Diligence Clauses and the Management of Uncertainty in Life Sciences Agreements

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In times of uncertainty and disruption, setting expectations for performance with business partners and contractual counterparties can be more complicated than ever. Companies that develop drugs, biologics and medical devices have considerable experience managing uncertainty in this aspect of their business dealings. While they remain optimistic about the next product in the pipeline, they enter into licenses and collaborations knowing that they cannot be certain where the science, regulatory landscape or market will lead, or precisely what sort of effort will be required to achieve the desired success.

One contractual term commonly used to help manage this uncertainty is the diligence clause, which often takes the form of a clause requiring a party to use commercially reasonable efforts (CRE). CRE clauses tend to be used when strict performance requirements are unrealistic and the precise needs of the project are unforeseeable. Through the use of a CRE clause, parties instead seek to define the level of effort and resources that each must dedicate to the project over time as it evolves and circumstances change. These terms often appear in licensing agreements and collaborations in the life sciences industry, where one party's financial returns depend on the other party's performance.

Understanding what these clauses mean and how they may be applied is more important now than ever, with a changing world that may increasingly challenge parties' expectations about what is reasonable.

Background: CRE Clauses and Their Meaning

CRE clauses are a close cousin to the many variations of "best efforts" clauses found in a wide range of commercial contracts. Over the years, courts in the United States have struggled to distinguish between "best efforts," "reasonable best efforts," "commercially reasonable efforts" and other variations in a consistent manner, leaving commercial parties vulnerable to the possibility that the courts will not take the same nuanced view that they did when negotiating the agreement.

This issue was noted in the October 2018 decision in *Akorn, Inc. v. Fresenius Kabi AG*, which concerned a merger agreement — another type of agreement where CRE clauses sometimes appear. The Delaware Court of Chancery stated that "[c]ommentators who have surveyed the case law find little support for the distinctions that transactional lawyers draw." *Akorn, Inc. v. Fresenius Kabi AG*, No. CV 2018-0300-JTL, 2018 WL 4719347, at *87 (Del. Ch. Oct. 1, 2018), *aff'd*, 198 A.3d 724 (Del. 2018). The agreement obligated Akorn, Inc. to use commercially reasonable efforts to carry on its business in the ordinary course pending the closing of the merger. Employing a standard that the Delaware Supreme Court had used for CRE and other "efforts" clauses, the Court of Chancery found that Akorn was required to "take all reasonable steps" to meet the contract's goals. Turning to the facts of the case, the court then compared Akorn's efforts to those of "a generic pharmaceutical company operating in the ordinary course of business."

When drafting license agreements and other types of collaborations, sophisticated parties in the life sciences industry frequently have attempted to manage the uncertainty surrounding the application of CRE clauses by defining the term "commercially reasonable efforts" in their contracts. These definitions often are intensely negotiated clauses in which the parties set out the factors and reference points to be considered in determining whether a party has met its contractual obligations.

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Internal vs. External Standard for CRE

When a company agrees to develop a drug, biologic or medical device, its obligation to use commercially reasonable efforts often is defined to require the same level of effort and resources that are committed to other similar projects. In some cases, the reference will be internal looking, requiring a party to use the same effort that it commits to other similar projects of its own. This often is referred to as a "subjective" clause. In other agreements, the reference will be external looking, with an "objective" standard requiring the party to use the same effort that generally is committed to similar projects by similarly situated companies.

Determining whether to use subjective or objective language is one of the substantial decisions parties make in drafting CRE clauses. Experienced pharmaceutical companies may prefer internal-looking clauses, seeking comfort that they can continue doing business as they ordinarily do and manage the project the same way they manage their other relevant projects, without concern that their approach may be different from other companies.

Some companies, however, worry that a standard focused on their own internal practices could expose them to broader and more intrusive discovery if the provision is ever litigated. The concern is that the other side may insist it needs to gain an extensive understanding of the company's practices in similar projects in order to make the necessary internal-looking comparison.

This issue was highlighted in the Delaware Court of Chancery's October 2019 decision in *Fortis Advisors LLC v. Allergan W.C. Holding Inc*., No. CV 2019-0159-MTZ, 2019 WL 5588876, (Del. Ch. Oct. 30, 2019). There, the plaintiff claimed that, among other things, the defendant had failed to use commercially reasonable efforts to obtain Food and Drug Administration approval for a particular indication for use for an ophthalmic device. The CRE definition in the contract was internal looking and required the defendant to use "commercially reasonable, diligent and good faith efforts and expend[] resources that [the defendant] would typically devote to, and with respect to, products of similar market potential at a similar stage in development or product life ..."

In its motion to dismiss the complaint, the defendant argued that the plaintiff failed to allege any facts about the defendant's efforts and resources for its comparable products. Rejecting the motion to dismiss, the court noted that "with the aid of discovery into [the defendant's] comparable efforts, [the plaintiff] may prevail on its breach of contract claim."

To be sure, even if there is an external-facing clause that requires effort and an expenditure of resources comparable to those made by similarly situated companies, a litigant still may attempt to obtain discovery about a company's own comparable commercial efforts.

Managing Lingering Ambiguity

Even with a carefully negotiated definition of CRE, substantial ambiguity may remain. This is to be expected. If the parties could agree upfront on the precise efforts and expenditures to be undertaken, there would be no need to rely on commercially reasonable efforts. But, if the parties later disagree about the level of effort required and find themselves in a dispute, this ambiguity can pose challenges.

Litigation over CRE as it relates to the development and commercialization of drugs, biologics and medical devices can be costly and time-consuming. In addition, in rapidly developing areas in the biopharmaceutical and medical device industry, the delay caused by litigation can significantly impair the commercial viability of a drug, biologic or device. As a result, in practice, many disagreements about commercially reasonable efforts in licensing and collaboration agreements do not end up in litigation. The more clearly an agreement defines the parties' obligations, the more likely the parties will be able to quickly agree on the efforts required and resolve any disputes.

With that in mind, companies may consider taking the following steps when crafting CRE clauses:

- Be clear about the factors to be considered in determining whether efforts are reasonable. For instance, what economic factors can be considered? Should the milestones, royalties and other contingent consideration be expressly carved out, or should the party tasked with expending the efforts be permitted to take those payments into account?
- Should the agreement include specific "safe harbors" or levels of effort or resource expenditures that will be deemed to satisfy the diligence obligations? Likewise, should the agreement specify certain minimum levels of effort or expenditure that must be undertaken irrespective of the circumstances?
- Should the agreement include clear "outs" for foreseeable circumstances that make the program unreasonable (*e.g.*, safety issues, or a change in law or failure of science that eliminates the viability of the drug)?

Even with maximum clarity, disputes still may arise. Parties may anticipate this and build in negotiation requirements or other alternative dispute resolution (ADR) procedures (such as mediation) prior to proceeding to arbitration or litigation. While multiple ADR steps can seem frustrating, they can be effective when they bring parties to the table in a scenario where both parties would benefit from clarity.

In addition, parties may consider providing for expedited arbitration to resolve issues surrounding CRE. An adjudication in arbitration or litigation will necessarily take time when complex

issues of science and market practice are involved. But, even if expedited arbitration takes six months to a year to achieve final resolution, it still may be far more efficient than litigation, which can take much longer and be subject to extensive appeals.

CRE, *Force Majeure* and Global Pandemics

Given the impact of COVID-19 and the widespread disruption it has caused, many businesses across industries are considering the impact of *force majeure* clauses in their commercial contracts. Although they are included in contracts for different reasons, *force majeure* and CRE clauses have something essential in common: Both clauses address the critical question of what obligations contracting parties have as circumstances change.

A *force majeure* clause is a "contractual provision allocating the risk of loss if performance becomes impossible or impracticable, especially as a result of an event or effect that the parties could not have anticipated or controlled," according to Black's Law Dictionary. Whether a *force majeure* event has occurred and relieves a party of any obligations under a contract is a fact-specific inquiry and depends both on the language in the contract and the circumstances surrounding the *force majeure* event.

Unlike a CRE clause, a *force majeure* clause "is not intended to buffer a party against the normal risks of a contract." *Urban Archaeology Ltd. v. 207 E. 57th St. LLC*, 951 N.Y.S.2d 84 (Sup. Ct.), aff'd, 68 A.D.3d 562, 891 N.Y.S.2d 63 (2009). Generally, the *force majeure* event must actually frustrate the contract's purpose and prevent the claiming party's performance, not simply make performance more difficult. Some courts have construed this as a high bar approaching impossibility of performance. *See Aukema v. Chesapeake Appalachia, LLC*, 904 F. Supp. 2d 199, 210 (N.D.N.Y. 2012). Courts may require a party seeking *force majeure* to "demonstrate its efforts to perform its contractual duties despite the occurrence of the event it claims constituted force majeure." *Phillips Puerto Rico Core, Inc. v. Tradax Petroleum Ltd*., 782 F.2d 314, 319 (2d Cir. 1985). Indeed, some *force majeure* clauses expressly require a party to use commercially reasonable efforts to resume activities as soon as it can after the *force majeure* event occurs. *See, e. g., Watson Labs., Inc. v. Rhone-Poulenc Rorer, Inc*., 178 F. Supp. 2d 1099, 1109 (C.D. Cal. 2001).

When a contract has both a CRE clause and a *force majeure* clause, and circumstances change so substantially that they materially impact an ongoing project, the party that is required to use commercially reasonable efforts must consider whether the changed circumstances constitute a *force majeure* event, or if they alter the picture of what efforts are commercially reasonable, or both. In the licensing and collaboration context, CRE clauses often take into account risks specific to the program, such as its commercial prospects, its scientific viability or changes in the standard of care. In contrast, *force majeure* clauses commonly refer to unforeseeable external issues that transcend industry-specific risks, like war, labor strikes and global pandemics.

But there also is overlap. For instance, changes in law or government action can be considered a *force majeure* event, but they also can impact the reasonableness of certain efforts under the contract. Where a type of event is enumerated in a *force majeure* clause but is not listed as a factor in a CRE clause, a party might argue that such an event should only be taken into account if it meets the standards for *force majeure*. On the other hand, if the event does not meet the high bar for *force majeure*, but it does have an impact on a party's performance under the contract, a party might argue that the event should be taken into account when determining whether a party's efforts are commercially reasonable.

There is little precedent in the case law for how an event like the COVID-19 pandemic would be viewed under a CRE clause. With an inward-looking clause, the parties may try to focus on whether a company is adjusting all of its relevant programs in a similar fashion to take the pandemic into account. With an outward-looking clause, the parties may focus more on whether the company's actions in light of the pandemic are consistent with actions being taken across the industry. Navigating these complex issues may be essential to keeping development and commercialization programs moving forward in a commercially reasonable fashion.