Your guide to synthetic drug royalty dealmaking

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- **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**

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 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.

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.

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.

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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