KEKER
VAN NEST
& PETERS

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

May 12, 2022

Introduction to Panelists: KVP/SRS

Laurie Mims
Partner
Keker Van Nest & Peters

Jennifer Huber
Partner
Keker Van Nest & Peters

Ann Byers
Director, Shareholder Advisory
SRS Acquiom

Milestone Earnouts

– Milestone earnouts: common in life sciences industry

- The norm in **bio/pharma deals** (87%) and in **medical device deals** (78%)
- Common in **diagnostics and research technologies** (64%)
- Only occasional in **other industries** (18%)

– These numbers are on the rise but have been fairly consistent over the past 10 years. ***SRSA 2021 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:

- **“Best Efforts”**
- **“Reasonable Best Efforts”**
- **“Every Effort”**
- Most common: **“Commercially Reasonable Efforts” or “CRE”**

– CRE: Subjective v. Objective

- Subjective: Inward-looking; efforts equivalent to company’s own efforts on similar products
- Objective: Outward-looking; efforts typical in the industry for a similar product

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

Alternatives to CRE Clauses

Alternatives to CRE

Alternatives to CRE

- 72% of development milestones subject to "CRE;" Only 6% did not have any diligence requirement. 25% subject to specific requirements, instead of or in addition to CRE, e.g.:
  - Minimum spend on marketing and sales
  - For X years, retention of key people, agreement on plan and budget
- 30% subject to Express Buyer Discretion sometimes includes on "out," e.g.:
  - Commitment to start Phase 3, or pay milestones unless there is a bona fide safety concern

SRS 2021 Life Sciences Study

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."

Poll: How has your company defined a milestone earnout?

A. Efforts clause, defined subjectively or objectively

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

C. Specific triggering event with an “out”

D. Avoidance of milestone earnout given uncertainty and disputes

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 2a/b or Phase 3, Registrational)
  - Industry-specific terms of art (e.g., “study report”)

Avoiding Ambiguity in Milestone Definitions

***Kabakoff v. Zeneca, Inc.*, C.A. No. 2017-0459-JRS, 2020 WL 6781240 (Del. Ch.) aff'd** 264 A.3d 214, (Del. Supr., Oct. 21, 2021)

- "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 of Defendants after a five-day trial.

Poll: Has a dispute over a milestone definition come up for your company?

A. Yes, a dispute over a milestone definition has come up

B. No, a dispute over a milestone definition has not come up

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 based disputes (supply chains)

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

A. More disputes headed to litigation

B. More cooperation in amending/re-drafting provisions impacted by pandemic

C. Although pandemic has caused issues, those have not led to litigation or amending/re-drafting

D. Pandemic has not had a major effect on existing agreements

SRSA Studies: Effects of Pandemic

2021 Life Sciences M&A Study

- While earnout disputes remain common (29% of deals), more than half of those deals have now been renegotiated
- Surge of more than $20B in aggregate earnout potential in deal set, almost entirely from Bio/Pharma
- Available here

2021 M&A Deal Terms Study

- Drafting: “Pandemic” added as Material Adverse Effect (75% of deals)
- Financial: Median earnout potential as % of closing payment increased significantly
- Available here

Litigation Example: COVID-19 Stalls Development

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.
  - **SRS Complaint**: Unpaid earnouts due for Alexion's failure to use CRE. Alexion and competitors continued clinical development of other products during pandemic
  - **Alexion MTD**: COVID-19 interrupted trials; claim not ripe because Alexion had seven years to use reasonable efforts
  - Court Ruling: Complaint alleged that Alexion stopped CRE in October 2019. Claim accrued on that date.

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, 2020 WL 4938035 (Del. Ch. Aug. 21, 2020)** (denying motion to dismiss claim that acquiror slowed sales processing to reduce projected net sales from $410 million to $393 million in order to avoid paying a $50 million milestone based on +$400 million in sales)

> *"Slowing down sales to avoid making a contingent payment is the polar opposite of using commercially reasonable efforts to market and sell a product. If it occurred it would constitute a breach."*

***Pacira BioSciences, Inc. v. Fortis Advisors LLC*, C.A. No. 2020-0694, 2021 WL 4949179 (Del. Ch., June 2, 2021)** (granting motion to dismiss claims that agreement imposed duty on former employees of acquired company who allegedly inflated device reimbursement numbers to claim entitlement to 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
- FDA filings
- Earnings calls

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?

Contact Us

Laurie Mims
Partner
Keker Van Nest & Peters
lmims@keker.com
(415) 676-2227

Jennifer Huber
Partner
Keker Van Nest & Peters
jhuber@keker.com
(415) 773-6668

Ann Byers
Director, Shareholder Advisory
SRS Acquiom
abyers@srsacquiom.com
(720) 709-1201