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Barriers to Entry in a Regulated Industry: Tackling Barriers to Entry with Limited Resources - The Entrant Perspective

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Karla Asikainen

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Department of Marketing
Aalto University
School of Business

Aalto University
School of Business

Aalto University, P.O. BOX 11000, 00076 AALTO
www.aalto.fi

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Author Karla Asikainen

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Abstract

OBJECTIVES OF THE STUDY

Earlier research on barriers to entry has strongly focused on the incumbents and explored strategies through which the incumbents are able to create or strengthen barriers to entry to deter entry from new competition to the industry. The objective of this research is to take the entrant perspective and study the implications of the barriers to entry for a *de novo* entrant seeking to enter a highly regulated marketplace. More specifically, the aim is to introduce the barriers to entry for a new entrant in the contextual background of market regulation and study how the entrant can tackle these barriers to entry to gain success in market entry. In addition, implications of high barriers to entry in relation to support for new company birth and growth are discussed.

METHODOLOGY

The study is built on a case study design, focusing on a Finnish small company seeking to enter the highly regulated medical device market with an innovative product offering. The data was collected in interviews with case company key personnel and Finnish innovation support system actors.

FINDINGS

Based on the case study findings, the earlier research has presented barriers to entry misleadingly as static obstacles in market entry from a small entrant perspective, and implicating little to no chance for the entrants to tackle the barriers to entry. The present study challenges the notion of barriers to entry as static obstacles and through the case study findings portraits the entrant's market entry efforts as a dynamic play in which the entrants can formulate strategies to gain entry in the same manner as the incumbents can formulate strategies to deter entry from new competition. In addition, the earlier research on barriers to entry has failed to appreciate the socio-economic implications of high barriers to entry for new company birth and growth. The case study findings support the implications that high regulation leads to severe barriers to entry and easily leads to consolidated market structures. This finding implies that especially in industries with wider social and economic welfare implications, the government should seek to lower the barriers to entry in these industries to contribute to improved net welfare

Keywords Barriers to entry, *De novo* entry, Market regulation, Innovation, Strategy

CONTENTS

PART I - INTRODUCTION

1. Introduction

This chapter introduces the background for the study, identifies the research gap for the study, and presents the research questions and objectives for the study. In addition, the scope of the study is defined. The chapter ends in the outlining of the structure for the study.

1.1. Background

The birth and growth of new companies is the prerequisite for entrepreneurship (Hitt et al. 1999) – a force that has been the seed of much of wealth creation during the past decades (Birch 1987; Kirchhoff 1991), responsible for the unforeseen rise in the quality of life of people in the Western world (Robinson & McDougall 2001). With regards to the current economic crisis and the threat it places for the sustainability of the current standards of living and social welfare, it has become even more important to create new ventures that will not only affect to job creation but can also serve as drivers of competitive advantage for countries and different areas.

This study focuses on the market entry of de novo ventures defined as companies new to the industry that are marketed and operated independently from incumbents and are not reliant on resources from incumbents (Helfat and Lieberman 2002). Thus the study focuses on new start-ups that are not owned by a parent nor linked to an incumbent. The interest of the study is on the barriers to entry these new entrants face whilst seeking to enter a highly regulated market with an innovative offering. Prior research has shown that only a small fraction of new ventures survive beyond the first years of their operation, with approximately 40 percent failing during the first year of operations (Timmons 1990), over 50 percent

within the first four years (Phillips & Kirchhoff 1989), with only less than half making it past the fifth anniversary (Dunne et al. 1989). These studies have included samples from various industries in different lifecycles and with different market entry strategies. The findings unanimously have shown that even though small-scale de novo entry of new ventures is fairly common in most industries, their survival odds independent of the industry are generally very low (Geroski 1991, 436). Cabral and Mata (2003) have argued that a combination of financial constraints and market selection forces are some of the most defining factors in the short life expectancy of these new ventures in most industries - both found to be major factors in deterring market entry in the corresponding research on the conditions for market entry and the barriers to entry in an industry (e.g. Bain 1956; Stigler 1968; Porter 1980; Porter 1985). This argument has also been supported by other authors, noting that the low survival rates of new ventures may well be linked to the more severe barriers to entry that they will face (Hines 1957; Gorecki 1975; Yip 1982, Hariharan & Brush 1999). Earlier research has also constantly shown a link between high barriers to entry and a low rate of innovation, mostly hampered by the high consolidation and low entry rates in highly regulated industries (Friedman & Taylor 2011). Prior research has also suggested that high entry barriers have a strong influence on the industry performance, reducing productivity, employment and increasing labor costs (Schivardi & Viviano 2010), decreasing R&D efficiency, hampering innovation and leading to suboptimal allocation of resources (Aghion & al. 2009; Cullman & al. 2012).

Over the course of decades of research on barriers to market entry, the view on what constitutes a barrier to entry has varied depending on the research stream and the researcher. Lately, *barriers to entry have been defined as factors that limit competition by preventing market entry of new firms and in the process often leading to an increase in the profits of the established incumbents in the marketplace* (Karakaya 2002). Earlier research is unanimous concerning a link between regulation and high barriers to entry, constantly showing that a higher degree of governmental regulation deters

entry from new competition and leads to decreased economic and social welfare (e.g. Shaffer 1995; Blanchard & Giavazzi 2003; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012)

A majority of earlier research on barriers to entry has taken the point of view of the incumbents, the established companies already in the industry (Robinson & McDougall 2001; Pehrsson 2009), and on the possibilities for these companies to use the barriers to entry as their benefit to mitigate the threat of new entrants (Porter 1979; 2008; Pehrsson 2009; Lutz & al. 2010). Thus the entrant perspective has largely been ignored. There is also a lack of research on the different industry characteristics and structures in relation to the types of barriers to entry that exist to new entrants in a given industry. In addition, even though strong theoretical linkages between high levels of industry regulation and high barriers to entry exists, empirical evidence on the effects of entry barriers in highly regulated industries is missing (Lutz & al. 2010). Prior theory has suggested that the importance of specific entry barriers on new company survival and performance is dependent on the industry life cycle and the entry strategy of the new venture (e.g. Bain 1959; Stigler 1968; Hofer 1975; Porter 1980; Hay & Morris 1991; Robinson & McDougall 2001; Pehrsson 2009), and also varies by products and industries (Karakaya & Stahl 1989; Yang 1998; Karakaya 2002; Pehrsson 2009). It has also been argued that the structural elements of an industry have different effect on a wide range of performance measures for a new venture entering a market (Robinson & McDougall 1998; Robinson 1999; Lutz & al. 2010). In addition, the timing of entry (Robinson & Fornell 1985; Kerin et al. 1992; Pehrsson 2009) and the size of the entrant can have an effect on the height of the barriers for a new entrant (Blees & al. 2003).

With only scant prior empirical evidence on barriers to entry in a specific industry setting of high regulation, there is a need for further research on the barriers to entry for a new entrant taking into account the structural characteristics, the type of market and the industry life cycle – and also the characteristics of the new venture entering the market. The effects of

barriers to entry become drastically emphasized for small entrants who usually have less or no prior experience of the market and suffer from lack of financial capital. The aim of this study is to add to the current literature by focusing on the barriers to entry for a *de novo* entrant in the context of a highly consolidated and regulated health care industry. The health care industry was chosen as a prime example of an industry with a highly consolidated market governed by a handful of strong existing incumbents with profit margins unfamiliar to almost any other market. In addition to the strong existing incumbents in the market earning above-normal profits, the industry also has a second singular characteristic, making it a very interesting setting for examination of barriers to entry in a contextual setting – a high level of regulation from different governmental authorities. An examination of the barriers to entry from the point of view of the *de novo* market entrant in the context of a highly regulated industry and specifically its means to tackle these barriers offers an interesting addition to the existing literature on the barriers to market entry.

The health care industry as a setting for the study is very topical also from the perspective of social welfare and public sector financial struggles globally. As welfare costs are taking up an increasing portion of countries' GDP (Hermans & al. 2009, 19), public sectors globally are facing a balancing act in accommodating its objectives of decreasing the costs of health care and at the same time increasing the quality of health care and the technologies used in health care management (Hermans & al. 2009, Preface). With the global health care megatrends - an ageing population, the explosion of new therapeutic technologies, and a critical shortage of clinical professionals – there is a portentous need for new technology and new solutions to more efficiently solve these problems facing most health care systems and government budgets currently. Schumpeter (1939, 7) wrote already in the late 30's that the industry changing innovations come almost without exception from new companies, with the incumbents rather focusing on finding new ways to raise the barriers to entry for new innovations than developing them themselves, a notion that still has its

validity today (e.g. Friedman & Taylor 2011). As the role of new companies as key drivers for economic growth and job creation, European level governmental initiatives have been started aiming for new support mechanisms for new venture companies (e.g. Edler & Georghiou 2007).

The previous literature on barriers to entry has shown the important role of government legislation on the height of the entry barriers and the success of new ventures in entering a market. This study further investigates the potential to influence the barriers to entry from the point of view of the entrant and also the government in aiding innovation diffusion in health care leading to improved social welfare consequences (e.g. Bertrand & Kramarz 2002; Hermans & al. 2009). The phenomenon is studied from the point of view of the entrant and its relations to the incumbents and governmental or authority bodies, disregarding the potential linkages between these actors non-related to the entrant.

The methodology used in this study includes a literature review and a single case study. First, the prior research on barriers to entry is reviewed in an extensive but by no means exhaustive literature review on prior research on barriers to entry, 42 barriers are identified and grouped based on the source of the barrier for the new entrant. In addition, the potential to influence these barriers for the entrant and for government actors is discussed. Secondly, the effect of regulation and consolidation on the industry characteristics is reviewed. As a second part of this study, a case study method is used to complement and add to the current theory by comparing the findings of the literature study to practice and seeking to add knowledge on the effects of entry barriers for a new entrant in a highly regulated industry and the entrant's potential to influence the barriers to gain entry. The primary data collection method in the case study is interviews with case company key personnel, industry experts and the Finnish innovation policy actors.

1.2. Objectives of the Study and Research Questions

The main objective of the study derives from the identified research questions. The objective can be summarized as follows:

To add to the existing knowledge on the barriers to entry from the perspective of a de novo entrant in a specific industry setting defined by high regulation; to discuss the effect of regulation and high entry barriers on the barriers to entry for a de novo entrant and to identify what potential does the entrant have in tackling these barriers to entry.

The main objective is achieved by combining the previous academic literature with empirical findings of the case study to produce new understanding of the conditions for market entry for new companies entering highly regulated markets. For companies the main objective of the study is to deepen the understanding of the relevant barriers to entry in a highly regulated industry, and to study whether the entrants will have the means to tackle the identified barriers to entry in the specific industry. The broader objective is to produce practical knowledge from the prior research and especially the empirical reality of the case study company in relation to the initiatives to foster new company growth which is much dependent on the conditions for market entry and post-entry success. The specific setting of a highly regulated industry is a novel context for research on barriers to entry that requires further research, especially from the entrant perspective.

The main research question:

***What* are the barriers to entry for a small-scale *de novo entrant* entering a highly regulated market and *how* can the new entrant influence these barriers with limited resources to gain entry?**

The main research question is examined by comparing the theories from the literature review to the specific industry setting and company experiences in

the case study. To support this aim, the main research question is broken down into four additional sub-research questions.

Sub-research questions:

RQ1: According to previous theory, what are the barriers to entry for a *de novo* entrant in a highly regulated industry?

RQ2: According to previous theory, how can a *de novo* entrant tackle these barriers to entry?

RQ3: What are the barriers to entry for a *de novo* entrant in a highly regulated industry based on the empirical findings?

RQ4: How can a small-scale *de novo* entrant tackle the barriers to entry with limited resources based on empirical findings?

1.3. Scope and limitations of the study

This study focuses on the market entry for a small *de novo* venture company and more specifically on the barriers to entry the company faces in entering a highly regulated market. For the purpose of adding new knowledge in respect to the identified main research question, a highly regulated industry serves as a model example of examining the effects of high barriers to entry for a small *de novo* company as the industry is very consolidated with only a few strong incumbents earning above-normal profits and aggressively protecting their market positions.

The case study focuses on a Finnish start-up company seeking to enter the health care market with an innovative new product for diabetes management. The particularity of the case study poses limitations to the generalizability of the results to other industries and applications. As a part of the objective of this study is to show the influence of the specific industry

and market characteristics on the barriers to entry, the specific nature of the case study serves the purpose of gaining a deeper understanding of barriers to entry in the specific highly regulated industry. It is also possible that some of the implications of the case study are applicable to other industries with similar industry and market characteristics. On the other hand, the theoretical section provides a needed review to the existing literature on barriers to entry from different research streams that are of beneficial nature also to other industries and settings. In addition, at least some of the case study implications have general application to the study on the barriers to entry and the effect of different industry settings to the height, importance, and influencability of the barriers.

Geographically, the study focuses on the European health care industry and more specifically on the European blood glucose monitoring industry. Even though the geographical distances are relatively small, there is a variety of different cultural and praxis settings in the focus area. Due to the nature of this study, the strong focus on the experiences of the entrant company in question, and on the general notion of Europe as a single market area within the industry, the between-country variances are not considered a limitation for this study. In addition, even though the characteristics of markets outside Europe may be different, the same industry incumbents control the market globally making at least some of the findings generalizable outside the European markets.

Thus, the scope of the study focuses on the barriers to entry that a single *de novo* venture company entering into a highly regulated and deeply consolidated industry faces and what are its chances of tackling these barriers to gain entry. In addition, the implications of government influence on the height of the barriers to entry are studied. The study strongly takes the view of the entrant.

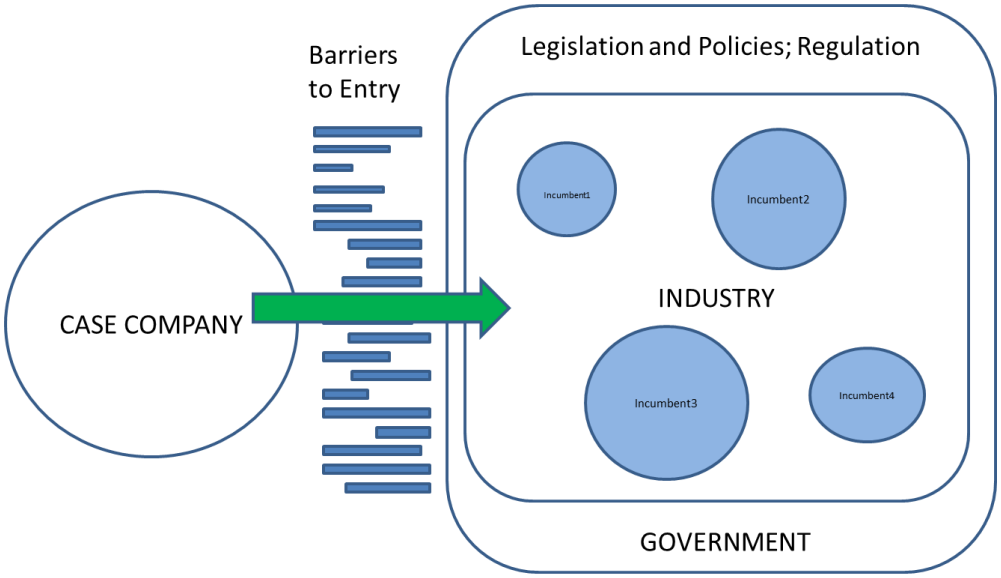


Figure 1: Scope of the Study and Actors Involved.

1.4. Structure of the thesis

The thesis consist of four parts: Part I – Introduction, Part II – Theoretical Background, Part III – Empirical Case Study, and Part IV – Discussion and Conclusion.

Part I – Introduction

Part II – Theoretical Background presents the key theoretical discussions on Barriers to Entry and the roles of different actors (entrants, incumbents and governments) in raising and tackling those barriers to entry. The context for the study is defined. This part answers the first and the second research questions.

Part III – Empirical Case Study is structured in a similar manner as the theoretical part, first defining the main barriers to entry for the company and then discussing the means for the company to influence i.e. tackle these barriers. III thus answers the third and the fourth research question.

Part IV – Discussion and Conclusion is used to evaluate the findings of the theoretical and empirical parts of the study. Theoretical contribution and empirical contributions are evaluated and discussed. In addition, further research implications are presented.

The main research question is discussed throughout the study first from a theoretical perspective and then with empirical findings. The main research question is thus linked to all parts of the study and is answered through the four sub-research questions. In part IV, the findings are discussed and summarized to answer the main research question.

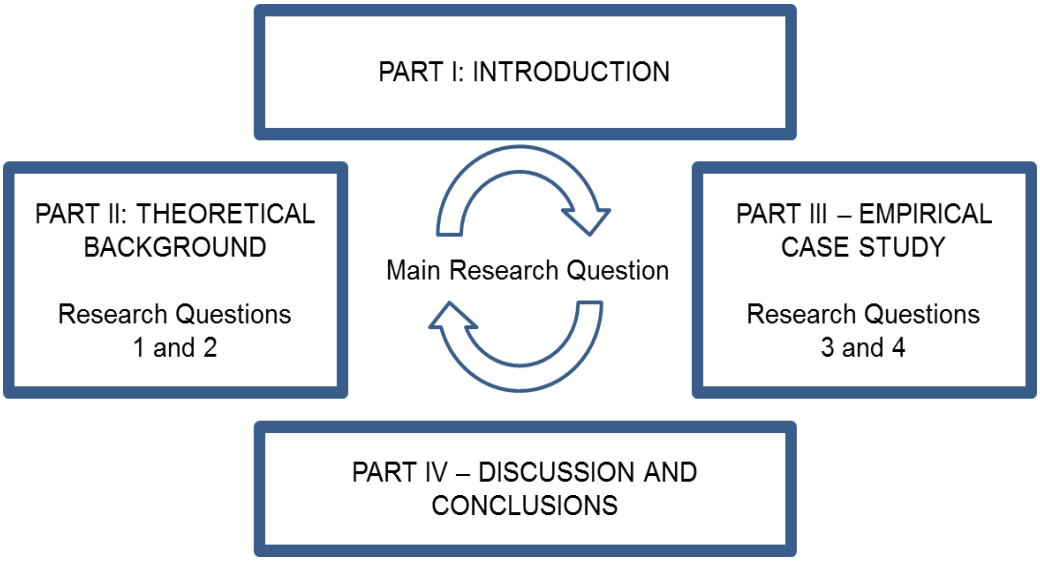


Figure 2 Structure of the Thesis

PART II – THEORETICAL BACKGROUND

In this part of the thesis the previous literature on barriers to market entry and the regulation of the market is reviewed. The focus is on identifying the barriers to entry for a new entrant based on prior research and to study theoretical implications of regulation in a market.

2. Market Entry and Barriers to Entry

In this section of the thesis the different forms of market entry are introduced and certain implications for post-entry success relating to the timing and scale of the entry are discussed.

Furthermore, the prior research on barriers to entry is reviewed and 42 barriers to entry for a *de novo* entrant are identified and categorized. Lastly, the potential to influence the barriers is discussed from the point of view of the incumbents, entrants and governments.

2.1. Market entry

The previous literature has identified different forms of entry. This study focuses on an entry by a *de novo* entrant to an industry in which it has no previous experience in. It is still beneficial to recognize the other potential forms of entry. The literature recognizes four different forms of entry (Geroski 1991):

1. *De novo* entry (also referred to as *green-field* or *start-up* entry) by a new company to a new industry
2. Existing company entering a new industry by building new capacity
3. Existing company entering a new industry by acquiring existing capacity

4. Existing company entering a new product market

Another potential way to look at the different types of market entry is to focus on whether the entrant is large or small. Even though both would be considered as new entrants to an industry, the conditions to entry are very different for the two, in a large part relating to the existing capabilities (Gaynor & Haas-Wilson 1998). Blees and al. (2003) have concluded that large entrants, usually entering through diversifying from another industry, will have existing experience, existing and well-established relationships with suppliers and customers, have access to distribution networks and usually have access to great amounts of financial capital. On the other hand, small entrants usually have less or no prior experience and suffer from a lack of financial capital.

Earlier research has also focused on identifying the most advantageous point of entry for companies. Lieberman and Montgomery (1988) introduced the concept of a first mover advantage which suggests that the first companies to market are able to obtain better profit margins, are able to negotiate lower costs of capital and can reach a head start over its rivals, placing them into an advantageous competitive position in relation to the later entrants. Much research has identified specific advantages for early entrants over later entrants (e.g. Robinson and Fornell 1985; Kerin et al. 1992; Frynas & al. 2006; Pehrsson 2009). Some studies have additionally shown explicit effects such as higher market shares of first movers than their followers (e.g. Kerin et al. 1992) thus advocating for an early entry into an industry.

The implications for *de novo*, small entrants have been that the industry life cycle and the timing of entry have more significant effects on the post-entry performance for small companies than large ones (Robinson & McDougall 2001). Research findings also suggest that especially in industries where the barriers to entry are high, a new company should enter in the very early stages of the industry life cycle as the effect of entry barriers on the early performance of the entrant is moderated when compared to entering at later

stages (e.g. Peltzman 1977; Porter 1980; Perhrsson 2009) – a finding that has even more emphasis in industries where economies of scale and capital requirements are large (Robinson & McDougall 2001).

Thus, the previous research would suggest that some entry barriers are much higher for small entrants compared to larger entrants with an even larger effect in case the small entrant is a *de novo* entrant with no existing capabilities or financial capital (Blees & al. 2003). The large, already existing companies can use their existing infrastructure and brand name when entering a new industry or a market. In addition to benefitting from existing capabilities and assets, the larger companies usually have much more financial leverage and are usually better in attracting new capital financing to support their entry (Robinson & McDougall 2001; Hochberg & al. 2010). Furthermore, they usually are large enough to influence the competitive positions in an industry (Gaynor & Haas-Wilson 1998; Pehrsson 2009; Lutz & al. 2010). Larger entrants will often have synergies with existing operations and are able to gain economies of scale and scope much earlier than the smaller entrants. As discussed in the following chapters, a successful entry usually requires significant capital to be able to meet the incumbents' market power and to be able to tackle the barriers to entry (e.g. Blees & al. 2003; Porter 2008; Pehrsson 2009). In many ways, small entrants are often first and most directly affected by the actions of the incumbents such as different types of retaliatory actions (Golodner 2001). Then again, small companies might be able to escape some of the more direct attacks as they might be seen as less of a threat than large scale entrants (Gaynor & Haas-Wilson 1998; Fan 2010). Still, post-entry performance has been positively associated with the scale of entry (Sharma 1998). More aggressive strategies have been associated with longer-term performance (Biggadike 1979) and the chance of moving down the learning and experience curve more quickly with broader scope (Robinson & McDougall 2001; Pehrsson 2009).

2.2. Barriers to Entry

According to current theoretical knowledge, barriers to entry are defined as factors that limit competition by preventing market entry of new companies (Karakaya 2002). These barriers can be either structural or strategic; the industrial organization research tradition has strongly focused on the structural barriers stemming from the characteristics of industry structure whereas the strategic barriers are discussed in the strategic management stream as a resource for creating competitive advantage for the incumbents in the market place (Lutz & al. 2010). The two research streams are strongly complementary rather than contradictive.

The industrial organization view (Bain 1956; Stigler 1968) takes the industry as the unit of analysis and focuses on the structural characteristics of an industry and the industry actors' reactions to these characteristics. Bain (1956) focused his attention to the characteristics of the market that deter entry from new competition and allow the incumbents to earn above-normal profits without inducing entry. Stigler (1968) later expanded Bain's view by adding the interest in the post-entry conditions and focused on the efficiency of the incumbents vs. later entrants by defining a barrier to entry as a differential cost that needs to be borne by later entrants. Geroski et al. (1990) also later added considerations for behavior as a determinant for market performance and market structure, thus emphasizing that the incumbent strategies can affect the structural characteristics of an industry in the long term.

The structural barriers in an industry can be any structural aspect that allows for the incumbents to raise their prices above the minimum average cost of the potential entrants, thus hampering the potential entry and decreasing competition (Han & al. 2001). These structural factors can include aspects such as economies of scale, level of technology, absolute cost advantages or governmental regulations present in an industry (Bain 1956; Stigler 1968).

There are many industries where the barriers to entry are high due to the structural characteristics of the industry such as in some oligopolies that have a high marketing intensity (e.g. cigarette industry), or high technological barriers due to patents (e.g. health care industry) (Blees & al. 2003). These industry structures are likely to serve the incumbents in an industry, creating barriers to entry for new competition.

The strategic management view (Porter 1980; 1985) focuses on individual companies as the unit of analysis, and their strategies on reaching to improve their performance and to find an advantageous competitive position in relation to others actors such as new entrants. In this view, the actors are proactive and through their strategies can build strategic barriers to entry and affect their competitive environment. Incumbent companies will seek to formulate such strategies that will allow is to outstand the competition from superior performance. This superior value creation ability is referred to as competitive advantage and is strongly linked to the company resources (Barney 1991). According to the strategic management view, the incumbents can use their superior resources as an advantage and create severe entry barriers to deter entry from new competition (Wernerfelt 1984, Peteraf and Bergen 2003, Ketchen et al. 2007). Thus the strategic barriers are a result from the incumbents' behavior and entry-deterring strategies (Lutz & al. 2010). These strategies might include retaliatory actions by incumbents or other direct attacks towards the new entrants, affecting both the entry decision and post-entry performance of the entrants.

In industries where the incumbents have strong market power and great accumulated resources, they are more likely to be able to gain sustainable competitive advantages through strategies exploiting their superior resource-base, that can only slowly and costly be matched by the entrants, to deter entry from new entrants and also to create barriers for growth for other incumbents (e.g. Grant 1991; Blees & al. 2003).

The two streams combined suggest that economies of scale, capital requirements and product differentiation would be the most important barriers to entry (e.g. Bain 1956; Hofer 1975; Porter 1980; Hay & Morris 1991; Pehrsson 2009; Lutz & al. 2010). Robinson and McDougall (2001) have further emphasized in their research that product differentiation is the key barrier in terms of post-entry success measured by profitability.

2.2.1. Types of barriers to entry

A review into previous literature on barriers to entry from both theoretical streams led to the identification of 42 different types of barriers to entry. Even though many identified barriers have a relation to other types of identified barriers, these 42 barriers have been clearly distinct in previous research. Many identified barriers can be considered both structural according to the industrial organization view but also strategic in terms of incumbent influence on the height of the barrier. This would support the complementarity of the two views on barriers to entry. The identified barriers are listed in the following table giving a description to a barrier, with a brief description and studied literature sources.

Table 1 Barriers to Entry

Barrier to Entry	Description of the Barrier	Literature source
Absolute cost advantage	Entrants' average costs of producing are higher than the incumbents' average costs discouraging entry.	Bain 1956; Salop & Scheffman 1983; Shepherd 1997; Gaynor & Haas-Wilson 1998; Karakaya 2002
Access and control over strategic resources	Control over strategic resources implies that incumbents can hold the necessary resources from potential entrants, preventing them from entering the market.	Grant 1991; Shepherd 1997; Gaynor & Haas-Wilson 1998; Blees & al. 2003; Karakaya 2002;
Access to distribution channels	Incumbents can block access to distribution channels for the entrant, leaving them with inferior sales channels.	Porter 1980; Porter 1985; Robertson & Gatignon 1991; Karakaya 2002
Asset specificity	Because specific assets cannot be sold and converted, these assets impose high losses if the entry fails.	Williamson 1996; Shepherd 1997
Availability of skilled labor	Shortage of skilled labor leads to shortage in human capital which is necessary to run the operations.	Gerlach & Wagner 1994; Arend 2001; Blees & al. 2003
Brand	Buyer inertia may lead to a sort of monopoly situation instead of competition, forcing entrants to spend heavily to overcome the incumbents' strong brand.	Krouse 1984; Netter 1984; Gaynor & Haas-Wilson 1998; Karakaya 2002; Blees & al. 2003; Pehrsson 2009
Bundling	Bundling products or services together, makes it harder for an entrant with only one of these goods to enter the market.	Nalebuff 2004
Capital intensity of the market / Investment risk	Due to the perceived risk of financiers, the imcumbents will find it easier and cheaper to collect financing when needed than it is for the entrants.	Dixit 1980; Porter 1980; Demsetz 1982; Veendorp 1991; Kleiweg & Lever 1996; Karakaya 2002
Capital requirements	The need to invest large financial resources in order to enter a certain market - the barrier is especially high in capital intensive industries.	Bain 1956; Eaton & Lipsey 1980; Porter 1980; Harrigan 1981; Karakaya & Stahl 1989; Kleiweg & Lever 1996; Shepherd 1997; Matthyssens & al. 1998; Karakaya 2002
Causal ambiguity	Causal ambiguity can prevent potential entrants from learning from incumbents and the market because it makes it hard to understand the link between resources and competitive advantage.	Reed & Defillippi 1990; Mosakowski 1997; McEvily & al. 2000; Alvarez & Busenitz 2001; King & Zeithaml 2001
Costs of operating in foreign markets	Transaction costs posed to the entrant when entering a foreign market compared to domestic incumbents.	Barkema & al. 1996

Cultural distance	High transaction costs for foreign entrants due to different attitudes, preferences and ways of doing things.	Madsen 1994; Blees & al. 2003
Customer loyalty	Strong customer loyalty for incumbents' brands can create an asymmetry of costs between the incumbents and the entrants. Customer loyalty can also be communicated by incumbents to scare off potential entrants.	Robertson & Gatignon 1991; de Ruyter & al. 1998; Karakaya 2002; Blees & al. 2003; Pehrsson 2009
Customer switching costs	Incumbents have a degree of monopoly power over their repeat purchasers due to high switching costs - entrants would have to invest heavily to overcome such a barrier.	Farrell & Shapiro 1988; Klemperer 1992; Shepherd 1997; Karakaya 2002; Lutz & al. 2010
Divisionalization	Incumbents with several brands have synergies over costs of managing these brands in an asymmetry with new entrants with only one product line. Incumbents can also benefit from sharing of the company brand between divisions.	Schwartz & Thompson 1986; Veendorp 1991
Dynamic limit-pricing	The price can be set to the average cost of the most efficient potential entrant i.e. the limit-price that will deter entry by making the market unprofitable for entrants.	Bain 1956; Gaskins 1971
Economies of scale	The decline of production and distribution costs per unit of output leads to asymmetries of costs. Incumbents can also drive the prices below profitable levels for entrants by increasing supply.	Bain 1956; Modigliani 1958; Stigler 1968; Karakaya 2002
Excess capacity	Structural forms of plant under-utilisation as a result of cyclical demand or economies of scale will induce over-supply to the market and drive the prices down, making it an unattractive market for entrants.	Spence 1977; Harrigan 1983; Lieberman 1987
Exclusive deals with customers	Customer lock-in to a single supplier - Time-factor essential as in whether the deals will delay the sales potential.	Gaynor & Haas-Wilson 1998
Expected retaliation by incumbents	Both gathering adequate reactions to possible entrants and communicating credibly about expected retaliatory actions can keep entrants away from the market.	Robertson & Gatignon 1991; Gatignon & al. 1997; Clark & Montgomery 1998; Gaynor & Haas-Wilson 1998; Prabhu & Stewart 2001; Karakaya 2002
Gaps and asymmetry of information / Trade secrets held by incumbents	Entrant firms will not have all the industry knowledge at their use and might make incorrect decisions on their entry strategies based on that incomplete information (e.g. costs of entry).	Schmalensee 1982; Milgrom & Roberts 1987; Clark & Montgomery 1998; Prabhu & Stewart 2001; Karakaya 2002

Government licensing requirements	Transaction costs often build up to significant sums due to administrative burdens and internal and external bureaucracy barriers increasing costs of entry and delaying entry.	Hall 1992; Karakaya 2002; Blees & al. 2003
Government policies	Restrictive government policies can increase economies of scale, capital requirements and other potential barriers and favor the incumbents in relation to the entrants or even deter entry.	Porter 1980; Porter 1985; OECD 1994
Government subsidies	Subsidies to incumbents who could finance from their cash flow will increase the cost asymmetry between the incumbents and the entrants.	Karakaya 2002
High profit rates earned by incumbents	Incumbents will be very defensive over their above-normal profit margins.	Karakaya 2002
High wages for employees and managers	Incumbents can increase the industry wage rate, making entry very costly for entrants due to the relative labor-intensity of their operations and their lack of economies of scale.	Williamson 1968; Gollier 1991
Incumbent learning curves, experience, org. capabilities, know-how	The accumulation of tacit knowledge into the incumbent organization through time can be an important source of sustainable competitive advantage for incumbents through efficiency gains.	Spence 1981; Devinney 1987; Lieberman 1987; Hall 1992; Madhok 1996; Chi & Roehl 1997; Gaynor & Haas-Wilson 1998; Karakaya 2002; Lutz & al. 2010
Incumbents with proprietary technology / level of technology	The technological lead gives an advantage to incumbents as the entrants require large investments to reach the same level of technology advancement.	Karakaya & Stahl 1989; Karakaya 2002
Location	Location is an important determinant that can lead to structural cost disadvantages in relation to the incumbents if the entrants need to settle for a less than suitable location concerning the industry, or a more costly one.	Van Noort & Reijmer 1999
Marketing intensity	Marketing costs are sunk costs, and effective marketing requires a large minimum scale. High prevailing levels of marketing create additional cost for entrants that are fixed for each level of outputs - Large incumbents will have scale economies over small entrants, and thus their marketing cost per product sold will be lower than the cost per product of the entrant. Marketing can result in imperfect consumer information The need for entrants to spend heavily to countervail this unbalanced supply of information.	Harrigan 1983; Schmalensee 1983; Karakaya & Stahl 1989; Gaynor & Haas-Wilson 1998; Karakaya 2002
Packing the product space / product scope	With a wide selection of varieties to customers, the entry is less attractive for new entrants with new differentiated products.	Giraud-Héraud & al. 2003; Pehrsson 2009

Patents	Gives the owner a certain degree of market power for a limited period of time, limiting entry during that period.	Harrigan 1983; Shepherd 1997; Gaynor & Haas-Wilson 1998; Lutz & al. 2010; Duchene & Serfes 2012
Political resources/relations	Policy setting will favor incumbents, leaving entrants even more vulnerable.	Frynas & al. 2006
Product differentiation	A differentiated offering from an incumbent can deter entry by entrants through brand loyalty and high need to spend heavily. In addition, the incumbents can raise the prices to the limit price without losing customers.	Bain 1956; Schmalensee 1982; Karakaya & Stahl 1989; Shepherd 1997; Matthyssens & al. 1998; Pehrsson 2009
Rate of technological change	Too rapid technological change in an industry can make the industry unattractive to entrants concerning new investments and earning those back. Too slow rate would suggest slow uptake of new technologies making entry unattractive for entrants with innovative offerings.	Harrigan 1981
R&D expense involved in entering / R&D intensity	Continuous investments into R&D can create a strong barrier to entry for the incumbents.	Harrigan 1981; Karakaya 2002
Seller concentration	In a highly concentrated industry, the incumbents will have more power to adjust the market pricing and impose limit-pricing and other actions on entrants.	Bain 1956; Modigliani 1958; Mann 1966; Karakaya 2002
Selling expenses involved in marketing	High selling expenditures by incumbents may increase customer loyalty and increase customer-switching costs thus making entry less attractive for entrants. In case of entry, makes it very costly for entrants to compete.	Gatignon & al. 1997; Karakaya 2002
Special risk and uncertainties of entry	Considerably higher business and financial risk for entrants compared to incumbents raises both operational and transactional costs for the entrant.	Shepherd 1997; Hochberg & al. 2010
Sunk costs	Costs that cannot be recuperated but are needed to enter the market can be a significant barrier to entry, especially if the needed investment is significant.	Gaynor & Haas-Wilson 1998; Karakaya 2002
Transaction costs	High costs involved in market exchanges especially if there are many stakeholders.	Williamson & Ghani 2012
Vertical integration	If there is vertical integration present in the industry, to match up to the incumbents, the entrant needs to make more investments and a larger commitment.	Williamson 1996; Shepherd 1997

Karakaya (2002) suggested grouping of different types of barriers to entry, identified in the previous work by Karakaya and Stahl (1989), in his research on the importance of the barriers to entry for executives from a wide range of industrial firms. Based on the results of a factor analysis, four underlying dimensions were chosen as the grouping factors; Firm specific advantages, Product differentiation, Financial requirements of cost of market entry, and Profit expectation of entering firms. Using Karakaya's factors as the basis for grouping but taking into account the 17 additional barriers to entry that have been identified in this literature review, five categories are suggested for the 42 identified barriers to entry.

1. **Company specific advantages** – Specific advantages of the incumbents in the market that cannot be easily achieved or duplicated by entrants
2. **Customer/market-based advantages** – Advantages of the incumbents deriving from product differentiation, brand and customer loyalty
3. **Financial requirements or cost of market entry** – Barriers rising from the high capital requirements
4. **Profit expectation of entrants** – The potential post-entry profitability of the entrants affecting the entry decision
5. **Industry characteristics** – The barriers rising from the industry structures and from the conduct of the actors in the environment

The company specific advantages are very hard to overcome for the entering company. The results of Karakaya's (2002) study imply that the executives studied considered the company specific advantages to include the most significant barriers to entry. Customer/market-based advantages make entering difficult as customers are loyal to an incumbent and are generally unwilling to switch to a new product – especially in industries where the risk associated with purchase is high and transaction costs for the search of a new supplier are high. Financial requirements are linked to the costs of entry but also to the size of the investments required by the entrant to be able to

compete in the market. The profit expectations of the entrants can influence the entry decision significantly. There are also two sides to the attractiveness of the industry, on one hand the high profit margins are encouraging entry but on the other the incumbent companies are more likely to be very defensive towards new entrants in market with high profitability.

The importance of the barriers to entry also depends on the characteristics of the industry, including the industry structure and the conduct of industry actors. For instance, some barriers to entry are different in industrial markets compared to consumer markets, a factor very much related to the industry characteristics (Karakaya & Stahl 1989; Karakaya 2002).

Following categories have been built from the identified barriers to entry basing on and augmenting the categorization suggested by Karakaya (2002), taking the view of the entrant:

Company specific advantages – Absolute cost advantage; Access and control over strategic resources; Causal ambiguity; Divisionalization; Economies of scale; Exclusive deals with customers; Gaps and asymmetry of information/Trade secrets held by incumbents; Government subsidies; Incumbent learning curves, experience, organizational capabilities, know-how; Incumbents with proprietary technology/level of technology; Political resources/relations

Customer/market-based advantages – Brand; Bundling; Customer loyalty; Customer switching costs; Product differentiation

Financial requirements or cost of market entry – Capital intensity of the market / Investment risk; Capital requirements; Costs of operating in foreign markets; Cultural distance; Government licensing requirements; High wages for employees and managers; Marketing intensity; R&D expense involved in entering / R&D intensity; Selling expenses involved in marketing; Special risk and uncertainty of entry; Sunk costs; Transaction costs

Profit expectation of entrants – Access to distribution channels; Dynamic limit-pricing; Excess capacity; Expected retaliation by incumbents; High profit rates earned by incumbents; Packing the product space / product scope; Rate of technology change

Industry characteristics – Asset specificity; Availability of skilled labor; Government policies; Location; Patents; Seller concentration; Vertical integration

2.2.2. Relevance of categories of barriers by entrant size

In this chapter, the five groups of barriers to entry are reviewed according to their relevance for a small de novo entrant in relation to a large scale entrant with existing operations in another industry. As discussed in chapter previous chapters, the large entrants tend to have a more advantageous position when entering a market, largely due to their existing resources and capabilities (Grant 1991; Robinson & McDougall 2001; Blees & al. 2003; Pehrsson 2009; Lutz & al. 2010).

Blees and al. (2003) have studied the relevance of some barriers to entry from previous literature based on the size of the entrant. In their research they have concluded that over 40 percent of the studied barriers are specific to small entrants whereas only 8 percent could be considered as specific to larger entrants. Half of the barriers were considered as barriers to both.

The barriers relevant for larger entrants all relate to the profit expectation of entrants; dynamic limit-pricing, excess capacity in the market and expected retaliation by incumbents are all factors that affect the potential profits in the market and thus would largely affect the entry decision for the larger entrants. The large entrants will benefit from their existing channels and relations through operating in other markets, and can usually encounter economies of scale far earlier than small companies. The large entrants

might also be able to divisionalize on their own, spreading the economic and business risk across a group of operations, not having to support the costs of entry to a new industry with outside financing but operate it from the cash flow from other operations. Thus the risks related to entry can be much lower for larger companies than they are for the small.

When looking at the smaller entrants, the barriers to entry rise from all five groups of barriers with a significant emphasis on the financial requirements/cost of entry. The study would indicate that over 50 percent of the small entrant specific barriers would fall under this category of barriers. Thus, the financial requirements and the cost of entry could be considered a major factor deterring small company entry. Concerning the barriers relevant for both entrants, large and small, the weight is on the company specific advantages of the incumbents vs. the entrants and on the industry characteristics, with these two groups making up almost 70 percent of the relevant barriers independent of size. This finding could implicate that these two groups are the "generic" barriers to entry independent of the entrant characteristics that could only be influenced by the incumbents and the governments.

Relevance of category of barriers for	**Large entrants**	**Small entrants**	**Both**
Company specific advantages	0 %	7 %	39 %
Customer/market based advantages	0 %	13 %	11 %
Financial requirements/cost of entry	0 %	53 %	17 %
Profit expectation of entrants	100 %	13 %	6 %
Industry characteristics	0 %	13 %	28 %

Table 2 Relevance of categories of barriers to entry by entrant size
(Adapted from Blees & al. 2003)

2.2.3. Influencing the barriers to entry

In this section, the categories of barriers to entry are discussed in relation to the incumbents, entrants and governments and their power to influence the existence and height of the barriers. Earlier literature on the subject has indicated that the conditions for entry are different depending on the size of the entrant largely due to the limited resources and lack of existing capabilities of smaller entrants (e.g. Gaynor & Haas-Wilson 1998, Robinson & McDougall 2001, Blees & al. 2003; Pehrsson 2009; Lutz & al. 2010). The entrants generally lack market power to be able to have an effect on the current competitive position in the industry (Gaynor & Haas-Wilson 1998; Pehrsson 2009). Sadly, as discussed in the previous chapter, most types of barriers to entry are specific to small companies.

Previous literature has mainly focused on the view of the incumbents and on their strategies on blocking new competition (Robinson & McDougall 2001; Pehrsson 2009; Lutz & al. 2010). In the same line, the potential to influence the barriers has largely focused on the incumbents' actions and has ignored the view of the entrant. In addition, the structural characteristics of the industry have largely been accepted as factors that cannot be changed either by the incumbents or the entrants but the role of the government has been dismissed. One of the objectives of this thesis is to study the phenomenon from a triangular point of view, taking into account firstly the entrant and the entrant's chances to influence the height of the barriers, secondly the incumbents and their power to influence the barriers, and thirdly the role of the government in terms of the structural barriers in an industry.

One of the few studies conducted on the influencability of the barriers to entry have strongly indicated the powerful position of the incumbents as the creator and raiser of most barriers (Blees & al. 2003). In their study, Blees and al. (2003) indicated not only that the incumbents would have the most chances to affect the creation and the height of barriers to entry but implied that a large number of barriers would be structural and could not be affected

by the incumbents, the entrants nor the governments. These 'uninfluencable' barriers make up for 36 percent of the barriers to entry identified in the study, most falling in the categories of company specific advantages, financial requirements/cost of entry and industry characteristics. The great number of barriers that according to the authors could not be influenced by any of the three actors is affected by the short-term view of the study in question. The researchers only took into account the barriers that could be influenced by one of the actors at *the point of entry* and not the longer term influence of the actors' behavior on the industry. As indicated by other studies (Hermans and al. 2009; Friedman & Taylor 2011), the government policies will have an effect on the industry structure that will over time change and affect the conduct of the actors and change the industry characteristics and dynamics. The study still does serve as an indication of the unbalanced power divide between the actors and especially the strong position of the incumbents as gate keepers to a market with only little chances for the entrants to influence the barriers. The incumbents influence sums up to 41 percent in total across all the identified barriers whereas the entrants would only have the chance to influence 2 percent of the barriers.

	Incumbent	Entrant	Government	None
Company specific advantages	22 %	0 %	22 %	56 %
Customer/market-based advantages	50 %	17 %	17 %	17 %
Financial requirements/cost of entry	33 %	0 %	17 %	50 %
Profit expectation of entrants	75 %	0 %	13 %	13 %
Industry characteristics	33 %	0 %	33 %	33 %
Total weighted influence:	**41 %**	**2 %**	**20 %**	**36 %**

Table 3 Influencability of categories of barriers by actor
(Adapted from Blees & al. 2003)

2.2.3.1. Incumbent influence

The incumbents' power to influence the barriers to entry is closely linked to the market power of the incumbents in the market. According to the industrial organization view, a company needs to be large enough to be able to affect the capacity in the market and be able to affect the market price through its actions (Bain 1956, Stigler 1968). Porter's strategic management view (1980, 1985) discriminates less on the company size but does note that large companies have many benefits as their strategic actions are more likely to have an influence on the industry structure and conduct than those of the smaller companies and they are likely to have accumulated a large resource-base that they can exploit in their strategies (Grant 1991; Blees & al. 2003). From both theoretical points of view, the incumbents are the most significant actors in relation to the barriers to entry. Later research on barriers to entry has offered support to this view (e.g. Robinson & McDougall 2001, Blees & al. 2003; Pehrsson 2009; Lutz & al. 2010).

As noted in the previous chapter, the incumbents have a strong chance to influence all five categories of barriers to entry. The means differ by industry and company size. Many advantages of the incumbents relate to different types of first-mover advantages (Harrigan 1981, 1983; Lieberman & Montgomery 1988). Getting to the market first, will allow the company to get ahead of the later competition and create very sustainable barriers affecting the industry structure. The incumbents can block distribution channels, affect the marketing intensity of the industry, build a strong brand and create intense customer loyalty and also be sure to communicate their powerful position in the market to potential entrants, affecting their judgment of the profit potential in the market (e.g. Schmalensee 1982; Karakaya & Stahl 1989; Shepherd 1997; Matthyssens & al. 1998). In addition, they are able to gain economies of scale and other cost advantages (Bain 1956; Stigler 1968). According to Gaynor and Haas-Wilson (1998), raising the costs for the entrants is one of the most efficient ways in which

incumbents can deter entry. The potential to affect the industry structures is more evident in oligopolistic markets where the few large incumbents usually have much power over the other actors in the industry value chain (Harrigan 1983).

Through their strategies, the incumbents can affect the consumer expectations on the product attributes in the market, can raise switching costs for the customers and affect the industry profit margins, making the potential entry costly and unattractive for entrants. One major aspect is also the control over resources in an industry – not only in terms of raw materials, machinery and other material resources but also in relation to immaterial resources, knowledge and other capabilities that will be very costly for an entrant to acquire, falling behind in competition (Grant 1991; Karakaya 2002; Blees & al. 2003; Pehrsson 2009; Lutz & al. 2010).

Fear of retaliation by incumbents is a strong discouraging factor in the market entry decision by an entrant. According to Robertson and Gatignon (1991), the incumbents will have four choices on how to react to a new entrant. Firstly, they can abandon the market themselves if the new entrant would have sustainable competitive advantage over the incumbents. Secondly, they could accommodate the new entrant by allowing the industry to change through innovation and more competition. Thirdly, they can choose to ignore the entrant in case the entrant is deemed harmless. As a fourth option, the incumbent may choose to retaliate, signaling to the new entrant that it is willing and powerful enough to fight back. Previous research has shown that retaliatory actions are usually successful, especially when the incumbents are large and have a strong position in the market. Sometimes even convincing signaling about the expected retaliation is enough to keep the competition out of the market as the entry decision cannot be based on actual retaliation due to imperfect information but rather on the expected one (Thomas 1999).

Porter (1985) summarized in his research the three defensive strategies and tactics for the incumbents. These include the raising of structural barriers, increasing the expected retaliation, and lowering the inducement for attack. The strategies geared towards these goals are summarized in Figure 3 below.

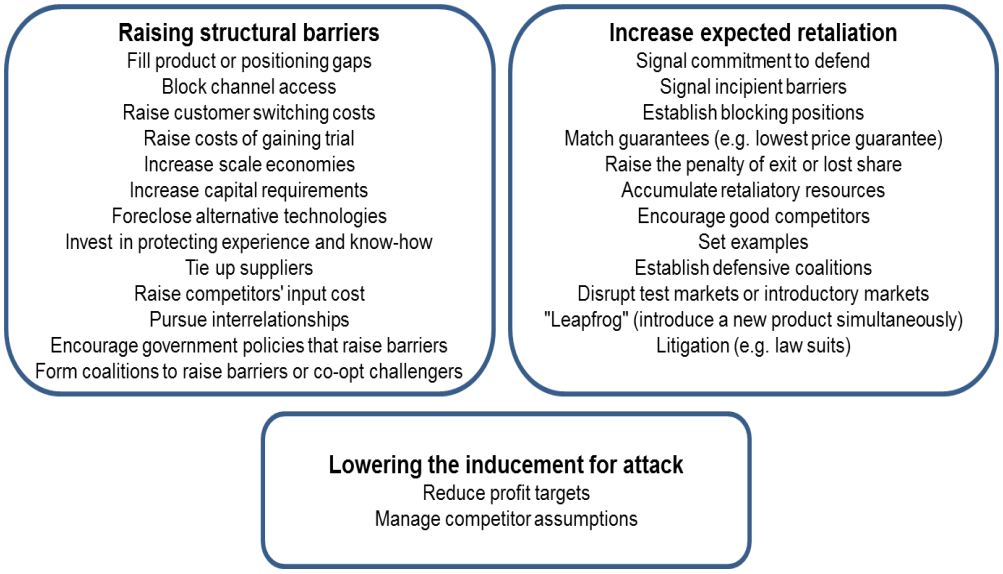


Figure 3 Defensive incumbent strategies
(Adapted from Porter 1985)

Both the raising of many structural barriers and the increasing of expected retaliation would lead to significant added costs for the entrants thus affecting the financial requirements/cost of entry category which is the most relevant for new entrants. As a summary, the previous literature is well aligned with the powerful position of the incumbents and their potential to influence the barriers to entry. The effect is even more pronounced in consolidated markets where the incumbents are large.

2.2.3.2. Entrant influence

The previous literature on barriers to entry has mainly focused on the incumbents and on their strategies for deterring entry from new competition. Much less focus has been given to the entrants (e.g. Robinson & McDougall

2001; Porter 2008; Pehrsson 2009; Lutz & al. 2010). The entrant's influence on the barriers can also be defined as 'breaking' or 'tackling' the barriers to entry. There are many indications in earlier research confirming that the entrants are in an asymmetrical position in relation to the incumbents and do not have many chances to influence the entry barriers created by the incumbents. Overcoming any of the barriers is very costly and time-consuming and in case of a *de novo* entrant, both are on short supply (e.g. Cabral & Mata 2003). Previous research indicates that the entrant should first be able to overcome the absolute cost disadvantage for instance by developing new, more efficient production technologies or finding innovative sales and distribution channels that have not yet been blocked (Blees & al. 2003). Only after solving the initial cost disadvantage, the entrant would have any chance of entering a market – a notion especially true in capital or production intensive industries. Recent research has also supported the implication that the entrant's innovativeness can decrease the capital needs and help in product differentiation (Han & al. 2001; Pehrsson 2009).

Fan (2010) has developed the idea of *arch incumbency* in his paper, implicating that a large market overlap of the entrant with an established incumbent has detrimental effects on the chances for survival on the new entrant. Other research has in addition shown that due to the lack of prior experience on the market, the *de novo* entrants are much more likely to face retaliatory actions from incumbents than other incumbents diversifying from another industry (e.g. Lieberman 1987; Simon 2005). According to the findings, this is largely related to the resource base and size of the entrant as there is also a cost involved in retaliating. Incumbent retaliation towards small *de novo* entrants can lead to pushing the new entrant out of business with fairly moderate costs for the incumbent and also discourage potential additional attempts of entry.

The concept of *arch incumbency* can be beneficial to the entrant as according to Fan's (2010) argument, entry forbearance from the arch

incumbent will likely lead to the acceptance of entry from other incumbents, too. He goes on to suggest that there are two potential strategies for the entrant to escape from retaliatory strategies displayed by the incumbents and thus increase its chances of survival. Adopting a different market positioning from the arch incumbent will likely lead to the chance of "going under the radar" and decreasing the possibility that the incumbent would consider it worthwhile to defend their position in the market. Focusing on a market niche, providing differentiation or adopting a low-cost strategy in opposition to the arch incumbent's strategy can increase the chances for survival for the small entrant. Another potentially successful strategy would be an aggressive large scale entry. Vis-à-vis the incumbents, the entrant might through this strategy signal that it has sufficient resources to fight back, implicating that the cost for any retaliatory actions would be high for the incumbents.

Blees and al. (2003) have suggested that the brand name barrier is the only one that can be lowered by the entrants' actions. Even that would require significant spending on advertising and selling.

Thus, the entrant is left with little power over the barriers to entry and in most instances can only hope to be able to jump over some of the barriers through formulating innovative strategies and ways of doing things that would catch the current industry status quo off guard, many times referred to as radical innovations that would change the industry structure and conduct (e.g. Chandy & Tellis 2000). Incumbents rarely are responsible for the industry changing innovations, strongly related to their unwillingness to cannibalize their own investments (Chandy & Tellis 1998) and their lack of strategic agility (Friedman & Taylor 2011). Still, the current research strongly suggests that only the incumbent strategies have the potential to affect the structural barriers to entry and the power to create strategic barriers to entry (Pehrsson 2009).

2.2.3.3. Government influence

The policy decisions that the government makes have a long term influence on the barriers to entry in an industry. As Demsetz (1982) defined it, the question for policy makers in relation to barriers to entry should be to focus on which costs for entrepreneurs are socially desirable, leading into higher social welfare. For long, the focus has been too narrow, only looking at the costs of physical outputs for the industry incumbents and has neglected the implications of current policy setting for future incentives for innovation. Some authors also note the important role of the government as certain structural and strategic barriers in an industry can only be affected in the long run through policy decisions (Blees & al. 2003; Friedman & Taylor 2011). These policies will in the long run determine the incentive for new entrepreneurs to innovate and try and enter an industry. Thus, they suggest that governments wishing to create an innovation friendly environment should focus on policies which will lower the structural and strategic barriers in an industry for new, small, innovative companies. High entry rates are also correlated with innovations and increases in production efficiency for the industry as a whole (Friedman & Taylor 2011). As birth and growth of new companies is the force keeping an industry competitive, leading into increased social and economic welfare (e.g. Porter 1990; Shaffer 1995; Blanchard & Giavazzi 2003; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012). New companies are also mainly responsible for innovations in a given industry and are almost solely the ones responsible for radical, industry changing innovations (e.g. Schumpeter 1939; Audretsch 2001; Friedman & Taylor 2011).

Edler and Georghiou (2007) have introduced a taxonomy of innovation policy tools for governments. The more traditional focus has been on the supply-side measures, including tax incentives, government support and funding for research and development and public sector research, training programs, networking and information diffusion support. In the recent years it has been noted that demand is a major driver of innovation but demand-

side measures have still not been recognized in public policies. One crucial side is state procurement, especially in industries where the public sector is a significant customer. Earlier research has shown that public procurement geared towards innovative solutions, creates even greater innovation incentives and in more areas that the traditional measures such as R&D subsidies, being a significantly more efficient innovation stimulus than any government subsidies (e.g. Geroski 1991; Edler & Georghiou 2007; Cullman & al. 2012). Focusing public procurement towards innovative solutions, the delivery of public services should improve also generating more positive innovative dynamics and creating a foundation for an innovation friendly environment (Edler & Georghiou 2007).

The positive influence of public procurement is three fold (Edler & Georghiou 2007): Firstly, public procurement forms a major part of local demand in many industries stimulating innovation and enhancing the competitiveness in an area (Porter 1990), also offering much needed references for small companies. Secondly, asymmetries between the incumbents and small entrants rising from various reasons such as information asymmetries between the suppliers and the purchasers can be mitigated through public procurement, also helping small companies to reach a critical mass for innovations and help them reduce market risks, and enable learning and reaching economies of scale sooner. Thirdly, the public infrastructure and public services in general would benefit from innovation procurement through translating needs from the market to clear market demands and serving as an innovation lever linking public and private demand.

Governmental authorities should set policies that would enhance the competitiveness of industries and companies within to simultaneously advance the social and economic conditions of the areas they operate in (Porter & Kramer 2011). A specific measure has been different anti-trust policies, with the aim of ensuring a level of competition in an industry, but governments should understand that they can also affect the strategic

barriers to entry, lowering the asymmetries between the incumbents and the entrants by e.g. limiting or expanding access to critical resources, creating distribution channels and ensuring channel access through policies, decreasing customer switching costs by prohibiting incumbents from creating costs for switching a supplier (Blees & al. 2003). Constant vigilance is also needed as the incumbents will find clever new ways to block entry for entrants (Hermans & al. 2009, 117). Thus most of the barriers deemed uninfluencable by either party (entrants, incumbents or governments) at the point of entry, can actually be influenced by governments in the longer term, not having to accept the structural characteristics of an industry as set (Blees & al. 2003; Friedman & Taylor 2011).

In the following chapter, a brief literature review on the prior research on regulation of entry is presented.

3. Regulation of Entry

The regulation of entry refers to the number of procedures, the time and the cost that a new company must go through and bear before it can operate legally in a territory (Djankov & al. 2002). These can include different licenses, permits or registrations that differ by the industry depending on the industry specific regulations. Some of the most common regulatory procedures are listed in Appendix 1.

Even though many studies have shown that regulation often has asymmetric effects on the market competition and allows for incumbents to create a strong protective position in the market in relation to potential entrants (e.g. Leone 1986; Friedman & Taylor 2011), the macroeconomic consequences of regulation have long been poorly understood (Friedman & Taylor 2011).

In this chapter regulation of entry is evaluated in terms of its social welfare and efficiency consequences, and through its effect on industry structure, market conditions, and competition.

3.1. Regulation of Entry and Social Consequences

These official costs of entry are very high in most countries but in reality represent only a small fraction of the total costs for entry for a *de novo* venture company. Reaching the license to operate is the first hurdle to entry has a significant effect on the industry structure, competition, and on firm-level on profitability (Shaffer 1995). In addition, regulation has social consequences for the public due to its detrimental effects on industry competition (Porter 1990; Shaffer 1995; Blanchard & Giavazzi 2003; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012).

Government regulation and legislation can often raise entry barriers and lead to favorable conditions for the incumbents (Shaffer 1995). The incumbents in an industry seek for beneficial legislation and regulation to

enhance their position vis-à-vis other industry actors and to protect themselves from potential entrants through what has been labeled as "strategic use of public policy" (Mitnick, 1981, Wood 1986).Companies can advance their political interest for instance by scanning the environment and selecting the markets to enter based on their political conditions, by lobbying, through political action committees or by building coalitions to mention a few (Shaffer 1995).

The rationalization for the need for the government to act in a role of a regulator has been based on the theory of public interest. Pigou's (1938 in Djankov & al. 2002) theory of regulation suggested that unregulated markets would be doomed to frequent failures and for social efficiency purposes, the government should pose regulation to protect the public from these failures. The government's role is to ensure that new companies would meet set minimum standards for the provision of goods and services. To achieve this, the companies would need to register and acquire an official approval, signifying good repute in transactions with the public and other companies (Djankov & al. 2002). According to the theory, a higher number of government regulations should lead to superior social welfare.

Later studies have focused on the effects of regulation on the industry competition and the outcomes and are defined as the public choice theory (Tullock 1967; Stigler 1971; Peltzman 1976). The variants of the public choice theory see the inefficiency of Pigou's public interest theory and have opposed the idea of regulation leading to social welfare by arguing that regulation is actually acquired by the incumbents in an industry for purposes of creating barriers to entry for new competitors and for increasing the profits for the incumbents. Due to stricter regulation leading to risen barriers to entry for new companies, the incumbents are left with greater market power and higher profits, with the social welfare decreased with higher prices and reduced consumer choice (Djankov & al. 2002; Schivardi & Viviano 2010; Friedman & Taylor 2011; Cullman & al. 2012; Prantl 2012). Thus regulation leads to social and economic inefficiency.

An additional view to the public choice theory, labeled the "tollbooth view" (McChesney 1987; Shleifer and Vishny 1993), argues that as well as the incumbents in the industry can use regulation to promote their own purposes, so do the politicians and bureaucrats. Politicians are willing to work in sync with the industry incumbents as they are able to extract campaign contributions, votes, bribes and support from the industry actors. Shleifer and Vishny (1993) have gone as far as suggesting that an important reason for the whole existence of permits and regulations is to give the officials the power to deny them and to collect brides for returning them. Thus the two views of the public choice theory are aligned with regulation leading to a significant decrease in social welfare and efficiency. In addition, both theories lead to favorable conditions to current industry status quo, leading to inferior treatment for new entrants, presenting the entrants with incomprehensible delays or a multitude of severe obstacles requiring large pay-offs to be overcome (Djankov & al. 2002).

The effects of regulation in a market have also been theorized. Blanchard and Giavazzi (2003) showed that the deregulation of the product market would lead to a lower price of goods and reduced barriers to entry, also creating new jobs and decreasing unemployment. In an indirect effect, it should also facilitate deregulation in labor markets. Felbermayr and Prat (2011) extended the findings by linking high unemployment to high costs of entry due to strict regulation. Shaffer (1995) modeled how the deregulation of price and entry in an industry would lead to positive social consequences by improving economic efficiency and consumer welfare, and elimination entry barriers at firm level. Herrendorf and Teixeirai (2011) argued that strict regulation leads to high barriers to entry which is a statistically significant explanatory factor in the development of countries, hindering both economic and social development. In addition to these studies, scholars agree that regulation is a key component behind structural barriers hindering competition and deterring entry (e.g. Djankov & al. 2002, Blanchard & Giavazzi 2003; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012).

As the previous literature has argued, regulation will not only lead to decreased social welfare and efficiency consequences but also to an asymmetric industry structure and to injured competition, especially in industries governed by high levels of regulation such as in the medical, automobile, telecommunications, and electric power industries. In the next chapter the characteristics of a highly regulated market are discussed.

3.2. Regulation of Entry and Industry Effects

The industry structure is a combination of many factors such as the number of companies, the nature of competitive environment, cultural, judicial, and political systems – and the government regulation either directly or indirectly affect each of these pieces (Hermans & al. 2009). The government's task is to determine which interventions and policies will in the longer term become net efficiency enhancing for increase social welfare and which ones will lead to market power enhancement and loss of social welfare (Gaynor & Haas-Wilson 1998, Friedman & Taylor 2011). These decisions can have far-reaching effects as governmental regulation in terms of policies and different interventions in an industry has a direct effect on the industry structure, often leading to oligopolistic structures and consolidation in the market (Blees & al. 2003; Hermans & al. 2009; Friedman & Taylor 2011).

Once the government wishes to shape the current industry outcomes and puts policies and laws into force that will lead to a restructuring of the industry. The changed structure will have an effect on the industry conduct i.e. on how the actors in an industry will act and how will they interact, leading to different competitive strategies by the companies in the industry. Industry actors can also affect the structure of an industry by changing their conduct, for instance through mergers and acquisition, or vertical or horizontal integration, often leading to consolidation and to higher barriers to entry (Gaynor & Haas-Wilson 1998). Such changes in industries have often been the consequences of fallen industry profitability and

performance. Thus, the industry structure and conduct will have an effect on the industry performance. Closing the circle, the industry performance will lead to different macroeconomic outcomes for societies. Whether the outcomes will be positive or negative concerning social welfare, is dependent on how the industry has reacted through its structure and conduct to the changes in the government regulation and whether the changes in the industry have led to a net efficiency gain or only to an increase in market power. (Hermans & al. 2009) Thus the economics of consolidation in an industry and the loss of competition is strongly related to social welfare and governments should be very aware of the far-reaching potential industry consequences of the regulations they pose (Gaynor & Haas-Wilson 1998; Blees & al. 2003; Hermans & al. 2009; Friedman & Taylor 2011).

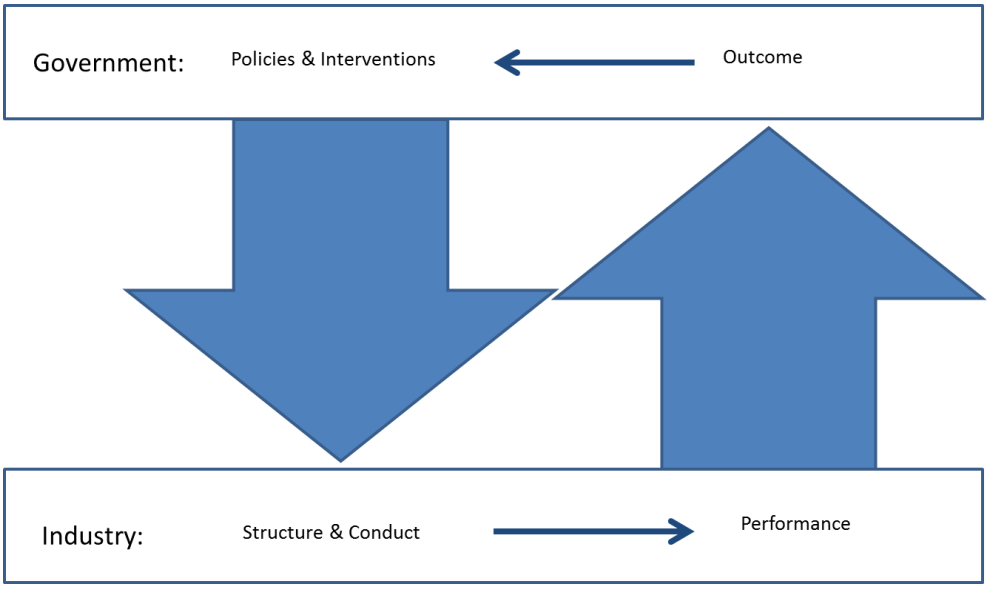


Figure 4 Government regulation effect on Industry
(Adapted from Hermans & al. 2009)

The impact of the barriers to entry does not only have implications to the loss of competition leading to improved profitability and market power for the industry incumbents but to higher prices and loss of social welfare for the public. In addition, Bertrand and Kramarz (2002) have argued in their research that high barriers to entry in addition to high levels of concentration in an industry are significant factors in the slow employment growth in Europe during the last decades. They criticize the thinking that the

simple reform of the labor markets would lead to improved job creation when governments should actually focus on eliminating entry regulation and barriers to entry to generate employment growth on sustainable basis (Bertrand & Kramarz 2002).

3.3. Regulation and Innovation

The birth and growth of new companies is an important prerequisite for wealth creation and quality of life (Birch 1987; Kirchhoff 1991; Hitt et al. 1999; Robinson & McDougall 2001) and by ensuring competitiveness in an industry, it can help in avoiding the negative social consequences of high consolidation in an industry. According to Schumpeter (1939), the industry incumbents are rarely driven to innovate but innovations primarily emerge from new companies. More recent studies have confirmed the continued validity of Schumpeter's research and labels the entrants as change agents responsible for bringing innovations to market (Chandy & Tellis 2000; Audretsch 2001; Friedman & Taylor 2011). Innovation is a number one driver for growth and a key factor in ensuring a nation's global competitiveness (Porter 1990).

According to Porter's (1990) Diamond Model, the innovation intensity is dependent on four key conditions: Factor conditions, demand conditions, related and supporting industries, and market structure. Porter argues that spatial competitiveness can be achieved through ensuring that there four factors are aligned to support innovating in an area. His argument goes that the interaction of highly specialized resources, sophisticated customers, internationally competitive supporting industries and intense domestic competition are the antecedents for innovation and the international competitiveness of a country Porter (1990). In highly regulated markets, the whole industry has been consolidated to serve the goal of higher profits and larger market shares and the innovation promoting structures, especially competition forcing companies to innovate to stay ahead, are largely

missing. As discussed in the previous chapter, the government regulation has a strong impact on the industry structure and conduct with also far-reaching effects that were unforeseen at the time of the regulation setting. High government regulation has been shown to lead to consolidated structures and low incentives for innovation, with incumbent companies rather focusing on building even higher barriers to entry than on innovation (Schumpeter 1939). Furthermore, high barriers to entry might discourage new companies from entering the market which might have a negative effect on competition and on the whole dynamics of the market, resulting in more consolidation. This in turn often will lead to higher prices for the public and to low rate and quality of innovation (Gaynor & Haas-Wilson 1998).

Government interventions on structure and conduct through actions such as price limiting are usually driven out of the short-term need for cost-cutting without taking into account the long-run influence on innovation (Hermans & al. 2009). Once the industry matures, the competition becomes more rigid and economies of scale become more important (Robinson & McDougall 2001). Industry restructuring for higher efficiency leads to high consolidation and higher barriers to entry for new entrants – the ones who are responsible for most innovations – and the rate of innovation in an industry withers (Gaynor & Haas-Wilson 1998). Introducing innovation to an industry will not only benefit the innovating company but the spill-over effects of learning and technological improvements can benefit the whole industry or even a country or a region (Edler & Georghiou 2007).

Economic theory and earlier research suggest that governments seeking to promote innovation and to build innovation-friendly environments for new companies to prosper in, should focus on the longer-term effects of the regulations on the industry. In addition, as innovation is largely driven by competition, the government should seek to lower the barriers to entry for new companies (e.g. Friedman & Taylor 2011).

According to Blees and al. (2003), entrants have two important functions to perform in an industry; entrants serve as equilibrating and disequilibrating factors. First of all, the profit levels in an industry will, according to economic theory, rise above long-run competitive levels in time, attracting new companies to enter the market. Once the new companies will enter, the profits should decrease to a long-run competitive level as a result of a balancing act created by the entrants. In this scenario, the entrants serve as the equilibrators in an industry. Secondly, the entrants serve as agents of change, being responsible for bringing new innovations to market (Audretsch 2001) and driving the incumbents to change and innovate due to the threat they pose. Thus, smaller companies are rarely created to imitate large incumbents but to serve as change agents through their innovative activities. In this scenario, the entrants serve as the disequilibrators in an industry (Audretsch and Mata 1995).

In freely functioning markets, the constant threat of disruptive innovations from new companies *should* work as incentive to innovate for the incumbents. In regulated and consolidated markets the mechanism is often sadly broken making it easier for the incumbents to focus on finding new ways to block entry for the innovative new companies than to innovate themselves (Hermans & al. 2009, 117). Thus the regulation leading to consolidation has a crippling effect on both the creation of new companies and on the rate of innovation and change in an industry. Without the equilibrating and disequilibrating effects, the market will not function at its optimal state, with allocative and dynamic efficiency (Blees & al. 2003). Due to the detrimental effects on industry dynamics and economic welfare, the main goal of competition policies in recent years has been the lowering of barriers to entry and preventing them from arising (Burke and To, 2001).

The barriers to entry are still very present in many industries, with the highly regulated industries as prime examples. In the next section, an overview of the previous literature on market entry and the barriers to entry is reviewed.

4. Synthesis of the literature review

In this literature study, the previous research on barriers to entry has been reviewed, especially to understand the antecedents for the industry structure of highly regulated markets and to study the role of different actors in the industry environment, namely the entrants, incumbents and governments.

The previous literature and economic theory understand that the creation and growth of new companies is essential to economic welfare (e.g. Hitt et al. 1999; Robinson & McDougall 2001) but still the survival odds for small companies are very low due to high barriers to entry (e.g. Porter 1980; Yip 1982; Geroski 1991) especially in regulated industries (e.g. Djankov & al. 2002).

Earlier research on the subject has focused on the point of view of the incumbents and on the strategies to defend their market positions in keeping new entrants out of the market (Porter 1979; Robinson & McDougall 2001; Porter 2008; Pehrsson 2009; Lutz & al. 2010), leaving the implications of barriers to entry for the entrant an important, yet understudied field. Understanding the implications of regulation on the industry structure and on the barriers to entry for entrants is vital for new entrants to be able to make more enlightened choices on the strategies and modes of entry, to ensure that innovation and new competition can enter and survive even in regulated industries. Ensuring competition in an industry through the entry of new companies will affect the rate of innovation in an industry and lead to increased social welfare for societies as a whole (e.g. Shaffer 1995; Blanchard & Giavazzi 2003; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012). As this literature review has suggested, unfortunately the current regulatory measures often do not serve their purpose but often lead to oligopolistic structures and consolidation in industries, promoting the current status quo favoring the incumbents over entrants.

In chapter 2, the 42 barriers to entry identified from previous research are gathered and categorized, based on the source of the barrier. The chances to influence the barriers are very few for the entrants and great many for the incumbents. Also the role of the government is discussed as the government has an important role in affecting the long term developments in an industry and can promote innovation friendly structures through policy setting keeping in mind the longer term consequences of such policies. Public procurement through demand-side measures geared towards innovations is one example of governments' means to lower the barriers to entry and support small company creation and balance the asymmetries between the incumbents and the entrants in an industry.

As discussed in the previous sections, barriers to entry can influence the industry profitability levels and the competitive structure significantly. In industries where the barriers to entry are high, consolidated and often oligopolistic structures are likely to form, decreasing competition in the market and leading to decreased economic and social welfare, and a lower rate of innovation (e.g. Shaffer 1995; Gaynor & Haas-Wilson 1998; Bertrand & Kramarz 2002; Blanchard & Giavazzi 2003; Blees & al. 2003; Hermans & al. 2009; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012).

As the previous theories have suggested a strong link between high regulation and high entry barriers, it is assumed that the barriers to entry for de novo entry in the health care industry would be a significant deterring factor. In addition, as the previous research suggests that the entrants have only very little chance of tackling the barriers to entry and only in very costly manners, the theoretical assumptions would deem entry by a small de novo entrant into the highly regulated and consolidated health care industry extremely difficult as the entrant would be imposed not only to high structural barriers but also to a variety of strategic barriers created by the strong incumbents in the industry.

Building on this literature review, an empirical section will follow in which a small company seeking to enter a highly regulated health care industry with an innovative offering is studied and through a case study structure the current academic understanding of the barriers to entry for *de novo* entrant in a regulated industry is extended and the entrant's chances of tackling the barriers to gain entry are examined. The case study takes the point of view of the entrant, seeking to add to the current understanding of the types of barriers to entry for the new entrant in an industry that is defined by much consolidation and very high barriers to entry. New knowledge is built by studying the history of the company and its struggles with different barriers to entry and the ways in which it has tackled these barriers to be able to break into the market. In addition, the role of the government as the regulator but also as an actor seeking to support growth and competitiveness leading to increased social welfare in an area is studied and implications are drawn to policy makers from studying the influence of different policy measures on the case company.

PART III – EMPIRICAL CASE STUDY

This section of the thesis introduces a case study on a *de novo* venture company, seeking to enter a highly regulated health care market. The aim of this section is to study the empirical reality concerning the barriers to entry in a regulated industry and especially identifying the barriers for a de novo entrant in a regulated setting and studying how can it tackle these barriers with limited resources. In addition, the role of the government in its dual role as a regulator but also as a supporter of new innovations in an industry is discussed.

The case study builds on the findings of the literature review and adds new knowledge to the current body of research by studying the empirical reality on barriers to entry for a small *de novo* entrant in a regulated industry. At the end of the empirical case study, the findings of the case study are discussed in comparison with the theoretical background.

5. Research methodology and approach

In this section, the research methodology used in this study is presented and the data collection methods are reviewed. In addition, the reliability and validity of the study are discussed.

5.1. Methodology

The study in question will utilize a case study as a research strategy. The justification of the method choice relies on work by Yin (2003), who argues that the selection of research method should depend on three criteria: the type of research question, the level of control that investigator has over the actual behavioral events and the degree of focus on contemporary as opposed to historical phenomena. Within these criteria case studies should

be preferred as the research strategy when the study is mainly answering to questions “how” or “why”, when the investigator has little control over events under the study and when the focus of the study is on a contemporary phenomenon within some real-life context (Yin, 2003). As the main research question of this study is to examine ‘how’ de novo venture companies can tackle the barriers of entry they face, that in addition is a phenomenon in a real-life context that has not been adequately studied previously, case study is the chosen method for this study.

Eisenhardt (1989) has developed a structure for conducting case studies. She argues that one of the strengths of the case study approach is its likelihood of leading to the generation of novel theory that is one of the research aims of this study. Building on the literature review, the empirical reality is studied in order to add to the current knowledge on the importance of the identified barriers to entry for small scale de novo entrants in a regulated industry and generate new theory on the chances for the entrant to influence the barriers to entry. In addition, the role of the government is studied and the findings are mirrored to the current body of literature.

Following Yin’s (2003) typology of the case study method, this study is explanatory in nature, with the aim of testing theories by identifying and explaining causal relationships of this new target phenomenon. This study also has some exploratory characteristics that refer to gathering of information and generating new theories on new and unexplored phenomena.

Firstly, the study aims to shed light on how companies with limited resources are able to break the barriers to entry in a highly regulated industry. Secondly, through combining current research knowledge and building from the practices of the case study company in question, this study has the aim to provide new knowledge on the market entry strategies of small companies with limited resources trying to break through the high regulatory barriers. Thirdly, the influence of the government policies on

these barriers to entry is examined and implications for future entrants and policy makers are introduced.

The unit of analysis of the study is how the case company tackles the barriers to entry they face to enter into the medical device industry that is one of the most highly regulated markets globally. As the case company is a small *de novo* venture company with limited resources, according to current theory, it has little chance in influencing the barriers to entry but the case study questions how it has still been able to break into the market through strategies and tactics it has exploited to tackle the obstacles. These means of tackling the barriers to entry are of specific interest in this study. From identifying these strategies used and building theory from these strategies, this study seeks to gather new knowledge on a market entry to highly regulated markets that would benefit small companies and any company with limited resources. Also, by contrasting the findings of the case study to current theory on market entry, the current theory can be critically assessed and possibly added to. To reach this end, a holistic single-case study design is used (Yin 2003).

The research philosophy of this study is strongly post-positivist with a focus of finding patterns, explaining phenomena and testing new theories while critically evaluating current theories. This critical realism focus is at the heart of this case study approach building on a theoretical background. Critical realism underlines the case study approach that seeks to understand the single setting that still cannot be even described and studied wholly. The case study approach as a modified experimental methodology suits the purposes of this study well.

5.2. Data collection

The primary data collection method is interviews with the case company's key personnel. In addition, different actors of the Finnish innovation support

system have been interviewed to understand the support structures in place and to assess the role of the government policies in the industry environment. The people interviewed are considered as "informed sources" relating to the questions present in this research. Interviews are the primary method of data collection but in addition different material internal to the company and also related material gathered from external sources will be utilized to gain a broad view of the industry, the barriers to entry and different actors in the company environment.

5.2.1. Interviews

The interviews with both the company key personnel and innovation system actors were the primary data collection method in this research. As the study focuses on understanding the barriers to entry present in a regulated industry and the strategies through which the company itself and the government actors can influence these barriers, the interviews focused on both the current situation but also on identifying chances for improvement. During the study, 26 interviews were conducted with 20 different individuals.

The first wave of interviews included open interviews with the case company key personnel designed to give an understanding of the industry, the case company history, its operations, products and current markets. In addition, some external informants were contacted in order to get insight to the regulation present in the industry. The scope of this study and the specific research questions were designed during this phase and the relationship between the literature study and the empirical study were designed.

The second wave of interviews included a wider range of company personnel from different functions to gain understanding of the barriers to entry affecting a range of operations within the case company. Representatives from Sales and Marketing, Quality and Regulatory, Clinical, Finance and Administration, Production, and Research and Development were interviewed. In addition, external experts in the

company's environment including Finnish innovation system actors were interviewed to assess the role of the government in relation to the barriers to entry and their support for small companies and innovations. The interviews in the second wave were conducted as semi-structured interviews. Some of the informants were contacted after the interview by email to clarify any comments once the data had been transcribed.

The third wave included confirmatory interviews with some of the key informants to assess whether the drawn implications and conclusions made sense and to determine areas for further research.

The interviews were primarily conducted face-to-face but with a few informants, they were conducted through a teleconference due to geographical distance. To facilitate deep understanding of the phenomenon, open ended questions were used and clarifying questions were asked during the interviews. Also, the interviewees were encourages to speak freely of any additional themes that might be related to the topic even if not touched upon by the interviewer. All the interviews were recorded and later transcribed by the interviewer. A list of the interviews conducted with both case company personnel and external actors is provided in References.

5.2.2. Secondary data sources

In addition to the interviews, documents received from the case company were used to gain a deeper understanding of the industry characteristics and the company history. Furthermore, the innovation system actors provided documents to aid in understanding the role of the support system actors and the Finnish government innovation policy. The additional material is listed in chapter 9, References.

5.3. Reliability and validity of the study

The reliability of the study refers to the imitability of the study in another point of time with the same results, i.e. if the study was repeated using the same protocol described in this study, would another researcher receive the same results and findings that those concluded in this study. Thus, reliability is a measure of research quality, aiming at reducing the bias and errors in the study dependent of the researcher. The validity of the research refers to the suitability of the study in explaining the phenomena it was used to study i.e. whether the study measures, researches and explains the phenomena it was used to explain. Validity can be divided into external validity, the establishment of the context in which the results of the study can be generalized, and to construct validity, referring to ensuring that the operational measures of the concepts used in the study are correct. (Yin 2003)

Interviews that have been used as the primary data collection method in this study, are a justified data collection method due to their character of allowing the researchers to gain an insightful understanding to the studied phenomenon but may raise questions relating to the reliability of the study as the reliability of the interviews relied strongly on the objectivity and truthfulness of the interviewees and the interviewer (Eisenhardt 1989). Yin (2003) has offered some recommendations on how to increase the reliability of a case study, through the use of a case study protocol and a case study database, which both have been used in this study. Firstly, the case study protocol was designed based on a research plan, the literature review and interview structures. Secondly, all the interviews were recorded and transcribed by the researcher directly after the interview, the latest the next day. All the transcriptions, including the notes made by the researcher during the interview, were saved into the case study database.

Yin (2003) has suggested that the external validity of a single case study can be increase through theory building. By nature, the generalizability of the

results obtained through a single case study is questionable but in order to increase the external validity of this study, one of the aims is to contribute to the current academic knowledge by extending and adding to the current theory on barriers to entry in a specific type of an industry setting. As there is a lack of previous research on the point of view of the entrant and as previous research has suggested that the industry characteristics affect the studied phenomenon largely, the chosen method is likely to offer a chance to develop new theoretical contributions to the current body of literature.

The construct validity can be problematic in case study research according to Yin (2003) but can be improved by using multiple sources of data, establishing a chain of evidence, and reviewing the work with key informants during the different stages of the study. The three methods have been used in this study to improve the construct validity, firstly by using a range of informants from different backgrounds both within the case company and also in its environment, secondly by following the case protocol and case database, and thirdly by reviewing the findings of the study and the process with key informants as a third wave of data collection.

6. Case study background

The empirical part of this study involves a case study focusing on the market entry of a Finnish medical device company and especially on identifying the barriers to entry the company has faced in the regulated market it is seeking to enter. First, an overview of the company background is given, followed by an introduction to the market.

6.1. Case company background – Mendor Oy

The case company is a small Finnish medical device company designing, developing, manufacturing and marketing advanced products for diabetes management. The company was founded in 2006 and after a successful presentation of their business plan in a national Venture Cup competition, the development of their first product began. After several years of intensive work together with specialists and end users, its first product – an innovative all-in-one portable blood glucose meter - was ready in close to the year end in 2009 and received a CE mark required to start the sales of the product in the EU area, in late 2010. (IV1)

The product is based on similar technologies already in the market but represents a usability innovation as the device is a first product in the market to have successfully integrated the needed components for daily blood glucose management, differentiating from the traditional solutions and offering value for the patients due to its ease-of-use, discreetness, non-medical appearance and fastness of measuring. (IV1; IV13; IV18) Due to the risks involved in innovation activities such as in gaining regulatory approvals, including extensive and costly trials for proving safety and efficacy of new technologies, the innovations in the industry are mostly focused on usability and only on incremental innovations in technologies. (IV4; IV17; IV23)

During the course of its research and development work, the company pursued support from different Finnish innovation support system actors, including funding for their R&D activities from TEKES (The Finnish Funding Agency for Technology and Innovation), and the services from business incubators such as Spinno. In addition, the company worked with an advisor from Keksintösäätiö (The Foundation for Finnish Innovations) in the early stages to develop the business plan and to seek assistance in gathering market information. (IV1)

Already very early in their research on the market the company understood the challenges posed by the differential health care systems in different European countries where much purchasing is done through public tendering procedures. For instance, in Finland the supplies for self-monitoring of diabetes are covered by the municipalities that procure the supplies through tender procedures aiming at lower costs held generally every 4-5 years. This combined with the small home market gave the direction for the company to start international market entry from the very beginning. (IV1; IV13) Very soon it became clear for the company that even with an innovative new offering with differential value to end-users, market entry is very difficult in a market characterized by high regulation, bureaucracy and conservatism with key stakeholders, significant consolidation and increased cost concerns throughout the value chain. (IV4; IV9; IV16; IV18; IV20)

Currently, the company employs approximately 30 people and is continuing its growth into different markets after securing important partnerships in key markets such as in the UK and is currently in the final stages of negotiating a pan-European distribution deal with an experienced partner. The company strategy is to work through distributors in foreign markets but have decided to keep their home markets, Finland and Sweden, as a part of their direct sales channel to maintain direct contact with end users (IV13). Nevertheless, the company continues to have significant challenges with the barriers to entry in this highly regulated and consolidated market as a small innovative

player in the market characterized by strong incumbents and fierce competition for market share. In the next section a brief introduction to the market is given.

6.2. Market overview

Diabetes is a chronic disease affecting over 200 million people globally – a number that is expected to double within the next 25 years. The current estimated value of the market for blood glucose monitoring is approximately 6.5 billion euros globally with continued growth of 3-4 % per year due to increased prevalence and awareness of diabetes, continued obesity epidemic, improved diagnosis, better insulin treatment requiring more frequent monitoring of blood glucose levels, and current suboptimal testing frequencies. The share of blood glucose monitoring is only some 3-5 % of the total economic burden caused by the disease, with the costs of complications making up for a lion's share of the total costs. (IV3; IV23; DOC1; DOC5) In Finland for instance, the total costs of diabetes are approximately 1.35 billion euros on yearly basis, some 10 % of the total health care costs. Out of the costs of diabetes, the costs of treatment are less than 30 % (medical supplies some 3 % of the total costs) whereas the costs of complications due to suboptimal treatment create 55 % of the total costs. (DOC3) Research in this area has shown that by focusing more resources on the early and improved treatment of the disease, including more intensive blood glucose monitoring, the chances of diabetic complications could be halved with a much greater decreasing impact on the total costs than the increase in costs due to optimal treatment. (IV23; DOC3)

The market for the blood glucose monitoring of diabetes developed in the 1980's as an answer to the growing diabetes epidemic with technologies for self-monitoring of blood glucose levels for purposes of guiding the treatment and also to help in insulin and oral drug dosage. The rate of innovation was fast in the past decades together with double digits growth rates in the market that were expected to continue with the explosion of the

disease with the key companies building their market share with introducing a plethora of new devices, through mergers and acquisitions, and taking control over distribution channels, driving the national health care systems onto the verge of bankruptcy. The basic technology has been the same since the mid-90's with the market being characterized by increased saturation and commoditization with little segmentation while innovation has been replaced by fierce competition over market share and tight control on costs. (IV3; IV13; IV18)

The basic business model in the market is based on significant initial costs with the meters being placed free of charge in to the market with the profit being made on test strip sales that would follow meter placement. The market offered huge margins to the key players until some 5 years ago when the national health care systems could not bear the costs anymore and started declining treatment based on the type of diabetes, putting price caps on reimbursement and restricting strip usage. Since then the four key incumbents, owning up to 80-85 % of the market share globally, have focused on cost control and maintenance of their position, now fighting over a slow and stabilized market in comparison to a hugely growing market. The key incumbents still have huge profit margins based on their proprietary strip technologies that are far beyond the competitive level, and have massive organizations and operations in place to support the massive profitability that they are ferociously defending. (IV3; IV4; IV8; IV13; IV18; DOC5)

The large incumbents have not a series of incremental innovations to the market in the past decade but small companies have been responsible for more radical innovations in the market, much as Schumpeter already has argued (1939). The possible explanations are many e.g. the unwillingness to cannibalize own market share or the risks and costs of developing products that might not gain the necessary regulatory approvals (IV16; IV18). The small companies often have the ability to innovate but are lacking the resources needed for market entry in this industry that has not traditionally

awarded innovation at its own right but requires significant sales and marketing muscle even with an innovative offering. The total financing need for getting the product ready is only a fraction of the costs of market entry. (IV4; IV11; IV16; IV19; IV23) Often the situation leads to small companies either dying once their cash runs out due to the significant time and the amount of resources that it takes to gain market entry or being bought by one of the large incumbents, further leading to continued consolidation. (IV23)

The high regulation in the industry has led to an environment of bureaucracy, conservatism and substantial risk aversion in the industry, labeling each stakeholder and decision maker. These more structural characteristics create significant barriers to entry for new competition in the industry, preserving structures that often favor the incumbents. The fierce competition in the market characterized by a few strong and powerful incumbents owning most of the global market share has led to severe strategic barriers to entry for new competition with the incumbents defending their share of the market with all they can, not only against the other incumbents but jointly against new competition. (IV13; IV16; IV23) As discussed in chapter 2.1., this rarely leads to favorable social welfare consequences, especially in the health care market where the public are the key stakeholders and the costs are being funded from the government budgets.

7. Barriers to entry at Mendor Oy

In the following chapter the barriers to entry faced by Mendor Oy in its international commercialization efforts are presented and analyzed. The key barriers to entry are also identified. The section is structured similarly to the theoretical part, by first defining the barriers to entry, then identifying their importance and then discussing the chances for different actors to influence these identified barriers. The entrant's influence on the barriers can also be defined as 'breaking' or 'tackling' the barriers to entry.

7.1. Company market entry and barriers

First, a brief description of the company's history since the start of their market entry efforts is provided and then the barriers to entry the company has faced in market entry are introduced.

7.1.1. Brief history of market entry efforts

The company started commercializing its new product directly after it gained the CE mark approval in late 2010. For the CE mark approval the company had had to undergo extensive clinical trials required by the applicable medical device and in-vitro diagnostics standards. Even before the research and development process for the product could start, the company needed to build a quality system to respond to the documentation requirements listed in the applicable standards for design and manufacture of medical and in-vitro diagnostic devices. (IV13)

The company's research and development efforts were funded using a mixture of public funding available from Tekes, the Finnish Funding Agency for Technology and Innovation, and private funding gained after the company had won a Venture Cup competition and managed to attract some private investments. (IV1; IV2) Once the product was ready and approved, the company started looking into market entry, with a plan to first cover the

European territory and then expanding their sales into other market areas. (IV1) Even though the CE mark guaranteeing the safety and efficacy of the device and serving as a sales permission on a European level, each country still has their own infrastructure for their health care organizations and purchasing. Even though the end user of the device will be a diabetic patient from the public, in each country the health care system is at least partly reimbursing the supplies for blood glucose testing for the diagnosed patients. (IV3)

In some European countries such as in Sweden and Finland, the municipalities are responsible for the purchase of the supplies for the local diabetic population that are procured for periods of 2-5 years through competitive bidding in tenders, based on a criteria of certain quality related requirements and price. The companies with the winning bids will be selected as the sole suppliers for the next tender period and the choice of blood glucose meter for the diabetes patient is restricted to the few options that were selected for the agreement period. The treating diabetes nurse will together with the patient decide which product would be the most suitable one for the patient and can also choose which meters they will present to the patient. (IV13; IV21; IV23) In some other markets such as in the UK, the National Health Service will reimburse a majority of the costs of the supplies to the patient who will have the choice in selecting their meter from a selection of products presented to them by their treating diabetes specialist nurse. Due to increasing cost cutting pressures, different areas have also started restricting the availability of the products to select from based on their price thus also limiting the choice for the patient and creating an extra step from the supplying companies to the end user. (IV16)

The private market for diabetes supplies is only a few percent consisting of people who would rather finance their supplies themselves to be able to choose their preferred product freely (IV13; IV16). Thus in the medical device market there are three key stakeholders that in many instances have different ambitions: the end users (the patient), the gate keepers (the health

care professionals) and the payers (municipalities or social insurance systems funded from the government budgets). The structure of the health care system varies from country to country as do the levels of reimbursement that will set a cap to pricing of the products in the respective market. (IV13; IV16; IV23)

As their understanding of the varied practices in each of the markets grew, the company realized that their own resources would not be sufficient to gain entry in several different markets and decided to start looking for distribution partners. A decision was made to still keep Finland as a direct sales market to stay in direct contact with the customers and a sales team consisting of two people started working with different Finnish municipalities in anticipation of the opening of the next tenders. Some companies from other countries became interested and negotiations on distribution started. During this time, the main goal was to start the sales in as many markets as possible and little criteria was used in the selection of the distributors, due to a combination of lack of market understanding and the need to start generating cash flow due to financial pressures. (IV1) In parallel with the search of distributor partners in many countries, the company also needed to build up their production capabilities and hired many new people to help with the production scale-up and commercialization activities, increasing the need for capital. The company started negotiations for additional funding both with existing and new investors, hoping to raise enough capital to secure their funding needs before their break-even point. The funding was secured in the spring of 2011, around the same time when the company started cooperation with its first distribution partner in Greece. (IV1; IV2)

Soon the company realized that their expectations of the time to market and the barriers that they would face to enter into any of the key markets were highly optimistic. Even though the company was discussing with several distribution companies in many countries, the progress seemed to be very slow. In addition, many resources were being tied to negotiations with

several different companies with no clear structure and with no visible progress. (IV1; IV2; IV16) Moving towards the latter part of the year 2011 without much success in the difficult home market in Finland or with the Greek distribution partnership, the company decided to take on a new strategy based on their increased understanding of the amount of knowledge, expertise and dedicated resources needed to be able to penetrate the market. The company understood that they will need a committed partner, already heavily involved in diabetes that will have the resources and the expertise that the company itself was lacking. (IV1; IV16)

The new strategic direction could be defined as moving away from a shotgun approach to targeted hunting of resourceful and experienced partners that could offer Mendor reach across many countries and real penetration in the difficult industry (IV16). Pressured by the need for immediate cash flow, also to convince the investors of positive developments, the company still continued negotiating with smaller distribution companies in single countries (IV1). The new targeted approach started bearing fruit once a large multinational pharmaceutical company got interested in the company's offering and in a potential distributorship across a pan-European area. After months of negotiation, the heavy internal structure and de-centralized decision-making of the potential partner company started hindering the progress of the deal mostly driven by the need for proof of concept that Mendor was still lacking and the need for the potential partner to then assess the market potential. (IV13; IV19) In an industry with few large incumbents in fierce competition with each other over market share, with profits being threatened not only by the competitors' actions but also by cost cutting programs of governments, the risk is extremely high for the large company to launch a product that has no proof of success or validation on the differentiating value of the offering. The UK of the pharmaceutical company decided to take that risk though and signed a distribution agreement with Mendor which opened the UK market to the product starting from April 2012. The UK is the first major market

where the product has been launched, almost 1.5 years after the start of the commercialization efforts. (IV13; IV16)

After the successful launch in the UK, the interest from other viable partners has grown and currently Mendor is in the last stages of negotiating distribution covering most European markets and a potential expansion to other territories with a strong multinational company (IV13; IV16).

7.1.2. Identified barriers to entry

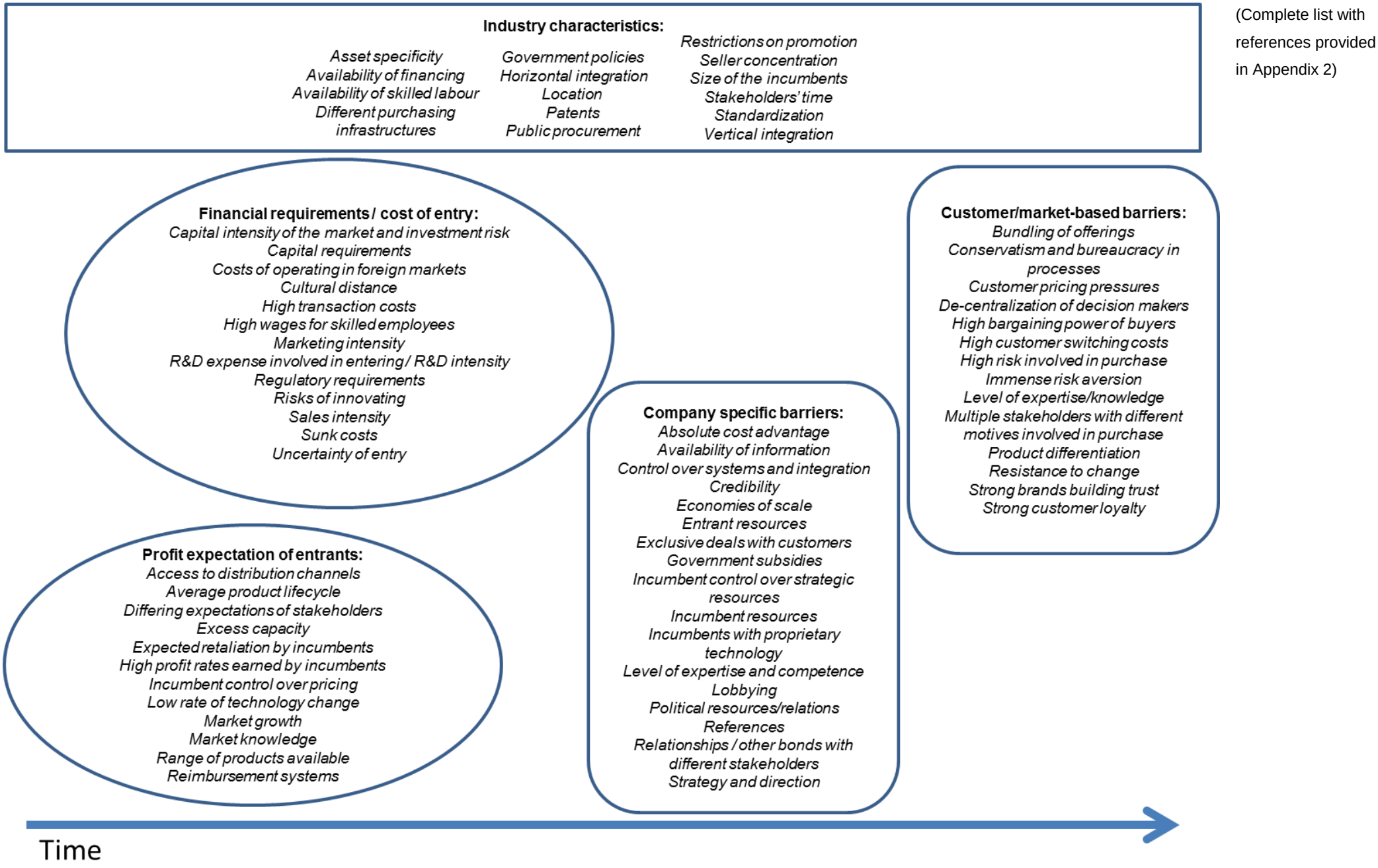
During its history, the company has faced significant barriers to entry. In this study, 71 different types of barriers to entry were identified based on the interviews with company key personnel and Finnish innovation support system actors. Many innovation support system actors described the challenges that Finnish biotechnology companies face as surprisingly similar even though the companies vary by industry, resources and other characteristics (IV4; IV7; IV9; IV11).

The identified barriers are grouped according to the categories developed in chapter 2.2.1. (adapted from Karakaya 2002), in the following figure 5. This categorization from earlier research focuses on the source of the barrier to entry, indicating the focus on the incumbent perspective in the past research. This is evident also in the labeling of the groups as '*advantages*' in comparison to '*barriers*'. What this categorization offers is a chance to link the case company barriers to entry to the same categorization as the identified theoretical barriers to entry and also presents the groups of barriers linked temporally to different stages of the company's market entry efforts. The first category, the profit expectations of the entrants defines the answer to the market entry decision – whether the company will deem the market lucrative enough to seek entry. The second category, the financial requirements/cost of entry should act as a decision point for the company in assessing whether the company will have the required financial resources needed in market entry. If the company decides to move beyond this second decision point, it will next face the specific barriers rising from the

incumbents and its own characteristics and resources. Only once the company would start its selling efforts, it would come face to face with the customer/market-based barriers. The industry characteristics will affect the process at each step of market entry.

In reality, the categories of barriers to entry are strongly intertwined and a company is likely to at least have indications of the barriers at each stage. Still, in Mendor's case, many of the barriers to entry, especially linked to the customer/market based barriers were not anticipated to pose such barriers as they proved to be – a learning that only became evident once the company had already made the entry decision and committed resources to market entry (IV13). Thus, the temporal presentation of the categories does serve as a presentation that some barriers to entry, and especially their severity, could only be judged much beyond the entry decision.

Figure 5 Barriers to entry in Mendor Oy



(Complete list with references provided in Appendix 2)

After the identifying *what* barriers to entry exist for a small company seeking to enter a highly regulated market, the next point of interest is *how* the small company can tackle these barriers to entry with limited resources, according to the main research question of this study. The categorization that has been adapted from Karakaya (2002) is based on earlier research that has strongly focused on the incumbents' position and in the *creation* of the barriers to entry for *deterring* new competition. For this reason the categorization is not a sufficient starting point for studying the entrant's potential to tackle the barriers to entry to gain entry. To achieve this end, we have to study the *challenges* posed by the barriers to entry from the entrant's perspective rather than solely discussing the *sources* for the existence of these barriers.

Thus, to be able to answer the second piece of the main research question - *how* a small-scale *de novo* entrant such as Mendor can tackle these identified barriers to entry, the barriers to entry are studied from a different perspective. In the next section, the identified 71 barriers to entry are grouped according to the types of challenges that their existence has created for Mendor. As will be discussed in the next section based on Mendor's experiences, most barriers to entry and especially their severity could not be reliably assessed before the market entry decision was made. Due to a combination of factors, the company had unrealistic expectations concerning the time to market leading to difficulties in forecasting their sales development which in turn led to challenges in managing stakeholder relations and expectations as the company needed to continually revise their forecasts once they gained more understanding of the market, the barriers, and the bureaucracy and conservatism of the market.

7.2. The challenges for Mendor Oy

In this section, the four main groups of challenges created by the identified 71 barriers to entry are discussed. The challenges for Mendor can be summarized in four groups: time, experience, sales and financial challenges.

7.2.1. Time

The first group of challenges is related to *time to market* and is an overarching challenge that is affected by all barriers to entry. As discussed in chapter 8.1.1, Mendor received the CE mark for its blood glucose meter already in late 2010, marking a European wide sales permission for the product. Despite its best efforts, the first significant distribution agreements, opening the UK market did not happen until some 1.5 years later. (IV1; IV3) In this section the slowness of a regulated market and other barriers directly related to time are discussed.

Figure 6 Barriers related to time

Time is a critical factor in market entry. Not only does regulation cause additional work but also creates the general slowness to the market due to

the required approvals and due to the heavy processes of other actors (e.g. notified body, quality systems, audits etc.). This time factor is also essential from the perspective of the economy and the market as the market changes very slowly. (IV1)

Time as a factor has affected Mendor's operations from the very start. The medical industry is very much characterized by slowness due to heavy regulated processes within all the major actors, their internal and external processes (IV1; IV2; IV3; IV9; IV17; IV18; IV21). The regulation linked to the very long product lifecycles, low rate of technology change, slowed market growth, and packed product space with fierce competition between the few large incumbents, the market has become highly consolidated and focused on rather maintaining the status quo than moving forward (IV3; IV16; IV18). The key incumbents have been the same in the market for decades and have invested significant amount of money and other resources into building relationships, brands and patent portfolios while strengthening their position in the market. (IV3; IV4; IV6; IV12; IV24) These incumbents have massive production volumes and with 80-85 % of the whole market being shared between these four key players, they have strong control over the industry value chains and have achieved both horizontal and vertical integration over time (IV13; IV16). The time it takes for a new entrant to build the needed operations and form the relations to its stakeholders will require a long time. Even with time, breaking the long lived relationships and other bonds the incumbents have built to suppliers, regulatory bodies, customers and other industry actors will pose a significant challenge. (IV6; IV16; IV21; IV23)

"*The incentives for innovation are few in regulated industries – due to the slowness of the market, it takes forever to achieve anything and in addition all the current structures serve the status quo and thus the incumbents. Challenge is to stay above the water long enough to get there…*" (IV13)

To be able to obtain and keep the needed regulatory approvals for the sales of medical products, companies need to follow certain standard requirements starting from the correct documentation of its research and development projects and go through extensive trials to validate the safety and efficacy of the product and its compliance with the standard requirements (IV1; IV22; IV24). One major challenge relating to the research and development of Mendor's innovative device was finding the fine line between compliance with standard requirements and being able to differentiate from current products available in the market (IV1). Regulations are built on the specifications of the current products and large incumbents are working heavily through their political relationships and through lobbying to be able to standardize their technologies and to create new requirements that will be hard for the entrants to comply with (IV13; IV22; IV23, IV24). The strict standard requirements based on current technologies decrease incentives to innovative as the risks involved in investing millions into the development of a new product without assurance that it will be able to obtain the needed approvals, at least in due time before the company funding runs out, is too great for many small companies and thus the innovations in the market have mostly been on other fronts than technology (IV13; IV16). The furthest form of entry deterrence through regulatory requirements is when certain incumbents have successfully managed to introduce requirements that correspond to their patents, creating a restrictive situation for any entrants for the time being with a specific technology (IV24). Any changes to the regulation requirements will take a very long time and as influence small companies will often be out of reach to changing the standards, they will often have no other option than to comply (IV11; IV20).

In addition to the approvals for the production and sale of the product, a process that usually takes for about a year in relation to health technologies, the company also needed to obtain reimbursement for its device in the markets it was targeting (IV8; IV16). Whereas the CE mark is granted as a sales permission for the whole EU area, the reimbursement systems vary by

country dependent on the structure of the health care systems. In some countries the application for reimbursement is only possible once in every quarter or even worse, once each year, and the processing time often takes several months. (IV16) Directly after receiving the CE mark for the product, Mendor started investigating the reimbursement systems in key EU markets and soon understood that it getting approved into the list of reimbursed products will require many resources due to the long lists of requirements dependent on the country, always required in the local language. The company needed to target those countries first where it considered the reimbursement applications would be less stringent but due to lack of robust data to show any differentiating value for the product, the product was granted the price level of generic products. (IV13; IV16; IV23)

In countries such as in the company home market of Finland, the reimbursement of the product is linked to the public procurement of the products through tenders. The municipalities procure diabetes supplies approximately each 3-5 years based on criteria combining price and quality considerations. Due to the de-centralization of the key decision-makers, the companies willing to bid in tenders need to start working with several different municipality decision-makers long before the tender is published, to be able to influence the tender requirements in advance of its publication. The de-centralization creates many challenges for small companies with innovative offerings as the selling needs to be done from door to door and many different actors with different motives need to be convinced (IV4). The tender is generally published several months before the start of the new tender period but the ground work with the decision-makers needs to be done long before this time period. If the company is successful in the tender and gets chosen, they will be able to enter into an exclusive agreement for a period of years thus seeming as a lucrative option for generating sales. (IV1; IV1; IV6; IV9; IV12; IV20; IV21) Unfortunately, as Mendor came to find out, this type of a market requires massive resources and entails a fair amount of risk in case the tender outcome will not be successful for the company. The tendering criteria are not based on the definition of a need but

rather on pre-set specifications that are based on the current known offerings. Thus, the basic tender legislations requirement for unequivocal assessment criteria often leads to the drafting of criteria that does not take into account innovations. For instance Mendor's integrated product has been excluded from bidding due to such compulsory requirements as having a separate vial for test strips even though the whole differentiating factor of the product is the integration of the separate components. (IV13; IV21)

Even though Mendor seeks to educate the procurement committee well in advance of the drafting of the specifications, producing change in the procurement chain is very slow (IV21; IV23). In addition, the heavy lobbying from the incumbents will affect the interpretation of regulations and steer new regulations towards more favorable conditions for incumbents. The most influential discussions on practices are had between professionals but incumbents will also try to affect these discussions in advance. (IV4; IV6; IV7; IV9; IV12; IV22; IV23; IV24)

In addition, once the tendering has been held for a respective tender period, the area in question is outside of sales potential for a number of years, thus making market penetration very difficult. (IV13; IV14; IV21; IV23 Different government policies and legislations regulate the daily operations of the public stakeholders such as the people responsible for procurement also creating a direct link to the time they have available to spend on familiarizing themselves with a new product (IV13; IV21; IV23).

As described in chapter 8.1.1, Mendor soon realized that it will be impossible for it to penetrate many markets at the same time given its small resources and decided to start searching for distribution partners. As the example of its negotiations with its UK partner described, due to the heavy processes of all the industry players, negotiating a significant contract in a regulated industry requires plenty of time and effort to be able to convince the potential partner to take the risk of launching a new product without extensive data on proof of concept, massive market research and experience

with the product to verify its market potential. (IV13; IV16) Even though the regulatory measures pose a significant time concern, the bureaucracy and slowness of the potential partners is an even more significant factor. Finding a credible partner, selling to them, negotiating with them and signing contracts with large pharmaceutical companies with multiple approval levels and hierarchical processes will consume a staggering amount of time in a crucial point of time while the company is struggling to stay alive as the R&D funding has run out. (IV16)

There is also significant lag time in the market compared to a consumer product. The blood glucose monitoring industry has developed into a razorblade business model, where the suppliers will give out the devices free of charge and make their profit from the consumable test strips that are compatible only with specific devices. (IV13: IV16; IV18) Thus a significant up-front investment is needed to place the meters into the market which all will not end up in active use. Working through a distributor, the lag time can be anything from 9-12 months before the product will first move from the distributor's warehouse into the hands of health care professionals, who will need to be trained by sales representatives before they can start handing out the devices to patients. (IV16)

Due to the variety of challenges related to time discussed in this section, average time to break even with a new product in a regulated market is between 3-5 years and the product lifetime can last up to 10 years. Even though these numbers give an idea of the terrible slowness of the market once seeking entry, products can become good cash cows for a relative long period of time if entry will be successful. (IV16; MY18) Still, from the point of view of a small entrant, the time factor is critical in relation to market entry. Entry into this regulated industry is gruesome due to the heavy processes and structures and slow pace of the market but if the company manages to fight through the many barriers to entry and can stay above the water during the lengthy process of seeking entry, the market can offer a good return and a fairly defensive position. (IV1; IV16; IV18)

7.2.2. Experience

The second group of challenges is related to the lack of experience in and of the market and refers mostly to the entrant's characteristics. As became evident in the interviews, the knowledge of the market and the right skills in the company is a necessary precursor for success in an industry that is very difficult to enter in and even more difficult to compete in (IV2; IV4; IV9; IV16; IV18).

As mentioned before in section 8.1.2, as a *de novo* entrant into a new industry, Mendor did not have previous experience on the industry but had to start its operations based on limited knowledge. The lack of experience in the industry is the defining factor for the challenges created by the barriers to entry related to experience.

Figure 7 Barriers related to experience

One of the first challenges related to experience marks the start of the company's operations. As the company started developing a medical device, it had to construct an extensive quality system as one of the first steps in the company operations (IV13; IV20; IV23). The challenge is that lack of expertise can lead to longer term challenges as the company does not have the option to gain the required competences in peace (IV20), often leading to the construction of quality systems that rather constrain that support the company operations, prohibiting agility (IV24). The quality system does not only control the company's R&D and other product related operations but also includes an extensive management system covering all functions of the company (IV22). Being able to construct processes that would serve the

company strategic goals already sets challenges for competence, understanding, financing and other resources. To be able to fulfill the needed requirements but leaving space for agility requires specific expertise which Mendor only learned later once the drawbacks of the initial system became evident in operations. (IV1)

Due to the difficult competitive environment in the medical device industry, special skills are needed to succeed. Attracting experts who have experience in the industry was an important step for Mendor in starting to understand where it strategic focus should lie and where its limited resources will be in the best possible use (IV13; IV18; IV23). Pressured by the short term need for sales, Mendor too has many times had to sacrifice its longer term strategy for its short term survival (IV1). Unfortunately inconsistency has caused some confusion within the company personnel and might have created some inefficiency in its operations (DOC4). Lack of deep market understanding also led the company to discard any strategies very quickly if they did not start producing results, lacking the understanding of the time that it takes to gain results in the slow market (IV18). Since finally starting to see its targeting strategy paying off with its distribution agreement with a large pharmaceutical company in the UK, the company has made the strategic consistency one of its key goals (IV1).

Choosing the right partners and suppliers was a challenge for Mendor as the performance could not be assessed in advance and as a new comer to the industry, the company did not have the access to up to date industry knowledge. The accumulation of market understanding and growing the level of expertise has been a challenge also due to limited resources and the ability to attract top class industry experts who are few in the specific industry. (IV1; IV18) With the market knowledge available through the right expertise, the company could have been more realistic in its expectations of the time to market and the sales growth (IV3; IV18; IV19).

"*Gaining access to information and to deep understanding of the market has been difficult due to resource constraints [time, money, and expertise] and many choices have had to be made knowing that there is a lot that we do not know. Many issues caused significant delays to original plans when they finally came apparent to us such as different market requirements for the device.*" (IV1)

The availability of the special skills in Finland has also been an issue. There is a great supply of technology experts but there is still lack of business skills. Finnish companies are often technology-driven but lack the understanding of strategy and internationalization. Without the skills enabling growth and expansion, the companies are often stuck in a small market. (IV2; IV4; IV6; IV9) The same challenges faced Mendor and pushed the company to seek expertise abroad. The most essential skill sets to succeed in such a market have been the expertise and experience in raising funding and international sales that are very hard to find in a technology driven country as Finland (IV1; IV2).

Also due to the slowness of the market, learning and accumulation of competence takes a long time. As the time factor is a constant in the industry, it needs to be accepted. Seeking the right kind of expertise to the company is essential to success but also finding the right people will take time – this time constraint has to be accepted to avoid hiring the wrong people due to pressures on resources. (IV20)

7.2.3. Sales

The third group of challenges is connected to the barriers to achieving sales. Even though all barriers to entry deter the success in sales, the factors discussed in this section are directly related to the nature of purchasing in the industry. As discussed in section 8.2.1, the same key incumbents have operated in the market for decades and spent a significant amount of

resources to build relationships and other bonds with their customers that are very hard to break (IV3; IV4; IV6; IV12; IV24). In this section the challenges for sales in a regulated industry are discussed.

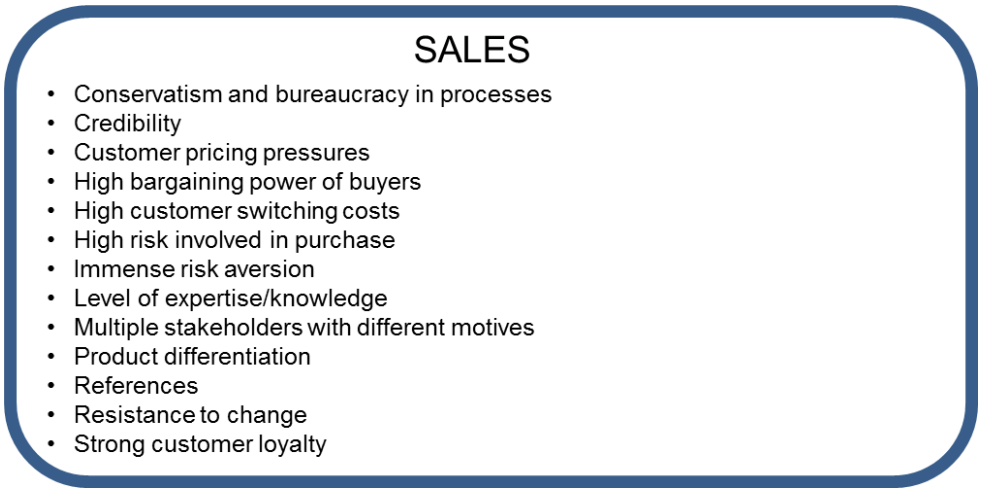


Figure 8 Barriers related to sales

The health care industry involves several different stakeholders with different objectives who are interested in the market outcomes unlike most consumer markets. The key stakeholders include actors such as influencers, deciders, patients, suppliers, providers, and payers who might all be separate organizations. (IV1; IV3; IV4; IV23) In addition to these actors, the whole society is interested in health care transactions (IV1; IV3; Kotler & al. 2008). Regardless of how the responsibilities have been organized between the different stakeholders in a given country, the large number of stakeholders creates complexity and a major distortion to the market. Whereas in consumer markets the customer's choice is driven by the perceived value of the offering, in health care the payer is often someone else than the end user of the product or the service (IV1; IV2; IV3; HKKLS09). The three key groups of stakeholders include the end users (individual patients), the payers (governmental/insurance budget or both) and health care professionals (nurses, doctors etc.) who all have different needs and objectives (IV1; IV2; IV3; IV21; IV23; HKKLS09). The degree of complexity within the stakeholder network reflects into the purchasing

process, creating challenges for sales and increased transactions costs for suppliers of the products such as Mendor who instead of a single decision-maker unit need to balance the different motives of three different stakeholders in order to produce a sale.

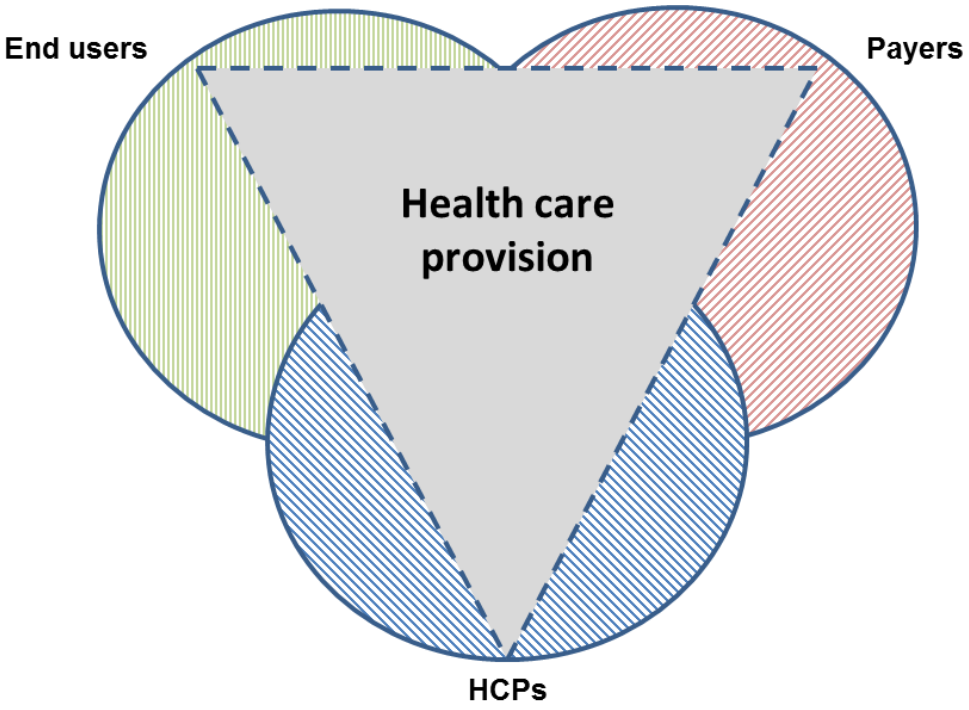


Figure 9 The key stakeholders in health care

In reality, all the objectives of the different stakeholders are not considered in the purchase decision in similar proportions but the sale is the result of a multiple level process (IV4; IV14; IV23). In markets such as in the UK, the health care professionals, namely nurses are in a powerful position as gatekeepers, presenting the choices of products to the patients. The nurses will need to be convinced about the product to ensure they will share the information to their patients. A key restricting issue is the availability of the nurses for consultations, restrictions on the promotion of medical devices, and the strong loyalty towards their preferred products. As the key driving motive for the nurses is the improved treatment balanced with concerns for their own resources and time, often leading to conservatism towards new solutions that would require additional work even though they would bring

long-term savings. (IV13; IV16; IV21; IV23) The traditional blood glucose measurement logic has been practically the same for decades and all the generic devices follow the same logic thus requiring no extra work from the nurses learning the use of a new generic device or showing it to their patients. Even though one of the key selling points of the Mendor device is its ease-of-use, it is based on a different logic than the traditional meters and thus often requires some time to start with to get familiarized with the use of the product. Due to the constant lack of time, old hierarchies and bureaucracies present in the health care system, the actors are often resistant to new things. (IV13: IV16; IV21)

Driven by cost concerns, the payers have started limiting the number of products available for the patients namely based on the price of the consumable test strips for the blood glucose meters. Even though the general reimbursement price is set in the UK on a national level, different areas are responsible for the health care costs and the reimbursed products locally. Thus in addition to the nurses, the de-centralized payers will need to be convinced of the differentiated added value of the product in relation to the plethora of other devices available. Especially with the current cost cutting pressures on national budgets, the main concern of the payers is the costs of treatment. Finally, the end users i.e. the patients need to be informed on the new device to encourage them to choose the new product over the current one they are using. The sale is produced after a long value chain; the payer has been convinced to allow the reimbursement of the new product in the area, the nurse has been trained on the device and convinced on the benefits of the device to recommend it to their patients, the patient will choose the product from the number of products their treating nurse will present to them, learn the use of the device, and be satisfied with the device to continue actively using the device then leading to test strip sales from pharmacies. (IV1; IV3; IV 16) These test strip sales are *the defining sale* within the value chain. As described earlier in section 7.2.1., a significant up-front investment is made depending on a razorblade business model where the meters are placed to the market free of charge in order to

produce the sales of compatible consumables, the strips for testing. After the initial sales to stock the value chain, reorders will only be produced if the defining sales events will take place.

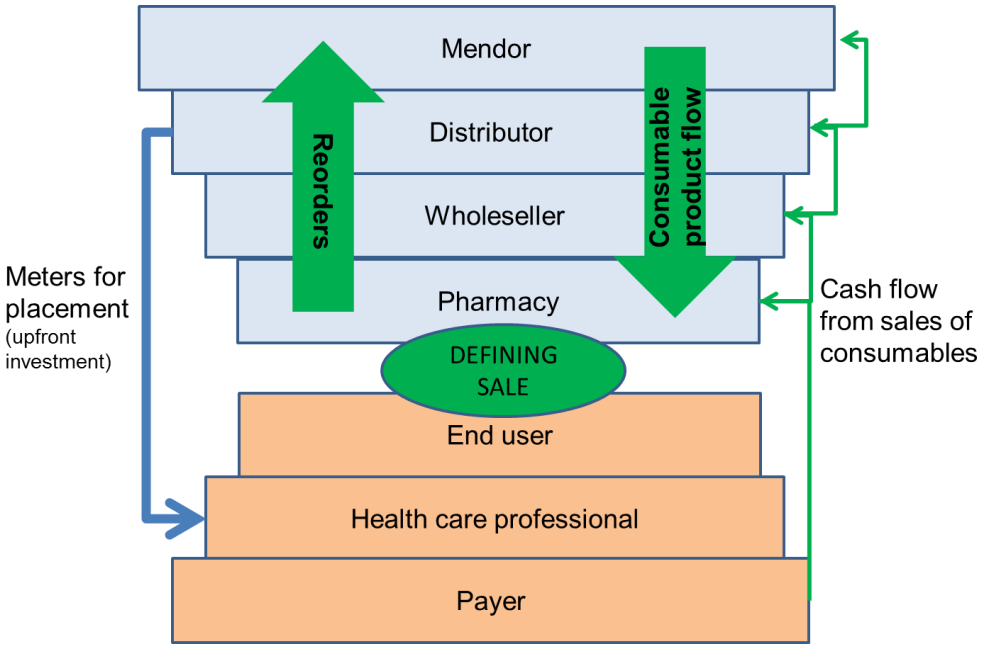


Figure 10 The sales flow in the UK

The markets operating on tendering such as Finland entail at least as many stakeholders but a different type of purchasing mechanism. As described in earlier sections, the products for purchase are selected based on preset tender criteria, combining price and quality considerations. The objective of the tender legislation is to use objective measures in the purchases and to increase transparency in public procurement decisions (IV1; IV21; IV23). Even though the basic principle of tendering is unbiased, the public procurement procedures have developed towards structures based on risk aversion even at the cost of the quality of the procured solution, with the procurer seeking safety balanced with up-front cost considerations first and foremost (IV1; IV14; IV23). Combining the regulation present in the medical field with the bureaucratic and hierarchical practices and operations of the public procurement offices, the system produces immense risk aversion behavior. The procurers will rather stick to the same old solutions

than take the risk of choosing something different even if the benefits would be greater to the patients. (IV1; IV12; IV21; IV23)

Even though the regulatory approvals guarantee the same level of safety and efficacy for the new device, validating the delivery ability and scalability of the new supplier's offering poses a risk that the public procurers are often not willing to take (IV1; IV14). To mitigate the risk, building credibility becomes very important in a regulated industry. In many consumer industries being a start-up company is a good thing but in this industry there is little chance in entering a market without proper infrastructure in place – even the regulation requires for certain resources and functions to be in place. Size is one indicator of credibility but professionalism is even more important. Credibility is not only required by customers but also investors, suppliers and the whole network of stakeholders. (IV6; IV18; IV19)

For a company commercializing innovations, gaining credibility creates a chicken and egg situation as the product will not be chosen before there are credible references but the references are difficult to gain in the difficult and bureaucratic home market (IV12). Due to the conservatism and bureaucracy present in the home market, Finnish companies need to go abroad to get cash flow where potential partners will ask for references and find it suspicious that the company could not succeed in its home market (IV9; IV10; IV12; IV13; IV20). This leads to very weak home market support for internationalizing companies.

The main problem is the level of expertise and knowledge within the procurement committee (IV8; IV9; IV12; IV14; IV21; IV23). The people responsible for the tender criteria do not necessarily understand the need for which they are purchasing or the meaning of the tender requirements to the patient or the treatment.

"*Often the same people are responsible for purchasing independent of whether the procurement is for food, socks or medical devices*." (IV1)

Thus tender criteria are often based on a long list of clinically irrelevant product specifications that do not improve the quality of the treatment or the value of the solution to the patient (IV8; IV21; IV23). Even though the procurement directives are meant to increase transparency and equality in procurement the wrongful interpretations made by the people responsible for the tendering criteria lead to favoring the old suppliers (IV9; IV23). The regulation itself is not a problem and is naturally needed to ensure the safety and efficacy of the medical solutions but the wrongful interpretations and illusions linked to the regulations are creating many challenges (IV23).

Often the practices in public procurement are justified based on fears and wrongful beliefs caused by the serious lack of professionalism and expertise in public procurement (IV1; IV8; IV9; IV12; IV14). The people responsible for procurement often believe that by setting strict requirements on the specifications of the product, they will be considered professional even though it often leads to the procurement of products that fit the preset specifications that are made times even fully derived from earlier tender specifications or from product specifications of products that are currently being supplied. This procurement based on specifications rather than on the actual need may many times lead to worse solutions being procured when considering the actual need, in the case of diabetes supplies, improved treatment outcomes, that is not based on certain product specifications. (IV12; IV14; IV23) Expert opinions are only rarely listened to in tenders or their weight in the total assessment criteria is very low. Then again, without having a wider group of expert opinions listened to, the biases of certain experts might lead to biased opinions. (IV23)

Another problematic issue relating to the structure of public purchasing is the focus on up-front costs instead of the total long-term costs. In the current system, working devices that are in use with patients are changed every 2-3 years regardless of the patients' preference or the effect on their treatment (IV23). Not only do the patients have to endure constant changes in their treatment but also the nurses have to spend a considerable amount of time

and other resources seeing each patient in order to switch them over to a new device in case the product being currently used is not in the list of selected products for the next tender period. In addition to the strain caused for the end users and the health care professionals, the resources being spent on the operating of the tender processes are massive, all leading to a huge waste of resources. (IV6; IV9; IV12; IV20; IV23) As significant switching costs are present, it can easily lead to favoring of current suppliers only to avoid having to go through the trouble caused by changes in the system (IV13; IV23).

Total lifetime costs are tricky concepts in public procurement for several reasons. Firstly, the municipality budgets are usually set up for a yearly period, driving the concerns to the short-term costs. Secondly, the budgets are usually separated for the costs of supplies, the costs of treatment and also for costs of investments and repairs. The dual structure does not encourage the considerations on the major increase in treatment costs caused by complications due to suboptimal treatment induced by the lack of concern for the patients' preference in relation to their treatment. (IV12) Short-term cost concerns also drive the tender criteria with the weight of the price often being some 70 % of the whole assessment criteria, only considering the up-front costs of the supplies, even though, as discussed in section 8.1.1., better treatment could prevent over half of the currently occurring diabetes complications that count up to over half of the total costs of diabetes whereas the costs of medical supplies only are approximately 3 %. (IV23; DOC3)

It should be understood though that it is difficult for an individual to start taking more risk in their purchasing decisions as long as all the incentive systems on the public level are based on risk aversion and not on ensuring the best possible solutions for use. Due to the high risk involved in health care procurement based on the length of the contract, high value of the purchase and the dependency on the procured solutions, the procurers often seek safety instead of the best possible solution. The incumbents also know

how to use the fear to their benefit and are not afraid of law suits involving any processes with unfavorable outcomes to them.

"The biggest fear in procurement is not that the best solution would not get purchased but the possible law suits" (IV12)

The public procurement directives do allow purchases outside the tender agreement in a yearly value below a certain threshold but the procurement people are often unknowledgeable about the possibilities beyond the tender agreements. This is again related to the lack of expertise and to the false interpretations made on the regulations, leading to avoidance of anything out of the normal operating procedures in the procurement chain. (IV12; IV13; IV14; IV21; IV23)

As the description above shows, much effort is needed in overcoming the barriers created by the complexity of the multiple stakeholders and the conservative and bureaucratic nature of the public procurement processes. There are strong, old hierarchies present in the health care market with the actors unwilling to change the structures. This leads to significant implications to innovation sales in this regulated market.

7.2.4. Financial

The final group of challenges deriving from the many barriers to entry relates to the financial resources needed in market entry into a regulated market. The industry is heavily consolidated with only a few large incumbents that, in the pressures of cost cutting from the national health care budgets, are fiercely competing over maintaining their market share and the huge profit margins. They have massive organizations in place to support the massive profitability and are very defensive of their market position. (IV3; IV16) In addition, they have the money, the power and the control to outspend, outshout, and outprice the new entrants, increasing the severity of many of the challenges (IV3; IV16). As a manufacturing

company, production capabilities and value networks need to be in place before entry, increasing the sunk costs and raising the investment risk related to entry. (IV2; IV19) The financial challenges of entry are discussed in this section.

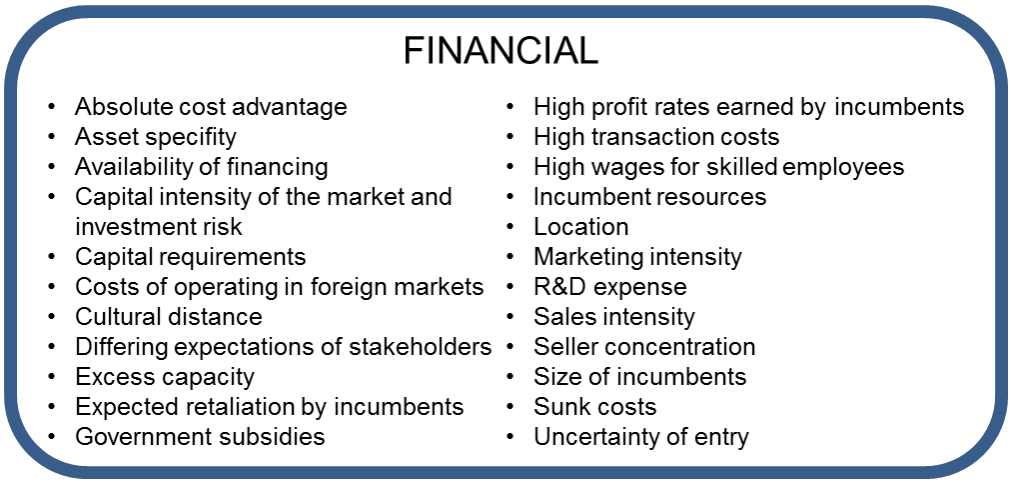


Figure 11 Barriers related to financials

The costs of entry to the market are significant in a regulated industry. Blood glucose meters are fairly complex devices combining electrochemistry, software and other technologies creating challenges for R&D which is often costly with such devices (IV18). Once the product is ready in compliance with the standard specifications and the project documentation complies with the heavy demands, the next costly hurdle is gaining the required regulatory approvals including costly trials and other data to prove the safety and efficacy of the new product (IV22; IV24). As discussed in section 8.2.1., the regulatory requirements are based on current technologies and thus there is always risk involved in innovating (IV13; IV22; IV23, IV24). In addition, changes in the standard requirements can swipe out a number of products from the market, leading to mass paralysis already out of fear of changes (IV1; IV2; IV16; IV20). These factors raise the uncertainty of entry significantly, directly affecting the investment risk (IV1; IV2; IV16; IV20) In parallel, the company needs to build up their supplier network, production capabilities and prepare for scaling up the business in preparation for the start of sales (IV13; IV19).

The heavy need for cash does not end once the operations have been set up for the start of sales. Taking the product to market is significantly more costly than R&D. For Mendor, some 20-30 % of the total financing needs were spent on getting the product ready and approved but between 70-80 % are estimated to go into entering the market (IV19). This is no anomaly in the field of medical technologies (IV1; IV2; IV16; IV18; IV20).

"*In the medical field, whereas 1x is needed for R&D, another 10x is needed for market entry – but a 100x for international growth!"* (IV11)

Huge finances and capital are needed for building the operations even before entry which in turn ties up significant amount of capital even before the regulatory approvals and first sales, making the uncertainty of entry a significant issue in terms of financing as the sunk costs are substantial (IV1; IV2). Still, the majority of the costs are related to the major up-front investment needed for success in the market.

Due to the heavy marketing and sales intensity of the market, relating to a great number of different stakeholders and to the significant chain of actors between the end user and the company, heavy marketing and sales investments are needed to drive success. The different objectives of the stakeholders require for convincing data which is also very costly to produce, including robust market research in the target markets. Due to the many difficulties related to selling in the industry, as discussed in the previous section on challenges for sales created by the barriers to entry, there is a need not only for massive sales muscle in terms of reach but in terms of the required skill level of the sales people. In order to be able to succeed in sales, highly specialized and experienced sales people are necessary, who are able to work with the different types of stakeholders with different needs. Finding the sales people who are skillful enough is one challenge but bearing the heavy costs of a specialized sales force is another. In addition to the investment in success through marketing and sales, a significant up-front investment needs to be borne due to the nature of the

market. As described in earlier sections (8.1.2. and 8.1.3.), the company needs to make a significant investment up-front by placing the blood glucose meters into the market free of charge, with a significant lead time before the sales of the consumables will follow due to the slowness and lag times created by the chain of stakeholders characteristic to the market. (IV3; IV16)

As estimation is that the financial overhead caused by the regulated market brings is approximately 60 % in comparison to less regulated markets, posing challenges for financing of the operations (IV13). When the time factor is taking into account, the challenge becomes even more crucial – how will the company finance its operations and stay above the water during the significant lag time it takes to produce sales in the market (IV9; IV17; IV19). In many cases, small companies do not have the money it takes to succeed. The typical development chain of medical innovations and their funding is presented in Appendix 3.

Mendor was able to raise financing for its R&D efforts with a combination of public and private financing. Using Tekes' loans and grants for R&D and the funds the company had secured from private investors after its win in a Venture Cup competition, it managed to get the product ready and approved. Once the R&D phase was over, the company found it significantly harder to find financing for its operations. They noticed that within the public investors there is an illusion that after the product is ready, funding will become available from private sources. In reality there is a big gap as the private investors often require proof of the concept and a level of cash flow before they become interested. As described in section 8.2.1, the slowness of the market affects the accumulation of the both proofs significantly and the company easily slips into a vicious circle in case the time between R&D financing and commercializing financing is long. The company will not have the money it needs for its commercialization efforts that are required to find suitable partners in different markets all while the

private investors are waiting for verification of the market potential before they invest in the company's market entry efforts.

Mendor's struggle in securing further financing after the R&D phase is a common challenge with many Finnish companies (IV1; IV2; IV5; IV8; IV9; IV17). The public support system offers plenty of funding for R&D but the companies are left alone to commercialize (IV14). TEKES is one of the only public funding agencies that offer any support for internationalization of companies. As such, the amount of financing available is only a very small fraction of the agency's R&D support as shown in the figure 13 below.

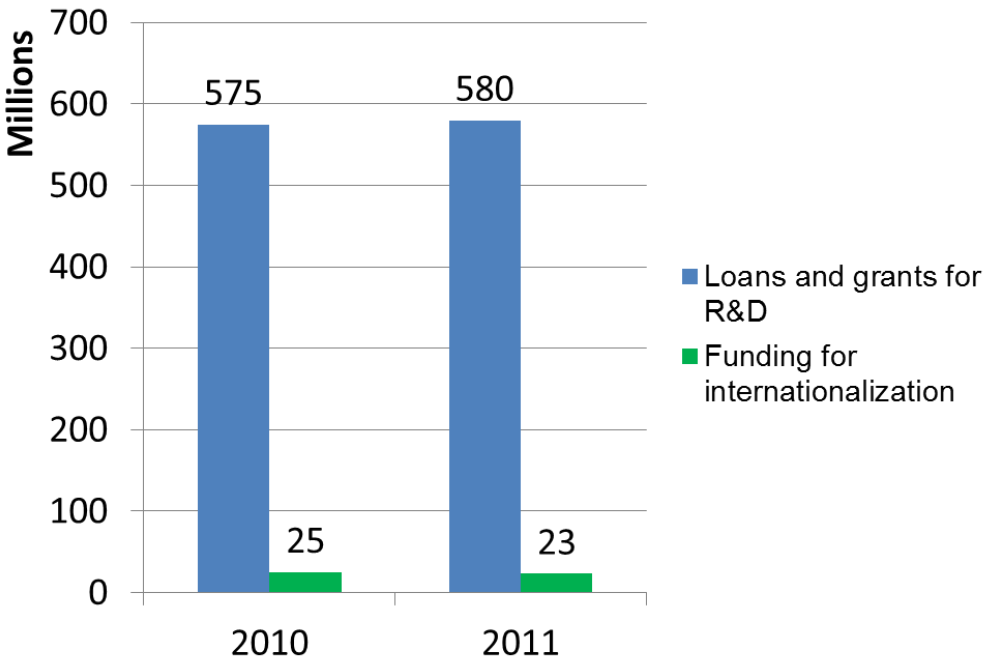


Figure 12 TEKES funding for R&D and internationalization of companies
(DOC 7)

"*The lack of money in Finland for commercialization is insane. At the same time as R&D funding is offered to all companies, including large companies with massive profitability, many small companies with great potential go under as their cash runs out*" (IV13)

Often the lack of public financing for operations after the R&D phase is justified by reference to EU anti-trust policies (IV4; IV7; IV8; IV9; IV13; IV17; IV19). When interrogated about the level of restrictions, it was evident that the legislation does not forbid all public support for activities related to commercialization but rather that different interpretations of the legislation make it easier to offer support for R&D (IV4; IV7; IV8; IV9; IV17). For instance, public funding could be used to support the preparations of market entry, including the search for partners and market research. Currently these funding options are scarcely used.

"The support for commercialization is so poor not because it would not be possible but because people interpret the regulations as black and white, and do not really understand what is possible and what is not. Explaining the lack of public support for commercialization with anti-trust issues is flawed as the regulation itself already disturbs the market as do any public grants given to large companies turning a huge profit." (IV13)

The amount of private venture capital is very little currently in the biotechnology field as many financing portfolios have quit in the recent years and new ones have not been born to fill the gap (IV11; IV17; IV20). The remote location also affects the amount of money available for Finnish companies as Finland is often considered too remote for financing from the US or other large venture capital markets, both geographically and culturally (IV8; IV9; IV19). Even though the situation has improved in the recent years, there are still too little risk investors in Finland and companies need to go abroad to raise funding which in turn requires more resources and skills (IV19).

Mendor has also faced challenges linked to managing the different expectations of its stakeholders, including its investors. Many investors often have unrealistic expectations on the returns and the time it takes in the medical device market in comparison with consumer market returns that they more familiar with (IV13). The complexity of the market with different

stakeholders, high sunk costs, the uncertainty of entry and the small number of investors who are knowledgeable about the market decreases the motivation to invest to start with (IV17; IV19). Managing the expectations of the investors has been a challenge for Mendor as some of its investors are more patient with their investment than others (IV13). This challenge has also been strongly linked to the difficulties the company has faced in forecasting the amount of money needed before the company will break even and the time it will take before the company would become profitable, related to the lack of deep market understanding and too much optimism when assessing the time to market as discussed in sections 8.2.1. and 8.2.2. The changing estimations from the company to its key stakeholders such as the investors or the suppliers relating to sales forecasts have been a major challenge for the company in maintaining its credibility (IV18; IV19). As many companies in the field, also Mendor was too optimistic concerning the time and the amount of resources needed to enter the market (IV7; IV9; IV11; IV18; IV19; IV20).

7.3. Tackling the barriers to entry

After the description of the four major groups of challenges to Mendor caused by the barriers to entry in the market – time, experience, sales and financial – the focus will now be on the chances of the small company to tackle the identified barriers to entry. This chapter will follow a similar structure as the previous section in the discussion on tackling the identified barriers to entry, while answering the second piece of the first research questions on *how* small companies with limited resources can tackle the barriers to entry in regulated industries.

7.3.1. Time

As the slowness of the market is one major industry defining characteristic, an individual company has little chance on affecting the time but has to accept the time factor. What a company can do is to mitigate delays by thorough preparation and focus.

First and foremost, the company should seek to investigate the potential barriers to entry in different target markets as the first steps of existence, to be able to make an enlightened decision on market entry and the key markets to target (IV9). Choosing the right target markets is paramount to success and the focus should be decided already in the very start to be able to take the regulatory requirements of each of the key markets into account already in the product development (IV7; IV11; IV13). The product should be designed keeping in mind the standard requirements as the approval process will be much easier if similar technologies are already in the market (IV11) and sometimes waiting for a similar technology to first get approved can be a strategic choice to avoid the heavy, costly and lengthy premarket acceptance process (IV22). Learning from the competitors' products can be useful to a certain extent, to save own strained resources. Mendor used this tactic especially in relation to its product materials, including user manuals

that heavily controlled by different directives in terms of their contents. The imitation needs to be balanced to avoid becoming too similar with the generic products already out in the market leading into pure pricing competition that the incumbents with their absolute cost advantage would most likely win. (IV13)

Entrepreneurs should understand to let go of the Finnish tendency of developing the products too far on their own before linking with the outside world (IV7). The company can gain many benefits from early collaboration with regulatory bodies and other industry actors, already sharing and gaining information during the development process. Often in technology focused companies there tends to be an element of naivety and stubbornness with entrepreneurs wanting to go too far on their own (IV17; IV18). Companies also often falsely rely on the uniqueness of their product but an extensive competitive analysis needs to be made in advance, especially in regulated markets where patents and licenses to operate are important considerations (IV7). In addition, the preparations for sales should be started already well in advance of the regulatory approvals to inform the stakeholders of the new product about to be launched in the market (IV20).

The selecting of the right markets to target is an essential consideration and can even define the company's future (IV7; IV9; IV16; IV20). This decision should be made based on proper market research and the company should focus on finding appropriate companies in those target markets who can give the financial or expertise leverage the small company will need (IV16). If the target markets are not selected early enough, the company will end up wasting time and resources and potentially lose the early sales that would have kept the company financially afloat (IV7). The focus should be on markets that will allow entry fast – the size of the market is not the only viable consideration but other considerations such as the organization of the purchasing infrastructure is essential (IV20). Often, due to locality, it is easier to start with nearby markets which unfortunately was not the case for

Mendor that is still struggling to create traction in the home market and needed to go abroad in order to produce sales (IV13).

Companies should understand that market entry takes up a lot of resources and a company should rather focus on specific markets at a time (IV9; IV20). Pressured by the need to generate cash flow in the short-term to keep the company alive, Mendor was targeting different local distribution companies without clear considerations on the suitability of the partner or the resources that need to be dedicated in the longer-term to manage the accounts in different countries with several different partners. Looking back, things could have been done much more efficiently by only focusing the resources on a few key issues - clearly and strictly targeting certain areas and not wasting the small resources by going too wide. (IV15) Finding the markets where the prices are still on an acceptable level and by targeting rather a niche category of suitable patients for the specific device to start with would have helped in keeping the internal costs done. After realizing the amount of resources being tied into producing sales from a number of different small areas through distributors who were not experienced or resourced enough to be successful in the markets, the company changed its strategic focus on realized that the only way to gain success is to find the right partners and focus all the company resources in finding those key partnerships. (IV15; IV16; IV18)

7.3.2. Experience

To tackle the challenges posed by experience related barriers, companies should focus on defining the key skills needed in the industry and on finding those key skills as early on as possible (IV9; IV18). The skill sets needed in different industries are often different (IV17). Experienced people who know the market should be consulted even before making the market entry decision. Even though the expertise will be a significant cost for the company in the early stages, it will often be an investment necessary to

make rather earlier than later. Otherwise the company will end up making wrong decisions and wasting time, money and resources on the market, only to realize later that they need these experts to succeed. All the expertise does not have to be in-house but outside consultants or other experts can also be used (IV7; IV22). Understanding the market better becomes critical and can save a lot of pain as the company can make the right decisions earlier on (IV15; IV18).

"*Defining the needed skills and competences and then making sure that these abilities are in the company is essential - good people are only needed in minority but without them nothing works*" (IV20)

To be able to attract these industry experts, small companies should have a really interesting idea which Mendor successfully managed to achieve. The larger incumbents in the market have earlier on tried to develop integrated products without much success in the area and thus Mendor's product is interesting for industry experts. Networks and relationships are essential in finding these key skills and incubators are good routes to these contacts. Networks and relationships also help in building trust and creating industry connections and a small company should try to find people to the company, or at least to serve as board members or advisors, who have strong networks in the industry (IV7; IV10; IV17). The personal networks of the company's investors also opened doors to Mendor in the start. (IV15)

Another thing that the company learned was that an international team is essential for international market entry and Finnish people rarely have the needed skills in international sales (IV15). Finnish people often are very skilled in the technology front but lack sales and marketing skills (IV4; IV7; IV9; IV10; IV15; IV17; IV19; IV20). A symptom of the lacking business skills is that Finnish people often try to go technology first without understanding that the customer need is what should be communicated (IV10). A top class international sales person is a must for a company

reaching to international markets – even though usually very expensive, it is essential (IV15).

The experience can also be gained through partnerships. Through partners, a small company can get access to competences and resources that can grow for decades. Key partners can also be willing to invest their own resources into a new company if they see the potential. The relationships and the bonds created between partners are very important and even in case of problems the partner would often be willing to offer their help. (IV20) After taking their targeted approach to seeking partners, Mendor has been able secure a partnership with a large pharmaceutical company who can leverage also Mendor's need for expertise and other support.

7.3.3. Sales

The relationships and the reference value that credible partners can offer should not be underestimated in relation to tackling the barriers related to sales. Not only will a carefully selected partner have the resources needed to penetrate the market, they will also serve as references to other stakeholders, including other customers (IV9; IV15; IV19). Thus also the key to the sales challenges is often in finding a suitable partner for each of the key target markets. The key driver should be partners who are able to offer what you are missing in terms of resources and expertise in the market (IV16; IV18). Choosing the right partner is an important consideration and should be based on a combination of resources, drive, channels and reach – without forgetting personal chemistry (IV4; IV9; IV15).

A good partnership does not produce itself though but sales skills are essential in being able to find and develop great partnerships. Even a good product does not sell itself even though this illusion still seems to be alive at least in Finland (IV7). Linking back to the last section on expertise, strong international sales skills truly are necessary to be able to succeed in the difficult regulated business (IV15; IV16; IV20).

Finnish companies also often are misled into believing that a Finnish name would be of value in international markets which is often not the case. This misbelief is often driven by patriotism and nostalgia. In reality, a local or a global brand and market entry with a locally well-known partner is very important to succeed (IV7).

To succeed in competition with decreasing prices and increasing restrictions, companies should try and prove savings for the whole health care system. These types of wholesome analyses are often impossible to conduct for a small actor but working through a larger partner these could be produced. In some cases that still might not be enough as there are often separate budgets for treatment and supplies (IV8).

The success in tackling the barriers to entry relating to sales are in many cases structural and dependent on the characteristics of the customers. A small company can through partnering with the right partners accumulate the best resources possible in terms of expertise and reach to succeed with the complex sales to customer organizations. (IV15; IV16)

A sustainable competitive advantage should be based on highly differentiated technologies able to generate cost reductions for the health care payers – the most effective strategy could be based on the highest health impacts for the patients and thus the highest potential long-run savings for the payers. (IV16; IV23) To be able to arrive to this point in time, significant changes are needed also in the customer organizations.

7.3.4. Financial

To tackle the financial challenges, having the right skills in the organization is as essential as in succeeding in sales (IV19). In raising capital, it is crucial to have a compelling presentation on the reasons why the company will be able to make an exit or become profitable itself - certain skills are needed to

sell the idea to assure the investors (IV15; IV19). The CEO of the company is an important person and needs to be a good motivator, both towards the investors and the potential partners, with a strong drive to take the company forward (IV19).

The chances for financing can be increased with a credible business plan and a strong sales pitch. The team is very important to investors, in terms of the right expertise, networks, motivations, drive, a good story. (IV8) Still, the problem often becomes the need for proof of concept which takes a long time in a regulated industry. The same as Mendor, many companies will struggle in raising more funding after the R&D phase. (IV1; IV13; IV19)

The huge investment need necessary in the market can be tackled by sharing the risk with investors, local governments, customers and other partners. Focus on target markets while trying to keep the internal costs down should be a number one priority for the company. Finding the specific market that do not require such significant investments and offer a quicker return should be strictly targeted. (IV16)

7.4. Government and innovation support system role

As the governments and societies as a whole are important stakeholders in health care market outcomes, the role of the government and the public innovations support actors is also briefly discussed. As an additional research question in this study, the role of the government as a supporter of new company birth and growth is examined. In the health care industry, the question is fairly complex as the government and its suborganizations are on the other hand the customers of the company through the municipalities and their health care supply procurement and on the other they represent the public innovation support actors such as the Finnish Funding Agency for Technology and Innovation (Tekes). In this section, potential for the

government to influence the barriers to entry in health care markets is discussed briefly.

As discussed in chapter 2.1., the governments and societies as a whole benefit from innovation and should seek to promote the birth and growth of new companies. This issue is even more apparent in the health care sector, where the outcomes of treatment are directly related to the social welfare of the society and thus the supporting of local innovation in the health care sector should lead to increased total welfare, also through the direct company taxes and jobs created. In addition, to be able to repair the current export gap of over 20 million euros caused by the global economic environment, Finland needs new companies generating growth. (IV9).

According to Blees et al. (2003), governments that want to stimulate entrepreneurship and competition should take into account that some barriers can only be influenced in the long run through public policy decisions. Many of the challenges faced by Mendor are specifically related to the structures that the government can improve.

For instance, in relation to Mendor's financial challenges, raising financing after the initial R&D phase is very difficult in Finland due to the low availability of funds. The public funding is strongly focused on R&D and invention support even though the real financing needs start only after the product is ready. The fear is that many good inventions will be missed as they will die as they will not have the sufficient funds required in market entry (IV19) and end up missing time, energy and business ideas in Finland as the support system gets weaker and weaker once the company develops towards potential growth (IV17). Currently, the public financing also seems to be geared towards certain "trend" industries at a given time, giving the funding a strongly present focus. Instead of focusing in the industries of today, public funding should be applicable to a wide variety of industries as the future industries cannot be defined today.

"*You cannot know in which field the next Angry Birds will come from and thus the focus of financing should be on a wide range of industries"* (IV17)

There is also considerable fragmentation in the field with of innovation support system whereas companies should be serviced as a whole and not in separate pieces. The cooperation between the actors should be increased and the number of actors should rather be decreased to ensure efficiency (IV6; IV7; IV8; IV9; IV11; IV12; IV17; IV19). The current support system, especially related to financing, does not consider the industry specific challenges that companies face. Due to the nature of the industries, the financial needs are not the same in for instance for a consumer software business and a regulated manufacturing industry. The public support system should recognize the different needs. (IV19)

As the challenges related to sales for Mendor showed, the bureaucracy and current conservative practices in public procurement focusing on procurement by specifications and not on the need are major barriers to entry for innovations, especially in the health care sector (IV1; IV6; IV9; IV12; IV20; IV21). As the current structures are very heavy and often lead into wasting of resources and into false cost savings as the focus is only on short term costs instead of the total lifetime costs or on the treatment outcomes (e.g. IV5, IV8).

As one of the actions of the Ministry of Employment and the Economy, an innovation policy has been developed, with the main goal of creating an innovation friendly environment to Finland to support new company birth and growth (IV12). The policy identified public procurement as one of the key chances of influencing the demand conditions locally and seeks to develop the public procurement practices towards demand-side procurement (e.g. Edler & Georgiou 2007; DOC6). One concrete change would be to use at least a few per cent of the € 35 billion euros spent annually for public procurement on innovations. (IV12)

The government's innovation policy is designed also to influence the public procurement practices to be able to move to demand-side procurement, taking into account the actual need in procurement. Public procurement is a major part of local demand and due to the difficulties present in the area currently, home market support is very weak for innovations in this area. (IV9; IV10; IV12; IV13; IV20) The improvement of public procurement practices should lead to improved outcomes for all the stakeholders as it would also improve the public infrastructure and public services in general, also providing supplies for the treatment of diseases that are based on the actual patient need (e.g. Edler & Georgiou 2007; DOC6). Towards this end, a wholesome change is needed in the public procurement system to enable such an approach. The system and all its structures should be changed to focus on the outcomes and long-term societal consequences instead of short-term costs. This requires significant purchasing skills that are currently not present in public procurement.

This case study should offer ground for considerations of innovation policies and the innovation support system from the point of view of a local entrant in the health care industry. Rather than offering ready solutions, the challenges faced by Mendor, in many cases related to the structural barriers of its home market, should offer food for thought for government decisions makers on issues related small company and innovation support in the health care industry.

"*Affecting lasting change in the health care arena is more like a marathon than a sprint*" (Hermans & al. 2009, 58)

7.5. Findings – Comparison of the theoretical background and case study findings

In this chapter of the study, the findings of the case study will be compared to the theoretical background. In chapter 5, a synthesis of the literature review on the barriers to entry was given. As described in the synthesis, the theoretical interest has mainly focused on the incumbents and on their strategies for deterring entry for new entrants in order to maintain their market position (Porter 1979; Robinson & McDougall 2001; Porter 2008; Pehrsson 2009; Lutz & al. 2010) whereas the barriers to entry from an entrant point of view have been studied less. In order to understand the implications of a high regulation to barriers for *de novo* entry, this case study was used to examine a specific setting of a highly regulated health care industry and the barriers to entry from the perspective of a small entrant with an innovative offering.

The case study in the specific industry setting produced 71 different types of barriers not only confirming that the types of barriers to entry vary by industry but also that the high regulation in the industry creates structures that easily lead to unfavorable conditions for new entrants. The findings also suggest that the barriers to entry are strongly linked to the industry but also to entrant specific characteristics. Furthermore, the barriers are not constant and stable over time but change through the interplay of the incumbent, entrant and government policy actions.

Whereas earlier theory has mainly focused on the incumbents' strategies for deterring entry and seen the entrant as subverting to the barriers to entry, this case study by focusing on the challenges that the barriers to entry create for the entrant, shows that the entrants can formulate strategies for tackling the barriers to entry to respond to the entry deterring strategies of the incumbents. The ways in which the company will tackle the barriers changes through time with a main goal of "*creating a customer*" (IV15; IV20).

Thus, the barriers to entry should not be seen as static and constant characteristics of a market but rather as dynamic conditions that are constantly being restructured by the incumbent and the entrant actions and facilitated by the government policy measures affecting the industry structure and conduct.

The findings of this case study broaden the theoretical understanding of the barriers to entry for the *de novo* entrant and point out the immense complexity and the inter-connectedness of the challenges that the barriers to entry pose for the small companies. Whereas the theoretical findings suggest the incumbent's strategies as the antecedent for strategic barriers to entry and government policy measures as the basis for the structural barriers to entry, the empirical findings offer a more vivid interpretation of the barriers to entry as changing in time and being affected also by the entrant strategies. In the case study, the barriers to entry are grouped according to the challenges and constraints that they pose for the entrant that in terms allow for the identification of the entrant's potential to influence these barriers.

Based on the theoretical findings, the only barrier that the entrant could influence through its actions would be overcoming the brand name barrier. The concept of 'arch incumbency' created by Fan (2010) also included a notion that a small entrant could improve its chances in market entry by focusing on small niches. In addition, earlier research has suggested that a very innovative entrant might be able to decrease the need for capital and be able to differentiate the offering in a beneficial manner (Han & al. 2001; Pehrsson 2009). The empirical findings suggest the strong industry specificity of the barriers to entry and suggest that indeed in highly regulated industries innovation might not always lead to favorable consequences but can actually increase the need for capital as the time to market is lengthened.

The findings of the case study would imply that in reality the conditions for market entry are much more dynamic and even though the entrant can

hardly affect the barriers to entry, they can, after identifying the main challenges posed by the barriers, formulate differential strategies for gaining entry in response to the incumbent strategies seeking to deter entry. An important consideration is the industry characteristics, including the target customers and entrant and incumbent characteristics. The interplay between the three actors, the entrants, the incumbents and the governments, affects the barriers to entry and as such serves as the antecedent for tackling the barriers to entry through differential and agile strategies that can beat the incumbent deterrence strategies.

The findings of the case study confirmed the important role of the government as the influencer of many barriers to entry, especially the structural barriers. An important finding from the health care industry is that the current structures do not serve the objective of support for birth and growth of new local companies and due to the bureaucratic structures focusing rather on specifications rather than the need, the health care outcomes that the current structures produce might be suboptimal too in the longer term. Instead of improved net social and economic welfare, the current structures may lead to false savings for the municipalities, decreased treatment outcomes for the patients and high structural barriers to entry for local innovation.

As the theory suggested, the studying of barriers to entry in a regulated industry confirms that a regulated environment reproduces the industry status quo and leads to high consolidations and the favoring of the incumbents. The lack of competition will lead to decreased social and economic welfare, especially in the case of health care market where the industry outcomes are directly related to the social welfare of the public. A key finding of the case study that by taking the entrant's perspective and identifying key challenges that the barriers to entry pose for the small entrants instead of only looking at their sources, these companies can formulate strategies for tackling the barriers to entry that need to change over time to address the key challenges of the moment. Another important

finding is the government can and should affect the industry outcomes by focusing on lowering the barriers to entry, to promote the birth and growth of new companies also in regulated industries. The comparative chart of the findings of the theoretical background and the empirical case study are summarized in Tables 4 and 5.

Table 4 Comparison of theoretical and empirical findings on barriers to entry

Theoretical barriers to entry	***Company specific advantages*** **11** barriers to entry based on incumbent advantages identified	***Customer/market-based advantages*** **5** barriers to entry based on incumbent advantages identified	***Financial requirements / cost of entry*** **12** barriers to entry identified	***Profit expectation of entrants*** **7** barriers to entry identified	***Industry characteristics*** **7** barriers to entry identified
Case company barriers to entry	***Company specific barriers*** **17** barriers to entry based on entrant challenges identified	***Customer/market-based barriers*** **14** barriers to entry based on entrant challenges identified	***Financial requirements / cost of entry*** **13** barriers to entry identified	***Profit expectation of entrants*** **12** barriers to entry identified	***Industry characteristics*** **15** barriers to entry identified
Difference	**In the case study, causal ambiguity and divisionalization did not pose barriers to entry for the entrant but are rather related to incumbent internal challenges.** **8 additional barriers to entry were identified in the case**	**All the theoretical barriers to entry were identified in the case study.** **9 additional barriers to entry were identified.**	**All theoretical barriers to entry were identified in the case study.** **Only one additional setting specific barrier was identified.**	**All the theoretical barriers to entry were identified in the case study.** **5 additional barriers to entry were identified.**	**All the theoretical barriers to entry were identified in the case study.** **8 additional barriers to entry were identified.**

Theoretical barriers to entry	***Company specific advantages*** Identified barriers to entry are strongly linked to the incumbent perspective i.e. "*the incumbent advantages*"	***Customer/market-based advantages*** Identified barriers are based on the incumbent's existing relationships and bonds with customers	***Financial requirements*** Financial barriers are a significant barrier to entry	***Profit expectations*** Profit expectations of entrants determine the attractiveness of an industry and thus affects the entry decision	***Industry characteristics*** Certain industry characteristics can lead to severe structural barriers to entry
Case company barriers to entry	***Company specific barriers*** The empirical findings suggest that the entrant internal characteristics can also pose barriers to entry	***Customer/market-based barriers*** The findings suggest that the customer characteristics can be a significant source of additional barriers to entry	***Financial requirements*** The findings suggest that the financial requirements are a significant barrier to entry and the costs of entry are massive in regulated industries	***Profit expectations*** The industry characteristics affect the profit expectations significantly, not only limited to the financial considerations of entry	***Industry characteristics*** The industry structure but also the industry conduct can lead to severe structural barriers to entry
Difference	The empirical findings suggest that the entrant characteristics such as the lack of previous experience constitute severe barriers to entry in addition to the previously identified barriers that arise from incumbent characteristics. The group of barriers should acknowledge both the incumbent and entrant company specific barriers.	The customer characteristics in a highly regulated industry posed significant challenges for the entrant company that created time and financial constraints and significantly delayed the start of sales and hindered the adoption of the innovative offering. The findings suggest that the industry setting is a crucial determinant of the types of barriers to entry especially with a differentiated offering.	The empirical findings correspond to the theoretical barriers to entry and confirm that the financial requirements constitute a significant deterrent for entry. Furthermore, the cost of entry is massive in regulated industries, coupled with financing challenges due to the uncertainty of entry and the significant slowness of the market. The findings suggest that financial barriers are significant but their severity also varies per industry.	The industry characteristics such as the time to market or the average product lifecycle affect not only the profit expectations but also the time to market, thus also having an impact on the financial and resource considerations of the entry decision. The industry characteristics need to be taken into account whilst making the entry decision to be able to make a realistic assessment of the barriers to entry.	The findings suggest that the industry characteristics of a regulated industry affect the conduct of the actors of the industry and lead to many severe barriers to entry. In the studied regulated industry, the industry characteristics have led to severe side effects such as extreme risk aversion and inefficient processes that resist change. The industry characteristics are the cornerstones of the industry conduct that will follow.

Table 5 Comparison of theoretical and empirical findings on 'tackling' the barriers to entry

Theoretical entrant influence on barriers to entry	• To have any chance of entering, the entrant needs to solve the absolute cost disadvantage • The entrant can only influence one barrier to entry – the brand name through heavy spending • The entrant can only formulate market entry strategies by varying the product/market scope and product differentiation • Innovativeness can lead to decreased need for financial capital
Case company tackling barriers to entry	• By focusing on the challenges that the barriers to entry pose for market entry instead of the sources of the barriers, the entrant can formulate strategies for market entry and overcome the barriers to entry • Whereas the incumbents can formulate strategies for deterring entry, the entrants can formulate strategies for gaining entry – these strategies change in time with the key objective of 'creating a customer' • In highly regulated industries, innovativeness can lead to greater need of financial capital as the time to market is delayed
Difference	• The barriers to entry are not static and constant characteristics of a market but rather dynamic conditions that are constantly being restructured by the incumbent and the entrant actions through the strategies they are formulating and executing, and by changing government policies affecting the industry structure and conduct

PART IV – DISCUSSION AND CONCLUSIONS

8. Discussion and conclusions

In this chapter, the thesis is concluded by synthesizing the findings. In addition, the academic and empirical contributions of this study and suggestions for further research on barriers to entry are discussed.

8.1. Synthesis and discussion of findings

This thesis focused on studying the topic of barriers to entry in a highly regulated industry from the perspective of a small entrant. A majority of the earlier research has focused on the incumbents and their strategies on creating and strengthening the barriers to entry in an industry. As such, the entrant perspective in this study offers a new context by studying the effects of barriers to entry for the entrants in a regulated industry setting. As an additional point of interest, the role of the government as the regulator but on the other hand as a supporter of new companies creation and growth is briefly discussed.

The main objective of the thesis was:

To add to the existing knowledge on the barriers to entry from the perspective of a de novo entrant in a specific industry setting defined by high regulation; to discuss the effect of regulation and high entry barriers on the barriers to entry for a de novo entrant and to identify what potential does the entrant have in tackling these barriers to entry.

This objective was studied with the main research question:

What are the barriers to entry for a small-scale *de novo entrant* entering a highly regulated market and *how* can the new entrant influence these barriers with limited resources to gain entry?

To be able to adequately answer the main research question, four additional sub-research questions were formulated. The first and the second research questions were answered through a literature review covering the existing research on barriers to entry. The third and fourth research questions were answered through the case study of Mendor Oy. The main research question is linked to all parts of the study and is answered through the four sub-research questions and further clarified in section 7.5. summarizing the findings of this study.

RQ1: According to previous theory, what are the barriers to entry for a *de novo* entrant in a highly regulated industry?

The first research question was studied through a literature view on the existing research on barriers to entry, taking into account the implications found on the effect of regulation in an industry, and also studying the effect of the size of the entrant on the theoretical barriers. 42 different types of barriers to entry were identified and are presented with their literature sources in Table 1. A categorization suggested by Karakaya (2002) was used as a basis for the grouping of the barriers to entry into five different groups including the company specific advantages, customer/market-based advantages, financial requirements/cost of entry, profit expectation of entrants, and industry characteristics.

RQ2: According to previous theory, how can a *de novo* entrant tackle these barriers to entry?

After the ‘what’ are the barriers to entry had been identified in the study on the first research question, the main objective of the second research question was to focus on ‘how’ the entrant could tackle the barriers to entry. The previous research strongly takes the incumbent perspective in the study

on barriers to entry and only scant attention has been given to the entrant's chances of tackling the barriers to entry. The limited research knowledge on the subject suggests that the entrant first has to overcome the absolute cost advantage of the incumbents and only then can have a chance in entering. The theories suggest that the entrant has very limited chance of tackling the barriers to entry and instead suggest that the entrant can only formulate strategies varying the product/market scope and product differentiation. Thus, the previous theory suggests that the entrant is rather helpless in terms of barriers to entry and in the face of the incumbents and has little chance of gaining market entry in industries where the barriers to entry are high.

RQ3: What are the barriers to entry for a *de novo* entrant in a highly regulated industry based on the empirical findings?

The third research question was tackled through a case study focusing on the market entry efforts of a small *de novo* entrant seeking to gain entry into the highly regulated health care industry. In the case study, 71 different types of barriers to entry were identified, offering empirical evidence to the theoretical models linking high levels of regulation to high barriers to entry. In addition, the industry specificity of the types of barriers to entry became evident. In regulated industries, the characteristics of all industry actors affect the barriers to entry and the severity of the challenges posed to new competition. The comparison of the theoretical and the empirical barriers to entry is provided in Table 4.

RQ4: How can a small-scale *de novo* entrant tackle the barriers to entry with limited resources based on empirical findings?

To be able to study the potential for the entrant to influence i.e. 'tackle' the identified barriers to entry, a shift in the focus was needed. Whereas much of the previous research takes the incumbent perspective and focusing on the sources of the barriers to entry to give recommendations to incumbents on how these barriers could be created or strengthened, the current study focused on the challenges that the barriers to entry create for the entrant. In the case study focusing on the specific industry setting, four main groups of challenges were identified, mainly time, experience, sales and financial related challenges. After the identification of the challenges, the potential for the entrant to tackle the challenges created by the barriers to entry were examined. As the findings in Table 5 suggest, according to the empirical reality, an entrant has the potential to formulate different strategies for tackling the barriers to entry that change in time to answer to the barriers to entry posed by incumbent strategies. Thus the findings of the case study suggest that barriers to entry are not static but rather dynamic, changing in time through the incumbent and entrant strategies. As such, the findings suggest that the entrant can indeed through formulating successful strategies, tackle the barriers to entry even if it could not affect the structural conditions of the industry.

8.2. Scientific contribution and suggestions for further research

The objective of the current study was to extend the previous academic research on barriers to entry firstly by taking the rather understudied entrant perspective and secondly by examining a specific industry setting of high regulation to offer empirical evidence to theoretical models suggesting a correlation between the level of regulation and entry barriers.

Whereas the earlier research on barriers to entry has largely ignored the potential for the entrant to influence the conditions for their entry (Porter 1979; Robinson & McDougall 2001; Porter 2008; Pehrsson 2009; Lutz & al.

2010), this study by studying a small scale entrant seeking to enter a market characterized by high entry barriers, adds to the previous theoretical understanding on the role on the entrant in relation to barriers to entry. Whereas the previous research suggests that the entrant is rather powerless in relation to the barriers to entry (e.g. Blees & al. 2003; Cabral & Mata 2003), the findings of this study suggest that the entrants can indeed formulate differential market entry strategies to respond to the entry deterring strategies of the incumbents. In addition, even though the earlier research implies that the incumbents through their strategies (Grant 1991; Robinson & McDougall 2001, Blees & al. 2003; Pehrsson 2009; Lutz & al. 2010) and governments through their policy measures (Blees & al. 2003; Hermans & al. 2009; Friedman & Taylor 2011) create the strategic and structural barriers to entry, the findings of this study suggest that the barriers to entry are indeed affected by the interplay between the three actors – the entrant and incumbents strategies and government policies. Thus through the changing strategies of the actors, also the barriers to entry change in time, creating new settings for entry.

Even though the government regulation has been acknowledged as a strong determinant of industry structure and conduct, and an antecedent to many structural barriers to entry (Blees & al. 2003; Hermans & al. 2009; Friedman & Taylor 2011), the phenomenon has not been studied before in a regulated industry setting. A body of research has modeled the link between regulation and high barriers to entry, assuming that a high degree of governmental regulation deters entry from new competition and leads to decreased social and economic welfare (e.g. Shaffer 1995; Blanchard & Giavazzi 2003; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012) but the empirical evidence has been largely missing (Lutz & al. 2010). This study seeks to add empirical evidence to the effect of regulation on the conditions for entry. The findings of the case study offer empirical support for the theoretical implications that high regulation leads to oligopolistic structures and high barriers to entry that in turn decrease the competition in the market and lead to decreased economic and

social welfare, also severely disturbing innovation in the industry (e.g. Shaffer 1995; Gaynor & Haas-Wilson 1998; Bertrand & Kramarz 2002; Blanchard & Giavazzi 2003; Blees & al. 2003; Hermans & al. 2009; Lutz & al. 2010; Schivardi & Viviano 2010; Cullman & al. 2012; Prantl 2012).

A third theoretical contribution is related to the industry specificity of the barriers to entry. Even though earlier research has acknowledged that the severity of barriers to entry varies by products and industries (Karakaya & Stahl 1989; Yang 1998; Karakaya 2002; Pehrsson 2009) and that the structural characteristics of an industry can affect the performance of a new entrant (Robinson & McDougall 1998; Robinson 1999; Lutz & al. 2010), the industry specific implications have been poorly understood due to the lack of empirical evidence on barriers to entry in specific industry settings. This study adds to the body of existing research by adding empirical evidence on barriers to entry present in a highly regulated industry setting and also examines the wide ranging effects of regulation on the number, severity and types of barriers to entry. The empirical findings also offer support for the theoretical notions of the characteristics of regulated industries as industries with high barriers to entry, low rates of innovation, and high consolidation (e.g. Friedman & Taylor 2011).

As a summary, firstly, the previous research on barriers to entry was combined in the literature study to summarize the rather fragmented research on the subject. Secondly, by studying a specific industry setting, the current study suggests that the barriers to entry have high industry specificity and that regulated industries are likely to pose a larger amount of barriers to entry for *de novo* entrants. Thirdly, the current study identified 31 additional industry specific barriers in the regulated industry setting thus implying the high contextuality of barriers to entry. Fourthly, the current study highlighted the relationships between regulation and barriers to entry and the combined effect on the incentives for innovation that are few in regulated industries. Lastly, the study added to the previous research on barriers to entry by focusing on the entrant perspective, an area of great

importance due to its effects on new company growth and survival but yet has remained understudied. Building on the entrant perspective, the current research criticized the previous theoretical understanding on the influencability of the barriers to entry and questioned the rather static presentation of barriers to entry in previous literature by offering a dynamic presentation of barriers to entry as changing in time through the combination of the incumbent and entrant strategies, and government policies.

Based on the findings of the current study on the dynamic nature of barriers to entry, further research is required on the entrant and incumbent strategies for affecting the barriers to entry from a combined perspective. Whereas the previous research has largely focused on the incumbents, and whereas the current study adds the perspective of an entrant, a study combining the two perspectives is suggested to understand the combined effect on barriers to entry. In addition, as the barriers to entry are suggested to vary across different industries, further research in specific industry settings is required, to allow for a wholesome examination of the subject. Further research is also required to understand the longer term social and economic effects of government policy setting on new company survival across different industries.

8.3. Recommendations for managers

The managerial recommendations of this study base strongly on the finding on the dynamism of the barriers to entry. Rather than accepting the barriers to entry as static and as permanent structures in a given industry, a key finding to managers is that they can increase the chances of gaining entry by formulating successful strategies that should be agile in time to respond to the challenges posed by the industry. As a small scale *de novo* entrant with limited resources, an additional implication is to focus strongly on gathering industry expert knowledge into the company at the very early stages to

avoid making costly and time consuming mistakes. The decision on the market entry strategy to pursue should be based on deep market understanding gained from industry experts that does not necessarily have to be in-house but can also be gained from external consultants.

In regulated markets, time is a key factor in relation to market entry. The managers of the de novo entrant company should understand this constant and the side effects that the slowness of the market creates. The company should focus on managing the stakeholder expectations from the very start after first gaining the market understanding it needs to make sophisticated forecasts on the time to market. Managers should avoid excessive naivety and optimism of the uniqueness and market potential of their offering and rather base their strategies on market data.

Selecting the target markets becomes an important issue in terms of the company survival and to be able to make the right decision on which markets to pursue, the company should use their scant resources in deep market analysis focusing on a wider range of issue than simply the size of the market. To be able to generate the initial cash flow needed to keep the company alive and drive the company forward, a targeted approach with only a few key markets should be executed. Clearly targeting the few resources is likely to lead into more optimal outcomes than a shotgun approach with multiple moving targets.

The case study findings show that by taking the perspective of the entrant and identifying the key challenges that the barriers pose rather than focusing on the sources of the barriers, companies can formulate competitive strategies to tackle these barriers. As the case study on Mendor's market entry efforts described, the main consequences posed by the barriers to entry for the company in the specific regulated industry setting were those related to time, expertise, sales and financial challenges. The identification of these challenges has allowed the company to formulate strategies that have allowed them to overcome these deficiencies through partnering and

competitive strategies and offers an improved focus for its resources into solving the challenges related to entry. A key finding continues to be that not all markets should be pursued at once but the company should find and target key markets based on a deep market analysis where it will have the possibility to generate sales when constrained by limited resources. The key recommendations are listed in Figure 13.

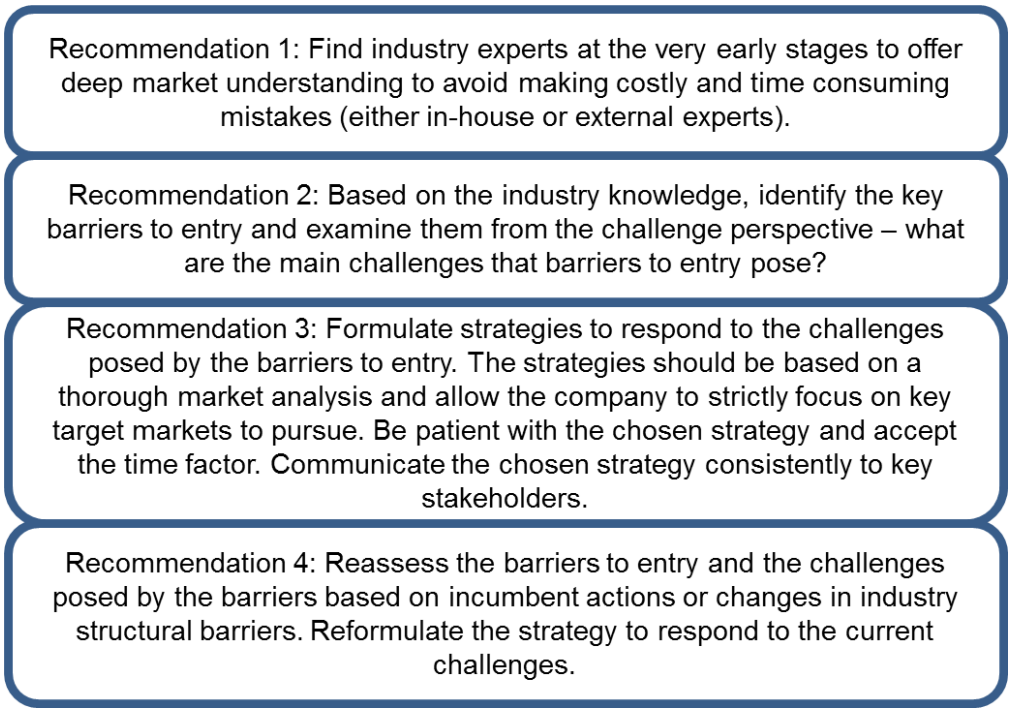


Figure 13 Key managerial recommendations

8.4. Implications for policy makers

The recommendations for policy makers are based on the multiple role of the government in a regulated industry. On one hand, it acts as a regulator, creating many structural barriers to entry. On the other hand, the government and its organizations have a role in supporting new company birth and growth in the economy that in turn would add to the net social and economic welfare through the paid taxes and employment created. In the

specific setting of the health care industry, the government is also a customer with a major effect on the demand conditions in the industry.

As the case study showed, the current regulatory environment and especially the practices that have been interpreted from the regulations pose very difficult challenges for small companies in the health care industry. The current environment reproduces the industry status quo, leading to high consolidation and the favoring of the incumbents. As discussed in the section 3.1. covering the relationship between regulation of entry and the social consequences, the consolidation of the industry and other detrimental side effects of high barriers to entry rarely lead to increased social or economic welfare. In addition, as described in section 3.3. on the relationship between regulation and innovation, high entry barriers created by regulation are 'killers' for innovation and as also confirmed in the case study, often make a market impossible to compete in for new entrants, forcing the companies to focus on other markets, as has been the case for Mendor in its home market of Finland.

The longer term industry effects and also the wider social and economic welfare implications should be considered when setting new policies or regulations. Also, a critical eye should be addressed to the potential wrongful interpretations of the regulations and the practices that will follow from these interpretations. The current state of public procurement is a model example of practices derived from regulations that due to multiple of issues have in time develop to only serve the short term financial concerns of municipalities instead of focusing on the social and economic welfare consequences in the longer term.

As a key driver of home market demand, the public procurement is excluding innovations, even local ones, making it very difficult for local companies to gain home market references that they need in international market entry. In addition, many companies end up dying before reaching sufficient growth due to the slowness of the market in an environment that

does not offer sufficient support for companies' market entry efforts in the lack of financing for market entry or support through local demand.

The implications for policy makers are clear. In order to support new company birth and growth, especially in industries that have a wider social consequences such as health care, the government structures should allow at least a fraction of the public demand to be used to support local innovations as a key driver of local demand. This would allow for the companies to create the much needed home market references but also add to increased public welfare through the support for local economy and local companies. In addition, the role of the Finnish innovation support system and the responsibilities of its actors should be streamlined to be able to offer new companies the support they need also after the R&D phase, ensuring adequate funding to make up for the lack of private funding in Finland.

8.5. Reliability and validity of the study

In this last section of the study, the realized reliability and validity of the study are assessed. The means executed in this study for ensuring the reliability and the validity are discussed in section 5.3.

As described in section 5.3., the data collection was planned carefully in advance and the case study protocol was designed based on a research plan, the literature review and interview structures. In addition, a study database was used for storing all the interview transcriptions, document and article references during the execution of this study. Thus, the reliability of the study can be assessed as good.

The construct validity was improved by ensuring the use of multiple sources of data, both internal to the case company but also external informed sources. The interviews within the case company covered individuals from all the company functions and the external interviews included discussions

with individuals from several different support system actors. In addition, the case protocol was followed and a case database was used. Lastly, the findings of the study were reviewed with key informants as a third wave of interviews towards the end of the study period. Thus also the construct validity can be evaluated as good.

Due to the case study specificity focusing on a single case study in a single industry setting, the scope of the study is restricted to one case company. This can limit the generalizability of the findings and the recommendations to only very similar companies as the case company. Thus the assessment of the external validity is rather low. However, as the key findings and the recommendations focus on the nature of barriers to entry and the chances for the entrant to influence these barriers without offering specific means but rather food for thought for companies seeking to enter a market with high barriers to entry, the study does provide implications to small companies across a wider range of settings. In addition, the findings of the literature review add to the general knowledge on barriers to entry. Careful documentation of the data collection procedure and the collected literature sources ensure the easy and accurate replication of the study. In addition, the general rather than specific recommendations offer ready frameworks for the testing of the study in other industry settings as well.

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9.2. Document references

Case company internal documents:

DOC1 Mendor Strategy – Powerpoint presentation

DOC2 Mendor financial statements 2010 and 2011

DOC3 Diabeteksen hoito on investointi – Powerpoint presentation by Medical Director Antti Virkamäki

DOC4 Mendor HR Survey

External documents:

DOC5 The Diabetes Device Market Outlook – Business Insights

DOC6 The Ministry of Employment and the Economy – Innovation strategy

DOC7 The Ministry of Employment and the Economy – R&D appropriations

9.3. Interviews

IV1	**Mr. K.R.**	**Mendor**	**16.5.2012 13:00**	**Preliminary planning of the study, Mendor strategy, company history**	**Informal discussion**
IV2	**Mr. H.U.**	**Mendor**	**17.5.2012 12:00**	**Preliminary planning of the study**	**Informal discussion**
IV3	**Mr. P.M.**	**Mendor**	**21.5.2012 14:00**	**Preliminary planning of the study, industry description**	**Informal discussion**
IV4	**Mr. K.K.**	**VTT**	**19.6.2012 13:00**	**Barriers to entry in medical device industry**	**Semi-structured interview**
IV5	**Mr. J.L.**	**VTT**	**20.6.2012 13:00**	**R&D in a regulated industry**	**Semi-structured interview**
IV6	**Mr. J.J.**	**Keksintösäätiö**	**26.6.2012 14:00**	**Barriers to entry in medical device industry**	**Semi-structured interview**
IV7	**Mr. J.T.**	**Tekes**	**27.6.2012 9:00**	**Barriers to entry in medical device industry, TEKES role in support system**	**Semi-structured interview**
IV8	**Mrs. H.L.**	**Tekes**	**27.6.2012 10:00**	**Barriers to entry in medical device industry, TEKES role in support system**	**Semi-structured interview**
IV9	**Mrs. L.P.**	**Finpro, Operations and Network**	**28.6.2012 15:00**	**Barriers to entry in medical device industry**	**Semi-structured interview**
IV10	**Mrs. M.M.**	**Finpro**	**28.6.2012 16:15**	**Barriers to entry in medical device industry**	**Semi-structured interview**
IV11	**Mr. N.S.**	**VTT**	**2.7.2012 10:00**	**Barriers to entry created by regulation in medical device industry**	**Semi-structured interview**
IV12	**Mrs. K.V.**	**Työ- ja elinkeinoministeriö / Elinkeino- ja innovaatio-**	**2.7.2012 14:00**	**Public procurement and government innovation policy**	**Semi-structured interview**

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IV13	**Mr. K.R.**	**Mendor**	**3.7.2012 11:00**	**Barriers to entry for Mendor**	**Discussion**
IV14	**Mrs. T.K.**	**FiHTA/ Teknologiateollisuus**	**4.7.2012 11:00**	**Barriers to entry in medical device industry**	**Semi-structured interview**
IV15	**Mr. K.R.**	**Mendor**	**4.7.2012 14:00**	**Tackling barriers to entry in Mendor**	**Discussion**
IV16	**Mr. P.M.**	**Mendor**	**5.7.2012 14:00**	**Barriers to entry and tackling barriers to entry for Mendor**	**Semi-structured interview**
IV17	**Mr. T.M.**	**Spinno**	**23.7.2012 10:00**	**Barriers to entry in medical device industry and role of incubators**	**Semi-structured interview**
IV18	**Mr. M.Y.**	**Mendor**	**23.7.2012 12:00**	**Barriers to entry and tackling barriers to entry for Mendor**	**Discussion**
IV19	**Mr. H.U.**	**Mendor**	**10.8.2012 10:30**	**Barriers to entry and tackling barriers to entry for Mendor**	**Discussion**
IV20	**Mr. O.R.**	**Mendor**	**21.8.2012 10:00**	**Barriers to entry in medical device industry and tackling the barriers**	**Semi-structured interview**
IV21	**Mrs. M.K.**	**Mendor**	**5.9.2012 10:00**	**Barriers to entry and tackling barriers to entry for Mendor**	**Discussion**
IV22	**Mr. M.J.**	**Mendor**	**11.9.2012 10:00**	**Barriers to entry in medical device industry and tackling the barriers - role of regulation**	**Semi-structured interview**
IV23	**Mr. A.V.**	**Mendor**	**20.9.2012 11:00**	**Barriers to entry and tackling barriers to entry for Mendor**	**Discussion**
IV24	**Mrs. N.V.**	**Mendor**	**20.9.2012 16:00**	**Barriers to entry in medical device industry and tackling the barriers - role of regulation**	**Semi-structured interview**
IV25	**Mr. K.R.**	**Mendor**	**4.10.2012 17:00**	**Preliminary study structure and findings**	**Informal discussion**
IV26	**Mr. P.M.**	**Mendor**	**8.10.2012 16:00**	**Preliminary study structure and findings**	**Informal discussion**

Appendix 1

1. Screening Procedures

- Certify business competence
- Certify a clean criminal record
- Certify marital status
- Check the name for uniqueness
- Notarize company deeds
- Notarize registration certificate
- File with the Statistical Bureau
- File with the Ministry of Industry and Trade, Ministry of the Economy, or the respective ministries by line of business
- Notify municipality of start-up date
- Obtain certificate of compliance with the company law
- Obtain business license (operations permit)
- Obtain permit to play music to the public (irrespective of line of business)
- Open a bank account and deposit start-up capital
- Perform an official audit at start-up
- Publish notice of company foundation
- Register at the Companies Registry
- Sign up for membership in the Chamber of Commerce or Industry or the Regional Trade Association

2. Tax-related requirements

- Arrange automatic withdrawal of the employees' income tax from the company payroll funds
- Designate a bondsman for tax purposes
- File with the Ministry of Finance
- Issue notice of start of activity to the Tax Authorities
- Register for corporate income tax
- Register for VAT
- Register for state taxes
- Register the company by laws with the Tax Authorities
- Seal, validate, rubricate accounting books

3. Labor/social security related requirements

- File with the Ministry of Labor
- Issue employment declarations for all employees
- Notarize the labor contract
- Pass inspections by social security officials
- Register for accident and labor risk insurance
- Register for health and medical insurance
- Register with pension funds
- Register for Social Security
- Register for unemployment insurance
- Register with the housing fund

4. Safety and health requirements

- Notify the health and safety authorities and obtain authorization to operate from the Health Ministry
- Pass inspections and obtain certificates related to work safety, building, fire, sanitation, and hygiene

5. Environment-related requirements

- Issue environmental declaration
- Obtain environment certificate
- Obtain sewer approval
- Obtain zoning approval
- Pass inspections from environmental officials
- Register with the water management and water discharge authorities

From Djankov et al. (2002)

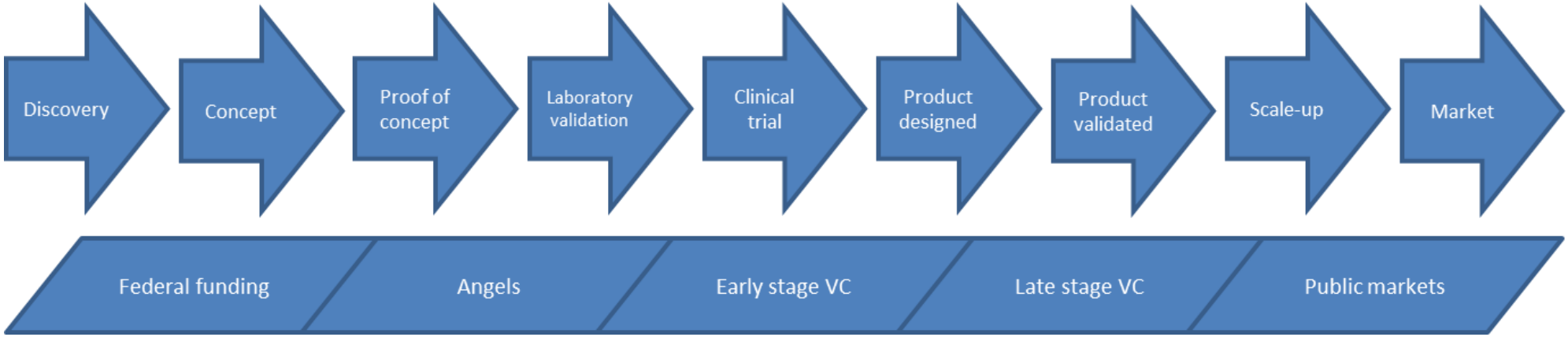
Appendix 2

Case company identified barriers to entry with interview references

Company specific barriers	
Absolute cost advantage	IV13; IV18
Availability of information	IV16; IV18; IV22
Control over systems and integration	IV4; IV5; IV13
Credibility	IV6; IV18; IV19
Economies of scale	IV13; IV18
Entrant resources	IV9; IV16; IV18; IV19; IV23
Exclusive deals with customers	IV13; IV21; IV23
Government subsidies	IV13; IV14; IV16
Incumbent control over strategic resources	IV4; IV13; IV16; IV18
Incumbent resources	IV16; IV18; IV20
Incumbents with proprietary technology / level of technology	IV4; IV9; IV12; IV13; IV23
Level of expertise and competence	IV2; IV4; IV9; IV16; IV18
Lobbying	IV4; IV6; IV7; IV9; IV12; IV22; IV23; IV24
Political resources/relations	IV7; IV9; IV23
References	IV9; IV12; IV19; IV20
Relationships / other bonds with different stakeholders	IV6; IV21; IV23
Strategy / direction	IV1; IV7; IV3; IV18; IV19
Customer/market-based barriers	
Bundling of offerings	IV9
Conservatism and bureaucracy in processes	IV1; IV6; IV9; IV12; IV20; IV21
Customer pricing pressures	IV3; IV13
De-centralization of decision makers	IV4; IV14; IV21
High bargaining power of buyers	IV1; IV16; IV23
High customer switching costs	IV3; IV4
High risk involved in purchase	IV12; IV23
Immense risk aversion	IV1; IV6; IV9; IV12; IV14; IV23
Level of expertise/knowledge	IV8; IV9; IV12; IV14; IV21; IV23
Multiple stakeholders with different motives involved in purchase	IV4; IV14; IV23
Product differentiation	IV3
Resistance to change	IV5; IV9; IV21
Strong brands building trust	IV3
Strong customer loyalty	IV16; IV23
Financial requirements / cost of entry	
Capital intensity of the market and investment risk	IV1; IV2; IV8
Capital requirements	IV1; IV2; IV16; IV18
Costs of operating in foreign markets	IV13; IV19

Cultural distance	IV7; IV9
High transaction costs	IV13; IV19
High wages for skilled employees	IV16; IV18
Marketing intensity	IV3
R&D expense involved in entering / R&D intensity	IV2; IV18
Regulatory requirements	IV1; IV22
Risks of innovating	IV13; IV16
Sales intensity	IV3; IV17; IV18; IV19
Sunk costs	IV16
Uncertainty of entry	IV1; IV2; IV16; IV20
Profit expectation of entrants	
Access to distribution channels	IV4; IV9; IV13
Average product lifecycle	IV13; IV16; IV18
Differing expectations of stakeholders	IV4; IV6; IV7; IV9; IV13; IV18; IV19; IV20; IV23
Excess capacity	IV18
Expected retaliation by incumbents	IV13; IV16
High profit rates earned by incumbents	IV13; IV16
Incumbent control over pricing	IV16
Low rate of technology change	IV18
Market growth	IV3
Market knowledge	IV3; IV18
Range of products available	IV3
Reimbursement systems	IV16
Industry characteristics	
Asset specificity	IV2; IV18
Availability of financing	IV1; IV2; IV5; IV8; IV9; IV17
Availability of skilled labor	IV18; IV19
Different purchasing infrastructures	IV3; IV18
Horizontal integration	IV16; IV19
Government policies	IV16; IV22; IV23
Location	IV8; IV9; IV19
Patents	IV4; IV6; IV12; IV24
Public procurement	IV1; IV6; IV9; IV12; IV20; IV21
Restrictions on promotion	IV16
Seller concentration	IV4; IV13; IV16; IV19
Size of incumbents	IV1; IV3; IV18
Stakeholders' time	IV1; IV2; IV3; IV9; IV17; IV18; IV21
Standardization	IV22; IV23; IV24
Vertical integration	IV16

Appendix 3



A typical development chain and funding of medical innovations
(Adapted from Hermans & al. 2009)