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Life Sciences Litigation: A Look at Milestone Disputes & Recent Trends

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Milestone Earnouts

– Milestone earnouts: common in life sciences industry
  - The norm in **bio/pharma deals** (80%), and in **medical device deals** (70%)
  - Common in **diagnostics and research technologies** (50%)
  - Only occasional in **other industries** (15-20%)
– These numbers have been fairly consistent over the past 10 years. ***SRSA 2019 Study***
– So common they've been coined **"biobucks"**

Disputes over Milestone Clauses are Common

"[A]n earn-out… typically reflects disagreement over the value of the business that it bridges when the seller trades the certainty of less cash at closing for the prospect of more cash over time… But since value is frequently debatable and the cause of underperformance equally so, an earn-out often converts today's disagreement over price into tomorrow's litigation."

***Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 132 (Del. Ch. 2009)**

Commercially Reasonable Efforts Clauses

Commercially Reasonable Efforts

General Background

- "Efforts" clauses are common in milestone agreements
- These include:
  - **"Best Efforts"**
  - **"Reasonable Best Efforts"**
  - **"Every Effort"**
  - Most common: **"Commercially Reasonable Efforts"**
- Contract drafters ascribe meaning to different terms, but courts frequently treat these as equivalent
  - ***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)** ("Commentators who have surveyed the case law find little support for the distinctions that transactional lawyers draw.")

Commercially Reasonable Efforts

"Commercially Reasonable Efforts"

- Parties often include some additional detail in definitions about what the "efforts" should entail
- Advantages and disadvantages with specific definitions:
  - flexibility vs. inflexibility
- Enforceable, except in Illinois:
  - ***Kraftco Corp. v. Kolbus*, 274 N.E.2d 153, 156 (Ill. App. Ct. 1971)** ("The mere allegation of best efforts is too indefinite and uncertain to be an enforceable standard.")
- Consider alternatives to CRE (more on this later)
- Careful documentation is critical
- The importance and challenge of identifying experts

Commercially Reasonable Efforts

Subjective CRE Definition

- Inward-looking definition
  - Efforts equivalent to company's own efforts on similar products

Pros:

- Less need to pay attention to competitors
- Company-specific factors relevant

Cons:

- Danger of far-reaching discovery into other products
- Can hamper ability to prioritize other products
- Possibility of few relevant comparators

Litigation Example: Subjective Definition

Banas v. Volcano Corp., No. 12- CV-01535 (N.D. Cal. March 31, 2014)

– 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.

Summary Judgment Granted in favor of Defendants

Footnote: "Plaintiffs failed to request information in discovery about products comparable to the OCT system."

Commercially Reasonable Efforts

Objective CRE Definition

- Outward-looking definition
  - Efforts typical in the industry for a similar product

Pros:

- Unlikely to involve far-reaching discovery into other products
- Allows for flexibility in portfolio prioritization among similar products with less risk

Cons:

- Company-specific downturns or changes in priorities more likely to lead to claims of failing to exert CRE
- Evidence of standard industry practice hard to obtain, and likely to become “battle of the experts”

Litigation Example: Objective Definition

Neurvana Medical, LLC v. Bait USA, LLC, 2020 WL 949917 (Del. Ch. Feb. 27, 2020)

- Neurvana alleged that Balt had failed to use commercially reasonable efforts to obtain CE Mark approval
- Balt's "efforts" obligation was defined as:

  activities using efforts and resources comparable to those which an entity in the medical device industry of similar resources and expertise as the Purchaser and its Affiliates (taken as a whole) generally use in the exercise of its reasonable business judgment to accomplish such activities and objectives in an expeditious manner for its own products ... of similar market potential at a similar stage in development or product life, considering conditions then prevailing.
- **Motion to dismiss granted**. Neurvana failed to include allegations about other entities in the medical device industry.

Litigation Example: Objective Definition

Himawan v. Cephalon, Inc., 2018 WL 6822708 (Del. Ch. Dec. 28, 2018)

- Commercially reasonable efforts was defined as
  - "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon], with due regard to the nature of efforts and cost required for the undertaking at stake."
- **Motion to dismiss denied**. Plaintiffs included allegations about "several companies with substantially the same resources as Cephalon" that were working on similar treatments

Alternatives to CRE Clauses

Poll: What approach has your company taken as to milestone earnouts?

A. Objective efforts clause

B. Subjective efforts clause

C. Specific requirements, in addition to or instead of efforts clause

D. Specific triggering event with an “out”

Alternatives to CRE

Alternatives to CRE

- 62% of deals apply “CRE” clause; 18% did not have any diligence requirement. ***SRS 2017 M&A Study***
- Specific requirements, instead of or in addition to CRE
  - Minimum spend on marketing and sales
  - For __ years, retention of key people, agreement on plan and budget
- Strict, time-based definition + “out”
  - Express buyer commitment to start and finish phase___, or pay milestones unless there is a bona fide safety concern

Litigation Example: Alternative to CRE

SRS v. Shire US Holdings, Inc. et al., C.A. No. 2017-0863-KSJM (Del. Ch.)

- "Commercially Reasonable Efforts" clause rejected during drafting in favor of "no obligation" clause and time-based payment provision subject to an exception:
  - No provision of the Merger Agreement "shall be construed to impose upon [Shire] any express or implied obligation, duty or expectation to test, develop, pursue, market, make any regulatory filings or seek any Regulatory Approvals with respect to, or otherwise advance [deferitazole]." § 2.9(g)
  - "Notwithstanding anything else in this Agreement to the contrary, in the event that the Company has not achieved Initiation of the Phase III Clinical Trial Milestone on or before December 31, 2015, other than as a result of a Fundamental Circumstance, then the Initiation of Phase III Clinical Trial Milestone shall be deemed to have been achieved on such date." § 2.9(f)
  - "Fundamental Circumstance" defined as "a material safety or efficacy concern related to the Product that would reasonably be expected to make production and sale of [deferitazole], or receipt of applicable Regulatory Approvals, impracticable."

Litigation Example: Alternative to CRE

SRS v. Shire US Holdings, Inc. et al., C.A. No. 2017-0863-KSJM (Del. Ch.)

Post-Trial Memorandum Opinion, Oct. 12, 2020:

- "Read together [Section 2.9(g) and] Section 2.9(f), these aspects of the Merger Agreement indicate that Section 2.9(f) is a FerroKin-friendly backstop. Section 2.9(f) requires generally that the … Milestone "be deemed to have been achieved" on December 31, 2015, even 'in the event that [Shire] has not achieved [it].'"
- "Given that (i) payment of the bulk of the Merger consideration was deferred post-close, (ii) Shire wielded control over "all respects" of the drug development and commercialization process, and (iii) there was no obligation, duty or expectation imposed on Shire to advance deferitazole in any way, it makes sense that Section 2.9(f) provides Shire with only a narrow escape."
- "Shire's failure to initiate Phase III clinical trials by December 31, 2015 did not come "as a result of" a Fundamental Circumstance."
- "The record reflects that, postclosing, Shire altered deferitazole's development timeline such that Shire's failure to initiate Phase III clinical studies by December 31, 2015, was inevitable, notwithstanding any Fundamental Circumstance that later occurred."

Milestone Definitions

Milestone Definitions

General Observations

- Disputes over definition of milestone triggering events a common litigation issue
- Contract-drafters should avoid ambiguity where possible
  - Don’t assume everyone has the same understanding of an undefined phrase
  - But beware of definitions that introduce more ambiguity
- Regulatory-related definitions source of ambiguity
  - Marketing approval (e.g., “drug indication”)
  - Types of clinical trials (e.g., Phase II or Phase III, number and type of trials needed)
  - Industry-specific terms of art

Avoiding ambiguity in milestone definitions

Kabakoff v. Zenca, Inc., C.A. No. 2017-0459-JRS, 2020 WL 6781240 (Del. Ch.)

- "Successful Completion of a Phase 1 study" defined in part as "completion of **a study report**."
- **Plaintiff's definition**
  - "any summary of findings and data from Phase 1 that would enable the defendant to proceed with further development."
- **Defendants' Definition**
  - Industry-specific "Case Study Report" – a comprehensive document describing the conduct and results of a clinical trial in a prescribed regulatory format.

Judgment in favor or Defendants after a five-day trial.

Avoiding ambiguity in milestone definitions

Calithera Biosciences, Inc. v. Incyte Corporation, CGC-20-584126 (Cal. Super. Ct)

- Collaboration and Licensing Agreement provides milestone payment for each indication cohort "[m]eeting (or exceeding) the efficacy bar outlined in the protocol for the second stage of a Simon 2-stage combination Phase I Study…." Am. Compl. ¶ 4
  - Calithera alleges that parties understood and that it is "common knowledge throughout the industry" that meeting the "efficacy bar" in the second stage of a Simon Two-Stage Study means rejecting the null hypothesis. Id. ¶¶ 5
  - Incyte has taken position that Calithera failed to meet the "efficacy bar" even though each trial had positive responses in sufficient numbers to reject the null hypothesis, and has pointed to other statistical terminology to justify its position. Id. ¶¶ 6, 84
- "efficacy bar" not defined in either CLA or protocol

Recent Trends

Recent Trends

General Observations

- Milestone disputes arise in many different contexts:
  - merger agreements, product acquisitions, collaboration and licensing agreements
- "Efforts" clauses consistently arise, but many other claims also at issue, and where other provision is breached case more likely to survive motion to dismiss
- Despite fact-intensive nature of these cases, some milestone dispute claims have been dismissed at the pleading stage
- While many cases settle, trials are still occurring
- Majority of life sciences milestone cases are in Delaware Chancery Court; arbitration also common
- COVID-19 Effects

Poll: How has COVID-19 affected your existing agreements containing milestones?

_____

A. More disputes that are headed to litigation
B. More cooperation in amending/re-drafting provisions impacted by pandemic
C. Nothing pandemic-related has come up yet

COVID-19

Effects on Deals

- Clinical trials have been significantly impacted
- Numerous studies have been placed on hold
- FDA extensions
- Development in some indications has been terminated because of delays
- Great interest in potential applications to COVID-19 research
- Uncertainty and potential turmoil re suspending patents on vaccine technology
- Pandemic may be encouraging settlement or re-drafting/amending agreements

COVID-19

Effects on Litigation Procedure

- Delays and changes, but litigation continues
- Delaware Court of Chancery (and many other courts) have adopted plans to allow in-person court appearances:
  - Screening of people entering courtrooms, social distancing, masks, limitations on number of people in courtrooms is typical
  - Judges have discretion to hold hearings telephonically and using video technology
- Depositions, court hearings are occurring virtually

COVID-19

Effects on Litigation Substance

- The cases being decided now primarily relate to disputes that arose pre-pandemic
- COVID-19 considerations are just starting to come into play
- Commercially reasonable efforts / time-based deadlines are expected to be impacted
- Other doctrines may arise, but contract language remains key
  - Force Majeure
  - Supervening Frustration
  - Commercial Impracticability
  - Mutual Mistake

Litigation Example: COVID-19 Effects on Litigation Substance

Shareholder Representatives Services LLC v. Alexion Pharmaceuticals, Inc., C.A. 2020-1069 (Del. Ch.)

- SRS sued Alexion Pharmaceuticals for failing to use CRE in the clinical development, regulatory approval, and commercialization of ALXN1830– an antibody drug candidate – in order to achieve certain milestone events under a merger agreement.
  - **Alexion MTD**: COVID-19 pandemic interrupted clinical trials for ALXN1830.
  - **SRS Complaint**: Many of Alexion's competitors have continued clinical development of products even during the COVID-19 pandemic, as has Alexion for other products.

Lessons From Recent Litigation

Lessons for Company Leaders from Recent Litigation

Overview

- Consider alternatives to CRE clauses
- Avoiding ambiguity in contract definitions
- Fee-shifting provisions
- Awareness of moral hazard with milestone obligations

Consider Fee-shifting Provisions

Shareholder Representative Services LLC v. Shire US Holdings, Inc. et al., C.A. No. 2017-0863-KSJM

"In this case, the contingent fee agreement allowed SRS to retain skilled and experienced counsel despite a lack of resources to fund the litigation, an arrangement that ultimately inured to the benefit of the former FerroKin stockholders. Shire could have contracted in the Merger Agreement to avoid this outcome. It did not. Shire provides no basis to avoid it now. See, e.g., *Johnson Controls, Inc. v. Edman Controls*, Inc., 712 F.3d 1021, 1027 (7th Cir. 2013) (enforcing a contractual fee-shifting provision to cover contingent fees, observing that "if the parties do not want to pay an opposing party's contingent fee, they are free to write an agreement under which the prevailing party will be obliged only to pay fees calculated in accordance with the lodestar method")."

Moral Hazard with Milestone Obligations

***Lunar Representative LLC vs. AMAG Pharmaceuticals*, C.A. No. 2019-0688 (Del. Ch.)** (Plaintiff alleges that the company slowed down sales processing to reduce projected net sales from $410 million to $393 million in order to avoid paying a $50 million milestone payment when sales exceeded $400 million)

***Pacira BioSciences, Inc. v. Fortis Advisors LLC*, C.A. No. 2020-0694 (Del. Ch.)** (Plaintiff alleges that former employees of the acquired company worked to artificially inflate reimbursement numbers for use of a medical device in order to obtain milestone payments)

Tips from the Trenches

Pre-dispute communications can be key evidence

- Drafts and negotiation correspondence
- Emails between non-lawyers about the meaning of the contract provisions, “justification” for position
- Accounting memos
- Minutes and presentations from internal development team meetings reflecting promising prospects for drug

Poll: Have you used, or are you familiar with, SRS Acquiom or another shareholder representative?

A. Yes, we have used SRS Acquiom

B. We are familiar with SRS Acquiom and/or another shareholder representative

C. No, we have not used or considered a shareholder representative

Tips from the Trenches

Game out potential disputes during contract drafting

- Consider hiring a professional shareholder representative to manage litigation or negotiations
- Consider whose consent will be needed if contract terms need to be renegotiated
- Consider who you want deciding the disputes (court vs. arbitration)

Success-based milestones may be less susceptible to dispute

- Sales milestones with longer timelines may be appealing to parties optimistic about business, but uncertain about near-term performance rather than shorter-term development and regulatory milestones

Any questions?

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