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Strategic Enforcement in Life Sciences:
Litigating Licensing Provisions, Development Agreements, and Missed Milestones

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Introduction to Panelists

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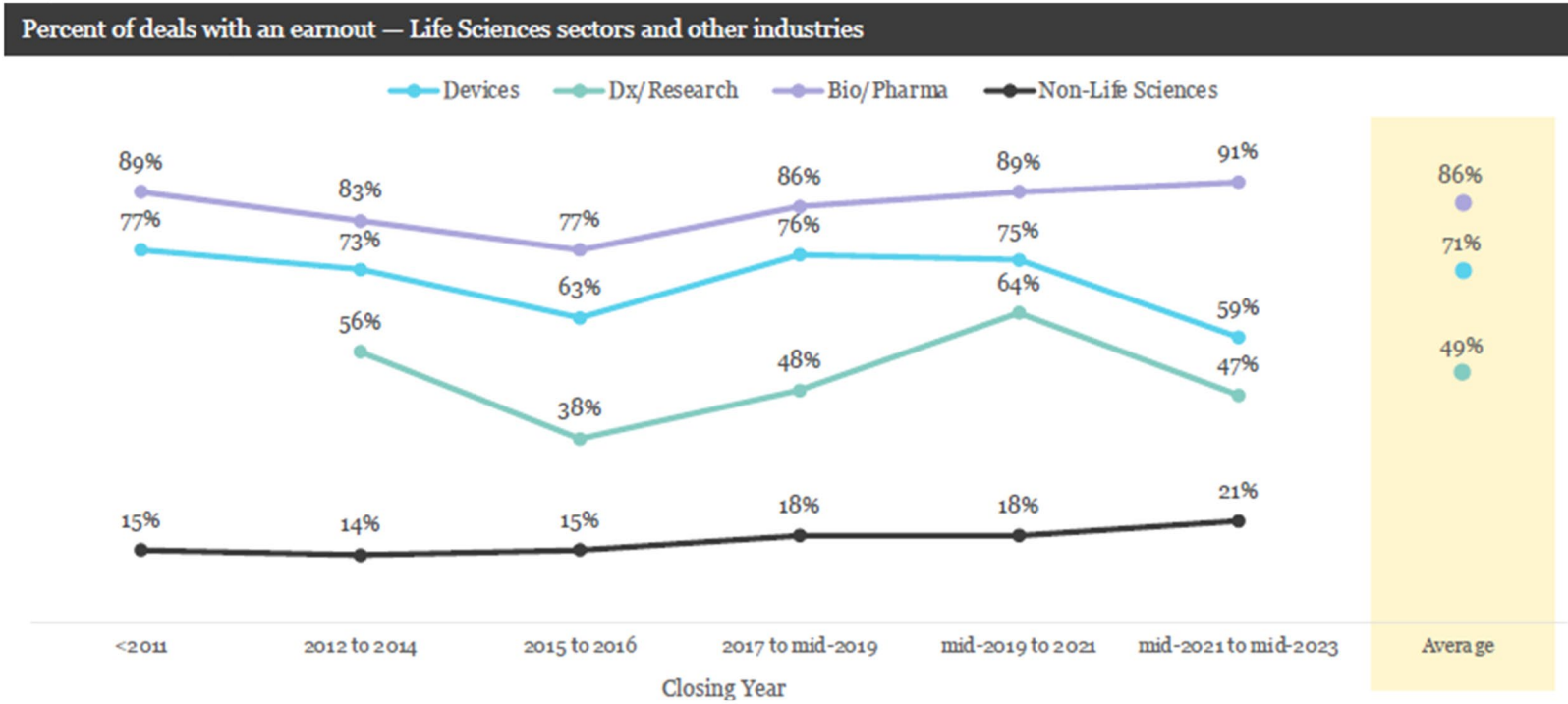
The Milestone and Earnout Landscape

Milestones in Context



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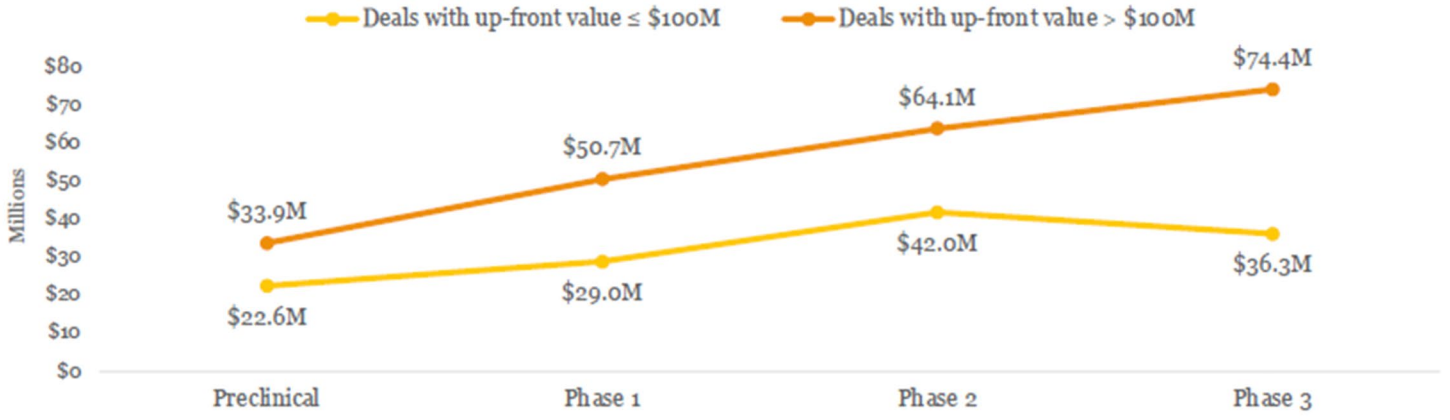
Milestone Values by Development Phase

Mean milestone values at each development phase for all Bio/Pharma deals – by up-front value



Milestone Values	Preclinical	Phase 1	Phase 2	Phase 3
Mean	$33.0M	$36.0M	$61.8M	$53.6M
Median	$21.0M	$25.0M	$49.0M	$32.3M

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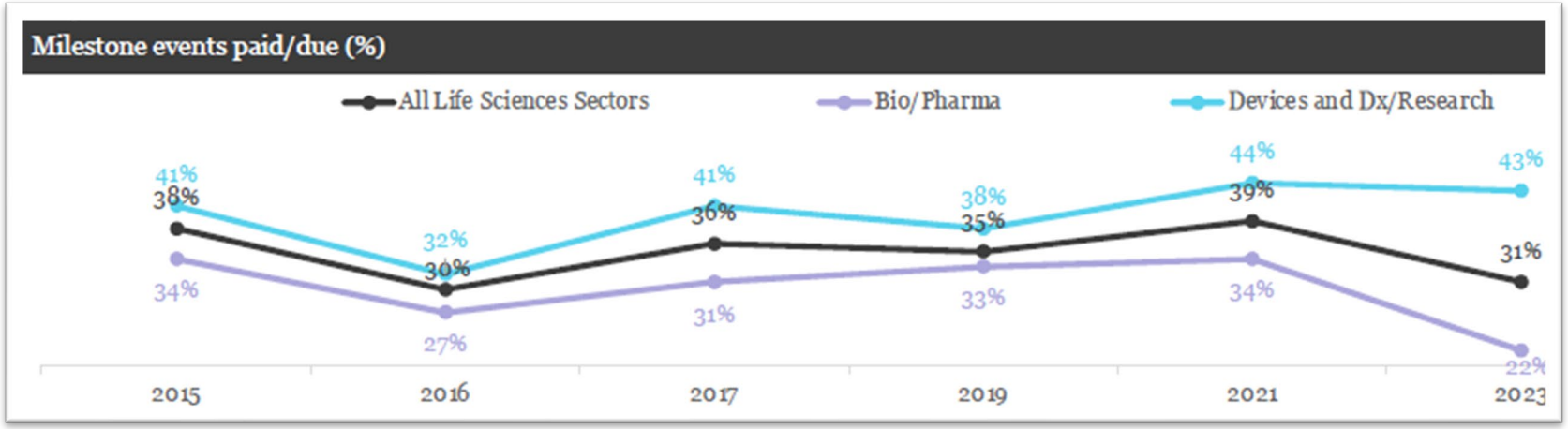
Milestone Achievement Rates Over Times



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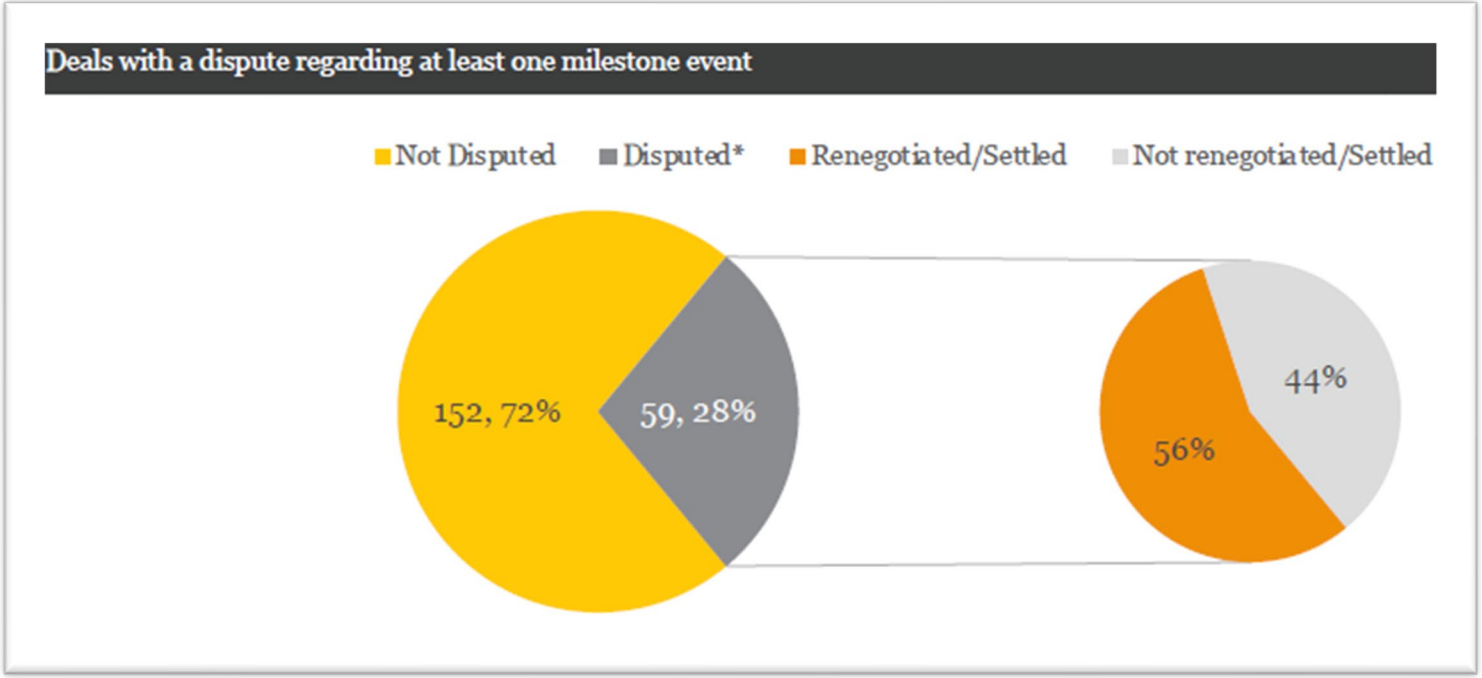
Earnout Disputes and Renegotiations



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Lessons From Recent Litigation

Lessons from Recent Litigation

Overview

- Avoid ambiguity in contract terms
- Maintain records of negotiation and course of dealing history—and be familiar with it!
- Leverage expert help early

Avoiding Ambiguity in Milestone Definitions

Potential sources of ambiguity in milestone-triggering events:

- Marketing approval (e.g., “drug indication”)
- Industry-specific terms of art (e.g., “study report”)
- CRE terms (subjective? objective?)
- Types of clinical trials (e.g., Phase 2a/b or Phase 3, Registrational)

Avoiding Ambiguity in Milestone Definitions: Case Study

SRS v. Astellas Pharma (Del. 2023)

4. In the Warrant Purchase Agreement, the Parties agreed to a specific definition for the term "Phase II Clinical Trial" for purposes of triggering the Milestone Payment obligations. While this contractual definition references guidance from the Federal Drug Administration (FDA) as to what generally occurs during a Phase 2 clinical study, it also employs additional language to create a more specific standard than the FDA for trigging the Milestones. Indeed, the contractual definition of "Phase II Clinical Trial" in the Warrant Purchase Agreement provides an even lower bar for achieving the Phase II Milestones than would the FDA description of Phase 2 itself.[2] But whether using the FDA description of Phase 2 or the contractual definition of Phase II Clinical Trial, Astellas has through multiple years of clinical development brought the assets it acquired from Potenza well into what would logically be considered a Phase II Clinical Trial.

SRS Complaint (Sep. 2023)

Avoiding Ambiguity in Milestone Definitions: Case Study

Calithera Biosciences v. Incyte Corp (Cal. Super. Ct. 2020)

- Collaboration and Licensing Agreement provided 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"
- "Efficacy bar" not defined
- Parties exchange discovery, and case settles in September 2021

Avoiding Ambiguity in Milestone Definitions: Case Study

Fortis Advisors v. J&J (Del. 2020)

The Merger Agreement required J&J to expend "efforts and resources" toward meeting the regulatory milestones "consistent with [J&J's] usual practice" for "priority medical device products of similar commercial potential at a similar stage in product lifecycle" to iPlatform and Monarch. JX-1620 § 2.07(e)(i)-(ii). J&J could not take or refrain from taking any action "with the intention of avoiding" or "based on taking into account the cost of" any earnout payments. *Id.* § 2.07(e)(iii).

The efforts provision subjected J&J to a *higher* standard than industry norms: J&J promoted itself as the gold standard for medical device development and commercialization. JX-0880 at -032. The Merger Agreement lists ten factors to "tak[e] into account" in the CRE analysis, JX-1620 § 2.07(e)(ii), but expressly requires J&J to use the efforts it would for its "priority" devices in meeting the regulatory milestones.

Fortis Pretrial Brief (Jan. 5, 2024)

Avoiding Ambiguity in Step-Down Provisions

Potential sources of ambiguity in step-down-triggering events:

- Extent of step-down (what is a “reasonable reduction”?)
- Category of licensed rights (patents? trade secrets? IP covering specific subject matter?)
- Reductions tied to sales (how are sales calculated?)

Avoiding Ambiguity in Step-Down Provisions – Defining the Scope of the IP at Issue

The *Brulotte* principle:

"A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly. But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent by tying the sale or use of the patented article to the purchase or use of unpatented ones."

Brulotte v. Thys Co. (1964)

Avoiding Ambiguity in Step-Down Provisions – Defining the Scope of the IP at Issue

But a licensor may continue collecting royalties at a *stepped-down* rate after patent expiration in the case of licenses covering both patents and trade secrets (i.e., "hybrid" licenses):

"[P]ost-expiration royalties are allowable so long as tied to a non-patent right—even when closely related to a patent …That means, for example, that a license involving both a patent and a trade secret can set a 5% royalty during the patent period (as compensation for the two combined) and a 4% royalty afterward (as payment for the trade secret alone)."

Kimble v. Marvel Entertainment, LLC (2015)

Ambiguity in Step-Down Provision: Case Study

Scripps v. Teva (S.D. Cal. 2021)

- November 2000: Scripps licenses IP concerning the manufacture, use and development of cladribine for the treatment of multiple sclerosis so that IVAX could further develop and commercialize the drug.
- Cladribine (under the name Mavenclad) receives regulatory approval for treatment of MS in 2017—after Scripps's patents had all expired
- Mavenclad becomes blockbuster drug

Ambiguity in Step-Down Provision: Case Study

Scripps v. Teva

Duration of Royalty Obligations. The royalty obligations of IVAX as to each LICENSED PRODUCT shall terminate on a country-by-country basis concurrently with the expiration of the last to expire of PATENT RIGHTS utilized by or in such LICENSED PRODUCT in each such country or, with respect to LICENSED PRODUCTS sold in a country for which there are no PATENT RIGHTS, ten (10) years after the date of first commercial sale of such LICENSED PRODUCT in such country; provided that the royalty payable with respect to such sales in such country shall be seventy-five percent (75%) of the royalty that otherwise would be payable pursuant to this Agreement.

Ambiguity in Step-Down Provision: Case Study

Scripps v. Teva

- November 2022: Judge Battaglia denied Teva's motion to dismiss: "The use and interpretation of the disjunctive 'or' gives rise to the parties' conflicting readings of the plain language in Section 3.7, both of which are nevertheless reasonable."
- Case settles in August 2023

Know Your Negotiation History and Course of Dealing

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
- Minutes and presentations from internal development team meetings reflecting promising prospects for drug
- Earnings calls
- Payment and accounting correspondence

Know Your Negotiation History and Course of Dealing: Case Study

Scripps v. Teva

- Teva's motion to dismiss: "In December 2019, more than two years after the launch of Mavenclad (cladribine), Scripps inquired as to why Teva had not paid royalties to Scripps on commercial sales in countries with Patent Rights that had expired ..."

- Scripps's opposition: "[T]he Complaint features allegations regarding extrinsic evidence that supports Scripps's interpretation of the Agreement or, at the very least, render the contract ambiguous. Notably, Scripps has alleged that … during contract negotiations, the parties considered and rejected a proposal to eliminate Ivax's obligation to pay royalties after Scripps's patents expired."

Leverage Expert Help Early

Experts can play a valuable role in shaping and informing your approach to a potential dispute

- Valuing potential royalties or milestone amounts
- Opining on industry standards to inform your interpretation of an ambiguous provision
- Substantiating failure to use CRE based on industry norms

Leverage Expert Help Early: Case Studies

- Opining on industry standards regarding reasonableness of contract interpretation
  - *Scripps v. Teva* Complaint: “This interpretation of Section 3.7 is also consistent with … industry standard practices for license agreements that license both patents and know-how. Drug development is a lengthy process, and licensors of intellectual property rights claiming or covering drugs, such as Scripps, frequently contemplate that the useful commercial life of a drug may extend beyond—or may even begin after—the initial patents protecting that drug have expired.”
- Substantiating failure to use CRE based on industry norms
  - *Neurvana Medical, LLC v. Bait USA, LLC*, 2020 WL 949917 (Del. Ch. Feb. 27, 2020): MTD granted for failure to present evidence such as expert opinion of industry standard practices

Any Questions?

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