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Diligence, Development, and Damages: Delaware's Latest Guidance on Commercially Reasonable Efforts

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Agreements to purchase or license unproven technology are often structured with an initial up-front payment and later progress-based payments that are contingent on certain milestones, such as a clinical result, a regulatory approval, or a sales threshold. This is often the template for drug discovery and medical devices related to underlying intellectual property. To keep the buyer or licensee from simply pocketing the technology or unnecessarily wasting patent term, these deals typically include a requirement that the buyer or licensee will use “commercially reasonable efforts” (“CRE”) to pursue those milestones.

But how hard of an effort is hard enough to be commercially reasonable? While that phrase has received limited judicial review, two recent decisions from Delaware courts, one involving a rare-disease drug and the other a medical device, have provided guidance to the question, spelling out at least one court’s view regarding what the promise demands, what kind of corporate conduct breaks it, and why the precise words the parties choose can be worth hundreds of millions of dollars.

What “Commercially Reasonable Efforts” Actually Requires

A CRE covenant is often the engine of a milestone deal: it obligates the buyer to use certain effort to achieve the milestones rather than let the acquired program quietly wither. One difficult question is what conduct to use as the benchmark for reasonableness.

One potential benchmark is outward-looking, asking the question: would a hypothetical, similarly situated company in the same industry have taken the same steps? That standard can be proven at trial through industry norms and expert testimony. Alternatively, an inward-looking benchmark can be applied: did the buyer treat the acquired program the way it treats its own comparable products and priorities? That standard can be proven with the buyer’s own internal records and conduct. Whether one of these tests should apply to a given contract can turn on how a particular CRE clause is drafted.

The rare-disease case of *Shareholder Representative Services LLC v. Alexion Pharmaceuticals, Inc.*, 2024 WL 4052343, at *1 (Del.Ch., 2024) illustrates the former. There, the agreement at issue required the buyer to use, for seven years, the efforts and resources “typically used by biopharmaceutical companies” for a comparable product at a comparable stage, taking into account the factors such companies typically consider. The court interpreted the provision as establishing a hypothetical reasonable-company benchmark rather than a buyer-specific standard. The

court reasoned that the provision required reference to industry norms rather than the conduct of any particular company and that no suitable real-world comparator existed. The choice mattered: it meant the buyer's conduct would be measured against what a reasonable industry participant would do, not against the buyer's own shifting internal priorities.

By contrast, the medical device earnout dispute in *Johnson & Johnson v. Fortis Advisors LLC*, 352 A.3d 229, 235 (Del.Supr., 2026), illustrates the opposite risk: a buyer-specific standard that courts will not allow the buyer to dissolve into open-ended business discretion. There, the merger agreement obligated the buyer to use commercially reasonable efforts to achieve the regulatory milestones, and it defined that standard by reference to the buyer's own "usual practice ... with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle," permitting the buyer only thereafter to weigh a set of enumerated business factors in calibrating its effort within that baseline. The Delaware Supreme Court rejected the buyer's argument that those enumerated factors could justify deprioritizing the milestones whenever profitability or competitive positioning cut the other way, holding that such a reading would invert the provision's structure by letting the "taking into account" factors swallow the priority-product baseline that preceded them, and would also strip a separate clause barring earnout-avoiding conduct of any meaning. The choice mattered: it meant the buyer's own historical practice with comparable priority products set the floor for its obligations, and the enumerated factors could only operate to select among reasonable paths to the milestone, not to excuse conduct that predictably undermined it in favor of other business objectives.

When Does a Buyer Cross the Line?

Both court decisions underscore a holistic and fact-intensive inquiry, rather than a checklist. In the rare-disease case, the court weighed safety, efficacy, the likelihood and difficulty of regulatory approval, the available clinical indications, and competitive positioning before concluding that the decision to terminate the program fell short of the required efforts. The court noted that although the drug was not the strongest candidate in its class and needed further work, it could still compete, posed no concrete safety risks, and offered an advantage for certain patients. Accordingly, a reasonable industry participant would not have abandoned the program. The court found the termination had been "influenced, motivated by, or driven by" the corporate parent's pursuit of merger synergies, which the court described as an idiosyncratic corporate motive, not a factor a reasonable developer would weigh.

The medical device case underscored the same point. There, the buyer steered the device away from a fast, narrow "minimally viable product" path that was most likely to achieve the contractual milestones and toward a fuller, more commercially attractive configuration. The court held that the strategic pivot breached CRE because the buyer was not entitled to prioritize commercialization, product differentiation, or short-term profitability over the pursuit of the milestones. Just as damaging were the buyer's own internal moves after a regulatory setback: it wrote the milestones down to zero (booking a roughly \$984 million accounting gain), realigned employee incentives away from the milestone targets, and treated a change in the FDA's approval pathway as reason to stop trying. The court viewed those actions as evidence that the buyer had abandoned the milestones rather than engaging in diligent pursuit.

Effort Is Not Enough: The Causation Catch

One qualification emerges from the rare-disease decision: proving a breach of the efforts covenant may be only part of the plaintiff's burden. When the seller argued that the buyer had improperly deprioritized the program during the early stages of the COVID-19 pandemic, the court agreed that the conduct fell below the contractual standard. The cost-cutting initiative that drove the decision reflected an idiosyncratic corporate objective rather than a consideration a reasonable developer would ordinarily weigh.

The court nevertheless found no liability because the seller could not establish that the deprioritization caused compensable harm amid the many external disruptions affecting development efforts at the time. The plaintiff must

still demonstrate that the breach caused a compensable injury. Here, the seller failed to consider certain confounding events, including the need for a new drug supply and COVID-related pauses.[\[1\]](#)

If the Covenant Is Broken, the Price Follows

Regarding damages, the rare-disease court case valued each lost milestone as an uncertain future payment: the milestone amount multiplied by the probability of achievement and then discounted to present value as of the breach date. The rare-disease court awarded approximately \$181 million using that methodology; the surgical-robot court awarded hundreds of millions more based on the same approach. A takeaway is that damages can be driven by the underlying effort determination. A defensible, well-documented effort record can be a helpful defense, because the damages inquiry begins only after the covenant has been found breached.

What This Means for Companies and for IP Practice

CRE can play a central role in determining whether the anticipated value of an innovation transaction is ultimately realized, and it sits squarely within the domain of the in-house intellectual property, regulatory, and licensing teams that define the technical and regulatory milestones in the first place. The same dynamics govern life sciences license agreements, in which a licensor grants rights to a patented asset and relies on the licensee's diligence covenant to develop it. Because patent value depends on a limited period of exclusivity, delay or reprioritization can diminish the economic value of the licensed asset itself. A lesson from these decisions is that "commercially reasonable efforts" is not merely boilerplate language: courts can scrutinize the comparator standard, the enumerated factors, and contemporaneous conduct.

Practice Tips

Define the Benchmark Up Front

The recent Delaware decisions demonstrate that the choice of comparator can determine the outcome of the dispute. Parties should consider indicating whether compliance with CRE will be measured against the conduct of a hypothetical, similarly situated industry participant or against the obligor's treatment of its own comparable products and programs. The identification of certain factors to be considered in evaluating performance can likewise be useful in certain circumstances.

Build a Record That Reflects Continued Diligence

In litigation, internal documents can be evidence of whether a company continued to pursue a milestone in good faith. Accounting write-downs, revised compensation metrics, portfolio reviews, budget decisions, and strategic planning materials can all be used to assess whether a program was being actively advanced or quietly deprioritized. Companies operating under CRE obligations should document decisions, including by providing legitimate business considerations.

In License Agreements, Pair Diligence Obligations with Self-Help Remedies

Milestone deadlines, reporting requirements, termination rights, and reversion provisions can provide practical protection if a licensee loses interest in development. Where patent rights remain with the licensor, these mechanisms may allow the asset to be recovered and redeployed while meaningful exclusivity remains, reducing the need to prove a costly and fact-intensive breach of a CRE.

Conclusion

For years, “commercially reasonable efforts” functioned as a catch-all commitment embedded in milestone transactions. Delaware’s recent decisions make clear that certain courts will not treat the phrase as self-defining. Instead, they will examine the contractual benchmark, the factors the parties chose to include or exclude, and the company’s contemporaneous conduct in deciding whether the obligation has been satisfied.

Footnotes

- ¹ *Shareholder Representative Services LLC v. Alexion Pharmaceuticals, Inc.*, 2024 WL 4052343, at *40 (Del.Ch., 2024) (“Even affording SRS a guess that the 2020 deprioritization caused a delay of several months, SRS falters on proving it was harmed by that delay. The only harm SRS identifies is Alexion’s failure to achieve Milestones 2 through 8. SRS has offered no evidence that delays from the 2020 deprioritization contributed to Alexion’s failure to achieve the milestones, at all or independently from Alexion’s termination of ALXN1830. SRS failed to substantiate any role the 2020 deprioritization played in Alexion’s failure to achieve the milestones. SRS has not proven the 2020 deprioritization harmed SRS as it must to obtain a judgment on its breach of contract claim”).

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