

Securitization of Pharmaceutical Royalties: A Prescription for Market Growth

Securitization techniques have been increasingly used in less traditional financings involving a wide variety of asset classes. Royalties generated by intellectual property (IP) assets are a class of securitization that has exhibited particularly robust growth over the past several years.

Like the rest of the securitization industry, royalty-based securitizations suffered a period of retrenchment following the collapse of the credit markets in 2008 and 2009. However, with the return of some degree of normalcy to the financial markets, royalty-based securitizations have staged something of a comeback, with both single-asset and diversified structures returning to the market.

Although a substantial number of media IP-related securitizations have been completed and the asset class appears to be increasingly popular for investors, securitizations related to pharmaceutical royalties have followed a more uneven trajectory. While there have been a relatively large number of single-asset securitizations of pharmaceutical royalty streams, these structures, as compared to diversified asset pools, involve more limited deal sizes and greater exposure to problems related to the underlying patented technology. As an example of the latter, BioPharma Royalty Trust completed a single-asset securitization in 2000 relating to the HIV drug Zerit; soon after closing, poor sales figures of Zerit led to collection shortfalls that put the securitization into early amortization. On the other hand, despite offering greater structural stability, there have been relatively few securitizations based on diversified pools of pharmaceutical patent royalties. The BioPharma Royalty Trust,

the Royalty Pharma Trust, Paul Capital's Royalty Securitization Trust and the DRI Capital Inc. transactions are the best-known examples of this type of securitization. It is estimated that global pharmaceutical sales in 2009 were as high as US\$800 billion; the licensing of patented technology is estimated to generate annual royalties in excess of US\$100 billion. A wide variety of categories of entities and individuals own the rights to these royalties, including major pharmaceutical companies, public institutions, small biotech companies and individual inventors. Given the size and growth potential of this dynamic sector and the significant financing and capital needs of the various entities owning these "drug royalty rights," securitization should be more widely considered as a financing vehicle.

Securitizing a patent royalty stream is, in the abstract sense, very similar to securitizing any other type of asset. However, in practice, the securitization of royalty payment rights presents a number of unusual challenges, increasing both the cost and relative risk of the transaction. These challenges include a variety of legal considerations such as the impact of state, federal and foreign statutes and regulations upon the asset's underlying value; complex and expensive due diligence processes to determine the nature of the asset; and

bankruptcy concerns that are unique to these types of transactions.

Pharmaceutical Royalty Rights and Asset Characteristics

Strong demand and increasing growth make the pharmaceutical industry a robust and dynamic market sector which is highly attractive to investors. Available information indicates significant growth in research and development (R&D) investment by pharmaceutical companies. Pharmaceutical companies develop technology for new drugs by internal R&D and also acquire such technologies from third parties by means of direct acquisition or licensing of IP. The licensing of IP rights creates the receivables, the royalty payments to the third parties based on sales of the drug products, which can be securitized. Public and private institutions, research companies and individual inventors are representative of third-party licensors entitled to the royalty rights. In the previously referenced BioPharma Royalty Trust transaction, a portion of the rights to royalties that Yale University received from a large pharmaceutical company relating to the sale of Zerit were securitized. In connection with this securitization, Yale received more than US\$100 million in respect of its royalty payment rights.

Regulatory Hurdles and Product Liability Issues

Royalties are typically based on the sales revenue of the patented pharmaceutical product, therefore, any change in regulatory oversight or the litigation environment may significantly impact the value of the royalty payment rights being securitized. Government regulation by the United States and other countries is a significant factor in the production, marketing and sale of the patented pharmaceutical related to the royalty payment rights. In the United States, the Food and Drug Administration (FDA) subjects approved drugs and their manufacturers to a continuing and ongoing review and discovery process. The identification of previously unknown problems with a given drug, or with the failure of the manufacturer of that drug to adhere to manufacturing or quality control requirements, may result in further restrictions on the manufacture, sale or use of that drug. In certain instances, the FDA may mandate the withdrawal of a problematic drug from the market.

In addition to regulatory restrictions, previously unknown problems with a drug may result in costly product liability suits. Such lawsuits are not uncommon; in the past five years there have been a number of voluntary or mandated withdrawals of pharmaceutical products from the market by several major pharmaceutical companies. Even in situations where a product liability claim against the manufacturer of a particular drug does not result in the drug's withdrawal from the market, the impact of the costs of such litigation may, nonetheless, significantly decrease the value of any associated royalty payment rights. Accordingly, a securitization vehicle, particularly one in a single-asset securitization, which is dependent upon the revenues generated by royalty payment rights, will likely be adversely affected if the underlying drug is the subject of lawsuits, regulatory restrictions or a withdrawal from the market.

Legal and Regulatory Challenges Posed by Generic Pharmaceutical Manufacturers

The licensing of IP generally forms the basis for the drug royalty payment rights that may be securitized. The licensed IP is typically represented by one or more patents. In the United States, the U.S. Patent and Trademark Office is the regulatory agency that grants patents which permit the patent holders to assert their rights to exclude others from making, using or selling the patented invention or process. In 1995, the term for most types of patents was extended. Prior to the 1995 extension of the patent protection period, a patent was typically in effect 17 years from its date of issue. Patents issued after June 8, 1995 generally have a 20-year life from the initial filing of the patent application. Because patents are typically obtained before the patented products are approved for marketing and sale by regulatory entities such as the Food and Drug Administration (FDA), Congress enacted legislation permitting the extension of certain patent lives in consideration of the marketing time lost while awaiting government approval. This extension period cannot be greater than five years (or such period as would effectively permit a marketing period of more than 14 years).

Regulatory Data Exclusivity Periods

FDA approval for a new drug application (NDA) or a biologics license application (BLA) is required to market a new drug or biologic in the United States. Market exclusivity may be accorded by the FDA for some period

of time, which is commonly termed the data exclusivity period, for a new drug or biologic. This data exclusivity period is independent of, and may be in addition to, any patent-related market protection. There are five distinct forms of data exclusivity that may be accorded by the FDA. The first type of data exclusivity is Orphan Product exclusivity, which is a seven-year data exclusivity period during which the FDA is precluded from granting approval for any other applications for the same drug or biologic for the given orphan indication. Orphan indications include diseases considered rare in the United States (afflicting fewer than 200,000 Americans), or which provide no reasonable expectation that the costs of development can be recouped through product sales. New Molecular Entity exclusivity (NME) is a five-year data exclusivity period during which the FDA is precluded from granting approval for a generic drug when the original drug was a molecular entity. This form of data exclusivity is not currently available for biologics. Other exclusivity is a three-year data exclusivity period for a change (a supplement which requires additional clinical trials). Pediatric exclusivity is six months of additional data exclusivity which is tacked onto other market exclusivity or patent protection for the product. This form of exclusivity is available for certain products, including both drugs and biologics, for which a pediatric clinical investigation is conducted in response to a written request from the FDA. The final category of exclusivity is patent challenge exclusivity which is a 180 day exclusivity period that only applies for Abbreviated New Drug Application if certain criteria are met.

The Impact of the Hatch-Waxman Act

A brand-name drug may also enjoy patent-related market protection in addition to the above-noted FDA mandated data exclusivity periods. An entity which intends to file an Abbreviated New Drug Application (ANDA) for a generic drug based on the approved New Drug Application (NDA) for a brand-name drug must, among other things, submit a patent certification for each patent listed for the brand name drug in the FDA's Orange Book. This patent certification requirement is mandated by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act). A patent certification must assert one of four certification grounds. The first ground is known as Paragraph I certification which applies in situations where no patent information has been filed for the previously approved product. Paragraph II certification pertains to expired patents. Paragraph III certification covers patents that will expire on a certain

date. Paragraph IV certification applies to situations where the patent is invalid or will not be infringed.

In a situation where an ANDA applicant files a Paragraph IV certification with the FDA, the applicant must give notice of such certification to the patent owner and NDA holder. The patent owner has 45 days from receipt of such notice to file suit against the ANDA applicant for patent infringement. The provisions of the Hatch-Waxman Act prohibit the FDA from approving the ANDA for 30 months if such a suit is brought.

Paragraph IV challenges to patents which give exclusivity to brand-name drugs are arguably encouraged to a certain extent by the Hatch-Waxman Act. Under certain circumstances, the Hatch-Waxman Act may provide a generic drug manufacturer that files an ANDA with such a Paragraph IV certification with 180 days of generic marketing exclusivity. Despite any due diligence performed relative to the validity of a given patent, there is no guarantee that any such patent will not be challenged and subsequently invalidated. The entry of a generic competitor following a successful challenge would likely lead to lost revenues for the brand-name drug through both market erosion and price erosion.

New Forms of Legal Challenges to Drug Patent Rights

Generic drug makers seeking to challenge pharmaceutical patents are not limited to the above-described certification challenges. In recent years, generic drug makers have begun filing legal challenges regarding a number of pharmaceutical products that are still within their applicable data exclusivity period. However, unlike the regulatory challenges described above, these legal actions typically do not challenge the patent's validity directly. Instead, in this type of action, the generic pharmaceutical manufacturers argue that their product does not constitute infringement because it uses a slightly different ingredient mix, even though the generic product has the same effect as the branded drug. A recent example of such a legal challenge occurred when the U.S. Court of Appeals for the Federal Circuit affirmed a decision of the district court for the District of Delaware that Teva Pharmaceuticals' formulation of a generic version of Takeda Pharmaceuticals' gastroesophageal reflux drug Prevacid® did not infringe Takeda's patent. The district court found that Teva's formulation for a disintegrating oral tablet did not contain both a swelling agent and a disintegrating agent, as required by the Takeda patent. This decision gave Teva the ability to create a functionally identical

dosage form of lansoprazole, the active ingredient in Prevacid®, that did not infringe Takeda's patent.

Risk of Technological Obsolescence

Although a pharmaceutical product may have historically high sales and a proven success rate, there nonetheless remains a substantial risk that the drug will become outdated during the term of the securitization. The pharmaceutical industry is a dynamic and innovative sector which is constantly developing improved versions of existing products. The rapid pace of medical advances often results in situations where a successful drug could become completely obsolete if, for instance, researchers discover a cure for the underlying medical condition. However, certain drugs do have characteristics which help to guard against this obsolescence risk. For example, the popularity of existing brands can be difficult for new market entrants to overcome, even when the new product is superior to the better-known one. This common market phenomenon erects a high barrier to entry to would-be competitors and thus a lower risk that a competitor will develop and successfully market a superior drug. Arguably more important for the long-term success of a pharmaceutical product than brand recognition, however, is that the drug have multiple applications. Patented pharmaceutical technology can potentially be applied to a number of uses and is often employed to treat a variety of underlying conditions. A pharmaceutical product with multiple uses increases the drug's revenue-producing potential and helps to alleviate the possible payment stream interruption if a competitor develops a superior drug to treat the primary condition for which the drug was developed.

Bankruptcy Issues in Securitizations

A securitization transaction typically involves an originating entity which owns rights related to certain payments. This originating entity transfers such rights to a newly formed special purpose vehicle (SPV). In a securitization of royalty payment rights, the SPV can "own" these payment rights in a variety of legal forms. In one case, the SPV could be the outright owner of the patents related to the product and would receive royalties under a license agreement with one of the product marketing companies. With respect to the other products in the portfolio, however, the SPV could, perhaps, not own a direct interest in the related patents, but instead own various "contingent payment rights," or

other interests representing the right to receive amounts based on the royalties payable pursuant to the licensing of the patents related to the products. The form in which the SPV owns the royalty payment rights directly impacts how its rights to receive payments from the royalties may be affected following a bankruptcy of any of parties to the contracts which created the royalty payment rights. In analyzing the effect of such a bankruptcy, it is of critical importance whether the contract which governs the payment royalty rights will be deemed by a bankruptcy court to be an executory contract, or a non-executory contract.

Executory Contracts

Pursuant to Section 365 of Title 11 of the United States Code (the Bankruptcy Code), executory contracts receive special treatment. Although the Bankruptcy Code does not define the term executory contract, most courts have adopted the view that a contract under which performance remains due and owing by both parties and the failure of either party to complete such performance would constitute a material breach excusing the performance of the other is an executory contract. Most types of license agreements are regarded by courts as being executory contracts.

Section 365(a) of the Bankruptcy Code provides that, after a contract is deemed executory, a bankruptcy trustee or debtor in possession is authorized to (i) assume; (ii) assume and assign; or (iii) reject an executory contract in order to maximize the profitability and value of the debtor's estate. In essence, as long as certain criteria are met, the bankruptcy trustee or debtor may assume (and subsequently assign) executory contracts it considers beneficial, and reject or terminate those it considers burdensome. This assignment right exists even if a non-bankrupt party to the contract objects and if the contract terms prohibit such an assignment. Prior to the confirmation of a plan of reorganization, the bankrupt entity is not required to reject or assume an executory contract within a specified time period. If, however, the bankrupt entity continues to perform under the contract, it must also continue to make any payments required pursuant to the terms of the contract. Assumed agreements will continue in force as written, including license rights, and the licensee does not need to take any action. In order to assume the contract, the debtor must cure all defaults under the contract and provide adequate assurance of future performance. If a debtor rejects an executory contract, the contract is deemed breached as of the date of the debtor's bankruptcy petition and the

non-debtor party may file a general unsecured claim for damages.

In a situation where a pharmaceutical company, which licenses IP from the securitization SPV, were a debtor in a bankruptcy, the bankruptcy trustee therefore has the following three options under Section 365 of the Bankruptcy Code with respect to the license: (i) assume the license; (ii) assume and assign it; or (iii) reject it. The decision as to which course to pursue relates directly to the economic viability of the licensing arrangement. In general, a bankruptcy trustee should assume or assume and assign the license if it would add value to the bankruptcy estate directly or by assigning the license to a third party. Conversely, a bankruptcy trustee should only reject the license if licensing arrangements were not economically viable.

Section 365(n) of the Bankruptcy Code constitutes an exception to the general rule that a bankruptcy debtor or trustee may freely assume or reject executory contracts. Section 365(n) applies specifically to the bankruptcy of a licensor and provides that if the debtor-licensor rejects the contract, the licensee has the option of either treating the rejection as a termination of the contract or retaining its rights under the rejected contract. If the licensee continues to retain its rights, it must continue to make all royalty payments pursuant to the terms of the license agreement. This election would be expected if the license continued to be a profitable arrangement for the licensee at the time of the licensor's bankruptcy. It is important to note, however, that only those license rights that exist on the date the licensor files for bankruptcy protection are subject to section 365(n) protection. Upon the decision to continue a license, therefore, a licensee will not have any rights in updates or enhancements created by the licensor after the bankruptcy filing unless the parties enter into a subsequent agreement.

Non-Executory Contracts

Courts have held that contracts in which one party has no obligation other than the payment of money are considered non-executory and, as such, are deemed to be completed transfers of an absolute right. Contingent payments rights agreements are generally considered to be non-executory contracts. Such contracts are not entitled to the protection set out in Section 365 of the Bankruptcy Code, may not be rejected by the bankruptcy trustee, and are subject to sale or other disposition by the bankruptcy trustee as part of the bankruptcy estate. Because non-executory contracts are not entitled to Section 365 protection, if the

manufacturer/patent owner of such a drug were in bankruptcy, the SPV would be considered a general unsecured creditor. As an unsecured creditor, the SPV may submit a claim against the manufacturer/patent owner, but there is no assurance that such claim would be paid in full.

Diligence Considerations Increase Transaction Costs

Securitization transactions involving patent-related royalty assets generally require a substantially more comprehensive diligence process than a standard securitization. It is vital that, before embarking upon a securitization of royalty payment rights, transaction participants review the underlying license agreement which memorializes the relationship between the patent holder and the manufacturer/marketer paying royalties for the use of the patented technology. It is crucial for transaction participants to gain an understanding of the relevant business entities and their various rights and obligations under the license agreement. For example, it is necessary to determine who is responsible for maintaining the patents and who is responsible for enforcing the patents. Transaction participants must also ascertain whether the party with these responsibilities has the necessary resources to maintain and/or enforce the patents. Also, it must be clear to the transaction participants exactly which patents are involved in the transaction and whether the underlying license agreements account for related technology developed subsequent to the execution date of the license agreement.

An effective diligence process also involves the substantive assessment of the patents involved, in addition to reviewing the contracts related to the royalty payment rights. Some transaction participants may choose simply to rely on the due diligence performed by the licensee on the underlying license agreement. The licensee generally aims to make substantial and continuing investments to commercialize the subject technology. Before investing sizeable funds and entering into a license agreement, however, the licensee will generally perform a comprehensive due diligence analysis and, one would expect, will not enter into the license agreement if the due diligence analysis does not yield positive results. Other participants in the securitization, perhaps recognizing that the technological environment can and does change rapidly, will opt to perform their own diligence assessment of the patents involved. This assessment can be as simple as a

determination of whether the maintenance fees have been paid up to date and otherwise relying on the diligence performed by the business entities involved in the underlying license agreement. Depending on the specifics of the deal, the assessment may also include a review of the chain of title, an assessment of the validity of claims in the subject patents, and a search of the public databases for any patent infringement litigation involving any of the patents included in the underlying license. In addition, a thorough assessment may include a search for any post-issuance patent office activity that may negatively influence the scope of the patent claims at issue, namely any interference, re-examination or reissue; an analysis of the claims in the subject patents relative to the royalty-generating commercial activities to gauge whether they might provide a commercially valuable exclusivity for the relevant market; a right-to-use analysis to assess whether the licensee will be free to practice the royalty generating commercial activities without infringing the patent rights of another party.

Not all of the aforementioned types of assessment would be needed in every situation. The degree of analysis of a transaction may vary from the very basic to the highly rigorous depending on the specifics of the deal involved and the amount of money at stake. For example, the analysis of the claims in the subject patents may simply involve a basic assessment of the claims on their face in view of the specification. Alternatively, it may involve a more formal claim interpretation with consideration of the prosecution history file and the references cited. It may also involve an assessment of a third party's ability to "design around" the patent claims to appropriate the technology disclosed in the specification without infringing the patent claims.

The diligence process is not limited to a review of the domestic legal and market environment. Many commercially valuable patent-related royalty assets will entail an international market. Each nation has its own intellectual property laws and there are no "international patents." While there are substantial similarities in the intellectual property laws of different countries, there are also many important distinctions. Accordingly, the methods of assessment described above ideally should be repeated for each national jurisdiction in which the subject royalty-generating commercial activities are likely to occur. However, in most instances, a decision will have to be made to focus the due diligence analysis on the patents in the most significant national markets for the given commercial activities.

Investment Company Act Issues

Securitizers of traditional asset classes (e.g., mortgage or auto loan receivables) are able to take advantage of the exception in Section 3(c)(5) of the Investment Company Act of 1940 (the 1940 Act) or Rule 3a-7 under the 1940 Act, which effectively expanded the exception contained in Section 3(c)(5). Until recently, it was not clear whether the royalty interest held by issuers of royalty-backed securities would fall within one of the exemptions from registration. Therefore, unlike securitizers of more traditional asset classes, securitizers of pharmaceutical royalty streams were historically forced to rely on a more reasoned analysis of the 1940 Act's coverage to get comfortable that an issuer would not be characterized as an investment company subject to the requirements of the 1940 Act.

Seeking to settle this uncertainty, Royalty Pharma sought, and on August 13, 2010 received, a no action letter from the staff of the Division of Investment Management (the "Staff") indicating that the Staff would not recommend an enforcement action against an issuer of royalty-backed securities for failure to register as an investment company under the Act if certain conditions were met. Royalty Pharma argued that its activities fit within the exception provided in Section 3(c)(5)(A) of the 1940 Act. Section 3(c)(5)(A) excepts from the definition of "investment company" any person not in the business of issuing redeemable securities, installment face-amount certificates or periodic payment plan certificates who "is primarily engaged in...[p]urchasing or otherwise acquiring notes, drafts, acceptances, open accounts receivable, and other obligations representing part or all of the sales price of merchandise, insurance and services..." Based on the representations made by Royalty Pharma in its request letter, the Staff agreed and concluded that Royalty Pharma could rely on the Section 3(c)(5)(A) exception.

Critical to the Staff's conclusion was whether a direct nexus existed between the obligation purchased and the sale price of specific merchandise or services. Royalty Pharma asserted that the royalty interests it purchased entitled it to collect royalty payments based directly on sales of specific products that relied on the use of the licensed intellectual property for their manufacture. The Staff agreed that this supported the finding that there is a direct nexus between the royalty interests and the sale of specific biopharmaceutical products. Also important to the Staff was the fact that royalty interests amounted to a significant portion (79%) of Royalty Pharma's total assets. From this fact, the Staff determined that Royalty

Pharma was “primarily engaged” in the business of purchasing royalty interests.

Based on this position, other issuers of royalty-backed securities can take greater comfort that they will not be required to be registered as investment companies under the 1940 Act so long as they avoid issuing redeemable securities (or other securities in the categories described in Section 3(c)(5)(A)) and are primarily engaged in the business of purchasing royalty interests payable from the sales price of specific products.

Summing Up

To date, while there have been a large number of single-asset securitizations backed by pharmaceutical royalty streams, there have been only a few publicly reported securitizations related to drug royalty payment rights, such as the BioPharma Royalty Trust, the Royalty Pharma Trust, Paul Capital’s Royalty Securitization

Trust and the DRI Capital Inc. transactions. Nonetheless, with the worldwide pharmaceutical market generating approximately US\$800 billion annually, securitization of drug royalty payment rights remains a field ripe for exploration. As described above, securitizing royalty payment rights presents a number of unusual challenges, including, among other things, assessments of the validity of the underlying patents, current litigation and regulatory impact and unique bankruptcy concerns. However, without doubt, the securitization industry will cultivate the potential of a new asset class—drug royalty payment rights—as it has with so many other once-unique asset types.

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