rebut the irrationality of its but-for construction, SRS asks this Court to affirm the Court of Chancery's decision by ignoring everything but the phrase "as a result of" considered in isolation. The mere fact that "as a result of" usually means "because of" in *other* contexts (Br. 23 & n.10) cannot overcome the many intractable problems that Shire has identified, all without any meaningful

rebuttal by SRS. *First Olefins L.P.*, 1996 WL 209719, at *7; *Chicago Bridge & Iron Co. N.V.*, 166 A.3d at 927. Shire's construction of the phrase "as a result of," by contrast, follows from the definition of Fundamental Circumstance, gives effect to all of the Agreement's provisions and the parties' underlying commercial relationship and risk allocation, and avoids the irrational and unfair consequences of SRS's construction.

In an attempt to bolster its but-for construction, SRS argues (Br. 24-25) that because the Agreement refers to the "occurrence" of a Fundamental Circumstance in Section 2.9(b) and a Milestone Event in 2.9(a), the phrase "as a result of a Fundamental Circumstance" in Section 2.9(f) must require a causal inquiry beyond whether a Fundamental Circumstance has occurred. Tellingly, however, SRS relies on *statutory*-construction authorities in making that argument. Br. 24-25 (citing *Dewey Beach Enters., Inc. v. Bd. of Adjustment of Dewey Beach*, 1 A.3d 305, 308 (Del. 2010)). When construing *contracts*, courts do not allow arguments about individual words to prevail over the way in which reasonable parties would understand the contract as a whole. *See, e.g., Shareholder Representative Servs. LLC v. Gilead Scis., Inc.*, 2017 WL 1015621, at *18 (Del. Ch. Mar. 15, 2017), *aff'd*, 177 A.3d 610 (Del. 2017) (rejecting SRS's argument that "indication" could not mean "disease" because that construction would render the phrase "cancer indication" redundant, and observing that "the reality of life is that human language

is not perfect"); *OSI Sys., Inc. v. Instrumentarium Corp*., 892 A.2d 1086, 1092 (Del. Ch. 2006) (rejecting reliance on a textual "infelicity" in favor of construing contract's other provisions to operate sensibly together); *FGC Holdings Ltd. v. Teltronics, Inc*., 2005 WL 2334357, at *6 (Del. Ch. Sept. 14, 2005) (rejecting argument based on contract's five-director limitation in isolation because that argument would undermine operation of other provisions). Here, reasonable parties would not conclude that wording differences between Sections 2.9(a)-(b) and Section 2.9(f) justify construing the Agreement as a whole to require Shire to pay $45 million for a drug that had already failed, solely as a penalty for responsible safety- and efficacy-related decisions that Shire had "sole" discretion to make under Section 2.9(g).

B. SRS does not dispute that the extrinsic evidence clearly supports Shire's interpretation of Section 2.9(f).

Because 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, the Court need not consider extrinsic evidence. But at the very least, the preceding discussion makes clear that Section 2.9(f) does not unambiguously require Shire to pay SRS a $45 million windfall. In that event, the Court may consider extrinsic evidence. *Nw. Nat. Ins. Co. v. Esmark, Inc.*, 672 A.2d 41, 43 (Del. 1996). That evidence is entirely one-sided: *every* witness who addressed the subject agreed that Shire would not be

obligated to make the Phase III milestone payment if a Fundamental Circumstance occurred. Opening Br. 37-39.

Indeed, SRS cannot muster even a single statement suggesting that any witness believed that the occurrence of a Fundamental Circumstance would not in itself relieve Shire of its obligation to make the Phase III milestone payment, or that Section 2.9(f) required a but-for causation inquiry into Shire's drug development decisions. Instead, SRS points to evidence showing that FerroKin wanted assurances that Shire would diligently pursue deferitazole. But that does not support SRS's construction for the reasons stated above. In all events, the evidence SRS identifies in fact supports Shire.

SRS points to the testimony of Armand Girard, Shire's Director of Business Development—but Girard described the Phase III milestone exactly as Shire now does, as an "event based off of the initiation of a Phase III study subject to a fundamental circumstance provision, which *provided an out to Shire if there was material change to the underlying assumptions that were core to the value of this asset*." B12 (emphasis added).[3] It was, in other words, the *occurrence* of a

[3] SRS's attorney expressed the same understanding in questioning Girard: B12 (Question: "My under – fundamental circumstance, if it occurs, would prevent the payment[?]"; Answer: "Correct."); *see also id.* (Question: "And was one of the ways that the issues . . . was [sic] resolved was that Shire and FerroKin agreed to a first milestone payment of $45 million that would be deemed payable on December 31, 2015, *unless there's a fundamental circumstance*?") (emphasis added); Answer: "[T]hat's how we actually ended up.").

Fundamental Circumstance that "provided an out to Shire." SRS also relies on the statement of FerroKin's CEO that Section 2.9(f) imposed "'a penalty associated with'" abandoning deferitazole. Br. 37 (citing A173 (Rienhoff)). But that statement referred to situations in which *no Fundamental Circumstance had occurred*. In the same exchange, he explained that "the first milestone, that had to be paid unless there was that exception," meaning that "there had to be a 'Fundamental Circumstance.'" A173.[4]

In sum, out of the entire negotiation history and trial testimony, SRS cannot find a single statement by anyone that so much as hints that the parties understood Section 2.9(f) as the Court of Chancery construed it. The but-for construction made its first appearance in SRS's trial briefing, and the Court of Chancery accepted it. But that is not what the parties agreed to, and no reasonable parties to a pharmaceutical merger agreement would ever structure their transaction in this way.

[4] SRS also quotes (Br. 37) Rienhoff as saying that there had to be "consequences for NOT making progress," but that statement, made in December 2011 during negotiations, expressed Rienhoff's desire for a "commercially reasonable efforts" clause that Shire rejected. B260.

II. SRS bears the burden of proving that the carcinogenicity findings and clinical hold did not constitute a Fundamental Circumstance.

Under the correct construction of Section 2.9(f), Shire's obligation to make the Phase III milestone payment turns on whether the carcinogenicity study and FDA clinical hold constituted a Fundamental Circumstance. This Court should hold that, on remand, SRS bears the burden of proving that those events did *not* rise to the level of a Fundamental Circumstance. That follows from the fact that, as Shire has explained, Section 2.9(f) establishes a condition precedent to Shire's duty to make the milestone payment: the Phase III milestone is not deemed achieved, and Shire's duty to pay never arises, unless the failure to initiate Phase III trials is "other than as a result of a Fundamental Circumstance"—that is, unless no Fundamental Circumstance has occurred. SRS's contrary contentions lack merit.

A. SRS first argues (Br. 39-40) that Shire must prove its entitlement to "benefit from an 'exception' to a 'clear payment obligation.'" Br. 39 (citing Ex. C at 35). But the cases on which SRS relies involve situations where a party to a contract had an *existing* performance obligation that it was attempting to excuse.[5] *See, e.g.*, *Hollinger Int'l Inc. v. Black*, 844 A.2d 1022, 1070 (Del. Ch. 2004).

[5] SRS also cites cases involving "material adverse event" clauses. But the law governing such clauses, and their associated burdens of proof, is "*sui generis*." *Hexion Specialty Chems., Inc. v. Huntsman Corp.*, 965 A.2d 715, 739 (Del. Ch. 2008).

Under Sections 2.9(a) and 2.9(f), the occurrence of a Fundamental Circumstance is not an exception to an existing duty of performance; rather, the Fundamental Circumstance prevents a duty on Shire's part from arising in the first place. Section 2.9(a) provides that a milestone payment comes due "[u]pon the first occurrence of the . . . 'Milestone Trigger Event,'" here, the initiation of Phase III trials. A489. Section 2.9(f) then provides that if the Phase III trials have not been initiated "on or before December 31, 2015," other than as a result of a Fundamental Circumstance, the "Initiation of Phase III Clinical Trial Milestone shall be deemed to have been achieved on such date." A492. Thus, Section 2.9(f) sets forth the conditions for deeming the Milestone Trigger Event "to have been achieved." To determine whether the milestone will be deemed achieved, Section 2.9(f) requires an inquiry into whether the failure to initiate Phase III trials is "other than as a result of a Fundamental Circumstance." Put another way, if the failure to initiate Phase III trials is "as a result of a Fundamental Circumstance," then the Milestone Trigger Event is not deemed achieved, and Shire's duty to make the Phase III milestone payment never arises. *See* Opening Br. 41-43. Thus, a Fundamental Circumstance is not an exception to an existing duty to pay.

B. For much the same reasons, SRS's argument (Br. 41-42) that Shire bears the burden of proof because Section 2.9(f) "creates a condition subsequent" also fails. SRS explains that "an event is a condition subsequent if 'an obligor's

matured duty will be extinguished on the occurrence of that event.'" Br. 41 (quoting Restatement (Second) of Contract § 230 cmt. a (1981)). But SRS acknowledges that Section 2.9(f) "provides that the Milestone is deemed achieved—*it matures*—on December 31, 2015." *Id*. (emphasis added). If that is correct, then in order to qualify as a condition subsequent, the Fundamental Circumstance would have to occur *after* December 31, 2015—because a "condition subsequent" is "an event which occurs subsequent to a duty of immediate performance, that is, a condition which divests a duty of immediate performance of a contract *after it has once accrued and become absolute*." 13 Williston on Contracts § 38:9 (4th ed.). But, of course, Section 2.9(f) contemplates that a Fundamental Circumstance affecting Shire's obligation to make the milestone payment will occur *before* December 31, 2015. SRS therefore has no coherent textual response to the straightforward conclusion that Section 2.9(f) states a condition precedent: *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.

SRS's remaining arguments are misplaced. First, SRS argues that the Fundamental Circumstance cannot be a condition precedent because conditions precedent are "typically" "easily ascertainable" objective facts, and the parties' dispute over whether a Fundamental Circumstance occurred shows that not to be the case here. Br. 41-42 (citing *Hexion Specialty Chems., Inc. v. Huntsman Corp.*, 965

A.2d 715, 739 (Del. Ch. 2008)). But the conditions precedent in this Agreement are not limited to facts unlikely to be the subject of litigation. For instance, determining whether the net sales milestones, A490—which SRS does not dispute constitute conditions precedent, *see* Br. 43—have been achieved requires an analysis of many complex accounting issues that could be the subject of litigation, A480.

Second, SRS argues (Br. 43-44) that placing the burden of proof on it would require it to prove a negative, which "cannot be done." Not so. Under the proper interpretation of Section 2.9(f), the critical question is whether the carcinogenicity findings and clinical hold rose the level of a Fundamental Circumstance. SRS merely must demonstrate that the events in question did not render further development impracticable. That burden can just as easily be framed as an affirmative one, i.e., SRS must demonstrate that despite the carcinogenicity findings and clinical hold, further development was practicable. This case therefore does not implicate any situation in which a court might hesitate to require a party to prove a negative. *Cf. Quantum Tech. Partners IV, L.P. v. Ploom, Inc.*, 2014 WL 2156622, at *19 (Del. Ch. May 14, 2014) (declining to require party to prove that information was never disclosed because of difficulty of proving that an event did not happen).

Finally, SRS complains that it would be "unfair" for it to bear the burden because Shire has greater access to information about its own decisions. But the issue in dispute is not "what motivated [Shire] to act," *Policemen's Annuity &*

Benefit Fund of Chicago v. DV Realty Advisors LLC, 2012 WL 3548206, at *11 (Del. Ch. Aug. 16, 2012), but rather what the carcinogenicity findings and clinical hold indicated about deferitazole's viability and whether further development was practicable. Indeed, the parties already focused on those very issues at trial, proceeding as though SRS bore the burden of proof (the Court of Chancery did not decide until after trial that Shire in fact bore the burden of proof). SRS's assertion of inadequate access to information therefore has no purchase here.

CONCLUSION

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

Of Counsel:

Donald B. Verrilli, Jr.
Ginger D. Anders
Dahlia Mignouna
MUNGER, TOLLES & OLSON LLP
601 Massachusetts Ave. NW, Ste. 500E
Washington, D.C. 20001-5369
Telephone: (202) 220-1100
Facsimile: (202) 220-2300
Donald.verrilli@mto.com

Timothy W. Mungovan
Colin G. Cabral
Michael R. Hackett
James R. Anderson
PROSKAUER ROSE LLP
One International Place
Boston, MA 02110
(617) 526-9600

BAYARD, P.A.

/s/ Peter B. Ladig
Peter B. Ladig (#3513)
600 N. King Street, Suite 400
Wilmington, Delaware 19801
(302) 655-5000

Attorneys for Defendants Below-Appellants Shire US Holdings, Inc. and Shire Pharmaceuticals LLC

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