

The Securitization of Drug Royalties: A New Elixir?

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The securitisation of drug royalties: a new elixir?

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Securitisation has been widely used as a financing technique since the 1970s, established with such core asset classes as mortgage loans, credit card receivables and automobile loan receivables. Increasingly, innovative securitisation techniques have also been utilised with more or less 'commoditised' asset classes. In particular, securitisations backed by royalties flowing from various forms of intellectual property (IP) have grown tremendously in recent years.

As an asset class, royalties have shown significant growth over the last decade. In 1992, securitisations based on royalties generated US\$417 million in financings; in 1994, US\$757 million; in 1996, US\$996 million; and over US\$2.5 billion in the year 2000 (Source: Bernard H Fischer's, *New Patent Issue: Biopharma Royalty Trust*, in *From Ideas to Assets: Investing Wisely In Intellectual Property*, Bruce Berman (editor) (New York, John Wiley & Sons, Inc) p485). Music royalties were one of the first forms of IP used as collateral, attracting much attention with the securitisation of royalties generated on a 25-album catalogue (consisting of approximately 300 songs of the musician David Bowie's recordings and song copyrights). Other securitisations have occurred in the film industry (film catalogues represent large, predictable assets with historical cashflows and little volatility).

While a significant number of music and film-related securitisations have been completed and the asset class seems as popular as ever, to our knowledge there has only been one securitisation related to pharmaceutical patent royalties, the BioPharma Royalty Trust transaction. The worldwide pharmaceutical market contains enormous potential: pharmaceutical royalties generate approximately US\$300 billion annually, out of a worldwide royalty market now estimated at between US\$7-10 billion annually. Various types of entities, and individuals, own these royalties rights, including big 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.

In theory, securitising a patent royalty stream is no different to securitising any other asset. In reality, however, securitising royalty payment rights presents a number of unusual challenges, increasing both the transaction's cost and its relative risk. These challenges include legal considerations such as the impact of regulatory and statutory authorities on the asset's underlying value; complex and expensive due-diligence processes to determine the nature of the asset, and unique bankruptcy concerns.

Origination of royalty rights and asset characteristics

The pharmaceutical industry is a dynamic market sector characterised by strong demand and increasing growth. Pharmaceutical companies invest more in R&D than ever before (R&D spending by US pharmaceuticals increased 19 per cent to US\$41 billion in 2001). In addition to internally developing the technology for new drugs, pharmaceutical companies acquire such technologies through the outright acquisition or licensing of IP developed from third parties. The licensing of IP gives rise to the securitisable receivables – the royalty payments to the third parties based on sales of the drug products. The third-party licensors entitled to the royalty rights range from public and private institutions, to research companies, to individual inventors. In the BioPharma Royalty Trust transaction, a major research university sold a portion of its rights to royalties it received from a large pharmaceutical company in connection with the sale of an HIV AIDS medication. The university reportedly received in excess of US\$100 million in respect of the royalty payment rights it sold via the securitisation.

Patents: challenges and competition from generic drug makers

The licensing of IP generally forms the basis for the royalty payment rights which may be securitised. The licensed IP is typically represented by one or more patents. The Patent and Trademark Office grants patents permitting the patent holders to assert their rights to exclude others from making, using, or selling the patented invention. Historically, patents in the US were issued with a 17-year term measured from the date of grant. On December 8, 1994, however, President Clinton signed into law the Uruguay Round Agreements Act which, *inter alia*, converted the patent grant in the US to a term of (a) 20 years from the earliest filing date for US applications filed on or after June 8, 1995; or (b) the greater of 20 years from the earliest

filing date or 17 years from grant for US patents that were either (i) in force on June 8, 1995 or (ii) grant from applications filed before June 8, 1995. Because patents are typically obtained before the related products are approved for marketing and sale by the United States 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).

To market a new drug or biologic in the United States, an FDA approval for a New Drug Application (NDA) or a Biologics License Application (BLA), respectively, is required. A new drug or biologic may be accorded market exclusivity for some period, which is commonly termed the data exclusivity period. This data exclusivity period is independent of, and may be in addition to, any patent-related market protection. There are five forms of data exclusivity that may be accorded, namely:

- **Orphan Product exclusivity** – 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)** – 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** – three-year data exclusivity period for a change (a supplement which requires additional clinical trials).
- **Paediatric exclusivity** – six months of additional data exclusivity 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.
- **Patent challenge exclusivity** – 180 days, only applies for Abbreviated New Drug Applications (ANDA's) if certain criteria are met.

In addition to the above-noted data exclusivity periods, a brand-name drug may also enjoy patent-related market protection. Notwithstanding such patent-related market protection, under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act), an entity wishing to file an ANDA for a generic drug based on the approved 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. A patent certification must comprise one of the following:

- Paragraph I certification that no patent information has been filed for the previously approved product;
- Paragraph II certification that the patent has expired;
- Paragraph III certification that the patent will expire on a certain date; or
- Paragraph IV certification that the patent is invalid or will not be infringed.

If the 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. Upon receipt of such notice, the patent owner has 45 days to file suit against the ANDA applicant for patent infringement. If such a suit is brought, the provisions of the Hatch-Waxman Act prohibit the FDA from approving the ANDA for 30 months.

The Hatch-Waxman Act offers an incentive for generic companies to institute Paragraph IV challenges to patents which give exclusivity to brand-name drugs. That is, under certain circumstances, the Act may provide a generic company 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 won't be challenged and subsequently invalidated. For example, the Wall Street Journal recently reported that 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, and profits at Eli Lilly plunged.

In addition, a related new challenge to patented drugs has recently emerged. Generic drug makers have begun filing legal challenges on a number of drugs that are still within their applicable data exclusivity period. Unlike the challenges

described above, however, these generic manufacturers don't challenge the patent directly; rather, they argue that their product doesn't infringe because – although the generic product has the same effect as the branded drug – it uses a slightly different ingredient mix. For example, a federal district court in New Jersey recently awarded the Indian drug company, Dr Reddy's Laboratories Ltd, the right to sell a drug that is nearly identical to the blood pressure drug Norvasc made by Pfizer Inc. Dr Reddy capitalised on the fact that Norvasc's patent extension protected only its chemical structure, but not similar sister compounds that work equally well. This loophole allowed Dr Reddy to create a lookalike drug that didn't violate the Norvasc patent.

Regulatory hurdles and product liability issues

Because royalties are typically based on the sales revenue of the related drug, any change in regulatory oversight or litigation may significantly impact the value of the royalty payment rights being securitised. Regulation by governmental entities in the US and other countries is a significant factor in the production, marketing and sale of the patented drugs related to the royalty payment rights. The 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 some instances, the FDA may mandate the withdrawal of a problematic drug from the market. Along with these 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, Wyeth entered into a settlement under which its potential liability may exceed US\$3.7 billion. Moreover, in the past five years, there have been a number of voluntary or mandated withdrawals imposed upon several other major pharmaceutical companies. Even in situations where a product liability claim against 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.

Risk of technological obsolescence

Even though a particular drug has historically high sales and a proven success rate, there nonetheless remains a significant risk that the drug will become outdated during the term of the securitisation. Rapid innovation in the pharmaceutical industry combined with frequent medical advances means that a drug could become replaced with a more effective version or could become completely obsolete if, for instance, researchers discover a cure for the underlying medical condition. Certain drugs do, however, have characteristics which help to guard against this obsolescence risk. For instance, superior technologies often have difficulty overcoming the popularity of existing brands, which provides a high barrier to entry to would-be competitors and thus a lower risk that a competitor will develop a superior drug. More important than brand recognition, however, is a drug with alternate uses. Patented technology can potentially be applied to a number of uses and is often used to treat a variety of underlying conditions. A drug 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 main condition for which the drug was created.

Diligence considerations increase transaction costs

The diligence considerations for a patent-related royalty asset are much more comprehensive than the diligence process undertaken in a more standard securitisation. In particular, before embarking upon a securitisation of royalty payment rights, transaction participants will need to 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 important to gain an understanding of the relevant business entities and their various rights and obligations under the licence agreement. For example, who is responsible for maintaining the patents? Who is responsible for enforcing the patents? Does the party with these responsibilities have the apparent resources to maintain and/or enforce the patents? What patents are involved in the transaction? Do the underlying licence agreements account for related technology developed subsequent to the execution date of the licence agreement?

In addition to reviewing the contracts related to the royalty payment rights, an assessment must be made of the patents involved. 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. Others, 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;
- 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;
- a search of the public databases for any patent infringement litigation involving any of the patents included in the underlying licence;
- 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 validity assessment of the claims in the subject patents; 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.

The actual level of analysis performed under each of the preceding items can vary from the very basic to the extreme 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.

In addition, many commercially-valuable patent-related royalty assets will entail an international market. There are no 'international patents'; rather, each nation has its own patent laws. While there are many similarities in these laws, there are also important differences. Accordingly, the items noted above could be repeated for each national jurisdiction in which the subject royalty-generating commercial activities are likely to occur. In most instances, however, 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.

Bankruptcy concerns

In a typical securitisation, the originating entity owns rights related to certain payments. This entity then transfers such rights to a newly formed special purpose vehicle (SPV). In a securitisation of royalty payment rights, the legal form in which the SPV will own these rights will likely vary. 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 would 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

Executory contracts receive special treatment under Section 365 of Title 11 of the United States Code (the Bankruptcy Code). The Bankruptcy Code does not define the term executory contract, but most courts have adopted the view that it is 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. Licence agreements are generally viewed by courts as being executory contracts.

Once a contract is deemed executory, Section 365(a) of the Bankruptcy Code authorises a bankruptcy trustee or debtor in possession to:

- assume;
- assume and assign; or
- 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.

If a pharmaceutical company, which licenses IP from the securitisation SPV, were a debtor in a bankruptcy, the bankruptcy trustee has three options under Section 365 of the Bankruptcy Code with respect to the licence:

- assume the licence;
- assume and assign it; or
- 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. Conversely, a bankruptcy trustee should only reject the licence if the 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:

- (a) treating the rejection as a termination of the contract; or
- (b) 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

Contracts in which one party has no obligation other than the payment of money are considered non-executory and courts have deemed them 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 relating to 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 fully-paid.

Summing up

To date there has only been one known publicly-reported securitisation related to drug royalty payment rights, the BioPharma Royalty Trust transaction. The BioPharma Royalty Trust did not perform according to expectations due to the unexpectedly erratic performance of the revenue stream from the one asset in the securitisation. 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 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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