Commercialization Strategies of Research Providers and their Realization in the Negotiation Process – An Exploratory Analysis
ABSTRACT

This paper shows the results of investigating what are the most common business practices in the commercialization of discoveries and technologies in the biotechnology sector, the allocation of control rights as a result of the negotiation process, the factors impacting the bargaining position of the companies during the negotiations, and the perception of risks by the business practitioners.

For this purpose, qualitative methods were applied. First, the extant theoretical literature was reviewed as part of the secondary research and the definition of the research framework for the primary research. Secondly, as primary research, in-depth semi-structure interviews were conducted to eight business practitioners in the biotechnology and pharmaceutical field to contrast the findings of previous literature with their opinions.

Overall, the findings are that the most common commercialization strategies of small biotech companies are licensing agreements and partnership and alliances with larger companies especially in the pharmaceutical industry, driven first by the lack of resources and complementarities of the small firm, and a trend of the large companies to search outside their walls for new technologies to fill their pipelines.

In the allocation of control rights, a large company usually tries to retain the rights to manage clinical trials, manufacture and market the product asking for exclusivity in certain markets. The right to sublicense will be retained by the large company, while the right to terminate contract or alliance is commonly included in the contract as a possibility for both parties in the agreement. The owner of the technology will normally try to partner with a company that has no intention to shelve the project. The original owner of a technology will commonly keep the right to ownership of that technology, whereas the ownership of subsequent developments inside an alliance will vary depending on each case.

With respect to the bargaining power, the interviewers remarked that the financial power of the firms, the value and level of breakthrough of the technology; the number
of potential licensees; the pressure of patent cost; the lack of complementary assets; and negotiation skills are some of the factors impacting the bargaining position of the firms.

Concerning the perceived risks when collaborating with other companies, the business practitioners show concerns when one of the parties involved might potentially: shelve the project or declare it out of strategic focus; use disclosed information to infringe, invent around or become a potential competitor; profit in an unequal and advantageous manner; invest without desired results. Some practices recommended to mitigate these risks are to have well written contracts -with openness to renegotiate-, to build a strong alliance management team and to conduct a robust due diligence by both parties previous to sign any collaboration agreement.

As a recommendation for future research, it is suggested investigating further on the factors influencing the selection of commercialization strategies by small biotech and large pharmaceutical companies, and the factors affecting the bargaining power in an negotiation.
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INTRODUCTION

Increasingly over time, Research and Development (R&D) and innovation are pursued in a collaborative interaction, usually in two types of innovation linkages. First, through business-to-business interactions in the form of contracted-out R&D practices, transactions in R&D services and technology alliances; and secondly through public-private R&D collaborations. According to the National Science Board, it is estimated that only in the United States in 2007, companies allocated approximately US$19 billion to R&D performed by external organizations located within the United States. This number compared to US$12.4 billion for 2006, represents a 53 per cent increase. The all-industries ratio of contracted-out R&D versus company-funded, company-performed R&D increased from 5.5 per cent in 2006 to 7.8 per cent in 2007. Across R&D-intensive industries, pharmaceuticals had the highest ratio of contracted-out R&D with a 21 per cent ratio in 2007 (Board, 2010).

In terms of worldwide business technology alliances, according to the Science and Engineering Indicators 2010 from the National Science Board, in year 2006 the Cooperative Agreements and Technology Indicators (CATI) database had registered around 900 newly formed alliances, 60 per cent of which was in the biotechnology sector. This, in addition to the increase of R&D funding from year 2006 to 2007, captures the importance of collaboration agreements worldwide (Board, 2010).

In the pharmaceutical industry, the pharmaceutical companies had traditionally developed their own technologies in-house (Chandler, 2005), in a closed innovation model (Chesbrough, 2003 & 2006). The surge of small biotech companies and the new regulation to access discoveries made by public research centers (BayhDole25, 2006) impacted the business model of the large corporations obligating them to rethink their strategies (Fisken & Rutherford, 2002). The new business configuration led the small companies to specialize on the early stages of the value chain such as the discovery and development, while the large companies, even though participating in all the value chain, they concentrated with more impetus in the later stages such as further development, manufacturing and commercialization in the end market (Granberg & Stankiewicz, 2002).
This meant that in order to complete the business cycle from the discovery to the end market, these two type of firms necessitated to increase the level of interactivity using collaboration strategies like licensing in and out or forming partnerships and alliances, strategies that deal with negotiation processes to allocate control rights (Aghion & Tirole, 2004; Lerner & Merges, 1998) influenced by the bargaining power of each party (Argyres & Liebeskind, 1999) and the perception of risks (Helm & Kloyer, 2004).

**Problem Statement**

A great deal of biotechnology research providers, specially in the pharmaceutical industry, is composed by young companies, which lack the complementary assets such as manufacturing know-how, sales forces, distribution channels, and a strong position on the market. This situation influences these firms to formulate their business models primarily based on the commercialization strategies of their discoveries and inventions with other companies by creating alliances or licensing deals. Regularly, this task involves a complex process of negotiation between the young research firm and the potential buyer/partner, where the bargaining power plays a vital role affecting the strategies of the parties involved. These strategies can sometimes be reflected in the different control rights each firm tries to retain and, or forgo. Control rights are defined as the ability of the firm to control the way a firm or alliance is run (Edwards & Weichenrieder, 2009). This situation leads us to the following research questions:

- What are the commercialization strategies of the research providers in the biotechnology sector?
- Which control rights do these research providers commonly retain and, or forgo during the negotiation process?
- Which are the main factors impacting the bargaining power of the research firms during the negotiation process?
- What are the perceived risks by the business practitioners during the collaboration process?

In the past 30 years, a wide variety of discussions about the allocation of control rights, especially in the biotechnology sector, have taken place. However, currently, there is a lack of updated qualitative research related to the analysis of commercialization strategies implemented by research firms, their realization during the negotiation
process considering the allocation of control rights, the definition of factors impacting the bargaining power during the negotiations and the perceived risks during the implementation of the commercialization strategies. This research intends to fill in this gap to demonstrate what the commercialization strategies of the research firms are and how they become tangible in the negotiation process through the allocation of control rights, involving the bargaining power as a catalyst on this process and the definition of the perceived risks by the firms.

**Structure of the Thesis**

The paper is divided into five sections. The initial section comprises the methodology of the research with an extended description of the employed primary and secondary research. The primary research consists of the qualitative component made through interviews to business practitioners on the biotech field. The secondary research provides an overview of the secondary information from the review of extant literature on the research topic. This section also highlights the limitations of the research considering the aspects of reliability and validity underpinning the conclusions of the research.

Subsequently, the third section provides a thorough review of the existing literature, setting a framework of prior knowledge and research on the topic conforming the conceptual foundations. For this purpose, relevant findings in previous academic and professional literature are highlighted and reported on this section.

The fourth section will render the analysis, discussion and interpretation of the research findings proceeding from the interviews made to business practitioners. This section also draws parts from extant literature to support, explain or contrast the findings of the interviews.

The last section covers the summary of findings and conclusions, as well as suggestions for relevant further research not in the scope of work of this thesis nor found on the previous art.
METHODOLOGY

The current thesis is constructed on qualitative research based on living experiences and personal knowledge acquired by practitioners in real life, and gathered via interviews. The main findings do not arrive from statistical procedures or other means of quantification. Also, valuable information has been collected from the review and analysis of extant literature. The research makes use in part of the methodology of grounded theory by Strauss and Corbin, though the purpose is not to build new theory, but rather help elaborate and extend the existing theory, potentially offer new insights, enhance understanding and provide a meaningful guide for further action (Strauss & Corbin, 1998).

Foundations of the commercialization strategies of biotech firms, the control rights commonly retained by those firms as well as the factors involved in the balance of the bargaining power in the negotiations of such control rights are obtained from the inductive procedures analyzing data from the interviews and the analysis of data from the extant literature.

The first part is integrated by the secondary research, which includes the literature review to help set the underpinning of the research. Later on, the primary qualitative research is explained, and finally some limitations of the research are described.

Secondary Research

A thorough research on existent articles was conducted on business-specialized databases and journals such as ScienceDirect, EBSCO, JSTOR, Scopus, Oxford Journals, among others. Keywords like open innovation, outsourcing of technology development, research suppliers, research agreement, negotiations, allocation of property rights, control rights, commercialization strategies, incomplete contracts, opportunistic behavior, hold up problem, moral hazard, royalties, specific investment, alliances, collaboration strategies, R&D outsourcing, licensing strategies, technology commercialization, and others were used. Special attention was given to research articles focused on commercialization strategies of technology in the biotech sector, control rights and bargaining power. The span of this task included the search of published books, professional publications and websites of biotech and pharmaceutical companies.
The information from the articles was then summarized extracting the main findings and contributions to the literature. This task helped to construct a conceptual framework on the field of study to be used for building the potential questions for the interviews to business practitioners. The main findings are divided into general concepts such as commercialization strategies, control rights, bargaining power and risks.

**Primary Research**

It comprises the qualitative and main substance of the research. A series of interviews was conducted to a total of eight business practitioners specialized in the area of biotechnology and pharmaceutical sector. Their level of experience, knowledge, location, organization/company, and position and roles played in their organizations diverge greatly. The interviewees include technology managers, technology specialists, business developers, investment managers and chief executive officers (CEO’s), all of them part of diverse organizations such as a technology transfer division, a contract research and development company, an organization for funding biotechnology start-ups, a consulting company for technology management in biotechnology sector, and pharmaceutical and biomedical device companies. The purpose to have a wide diversity among respondents was to have different perspectives on the research topic. The sampling of potential interviewee was drawn from several directories of companies and organizations mainly in Denmark and Mexico. Some other contacts were obtained through references of personal connections and second-tier connections. Approximately forty potential interviewees were contacted via e-mail explaining the purpose of the research as well as the intention to conduct an interview. Eight people responded, four of which were located in Denmark and interviewed in person, whereas the other four were located in Mexico, U.S. and Sweden, and interviewed by telephone. Additional exchange of information took place via e-mail in order to clarify insight from their responses.

The interview was semi-structured, meaning that the basic concepts defined in the conceptual framework were brought at the beginning of the interview through general questions. Later on, as the interview proceeded, specific questions arose out of the direction of the conversation, yet respecting the defined framework of themes and guide. After each question, the interviewee was allowed to describe freely on the topic. During the conversation, the interviewees may have elaborated on some of the topics without
the need to specifically ask the elaborated questions. Due to the use of academic terms, there was a need to explain and orient the interviewee for their full understanding on the questions. Examples of this may include the explanation of the term *bargaining position* and the factors affecting it positively and negatively. Practical examples using a business context may have also been used. The information from each interview was collected in a note-taking form and audio recorded for posterior review and analysis.

For the analysis, the information was categorized using the conceptual framework defined in the literature review to support or contrast such findings.

**Limitations of the Research**

The limitations on the use of the knowledge gained through the research are to be considered before the generalization of the results herein presented. The literature review is built upon the analysis of the prior art bearing a load of relative validity and reliability concerns. Also, some limitations and constraints to the quality of knowledge gained from the secondary sources apply. For this reason, the findings of the secondary research were triangulated with the findings from the primary research. On the other hand, the primary research was sourced from in-depth interviews to high-level business practitioners from different organizations. This allows minimization of reliability problems; however they cannot be excluded fully. Each interview was made in a semi-structure with open-ended questions in order to prevent bias questions by the interviewer. Nevertheless, full disclosure of information may have not been shared given confidential information. In order to minimize this issue, the interviewees were notified that the information would be treated as confidential without quoting the interviewees’ names or their organizations. The interviewers may still not disclose certain information or opinions. To avoid handwritten mistakes, each interview was audio recorded.

The validity might be also restricted upon the limited number of interviews. The non-representative size of the sample may prevent direct generalization. Dissimilarity among the type of companies and organizations may also affect the validity. However, due to the small amount of extant qualitative research on the topic, this thesis represents an opportunity to find some future research questions that has not been explored in the extant literature.
LITERATURE REVIEW

This section helps set up the basis of the research to answer the research questions. It starts describing the background of the evolution of biotechnology and how some technological changes and other factors affected the value chain of businesses in this field. Later on, there is a description of the different commercialization strategies implemented by small and large companies, followed by the definition of some business models used by companies. Immediately later the collaboration forms are considered together with the form of transactions and risks, continuing with the description of control rights, just to finalize with the discussion of bargaining power.

Background

Research and development commercialization is one of the most crucial business practices between start-ups and established companies. Firms around the world thrive constantly to develop the best technologies and situate them in a better position with respect to their competitors. The commercialization of technologies tends to be more competitive as the number of technology-based companies is larger; such is the case of the biotechnology sector\(^1\). The use of biotechnology has expanded at a great pace during the last 40 years. It went from practicing biotechnology at a macro level – breeding animals and crops for example- to working the micro level. The development of technologies that were used by biotech practitioners allowed for a series of important discoveries, unleashing the development of this industry in a private form. The new companies being created allowed the exploitation of discoveries and technologies applicable in health, agricultural, environmental and industrial applications (Strauss & Corbin, 1998), which evolved through decades of basic research and product development in several existing industrial sectors (U.S. Congress, 1991). During this time, the biotechnology field has been populated with diverse types of companies, whose business models have evolved rapidly. The immediate development of biotechnology helped change -and is still changing- the structure of the pharmaceutical and healthcare industry based on the rise of expenditures on R&D.

\(^1\) Biotechnology is not defined as a sector per se, but a set of biological techniques and technologies. A more appropriate modern definition of biotechnology would be “the use of cellular and biomolecular processes to solve problems or make useful products” (Guilford-Blake, 2007).
Over the past 40 years, some pharmaceutical firms have consolidated into the market, but also many newly competitive biotechnology firms have entered the game. The collaboration of these two types of companies accompanied with the non-profit sector has allowed a rapid evolution.

Up to the mid-1970’s, the companies that dominated the pharmaceutical industry came from the old-school fashion of the chemical sector, in their majority fully-integrated large companies with units covering all the value chain ranging from drug discovery to clinical development, manufacturing and commercialization. Most of the drug discovery activities were made in-house, whereas the licensing activity was driven downstream with rights to commercialize proven products and drugs. The knowledge and technology were frequently acquired from the academic sector through different sources opened publicly. Whether the type of transaction was integrated or not, depended greatly on the nature of the assets involved in the transaction (asset specificity), uncertainty and the regularity of the transactions. In general, those transactions conducted less frequently, involving more specific assets and having more uncertain outcomes were more likely to be integrated (Rasmussen, 2010). According to Mowery (1983), during the period of 1900 to 1940 the cost of organizing innovation inside the U.S. manufacturing companies was lower than contracting with an interdependent supplier in the market, allowing for the retention of all the residual rights in-house (Mowery, 1983).

The subsequent waves of development in biotechnologies affected the value chain of the health industry. During the 1980’s, there was a more complex development of the industry with the birth of thousand of biotech ventures, many of them supported by the non-profit sector such as the academic institutions, increasing the competition for knowledge and new technologies. While some of the newly created biotech firms thrived to follow the same business model of the big pharmaceutical, just a few succeeded in doing so, and most assumed the role of specialized suppliers of leading-edge technologies (Cockburn, 2004).

The entire new economical-business phenomenon was supported by the implementation, in 1980, of the Bayh-Dole Act or University Patent Patent Procedure Act in the United States, legislation regarding to intellectual property funded by the federal government.
The Act gave the universities, small business and non-profits intellectual property control of their inventions and other intellectual property that resulted from federal funding (BayhDole25, 2006).

**Configuration of a New Value Chain**

The economical and business changes aforementioned affected the configuration of the biotechnology sector, especially related to the pharmaceutical industry, generating a great number of specialist start-up companies. In the figure 1, Granberg and Stankiewicz (2002) show a scheme of the value chain incorporating what they call the specialist companies. The specialist companies such as platform, therapy, informatics, supplier and drug delivery concentrate mainly in the discovery and development links, the initial sections of the value chain (Granberg & Stankiewicz, 2002).

![Figure 1. Pharmaceutical industry value chain and the set of specialist firms. Granberg & Stankiewicz, 2002.](image)

More specifically, Mehta (2008) schematizes the different links in the value chain for drug development in the figure 2 (next page). In brief, the drug development process starts with the discovery project of a target’s key involvement in a disease; this target is commonly a protein, enzyme or a receptor in a cell or tissue that has been discovered to play a central role in the development of the disease or symptoms. The potential drug, then, is submitted to tests on toxicology and validation on animals.
Later, the potential drug needs to be presented to basically three clinical trials on humans evaluating the toxicity, effects of the drug on humans and efficacy at treating the disease. Once the clinical trials are complete, it is submitted to approval to the FDA. A fourth phase takes place when marketing the drug in the market, usually required by the FDA to corroborate the efficacy of the drug on its use. All this whole process can take from twelve to sixteen years, and hundreds of millions of dollars (Mehta, 2008).

The large pharmaceutical companies, even though today continue participating in all the stages of development from the discovery to marketing and sales, in the past they were the only players controlling the market. Nowadays, on each link of the value chain they look for complementarities from other newly small companies, especially in the early stages of development, such as discovery and development. On the other hand, the small specialist companies focused on the early stages look for complementarities to continue to later stages via partnering, licensing out or selling their technologies to the big pharmaceutical companies (Bianchi et al., 2010).

Also, Helm and Kloyer (2004) state that in high technology industries, such as biotechnology, the R&D suppliers are usually specialized in the early stages of the innovation process, i.e. basic research and applied research, whereas the pharmaceutical companies or R&D buyers aim at the later stages of the process performing activities in the development, production and commercialization of final products (Helm & Kloyer, 2004).

As the number of big pharmaceutical companies and small biotech ventures increased, they realized that to continue in the game, they needed to enhance the level of
interactivity among them and other external sources of innovation to have access to new knowledge and technologies. These strategies range from simple collaborations and exchange of information to in licensing deals and strategic partnerships, all of them depending on the market structure and the competitiveness of the companies. Their business model flexed toward a more open concept, using external sources and not necessarily developing the technologies in-house as in the past, evolving from the concept of the closed innovation to open innovation -defined by Chesbrough as “firm level strategies where purposive inflows and outflows of knowledge are used to accelerate internal innovation, and expand the markets for external use of innovation” (Chesbrough, 2003). An example of this new strategy is found in Merck Pharmaceutical, which has implemented an open model of innovation using alliances and licensing according to its booklet of partnerships: “Our licensing strategy has resulted in high-value alliances. Approximately 63 per cent of Merck’s 2009 sales were attributable to alliance products and patents, including some of our biggest blockbusters”. We have applied our marketing and sales expertise to achieve extraordinary commercial success with our partners” (Merck Sharp and Dohme Corp., 2009).

This phenomenon was provoked by the fact that external scientific knowledge expanded in the recent years in universities, research institutions and other private companies, not only in terms of basic but also in applied research, bringing to life serious breakthroughs that endangered the profitability of small and large firms on this industry.

Malik (2009) observed that leading pharmaceutical companies have recently begun to focus on filling their pipelines with innovative protein-based drugs, which were particularly risky to develop and because up until now big pharmaceutical companies could generate good profits from small molecule drug alone, so they had no real need to use other technologies (Malik, 2009). For that reason, pharmaceutical companies have been late entering the biotech space, forcing them to use other strategies to acquire technologies to robust their pipelines (Aitken et al., 2000). Some reasons why the large pharmaceutical companies partner with biotech companies –and usually acquire after the biotech company turns out to be a good strategic fit for the drug market- are: first, it lets the pharmaceutical company enter a new therapeutic area, in which it has no presence; second, it can fortify a drug maker’s existing franchise in a particular

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2 A drug is called “blockbuster” if it generates more than US$ 1 billion annually. Source: Malik (2009)
therapeutic class allowing it to become strengthen its global leadership; third, it gets access to the proprietary drug discovery platform of the biotech company; fourth, it harnesses the innovative culture at biotech firms to help them replenish their pipeline; fifth, non-U.S. companies use this strategy to gain access to the American market, among other reasons (Malik, 2009; Fischette, 2004; Taunton-Rigby, 2001).

Nevertheless, these reasons might not be static. McCutchen and Swamidass (2004) found out that the motivations for strategic alliances in the pharmaceutical/biotech industry suffered variations considering different periods of time. As for example, during the 1980’s, the main motivation was market access, whereas the need for risk reduction played the major motivation for strategic alliances in early 1990’s (McCutchen & Swamidass, 2004).

**Commercialization Strategies**

The rapid development of technologies and the access to external sources made the firms to rethink the way they were doing business and to concern about the necessary assets they needed to be profitable.

According to Smith and Parr (2004), every company comprises three basic assets: monetary assets, tangible assets, and intangible assets. The monetary assets or working capital refers to cash, short-term investments, inventories, raw materials, work in progress and finished goods. Tangible assets are composed of plant, property, and equipment, etc. Intangible assets and intellectual property usually do not appear in a balance sheet of a company. Rights, relationships, human capital and intellectual property integrate the group of intangible assets, which commonly is the most important part of an R&D intensive company. Rights are acquired through contractual agreements with other businesses, individuals, and governmental bodies. These rights exist according to the terms of a written contract that define: the parties to the agreement; the nature of the rights, goods, or services transferred; the transfer consideration; and the duration of the agreement. A contract may have little value unless its provisions result in an exchange that is of economic benefit to the business. The rights are a mean of control in a collaborative strategy Intellectual property includes patents, copyrights, industrial secrets, trademarks, and computer software, among others.
For that reason, two of the major concerns of any biotech company is the protection of its intellectual property, since most of them are R&D intensive, and any discovery and new developed technology, if not protected properly, might make it lose in the market; and the access to the three type of basic assets through collaborative strategies with other parties (Smith & Parr, 2004).

As above-mentioned, the small biotech firms assumed the role of specialized suppliers, which often are bound by the scarcity of resources, specially to take the discoveries to a further development or, even more difficult, to reach their commercialization in the end market. This situation commonly inhibits to market the biotech products just on time if done lonely. The R&D intensive firms need to access to technological assets, acquire market knowledge, overcome barriers to entry, expand horizontally, achieve economies of scale, co-opt and block competitors, share costs, and in general access to complementary assets (Narula & Dunning, 1998).

Under this situation, a new biotech firm must choice between two options, which are not necessarily mutually exclusive. First, continue the race alone reinvesting in a product progression, starting offering cheap products such as monoclonal cell lines, then moving onto reinvesting in more capital intensive products such as diagnostic kits, later on jumping into developing and producing drugs for human use, which require very high amounts of resources and capital (Smith, 1988). Second, play a series of collaborative strategies as a form of exploiting intellectual property, involving relationships with other firms and institutions such as: licensing, R&D cooperation, research joint venture and research corporation.

Both options can be achieved in parallel if planned in a strategic form into the business model of the company. For example, a company could be working in a diagnostic kit while doing a collaborative research with a big pharmaceutical firm, while extracting explicit and tacit knowledge (Sanchez, 2004), and resources to scale up on the development of more profitable products.

**Business models and type of companies**

A business model describes the rationale of how an organization creates, delivers, and captures value (Osterwalder & Pigneur, 2009). When classifying the type and business
models of a biotech company, it is important to understand the commercialization strategy that the firm chooses. There are several classifications given by academics and practitioners depending from the point of view.

For example, Libaers and Hicks (2002) define one of the types of companies as a ‘small development stage firm in bioscience’ with a pipeline, though perhaps no actual products at present, often no revenue and no commercialization, though it is often public. One example of this is a biopharmaceutical company focused on the development of monoclonal, antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. This company is a trader of ideas that identify itself as a product firm, and its R&D may generate revenue. Another type defined by Libaers and Hicks is the “R&D organization or contractor”, which is a small firm with profound expertise in narrow research areas in which they conduct basic/applied research with a commercial orientation, and sells prototypes, patents, or novel production, processes, and tacit know-how (Libaers & Hicks, 2002).

Similarly, Rasmusen (2010) and Orsenigo (2001) classify the biopharmaceutical companies in drug discovery and platform technologies. The former is based on biological hypotheses and molecules that tend to be specific to given fields of application (co-specialized technologies), while the latter is characterized by the emergence of new generic tools (transversal technologies) (Rasmussen, 2010; Orsenigo, 2001). Many times the business model of the platform technologies is based on contract research and services to other biotech or pharmaceutical companies.

Other types of companies involve also devices and diagnostics. According to Mehta (2008), nowadays the term biomedical technology companies is used to refer to companies whose product need the Food and Drug Administration (FDA) approval to get to market. The technologies include engineering and various sciences, including natural (e.g., life sciences or biology) and applied sciences (e.g., materials science). In that sense, the term biotechnology and device have been blurring boundaries today, as an increasing number of leading medical device companies are incorporating biological therapeutics such as cells, DNA, or proteins, and pharmaceutical companies are increasingly tying their products to diagnostic or delivery devices. The integration of several technologies into one is called combination product (Mehta, 2008).
Medical devices, according to the FDA, range from simple tongue depressors and bedpans to complex programmable pacemakers with microchip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general-purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers (Health, 2011).

For the case of diagnostic kit business, the commercialization process is a bit different and less strict in terms of regulation than a drug development business. Mehta (2008) defines six steps shown in the figure 3, starting with a biomarker identification and validation, clinical test development, then going through a process of manufacturing for research use only to finally validate the diagnostic in retrospective clinical (Mehta, 2008).

Collaboration forms

As mentioned before, most of small biotech companies are usually constrained by resources to continue with the development of its discoveries, technologies and their commercialization, needing to get access to co-specialized and complementary assets that other parties possess (Deeds, 1996; Silipo, 2008). Complementing the above-mentioned definitions of assets, Teece (1986) defines complementary assets as those...
required to successfully exploit a new innovation (Teece, 1986). They include manufacturing, marketing, organizational, and financial assets (Deeds & Hill, 1992).

Extracted from Narula & Hagedoorn (1999), a complete list of possible agreements in R&D collaboration is shown in the following 4.

At the top, it is found the wholly owned subsidiary, which is a branch of another company, its governance is completely interdependent of the parent company, and their projects are a strategy of internalization of R&D. In the next level, the equity agreements are integrated by equity joint ventures such as research corporations and joint ventures, and lesser equity agreements such as minority holding and cross holding. For a strategy of a minor degree of interdependence and internalization of R&D, the companies opt for non-equity agreements, which could be joint venture R&D agreements such as joint research pacts or join development agreements, where in this case, the companies remain independent. Another strategy, in this same level of interactivity, is the customer-supplier relation conformed by R&D contract, co-
production contract and co-marketing contract. Later on, cross-licensing strategies, technology sharing and mutual second sourcing or projects integrate the bilateral technology flows. For a strategy of unilateral technology flows, the companies use the second sourcing agreements or simple technology licensing. At the bottom of all these strategies in terms of interdependence and internalization of technology, the companies use spot-markets, which is defined as a wholly arms length agreement.

In general, the most common contractual collaborative strategies that a biotech firm could use are described in the following paragraphs.

**Licensing deals.** Caglio and Ditillo (2009) describe licensing as a centralized form part of the bureaucratic collaborative inter-firm relationships formalized in an exchange arrangement or associational arrangements, where the strength of this form of relationships derive from the legal system, which protects the parties reciprocal rights to complaint behavior (Caglio & Ditillo, 2009). Licensing is a form of market contract that includes numerous organizational clauses, accompanied by extra-contractual organizational relations (Grandori & Soda, 1995). This is the most common form of exchange. The owner(s) of the rights to intellectual property agrees to transfer some of the rights to another in exchange for money, goods or services. This is contractual with terms specified in a written contract. Among the main advantages of this strategy is the small investment required, the owner can retain some rights and control over the property and it does not require a long-term commitment. On the other hand, the disadvantages are the loss of control over those rights granted to the other party, administrative cost, spillover of important knowledge and the possibility of a poor licensing contract (Smith & Parr, 2004). This mode of cooperative commercialization is also defined as a non-equity mode of organizing collaborative relationships, and it may include alternative forms like supply arrangements, and other non-R&D activities (Aggarwal & Hsu, 2009).

The other modes of cooperative R&D commercialization involve a partnership between companies defined as ‘R&D partnerships and alliances’. They are part of the parity-based bureaucratic collaboration forms. Hagedoorn (2002) defines an R&D partnership as the specific set of different modes of inter-firm collaboration where two or more firms, that remain independent economic agents and organizations, share some of their
R&D activities (Hagedoorn, 2002), such as groups of researchers that collaborate in firms, while maintaining strong contacts with other firms and universities in the biotechnology industry (Caglio & Ditillo, 2009). An R&D partnership is a part of a group of inter-firm relationships found in between standard market transactions of unrelated companies and integration by means of mergers and acquisitions. One main difference between a partnership and an alliance is that in the alliance, besides all the features of a partnership, the development or transfer of technologies is in place. The large pharmaceutical companies make an extensive use of alliances with small R&D firms.

Alliances cover several governance modalities ranging from market transactions to organizational hierarchy. An alliance is defined as any inter-firm cooperation that falls between the extremes of discrete, short-term contracts and the complete merge of two or more organizations (Contractor & Lorange, 2002).

![Figure 5. Alliances types. Contractor & Lorange, 2002.](image)

The figure 5 shows that alliances can be horizontal or vertical. In the case of horizontal alliances, the firms can be competitors and cooperate in R&D, or the R&D divisions of two firms may cooperate on joint work. A vertical collaboration occurs frequently between firms located at different levels of the value chain, for example in research-intensive businesses such as in biotechnology, where innovative start-up firms hand over the fruits of their research to established pharmaceutical companies for commercialization and marketing (Powell, 1998).

To summarize, Hagedoorn (2002) defines two types of ‘R&D partnerships and alliances’ depending on the inclusion or not of equity, i.e. contractual partnerships such as joint R&D pacts and joint development agreements as non equity collaboration, and equity
Commercialization Strategies of Research Providers and their Realization in the Negotiation Process

joint ventures such as research corporations (Hagedoorn, 2002). These types are described below.

**Joint Research and Development.** These are parity-based bureaucratic forms (Caglio & Ditillo, 2009) using contractual arrangement such as joint R&D pacts, contract research or consortia to cover non-equity agreements that are created so that firms and other organizations can pool resources in order to undertake joint R&D activities. Although the success of such agreements is dependent upon a strong commitment of the partners, the organizational interdependence is usually less than in a research corporation because no new organizational entity is established (Hagedoorn, Link, & Vonortas, 2000).

**Research Corporation or R&D Joint Venture.** At least two firms combine their R&D skills and resources in this mode of cooperation through equity joint ownership of a separate firm, and generally this new firm or child performs only R&D that fits within the broader context of the research agenda of the parent firms. It is important to note that this form of collaboration has been decreasing recently due to its high organizational cost and high failure rate (Narula & Hagedoorn, 1999). These forms of collaboration pertain to the parity-based proprietary forms, and the holding of equity or rights is normally formalized and fosters cooperation particularly in settings characterized by uncertain conditions and risks of opportunistic behavior (Hiil, 1990) (Caglio & Ditillo, 2009).

**Form of Transactions and their Risks**

The collaborative strategies that a biotech firm chooses will always imply a form of transaction with other parties linked through formal or informal contracts (Argyres & Liebeskind, 1999). Each of these strategies will demand a different level of relationship, sharing of information, knowledge spillovers and hence risks of opportunistic behavior by the parties involved, engaging in lying, deceit or cheating. Opportunism, as Williamson (1985) defines it, “...is the self-interest seeking with guile... More generally, it refers to incomplete or distorted disclosure of information, especially to

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3 In many cases a simple contract research does not involve necessarily a partnership or alliance, but simply a subcontracting of services, which are defined contractually. On this case, this form is not parity-based but a centralized form (Caglio & Ditillo, 2008)
calculated efforts to mislead, distort, disguise, obfuscate, or otherwise confuse” (Williamson, 1985). The opportunism might be inherent in many transactions.

Any collaborative strategy will require transaction costs, which are the cost of negotiating, monitoring and enforcing a contingent claims contract. According to Hill (1992), there are three types of concerns in transactions costs: uncertainty of the real value of the technology, costly monitoring, and second-order diffusion. He posits that a firm could have no complete information about the real value on the market for the technology, suffering the consequences of uncertainty during the negotiation at giving it away at a lower price. Additionally, once the collaboration is on course, the company runs the risk of opportunistic behavior of the other party, reason why the company could be obliged to spend resources at monitoring the behavior and enforcing the contract with the other party(ies). The second-order diffusion refers to diffusion of the general know-how underlying the technology to be transferred, which could occur when the firm owning the technology discloses information during and after the deal, which could be used by other parties to their advantage. Finally, a firm ends up facing transaction costs of contracting and expected loss anticipated by the firm due to unanticipated contingences and opportunism by the other party (Hill, 1992).

In the same logic, Helm and Kloyer (2004) posit that one of the main objectives in the externalization of R&D is to reduce opportunism motivation of R&D suppliers, which is caused by exchange risks denominated ‘profitability risk’ and ‘competitor creator risk’. The former constituting the danger to obtain a lower profitability than the exchange partner, while the latter would be the result of unintentional, one-sided knowledge flows, which help the exchange partner to become a competitor. So, a firm will try to control opportunism to avoid or minimize agency and transaction costs (i.e. exchange coordination, monitoring and adaptation). They suggest that the perceived exchange risks could be reduced by contractual provisions (see Helm & Kloyer, 2004).

The selection of internal (hierarchical) and contractual (market) modes of exploitation of technology depends on series of crucial factors that have to be put in a balance. Among those elements are: the business model of the company; capital investment required to commercialize the technology; expected profitability; prior licensing and partnering experience; competitive environment and market growth; the regime of
appropriability—which refers to the environmental factors, excluding firm and market structure that governs an innovator’s ability to capture profits generated by an innovation, such as nature of technology, and the efficacy of legal mechanism of protection (Teece, 1986); transaction costs and; bargaining problems (Pisano, 1990), among others.

Control Rights

So far, a description of the most common commercialization strategies and risks has been presented. If after the evaluation of all the aforementioned factors, the firm decides to enter into a formal collaboration agreement through a contractual arrangement with another company -using some of the commercialization strategies mentioned before-, a negotiation is an unavoidable step where both parties engage in defining the numerous clauses of the contract. Such clauses will include the rights and obligations of each firm to perform the project, object of the agreement. It is through these rights and obligations that a firm can exert or give away control, affecting its benefits and wealth, which is the main objective of any for-profit business.

For Edwards (2009), there are two different types of control in a contractual form. The control rights, which are defined as the owner’s ability to influence the way a firm/project is run, whereas the second type is the cash-flow rights of ownership, which refer to the fraction of the firm’s profits to which an owner is entitled. These two terms are commonly referred simply as control and ownership (Edwards & Weichenrieder, 2009). For the purpose of this paper, we will simply name both as control rights, unless specified differently.

The allocation of control rights among the parties becomes strategic and particularly critical in alliances among firms developing new technologies (Lerner & Merges, 1998). Aghion and Tirole (1994) analyzed the challenges posed by the allocation of control rights between small research firms and larger corporations in an incomplete contract framework studying how such allocation of control rights on innovations can affect the frequency and the magnitude of these innovations when their exact nature can not be contracted upon ex ante, and defining a number of common contracting and legal features of the organization of R&D. Their work is also based on the scarcity of
financial resources that a small research supplier has or its limited ability to access outside financing. They found that control rights are allocated according to two factors:

- Underinvestment by both parties. Property rights are allocated to the research supplier when the marginal efficiency of its efforts is large enough relative to that of the customer’s investment.
- The relative ex bargaining power of the two parties. The allocation of property rights is always efficient when the research unit has the bargaining power ex ante, while the research unit’s cash constraint may induce the customer to efficiently retain ownership when having the bargaining power ex ante (Aghion & Tirole, 2004).

Their analysis is made in an incomplete contract framework, positing that the exact nature of the innovation is ill-defined ex ante and that the two parties can not contract for delivery of specific innovation, including that it is costly for agents to write detailed long-term contracts that precisely specify current and future innovations as a function of every possible eventuality and that, as a result, the contracts written are incomplete and will be subject to renegotiation later on (Hart & Moore, 1990). Thus, involving two scenarios on which the bargaining power takes effect: the integrated case and the nonintegrated case. In the integrated case, the customer owns and freely uses the innovation, while in the nonintegrated case, the research supplier owns the innovation and, once the innovation is made, bargains with the customer over the license fee.

Additionally, Aghion and Tirole recommended that giving property rights to the research firm is optimal when it is more important to incentivize the firm’s effort to discover than to benefit the customer’s financial investment in the research. They also posit that as the value of innovation increases, the customer may either insist on keeping or acquiring property rights to fully capture the whole value of innovation, or instead want to relinquish property right to the research supplier to elevate the research unit’s incentives to innovate through the nonintegrated case, whereby the research unit retain the property rights.

4 The term customer is used in Aghion and Tirole (1994) to refer to the party benefiting directly from the innovation; namely the manufacturers who commercialize the innovation, the users who purchase the resulting product, and the suppliers of complementary products or of inputs used by the manufacturer.
Moreover, Lerner and Merges (1998) made and exhaustive research in terms of the allocation of control rights in alliances among firms in the biotechnology industry seeking to develop new technologies. They suggest that control rights should be assigned to the R&D firm when the marginal impact of its effort on the value of the final output is greater than the marginal impact of the financing firm’s financial investment. Also they observe a positive relationship between the financial health of the R&D firm and the number of control rights that it retains. In this same sense, Lerner and Merges enlisted 25 possible control rights – shown in the figure 6- that firms usually negotiate in an R&D alliance agreement, classifying them in terms of four dimensions: key aspects of alliance management, determination of alliance scope, control of intellectual property, and governance structures.

<table>
<thead>
<tr>
<th>Key aspects of alliance management:</th>
<th>Control of intellectual property:</th>
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</thead>
<tbody>
<tr>
<td>1. Right to manage clinical trials</td>
<td>1. Ownership of patents</td>
</tr>
<tr>
<td>2. Right to undertake process development</td>
<td>2. At least partial patent ownership</td>
</tr>
<tr>
<td>3. Right to manufacture final product</td>
<td>3. Control of patent litigation</td>
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<tr>
<td>4. Right to market universally</td>
<td>4. Right to know-how transfer</td>
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<tr>
<td>5. Right to market product alone</td>
<td>5. Ownership of core technology</td>
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<td></td>
<td>6. Right to delay publications</td>
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<td></td>
<td>7. Right to suppress publications</td>
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<tr>
<th>Determination of alliance scope:</th>
<th>Governance structures:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Right to expand alliance</td>
<td>1. Control of top project management body</td>
</tr>
<tr>
<td>2. Right to extend alliance</td>
<td>2. Seat on R&amp;D firm’s board</td>
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<tr>
<td>3. Right to terminate alliance without cause</td>
<td>3. Equity in R&amp;D firm</td>
</tr>
<tr>
<td>4. Right to terminate particular projects</td>
<td>4. Right to participate in R&amp;D firm’s financing</td>
</tr>
<tr>
<td>5. Right to sub-license</td>
<td>5. Right to register R&amp;D firm’s stock</td>
</tr>
<tr>
<td>6. Right to license after expiration / termination</td>
<td>6. Ability to make public equity purchases</td>
</tr>
<tr>
<td>7. Right to shelve projects</td>
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Figure 6. List of control rights. Lerner & Merges, 1998.

Of all these 25 control rights, Lerner and Merges gave critical importance to the first five control rights in the dimension of key to management of alliance.

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5 Lerner and Merges (1998) defined these control rights as the most important ones in an alliance negotiation of biotech companies.
Lerner and Merges’s results show that when a research supplier has an early-stage technology and makes an alliance with a much larger financing firm, the research supplier usually tends to forgo more control rights. The same happens when the research unit has fewer patents, an indication that it may also have few financial resources (Lerner & Merges, 1998).

**Bargaining Power**

Some other researchers have also argued that the bargaining power also influences the allocation of control rights in a negotiation. Argyres and Liebeskind (1999) define bargaining power as ‘‘the ability of one party to a contract to be able to influence the terms and conditions of that contract or subsequent contracts in its own favor’’ (Argyres & Liebeskind, 1999).

It is unlikely that two firms, especially if one is small and the other one is larger, will have their interests perfectly aligned in a negotiation of contracts (Bosse & Alvarez, 2010). Many scholars have studied the different factors affecting the bargaining power of the firms, some of them focused on the study of R&D on the biotechnology field (e.g. Gans & Stern, 2000).

Once again in Aghion and Tirole (1994), considering the proposition 1 - ‘‘the research unit’s cash constraint may induce the customer to inefficiently retain ownership when having the bargaining power ex ante’’ (Aghion & Tirole, 2004). Higgins (2007) revealed that the condition of public equity markets and financial health are important determinants of the allocation of control rights; and the pharmaceutical firms that have research pipeline concerns tend, on average, to give up control rights in later stage alliances. He also discovered that biotechnology firms relinquish more rights in earlier stage projects (Higgins, 2007). In Lerner and Merges (1998), the sample resulted that small biotechnology firms that have more financial resources are allocated more control rights in their alliances (Lerner & Merges, 1998).

Most of the literature measuring bargaining power is based on quantitative studies, ignoring the potential of qualitative research based on the point of view of real practitioners trying to extract other factors affecting the bargaining power of a firm. This quantitative studies usually intent to find relationships between variables such as
the level of cash of a firm when signing the agreement, or analyzing the external financing options on the market for biotech firms as a basis to define the bargaining power of the firm and the allocation of property rights (Lerner, Shane, & Tsai, 2003); or simply the stage of development of the technology when doing the alliance (Higgins & Rodriguez, 2006). Roger Fisher and William Ury, members of the Harvard Negotiation Project, state in their bestseller book ‘Getting to Yes’ (1981) ‘People think of negotiating power as being determined by resources like wealth, political connections, physical strength, friends, and military might. In fact, the relative negotiating power of two parties depends primarily upon how attractive to each is the option of not reaching agreement.” Then, they continue providing an example as a conclusion: ‘The relative negotiating power of a large industry and a small town trying to raise taxes on a factory is determined not by the relative size of their respective budgets, or their political clout, but by each side's best alternative.” In the same sense, they state that the ‘Resources’ are not the same as ‘Negotiation Power’. Fisher and Ury define negotiation power as the ability to persuade someone to do something (Fisher & Ury, 1981).

There are a large number of interrelated factors that affect the relative power of contracting parties (Argyres & Liebeskind, 1999). Some of these factors could be reputation of the firm, possession of skills and knowledge, value of the innovation, control and access to specialized tangible and intangible assets, alternatives to selection, existence of few options available also known as small numbers bargaining (Pisano, 1990; Caves, Crookellandj, & Killing, 1983), and specific investment made by the parties (Argyres & Liebeskind, 1999).

Research literature abounds in terms of how the bargaining power affects the allocation of property rights in the negotiation of agreements. But it is poorly studied in terms of the whole variables factors intervening in such bargaining power of a firm. Most of the literature describing such factors is mostly found in professional publications made by business practitioners and negotiation experts presented on a qualitative form and in a case study basis.
ANALYSIS AND DISCUSSION OF PRIMARY FINDINGS

This section addresses the analysis of the primary findings obtained through the qualitative research using in depth-interviews to business practitioners. The business practitioners were: a technology manager of a Danish university technology transfer office; a manager of a Danish platform technology company for biotechnology research purposes; a business developer manager in a Mexican contract research and development company; an investment manager in a Danish pre-seed investment organization for start-ups; a technology management specialist in the U.S.; a manager of a Danish biomedical (diagnostic kit) company; a business developer of a large pharmaceutical company; and a marketing director of a Mexican pharmaceutical company.

This section is divided into four parts, each one addressing each research question starting with the commercialization strategies used by the research suppliers. Later on, the control rights that the R&D providers try to retain and forgo in a negotiation are discussed. Immediately later, the topic of the bargaining power in the negotiation process is presented. Finally, the perceived risks by the practitioners during the collaboration process are addressed together with the mitigation strategies that should be implemented. It is important to note that along this section you might find also an extensive used of literature and personal observations to support or contrast some of the findings of the primary research.

Commercialization Strategies

The technology specialist confirmed that the model of in-house research and development, used for long time by the large pharmaceuticals, has been declining over the past decade; nowadays, the firms can go out and shop the technologies that they are interested in at the universities or small companies.

In the literature review we discussed that an R&D provider has several strategies to follow depending on: the external circumstances, the company strategy, its management, and the stage of technology development, among other factors. Those strategies could

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6 For information about the profile of the interviewees, a summary of the interviews and the complete interview transcripts go to the appendix section.
be: licensing-out agreements, sale of the technology, a direct commercialization to an end market, or collaborative strategies such as R&D joint venture or joint R&D.

According to the interviewees, the two most used strategies of the small biotech companies are ‘licensing-out deals’ and R&D collaborative forms specially ‘partnerships and alliances’. But all in all, they vary depending on each case. For example, when the technology belongs to a university or research center, it is more probable that the firm acquiring the technology will be through in licensing, getting the authorization by the university to exploit the technology in a certain market or application. On the other hand, if the technology belongs to a private small firm and it has the resources and capabilities to commercialize it, it will probably do so. By doing this, the company might secure to maximize the profits exploiting directly the technology. Nevertheless, if the small company does not have the resources or complementary assets to commercialization it, it will have to implement other strategies. Though, as mentioned in the literature review, there might be other companies with hybrid strategies, i.e. providing research services while working on owned projects and developing their own capabilities and complementary assets.

For example, the CEO of the Danish technology platform company mentioned that the main strategy of the company is to commercialize their own technologies directly; meanwhile, as a secondary strategy it offers research services using their platform technologies and capabilities. Similarly, the Mexican research and development contract organization provides R&D services to customers as part of its main business, but it also acts as an incubator with some projects brought by customers. These are examples of organizations using a combination of commercialization strategies including the collaboration as part of their business strategy.

For the case of small companies with proprietary technology and not capable of doing their own commercialization in an end market, the option left is by using collaborative forms. However, according to the interviewees and the reviewed literature, it is common to find hybrid models that include licensing and partnering at the same time. This is a common case when it comes to partnering with large pharmaceuticals.

The interviewed investment manager commented that “…in the business of drug development, the small companies lack the financial requirements, and they will be far
beyond what they can provide in terms of economical resources considering that around a development of a drug could take up to between 2.4 to 3 billion Danish kroners\(^7\)”. That is one of the reasons why a small firm could not be able to take a product into the final market alone, and only a few have reached this goal and become a full-fledged biotech company such as Genentech, Amgen, Genzyme, to mention some. This is consistent with the appreciations of Humphrey (1996). Thus, many of the small biotech companies on this business need first to answer the question “Can we develop this compound to a stage where we can make big pharmaceutical or big biotech interested in our technology?” That stage is usually the point of proof of concept\(^8\) of the drug. The figure 7 shows the point of inflexion as the investment manager explained during the interview.

![Figure 7. Position of the proof-of-concept point of inflexion in the stages of drug development. Own creation with information provided by the interviewees.](image)

In the proof-of-concept inflexion point the value of the technology rises, since it promises to work properly as planned and producing no toxicity in animals, and in a first sample of humans. For that reason the small firm tries to reach this point to be able to attract the attention of the large companies with a stronger valuation, while having a stronger valuation of the technology.

\(^7\) From € 321,900 to € 400,000 on May 13th, 2011.

\(^8\) A proof of concept or a proof of principle is the realization of a certain method or idea(s) to demonstrate its feasibility or a demonstration in principle, whose purpose is to verify that some concept or theory is probably capable of being useful. A proof-of-concept may or may not be complete, and is usually small and incomplete. Source: Investorwords (2011)
The business developer of the large pharmaceutical mentioned that the large pharmaceutical company is usually open-minded when searching for opportunities to partner with small firms that own interesting technologies, and it considers companies in all stages of development and all types of projects. Although the main focus of the large company will be to be platform companies as partners, and the most common practice to acquire technologies is through licensing deals. He also commented that when a small company has only one product, the acquisition could work as a better option if that makes more business sense. This last strategy, according to Narula and Hagedoorn (1999), works as a complete internalization of the technology increasing the interdependence of the two entities (Narula & Hagedoorn, 1999). Malik (2009), states that the acquisition of a biotech firm by a pharmaceutical manufacturer often follows an earlier alliance between the two parties, since a partnership permits drug makers to test the waters to establish whether companies are a good strategic fit, but also they help to drive away other potential acquirers (Malik, 2009).

As a recommendation, the marketing director of the pharmaceutical company argues that the most popular business practice in this sector is when the small biotech company establishes a collaboration strategy with a large pharmaceutical defining a set of milestones together with a payment mechanism in a plan. Thereby, the small company receives the resources from the large company once it accomplishes the defined goals.

More detailed descriptions of the most relevant commercialization strategies mentioned by the interviewees are unfolded below.

**Licensing strategy**

This strategy is commonly the case of small R&D companies that have discovered and developed a technology that is attractive to other companies, and they do not have the complementary assets such as manufacturing facilities, market channels, capital, etc. to commercialize it in an end market. This strategy helps diffuse the technology in a sooner mode, and to impede other firms in the industry to impose their own standards if done in the early stages (Caglio & Ditillo, 2009).

This strategy is also executed in developments and discoveries made inside public centers for research and universities, on which the main goals are the discovery and
development of new technologies, not necessarily the commercialization in end markets; nonetheless this could vary also depending on the strategy of the university.

The business developer of the large pharmaceutical stated that the majority of the deals are by acquiring the license of the small firm, even though each case is evaluated in order to decide to make a licensing agreement, an alliance, or if it makes more business sense, to acquire the whole company. An acquisition, according to the investment manager, is usually when the small company has a pipeline of products in development that are potential products to be incorporated in the business portfolio of the large company. One example of these cases commented by the marketing director of the Mexican pharmaceutical is when the large pharmaceutical Pfizer acquired Warner-Lambert in 2000 to get access not only to the drug Lipitor®, which became the largest selling pharmaceutical of any kind worldwide (Pfizer, 2000; Economist, 2002), but also to and other smaller products and sales capabilities (Kang & Afuah, 2010).

The investment manager and the technology specialist also mentioned the licensing strategy as one of the main strategies sought by the small firms. Usually, the small firm will try to get the patent of its technology as soon as possible, since that is its main asset. Later on, if the firm does not have the complementary assets to proceed with the development or commercialization, it will approach a larger company potentially interested in that technology to make a licensing deal. The business developer of the large pharmaceutical confirmed this information saying that they get many unsolicited proposals from small firms, even though they also try actively to reach them out aiming for what could be a good technology for their portfolio.

**R&D partnerships and alliances**

These strategies are contractual arrangements between two or more companies without losing each other’s independence. Nowadays, this strategy is commonly used by the contract research and development organizations, which offer services of R&D development to a third party, by small R&D suppliers and by large pharmaceuticals with the purpose of not only licensing in the technology of a small R&D supplier but also using its built-in capabilities.
The two interviewed Danish companies mentioned that the main focus of their firms is to commercialize their own technologies through a direct sale of their products or by licensing deals. When it comes to partnering with a client that needs to make use of their facilities or requiring a customized development, they mentioned to be using strict contractual arrangements as part of the collaboration process in order to protect their assets. However, one of the firms remarked to be applying, in some cases, more informal and looser forms of collaboration with no contracts involved, having interactions with external sources especially ‘researchers’, as part of the open innovation strategy of the company. Subsequently, when finding ideas in a partnership with another party, they evaluate who might retain the idea in an open way. If the idea is mostly related to the company’s business, then they retain the new development, otherwise they just let it go to the partner. Literally, the CEO of this company said during the interview: ‘Every week we have more ideas that we can’t use, so we rather give them away and see them used than seating on them. If those are good ideas, then we file a patent.’

Moreover, none of the interviewed companies and specialists highlighted the research corporation as a commercialization strategy. Most of the collaboration forms are through partnerships such as joint research and development, and licensing deal for the case of technologies owned by small companies. These forms are commonly used in a formal basis with contracts defining the projects, while in some other cases the collaboration can be present in an informal basis.

For the case of the pharmaceuticals companies, they remarked to be using alliances and licensing deals -usually in a combined form- especially when the technology owned by the small firm is part of its main business stream. A company with a technology at the stage of proof of concept is routinely the main target, although the large pharmaceutical could be open to earlier stages such as basic research, according to the interviewed business developer of the large pharmaceutical, exclusively if it has a great market potential and it offers a competitive advantage. For example, Merck Pharmaceutical states in one of its booklets about partnerships available on its website that approximately 63 per cent of its revenues in 2009 came from external sources such as alliance products and patents, including one of its blockbusters (Merck Sharp and Dohme Corp., 2009). Checking upon the information contained in the websites of the
major pharmaceutical companies related to partnerships and alliances, the implementation of strategies for hunting ideas in the market seems to be an increasing business practice. These companies have set up strong business development departments that search outside the company for potential ideas and technologies being developed. Additionally, once the partnership has been signed with a small firm or R&D supplier, the pharmaceutical companies establish a special team to manage the alliance to secure the achievement of the defined goals and commitments always using contractual arrangements as a measure to protect their intellectual property rights.

By contrast, one Danish CEO stated, “there is a trade off between openness and size, the larger you are the more you have to protect your ideas. We are small, which means we gain a lot from being open and interact with researches all over the world…”

Furthermore, the investment manager pointed out that the alliances happen mainly when the large pharmaceutical is interested in the firm as a whole and its portfolio instead of only one of its compound, and in using the small company as a feeder of more products into their own pipeline. Doing so, the large pharmaceutical avoids carrying the fixed costs since the small firm remains independent. Supporting this observation is the arguments provided by the marketing director of the Mexican pharmaceutical, who remarked that the type of collaboration depends strongly in the phase of development of the technology and its market potential. Thus, for example when the drug is at early stages previous to the point of proof of concept, the large company could negotiate with the small firm setting a set of milestones attaching payments as incentives to improve the technology to take it to further stages. Whereas, when the collaboration takes place with a product or drug at late stages –i.e. pre-approval by FDA-, the large company might extend an upfront payment and a combination of expenses and complementary assets to be used.

**Control Rights**

Retaking the definition of control rights given by Edwards (2009) as the ability of the firm to control the way a firm or alliance is run (Edwards & Weichenrieder, 2009), the allocation of control rights plays a vital role in the achievement of goals in a contractual agreement either it is a licensing agreement or an alliance agreement. This section shows the allocation of control rights according to the information provided by the
practitioners contrasting it with the extant literature. In special, it pays close attention to the works done by Lerner and Merges (1998), Aghion and Tirole (1994) and Higgins (2006). Eight out of the nine control rights commented in this section were taken, based on their level of relevance, from Lerner and Merges (1998) shown in the figure 6 in the section of the literature review, while the 9th control right was a personal inclusion.

In general, all the practitioners agreed that the allocation of control rights vary from deal to deal depending on factors like the stage of technology development, resources of the small firm, negotiation skills and market potential of the technology, among other factors.

**Right to manage clinical trials**

Out of the US$800 million necessary to develop a drug, US$568 million or 71 per cent of the cost occurs during the clinical development and FDA approval stages. This is one of the reasons that most alliances between pharmaceutical and biotech companies occur at the phase I or later in the drug development process. The chances that a drug entering the discovery stage of the process will fail to go through FDA approval is over 90 per cent; only one in 15 makes it through. The chance that a drug passes Phase I fails to FDA approval is 75 per cent; only one in four makes it through. One of every two drugs in Phase II receives FDA approval (Tyebjee & Hardin, 2004). Therefore, this is one of the control rights that large pharmaceutical usually retain, as revealed in the Lerner and Merges’s work, showing that in average 57 per cent of the financing companies keep this right. The business developer of the large pharmaceutical corroborated this information, though he also commented that it could vary on each case. According to this practitioner, many deals are with small biotech companies that do not have the resources to undertake clinical trials, added to that the lack of knowledge, expertise, competencies that a large pharmaceutical has (i.e. vast experience in dealing with FDA and shepherding drugs through the FDA approval process). In some cases, a small biotech will have the resources and will desire to develop the clinical trials. In that case, the large pharmaceutical will evaluate if that makes sense and if the small firm has the competences to accomplish the task. In many cases, the small firms usually want to participate in one way or another, since they could be interested in growing and being like a large pharmaceutical in the future. Although there is also the possibility to
outsource this task to a contract research organization, the large pharmaceutical, at retaining this right, could decide how to manage it.

Again, according to the investment manager, the lack of resources of the small biotech firm forces it to look outside the firm to take its technology to a further development. Once the small biotech firm reaches the point of proof of concept, it may attract the attention of large pharmaceutical in order to proceed with the phases of clinical trials. This coincides with the assumption of Aghion and Tirole (1994) that the research unit lacks financial resources, having to turn to a financial company (customer) for resources. In some cases, when the small firm has conducted clinical trials, a large company acquiring the license would even repeat some of the clinical trials since the company wants to be sure that everything is according to the rules and regulations.

However, another factor that influences the need for resources to proceed with the development of a drug is the therapeutic class and the population available to apply clinical trials, according to the marketing director of the Mexican pharmaceutical. For example, a product for a condition such as heartburn requires a large size of population to apply clinical trials in the phases III and IV demanding a high amount of resources. Small companies on these markets try to ally with the large companies. If the therapeutic class is of smaller dimensions such as oncology or HIV, which are more specialized classes, the number of patients is not so high, thus the company can prove the effectiveness of the drug with less patients, hence demanding less resources. For this reason, the small companies tend to focus more on niche markets or therapeutic classes.

**Right to process development and manufacture final product**

Similar to the right of management of clinical trials, the rights to perform the development and manufacture the final product are also sought by the large pharmaceutical. As highlighted in the literature review, the large pharmaceutical will be more specialized and will have more resources to dedicate to later stages of development, while the small firms specialize in the early stages of development.

The investment manager highlighted that in many cases a pharmaceutical company buys the technology at the level of proof of concept, to later continue with its following phases of development. For the technology specialist, the process development is done
primarily by the pharmaceutical company, and usually not even discussed in a licensing arrangement. But it also depends on the size of the company, its capabilities and therapeutic class, according to the marketing director of the Mexican pharmaceutical company.

The business developer of the large pharmaceutical agreed that the small firms are busy in the discovery and development phases, and most of its resources will be spent on that without reaching to build manufacturing capabilities, meanwhile the large pharmaceutical will have already installed capacity. This is also a matter of knowledge and expertise, since a learning curve could take up years to be at the same level of the large pharmaceuticals. Nonetheless, every time there are more cases on which the small firm claims to be involve somehow on these links of the value chain to acquire knowledge for future developments.

For the case of small companies counting with manufacturing capabilities, one factor influencing this control right is if the therapeutic class is of a small or large size. If the population demanding the product is large, then usually the large company has the manufacturing capabilities. However, if the population with certain disease or condition is small, and the small firm has the manufacturing capability, then the small will try to retain this right, a remark done by the marketing director of the Mexican pharmaceutical.

Right to market universally

The technology specialist emphasized that the whole idea of the pharmaceutical company getting the license from the small firms is to have access to the manufacturing, marketing and sales rights, since that is where they make money. In general, the large pharmaceutical will want exclusive rights to market universally overall, but especially in markets such as United Stated, Canada, Germany, Italy, Spain, United Kingdom, France and Japan with strong emphasis where the firm has a strong presence. For the rest of the world, the license is usually offered in packages of regions, for example Latin America, Asia-Pacific, Rest of Europe, Middle East and North of Africa.

If the large pharmaceutical claims for a worldwide license, the small firms can still stipulate in the license that the licensee must sell sublicenses to companies with presence in markets where the licensee does not have a strong presence. So, there are
different ways to arrange a license. Another strategy of the small firm is to license out the application of the technology for a particular field of use. Thus, for example the small firm can give away rights in a worldwide basis but only for its use in a specific disease or application. The interviewees all agree that the forms of licensing vary case by case, though the study by Lerner and Merges suggests that in 67 per cent of the cases, the financial company retains this right.

**Right to market product alone (Exclusivity)**

This is another right that the large pharmaceutical looks for, especially in technologies in the field of its disease or business focus, and it is strongly related to the right to market universally. A large pharmaceutical will desire to have unique rights to exploit the technology, if not universally, in a specified territory or market, disease or application. Lerner and Merges (1998) found in their study that 80 per cent of the cases the financing company owned this right.

However, Dennet (2007) states that the structure of the biotech alliances has been evolving from the traditional straight licensing to the co-promotion arrangement, in which the biotech firms participates in marketing and distribution the pharmaceutical companies changing their partnering models (Dennet, 2007). Surveying the information available in the websites and booklets by the largest pharmaceutical, this feature is clear. For example, Lilly has in their partnering models the co-promotion/co-marketing option, where they include not only small firms into that possibility but also other large companies in the pharmaceutical industry. The same case is for Pfizer. The business developer of the large pharmaceutical stated that just like in the same case of the small firm claiming to participate in the management of clinical trials, the right to market would also be evaluated and find how the small firm could be involved in the marketing of the final product if it makes business sense. In the same sense, Dennet (2007) found out that a small biotech firm will likely try to retain co-promotion rights when it has more prior R&D activity in the disease field of the alliance, and that retaining co-promotion rights means the technology firm is more likely to engage in the commercialization of subsequent products (Dennet, 2007).

One incentive for the small biotech firm is that claiming to be part of the commercialization of the final product will decrease the risk that the large company
shelve the technology, ensuring at the same time to acquire the capabilities necessary to commercialize future innovations alone in the disease field of the alliance.

The technology specialist highlighted the importance for the technology owner to study and understand the different market applications and market demand in different territories of the technology in order to define the best strategy for the firm when defining the rights to retain or forgo that will yield the best paybacks. Hence, reducing the profitability risk for lack of information described by Helm and Kloyer (2004), which is the danger to achieve a lower profitability than the exchange partner.

Additionally, another strategy used by the large pharmaceutical is to make an agreement with the small firm to provide resources and knowledge in exchange of the right of ‘first refusal option’. This mechanism allows the large pharmaceutical enter into a business transaction with the small firm, according to specified terms, before the small firm is entitled to enter into that transaction with a third party (Kahan, Leshem, & Sundaram's, 2007). This mechanism secures the large pharmaceutical to invest only the resources required per phase in the case of clinical trials.

**Right to sublicense**

This is another right that turned out to be very variable in the responses of the interviewees. In the case of the university tech transfer office and the contract research & development organization, the most common practice is that the right to sublicense is taken by the licensee, whereas the large pharmaceutical mentioned that it depends on the deal. The investment manager assured that the large pharmaceutical would retain this right most of the times; meanwhile the technology specialist commented that the small firm when licensing to a company in a worldwide basis, even to markets where the licensee does not have presence, the small firm could specify that the licensee must sublicense to other company with stronger presence in those markets. This means that the small firms might use a sublicensing option as a strategy to increase the paybacks.

**Right to terminate contract or alliance**

This right refers to the possibility to end the continuation of the contract or the alliance. In some cases the clause includes the termination without cause by any of the parties involved in a project. It is usually the party with more bargaining party the one retaining
this right. However, the interviewees indicated that in all the cases there is usually at least one cause motivating the termination of an alliance/contract by any of the parties involved. For example, in the case of the tech transfer office, commonly the contract specifies that any party can terminate the contract with a 3-month period notice. If that is the case, the university gets the license and all the intellectual property rights back. In the case of the contract research and development organization, the contract can be ended on a bilateral form with 45 days period notice. Some causes to terminate a contract according to most of the interviewees are: to reach the purpose of the contract or alliance, to breach the contract by one of the parties, and technological or market failure. A technology failure refers to the non-satisfaction of the requirements of the FDA, turning out to be toxic or not helping with the disease in question. Market failure is the non-acceptance of the product in the market.

In specific, the business developer of the large pharmaceutical mentioned that regularly his company retains this right since the large company is the one taking the product through the clinical trials, testing the prospected drug and taking it to the market, having by this mean the information they require to evaluate to proceed or discontinue the product to go to a further phase.

Furthermore, the marketing director of the Mexican pharmaceutical commented that the contracts usually include inside the termination clauses and sub-clauses penalizing the termination without cause. In some cases, the penalty could include one-year production costs.

**Right to shelve the project**

On this right there is such a high contrast comparing the findings of Lerner and Merges (1998) and the opinions of the interviewees that it can be suggested that in the last decade the balance in the negotiations has changed toward the small firms. Lerner and Merges found that in the 93 per cent of the studied cases the financing company retained the right to shelve the project, whereas the interviewees commented that the contract regularly includes a plan of execution with defined milestones to meet in time and resources. If the licensee does not meet the milestones, then the contract can be terminated by the licensor getting the rights back. In particular, the technology specialist highlighted that the small firm will usually try to avoid the large firm to shelve the
project. In the same sense, the business developer of the large pharmaceutical opined that the small companies want to partner with a company that can continue the process of development of the technology and not to shelve it. The pharmaceutical company should have an obligation to market by contract, or in case the technology does not work, the license goes straight back to the small company. These conditions can be included in the contractual arrangement, and according to the interviewees, nowadays it is a common practice used by both the licensor and licensee.

Right of ownership of the technology and its subsequent improvements

This right cannot be straightforward defined without previously delimitate some cases. The first case is when the small firm has already the intellectual property rights of the technology previous to signing an alliance with the other company or licensing out such technology. In this case, all the practitioners agreed upon the fact that the small firm will retain the ownership unless the small firm sells the technology with all the property rights.

The second case is represented by a joint research and development strategy in which the technology is still in process of development, hence no patent involved at the moment signing the contract. In this case, the ownership could vary presenting different modes: 1) owned by the firm providing the financial resources; 2) owned by the firm providing the knowledge, expertise and R&D facilities; 3) owned by the two parties, also named as co-ownership.

All the practitioners coincided that in the case of simple licensing deals, the party making the further development of the technology is the one retaining the rights for that new technology. They also coincided that in the partnership or collaboration modes, the development or improvement belonged to the party doing such improvement of the technology. Thus, the party using their own resources is usually the one retaining ownership for the new development even during the partnership. The same case would be for the other party. But in cases where the development is made using a combination of resources of both parties, then the co-ownership is usually the outcome. But then again, the practitioners tried to save some face arguing that every case is different and it can vary from deal to deal; and every time there are uncertainty about which party made the developments, negotiations is the best way to go. It is important to note that this
decision is also part of the strategy of a company, as the CEO of the Danish company mentioned that when they collaborate with another party, and they produce new technologies or ideas, if those ideas are only of business concerns to the other party, then they permit the ideas go with the that party. When the ideas are of business concerns to the Danish company and not to the other party, the Danish company retains the rights over those new ideas. Whereas, when the ideas are of interest of both parties, then negotiations take place to define who will retain those property rights.

Another element not discussed in previous studies of the intellectual property rights is the creation and recognition of brands generated during the commercialization of new drugs and technologies. When the large company licensed in a new technology, it regularly attaches a brand to that product during the commercialization. That trademark and brand recognition belongs to the large company, since this is the true value of the product for the large company. The small company could retain the right for the patent but the large firm, which invested on the marketing, sales effort and customers, is the one holding the right over the brand.

**Right to patent litigation**

When happens when a licensed technology is infringed by a third party? It certainly affects not only the interests of the licensor but also damages the benefits of the licensee. But which of the two parties involved in collaboration has the right –or obligation- to fight the infringer and/or take it to court assuming all the costs required to do so?

According to the answers of the interviewees, this is another right that seems not to have a fixed rule, and it varies according to each case. For example, the technology manager of the technology transfer office commented that the university is usually the one in charge of the litigation, but still it is a negotiable part. The CEO of the Danish company agrees that the responsibility should be shared between both parties, whereas the contract research and development organization argues that the owner of the technology (customer) is the one that retains the right to litigate a patent infringement.

In case of the large pharmaceutical, the business developer declared that they are the ones retaining the rights since a patent litigation demands a great sum of resources that a small firm does not count with. The last observation was also shared by the investment manager, who mentioned that in many cases the small firm will not have the resources
to take an infringer to court; therefore it will need to negotiate that part with the large company. Contrasting with all the previous opinions, the technology specialist declared that even though the responsibility to file a lawsuit against an infringer is habitually shared between the two parties, the large company will tend to have the first right; while the small company or the university will take a secondary position. So, if the large company chooses not to pursue a patent infringement lawsuit, then the university or small company can assume the responsibility.

Meanwhile, the work of Lerner and Merges indicated that only 25 per cent of the analyzed cases revealed that the financing company retains this right. It is clear then that based on the practitioners opinions and previous studies that this right has no a strict rule or a standard business practice.

**Right to delay publications**

This right refers to the possibility to oblige one of the parties to not publish, release or disclose information related to the technology involved in the collaboration. This right usually works on cases where research and development are still on progress and are the main part of the collaboration between the parties. It does not apply for simple licensing since a license has been already disclosed at the moment of its filing. However, it applies for cases where the licensed technology is being improved by any of the parties while still in the collaboration process. The companies paying a R&D project will normally retain this right, since they are providing the resources to execute the development. When collaborating with a university, the financing company at least would like to check any information previous to its publication.

**Bargaining Power**

As aforementioned in the literature review, the bargaining power plays a vital role on any negotiation. It is said that the party with more power will have the highest benefit on a collaboration agreement. That is why this concept is relevant in the allocation of control rights. Some authors measure the bargaining power in terms of the financial power of the parties, whereas there are others who argue that there are more variables or factors to consider. Bargaining power is more a latent variable when it comes to measurement. On this study, the practitioners were asked what are the factors they considered affect the position of the parties in the negotiation of collaboration.
agreements. Some of the answers coincided that the financial power of a party affects its bargaining power in comparison with the other one, however they also mentioned other factors that push up or down the balance of the parties along the process of negotiation. In the next section you will find a list and description of the factors mentioned by the practitioners that influence either in a positive or a negative way the position of the small firm depending on the point of view. Although the order of appearance does not represent the importance order, all the interviewed practitioners mostly mentioned the first two as first answers.

**Financial power**

This is the most common factor mentioned not only by previous studies but also by the practitioners. A small company, lacking the resources to proceed with the development of the technology and to build the complementary assets for the manufacturing and commercialization, turns to financial organizations to access those resources. In most of the cases the small firm searches not only for financial resources, but also for complementary assets available by other firms. Moreover, according to Lerner et al. (2003), in periods characterized by diminished public market financing appear to be more likely to fund R&D through alliances with major corporations rather than with internal funds (raised through the capital markets). The internal shortage of theses resources in the small firm and low external availability of public funding oblige the small company to look outside the firm, which initially could be seen as a factor affecting its bargaining power (Lerner, Shane & Tsai, 2003). A support of this argument is found in the study of Aghion and Tirole (1994), which defines as a determinant of control rights in an alliance between a research unit and a customer (financing company) as follows: *the greater the financial resources of the R&D firm, the fewer control rights allocated to the financing firm.*

**Value and level of breakthrough of the technology**

As stated by the technology specialist, the value and potential of the technology compared to what already exists in the market is of great importance in a negotiation to allocate control rights. If the technology or discovery is or has the potential to become a breakthrough in the market, the small company has a strong position in the negotiation process, whereas if the technology is a simple improvement of what exists on the
market, then the bargaining position could be minor. An example is the case of the drug Lipitor®, acquired by Pfizer from Warner-Lambert. Lipitor entered into the market in 1997, and it easily became the market leader controlling around 42 per cent of the market as of December 1999. The drug, developed by Warner-Lambert and co-marketed with Pfizer, was so popular for two reasons—it seemed to have been working rapidly and very good from the standpoint of side effects. This level of breakthrough increased the valuation of the technology, reason why Pfizer decided to propose a US$90 billion buyout for taking over Warner-Lambert (CNNMoney, 2000). Certainly, the bargaining power was on Warner-Lambert’s side.

Furthermore, previous studies have unfolded what determines the value of a patent using distinct approaches such as the cost-based, market-based, design-based and income-based, the relief from royalty, the technology factor, the real options and the Monte Carlo simulation method approaches (Ernst, Legler, & Lichtenthaler, 2010). In more practical terms, Reitzig (2003) makes a set of measurements to define what determines a patent value in the semiconductor industry. Among the elements that Reitzig evaluates are: technical importance—novelty and inventive activity, which are related to the technical quality of the patented product; the technical difficulty to legally “invent around” the patent-protected invention; the portfolio position, evaluating how the patent serve as a basis for further patents and how many; difficulty to estimate the proof of infringement of the patent; how much can the competitors learn from the disclosure of the patent; lifetime; breadth of a patent; uses of functions of patents; exclusion rights. Reitzig found out that the importance of the patent-protected invention for current or future technical development plays one of the most important roles as a value determinant on the semiconductor industry (Reitzig, 2003). Therefore, if the extrapolate Reitzig’s findings to the biotech industry, it might be inferred that if the biotech patent supports the development of current and future patents, such as the case of what is called platform technologies, then the value of that technology increases.

In the same sense, Austin (2008), and Arora and Ceccagnoli (2006) argue that the value of a license is related to its ability to maintain a barrier to competitive entry to a market,

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9Reitzig warns that the results of the study are focused on “bargaining chips”, which allow companies to enter cross-licensing negotiations which are inevitable prerequisites for the survival of a company within the sector driven by cumulative-technology, and it might not be generalized and applied to other sectors. However, I found important to highlight Reitzig’s findings as an example of what it takes to measure the value of a technology. Reitzig (2003).
the risk and the realization of the value of the product on that market. Austin also suggests that before entering into full negotiations with a company, it is essential to establish that the claims made for the asset are both true in the sense of being represented honestly and that the scientific basis and regulatory requirements have been satisfied appropriately. A technology complying with these features increases its strength, so its value (Austin, 2008; Arora & Ceccagnoli, 2006).

It might be suggested that the value of the technology or discovery is affected not only by a single element, but a combination of them, each one either adding value or subtracting it depending on the robustness of the technology.

**Number of potential licensees**

According to the technology manager of the university technology transfer office, when a small firm has a discovery or technology patented for a niche market where there could be several large companies that could be interested in that technology and its commercialization, then the small firm could have an advantage at playing off those potential buyers. Thus, the small firm could engage in a negotiation with a first company without reaching a deal, but getting information relevant to be used in a negotiation with a third company. In the same sense, the technology specialist remarked that the small firm should always qualify the potential licensees asking some of the following questions: “why should I license out this technology to you and not other company?” how can I be sure that your are going to make this technology move forward quickly and timely fashion at getting into the market to start making money? Justify to me why I should license this to you.”

For that reason, the small firm needs to do an extensive research on all the potential licensees, evaluate the best candidates in order to select the best one for the exploitation of the technology. According to the technology specialist, sometimes the best licensee for a certain technology happens to be the second best company in the market instead of a market leader.

On the other hand, when the discovery or technology has only one potential buyer, the bargaining power is considerably reduced considering the small firm does not have a
leverage of comparison. Nevertheless, this is not strongly necessary, since there are other factors influencing such bargaining power.

Jim Camp (2002), an expert on negotiation, recommends collecting information about the potential buyer or adversaries before engaging on any negotiation, thereby the company will know their adversaries and their needs, reducing the risk of information asymmetry (Camp, 2002).

**Pressure of patent cost**

The cost of filing and maintaining a patent can be a burden to a small company. Whereas filing a domestic patent can cost up to US$20,000 in patent and legal fees, a worldwide patent right can take up to US$100,000, without considering the expenses along the patent process depending on the complexity of the technology. Even when a company has the resources to pay for maintaining the patent fees, the goal is the commercialization of the technology to get the expected revenues. As stated by Teece (1992) “Innovative products will not yield value unless they are commercialized” (Teece, 1992). This factor is strongly linked with the lack of financial resources of the company, though the main purpose of any innovative company is the commercialization and not the mere maintenance of their technologies.

For the case of the university, where the main purpose is the licensing of its discoveries, the burden of the patent cost is an important issue that puts under pressure the institution to reach deals with the private sector somehow.

**Time to market and opportunity cost**

A patent has a time period of 20 years after its filing date. Once a potential drug has been discovered, the small company will apply to get a patent, but that does not mean the discovery or technology is ready to be commercialized. It still needs to get through all the process of proof of concept and clinical trials. In the case of drug development, in the United States, it takes an average of 12 years for an experimental drug to travel from the laboratory to the medicine cabinet (MediciNet.com, 1999). Thus, this situation leaves the small company with a constraint of time of around 8 years to fully exploit the patent and obtain the revenues from the market. Once off patents, sales from the technology will sharply drop because of competition from cheaper generic (Malik,
2009). For this reason, the more the small company delays the time to market, the higher the opportunity cost it bears. The race for the market presses on the small company to look for alliances with better-positioned companies, putting the time to market and the opportunity cost against the patent owner.

Some studies suggest ‘increased speed to market’ as one important benefit of inter-firm cooperation (Grant & Baden-Fuller, 2004; Teece, 1992). Though Hoang (2006) found out that from the point of view of the large pharmaceutical, there is not statistically significant difference between the speed to market of collaborative biotech projects and biotech project conducted alone by pharmaceutical companies begun at early stages of the process (Hoang, 2006). From the point of view of the small company, the speed to market is accelerated in a collaboration project with a large company, since the small company does not count with the complementary assets required to access the market in a fast manner.

**Lack of complementary assets**

This is one of the main factors that take a small firm to look for inter-firm collaboration agreements with other companies, and it is strongly linked with the lack of resources and the restraint of time to market. The development of the necessary complementary assets takes time and resources, elements that are not usually on the side of the small firm. The experience curve could be extended depending on the type of technology, existing competition, barriers of entry, market structure, among other elements. Mostly all the interviewed practitioners mentioned this factor as a disadvantage of the small firm affecting its bargaining position.

One of the strengths of the large pharmaceutical is found on its complementary technologies, competitive manufacturing, reputation, commercialization muscle, domination of market channels, service, and after-sale support. The profitable commercialization of technology requires timely access to those complementary assets in competitive terms (Teece, 1992). This factor becomes more critical for the small firm when a successful commercialization of the innovation may depend critically on a bottleneck asset that has only one possible partner, downgrading its bargaining power in a negotiation.
Small number of research suppliers and specialization

Another factor that affects the balance of the bargaining position of the research suppliers is the number of them available on the market with similar capabilities, technologies and discoveries. For example, if there are several companies investigating drugs for skin cancer, a large company can approach several of them to play them off to get better deal. This is a reverse case when there are several potential licensees for a technology owned by a single small company, situation that gives more negotiation power to the latter. Thus, the small company can negotiate deals with more than one company and play those companies off (Caves, Crookellandj, & Killing, 1983). The business developer of the large pharmaceutical commented that the competition is important to benchmark prices offered by R&D suppliers. Contrasting with this asseveration, a study by Bakos and Brynjolfsson (1993) in the information technology sector concluded that instead of playing off dozens of competing suppliers against each other, many firms are finding it more profitable to work closely with only a small number of partners, focusing on the critical importance of providing incentives for suppliers, thereby reducing search costs (Bakos & Brynjolfsson, 1993).

The CEO of the Danish company remarked that two of the factors that give his firm a good balance in the negotiation power is the network of relationships and the level of specialization of the discoveries and technologies, assets not so easy to find in other competing suppliers. The same case was pointed out by the business developer of the Mexican contract research and development organization, who responded that the connections the company has in the health industry, the level of expertise in terms of regulation and technology knowledge give to the company positive points in the negotiation balance.

Expertise and market knowledge (market power)

This is a factor, commented by some the practitioners, related to the time to market and complementary assets. A large company will have the access to the market through its different tentacles of its structure created through the years and resources. The access to market is based on the domination of channels, contacts with stakeholders, reputation, market knowledge, and financial resources that give the large company the impetus and power. These tangible and intangible assets are the necessary complements that a small
firm needs to progress downstream in the value chain and obtain the sought revenues of its discoveries and technologies. Grant and Badent-Fuller (2004) argue knowledge accessing is the primary motivation for knowledge-based alliances, which help increase their knowledge specialization of both firms (Grant & Baden-Fuller, 2004). Therefore, a strong need to access the expertise and market knowledge of the large company to fully exploit the discoveries of the small firm may at the same time affect bargaining position of the small company in the negotiation process.

**Negotiation skills**

Negotiation skills are rarely cited by researchers on the set of factors influencing the allocation of control rights. However, the negotiation skills may be crucial elements during the negotiation process. Cellich (1993) suggest that executives of small and medium firms often lack the required business negotiation skills (Cellich, 1993). And Austin (2008) explains that the subject of negotiations involves discussion of techniques including social psychology, games theory and personality (Austin, 2008). No matter if the technology is a potential breakthrough in the market, if the small company owning the patent does not have or include in the process of the alliance the negotiation skills, the firm might let go the value immersed in the technology.

As the investment manager states: “if you are an experience deal maker, you are more likely to strike a good deal, for that reason, the business developer plays an important role in the negotiation process and is a key person to the biotech company. A biotech company, aiming at getting the most out of its main asset, needs to include experienced business development people in the firm.” In many cases, the business developer negotiating a deal is hired by the firm as an external consultant, who will be in charge of the negotiation process. In many other cases the business developer or negotiator will be part of the staff of the small firm. Nevertheless, any business developer or negotiator not only is required to have great negotiation skills, buts also to have a broad knowledge and expertise on the field of the technology in question.

**Final thoughts about bargaining power**

Finally, based on the factors described above that influence the bargaining power it might be inferred that there is no a single factor driving all the negotiation power of a company, but a set of factors that work jointly, each one having their own positive or
negative load on the bargaining power. Moreover, there might be other idiosyncratic factors that were not mentioned by the interviewed practitioners important that apply to particular negotiations and on a case basis.

**Risks**

As part of any transaction, come risks. Those risks, as defined in the literature review section, could be based on opportunistic behavior of any party on an alliance or licensing agreement, or by failure of a project due to other circumstances not based on opportunistic behavior. In this section, a summary of those risks commented by the practitioners is provided complementing with extant theoretical literature.

**Risk of collaboration becoming out of strategic focus or shelve of project by the large company**

Any company licensing out or being part of a strategic alliance can be harmed by the behavior of the second party, when the latter decides that the project is no longer a strategic focus, therefore reducing the flow of important resources (i.e. financial resources and capabilities) to continue supporting the project or even stopping completely the project and shelving it. This might be due to other products in the pipeline of the large company producing better results and/or demanding more resources obligating to cannibalize the collaboration project with the small company. It might also be due to an increase on the competition with better products. The survival of the small company could depend heavily on one or just a few main technologies, whereas the large company usually sustains a pipeline of products from which it extracts the necessary revenues. This situation endangers the survival of the small firm, which depends on a short pipeline, and especially when it has made specific investments. Similar is the case of the university, even though its survival does not depend strongly by the sale of its licenses, it also runs the risk of opportunistic behavior (hold up) (Goldberg, 1980) by the licensees when trying to stop or shelve technologies acquired from the university’s research centers. According to the business manager of the university tech transfer office, the main risk of collaboration with a big pharmaceutical company is that the collaboration becomes out of strategic focus meaning that funding and/or development is discontinued. For the case of the small firm, if the large company has the right to shelve the project or simply stop the flow of resources for change in strategic focus (hidden intention), then the small firm suffers the
hold up problem if it has made specific investments on the technology and the contract
does not specify how to safeguard this problem (incomplete contracts) (Hart & Moore,
1999).

**Use of small firm’s disclosed information by the large company to
infringe, invent around or become a potential competitor**

As discussed previously, a small firm is usually constrained by resources weakening its
position when it is required to respond investing resources to defend its assets against
potential infringers. Furthermore -as the technology specialist declared-, if the large
company in the alliance infringes the small firm’s patents, the latter will not be able to
respond to battle for its rights if taken to court. When collaboration is signed and
executed, there is a transfer of information and knowledge that could be key to the other
partner to use in its own favor. The disclosure of secret information and the risk of
second-order diffusion (Hill, 1992) about the technology could lead to opportunistic
behavior (hidden intention) of the other party, which could use the information to invent
around the patent, infringe the technology or become a potential competitor (Helm and
Kloyer, 2004).

**Profitability risk**

Any collaboration and licensing project are also affected by the profitability risk (Helm
& Kloyer, 2004). The marketing director of the Mexican pharmaceutical pointed out
that one of the biggest risks when dealing with collaborations in the drug development
business is that the uncertainty produced by the lack of market information and potential
uses of the drug could lead to the small firm to license out, sell and lose rights of its
technology to large companies which could further develop and commercialize it, and
produce a blockbuster leaving the small firm with a low participation on the share of
profits. R&D alliances are often marked by high levels of uncertainty and frequently
require participants to invest in transaction-specific assets (Dickson, Weaver, & Hoy,
2006). A weak deal could leave the small company with a very small portion of the
gains, and the large company enjoying the business of its life with a blockbuster
technology. This problem could be present especially when the large firm has more
information about the business opportunity and the market, and it manages to strike an
advantageous deal with a less informed partner, e.g. defining a low payment or low
royalties for the technology, and after further development and commercialization, the
large company extracts a bigger portion of profits from the market (hidden intention due to information asymmetry).

**Risk of project failure or investing without desired results**

This is a risk not based on opportunistic behavior, but externalities such as market or technology failure. This is also known as risk type II, which accounts for the possibility and the consequences that the objectives of inter-firm alliances are not successfully achieved, although all partners cooperate fully (Das & Bing-Shen, 1986). As stated by the CEO of one of the Danish companies - "the major risk is investing without result". A drug candidate could not provide the desired results on patients causing the rejection and writing off the project. As mentioned previously, the chances that a drug entering the discovery stage of the process will fail to go through FDA approval is over 90 per cent (Tyebjee & Hardin, 2004).

Furthermore, it is important to note that there might be other risks mentioned in the extant literature but not by the practitioners in an explicit form, though they could be part of the commented risks. Some of them are, for example, the competitor creation risk, selection of weak partners, use of resources for other purposes, and others.

**Strategies to Mitigate or Reduce Risks**

**Well written contracts**

The best mitigation or reduction of risks based on opportunistic behavior, according to most the practitioners interviewed is the construction of well written contracts that contain clauses to protect the interests of both firms. Literally, the technology specialist stated - "a strong, well written license is the biotech firm’s best protection”.

The technology manager of the university technology transfer office also suggests that the small firm should build agreements that, in case of breach or termination, should: a) enable to have project assets (intellectual property, instruments, know-how) returned to the owner of the technology (small company or university), so it can partner with someone else; b) ensure sufficient termination periods to find alternate funding for the projects; c) ensure that agreements do not stop the owner from working with someone else (i.e. no competition clauses) and; d) in specific for the university case, ensure that any funding for PhD students is secured and continue to be paid regardless of
termination of agreement. One practitioner commented that a common strategy used by his company is to have the contract guaranteed by bank to protect against failure of payment by the other party.

These strategies supports what Helm and Kloyer (2004) established in their paperwork, arguing that contractual provisions can reduce exchange risks perceived by R&D suppliers (Helm & Kloyer, 2004).

**Openness to renegotiation**

Another feature of these contracts is the possibility to renegotiate as the collaboration evolves to redefine conditions, responsibilities and benefits for both sides of the agreement (Reuer & Ariño, 2002). A door open for renegotiation could better the position of the small firm if the large company finds out that the licensed technology could become a blockbuster and produce large profits, hence reducing the risk of profitability.

One more feature of a good contractual practice to reduce risk of profitability is to include incentives such as royalty-based milestones, according to the marketing director of the Mexican pharmaceutical. As the development produced by the large company on the small company’s technology moves further and offers a clearer vision of the market potential, then the royalty rate may increase.

**Alliance management**

Sadowski and Duysters (2008) posit that most reasons for strategic alliance failure have their origin in a badly managed partnership, which no trust and goodwill is created between the partners involved (Sadowski & Duysters, 2008). As a response to manage the increasing number of alliances, the large companies have been obliged to improve their alliance management capabilities, defined this as ‘the firms ability to effectively manage multiple alliances’ (Rothaermel & Deeds, 2006). In many cases this situation has led firms to create inside their hierarchical organizations ‘alliance management teams’ or to appoint dedicated ‘senior scientists’ for research collaborations. These figures are in charge of monitoring, executing and bringing in the required resources to accomplish the tasks for the project.
It is important to note that the relevance of this management problem has led to the existence of a great deal of consulting companies specialized in alliance management. Additionally, large firms like Amgen, Pfizer, Johnson & Johnson, Eli Lilly, Bayer, Novartis, GlaxoSmithKline and others include in their websites explicit information about the use of alliance management along the duration of partnerships. An example of this is Amgen, which describes the alliance management as a “mechanism between the representatives of both parties to work across all functions to establish project objectives and decision-making procedures before research or project work begin on the program. As the project gears up, the alliance management works to ensure that questions are channeled quickly through the company’s law, licensing, corporate communication, and finance and information services department, as needed. It is also in charge of identifying and resolving issues that might otherwise strain the relationship, and ensuring consistent and transparent interactions across the project team” (Amgen, 2011).

Even though this mechanism might represent coordination and monitoring cost for both parties, literature shows that the management of alliances play a crucial role in securing the success of partnering (Ziegelbauer & Farquhar, 2004; Rothaermel & Deeds, 2006), keeping the project inside the right track without losing control over the development process, and reducing the risk of opportunistic behavior of both parties. Dyer and Kale (2001) highlights four roles that a dedicated strategic-alliance function performs: it improves knowledge-management efforts, increases external visibility, provides internal coordination and eliminates both accountability problems and intervention problems (Dyer & Kale, 2001).

The alliance management function is also in charge of defining a clear plan setting up goals, responsible staff, time, schedule, knowledge, resources and in general deliverables to be provided by each party in the collaboration.

**Robust due diligence**

Due diligence analysis was mentioned by some of the practitioners as a factor to reduce risk in a deal. Even though the due diligence process might be a function of the alliance management defined for each project, it is worth to mention it apart. A due diligence is a management practice commonly performed in the biotech industry and its main
purpose is to conduct an investigation of a business before signing a contract. A robust due diligence, by both parties in a negotiation, permits the small and large firms to extract the required information they might need in a future negotiation. Though any due diligence demands resources and search costs, if it is well defined and executed, it might save future dollars. A due diligence is a practice to acquire information to reduce bad making-decision processes, and information that could potentially lead to opportunistic behavior afterwards.

One of the main emphases in a due diligence process is the analysis of the intellectual property rights involved, essentially when the transfer of technology is the purpose of the collaboration. Hantos (2010) states that a noticeable trend has emerged within the patenting arena in which those seeking to acquire, license or invest in patented technology are asking more focused and detailed questions in order to assess whether commitment is warranted (Hantos, 2010). Parties confront a variety of risks having the potential for reducing the value of the deal. Through due diligence, parties open up information to one another so that they can identify and minimize those risks. Due diligence analysis is an investigation of three major issues. First, ‘ownership’ -are the intellectual property rights owned by the appropriate party? Second, ‘use’ -can the technology covered by the intellectual property rights be used, or is it dominated by patents belonging to others? Third, ‘transfer’ -does the party offering the intellectual property rights have the lawful rights to do so? (Sonnenfeld, 2001). It is important to inspect all files regarding patents, trade secrets, and copyrights, as well as license agreements, confidentiality agreements, joint venture agreements and other type of deals (Silverman, 2004). These recommendations agree with what the investment manager explained during the interview –“they want (large pharmaceutical companies) to be sure that the rights are placed in the small company, or at least that they can go back to the license source, the university, and say -“Is it true that you have licensed the rights to this compound to this small company, which we are now interested in buying?”- So they want to check a lot of things to make sure that they legally will also own the rights to the products. And that is part of the due diligence.”

By identifying as many facts concerning these issues as possible during due diligence, both parties increase their level of security and the probability of a successful closing on a valuable deal. But it also helps the value of the technology of the small firms if during
the due diligence the potential buyer/licensee finds out that the work has been done properly by the licensor.

The next figure 8 displays succinctly the list of the risks and their mitigation strategies commented above.

<table>
<thead>
<tr>
<th>Mitigation</th>
<th>Risks</th>
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<tbody>
<tr>
<td>Collaboration gets out of focus or shelve projects</td>
<td>Use of disclosed information by large company to infringe, invent around or become a potential competitor</td>
</tr>
<tr>
<td>Well written contracts</td>
<td>□</td>
</tr>
<tr>
<td>Openness to renegotiation</td>
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<tr>
<td>Alliance management</td>
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<td>Robust due diligence</td>
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**Figure 8.** Potential risks and their mitigation strategies proposed by the interviewed business practitioners. Own creation.

Thus, a well-written contract could help reduce an opportunistic behavior by any of the parties including clauses that could avoid fine holes in the collaboration such as possibility to shelve projects, misuse of acquired information, inventing around the patent, or becoming a competitor in the near future.

Meanwhile, a good practice to include in the contract is the possibility to renegotiate a deal, which might leverage the danger of profitability risk that affects mainly to the licensor or owner of the technology. The opportunity to negotiate terms and conditions such as royalties in case of an increase of a market of the technology could serve as an incentive to the small company or owner of the technology.

An alliance management team offers to help all the risks above mentioned. The management of an alliance allows firms to keep the collaboration close, detect potential threats to the projects and define rapid solutions, increase trust between the parties, identify potential opportunistic behavior and other externalities and contingencies, and act in response.

Finally, a robust due diligence conducted by both parties in a negotiation provides information in order to reduce uncertainty, therefore reducing opportunistic behavior by
one side of the table when defining the market size, royalties, and future profits. Also, it helps to evaluate and estimate the viability of the project, or possibly its failure due to lack of information.
CONCLUSIONS AND FURTHER RESEARCH

This thesis shows a qualitative study on which are some of the commercialization strategies used by companies in the biotechnology field, how the most common control rights are allocated in a negotiation between those companies, the factors influencing the bargaining power during the negotiation process and some potential risks perceived by the business practitioners during the agreements.

The study relies first on secondary research doing an analysis of extant literature, which helped to create the required framework for the research. Later on, as primary research, a series of eight semi-structured in-depth interviews was conducted with business practitioners in the biotech field ranging from a technology manager of a technology transfer office to business developers of pharmaceutical companies, also including chief executive officers and marketing directors and consultants of small biotech companies.

Several points of criticism can be made. First, the review of literature is built upon analysis of prior art, which at the same time bears a load of relative validity and reliability concerns. Second, the number of interviews was limited. Third, the interviewee might not express entirely their real opinions and point of view in order to hide confidential information. Fourth, the interviewees perform unequal positions in different companies/organizations in the biotech field, situation that affects the possibility to generalize the results to all the cases in the biotech business field.

With respect to the commercialization strategies, the primary findings agreed with the theoretical literature in terms of the increase on collaboration strategies implemented by both small and large companies in the biotech sector, being among those strategies the use of licensing deals and R&D partnerships and alliances the most used by those companies. Some of the reasons mentioned to explain this phenomenon are the scarcity of resources in the small company to continue with the development and/or commercialization of its technology or discovery, whereas the large company is tending to search for new technologies outside its walls, commonly buying technology, allying with small companies and universities or acquiring entire companies if it makes more business sense. Licensing is the most common deal; whereas companies trying to develop their own capacities for future developments and commercialization capabilities absorbing knowledge from the partner seek partnership and alliances.
Regarding the allocation of control rights, most of the practitioners agreed that there is not a fixed or standard rule on how to distribute the rights, however there are some common practices observed in the field. For example, a large company usually tries to retain the rights to manage clinical trials, manufacture and market the product, since these are the reasons why they search for technologies and how they make money. Together with this, the large company will also ask for exclusivity in certain markets. All of these primary findings are in accordance to the findings provided by Lerner and Merges (1998).

Moreover, the right to sublicense will be retained by the large company, but usually paying royalties for sublicenses to the owner of the technology. The right to terminate contract or alliance is commonly included in the contract as a possibility for both parties in the agreement, always requiring to indicate the cause of termination with a previous notification. In some cases, a penalty fine is levied on the party terminating the contract. With respect to the right to shelve a project, some of the comments by the practitioners are that the owner of the technology will normally try to partner with a company that has the intention to continue the development and commercialization of the technology, and that the large company should have an obligation to market by contract, otherwise the license should go back to the owner of the technology. This finding contrasts strongly with Lerner and Merges’s, where 93 per cent of the large or financing companies retain this right.

The original owner of a technology will commonly keep the right to ownership of that technology, whereas subsequent developments inside an alliance will vary. If one company made solely an improvement, then the right may belong to this company. However, if the improvement used resources from both parties in an agreement, though it can vary from deal to deal, then both parties share the property through a co-ownership form. Regarding the right to delay publication, a financing company will try to retain this right or at least to reserve the right to review any information previous to be published.

Regarding the analysis of the bargaining power, it is important to note that most of the previous studies include the financial power as the only factor affecting the balance in a negotiation. Nevertheless, the results of the interviews show that there could be more
factors such as: 1) value and level of breakthrough of the technology; 2) number of potential licensees; 3) pressure of patent cost; 4) time to market and opportunity cost; 5) lack of complementary assets; 6) small number of research suppliers and specialization; 7) expertise and market knowledge (market power) and; 8) negotiation skills.

Finally, the main concerns of the business practitioners with respect to risks when collaborating with other companies are: 1) one of the parties shelves the project or declares it out of strategic focus; 2) use of disclosed information to infringe, invent around or become a potential competitor; 3) profitability risk and; risk of failure or investing without desired results. In order to mitigate these risk, the business practitioners highlighted the importance of having well written contracts -with openness to renegotiate-, building a strong alliance management team that follows up the collaboration process and conduct a robust due diligence by both parties previous to signing any collaboration agreement to reduce information asymmetry and increasing the chances to make better decisions.

Further Research

With respect to further research, the thesis hints at the need to carry out a more extensive analysis of the allocation of control rights increasing the quantity of interviewed business practitioners in similar positions and firms improving the possibility to generalize results. Also, it is recommended an updated and improved version of the empirical work of Lerner and Merges (1998) considering more factors other than merely the financial power as variables affecting the bargaining power in a collaboration strategy. It also suggests investigating deeply on the factors influencing the selection of commercialization strategies by small biotech companies and large pharmaceutical companies.
LIST OF REFERENCES


APPENDICES

Appendix I – Profile of interviewees
Appendix II – Summary of Interviews
Appendix III – Interview Transcripts