

Pharmaceutical royalties: a new securitisation frontier

There are a number of specific issues that need to be considered when contemplating the securitisation of royalties from pharmaceutical-related patents

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Securitisation techniques have been increasingly used in less traditional financings involving a wide variety of asset classes. Royalties generated by intellectual property assets are a class of securitisation which has exhibited particularly robust growth over the past several years.

Royalties in general have demonstrated substantial growth since the 1990s. Securitisations based on royalties generated US\$417 million in financings in 1992. By 1994, the figure had increased to US\$757 million. By 1996, royalty-based securitisations generated US\$996 million, increasing to over US\$2.5 billion in the year 2000.

Although a substantial number of media IP-related securitisations have been completed and the asset class appears to be increasingly popular for investors, there have only been two known securitisation related to pharmaceutical patent royalties. These securitisations were the BioPharma Royalty Trust and the Royalty Pharma Trust transactions, in which the originators are affiliated entities. The global pharmaceutical market contains enormous potential. It is estimated that the worldwide pharmaceutical market generates approximately US\$300 billion annually, with the worldwide royalty market now estimated at between US\$7 billion to US\$10 billion annually. A wide variety of categories of entities, and individuals, own the rights to these royalties. The owners of these rights include 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, securitisation should be more widely considered as a financing vehicle.

Securitising a patent royalty stream is, in the abstract sense, very similar to securitising any other type of asset. However, in practice, the securitisation of royalty payment rights presents a number of unusual challenges, increasing both the cost and relative risk of the transaction. In the US, for example, these challenges include a variety of legal considerations such as the impact of state, federal and foreign statutes and regulations on the asset's underlying value; complex and expensive due-diligence processes to determine the nature of the asset; and bankruptcy concerns which 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. Investment in research and development by pharmaceutical companies has increased to unprecedented levels. R&D spending by US pharmaceutical companies increased 19% to US\$41 billion in 2001. 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 securitised. Public and private institutions, research companies and individual inventors are among the types of third-party licensors entitled to the royalty

rights. In the previously referenced BioPharma Royalty Trust transaction, a portion of rights to royalties a major research university received from a large pharmaceutical company in connection with the sale of an HIV/AIDS medication was securitised. More than US\$100 million was received by the university in respect of the royalty payment rights it sold via the securitisation.

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 securitised. Government regulation by the US 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 US, 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. For example, the pharmaceutical company Wyeth (formerly American Home Products Corp) was the subject of thousands of lawsuits relating to the diet drugs Redux and Pondimin, which were withdrawn from the market after some users developed heart-valve problems. In connection with the lawsuits arising from this significant side-effect, Wyeth entered into a settlement under which its potential liability may exceed US\$3.7 billion dollars. The Wyeth case is not unique: in the past five years there have been a number of voluntary or mandated withdrawals of pharmaceutical products from the market by several other 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 securitisation vehicle 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 manufacturers

The licensing of IP generally forms the basis for the drug royalty payment rights which may be securitised. The licensed IP is typically represented by one or more patents. In the US, the US Patent and Trademark Office is the regulatory agency which 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 for 17 years from its date of issue. Patents issued after 8 June 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 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 licence application (BLA) is required to market a new drug or biologic in the US. 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 termed 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 US (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. New clinical study exclusivity is a three-year data exclusivity period for a change (ie, a supplement which requires additional clinical trials). Paediatric 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 paediatric 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 Applications (ANDA) 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 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. For example, in 2001, Barr Laboratories Inc successfully challenged the patent protection on Eli Lilly & Co's anti-depressant drug Prozac and took in US\$366 million in revenue during its 180-day exclusive sale period. This event caused profits at Eli Lilly to plunge.

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 in 2001 when a federal district court in New Jersey awarded Dr Reddy's Laboratories Ltd, an Indian pharmaceutical company, the right to sell a drug that is nearly identical to the brand-name blood pressure drug Norvasc, which is produced by Pfizer Inc. The district court found that Norvasc's patent extension protected only its chemical structure, but not sister compounds that are nearly identical and that work equally well. This decision gave Dr Reddy the ability to create a functionally identical drug that is not in violation of the Norvasc patent. Although the district court's holding was recently reversed by the US Court of Appeals, a patent challenge of this nature may remain viable.

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 securitisation. 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 for 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 securitisations

A securitisation 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 securitisation 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 licence 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 analysing 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 licence 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 authorised to: (1) assume; (2) assume and assign; or (3) reject an executory contract in order to maximise 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 reorganisation, 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 licence 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 securitisation SPV, was 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 licence: (1) assume the licence; (2) assume and assign it; or (3) 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 licence if it would add value to the bankruptcy estate directly or by assigning the licence to a third party. Conversely, a bankruptcy trustee should only reject the

licence 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 licence agreement. This election would be expected if the licence 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 licence 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 licence, 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

Securitisation transactions involving patent-related royalty assets generally require a substantially more comprehensive diligence process than in a more standard securitisation. It is vital that, before embarking upon a securitisation of royalty payment rights, transaction participants review the

underlying licence agreement which memorialises 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 licence 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 licence agreements account for related technology developed subsequent to the execution date of the licence 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 licence agreement. The licensee generally aims to make substantial and continuing investments to commercialise the subject technology. Before investing sizeable funds and entering into a licence agreement, however, the licensee will generally perform a comprehensive due-diligence analysis and, one would expect, will not enter into the licence agreement if the due diligence analysis does not yield positive results. Other participants in the securitisation, perhaps recognising 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 licence 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 licence. 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; and a right-to-use analysis to assess whether the licensee will be free to practise 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 the ability to design around the patent claims; thus appropriating 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.

Summing up

As noted, there have only been two known publicly reported securitisations related to drug royalty payment rights, the BioPharma Royalty Trust and the Royalty Pharma Trust transactions. Nonetheless, with the worldwide pharmaceutical market generating approximately US\$300 billion annually, securitisation of drug royalty payment rights remains a field ripe for exploration. As described above, securitising royalty payment rights presents a number of unusual challenges, including, among other things, assessments of the validity of the underlying

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patents, current litigation and regulatory impact and unique bankruptcy concerns. However, without doubt, the securitisation 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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