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#### NOTES

1. We note that the proper handling of employee data also is a critical diligence point but is beyond the scope of this article.

## “Commercially Reasonable Efforts” Diligence Obligations in Life Science M&A

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More than 80 percent of all deals in the pharmaceutical, medical device and biotech industries include an earnout structure that provides some type of contingent or delayed payment of proceeds to the sellers.<sup>1</sup> Trends vary widely, but in many transactions, the earnout consideration can far exceed the up-front payment to the sellers. This earnout consideration is frequently contingent on post-closing achievement of certain clinical study results, product approvals, reimbursement or sales. As a result, sellers during transaction negotiations intensely focus on the obligations of buyers to use corresponding “diligence” to achieve the goals that will trigger the contingent payment to the seller. This focus frequently comes to rest on the obligation of a buyer to use “commercially reasonable efforts” and the related definition of this obligation in transaction documentation. This article reviews the common approaches to defining “commercially reasonable efforts” and analyzes several recent cases interpreting the definitions in deal documentation.

### Common Approaches to Defining Commercially Reasonable Efforts

#### Outward Facing Definition

An outward facing definition of commercially reasonable efforts applies an industry-standard

requirement or looks to other participants in the industry to define the diligence obligations of the buyer. An example of this type of definition is:

**“Commercially Reasonable Efforts” means the efforts consistent with the past practice of similarly situated pharmaceutical companies with respect to similarly situated pharmaceutical products.**

This definition is generally viewed as more favorable to the seller of a technology, as it enables the seller to point to other industry standards that would have the buyer take additional steps to achieve the goal that would result in a payout on the earnout.

### Inward Facing Definition

In contrast, an inward facing definition applies the buyer’s own standard for undertaking research, regulatory approvals, and sales and marketing efforts. An example of an inward facing definition of commercially reasonable efforts is:

**“Commercially Reasonable Efforts” means efforts consistent with the past practice of Buyer related to research and development, regulatory approval, commercialization, sales and marketing of similar oncology therapeutic products with similar market potential at a similar stage in its development.**

This definition is more favorable to a buyer because it allows the buyer to point to its own investment thresholds and decision processes. Buyers can typically point to a similar situation where a step or expenditure of funds would not have been taken.

### No Definition

An option for buyers and sellers is to leave the term undefined. In the event of a dispute, a judge or mediator would look to case law and the facts of the situation to determine whether the appropriate level of diligence was utilized. It should be noted, however, that some states’ courts (most notably, Illinois) have interpreted terms such as

“best efforts” and “commercially reasonable efforts” to be so vague as to be unenforceable.<sup>2</sup> For an excellent discussion of courts’ varying interpretations of different due diligence standards, including commercially reasonable efforts requirements, see Kenneth A. Adams’ 2004 article.<sup>3</sup>

### Recent Cases

Many transaction documents incorporate mandatory arbitration provisions. In fact, sophisticated buyers understand that there are frequently dramatic changes post-closing related to medical products and, therefore, include a variety of structures to amicably settle earnout related disputes outside the courtroom. As a result, most disputes related to diligence obligations are handled out of court, which results in a limited number of cases that directly address the interpretation of commercially reasonable efforts obligations. Two recent cases, however, have given insight to judges’ review of these obligations.

#### *Volcano Corporation/CardioSpectra*

In *Banas v. Volcano Corp.*, the former owners of CardioSpectra, Inc. challenged whether Volcano Corporation used appropriate diligence to develop and sell CardioSpectra’s medical device system.<sup>4</sup> The merger agreement required Volcano to use “commercially reasonable efforts” and to “act in good faith” when working to achieve the goals that would result in additional merger consideration payable to the former shareholders of CardioSpectra. The merger agreement defined commercially reasonable efforts as:

**...the use of efforts, sales terms, expertise and resources normally used by [Volcano] for other products, which, as compared with the OCT Products; are of similar market potential at a similar stage in its development or product life, taking into account all reasonable relevant factors affecting the cost, risk and timing of development and the total potential of the applicable OCT Products, all as measured**

### by the facts and circumstances at the time such efforts are due...

The definition used in the CardioSpectra merger agreement was inward facing and required the sellers to demonstrate that commercially reasonable efforts were not used compared with efforts made for other similarly situated Volcano products. The court granted summary judgment to Volcano because the sellers failed to present any evidence that demonstrated Volcano's efforts with similarly situated products. The judge determined that without such evidence, the sellers could not make claim for breach of the merger agreement.

In addition to addressing commercially reasonable efforts, the judge examined whether Volcano failed to act in good faith in development efforts. The merger agreement did not define act in good faith, so the court looked to case law to determine the standard. Examining the evidence, the court found that Volcano had expended significant resources, hired sufficient personnel and had not willfully abandoned the development of the CardioSpectra system. As such, it determined that Volcano had not breached the merger agreement by failing to act in good faith.

### *Sekisui / America Diagnostica, Inc.*

Also in the first quarter of 2014, a judge examined counterclaims in a lawsuit brought by Sekisui America against the former shareholders of America Diagnostica, Inc. (ADI).<sup>5</sup> In counterclaims against Sekisui, the former shareholders of ADI alleged that Sekisui America had breached the stock purchase agreement by failing to use "commercially reasonable efforts" and omitting actions "with the intent of preventing [ADI] from meeting ... revenue targets ..." The term commercially reasonable efforts was not defined in the stock purchase agreement.

The court found that the sellers had failed to prove a breach of the diligence obligations because they did not present evidence establishing the objective standard for commercially reasonable efforts in the regulatory context of the U.S. Food and Drug Administration, nor did they explain how Sekisui America deviated from that standard. Further, the court found that there was

no evidence demonstrating that Sekisui America intentionally omitted actions to prevent the revenue targets from being met.

## Tips and Takeaways

### Inward Facing Definitions Add Hurdles for Sellers

As demonstrated by *Volcano*, an inward facing definition of commercially reasonable efforts adds significant hurdles for the sellers attempting to prove that diligence requirements were breached.

### Additional Requirements to Use "Good Faith" Should Be Defined

Sometimes drafters will toss in additional references or requirements to use good faith in the diligence obligation section of an M&A document. Such terms should be cautiously used because, as seen in both *Volcano* and *Sekisui America*, this allows a seller to further attack the buyer's effort. If good faith is an obligation of the buyer, consider defining the requirement further.

### Define the Impact of a New Technology Acquisition

Acquisition documentation frequently fails to address the impact of newly acquired technology. If it is not specifically addressed in the document, courts will be left to discern the intent of the parties if a new acquisition is made that impacts existing diligence or milestone obligations. Ideally, a buyer would have a clear statement that the acquisition of a new technology involving the same therapeutic area is permitted.

### Business Teams Should Be Aware of Implications of "Shelving" the Acquired Technology

Although not examined in either *Volcano* or *Sekisui America*, other litigation and mediation involving diligence obligations have shown that sellers can win large damage awards if the buyer's business team "shelves" or otherwise abandons an acquired technology where the acquisition

documentation included a diligence obligation. It is worth the additional time and effort to avoid protracted litigation to establish strong documentation as to why development, regulatory or sales efforts related to a technology were shelved.

## Consider the Impact of Specific Diligence Milestones

In addition to requiring a buyer to use commercially reasonable efforts, sellers will often require a buyer to meet certain specific diligence milestones, regardless of whether buyer is using commercially reasonable efforts. The diligence milestones are typically key product development or commercialization events, and will often trigger one or more earnout payments. A buyer's failure to achieve a milestone may result in breach of its obligations to a seller, even in the event that a buyer was otherwise using commercially reasonable efforts to meet such milestone.

## Buyers Should Consider the Benefit of Safe Harbor Provisions

In the event that the buyer satisfies a specified milestone in a timely manner, a safe harbor provision can deem a buyer to have used commercially reasonable efforts in achieving such milestone. This will relieve the buyer of all or part its obligation to use commercially reasonable efforts. Such milestones may include development achievements, regulatory approvals or financial events such, as net sales achievements. Preferably, a buyer will want to negotiate optional safe harbor events that, if met, will demonstrate the buyer's use of commercially reasonable efforts without creating mandatory obligations.

## Consider Third Party Diligence Obligations

Buyer should be aware that, to the extent that it acquires intellectual property through a sublicense issued by a seller (*i.e.*, seller has in-licensed intellectual property from a third-party licensor), the seller may have its own diligence obligations it owes to its third-party licensor that will need to be satisfied to retain its in-license. It is also likely

that, with respect to the technology sublicensed to the buyer, the seller will rely on the buyer's diligence to satisfy the seller's obligations to its licensor. Therefore, the seller's hands may be tied when it comes to negotiating a buyer's diligence obligations and remedies. If such diligence obligations and remedies are unacceptable to the buyer, the only acceptable alternative may be for the seller to renegotiate its diligence obligations with the third-party licensor.

## Define Specific Circumstances Under Which Buyer Will Be Excused

Despite good faith intentions, events can occur that make unreasonable the continued use of commercially reasonable efforts. In addition to *force majeure*, such events can include failure to obtain regulatory approval as expected, unexpected safety concerns, unexpected market shifts or unfavorable commercial circumstances that adversely affect product viability, and inability to obtain commercially viable reimbursement levels. It is best to anticipate the possibly of such events and provide reasonable tolling and other remedial provisions.

## Consider Disclaimers

If a buyer and seller agree that no specific diligence standard will be required (*i.e.*, the buyer will not be required to use commercially reasonable efforts, or any other level of efforts for that matter), the agreement should include a disclaimer on point. It is otherwise too easy for a court to imply at least some level of good faith efforts into the agreement that were never intended or agreed to by the parties.

### NOTES

1. 2012 SRS Life Sciences M&A Study (*available at: <https://www.srsacquiom.com/>*).
2. See *Kraftco Corp. v. Kolbus*, 274 N.E.2d 153, 156 (Ill. App. Ct. 1971).
3. Kenneth A. Adams, "Understanding 'Best Efforts' and Its Variants (Including Drafting Recommendations)," *The Practical Lawyer*, August 2004.
4. *Banas v. Volcano Corp.*, 2014 WL 1309720 (N.D. Cal. 2014).
5. *Sekisui America Corp. v. Hart*, 2014 WL 687222 (S.D. N.Y. 2014).