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The Role of Open Innovation:

Focus on the Pharmaceutical Industry

Bachelor thesis

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Abstract

This thesis deals with how companies in the pharmaceutical industry are allocating the development of innovations and what benefits there are by implementing Open Innovation strategies. Two principal companies, AstraZeneca and Eli Lilly and Company, have been investigated. This thesis aims at finding answers to how Open Innovation is performed within AstraZeneca and Eli Lilly and Company, what incentives there are for these companies to engage in Open Innovation and to investigate whether there are complications considering Intellectual Property (IP) for these companies when it comes to Open Innovation.

The two pharmaceutical companies are both highly depending on innovations and have approached different strategies towards Open Innovation and these strategies are examined in the case study of this thesis. It can be concluded that the pharmaceutical industry is changing and that pharmaceutical companies need to find new approaches of innovating in order to stay competitive, something that both AstraZeneca and Eli Lilly and Company are looking into. This thesis further concludes that there are different interpretations of Open Innovation in the pharmaceutical industry; however, the development of innovation strategies indicates that openness is imperative in order to stay competitive.

Key words: Open innovation, innovation, pharmaceutical industry, intellectual property, crowdsourcing, AstraZeneca, Eli Lilly

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1. Introduction

The first chapter presents the background and purpose of this thesis. The research questions are presented as well as the used limitations. This chapter also illustrates the outline of all chapters of the thesis in order to provide the reader with an overview.

1.1 Background

Innovation is an extremely important tool for companies in different industries around the world and Baumol (2002) points out that almost all economic growth in the last centuries can be traced back to innovation. Innovation has a number of definitions and one of the most influential actors in this area, Peter Drucker, defines innovation as a "*change that creates a new dimension of performance*" (Hesselbein, Goldsmith & Somerville, 2002).

Companies need research and development (R&D) to develop new products in order to stay ahead of competitors. Traditionally, R&D has been conducted internally within companies that have been careful not to display any knowledge or company secrets to competitors (although, there have been examples of collaborations in industries that required technology transactions in the birth of that industry (e.g. chemicals), these were very few exceptions a long time ago (Lichtenthaler, 2012)). In recent times companies have started to rethink, and have come to an understanding that themselves only employ a small fraction of the scientists in their specific area, and that they can gain from collaborating with other companies with similar activities. This all falls in place with the use and realization of the phrase "*not all the best people work for you*" (Chesbrough, 2003).

Henry Chesbrough (2003) coined the term "Open Innovation" and explains how companies open up and start to collaborate with each other in order to create and profit from technology. There are a number of examples in the IT, electronics and the pharmaceutical industry (Chesbrough, 2003; Hunter & Stephens, 2010; Sloane, 2011) among others and Open Innovation is an upcoming, up-to-date and different way of dealing with new product development.

The topic Open Innovation also raises issues that are complex to explain without further research and understanding. It is mainly the problem of protecting IP that comes to mind when companies share information and technology. Along with an increasing number of

collaborations, the complexity of conducting innovations increases as well and many companies still claim that they do better without outside intervention (Remneland, 2010). In this thesis the meaning of Open Innovation will be clarified and the role of Open Innovation in the pharmaceutical industry closely investigated.

1.2 Problem discussion and purpose

Industries that are knowledge intense are particularly interesting to observe when it comes to Open Innovation since Open Innovation allows companies to spread risks and reduce lead times and thus increase their competitiveness. Open Innovation has evolved in the last decade and has become increasingly common and it is interesting to examine the reasons for this occurrence. Companies in the pharmaceutical industry rely on innovations in order to stay profitable and ahead of competitors, and this thesis aims to investigate whether Open Innovation is beneficial for companies in the pharmaceutical industry or if sharing knowledge makes these companies more vulnerable to competitors.

This thesis aims to provide a view of Open Innovation in general and how it is used in the pharmaceutical industry in particular, with specific focus on the two pharmaceutical companies AstraZeneca and Eli Lilly and Company (hereafter named Lilly). To find answers to these inquiries, case studies on how the companies perceive and adopt Open Innovation will be conducted. In addition, information about the pharmaceutical industry and drug development will be used to support the problem discussion.

Open Innovation is a topic with many different definitions depending on the background of the spectator. As a consequence, a conceptual framework is necessary and will be presented in order to clarify the definition of Open Innovation in this thesis and why it should, or should not, be considered as a strategy by companies and investors. Open Innovation can be conducted in several ways and a number of issues such as protection of IP, collaboration contracts and the Open Innovation process will be explained and examined in this thesis.

In order to investigate the problem, the following research questions have been set out to narrow down the approach:

- 1. How is Open Innovation performed within AstraZeneca and Lilly?
- 2. What incentives do these companies have to engage in Open Innovation?

3. How do these companies handle issues with IP rights when engaging in Open Innovation strategies?

1.3 Limitations

The subject of innovation is extremely vast; therefore this thesis will be focusing on one segment; Open Innovation within the pharmaceutical industry. The limitation and focus on the pharmaceutical industry is mainly due to the importance of innovation within this industry and the fact that R&D of drugs is expensive and need new approaches. This thesis is limited to what Open Innovation means for the pharmaceutical companies AstraZeneca and Lilly based on the fact that shorter product lifecycles force companies to increase investments in innovations in order to stay competitive. Open Innovation has different interpretations in different companies and a conceptual framework will be presented in the theoretical framework order to clarify the meaning.

The case study of this thesis is limited to the exploratory study of AstraZeneca and Lilly, and how these companies relate to Open Innovation. These two companies are among the biggest in the pharmaceutical industry and the findings can provide an indication on how Open Innovation is perceived within the industry as a whole. Additional information from the industry serves as support to the chosen companies and the analysis.

1.4 Thesis outline

The first section provides a short introduction to the subject that leads up to the problem discussion and purpose. It is important to create a well developed and detailed background section since it is an essential part of this thesis and will lead up to the theoretical framework. The second section describes the use of method and how the thesis is conducted, as well as arguments for the choice of method and method criticism. The third section covers the theoretical framework on which the empirical study will be based. The most relevant and influential theories considering Open Innovation will be presented in the theoretical framework. The fourth section will be divided into three parts; the first will explain the nature of the pharmaceutical industry and drug development, the second part will cover the case of AstraZeneca and the third part illustrates the case of Lilly. The fifth section will provide a thorough analysis of the empirical studies performed in the fourth section and be complemented with a discussion considering the future of the pharmaceutical industry regarding innovations in general and Open Innovation in particular. In the sixth section, the

conclusion of the analysis will be presented and connected with the research question presented in the opening of this thesis. The sixth section will be wrapped up by presenting the authors' recommendations for future research within the same field.

2. Method

The second chapter illustrates the methods used in order to conduct this thesis. In addition, arguments for why the authors have found these methods best suited will be explained as well as alternative methods and method criticism.

2.1 Research design

Innovation is important for any knowledge intense company, and the globalized world today increases competition, which further motivates innovation. The aim of this thesis is to visualize the Open Innovation process in general and explain and clarify why Open Innovation has developed with a focus on the pharmaceutical industry by explaining these forces. In order to execute the empirical research on the pharmaceutical companies AstraZeneca and Lilly, an exploratory approach by using a qualitative research method has been chosen. A qualitative research study is believed to be better suited than a quantitative method since a deeper understanding of the examined companies' point of view of Open Innovation is the primary purpose of this thesis. A quantitative method is normally used in order to collect statistical data and conduct statistical analyses. The motives for the choice of method lie within the nature of the research questions; why the strategy and phenomenon of Open Innovation occurs and from a theoretical, motivational point of view that connect the results back to the empirical results.

This research consists primarily of literature of different characteristics such as textbooks, articles and dissertations. Furthermore, case studies of AstraZeneca and Lilly will be conducted. The aim of using this approach is to gain a thorough understanding of the subject and of how these companies relate to Open Innovation.

2.2 Research approach

The method explains the scientific base and the execution of the work of this thesis. There are three different methodological approaches to apply in order to execute a thesis. A deductive approach implies that theories are used as the starting point for the research study and used by the researcher in order to reason a hypothesis by logic based on the theoretical framework. In turn, execute an empirical study based on these facts. Critique for applying a deductive method approach is that it is challenging for the researcher not to find data and information that confirms the already outworked and stated theory (Jacobsen, 2002). The results of the

empirical study might thus be angled in order to confirm existing theory. The contrasting methodological approach to deductive is inductive which means that theory and conclusions are developed through empirical research and data collection; hence the role of the empirical study plays a significant role while using the inductive method approach. The abductive approach is a mix of the two previous in the way that much emphasis is put into the existing theoretical framework, but the empirical study is the tool in order to revise what has been stated as theory (Eriksson & Kovalainen, 2008).

This thesis is based on an inductive, exploratory approach due to the fact that the conclusions are based on the empirical observations of AstraZeneca and Lilly. Theories and analyses that have been developed considering innovations and the motives behind innovations will be included as well as the role of globalization on competition, and the definition and development of the Open Innovation paradigm. Moreover, it is possible to conduct a research with either a descriptive or interpretational approach, and it is found that the descriptive approach is better suited as the purpose of this thesis is to understand and explain Open Innovation in the pharmaceutical industry.

2.3 The case studies

Case studies should be executed if the research question tackles complex managerial and/or organizational business concerns since these subjects need to bee examined from more than one perspective and thus can be difficult to investigate while using a quantitative research approach (Eriksson & Kovalainen, 2008). This thesis aims at illustrating the subject of Open Innovation as well as controlling whether existing theory on the subject is representative of the point of view of concerned businesses. With a research question that "deals with operational links needing to be traced over time", a case study of qualitative nature is desired (Yin, 2009).

In this thesis case studies have been performed in order to investigate what Open Innovation means for knowledge intense companies in the pharmaceutical industry with the purpose to confirm or dismiss the theories in the theoretical framework. Two large pharmaceutical companies, AstraZeneca and Lilly, have been chosen for this purpose. AstraZeneca was selected because it is a big company with roots in Sweden where it employs 7,600 people (AstraZeneca, 2012a). Lilly was selected due to the fact that is a prominent company within Open Innovation (Chesbrough & Garman, 2009). The two companies are among the "Big

Pharmas", which refer to the big, globally well-established and capital strong pharmaceutical companies, and are thus, to a certain extent, considered to represent the industry. Case studies have been performed by thorough interviews with informed and influential personnel at AstraZeneca, as well as literature research of both companies. Lilly has an apparent approach to Open Innovation and information was found with minor difficulties. Conversely, AstraZeneca's approach is less clear and required further explanations and information, which is the reason why interviews were held with AstraZeneca but not with Lilly.

2.4 Data collection

Primarily this thesis has been conducted on a basis of literature in the form of textbooks, research papers, documentations and dissertations from the field of both innovation and Open Innovation and articles considering pharmaceutical companies and the importance of openness in this industry. These readings have been the foundation for this thesis, and interviews with Anders Ekblom and Mats Sundgren, personnel in managerial positions at AstraZeneca in Södertälje and Mölndal, Sweden have assembled the data for the qualitative, empirical study. This information has made it possible to connect real-life situations considering strategy in the pharmaceutical industry with literature in the same field. The purpose with the interviews has been to investigate the correspondence and reliability of the theory on this subject.

In order for the authors to gain a better understanding of how Open Innovation in the pharmaceutical industry is adopted, interviews with Björn Remneland, and Alexander Styhre, researchers and professors at the School of Business, Economics and Law at the University of Gothenburg, have been held.

In addition, data has been collected through thorough research of Lilly and its different innovation processes.

2.5 Method criticism

Any chosen method of approach comes with certain disadvantages. The same goes for the chosen practice of a qualitative case study when scrutinizing the subject of Open Innovation. When using a qualitative approach the perception and point of view of a limited number of actors on the market is reached and this in turn will provide a somewhat non-faceted observation to base the analysis on. The inductive approach can be criticized since the

observed empirical material is limited (here the two companies) and thus hard to interpret as representative. However, the conviction is that the method chosen is the most appropriate one for this thesis and its purpose. The conclusion and research of this thesis is based on the interviewees' perception regarding Open Innovation and in turn by the authors and compared to existing literature on the subject in question. The conceptual framework is thus an important element since the interpretation of the term Open Innovation might differ depending on the interviewee.

2.6 Reliability and validity

A reliable thesis implies that the results that emerge from the research study would be the same if the same research were to be done by another researcher, i.e. replicable (Yin, 2009). For this particular thesis that treats an up to date and debated topic, the importance of time and place must be emphasized. This research is assumed to be reliable to a great extent due to the thorough development of the theoretical framework and later on the direct connection between theory and empirics. As the approach of this thesis is descriptive, it is possible to consider the level of reliability of the analysis as relatively high, since it should be possible to replicate the analysis if the same empirical material was used. However, the world of pharmaceuticals today stands before great change (Hedner, 2011), which means that even if it is possible to replicate the analysis, a future empirical study on the same companies would probably not generate the same answers. Therefore it might not be appropriate to discuss the reliability of the results of this research other than the connections made between the stated theory and the developed analysis.

The validity of a study determines how well the research questions have been answered and how well the tools used in the research measures what they are intended to measure (Cohen, Manion & Morrison, 2007). Which means that if the study achieves to answer what it was set out to answer. In order to reach as high validity of this thesis and of the case study as possible, an explanation of the phenomenon and definition of Open Innovation and other related theories in the theoretical framework will be presented. Throughout the development of this thesis the research questions and the purpose have been continuously considered in order to maintain a common thread from start to finish.

3. Theoretical and Conceptual Framework

The third chapter explains the theories and models used in order to understand Open Innovation. A conceptual framework is also presented in order to give the reader a clear definition of the authors' perception of Open Innovation, and the critique against the novelty of Open Innovation will be introduced. Additionally, the importance of IP rights will round off the theoretical framework.

3.1 Conceptual framework

The definition of Open Innovation can be vague and difficult to grasp, therefore it is important that this thesis early defines how the term Open Innovation will be handled in the following sections. Open Innovation should not be confused with "Free Innovation", which means that R&D and investments will be available in the open space and thus free for anyone to employ, therefore many researchers on the subject (e.g. O'Connell, 2011) distinguish the terms Open Innovation and External Innovation in order not to confuse the word "open" with "free". However, this thesis will employ the terminology "Open Innovation" as coined by Henry Chesbrough (2003), thus Open Innovation refers to two principal implications;

- 1. To acknowledge and look for extern knowledge, skills, innovations and talents.
- 2. To be willing to open up the, until recently, closed bank of IP rights within a company and sell or license out IP rights that the company is not using.

3.2 The novelty of Open Innovation

The phenomenon of Open Innovation is stated to be novelty and to differ from the traditional attitude and approach towards innovations (the differences between the traditional, closed model for innovation and the new, open model are explained below). However, many researchers in the field of strategy and innovation agree on one thing; the idea of looking for beneficial external ideas and proficiency in order to facilitate the internal innovation process is neither new nor ice breaking (Kielstra, 2011; Remneland, 2010). Companies have been collaborating, sharing IP rights by contracting and licensing as well as recruiting and working close with academia for a long time. Especially academic research has been of great importance for the development of many highly technological products, nonetheless for drug discovery and innovations. Universities have the potentials to conduct R&D of new molecular entities that are needed to develop new drugs. However, they do not have the finances neither to further develop the drug, nor to bring the new product to the market. This is where big

pharmaceutical companies can contribute. These companies have the finances and the marketing and development proficiencies to invest in the development of new molecular entities and bring them to the market, something that universities normally lack of. These are all activities that are neither foreign nor new by content to any actor in highly innovative industries such as pharmaceuticals. Therefore there is critique to address the phenomenon of Open Innovation coined by Chesbrough (2003), and it is legitimate to question if Chesbrough pointed out and termed something that has been done for decades, and if the novelty of Open Innovation is the terminology rather than the function. Hullmann (2000) discusses the collaborations of pharmaceutical companies and states that external knowledge has always been seen as a supplement to own research and that scientific research in universities has created a source of information and innovations with lower costs and risks for the pharmaceutical companies. However, Chesbrough is not to be entirely criticized since there is a new need for how to proceed with innovations that differs from earlier needs. This has to do with shorter product lifecycles, increased competition and globalization, thus the novelty of the Open Innovation paradigm lies in the necessity of acquiring ideas and innovations to a lower budget as well as the role of trade of IP rights.

3.3 The product lifecycle

The life of a new product today is becoming shorter and shorter, consumer needs are becoming more and more complex and diverse, and these are factors that indicate higher pressure than ever before on innovators and innovating companies (Christensen, 2011). It is important to understand the life of a product in order to understand the importance of innovation, may it be radical or incremental. The product lifecycle in an existing market is a theory explained mostly by marketing literature. The theory explains that uncertainties of a product, and thus uncertainties considering the profits of this product are deeply interlinked with the market in question. There are five stages in the product lifecycle that represents the phases a product goes through, and each phase plays a different role considering the profitability of a product (Figure 3.1). 1) The first stage is the development stage where the product is being developed and tested to get ready to be launched on the market. 2) The second stage is the introduction stage which is, as understood, the phase that starts when a product is introduced to a new market. The characteristics of the introduction stage imply low sales and thus low (or even negative) profits, high costs per customer and few competitors. 3) The next stage is the growth stage where costs per customer start to decrease, profits are increasing along with quickly increased sales. 4) Thereafter comes a product's maturity stage

where sales and profit peak and the number of competitors is stable. 5) The last stage is when a product is in decline, this phase is characterized by weaker sales and increasing costs per customer (Baines, Fill & Page, 2008; Kotler, Keller, & Brady, 2009). For a company to maximize sales it is important to make sure that a product does not enter the decline phase. Therefore the maturity stage needs to be prolonged either through new innovations, adapted products or by finding new target markets or segments (Afuah, 2003).

The explanation of the product lifecycle is necessary since it allows us to understand the meaning and importance of innovations. Innovations are interlinked with profitability when a prolonged maturity phase is realized, and today's competitiveness and increased power of the consumer makes innovations crucial for any company that wants to maintain a high profit margin.

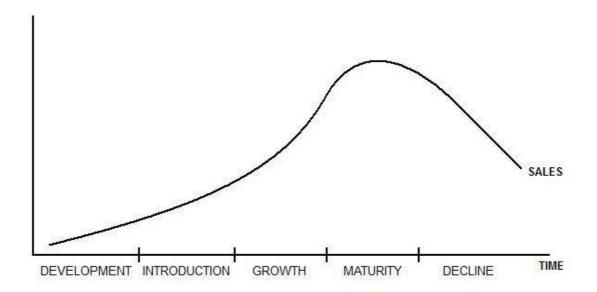


Figure 3.1 The Product Lifecycle (Baines, Fill & Page, 2008) elaborated by the authors

3.4 Traditional vs. Open Innovation

In this section the different frameworks of innovation will be outlined. In order to understand how Open Innovation has emerged, the traditional way of innovating and the reason why it has been considered to be the best way of conducting R&D will be presented. A clarification of the different approaches of Open Innovation will be described as well as the different theories within these approaches.

3.4.1 Closed Innovation

The traditional way of creating innovations has been to innovate and develop products inhouse, i.e. Closed Innovation (Chesbrough, 2003). Companies have been keen on keeping knowledge and talent within company walls and on making sure that innovations, intellectual capital and IP are created and retained within the company. Benefits from implementing a Closed Innovation model are control over the innovation process from start to finish as well as creation of IP rights (Motzek, 2007). In addition, the perception that "successful innovation requires control" motivated companies to conduct all innovations internally to be sure that other parties' lack of quality or capabilities would not affect internal operations (Chesbrough, 2003). Companies also had the attitude that "all the smart people work for me" (Chesbrough, 2003; Chesbrough, Vanhaverbeke & West, 2006). Chesbrough (2003) further mentions a number of implicit rules that companies followed such as hiring the best talents, that the first to innovate will be the first in the market and gain large market shares, and that leading the R&D within an industry will produce the most successful innovations. All of this led to a virtuous circle; fundamental breakthroughs brought new products, which boosted sales and profits, which led to increased investment in R&D and then on to new fundamental breakthroughs.

The Closed Paradigm shows the flow of innovations from start to finish where resources are put into an innovation funnel (figure 3.2). The R&D take place within the boundaries of the firm and no external parties are involved (Grönlund, Rönnberg Sjödin & Frishammar, 2010).

This way of relying on a company's own capacity is still, to a great extent, implemented in many companies. However, a shift of this trend can be seen towards alternative ways of attaining knowledge and access to external talents, and it is obvious that not all the best talents in the industry could possibly work for the same company. In the late 20th century, a number of changes in the business environment made companies rethink their R&D processes (Chesbrough, 2003). It became harder to retain knowledge within the firm due to growing mobility among skilled people who brought their experience along to other companies. The increase in venture capital was another factor that had an impact. Venture capital was used to create new companies that specialized in commercialising external research, and hence new competitors emerged. On top of this, the products' lifetime decreased, and as new competitors arose from other regions in the world it became more important to come up with new

technology and ideas faster. All of this led to a drive to search for knowledge and talent outside company walls.

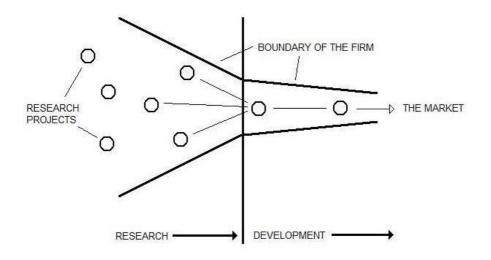


Figure 3.2 The Closed Innovation Paradigm (Chesbrough, 2003) elaborated by the authors

3.4.2 Open Innovation

The above-explained changes in the business environment gave inventors an alternative option after a fundamental breakthrough; to form a new company to develop the innovation with help from venture capital. If the innovation became successful, it was sold off; hence it did not generally reinvest its profit and the virtuous circle was broken (Chesbrough, 2003). Where this took place, a new framework was needed due to the lack of funding for R&D, and this is where the Open Innovation Paradigm is introduced.

Henry Chesbrough's (2003) definition of Open Innovation is:

"Open Innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology."

Open Innovation can be performed in a large number of ways, however, the general idea is to use external sources and thus remove the boundaries of the firm, making information and knowledge flow in and out of the company (figure 3.3). In the end, projects can be spun out of the company through start ups of new firms with employees from the own company in order to target new markets (Chesbrough, 2003). Other ways to handle potentially useful

innovations that are not being used in the company's activities could be through licensing, collaborations with other firms or through starting up joint ventures (Hedner, 2012). A company also has to realize that internal research may fail and that other parties may come up with better solutions. Hence, companies have to be ready to acquire innovations or knowledge (e.g. patents) and continue to develop these in-house (Hedner, Thornblad, Remneland & Klofsten, 2011). Companies should also be prepared to sell off IP rights such as patents in order to make money from underused assets.

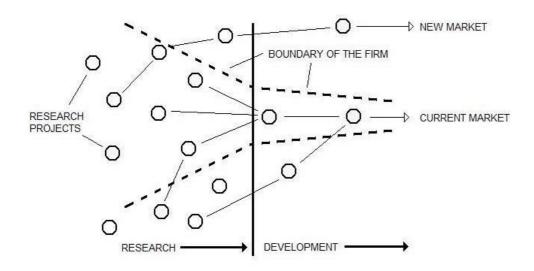


Figure 3.3 The Open Innovation Paradigm (Chesbrough, 2003) elaborated by authors

Gassmann and Enkel (2004) have identified three core Open Innovation processes. The outside-in process, the inside-out process and the coupled process strategy. The outside-in process enriches a company's own expertise by integrating external parties in the innovation process. Conversely, the inside-out process 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 specific 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 (Gassmann & Enkel, 2004).

In order to utilize this model effectively, companies need to be able to capture all the benefits of their relationships with external technology providers (Fetterhoff & Voelkel, 2006). This

can create value and five key stages that generate value can be found. 1) Companies need to seek opportunities; the bigger the inflow of ideas the greater the chance to come up with successful innovations. 2) Companies have to rapidly evaluate their opportunities. One has to assume that competitors are searching for the same opportunities as well and that there will be pressure to quickly evaluate, sometimes even without complete data, in order to get a head start. 3) The recruitment process is taking place. Competitors are likely to opt for the same opportunity, thus to pursue the wanted partner of collaboration to enter a relationship is vital. This could be done through offering more money, by having a better reputation, the use of marketing strength, promotion of synergy etc. 4) Companies need to capture value. This is done through rapid commercialization where the uniqueness and utility of the innovation are shown. 5) The extension of the offer takes place by either finding new markets for the innovation or finding new additional features to it. This will nurture the relationship and open up for higher returns.

3.5 Crowdsourcing

Crowdsourcing means that many people outside the company (i.e. the crowd) are involved in the process of innovation. It could be customers, independent scientists or anyone who is interested in solving problems. The concept has become useful since companies have started to understand that there is wisdom to acknowledge outside company walls. Crowdsourcing is a type of Open Innovation as well as co-creation and user-creation, and a tool for companies to put outside ideas into their technologies and products, and moreover into processes too (Sloane, 2011). Pharmaceutical companies can use crowdsourcing to e.g. determine drug safety where patients' opinions are valuable (Mintz, 2011).

Crowdsourcing consists of four primary categories (Howe, 2008). 1) Collective intelligence (or crowd wisdom) which means that groups possess more wisdom than individuals. The crowd has talent and expertise that could earlier only be found within an academic environment, and these intellectual capital assets are now being tapped by progressive companies. 2) Crowd creation refers to the creativity among the crowd. The emergence of new technology in communication, first radios and later the Internet, created a platform for participation where committed and connected individuals were able to put up their ideas. A strive to exceed the existing standards or incentives such as enhanced status when solving a problem contribute to the creativity. 3) Crowd voting implies that crowds have the possibility to organize and handle enormous amount of information. Websites use systems that rank their

content after views, likes or downloads in order to make it easier for people to see what is most popular. 4) Crowdfunding makes it possible to fund projects or organizations without having to rely on banks or other traditional sources. An example is the emergence of micro-lending, generally performed by philanthropists from the Western world who fund small businesses from the developing world.

Thomke and von Hippel (2002) put forward a user-creation approach where customers should act as innovators. First, the company needs to develop a tool-kit for the users that enables them to innovate. These tool-kits have to provide four capabilities; 1) some kind of simulation technology where the users can complete series of design cycles. 2) They need to be user-friendly and within the design language of the users. 3) A collection of earlier tested products so the users do not have to try something that has already been tried. 4) Information about the company's processes in order to avoid products that cannot be produced. Thomke and von Hippel (2002) state that there is a win-win situation here where a company can benefit from getting help to solve a problem at the same time as the user gets the product he or she wants.

3.6 Protection of Intellectual Property

In this section the meaning, importance and usefulness of IP rights will be explained. Furthermore, this section brings up the complexity that arises when referring to the protection of ideas and innovation at the same time as this should be implemented into a more open environment.

To mention IP and Open Innovation together might seem contradictory since IP normally is associated with Closed Innovation and exclusivity while Open Innovation, as the name suggests, aims towards opening up the innovation process and to making ideas accessible for other actors. There are many kinds of IP rights that are used throughout today's business environment such as patents, trademarks, copyrights and trade secrets, which normally aim at excluding others from the access to a company's ideas and investments in R&D. Therefore, it is likely to be a conflict when trying to combine the two since Open Innovation allows for inflow and outflow of ideas while IP rights is set up in order to protect and keep innovations internally (Hall, 2010). However, IP rights and Open Innovation do not have to exclude each other, as a matter of fact, a freer market for trade of IP rights is one of Chesbrough's definitions of Open Innovation (Chesbrough et al. 2006). Therefore, in order to fully be able to buy and sell innovations it is important that ideas are well packaged (i.e. detailed, concrete

and clearly defined) and come with a protection right.

IP rights are considered as motivators for innovation, since innovation itself is very costly, the innovator needs to make sure that his invention is protected from being imitated in order to be able to take advantage of the success. This discussion, from here on, is limited to focusing on patents as protection of IP, which, however, is a big device itself.

3.6.1 Patents

A patent is a private right for the owner of the patent to exploit an innovation, and no one else is permitted to take use of the innovation in any form without the owner's permission. Patents are also essential tools of innovation output since the inventive performance of countries, regions, technologies and firms are reflected within a patent (OECD, 2004; Intellectual Property Office, 2012).

A patent is an intangible asset that has a certain value for the owner. There is no single answer to what the value of a patent is; it depends on the appreciated present value of the future sales of the product being patented or the investments the patent will attract (Reitzig, 2003). The rights to a patent can be sold and traded freely, and the importance of intangible assets for companies today is growing and can even exceed the value of tangible assets. In the mid '70s, an average company portfolio was composed of 20 per cent intangible assets and 80 per cent tangible assets, and today these numbers are reversed giving intangible assets a portfolio importance of approximately 80 per cent for many companies (O'Connell, 2011).

A patent makes it possible to package an innovation, as opposed to e.g. trade secrets, and therefore a patent is tradable between the innovator and society, which makes IP protection in the form of patents an important element. Patents have many qualities, O'Connell (2011) lists, among others, five aspects that come with patent rights. 1) The exclusive right granted to the inventor. 2) The right to stop others from copying an innovation. 3) The means to clarify ownership. 4) The buying, selling and licensing of patents. 5) The return on R&D investment.

For high tech companies, and pharmaceutical companies, patents play an important role in the question of profitability since a company needs to make sure that its high cost investment will be exclusive on the market for long enough to cover the high R&D costs of an innovation. For

low tech industries patents are not what is most important in order to be profitable; in these industries, focus is instead put into markets, customer base etc. (Mazzoletti & Nelson, 1998).

3.6.2 Complications of Intellectual Property rights

Jurisprudence is an important and non-neglectable part of the innovation process and even more so when it comes to Open Innovation. Chesbrough et al. (2006) define Open Innovation such as the inflows and outflows of ideas and IP rights in a company. In order to be able to buy and sell IP rights, ideas must be well packaged which means that a well-defined and detailed patent should exist. This implies that the innovation is easily transferable and thus tradable. However, innovating together with competitors, academia etc. brings up the question of how IP rights should be handled. There is a risk that needs to be taken into consideration about which one of the parties involved in the process that should receive the ownership rights. The best solution to get around this sensitive but crucial issue is to be clear about how IP rights should be handled in the early phases of the project/collaboration, before any of the parties start investing time and efforts with a misconception about the situation. Some companies have very special rules considering IP, and it is thus necessary that all parties are clear about the conditions considering the new collaboration in order to avoid misunderstandings and unnecessary costs (O'Connell, 2011).

Open Innovation has many advantages but there are also risks and disadvantages connected to a more open mindset about innovation and about taking on and sharing ideas with the external environment. First of all, if an innovation has been created in the open space, it might not be possible to call it a novelty and neither is it possible to apply for a patent for information that is public. Ownership is important, and it is crucial to decide which party that should receive the patent of a certain innovation (Hedner et al. 2011). When there are many stakeholders involved, contracts are usually set up before the collaboration begins in order to settle issues considering ownership rights, revenues from sales, access to the idea etc.

When it comes to the question of treating IP rights as a part of Open Innovation and openness in the pharmaceutical industry, Kielstra (2011) states that this aspect of openness is the most complex and difficult of the two aspects of Open Innovation (the other one being to look outside company walls for external knowledge, ideas and skills). He also stresses the importance for pharmaceutical companies of allocating the IP from their own research effectively. The fact is that many companies develop ideas that are not directly useful or connected to that company's core business, and the innovation and idea might thus not be useful to the own organization at the end, even though it has been protected by e.g. a patent. If these innovations, in the form of IP rights, were to be easily tradable, companies would be able to make revenues on these investments, and thus increase cash flows and minimize their stock of unused IP rights. Only until recently, companies have been patenting as many ideas and innovations as possible, all according to the earlier mentioned closed innovation model, thus nothing was more important than a big IP rights-bank. Today, according to the Open Innovation paradigm, there is a slight shift of this attitude occurring. Kielstra (2011) also concludes that today, an increasing number of companies have started to understand the difference between freedom to operate and of owning a certain patent.

4. Empirical Study

The fourth chapter begins with a description of the pharmaceutical industry and the process of drug development. The chapter continues with case studies of two pharmaceutical companies, AstraZeneca and Lilly, and their respective approaches to Open Innovation.

4.1 Pharmaceutical industry

Since the mid 20thcentury the pharmaceutical industry has delivered significant products and remedies to decrease human diseases and increase health worldwide (Munos, 2009). However, there is a decrease in productivity per dollar spent on R&D and innovations in the pharmaceutical industry today, and there are signs of stagnation (this issue will be further discussed below). Traditionally, drug development is characterized by close control of IP rights and of not allowing any transparency (Hedner, 2012). Due to the loss of productivity in the pharmaceutical industry as a consequence of increasing demands from costumers, the development of generic drugs and high failure rates, the traditional model of innovations has been increasingly questioned.

When looking into the pharmaceutical industry, there are smaller and larger biotech and biopharmaceutical companies and there are the companies referred to as Big Pharma. As mentioned, these two groups can take advantageous use of each other. Biotech companies invest in particular R&D but lack of finances, knowledge of further development and of bringing an innovation from the laboratory to the market. Big pharmaceutical companies, in turn, are capital strong and established companies that have the capabilities to develop innovations and can thus provide smaller biotech companies with these capabilities. In sciences such as biotechnology, pharmaceutical companies cannot fall back on any incorporated knowledge and are thus dependent on collaborations with biotech companies. As an example, most advances in molecular biology and genetic engineering have been made not by pharmaceutical companies in-house but by specialized biotechnology firms and scientists (Senker, 1996). Big pharmaceutical companies have not succeeded fully in building up their own competencies when it comes to biotech, and thus make more efficient use of both their own resources and of those of biotech companies when exploiting the knowledge of the latter.

The pharmaceutical industry is knowledge intense, and it takes a long time to develop and introduce a new drug to the market as a result of long and expensive R&D. This is given

considering the nature of this industry, which has its roots in herbal medicines and natural remedies. Pharmaceuticals once emerged only in order to cure diseases but have, as time has proceeded, become more and more an issue of business and a product of the investment policy of any given pharmaceutical company. Today, there is no industry as complex as the pharmaceutical industry when it comes to doing business and making money. This has a lot to do with, as mentioned, the origin of pharmaceuticals. The reason for the complexity of the pharmaceutical industry thus emerges from the moral dilemma created by the requirement of profit maximization from a product that in its nature is purely philanthropic. However, profits and revenues are crucial for any company that wants to stay in business and develop its strategy, and the reason why return on investment is so important for a company in the pharmaceutical industry will here be further discussed.

It is easily understood that in order to survive as a business, costs and revenues need to be at least on a break-even basis (it is of course preferable to have revenues exceeding costs in order to make profit and thus be able to invest in future projects, product development, innovations and other ventures). As a fact, a new molecular entity takes on average, from idea to market launch, about 12 years and require investments from \$ 800 million up to \$ 4 billion (Hedner, 2012). A patent normally lasts 17-20 years from the registration date (which normally is when the idea of the new combination of molecules is dated), which means that the investment costs need to be covered during the 5-8 years that are left of the patent when the new pharmaceutical is launched (Swedish Patent and Registrations office, 2012). It is simple to understand that all costs need to be covered during the lifetime of the patent; however, the complexity lies within the difficulty of covering these high costs in such little time. These numbers clearly indicate that the drugs beneficial enough to develop are those that cure relatively common diseases that are high in demand of a clientele with strong purchasing power. The questions are consequently; 1) What about diseases that are rare? 2) What about diseases that strike those with less or no purchasing power? The fact is that the minor incomes these medicines would generate are much too small in order to cover R&D costs, nonetheless to provide a pharmaceutical company with profit margins. Therefore so called blockbuster pharmaceuticals (e.g. Viagra and Prozac) are drugs that pharmaceutical companies are most willing to invest in since these are high in demand of a rich segment of the world's population who will be able to pay enough in order to cover the high costs of R&D (Kielstra, 2011). (Naturally, more narrow and specific diseases are weaker in demand and thus less likely to be able to cover costs of investment, and the same goes for common

diseases, such as malaria, that strike people with low purchasing power.) To summon this up it can be said that there is a decline in the development of pharmaceuticals today at the same time as larger and larger investments are observed, thus the need for new innovations is ever so strong but the power of capital and blockbuster medicines thwarts further innovations as the situation is today. Chesbrough (2011) concluded this dilemma in a suitable way by saying that the perceived need for blockbusters has shattered many promising compounds that could have been profitable products. According to Chesbrough (2011), it is true that only so called blockbuster drugs can raise the kind of money needed to generate profit as return on investment for pharmaceutical companies. What Open Innovation can do for a company in this situation is that it allows for companies to learn from each other about what could go wrong in a certain research process and thus it does not have to invest time and money in executing the same experiments. Open Innovation can be a tool for developing new innovations and decreasing investment costs. This leaves more room for researching other profitable ideas that are of non-blockbuster characteristics (Chesbrough, 2011).

4.1.1 Drug discovery and development process

In order to understand the empirical results of this thesis, a thorough review of the drug discovery and development process will be outlined below. The chapter explains the process in USA, but should serve as an overview of the process in general.

According to the Pharmaceutical Research and Manufacturers of America (Phrma) (2007), the first part of drug discovery and development process is called discovery and starts by gaining an understanding about the disease that is going to be treated. When scientists have enough information about the disease it is time to select a target, which generally is a single molecule that is going to be targeted with the potential drug. The target is then tested and validated to make sure it is promising as well as to prevent companies from proceeding with targets that will lead to dead ends. Next step is to develop a molecule, which is called lead compound, which will interact with the target. The compounds will go through a number of tests to make sure that they are safe and that the finished drug can be absorbed into the bloodstream, metabolized effectively and shown not to be toxic. Scientists also have the possibility to alter the structure of compounds in order to improve them.

After these steps, it is time to start testing the compounds more intensively. There are two types of tests within this stage: in vitro and in vivo. In vitro means that a compound is being

tested in a test tube and in vivo refers to tests on living cell cultures and animal models. It is extremely important to find out that the drug is safe enough to later be tested on humans. In this step the process of large quantity production will be figured out as well. In the end, the initial 5,000 to 10,000 compounds will be scaled down to between one and five potential candidate drugs.

The pharmaceutical company then proceeds to development, which consists of clinical trials. First, the company must file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) where the results from its pre-clinical testing are included, chemical structure, how it will work, side effects, a detailed trial plan and manufacturing information. The company also needs an approval from the Institutional Review Board (IRB) who will ensure that all the people in the trial consent to the tests and know what they sign up for. FDA has the power to stop the trial if problems occur and reports how the trial proceeds need to be sent to them.

The clinical trials consist of three phases. In the first phase a small number of healthy persons take part in it and the main goal is to find out whether the drug is safe for humans or not. Scientists also make an effort to determine if the drug can be absorbed by the bloodstream and other features as those mentioned above. In the second phase, the researchers evaluate the drug's effectiveness by testing it on patients with the disease it is suppose to treat. Further, scientists look at the risks and side effects to decide if they will continue to the third phase. In the third phase the researchers test the drug on a larger number of people with the disease where they, to a greater extent, can confirm that the drug is safe for humans and that it is efficient for the intended disease. This is the phase that takes the longest time and carries the highest costs.

After the third phase is completed, the company sends a request to FDA to get the drug approved. The FDA addresses three major concerns: if the benefits outweigh the risks, what information the package should contain and if the manufacturing process is good enough to ensure the quality of the product. After an approval, the company can start manufacturing the drug, which could be complicated due to the large scale. The company will subsequently monitor the drug after it is produced and report periodically to the FDA. There could also be a fourth phase where the company conducts additional studies to investigate, for instance, long-term safety (Phrma, 2007). The whole process is summarized in figure 4.1.

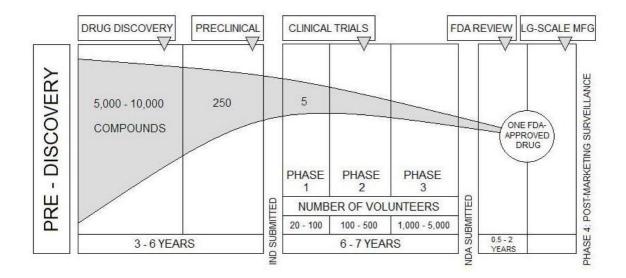


Figure 4.1 Drug Discovery and Development Process (Phrma, 2007) elaborated by the authors

4.2 AstraZeneca

Astra AB was founded in 1913 with the headquarters in Södertälje, Sweden (AstraZeneca, 2012b). It started as a simple manufacturing pharmaceutical company but turned its focus towards being a more research oriented firm in the 1930s. This led to the invention of Xylocaine, a local anaesthetic, which in 1948 became the company's breakthrough on the market of pharmaceuticals (Schön, 2009). Another pharmaceutical that Astra is known for is Losec, an ulcer drug that was the world's top selling pharmaceutical in the early 2000's (Macalister, 2001).

Zeneca Group PLC was spun out as an independent company from chemical giant Imperial Chemical Industries (ICI) in 1993 to focus on pharmaceuticals, agrochemicals and specialties (AstraZeneca, 2012b). Zeneca had a wide-ranging international development and key products within oncology and the cardiovascular medicine (AstraZeneca, 2012b).

In 1999, the two companies merged to form AstraZeneca. The merger was due to the fact that the two companies were both involved in the same fields of research such as cardiovascular and respiratory pharmaceuticals, as well as to enhance long-term growth and sustain shareholder value (AstraZeneca, 2012c). The company set out three main focuses where these objectives would be met; combining global power in sales and marketing in key areas such as

cardiovascular, oncology, anaesthesia and respiratory medicine, focus on improving and enhancing R&D, and use increased financial strength to improve strategic flexibility.

In 2011 AstraZeneca had revenues of \$33.6 billion and was ranked as the 8th largest pharmaceutical company in the world according to Forbes (2012). The company spent \$5.5 billion on R&D in 2011 and it involved 11,300 people in 14 research centres in eight countries (AstraZeneca, 2012d). AstraZeneca's mission statement is: "to make the most meaningful difference to health through great medicines that bring benefit for patients and add value for our stakeholders and society" (AstraZeneca, 2012e).

Lately, AstraZeneca has been restructuring its business and the restructuring has involved many layoffs in Sweden (Kollewe & Neate, 2012). The reason why the company is undertaking these actions will be further explained in interviews with company representatives and is mainly due to the need of being flexible in order to be able to adapt to changes in the industry globally.

4.2.1 Innovations at AstraZeneca

In order to reach its over-all goal, to improve health worldwide by creating medicines that aids the world's growing and aging population, AstraZeneca looks outside company walls and commits to partnerships (AstraZeneca, 2012f). To AstraZeneca, as to any company in the same industry, innovation is one of the most important aspects of the company's business and future profitability. AstraZeneca has, according to the company's CEO of Sweden, Anders Ekblom (also Executive Vice-president for Global Medicines Development), always been engaging in collaborations and partnerships with different institutions and companies. To Dr. Ekblom, the definition of Open Innovation; "to acknowledge and look for external knowledge, skills, innovations and talents" is thus nothing new for AstraZeneca. Dr. Ekblom also adds that today AstraZeneca has more than 1000 different collaboration/partnership agreements globally, where about 200 of these have been set up in Sweden (see table 4.1).

5	Key late-stage deals 2009-2011
60	Significant deals completed 2008-2011
67 %	Of potential near term launches through collaborations
50 %	Of projects in phase II are sourced from alliances
40 %	Of our pipeline is sourced from outside our laboratories

Table 4.1 Numbers of AstraZeneca's Collaborations and Partnerships (AstraZeneca,2012f) elaborated by the authors

AstraZeneca is a company that invests a lot in partnerships and collaborations. Shaun Grady, AstraZeneca's vice president of Strategic Partnering and Business Development, states that the company has engaged in collaborations for over 30 years, both with other companies, investors, non-profit organizations, institutions and authorities and with patient groups (AstraZeneca, 2012g).

4.2.2 External knowledge

Collaborations are essential for companies like AstraZeneca that aims to work with the world's best scientists and researchers. In order to always stay updated about new innovations and possibilities to invest, AstraZeneca has developed the so-called iMed-group that continuously searches externally produced/invented medical preparations that can contribute to the internal development of AstraZeneca's own innovations, either as a complement to the companies existing products or as something to develop in-house. AstraZeneca states that the company possesses the knowledge and the resources required in order to enable strategic partnerships with other actors irrespective of their size. These partnerships serve as complement to AstraZeneca's own business activities, and the company claims that these collaborations contribute as a step towards becoming the leader of R&D when referring to human diseases (AstraZeneca 2012h).

There are two aspects of the process when AstraZeneca is looking for external knowledge and partners to collaborate with. First of all it is necessary to realize that in an organization with many researchers, such as AstraZeneca, a big part of the company consists of researchers coming directly from universities. These researchers come from an academic environment

and have disputed and worked at the university before coming out to the company. They are thus already used to collaborating, have their own network of skilled peers and know how to socialize and collaborate in both virtual contexts and conferences. Dr. Ekblom explains that this fact implies that the researchers, on their own, look for external knowledge and that the active search for external knowledge, ideas and talents is something that AstraZeneca's employees conduct on a daily basis. However, this is not the only way AstraZeneca is looking for the best research on the market. The company has also developed groups called Business Development Groups for five different medical units that focus on different disease areas where scientists and strategists scout the world for the best ideas, the newest research, the most profitable companies and analyze current situations on the market of pharmaceuticals. There are also certain researchers that focus not on specific diseases but on specific companies in order to map out what these certain companies currently have in their pipeline. In addition to these two processes of looking for external ideas, researchers continuously read articles and new reports in order to detect new ideas and thus create an internal eco system.

How external knowledge and sources are evaluated can be explained by two factors according to Mats Sundgren, Principal Scientist within Global Clinical Development at AstraZeneca R&D: 1) a safety perspective is considered when evaluating whether an external innovation/project/drug should be acquired. This means that AstraZeneca values innovations/projects/drugs higher if the information given about these can assure that there will be no side effects, i.e. the rate of development of the drug affects the value of it since a drug with high rate of development implies less costs and risks than a drug in the early development phase. 2) AstraZeneca also evaluates different innovations/projects/drugs from what existing competition this product in particular faces. Also, patents are an important part of the evaluation process and AstraZeneca always wishes to be able to acquire the ownership rights.

4.2.3 AstraZeneca and Open Innovation

AstraZeneca is strategically located in two places in Sweden; Södertälje outside Stockholm and Mölndal outside Gothenburg (AstraZeneca 2012i). These locations are geographically close to prosperous universities, university hospitals and research units. Dr. Ekblom explains that in environments where academia is accessible, Open Innovation processes and collaborations in general are more easily enabled. He adds that AstraZeneca originally collaborated with universities in order to develop new drugs and lately the company's collaboration portfolio has become more diversified and now includes many bigger companies too, so-called peer-to-peer collaborations. In the pharmaceutical industry today, and especially for Big Pharma, there is a need for external research and innovations from both other companies in biotech and from academia in order to decrease lead times and implement more efficient research strategies to escape the trap of low productivity. Academics and their knowledge are very important and open source plays a big and significant role in new innovations. (Kielstra, 2011)

According to Dr. Sundgren, Open Innovation has three imperative parts; 1) Self direction; those working with a project can do so in an independent way which leads to engagement and collaboration. 2) Mastery; those working with a project get the chance to improve what they are doing. 3) Purpose; a higher utility than the project itself needs to exist in order to participate. If the three parts exist, a collaboration has every opportunity to become successful. Dr. Sundgren explains that this openness interrupts the classic model where a company considers itself to possess most knowledge and talents in-house. There are several levels where openness can occur such as in the earlier phases of R&D and in other stages later in the development phase. However, he adds that the definition of "openness" is vague and must be seen as the opposition of "closed" in order to make any sense. Examples that illustrate openness and Open Innovation at AstraZeneca are alliances and partnerships that the company conducts to a greater magnitude than earlier. One example in particular is the development of a drug created in order to treat type II diabetes, where AstraZeneca collaborates with the pharmaceutical company Bristol Myers Squibb. The two companies share the work in the clinical process and they both benefit from reduced risks and costs. All AstraZeneca's collaboration projects are deeply depending on well-detailed and worked-out contracts, states Dr. Sundgren.

In a press release published in January 2012, AstraZeneca presented a new R&D function that focuses on access to new technology and innovations in the industry and on Open Innovation. This new initiative is called the Science and Technology Integration Office and Dr. Ekblom is announced the head of the new R&D function. One of the focus areas of the Science and Technology Integration Office is to identify and develop future trends within science and technology, Open Innovation and on strengthening AstraZeneca's inputs around collaborations before market launch (AstraZeneca, 2012j).

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AstraZeneca needs to focus on coordinating its inputs more efficiently and focus on a smaller number of research projects in order to reach faster, better and cheaper results. Dr. Ekblom states that it will be important for AstraZeneca to break new grounds, to be where cutting edge innovations emerge and to get there with an opened mindset and the acknowledgement of the phenomenon Open Innovation (Kielstra, 2011).

As other sources confirm, both Dr. Ekblom and Dr. Sundgren explains that as a consequence of globalization, the fierce competition in the pharmaceutical industry becomes murderous. The competition is a consequence of increased living standards which lead to more developed education systems in emerging countries which in turn means that there will be more competent people around to develop new molecular units. Dr. Sundgren adds that it is of great importance to prolong the product lifecycle of the company's products in order to extend the time any given product generates incomes. Furthermore, he adds that he believes AstraZeneca to have succeeded in doing this when it comes to certain products by successful positioning providing customers/patients an advantage in using the particular drug.

4.2.4 Pre-competitive collaborations

As previously mentioned, the conception of how Open Innovation is defined is an important element of this thesis. AstraZeneca's conception of Open Innovation leans towards a combination of Open Innovation and so-called "pre-competitive collaboration". Pre-competitive collaboration refers to the situation where companies collaborate in order to develop methods and techniques that are needed in the industry without competing (Weigelt, 2009). Furthermore, Dr. Ekblom states that AstraZeneca's goal is to achieve faster results and initiate new collaborations with other companies, academia, non-profit organizations, authorities and investors.

Dr. Ekblom explains that what will be new in this R&D function will not be the collaborations but rather something called pre-competitive collaboration projects. The idea is that standards and instruments for measurements, such as biomarkers, should be developed to a lower cost when many companies invest in the development instead of just one. One example is the development of a drug to treat Alzheimer's disease. Today there are no biomarkers to measure certain reactions in the brain or in the blood of patients with Alzheimer's disease and therefore companies collaborate to develop a standardized measurement system of biomarkers that allows for all pharmaceutical companies that do research within the field of Alzheimer's disease to use these biomarkers. Later on, when a company like AstraZeneca performs clinical test studies, which it conducts in over 50 countries and with over 1000 hospitals, it is beneficial to have a standardized and accepted way of measuring these biological reactions. Dr. Ekblom explains that for AstraZeneca, the development of biomarkers like this is nothing the company wants to engage in solely; on the contrary he explains that AstraZeneca competes with the development of the best drug, not the best biomarker. However, Dr. Ekblom states that AstraZeneca also invests in so-called pre-competitive/competitive collaborations where a number of companies collaborate to develop new biomarkers for tests made when developing drugs. The difference between pre-competitive collaborations and precompetitive/competitive collaborations is that in the former it is normative that all data is published when the latter allows for the involved companies to exclusively exploit the new innovation. The benefits of collaborating to develop measurement instruments, such as biomarkers, are decreased time and costs of development. After the development of these instruments the data will normally be published and opened for any hospital or pharmaceutical company to apply. This is thus what is called pre-competitive collaboration and is, according to AstraZeneca, Open Innovation.

4.2.5 Private-Public Partnerships

Something else that is new to AstraZeneca and to the pharmaceutical industry in general is socalled Private-Public Partnerships (PPPs). These are projects conducted between a few companies together with governments, non-governmental organizations (NGOs) or other public instances. The difference between a PPP collaboration and a pre-competitive collaboration is that something developed in a PPP agreement will almost exclusively be truly open since tax money cannot finance competitive projects. This implies that data developed in a PPP agreement will be available for anyone, and within a pre-competitive collaboration exclusivity can be created and data can be available only for those who invested in the project. Dr. Sundgren comments that due to the nature of most PPP collaborations, i.e. that they are fully transparent, pharmaceutical companies could take use of PPPs in order to improve their reputation. One example of a PPP collaboration is Innovative Medicines Initiative (IMI) that is a European collaboration project where big pharmaceutical companies collaborate with smaller biotech companies, academia and institutions to develop new drugs. Dr. Ekblom and Dr. Sundgren agree that these kinds of collaborations are important to AstraZeneca since the company gains much knowledge by participating. IMI is also significant since it contains immense finances and it is of interest for AstraZeneca (and other companies) to get access to expensive research that is not possible for the company to achieve otherwise since essential information is shared within an IMI-project by prominent companies in the industry as well as by qualified academia. Dr. Sundgren states that the usage of PPP collaborations such as IMI is a new way for the industry to work and differs to great extent from traditional, in-house R&D. Furthermore he denotes that the IMI projects apply three aspects: 1) Background, which determines what knowledge the company is entering a certain collaboration with. 2) Foreground, which explains what is generated from this particular collaboration. And 3) Sideground, which is the additional factors needed to be considered, such as IP rights. These three bullet points of IMI collaborations are needed in order to clearly demonstrate the benefits and/or uncertainties of a particular collaboration. The lower costs and the spreading of risks are essential factors. There are, despite the advantages of PPP, certain disadvantages that cannot be ignored. Dr. Ekblom explains that critique directed towards IMI and other PPP projects is that much bureaucracy is involved which leads to long lead times and makes the process complicated.

4.2.6 Crowdsourcing

When it comes to the subject of crowdsourcing in the pharmaceutical industry, open platforms such as Patientslikeme.com (a digital platform where patients share experiences concerning their diseases) are often discussed. Dr. Ekblom and Dr. Sundgren both agree that the industry, and AstraZeneca in particular, needs to begin to connect to patients in a new way in order to attain the existing information they possess. Dr. Sundgren explains that patient information in general, e.g. re-use of patient data, could aid AstraZeneca in the R&D process. In order for such a function to be beneficial for the company the re-use of patient data would have to be executed with great transparency.

Dr. Sundgren adds that he believes such user platforms to have gotten much attention due to the fact that the users see a personal benefit in using the platform. He adds that if AstraZeneca could learn how to further engage patients in an ethical and legal way many costs could be reduced and make big difference for the company in the innovation R&D process. Dr. Ekblom considers platforms such as Patientslikeme.com something that AstraZeneca could take use of when it comes to developing remedies for so called orphan diseases. The World Health Organization defines orphan diseases as rare diseases that trouble 0.65-1 in 10,000 people (Lavandeira, 2002). If a drug to cure an orphan disease is developed, the legal aspects of this drug look a little different than those of drugs to cure normal diseases. There are fewer

requirements for orphan drugs, and the period for exclusivity is prolonged in order to allow for the company to have a better chance at covering high R&D costs. However, Dr. Ekblom comments, the problem in cases like this is that in the end the R&D costs for orphan drugs are still very high and create problems. Dr. Ekblom further states that AstraZeneca is sure to use crowdsourcing to a higher extent in the form of open platforms in the future, however, he admits that the company does not have the knowledge of how to take advantage of open source information as it is today. Today, AstraZeneca uses platforms and crowdsourcing when evaluating already existing drugs; one example of this is the Internet site astma.com. Dr. Ekblom says that he sees a future for crowdsourcing at AstraZeneca and in the pharmaceutical industry in general when it comes to developing orphan drugs and in monitoring diseases over time.

When talking about AstraZeneca and Open Innovation it can be said that it is important for a company to innovate but also to learn how to innovate and look for new ideas. Dr. Ekblom explains that AstraZeneca continuously works with examinations of other companies' strategies and ways to innovations and success, not only in the pharmaceutical industry. AstraZeneca's leadership teams have a lot of out-visits and in particular to companies outside the pharmaceutical industry in order to understand what other people are doing and what there is to learn. Dr. Ekblom also states that it is important to ask questions like "Why can Google be successful?" And "What would that mean for us?" (Kielstra, 2011). Thus Open Innovation is a phenomenon that is not exclusively adoptable for one industry, but a strategic tool that companies from different industries can benefit from and also learn from each other's adaptations of this strategy.

The pharmaceutical industry is slow to adapt to the Open source and the crowdsourcing models, and Dr. Sundgren states that there are several examples of crowdsourcing where companies do not take any risks at all and in return achieve less complicated knowledge provided from "the crowd". Therefore, he suggests, a more sustainable approach that focuses on continued collaborations that provide value for all parties involved would increase the results of the usage of crowdsourcing. The value chain between producer and consumer has changed lately, denotes Dr. Sundgren. Earlier the communication between the pharmaceutical company and the patient has been more or less a one way such. However, today it is of great importance that the consumer, i.e. the patient, receives more attention. The development of Information and Communication Technology (ICT) has empowered the role of the individual

and Dr. Sundgren states that he believes it to be necessary for the whole industry to realize this and go towards a more patient centered and market driven business model.

4.2.7 Future challenges

In the pharmaceutical industry, the market launches of new drugs per dollar invested have decreased lately and it is clear that managerial and strategic actions need to be undertaken in order to cover R&D costs (Hedner, 2012). Open Innovation has been discussed as a solution to this kind of complexity that could help both smaller biotech companies and Big Pharma to remain profitable and innovation strong. AstraZeneca, too, acknowledges this by admitting that increased R&D costs and decreased revenues are problems both for AstraZeneca but also for the entire industry. Every year the company invests billions of dollars in R&D that needs to be covered by drug sales (AstraZeneca, 2012h). Therefore AstraZeneca is firmly determined to focus on the core areas of its business, i.e. cancer, infections, heart/blood-vessels, stomach/colon, neuroscience and respiratory ways and inflammations in order to better assure that R&D costs will be covered.

When it comes to the future of Open Innovation in the pharmaceutical industry, the question can be posed such as "will companies collaborate further in the future?". The answer to this question is, according to researchers and strategists in the pharmaceutical industry, doubtlessly yes. The question then is why? There are a few explanations that all play important roles. Firstly, people realize that knowledge is wide spread today due to emerging markets such as the BRIC- countries (Brazil, Russia, India and China) and the number of intelligent people who have something to contribute with is continuously growing. Pharmaceutical companies then want to be where break trough science arises, and Dr. Ekblom means that this fact will be a driving factor of future development of Open Innovation. In addition, Dr. Sundgren states that Open Innovation is believed to become a natural part of the pharmaceutical industry and will, to great extent, affect how companies engage in collaborations. He adds that the industry is going through certain changes, and that collaborations, partnerships and alliances will become a given factor in the product innovation process. The second aspect of further collaborations is that the costs of driving innovations is constantly increasing, and it is thus crucial for the business and for the industry to become better at finding more cost efficient solutions. Dr. Ekblom illustrates the problematic by saying that output from the industry has been constant for the last 20-30 years with about 25 new drugs launched on the market every year globally, and when looking at the research

budget for each year it has increased dramatically. There is hence no increase in product development even though there is an increase in costs, which implies a decreasing productivity. In addition to this, incomes from sales have also decreased due to the fact that consumers of drugs demand more per dollar spent and also the competition of generic drugs has become more and more efficient. This means that when the lifetime of a patent comes to an end, the producers of generic drugs quickly launches their version of a drug to the market but to a much lower price. Dr. Ekblom states the example of an American actor in the pharmaceutical industry that was getting incomes from sales of \$1 billion one day, 14 days after the company's patent became too old sales would drop to \$100 million and in another 14 days sales would be no more than \$60 million. This is a serious change in income today that used to take a couple of years. Today, healthcare and hospitals are aware of the expiration of patents and make sure to shift their consumption from the original brand to a generic brand the day of expiration of a patent.

Gazing to the future, AstraZeneca is open to engage in more projects such as IMI and Dr. Ekblom and Dr. Sundgren state that it is imperative to join the trend of increased collaborations in order for the company to be considered an attractive partner. However, Dr. Sundgren adds that it is still important for AstraZeneca to find a portfolio balance between inlicensed, external innovations and innovations developed in-house, i.e. closed innovation. He suggests a balance of 30 per cent of the portfolio to consist of products developed in-house in order to maintain the control of the vision of what direction the company wants to drive its innovations.

The industry as a whole is going through changes; however it is hard to determine what is the root and what is the reaction when it comes to the case of AstraZeneca. What is clear is though to have an organizational structure that is adaptable to these changes, and thus to different kinds of collaborations and partnerships and Dr. Sundgren is convinced that this is a central factor for the future of AstraZeneca. He denotes that the organizational structure thus should be self-directed and have smaller, faster units that are more easily connectable. Organization wise it is also important to change and if smaller companies are acquired these companies still need to work as independent and efficient units. Thus, an organizational structure that meets these requirements of Open Innovation needs to be implemented. It is a big challenge to adapt such a business structure, however, AstraZeneca has realized the

importance of smaller, independent units of the company, such as the Business Development groups, in order to be a more flexible and adaptable organization rather than one big entity.

4.3 Eli Lilly and Company

Eli Lilly and Company (referred to as Lilly) was founded in 1876 in Indianapolis, USA (Lilly, 2012a). Throughout the years, Lilly has come up with a number of well-known products where Prozac is the most prominent and the company was also the first company to mass-produce penicillin (Schwartz & Huff, 2010).

Today the company has more than 7,400 employees working with R&D and its products are marketed in 125 countries. In 2011, Lily spent more than \$5 billion on R&D in its facilities in eight countries around the world and R&D costs represented as much as 21 per cent of the company's sales that year. Lilly is the world's 9th biggest pharmaceutical company and thus one of the Big Pharmas (Forbes, 2012).

In the late '90s Lilly initiated a more open approach in its R&D. It had already conducted successful collaborations, as in the case of the mass-production of penicillin together with the University of Toronto, and now it wanted external ideas into its development of new products. An Office of Alliance Management was created to imply this strategy and Lilly was the first company in the pharmaceutical industry to establish this and to use Alliance Managers to supervise partnerships (Schwartz & Huff, 2010). Lilly chose to be very open in its approach and the company hoped that this would lead to a reputation of Lilly being among the best in the industry as well as a company that wanted to collaborate with other companies. The strategy turned out to be successful and led to the production of pharmaceuticals such as Cialis (with ICOS) and Byetta (with Amylin), and these drugs were developed because the companies were able to align their strengths (Schwartz & Huff, 2010). In addition, partnerships that led to in- and out-licensing of technology rather than drug development were also formed.

Schwartz and Huff (2010) point out that one of the key factors of these partnerships was that Lilly consistently used "alliance health scorecards" (see figure 4.2), which made it possible to see the performances of different dimensions over time within the partnerships. The levels to which the lines in the figure are drawn show to what extent different aspects are achieved within a partnership. The data was compiled through surveys among those related to the partnership. These scorecards have helped Lilly to minimize risk and to establish itself as a company that is willing to collaborate with others.

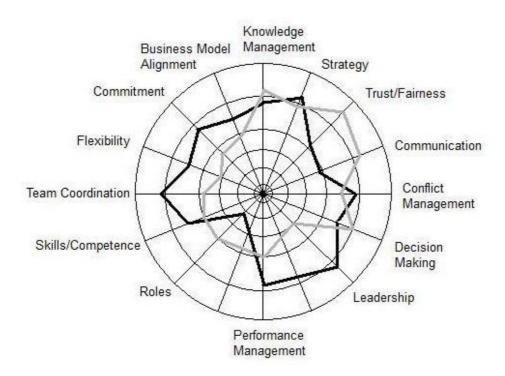


Figure 4.2 Lilly's Balance Scorecard (Schwartz & Huff, 2010) elaborated by the authors

4.3.1 InnoCentive

Lilly was facing the same issues as other pharmaceutical companies when trying to develop new products, and in 2001 Lilly's patent for Prozac expired. Prozac made up for 34 per cent of the company's revenue, thus it had to come up with a new market-leading product to remain competitive in the industry (Breen, 2002). Besides trying to invent a new blockbuster drug the usual way with internal R&D, Lilly also tried a different approach. In 2001, Lilly created InnoCentive, a problem-solving platform, which would increase its access to far more scientists and ideas.

In the beginning InnoCentive was a web site where scientists from Lilly could post their ideas and other scientists all over the world would have the possibility the view the problems and try to solve them (Schwartz & Huff, 2010). InnoCentive grew fast and other pharmaceutical companies as well as companies from other industries began to post their problems on the site, and today InnoCentive works as an independent company (Wessel, 2007). By letting other companies use the problem-solving platform, Lilly was able to share the risks and costs of the project with them (Chesbrough & Garman, 2009). Companies that post their problems are called "seekers" and the scientists who try to solve them are called "solvers" (Allio, 2004). The solver needs to sign an agreement before he or she is able to see problems (which are posted anonymously) (Breen, 2002). The solver with the best solution is then given a reward. The reward is usually between \$10,000 and \$20,000 if the problem is solved without the need of a laboratory, and from \$35,000 to \$100,000 if the problem is more complicated and requires a laboratory to be solved (Allio, 2004). In the end, it is up to the seeker to determine the amount.

The CEO of InnoCentive, Darren J. Carroll, explains it is an innovative approach because it asks research questions that earlier was handled secretly within the company (Allio, 2004). InnoCentive has also found a way to make the research problems available to external scientists all over the world and convinced them that this marketplace could give them something in return if they contribute. He further describes how InnoCentive has qualified scientists with skills in different areas that help to attract seekers by making posted problems easier to understand and to screen out the solutions that do not meet the criteria (Allio, 2004). The seeker scientists have the final say and write a report to InnoCentive who gives feedback to solvers on their solutions.

Carroll also explains how solvers are protected (Allio, 2004). Solutions that are sent in will remain confidential as well as the solvers communication with InnoCentive. Seekers have 90 days to use a solution that is submitted by a solver. If the seeker chooses to use it; the seeker receives the patent if the solver accepts the reward. If the seeker does not choose to use it, the scientific staff makes sure that the seeker does not use the solver's patent. InnoCentive also has an audit provision that ensures that solvers are not being mistreated.

Even though InnoCentive is an independent company today, Lilly has been able to use the platform in its Open Innovation process differently than it first did. Lilly collaborated with InnoCentive to create a tool to get hold of ideas within the company (Schwartz & Huff, 2010). It is called InnoCentive@Lilly and is a platform where inside seekers are being matched with inside solvers - an Open Innovation approach of reaching its internal employees. The problem-solving rate was 80 per cent in 2009, which was the same as Lilly's problem solving rate in the external InnoCentive network.

InnoCentive has been criticized for its model. A chemist who has been awarded for a solution believes that the solver is taking too much of a risk because he or she could be working for months without getting anything in return, while the seeker takes on no risk at all (Breen, 2002). Carroll responds that this is the idea and that it is up to the solver to determine whether the risk is worth taking.

InnoCentive can also be seen as a way of crowdsourcing. Howe (2008) points out that there are 140,000 scientists from more than 170 countries that log on to the website to find problems they are eager to solve. Companies reach out to anonymous people instead of looking for potential collaborations with smaller enterprises (or universities as in the case of the "Open Innovation drug discovery" below). Howe (2008) further mentions two aspects that make InnoCentive work and how it operates: 1) It takes down barriers to participation which leads to access to intellectual capital all over the world that otherwise would be hard to reach. 2) It does not matter if you are a professional or an amateur. Since actors in the network come from all corners of the world they all have different experiences and can see things in other ways than the scientists in a company. Today giant companies such as P&G, DuPont, NASA, Roche and BASF are posting their problems on the web site, which show how successful it has become (Busarovs, 2011; Howe, 2008).

4.3.2 Chorus

Chorus was created as an autonomous experiment division in 2001 with the aim to improve the early-stage drug development within Lilly (Bonabeau, Bodick & Armstrong, 2008). The team consists of industry professionals with many years of experience in areas such as toxicology, clinical operations and quantitative pharmacology (Chorus, 2009). The model evaluates a portfolio of molecules and only sends the most promising through to late-stage development where failures are extremely costly and hard to recover from. Chorus supports Lilly by generating proof-of-concept data quickly and cheaply, so that it is able to choose molecules more effectively and reduce uncertainty, and hence reduce the risk (Longman, 2007). The term "proof-of-concept" means that a drug must be effective and show no signs of serious side effects (Bonabeau et al. 2008). Chorus plans for failure, i.e. it expects that most of the molecule compounds will fail (Longman, 2007). As a consequence, it will only make a minimum effort to figure out if a compound is going to succeed. It is expensive and unnecessary to figure out the manufacturing process and other related steps, when the chance of failure is high. These steps can be solved later when/if the drug is approved. All in all, Chorus accelerates the process (see figure 4.3).

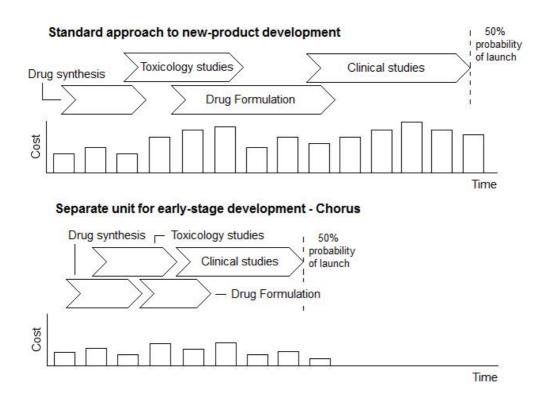


Figure 4.3 Chorus's Early-Stage Development (Bonabeau et al. 2008) elaborated by the authors

In order not to let any capacity slip away, Chorus uses external experts as well in its research, making it an Open Innovation approach. These experts take care of experimental design and drug delivery, and there are also external vendors who provide manufacturing and toxicology for instance, which give the Chorus's staff the possibility to focus on the evidences found in current trials (Bonabeau et al. 2008).

There are a couple of examples that show the effectiveness of Chorus: the molecule compounds X32 and 4AB (Bonabeau et al. 2008). X32 was a molecule for treating psychosis that had not shown enough effectiveness. Lilly worked with it for five years and without a definitive result, it passed in on to Chorus. It took Chorus seven months to determine that the drug had no sufficient effect and it was cancelled. 4AB was a molecule for neurological disorders that had shown signs of affecting the vision. Chorus was able to dismiss that concern and the molecule was sent back to development. These are good examples of what Chorus was created for; reduce uncertainty quickly and cheaply.

Longman (2007) points out that the Chorus approach is not suitable for all types of drugs. It does not work well with molecules that demand more extensive work or novel compounds where the biomarkers are hard to predict. There is also a concern that problems can occur when an asset is moved between Lilly's R&D department and Chorus due to operations within different expectation levels.

4.3.3 FIPNet

FIPNet stands for Fully Integrated Pharmaceutical Network and was the next step after FIPCO – Fully Integrated Pharmaceutical Company, which it had positioned itself as until 2006. Lilly had understood that not all activities took place within the company and this term was a better fit (Schwartz & Huff, 2010). A network with other companies was built in order to let Lilly take part of technology and make it easier for collaborations. The companies in the network could collaborate with each other as well, which later could lead to benefits for Lilly due to its position as creator of the network. One example shows two companies that found each other through the network and then developed a service that benefited Lilly, and this was exactly the reason why this network was created (Schwartz & Huff, 2010).

Sidney Taurel, Chairman of Lilly between 1999 and 2008, said in 2008 that he believed Lilly to be a pioneer within this area in the pharmaceutical industry because a high percentage of compounds are created outside the company as well as the fact that Chorus has been able to attract a large number of external scientists while at the same time decrease time and reduce costs (Lilly, 2012b). Lilly has found a third way apart from continuing the development under high financial risk or abandon it and sell it off when finding a promising discovery, namely to use firms in China and India who are willing to share the risk. In exchange these firms are offered payments and royalties when a successful molecule is invented as well as increased skills to their own employees while Lilly receives the IP rights.

Sidney Taurel further believes that Lilly can benefit from the fact that high populous countries like India and China are producing an increasing amount of highly educated individuals. These countries still lack experience but an increasing number expatriates with that experience are returning and there Lilly has found opportunities to spread its development of FIPNet (Lilly, 2012b).

Schwartz and Huff (2010) concludes that FIPNet still is a relatively new initiative and that this network strategy might not be the final step for all companies. However, Lilly is a company that during the last 15 years has found an Open Innovation model that has shown to increase value.

4.3.4 Open Innovation Drug Discovery

Due to a number of challenges facing the pharmaceutical industry such as patent expirations and increasing restrictions as well as the ageing population and the rise in demand from emerging countries, pharmaceutical companies face extraordinary pressure (Lilly, 2012c). To deal with this pressure, new and different approaches are needed. Lilly founded InnoCentive as mentioned above and it recently started two new initiatives; a phenotypic drug discovery initiative called PD^2 in 2009, and a target drug discovery initiative called TargetD² in 2011. These two approaches are very complex, but they basically give opportunities for external scientists to use Lilly's testing modules. These modules make it possible for the external scientists to identify biological activity of interest in order to formulate hypotheses in that field (Lilly, 2012d).

As stated above, these two different approaches are very complex to understand, but the important aspects to understand in a business oriented way are the advantages that come with these approaches. Lilly uses research universities and institutes to get hold of test molecules that are used in the research process. These test molecules are then available for the external scientists to evaluate and will hopefully lead to breakthroughs (Lilly, 2012c). The PD² and TargetD² initiatives include testing modules where the external scientists can test their hypotheses (Lilly, 2012e). In this case, the external investigator/scientist will keep the IP right to his or her molecule solution. The goal is to receive thoughtfully considered hypotheses rather than a high quantity of submissions, and Lilly provides research tools to make it easier for these investigators' experimentation. After the evaluation is completed, Lilly holds the right to negotiate first with scientists that come up with promising discoveries (Lilly, 2012e).

To begin, the external investigator needs to sign up and accept a Material Transfer Agreement to become a member of the Open Innovation Drug Discovery platform. The investigator will then receive information about the process, how to submit compounds of molecules and what Lilly requires. If the compound models submitted are of sufficient quality, the investigator will move to the next step where he or she will be able to submit a physical sample (a more detailed description of how the compounds are being evaluated is shown in figure 4.6). If Lilly too, finds the compound to be promising, Lilly and the investigator will proceed to negotiations about how to continue. Since the investigator will keep the patent, the negotiations will include discussions how they both can leverage on the discovery, i.e. through licensing or collaboration, but the investigator is free to leave with the patent as an option as well which raises questions how Lilly avoids that scenario (Lilly, 2012c).

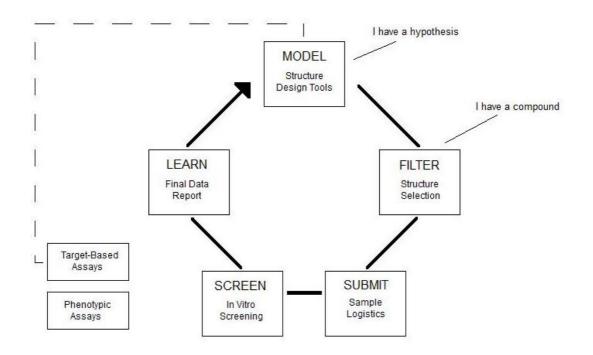


Figure 4.4 Open Innovation Drug Discovery Evaluation Cycle (Lilly, 2012f) elaborated by the authors

The PD^2 panel focuses on endocrinology and oncology diseases such as diabetes and cancer (Lilly, 2012c). The modules are further broken down into different compounds of molecules within these diseases and are used as starting points for external scientists and drug discovery. The TargetD² panel works within the same branches in medicine as the PD² panel and additionally with cardiovascular and neuroscience. It is important to bear in mind that these compounds of molecules being investigated and examined within these panels are rather complex and the important aspect here is what the Open Innovation process looks like due to the purpose of this thesis.

Lilly also has a special initiative towards the fight against tuberculosis (TBC) within the Open Innovation Drug Discovery initiative. The programme is called The Lilly TB Drug Discovery Initiative (TBDDI) and aims to accelerate the early-stage drug development and find tomorrow's drug to fight the disease (Lilly, 2012g). It is a non-for-profit public-private partnership and gives the opportunity to the external investigators involved in the Open Innovation drug discovery to contribute to this initiative (Lilly, 2012c). Compounds submitted to the PD² panel or the TargetD² panel will automatically be sent to the Lilly TBDDI for consideration.

5. Analysis

The fifth chapter provides an analysis of the case studies from the perspective of the theoretical framework and the empirical results. A discussion of reasons for the results will also be presented.

5.1 Incentives for Open Innovation

As stated by Chesbrough (2003), companies go outside their own walls to reach more qualified scientists and better ideas, and due to the cutbacks in the global economy all businesses and industries have had to reconsider their business models in order to maintain profit levels. Globalization and fiercer competition on the market have forced companies into working more efficiently with R&D in order to increase the number of innovations presented to the market. Furthermore, a decrease in productivity can be seen in the pharmaceutical industry today. R&D costs still need to be covered, and in order to do that there is no room in investing in development of drugs that are in low demand or in demand of people with low purchasing power. Open Innovation is something that could change this and solve the problem of pharmaceutical companies only investing in blockbuster drugs. Today, about one out of three drugs covers its own costs and generates profit, but before a drug gets launched to the market roughly 30 projects need to be invested in, which implies a success rate of about 3 per cent. This means that when looking at the costs of one drug, not only does one have to calculate the drug's proper costs, but also include the costs of failed projects. These costs need to be compounded and seen as the total costs that need to be covered by the sales. In addition, which has also been discussed earlier, the lead-time for a drug to reach the market is becoming longer and longer due to an increased demand for documentations. The effective lifetime of a patent in the pharmaceutical industry therefore decreases and furthermore, generic drugs are taking over earlier than before which creates additional difficulties of covering R&D costs. The role of Open Innovation and increased collaborations could help the innovation processes by decreasing the lead times and costs of R&D.

For many diseases where there is no monetary profit to be made, such as malaria and TBC, collaborations and Open Innovation is a way for society and for pharmaceutical companies to reach out to these diseases without having to bare all costs alone. The R&D costs are too high for one company to take on solely, but together in a partnership with other companies and institutions, investment in remedies for these diseases is feasible.

Even though the investments in R&D in the pharmaceutical industry have increased, the number of successful products has stayed the same for the last 20-30 years. Companies know that changes are necessary in order to be more competitive and Lilly is in the forefront of finding new ways. Lilly wanted to find other ways to solve more problems, to be more efficient in its drug development and to be able to leverage on others' capabilities. Lilly found the motivation and was able to transform them into goals, which it was later capable of reaching in many aspects when looking at the results.

The incentive for InnoCentive was to reach more scientists and solve more problems, which it was able to do. Lilly started Chorus to be more effective in its early-stage drug development and results show it has been. FIPNet and Open Innovation Drug Discovery are still new projects, but the intention illustrates Lilly's constant search of finding new ways and implementing them.

5.2 Searching for Open Innovation

AstraZeneca has realized that, in order for the company to continue on as one of the world's biggest pharmaceutical companies, it needs external innovations in more ways than the company's traditional collaborations with academia and smaller pharmaceutical or biotech companies. The company has a goal of having at least 40 per cent of its innovation portfolio licensed in from external sources and it has commenced with more complex collaborations such as PPP and pre-competitive collaborations in order to further access innovations from other prominent researchers and companies, i.e. the best talented. AstraZeneca is still one of the world's biggest companies within the industry, however, there is an openness within the company of moving further towards Open Innovation processes, which is an essential mindset in order to stay competitive in today's business environment.

AstraZeneca has, in general, three ways of looking for external knowledge; 1) Researchers bring their own network of important people and talents to the company. 2) Business Development group focusing on different diseases that scouts the global market for new innovations and solutions to problems and sees how the company itself could benefit from these new, external innovations. Another part of the Business Development group is the one who is focusing on other pharmaceutical companies to see what is in the competitors' pipelines. 3) Researchers at AstraZeneca are continuously taking part of new research within

their field by reading recently published articles, going to seminars etc. As a consequence, AstraZeneca's internal researchers are introduced to new ideas and innovations. These approaches illustrate the willingness to integrate external knowledge in the company's business model.

Lilly is a pioneer in Open Innovation within the pharmaceutical industry and InnoCentive and FIPNet are two examples of this. R&D in the pharmaceutical industry is crucial but also expensive and time consuming, and Lilly's approaches of finding new ways have put it in its market leading position. Lilly started with InnoCentive where it tried to solve difficult problems and was able to reach its goal with a higher rate of solved problems. The project proves that searching will lead to finding and that outside parties can play significant roles in this industry.

The way Lilly has been able to find other companies or other scientists through establishing a network (FIPNet) or starting up an Internet forum (InnoCentive) clearly illustrates the advantages of having a good reputation. Lilly has built it up over the years by inventing well-known pharmaceuticals and has been capable of bringing companies into the network and attract scientists to its InnoCentive platform. The success can further be related to Fetterhoff and Volkel's (2006) ideas on how to create value through seeking, evaluating, recruiting, capture value and continue to extract value. In Open drug discovery Lilly is able to recruit and capture value by having the rights to negotiate first with scientists who come up with molecule solutions. The seeking and evaluating processes of InnoCentive are other examples that demonstrate its ability to search and grasp opportunities.

5.3 Openness and collaborations

Based on interviews with influential people at AstraZeneca, the perception is such that the company still, regardless investments in PPP and pre-competitive collaborations, keeps a traditional mindset of wanting all the best people to work for the company. The difference between Open Innovation and AstraZeneca's definition is that the traditional/closed model's appraisal of internal innovations still lingers at the backbone of AstraZeneca, and the company explains that it is looking for the best talents and the best scientists in the industry. However, it has been shown that AstraZeneca is opening up innovation processes by looking for external knowledge to a larger extent than earlier, and the company puts much effort into looking for external knowledge to further develop in-house (AstraZeneca, 2012f).

As seen in the case study of Lilly, the company is trying to be open and has tried a number of new approaches in the last decade. It is interesting to see that Lilly is not trying to search for single companies to work with; instead it tries to build networks and incorporate ideas from individual scientists. Collaborations with companies is not a new phenomenon, which Lilly is aware of and has chosen to try other ways to improve R&D with the purpose of becoming more profitable.

In the last years, Lilly has started to look Far East (e.g. China and India) in its attempts to expand its Open Innovation approach. There are many small pharmaceutical firms in these countries where scientists, who have been working in the Western world for prominent pharmaceutical companies, are bringing knowledge back to Asia. In its FIPNet approach, Lilly has been working with these companies and the results show that there are resources in those countries that can be tapped by Big Pharma. Lilly also knows that these companies want to gain further knowledge from western companies, which is something that Lilly can offer and in return receive IP rights. Both parties understand that this allows for a win-win situation and these relationships could give Lilly an advantage over other Big Pharma unless these competitors take the same path.

There are dangers of being too open as well, and these dangers are related to IP rights in particular. However, because of the importance of patents in this industry, companies keep them well protected. Openness is more likely to create opportunities to share technology and other services as the case of FIPNet, and by being the creator of such a vast network; Lilly has the possibility to leverage on collaborations taking place.

AstraZeneca talks about relationships and collaborations in a way it always has to a large extent. Lilly on the other hand, has put much effort the last decade to find alternative ways to innovate, and future outcomes of these projects will tell if Lilly will become more successful. However, it is interesting to see that AstraZeneca and Lilly perceive Open Innovation in two, more or less, different ways.

5.4 Crowdsourcing

As mentioned, AstraZeneca is a traditional company in the pharmaceutical industry in terms of innovation and when it comes to crowdsourcing as new grounds for exploring new innovations and initiatives, AstraZeneca has yet to learn more. Today, AstraZeneca is not employing any specific strategy in order to take advantage of crowd knowledge. Dr. Ekblom, however, states that crowdsourcing is something that the company would like to become better at as it sees many of its competitors going towards a more Open Innovation process that includes crowdsourcing and crowd knowledge. There are many successful examples of crowdsourcing, both within the pharmaceutical industry and in other industries, which have affected the company's view on openness towards crowd knowledge. At AstraZeneca, collaborations take place to a great extent, yet the pharmaceutical industry is much more complex and requires much more expert knowledge than e.g. the IT industry, where it is possible for anyone to come up with new ideas, programs and solutions at home. This, naturally, is not the case in the pharmaceutical sector where the usage of crowd knowledge is more difficult to adopt.

The approach of using the crowd's knowledge is, however, certainly something that Lilly is aware of. The company started InnoCentive, which has made it possible to reach a large number of independent scientists regardless of their geographical location who have been able to come up with solutions for Lilly's problems. As well as crowd creation, crowd wisdom undoubtedly plays a big role here, and results show that these researchers have solved many problems that could not be solved in-house.

InnoCentive makes it possible for external parties to understand the problems, which Thomke and von Hippel (2002) point out as important. The platform is user-friendly due to skilled employees who are able to explain problems to the solvers and this makes the problems available to a greater number of people (140,000 users all over the world). In addition it is simple to understand the rules when engaging; one either solves the problem and receives a reward, or fails and is left without any compensation. Even though this has been criticized, the reward certainly motivates people to try to solve the problems.

Today, InnoCentive is an independent company, yet Lilly still uses it and the success rate when referring to posted problems shows that there are problems within a pharmaceutical company that external sources are able to solve. Everything is not about developing complicated molecule compounds that demand qualified scientists, and that is something that Lilly has taken advantage of. Crowdsourcing is a relatively new concept, and this is possibly the first of many similar attempts within this area in the pharmaceutical industry.

5.5 The managing of Intellectual Property rights

The pharmaceutical industry is an industry where IP rights play an important role for the survival of the involved companies. When it comes to AstraZeneca and how the company sees in the case of Open Innovation, it can be said that many of the company's collaborations are executed in the open space. This means that in projects like Innovative Medicines Initiative (IMI) and Medicines for Malaria Venture (MMV) where the company collaborates with both other companies and institutions such as the EU (the Commission) or the UN, innovations become open i.e. all data is published. This in turn indicates that none of the parties involved is able to apply for the patent of the innovation. The same goes for precompetitive collaborations where governments or other non-profit organizations are involved. According to Dr. Ekblom, there are two reasons why AstraZeneca engages in projects where no patent can be received: 1) To engage in projects such as IMI or MMV is rather considered as a part of the company's CSR than being a source of income. 2) For pre-competitive collaborations it is beneficial for AstraZeneca, as well as for other pharmaceutical companies, that the biomarkers developed within these collaborations become published and broadly accepted since this leads to decreased lead times for the development of a drug. However, in pre-competitive/competitive collaborations it is easily understood that issues of IP rights will emerge. These issues prolong the innovation process and the companies involved risk high costs in time lost and in legal costs. These issues are normally solved with the creation of a new enterprise that will be the juridical owner of the patent created.

Lilly tries to clarify ownership rights before starting up a project or engaging in co-operations. Lilly's first Open Innovation project, InnoCentive, solved the issue through a contract stating that the patent belonged to the seeking company. All external scientists trying to solve problems have to sign this contract before having the possibility the view a problem. Lilly knows that the patent is crucial in this industry and individual solvers are satisfied with a cash reward or just the satisfaction of solving a complicated problem.

Chorus is not a typical Open Innovation approach that tries to reach out to external parties for innovation that leads to patents. External scientists contribute with knowledge around the molecules such as toxicology and experimental design while Chorus's employees focus on trials of portfolios of molecules. The findings are later sent back to Lilly's R&D department for further development. Chorus basically uses external knowledge to speed up the

development process, but since core operations are kept within the firm and final products are developed in-house, there are no issues regarding IP rights.

The recently established FIPNet fuels this issue since it makes these questions more complicated to solve. Companies set out collaborations in a number of different ways and it is hard to understand how contracts are written and detailed. It is most likely that these companies work out patent issues between themselves, while Lilly is able to take part of technology, services or other related features. When it comes to collaborations where Lilly is directly involved, it has been able to get hold of patents while the co-operating firm can take advantage of the knowledge learned from Lilly as well as royalties and cash rewards. This is the case when a co-operation has led to a successful drug as in the case with inexperienced Asian pharmaceutical companies.

In Lilly's new approach, Open Innovation Drug discovery, the company has chosen another way of managing patents. The scientist that comes up with a molecule discovery or innovation when using Lilly's testing modules will receive the IP rights and is free to leave with it. The goal for Lilly is to pursue this person with an offer they both can profit from and establish some kind of collaboration. As a result of having the first negotiation rights, Lilly has a good possibility to establish a relationship, and in addition, the company understands that it has the financial and operational resources to develop this molecule. The scientist is also aware of the parties' different capabilities. The risk is that the scientist turns down the offer and turns to other companies, but since everything is developed by using Lilly's equipment, other companies may be uncertain of the molecule's possible use. In addition, if Lilly finds the molecule to be highly promising, it will certainly propose an offer that is hard to refuse.

6. Conclusion

In this chapter the findings of the empirical study will be concluded, furthermore recommendations for future research on the subject will also be presented.

To refer back to the research questions for this thesis; how is Open Innovation conducted in companies (AstraZeneca and Lilly) in the pharmaceutical industry? What are the incentives for these companies to engage in Open Innovation? And, are there any difficulties concerning IP rights when engaging in Open Innovation? This thesis has illustrated the innovation processes of two global companies in the pharmaceutical industry, AstraZeneca and Lilly, and explained what strategies these two companies employ in order to deal with the current situation of increased competition, increased costs and decreasing incomes. To illustrate this, the Closed and Open Innovation paradigms have been presented as well as the importance of IP rights in the pharmaceutical industry. Furthermore, the theory of the product lifecycle has been explained in order to illustrate the increasing need for new innovations.

Globalization has increased competition by increasing the number of educated and talented people and scientists, and it has also decreased product lifecycles due to the number of competing firms on the global market. This thesis concludes that there is a need for companies in the pharmaceutical industry today to be close to breakthrough science in order to stay competitive. AstraZeneca is doing this by being physically located close to academia, engaging further in collaborations such as IMI and MMV and is currently restructuring its activities in Sweden in order to increase the company's flexibility, and Lilly has initiated several digital platforms such as InnoCentive and Open Innovation Drug Discovery. It also concludes that the characteristics of smaller biotech firms and larger pharmaceutical companies, such as AstraZeneca and Lilly, can complement each other in order to decrease lead times and R&D costs.

In order to illustrate the need for change in the industry, this thesis concludes that Open Innovation has a role in achieving companies' goals of enable faster and cheaper R&D. Lilly has initiated a number of Open Innovation projects the last decade that have been successful. AstraZeneca is in the preface of engaging in Open Innovation by commencing projects such as IMI and other pre-competitive collaborations that have led to faster and cheaper development of biomarkers.

Considering the issue of IP rights, one part of the purpose of this thesis has been to investigate whether this implies any problems or complications when engaging in Open Innovation projects. The findings show that IP rights are essential, especially for companies in the pharmaceutical industry, and it is clear that the examined companies realize this. It can be concluded that in general, both AstraZeneca and Lilly have legal experts that assists in developing and setting up clear and well defined contracts before any collaboration begins, regardless the nature of the collaboration. However, the party to receive the patent can vary and depends on the project, and if an innovation has been created in a fully transparent, open space it is hard to create any ownership rights at all. In addition, it has been shown that the two companies are engaging in projects where the gain of IP rights is not the most important factor, which implies that there is an ongoing change considering the perception of patents.

AstraZeneca and Lilly do not adopt the same approach towards Open Innovation. AstraZeneca still operates in a more traditional way of collaborating and is a little more concerned of opening up for alternative ways. Lilly has been, and still is, a pioneer who has been involved in or initiated a number of Open Innovation projects. AstraZeneca has lately started to look for new ways and time will tell if the company will be able to come up with successful approaches.

6.1 Recommendations

AstraZeneca and Lilly are only two of many Big Pharmas, and even though they provide examples of how Open Innovation can be performed and why companies are trying to attract external knowledge they do not represent a general approach to Open Innovation in the pharmaceutical industry. Further there is a difference between these two companies in terms of how they perceive Open Innovation, which makes it even more difficult to draw general conclusions that apply to the whole industry and might indicate that there could be, in addition, other alternative ways Big Pharmas approach this subject. Therefore it would be interesting for future research to investigate additional companies in the pharmaceutical industry in order to provide a more generalized overview.

What can be said after examining these two companies as well as having discussions with researchers and professionals within the subject is that there is a general perception that Open Innovation will play a big role in the future within the pharmaceutical industry. This thesis

gives an idea of where two of the largest pharmaceutical companies stand in this relatively new area, and future research should focus on trying to create an overview of the whole industry. In that way, patterns and dissimilarities can be discovered and provide a deeper understanding of Open Innovation, and why and how companies are trying to obtain and attract external knowledge.

In addition, the changes and the restructuring of the pharmaceutical industry is something that has only been mentioned shallowly in this thesis, however, it is an essential aspect that deserves further attention.

Finally, future research should try to link Open Innovation within the pharmaceutical industry with other industries in order to find out where potential collaborations can be performed as well as where pitfalls exist.

7. Appendix

Appendix 1. Interview template

Interview for the bachelor thesis "*The Role of Open Innovation -focus on the Pharmaceutical Industry*", School of Business, Economics and Law, University of Gothenburg.

Interviewees: Anders Ekblom, CEO AstraZeneca Sweden, AstraZeneca, Södertälje. Mats Sundgren, Principal Scientist within Global Clinical Development, AstraZeneca R&D, Mölndal.

1. AstraZeneca's definition of Open Innovation.

- What are the advantages of Open Innovation to AstraZeneca?
- What are the disadvantages of Open Innovation to AstraZeneca?
- 2. External knowledge.

How does AstraZeneca proceed in finding potential partners, collaborations and external sources? Is the company actively searching?

- How are these partners and external sources evaluated? What does the organization look like?
- Concrete examples?

3. Crowdsourcing.

What does AstraZeneca think about the usage of "crowd-knowledge", i.e. crowdsourcing, in order to solve problems and create innovations in the pharmaceutical industry? Examples of crowdsourcing as open platforms are www.patientslikeme.com and Lilly's InnoCentive.

4. The future.

What do You see in the future for Open Innovation within the pharmaceutical industry?

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