**MS. Dissertation in Engineering**

# Determinants Affecting the Outbound Innovation Strategies : Focused on the Pharmaceutical Industry

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# Determinants Affecting the Outbound Innovation Strategies : Focused on the Pharmaceutical Industry

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이 논문을 공학석사학위 논문으로 제출함

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# Abstract

The pharmaceutical industry is a high-technology industry that requires a combination of in-depth knowledge from various fields. It is characterized by high cost, high risk and a long term perspective due to the high level of regulation. In addition, it is known that R&D productivity is deteriorating in the industry. Under these conditions, more than in other industries, the importance of open innovation strategies has been emphasized. Under an open innovation system, it is essential for firms to develop several dynamic capabilities to effectively manage their resources both internally and externally. Lichtenthaler and Lichtenthaler(2009) suggested a systematic framework for such dynamic capabilities.

This study focuses on the determinants affecting firms' desorptive capacities, which are measured as the number of out-licensing deals, as an indicator for the performance of their outbound innovation. This approach focuses on firms that have already been licensing-out their knowledge. Thus, it does not regard the decision as to whether or not to out-license, but rather focuses on the decision of existing licensors to further promote their out-licensing activities. For the analysis, negative binomial regression is employed and inventive capacity and connective capacity are selected as the determinants of the licensors' desorptive capacity. These dynamic capabilities are adopted from the knowledge management capacities framework suggested by Lichtenthaler and Lichtenthaler(2009) to

identify how they affect the out-licensing decisions as a means of knowledge exploration and knowledge retention. The results of regression analysis reveal that inventive capacity does not have a significant effect on desorptive capacity and that only connective capacity has a significant positive effect on desorptive capacity.

**Keywords: Pharmaceutical Industry, Licensing, Outbound Innovation, Open Innovation, Exploitation, Knowledge Retention, Desorptive Capacity, Connective Capacity**

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# 1. Introduction

## 1.1 Research Background

The pharmaceutical industry is traditionally known as a knowledge-intensive industry in which various technologies are combined. It entails astronomical R&D costs, and a long time perspective attributed to the regulatory approval required for the production of new drugs. It is characterized by a technology-push model which depends on a complicated path of scientific breakthroughs with unsettled timing and hard-to-anticipate outcomes(Petrova, 2014).

Although firms possess technological competency, abundant interdisciplinary research, and a deep understanding of consumer needs, the discovery and development of new drugs are accompanied by severe uncertainties. This is attributed to the ethical problems and social responsibilities inherent in the industry. It is hard to think of other industries where the processes and products have such direct impacts on human health. This leads to the high regulation of the drug development process. A single drug compound has only a probability of around 3% to make it through all stages to commercial release (Phrma, 2017) and the R&D expenditure rates are the highest among the high-technology industries. In short, the pharmaceutical industry is a high-regulatory, high-risk, high-profit industry, and is one of the industries where open innovation strategies are most

important and actively employed.

## 1.2 Problem Statement

The extremely technology-driven, risky, costly and long drug development process used to be dominated by large pharmaceutical firms, something refered to as the 'Blockbuster Model'[1]. However, this traditional vertical model conducted by the large pharmaceutical firms has become increasingly hard to maintain since the 1980's. The large pharmaceutical firms have been faced with the (1) patent expiration of their main blockbuster drugs, and also the overall pharmaceutical industry is in the situation of (2) lowering R&D productivity (a reduction in the number of approved New Molecular Entities).[2] This indicates that the strategy of sourcing the whole required knowledge and skills to develop a new drug within the firm is becoming hard to execute (Hedner, 2012).

In order to overcome this situation, the cooperation and partnerships among the various actors has been increasing. In particular, the relationships among small biotech firms, which are research-intensive institutes, and large pharmaceutical firms are getting stronger. Since the advent of the late 1980s, biotech firms have

[1] Blockbuster drugs are medicines designed to treat disease such as high blood pressure, asthma, and arthritis, which are prevalent in developed countries with a high level of national purchasing power. It usually guarantee sales of at least $ 1 billion..(Humira of Abbvie , Lipitor of Pfizer, Advair of GSK, and so on).

[2] This is because the most of easy medical problems had been solved, leaving the more complicated and diseases such as obesity, cancer, HIV/AIDS, Parkinsons, Alzheimers, and diabete(Petrova, 2014).

played an important role in providing innovative biomolecules through applied research.

Most biotech firms are not able to perform the long development process of new drugs. This is because they lack the required downstream assets such as marketing capabilities, professional networks, and other resources to bring their own technologies to the market. Thus, when they start their business, they consider exit strategies such as licensing, IPO, and the acquisition by large pharmaceutical firms. Large pharmaceutical firms not only perform in-licensing from biotech firms, they also license out their products and technologies to supplement their financial resources and reorganize product lines. These industrial characteristics and the changing landscape are the reason why open innovation strategies are so crucial to the pharmaceutical industry.

## 1.3 Research Question

Under the open innovation paradigm, it is essential for firms to build up their dynamic capabilities to correspond with the kaleidoscopic environment. Conventionally, in the context of inbound innovation, studies mainly focused on the concept of the absorptive capacity suggested by Cohen and Levinthal(1990). However, as firms began to have increasing interest in selling their technologies as a way of outbound innovation, the research on open innovation has moved

from mainly considering the inbound process to investigating the outbound process and stressing the need for empirical studies on knowledge capacities (Shin et al., 2018).

Reflecting these demands, numerous studies have been conducted and proved that the various capacities of firms have positive effects on the firms' performance (Lichtenthaler, 2009; Mazzola et al., 2012; Shin et al., 2018). However, there exist only limited analysis with regard to the determinants affecting the out-licensing decision itself.

In spite of the growing importance of out-licensing activities, the hurdle for the firms to license out their technology as an outbound innovation strategy is quite steep. The success rate between the decision to out-license technologies and the actual conclusion of the deal is below 60% (Gambardella et al., 2007). This is due to the complexities of these activities which are mainly attributed to information asymmetry problems.

Under these circumstances, 'inventive capacity' and 'desorptive capacity' as dynamic capabilities of firms have been identified as main determinants of out-licensing propensity (Hu et al., 2015). Inventive Capacity refers to the firms' capabilities to internally generate new knowledge. This capacity is related to the prestige, noticeability, and visibility of the licensors to the potential licensees. Desorptive capacity is related to the firms' knowledge exploitation capabilities (Lichtenthaler et al.,2009). The capacities which firms should build up under the

open innovation systems are systematically suggested by Lichtenthaler and Lichtenthaler (2009) in their 'knowledge management capacities' framework. This mainstream does not include the knowledge retention capability, which is called 'connective capacity.' Connective capacity and how it affects the out-licensing decisions as a means of knowledge retention has received less scholarly attention.

This study focuses on connective capacity of the licensors as the determinant which affects desorptive capacity itself as an indicator of the performance of their outbound innovation.

The research questions of this study are as follows;

(1) *What capacities does a particular firm need to possess in order to actively out-license?*

(2) *Does knowledge retention have an effect on the out-licensing decisions?*

## 1.4 Research Objectives

This study focuses especially on the out-licensing in the overall perspective of the outbound aspects of open innovation. The aim of this study is to analyze the determinants of out-licensing deal making strategies of firms in the pharmaceutical industry.

As mentioned above, the research flow of open innovation has moved from the inbound process to the outbound process and a number of studies dealing with the effects of dynamic capabilities on firm performance have been conducted (Lichtenthaler, 2009; Mazzola et al.,2012; Shin et al.,2018). Therefore the main purpose of this research is to identify the determinants of out-licensing decisions by adopting the 'knowledge management capacities' suggested by Lichtenthaler and Lichtenthaler (2009). Previous research on the determinants of out-licensing have focused on the 'inventive capacity' and 'desorptive capacity' of the licensors.

This study differs from the previous studies in the following aspects: First, previous studies have focused on the effects of dynamic capabilities on firm performance. The number of out-licensing used as dependent variable corresponds to the desorptive capacity that indicates to what extent firms can actively perform outbound innovation. Therefore, considering other capabilities as determinants of the desoptive capacity, this study performs inter-capability analysis.

Second, previous studies dealing with the determinants of the amount of out-licensing were limited to investigating inventive capacity and desorptive capacity (Hu et al., 2015). According to Lichtenthaler and Lichtenthaler(2009), the inventive capacity is related to the firm's internal knowledge exploration, and in case of desorptive capacity, it is related to external exploitation of the firm. Therefore, this study will complement the previous literature on out-licensing

determinants by adding a study on connective capacity as an additional viewpoint of knowledge retention.

In summary, the objective of this study is to identify the required capabilities of pharmaceutical firms to carry out active outbound innovation. As forming a variety of partnerships including out-licensing is driving firm performance and survival, analysis on the determinants for out-licensing can serve as a guide for firms to cope with the dynamic open innovation ecosystem.

# 2. Literature Review and Hypotheses Development

## 2.1 Overview of the Pharmaceutical Industry

### 2.1.1 Drug Development Process

Since the mid-20th century, the pharmaceutical industry has been contributing to the improvement of human health by developing treatments against various human diseases. It formed a complex network of organizations involved in drug discovery, development, and manufacture. Drug innovation is conducted using the state-of-the-art technologies and discoveries in life sciences, supported by related fields such as molecular biology, physiology, biochemistry, chemistry, engineering, informatics, and others (Petrova, 2014).

To the pharmaceutical industry, World War II was a large watershed. Before World War II, most of the new drugs were made from natural resources or organisms. However, the rapidly rising market demands in the post-war period transformed the pharmaceutical industry. The war provided the industry with an opportunity to deal with various diseases for which therapies were yet unknown. The pharmaceutical industry has relied on the 'random screening' method, a very inefficient way of producing lead compounds by accident through thousands of trials and errors.

Since the mid-1970s, advances in pharmacology, physiology, enzymology and

molecular biology have led to a greater understanding of various diseases and new drugs have been developed to treat them. In other words, the importance of cooperation beyond the boundaries of organization, department, and therapeutic categories has become increasingly important(Cockburn et al., 2001). In the 21st century, new drug development no longer relies on coincidence, but has become a systematic process, the 'rational drug design' approach.

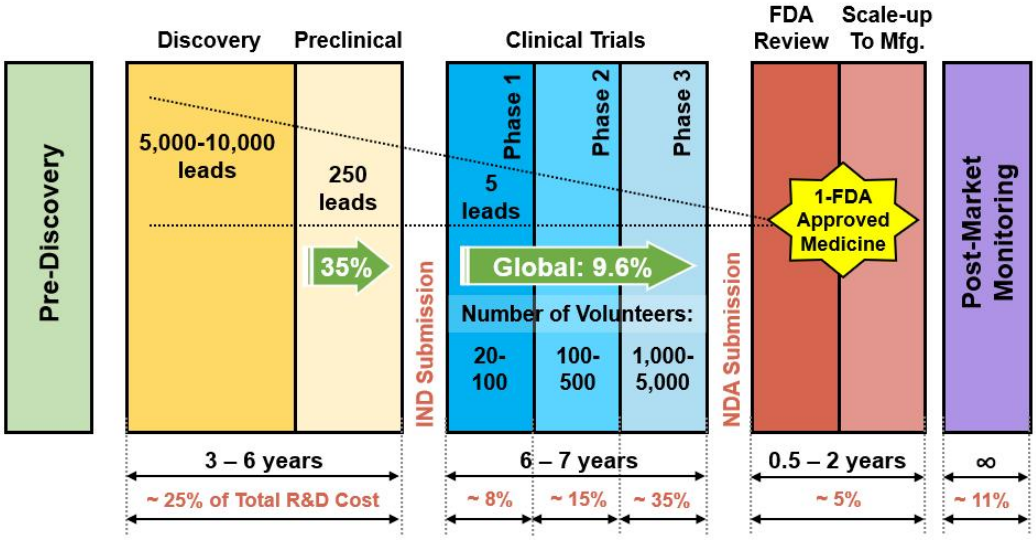


**Figure 1.** Drug Development Process (Dimasi et al., 2014)

Figure 1 shows the entire process of bringing a medicine to the market. The process can be roughly divided into three parts: The first part includes the 'pre-discovery', 'discovery', and 'pre-clinical' stages. The overall understanding of the diseases (at the molecular level) and the design of lead compounds which are to

be applied to the targeted disease are conducted in the pre-discovery stage. After checking absorption and excretion in the human body, the final compounds are selected as 'drug candidates' in the drug discovery stage. In the preclinical stage, scientists conduct in vitro and in vivo tests[3] to assess the toxicology, safety and efficacy of the selected compounds.

Then, more detailed and stringent verification of drug candidates is carried out in the second part, the so called 'clinical tests.'. This stage takes the longest time and incurs the highest costs among the whole drug development process. This step also represents a unique feature of the pharmaceutical industry. The product of the pharmaceutical industry is a new drug that has a profound impact on human health. Therefore, it requires higher regulation and safety than any other industry. Numerous new drug candidates fail to pass this stage, and firms are often unable to recover their invested R&D costs. It is a step that requires complete validation of safety and efficacy, which is an essential characteristic of any new drug.

Firms should submit an IND (Investigational New Drug) application to the FDA (Food and Drug Administration). This document contains the results from the whole previous processes, the chemical structure, expected side effects, and a detailed manufacturing plan. In the first phase of clinical trials, the initial test towards a small number of healthy volunteers (20-100) is conducted. The goal is

[3] Vitro tests are the experiments which are usually conducted in test tubes and beakers of the laboratories. In vivo tests, experiments on the living cells and experimental animals in order to evaluate the effects of the drug candidates on the metabolism and the other systems are carried out (Petrova.2014).

to identify whether the drugs are harmful for humans. In the second phase, the effectiveness of the drugs are assessed by researchers through testing it on patients with the corresponding disease. Further, the risks and side effects are investigated to decide whether to continue to the third phase. Last, in the third phase, the researchers test the drug on a larger number of people (1,000-5,000) to establish both safety and efficacy. The significant data regarding rare side effects should be complemented. This phase is the most expensive and the longest trial in clinical tests. The whole clinical stages account for about 60% of the total R&D cost. Firms submit NDA (New Drug Application) or BLA (Biologic License Application) to the FDA, which requests admissions to commercialization of the drugs. In summary, an initial 5,000 to 10,000 lead compounds that are screened result in only one to five drug candidates (Phrma, 2007).

When a drug candidate is approved, a scale-up process for mass production and post-monitoring takes place as the last part. Firms should transform themselves such as being equipped with new manufacturing facilities. In this stage, as the number of people taking the new drug increases, the firm must constantly monitor whether side effects occur. For the first three years, they are required to submit a quarterly report to the FDA, followed by annual reports thereafter.

This whole process takes on average 12 years and requires a tremendous amount of investments ranging from $ 800 million to $ 4 billion (Hedner, 2012). To go through this process, firms' new drug molecules should be protected by

patents. Firms normally apply for patents for their innovative molecules. Patents of drugs generally last for 17-20 years from the time of registration. This means that the investment costs of the firms should be covered during the 5-8 year period of exclusitivity. After the expiration of the patents, the branded drug is rapidly replaced by lower-priced generic drugs of the same quality.[4]

### 2.1.2 The Changing Landscape of the Pharmaceutical Industry

This extremely technology-driven, risky, costly and long process used to be dominated by large pharmaceutical firms, the so called 'Blockbuster Model'[5]. However, this traditional vertical model led by the large pharmaceutical firms has become increasingly hard to maintain as large pharmaceutical firms came to face (1) patent expiration of their blockbuster drugs, and also the overall pharmaceutical industry is experiencing (2) reduced R&D productivity (a decline in the number of approved New Molecular Entities). Additionally, R&D investment costs have consistently increased since the 1970s. This indicates that the strategy of sourcing all the required skills and knowledge to create a new drug within the firm is becoming hard to execute (Hedner, 2012).

In order to overcome this situation, cooperation and alliances as well as licensing deals among the various actors have increased. In particular, the

[4] When the drug patent expires, generic drugs appear immediately at prices that are nearly 50 % lower than those of the original branded drugs (Griliches et al., 1994).

[5] Blockbuster drugs are medicines designed to treat disease such as high blood pressure, asthma, and arthritis, which are prevalent in developed countries with a high level of national purchasing power. They guarantee sales of at least $ 1 billion.( E.g., Humira by Abbvie , Lipitor by Pfizer, Advair by GSK, etc.)

relationship between small biotech firms, which are research-intensive institutes, and large pharmaceutical firms is getting stronger. Since the advent of the late 1980s, biotech firms have played an important role in providing innovative biomolecules through applied research.

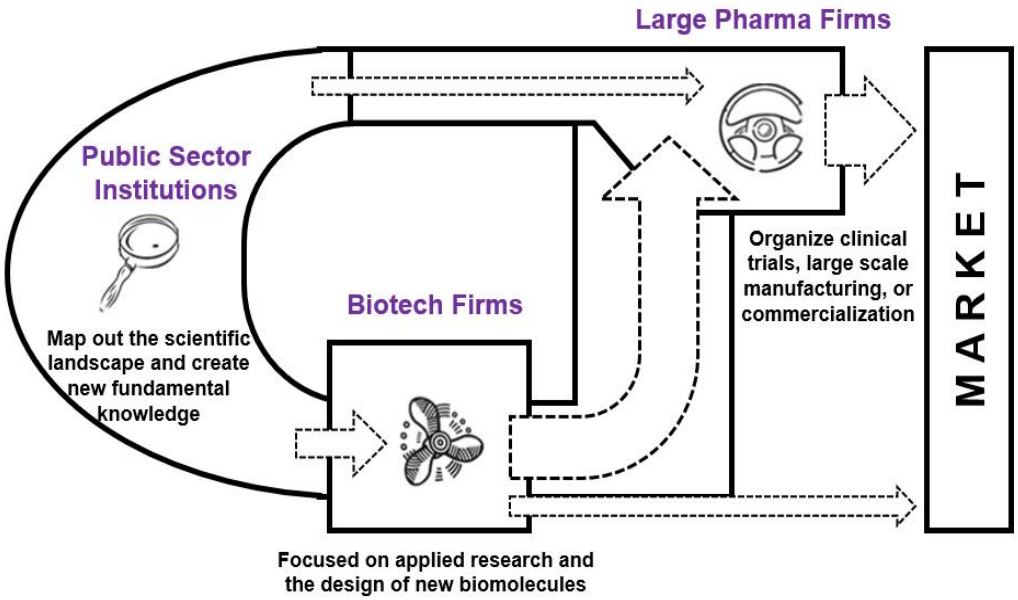


**Figure 2.** Collaborations in the Pharmaceutical Industry(Petrova, 2014)

Biopharmaceuticals are therapeutic or diagnostic products made by living organisms based on biotechnology. Biopharmaceuticals have the advantage of being able to detect, diagnose, and affect only the target disease and have less side effects than the usual chemical synthetic medicines which affect the whole human body after the absorption through the digestive system. In addition, because of

their molecular complexities, the price of products is held higher than that of the chemical synthetic medicine (Radar, 2013).

Biotech firms focus on applied research and supplying novel biomolecules. The large pharmaceutical firms, owing to their vast scale of operations, professional networks, and experience, are adept at designing and overseeing extensive clinical trials, and can organize and conduct them faster than any other players. In addition, their sizable marketing skills and already established sales forces can ensure a more effective end-product commercialization. Thus, large pharmaceutical firms are aggressively tapping into biotech firms to search for new opportunities and to maximize future opportunities in upcoming therapeutic areas. The biologics business is not vulnerable to generic competition due to the high degree of molecular complexity which makes it hard for competitors to imitate drugs (Ding et al., 2016).

## 2.2 Open Innovation in the Pharmaceutical Industry

The changing value chain can be explained by ‘open innovation’ which was first suggested by Chesbrough (2003). It became common-sense that firms need R&D to develop new products in order to stay ahead of competitors. Traditionally, R&D has been conducted internally within firms to ensure that the process and the outcome were not revealed (Lichtenthaler, 2012). This is called ‘closed

innovation'. At the end of the 20th century, however, a number of factors led to the erosion of the closed innovation paradigm (Adelhelm et al., 2009)

First, globalization resulted in a higher labor mobility and competition across multiple organizations. Due to technological innovation, the restrictions on time and space around the world have been eliminated, and connectivity among firms increased. Individuals no longer stay in one company in their own country. In addition, this resulted in a severly more competitive environment (Chesbrough, 2003). Second, convergence among technologies is becoming ever so common. As the complexity of technologies increases, firms need to focus on their competencies and build up their professionalism. This implies that the interdependencies among firms are intensifying (Gassmann et al., 2004). Last, the life cycle of products is continously shortening as firms are facing a continuously-innovative environment. This causes products to become obsolete much faster than before (Harvey, 2010). Shorter product lifecycles force firms to increase their investments in innovation to stay competitive. For these reasons, firms in various industries are advised to open up their boundaries and form relationships with other firms.

Chesbrough noticed this phenomenon and first coined the term, 'open innovation' as the antithesis of the traditional vertical integrated model in which internal R&D leads to internal products. Specifically, he defined it as "the use of purposive inflows and outflows of knowledge to accelerate internal innovation,

and expand the markets for external use of innovation (Chesbrough et al., 2006)".

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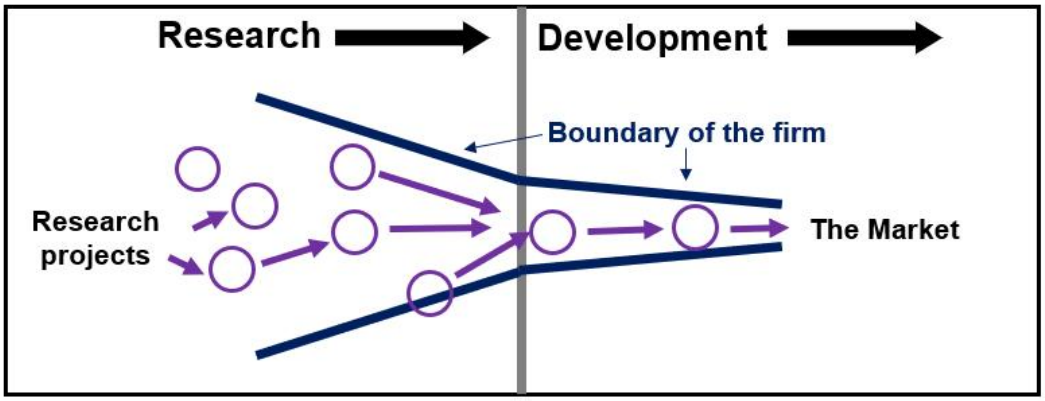


**Figure 3.** Closed Innovation(Chesbrough 2003)

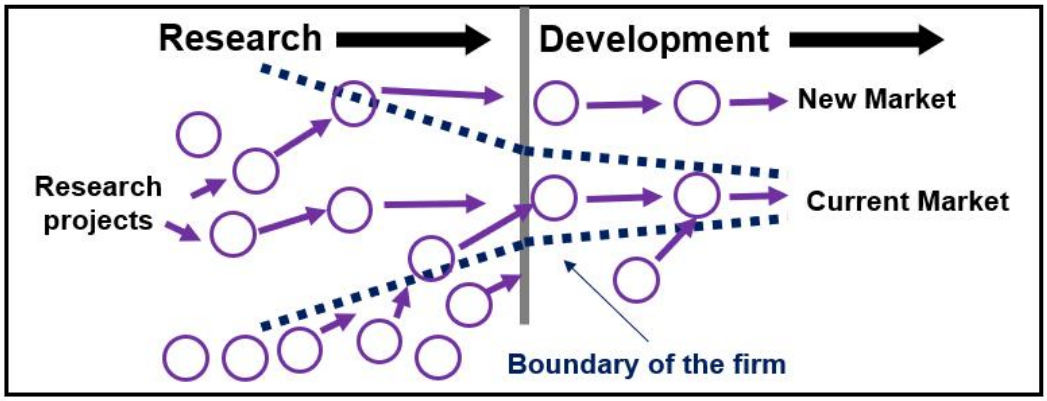


**Figure 4.** Open Innovation(Chesbrough, 2003)

As depicted in the above figures, under the open innovation paradigm, the boundaries of firms are depicted as permeable, allowing them to interact with external resources and partners. On the other hand, under the closed innovation system, the whole R&D processes are executed within the boundaries of the firms

with no external partners (Chesbrough,2003). Firms can benefit from opening up their boundaries in a variety of ways; they can save on their time and cost for the innovation process, maximize their profits by selling their intellectual properties, form new technological standards in their industry, and so on (Ahn et al., 2016). New knowledge in each industry is being derived from various collaborations and interactions among the actors from the academic, scientific and business sectors (Abbasi et al., 2011a) and the pursuit of each agent enhances the capability of the whole system (Kim et al., 2013). On top of that, because of the strengthening of interdependencies across the firms, the importance of networks is also increasing (Kim et al.,2015).

The pharmaceutical industry is one of the fields in which the importance and necessity of open innovation are most prominent. This can be explained by two aspects: the intrinsic characteristics of the industry and the recent crisis it is facing. First, in terms of its inherent industrial properties, the pharmaceutical industry incurs the highest R&D costs among all industries.

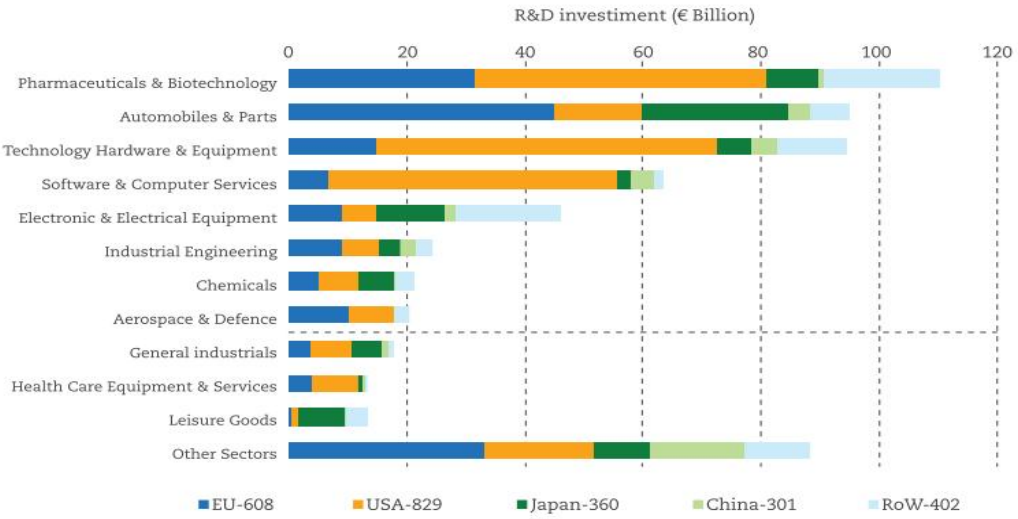


**Figure 5.** R&D Investment by Industries(IPFMA, 2017)

According to the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), pharmaceutical R&D spending accounts for about 19% of all business spending on R&D worldwide, the most for any industry. Compared to other high-technology industries, the annual spending of the pharmaceutical industry is 5.5 times greater than that of the aerospace and defense industries, 5 times more than that of the chemical industry, and 1.8 times more than that of the software and computer services industry (IFPMA, 2017). On top of that, the overall R&D costs have consistently increased since the 1970's (DiMasi et al., 2003). The average R&D investments in the 1970s were 179 million dollars, which is well below the 2017 level of 2.6 billion dollars. Additionally, as seen in Figure 6, the success of each stage of the clinical drug

development is low.

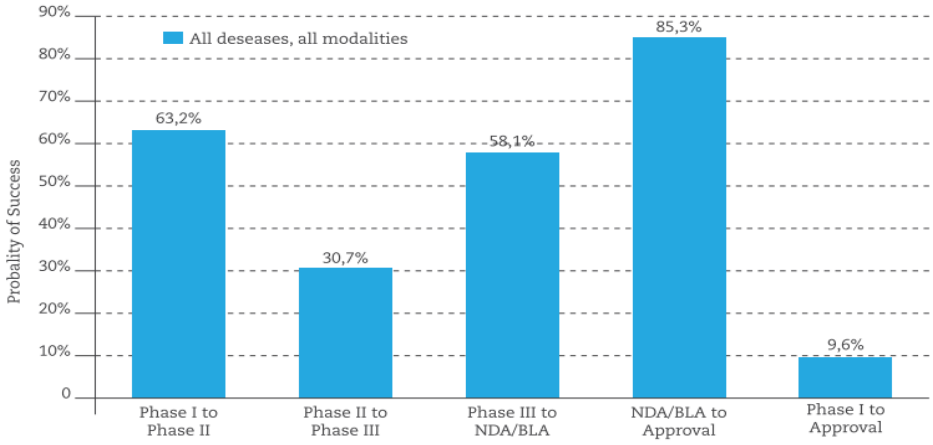


**Figure 6.** Success Rate of Approval(IPFMA, 2017)

Second, in terms of the crisis the industry faces, the whole industry suffers from the expiration of key patents and a lower R&D productivity. The 'Blockbuster Model' of large pharmaceutical firms is hard to be sustain because of the patent expiration of blockbuster drugs. In addition, sufficiently good solutions are already identified for most relatively easy medical problems, leaving the more challenging and complex diseases such as cancer, HIV/AIDS, obesity, Alzheimer's, Parkinson's, and diabetes (E.Petrova, 2014). For these reasons, the importance of open innovation is increasingly emphasized and more kinds of collaborations are being actively undertaken in the pharmaceutical industry than in any other industry.

Open innovation emphasizes on the various types of co-operations with other

external parties for the innovations. Gassmann and Enkel (2006) specified the directions of open innovation. The outside-in (inbound) process, which is known as 'exploration', enriches a company's own capabilities by integrating external parties in the innovation process. Conversely, the inside-out (outbound) process so called 'exploitation' implies that internal knowledge becomes accessible for external actors by selling or licensing IP rights or investing in collaborations with external actors. The coupled process is a linkage between the outside-in and the inside-out processes and implies that two or more parties merge for a project to take advantage of each party's knowledge. The importance of both giving and receiving in the coupled process in order for the parties to benefit from the collaboration to a greater extent is also emphasized.

**Table 1.** Types of Open Innovation (Gassmann et al., 2006)

| Type | Description | Mechanisms |
|---|---|---|
| Outside-In(Inbound) | Involves opening up the firms' own Innovation processes to various kinds of external | In-Licensing<br>Scouting<br>Crowdsourcing |
| Inside-Out(Outbound) | Involves letting unused of under-utilized resources go outside the firms to other firms Innovation processes to various kinds | Out-Licensing<br>Spin-offs<br>Corporate VC |
| Coupled | Involves combining inflows and outflows of collaboratively development or | Strategic Alliances<br>Joint Ventures |

| | | |
|---|---|---|
| | commercialization | Networks |

As the environment surrounding the firms became more dynamic and complex from the 1990s, large pharmaceutical firms initially focused on the inbound process to replenish their exhausted resources by exploring from biotech firms. After a certain amount of technology and resources were accumulated through the inbound process, they began to have interest in selling their resources which are less important or peripheral technologies to external parties. This is important for them, because selling their technologies is an immediate way for evaluating their technological value and also they could occupy dominating positions by subordinating the licensees (Petrova, 2014).

Open innovation is also closely related to the dynamic capabilities which stem from the resource-based view. The notion of dynamic capabilities complements the resource-based view, and has invigorated numerous empirical research in the last decade (Wang et al.,2007). According to the resource-based view, if firms are to obtain competitive advantages, they must acquire and control valuable, rare, inimitable, and non-substitutable (VRIN) resources. These resources are heterogeneously distributed across the firms and persistent over time due to their imperfect mobilities (Penrose, 1959; Barney, 1991).

As the business environment has become more dynamic and complex since the 1990s, the mere resource advantages have become insufficient for firms to survive

since they neglect the influence of market dynamism (Eisenhardt and Martin 2000). Firms need to adopt to changing business environments and renew their competences in order to stay competitive (Teece et al., 1992, 1997; Eisenhardt et al., 2000). The dynamic capabilities encompass this necessity and are defined as "the firm's ability to integrate, build, and reconfigure internal and external competences to address rapidly environment (Teece et al., 1997)."

In this context, firms in open innovation systems need to develop their own capabilities to internalize and externalize knowledge to maintain their comparative advantages. In regard to the inbound process, the well known concept of absorptive capacity has been successfully applied in numerous studies. The term 'absorptive capacity' was first coined by Cohen and Levinthal (1990) and is defined as "a firm's ability to recognize, evaluate, assimilate, and apply external knowledge." The inbound process and the firm's absorptive capacity have been comprehensively studied in previous research (Danzon et al., 2005; Lichtenthaler et al., 2009; Mortara et al., 2011).

The direction of the research is recently being extended to the other capabilities in regard to the outbound processes in specific industries (Hu et al., 2015). In accordance with this trend, this research focuses on outbound innovation, especially the out-licensing strategies as dynamic capabilities in the pharmaceutical industry.

## 2.3 Out-Licensing in the Pharmaceutical Industry

### 2.3.1 Definition and Motivation of Out-Licensing

According to LES (Licensing Executives Society, 2005), technology licensing is defined as "granting the rights to make, use, or sell a proprietary product, process, or service in return for payment.". It represents a simple, short-term transactional relationship between the licensor and the licensee where control over the asset being licensed is restricted by the terms stipulated in an agreement with limited time and scope. Out-licensing is specifically considering the licensing activities from the perspective of the licensors, who are granting their technologies to the licensees.

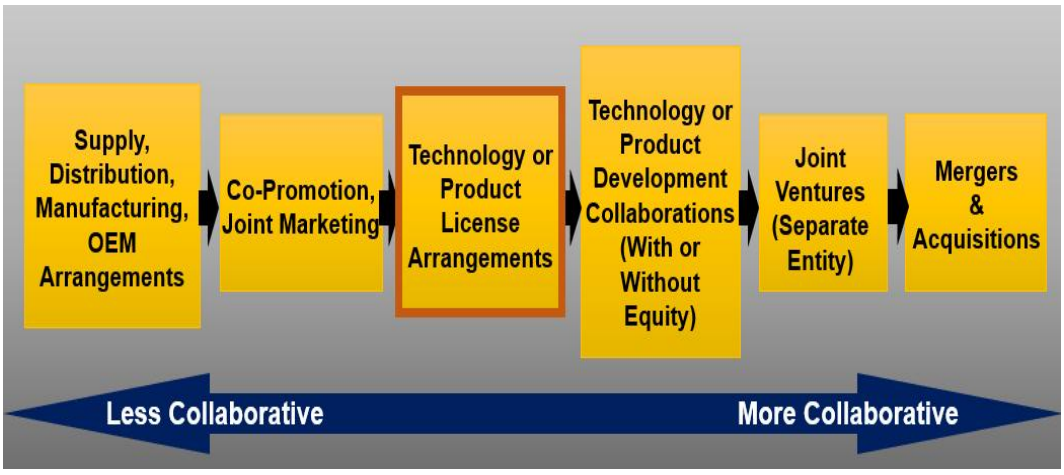


**Figure 7.** Common Types of Partnering Relationships(Wong, 2008)

Out-licensing assures the ownership of intellectual properties such as patents, trademarks, copyrights, and trade secrets. It also transfers not only explicit knowledge but the protected or unprotected know-how, training of specialists, transfer of procedures and so on. Licensing agreements are comprised of the sourcing firm purchasing the rights to another firm's patents or technology for a monetary payment (Hagedoorn et al., 2007). After the licensing agreement is set up, the licensor still remains the owner of technological knowledge and receives monetary payments from the licensees. Typical payments in a licensing deal are dissected into the following categories: Upfront or lump-sum payments, milestone payment, and royalties.

Upfront payments are paid when the contract is concluded. They are usually paid in cash, but occasionally equity investments are made. Milestone payments are paid based on the success at each stage of drug development. Last, royalties are related to the sales after the commercialization of products. They could be paid as a fixed percentage or an increasing percentage corresponding with sales performance. The contents of licensing typically include the scope of the contract (e.g. territorial extent of rights or fields of usage) and the exclusivity of rights (preventing the technology owner from licensing the technology to any other entity) (Sikimic, 2013).

Out-licensing can play a critical role in accessing diverse sources of innovation in the new pharmaceutical R&D landscape (Allarakhia et al., 2011). As mentioned,

the overall pharmaceutical industry is in a crisis of declining R&D productivity. Firms seek to lower their total costs and risks of new drug creation and to shorten the time to reach the market through strategic alliances and licensing agreements (Petrova, 2014). In particular, licensing agreements between pharmaceutical firms and research-intensive biotech firms are being actively conducted and strengthened.

As pharmaceutical firms strive to maintain their annual revenue-growth rates, they focus on replenishing the flow of new drug candidates into their research pipeline and on increasing the number of products for commercial launch each year. To achieve these objectives, a growing number of pharmaceutical firms are in-licensing proprietary compounds or drug discovery–related technologies from other firms to supplement their internal R&D efforts (Wong, 2008). On top of that, they license out their technologies or products to supplement financial resources and reorganizing product lines that have become less important to the firms.

In contrast to the pharmaceutical firms, biotech firms in general lack the resources to maintain a diverse project portfolio and often lack downstream assets such as marketing skills and networks due to their small size. Therefore, licensing out their newly developed technologies might be their only viable route to market, as the majority of them have no significant sales structure or marketing capacity in place. Thus, licensing fees constitute their main source of revenue (Petrova, 2014).

### 2.3.2 Out-Licensing Process in Pharmaceutical Industry

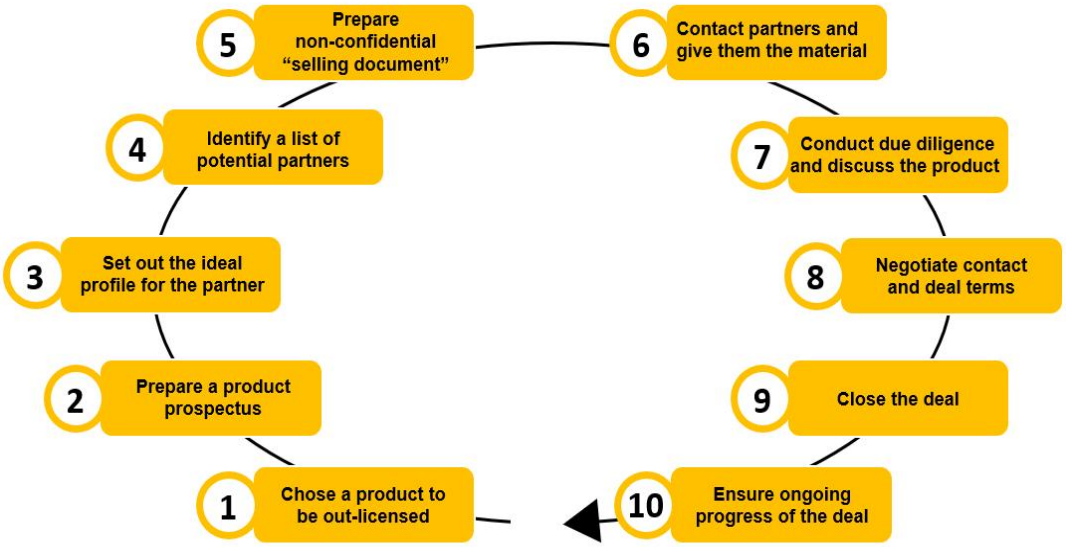


**Figure 8.** Out-licensing process in the pharmaceutical industry (Wong, 2008)

Out-licensing consists of various sub-activities which include strategic planning, preparation of material, targeting of potential opportunities, evaluation of the partners and products, contacting potential partners, discussion regarding products, due diligence, negotiation and the maintaining and management of the deal once it is set in place (Reepmeyer, 2006). Figure 6 visualizes the whole process of out-licensing.

The first step of an out-licensing process is choosing the products which are potentially to be licensed out. The factors which should be taken into account are status of the intellectual properties and the overall understanding of the uniqueness of the products. The data for the prospectus is gathered during this

step and this leads to the document that is reviewed internally to access and evaluate the opportunity (Reepmeyer, 2006).

After the prospectus document has been prepared through internal scrutiny, the identification of the partner profile is conducted. Once the characteristics of the optimal partner have been constructed, the licensing department sets up a list of potential partners.

From this stage, firms are in the actual phase of business development. Thus, before the compilation of the non-confidential selling documents, rigorous scrutiny of the markets is required. Then, the selling documents are compiled based on the data collected in the previous stages and the accurate information of market status. The documents consist of a description of the market and the potential of their own products. The identification of potential partners and quality and format of data which is supplied to the potential partners are known as the most important factors in the out-licensing process (Megantz, 2002)

The completed selling documents are then distributed to the potential partners. Once the partner firm is selected and the non-disclosure agreement is signed, the licensor firm could make a decision to share more confidential and critical information with the partner firm. This is the initiation of the due diligence process and this often includes close communication and the exchange of critical information and knowledge between the licensor and the licensee. The licensor also typically provides the product for test trials at the partner's own research

locations enabled by a material-transfer agreement and site visits in an effort to convince the partner to acquire the license (Hofman et al., 2016).

Once the due diligence process is completed, the two actors need to reach consensus on the contractual details by negotiating the deal terms and structure. Term documents are exchanged in the initiation of negotiations as a suggestion of deal structure, scope and financial terms of the deal. Once an agreement has been reached and a licensing agreement has been signed, the deal is completed. What remains is to maintain and support the partner during the agreement period (Powell, 1996)

## 2.4 Previous Research on Determinants of Out-Licensing

It has been demonstrated that when firms establish partnerships, including out-licensing, they have a higher success rate in the drug development process. According to Danzon (2005), the inter-firms cooperation in Phase 3 of clinical tests shows a 15% greater probability of approval compared to independent efforts. In addition, drugs developed through partnerships exhibit a more significant success rate in passing through Phases 2 and 3 of clinical tests.

As mentioned above, biotech firms are small and medium-sized enterprises specialized in research, so they seek out appropriate partners such as other biotech firms or pharmaceutical firms to out-license their technologies. It allows them to

recover their investment costs and develop new compounds through exit strategies.

For pharmaceutical firms, they try to secure their profits by purchasing technologies from biotech firms and other pharmaceutical firms to counter their declining R&D productivity. According to Motohashi (2012), the wider the R&D pipelines of the pharmaceutical firms, the more likely they are to succeed at commercializing drug compounds. Furthermore, pharmaceutical firms are also securing their profitability by licensing out their less important products or technologies to other firms.

However, the hurdle for firms is that licensing out their technology as a strategy of outbound innovation is quite challenging. The attrition rate between the decision to out-license a technology and the actual conclusion of the deal is nearly 40% (Gambardella et al., 2007). This results from the complexities of the activities. Previous research on outbound open innovation focused on 'inventive capacity' in the technology exchange markets and 'desoptive capacity' of the licensors which were theoretically first suggested by Lichtenthaler and Lichtenthaler (2009). It has been demonstrated that these capacities have positive effects on firms' licensing propensities.

### 2.4.1 Inventive Capacity

| | Knowledge exploration | Knowledge retention | Knowledge exploitation |
|---|---|---|---|
| **Internal (Intrafirm)** | Inventive capacity | Transformative capacity | Innovative capacity |
| **External (Interfirm)** | Absorptive capacity | Connective capacity | Desorptive capacity |

**Figure 9.** Knowledge Management Capacities (Lichtenthaler et al., 2009)

According to Lichtenthaler and Lichtenthaler (2009), knowledge management capacity is defined as 'firm's ability to dynamically manage its knowledge base over time by reconfiguring and realigning the processes of knowledge exploration, retention, and exploitation inside and outside the organization.' They built up a framework which supplements the existing notion of absorptive capacity (Cohen and Levinthal, 1990) and also stresses the necessity of knowledge retention.

Inventive capacity is defined as 'firm's capability to generate new knowledge inside the firm (Lichtenthaler et al., 2009).' Creating new knowledge is generally the outcome of perceiving opportunity or unmet needs for that knowledge.

Therefore, the creation of new knowledge is affected by the firm's existing knowledge base (Shin et al., 2018). As new knowledge and technologies arise from the firms' knowledge bases, this is highly reflected in the patent characteristics of firms such as forward citations or technological breadth.

Licensing technologies in the technology-intensive environments across the firms is complex due to the cognitive, intangible and tacit nature of technological knowledge (Hu et al., 2015). Limited transparency and inefficiencies in the technology market impede the identification of potential partners. On top of that, the process of contracting and negotiating with partners is not an easy tasks due to the problem of information asymmetry (Kani et al., 2012).

Under this market condition, inventive capacity is related to the 'prestige' of the licensors and serve as a sign of the competencies in terms of the resources or capabilities they possess. Gambardella(2007) listed patent characteristics affecting the licensing propensity, including the generality of a technology along the spectrum of potential applications, the economic value of a technology, and patent breadth measured by the technology classes covered by the patents.

There are several reasons why the inventive capacity of licensors make them more attractive to potential licensees. First, the patent stock or famous researchers of the licensors act as a "halo effect"[6] that makes the licensee view the potential of the licensor's resource management capabilities or potentials. It provides the

[6] This effect is a cognitive bias about a firm's reputation, which allows firms to better attract resources and opportunities (Ruckman et al. 2016)

collective perceptions of potential partners with trustworthiness and promising opportunities. This leads to a high “noticeability” and “visibility” of licensors to the licensees.

Second, licensees consider their own prestige to be higher by making transactions with licensors possessing stronger inventive capacities. Conducting a deal with licensors of high inventive capacities means that it is perceived as being an equal trust relationship from the standpoint of other firms. For example, biotech firms borrow prestige of well-known large pharmaceutical firms by forming partnerships (Ruckman et al., 2016). In summary, licensors with high inventive capacity will have a higher chance of out-licensing because licensees are more likely to recognize and be attracted to them due to the increase in noticeability, trustworthiness, and perceived benefits (Sine et al., 2003).

### 2.4.2 Desorptive Capacity

The second determinant is desorptive capacity, which is defined as ‘an organization’s ability to identify technology transfer opportunities based on a firm’s outward technology transfer strategy and to facilitate the technology’s application at the recipient.’ by Lichtenthaler and Lichtenthaler(2009).

Desorptive capacity is related to external knowledge exploitation which refers to the outbound knowledge transfer. It is also a type of dynamic capabilities as it indicates that the firms intentionally create, extend or modify their resource bases

(Helfat et al., 2007). According to Teece (2007), dynamic capabilities can be disaggregated into sensing, seizing, and transforming capacity.

To build up a strong desorptive capacity, sufficient prior experience is required (Fosfuri, 2006). As mentioned above, as the problem of information asymmetry is prevailing in the technology market, prior exposure to dealing with out-licensing can lower the transaction costs. Experience in gathering information about expenditures of prospective licensees, negotiating, or writing contracts will cut down the cost of out-licensing for the licensors (Vornotas et al., 2006).

The method for building up a strong desorptive capacity is learning from the firm's own technological trajectory (Dosi, 1982). Firms usually face their own problems in reacting to turbulent and competitive environments. According to Rosenberg (1982), the innovation here can be defined as the cumulative and firm-specific process of problem defining and solving activities. Due to the uniqueness and cumulativeness of firms learning experience, their technological trajectories are distinctive and path-dependent (Garud et al., 2002).

### 2.4.3 Connective Capacity

Regarding a firm's knowledge management processes, several authors have distinguished knowledge exploration or creation on one hand, and knowledge exploitation on the other hand, sometimes mentioning the need for retaining knowledge over time (Nonaka et al., 1994; Lichtenthaler et al., 2009; Shin et al.,

2018).

As mentioned above, Lichtenthaler and Lichtenthaler(2009) proposed a framework of knowledge management capacities to give guidance to the firms on how to manage their knowledge related capacities and embraced the standpoints of exploration, exploitation and retention.

Connective capacity refers to a firm's ability to retain knowledge in interfirm relationships. It encompasses alliance capability and relational capability (Lichtenthaler et al., 2009). In contrast to absorptive capacity, external knowledge retention does not assume an inward knowledge transfer. Instead, licensors are ensured having privileged access to the external knowledge base of licensees without completely acquiring it. The more alliances firms form, the easier it is for them to manage interfirm relationships and to profit from external knowledge retention (Lichtenthaler et al., 2009).

### 2.4.4 Other Determinants

Aside from this main classification, previous studies on out-licensing decisions, have also researched other firm-level determinants. In this study, these determinants are added as control variables due to their well-established effects on the out-licensing process. First, the size of the licensor has been considered (Arora et al., 2005; Vonortas et al., 2006; Gambardella et al., 2006; Kani et al., 2012; Nishimura et al., 2014). Firm size was used as an indicator of the degree of

complementary assets held by the firms. The effect of firm size has been observed to be different in previous studies.

This determinant has been well established in its negative influence on out-licensing activities (Gambardella et al., 2007; Kani et al., 2012; Ruckman et al.,2016) The reason is that the incentives of large firms to out-license are relatively less than for small firms. In the pharmaceutical industry, biotech firms are actively engaged in selling their technologies to other players and the licensing fees constitue their main source of revenue (Petrova, 2014). Conversely, large pharmaceutical firms typically own abundant complementary assets for innovation and can access the financial market at less cost than biotech firms (Gambardella et al., 2006). In contrast, Kim and Vonortas (2006), and Kani and Motohashi (2012) discovered that large licensors are more likely to license-out because they have greater tendencies to sell their non-core technologies to complement their revenue. This is attributed to the fact that large firms have a larger patent portfolio than smaller firms.

The second established determinant is 'R&D intensity'. Basically, innovative outputs stem from the R&D activities of firms (Cohen et al., 1990) and R&D intensity indicates the concentration of biopharmaceutical firm's total R&D investments regarding their innovation process. For technology-based firms, the spending on internal R&D tends to promote inter-firm relationships and stimulate the firms' motivation to license out (Ruckman et al. 2016). In summary, the

licensor's R&D intensity is expected to have a positive effect on the likelihood of licensing (Kani et al., 2012). Since licensors have different degrees of investment in R&D, these heterogeneities of licensors are controlled for in this study.

**Table 2.** Previous studies on determinants of out-licensing propensity in pharmaceutical industry

| Literature | Determinants |
|---|---|
| Arora et al .2003 | R&D expenditure(+), Complementary assets(+), Firm size(+), Market Competition(+) |
| Vonortas et al. 2006 | Prior experience(+), Firm size(+), Industry conentration(+), R&D Intensity(+) |
| Fosfuri, 2006 | # of patents(+), Prior Experience(+), Firm size(+), Industry concentration(+), R&D intensity(+) |
| Gambardella et al. 2007 | IPC counts(+), # of Forward citation(+), Firm size(-), # of inventors(+) |
| Wuyts et al. 2008 | Prior experience(Inverted U), R&D expenditure(+), technological breadth(+), # of patents(+) |
| Kani et al. 2012 | # of patents, IPC counts(+), Degree of competition(+), Firm size(-) |
| Nishimura et al. 2014 | # of drug candidates(+), Firm size(+), # of patents(+), Market Competition(+) |
| Hu et al. 2015 | # of forward citations(+), # of alliance(+), # of co-inventors, Scale of R&D portfolios(Inverted U) |

| | |
|---|---|
| Ruckman et al. 2016 | # of patents(+), Technological breadth(+), technological depth(+), firm size(-), prior experience(+), # of forward citations(+) |

## 2.5 Hypotheses and Research Model

### 2.5.1 Hypotheses

As licensing technologies is an act between the licensors and licensees, there always exists inefficiency and an information asymmetry problem. This is attributed to the cognitive, intangible and tacit nature of technological knowledge (Hu et al., 2015) which affects the licensing activity consisting of activities such as the evaluation of technologies and negotiation with the potential partners (Wong, 2008). Limited transparency in the technology market impedes the identification of potential partners, and leads to the 40% attrition rate with regard to the number of licensing decisions and the number of actually concluded contracts (Gambardella et al., 2007).

Under this market condition, inventive capacity is related to the ‘prestige’ of the licensors and serves as a signal of the quality in terms of the resources or capabilities possessed by the firms. As mentioned earlier, the prestige is deeply associated with the ‘noticeability’, ‘visibility’ and ‘trustworthiness’ of the licensors. In previous studies it has been measured as the value of the firms’

patents or technological breadth and it has a positive effect on the out-licensing decisions.

Gambardella 2007) listed patent characteristics affecting the licensing propensity, including the economic value of a technology, and the patent breadth measured by technology classes covered by the patents. Hu et al. (2015) have identified the licensors' prestige through forward citation and found that it enhances the licensing propensity. Ruckman and Mccarthy (2016) also measured the determinants of out-licensing as number of forward citation, technology depth and breadth.

First, the patent value is measured as the number of forward citations of the licensors' patents (Gambardella et al., 2007; Hu et al., 2015; Ruckman et al., 2016). A larger number of forward citations implies the outstanding status in the knowledge domain, providing signals to potential licensees that the patents underpinning the firm's out-licensing activities ensure generating more economic returns (Hu et al., 2015). Therefore, firms with a high number of forward citations of their patents will have a larger number of out-licensing deals.

*H1: For licensors, the number of forward citations of their patents has a positive effect on the number of out-licensing deals.*

Regarding technological breadth, it is strongly related to the 'noticeability' of the licensors to the licensees. It is related to the variety and scope of technological areas the firms have dealt with (Ceccagnoli and Battaggion, 2015; Ruckman et al., 2016). Licensors with a broad technological knowledge base are more adept at disseminating their technologies to external parties. This can be also interpreted as an increased attractiveness to the potential licensees.

*H2: For licensors, the technological breadth of their patents has a positive effect on the number of out-licensing deals.*

According to Lichtenthaler and Lichtenthaler(2009), connective capacity implies external knowledge retention, i.e., the firms extending their knowledge bases by forming interfirm relationships. It is constituted as alliance capability and relational capability.

The mainstream of determinants of out-licensing have neglected this point of view. Firms not only conduct inward knowledge transfer, they also enter into various alliances with external parties to gain privileged access to their knowledge base. Therefore, by extending their knowledge through this capacity, firms can efficiently enjoy specialization in the creation of new knowledge (Gulati, 1999). In other words, licensors with a stronger connective capacity are also likely to show stronger desorptive capacities.

Previous studies related to the connective capacity measured it as the number of backward citations of the patents or the number of R&D collaborations (Mudambi et al., 2010; Ahn et al., 2015; Shin et al., 2018)

*H3: For licensors, the number of backward citations of their patents has a positive effect on the number of out-licensing deals.*

*H4: For licensors, the number of R&D collaborations has a positive effect on the number of out-licensing deals.*

### 2.5.2 Research Model

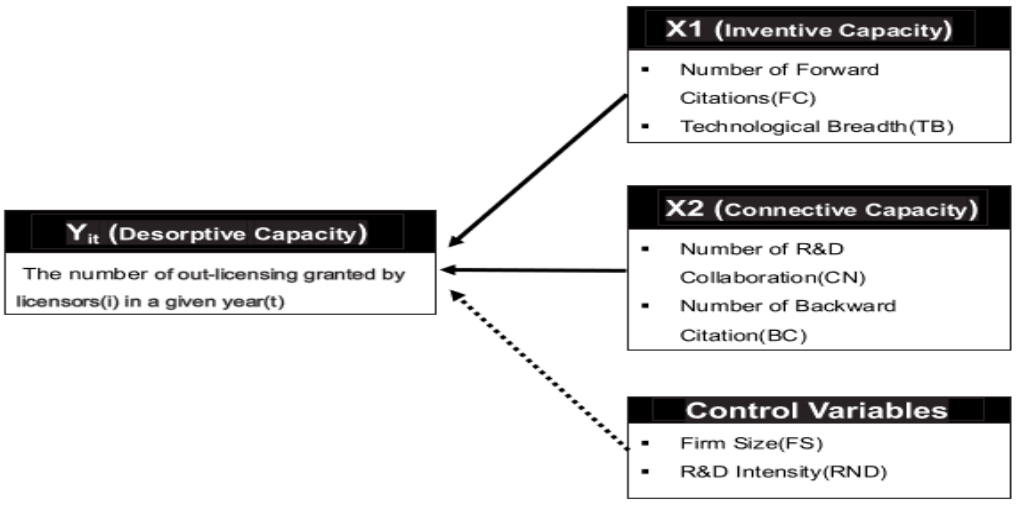


**Figure 10.** Research model

Based on the above discussion, the research model for the analysis is presented. To be specific, this research developed an econometric model with the licensor's desorptive capacity as the dependent variable and inventive capacity and connective capacity as the independent variables.

The dependent variable is the out-licensing number of each licensor(DC), which is the outcome of outbound innovation. Regarding inventive capacity, as it is related to internal knowledge exploration, it is reflected by the qualitiy of the licensor's patents. In this study, inventive capacity is measured by the number of forward citations(FC) that represents the value of the patent and also by breadth(TB) corresponding to the qualitative information of the firm's patent stocks. Another independent variable, connective capacity, is the ability of knowledge retention resulting from the inter-firm relationships, which is measured by the number of R&D collaboration(NC) and the number of patent backward citation(BC). Additionally, the analysis controls for the effects of firm size and R&D intensity.

# 3. Methodology

## 3.1 Data

The data this research utilizes is extracted from three sources: Medtrack, Wharton Research Data Services(WRDS) and G-pass data. First, deal data is extracted from the Medtrack database from UK INFORMA. This database covers various deal information on 16,000 biopharmaceutical industry firms such as deal type, deal year, deal industry, deal value, etc.. In this research, deal type is confined to partnerships and licensing agreements, and specifically data on the deal year and the number of R&D collaborations is utilized.

Second, the WRDS database contains financial information of each firm in a given year. Various information such as R&D investments, sales, assets, debts, the number of employees are available. I extracted R&D investments, sales, and number of employees for the econometric analysis.

Last, G-pass data covers the patent information. The G-Pass database is a worldwide patent database built up by the Korea Institute Science and Technology Information (KISTI) and it is based on a database provided by LexisNexis. From this database, I made use of the reference, citation, IPC information of patents granted to each firm.

**Table 3.** Data Sources

| Database | Extracted Data |
|---|---|
| Medtrack | Deal information (number of out-licensing deals, deal year, number of R&D collaboration) |
| WRDS | Financial information (R&D investment, sales, employees) |
| G-pass | Patent information (citations, references, granted year, IPC counts) |

## 3.2 Variables

### 3.2.1 Dependent Variable

The main interest of this study is to identify out why some firms are superior in successfully out-licensing than other firms in spite of the fact that licensing activities are confronted with a high attrition rate. As this is related to the licensors' competencies to exploit their technology, it could be seen in the context of desorptive capacity. By definition, desorptive capacity refers to the capabilities of firms exploiting their resources to external partners (Lichtenthaler et al., 2009) and features path-dependencies which stem from previous experiences. Previous studies have used the number of prior out-licensing deals (Gambardella et al., 2006; Fosfuri, 2008; Lichtenthaler et al., 2010; Shin et al., 2018) as a proxy for desorptive capacity.

In this study, it is measured by the number of out-licensing deals of licensors in a given year (DC). In addition, it is important that this study does not take into account the case of licensors with zero out-licensing.

### 3.2.2 Explanatory Variables

#### 3.2.2.1 Inventive Capacity

Inventive capacity in this study is measured by the patent characteristics of each firm; specifically, the forward citation number of granted patents(FC) and technological breadth(TB) of licensors. The inventive capacity is strongly related to the licensors' visibility, noticeability to the potential licensees and reflects the quality of their technologies (Ruckman et al., 2016). Previous studies have measured the quality of patents in perspective of the number of forward citations (Gambardella et al., 2006; Hu et al., 2015;) and technological breadth(Gambardella et al., 2006; Kani et al., 2012; Ceccagnoli et al., 2015; Ruckman et al., 2016) of licensors.

In detail, as the number of citations qualifies the quantity of publications and patents (Abbasi et al.,2011b), FC is computed as the sum of forward citations number of patents for the 5-year period before the execution of the out-licensing deals. The TB is calculated as the number of different IPC classes. To measure this, I followed Harhoff(1999)'s approach as the number of identical four-digit

IPC classification codes in the granted patents. To be specific, TB is measured as the accumulative number of different 4-digit IPC codes of patents in the 5 years before the execution of out-licensing deals.

#### 3.2.2.2 Connective capacity

According to Lichtenthaler and Lichtenthaler(2009), connective capacity is the firms' ability to link with other external partners to facilitate the innovation process. It is associated with knowledge retention which excludes the complete knowledge transfer. Connective capacity includes not only relational capability but also alliance capability, which further ensures access to external knowledge bases.

Previous studies used the number of R&D collaboration at the firm-level, or the number of backward citations of firms to measure connective capacity (Mudambi et al., 2010; Ahn et al., 2016; Shin et al., 2018). Therefore, in accordance with these mearsurements, this study measures connective capacity in two ways. The number of R&D collaboration(CN) is defined as the sum of R&D collaborations in the 5 years before the execution of the out-licensing deals. The number of backward citation(BC) is calculated as the sum of backward citations in the 5 years before the execution of the out-licensing deals[7].

[7] Self-citations are excluded.

### 3.2.3 Control Variables

This research includes two control variables; (1) Firm size and (2) R&D intensity. Previous research has measured the firm size as the amount of sales or the number of employees. Since the dependent variable used in this study is a countable integer, firm size was measured as the number of employees in the intention to match the unit of measurement. There is also the intention to avoid a duplication problem because the R&D intensity is calculated as the R&D expenditure normalized by sales. The R&D intensity is usually measured as the R&D investment divided by the firm size (Ruckman et al., 2016). It represents the concentration of the firms' innovation activities. Thus, the higher the R&D investment of biopharmaceutical firms, the more likely they are to increase their technological innovation or financial performance. In this context, the R&D intensity in this study is calculated as the R&D expenditure of each licensor in a given year normalized by its sales.

**Table 4.** Specification of variables

| | Variable | | Measurement | Source of data |
|---|---|---|---|---|
| **Dependent Variable** | *Desorptive Capacity(DC)* | | The number of out-licensing deals of each licensor in a given year | Medtrack |
| **Explanatory Variables** | **Inventive Capacity** | *Number of Forward Citations(FC)* | Accumulative number of Forward Citation of each firm for 5 years before the execution of deal | Gpass |
| | | *Technologial Breadth(TB)* | Accumulative number of different IPC codes of each firm for 5 years before the execution of deals. | |
| | **Connective Capacity** | *Number of Backward Citations(BC)* | Accumulative number of Backward Citation of each firm for 5 years before the execution of deal | Gpass |
| | | *Number of R&D Collaborations(CN)* | Accumulative number of R&D collaboration of each firm for 5 years before the execution of deal | Medtrack |
| **Control Variables** | *Firm Size(FS)* | | The number of employees of each licensor in a given year | WRDS |

| | |
|---|---|
| *R&D Intensity(RND)* | R&D Expenditure of each licensor in a given year / sales of each licensor in a given year1In case of measurement of Desorptive Capacity, the cases of zero number are excluded |

[1] In case of measurement of Desorptive Capacity, the cases of zero number are excluded

## 3.3 Sample & Econometric Model

### 3.3.1 Sample

The samples were selected from the three data sources mentioned above (Medtrack, GPASS, WRDS). Since the name of each firm is different for each data source, it is necessary to match them. Data sorting has been carried out to extract necessary the information for each data source prior to the firm name matching.

Regarding the Medtrack database, as it contains comprehensive deal types such as merger, acquisition, partnership, public offering, and venture financing, this study only considered the partnership type. In addition, deals which indicate a status of 'Terminated' are excluded. As for the GPASS database, the type is contains entries classified as 'Grant' and 'Application'. As patents which are in

the status of 'Application' are not completely acknowledged as official patents, they are excluded from the analysis.

After the firm matching, the final sample contains 1,094 observations of 514 firms on deals from 2009 to 2016. Table 5 shows the descriptive statistics of the variables.

**Table 5.** Descriptive Statistics of variables

| Variables | Obs. | Mean | Std. dev. | Min | Max |
|---|---|---|---|---|---|
| **Dependent Variable** | | | | | |
| Number of out-licensing | 1,094 | 1.641682 | 1.439712 | 1 | 13 |
| **Explanatory Variables** | | | | | |
| FC(Forward Citation) | 1,094 | 68.00274 | 542.107 | 0 | 8774 |
| TB(Technolocial Breadth) | 1,094 | 33.18282 | 210.6407 | 0 | 4024 |
| BC(Backward Citation) | 1,094 | 9.13528 | 97.9298 | 0 | 2256 |
| CN(R&D Collaboration) | 1,094 | 0.81444 | 1.1094 | 0 | 9 |
| **Control Variables** | | | | | |
| FS(Firm Size) | 1,094 | 10604.85 | 26537.75 | 0 | 163000 |
| RND(R&D Intensity) | 1,094 | 0.17953 | 0.69722 | 0 | 9.266831 |

### 3.3.2 Econometric Model

Considering the dependent variable is a countable, nonnegative, and integer variable (the number of firm *i*'s out-licensing deals in a given year *t*), the conventional linear regression models are not appropriate for the analysis. The simplest model to deal with countable data is the Poisson regression model. However, the Poisson distribution estimation should meet the prerequisite of equality between mean and variance. This condition, however, has been criticized for the problem of 'overdispersion'. This occurs when the conditional variance is larger than the conditional mean, which is attributed to unobserved 'heterogeneity'.

The solution for this problem is to include 'fixed' or 'random' effects into the Poisson model. As the sample mean is smaller than the sample variance in the descriptive statistics in Table 5, the negative binomial model is specified in this study (Hausman et al., 1984). The more efficient estimator is used in the situation of overdispersion by adding a parameter that reflects unobserved heterogeneity among observations(Vonortas et al., 2006). I adopted the most general negative binomial model used in econometric applications with the mean function $\lambda_i$ and variance function $\lambda_i + \alpha \lambda_i^2$(Cameron & Trivedi, 1986):

$$f(y_{it}|\lambda_{it},\alpha) = \frac{\Gamma(y_{it}+\alpha^{-1})}{\Gamma(y_{it}+1)\Gamma(\alpha^{-1})}\left(\frac{\alpha^{-1}}{\alpha^{-1}+\lambda_{it}}\right)^{\alpha^{-1}}\left(\frac{\lambda_{it}}{\alpha^{-1}+\lambda_{it}}\right)^{y_{it}}$$

Is the model used in econometric applications with a mean function $\lambda_{it} = \exp(x_{it'}\boldsymbol{\beta})$, where $x_{it'}$ denotes a matrix of explanatory variables (FC, TB, CN, BC, FS, RND) and $\boldsymbol{\beta}$ denotes a vector of unknown parameters. The estimation method is conducted through MLE.

# 4. Results

**Table 6.** Correlation of variables

| Variables | CN | BC | FC | TB | RND | FS |
|---|---|---|---|---|---|---|
| CN(R&D Collaboration) | 1 | | | | | |
| BC(Backward Citation) | 0.0949 | 1 | | | | |
| FC(Forward Citation) | 0.0645 | 0.0646 | 1 | | | |
| TB(Technological Breadth) | 0.0433 | 0.4610 | 0.5838 | 1 | | |
| RND(R&D Intensity) | 0.0079 | - 0.0169 | - 0.0248 | - 0.0288 | 1 | |
| FS(Firm Size) | 0.4928 | 0.1703 | 0.1786 | 0.1090 | - 0.0417 | 1 |

**Table 7.** Negative binomial regression results

| Variables | Model 1 | Model 2 | Model 3 |
|---|---|---|---|
| FC(Forward Citation) | 0.00006(0.00007) | | - 0.0001(0.0001) |
| TB(Technological Breadth) | - 0.0005(0.00005) | | - 0.0001(0.0004) |
| BC(Backward Citation) | | 0.00004(0.00001)*** | 0.0008(0.0003)*** |
| CN(R&D Collaboration) | | 0.3885(0.0399)*** | 0.3859(0.0399)*** |
| FS(Firm Size) | 0.00001(1.14e-06)*** | 6.97e-06 (1.15e-06) *** | 7.08e-06(1.15e-06) *** |
| RND(R&D Intensity) | 0.0306(0.059) | 0.0228(0.0401) | 0.0220476 (0.0404) |
| Log pseudolikelihood | - 11114.2593 | - 923.87547 | - 922.80171 |
| Wald $chi^2$ | 261.75 | 499.75 | 623.50 |
| Pseudo $R^2$ | 0.2282 | 0.3601 | 0.3608 |

[1] ***indicates significance at<1%, **<5%, *<10%.

[2] Number of observations: 1,094.

[3] Standard deviations are in parentheses.

Table 7 reports the negative binomial regression results for the licensors' desorptive capacities. Because an 'overdispersion' problem is present in the sample, negative binomial regression has been adopted. In order to examine the effect of each explanatory variable in detail, the regression is conducted in three ways. In Model 1, connective capacity is excluded, and Model 2 is the result of

analysis excluding inventive capacity. Model 3 is the full model incorporating all variables.

First, from Model 1, FC(Forward Citation), RND(R&D Intensity) and FS(firm Size) of the licensors show a positive coefficient value, but only FS is statistically significant at the 1% significance level. On the other hand, TB(Technological Breadth) has negative signs but is not statistically significant.

In Model 2, both BC(Backward Citation) and CN(R&D Collaboration), which represent the connective capacity of the licensors, show positive coefficients at the 1% significance level ($p < 0.01$). FS (Firm Size) is also positive at the significance level ($p < 0.01$). RND (R&D Intensity) shows a negative coefficient value but is not statistically significant.

Last, the result of Model 3, the full model, are as follows: The coefficient values of the FC(Forwrad Citation) and TD(Technological Breadth), the inventive capacity of the licensors, are negative but not statistically significant. On the other hand, BC and CN, which represent connective capacity, show a positive coefficient value at the 1% significance level ($p < 0.01$) as in Model 2. FS (Firm Size) is also positive at the significance level ($p<0.01$). RND (R&D Intensity) shows a positive coefficient value but is not statistically significant.

Looking at the results based on the variables, the coefficients of FC and TB, which represent the inventive capacity of the licensors are showing inconsistent results, and are statistically insignificant in both Model 1 and Model 3. This result

implies that inventive capacity, with or without the influence of connective capacity, has no substantial effect on the desorptive capacity of licensors. Therefore Hypothesis 1, which stated that inventive capacity positively affects desorptive capacity, is not supported. This contradicts the results of previous studies which found that the inventive capacity of licensors positively affects the licensing propensity (Gambardella et al.,2006; Kani et al.,2012; Hu et al.,2015; Ruckman et al.,2016).

Concerning the connective capacities of the licensors, both CN and BC showed consistent results. Both coefficients are positive at the 1% significance level ($p<0.01$). In other words, the connective capacities of licensors has been proven to have a positive effect on their desorptive capacities. As licensors actively engage in R&D collaboration, they can share the R&D results of the partners, which in turn activates their backward citations and enriches their knowledge base. Consequently, out-licensing deals are conducted more actively (Lichtenthaler et al., 2009).

Regarding the control variables, coefficients of FS are positive at the 1% significance level($p<0.01$). This results follows Kim and Vonortas(2006), and Kani and Motohashi(2012) in that large licensors are more likely to license-out because they have a greater tendency to sell their non-core technologies in order to complement their revenue. This is attributed to the fact that large firms have larger patent portfolios than smaller firms. On the contrary, RND is found to be

not statistically significant.

In summary, the results imply that existing licensors should strengthen their connective capacities rather than their inventive capacities to facilitate out-licensing activities. By forming collaborations the firms could benefit from their partners' R&D outcomes, and utilize these to further strengthen their knowledge base. Consequently, this facilitates active out-licensing This suggests that different strategies are needed for out-licensing depending on whether a firm is already conducting out-licensing or not.

# 5. Conclusion

## 5.1 Theoretical Contribution

The pharmaceutical industry is a high technology industry that requires a combination of in-depth knowledge of various fields and is characterized by high cost, high risk and long term perspectives due to high regulation. It also faces the problem of deteriorating R&D productivity (E.Petrova,2014). Under these conditions, the importance of open innovation strategies has been emphasized more than in any other industry, and under the open innovation system, it is essential for firms to develop several dynamic capabilities to effectively manage their resources both internally and externally. Lichtenthaler and Lichtenthaler(2009) suggested a systematic framework for such dynamic capabilities.

Among the capabilities, the absorptive capacities of firms related to the inbound process and external exploration have been a focus of research since the 1990s. As firms have shifted their focus to outbound innovation, several studies have been conducted on Desorptive Capacity (Hu et al.,2015), which is related to knowledge exploitation. The mainstream of the previous studies are studies on how these dynamic capabilities affect firm performance (Lichtenthaler, 2010; Mazzola et

al.,2012; Shin et al., 2018) and licensing propensities (Fosfuri 2003; Vonortas et al.,2006; Kani et al.,2012; Hu et al.,2015).

Therefore, the academic implications of this study are as follows: First, it differs from the previous studies which have focused on the effects of dynamic capabilities on firm performance or licensing propensities. These studies have showed that the more capabilities firms build up, the higher performance they achieve. However, the Desorptive Capacity itself that indicates the performance of outbound innovation has received less attention as a dependent variable. Therefore, this research can be said to perform inter-capabilities analysis, which differs from the mainstream of dynamic capabilities research.

Second, previous studies dealing with the determinants of out-licensing propensity are limited to Inventive Capacity and Desorptive Capacity (Hu et al., 2015), which are related to knowledge exploration and exploitation. The perspective of the knowledge retention was not considered as a determinant of out-licensing decisions. These days, it is not hard to see the landscape in which biotech firms' knowledge is externally retained by the pharmaceutical firms without an immediate knowledge internalization. However, pharmaceutical firms have ensured exclusive access to the results of the partners' R&D in this field by establishing collaboration agreements (Shin et al., 2018). In other words, the determinants of out-licensing have been more systematically organized and complemented in this research.

## 5.2 Managerial Contribution

This study identified which competencies the licensors should built up in the pharmaceutical industry to actively conduct out-licensing deals. The important point here is that it focuses on the firms that have already been licensing-out. Thus, it does not cover the decision of whether or not to out-license, but rather focuses on existing licensors to investigate whether they are further promoting their out-licensing activities. Thus, as the determinants of out-licensing, inventive capacities and connective capacities of the licensors were measured by the characteristics of their knowledge such as patents and R&D-related activities.

The empirical results of this study provide important implications for firms engaged in the pharmaceutical industry. Inventive capacities of licensors are core competencies to form a knowledge base and reach the licensees with signals. Previous studies have shown that this positively affects the out-licensing propensity (Fosfuri 2003; Vonortas et al.,2006; Kani et al.,2012; Hu et al.,2015).

However, according to the results of this study, inventive capacity does not have a significant effect on the licensors which are already out-licensing. On the contrary, connective capacity has a positive effect on desorptive capacity. Thus, in order to promote out-licensing activities of already out-licensing firms, additional efforts should be put into forming alliances or R&D collaborations with other external parties rather than into internal R&D capacity improvement. In order to

stimulate out-licensing activities, it is necessary for licensors to replenish their knowledge base through new innovations. However, there is no meaningful effect through the internal capabilities of the firms, and only the reconstruction of the knowledge base through the influx from inter-firm relationships has confirmed positive effects.

This can be explained in two ways: First, if the licensor is already engaged in out-licensing activities, this indicates that they have established some positioning in association with prestige, noticeability and technology fields related to the abilities to generate new knowledge internally. The next point is that the overall pharmaceutical industry is facing reducing R&D productivity. Strengthening regulations on new drugs and developing treatments for most diseases are making it more difficult to maintain innovation (Ding et al., 2016). Therefore, it is more efficient and time-saving for licensors to build up their knowledge base by sharing R&D outcome through various alliances or R&D collaboration with other partners, and actively citing the other partners' knowledge.

In summary, as the desorptive capacity of licensor drives firms performance (Lichtenthaler, 2010; Mazzola et al.,2012; Shin et al., 2018), the analysis on the determinants of desorptive capacity itself is meaningful for firms wanting to know how to best actively participate in the outbound process. This will provide licensors with some guidance for sustainability in dynamic open innovation ecosystems.

## 5.3 Limitations and Future Study

The limitation of this study is that the determinants of out-licensing are confined to the firm-level knowledge management capacities. It has been proven through several previous studies that the effects of industry-level characteristics also affect out-licensing (Arora et al., 2005; Fosfuri, 2006; Vonortas et al., 2006; Kani et al.,2012). According to these studies, the licensors should consider not only their capabilities but also the characteristics of the industry when out-licensing. Depending on how many competitors are in the market, the licensor's out-licensing incentive will vary, with two effects; The revenue effect (the degree of profits they earn from out-licensing) and the rent dissipation effect (the extent to which market share is reduced by increasing competitors in the market).

In addition, another limitation of the study is that the interpretation of the analysis result is not rigorous because of the missing classification among the firms. As mentioned earlier, the pharmaceutical industry consists of large pharmaceutical firms and small and medium-sized biotech firms. They have different incentives for out-licensing because they exhibit differences in the holdings of downstream assests. Large pharmaceutical firms tend to license out technologies that are less important to them, because they have a wealth of resources, marketing capabilities, and networking capabilities compared to biotech companies. On the other hand, in terms of biotech firms, out-licensing

newly developed technologies might be their only viable route to the market, as the majority of them have no significant sales structure or marketing capacities in place. Thus, licensing fees are their main source of revenue (E.Petrova, 2004). Therefore, an analysis covering such firm-level, industry-level factors and classification of licensors should be undertaken in the future.

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# Abstract (Korean)

제약 산업은 다양한 분야에 대한 심층적인 지식을 요하는 첨단 기술 산업으로 그 어떤 산업보다 개방형 혁신의 도입과 필요성이 부각된다. 이는 제약 산업의 기술혁신이 높은 규제로 인하여 장기간, 고비용, 고위험의 특성을 보이고 최근 산업 전반에 걸쳐 R&D 생산성이 떨어지는 문제에 직면하고 있는 데에 기인한다. 개방형 혁신 시스템 하에서 기업은 역동적으로 변화하는 외부 환경에 대하여 내부적으로 혹은 외부적으로 자원을 효율적으로 관리할 수 있는 dynamic capabilities를 개발하는 것이 필수적이다. Lichtenthaler와 Lichtenthaler(2009)는 이런 dynamic capabilities를 체계적으로 정리한 프레임워크를 제시했다.

본 연구는 개방형 혁신 중, 기업의 외향혁 혁신으로써 아웃라이센싱에 영향을 미치는 기업수준의 요인들에 초점을 맞춘다. 아웃라이센싱을 잘할 수 있는 역량은 desorptive capacity와 관련이 있으며 이는 해당기업의 아웃라이센싱 수, 즉 outbound innovation의 성과로 해석될 수 있다. 이는 아웃라이센싱을 하는지에 대한 여부를 나타내는 기존의 licensing propensity와는 다른 개념으로 기존에 아웃라이센싱을 하고 있는 기술제공자들이 그들의 아웃라이센싱을 더욱 촉진시키는 영향요인들이 있는지를 규명하고자 했다. 분석을 위하여 음이항 회귀(negative binomial regression)를 사용하였고 기술제공자의 inventive capacity와 connective Capacity가 desorptive capacity의 결정요인으로 어떤 효과를 보이는지를 분석했다. Inventive capacity는 기업이 자

사 내부적으로 새로운 지식을 창출해낼 수 있는 능력으로 knowledge exploration과 연관되고 connective capacity는 기업이 기업간 관계를 통해 지식을 보유할 수 있는 knowledge retention과 관련이 있다. 기존의 licensing propensity에 대한 영향요인 분석은 knowledge retention에 대한 것을 고려하지 않았다. Desorptive Capacity에 대한 분석 결과는 다음과 같다. 기술제공자의 inventive capacity는 desorptive에 유의미한 변인으로 작용하지 못한 반면, connective capacity는 양의 영향을 보였다.

**주요어 : Pharmaceutical Industry, Licensing, Outbound Innovation, Open Innovation, Exploitation, Knowledge Retention, Desorptive Capacity, Connective Capacity,**

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