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More Tips for Milestone Disputes

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The *Lesh v. ev3 Inc.* case in 2014 illustrated the significant risks associated with agreeing (but failing) to achieve certain performance milestones pursuant to a merger agreement. There, defendant ev3 was obligated to fund and pursue regulatory milestones in its "sole discretion, to be exercised in good faith."[1] At trial, the jury found that ev3 had breached this obligation and awarded $175 million.[2] Although the Delaware Supreme Court ultimately reversed and remanded for a new trial due to an evidentiary issue,[3] and the case settled thereafter, the initial jury verdict was a wake-up call for companies with similar milestone obligations.

In the decade following *Lesh*, milestone payment clauses have remained a mainstay in purchase agreements and licensing agreements involving pharmaceutical and medical device companies.[4] And rather than simply leave the obligation to achieve the underlying milestones to the exercise of good faith, parties have negotiated commercially reasonable efforts (CRE) clauses as guardrails.[5] But, whether the goal is

to avoid milestone disputes or to win them, having a carefully crafted CRE clause is only half the battle.

This article, which is an update to the August 15, 2014 *Health Law Weekly* article, Tips for Milestone Dispute Avoidance, and is informed by recent milestone-related cases since then, identifies a number of additional practical considerations both when negotiating CRE clauses and when making strategic decisions in view of applicable CRE obligations.

Carefully Consider Objective vs. Subjective Standards

As previously explained, CRE clauses may contain either an objective or a subjective standard of performance. If objective (or "outward facing," per Delaware courts[6]), the required level of effort is set in relation to the level of effort amongst similarly situated companies developing similar products. Objective CRE provisions are often "viewed as seller-friendly, as they allow the seller, when attempting to plead or prove that the buyer has breached its obligations, to point to an objective metric—comparable industry standards—rather than the buyer's subjective intent or state of mind."[7] Indeed, a subjective (or "inward facing") standard ties the required level of efforts to the CRE-obligated party's own standards, and the CRE definition can include specific factors that the party typically considers when making determinations of commercial reasonableness, such as the likelihood of obtaining the necessary regulatory approval, market competitiveness, and the expected and actual profitability of the product.[8] As a result, subjective CRE provisions are often viewed as buyer- or licensee-friendly.

However, the mere classification of a CRE clause as objective or subjective is not determinative of the likelihood of success of one party over the other in a milestone dispute. Even a multi-factorial subjective CRE standard that is meant to be more buyer-protective can create a foot fault by making the point of reference too specific, such as requiring the level of effort for a "priority" product of the buyer.[9] In the reverse, an otherwise objective CRE standard can be drafted to incorporate some subjective flexibility—including consideration of the cost of the milestone payments themselves.[10]

In addition, when negotiating a CRE provision, companies should carefully consider whether the comparator being called for is readily ascertainable. For example, if a subjective CRE clause refers to a product within the buyer's portfolio at a similar life stage with a similar commercial potential, the parties should be sure that such a reference product exists. Without one, the defendant is at risk of not knowing whether or not it is in compliance with the CRE obligation even as it undertakes such efforts, whereas, as flagged in the prior article, the plaintiff is at risk of being unable to establish a key part of its breach of contract claim.[11] Likewise, if an objective CRE clause requires efforts comparable to those of a similarly situated company in the same industry with a similar product in a similar life stage, even a failure to

sufficiently *allege*—let alone prove—a comparator company and a comparator product could result in the dismissal of the CRE claim, which is what happened to the buyer in *Neurvana Medical, LLC v. Balt USA, LLC*.[12]

Create Internal Alignment and Build the Best Evidentiary Record

There may be only so much that can be done at the deal-making phase, and the resulting agreement will inevitably end up having CRE-related provisions that are more favorable to one side than the other. At that point, the key to both preventing and, if necessary, litigating a potential milestone dispute continues to be diligent documentation of the company's efforts and its rationales when a decision is made to stop pursuing certain development activities relevant to a contractual milestone. Moreover, a buyer today might be a seller tomorrow, and the subsequent acquiring company should be wary of merely pursuing "merger synergies" without due consideration of existing CRE obligations.[13]

What should companies do if, at the point of negotiation, they suspect that certain post-transaction milestones may be too aggressive or otherwise difficult to meet, and a decision to terminate the corresponding development activities might follow in the near-term? First, any such observations and reservations should be clearly communicated across all relevant divisions of the buyer/licensee company, including, but not limited to, business development teams, regulatory teams, and legal teams. This will help ensure that, at a minimum, there is a consistency in messaging between buyer/licensee and seller/licensor at all levels of each company and avoid potential pitfalls resulting from any lack of consistency.[14] The CRE clause should also be drafted in a way that contains either sufficient discretion or all relevant factors that might impact the decision to terminate or wind down efforts.

After the deal closes: Document, document, document any and all decisions and rationales that are consistent with the CRE obligation. Hiring an external consultant to evaluate regulatory and/or commercial viability also may help bolster the record, particularly if the CRE standard is an objective one. For example, in *Himawan v. Cephalon, Inc.*, defendant Teva Pharmaceutical Industries Ltd. decided not to further develop an antibody called Reslizumab (RSZ) for the treatment of eosinophilic esophagitis (EoE) in part because the analysis of its third-party consultant concluded that the likelihood of successful development for regulatory approval was low.[15] At the time of the consultant's analysis, no other company had obtained Food and Drug Administration approval for treating EoE.[16] The Delaware Chancery Court credited evidence of such guidance, among other things, in finding that the objective CRE obligation had been upheld.[17]

Of course, the company should still try to pursue the milestones in accordance with the applicable CRE standard. Sometimes there is a misperception among a company's

business people that once the deal is done, any obligations end as of the closing. But where milestones and CRE obligations are involved, that is simply not true. And as recent cases show, how a CRE-obligated company behaves coming out of the gate once it has the acquired/licensed product in hand likely will have considerable weight in the overall question of whether it exercised CRE before choosing to direct its efforts elsewhere.[18]

Critically Assess the Probabilities of Milestone Achievement

Should breach of a CRE obligation be found, whether and to what extent there are any damages awarded against the CRE-obligated party will frequently depend on the probability that the milestone(s) at issue would have been achieved had CRE been used. For example, in *Shareholder Representative Services LLC v. Alexion Pharmaceuticals*, *Inc.*, after finding liability in a September 2024 opinion, the Delaware Chancery Court recently issued an extensive damages decision where the court awarded over $180 million in damages "by weighting each milestone's earnout payment by its probability of success, discounted to present value at the time of breach."[19] In addition to the testimony of plaintiff SRS's experts, the court also considered the valuations of the right to future distributions by the seller's largest former stockholder, as well as defendant Alexion's "internal metric for probability of technical and regulatory success."[20] Along those lines, any CRE-obligated company should critically assess what internal analyses exist regarding the likelihood that relevant milestones will be achieved since such documents are unlikely to be protected by privilege, and will not only potentially bear on the question of liability but also on damages.

Consider Alternative Dispute Resolution Paths for Milestone Issues Only

Given the established corporate law jurisprudence and the high level of expertise with commercial disputes, it is no surprise that countless merger and licensing agreements designate Delaware law as the governing law and give Delaware courts exclusive jurisdiction over disputes. But in light of multiple shareholder-friendly decisions and sizable damages awards in recent years, it may be risky for a CRE-obligated party to litigate a milestone dispute in Delaware. As an alternative, the parties may wish to use a separate dispute resolution pathway solely for any milestone disputes arising under the agreement at issue, while keeping all other disputes in Delaware courts. For example, as noted in the prior article, the parties could utilize multi-level dispute resolution clauses that require the parties to first negotiate for a set period of time before escalating to a third-party neutral (which could be first a mediator and then an arbitrator) or the courts. The parties also could submit the final, binding decision on a milestone dispute to an arbitrator with specific industry expertise, the same way that working capital disputes are often submitted to an independent accounting expert. Party and expert discovery could also be tailored to the type of CRE clause at issue, which would

help avoid years-long litigation with extensive discovery. In sum, pre-litigation and out-of-court processes along these lines could be particularly useful for industry players that buy and sell products on a regular basis.

Conclusion

Milestones and earnout payments will undoubtedly continue to be part of future transactions for pharmaceutical and medical device companies. To be in the best position for a milestone dispute, buyers and licensees in particular should continue to be vigilant both during and after the deal: a strong CRE clause is only as good as the commensurate efforts and disciplined documentation that follow.

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[1] *See Lesh v. ev3 Inc.*, 114 A.3d 527, 528 (Del. 2014).

[2] *See id.* at 528-29.

[3] *See id.* at 530. The Delaware Supreme Court found that a non-binding letter of intent had been improperly considered by the jury as either creating a separate milestone-related obligation that also was breached or lowering the "sole discretion" standard in the merger agreement. *See id*.

[4] *See, e.g.*, Agreement and Plan of Merger by and among Checkpoint Therapeutics, Inc., Sun Pharmaceutical Industries, Inc. and Snoopy Merger Sub, Inc., dated as of March 9, 2025; Agreement and Plan of Merger among Eli Lilly and Company, Ridgeway Acquisition Corporation and Verve Therapeutics, Inc., dated as of June 16, 2025.

[5] *See id.*

[6] *See, e.g.*, *Shareholder Rep. Servs. LLC v. Alexion Pharmaceuticals, Inc.*, C.A. No. 2020-1069-MTZ, 2024 WL 4052343, at *36 (Del. Ch. Sept. 5, 2024) (*Alexion I*); *Neurvana Med., LLC v. Balt USA, LLC*, C.A. No. 2019-0034-KSJM, 2020 WL 949917, at *16 (Del. Ch. Feb. 27, 2020).

[7] *Neurvana Med.*, 2020 WL 949917, at *16.

[8] *See, e.g.*, *Fortis Advisors LLC v. Johnson & Johnson*, C.A. No. 2020-0881-LWW, 2024 WL 4048060, at *23, *25 (Del. Ch. Sept. 4, 2024).

[9] *See id.* at *23 ("Efforts to achieve the regulatory milestones must [have been] at the high level J&J—a top company in the industry—set for itself, and for 'priority' devices within J&J.").

[10] *Himawan v. Cephalon, Inc.*, C.A. No. 2018-0075-SG, 2024 WL 1885560, at *4, *9, *11 (Del. Ch. Apr. 30, 2024), *aff'd*, 2025 WL 287772 (Del. Jan. 15, 2025) (where CRE was defined as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [the defendants], with due regard to the nature of efforts and cost required for the undertaking at stake," the phrase "due regard to the nature of efforts and cost" permitted the defendants to consider "all the costs and risks involved, including the milestone payments and the opportunity costs faced by [the d]efendants").

[11] *Cf. Russell v. Zimmer, Inc.*, No. 2:20-cv-200-TLS-JEM, 2022 WL 3359343, at *7 (N.D. Ind. Aug. 15, 2022), *aff'd*, 82 F.4th 564 (7th Cir. 2023) (dismissing CRE claim where the CRE definition at issue was subjective but the plaintiff failed to "identify any efforts the Defendant normally takes based on its reasonable business judgment in regard to a similar product, nor [did] they show why the efforts with the Earnout Products were not commercially reasonable when measured against the Defendant's normal 'business, operations and product portfolio.'").

[12] *See Neurvana Med.*, 2020 WL 949917, at *16-17 (dismissing the CRE breach of contract claim on the basis that the complaint at issue failed to identify, in accordance with the CRE definition, "a single 'entity in the medical device industry of similar resources and expertise as'" the buyer or "any 'products . . . of similar market potential at a similar stage in development or product life'" as the product at issue).

[13] *See, e.g.*, *Alexion I*, 2024 WL 4052343, at *47-48 (finding that termination of developmental efforts soon after AstraZeneca plc's acquisition of defendant Alexion Pharmaceuticals, Inc. was a breach of CRE, where the underlying rationale behind the termination appeared to be "influenced, motivated by, or driven by AstraZeneca's pursuit of merger synergies").

[14] For example, in one recent case, the plaintiff shareholders successfully argued that their company was fraudulently induced into agreeing to a particular milestone based on representations from certain of the buyer's representatives that there was a "high certainty" that the milestone would be achieved, to the point that the earnout payment should be viewed as upfront consideration for the deal. *See Fortis*, 2024 WL 4048060, at *11-12, *49. The seller company allegedly discovered only after closing that there was a patient death in a related clinical study that, in fact, put achievement of the milestone at risk. *See id.* This decision from the Delaware Chancery Court, however, is currently on appeal.

[15] *See Himawan*, 2024 WL 1885560, at *7.

[16] *See id.*

[17] *See id.* at *14.

[18] *Compare Himawan*, 2024 WL 1885560, at *13 (noting favorably that, after acquiring the seller company, defendant Cephalon Inc. immediately took steps to develop RSZ for EoE by meeting with and hiring former seller company employees to determine a pathway for Food and Drug Administration approval) *with Alexion I*, 2024 WL 4052343, at *47-48 (finding a breach of CRE where, shortly after defendant Alexion was acquired by AstraZeneca, a "full portfolio review" led to a shutdown of the development program at issue, despite no known safety issues).

[19] *Shareholder Rep. Servs. LLC v. Alexion Pharmaceuticals, Inc.*, C.A. No. 2020-1069-MTZ, 2025 WL 1661215, at *1 (Del. Ch. June 11, 2025) (*Alexion II*).

[20] *See id.* at *2-5.