Successfully navigating ‘commercially reasonable effort’ obligations in IP agreements

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02 November 2022

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- **Litigation exposure arises from amorphous scope of obligations to use ‘commercially reasonable efforts’**
- **A thorough review of caselaw shows best practices for drafting specific benchmark requirements to protect the parties’ interests**
- **Impeccable project planning can avoid disputes, but should litigation arise, we show how to deploy key legal strategies for an optimal outcome**

Pharmaceutical and medical device companies often enter into agreements, such as merger or licence agreements, that shift or impose product research, development, or commercialisation responsibilities onto one party in exchange for deferred compensation for the other. This deferred compensation may be tied to achieving specific milestones, like development or sales milestones, or royalty payments upon commercialisation (among a variety of ways such compensation may be structured).

In such circumstances, the parties may choose to define the obligations of the developing party to research, develop, and/or commercialise the product by using "commercially reasonable efforts" – often referred to in shorthand as "CRE obligations". Parties may choose to define development obligations in terms of commercially reasonable efforts for a variety of reasons, such as the absence of more clearly definable obligations, as a catch-all to ensure that other obligations are met, and/or as a concept that allows for flexibility in view of future, commercial realities.

The result is that the scope of the obligations to use commercially reasonable efforts can be amorphous and open to debate. The lack of clear guideposts can create litigation exposure and, depending on the remedies available under the agreement, forfeiture of valuable intellectual property or damages.

This article discusses how courts have interpreted these obligations, gives guidance on how to comply, and provides tips on winning after litigation commences.

What are commercially reasonable efforts?

There are three common ways that parties draft commercially reasonable efforts provisions with:

1. an external and objective benchmark;
2. an internal and subjective benchmark or;
3. an undefined benchmark, with both objective and subjective elements.

Objective Benchmarks

Often, an external-looking, objective benchmark defines a party's obligations by reference to efforts that a "similarly situated company" would use to develop a "similarly situated product", as the Delaware Court of Chancery explained in 2020's ***Neurvana Medical v Balt USA***, and 2018's ***Himawan v Cephalon Inc***. Put differently, the developing party must use efforts commensurate with what similar companies operating in the same industry would use to achieve the same or a similar objective. When commercially reasonable efforts provisions are defined this way, they may be considered seller-friendly because they allow the seller (the party not required to perform the obligation) to point to an objective metric to support allegations of a breach. By contrast, as discussed below, a subjective, internal benchmark depends on facts and information that are potentially unavailable and unknowable to the seller.

That said, an objective benchmark has benefits to the developing party as well. If litigation commences, the seller may have to develop facts, with expert testimony, to show what constitutes reasonable efforts under an industry standard, according to 2020's Delaware Chancery Court ruling in ***Kabakoff v Zeneca Inc***, which granted summary judgment where a plaintiff failed to offer expert testimony regarding an industry standard. In certain circumstances, the seller may also not be able to obtain discovery into the developing party's efforts for its own separate medical devices or drug products that are not part of the merger or licence agreement—the objective standard makes those efforts irrelevant in certain circumstances, as seen in the 2021 case ***Avalyn Pharma Inc v Vincent***, from the US District Court for the Southern District of California. This may preclude an adversary (who might also be a competitor) from accessing highly confidential intellectual property that is otherwise irrelevant to the dispute. Correspondingly, the objective standard may also decrease discovery costs because documents and deposition testimony related to development of the defendant's own devices or drugs may not be relevant.

Subjective Benchmarks

An internal and subjective benchmark requires a party to use efforts consistent with those it normally uses to develop its own similar products at a similar stage of development, says the 2014 ruling in ***Banas v Volcano Corp*** by the US District Court for the Northern District of California. These provisions may be seen as buyer-friendly because the developer's efforts need not meet typical industry standards. But, unlike with the objective standard, these provisions make a company's own efforts to develop other devices and drugs relevant to whether the efforts requirement has been met.

In litigation, such a standard may subject the company to the time and expense of responding to discovery about its own drug or device development programs, including producing documents and information, and making key employees subject to depositions. And, of course, the seller-competitor may obtain access to sensitive information about other projects that the company would otherwise keep secret.

Undefined Benchmarks

Finally, parties sometimes leave the commercially reasonable efforts provision undefined – that is, the agreement may simply state commercially reasonable efforts are required without further explanation or definition. When undefined, courts may interpret these provisions as containing both objective and subjective components, as held by the Southern District of New York in 2018's ***Holland Loader Co v FLSmidth A/S*** and 2022's ***Menn v ConMed Corp*** by the Delaware Chancery Court. In such situations, like with external, objective provisions, the party may be required to use similar efforts as others operating in the same industry to develop a similar product, according to *Holland Loader*. Although, in some circumstances, bounds may be imposed that appear subjective or inward-looking, such as the consideration that a developing party need not undertake actions that "jeopardize its own business interests", as the Southern District of New York held in 2022 in ***3DT Holdings v Bard Access Systems Inc***. These same bounds will likely apply even where the CRE provision is specifically defined as well.

Ultimately, the obligations created by these undefined provisions may vary by the governing law. In New York, for example, a party must take some conscious effort to accomplish the agreed goal, as both *Holland Loader* and *3DT Holdings* explain, which describe the standard under New York law as "fairly lenient". In Delaware, however, in certain circumstances, courts have interpreted the term to require a party to do "everything in its power to fulfill its obligation", according to *Menn*.

It is important to understand at the outset of a relationship which standard the governing agreement sets. This will help ensure that development efforts follow contractual requirements and help defend against allegations of breach.

Operating under and complying with CRE requirements

Although commercially reasonable efforts provisions vary in the precise requirements they impose, there are certain topics that arise recurringly in litigation when the selling party seeks to enforce the obligation. These include the adequacy of:

1. funding;
2. staffing;
3. planning;
4. the focus on the project.

Adequate Funding

Parties alleging breach of commercially reasonable efforts provisions often point to purportedly insufficient funding to support their claim. With that in mind, parties operating under these provisions should strive to maintain budgets and spending practices that correspond to the device's or drug's stage of development. For example, the costs associated with preclinical development of a potential therapeutic product are significantly lower than at later stages of development—like clinical trials. Courts have therefore held that it is not commercially unreasonable for budgets and spending to reflect these common-sense considerations. Nor is it unreasonable for budgets and spending to fluctuate throughout development, according to ***InspiRx Inc v Lupin Atlantis Holdings SA***, a 2021 Southern District of New York ruling.

Adequate Staffing

Another common dispute arises over whether the development project was adequately staffed. This includes not just the number of individuals staffed on the project, but their expertise as well. Even when a company devotes an appropriate number of employees to advance a project, it may fall short of its efforts requirement if those employees are not sufficiently trained to accomplish the task. For example, compare *Holland Loader,* which discussed the failure to adequately train employees and evinced a lack of commercially reasonable efforts with *Menn*, which concerned altering engineers (who were competent to perform the required tasks) on the development team being commercially reasonable. Here too, adequately staffing a project does not require staffing to remain constant over the life cycle of the project—either in terms of headcount or expertise. In fact, complying with a commercially reasonable efforts provision (or protecting the company's own business interests) may require those fluctuations.

Adequate Planning

Creating a well-thought-out development plan can mitigate and avoid obstacles that arise along the way. With that in mind, sellers in commercially reasonable efforts cases will sometimes point to a lack of planning as a reason for disruptions and delays—and ultimately breach of a party's obligations, says *Holland Loader*. Companies can thus mitigate their risk by creating a development plan at the outset and, if appropriate, inform or involve the contractual counterparty in developing the strategy, shown in *InspiRx*. This can make it difficult for a seller to later challenge the reasonableness of the approach adopted.

Adequate Focus

Sellers alleging breach of commercially reasonable efforts requirements also often contend that the development project was neglected in some manner. They might allege that development lagged from the start, or that the company shifted its focus to develop its own products at the expense of others. Courts have recognised that in medical device and drug development, there will be times when workload fluctuates and that projects confront obstacles. Thus, courts have explained that commercially reasonable support for a project is not a 'stagnant concept' requiring the same level of focus and support throughout development, as explained in *3DT Holdings*, and 2014's ***Sekisui America Corp v Hart*** by the Southern District of New York. And courts have recognised that companies are allowed to consider their own business interests—including by diverting resources to other projects—at various points in time, according to *3DT Holdings*. What appears to be important is that there is some conscious, diligent effort to achieve the agreed-upon goal—even if there are periodic fits and spurts along the way.

These are just four common factors at issue in many development disputes. None are dispositive and not all will be relevant in every case. But considering these factors throughout the development process will help ensure that the company has sound defences in the event of litigation.

Litigating CRE obligations

For buyers, even the most diligent and competent development efforts will not always prevent litigation. And even weak claims can survive if there is not a sound understanding of the contractual requirements, controlling law, and the facts of the case.

For sellers, if the agreement does not involve clear audit or notice rights, litigation may be the only option to gain insight into the development efforts of the buyer. With that said, there are a few things that should be done early to increase the chance of success.

Conduct an investigation

With help from outside counsel, both suspicious sellers and buyers facing a lawsuit should investigate the allegations underlying the claim as soon as possible. It is critical to gain an early understanding of the key players, facts, and weaknesses in the claims or defences. Gaining an early, thorough information advantage is a key strategic asset to guide a company’s approach to a lawsuit.

Consider motions to dismiss

While conducting an initial investigation, companies should consider moving to dismiss or the potential for facing one. Although not all cases are ripe for early dismissal, plaintiffs in commercially reasonable efforts cases sometimes overlook required elements of the claim. This often stems from misunderstanding the contract’s requirements. For example, in *Neurvana Medical*, the efforts clause created an objective yardstick—that is, the developing party had to undertake efforts consistent with an industry standard. Although the plaintiff pled facts that purportedly showed breach, it failed to describe how the conduct alleged fell short of industry standards. The plaintiff did not identify a single entity with similar resources and expertise as the defendant, a single product of similar potential at a similar stage of development, or what similar companies would do to develop the product. The court thus dismissed the claim. While these types of pleading failures may be cured through an amended complaint, a successful dismissal can buy more time to investigate facts and negotiate settlement for a buyer and, for sellers, can be an expensive, early setback.

Consider counterclaims

In litigation, the claimant is often in the driver’s seat, and in some circumstances, other than the cost of the litigation, they have little at risk. Counterclaims by the seller are one way to level the playing field. Whether the buyer or seller, the potential for counterclaims—especially a breach by the seller—should be considered.

Plan for summary judgment and trial

From the start, the company and its attorneys should identify the information critical to winning on summary judgment or at trial. And there should be a plan for how to develop that information in a format that can be used on summary judgment—whether through depositions, interrogatory responses, documents, or declarations.

Identify experts early

Nearly all commercially reasonable efforts cases in drug or medical device development will require experts, especially in the complicated technical fields of drug and medical device development. Indeed, cases can be won or lost based on the quality of the expert. The company may need an expert to opine on pre-clinical development, the commercial potential of the product, or regulatory issues. Identifying potential experts early will help the company better understand the information needed, either from the company or the opposition, to create the strongest defence.

Conclusion

Although commercially reasonable efforts clauses provide benefits to both buyers (flexibility in development efforts) and sellers (contours around what those development efforts must be), they also create uncertainty. But that uncertainty can be mitigated by developing a thorough understanding of how courts interpret these provisions—and keeping a close eye on whether a project lacks the required funding, staffing, planning, or oversight to meet the underlying objective.

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