Synthetic Royalty and Drug Development Financing Study

2019-2022

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Overview

The cost for research and development of new drugs has increased exponentially since the 1950s. The reasons for the increase may be subject to debate, but what is not in question is that the cost to obtain FDA approval for novel pharmaceutical products can run into the hundreds of millions of dollars.

Many of these new medicines are developed by biotech companies, who have historically financed their businesses with equity and debt capital, and out-licensing transactions with large pharmaceutical companies.

However, there is a relatively new form of financing that avoids the dilutive impact of equity and convertible debt financings, the required interest and principal payments of debt, and the loss of control that may result from out-licensing. In exchange for the agreement by a biotech company to pay milestone and/or royalty payments, specialized investors are willing to provide significant amounts of capital in the form of “synthetic royalty” or drug development financings.

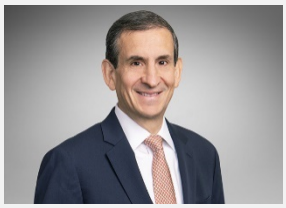
The market for these transactions has developed significantly over the last decade, but still remains opaque. In order to shed some light on the transaction architecture, we have reviewed financings of this type of at least $25 million entered into by public biotech companies in the last four calendar years (January 1, 2019 to December 31, 2022).

Although commercially sensitive information was redacted from some of these publicly filed documents, the agreements include sufficient information on material terms to provide a good sense of the state of the market.

In the following pages, we present a summary of our key findings.

Contacts and Further Information

If you would like to learn more details about our study and this growing market, please feel free to reach out to us. In addition, for a primer on synthetic royalty financings, please see the recent article we authored for IAM Media.



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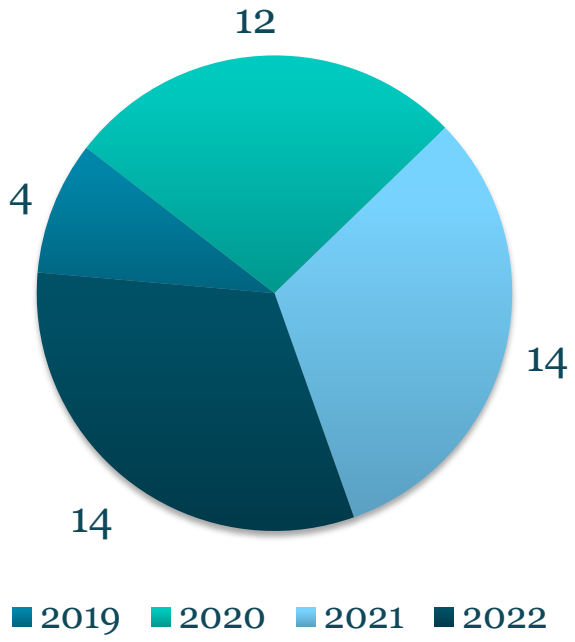
This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Summary of Transactions Reviewed

44
Total Transactions

23
Unique Investors



Key Finding

Transaction volume has increased steadily from 2019 through 2022, and we see interest in these financings from a growing universe of investors.

13
Investors with Two or More Transactions

6
Investors with Three or More Transactions

5
Investors with Four or More Transactions

2
Investors with Five or More Transactions

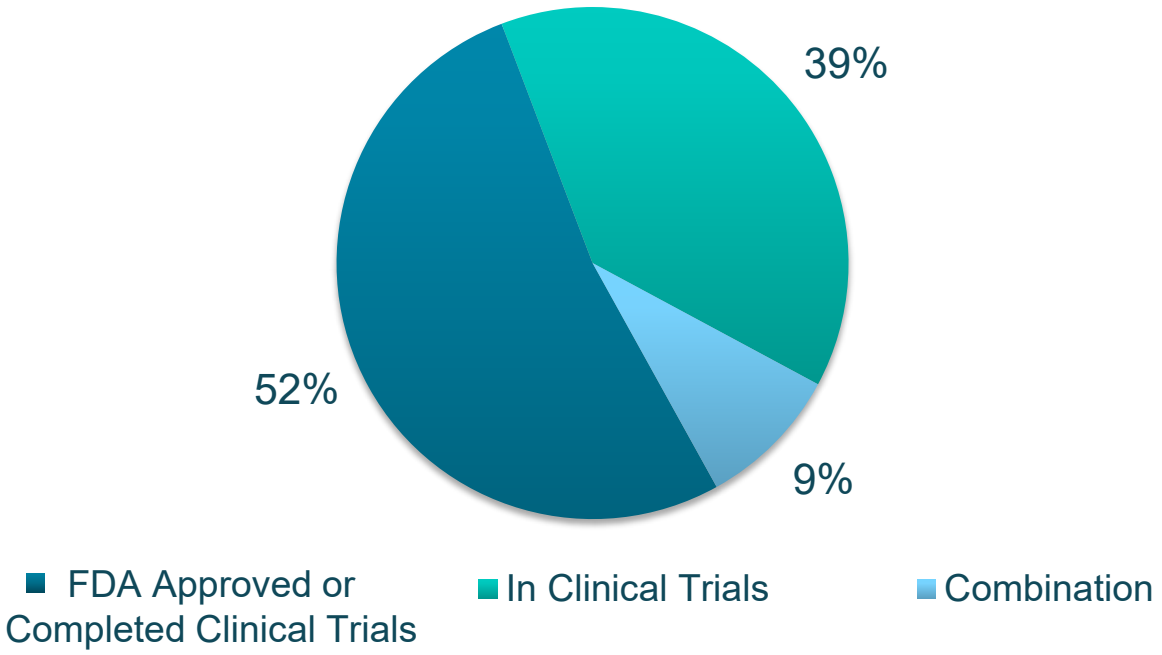
Summary of Transactions Reviewed

$60,000,000
Median Up Front Payment

$120,000,000
Median Total Commitment

$25,000,000
Smallest Total Commitment

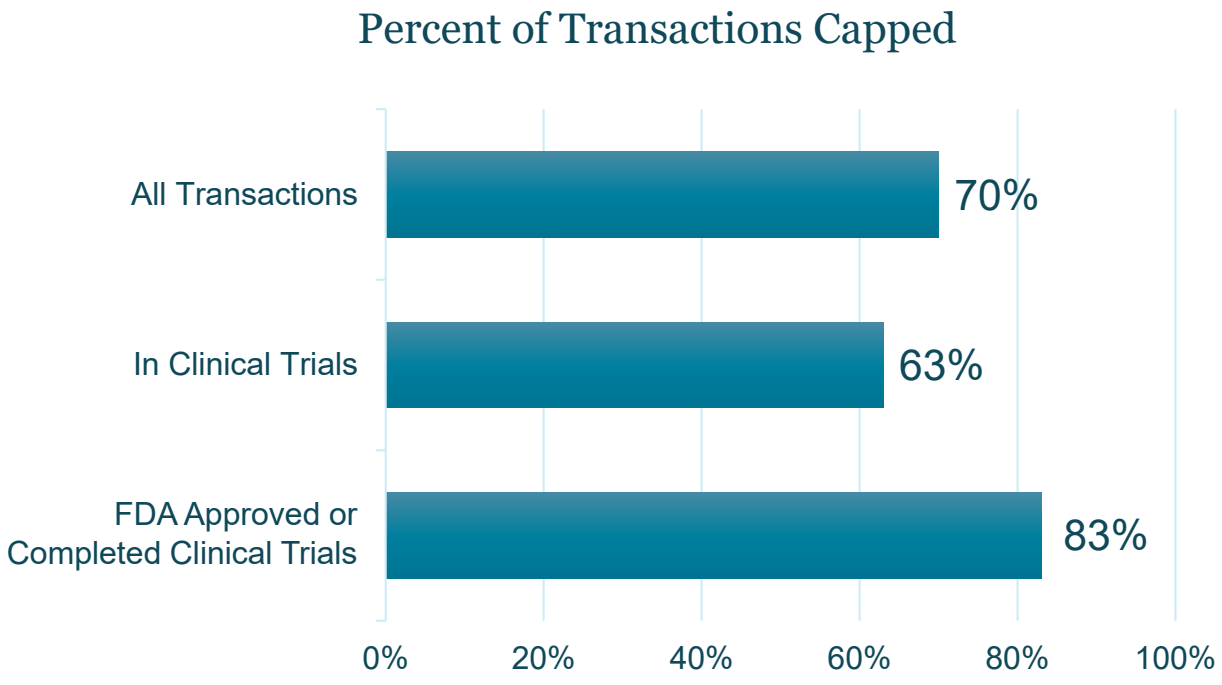
$325,000,000
Largest Total Commitment



Key Finding

Transactions primarily involved drugs either in or starting pivotal trials or already approved by the FDA.

Maximum Return Multiple for Capped Transactions



1.95 Times
Median Return Cap Multiple
FDA Approved or Completed Clinical Trials

4.25 Times
Median Return Cap Multiple
In Clinical Trials

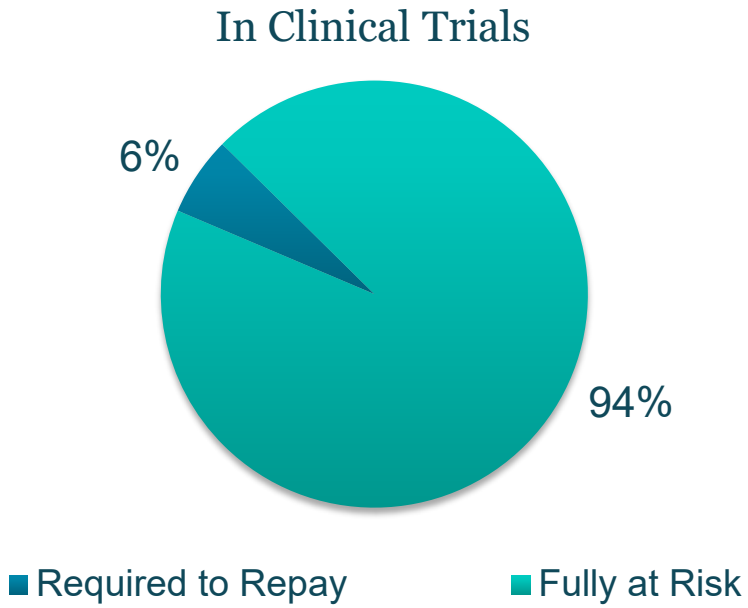
1.55 Times
Return Cap Multiple
Lowest Multiple

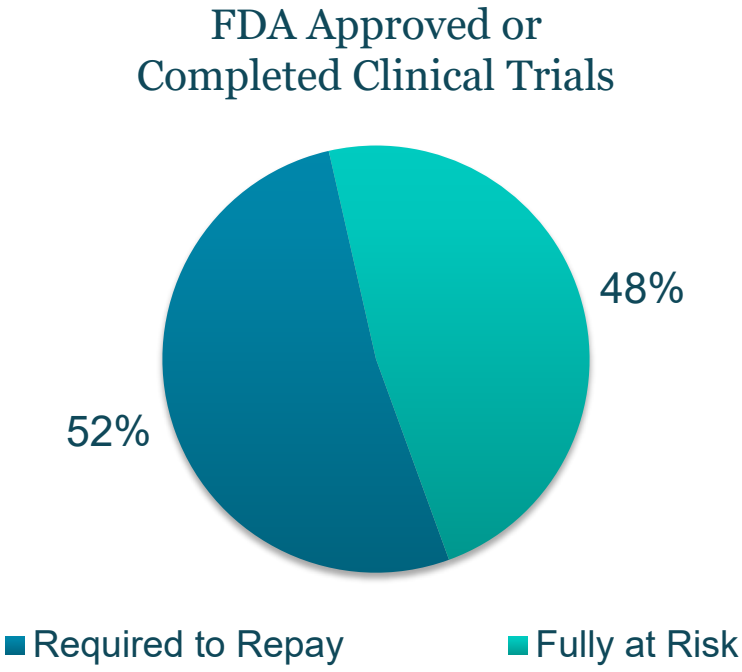
11.14 Times
Return Cap Multiple
Highest Multiple

Key Finding

A significant majority of the transactions capped the return available to the investor at a multiple of the invested amount. When included, the size of this cap was generally inversely related to the stage of regulatory approval of the drug at issue, with debt-like investor returns for established products and equity-like investor returns for riskier products under development.

Required to Repay Financing



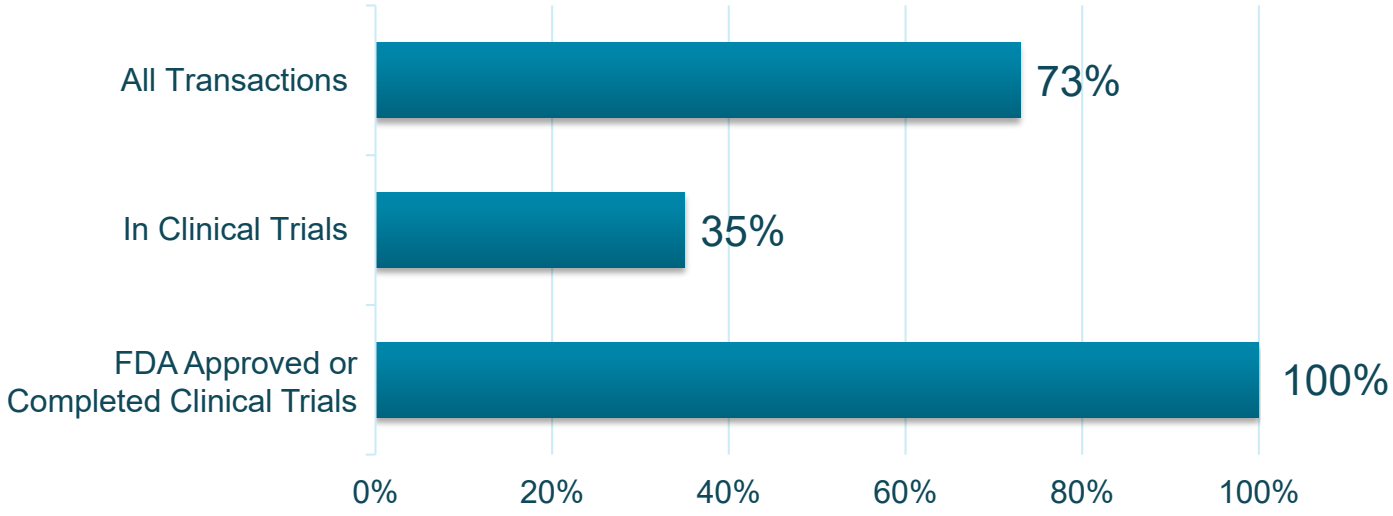


Key Finding

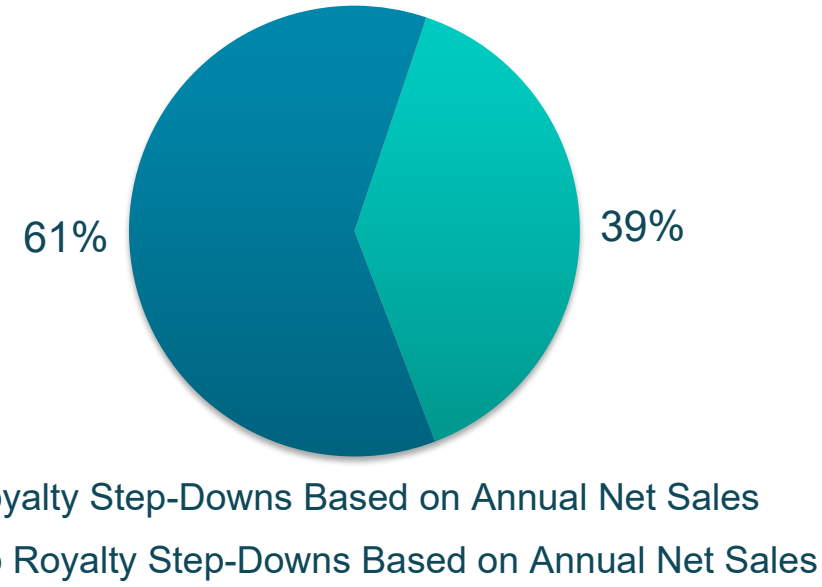
Transactions involving drugs at an earlier stage of development generally did not have any absolute requirement to repay the funded amount, while those involving drugs near or with FDA approval were evenly split between transactions with and without that requirement.

Royalty Rate Economics

Percentage of Transactions with Solely Synthetic Royalty Compensation (No Milestone Success Payments)



Within Solely Synthetic Royalty Compensation Transactions

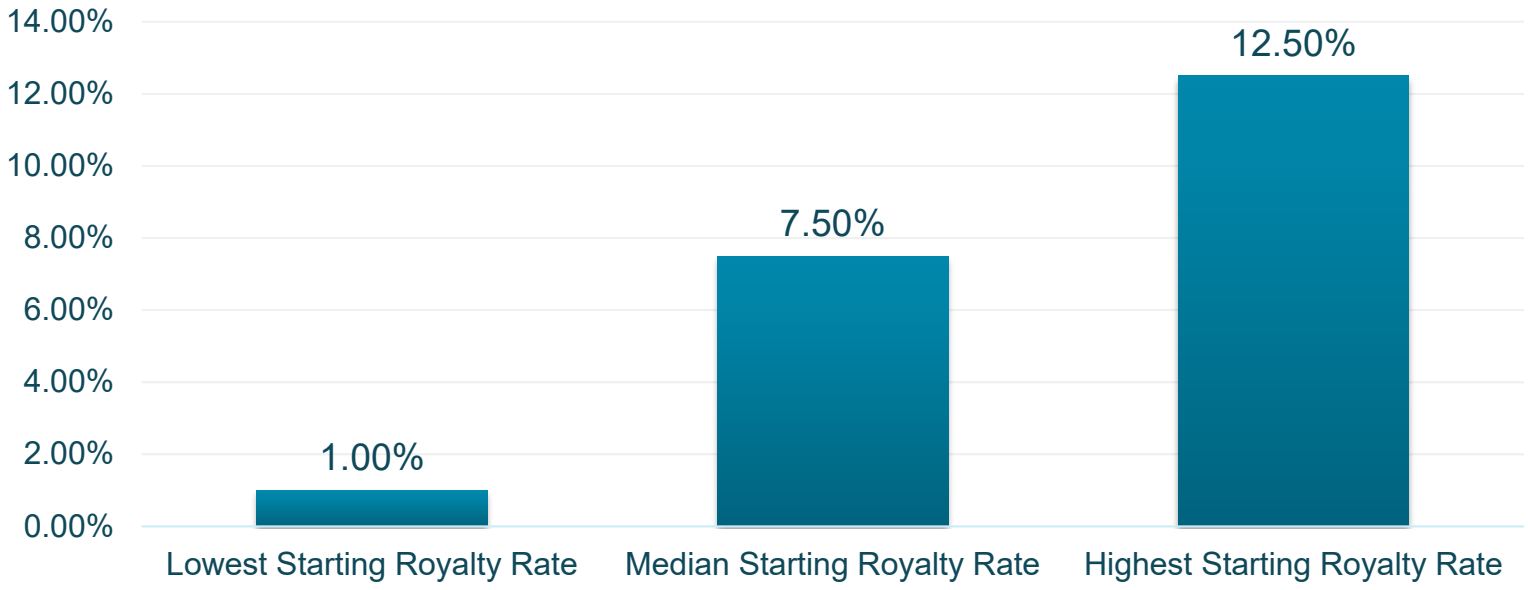


Key Finding

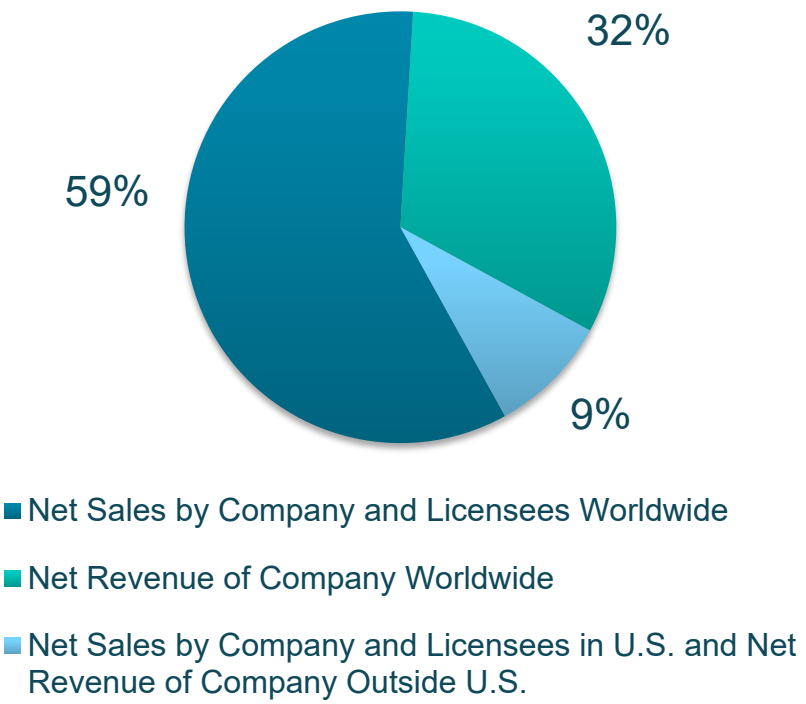
Royalty payment economics in the transactions demonstrated a broad range of structures, with a fully synthetic royalty structure the norm for products that are FDA approved or have completed clinical trials.

Royalty Rate Economics

Within Solely Synthetic Royalty Compensation Transactions



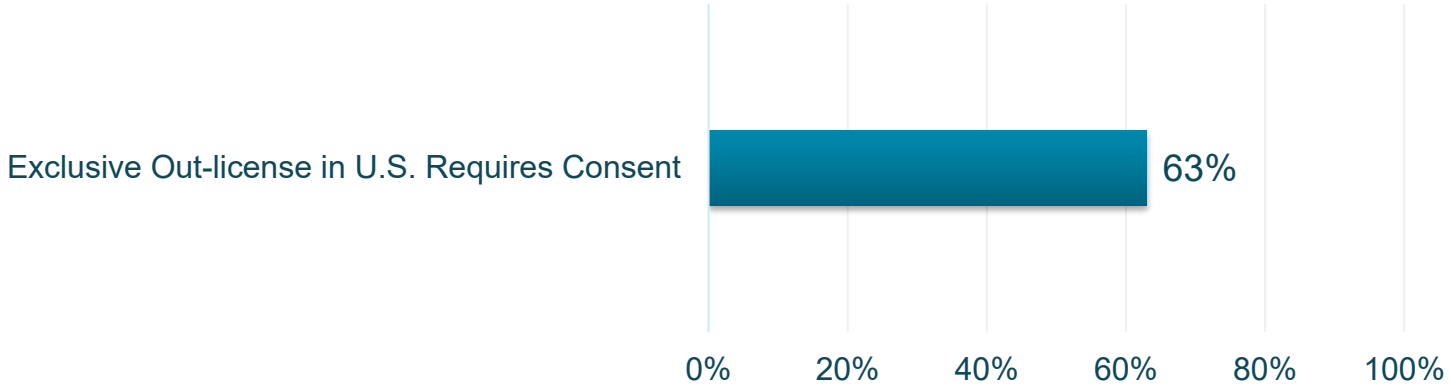
Synthetic Royalties Calculated Based On



Key Finding

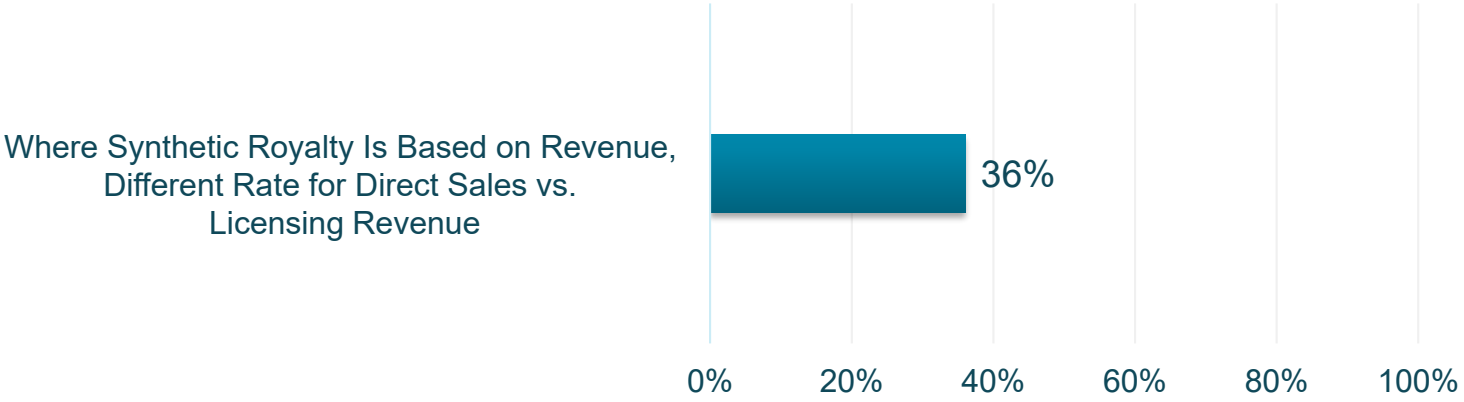
Although a majority of the transactions calculated the synthetic royalty based on net sales by the Company and its licensees, a number of transactions calculated the synthetic royalty solely based on revenue received by the Company, in particular with respect to sales outside of the U.S.

Synthetic Royalty Rate Calculation



Key Finding

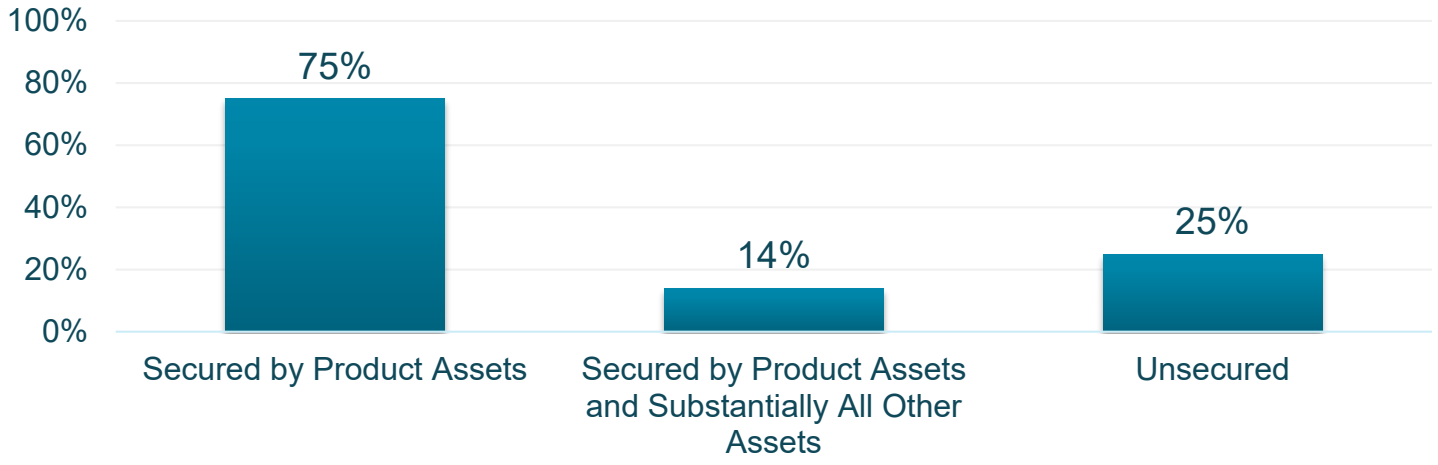
The majority of agreements prohibited exclusive U.S. out-licensing without investor consent.



Key Finding

The synthetic royalty rate did not differ in a majority of the transactions for direct net sales revenue vs. licensing revenue (licensing revenue typically being lower than direct sales revenue). The differing treatment may be due to whether the parties desired differential synthetic royalty rates for sales and licensing revenues or preferred a blended royalty rate.

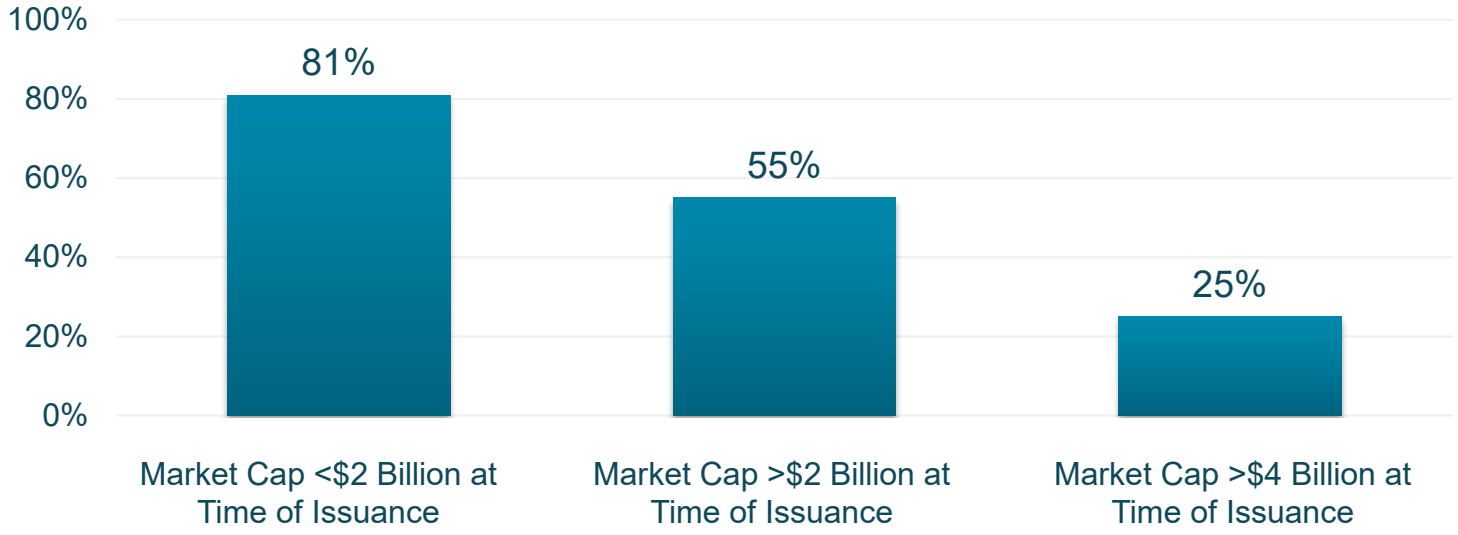
Collateral



Key Finding

These transactions are commonly (but not universally) secured by product assets (such as intellectual property, contract rights, and related assets), and in some cases by all assets.

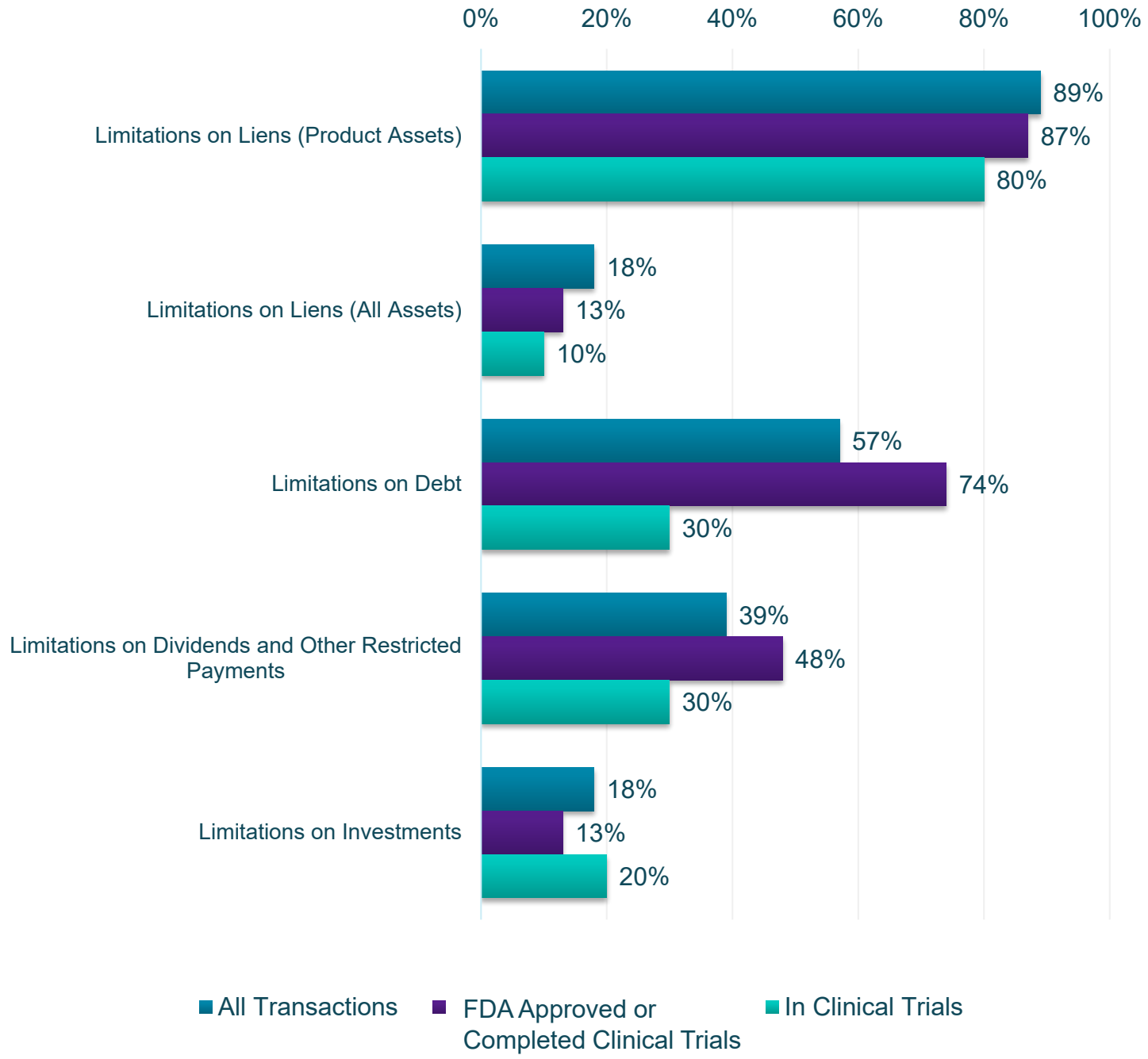
Transactions Secured by Product Assets



Key Finding

Larger (and presumably more credit-worthy) companies were more likely to enter into product or synthetic royalty financings on an unsecured basis.

Negative Covenants

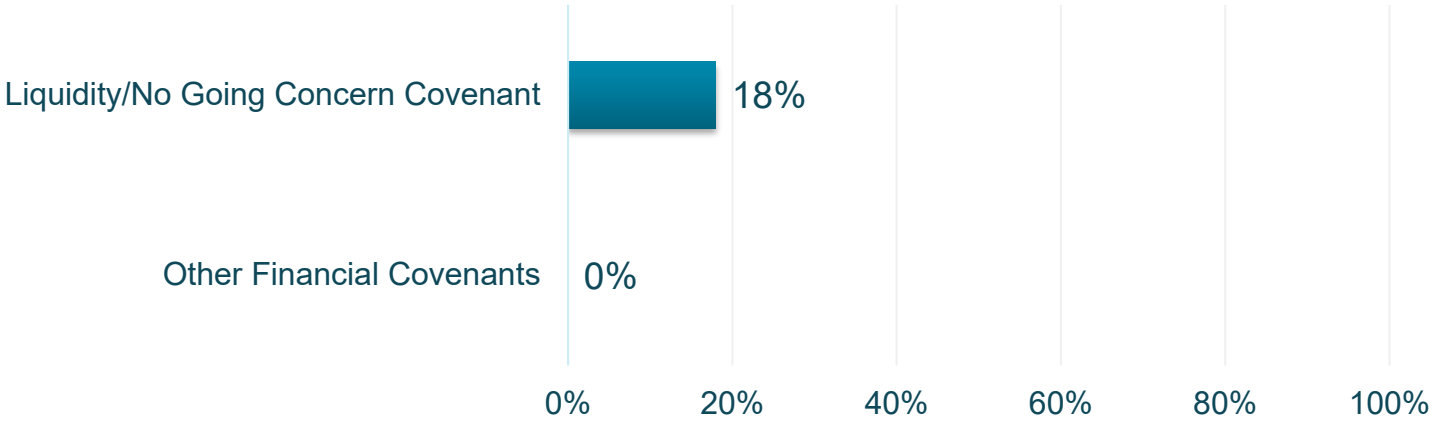


Key Finding

Covenants were generally less restrictive for these transactions as compared to debt transactions.

Negative Covenants

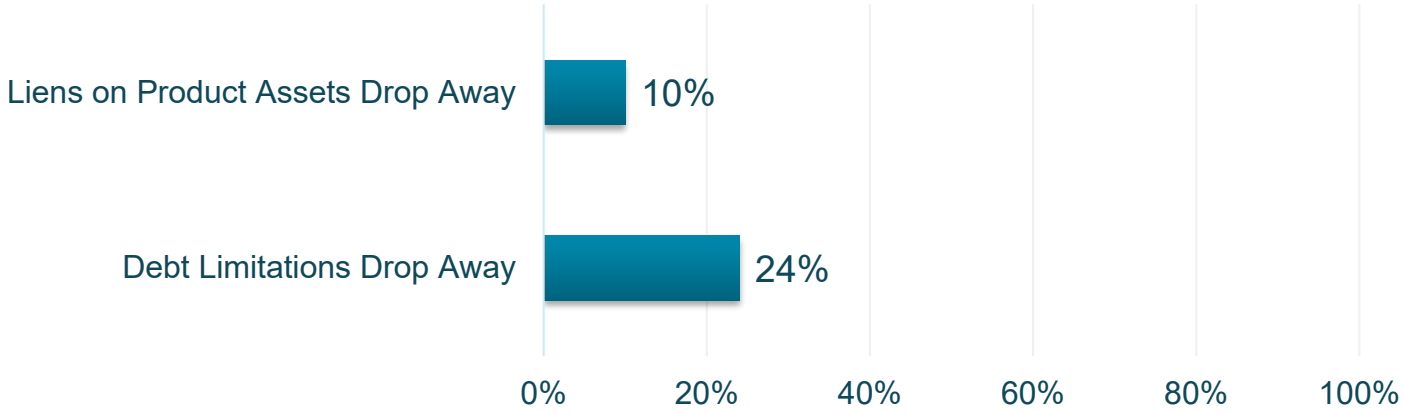
Financial Covenants



Key Finding

Financial covenants were rare in these transactions, and when included were limited to liquidity or related concepts.

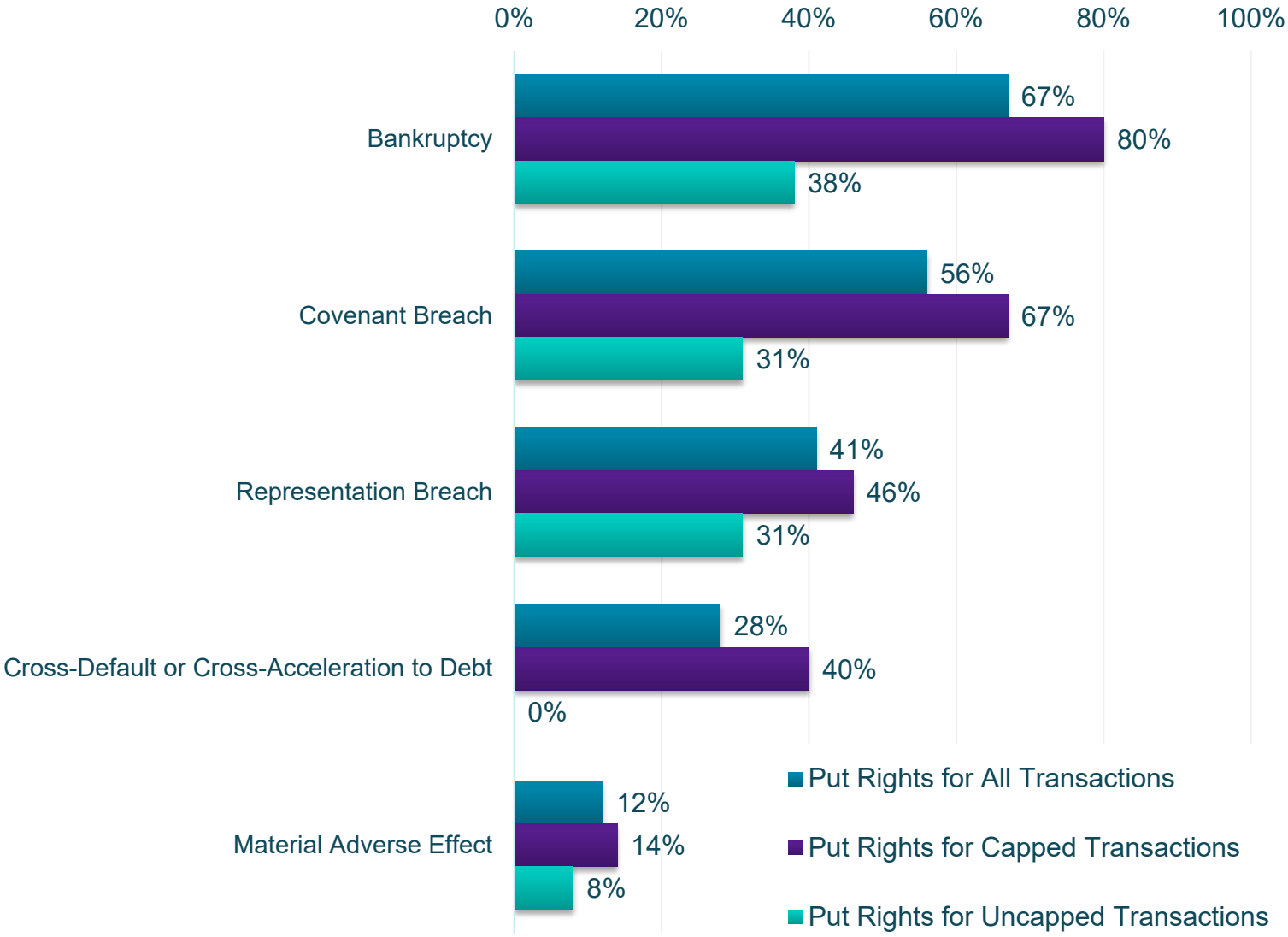
Investor Protections Drop Away on Specified Investor Returns



Key Finding

Some agreements had certain investor protections fall away upon the achievement of specified returns.

Investor Put Rights



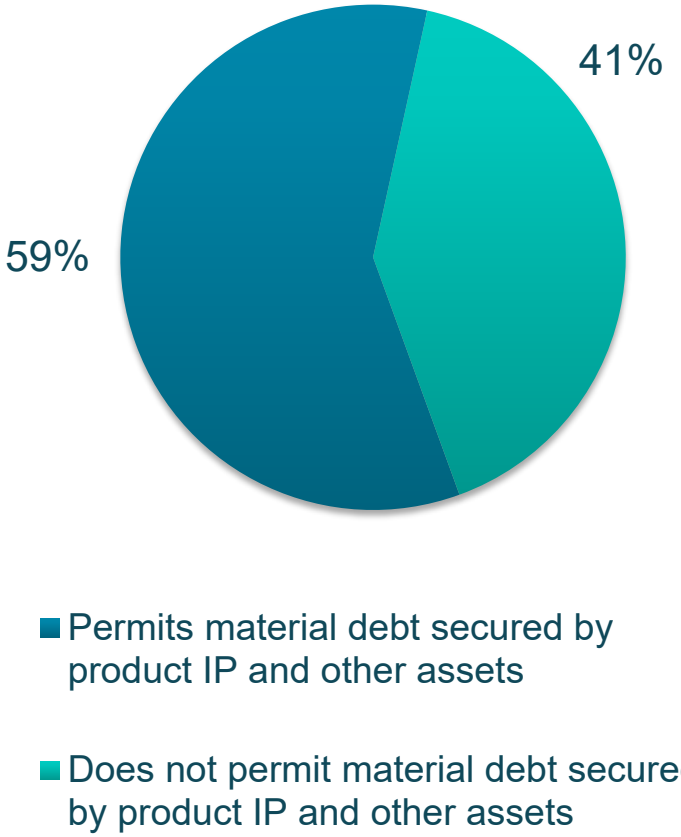
Key Finding

Put rights give the investor a return of their capital plus an agreed multiple upon certain events, which are comparable to events of default in debt transactions.

Absent a put right, the typical remedy for the investor would be an indemnity or breach of contract claim for damages.

Transactions vary widely on their inclusion and details of put rights.

Intercreditor Issues



Key Finding

A majority of the transactions permitted material debt to be secured by product assets. In such cases, there is usually an intercreditor agreement put into place that spells out how the transaction will co-exist with this other debt, in particular if the company encounters financial distress or files for bankruptcy protection.

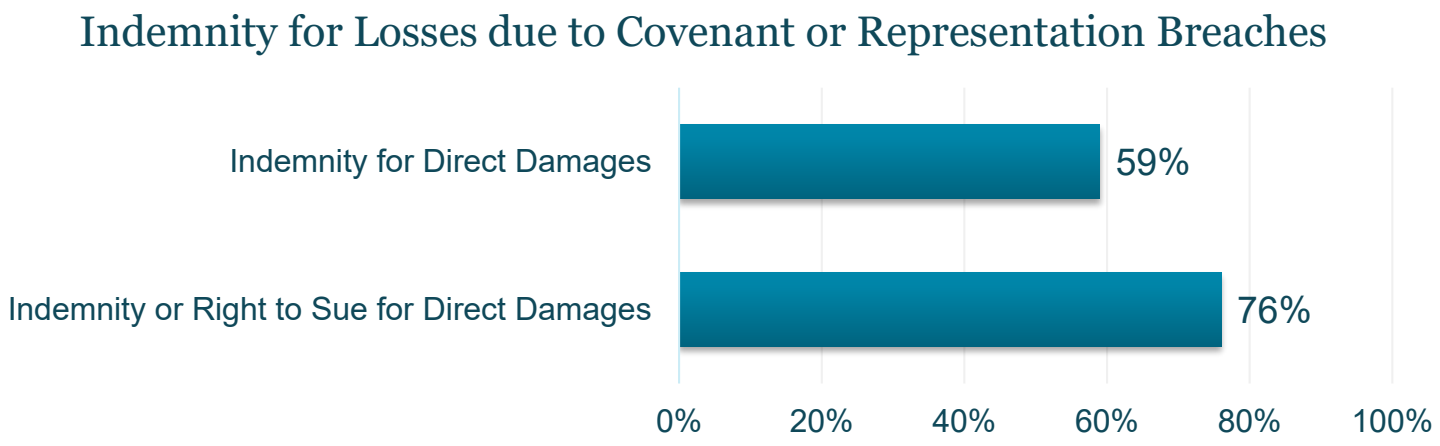
Key Finding

Because intercreditor agreements are not typically publicly filed, there is limited public data on those agreements.

From a business perspective, parties often desire that the investor remain entitled to synthetic royalty and milestone payments, even after an asset sale or bankruptcy.

However, in the event that bankruptcy courts do not honor this desired treatment, intercreditor agreements often provide in the alternative that proceeds from a sale, restructuring or bankruptcy be allocated among the investors and secured lenders according to an agreed waterfall.

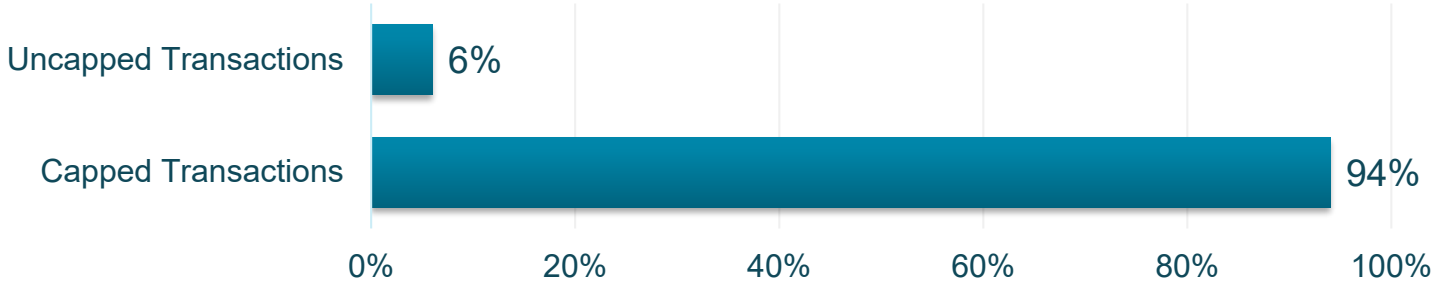
Indemnities



Key Finding

Companies generally agreed to indemnify investors from third party claims caused by breaches, but a majority also indemnified investors for all (not just those from third party claims) losses due to breach. An additional subset contemplated the possibility of suing for damages (even if there was no direct indemnity).

Company Buy-Out Rights

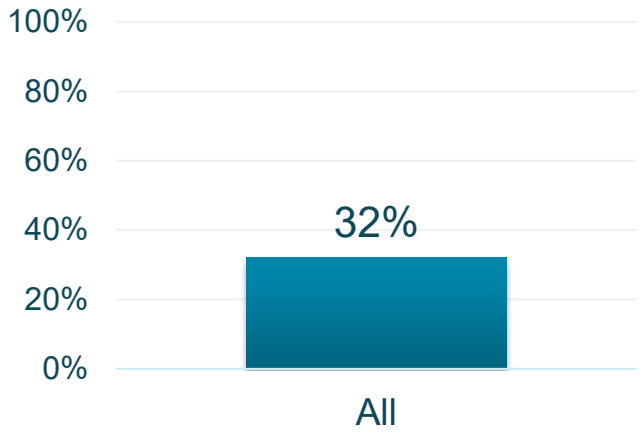


Key Finding

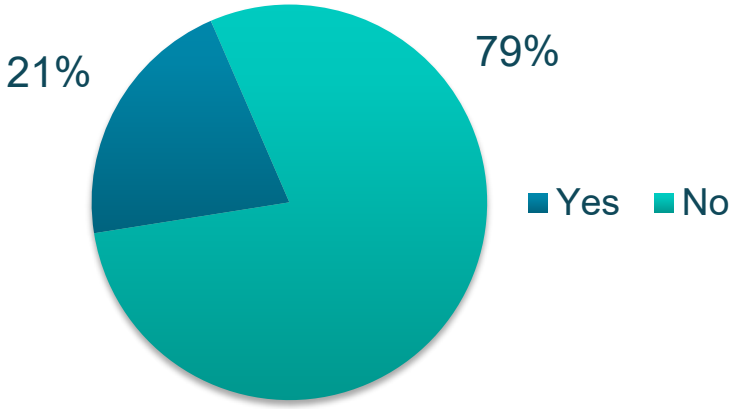
Given that capped transactions set a ceiling on returns, most of these transactions included the ability for the company to terminate the contract early by paying a specified amount. This flexibility is much less common for uncapped transactions, where the upside potential for the investor is greater and a buyout price more difficult to calculate.

Structural Considerations

Documented as a True Sale



Also Includes Back-Up Security Interest in Product Assets



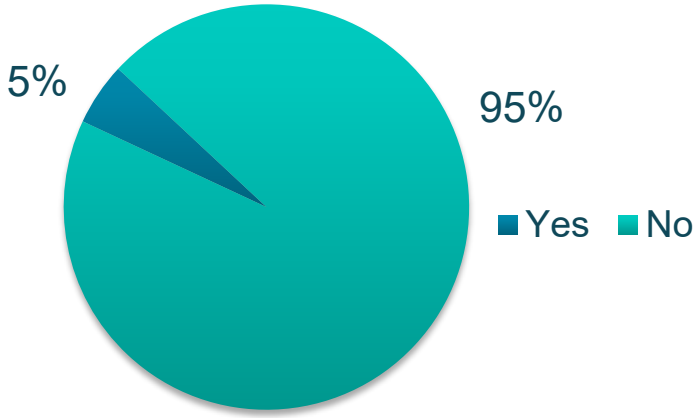
Key Finding

Approximately a third of the transactions contemplated "true sale" treatment whereby the investor is purported to become the legal owner of all future accounts receivable comprising their synthetic royalty investment. Some of the true-sale transactions included a back-up security interest in IP and other product assets, which provide down-side protection in case the true-sale structure is recharacterized as a loan in a bankruptcy. Many of the transactions without that protection were for larger market cap issuers, with investors presumably considering the risk of recharacterization in their credit analysis.

Key Finding

Most transactions did not require a special purpose vehicle structure to be put in place to hold the product assets, thus simplifying and streamlining execution.

Special Purpose Vehicle Structure Required



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