Financing Life Sciences

Insights

Winter 2025

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Contents

An Overview of Debt and Royalty Financing Structures for Life Sciences Businesses

As a supplement to equity capital and licensing and collaboration revenues, there is an increasingly broad array of evolving methods for life sciences companies to raise money to fund their drug development and commercialisation activities. These include venture lending, growth lending, synthetic royalties, drug development financings and royalty monetisations. Each of these are available to life sciences companies in different stages of development, have unique structures, involve varying degrees of contractual restrictions, and provide different risk/return profiles for investors. In this article the authors consider these key methods for raising non-dilutive financing.

Key Points

- The five key methods for raising non-dilutive financing for life sciences businesses vary in deal size, company features, structure and economic terms, and covenants and collateral terms.
- Where life sciences businesses are entering into or have completed pivotal clinical trials (after which data is or will be available to support regulatory approval), they can access drug development finance and synthetic royalty finance, respectively.
- Recent court decisions in the US have caused most synthetic royalty and drug development financings to require security over IP and other product assets.
- Many royalty monetisations remain unsecured.

Introduction

Life sciences companies require ever-growing resources to discover, develop, obtain regulatory approval for, and bring to market new life-saving drugs. As global populations age and both medical expenditures and the pace of healthcare innovation increase, these expenditures are likely to continue to increase. In fact, notwithstanding advances in technology, as drug discovery, development and regulatory approval have become more complex, the expenses for these efforts have multiplied. Researchers at Sanford C Bernstein (now part of AllianceBernstein) coined the term “Eroom’s Law” – the inverse of Moore’s Law – to describe this phenomenon. Over the 60-year period studied, the inflation-adjusted cost of developing new drugs broadly doubled every nine years. In this environment of ever-expanding costs, the valuations of many public and private biotech and pharma companies continue to remain at levels that make equity raising a

This article was first published in the May 2025 issue of *Butterworths Journal of International Banking and Financial Law*

less attractive source of funding. For those life sciences companies that are not of sufficient scale to tap traditional debt markets, or have valuations that cannot support meaningful equity financings, the need to find ways to support the capital intensive needs to produce a viable product has become imperative. As a result, in recent years, debt and royalty-focused investors have stepped into that funding void. This article explores five of the key methods used by life sciences companies to raise non-dilutive financing from these investors:

i. venture lending;
ii. growth lending;
iii. synthetic royalties;
iv. drug development financings; and
v. royalty monetisations.

These types of financings are often referred to as "non-dilutive" because they do not require the company to give up a significant ownership interest in exchange for the investment and thereby "dilute" the equity interests of other investors. Instead, investors earn their returns primarily from interest, fees, royalties and other cash payments. In this overview of the key features of these non-dilutive financing alternatives, we reference elements of both English and New York law, as these tend to be the most common governing laws for such transactions.

Venture Lending

Typical deal size

$5m to $25m (or equivalent).

Company features

Companies that raise venture debt financing typically do not yet have a revenue stream, but have the potential for significant growth in the short- to medium-term. Lenders often base their principal lending criteria on the scope and potential value of key company assets, often focused on patents and other intellectual property (IP). As such, venture debt lending is well suited to the life sciences industry, where businesses often have valuable IP, but do not have positive cashflow (or often any revenue at all). In addition, given that companies that raise venture debt often require equity finance as part of their business plans, lenders will need to be comfortable that existing investors are credible suppliers of this future equity investment. As a result, venture debt will generally not be suitable for businesses until they have done one or more significant rounds of equity financing.

Structure and economic terms

Venture debt is typically structured as a term loan, with a three- to four-year maturity (with an agreed amortisation schedule), sometimes with the ability to draw additional tranches over time. Interest is typically charged at a floating rate, tied to a relevant market benchmark. Interest-free periods (during which interest accrues and is added to principal (PIK interest) for a defined period of time) or interest-only periods (during which no capital repayments are required) can be negotiated to give the borrower more flexibility to grow its business in the early life cycle of the loan. Such periods are generally in the region of 3-18 months depending on the overall terms of the transaction. The loans will often also have upfront, prepayment and/or exit fees. In addition to cash fees, venture debt lenders commonly require a modest amount of warrants to purchase shares of stock in the borrower, thereby giving the lender some economic upside in the event of the borrower's subsequent growth. Occasionally, some portion of the debt is convertible into equity of the borrower, although the secured loan package supplemented with an "equity kicker" in the form of the warrant instrument is the more common structure.

Covenants and collateral

Venture debt financings do not have financial covenants, but will frequently include a requirement that the company maintain a significant amount of cash liquidity (given their lack of revenue to fund the business). Venture debt is invariably secured over substantially all assets of the borrower's business, although in some circumstances certain assets may be excluded from the security package (eg particular parts of the IP, if there are good commercial reasons for it to remain unencumbered).

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As with most secured debt financings, venture debt will also include a significant series of representations and covenants that, among other things, will restrict the amount of further debt that can be drawn, material asset sales (including out-licences which grant another organisation the right to use the company's product), material acquisitions (including in-licences where the company acquires the rights to a product from another organisation), and dividends and other payments to shareholders and junior creditors.

Growth Lending

Typical deal size

$25m to $500m (or equivalent).

Company features

These types of loans are for a larger quantum than venture debt loans, and suitable for borrowers that have marketed products, or at the very least have later-stage products in development that expect to be marketed during the term of the loan. These companies may have recurring revenue streams, but typically still have negative cash-flow. Like venture loans, in these arrangements, lenders are generally focused on asset value – ie in a down-side scenario they believe the assets of the company could be sold for a value that is in excess of the amount owed on the loan. Sometimes this type of financing is planned or expected to bridge the company to a future period when they expect to be cash-flow positive.

Structure and economic terms

Like venture debt, growth lending is typically structured as a term loan, but the term is normally longer, often up to five years, and sometimes has a bullet maturity rather than a fixed amortisation schedule. These loans are also often offered with delayed draw tranches, and interest is charged at a floating rate, tied to a relevant market benchmark. Interest-free and interest-only periods are sometimes included, and the loans will often also have upfront, prepayment and/or exit fees. Sometimes there is also warrant coverage or convertible loans, as in the venture loan arena. And these loans also sometimes include a small, and capped, participation in revenue or product sales.

Covenants and collateral

Growth loans have a similar set of representations and covenants as are found in venture debt documents, but sometimes they also have revenuebased financial covenants. Transactions are typically secured against all assets of the business, and this will usually include all material IP.

Synthetic Royalty Financings

Typical deal size

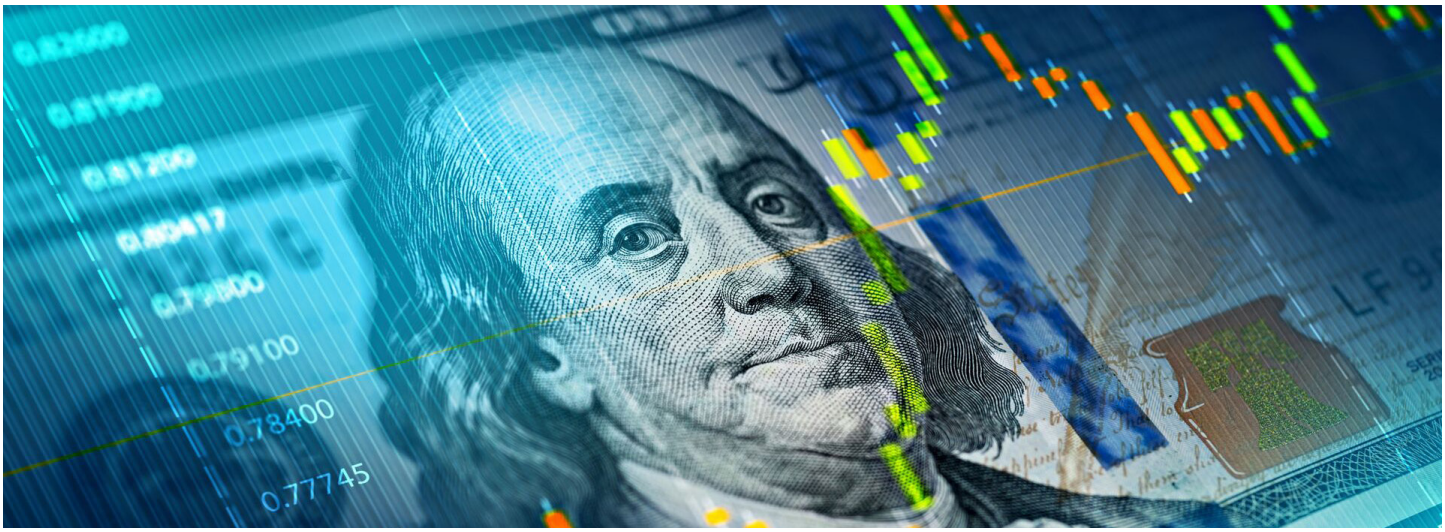
$10m to $500m (or equivalent).

Company features

Synthetic royalty financings are available to companies that have marketed products or have completed pivotal clinical trials and are awaiting regulatory approval.

Structure and economic terms

A synthetic royalty financing transaction involves the purchase of the right to receive a "synthetic royalty" on net sales of a product owned by the synthetic royalty seller. The investor will pay an upfront purchase price (akin to the principal amount of a loan) in exchange for



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periodic future payments equal to a percentage of the seller's net sales of a specific product in the applicable period. As opposed to "drug development" financings, discussed below, synthetic royalty financings are typically only funded once a drug has received regulatory approval. However, it is not uncommon for a company to enter into a synthetic royalty financing after pivotal clinical trials are complete but prior to regulatory approval, with a condition to closing and funding that the regulatory approval be received. A synthetic royalty differs from traditional debt finance in a number of ways:

- the synthetic royalty will have variable payments over time (which are based on a percentage of fluctuating net sales of the product in question), rather than on a fixed interest rate as with a loan;
- there may or may not be an obligation to repay the principal amount (ie the original purchase price) and/or some premium representing a fixed return for the investor;
- credit support is frequently limited to just the IP and assets relating to the product and not all assets of the seller; and
- financial and operating covenants upon the seller are much more variable and can be less restrictive and onerous than would be the case with a typical loan arrangement, particularly in cases where the synthetic royalty is expected to be outstanding for a longer period of time than a term loan.

Most synthetic royalty financings have a cap on the total returns available to the investor. Typically, the median return cap for such transactions is in the region of 2x the initial purchase price, although the cap can be significantly lower or higher, depending on the time period expected to be required for the investor to receive the return on its investment, and the risk borne by the investor in the particular transaction. A significant number of such transactions include a requirement that the seller repay at least the original purchase price by a designated catchup payment date (although others do not require any payment in excess of the amount of royalties received). The royalty rates themselves can be quite variable depending on the product in question and may have different rates if a distinction is drawn between direct sales and revenue generated from licensing transactions.

Covenants and collateral

Recent case law in the US has had an impact on the structure of synthetic royalty financings and similar transactions both in the US and across Europe. Where a transaction similar to a synthetic royalty transaction was structured on an unsecured basis, a US bankruptcy proceeding, *Sanofi-Aventis U.S. LLC v Mallinckrodt plc (in re Mallinckrodt),* 646 F. Supp. 3d 565 (D. Del.2022) *(Mallinckrodt)*, treated the outstanding royalty payments due to the recipient, Sanofi-Aventis, as an unsecured claim in the debtor-payor bankruptcy that was discharged when the bankruptcy court approved the debtor-payor Chapter 11 plan, rather than a "true sale" of the future revenue stream (which would have given Sanofi a proprietary interest that was protected in the debtor-payor bankruptcy).

So, while historically some synthetic royalty transactions were done on an unsecured basis (sometimes in

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circumstances where one or more of the parties was seeking to obtain "true-sale" treatment), given the ruling in *Mallinckrodt* in the US, and the inherent difficulty in structuring a transaction as a true-sale in jurisdictions outside of the US, the trend since 2023 is for transactions with less than investment-grade companies to always be secured. Such security is typically over the IP and assets relating to the product that is the subject of the synthetic royalty. The covenants in these transactions are often (but not always) more limited than those in debt financings. Likewise, financial covenants are exceedingly rare. Unlike venture and growth lending transactions, synthetic royalty deals do not normally include additional warrant or similar equity participation for the purchaser.

Drug Development Financings

Typical deal size

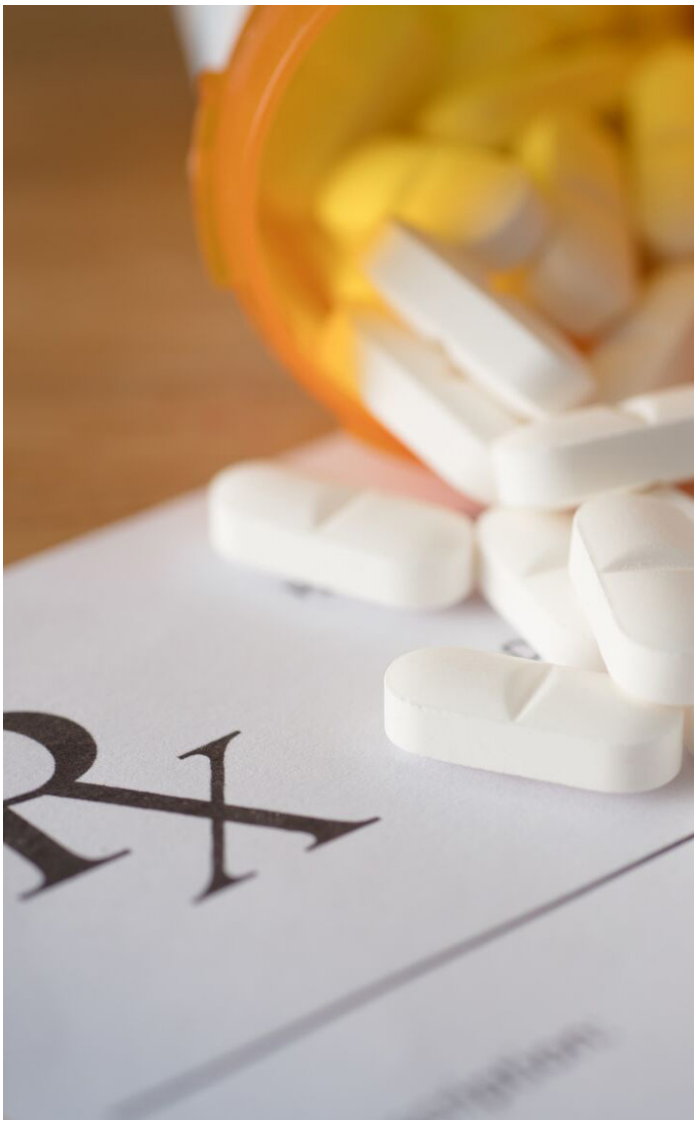
$150m to $500m (or equivalent).

Company features

Drug development financings are most readily available to companies that have drugs entering pivotal clinical trials (ie clinical trials after which data could be available to support regulatory approval), although some drug development financings are done with earlier-stage products. Drug development financings are utilised by both biotech and big pharma companies. When big pharma companies enter into drug development financings, it is often critical for them to get acceptable (often off-balance sheet) accounting treatment. The accounting treatment is beyond the scope of this article, but it is important to align on the proper accounting for these deals up front, and it can make or break the viability of a deal.

Structure and economic terms

These transactions are generally structured in a similar manner to synthetic royalty financings, although the compensation provided to the investor can often include milestone payments (related to product approval and/or sales) in addition to royalty payments. As opposed to synthetic royalty financings, drug development financings rarely guarantee payment of principal or any fixed return to the investor – instead, investors typically take the risk that if the product is not approved for sale, they will not receive their money back or any return on their investment. As a result, although the returns for drug development financings are often capped, the caps are closer to 4x (or higher) the initial purchase price, rather than the 2x typical for a synthetic royalty.



Covenants and collateral

The approach to covenants and collateral in drug development financings is similar to that for synthetic royalties, but the covenant package has fewer debt-like covenants. In their place are covenants surrounding the drug development process. For instance, there is often a joint development committee set up to oversee the drug development efforts.

Typically, though, the company will have ultimate control and decisionmaking authority over the drug development process. But some investors will offer to take over significant portions of clinical trial management, or share their expertise in the process.

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Royalty Monetisations

Typical deal size

$10m to $1bn+ (or equivalent).

Company features

Royalty monetisations are available to companies that have contractual rights to future payments under existing licence or partnering agreements and are not normally an option for companies at an earlier stage of growth. For example, royalty monetisations may be an attractive source of finance to a biotech company that has developed and out-licensed innovative technology but is seeking a way to accelerate those future payments in order to invest further in its business now.

Structure and economic terms

In a royalty monetisation transaction, an investor purchases the right to receive a future stream of payments pursuant to an existing third-party agreement. As with a life sciences debt financing transaction, the investor expects to earn a return by providing funding up front in exchange for the right to receive these future payments. A royalty monetisation differs from a straight debt financing transaction in that the seller is not typically responsible for the investor's payments; instead, the investor looks primarily to the product that underpins the royalty stream. Such transactions permit sellers to raise capital while retaining ownership and control of their businesses without the restrictive covenants that might typically be seen in debt financing transactions or the equity dilution inherent in raising capital from equity-based financing. Some royalty monetisation transactions are structured so that the investor purchases the entire amount of the royalty stream for a given product without a cap, while others provide that the royalty stream reverts back to the seller once a particular return cap has been reached. In the context of those deals with return caps, typically these caps for royalty monetisations involving approved drugs are in the 2x range (similar to synthetic royalty financings), although the caps can vary significantly from case to case.

Covenants and collateral

Unlike more traditional debt financing transactions, royalty monetisations tend not to have any liquidity covenants or other financial covenants. They are also often unsecured arrangements, although there can be some bankruptcy risks in this structure, which need to be closely analysed on a caseby- case basis. They also do not usually have covenants precluding the incurrence of additional debt, asset sales, or the creation of security on

behalf of the seller, save as in respect of the assets that form the product underling the monetisation. It is also not customary for there to be any additional warrant or similar equity incentive for the purchaser as there would be in venture or growth debt financings of the type noted above.

Conclusion

The foregoing methods are certainly not the only forms of finance available to life sciences businesses. Many companies will no doubt be of sufficient scale that they can make use of more traditional financing or have equity values that support equity rather than nondilutive financing alternatives. However, with venture and growth debt, and various flavours of royalty financing, there is a broad menu of options for a chief financial officer to consider as they look to fund the insatiable capital needs of life sciences companies.

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This article was first published in the May 2025 issue of *Butterworths Journal of International Banking and Financial Law*

Growth and Venture Lending Study

2021-2024

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Overview

The life sciences lending market has evolved at a rapid pace in recent years, amid capital-raising challenges and scientific advances that continue to define the sector. This inaugural Growth and Venture Lending Study analyzes publicly filed debt financing agreements of $25 million or more entered into from 2021 to 2024 by U.S. and foreign biotechnology, medical device, diagnostics and related companies with stock listed in the United States. The focus of the study is primarily on companies that are not yet cash-flow positive, and the lenders who cater to those borrowers.

Venture and growth credit has become an indispensable financing tool for companies seeking to extend their cash runway without the dilution of a traditional follow-on equity offering. The pages that follow dissect some of the principal terms seen in this market and recent trends across a diverse set of lenders, including venture debt funds, credit arms of large asset managers and life science focused multi-strategy investment firms.

Deal terms have converged around a core set of protections for lenders, with most transactions now secured by substantially all company assets (including intellectual property rights), and financial covenants comprised of liquidity, and, when applicable, revenue covenants. Other terms, however, remain highly bespoke. Borrower profiles have likewise evolved. While venture-backed, pre-revenue biotech companies still account for some of the loans, a majority of the loans now involve companies with at least one approved product.

While some portions of the underlying documents were redacted, the publicly available disclosures still provided a robust foundation for analyzing current market trends. We hope this study serves as a practical tool for borrowers, lenders and their advisors as they navigate this specialized market.

Contacts and Further Information

If you would like to learn more about the findings in the study, please feel free to reach out to us.

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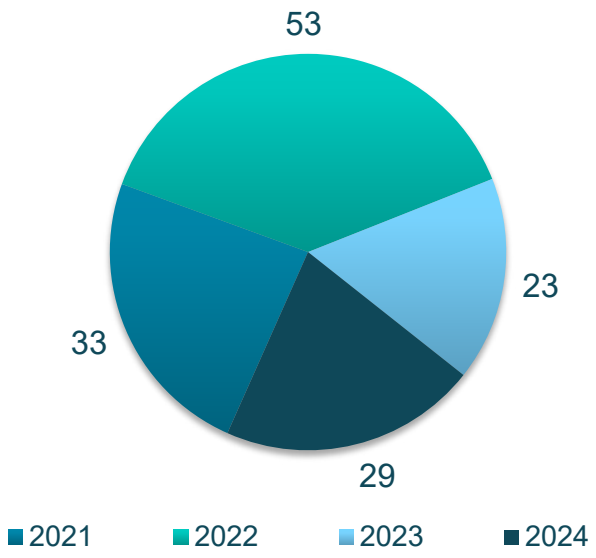
This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the information in this study.

Summary of Transactions Reviewed

138
Total Transactions

29
Unique Lenders



12
Lenders with Five or More Transactions

Key Finding

There is a broad range of lenders in this market, with twelve lenders showing up in at least five transactions in the study.

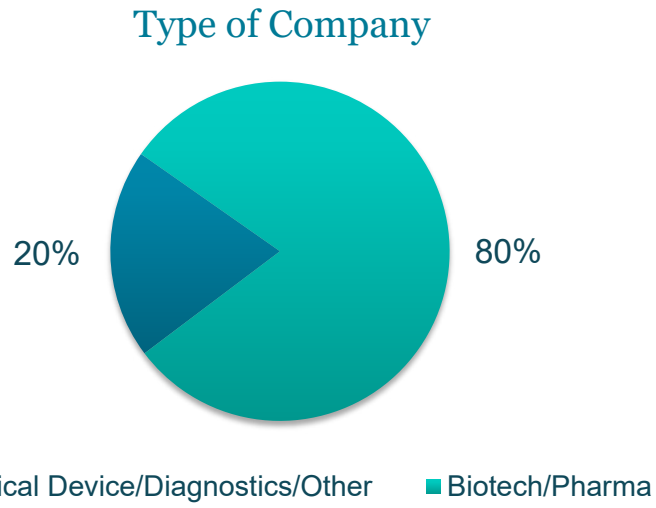
$30 million
Median Initial Loan

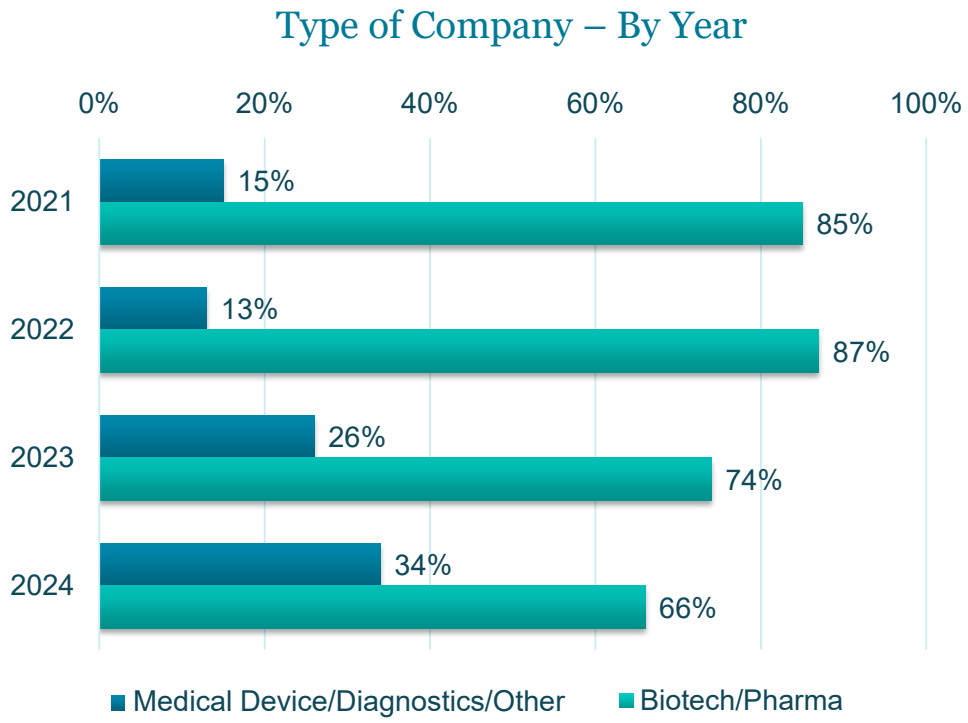
$75 million
Median Commitment

$750 million
Largest Commitment

$25 million
Smallest Commitment

Type of Company



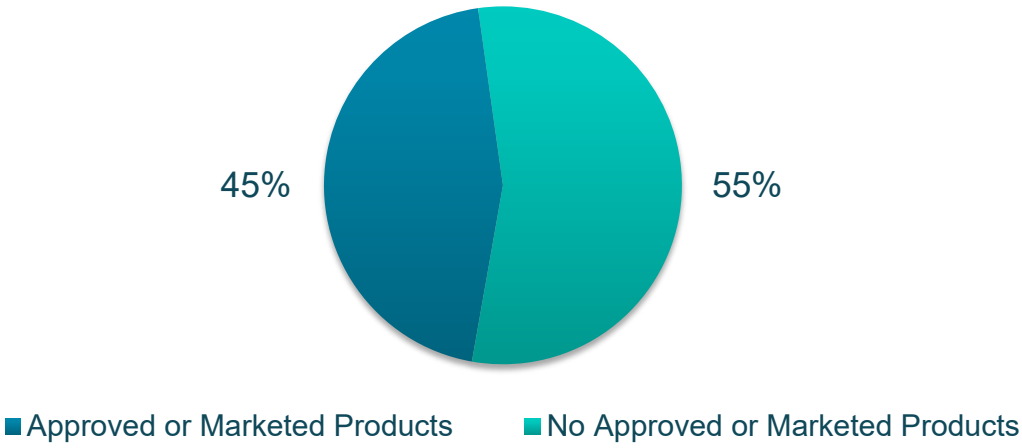


Key Finding

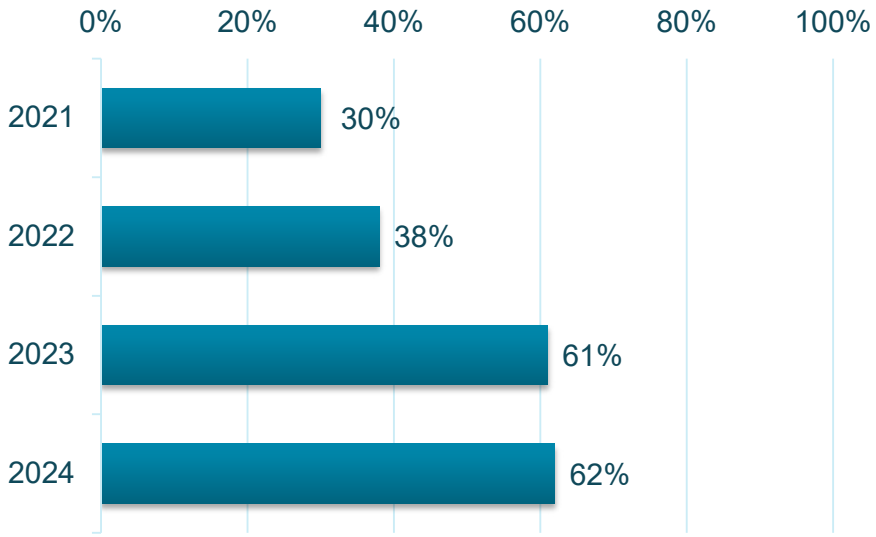
As lenders look for opportunities to loan to businesses with marketed or approved products, the relative percentage of loans to medical device, diagnostics and other non-biotech companies has increased.

Borrowers with Approved or Marketed Products – All Loans

Borrowers with Approved or Marketed Products Upon Initial Loan



Borrowers with Approved or Marketed Products Upon Initial Loan – By Year



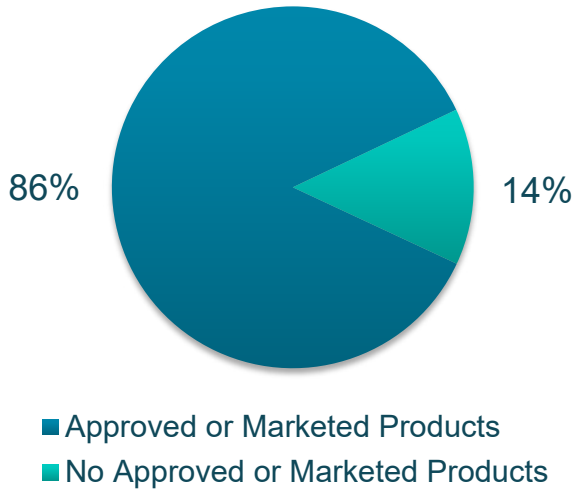
Key Finding

There is a clear trend toward loans being made to companies with approved or marketed products. Loans are still available to other companies, but lenders are more selective, and may require a near-term expected approval or smaller initial loan prior to approval.

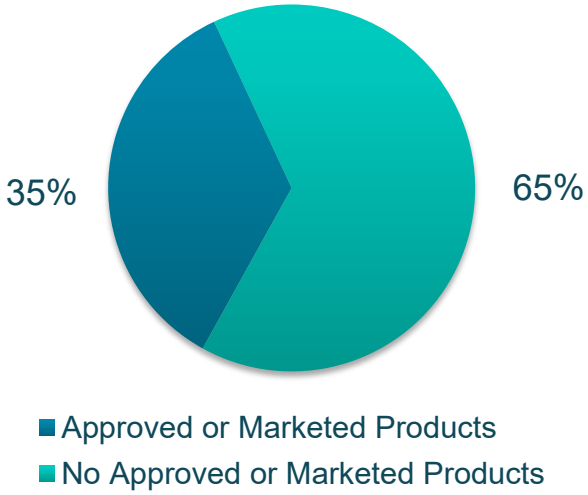
*Note that where this Study lists percentages, we generally excluded transactions in the limited cases where the applicable data was redacted. Percentages may not sum to 100% due to rounding.

Borrowers with Approved or Marketed Products

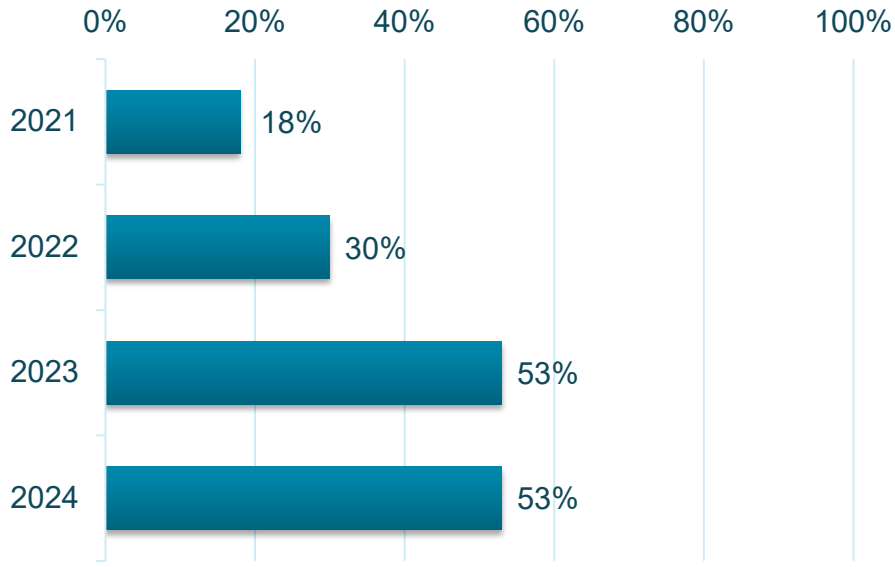
Medical Device/Diagnostics/Other Borrowers



Biotech/Pharma Borrowers



Biotech/Pharma Borrowers with Approved or Marketed Products



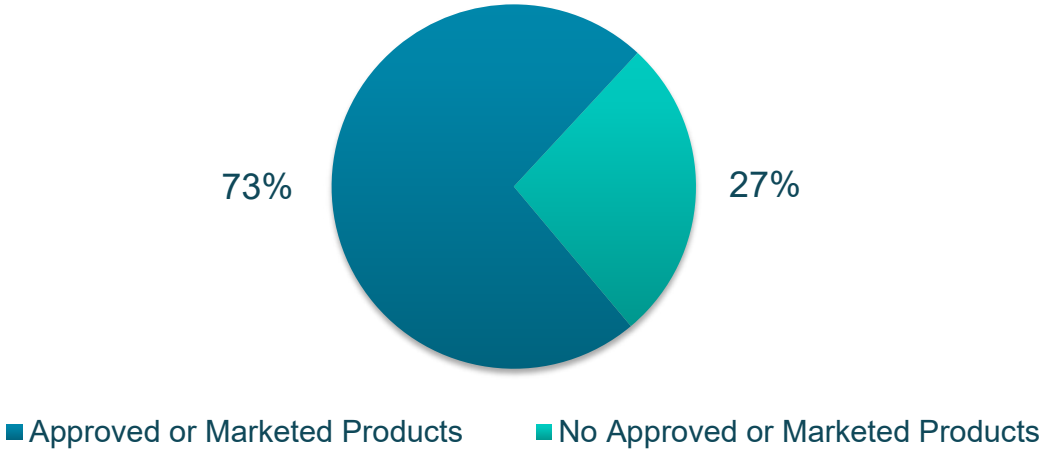
Key Finding

In recent years, the trend toward loans to companies with marketed or approved products is clear in the biotech sector, although almost half of the loans are still to companies with no approved products.

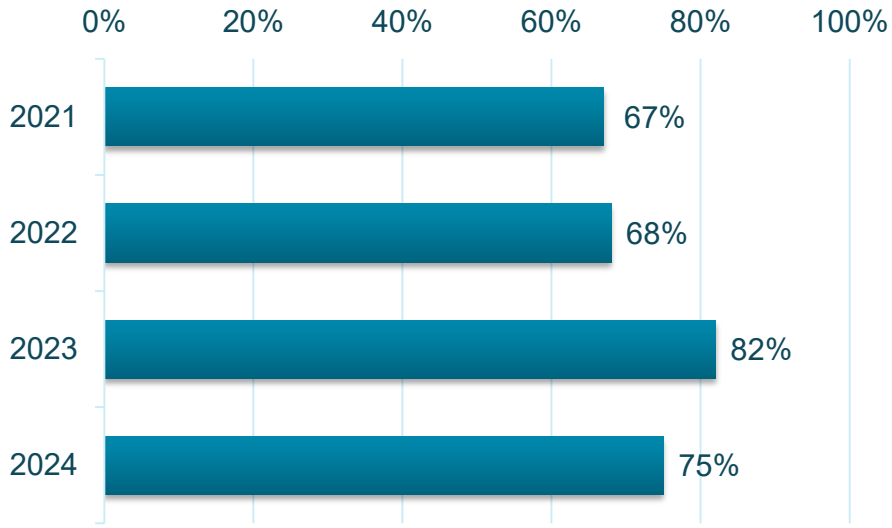
Growth and Venture Lending Study 2019-2024

Borrowers with Approved or Marketed Products – At Least $25 Million Initial Loan

Approved or Marketed Products Upon Initial Loan – At Least $25 Million



Approved or Marketed Products Upon Initial Loan At Least $25 Million – By Year

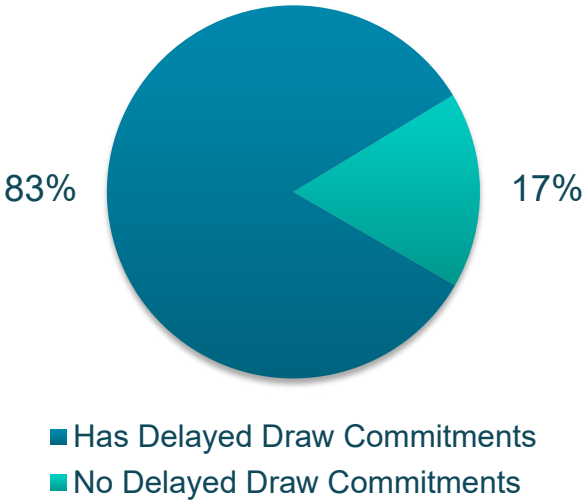


Key Finding

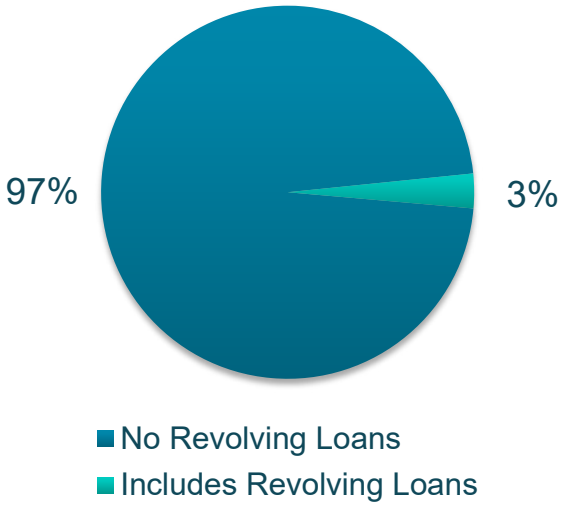
For larger initial loans, it is even more common for lenders to require some current or near-term revenue from approved or marketed products.

Delayed Draw, Revolving and Discretionary Loans

Delayed Draw Commitments



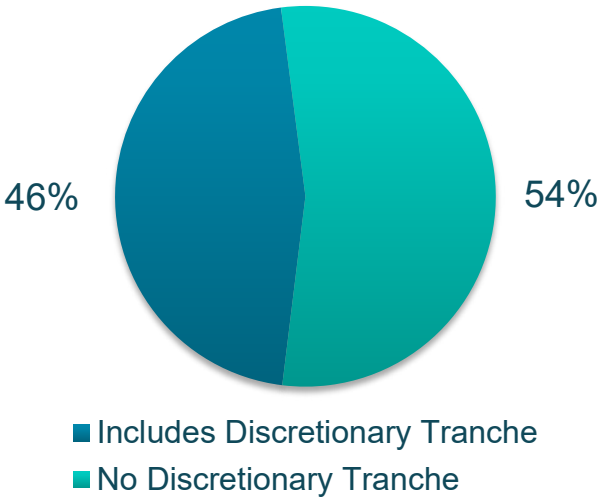
Revolving Loans



Key Finding

Most facilities have delayed draw commitments, which often require the satisfaction of certain regulatory, sales or other performance milestones. Very few facilities include a revolving facility, which would give the buyer the ability to borrow, repay and reborrow loans as needed. Separate revolving facilities from other lenders are permitted in limited cases.

Discretionary Tranche



Key Finding

Almost half of the facilities include a discretionary tranche of loans. This is documented as an amount of loans that can be provided only by the existing lenders at their sole discretion, with the agreement of the borrower. There is little legal impact of this provision, which is different from a traditional “accordion” feature, seen in cash flow loans (often for private equity backed companies), where the borrower can access the discretionary tranche without the consent of the existing lenders, so long as they can find a lender willing to provide it and satisfy a financial ratio test.

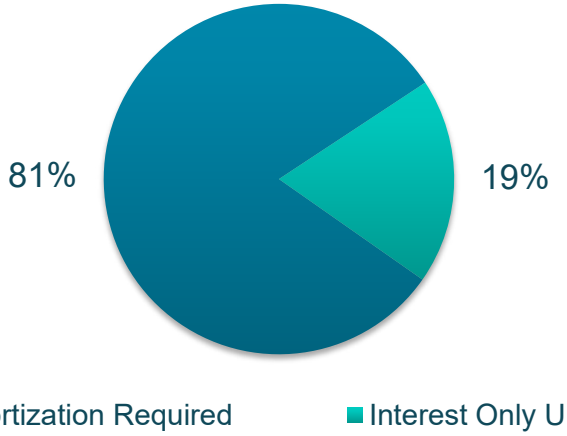
Term of Loans and Amortization

Median Term
5 Years

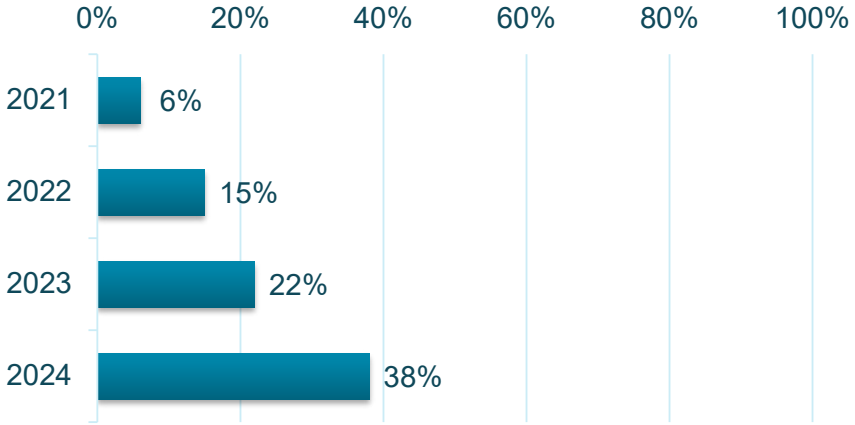
Minimum Term
3 Years

Maximum Term
7 Years

Amortization Required Prior to Maturity



Interest Only Until Maturity (Excluding Springing Maturity)

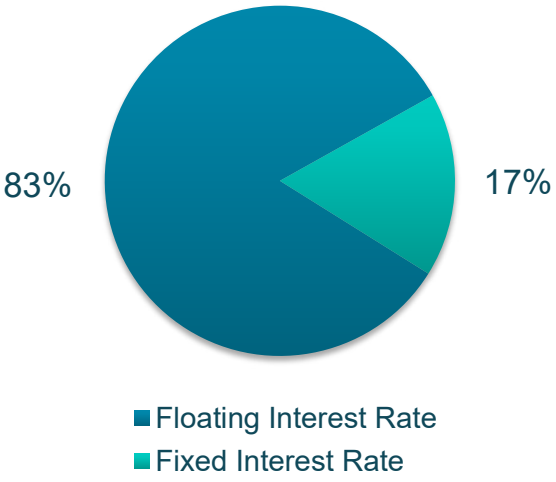


Key Finding

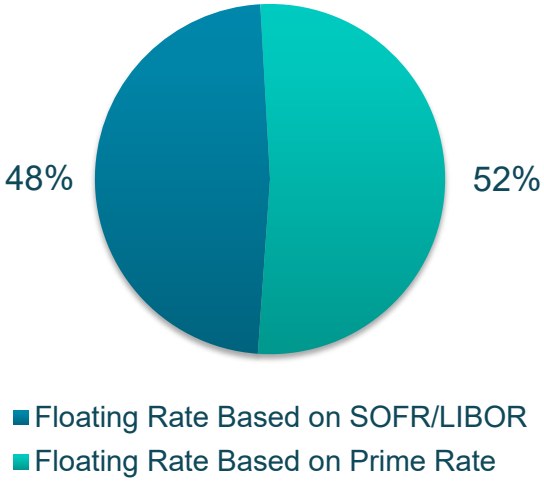
Although a majority of loans require some amortization prior to maturity, there has been a trend toward more loans being interest only until maturity (unless some triggering event requires amortization to start prior to maturity). These triggering events can include revenue and/or product development milestones, among other things.

Interest

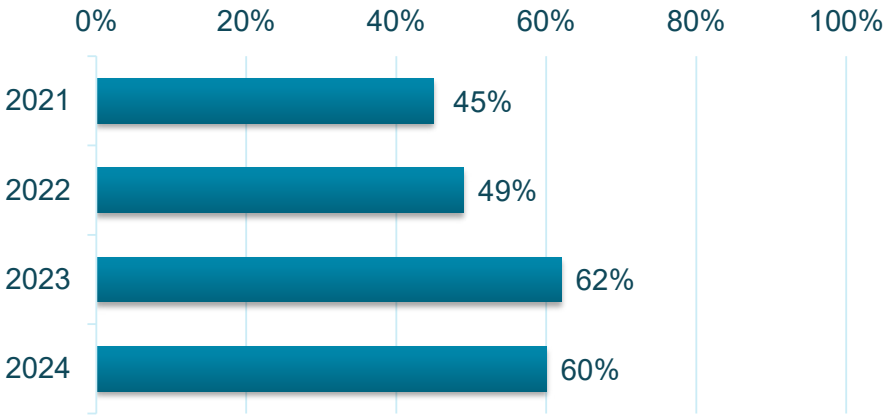
Floating vs. Fixed



Prime vs. SOFR/LIBOR



Loans with Floating Rate Based on SOFR/LIBOR



Key Finding

Most of these facilities have floating interest rates, which adjust based on the prevailing rate (often no lower than a floor). The choice of Prime vs. SOFR (previously LIBOR) is generally driven by the identity of the lender, with traditional venture lenders often using the Prime Rate rather than SOFR (with the difference between those floating rates reflected in different margins paid in addition to the floating rate).

Interest

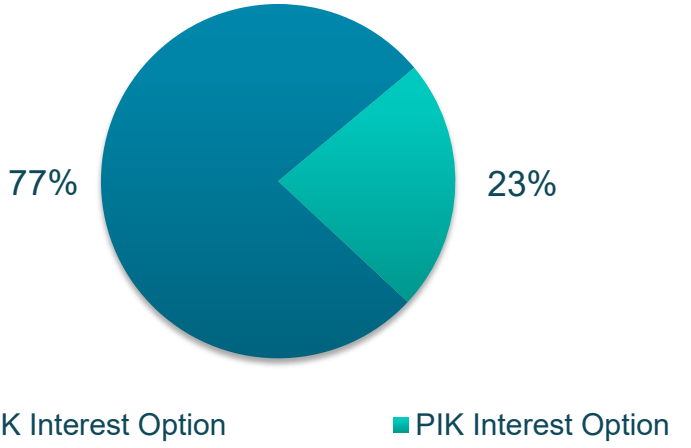
Interest Only for Initial Period

99%

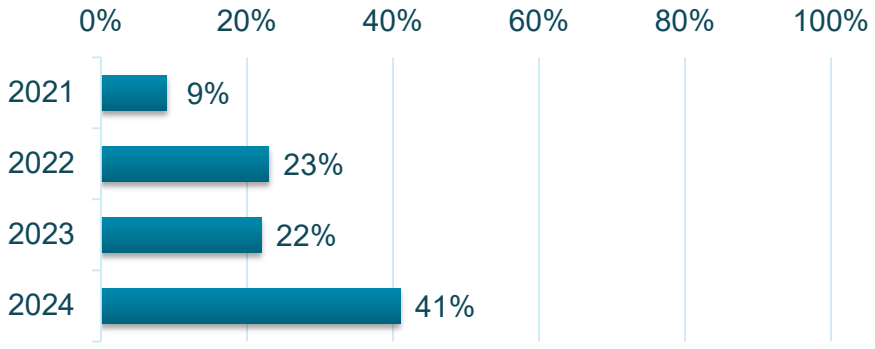
Median Length of Interest Only Period for Loans that Amortize

36 Months

Permit Some Interest to be Paid in Kind (PIK)



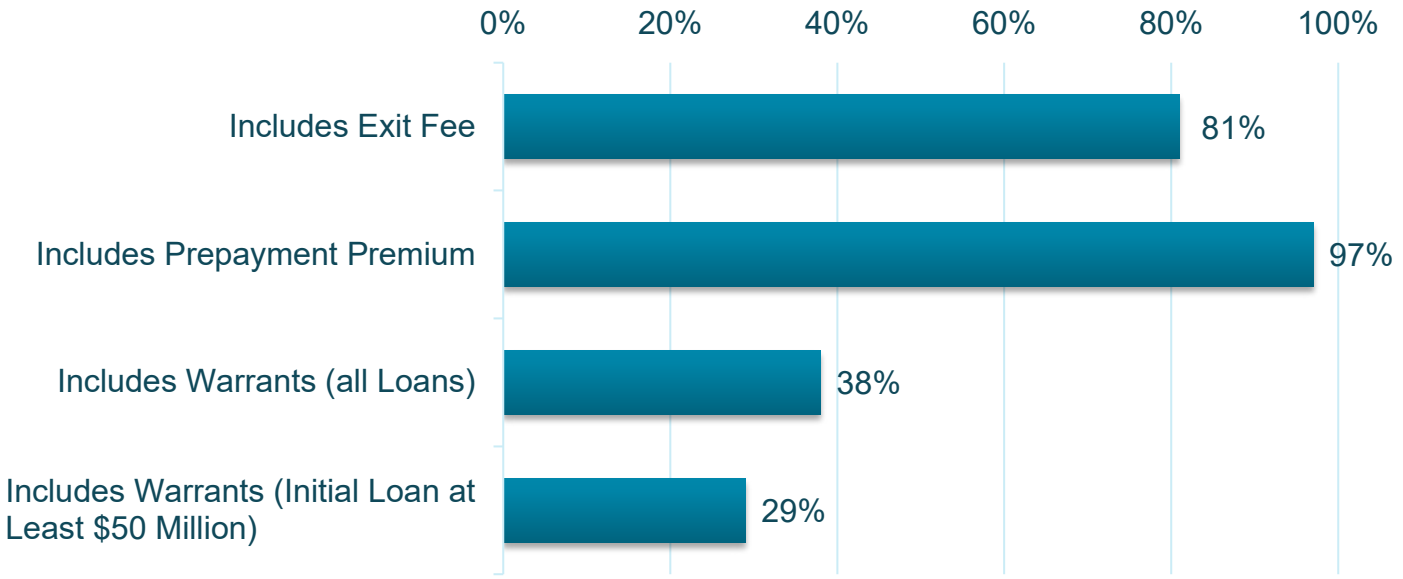
PIK Interest Option



Key Finding

Most loans are interest-only for a significant period. Although a majority of loans still require interest to be paid all in cash, an increasing minority allow some portion to be paid in kind (PIK). This allows the borrower to preserve cash, but also sometimes comes with a higher interest rate margin.

Fees, Call Protection and Warrants

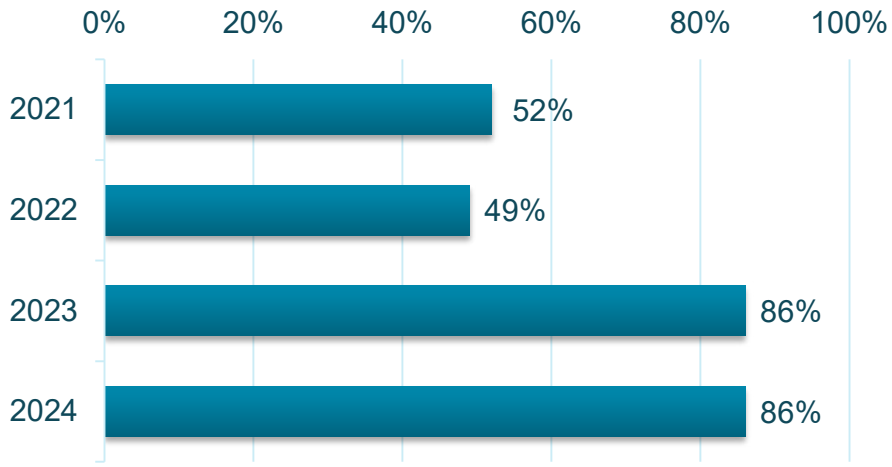


Key Finding

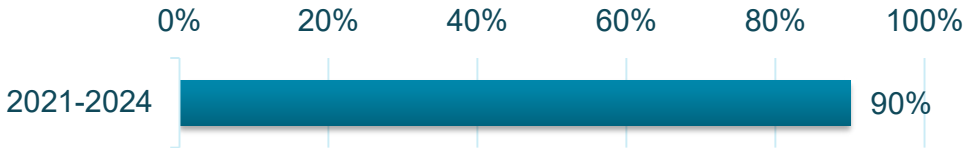
The overall compensation to lenders in these financings includes some or all of the following: up-front fees, interest, exit fees, prepayment fees and warrants. Most of these financings include up-front and exit fees, and prepayment premiums. Prepayment premiums can be a fixed percentage of the amount prepaid and/or a "make-whole," whereby the lender is guaranteed a certain number of months of interest payments, whether or not the loan is prepaid prior those months elapsing. Warrants are also included as a portion of the compensation to lenders in a significant minority of the financings, with a very small percentage of the deals having a portion of the loans convertible into equity.

Intellectual Property Security

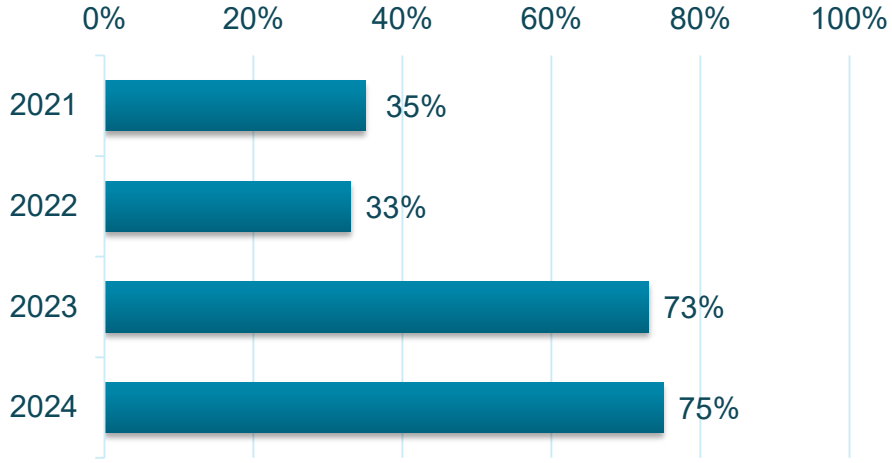
Secured by Intellectual Property



Secured by Intellectual Property (Initial Loan at Least $50 Million)



Secured by Intellectual Property (Initial Loan Less than $50 Million)



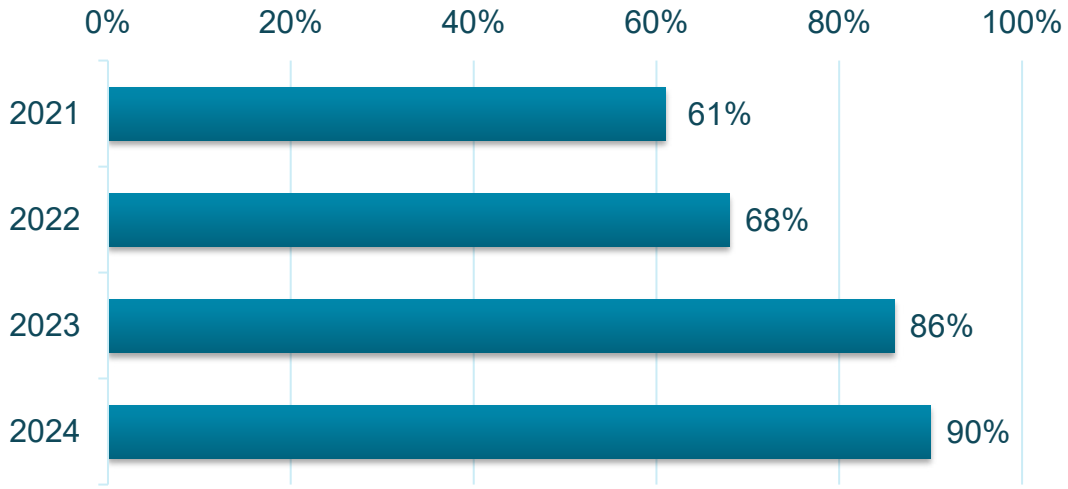
Key Finding

Although venture lenders historically often did not take security interests over intellectual property, there is a clear trend toward intellectual property being included in the collateral package, in particular for larger growth financings.

Growth and Venture Lending Study 2019-2024

Subsidiary Credit Support

Requires Guarantees from Domestic and Foreign Subsidiaries

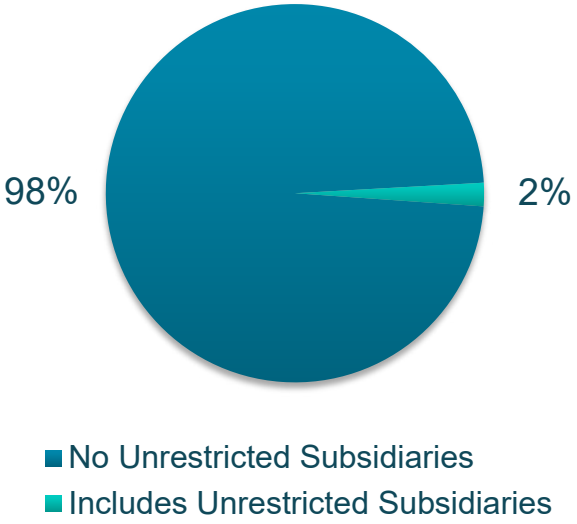


Requires Guarantees from All or Only Material Subsidiaries

Key Finding

Because the companies in these financings are often not cash-flow positive, the loans are based on the value of the assets owned by the companies. Therefore, domestic and foreign subsidiaries are typically included as guarantors—in particular if they own material assets, including intellectual property. This can add complexity and cost for companies that have significant foreign operations.

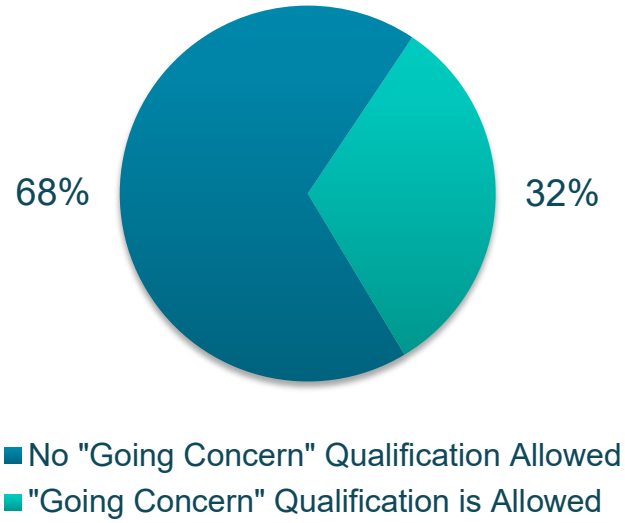
Unrestricted Subsidiaries Excluded from Covenants



Key Finding

Almost none of these financings include the ability for the borrower to designate subsidiaries as "unrestricted," and not subject to the covenants, guarantee, and security requirements under the financing agreements. This stands in stark contrast to the flexibility on this point seen in cash-flow loans for private equity-backed businesses.

Going Concern Qualification in Annual Audit

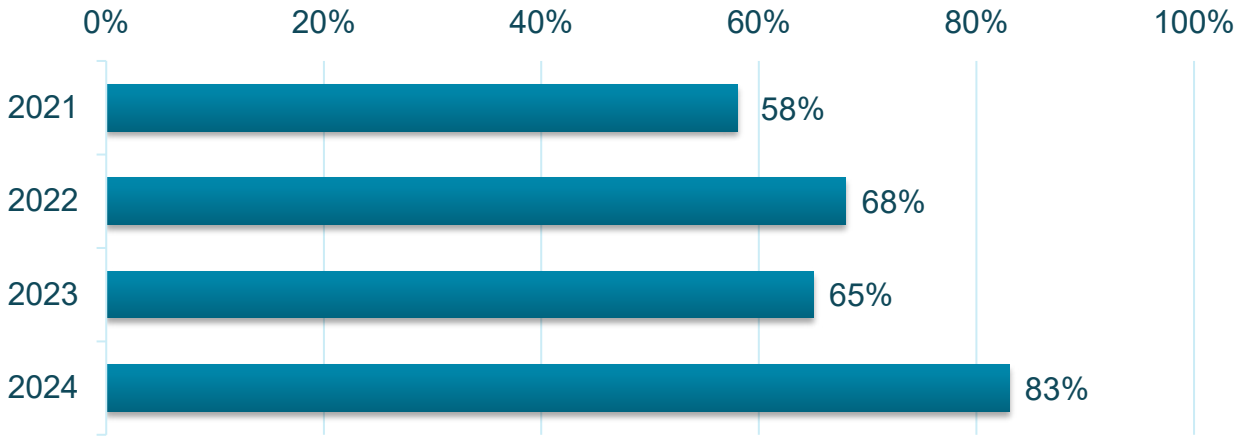


Key Finding

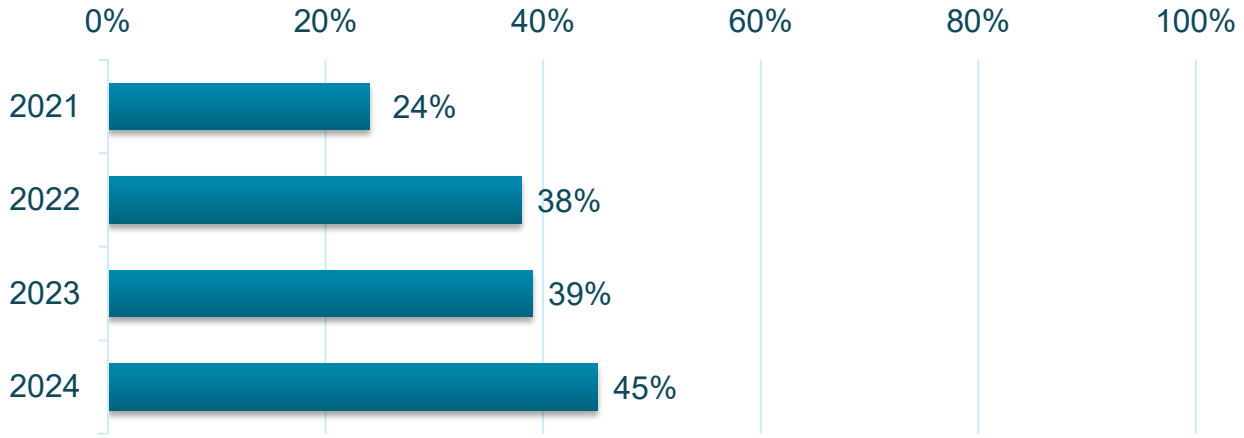
A majority of the financings require that the borrower's annual audit not contain a "going concern" or similar qualification, which requires the borrower to have enough cash to allow it to operate for 12 months following the date of the audit.

Financial Covenants

Includes Liquidity Covenant



Includes Revenue Covenant

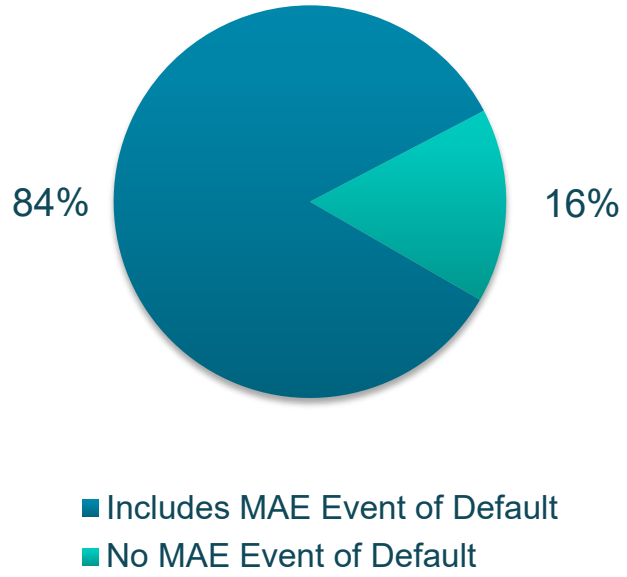


Key Finding

The two types of financial covenants seen in these financings are liquidity and revenue covenants, both of which are becoming more common, as lenders look for ways to mitigate their risks.

Events of Default

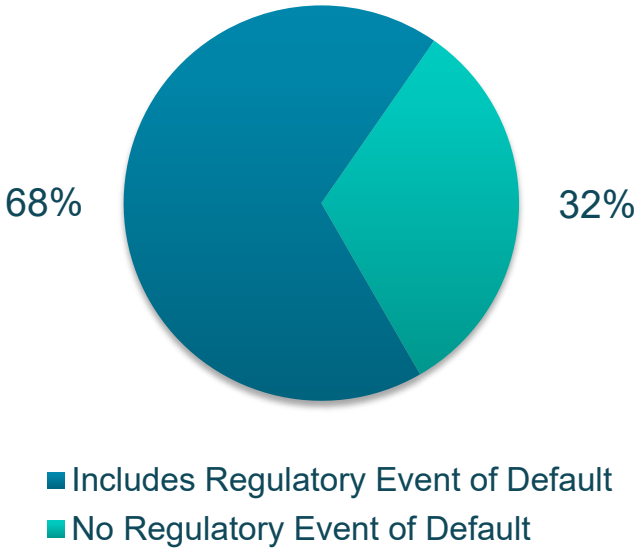
Material Adverse Effect Event of Default



Key Finding

Most financings include a stand-alone Event of Default if a Material Adverse Effect occurs. This is important protection for lenders, given the lack of leverage or coverage based financial convenants.

Regulatory Event of Default



Key Finding

Because these borrowers often rely on critical regulatory approvals for their products, an adverse regulatory event (such as the withdrawal of an important governmental approval) is often an Event of Default.

Lenders Included in the Study

COVINGTON

BEIJING BOSTON BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON
LOS ANGELES NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

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Third Annual Synthetic Royalty and Drug Development Financing Study

2019-2024

COVINGTON

BEIJING BOSTON BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON
LOS ANGELES NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

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Overview

The publication of this study marks the third consecutive year in which we have examined the prevailing trends in the public "synthetic royalty" and drug development financings markets. Over the course of the six-year period now encompassed by this report, companies have continued to turn to these financing structures to meet the ever-increasing costs for research and development of new drugs, and financing providers have continued to refine the terms on offer.

With an anticipated rebound in equity markets having failed to materialize in 2024, more and larger public companies decided to turn to these structures, as demonstrated by a modest uptick in deals and a more significant increase in deal size, led by a $500 million financing early in the year.

In our review, we have seen the market coalesce around a minimum level of bankruptcy protection in the form of security interests over intellectual property and other product assets, but other elements of these transactions remain very much open to customization. This is reflected in our new comparison of negative covenants and put and other repayment obligations across different investors.

In the following pages, we present our updated study, which covers the period from January 1, 2019 to December 31, 2024, for transactions involving at least $25 million entered into by public biotech companies.

Although commercially sensitive information was redacted from some publicly filed documents, sufficient information was available to provide a good sense of market terms.

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.

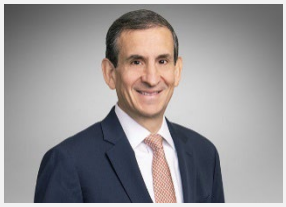

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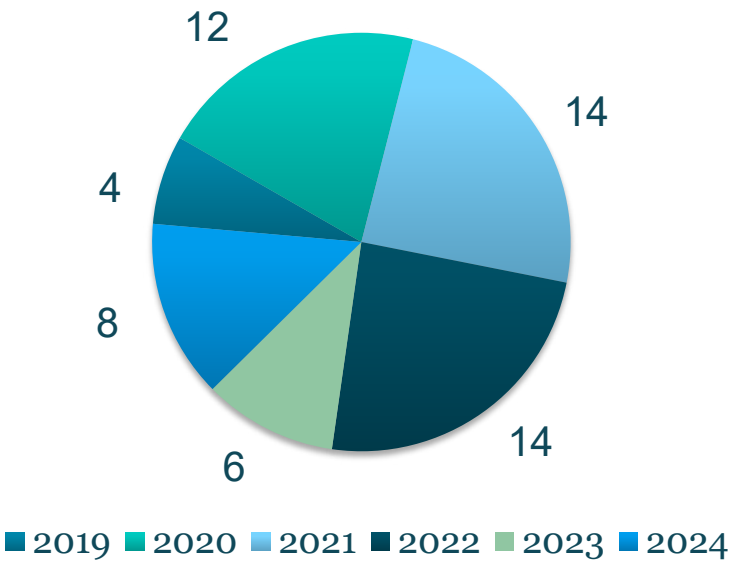
Table of Contents

Summary of Transactions Reviewed

58
Total Transactions

24
Unique Investors



Key Finding

While transaction volume was only slightly up in 2024 after decreased activity in 2023, we see continued interest in these financings from a growing universe of investors.

15
Investors with Two or More Transactions

9
Investors with Three or More Transactions
(Increased by 1 since the last study)

7
Investors with Four or More Transactions
(Increased by 1 since the last study)

4
Investors with Five or More Transactions
(Increased by 1 since the last study)

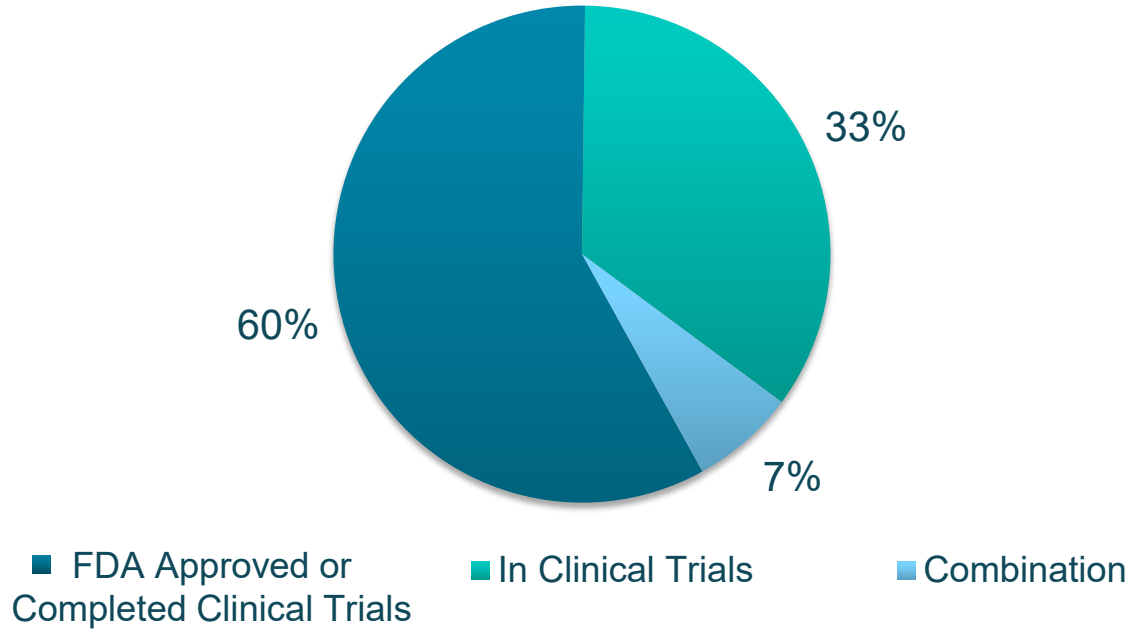
Summary of Transactions Reviewed

$60,000,000
Median Up Front Payment

$125,000,000
Median Total Commitment

$25,000,000
Smallest Total Commitment

$500,000,000
Largest Total Commitment



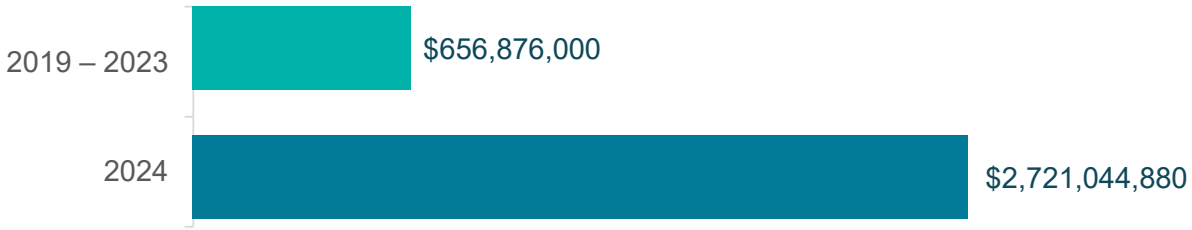
Key Finding

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

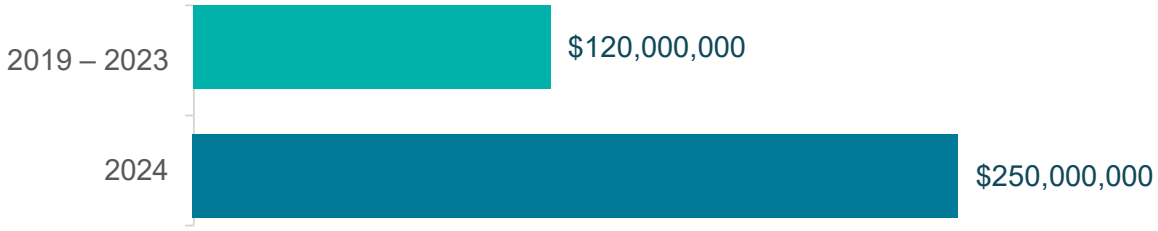
Synthetic Royalty and Drug Development Financing Study 2019-2024

Trends in 2024

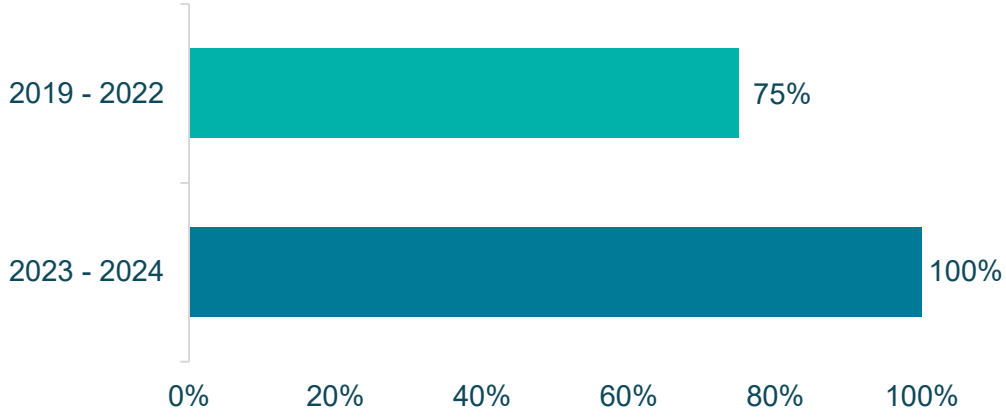
Median Company Market Capitalization



Median Deal Size



Secured by at Least Product Assets

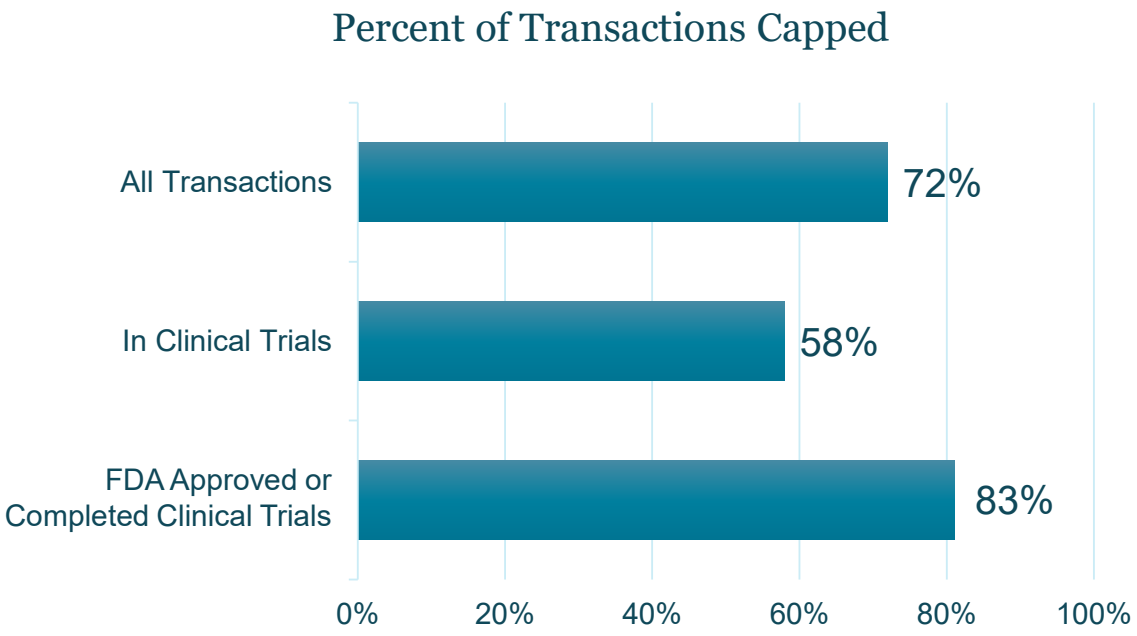


Key Finding

The size of companies and transactions were larger in 2024, and the provision of at least some level of security remained a market standard.

Synthetic Royalty and Drug Development Financing Study 2019-2024

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

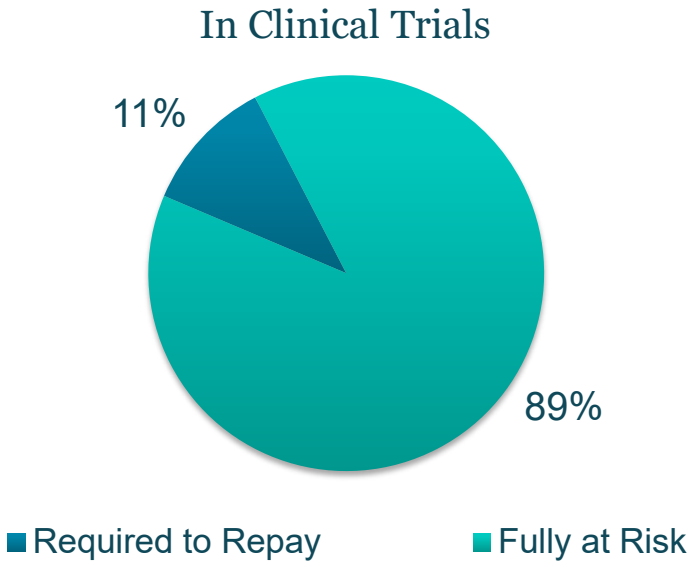
11.14 Times
Return Cap Multiple
Highest Multiple

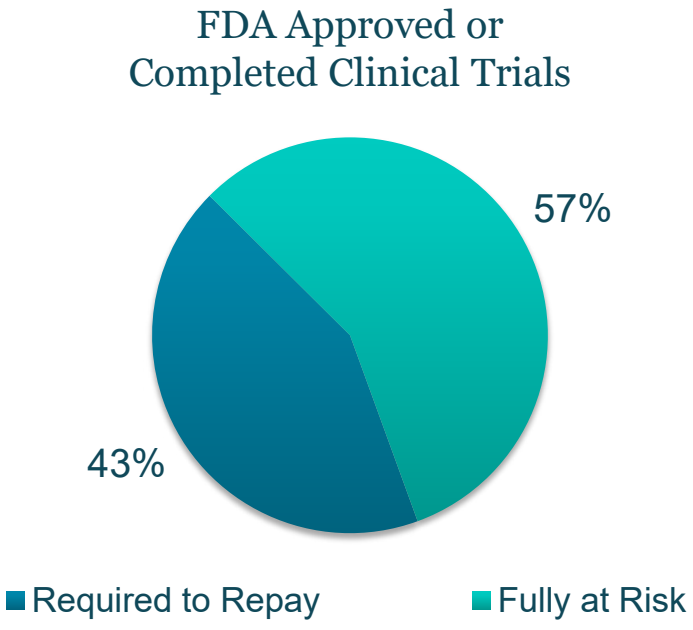
Key Finding

A significant majority of the transactions capped the return available to the investor at a multiple of the invested amount. 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.

Synthetic Royalty and Drug Development Financing Study 2019-2024

Requirement to Repay Financing





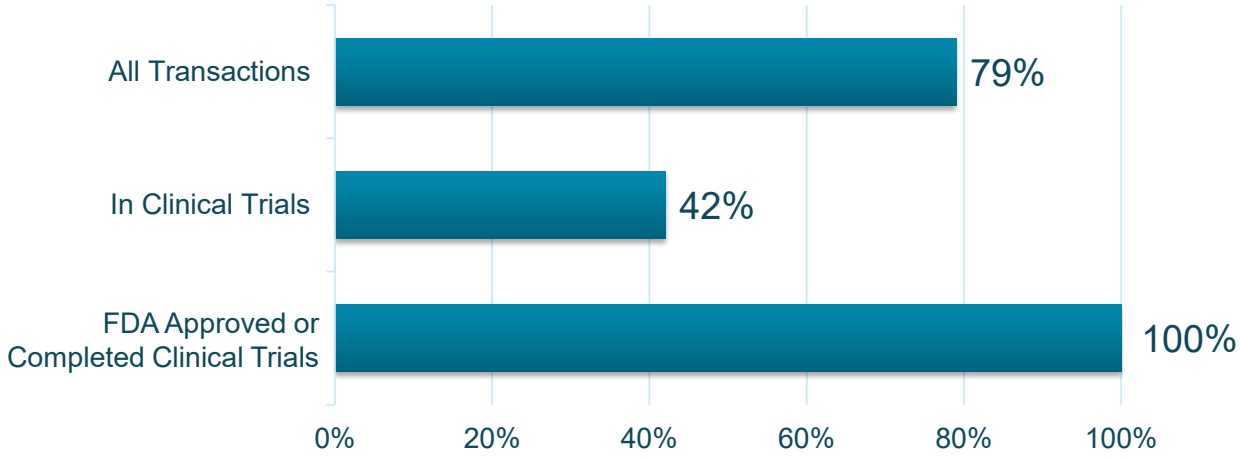
Key Finding

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 more closely split between transactions with and without that requirement.

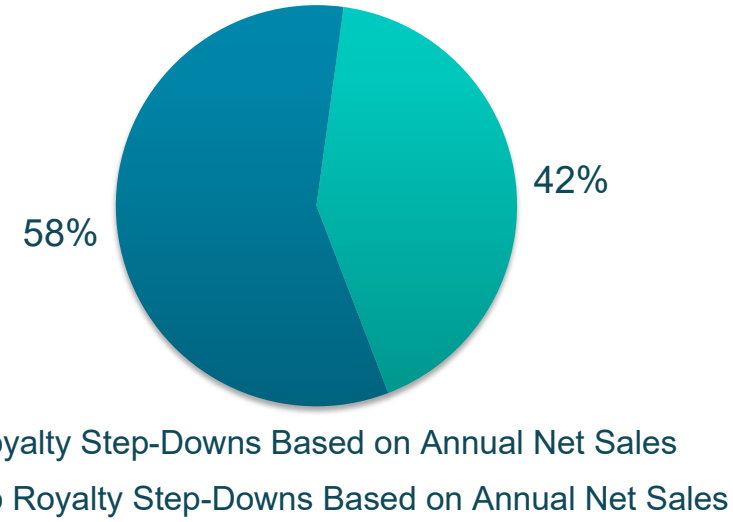
Synthetic Royalty and Drug Development Financing Study 2019-2024

Royalty Rate Economics

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



Within Solely Synthetic Royalty Compensation Transactions



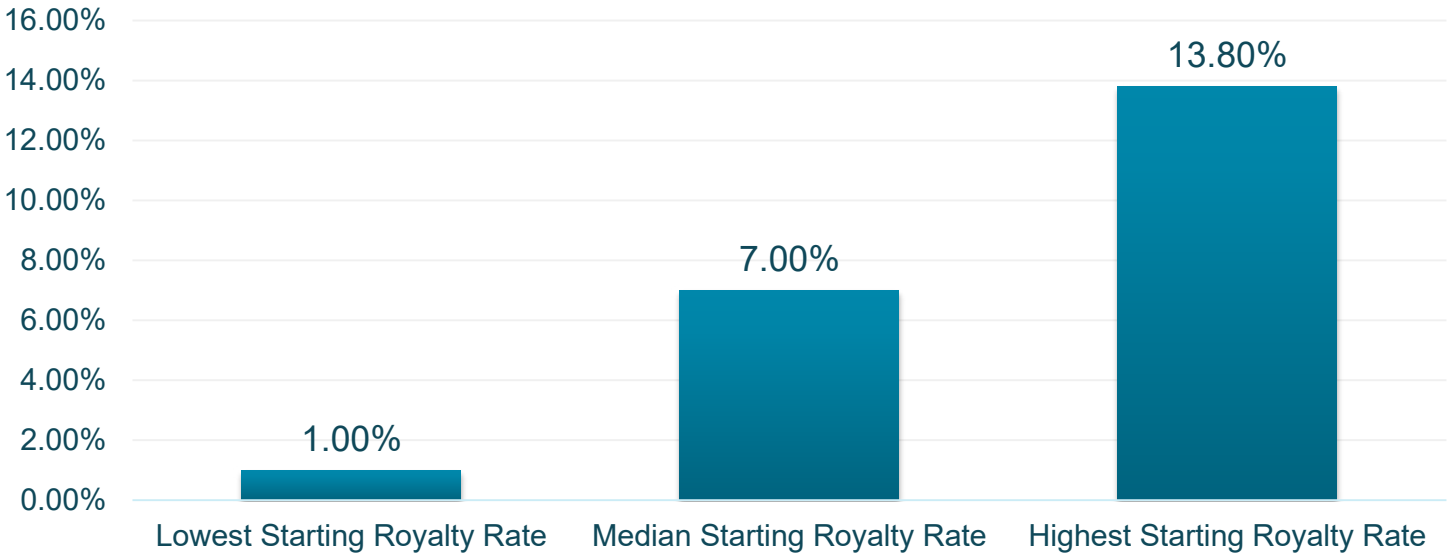
Key Finding

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.

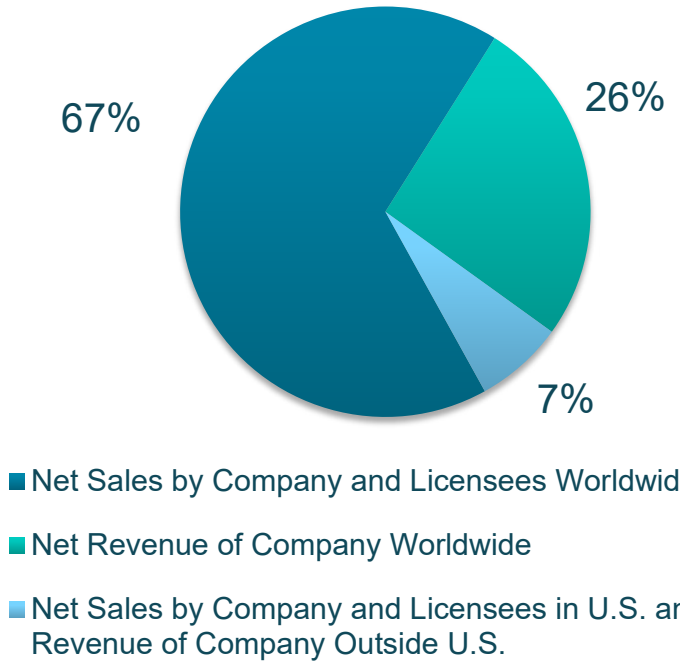
Synthetic Royalty and Drug Development Financing Study 2019-2024

Royalty Rate Economics

Within Solely Synthetic Royalty Compensation Transactions



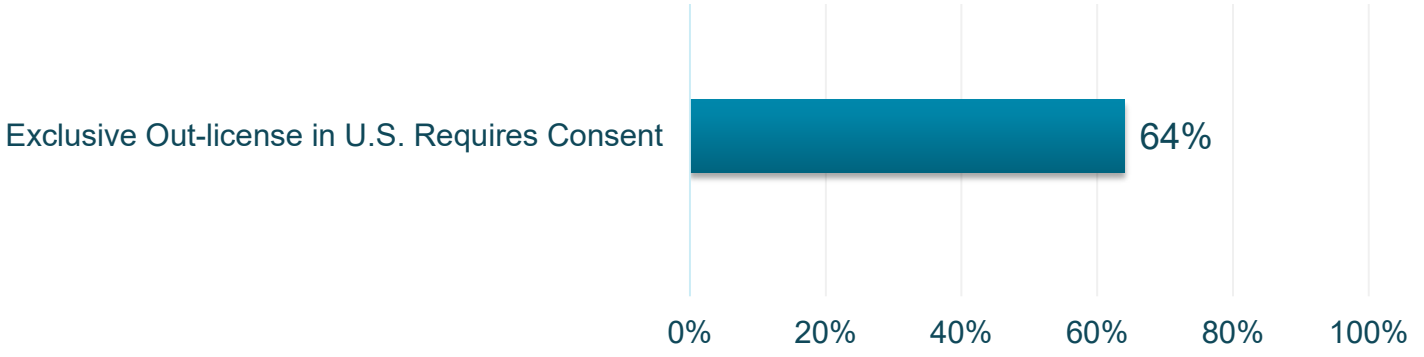
Synthetic Royalties Calculated Based On



Key Finding

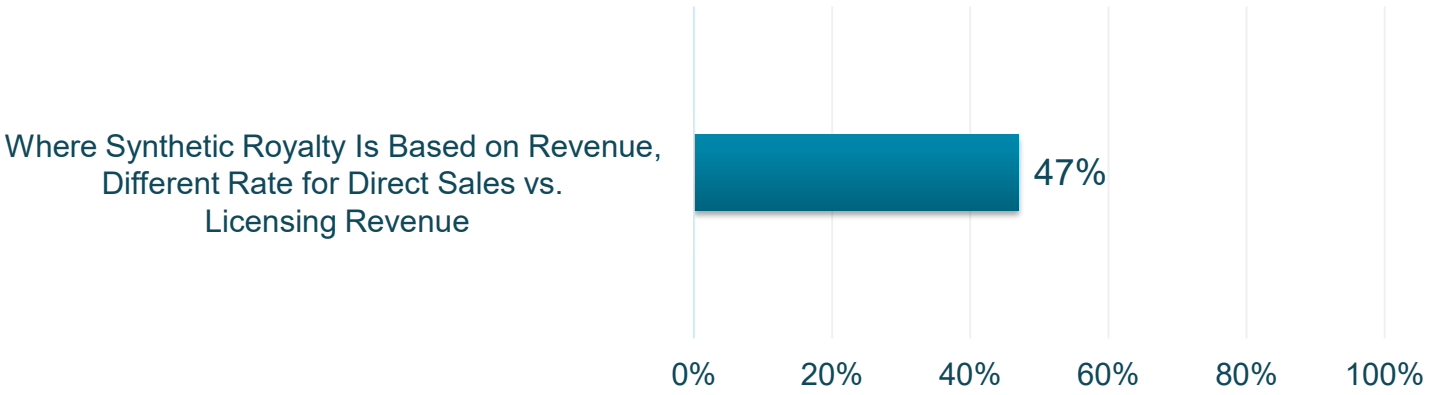
Although a majority of the transactions calculated the synthetic royalty based on net sales by the Company and its licensees, a number of transactions calculated the synthetic royalty solely based on revenue received by the Company, in particular with respect to sales outside of the U.S.

Synthetic Royalty Rate Calculation



Key Finding

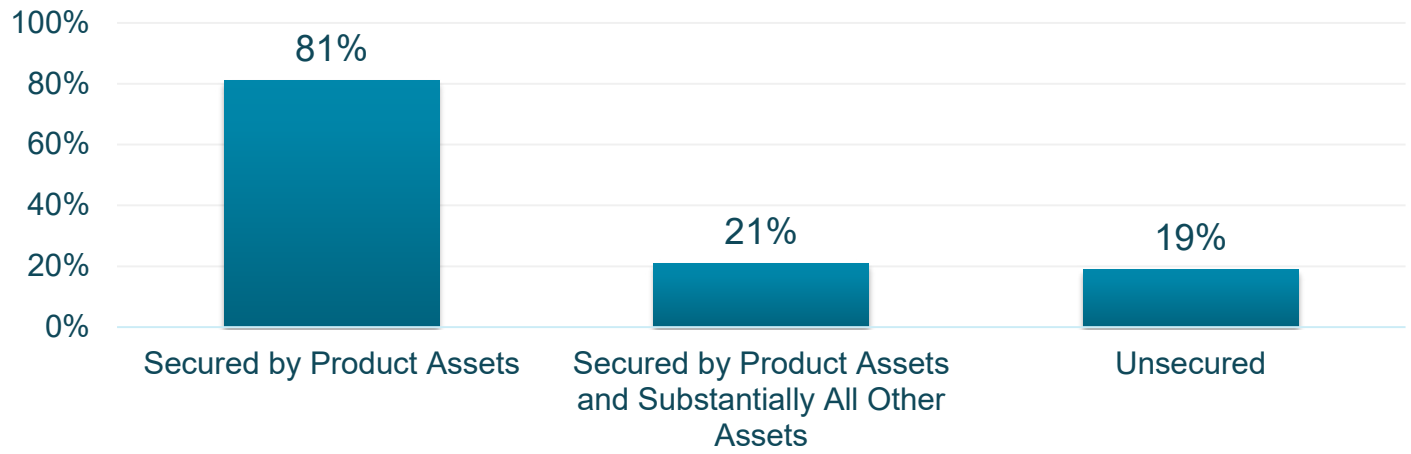
The majority of agreements prohibited exclusive U.S. out-licensing without investor consent.



Key Finding

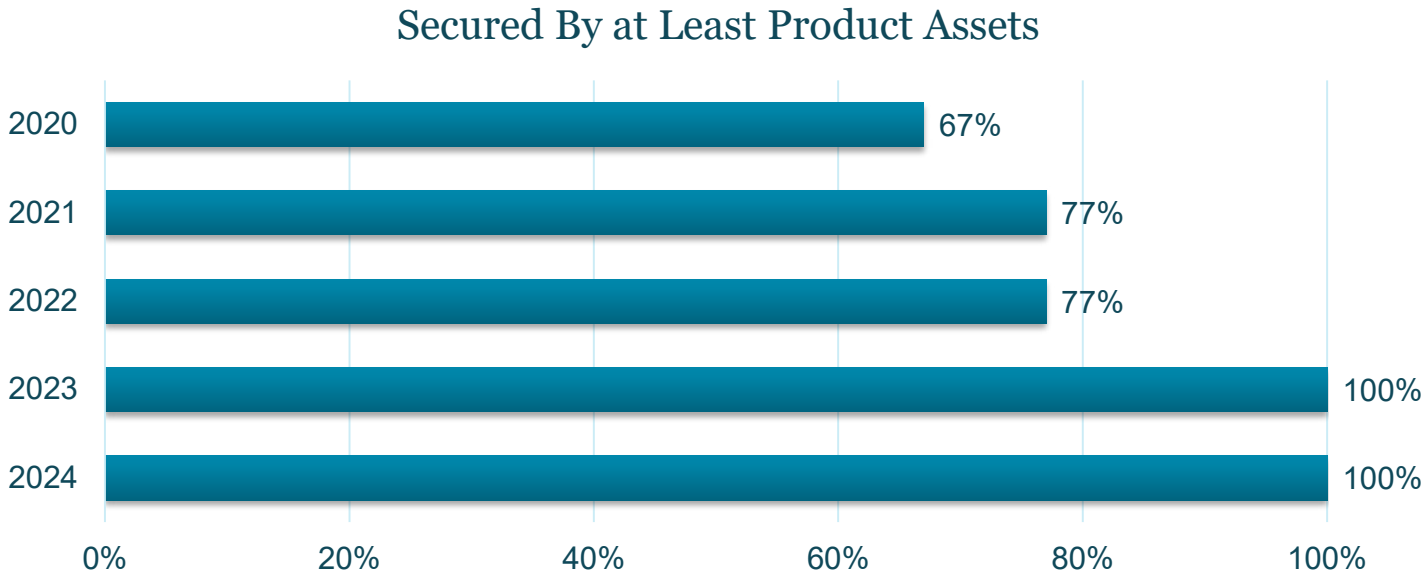
The synthetic royalty rate did not differ in approximately half of the transactions for direct net sales revenue vs. licensing revenue (licensing revenue typically being lower than direct sales revenue). The differing treatment may be due to whether the parties desired differential synthetic royalty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

Collateral



Key Finding

These transactions are normally secured by product assets (such as intellectual property, contract rights, and related assets), and in some cases by all assets.

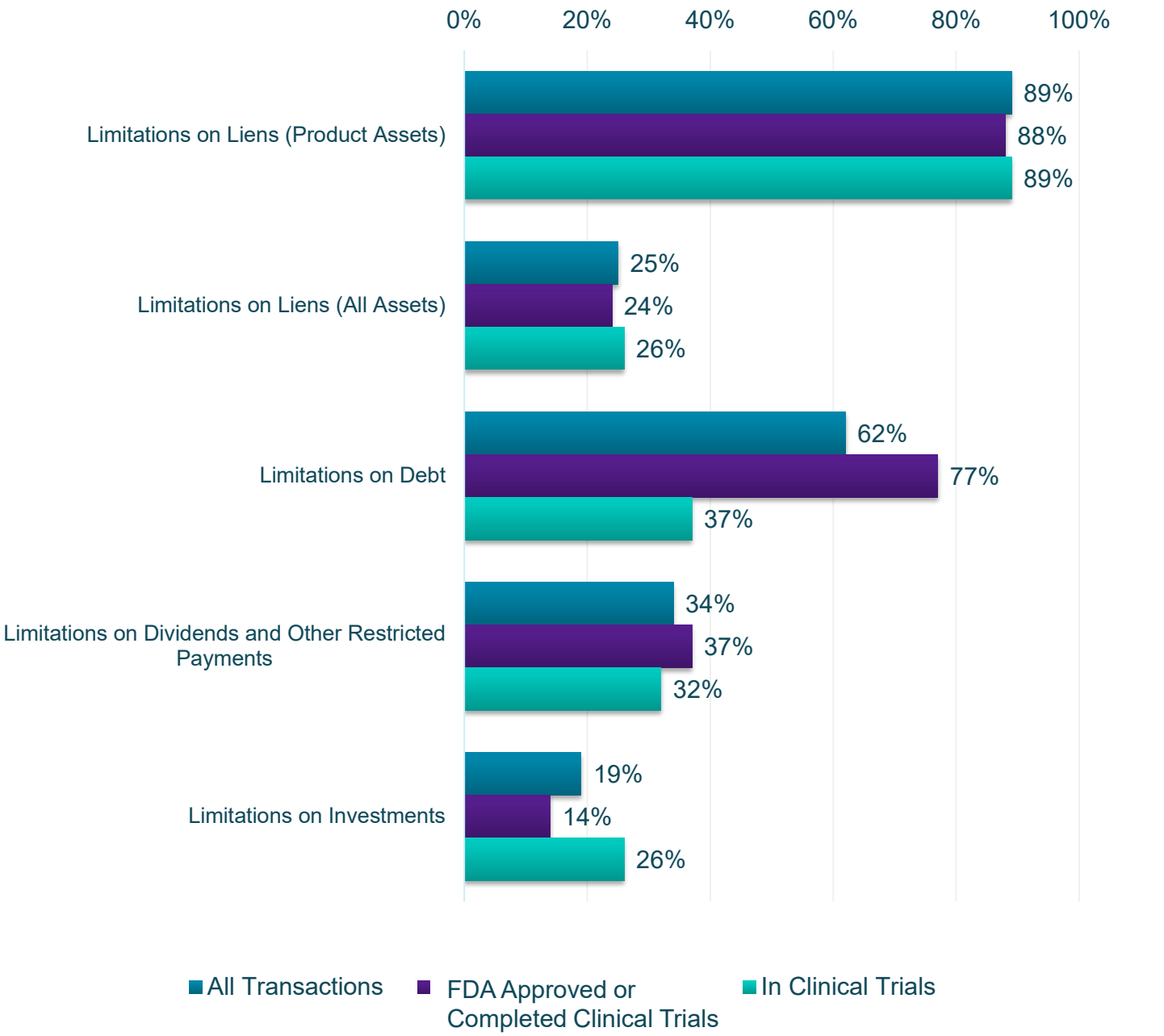


Key Finding

There is a clear trend toward these transactions being secured by intellectual property and other product assets.

Synthetic Royalty and Drug Development Financing Study 2019-2024

Negative Covenants



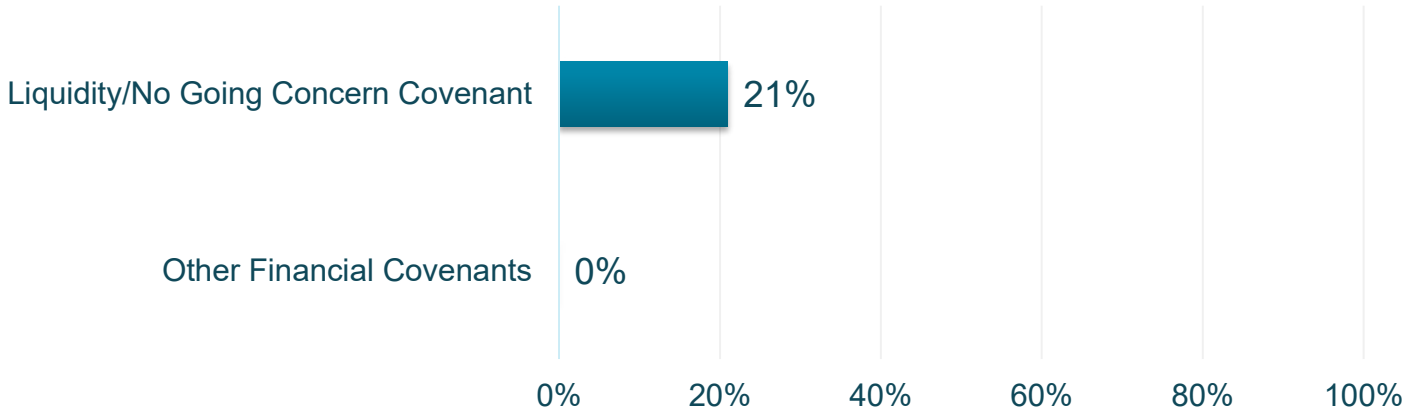
Key Finding

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

Synthetic Royalty and Drug Development Financing Study 2019-2024

Negative Covenants

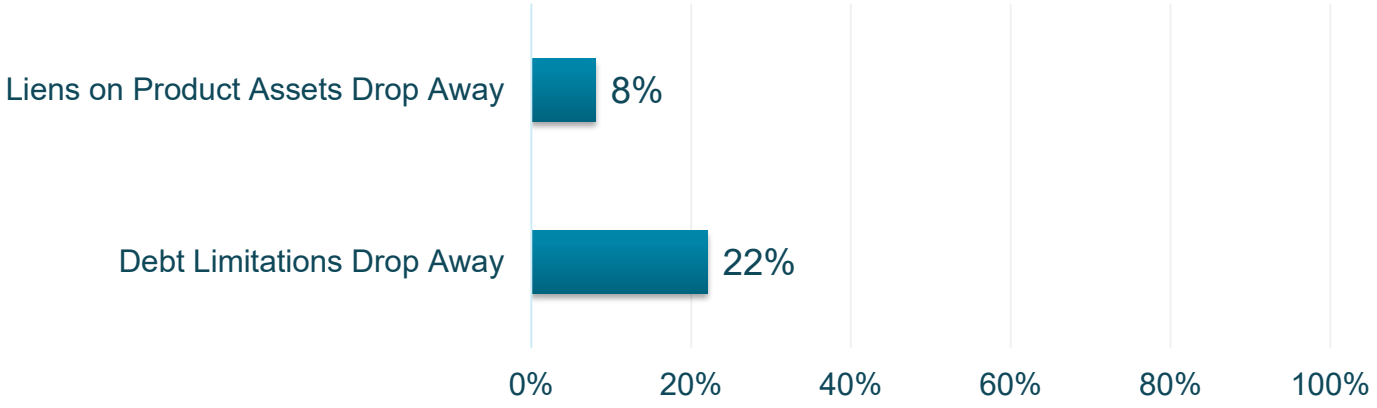
Financial Covenants



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.

Synthetic Royalty and Drug Development
Financing Study 2019-2024

Synthetic Royalty Financing Covenants (Approved Products or Completed Phase III) Selected Terms – By Investor (2 or More $100M+ Transactions)

Debt-like covenants in synthetic royalty deals vary from investor to investor. The chart below shows, by investor, how often debt-like covenants are included.

	Overall	Investor 1	Investor 2	Investor 3	Investor 4	Investor 5	Investor 6	Investor 7
Required to Repay	**50%**	All	Most	All	Some	Some	None	None
Put Right for Change of Control	**85%**	All	All	All	All	All	All	Some
Put Right for MAE	**18%**	All	Some	None	None	None	None	None
Put Right for Covenant Breach	**58%**	All	Most	All	All	Some	Some	None
Put Right for Rep Breach	**41%**	All	Some	Some	Some	Some	Some	None
Put Right for Other Debt Default or Acceleration	**47%**	All	Most	All	None	Some	Some	None
Limitations on Debt	**80%**	All	All	Some	All	All	Some	Some
No Other Debt Allowed With Lien on Product IP	**40%**	All	Most	Some	None	None	Some	None
Limitations on Investments	**15%**	All	None	None	None	Some	None	None
Limitations on Dividends	**45%**	Some	Most	Some	None	All	Some	None

Synthetic Royalty and Drug Development Financing Study 2019-2024

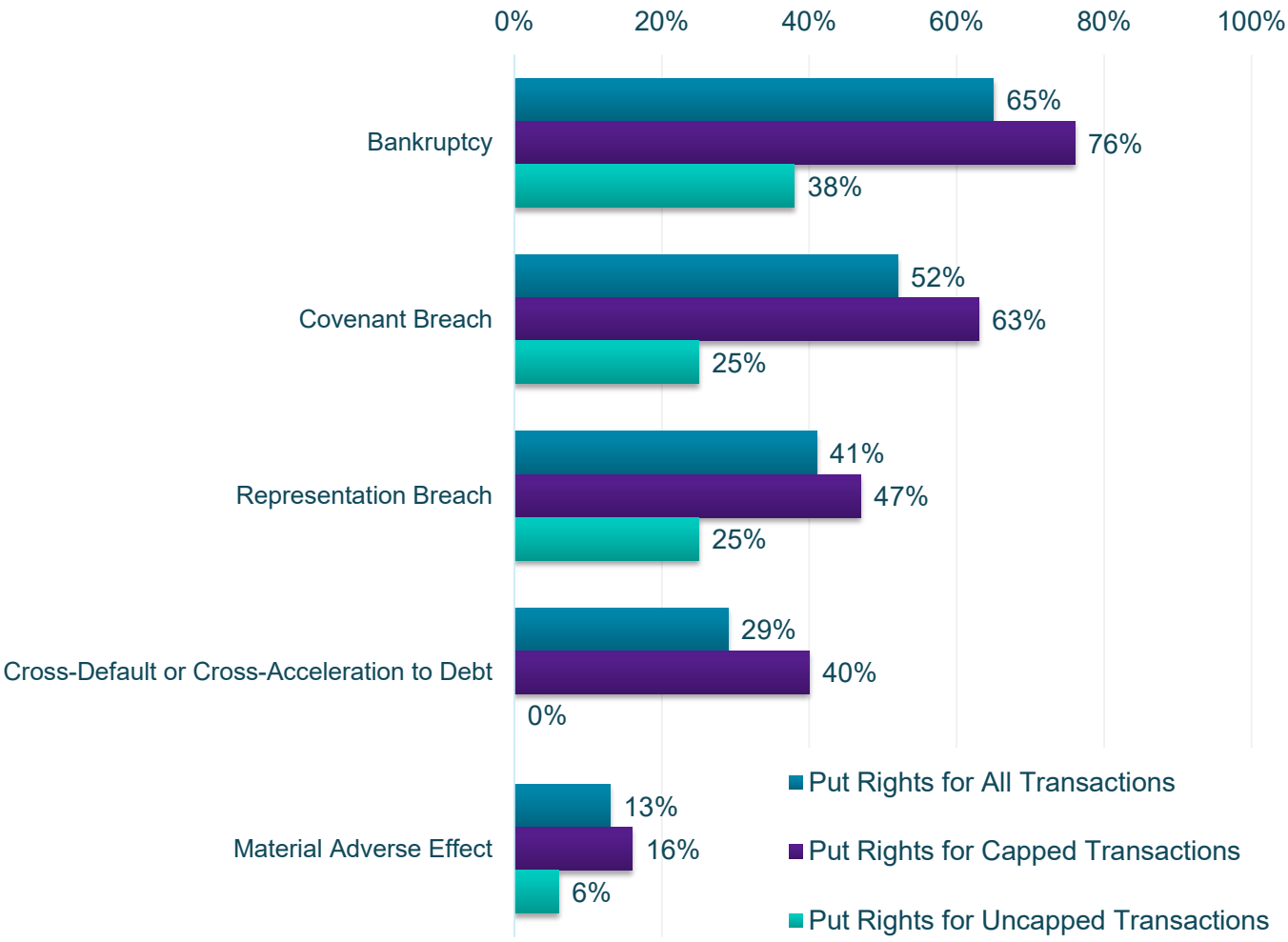
Drug Development Financing Covenants (In Clinical Trials) Selected Terms – By Investor (2 or More $100M+ Transactions)

Debt-like covenants in drug development financings vary from investor to investor. The chart below shows, by investor, how often debt-like covenants are included.

	Overall	Investor 1	Investor 2	Investor 3	Investor 4
Required to Repay	**0%**	None	None	None	None
Put Right for Change of Control	**67%**	All	All	Some	Some
Put Right for MAE	**8%**	None	None	Some	None
Put Right for Covenant Breach	**42%**	All	Some	Most	None
Put Right for Rep Breach	**42%**	All	Some	Most	None
Put Right for Other Debt Default or Acceleration	**0%**	None	None	None	None
Limitations on Debt	**50%**	All	Most	Some	Some
No Other Debt Allowed With Lien on Product IP	**33%**	All	Some	Some	None
Limitations on Investments	**33%**	All	Most	None	None
Limitations on Dividends	**33%**	All	Most	Some	None

Synthetic Royalty and Drug Development Financing Study 2019-2024

Investor Put Rights



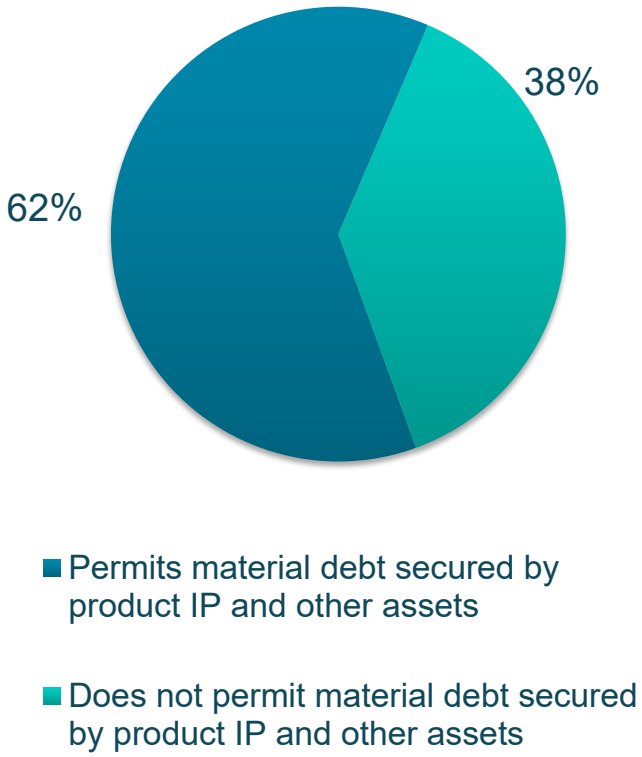
Key Finding

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

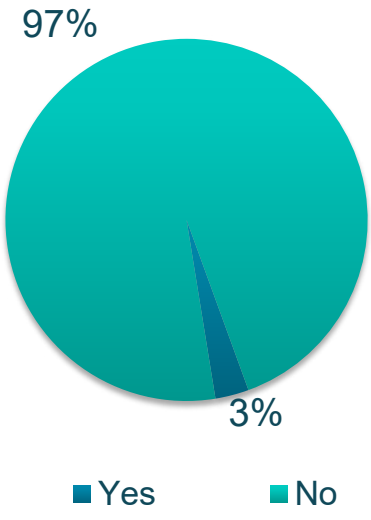
A majority of the transactions permitted material debt to be secured by product assets. In such cases, there is usually an intercreditor agreement put into place that spells out how the transaction will co-exist with this other debt, including in a bankruptcy.

In the event that bankruptcy courts do not preserve the investor's entitlement to payments following a bankruptcy, 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.

Special Purpose Vehicle Structure Required

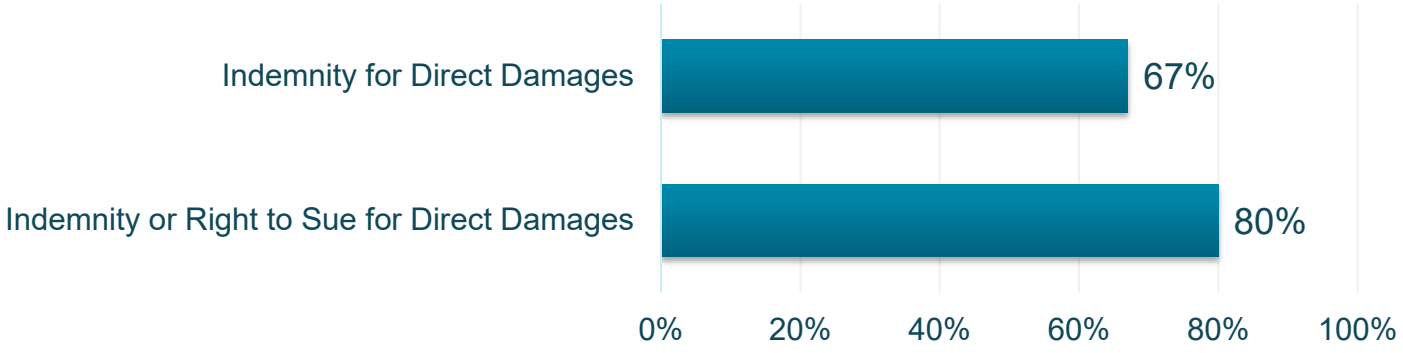
Key Finding

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.



Indemnities

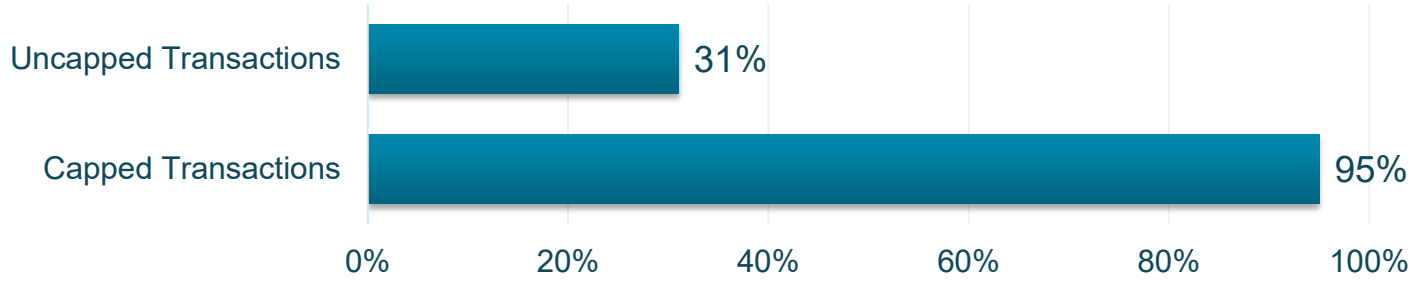
Indemnity for Losses due to Covenant or Representation Breaches



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.

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Financing
Life Sciences

Second Annual Royalty Monetization Study

2019-2024

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Overview

The publication of this study marks the second consecutive year in which we have examined the prevailing terms available to biotech companies to address a pressing question they face: what to do with potentially valuable incoming royalty and milestone payments arising from out-licensed or otherwise transferred technology that may stretch far into the future?

If the company wants to accelerate those future payments to invest in its business now, a royalty monetization transaction provides a solution that blends aspects of asset sales and debt financings, in which an investor looks primarily to the product underlying the royalty stream as a source of repayment. A small subset of these transactions involve funding prior to regulatory approval or even the completion of clinical trials, which presents a distinct risk and return profile for investors.

In examining transactions completed in 2024 against prior trends, we observe that even in the face of headwinds against most forms of financing over the past year, the royalty monetization market remained steady. This updated study reflects a market that is relatively mature, with a number of terms and practices that are widely, if not universally, accepted by buyers and sellers alike. These results distinguish this market from the synthetic royalty market, which continues to evolve, and has significant variability across deals and investors.

Because of the limited universe of companies that can engage in these transactions, royalty monetizations remain a smaller and less well understood market than other more conventional forms of financing. We have reviewed deals of this type involving commitments of at least $15 million entered into by biotech companies with equity listed on U.S. stock exchanges in the last six calendar years (January 1, 2019 to December 31, 2024). As a separate segment of this market involves sellers that are not public filers (such as universities, non-profit organizations, inventors and private companies), and big pharma companies for which the underlying agreements are not of sufficient materiality for them to be publicly filed, this is necessarily only a snapshot 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 about the findings in the study, please feel free to reach out to us.

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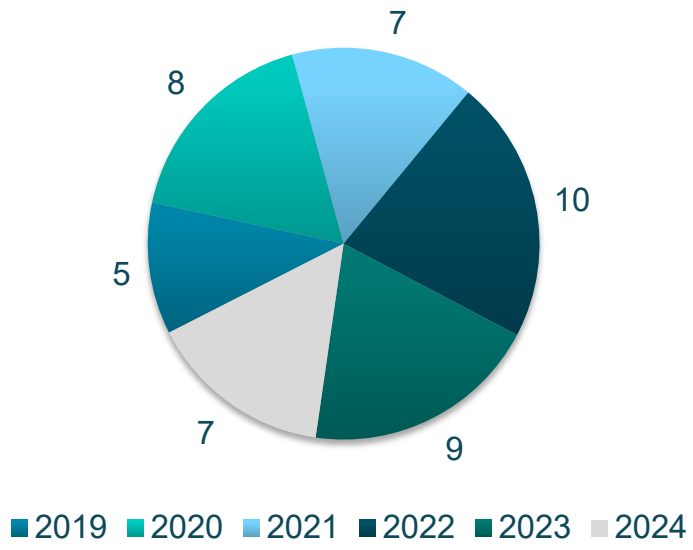
Summary of Transactions Reviewed

46
Total Transactions

15
Unique Investors



4
Investors with Five or More Transactions

Key Finding

New investors continue to enter this market, with four investors now showing at least five transactions in the study.

$115 million
Median Up Front Payment

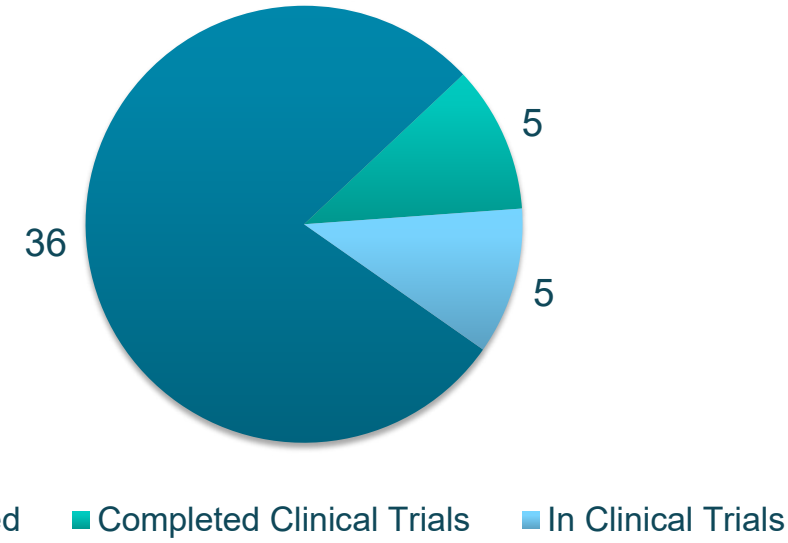
$155 million
Median Commitment

$1.125 billion
Largest Commitment

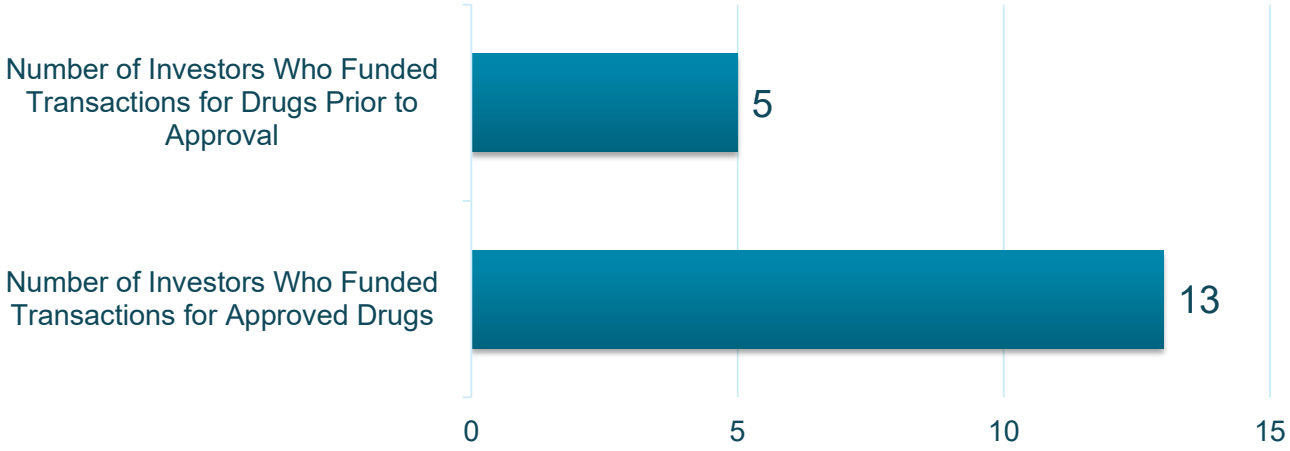
$17 million
Smallest Commitment

Approval Status

Drug Approval Status Upon Initial Funding



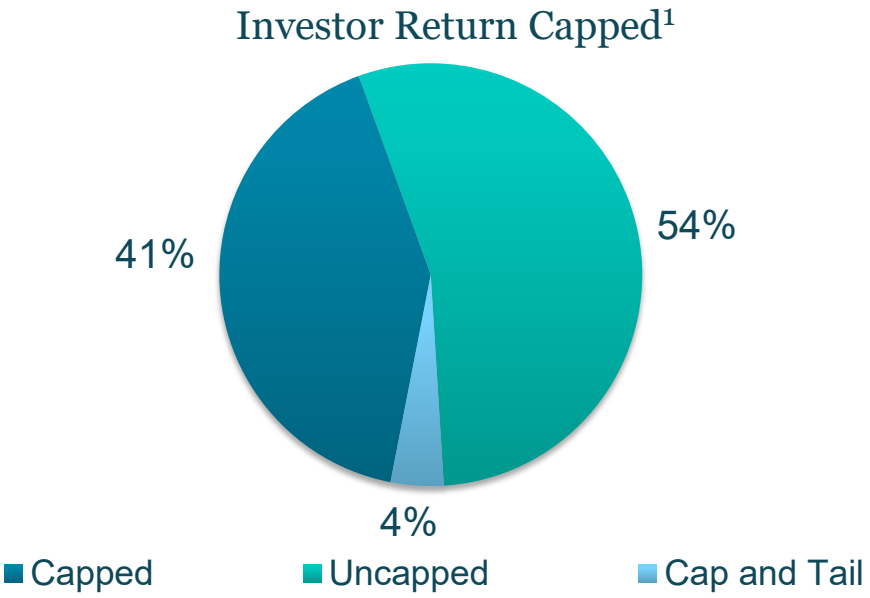
Unique Investors Who Funded Transactions

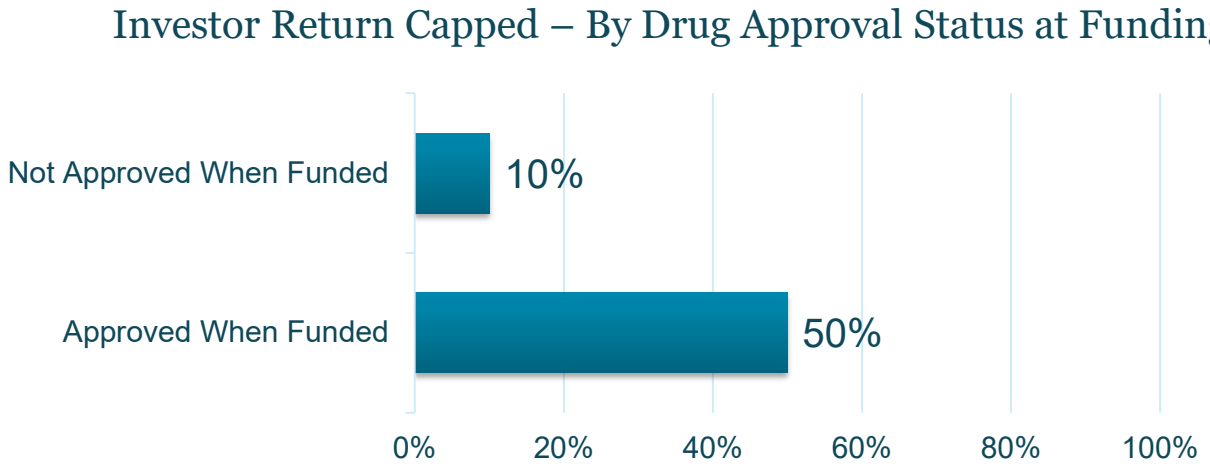


Key Finding

Most of the transactions involved drugs approved in at least one material jurisdiction. Although pre-approval transactions can get done, there are fewer investors interested in that structure, given its greater risk profile (although that number has increased from four to five in the past year).

Return Caps and Termination Dates





Key Finding

Some transactions involved the purchase of the full amount of a royalty stream, while others had the royalty stream revert back to the seller once a particular return cap was met. Return caps were less common for transactions involving unapproved drugs, where the investment risk was higher.

[1]Note that where this Study lists percentages, we generally excluded transactions in the limited cases where the applicable data was redacted. Percentages may not sum to 100% due to rounding.

Return Caps and Termination Dates

Maximum Return Multiple for Capped Deals

1.3 Times
Lowest Multiple

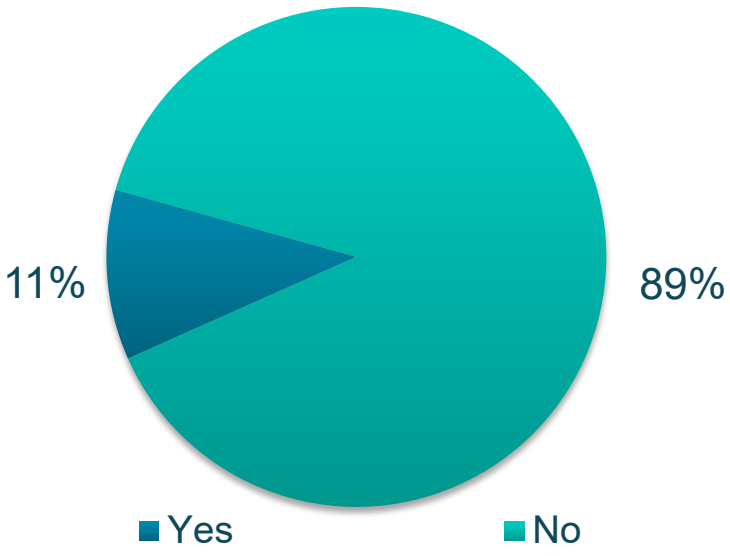
2.25 Times
Median Multiple

3.4 Times
Highest Multiple

Key Finding

The return multiples are somewhat similar to those found in our Synthetic Royalty and Drug Development Financing study for synthetic royalty financings (Median – 1.95x; Lowest 1.55x).

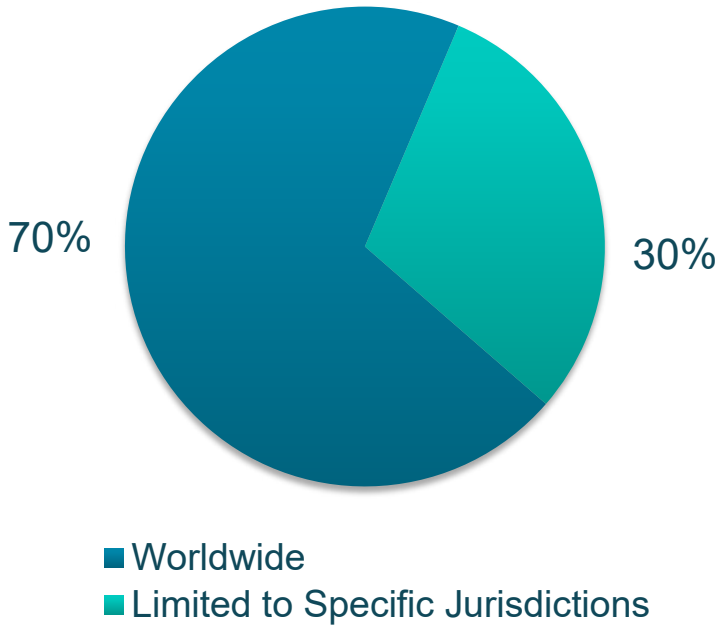
Fixed Date for Termination of Royalty Payments



Key Finding

Although a number of transactions had caps on investor returns, very few fixed the limits for the purchased royalty period.

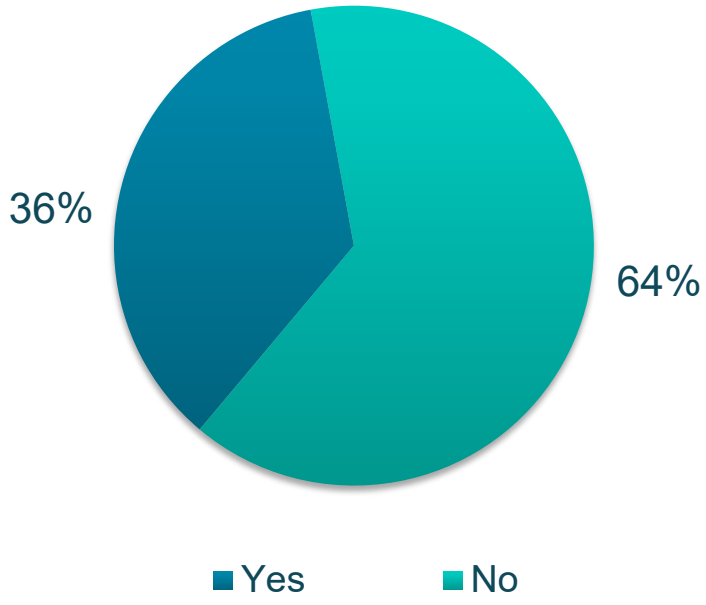
Geography of Royalties Sold



Key Finding

Most transactions included a sale of worldwide royalties, but a minority focused on specified jurisdictions.

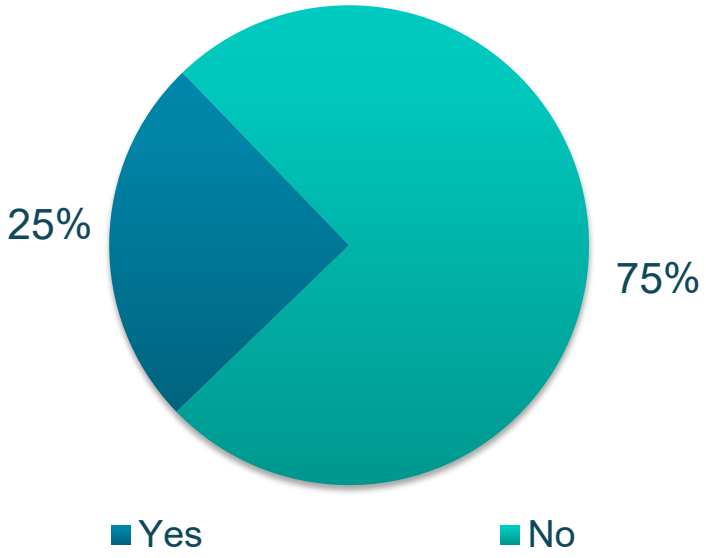
Milestones Included



Key Finding

A minority of transactions included the purchase of milestones, and those that included purchased milestones did not necessarily include all milestones payable under the relevant agreement, highlighting the ability of sellers to retain certain economics.

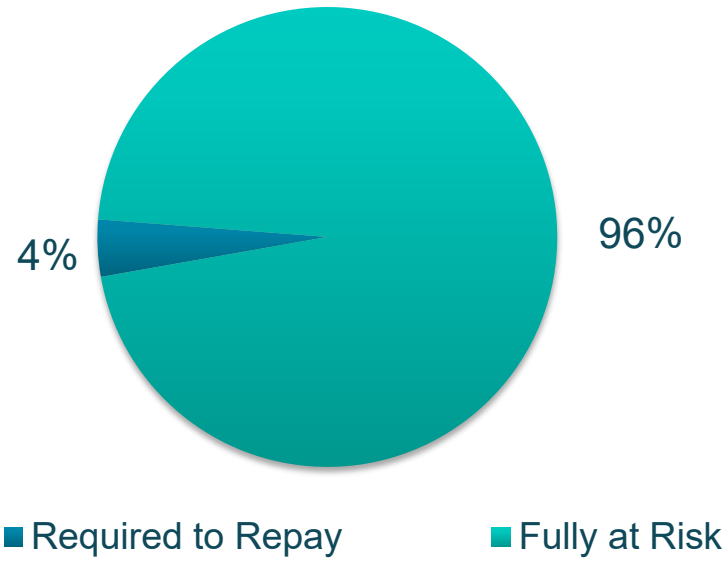
Royalty Limited to Specific Product



Key Finding

A significant majority of transactions contemplated (or did not explicitly exclude) royalties in respect of new licensed products under the applicable agreements, rather than confining the royalty stream to a specific product.

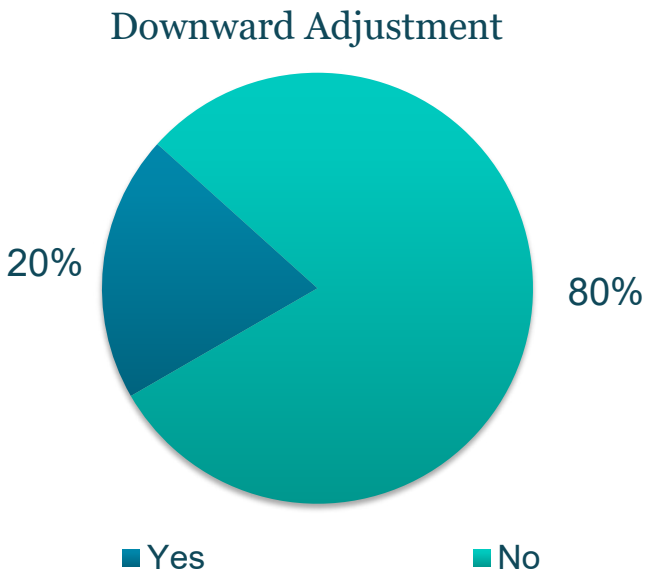
Requirements to Repay

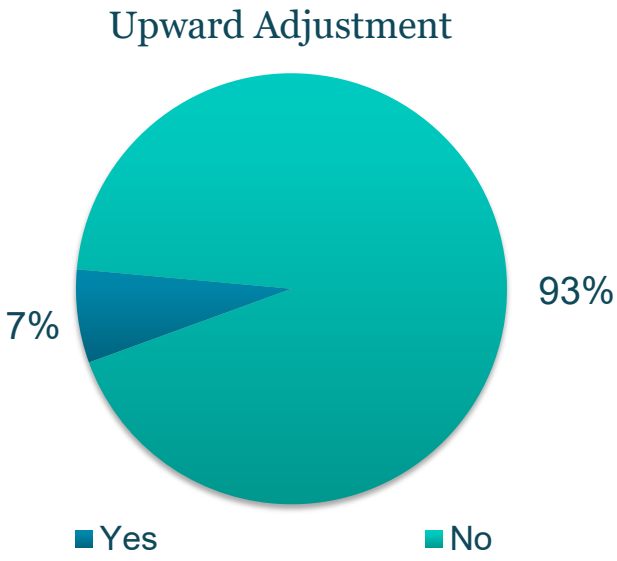


Key Finding

Given that traditional royalty monetizations rely on the royalty stream as a source of repayment, it is not surprising that only in very rare cases do sellers have any fixed obligation to repay any of the advanced funds, regardless of the amount of royalties received. This is an important distinguishing factor of these transactions from debt financings.

Adjustments in Percentage of Royalties Sold

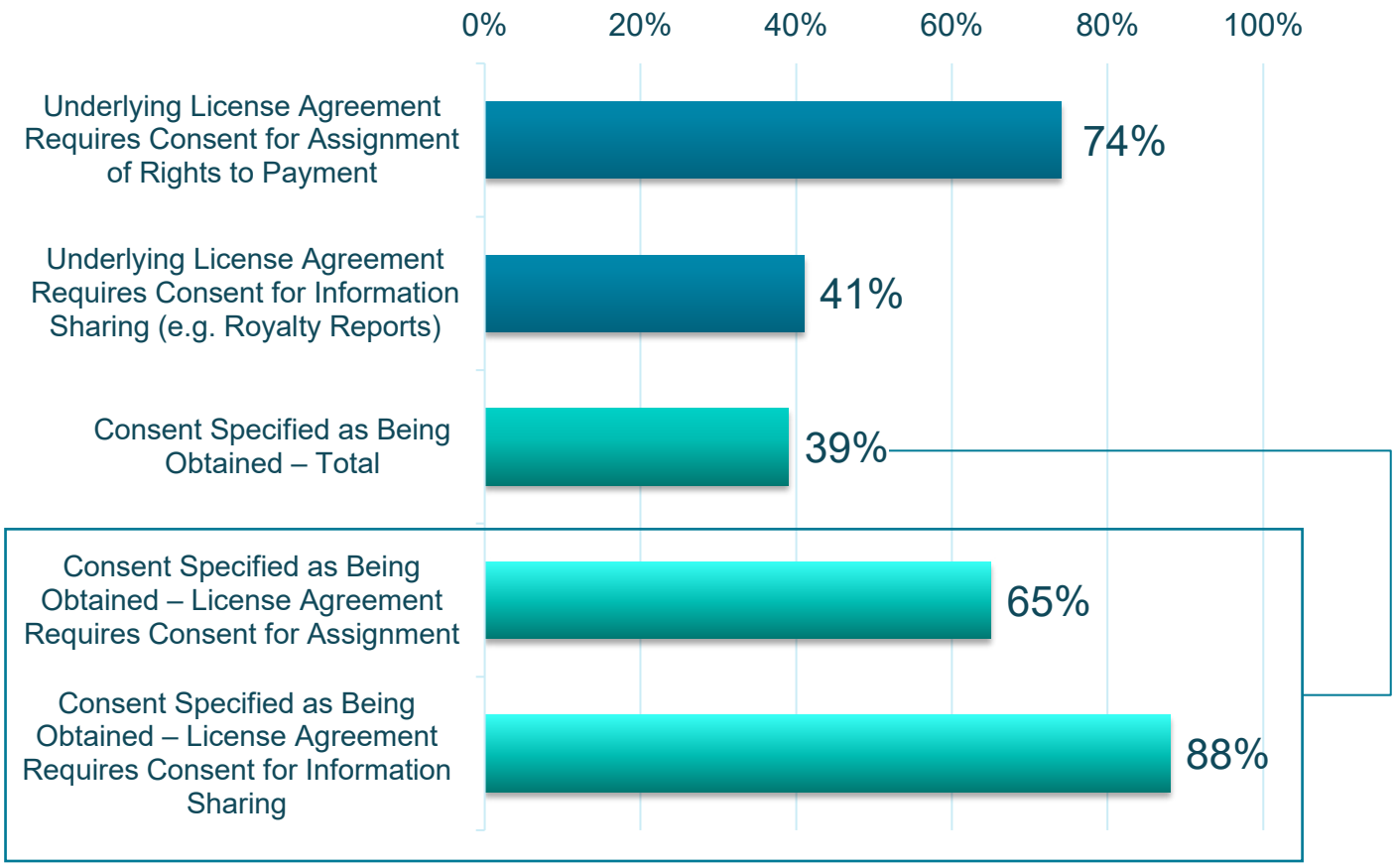




Key Finding

A small minority of royalty monetization transactions increase the percentage of royalties sold in the event certain metrics aren't met—typically return thresholds as of a specified date. They may also step down based on the achievement of certain economic thresholds. However, most transactions reviewed did not provide for adjustments to the percentage of royalties sold.

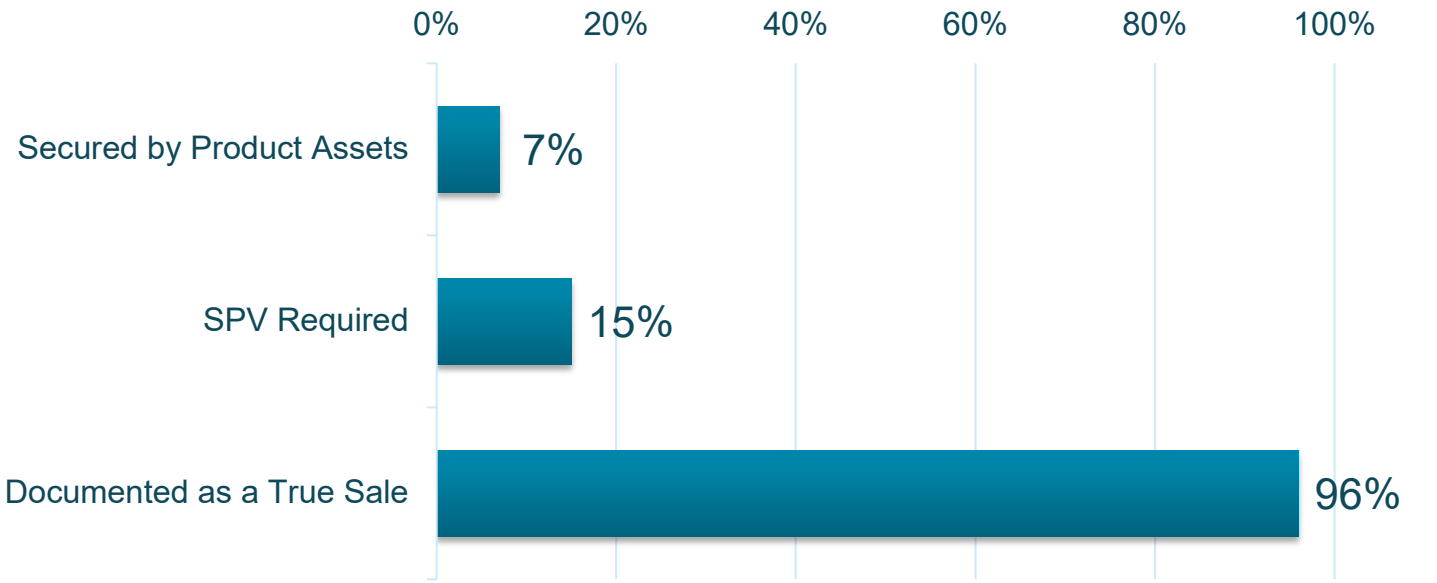
License Agreement Consents



Key Finding

While the underlying license agreements under which royalties are paid required consent to assignment in a majority of cases, the data suggests the parties may not have always obtained such a consent. In such circumstances, buyers may rely on a statutory Uniform Commercial Code override (UCC Section 9-406), which provides that contractual restrictions on the assignment of rights to payment are generally ineffective. This override does not apply to other contractual terms (such as confidentiality provisions) however, and therefore to the extent a consent is required for information sharing, such a consent may still be critical to getting a deal done.

Collateral Matters, SPVs and True Sale Considerations



Key Finding

Substantially all of the transactions stipulated that they constituted true sales, consistent with the view of these transactions as the sale of contractual rights to payment under the applicable license or other agreements. A subset either required a security interest in assets related to the product or required that a special purpose vehicle be set up to hold the royalty stream and/or related product assets, which can further protect the royalty buyer in the event of a seller bankruptcy.

The SPV structure or security interest in product assets (including IP) can help guard against two risks:

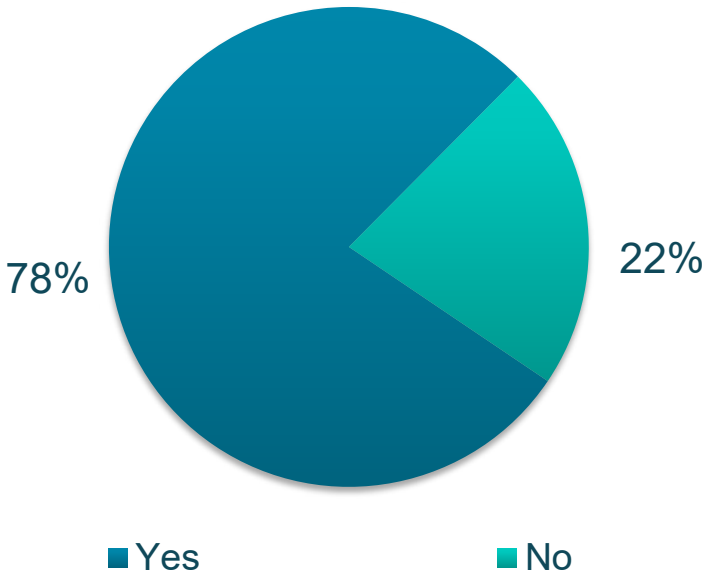
1. A capped deal is susceptible to the risk that it would be recharacterized in a bankruptcy of the seller as a loan – while this risk is somewhat mitigated by the back-up security interest in royalty payments seen in most transactions, if the entire royalty stream is moved to a bankruptcy remote SPV and the SPV sells the capped royalty, the risk can be further limited, as a purchaser would not expect the SPV to file for bankruptcy protection. (Continued)

Collateral Matters, SPVs and True Sale Considerations

Key Finding (Continued)

2. Even in an uncapped true sale of a royalty stream, there remains a risk that the license agreement under which the royalties are paid is rejected by the royalty monetization seller in a bankruptcy and the seller disposes of the licensed patents to the former licensee under the license, thus potentially impairing the purchaser's rights to the purchased royalty stream.[2] An SPV or security interest in the underlying IP can mitigate against this risk.

Patents Licensed to Payor



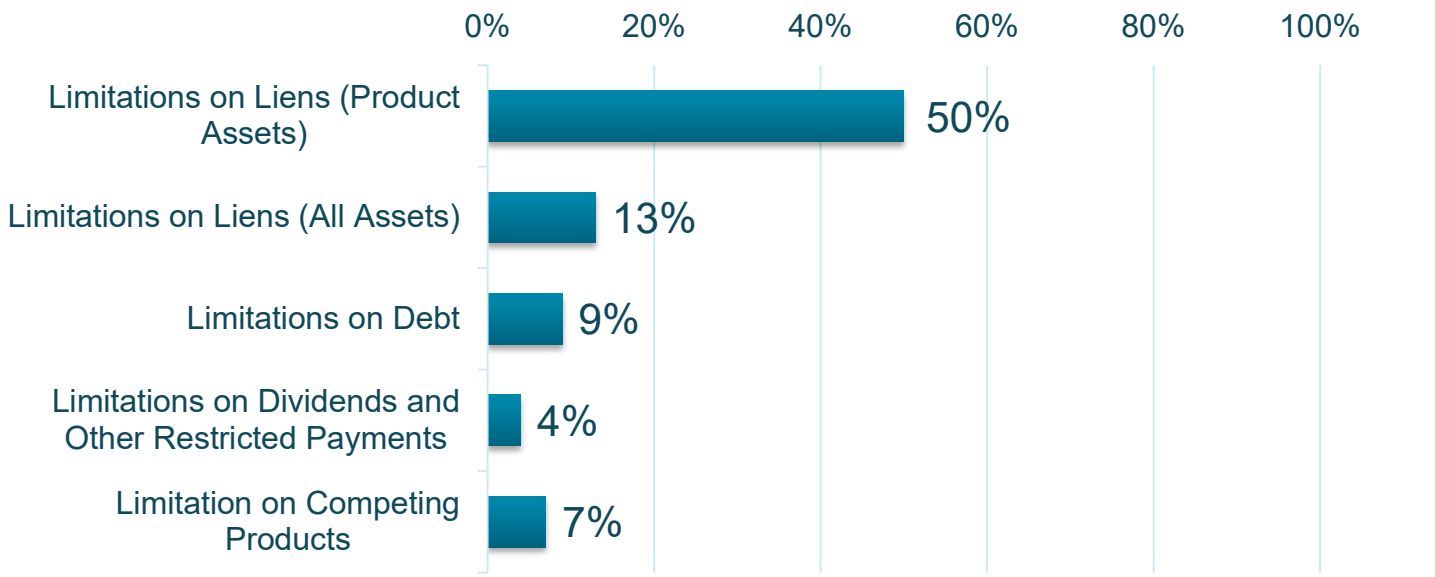
Key Finding

A majority of transactions involved an underlying licensing arrangement in which the seller licensed patents to a licensee, who is then responsible for paying royalties. The alternative scenario – in which patents were sold, rather than licensed – is more complex, and introduces a risk, in particular where the royalty payor is less credit-worthy, that in a bankruptcy of the royalty payor, the royalty purchaser could be left with an unsecured claim of uncertain value.[3]

[2] We discuss this risk in the following article: https://www.cov.com/-/media/files/corporate/publications/2024/07/structuring-royalty-monetizations-bankruptcy-and-the-risk-of-contract.pdf

[3] We discuss this scenario in the following article: https://www.cov.com/-/media/files/corporate/publications/2023/06/royalty-rights-as-unsecured-claims--banking-law-journal.pdf

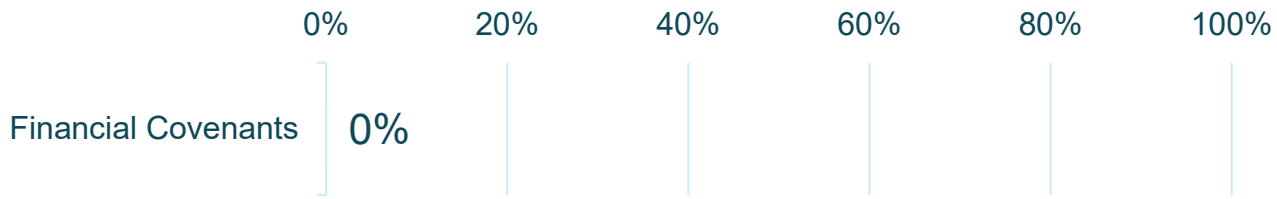
Negative Covenants



Key Finding

The negative covenant package for this type of transaction is generally very limited and less restrictive than would be the case in debt transactions or synthetic royalty financings, which reflects the investor's reliance on the royalty stream rather than the seller's ability to pay.

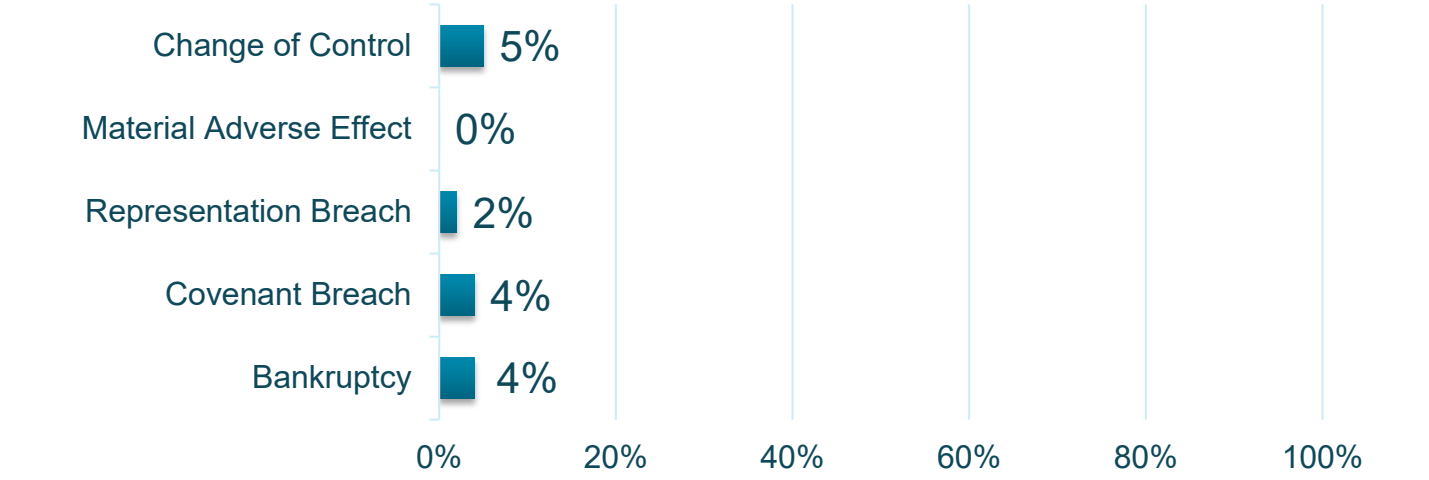
Financial Covenants



Key Finding

Financial covenants continue to not be included in these transactions, reflecting a focus on the royalty stream rather than the seller's ability to pay.

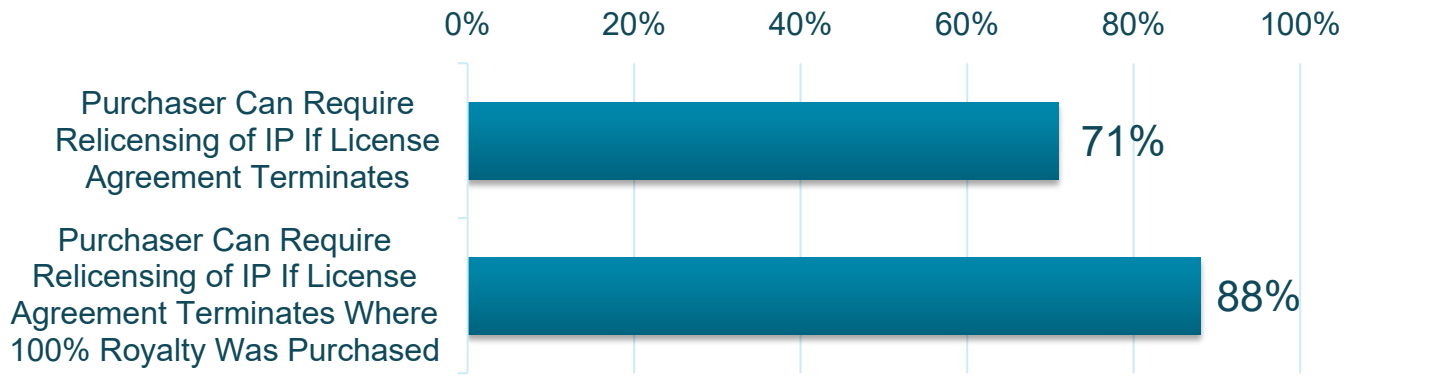
Investor Put Rights



Key Finding

As with negative covenant coverage, these transactions rarely included put rights (equivalent to customary events of default in debt deals). This again reflects the investor's reliance on the royalty stream rather than the seller's ability to pay.

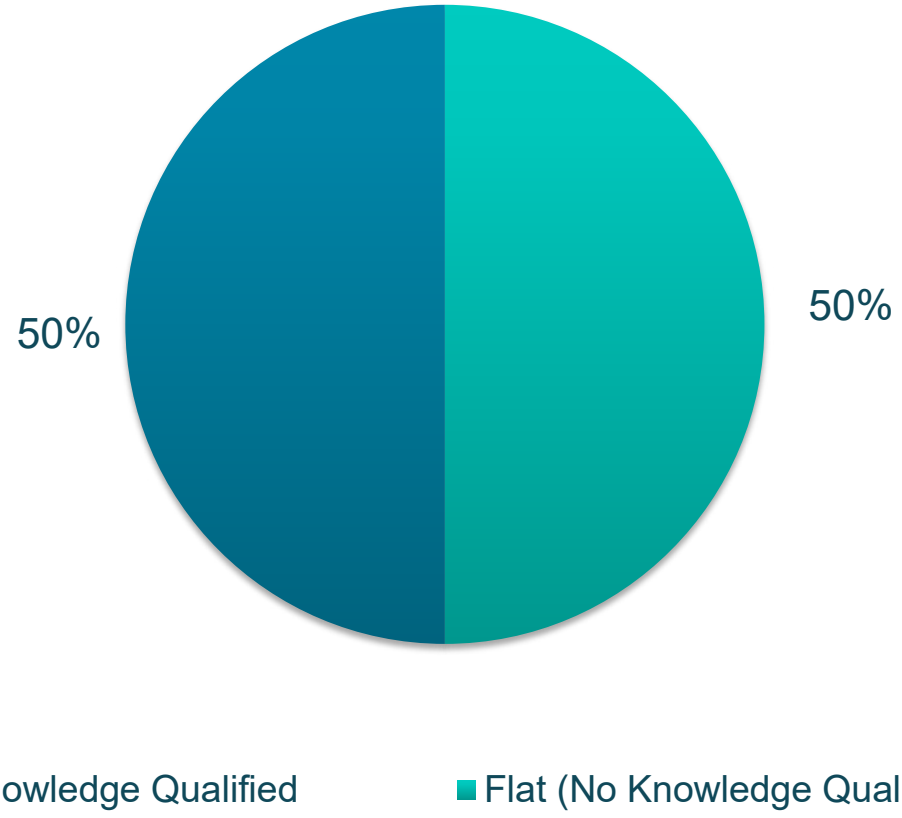
Obligation to Use Efforts to Replace License Agreement



Key Finding

Purchasers and sellers can have divergent incentives with respect to establishing a new licensing and royalty relationship if the original license agreement terminates, as the purchaser often has a much larger financial stake in the royalty stream. This is particularly the case where the seller has transferred the entirety of its future royalty stream to the purchaser, in which case purchasers look to contractual mechanisms to protect themselves.

Representation on Enforceability of License Agreements



Key Finding

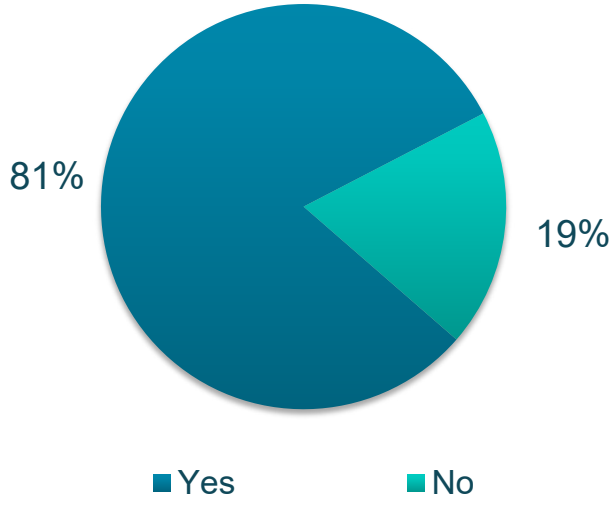
A central due diligence focus in a royalty monetization transactions is the license agreement, and its enforceability is a critical aspect of any such review. For example, intellectual property case law[4] has cast doubt on the enforceability of royalties on licenses of U.S. patents that remain constant after patent expiration.

From a buyer's perspective, the royalty stream is the purchased asset, and therefore the enforceability of this agreement is the bedrock of the royalty monetization. However, sellers often argue that they are no better placed than a buyer to make a final evaluation of enforceability against the royalty payor.

[4] *See Brulotte v. Thys Co., 379 U.S. 29 (1964) and Kimble v. Marvel Ent't LLC, 133 S. Ct. 2401 (2015).*

Indemnities

Indemnity Caps



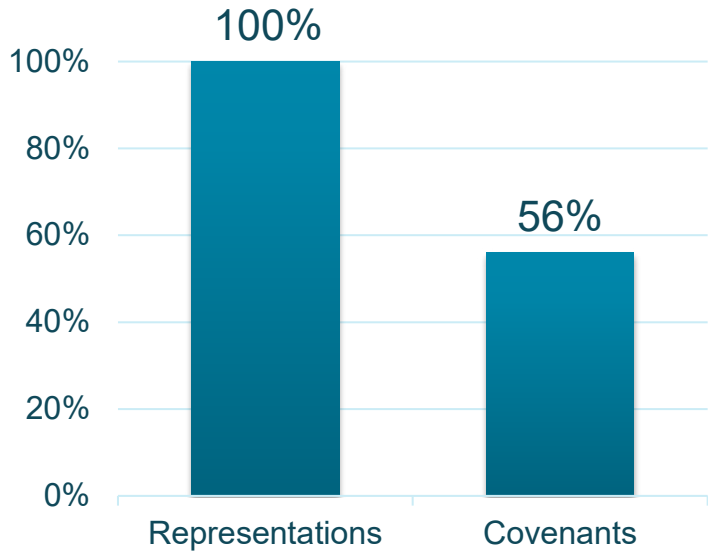
Lowest Cap
100%
of the Purchase Price Minus Royalties Received

Highest Cap
250/330%
(Depending on Type of Claim)
of the Purchase Price Minus Royalties Received

Key Finding

Most transactions under review included a cap on the indemnity obligations of the royalty seller in the event of a breach of the royalty purchase agreement. 100% of the purchase price minus royalties received was the most common cap, but there was some variation among transactions (including 100% of the purchase price minus royalties received after a certain number of years).

Indemnity Cap Scope



Key Finding

A majority of indemnity caps applied to both representations and covenants. That being said, the cap more commonly limited the seller's exposure on representations (where not all facts may be known and some degree of risk allocation may be appropriate), as opposed to covenants, which are more often in the control of the seller.

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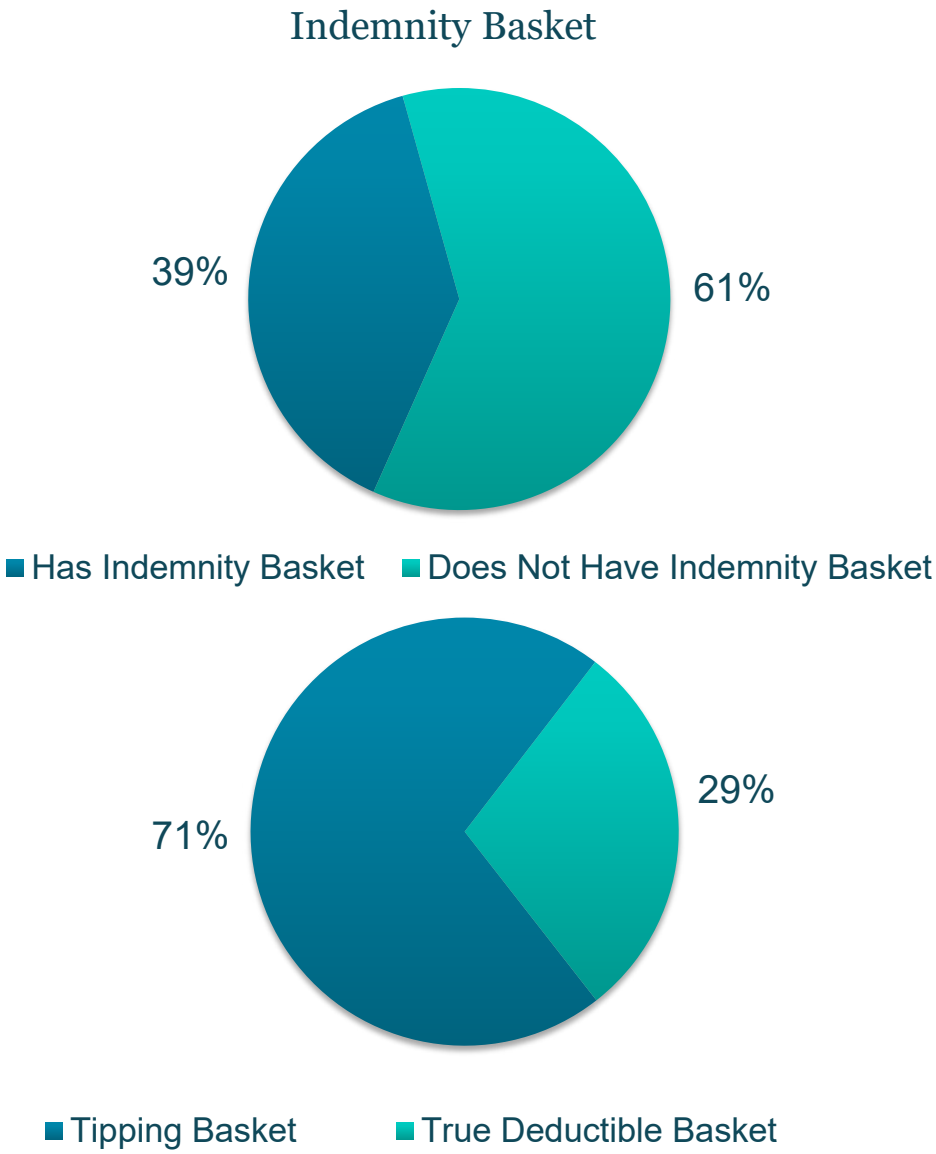
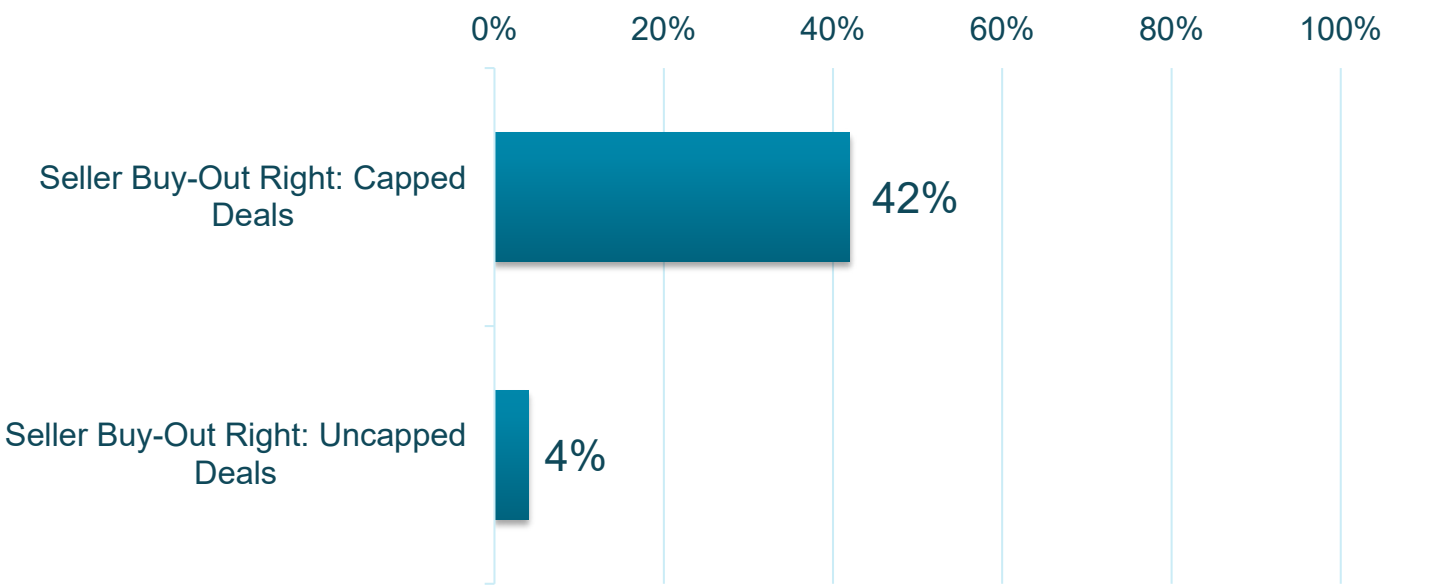
Indemnities



Key Finding

A significant minority of the deals under review included an aggregate monetary threshold below which an indemnity claim could not be made (the "indemnity basket"). In most transactions, once claims crossed that threshold, the entire set of claims would be indemnifiable (commonly referred to as a "tipping basket"), but some transactions deducted the threshold amount from the amount of the claims (commonly referred to as a "true deductible").

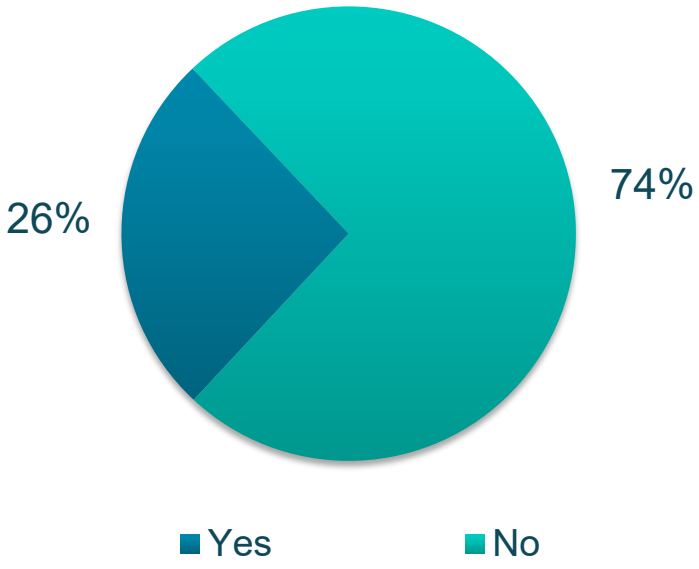
Seller Buy-Out Right



Key Finding

Given that capped transactions set a ceiling on returns, many of these deals included the ability for the issuer to pay a fixed amount and terminate the royalty monetization early. This flexibility is much less common for uncapped deals, where the upside potential for the investor is greater and a buyout price more difficult to calculate.

Royalty Payor Pays Buyer Expenses

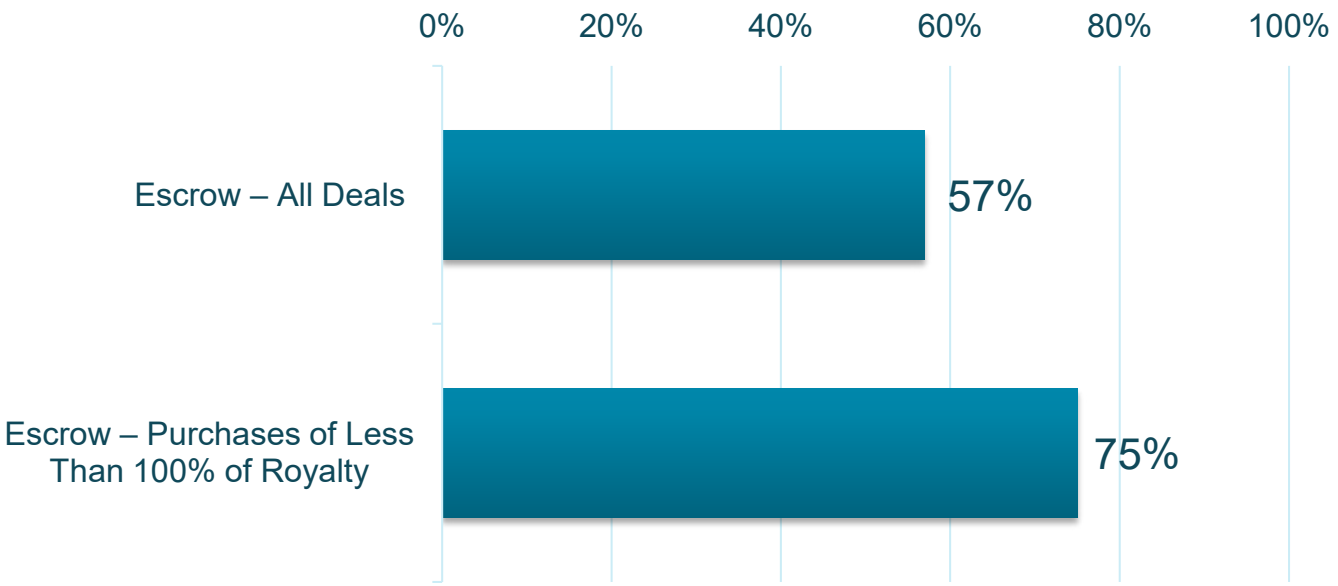


Key Finding

While present in a minority of deals, most transactions did not provide for reimbursement of buyer expenses, similar to most M&A transactions and differentiating these transactions from debt financings, in which borrowers typically pay lender expenses.

Second Annual Royalty Monetization Study 2019-2024

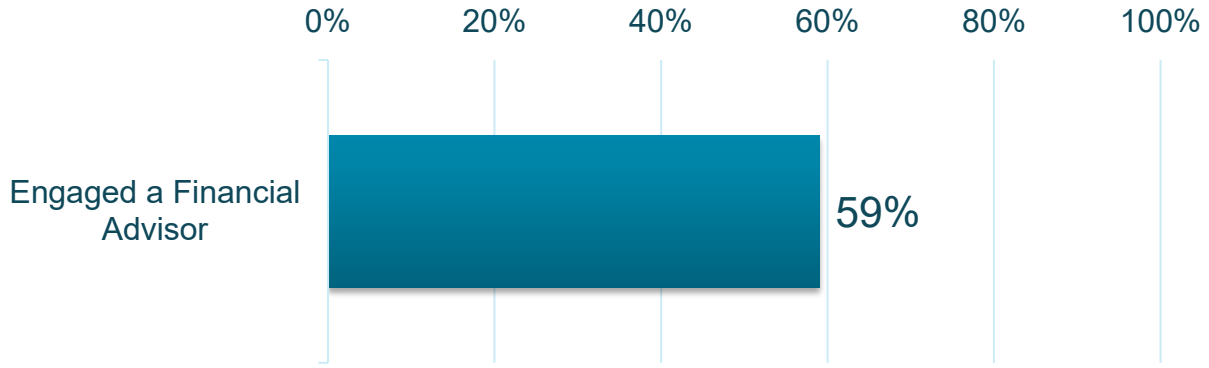
Escrow Account Structure



Key Finding

A majority of transactions reviewed included an escrow account structure into which the royalty payor would remit the purchased royalties rather than having payments made directly to the purchaser. These structures can be used in various circumstances, such as where a royalty payor may be unwilling to pay a purchaser directly, where a seller retained a portion of the royalty in question or where other payments to third parties need to be made from the royalty revenues.

Seller Engagement of Financial Advisors[5]



Seller Engagement of Financial Advisors[6]

2

Named Financial Advisors with Five or More Transactions

14

Named Financial Advisors with At Least One Transaction

Key Finding

Financial advisors can play a role in structuring royalty monetizations, as well as sourcing potential buyers and setting up a competitive dynamic. In most years under review, a majority of transactions used one. A small number of financial advisors are repeat players in this market, although recent years have witnessed a widening field.

[5] Includes instances in which seller engaged a financial advisor, but the identity of the financial advisor was not publicly disclosed.
[6] Joint representations counted as two or more individual representations.

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Financing Life Sciences

Debt, Royalty and Related Funding Structures

Structuring Royalty Monetizations

Bankruptcy and the Risk of Contract Rejection

A biotech company discovers a novel compound that could lead to a promising new drug. After several years of development, the company licenses patents on the compound to a pharmaceutical company for further development. In return, the pharmaceutical company agrees to pay royalties on sales of the product to the biotech company if the drug is successfully commercialized. The drug is approved and brought to market, performs well, and begins to generate royalties. In order to raise funds for its other activities, the biotech company sells the future royalty stream (a "royalty monetization") to a buyer in exchange for an upfront cash payment.

The biotech company that sold the royalty stream later files for bankruptcy protection. What happens to the royalty payments?

Scenario

- A biotech company sells a pharmaceutical royalty stream
- Later, the biotech company files for bankruptcy protection
- What happens to the royalty payments?

Ways to Limit the Risk of Rejection

- Use a bankruptcy remote SPV
- Take a security interest in the underlying IP
- Require an agreement with the licensee
- Ensure that critical ancillary assets and services will be available in bankruptcy
- Take an active role in any applicable bankruptcy case

Rise in Royalty Sales and Biotech Bankruptcies

Biotech companies had a difficult 2023, with fundraising proving to be a particular challenge. This has caused many companies to look for creative financing structures, including royalty monetizations.

The most important consideration for a purchaser in any royalty monetization is the future sales outlook for the licensed products. But following a record year for biotech

This article was first published in the July-August 2024 issue of *Pratt's Journal of Bankruptcy Law*

bankruptcies in 2023,[1] bankruptcy risk has come into focus as another potential concern, with two of those bankruptcy filings involving companies with royalty monetizations.[2]

Basic Royalty Monetization Structure

In its simplest form, a royalty monetization involves the sale by a licensor of its right to receive future royalty payments under a license agreement. In this structure, the buyer does not become a party to the license agreement, but instead simply purchases the right to those future payments.

The treatment of this structure in bankruptcy seems like it should be straightforward. During the course of the bankruptcy case, the biotech company will need to either "assume" or "reject" the license agreement.[3] If an agreement is "assumed", the agreement remains in effect and can be used in the reorganized business or assigned to a buyer in bankruptcy. If it is "rejected," the agreement is treated as having been breached by the debtor as of the date of the bankruptcy filing, and the licensor-debtor is no longer obligated to perform its obligations. Upon rejection of a license of "intellectual property," as defined in the Bankruptcy Code[4] the licensee can elect to either accept the rejection and assert a claim against the bankrupt company for any damages resulting from the rejection, or assert its rights under Section 365(n) of the Bankruptcy Code, which, in summary, allow it to continue to use the licensed intellectual property, as it existed on the date of the bankruptcy filing, so long as it continues to make required royalty payments.

Rejection Risk in the Basic Monetization Structure

At first glance, it appears that the royalty buyer in this basic monetization structure would continue to be paid the royalty payments by the licensee following the bankruptcy of the biotech company. If the license agreement is assumed, the licensee must continue to make royalty payments under the terms of the agreement; and if it is rejected and—crucially—the licensee elects to continue to use the licensed intellectual property, the licensee will be required to make royalty payments under Section 365(n). However, the situation may not always play out this way.

If a company sells its economic rights under a license agreement to a buyer and files for bankruptcy protection, it may no longer have a reason to continue the licensing and royalty sale transactions and decide to reject any applicable executory contracts. Assuming that the licensed intellectual property generates revenue for the licensee, you might expect the licensee to exercise its rights under Section 365(n). But consider what would happen if the licensee chooses not to do so, and instead proposes to purchase the underlying intellectual property from the company in exchange for up-front cash and/or future royalties. The licensee could obtain ownership of the intellectual property it needs to continue selling the licensed products, without having to rely on the imperfect protections of Section 365(n), and the company could raise additional cash to satisfy claims of its creditors.

1 Forty one biotech companies filed for bankruptcy protection in 2023, up from twenty in 2022 and nine in 2021. Kate Goodwin, Athersy Adds to Surge of Biotechs Filing for Bankruptcy, Sells to Healios, BioSpace (January 9, 2024), https://www.biospace.com/article/athersys-adds-to-surge-of-biotechs-filing-for-bankruptcy-sells-to-healios-/.

2 In re Athenex, Inc., et al., Case No. 23-90295 (Bankr. S.D. Tx.); In re Infinity Pharmaceuticals, Inc., et al., Case No. 23-11640 (Bankr. D. Del.). Athenex is discussed further below. The treatment of the royalty monetizations in the Infinity case is pending final resolution of that case.

3 Executory contracts are contracts under which both parties have material unperformed obligations. License agreements are typically executory contracts. Bankruptcy law gives the debtor broad discretion to determine whether to assume or reject an executory contract. As a general rule, if an executory contract provides an ongoing burden to the company that outweighs the benefits of the contract, it will be a good candidate for rejection.

4 Under Bankruptcy Code section 101(35A), "intellectual property" includes certain trade secrets, patents, patent applications, plant varieties, copyrights, and mask works.

This article was first published in the July-August 2024 issue of *Pratt's Journal of Bankruptcy Law*

Where does that leave the royalty monetization buyer? It purchased a right to royalties payable under the license agreement, but that license agreement has been rejected, with no further royalties payable to it. The buyer presumably has a significant claim against the bankruptcy estate related to its obligations under the royalty purchase agreement. But this claim will be unsecured, and if there are other significant creditors, an unsecured claim could be worth pennies on the dollar. Perhaps the buyer also has breach of contract, tortious interference, or some other type of claim against the licensee or the bankrupt company, but it faces potentially expensive litigation with no certainty that those claims will be resolved in its favor.

Athenex – SPV with Potential Rejection of Supply Agreement

An alternative to the basic structure outlined above involves the use of a bankruptcy-remote special purpose vehicle (SPV). In this structure, the biotech company transfers the license agreement and the underlying licensed patents to an SPV, which then sells the royalty stream under the license to the royalty buyer. The SPV structure separates the license and royalty stream from the bankruptcy risk of the company by removing ownership of the license and patents from the company, thus allowing the royalty monetization to operate on a stand-alone basis.

Complications can arise, however, when the separation of the royalty producing assets owned by the SPV is incomplete and a critical part of the licensing transaction remains subject to contract rejection, which happened in the Athenex bankruptcy case.

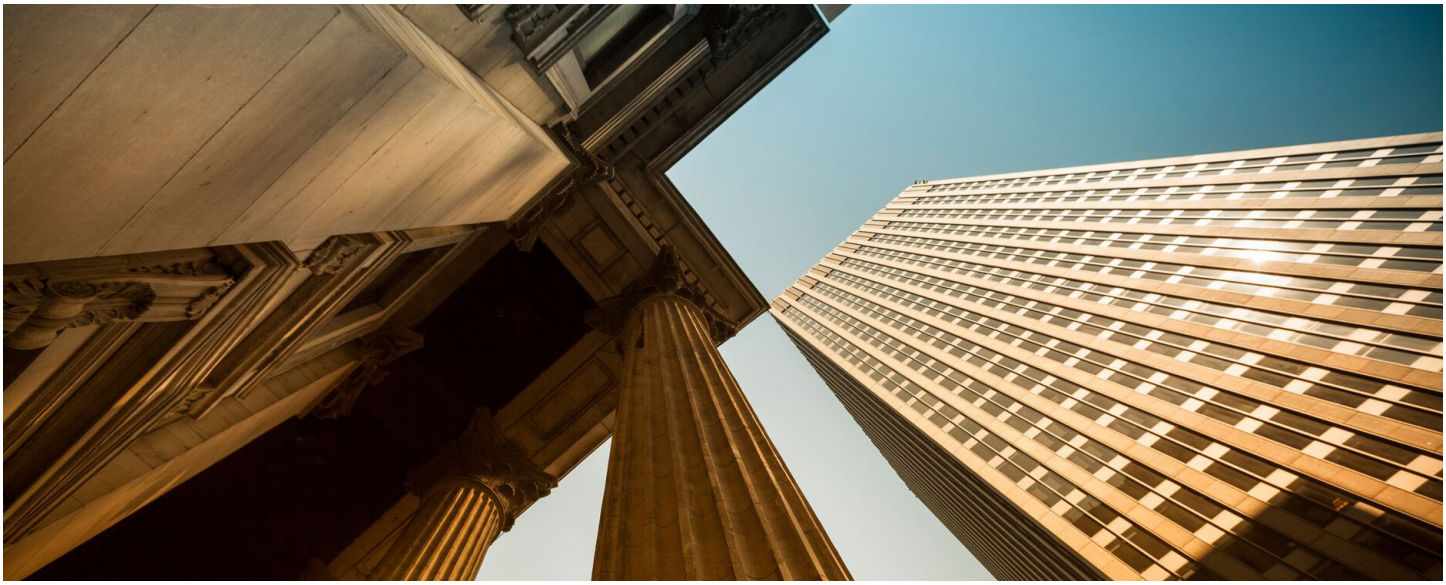
Athenex, a public biotech company, entered into an agreement in 2017 with a pharmaceutical company under which Athenex licensed the patent and other rights to a compound that would become the prescription drug Klisyri. Under a separate agreement (the "Supply Agreement"), Athenex agreed to provide the licensee with the active pharmaceutical ingredient ("API") for the drug. In turn, the licensee agreed to pay Athenex future royalties and milestone payments related to sales of Klisyri, and, under the Supply Agreement, to pay separate consideration for the API as purchased from time to time.[1]

Seeking to raise capital, Athenex sold its rights to certain royalty and milestone payments under the license agreement in 2022 to two investors (the "Klisyri Purchasers") for $85 million. To structure the royalty purchase, Athenex placed the license agreement, the underlying patents, and certain related assets into a bankruptcy-remote SPV that was jointly owned by Athenex and the Klisyri Purchasers. The SPV then sold the rights to the purchased royalty and milestone payments to the Klisyri Purchasers.[2]

1 See Debtors' Emergency Motion for Entry of an Order Approving Debtors' Entry into Global Settlement Agreement Relating to Athenex Pharma Solutions, LLC and Authorizing Actions Consistent Herewith, Dkt. No. 250 at ¶ 1.

2 Id. at ¶ 13.

This article was first published in the July-August 2024 issue of *Pratt's Journal of Bankruptcy Law*



Following the Klisyri royalty purchase, Athenex faced challenges related to drug approvals and suffered major cash-flow problems. In 2023, Athenex and certain affiliated companies filed for chapter 11 bankruptcy protection. Athenex, operating at a net loss under the Supply Agreement and having sold most of the Klisyri related economics to the Klisyri Purchasers, no longer had an economic incentive to continue the API supply. The Supply Agreement thus appeared to be a good candidate for rejection. But rejection would have cut off supply of Klisyri to the market, cut off the Klisyri Purchasers' access to royalty streams from the marketing and sale of Klisyri[1] and in turn exposed Athenex to indemnification claims by the Klisyri Purchasers.[2]

Rather than reject the Supply Agreement, Athenex, the licensee and the Klisyri Purchasers negotiated a settlement under which Athenex agreed to continue manufacturing the API for a short period of time, the licensee agreed to pay for existing inventory of API and the continued manufacturing activities, at a negotiated price that provided a profit to Athenex for its continued efforts, and the Klisyri Purchasers agreed to release funds from an escrow account that had been set up at the closing of the royalty purchase to pay for a future transfer of manufacturing obligations to a third party. The Klisyri Purchasers also agreed to waive their indemnification and all other claims against Athenex.[3]

Athenex illustrates a number of bankruptcy issues that could arise in royalty deals. First, the bankruptcy remote SPV structure was validated: the SPV did not become a party to the bankruptcy case, and as a result the license agreement, which had been placed in the SPV, remained in effect and was not subject to rejection by Athenex. Second, the case highlights the risk that royalty purchasers and third parties face when the economics of a license agreement are sold, but supply or other material obligations remain with the seller. The threat of losing supply of the Athenex API put the ongoing value of the royalty stream at risk. Because of that risk, the licensee and the Klisyri Purchasers had to provide funding to ensure the continued supply of the API. Finally, although Athenex involved the potential rejection of a supply agreement and not a licensing agreement, it is instructive to see how a bankrupt company will treat an agreement that it has no economic incentive to keep extant. From the Athenex debtor's point of view, the settlement deal allowed it to generate additional cash flow to the estate and eliminate substantial claims. Finally, the case illustrates the need to carefully assess the timeline for the transition of essential technology and manufacturing obligations from a licensor to a licensee. Any delay in that process could expose the licensee and royalty buyer to the insolvency risk of the licensor.

1 Id.

2 Id. at ¶ 2.

3 Id. at ¶ 3.

This article was first published in the July-August 2024 issue of *Pratt's Journal of Bankruptcy Law*

Takeaways

No one expects their contract counterparty to go bankrupt. But the current economic environment has illustrated the need for buyers, sellers and license counterparties to consider bankruptcy risks when negotiating and evaluating royalty monetization transactions. Fortunately, there are structures that can be used to mitigate against those risks in the appropriate circumstances.

Use a bankruptcy remote SPV. As we saw in Athenex, one of the best ways a buyer can protect against the risk of rejection of a license agreement is to place the agreement and underlying IP into a bankruptcy remote SPV. This can add time and complexity to the transaction, however, and must be permitted by the underlying commercial agreements.

Take a security interest in the underlying IP. Another potential avenue for protection is for the royalty purchaser to take a security interest in the underlying intellectual property. This will prevent the biotech company from transferring or licensing intellectual property after rejection of the related license and royalty agreements without adequate protection for the royalty purchaser.

Require contractual privity with the licensee. A buyer may be able to protect itself by requiring the seller to obtain the agreement of a licensee that it will continue to pay royalties to a buyer, even after the rejection of the license agreement in bankruptcy. But this may be difficult to achieve, because the licensee may not be willing to agree to the arrangement.

Ensure that critical ancillary assets and services can be used by the licensee. Commercial considerations will determine whether a licensee can obtain all of the supplies, technical know-how and other assets and services necessary to fully exploit the licensed IP. If possible within these commercial constraints, however, these ancillary assets and services should be transitioned to the licensee or a creditworthy third party.

Be prepared to take an active role in any licensor bankruptcy case. Bankruptcy cases can move quickly and result in relief that impairs other parties' rights with shortened notice and, in some instances, limited rights of appeal. A licensee or royalty buyer should monitor the licensor's financial situation to the extent possible and, if aware of a bankruptcy filing, seek the advice of bankruptcy counsel and be prepared to take an active role in the bankruptcy case in order preserve its rights.

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This article was first published in the July-August 2024 issue of *Pratt's Journal of Bankruptcy Law*

U.S. Court of Appeals for the Third Circuit Agrees with Lower Court:

Royalty Obligation Not Tied to Intellectual Property License Is a Dischargeable Unsecured Claim

A decision arising out of the Mallinckrodt plc bankruptcy cases[1] has broad implications for any transaction involving rights to future payment streams, including royalty or revenue interest financings and other deals with contingent or deferred payment rights. The *Mallinckrodt* court held that royalty payments to a seller of intellectual property were dischargeable unsecured claims in bankruptcy. That holding meant that the buyer could continue to sell the drug developed from the acquired IP during and upon emergence from bankruptcy without paying the seller its contractual share of the revenue. The seller was instead left with an unsecured claim to be paid pro rata out of the funds available to other unsecured creditors, with an estimated recovery on the claim of about 4%.

Key Points

- A court decision that has broad implications for any transaction involving rights to future payment streams, including royalty or revenue interest financings and other deals with contingent or deferred payment rights.
- The U.S. Court of Appeals for the Third Circuit decisions

Circuit Court Ruling

The U.S. Court of Appeals for the Third Circuit recently affirmed the decision of the *Mallinckrodt* district court.[2] The crux of the seller's argument on appeal was that Mallinckrodt's obligation to pay the seller royalties arose as the sales occurred and therefore had to be satisfied in real dollars going forward if Mallinckrodt wanted to continue to sell the drug.

1 Sanofi-Aventis U.S. LLC v. Mallinckrodt plc (In re Mallinckrodt), 646 F. Supp. 3d 565 (D. Del. 2022).

2 In re Mallinckrodt plc, – F. 4th – (3d Cir. 2024), Case No. 23-11112024 (April 25, 2024).

This article was first published in the November 2024 issue of *Pratt's Journal of Bankruptcy Law*

Largely adopting the reasoning of the lower courts, the Third Circuit held that the debtor's obligation to make the royalty payments, "like most contract claims," arose when the parties signed the agreement: "Once the parties agree to a contingent right to payment, the claim exists. And once the claim exists, bankruptcy can reach it."

The court of appeals noted, like the district court, that the seller could have protected its claim, and it ended with words of warning for creditors contemplating similar deal structures:

- To protect itself, [the seller] could have structured the deal differently. It could have licensed the rights to the drug, kept a security interest in the intellectual property, or set up a joint venture to keep part ownership
- Bankruptcy frees debtors from lingering claims like this one. [The seller] kept no property or security interest in Acthar Gel, but only a contractual right to a royalty. Because that contingent claim arose before Mallinckrodt went bankrupt, it is dischargeable in bankruptcy.

Conclusion

The outcome in the *Mallinckrodt* cases throws in sharp relief the difference between deal structures that are wholly unsecured – and thus exposed to the bankruptcy risk of the buyer – and other structures, such as out-licensing or secured transactions, that offer more favorable downside protection.

It is worth noting that it appears that no unsecured synthetic royalty financings by public biotech companies have hit the market since the *Mallinckrodt* district court decision came down in December 2022.

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This article was first published in the November 2024 issue of *Pratt's Journal of Bankruptcy Law*

Royalty Rights as Unsecured Claims:

The Relevance of *Mallinckrodt* to M&A, Revenue or Royalty Interest Financings, and Other Transactions Involving Future Payment Streams

A recent decision from the Chapter 11 case of Mallinckrodt plc illustrates the material downside risk that a seller faces when it receives consideration in the form of future payment rights. Although the *Mallinckrodt* case only directly addresses the treatment of royalty rights under an asset purchase agreement for IP, the holding is relevant for any deal structure in which a party bargains for a right to receive future payments. The outcome in *Mallinckrodt* throws in sharp relief the difference between deal structures that are wholly unsecured –and thus exposed to the bankruptcy risk of the buyer – and other structures, such as out-licensing or secured transactions, that offer more favorable downside protection.

Takeaways

- The *Mallinckrodt* decision highlights the bankruptcy issues that an investor needs to assess as it considers the value of an unsecured right to future royalty or other payments related to the development and sale of products backed by valuable IP.
- Contingent future payment rights could be considered dischargeable prepetition claims.
- A transfer of IP subject to contingent "royalty" rights will not vest any property rights in the seller unless the transaction documents expressly and legally provide for such a right.
- The buyer/owner of the IP post-bankruptcy may be able to continue to use and monetize the IP without making the required future payments.

Pre-bankruptcy Sale of the Acthar Gel IP

In 2001, sanofi-aventis U.S. LLC (Seller) entered into an asset purchase agreement (APA) with Mallinckrodt under which the Seller agreed to sell to Mallinckrodt intellectual property relating to Acthar Gel, a therapeutic product for the treatment of inflammatory and autoimmune conditions.

The purchase price for the Acthar Gel IP consisted of a $100,000 up-front payment plus annual royalty payments equal to 1% of all net sales of the product exceeding$10,000,000 in each year. The future royalty payments were unse

This article was first published in the June 2023 issue of *Pratt's Journal of Bankruptcy Law*

Mallinckrodt Bankruptcy

In addition to Acthar Gel, Mallinckrodt produced and distributed a wide variety of other products, including opioids. As with other drug manufacturers and distributors involved in the nationwide opioid crisis, Mallinckrodt was subject to widespread litigation and faced enormous liabilities. In October 2020, it filed for bankruptcy protection in the U.S. Bankruptcy Court for the District of Delaware to resolve these liabilities. In connection with the confirmation of Mallinckrodt's bankruptcy plan, the Seller made a number of arguments in an effort to retain the right to its future royalty payments. First, it filed a motion seeking a determination that the royalty payments due under the APA could not be discharged in bankruptcy. The Seller then claimed that its royalty claim should be considered a trade claim rather than an unsecured claim.[1] The bankruptcy court ruled against the Seller on all issues.

What Was at Stake: Value of the Royalty Rights

Sales of Acthar Gel generated royalty payments due to the Seller totaling approximately $71.4 million from 2014 to 2020, ranging from a low of about $7.8 million in 2020, to a high of almost $12 million in 2016.[2] The debtors' disclosure statement for the plan of reorganization included financial projections that showed a healthy continuing revenue stream from Acthar Gel sales, which constituted an important cash resource for the reorganized business.[3]

The Bankruptcy Discharge

One of the principal benefits for a debtor in a Chapter 11 case is the ability to discharge claims against the company that arose prior to the confirmation of a plan of reorganization. If a claim is discharged, the debtor is relieved of any post-bankruptcy liability on the claim and the creditor is barred from enforcing the claim against the debtor, and is limited to sharing on a pro rata basis in the assets that are available for distribution to similarly situated creditors in the bankruptcy case for recovery. The distribution to unsecured claimants often amounts to pennies on the dollar of the claim amounts. Indeed, under the Mallinckrodt plan, the estimated recovery for general unsecured creditors – the class that Seller's claim would fall into if its arguments failed – was estimated at around 4% of the allowed claim amount.[4] By contrast, trade creditors would receive 100% of their prepetition claim amounts.

The bankruptcy court justified this radically different treatment of unsecured creditors because Mallinckrodt continued to receive goods and services from the trade creditors that were essential to the reorganization plan.[5]

1 In re Mallinckrodt plc, 639 B.R. 837 (Bankr. D. Del. 2022) (Confirmation Opinion).

2 Order Approving Stipulation Between the Debtors and Sanofi-Aventis U.S. LLC Regarding Historical Royalty Amounts in Connection with Confirmation Hearing, Dkt. No. 5693.

3 Confirmation Opinion, 639 B.R. at 857.

4 Id. at 911, appx. 1 (estimated recoveries waterfall).

5 Id. at 856-58.

This article was first published in the June 2023 issue of *Pratt's Journal of Bankruptcy Law*

The bankruptcy court concluded that the Seller did not continue to supply any goods or services, or otherwise provide benefits, under the APA that could render it a trade creditor for plan purposes. To the contrary, because the debtor owned the Acthar Gel IP in full, it did not need the Seller's participation in any way to continue to monetize the property, and any royalty payments due to the Seller only burdened the debtor with future liabilities.[6]

The Royalty Claims Arose When the APA Was Executed

Bankruptcy court decisions are subject to review, in the first instance, by U.S. federal district courts, and the Seller appealed the rulings against it. The main question on appeal was whether the contingent royalty claims under the APA could in fact be discharged under the plan as proposed by the debtor.[7] The court held that under the applicable statutory provisions, "a contingent right to payment arising before the date of a plan's confirmation may be discharged by that confirmation."[8] Straightforward enough, but the more difficult question remained: when did the claims to future royalty payments – which related to sales that would continue for years after the confirmation date – arise?

Decisions from the U.S. Court of Appeals for the Third Circuit, which governed this dispute, have generally opted to give this question an "expansive treatment" that would maximize the types of claims subject to discharge.[9] In the context of contract claims, contingent claims are considered dischargeable prepetition claims if the claims referred to obligations that "will become due upon the happening of a future event that was within the actual or presumed contemplation of the parties" at the time of contracting.[10]

The Seller argued that the royalty payments did not constitute dischargeable contingent claims because they did not depend solely on extrinsic events over which the debtor had no control, but instead flowed from voluntary actions taken by the debtor – e.g., its decision whether to market and sell Acthar Gel at all, and if so under what conditions. The court rejected this proposed distinction, explaining that limiting dischargeable claims to those depending largely on the debtor's voluntary actions gave "far too narrow a construction to the word 'contingent.'"[11] The future royalty payments constituted a key feature of the purchase-price structure under the APA and were clearly in the contemplation of the parties when the APA was signed. Most importantly, the parties' rights and obligations became fixed at the time of the sale under the APA.

6 Id. at 857.

7 District court decision.

8 Id.

9 Id.

10 Id. (quoting Olin Corp. v. Riverwood Int'l Corp. (In re Manville Forest Products Corp.), 209 F.3d 125, 128-29 (2d Cir. 2000)).

11 Id.

This article was first published in the June 2023 issue of *Pratt's Journal of Bankruptcy Law*

At that time, Mallinckrodt acquired full title – rather than a license or some other lesser property right; in exchange the Seller received the contractual right to royalty payments, "and having done so, it assumed the risk of Mallinckrodt's creditworthiness."[12]

The Royalty Obligations Did Not Create Any Property Right of the Seller in the Transferred IP

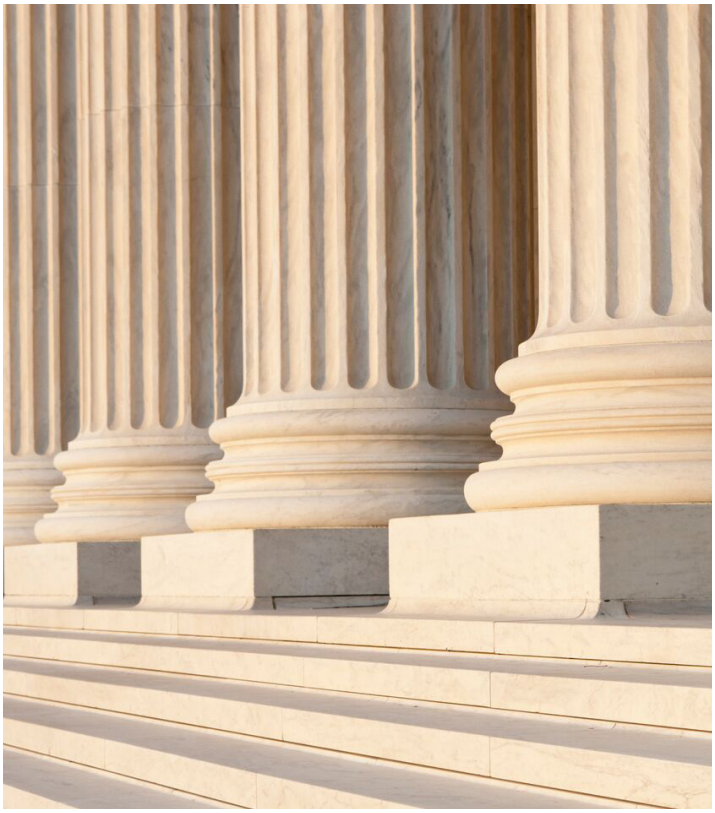
As an alternative, the Seller argued that by virtue of the royalty obligations it held a property right – as distinct from a contractual claim – in the Acthar Gel IP that could not be "discharged" by confirmation of the plan and thus continuing royalty payments were due so long as Mallinckrodt sold Acthar Gel. The Seller analogized the sale of intellectual property under the APA to sales and leases in the oil-and-gas context, in which the ownership and use of mineral rights may be (depending in large part on the treatment under state law) encumbered by royalty rights that are deemed covenants that "run with the land."[13] The court held that the "boilerplate" language that the Seller relied upon –a statement that the sale of the IP was "subject to" the terms and conditions of the APA – was only general language that could not be construed to override or conflict with the very specific terms of the APA. Specifically, it did not override the provisions that set out the structure of the purchase price, including the payment of royalties, and the exchange of that price in return for the full and unconditional ownership of the IP. There was thus no basis in the text of the APA that supported the purported property interest in favor of the Seller.

Unsecured Contingent Royalty Rights Would be Estimated to Fix the Claim Amount

The Seller only had an unsecured prepetition claim against the estate, but it still had the right to have the value of the entire future royalty stream valued for purposes of calculating its claim. How should it be valued? As the district court pointed out, the Bankruptcy Code expressly addresses this situation. Section 502(e) authorizes the bankruptcy court to "estimate" contingent or unliquidated claims for purposes of fixing distribution amounts under a plan. The court acknowledged that the estimation process "is certainly not certain," but the bankruptcy court could presumably extrapolate past sales to estimate the present value of the unsecured claim for future royalties.[14]

Appeal to Third Circuit

The Seller has appealed the district court's decision to the Third Circuit. Although this further appeal remains in its early stages, in its initial filings, the Seller identifies the issue on appeal as whether "a reorganized debtor's voluntary, post-confirmation conduct under a non-executory contract gives rise to a post-confirmation obligation that is not discharged under a Chapter 11 plan."[15]



12 Id.

13 Id.

14 Id.

15 See Appellant's Concise Summary of the Case, Dkt. No. 13, Case 23-1111 (3d Cir. Feb. 6, 2023). The Seller also asserts on appeal that the bankruptcy court entered an inconsistent ruling under the "law-of-the-case" doctrine because it had ruled that certain antitrust claims related to sale of Acthar Gel arose at the time of each sale, despite the anti-competitive conduct occurring prepetition.

This article was first published in the June 2023 issue of *Pratt's Journal of Bankruptcy Law*

The district court itself noted a couple of structuring points that could have led to a better outcome for the Seller.[16]

These points can be generalized to other transactions in which a contingent future payment right constitutes a material part of the exchange.

Secure the Claim. Take a security interest in the IP that was sold in order to secure the royalty payments. Even though the claim may still be discharged, the investor will have the right to the value of the IP collateral, rather than sharing pro rata with unsecured claimants in what is usually a limited pool of unencumbered assets.

Out-License. Retain ownership of the IP and grant a license that generates royalty payments. If the debtor wants to continue to use the IP, it generally will need to continue to make royalty payments.

Joint Venture or Similar Structure. Form a structure that allows the seller to retain part ownership of the assets while sharing some portion of the profits.

16 Id.

Each of these options, though, carries with it costs and limitations that may not comport with the business objectives in a given deal. The fundamental takeaway of the *Mallinckrodt* decision is that parties that enter into royalty or revenue interest financings, or other deals with contingent or similar deferred payment rights (whether styled as "royalty" payments or something else), need to work closely with knowledgeable counsel to understand the bankruptcy ramifications of various deal structures.

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This article was first published in the June 2023 issue of *Pratt's Journal of Bankruptcy Law*

PhaseBio – A Drug Development Financing (Almost) Tested in Bankruptcy

As 2022 drew to a close, a Delaware bankruptcy court approved a settlement between PhaseBio Pharmaceuticals and SFJ Pharmaceuticals over their ill-fated drug development financing partnership. This court approval ended a legal saga that began two years ago, when PhaseBio, a public biopharmaceutical company developing a novel drug to control bleeding in certain patients, entered into an agreement with SFJ, a company that finances and supports drug development, to fund up to $120 million to advance PhaseBio's pivotal Phase III trial for the drug. The dispute and settlement highlight some risks inherent in these deals, and how their structure may be treated in a bankruptcy proceeding. Drug development financing deals have been around for a number of years. But until now, the deals had eluded any notable challenge in bankruptcy court.

Key Points

- Drug Development Financings in Brief
- Background of the PhaseBio Dispute
- Order Approving Settlement
- Lessons Learned

Drug Development Financings in Brief

Drug development financings are one of the sources of capital available to biotechs and established pharmaceutical companies to help fund the time consuming and expensive clinical trial process necessary for the regulatory approval and launch of promising new medicines. In these deals, investors agree to provide capital for drug development in exchange for milestone and/or royalty payments that are earned in the event the drugs are ultimately approved for sale.

These are primarily financial arrangements, as compared to licensing and collaboration agreements, common in the life sciences industry, where intellectual property necessary for drug development is an integral part of the transactions. Given the risk taken in these deals for products still in clinical trials, the returns earned by investors for successful drugs generally range from two to five times, or more, of invested capital.

Background of the PhaseBio Dispute

In the PhaseBio case, SFJ provided $120 million of capital to PhaseBio in exchange for up to $600 million, payable in tranches once PhaseBio obtained approval to sell its product in relevant markets. This significant potential return on investment for SFJ suggests a high level of risk in the deal. To secure its promise to make the agreed milestone payments, PhaseBio provided SFJ with a perfected security interest in the intellectual property and other principal assets underlying the drug under development.

The PhaseBio arrangement had a couple of additional distinguishing features. The first one, which is somewhat unique for a transaction of this type, involved an obligation on the part of PhaseBio to transfer to SFJ the product and related assets upon SFJ's request if PhaseBio included a "going concern" footnote in its quarterly or annual financial statements or otherwise became unable to meet its obligations as they became due within the next 12 months, in each case subject to a 180-day cure period. In addition, the agreement provided that the data resulting from the clinical trial was to be owned by SFJ and transferred to PhaseBio only upon regulatory approval and the making of a milestone payment by PhaseBio.

This transfer right became effective as a result of an uncured going concern qualification issued when PhaseBio filed its 10-K on March 24, 2022. The parties attempted to negotiate a consensual transfer of the drug development program to SFJ when it became clear that the transfer right would be triggered. But PhaseBio appears to have sought terms different from those specified in the development agreement. When SFJ and PhaseBio could not come to an agreement, SFJ sent a demand to PhaseBio to transfer the program pursuant to the terms of their agreement, and then sued PhaseBio on October 7, 2022 in federal district court to enforce that demand. PhaseBio consequently filed for bankruptcy protection, with a plan to sell the drug under development (PhaseBio's principal asset) in a Section 363 sale, with a stalking horse bidder lined up to pay $40 million up-front with $60 million in potential milestone payments.

To facilitate this sale, PhaseBio commenced litigation[1] on an expedited schedule in the bankruptcy court seeking to recharacterize the drug development financing as an equity investment, and to declare SFJ's ownership of the trial data package invalid as a legal fiction. To support the recharacterization claim, PhaseBio pointed to the pure risk-capital nature of the investment, highlighting the five-times return SFJ could receive and the fact that SFJ would get *nothing* if the product was never approved. PhaseBio also noted the "never-before-tested" nature of this drug development structure in bankruptcy. For its part, SFJ argued[2] that the agreement between SFJ and PhaseBio was an arms-length, industry-standard pharmaceutical development agreement that gave certain bargained for rights to SFJ, secured by a perfected first priority security interest over substantially all of PhaseBio's assets. But, as compared to pharmaceutical licensing and collaboration agreements that include a license of intellectual property, the SFJ arrangement was primarily a financial accommodation, which made it more susceptible to challenge under applicable bankruptcy law.

Order Approving Settlement

On the last day of 2022, and after a court arranged mediation, the bankruptcy court issued an order[3] approving a settlement of the dispute between PhaseBio and SFJ on the following terms, pursuant to which SFJ obtained the assets it was seeking, but at a financial cost:

- The transfer of the drug under development and other program assets to SFJ, free and clear of all liens,
- The ownership by SFJ of the trial data package,
- Payment by SFJ of $32.9 million in cash, which will be used to pay the expense reimbursement of the stalking horse bidder, certain vendor payments and the costs necessary to wind down the chapter 11 estate, including the repayment of DIP facility entered into to finance the bankruptcy case,
- Payment by SFJ of up to $8.3 million in cash for certain other expenses, and
- Payment by SFJ to PhaseBio or its assignees of a royalty of 2.5% of worldwide net sales in excess of $300 million of products covered by the program.

Lessons Learned

Companies considering product development financing, and investors in those deals, can take-away a few lessons from the PhaseBio dispute and its ultimate resolution in bankruptcy:

- *Be Mindful of Financial and Other Covenants*. Careful attention should be given to any liquidity, financial or similar covenants, and other legal terms, that may be included in these deals. These terms can have significant consequences - in this case the going concern transfer right seems to have been a precipitating factor in the bankruptcy filing.
- *Consider the Importance of Perfected Security Interests*. Security interests over intellectual property and other product assets can be an important protection for investors. In this case, perfected security gave SFJ significant leverage in its fight to ultimately obtain control over the principal asset of the company.
- *Downside Often Plays Out in Bankruptcy Court*. The bankruptcy treatment of important legal terms needs to be considered. For example, unless the underlying contracts are assumed in the bankruptcy proceeding, material contractual rights (such as the right, in this case, of SFJ to a transfer of the program assets) will likely not be specifically enforced in bankruptcy.
- *Structure Matters*. There are a number of ways to raise capital, including equity, secured and unsecured debt, true royalty monetizations and synthetic royalty or drug development deals. A true royalty monetization, where there is an incoming future royalty stream from a creditworthy payor, can often be structured in a way to insulate the royalty purchaser from the risk of the development company's bankruptcy proceeding. The other structures, however, usually remain subject to significant bankruptcy risk, which can result in uncertain and expensive litigation for all parties, even those with first priority security interests over valuable assets. SFJ walked away with the asset that it believed it had a right to, but at a significant additional cost as compared to that specified in its drug development deal with PhaseBio.

With equity valuations down and fundraising for biotech companies a more difficult proposition than it has been for a number of years, we are seeing and expect to continue to see creative biotech financing structures in the coming year, and more biotech companies with structured deals who may be facing financial distress.

If you have any questions concerning the material discussed in this client alert, please contact members of our finance and bankruptcy practices.

Your Guide to Synthetic Drug Royalty Dealmaking

The process of discovering, developing and commercialising pharmaceutical innovations requires significant financial investment. After years of buoyant market conditions for biotech companies, capital for these activities has become scarcer, with the cost of debt and equity financing at multi-year highs when it is available at all. Companies with products currently or imminently in the market are increasingly turning to a new intellectual property-driven form of financing that, unlike many other forms of investment, is non-dilutive to equity, does not require stable earnings, and provides those companies with operational control over their drug development and commercialisation activities: synthetic royalty monetisations.

What is a Synthetic Royalty Monetisation?

If you've ever watched Canadian entrepreneur 'Mr. Wonderful' offer up a royalty deal on Shark Tank, you'll recognise the basics of a synthetic royalty monetisation. These transactions focus on the sale by a company of a portion of the net sales of one or more of its products, typically protected by patent and/or regulatory exclusivity. The "synthetic royalty" is the seller's obligation to make payments, typically quarterly, based on net sales of the relevant products in exchange for an upfront payment and, sometimes, future milestone payments. These transactions can best be described by how they differ from other products. Synthetics differ from debt financings based on the

Key Points

- Synthetic royalty sales increasingly popular way to monetise pharma innovations
- Having the right IP is crucial to securing this form of investment
- Several pitfalls must be avoided

This article was first published in iam-media.com on November 2022

absence of fixed interest and principal payments and their focus on a single product or set of products as a source of payment and covenant protection. They diverge from traditional royalty monetisations, which involve the sale of a third-party royalty stream payable to the seller, in not requiring a pre-existing incoming royalty stream. In contrast to out-licensing transactions, synthetics allow the seller to retain control over intellectual property and the commercialisation of their products. And, of course, synthetics differ from equity financings in that they are non-dilutive to existing equity and instead include a contractual obligation to make specified payments.

Key Ingredients for Royalty Deals

Financial Terms

The most important feature of a synthetic royalty is the royalty rate. The rate is often determined in a manner that will allow the purchaser to receive its principal and a reasonable return within a specified period of time, often five to eight years. Royalty rates are commonly in the middle single digits, and rarely go into double digits. Synthetic royalties may be capped, where payment obligations cease upon the purchaser receiving an agreed cumulative return, sometimes by a specified date. If revenue payments to the purchaser do not reach the level by that date, the cap level may increase. For marketed products, the caps are often in the range of 1.5 to 2.0 times the invested capital. For synthetic royalties on products that are not yet approved, caps can be 3.5 times or higher. A purchaser may also require top-up payments, which serve as a floor for its return, in the event it has not received a baseline amount, often equal to the invested capital, by a specified date. The purchaser may also seek 'put' rights to require immediate payment of an agreed return upon the occurrence of certain specified events. These put events are often triggered by bankruptcy and change of control, but can also be triggered by breaches of the synthetic royalty agreement. For its part, a seller may have a call right, which enables them to discharge their payment obligations by paying a pre-agreed buy-out price, typically at the same level as the purchaser put price.

Intellectual Property

The value and certainty of a seller's intellectual property portfolio factor significantly into the viability and economic terms of any synthetic royalty monetisation transaction. We have outlined above a number of transaction terms – from collateral grants to restrictive covenants – that protect the purchaser's interest in that intellectual property. These transactions can be concluded on the basis of revenues from an array of patent-protected products, and those patents can include compound, formulation or method of use patents, among others. Purchasers are typically most interested in US intellectual property given the importance of the American pharmaceutical market for the sales and profitability of patent protected products, but other markets, such as the European Union and Japan, are also often included.

Sellers would be advised to prepare for a potential synthetic royalty monetisation by "cleaning house" and ensuring their patents are properly assigned and (as much as possible) not subject to challenge. A purchaser's intellectual property diligence will typically focus on the ability of the subject patents to survive challenge, both in US federal court and in front of the US Patent and Trademark Office. They will be particularly concerned about the potential for generic product entry during the time horizon through which a purchaser expects to receive its desired return. Purchasers will in turn determine that time horizon on the basis of the original expiry date of the patents (taking into account the likelihood of any patent term extension) and the risks outlined above. Due to the uncertainty involved in any adversarial proceedings, pending patent challenges would make completing a synthetic royalty transaction quite challenging.

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Collateral

Depending on seller creditworthiness, synthetics may be secured or unsecured to support the payment obligations at issue. The collateral, when included, is typically limited to the specific accounts receivable, intellectual property and other assets related to the products generating the royalty payments, although it could include other assets of the seller, and could also just include a promise that the seller will not provide those underlying assets as collateral to anyone else. Many synthetics also purport to be structured as a "true sale" of the revenue stream at issue – which we address further as part of bankruptcy considerations below with the investor taking the position that in a seller bankruptcy they will continue to "own" that revenue stream.

Covenants

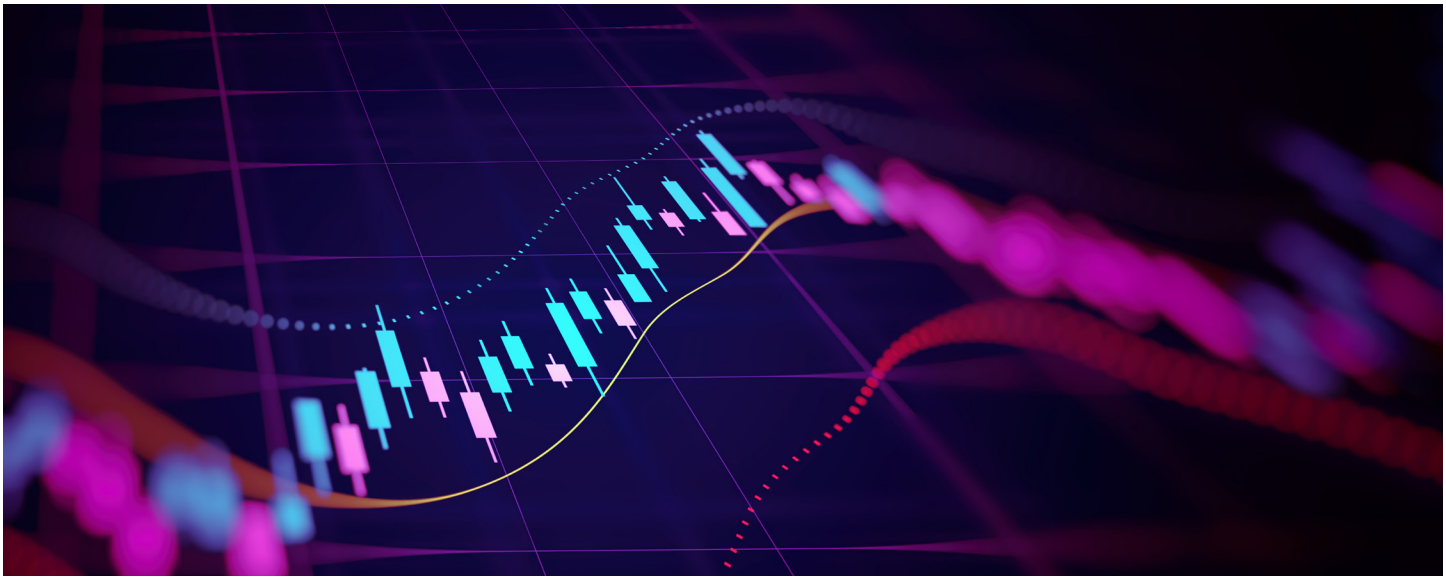
As noted above, synthetics tend to have a more limited set of restrictive covenants than would typically be included in a biotech debt financing. Affirmative covenants often focus on the operations of the seller with respect to the commercialisation of the relevant products, including reporting, revenue payments, inspections and audits, the prosecution and enforcement of relevant intellectual property, notice of in-licences and out-licences, use of proceeds, tax and other regulatory matters. Negative covenants often concentrate on protecting the purchaser's right to net sales payments through restrictions on sales and licences of, and liens on, product assets. However, purchasers also sometimes seek restrictions on overall business operations, including limitations on debt, liens, dividends and asset sales, in particular where there may be concerns over the seller's creditworthiness. As one of the most attractive features of synthetic royalty financings is their variable financial obligations, tied to net sales of the relevant products, synthetics rarely include financial covenants, as those would be inconsistent with the financial flexibility companies seek in the synthetic royalty market.

Avoiding Pitfalls

In considering a synthetic royalty transaction, companies should take heed of a number of traps for the unwary. As terms continue to evolve, there is not a definitive market standard for a number of these features. Synthetic royalties are often designed for the particular requirements of the seller, and given this broad palette of terms, there will likely remain a need to examine the particular features of each transaction closely to determine how it fits within the analyses below.

Intercreditor

Synthetics would normally be considered by creditors as debt obligations of the seller, and therefore would require consents from any existing lenders to the seller. In addition, if both the seller's existing debt and the synthetic are secured, the parties would need to establish an intercreditor agreement outlining respective rights and obligations, in particular with respect to the relevant product assets, which frequently secure both the synthetic royalty interest and the other debt. The parties would need to consider carefully and negotiate the recovery that the synthetic purchaser would obtain in a foreclosure or bankruptcy sale of the product assets and the treatment of the rights of synthetic holders in bankruptcy reorganisations that do not maintain the synthetic purchaser's interest in future revenue payments.



This article was first published in iam-media.com
on November 2022

Bankruptcy

A number of questions arise from the bankruptcy of a synthetic royalty seller. Given the relatively new nature of these transactions, many of these questions have yet to be considered by bankruptcy courts.

True Sale

In a seller bankruptcy, any enforcement of collection actions would be stayed upon the filing of the case under the "automatic stay" provisions of the Bankruptcy Code. One benefit of structuring a traditional royalty monetisation transaction as a true sale, rather than a loan, is that it removes the financial asset from the seller's estate, avoiding the automatic stay and allowing the purchaser to continue collecting payments. Whether a transaction qualifies as a true sale for bankruptcy purposes requires a fact-intensive analysis of terms and structure. Under prevailing true sale standards, many common features of synthetics, including the structure of the transaction itself, which is in effect the purchase of portion of a company's future revenues, may weigh against true sale treatment. Other features, such as top-up payments, put rights, and other types of recourse to recover a guaranteed return amount, also suggest a financial asset rather than a true sale.

Intellectual Property Licence Rights

One material difference between the traditional royalty monetisation structure and a synthetic structure is the treatment in bankruptcy of the payment stream generated by the intellectual property that anchors the royalty interest. In the traditional structure, a third-party licensee exploits the intellectual property and is obliged to make the assigned royalty payments. In a bankruptcy of the seller in such a case, the seller may "reject" the underlying licence agreement, but under special protections granted to licensees under the Bankruptcy Code, the licensee has the right to retain the licence so long as it continues to make royalty payments. This serves to provide significant protection to the assignee. In a synthetic deal, the synthetic purchaser does not have the benefit of those special intellectual property protections. As a result, a bankrupt seller could reorganise or sell the underlying intellectual property, leaving the synthetic purchaser with a bankruptcy claim but no ongoing rights to royalty payments.

Secured Claim

In a synthetic that is secured, the purchaser will retain its rights under any perfected security interest in its collateral. For this reason, many synthetic investors will seek collateral, such as patents and other product assets, in addition to the royalty stream itself. As a secured creditor, the purchaser has the right to either retain its collateral or to be paid the value of the collateral; it will also have consent rights with respect to dispositions of the collateral in bankruptcy. This collateral protection is subject to a material caveat: the Bankruptcy Code invalidates most "after-acquired property" clauses, which means that the synthetic purchaser's security interest may not extend to revenue arising after the date of bankruptcy filing.

Claim Amount

Determining the total amount a synthetic purchaser would be entitled to recover in a bankruptcy of the seller poses a challenge, because of the variable nature of required payments in synthetic royalty transactions. In debt transactions, the Bankruptcy Code generally makes allowance for the full principal amount that would have been due at maturity, plus any interest accrued and unpaid through the date of the bankruptcy filing. Contingent payment obligations are estimated and discounted to present value as of the filing date. Finally, prepayment and other premiums may be allowable in bankruptcy as "liquidated damages" depending on the particular facts and circumstances. Synthetic royalty obligations do not fit neatly within these recognised categories. For example, the initial investment amount could be characterised as principal if there is an obligation to repay. On the other hand, if there is no obligation to repay, all of the seller's obligations could be considered contingent. A possible strategy to maximise the claim amount would therefore be to bolster the right of the buyer to recover its investment and a reasonable return, whether through top-up payments, automatic put/acceleration rights or similar fixed payments triggered upon default.

This article was first published in iam-media.com
on November 2022

Bankruptcy Remote Structures

In a structured financing, insolvency risk may be mitigated by isolating key assets in an entity that is legally and operationally separate. Although not currently a common feature in the market, this structure could apply to a synthetic royalty transaction and mitigate the risk described above. Many companies house their intellectual property in a subsidiary separate from the legal entities that commercialise the relevant product. This subsidiary could act as the seller in a synthetic deal, enter into a licence agreement with the operating company, and royalty payments under the licence agreement would fund payments under the synthetic deal. But this structure could be subject to challenge, particularly if the subsidiary is solely formed to enter into the financing.

Accounting

The accounting treatment of synthetics is not an exact science, and we are not experts in accounting. However, market practice shows that synthetics are normally treated as balance sheet liabilities rather than sale transactions for accounting purposes. This accounting treatment does not seem to be problematic for smaller biotech companies, as they are not often valued on traditional earnings per share metrics, but we have seen this as an impediment to these transactions for larger public companies, given the balance sheet and related income statement impact.

Tax

There is no single unique US federal income tax treatment covering synthetic royalty monetisations. From the seller's perspective, the question is whether income is recognised at the outset when the purchaser advances the upfront payment (as a sale of the underlying revenue stream), or whether it is recognised over time as income from sales is realised (generally, as debt). Where the transaction is treated as a sale of a revenue stream, the seller generally should not be treated as selling property but rather as accelerating a portion of its income from the sale of the related products. As a result, the upfront payment would give rise to income to the seller when received. Certain features of synthetic royalty monetisation such as a cap, put rights or top-up payments, however, may point towards debt treatment. Under this characterisation, the purchaser's payments are treated as funds advanced in exchange for the issuance of a debt instrument. Accordingly, the seller would not recognise income on receipt of the upfront payment, but instead would include the revenue stream subject to the monetisation transaction in its gross income as it is received, and would accrue interest expense in respect to the synthetic royalty monetisation transaction. Limitations on the deductibility of interest expense may be relevant in this case. Because of uncertainty regarding the timing of payments to the purchaser, the yield to maturity of the instrument usually cannot be ascertained at the time of issuance, and the transaction may be within the scope of complex rules governing interest accruals for contingent payment debt instruments. And, finally, non-US tax implications will need to be considered, if relevant.

Becoming more mainstream

Over the past few years, synthetic royalty monetisations have evolved from a little-known niche product to an increasingly popular financing option with its own market dynamics. As the practice continues to evolve, keeping the issues highlighted above in mind will help buyers and sellers ensure the structure is used to its full potential.

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This article was first published in iam-media.com
on November 2022