

Patent backed securities in pharmaceuticals: what determines success or failure?

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Abstract

[Recently, there has been growing interest in new financial tools that leverage on intellectual property assets, such as patent backed securitizations (PBSs). In this paper we study the potential determinants leading to the success or failure of securitization deals having patents as underlying assets. We develop a conceptual framework that we test on two well-known US patent securitization deals in the pharmaceutical industry, by using a fuzzy set approach. Results highlight that factors related to the market size, level of competition and expected market life of the assets underlying a PBS can reasonably increase the probability that a deal will succeed. Moreover, a higher quality of the underlying invention and longer patent residual life are likely to reduce the risk of technical obsolescence and sales losses. Finally, the strength of the credit enhancement mechanisms, the flexibility of the deal architecture and the adoption of a diversification strategy are other key factors determining the success of the securitization.]

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1. Introduction.

It is widely accepted that intangible assets are the major drivers of growth in most economic sectors (Hand and Lev, 2003). The increasing role they are playing in terms of company value is confirmed by Standard & Poor's, which reports that since the mid-1980s, there has been a large increase in the ratio of market to book value (Standard & Poor's 500, 2008).

Although intangible assets might be actively managed and exploited much like tangible assets, they are not yet considered to be important drivers in company funding processes. This is confirmed by recent studies (Ughetto, 2008), which highlight that the banking system is still disregarding intangibles when assessing borrowers' creditworthiness. Moreover, the very little information provided by financial statements about these assets prevents banks from having a true estimate of the value of companies (Cañibano et al., 2000).

This often results in a limited capability of traditional financial intermediaries in sustaining investments in R&D and innovation. Being unable to appreciate the actual innovation potential of a company, banks observe only financial accounting ratios rather than future expected cash flows determined by the innovation activity. Credit constraints are particularly acute for innovative firms because their investment returns are uncertain, they have little collateral to secure debt, they are subject to higher informational frictions and their capital, which is mostly intangible, difficult to redeploy and characterized by relevant bankruptcy costs (Carpenter and Petersen, 2002; Hall, 2002). While the new rules on regulatory capital requirements recently introduced by the Basel II Accord do not seem to have a positive significant impact on lending conditions for innovative SMEs (Scellato and Ughetto, 2009), the current situation of credit markets is likely to exert its negative impact in the long run as well, due to the contraction of financial resources for innovative ventures. The lack of financial resources from the credit market for these kinds of companies appears to be particularly critical given that only a small number of them are able to go public and to raise money on the stock market and that the venture capital industry still plays a limited role in many countries.

Recently, there has been growing interest in new financial tools that might significantly help ease financial constraints on innovation, at least in principle. These products are based on a particular category of intangible assets: intellectual property rights (IPRs). The value embedded in intellectual property rights often extends beyond directly profiting from them through their commercialization or licensing. IPRs are revenue-generating assets and as such, they can be exploited as a source of capital collateralized by the royalty streams they generate (Hillery, 2004; Agiata, 2002; Kirsh, 2005). The question of whether financial tools based on IPRs might be valid alternatives to the problem of financing constraints for firms engaged in relevant innovation activities appears to be fairly significant and of considerable interest for both policymakers and researchers.

One way to leverage IP assets is to securitize them. IP securitization is a device of structured financing where IP assets or rights to receive future payments originated by IP are converted into marketable securities.¹ Securitization is supposed to provide new opportunities for the corporate funding process and the leverage of IP portfolios. Despite their potential, the number of IP securitization deals established so far is limited, and mostly confined to copyrights and trademarks (Calderini and Odasso, 2008; Hillery, 2004), while patents represent the smallest area.

The literature on IP securitization is scarce and existing studies limit themselves to describing the distinctive features of these new types of instruments, implications and roles of different stakeholders (Frank, 2005; Hillery, 2004; Watanabe, 2004; Edwards, 2001; Dorris, 2003). A few additional studies focus on legal issues affecting asset backed securities and on the use of patents as collateral to raise debt finance (Bezant, 1997; Davies, 2006). The literature in this field

¹ The basic structure of a patent securitization is the following. The Originator, namely the party initiating the transaction, identifies a single patent or a pool of patents showing reasonably predictable cash flows to be securitized. Then, he sells the asset itself or the cash flow rights to a legally separate entity known as a Special Purpose Vehicle (SPV) in order to separate future receivables from its own corporate risks. The SPV, with the help of legal and financial advisors, designs the securities to be sold: a wide range of possible securitization structures exist and can involve some combination of equity and debt (either one class or multiple classes with senior and subordinate tranches). Finally, the SPV issues securities backed by the stream of patents' royalties on capital markets.

has been constrained by the limited number of IP securitization deals², by the lack of available data and by the high level of secrecy surrounding existing transactions.

A wide range of issues limits the applicability and diffusion of patent backed securitizations (PBSs) and reduces both borrowers and sellers' confidence in these kinds of tools (Throckmorton, 2004; Hillery, 2004; Fishman, 2003; Watanabe, 2004). First, PBSs are complex instruments of financial engineering, which involve high structuring costs. Second, assessing the value and risk profile of a patent portfolio is a key challenge for the development of these solutions. Lack of generally accepted methodologies for the valuation of intellectual property rights and the high degree of uncertainty to which patent value is subject strongly affect the confidence in PBSs.

While leaving this substantive examination to future work, in this paper we address a related topic, namely the study of the potential determinants leading to the success or the failure of securitization deals having patents as underlying assets. To our knowledge there is no prior evidence on this side either.

More precisely, we wanted to investigate how and under which conditions a patent backed securitization transaction can create value for both the issuer and the investors. A successful transaction is defined as one in which the issuer has monetised its IP assets in an efficient, cost-effective manner, with the investors receiving a well-structured, highly-rated investment which provides a favourable risk/return trade-off (Walsh and Cohen, 2007). Since PBSs are customized financial solutions and their number is too small to support statistical evidence, a traditional empirical analysis could not be implemented. Therefore, we developed a conceptual framework that we tested on a set of recent patent securitization deals in the pharmaceutical industry. In particular, we referred to two cases of securitization transactions based on patent drugs originating from the same company, Royalty Pharma AG, and which represent a failure and a success respectively.

² Kirsch (2005) reports that between 1997 and 2004 only 38 IP securitization deals were established, and among them only 5 were PBSs.

Our theoretical framework consists of a set of variables which we assumed could explain the potential outcomes that a PBS might have in the field of pharmaceuticals. The identification of the most relevant determinants of failure and success of a PBS was based on the thorough analysis of extant literature, on patent information derived from the Delphion dataset and on direct interviews with experts on structured finance and pharmaceutical industry. To build the framework of the analysis, we adopted a fuzzy approach. Fuzzy logic has been widely exploited in engineering, management and business studies over the last 20 years (Minola and Giorgino, 2008; Wang and Hwang, 2007; Chen, 2001; Chan et al., 2000) to model systems which are hard to define precisely. This method is in fact a useful tool to represent and analyze qualitative information and to deal with complex phenomena (Zadeh, 1965).

Results highlight that factors related to the market size, level of competition and expected market life of the assets underlying a PBS can reasonably increase the probability of success of a deal. Moreover, a higher quality of the underlying invention in terms of scope, technical novelty and technological importance and a longer patent residual life are likely to reduce the risk of technical obsolescence and sales losses. Finally, the strength of the credit enhancement mechanisms, the flexibility of the deal architecture and the adoption of a diversification strategy are other key factors determining the success of a securitization.

The paper is organized as follows. Section 2 provides a description of the methodology employed. Section 3 introduces the model. Section 4 discusses the results.

2. Methodology

In order to understand which factors might affect the likelihood of success of a PBS, we developed a conceptual framework that we tested on two recent patent securitization deals built on pharmaceutical patents. The unique nature of patents implies a case by case assessment of their value and risk profile; as a consequence, the design of a PBS transaction does not usually involve a standard process as happens with asset-backed securitization (ABS) deals. Since PBSs

are highly specific and customized financial solutions³, we necessarily had to refer to a set of well-known examples of patent securitizations that would allow us to draw some relevant conclusions to be generalized to the whole category of PBSs.

The first step of our research was therefore the selection of two relevant cases of PBSs. An in-depth analysis of just one single case might not have been representative to delineate the relevant factors affecting a PBS deal outcome. Therefore, we decided to study two PBS transactions, which we feel are particularly important for assessing the factors that influence the applicability and diffusion of PBSs. The two deals, both originating from the same company (the Royalty Pharma AG) and based on pharmaceutical patents, represent the first two patent backed securitization deals historically established. Our interest in the two deals stems from the fact that they can be considered antithetic deals for both their transaction design and final results since they represent respectively a failure and a success.

The second step of the work was to define the several potential factors deemed to affect the outcome of a PBS deal. A well-formulated theory is actually missing and the literature on PBSs is sparse and lacks a comprehensive analysis of the phenomenon. Therefore, we had to define the conceptual framework of analysis leveraging not only on a throughout analysis of extant literature, but also on hand-collected data (on patents, drug history, licensing contacts, industry reports) and on direct interviews with experts on structured finance and the pharmaceutical industry.

Finally, the last step was to analyze the information collected with the help of a methodology that could capture the high level of complexity and uncertainty characterizing this research topic. For this reason, we decided to adopt the fuzzy logic approach. Fuzzy logic has been widely used to represent uncertainty or to analyse qualitative information in a broad range of applications. Numerous scholars have underlined the benefits of using it for managing the heterogeneity and ambiguity of the natural language, enabling a formal structure that allows a

³ Given the particular features of patents in comparison to other physical assets, designing a standard process is quite challenging. The cash flow generation streams are the only similarity between patents and other asset classes used for ABS deals (Hillery, 2004).

quantitative representation (Chen, 2001; Wang and Hwang, 2007; Chan et al., 2000).⁴ The specificity and complexity of the topic under investigation, as well as the lack of complete historical data or the qualitative nature of some variables makes the use of the fuzzy approach particularly suitable.

In the following paragraphs we will describe the above-mentioned steps in greater detail.

2.1 The selection of the cases: Zerit® and 13 Drugs Pool

The first step was to select two relevant examples of PBSs, sufficiently similar to be compared but differentiating in their final outcome and transaction architecture. The two deals, both originating from the same company (the Royalty Pharma AG, an investment company specialized in the pharmaceutical industry) and based on pharmaceutical patents, can be considered antithetic deals both because of their transaction design and the final results, since they represent respectively a failure and a success. In addition, they are the first two patent historically established backed securitization deals.

The first PBS (Zerit®) goes back to 2000, when Royalty Pharma entered into an agreement with Yale University to purchase and securitize the royalty stream associated with Zerit®, a drug for the treatment of HIV infection developed by Bristol-Myers Squibb. In 1985, Yale University received a patent for its d4T discovery, a novel technology for the treatment of the HIV virus. A few years later, the University granted an exclusive license to Bristol Myers Squibb for the development of Zerit®, which was later approved by the US Food and Drug Administration (FDA) in 1994. Yale University maintained the ownership of the patent and obtained 70% of the royalties, while the remaining 30% was paid to the two inventors (Fischer, 2002).

⁴ Chen (2001) argued that the fuzzy theory provides a valuable tool to deal with the ambiguity involved in the data evaluation process. Wang and Hwang (2007) underlined that it is a useful alternative framework for dealing with uncertain project parameters in situations where there is lack of certainty in data or even lack of available historical data.

The royalty stream owned to the University was sold to Royalty Pharma and became the underlying asset for the first PBS transaction historically established. A bankruptcy-remote vehicle (the BioPharma Royalty Trust) was created primarily for the purpose of funding the purchase payment. The trust issued \$115 million in debt and equity securities. Leveraging on the royalties deriving from the drug sales, BioPharma Royalty Trust obtained a six-year loan (from September 2000 to June 2006) for a portion of the purchase price (\$100.3 million in senior, mezzanine and junior notes), while the remaining amount of \$14.69 million was covered by three equity partners, Royalty Pharma, BancBoston Capital and Yale University. Yale University received a cash payment (\$100 million) in addition to equity in the trust, which was then used to fund the construction of a research facility at its medical center. Besides the Originator and the licensing partners, several other stakeholders were involved in the deal: Bankers Trust Corp. was the transaction's trustee, West LB was the lead arranger, Clifford Chance was the legal advisor and Wilmington Trust Company was the servicer (Kirsh, 2005; Hillery, 2004).

Standard & Poor's gave the deal a single A rating, largely due to the good credit standing of Bristol-Myers Squibb and to the projections of sales of Zerit®. In 1999 worldwide sales of Zerit® reached \$605 million with an average growth rate of 26% since 1997. The patent licensing agreement generated royalty payments for \$41.6 million. In 2001 Standard & Poor's considered BioPharma Royalty Trust as a "model for future deals going forward".⁵ However, in the subsequent years, Zerit® sales projections were systematically missed and revenue streams were lower than expected. In 2002 Zerit® sales declined to \$443 million. In addition, during the second half of 2001 Bristol-Myers Squibb started selling its entire portfolio of Zerit® at a discount to wholesalers, in order to achieve corporate financial benchmarks. As a result, although royalties were high in that period, the excess cash flows (after covering debt service) were paid out to the marketers and were unavailable to investors when sales declined (Eisbruk, 2002). Bristol-Myers Squibb was downgraded to AA from AAA by S&P in June 2002. The transaction

⁵ Standard & Poor's New Asset Hot Topic Seminar, 2001.

definitively failed in November 2002 when BioPharma Royalty Trust entered into early amortization, after breaching covenants for three consecutive reporting periods (Hillery, 2004).

In July 2003 Royalty Pharma issued a second PBS, leveraging on the royalty stream of a pool of thirteen drugs.⁶ At the time of the deal, only nine drugs were generating royalty payments; the other four drugs were in the final phases of the FDA approval process, but not yet on the market. Through the SPV, the Royalty Pharma Finance Trust, the 13 Drugs Pool transaction raised \$225 million of variable funding notes and was structured by Credit Suisse First Boston. The trustee for the transaction was Deutsche Bank Trust Co. Americas (Moody's Investor Service, 2003). The transaction included a three-year revolving borrowing period with an expected maturity of July 31, 2010 and a final maturity of July 31, 2012. During the revolving period, additional royalty assets could be included in the trust if they met the approval process. The deal was rated AAA by both Moody's and Standard & Poor's, largely because of the insurance provided by MBIA Insurance Group, which guaranteed timely payments of interest and ultimate repayment of principal on the notes. At the present time the deal is still on the market and its size has been increased several times reaching \$2.2 billion and has a BBB- rating. The deal is considered a case of success because of the progressive increase in the capital raised after the first issuance and because of its longer life compared to the Zerit® deal.

Despite being well-known deals, most existing works simply provided a general description of them (their history, structure and the role played by different stakeholders), without highlighting the theoretical reasons at the basis of their sustainability. Edwards (2001) presented the Zerit® deal as an example of a patent securitization process, focusing on transaction details and main impediments to success. Eisbruck (2002) gave a detailed description of the Zerit® case in terms of credit rating due diligence and deal architecture. Walsh and Cohen (2007) mentioned the two deals along with a broader discussion about the market potential for IP

⁶ The thirteen drugs included in the second patent securitization were: Genentech's and Biogen Idec's Rituxan®; Cellegen's Thalomid®; Eli Lilly's and J&J-Centocor ReoPro®; Centocor's Retavase; Chiron's TOBI®; Novartis' Simulect®; Roche's Zenapax®; Ligand's Targretin Capsules®; Memorial Sloan Kettering's Neupogen and Neulasta; Organon's Variza®; GSK and Adolor's Entereg®; Pfizer's lasofoxifene; Wyeth's bazedoxifene.

backed financial instruments. A much more thorough investigation and explanation can be found in Kirsch (2005) and Hillery (2004). While the first one presented the most relevant features characterising the Zerit® transaction, the second work, which represents the only relevant contribution for the 13 Drugs Pool deal, made an effort to identify the reasons supporting the rationales and the underlying patent features of the two deals.

2.2 The definition of the theoretical framework

In order to compare the feasibility of the two different transactions, we complemented information taken from different sources by following three steps.

First of all, we analyzed the existing literature, drawing information from both academic and business journals. This overview gave us a widespread perspective on the main issues related to patent securitization and represented an important source of information. Through a backward intelligence process we collected data on each compound, identifying the original inventors, further developers, and the relevant licensing agreements on IPRs and core patents. The Zerit® transaction was based on two US patents and on several other non U.S. patents. The second PBS deal was established on royalties deriving from 13 drug patent licensing agreements or contingent payment rights. Using Delphion dataset, we collected information about the patents underlying each deal: the date of the first application; the date the patent was granted; the number of claims; backward references and forward citations; number of family members.

Secondly, we selected some independent experts in the field of structured finance and the biopharmaceutical industry to complete our background knowledge and to review and confirm the results on the identified patents. We then conducted a first run of face-to-face interviews. According to the results of the interviews and the revision process, and given the main issues raised from the literature, we built the framework of analysis on which the fuzzy model was based. Finally, we asked experts to review the framework and express relative judgments on the two deals.

2.3 The analysis: a fuzzy approach

The evaluation of patent backed securitization deals is extremely complex and relies heavily on subjective judgments. Due to the uniqueness of patents as underlying assets, of the transaction architecture, and of the main stakeholders, each case is different from the others and a high degree of uncertainty is involved. Moreover, a large number of exogenous factors are likely to influence the final outcome. Hence, it is difficult to assess the factors which are deemed to determine the success of a PBS deal, and appropriate methodologies that can cope with complex phenomena are needed.

Fuzzy set theory is a useful tool to represent and analyze qualitative information and to model systems which are hard to define precisely. While Boolean logic is based on the true-false paradigm, the fuzzy approach leverages on all possible values between these two extremes. Resembling human reasoning in its use of approximate information, it converts linguistic variables to fuzzy numbers under ambiguous assessments (Zadeh, 1965). This technique is suited to quantifying assessments made by experts, who tend to make evaluations based on their knowledge, past experience and subjectivity (Chan et al., 2000).

Since this original contribution by Zadeh (1965), fuzzy logic has been studied extensively. While first used to represent uncertainty in human cognitive processes, over the past 20 years it has also been applied extensively in engineering, management and business studies (Minola and Giorgino, 2008; Wang and Hwang, 2007; Chen, 2001; Chan et al., 2000; Kaufmann and Gupta, 1988⁷). In particular, fuzzy methods are commonly used to solve complex problems and to process undefined qualitative datasets in the field of artificial intelligence systems applied to financial markets.

Our analysis is not based on an advanced application of the fuzzy method. It is meant to be a first attempt to interpret the complex and emerging phenomenon of PBSs in a structured

⁷ The study where Kaufmann and Gupta (1988) state that since 1965 more than 7,000 works on fuzzy set theory have been published, is just one example showing how extensively it has been applied in recent years.

and comprehensive way, without the limits imposed by traditional methodologies. Therefore, we identified a set of variables for each dimension of analysis that we considered to be relevant determinants in explaining PBSs feasibility. Each variable was given a numeric value, based on expert judgments, closeness to the theoretical assumptions, and data evidence. The different values were aggregated to produce a synthetic index, which can be regarded as an indirect measure of the likelihood of success of a PBS.

3. The model

3.1 The theoretical framework

As mentioned, we tried to understand which factors might affect the likelihood of success of a PBS, by defining a theoretical framework that we tested on the two previously mentioned patent securitization deals by using a fuzzy inference process. This process consists in the elaboration of given inputs into a single numerical output using fuzzy logic. The main issues for which a PBS becomes an efficient solution for firms needing funding and a favourable investment for investors, were selected according to a thorough review of the literature and face-to-face interviews with experts in the fields of structured finance and biopharmaceuticals.

We defined a three level dimension tree (Figure 1), in which each level corresponds to a macro category affecting a PBS outcome. Each node of the tree was further divided into sub-dimensions, for which we identified the most relevant parameters. For each variable we collected information on both deals, considering the deal year as the reference year for the analysis. The model presents a synthetic index summarizing the suitability and strength of each deal in comparison to an optimal case. Indirectly, the index is a measure of the likelihood of success of a PBS transaction.

[Insert Figure 1 here]

The first dimension (DRUG) refers to the characteristics of the asset(s) underlying a pharmaceutical patent royalty securitization for which it is important to consider all the relevant

features of the market addressed by the drug, as well as its economic and regulatory attributes. The second dimension (PATENT) relates to patent characteristics, such as patent status and value, which are crucial for a securitization to be attractive for both issuers and investors. The last dimension (DEAL STRUCTURE) concerns the deal architecture: the financial structure, the legal framework, the credit enhancement mechanisms, and the credit merit of the involved actors are key variables affecting the strength and rating of a deal. In the first two macro-areas, the analysis of existing information and data has been conducted at a drug level, considering one single drug for the Zerit® deal and thirteen drugs for the 13 Drugs Pool deal, while in the last dimension we referred to the whole transaction.

The hierarchical structure used to design the fuzzy model is detailed below.

D1. DRUG

Patent backed securitizations generally imply high structuring costs due to the low level of standardization and to the uniqueness of the IP assets involved. In order to achieve an economically efficient transaction, the underlying asset size has to reach a break-even point (Watanabe, 2004), where steady and consistent cash flows are generated to cover the costs of issuance and debt service.

According to Hillery (2004), New Biological Entities (NBEs) can be more suitable for securitization than New Chemical Entities (NCEs) because they are more effective in treating targeted diseases and more difficult to be developed and manufactured, thereby creating additional barriers to competitors entering the field. Biologic-based drugs also differ from chemical-based drugs in their approval process (DiMasi and Grabowski, 2007). However, the development, release and market success of new compounds is largely affected by exogenous scientific, regulatory and economic factors, which ultimately determine the feasibility that a drug can be securitized. Considering the differences that exist among drugs and the risks to which they are subject, in this macro-area we included all the relevant drug-related factors that can significantly influence the likelihood of success of a deal. They have been grouped into two

categories: the first refers to the market potential of the drug, while the second is focused on the drug life and on its approval process.

D1.1 Market Potential

- *Market size.* All else being equal, drugs that address large and low competition markets are more likely to be successful and to generate sufficient cash flow to be securitized (Hillery 2004). As a proxy for market size we considered the average worldwide sales in the period 2000-2003 for the top Anatomical Therapeutic Classes (ATC). Data on sales were collected from IMS HEALTH (Top-Line industry data). We carefully checked whether the drugs underlying the two securitizations belonged to these top selling classes, according to a three-digit level ATC classification. We assigned the scores based on the average size of the considered market segments.
- *Competition in the therapeutic class.* The stronger the market position of a drug, the higher the possibility of high and sustained revenues. Empirical evidence generally supports the first-mover advantage theory in pharmaceuticals (Berndt et al., 1997; Hurwitz and Caves, 1988; Grabowski and Vernon, 1992). As such, products that come to the market earlier have a competitive advantage over later entrants, which face the risk of being dropped out of the market. Being a first-in-class drug it is therefore a key element which ensures revenue gains and a sustained market share. NBEs have a significantly higher likelihood of being first-in-class drugs compared with NCEs (Grabowski, 2007). As a proxy for the level of competition, we considered whether the drugs underlying the two securitization deals were first-in-class or follower molecules. To assess this, we checked the number of compounds already marketed in the US in the same ATC class (4-digit level) of each of the 14 drugs before their approval.
- *Downstream assets.* A firm with downstream marketing capabilities may be able to extract greater value from a drug than a firm that lacks them. To ensure that its downstream

assets are fully utilized, the firm will probably develop many compounds in the same therapeutic class (Arora et al., 2009). Therefore, the positive revenue-generating effect due to the success of a new compound might be offset by the decline in sales of equivalent products already on the market. For each of the 14 drugs underlying the considered PBS deals, we identified the portfolio of medicines in the same 3-digit ATC already marketed by the commercializing company before the FDA approval of the analyzed drugs. The number of portfolio ATC-equivalent drugs was considered as a proxy of the presence and exploitation of downstream assets.

D1.2 Development and commercialization

- *Maturity.* The expected market life of a drug positively influences its securitization potential. In fact, the longer the residual life of a compound, the broader the time window in which it generates revenues. For this reason, for each drug, we considered its expected residual market life at the time of the deal. We referred to an average expected market life of 20 years, given the shortening of drugs' life cycles and the increasing competitive pressure in pharmaceuticals (Grabowski and Vernon, 2000).
- *Degree of cooperation.* Many companies in the pharmaceutical sector have turned to development partnerships, joint-ventures and licensing to acquire technological know-how and to transfer resources for product commercialization. Several scholars have highlighted the benefits of collaborative arrangements in the research and development of drugs (Hamel et al. 1989; Ohmae, 1989; Kanter, 1989). However, these arrangements involve costs and risks associated with their definition, coordination of common activities and IPR management (see among others Williamson, 1975; Pisano, 1991). Frictions between involved parties could be caused by appropriability issues, when intellectual property is not adequately protected through patents, or by problems of coordination and asymmetric information about the project. According to Pisano (1997),

a potential “lemons problem” can arise if projects with fewer market opportunities are licensed to collaborative partners, while those with better prospects are internally developed. We relied on two measures approximating the degree of cooperation among parties: whether a drug was internally developed or licensed out and the number of licensing steps established until its market launch.

- *Success in the approval process.* In pharmaceuticals, R&D is a multi-phase process, involving experimentation, modelling and testing. The full-scale development of a drug involves the transition from Phase I to Phase III before becoming a commercially viable product. Moreover, both generic and brand name drugs are subject to approval by the Food and Drug Administration. Drugs also need to be manufactured in accordance with FDA regulations. Transition probabilities for each clinical phase and overall success rates vary significantly depending on the drug type (NCEs or NBEs), on the historical period (DiMasi and Grabowski, 2007) and on the therapeutic class (DiMasi, 2001). At the time of the 13 Drugs Pool deal, some of the involved drugs were still under investigation by the FDA. Therefore, assessing their likelihood of success in gaining approval was at that time a relevant matter. When available, we considered the probability of success in clinical development for the Anatomical Therapeutic class that our sample drugs belonged to. Alternatively, we assigned a probability of success to the drug category, relying on the fact that NBEs, on average, have higher overall rates of success than NCEs, but are characterized by a lower transition probability in the most expensive Phase III.⁸

D2. PATENT

The quality and obsolescence of the assets underlying a securitization are key risk factors, which need to be taken into account when defining the credit merit of a deal (Hillery, 2004;

⁸ Biopharmaceuticals yield an overall clinical approval success rate of 30.25% (as opposed to 21.5% for NCEs), but their transition probability from Phase III to approval is 64.2% against 68.5% of NCEs (DiMasi and Grabowski, 2007).

Kirsh, 2005). In a PBS, it is important to assess the ability of a patent to generate sufficient cash-flow to pay interests and amortization. Consequently, the quality and residual life of patents deeply influence the sustainability of a PBS deal.

D2.1 Patent value

- *Quality Index.* It has long been recognized that patents, and the innovations they protect, vary enormously in their economic value, and that the distribution of such value is extremely skewed (Hall et al., 2000). From a theoretical point of view, the higher the value of the patent, the greater the probability it can originate consistent cash flows to be securitized. As previously mentioned, we collected patent data underlying the two PBS deals. For each patent, we studied its breadth (Lerner, 1994), technical novelty (Lanjouw and Schankerman, 2001) and technological importance (Hall et al., 2000). For each patent, we estimated the Lanjouw-Schankerman quality index (Lanjouw and Schankerman, 2004), which is a composite index built on the number of claims, backward references, forward citations received in the first five years of patent life and family scope. The index is correlated with the economic value of a patent and can be considered an indirect measure of the probability that a patent can generate enough cash flows to be securitized.⁹

D2.2 Patent life

- *Time to expiration.* In the biopharmaceutical industry, a key time point in the sales life cycle of a drug is the year of patent expiration. Drugs with substantial market shares are expected to face strong generic competition and sales losses after a patent expires

⁹In calculating the index we applied different weights for pharmaceutical and biotech drugs. The weights derive from the common factor analysis applied to the technological field in the paper by Lanjouw and Schankerman (2004). They are applied to each indicator on which the index is constructed, and show the expected value of quality associated with a unit increase in the considered indicator.

(Grabowski and Vernon, 2000).¹⁰ The short life of a patent makes it difficult to securitize it (Hillery, 2004). Under the hypothesis that a patent owner could pay renewal fees until his patent expires, we estimated the relative residual life for each patent from the date of the application.

D3. DEAL STRUCTURE

PBS architecture is another essential element for properly understanding and interpreting the outcome of a deal. Since PBSs are ad hoc transactions, the underlying financial and legal structure is customized and each deal is different from the others. IP deals require a proper legal framework, professional servicing, highly specialized financial, legal and tax advisers, the choice of appropriate credit enhancements. The deal strength and rating assessment is also influenced by the Originator's degree of experience, by the financial situation of the licensees and licensors and by the strength of collateral guarantees.

D3.1 Stakeholders

- *Licensee/licensor financial condition.* Since patent securitizations are often based on licensing agreements, assessing the financial stability of both the licensee and the licensor is a key issue. In particular, the financial strength of a licensee is important because interest payments on securities depend on its performance. If the asset is not successful enough to generate the anticipated cash flows, the licensee can continue paying its license fees. For that reason, financially stable drug companies are more likely to exploit licensed drugs and to afford interest repayments (Hillery, 2004). We measured the degree of the financial strength of both licensees and licensors in the examined deals using a synthetic

¹⁰The sales percentage decline in the first two years after patent expiration for drugs with \$50 million sales or more at the time of patent expiration is estimated to be, on average, 43% and 42%, respectively (Grabowski and Vernon, 2000).

rating indicator built on the interest coverage ratio of each licensee/licensor in the deal year.¹¹

- *Originator's degree of experience.* The Originator's degree of experience in handling a securitization process can determine the success of a transaction. The accumulated knowledge on how to structure the process might reduce the risk of failure. The more experience in the field, the higher the chance to properly structure an IP deal. Moreover, each new deal requires setting up trust among investors, which is costly. Long and consolidated knowledge in managing IP securitizations can make a new transaction more efficient and cost effective (Kirsh, 2005). In fact, an Originator's second deal is typically much easier and cheaper than the first one, as documentation and covenants are simply adjusted to the new pool. We approximated the Originator's degree of experience with the number of similar transactions in which he was involved in the years prior to the considered deal.

D3.2 Collateral

- *IP Pooling Arrangement.* The major benefit in aggregating royalty streams coming from a pool of drugs (rather than just one) is that diversification lowers the risk that underperformance of any one income stream will cause the deal to default (Walsh, 2007). In order to assess the diversification potential of the studied PBSs, we considered the number of drugs involved in the deals.
- *Diversification.* The risk of underperformance of patent-backed securities is mitigated by the diversity of the overall pool of assets, the underlying patents and the license agreements. We accounted for the diversification of underlying drugs by analyzing the

¹¹ The interest coverage ratio is expressed as the ratio between a company's EBIT and financial interests in the deal year. The ratio is an index of a company's ability to repay debt interests. According to the value of the interest coverage ratio, a "synthetic" rating and a default spread can be defined (for more details on rating ranges see Damodaran data on "Ratings, Interest Coverage Ratios and Default Spread").

number of ATC classes for the 14 drugs, the difference in their residual market life and the different types of molecules.

D3.3 Transaction Architecture

- *Vehicle structure.* In a standard securitization process, the Originator sells the asset itself or cash flow rights to a bankruptcy-remote entity known as a Special Purpose Vehicle (SPV) in order to separate future receivables from its own corporate risks. SPV are not usually created for single transactions but usually are revolving and multi-purpose organisms. However, the unique nature of patents implies a case by case assessment of their value and risk profile and, as a consequence, the design of a PBS transaction cannot be a standardized process. Flexibility and customization of the vehicle can add solidity to the deal structure and increase the overall probability of success of the transaction. We assessed the vehicle structure by analyzing the degree of flexibility of the SPV and the possibility of further modifying the asset pool after the first issuance.
- *Credit enhancement.* Securitizations are structured with a number of credit enhancements that should further improve the attractiveness of asset-backed securities.¹² Due to the use of credit enhancements in securitization structures, it is possible to achieve a larger separation between the asset risk and the company risk (Moody's Investors Service, 2000). By virtue of these tools, a security's credit quality can be raised above the quality of the underlying asset pool or of the entity originating the assets. As a consequence, the use of tailor-made credit enhancement tools is assumed to significantly increase the likelihood that a deal will be successful. We assessed the presence of internal and external credit enhancement mechanisms and their efficacy to secure each deal.
- *Legal framework.* In examining the feasibility of a deal, attention must be paid to a variety of legal issues, such as the impact that country regulations have on the asset's underlying

¹² Credit enhancement mechanisms can be either internal (subordination, overcollateralization, excess spread mechanisms, reserve accounts, internal guarantees) or external (basket credit default swaps, third-party guarantees).

value, specific bankruptcy concerns and legitimacy over patent rights. Decoupling the assets from the bankruptcy risk of the Originator requires an appropriate legal structure. Moreover, legal due-diligence on patent ownership is essential to ensure effectiveness against the risk of patent infringement (Walsh, 2007). We compared the legal structure of the two deals and focused the analysis on the underlying asset ownership and on royalty contracts discipline.

3.2 Model implementation

Following the fuzzy approach, each of the identified variables is defined by five elements $(X, T(X), U, G, M)$. X is the variable, $T(X)$ is the “term set”, namely the set of values (single values are called “fuzzy variables”) that the variable can take, U is the universe of values upon which each set is defined, G is a grammatical rule to generate the variables’ names, M is a semantic rule linking each linguistic variable to its meaning. A fuzzy set is defined by its elements and by their degree of membership: for example in the fuzzy set $T1 = \{(x, \mu(x))\}$, x belongs to the universe and $\mu(x)$ is its degree of membership to $T1$. The function that represents the relationship between a value and its degree of membership in a specific set is called “membership function”. It often depends on the context, on the problem under investigation and on the researcher’s subjectivity.¹³

For example, in our framework the variable “*Market size*” is a linguistic variable, defined as between \$ 0-20 billion, the term set of which is “Narrow, Medium, Wide”.¹⁴ We used a set of fuzzy numbers from 0 to 20 to capture the fuzzy range of magnitude.¹⁵ Within this term set, the fuzzy variable “Medium Market size” relates the potential market size of a drug to a degree of

¹³ The shape of the membership function can be linear, nonlinear or discrete: the only requirement is that the degrees of membership should range from zero to one.

¹⁴ The upper bound is equal to the average market size of the first therapeutic class in the period between 2000 and 2003.

¹⁵ Each membership function is defined by some values according to its shape. For a trapezoidal shape, the membership function is defined by lower and upper base values. For a Gaussian shape, the membership function is defined by mean and standard deviation values. For instance, “*Market size*” shows 3 bell-shaped functions defined by (0, 3.4) for “Narrow”, (10, 3.4) for “Medium” and (20, 3.4) for “Wide”.

membership in the fuzzy set. For instance, the target market of the therapeutic area that the drug Rituxan (one of medicines used in the 13 Drugs Pool Deal) refers to was, on average, \$7.3 billion between 2000 and 2003. This value determines its degree of membership to “Medium Market size”. Figure 2 illustrates the example: the higher the expected size of the target market of the therapeutic area to which the drug belongs, the higher the degree of membership.

[Insert Figure 2 here]

Table 1 reports the fuzzy system we used to compare the two patent securitization deals. The Table shows the membership function shape (Gaussian or Trapezoidal)¹⁶, the universe of values upon which each term set was defined and the fuzzy numbers for each macro-area, sub-dimension and variable analyzed. The selection of the explanatory variables, of the term set and of the degree of membership relied both on data collection and on subjective judgment. In order to reduce arbitrariness in assigning degrees to the different dimensions and variables, we made a second run of interviews with industry and financial professionals. Experts’ opinions helped us to interpret the evidence and to validate the model.¹⁷

[Insert Table 1 here]

The model is based on Mamdani’s fuzzy inference method (see Mamdani and Assilian, 1975). We used simple trapezoidal or bell-shaped membership functions according to the discrete or continuous nature of linguistic variables. The model has been implemented on each hierarchical level for all the three macro dimensions. Starting from lower level variables, it generates a numerical value by aggregating the generated numbers into superior hierarchical stages. The final number is used to appraise the deals under investigation.

The model works in a simple way.¹⁸ The first step is the fuzzification of the inputs, which consists in determining the degree to which each input belongs to each fuzzy set through the membership functions (see Figure 2). Second, a series of rules to connect inputs to the final

¹⁶ We chose to use simple functional forms (bell-shaped and trapezoidal), depending on the continuous or discrete nature of the variables.

¹⁷ Scores and judgments for “Drug” and “Patent” dimensions were formulated at single drug level and aggregated afterwards. Instead, we considered the whole transaction when dealing with the “Deal structure” dimension.

¹⁸ The fuzzy system has been developed and implemented with MATLAB.

output must be defined. For instance, the variable “*Market potential*” can be considered as the output deriving from the combination of three inputs: “*Market size*”, “*Competition in the therapeutic class*” and “*Downstream assets*”. A set of rules which define the output level according to inputs’ values is required. These rules are expressed in the form of If-Then constructs and are built on linguistic variables that can take the verbal values. Here is an example: “If *Market size is Narrow AND Competition in the therapeutic class is Low AND Downstream assets is Low, THEN Market Potential is Low*”. In general, we considered all possible scenarios deriving from the combination of different inputs’ levels and we aggregated them using the AND operator. In the upper hierarchical level we adopted a more conservative approach by reporting a *Low* state for the final output each time that a linguistic variable recorded *Low*. This was done so that DRUG, PATENT and DEAL STRUCTURE dimensions would all be considered necessary conditions for a successful transaction. All the input combinations and rules we set for the exemplificative variable “*Market potential*” are reported in Table 2.

[Insert Table 2 here]

Third, the If-Then rules are interpreted in classical logic by the implication operators, such as fuzzy union, intersection and complement and the output of each rule is aggregated into a fuzzy set.¹⁹ Lastly, this aggregate output fuzzy set is defuzzified with a centroid method and the final result is a single number.

4. Discussion of results

Table 3 summarizes final scores at the different hierarchical levels and Figure 3 compares the suitability and strength of the analyzed PBSs. Considering the DRUG dimension, results highlight an overall little distance in *Market Potential* between Zerit® and the 13 drugs of the second deal (respectively, 4.76 and 5.27). However, if we look at the variables in which the sub-dimension is divided, some significant differences emerge.

¹⁹ The implication method has been implemented through min. operator (minimum), which truncates the output fuzzy set. The output aggregation process has been implemented through max. \ operator (maximum).

[Insert Table 3 here]

[Insert Figure 3 here]

Even though Zerit® was addressing a large market, its sales heavily declined after 2000 and dropped to \$426 million in 2003. On the contrary, the nine drugs which were already on the market at the time of the second deal generated \$ 4.4billion in sales and \$49 million in royalties in 2002 (Hillary, 2004). The market size of the therapeutic classes of the other 13 drugs between 2000 and 2003 was higher on average. Given these premises, the *Market size* dimension shows final scores of 3 for the first deal and 4.54 for the second.

Most of the second deal drugs are NBEs, which have a greater likelihood of becoming first-in-class medicines. However, NBEs also require more stringent production standards and a more complex development and manufacturing process. Some of the 13 drugs were the only medicines available for certain indications, but the others were follower molecules. At deal time, three compounds in the same therapeutic class of Zerit® (4 digit level) had already been approved. Weighing all of these issues, we computed that the distance between the Zerit® score and 13 Drugs Pool deal for the *Competition in the therapeutic class* dimension was less than 1 point.

While there is not a significant difference in the results concerning the presence of downstream assets (scores are 0 for Zerit® and 0.43 for the 13 Drugs Pool) and the degree of cooperation in drugs development (scores are 2.5 for Zerit® and 4.11 for the 13 Drugs Pool), the expected life of a compound is a critical and differentiating factor. Zerit was approved for market launch in 1994. Considering an average expected market life of twenty years, its residual market life was 14 years at the start of the deal. At the time of the second deal, nine drugs were already on the market, while four compounds were under approval. In 2003, the average time from final approval of the nine drugs was 6 years²⁰ and the potential residual life for the other four compounds still under the approval process was 20 years. *Maturity* scores are respectively 14 (first deal) and 15.64 (second deal). Considering the typology and ATC of each drug, we estimated the

²⁰ The years of the approval of the nine marketed drugs were: 1991 for Neupogen; 1994 for ReoPro®; 1996 for Retavase; 1997 for Rituxan®, TOBI®, Zenapax®; 1998 for Thalomid® and Simulect®; 1999 for Targretin Capsules®; 2002 for Neulasta (FDA-CDER data).

probability of *Success in the development and approval process* at deal time to range between 30.25% and 33.3% for the four compounds awaiting approval (scores are 24.8 for Zerit® and 27.5 for the 13 Drugs Pool).

The aggregation of the three sub-dimensions resulting into the macro-area *Market Potential* leads to a final degree of 4.76 (deal 1) and 5.27 (deal 2), while the macro-area *Development and Commercialization* reached 5.14 (deal 1) and 6.56 (deal 2). The final scores of the DRUG dimension are respectively 5 for Zerit® and 5.15 for 13 Drugs Pool.

Results for the PATENT macro-area point to a more pronounced difference between the Zerit® deal and the 13 Drugs Pool deal (1.65 and 8.19 respectively). The Lanjouw-Schankerman quality index for the patents on which the Zerit® transaction was based, is lower (0.40) than the average value of the index for the other 13 drugs (0.78), indicating that, overall, the quality of the underlying invention is lower in terms of scope, technical novelty and technological importance. Concerning *Time to expiration*, patents of the second deal have a longer residual life on average than Zerit® patents. Given these considerations, the first deal scores 8, while the second scores 12.76.

In the DEAL STRUCTURE, the last macro-area, considerable differences between the two patent securitizations can be seen (Zerit® deal scores 5 and the 13 Drugs Pool deal scores 7.02). Clearly the financial situation of the licensor, and the licensee in particular, are important elements to ensure the generation of cash flow. At the time of the Zerit® deal, both Bristol-Myers Squibb (the licensee) and Yale University (the licensor) were AAA rated by S&P (Fisher, 2002). For the second deal, licensors and licensees were a diversified group of investment-degree companies (Hillery, 2004). According to our synthetic rating index (built upon companies' interest coverage ratios at deal year) scores for *Licensee/licensor financial condition* were respectively - 0.45/51.58 for the Zerit® deal and 4.58/35.6 for the 13 Drugs Pool deal.

Another important factor which is likely to determine the success of a PBS is the Originator's degree of experience in handling a securitization process. Since 1996, Royalty

Pharma AG has been working with research institutes and science-based companies to acquire revenue-producing intellectual property, principally royalty interests in marketed and late-stage biopharmaceutical products. At the time of the Zerit® deal, the company owned a diversified portfolio of assets and was quite expert in the acquisition of royalty interests in industry leading life-science products. However, the Zerit® deal was the first securitization transaction the company had engaged in that had ended up in failure. As Royalty Pharma management declared, the first patent securitization failure was considered a useful lesson to secure expertise for this kind of financial solutions (Hillery, 2004). Therefore, we assumed that the company's expertise would increase with the second deal and consequently we assigned scores 2 and 5 for deal 1 and deal 2 respectively. The aggregation into the macro-area *Stakeholders* leads to a final score of 5 (deal 1) and 8.68 (deal 2).

The first transaction was backed by the patent rights on a single drug (Zerit®), while the second deal was built on the patent rights of thirteen biopharmaceutical drugs, all very diversified in terms of typology (NCEs vs. NBEs), ATC classes and residual market life. In both *Asset Pool* and *Diversification*, the second deal displayed superior scores (13 vs. 1 and 8.5 vs. 1, respectively); therefore the scores of the *Collateral* macro-area are 1.35 for Zerit® deal and 8.55 for the 13 Drugs Pool deal. The more difficult it is to predict how much exogenous factors are likely to affect patent value and drug performances, the more an Originator needs to diversify its asset portfolio to reduce the volatility of the expected cash-flows (Kirsh, 2005). Leveraging on multiple drugs with proven market acceptance has a good diversification potential and helps to reduce the risk of underperformance.

The two securitization deals also differed in their transaction architecture. Considering the *Legal framework* dimension, the characterization of the Special Purpose Vehicle in charge of the transaction was rather different. In deal 1, Yale University, which was the sole owner of the underlying asset, sold 70 percent of the royalties from the licensing agreement with Bristol-Myers Squibb for the Zerit® drug to SPV (BioPharma Royalty Trust). In deal 2, instead, even though

the legal aspects related to the treatment of royalties under the bankruptcy code were the same, the SPV (Royalty Pharma Finance Trust) owned not only a percentage of royalty rights deriving from the licensing contracts, but also the underlying patent in some cases. For example, the antigen technology underlying the drug Rituxan was developed by Xoma Corporation, which licensed it to Genentech, Inc. Rituxan was further developed by Genentech and Idec and Royalty Pharma purchased the licensed patents from Xoma, assigning the ownership to Royalty Pharma Finance Trust. The legal framework of this second deal was judged superior by the experts we interviewed; consequently, we assigned the score 8 to the 13 Drugs Pool Deal and 7 to the Zerit® deal.

Another difference between the two deals consisted in the structure of the Special Purpose Entity. BioPharma Royalty Trust was an *ad hoc* vehicle, with a fixed structure that was established with the sole purpose of funding the acquisition of the Zerit® patent rights. On the contrary, Royalty Pharma Finance Trust was structured to be a warehouse facility, not only thought to handle the 13 Pool Deal, but also allowing for the inclusion of other patent rights by Royalty Pharma. Even after the deal, the company could continue acquiring new royalty interests and issuing new securities to the investors (Hillery, 2004; Eisbruck, 2002). In fact, in January 2004, Royalty Pharma acquired a portion of the Memorial Sloan Kettering Cancer Center's royalty interest in Neupogen/Neulasta drugs, adding it to the trust. Since this trust was adjustable, expandable, and scalable, and thus more flexible than the BioPharma Royalty Trust, we assigned a score of 7 to the 13 Drugs Pool Deal and 1 to the Zerit® deal.

In order to obtain a higher credit merit, the Zerit® deal relied on some internal credit enhancement mechanisms: overcollateralization and subordination through the issuance of three tranches of senior notes, mezzanine notes and equity.²¹ The agreement also included a senior

²¹ Kirsh (2005) reports the following amounts: \$ 57.15 million senior tranches, \$22 million mezzanine and \$21.16 million junior tranches. The additional 14.69\$ million were provided as equity investment. Moreover, BioPharma Royalty Trust secured cash flows to a collateral trustee, Bankers Trust Co., which created various operating accounts to collect and distribute the funds. Quarterly distributions first covered collateral trustee service expenses, then senior note holders' interest and principal, and finally mezzanine, junior and equity holders.

coverage ratio test covenant,²² which could lead to early amortization and default unless requirements were fulfilled for three consecutive payment dates. This solution had the limitation of being too complex to be handled (Kirsh, 2005). The 13 Drugs Pool securitization was primarily backed by the MBIA Insurance Corporation, which provided protection against issuer default and downgrade risk. As one of the largest worldwide financial guarantors of structured financings, MBIA (AAA rated) provided credit enhancement for a wide variety of asset classes and was very active in the IP backed market. Royalty Pharma Finance Trust also benefited from a dynamic borrowing base calculation, and various reserve accounts. Finally, if some of the royalty streams underperformed, Royalty Pharma could request an indemnity from the companies selling their royalty interests. As the second deal was stronger in terms of credit enhancement mechanisms, we assigned it a score of 5 and gave a score of 8 to the Zerit® deal. The final score of *Transaction Architecture* is 5 for the Zerit® deal and 7.23 for the 13 Drugs Pool deal. Finally, these values resulted in a DEAL STRUCTURE degree of 5 (first deal) and 7.02 (second deal).

As previously described, the model generates a numerical value by aggregating the scores of lower level variables into superior hierarchical stages. The final number is used to appraise the suitability and strength of the two deals under investigation. The results pointed to a higher final score for the 13 Drugs Pool securitization (5.37 vs. 2.94 for the Zerit® deal), suggesting that this second financial solution was more likely to create value for both the issuer and the investors.

To sum up, several factors explain the relative success of deal 2 compared to deal 1. Royalty Pharma Finance Trust was able to mitigate all the risks related to the regulatory background and to the market performance of the underlying assets by leveraging on external credit guarantees, the high diversification of the drugs and the flexibility of the transaction architecture. On the other hand, BioPharma Royalty Trust underestimated the risk affecting the projected Zerit® revenues and failed to adopt an asset diversification strategy.

²² The ratio is expressed as 70% of the amount of royalties payable by the licensee, assuming net sales were equal to four times net sales in a quarterly report, divided by the amounts required in the cash flow distribution through, and including, the principal on the senior notes (Fischer, 2002).

These results, which are tested on the two PBSs presented, point to some general conclusions. In a securitization transaction, advantages in terms of market potential, level of competition and expected market life of the underlying assets can reasonably increase the probability to generate stable and consistent cash flows to cover the debt service and principal payments. Moreover, a higher quality of the underlying invention in terms of scope, technical novelty and technological importance and a longer patent residual life are likely to reduce the risk of technical obsolescence and sales losses. Finally, the strength of the credit enhancement mechanisms, the flexibility of the deal architecture and the adoption of a diversification strategy can increase the overall probability of success of a transaction.

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6. Tables and Figures

Table 1- Description of the Fuzzy model

LINGUISTIC VARIABLES		MEMBERSHIP FUNCTION SHAPE *	UNIVERSE **	FUZZY NUMBERS ***		
DRUG		Gauss (μ,σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)
Market Potential		Gauss (μ,σ)	[0-10]	Low (0, 1.7)	Medium (5, 1.7)	High (10, 1.7)
Market size	Size of the considered market segments (billion \$).	Gauss (μ,σ)	[0-20]	Low (0, 3.4)	Medium (10, 3.4)	High (20, 3.4)
Competition in the therapeutic class	Number of compounds already marketed in the US in the same ATC 4-digit.	Trap (a,b,c,d)	[0-14]	Low (-4.51, -1.09, 1.09, 4.51)	Medium (2.49, 5.91, 8.09, 11.51)	High (9.49, 12.91, 15.09, 18.51)
Downstream assets	Number of drugs in the same ATC 3-digit already marketed by the commercializing company before FDA approval.	Trap (a,b,c,d)	[0-2]	Low (-0.64, -0.156, 0.156, 0.64)	Medium (0.36, 0.84, 1.16, 1.64)	High (1.36, 1.84, 2.16, 2.64)
Development and commercialization		Gauss (μ,σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)
Maturity	Years of residual market life at the time of the deal (with 20 years of expected market life).	Trap (a,b,c,d)	[0-20]	High (-6.44, -1.559, 1.559, 6.44)	Medium (3.56, 8.441, 11.56, 16.44)	Low (13.56, 18.44, 21.56, 26.44)
Degree of cooperation	Synthetic index of development process information (internal vs external) and of number of licensing steps established until market launch.	Trap (a,b,c,d)	[0-10]	Low (-3.22, -0.78, 0.78, 3.22)	Medium (3.56, 8.44, 11.56, 16.44)	High (13.56, 18.44, 21.56, 26.44)
Success in approval process	Probability of success in the overall clinical drug category.	Gauss (μ,σ)	[15.4 33.3]	Low (15.4, 3.041)	Medium (24.35, 3.041)	High (33.3, 3.041)
PATENT		Gauss (μ,σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)
Quality index	Lanjouw-Schankerman quality index.	Gauss (μ,σ)	[0.4-1.27]	Low (0.4, 0.15)	Medium (0.83, 0.15)	High (1.27, 0.15)
Time to expiration	Years of residual patent life from the application date.	Gauss (μ,σ)	[2-13.14]	Low (2, 1.89)	Medium (7.57, 1.89)	High (13.14, 1.89)
DEAL STRUCTURE		Gauss (μ,σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)

Stakeholders		Gauss (μ, σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)
Licensee financial condition	Synthetic rating indicator: ratio between a company's EBIT and financial interests in the deal year.	Trap (a,b,c,d)	[-300-300]	Weak (-300, -300, 0.8, 1.25)	Quite solid (0.8, 1.25, 2.5, 3)	Solid (2.5, 3, 300, 300)
Licensor financial condition	Synthetic rating indicator: ratio between a company's EBIT and financial interests in the deal year.	Trap (a,b,c,d)	[-300-300]	Weak (-300, -300, 0.8, 1.25)	Quite solid (0.8, 1.25, 2.5, 3)	Solid (2.5, 3, 300, 300)
Originator experience	Similar transactions in which the Originator was involved in the years prior to the considered deal.	Trap (a,b,c,d)	[0-10]	Low (-3.22, -0.78, 0.78, 3.22)	Medium (3.56, 8.44, 11.56, 16.44)	High (13.56, 18.44, 21.56, 26.44)
Collateral		Gauss (μ, σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)
IP Pooling Arrangement	Number of drugs involved in the deals.	Trap (a,b,c,d)	[1-20]	Narrow (-5.12, -0.48, 2.48, 7.12)	Medium (4.38, 9.02, 11.98, 16.62)	Wide (13.88, 18.52, 21.48, 26.12)
Diversification	Synthetic index of drugs diversification in terms of ATC classes, residual market life and types of molecules.	Trap (a,b,c,d)	[0-10]	Low (-3.22, -0.78, 0.78, 3.22)	Medium (3.56, 8.44, 11.56, 16.44)	High (13.56, 18.44, 21.56, 26.44)
Transaction Architecture		Gauss (μ, σ)	[0-10]	Unsuitable (0, 1.7)	Quite suitable (5, 1.7)	Suitable (10, 1.7)
Vehicle structure	Synthetic index of flexibility of the SPV.	Trap (a,b,c,d)	[0-10]	Low (-3.22, -0.78, 0.78, 3.22)	Medium (3.56, 8.44, 11.56, 16.44)	High (13.56, 18.44, 21.56, 26.44)
Credit enhancement	Synthetic index of efficacy of internal and external credit enhancement mechanisms.	Trap (a,b,c,d)	[0-10]	Low (-3.22, -0.78, 0.78, 3.22)	Medium (3.56, 8.44, 11.56, 16.44)	High (13.56, 18.44, 21.56, 26.44)
Legal framework	Synthetic index of the legal structure of the two deals.	Trap (a,b,c,d)	[0-10]	Low (-3.22, -0.78, 0.78, 3.22)	Medium (3.56, 8.44, 11.56, 16.44)	High (13.56, 18.44, 21.56, 26.44)

* Gaussian membership functions are defined by mean and standard deviation values (μ, σ); trapezoidal membership functions are defined by the values of basis orthogonal projection on the abscissa (a,b,c,d).

** Universe represents upper and lower bound for each variable on the two PBSs. A [0-10] has been used when a variable is mainly based on qualitative judgments or is a synthetic indicator of different parameters.

*** Fuzzy numbers represent membership function parameters for each fuzzy variable.

Table 2 - Input combinations and rules for the variable “Market Potential”

	IF	PROPOSITION 1	AND	PROPOSITION 2	AND	PROPOSITION 3	THEN	OUTPUT
1.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS Low)	THEN	(Market Potential IS Low)
2.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS Medium)	THEN	(Market Potential IS Low)
3.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS High)	THEN	(Market Potential IS Low)
4.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS Low)	THEN	(Market Potential IS Low)
5.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS Medium)	THEN	(Market Potential IS Low)
6.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS High)	THEN	(Market Potential IS Low)
7.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS Low)	THEN	(Market Potential IS Low)
8.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS Medium)	THEN	(Market Potential IS Low)
9.	IF	(Market size IS Narrow)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS High)	THEN	(Market Potential IS Low)
10.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS Low)	THEN	(Market Potential IS Low)
11.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS Medium)	THEN	(Market Potential IS Low)
12.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS High)	THEN	(Market Potential IS Low)
13.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS Low)	THEN	(Downstream assets IS Medium)
14.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS Medium)	THEN	(Downstream assets IS Medium)
15.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS High)	THEN	(Downstream assets IS Medium)
16.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS Low)	THEN	(Downstream assets IS Medium)
17.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS Medium)	THEN	(Downstream assets IS High)
18.	IF	(Market size IS Medium)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS High)	THEN	(Downstream assets IS High)
19.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS Low)	THEN	(Market Potential IS Low)
20.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS Medium)	THEN	(Market Potential IS Low)
21.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS Low)	AND	(Downstream assets IS High)	THEN	(Market Potential IS Low)
22.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS Low)	THEN	(Downstream assets IS Medium)
23.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS Medium)	THEN	(Downstream assets IS High)
24.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS Medium)	AND	(Downstream assets IS High)	THEN	(Downstream assets IS High)
25.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS Low)	THEN	(Downstream assets IS High)
26.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS Medium)	THEN	(Downstream assets IS High)
27.	IF	(Market size IS Wide)	AND	(Competition in therapeutic class IS High)	AND	(Downstream assets IS High)	THEN	(Downstream assets IS High)

Table 3 - Final scores

LINGUISTIC VARIABLES	Zerit® PBS	13 Drugs Pool PBS
DRUG	5.00	5.15
Market Potential	4.76	5.27
Development and Commercialization	5.14	6.56
PATENT	1.65	8.19
DEAL STRUCTURE	5	7.02
Stakeholders	5	8.68
Collateral	1.35	8.55
Transaction Architecture	5	7.23
PBS RESULT	2.94	5.37

Figure 1 – Framework of analysis

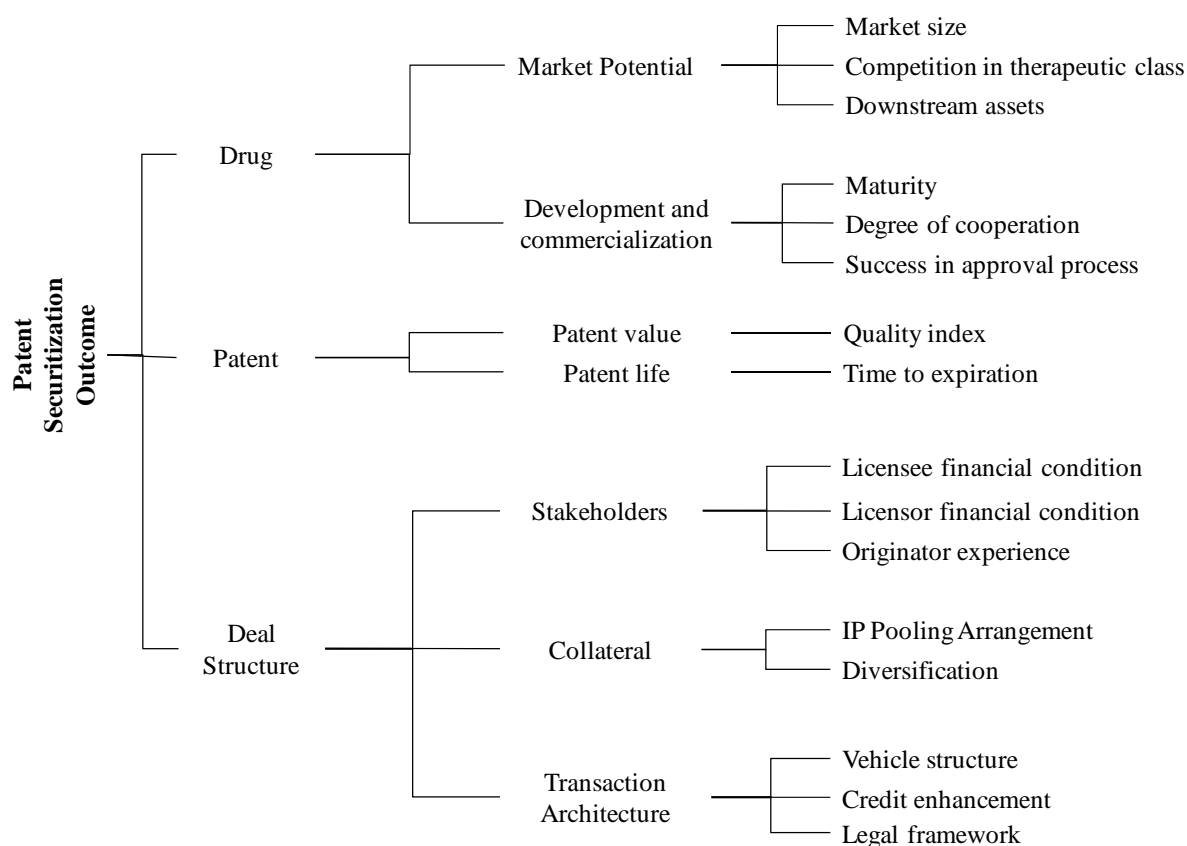


Figure 2 – Membership Function “Market Size”

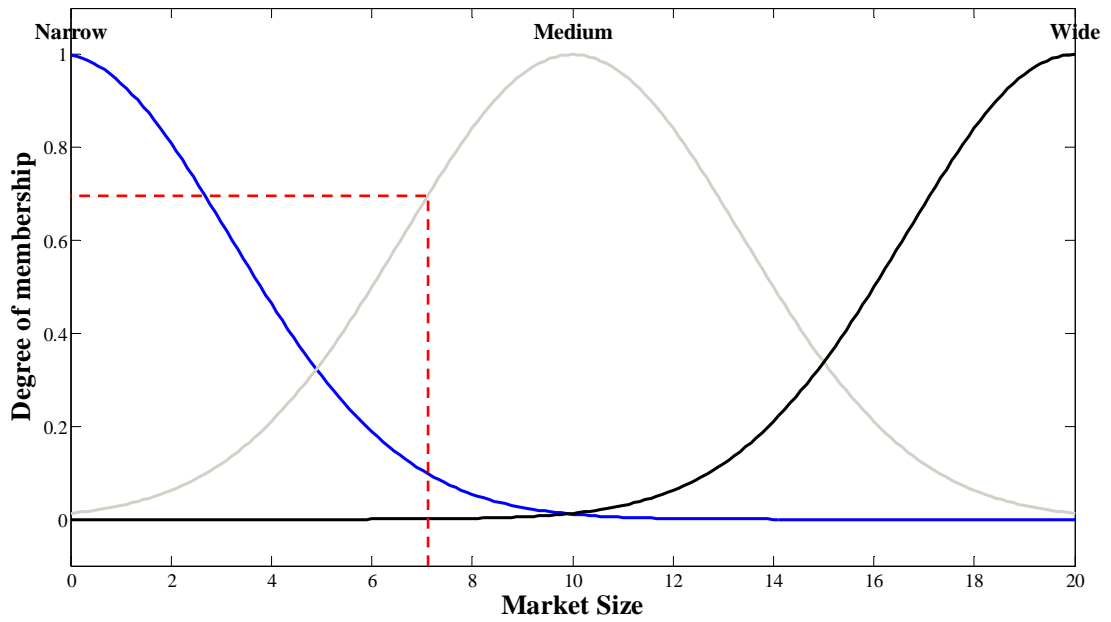


Figure 3 – Output of the two PBS deals

