

**UNIVERSITA' DEGLI STUDI DI MILANO BICOCCA**

ISTEI – Sezione di Economia e Gestione delle Imprese

DEMS - Dipartimento di Economia, Metodi Quantitativi e Strategie di Impresa

Dottorato di Ricerca in Marketing e Gestione delle Imprese

CICLO XXVI



**BUSINESS DEVELOPMENT IN GLOBAL MARKETS**

**THE CASE OF BIOTECHNOLOGY**

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Anno Accademico 2012 – 2013

**Declaration of originality**

The work referred to in this PhD thesis has not been submitted in support of an application for another degree or qualification of this or any other University or Institute of learning.

I declare that this thesis embodies the results of my own work. Following normal academic conventions, I have made due acknowledgement of the work of others.

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## **Acknowledgements**

*First of all, I wish to express my gratefulness to my tutors, Professore Silvio Bronondi and Professor Antonella Zucchella, who constantly guided and supported my research for the past three years.*

*My deepest thankfulness goes to Professor Gary P. Pisano and Professor Michael M. Hopkins, my precious supervisors during my visiting periods at Harvard Business School and at SPRU – University of Sussex. They have always been available to inspire me, to review the progress of my work and to give me support and suggestions.*

*I also feel indebted to Professor Stefano Denicolai, great friend and colleague, who has looked after me since the beginning of this academic journey and has given shape to my unclear thoughts when I was stuck. He believed in me and gave me strength also in the most difficult moments: I will never forget that.*

*I am particularly grateful to Professor Margherita Balconi, for her extremely valuable advices and her sincere affection, which I fully share.*

*My deepest gratitude goes to my parents Dianella and Mauro, who have given me love and support every single moment of my life. Thanks to my aunt Mara, who has always shared with me her knowledge and experience.*

*A special thought goes to Davide, who has deeply loved me, every single day of the past 6 years, and with whom I've grown up better and stronger.*

*Big thanks to my “sisters” Manuela, Alice, Silvia, Fernanda, H el ene, Letizia, Marilisa and Stefania, who have been ALWAYS there when I needed them, giving me love and precious advices. Thanks to Umberto, Giovanni, Christian, RickyDj and DavideDj, my “boys”, who have entertained and looked after me during these years.*

*I would also like to thank all the professors and colleagues at the Department of Economics and Management of the University of Pavia, who made me feel part of a family since the first day of my academic experience: Antonio Majocchi, Enrico Cotta Ramusino, Birgit and Elena. A big thank also to the ISTEI group of the University of Milan-Bicocca, with whom I shared many pleasant moments.*

*Finally, I wish to extend my thanks and appreciation to all those who, directly or indirectly have contributed to the completion of this PhD thesis.*

*“Business Development is so many things..*

*But still, nobody can really say what it is.”*

Gary P. Pisano, Harry E. Figgie Professor of Business Administration at the Harvard Business School

## Table of Contents

|  |     |
|--|-----|
| Declaration of originality and Copyright Statement | II  |
| Acknowledgements                                   | III |
| Table of Contents                                  | V   |
| List of Tables                                     | IX  |
| List of Figures                                    | X   |
| Acronyms and abbreviations                         | XI  |

### **CHAPTER 1. INTRODUCTION**

|  |    |
|--|----|
| 1.1 Background of the research                 | 12 |
| 1.2 The research context                       | 14 |
| 1.3 Theoretical underpinnings of the study     | 15 |
| 1.4 Research framework and research objectives | 19 |
| 1.5 Research approach                          | 21 |
| 1.6 Structure of the thesis                    | 22 |

### **CHAPTER 2. BUSINESS DEVELOPMENT: BLURRED LINES BETWEEN ENTREPRENEURSHIP AND MARKETING**

|   |    |
|---|----|
| 2.1 Introduction  | 24 |
| 2.2 “Business Development”: literature review                       | 25 |
| 2.3 Two different theoretical perspectives                          | 32 |
| 2.4 The evolution of marketing research: a brief overview           | 33 |
| 2.5 Entrepreneurship  | 37 |
| 2.5.1 Entrepreneurship and opportunities: an individual-level focus | 39 |
| 2.6 Markets for technology, entrepreneurship and marketing          | 44 |

## 2.7 Entrepreneurship/marketing interface and Business development

46

### **CHAPTER 3. OVERVIEW ON RESOURCES AND CAPABILITIES: TOWARD A FRAMEWORK TO STUDY BUSINESS DEVELOPMENT**

|  |    |
|--|----|
| 3.1 Introduction   | 49 |
| 3.2 Capability development: exploring different approaches                 | 50 |
| 3.2.1 The Resource Based View  | 52 |
| 3.2.2 Dynamic Capabilities View  | 56 |
| 3.2.3 Knowledge Based View   | 60 |
| 3.3 Discussing the different approaches                                    | 63 |
| 3.4 Toward a model to study dynamic capabilities in markets for technology | 65 |
| 3.5 Rationale of the Model   | 68 |
| 3.5.1 Microfoundations: Organization                                       | 71 |
| 3.5.2 Microfoundations: Process  | 72 |
| 3.5.3 Microfoundations: People   | 73 |

### **CHAPTER 4. THE BIOTECHNOLOGY INDUSTRY**

|  |    |
|--|----|
| 4.1 Introduction                                 | 75 |
| 4.2 Market for technologies.                     | 75 |
| 4.3 Biotechnology as a Science-Based Business    | 79 |
| 4.4 Biotechnology Industry Structure             | 80 |
| 4.5 The Biopharmaceutical Segment                | 82 |
| 4.5.1 Main Players in the Value Creation Process | 85 |
| 4.5.2 The Product Development Process            | 88 |
| 4.5.3 Alternatives to develop the business       | 92 |

## **CHAPTER 5. RESEARCH DESIGN AND METHODOLOGY**

|   |     |
|---|-----|
| 5.1 Introduction                              | 94  |
| 5.2 Research Philosophy                       | 94  |
| 5.2.1 Positivism versus constructivism        | 95  |
| 5.2.2 Qualitative versus quantitative methods | 96  |
| 5.3 Philosophical posture of the thesis       | 98  |
| 5.4 Selection of particular research methods  | 99  |
| 5.4.1 The case study method                   | 101 |
| 5.5 Qualitative Research                      | 102 |
| 5.5.1 The selection of cases                  | 103 |
| 5.5.2 Data collection                         | 105 |
| 5.5.3 Case study summaries                    | 106 |
| 5.5.4 Integrity of the case study research    | 117 |

## **CHAPTER 6. RESULTS AND DISCUSSION**

|  |     |
|--|-----|
| 6.1 Introduction   | 119 |
| 6.2 How do the investigated firms define Business Development? | 120 |
| 6.3 Core dimensions of Business Development                    | 125 |
| 6.3.1 Opportunity focus  | 126 |
| 6.3.2 Innovation drive   | 129 |
| 6.3.3 Risk attitude  | 130 |
| 6.3.4 Proactive orientation                                    | 131 |
| 6.3.5 Resource leverage  | 132 |
| 6.3.6 Network focus  | 134 |
| 6.3.7 Value creation   | 135 |

|   |     |
|---|-----|
| 6.4 The interaction among dimensions    | 136 |
| 6.5 Business Development capability     | 140 |
| 6.5.1 Microfoundations: BD Organization | 143 |
| 6.5.2 Microfoundations: BD Process      | 148 |
| 6.5.3 Microfoundation: People           | 156 |
| 6.6 A refined model of BD capability    | 161 |

## **CHAPTER 7. CONCLUSIONS AND EMERGING ISSUES**

|                                     |     |
|-------------------------------------|-----|
| 7.1 Result summary                  | 163 |
| 7.2 Theoretical implication         | 167 |
| 7.3 Managerial contribution         | 172 |
| 7.4 Limitations and future research | 174 |
| References                          | 177 |



## List of Tables

|  |     |
|--|-----|
| Table 2.1: Theoretical contributions on Business Development: an overview                    | 30  |
| Table 2.2: Theoretical perspectives on opportunity identification and their main focus       | 43  |
| Table 3.1: Main contributors to the different theoretical perspectives                       | 51  |
| Table 3.2: RBV summary   | 55  |
| Table 3.3: Definitions of Dynamic Capabilities   | 57  |
| Table 3.4 DCV summary  | 60  |
| Table 3.5: KBV summary   | 63  |
| Table 5.1: Qualitative versus Quantitative Research Methods                                  | 97  |
| Table 5.2: Evaluating different research methods   | 100 |
| Table 5.3: Overview of the case study companies  | 105 |
| Table 6.1: Business Development definitions and outcomes                                     | 122 |
| Table 6.2: Differences between Marketing, Entrepreneurial marketing and Business Development | 139 |
| Table 6.3: Supporting evidence regarding BD Organizational structure                         | 147 |
| Table 6.4: Supporting evidence regarding the BD Process                                      | 155 |
| Table 6.5: Supporting evidence regarding BD People   | 160 |
| Table 7.1: Research propositions summary   | 167 |

## **List of Figures**

|   |     |
|---|-----|
| Figure 1.1: Identification of literature gaps                                     | 18  |
| Figure 1.2: The conceptual research framework                                     | 20  |
| Figure 3.1: Theoretical framework proposed for studying BD capability             | 68  |
| Figure 4.1: The value chain of the biopharmaceutical industry                     | 87  |
| Figure 4.2: Timeframe of the Biotechnology Drug Discovery and Development Process | 89  |
| Figure 6.1: Dimensions of Business Development in markets for technology          | 137 |
| Figure 6.2: The BD process  | 151 |
| Figure 6.3: Refined model explaining Business Development capability              | 162 |

## **Acronyms and Abbreviations**

|     |                            |
|-----|----------------------------|
| BD  | Business Development       |
| EM  | Entrepreneurial Marketing  |
| OI  | Opportunity identification |
| DC  | Dynamic Capabilities       |
| RBV | Resource-Based View        |

## CHAPTER 1

### INTRODUCTION

#### 1.1 Research background

High levels of scientific and technological complexity along with extremely uncertain and long R&D processes make firms growth in the biotechnology industry a particularly tough goal to pursue. Furthermore, early stage studies on biotechnological platforms exploration and exploitation, make it clear that knowledge bases are still heterogeneously dispersed among diverse organizations (Malerba and Orsenigo, 2001; Pisano, 2007) and spread all over the world; space, as a factor of corporate strategy and operations, loses every physical connotation, reducing the constraints that once limited corporate activities (Gnecchi, 2009).

In such a context, globalization requires companies to operate according to a competitive market-oriented management (market-driven management), which leads to the development of an “outside-in” thinking process (Day, 1998; Brondoni, 2007; Sciarelli, 2008). The latter stimulates firms to continuously investigate the market in order to identify new business opportunities and adapt their strategies to changing conditions (Lambin, 2008, Vallini and Simoni, 2009; Doz et al., 2001). It follows that organizations able to timely monitor information derived from the outside, have a greater aptness to perform “before and better than competitors” (Brondoni, 2008, p. 25) in sensing and seizing new development projects. At the same time, firms need to maintain a high level of innovation, risk taking and proactive orientation, in order to grow in dynamic contests such as Markets for Technology. To such a purpose, firms in high-tech industries perform particular “Business Development” (BD) activities to support identification and management of new business opportunities.

Nowadays, although the term BD is well known within many operative enterprises, (often with individual interpretations in the minds of various practitioners), the concept of Business Development has, up to now, little presence in the academic literature. Accordingly, Davis and Sun (2006) sustain that Business Development has received little attention in scholarly works regardless of its importance to firm growth, and Giglierano et al. (2011) argues that due to the early stage of the concept, no common language or definition has yet emerged. The few academic approaches that have explored the BD phenomenon agree on its connection to the identification of business opportunities leading to the creation of additional revenues for the company (Giglierano et al., 2011; Kind and Zu Knyphausen-Aufseß, 2007; Davis & Sun, 2006). However, little has been done to provide a comprehensive theoretical background in the study of BD and to explain how firms can build a BD capability (Davis and Sun, 2006).

With the aim of expanding our knowledge on these emerging management issues, this thesis has drawn both from entrepreneurship and marketing literature as well as from firm's Dynamic Capability View.

In terms of outcomes, the present research makes its own the concept of Business Development as interface between the broad fields of entrepreneurship and that of marketing. The marketing/entrepreneurship interface brings together researchers who have an affinity and understanding of the rich heritage of both marketing and entrepreneurship. While both literatures have their own distinctive characteristics, the interface recognizes substantial commonality between the two.

In addition, it proposes Business Development study models in Markets for Technology, where continue recombination and integration of resources is fundamental in facing a dynamic competitive environment. Thus, on the basis of relevant recommendations from the above mentioned literature, this study examines BD at two distinct levels: *Firstly*, it provides a solid definition of the Business

Development phenomenon and its related dimensions, descending theoretical background from both entrepreneurship and marketing literature. *Secondly*, it examines the microfoundation of a BD capability, which is essential to increase the rate of new product development and gain competitive advantages in Markets for Technology .

## **1.2 The research context**

Among others, I've chosen to analyse the Business Development phenomenon within the biotechnology industry, because in such a contest BD shows features that are highly representative of high-tech industries (Carey *et al.*, 1997), and because biotechnology has become a key industry of the future (Shan and Song, 1997). The growing interest in high-tech businesses in general, and biotechnology in particular, is based on the special characteristics of the sector, where the challenges of globalized world economy are extremely emphasised. By definition the high-tech firms creates products and services with leading edge technologies (Bell, 1995). Mohr et al. (2005, p. 9) defines high-tech more specifically: "high-tech is engaged in the design, development, and introduction of new products and/or innovative manufacturing processes through the systematic application of scientific and technical knowledge". This makes dependence on the latest technologies the central feature of high-tech. This typically means that the firms are highly specialised, high quality producers, with products or technologies having short life cycles and specialised niche markets spread thinly across the world (Bell, 1995; Crick and Jones, 1999; Madsen and Servais, 1997). According to Mohr (2001), high-tech industries also face greater market instability, technological uncertainty and competitive volatility than more traditional industries. He sees high-tech business environment are characterised by expanding complexity and ambiguity, high knowledge intensity and high level of tacit knowledge, and often systemic nature of the products.

Today, such context represents an increasingly explored territory, where scholars in economic disciplines address the nature and dynamics of Markets for Technology, (Serrano 2010, Lamoreaux & Sokoloff 2003); here, companies basically exchange IP rights with other globally dispersed organizations in order to develop and grow (Gambardella et al. 2006). Market for Technology is usually characterized by a dense network of companies specialized in single stages of the R&D pipeline. Given the high risks and costs of innovation, such companies prefer in fact buy, sell or co-develop technologies rather than to invest in upstream or downstream assets (Gambardella et al. 2006; Arora et al. 2001). Despite the increasing relevance of Markets for Technology, *there is still a lack of advices from management literature on how managers should act in Markets for Technology* (Arora et al. 2001). The present PhD thesis wishes to narrow this research gap, taking as study context the biotechnology industry, a widely adopted example of the functioning of Markets for Technology (Arora et al., 2001).

### **1.3 Study theoretical underpinnings**

In examining the notion of Business Development, this study essentially draws from both marketing and entrepreneurship literature in order to identify the core dimensions of the phenomenon. In addition, using a Dynamic Capability View (DCV), the research *explores the microfoundations underpinning the development of a BD capability*.

Entrepreneurship literature has emphasized the concept of Opportunity Identification (OI) as lying at the heart of entrepreneurial activity (Shane and Venkataraman, 2000) and as a major theme of study within the research field (Zahra and George, 2002; Dimitratos and Plakoyiannaki, 2003; Oviatt and McDougall, 2005; Dimitratos and Jones, 2005). Since Opportunity Identification is what drives Business Development as well (Davis and Sun, 2006), I adopt entrepreneurship as part of the literature background for defining the phenomenon. However, regardless of its criticality, the concept of OI as an

entrepreneurial firm-level phenomenon, still lies at an early stage of investigation. Indeed, research on OI within the entrepreneurship literature tends to examine the particular notion at a entrepreneurial level rather than at a corporate level. .

On the other hand, the lack of marketing studies in Markets for Technology suggests that, in such context, marketing practices may result particularly difficult to grasp if analyzed under the lenses of classical marketing approaches. Since commercialization and relationship management come out to be among BD's main tasks (Kind and Zu Knyphausen-Aufseß, 2007), I resolved to include marketing literature in my study and integrate the two above mentioned tasks to explain the nature of the BD phenomenon.

A particularly unexplored topic in marketing literature is the study of marketing in high tech industries. In particular, even though there is plenty of literature on marketing and its features have been tested in a variety of empirical settings, research has been very silent on what constitutes marketing in the biotech industry. In such context, technological advancements result into products and markets that differ in their characteristics from traditional markets and, hence, a different type of marketing is needed for them (Moriarty and Kosnik, 1989). Previous researches have introduced the idea that, given the specific nature of Markets for Technology, biotechnology marketing might differ from what classical theories and common industrial works consider as marketing (Eriksson and Rajamaki, 2009). According to recent research, “this raises the question whether there are deficiencies in biotechnology marketing or whether the meaning of biotechnology marketing still remains unexplored” (Eriksson and Rajamaki, 2009, p. 99). Business Development is a phenomenon which has been mainly studied in high tech industries (Giglierano et al., 2011). The tasks and activities described by authors who elaborated on the topic, include communication, commercialization and relationship management, as typical responsibilities of a marketing function. In addition, Business Development

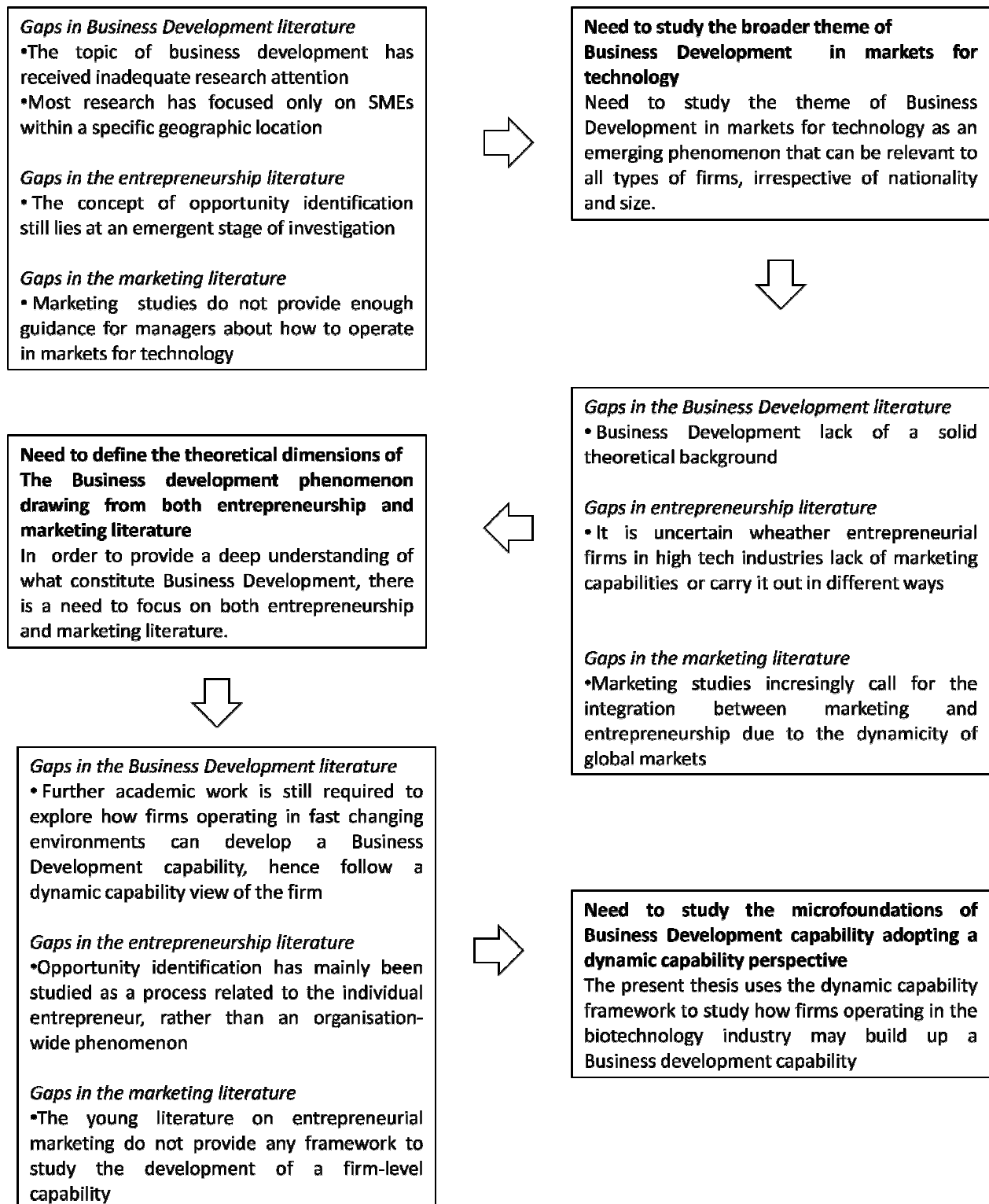


concerns the management of the firm pipeline, i.e. the identification of new in-licensing, out-licensing and co-development opportunities, (endogenously high risky and innovative), which will impact on the rate of new product development of the firm. Thus, BD appears as a multidimensional phenomenon that may help to redefine the concept of marketing in Markets for Technology .

Also, to my best knowledge, there is a lack of study on capability development within the marketing literature, particularly when coping with high velocity, rapidly changing environments (Bourgeois and Eisenhardt, 1988; Day, 1994). As suggested by Day (1994), the identification of distinctive capabilities of market-driven organization is one of the most promising research streams to pursue, since its enable firms to outperform their competitors.

The importance of internal capabilities is rooted in evolutionary economics view (Nelson and Winter, 1982), which implies that the superior ability of certain firms to sustain innovation and, as a result, to create new knowledge, leads to the development of organizational capabilities, consisting of critical competences and embedded routines (Knight and Cavusgil, 2004). However, the Dynamic Capability approach (Teece et al., 1997) has demonstrated that a sustainable competitive advantage do not necessarily rise from the accumulation of scarce and difficult to imitate resources. Indeed, firms need particular and identifiable strategic and organizational processes that continuously integrate and recombine resources, in order to compete in risky and rapidly changing environments (Eisenhardt and Martin, 2000; Teece et al., 1997). Consistently with this ideas, the Dynamic Capability perspective has been adopted , in this thesis, to explore the microfoundations of Business Development. This constitutes an innovative approach, in terms of both entrepreneurship and marketing literature. Figure 1.1 depicts the development of the theme under investigation through identification of key gaps in relevant literature.

**Figure 1.1: Identification of literature gaps**



Source: author's elaboration

#### **1.4 Research framework and research objectives**

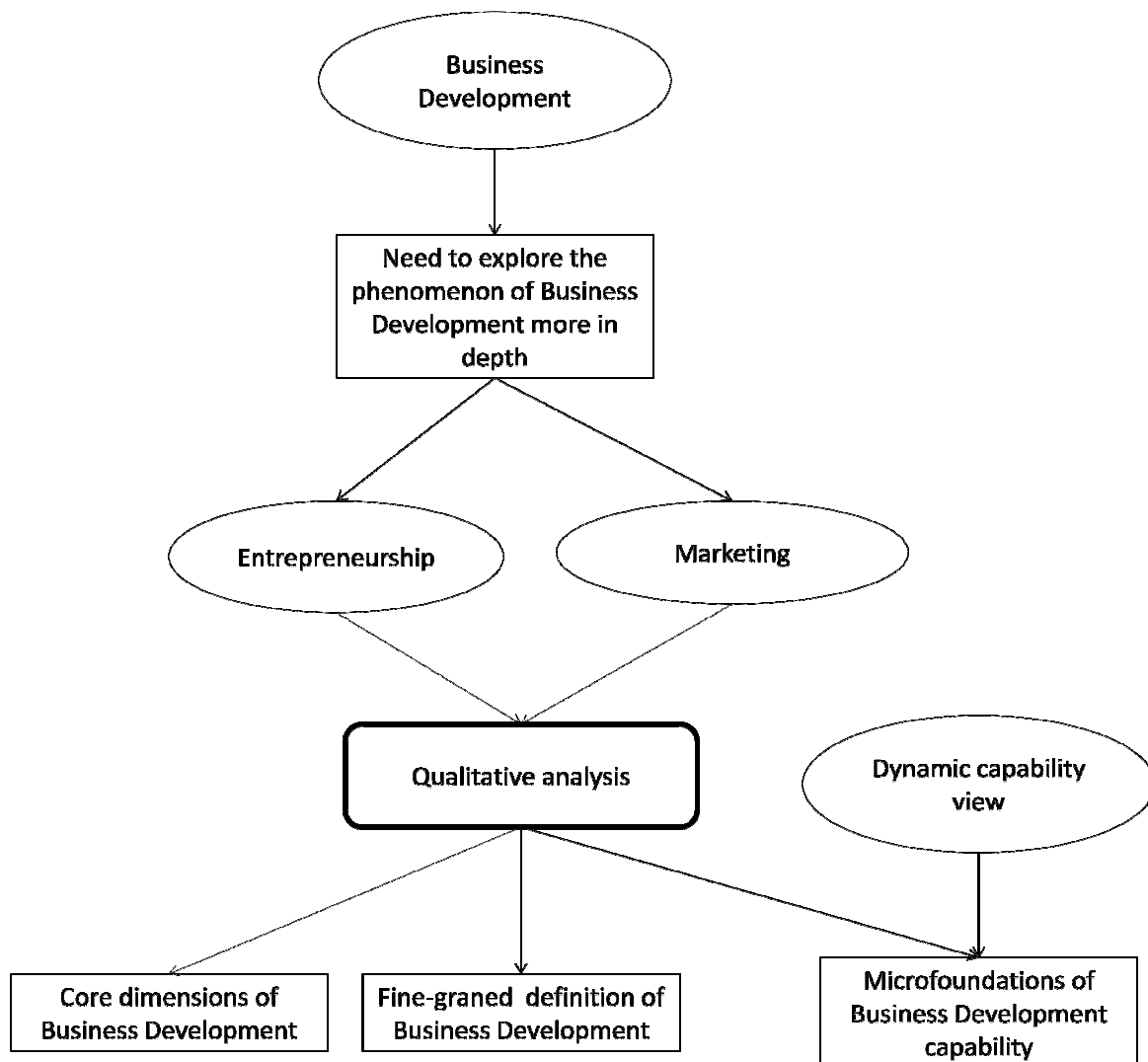
Business Development is a concept that has received limited direct attention in the academic literature (Davis and Sun, 2006). However, many high tech companies devote part of their organizational structure to BD. While the definition varies from company to company, BD has generally involved activities and processes related to the identification and management of new business opportunities. However, as some authors emphasize, there is contrasting evidence on the way such practices are carried out:

Although marketing and entrepreneurship have been conventionally regarded as two separate areas of research, marketing/entrepreneurship interfaces has constituted one of the most promising emerging issues in management during the last two decades (Collinson and Shaw, 2001). This is due to the growing awareness surrounding the significance of marketing tools and practices for entrepreneurs (Murray, 1981; Hills, 1987); similarly, given the increasing dynamic of market environments, entrepreneurship can inspire marketing to adopt more innovative and proactive behaviors. Firms that report a combination of both Market Orientation (MO) and Entrepreneurial Orientation (EO) have shown a greater performance compared to those oriented to MO only (Eggers et al., 2012; Grinstein, 2008). Limited research on how firms operating in Markets for Technology perform and manage marketing activities (Battistella et al., 2012; Zortea-Johnston et al., 2012) is an additional motivation to explore BD.

According to some authors, fast growth high-tech firms use new methods, along with new integrative business models to promote and sell their innovations (Mohr, 2001; Viardot, 2004; Davidow, 1986). In particular, interactive processes, alliances and networks are considered particularly used and useful to maintain flexibility in order to meet the demands of highly competitive and dynamic marketplaces. Moreover, particularly in such highly competitive and risky environments (Nelson and

Winter, 1982), firms need dynamic capabilities to constantly integrate, reconfigure and exploit their basic resources and achieve superior performance (Teece et al., 1997), Therefore, in order to study how companies build a BD capability in rapidly changing markets, this thesis adopts a Dynamic Capability approach, considering three focal dimensions as constitutive of Dynamic Capability: 1. organizational structures, 2. processes and 3. people.

**Figure 1.2: The conceptual research framework**



*Source: author's elaboration*

In conclusion, there is a need to further explore the theme of Business Development at a firm-level, as a value creating phenomenon. Given the lack of a strong theoretical base, I decided to identify the core dimensions of BD by drawing from both entrepreneurship and marketing literature. In addition, once we deal with a clearly defined phenomenon, this thesis further explores how firms develop BD capability in order to maintain a sustainable competitive advantage. Such issues are addressed through the following three research questions.:

1. *What is Business Development in the biotechnology industry?*
2. *What are the theoretical dimensions characterizing the Business Development phenomenon?*
3. *What are the microfoundations underpinning a Business Development capability?*

### **1.5 Research approach**

This study follows a qualitative methodology in addressing its research objectives. The first stage involved conducting *multiple exploratory case studies*. Given the scarcity of empirical work on the theme of OI in corporate entrepreneurship literature, the exploratory method was deemed most appropriate in addressing research purposes. Indeed, exploratory studies are particularly useful when little knowledge exists on a topic and hence there is limited empirical data to form a sound basis for drawing propositions (Bryman and Burgess, 1995; Easterby-Smith et al, 2001; Ghauri and Grønhaug, 2002). Also, multiple case studies are generally preferable, in that they offer advantages such as increased robustness (Herriott and Firestone, 1983; Yin, 2003) and generality of findings (Patton, 1990; Miles and Huberman, 1994).

More specifically, detailed case studies were conducted in the global biotechnology industry. The underlying principle in choosing the case study firms has been to select “information rich cases” worthy of in-depth investigation (Patton, 1990, p. 181), i.e. highly competitive firms with an

institutionalized business development function. The addition of new case studies to the sample stopped when theoretical saturation was reached (Eisenhardt, 1989). Specifically, this study has considered ten small and large firms from different countries (UE and Europe), which facilitated the generalization of findings. Based on a review of existing literature in the fields of entrepreneurship, relevant previous theories were taken into consideration during this qualitative stage, particularly in developing interview guidelines and in analyzing qualitative data. Exploration into the topic of Business Development (resulting from qualitative research) helped in the development of specific research propositions.

### **1.6 Structure of the thesis**

This PhD dissertation is structured as follows:

This first introductory chapter resumes the research topic, the main research question, the literature gap and the methodology followed in the study.

In chapter 2 the few empirical studies on Business Development are in depth analysed, thus providing a brief overview on the evolution of marketing literature and on its increasing relatedness to entrepreneurship, together with a review on entrepreneurship studies on Opportunity Identification (OI). Finally, an overview of related studies on Market for Technology along with emerging studies on entrepreneurship/marketing interfaces is provided.

In order to identify the best approach to investigate BD capability, Chapter 3 analyses the main theoretical arguments of the Resource based view, dynamic capability view, competence-based view and knowledge based view. The goal is to identify what best fits the nature of Business Development, in order to create a theoretical framework apt to reveal the factors underlying a BD capability.

Then Chapter 4, explores the biotechnology industry and its unique features. In addition, it provides an overview of the characteristics of the biopharmaceutical sub-sector, i.e. the main context of the present study.

Chapter 5 articulates the research methodology. It describes the philosophical stance behind the study as well as the research process, starting from the selection of cases and the data analysis. The chapter also summarizes ten case studies of small and large biopharmaceutical companies located in Europe and US, enlightening BD best practices among the observed firms.

Chapter 6 presents the research results. In particular, it provides an updated definition of Business Development on the light of the case study testimonies collected, describing seven core dimension that underlie the phenomenon. In addition, by combining literature and case studies, makes it possible to articulate different propositions regarding the microfoundation of a BD capability.

Chapter 7 provides a research summary, followed by an overview of the theoretical and managerial contributions of the thesis. The chapter concludes with a scrutiny of some study limitations and granting a few advices for future researches on the subject.

## **CHAPTER 2**

### **BUSINESS DEVELOPMENT:**

#### **BLURRED LINES BETWEEN ENTREPRENEURSHIP AND MARKETING**

##### **2.1 Introduction**

The purpose of the present chapter is to advance one step further the study of Business Development, utilizing both marketing and entrepreneurship literature as supportive theoretical background (Shane and Venkataraman, 2000; Gaglio and Katz, 2001; Ardichvili et al., 2003; Davis and Sun, 2006). In fact, an in depth scrutiny of previous researches on BD, shows various interconnections between Business Development and both Market Orientation (MO) and Entrepreneurial Orientation (EO) dimensions (Sørensen, 2012; Murray, 2012; Austin, 2006; Kind and zu Knyphausen-Aufseß, 2007).

Although marketing and entrepreneurship have been conventionally regarded as two separate areas of research, exploring marketing/entrepreneurship interface has represented one of the most promising emerging issues in management during the last two decades (Collinson and Shaw, 2001). This is due to the growing awareness surrounding the significance of marketing tools and practices for entrepreneurs (Murray, 1981; Hills, 1987); similarly, given the increasing dynamism of market environments, entrepreneurship can inspire marketing to adopt more innovative and proactive behaviors. Moreover, firms that make use of a combination of both Market Orientation and Entrepreneurial Orientation have shown a greater performance compared to those who have used only Market Orientation (Eggers et al., 2012; Grinstein, 2008). Limited research on how firms operating in Markets for Technology perform and manage marketing activities (Battistella et al., 2012; Zortea-Johnston et al., 2012) is an additional



motivation to explore BD. According to some authors, fast growth high-tech firms use new methods, along with new integrative business models to promote and sell their innovations (Mohr, 2001; Viardot, 2004; Davidow, 1986). In particular, interactive processes, alliances and networks are considered particularly valid and now amply utilized methods to maintain flexibility in meeting demand in highly competitive and dynamic marketplaces.

In order to provide a more comprehensive literature background, it seems then worthy to explore BD concept by taking into consideration both marketing and entrepreneurship studies.

## **2.2 The concept of “Business Development”: literature review**

Aim of this part of the thesis is to analyze all available contributions on the subject matter, in order to identify common features that may help to set up a framework for exploring the BD construct. Business Development is a concept that has received limited direct attention in the academic literature (Davis and Sun, 2006), in spite of the fact that many high tech companies devote part of their organizational structure to BD. Although not uniquely identified and defined by each company, BD has generally involved activities and processes related to the identification and management of new business opportunities.

The first attempt to explore the theme of BD per se, is the work by Davis and Sun (2006), who conducted an exploratory study involving surveys on 26 IT SMEs in Canada. The study demonstrated that BD was a recognized concept in all the enterprises surveyed, BD being defined as a set of “routines and skills that serves to enable growth by identifying opportunities and guiding the deployment of resources to extend the firm’s value-creation activities into technological or market areas that are relatively new to the firm” (Davis and Sun, 2006, p. 146). While documenting BD careers, functions and attributes, Davis and Sun (2006) identified different BD tasks all directed to

increase the customers base through the use of a rich business network and through the combination of knowledge about products, technologies and industry dynamics (Davis and Sun, 2006).

In line with that, Kind and Zu Knyphausen-Aufseß (2007) described the BD process identifying the following phases: 1) the identification of new business opportunities – such as a licensing partner and companies to acquire - through a screening of market information and networking activity; 2) evaluation of the most profitable opportunities, by analyzing potential partner profiles and markets, financial evaluations and strategic fit with the company; 3) negotiation of terms and conditions and adaptability of internal resources to enable implementation.

Merrilees et al. (1998) explain SMEs' international market selection by proposing a similar multiple stage process: 1) networking, i.e. the participation to formal and informal meetings through which entrepreneurs open their outlooks and get the chance to identify new potential opportunities; 2) identification of emerging opportunities; 3) quick response to pivotal opportunities; 4) adaptation of resources to external environment. This is similar to the progression of BD activities, but still lacks formalization in terms of “dedicated BD function” (Davis and Sun, 2006), which entails specific activities, practices, and routines (Nelson and Winter, 1982). More in line with the latter concept, Kale et al.'s 2002 seminal work starts from the concept of “alliance capability” (Anand and Khanna, 2000), which, according to the authors, has empirical meaning only when we find what they call “dedicated alliance functions” within the firm. Clinical development and product maturation are not precise sciences and inter-firm knowledge transfer is extremely complex. Several authors have discussed the difficulties of transferring tacit knowhow (Winter, 1988; Jensen and Meckling, 1991; Szulanski, 1996), and others have emphasized that such difficulties are likely to be more pronounced in an inter-firm setting than in an intra-firm setting (Baker et al., 1997). This is why keeping the communication open with the partner and constantly monitoring the alliance is required from time to time over the lifetime

of the agreement (Murray, 2012). Whenever formalized, the alliance management function constitutes a device for learning, observing markets, mobilizing internal resources and evaluating alliances performance. Such function has only been studied in big organizations and it constitutes only a part/sub-activity of Business Development (Kale et al., 2002). Another study by Keil et al. (2008), concerning established companies, considers BD as a synonymous of external venturing operations: corporate venture capital, mergers, acquisitions, and strategic alliances. This is a common perspective on BD, largely subsumed in the literature on strategic alliances in large and established companies. But, according to recent literature on the topic, BD appears to be more than a pure business operation.

In fact, when Kind and Zu Knyphausen-Aufseß (2007) examined a sample of 15 Germany-based SMEs operating in the biotechnology industry, they tried to clarify the nature of the BD organizational function. In particular, according to the size of the firm, they observed three different levels of BD function configurations: implicit, established, and institutionalized. Moreover, the case studies showed that BD “entails all activities that aim at creating value and revenue potentials for the company, developing products and technologies so that they can be commercialized, building relationships with potential partners, customers and other stakeholders, and maintaining and enhancing those relations in the interest of the company” (Kind and Zu Knyphausen-Aufseß, 2007). The authors suggest that business developers performing the above mentioned functions possess personal skills that are rooted in a solid scientific education, along with a work experience that has also been related to the business side of the industry. At the same time, they tend to have strong external network links that bring new and sensitive information into the company. Accordingly, BD function in biotechnology companies is often led by a vice president who is also a member of the board.

Austin (2008)’s book on Business Development in the biotechnology industry defines BD as “any activity that alters the status quo of the business.” (p. 1). According to the author, activities underlying

the BD function include planning, adding for growth, subtracting for profit, business process improvement, competitive awareness and advantage. Drawing from a pharmaceutical business development course of which he is in charge, Austin (2008) analyzes and explains in depth each step of the BD process, i.e. portfolio planning, search and evaluation of new opportunities, due diligence and negotiation of the contract's terms and, finally, alliance management.

Gigliero et al. (2011) tried to understand the impact of BD on the early commercialization of disruptive innovations by using corporate entrepreneurial approach as suggested by Davis and Sun (2006). BD includes external contacts, in most cases customers. This "commercial function" associated to BD (Davis and Sun, 2006; Gigliero et al., 2011; Uittenbogaard et al., 2006; Murray, 2012) is very much in line with the concept of "External Technology Commercialization" (ETC), which refers to a contractual-regulated transfer of technological assets from one firm to another in return of a specific compensation (Lichtenthaler, 2005). In situations where knowledge bases are widely distributed, such as in Markets for Technology, firms increasingly base their development on external innovative assets (Chesbrough, 2003). The topic of ETC as a development strategy has stimulated the curiosity of management and economics scholars only recently (Lichtenthaler and Ernst, 2007; Bidault and Fischer, 1994; Teece, 2000) leaving many theoretical and managerial issues still unexplored (Gassmann, 2006). The commercialization of internal assets is in line with Sørensen (2012)'s definition of BD, as a set of "tasks and processes concerning analytical preparation of potential growth opportunities and the support and monitoring of the implementation of growth opportunities" (p. 26), excluding from BD the decisions on strategy or implementation of opportunities. In particular, Sørensen underlines the differences between BD, sales, marketing and entrepreneurship, specifying that the nature of contacts with prospective customer partners is quite different from sales contacts because it involves investigating the needs and gaining the understandings of the partner's situation, both current and future. Thus, BD implies an interaction focused much more on learning than on selling.

In general, all the above mentioned works adopt a descriptive approach to BD, concentrating on the analysis of functions, attributes and skills related to it. Moreover, a summary of BD specific definition as given by various authors is reported in Table 2.1.

**Table 2.1: Theoretical contributions on Business Development: an overview**

| Theoretical contribution                     | Definition of Business Development  | Main themes                      | Orientation of Business Development | Number and type of firms analyzed | Methodological approach | Industry      |
|--|---|----------------------------------|-------------------------------------|-----------------------------------|-------------------------|---------------|
| Kind and Zu Knyphausen-Aufseß (2007: p. 185) | Business development describes a business function which has been widely established in biotechnology companies. Under the strategic guidance of top management, its principal task is to prepare and realize input, throughput and output deals. BD entails all activities that aim at creating value and revenue potentials for the company, developing products and technologies so that they can be commercialized, building relationships with potential partners, customers and other stakeholders, and maintaining and enhancing those relations in the interest of the company. | Technology exchange              | Market orientation                  | 15 SMEs                           | Qualitative             | Biotechnology |
|  |   | Relationship management          |                                     |                                   |                         |               |
|  |   | Communication                    |                                     |                                   |                         |               |
|  |   | Value creation                   |                                     |                                   |                         |               |
|  |   | Relationship building            |                                     |                                   |                         |               |
| Davis and Sun (2006: p. 146)                 | Business Development is a set of routines and skills that serves to enable growth by identifying opportunities and guiding the deployment of resources to extend the firm's value-creation activities into technological or market areas that are relatively new to the firm  | Opportunity identification       | Entrepreneurial orientation         | 26 SMEs                           | Qualitative             | IT            |
|  |   | Relationship building            |                                     |                                   |                         |               |
|  |   | Relationship management          |                                     |                                   |                         |               |
|  |   | Market intelligence              |                                     |                                   |                         |               |
|  |   | Value creation                   |                                     |                                   |                         |               |
| Sorensen (2012: p. 26)                       | "Business development" refers to the tasks and processes concerning analytical preparation of potential growth opportunities, the support and monitoring of the implementation of growth opportunities, but does not include decisions on strategy and implementation of growth opportunities   | Opportunity preparation          | Market orientation                  | -                                 | -                       | High tech     |
|  |   | Coordination                     |                                     |                                   |                         |               |
|  |   | Business Planning                |                                     |                                   |                         |               |
|  |   | Growth                           |                                     |                                   |                         |               |
|  |   | Integration of general knowledge |                                     |                                   |                         |               |

| Theoretical contribution (cont.)   | Definition of Business Development   | Main themes   | Orientation of Business Development | Number and type of firms analyzed | Methodological approach | Industry      |
|------------------------------------|--|---|-------------------------------------|-----------------------------------|-------------------------|---------------|
| Austin (2008: p. 1)                | Business Development is any activity that alters the status quo of the business.   | change<br>Portfolio management<br>Communication<br>Project management | Market orientation                  | -                                 | -                       | Biotechnology |
| Gigliano et al. (2011: p. 29)      | Business development is an activity different from selling or key account management, intended to find and develop new revenue opportunities.  | Commercialization<br>Disruptive innovation                            | Entrepreneurial orientation         | -                                 | Theoretical             | -             |
| Uittenbogaard et al. 2005: p. 259) | Business development involves the actual development of product-market combinations, in other words it involves the 'execution of the innovation process'  | Innovation<br>Networking  | Entrepreneurial orientation         | 5 MNE                             | Qualitative             | High tech     |
| Murray (2012: p. 312)              | BD can be defined as the totality of activities undertaken to get a nascent product licensed or sold to a go-to-market partner. Once the product has been refined and approved for the market, the sales process starts. | Commercialization<br>Market intelligence<br>Networking                | Market orientation                  | -                                 | -                       | Biotechnology |

*Source: Author's elaboration*

### **2.3 Two different theoretical perspectives**

All previous works on the matter agree on the “processual” nature of Business Development. Such business practice starts with the identification and evaluation of development options, followed by negotiation of deal terms related to the best options.

However, there is contrasting evidence on how this process should be carried out; in fact, a clear tradeoff between break up and stabilization of routines emerges. A group of authors sees BD as driven by an entrepreneurial orientation, describing it as a set of unstructured activities, whose effectiveness depends upon personal skills of entrepreneurs (Davis and Sun, 2006, p. 148; Uittenboogard et al., 2005). Such view stresses the firm’s tendency to depart from established practices (Lumpkin and Dess, 1996; Jantunen et al., 2005), assuming innovative, proactive and risk-taking behaviors. In this case, the BD process lies at the heart of entrepreneurship literature (Ardichvili et al., 2005; Shane and Venkataraman, 2000). On the contrary, other authors (Sorensen, 2012; Kind and Zu Knyphausen-Aufseß, 2007) sustain that BD is a market-oriented process that guides the commercialization and exchange of products and technologies with long-term partners, thus including marketing related activities such as promotion, communication and commercialization (Murray, 2012 ; Kind and Zu Knyphausen-Aufseß, 2007; Austin, 2008 ); in addition, BD main tasks include gathering technological knowledge through market intelligence and vehiculate value in a market oriented perspective focusing on both firms’ and customers’ needs (Murray, 2012). The emphasis on market intelligence and customers focus is instead the common ground of marketing literature (Jaworski and Kohli, 1993; Day, 1994; Narver and Slater, 1990).

Such theoretical inconsistency among previous works suggest that phenomenon investigation needs a broader or different theoretical base (Fraser, 2000).



While historically considered very different in nature, marketing and entrepreneurship are becoming more and more interacting and complementary. Evolution of economic and environmental contexts have recently increased the number of studies which examine their relationship, which in fact, appears consistent with each other (Miles et al., 2011; Haltman and Hillis, 2011; Shaw, 1999; Stokes, 2000).

Thus, I suggest that BD should be explored using both marketing and entrepreneurship theories in order to capture its blurred nature. The following paragraphs provide an overview of the salient topics observed by exploring the two disciplines interconnections, as well as their evolution and interfacing over time.

#### **2.4 The evolution of marketing in research: a brief overview**

There is a wide agreement in the literature over the fact that the marketing function plays a pivotal role in firm support in an ever increasingly competitive global market. The marketing function constitute the unique and primary link between a company and its customers (Day, 1994; Moorman and Rust, 1999), ensuring that the flow of revenue from the latter to the former remain constant (Harrison-Walker and Perdue, 2007). However, marketing is an activity that has experienced a great evolution over time (Webster, 1992). Based on differences in market factors (customers, competitors, environment, etc), marketing shifted from an economics-based perspective (Marshall 1927; Shaw, 1912; Smith, 1904), to a customer-oriented (Drucker, 1954; Levitt, 1962) and to a network-based rationale (Achrol, 1991; Anderson et al., 1994).

Today prevailing conceptualizations of marketing center on a series of activities that facilitate the exchange relationships. A widely accepted definition from the American Marketing Association (AMA) reads: "Marketing is the activity, set of institutions and processes for creating, communicating, delivering and exchanging offerings that value for customers, clients , partners and society at large" (AMA, 2008). Taking a similar point of view, Pride and Ferrell (2000, p. 14) describe marketing

management as "the process of planning, organization, implementation and control activities to facilitate exchanges effectively and efficiently". Zikmund and D' amico (2001) suggested that the attempt of explaining marketing concepts should always consider five assumptions: 1) at least two parties are involved; 2) all parties have to give up something; 3) all parties have to receive something; 4) same sort of communication must exist between the parties; 5) a mechanism must regulate the exchanges. The marketing challenge is to shape the element of the marketing mix (i.e. the "4Ps": product, price, place and promotion) in a way that better suits target customers' needs, simultaneously granting to companies distinctive features which differentiate them from the competitors. In addition, the 4Ps must be continually adapted to reflect market dynamicity and technological evolution.

Given the fact that customers needs and expectations change over time, delivering products and services with regular high standards requires updated knowledge and quick responsiveness to such changing conditions, i.e. the firm need Market Orientation (Jaworski and Kohli, 1993). Marketing scholars mostly describe Market Orientation (MO) as the process by which companies (1) create and spread market information throughout the organization (Hills and Sarin, 2003), and (2) act upon this knowledge back in the market (Kohli and Jaworski, 1990; Narver and Slater, 1990; Deshpande et al., 1993). Almost all the vast marketing literature recognizes the positive relationship between MO and Business Performance (Deshpande, 1999; Jaworski and Kohli, 1993; Kotler, 1984; Narver and Slater, 1990; Slater and Narver, 1999) and explores the extent to which companies behave, or tend to behave, according to the marketing concept (Kohli and Jaworski 1990). Even though literature has provided a variety of definitions of MO, most authors adopt one of two perspectives (Verhees and Meulenber, 2004; Homburg and Pflesser 2000). The behavioral perspective, proposed by Kohli and Jaworski (1990), concentrates on organizational activities related to the generation, dissemination of and responsiveness to market intelligence (Kohli and Jaworski 1990). The cultural perspective focuses instead on customers as central elements and describes organizational rules and values that support

behaviors consistent with MO (Narver and Slater 1990; Deshpandé et al. 1993), namely customer orientation, competitor orientation and inter-functional coordination.

Although both views are extensively adopted in the literature, in recent years, such marketing interpretations have experienced a variety of criticisms. (Davis et al., 1991; Hamel and Prahalad, 1992; McKenna, 1991; Moorman and Rust, 1999; Morris and Davis, 1988; Webster, 1997). Examples include “an over-reliance on established rules of thumb, encouragement of formula-based thinking, lack of accountability, emphasis on the so-called supporting elements of the marketing mix over product value, a focus on the superficial and transitory whims of customers, a tendency to imitate instead of innovate, concentration on selling products instead of creating markets, and the pursuit of short-term, low-risk payoffs” (Morris et al., 2002, p. 2)

The relevance of such criticisms along with the increasing awareness of radical changes in the competitive environments faced by the majority of contemporary organizations, induced several researchers to admit that marketing discipline have to move forward and look at new directions (Day and Montgomery, 1999; Webster, 1992).

In particular, specific advices have been made to stimulate a more inter-functional and inter-disciplinary orientation to marketing (Deshpande, 1999; Kinnear, 1999). Among others, the study of strategic alliance and networks dynamics emerges as the most prominent direction for marketing literature, in opposition to the classic, “one-shot”, buyer-seller transaction (Achrol and Kotler, 1999; Morris et al., 2002), which *overlooks market actors other than customers and competitors* (Lambin and Chumpitaz, 2000).

In line with Brondoni and colleagues from the Bicocca School of Management, Best (2009) sustains that market orientation presumes a *market-driven management* attitude, which calls for a managerial culture built around the market, rather than the product (Brondoni, 2001), along with a prominent focus

on intangible resources, considered the main source of competitive advantage (Brondoni, 2010). In particular, as supported by Arrigo (2012), market-driven management is a corporate, market oriented development strategy that embraces the open innovation paradigm (Chesbrough, 2003) “to draw knowledge insights from external partners through a better interaction with suppliers, universities, competitors, customers,” (Arrigo, 2012, p. 63). Accordingly, market-driven firms are characterized by the ability to sense market opportunities more efficiently and effectively, compared to their competitors (Day, 1994, Brondoni, 2001). This anticipatory capability is achieved “through open-minded inquiry, synergistic information distribution, mutually informed interpretations, and accessible memories” (Day, 1994, p. 44).

Inspired by the similarities between entrepreneurship and market-driven management, Zucchella and Majocchi (2008), show that the outside-in viewpoint which characterizes the latter (Brondoni, 2007) fits properly with the entrepreneurial outward perspective towards opportunities.

In line with these views, in his early contribution Bonoma (1986) suggests that marketing should become a “boundary function”, in charge of maintaining a constant relationship with key stakeholders. He suggests that, as market conditions become more dynamic and complex, marketing is forced to become more flexible and opportunity driven. According to Murray (1981) marketing has a unique perspective on customers, competitors, and products and that it must become the natural “home” for the entrepreneurial process in established firms, translating its observations into the redesign of the corporate resource base and product/market mix. More recently, Moorman and Rust (1999) indicate that marketing should take the lead in defining new market opportunities and rallying the entire firm to pursue these opportunities.

Ronstadt (1985) argues that “there can be no significant wealth nor major increase in the level of wealth without entrepreneurship.” (p. 27). He and other scholars have provided evidence that

entrepreneurial firms account for a greater share of new jobs and innovations, as well as a high percentage of the exports and tax revenue produced in the United States (Birch, 1981; Timmons, 2000). As I will explain later, entrepreneurship is what drives change in the economic system. This change is expressed by new combinations of resources (i.e. innovations), which may push existing products/processes out of the market.

## **2.5 Entrepreneurship**

Traditional marketing is considered as an intentional, planned process; it assumes that new product/service development is responsive of a meticulous identification phase, where customer needs are identified through formal market research (Webster, 1992).

Entrepreneurial behavior, on the other hand, is seen as a much more informal, unplanned activity based on the capability to chase innovation, manage risk and act proactively (Chell et al., 1991).

The majority of scholars interprets entrepreneurship as an individual-level phenomenon - typical of managers and firm owners - which “declare” itself whenever a person provides an innovative response to environmental challenges. However, entrepreneurship can be significant not only for individuals, but also for organizations (Hamel and Prahalad, 1989; McGrath et al, 1996). This firm-level approach is consistent with classical economics where individuals with entrepreneurial behaviors are compared to firms. Schumpeter (1942) moved the focus from the individual to the firm level , by suggesting that entrepreneurship eventually would be led by organizations that are able to invest more resources in innovative projects and/or activities. More recent literature also recognizes that entrepreneurial activities are not relevant only to start-ups or SMEs, but it may also take place within larger firms (Ahuja and Lampert, 2001). Corporate entrepreneurship is in fact pivotal to the survival, renewal and growth of established organizations (Guth and Ginsberg, 1990; Kuratko et al., 1990; Zahra and Covin,

1995; Lumpkin and Dess, 1996; Zahra et al, 1999; Ahuja and Lampert, 2001; Miles and Covin, 2002; Dess et al., 2003).

Thus, entrepreneurship can also be present in established firms that need to constantly identify new opportunities, beyond existing competencies, in order to survive and prosper (Hamel and Prahalad, 1989; McGrath et al, 1996), constituting a phenomenon that occurs in organizations of all sizes and types (Bygrave, 1989; Cornwall and Perlman, 1990; Morris and Kuratko, 2001; Pinchot, 2000).

Researches on corporate entrepreneurship call attention to the multidimensional nature of entrepreneurship. In order to explain the processes and mechanisms that firms use when they behave entrepreneurially, scholars tend to adopt such terms as entrepreneurial posture (Covin and Slevin, 1991), entrepreneurial style (Naman and Slevin, 1993), entrepreneurial orientation (Lumpkin and Dess, 1996), entrepreneurial management (Stevenson and Jarillo, 1990) or entrepreneurial strategy-making (Dess et al., 1997). More specifically, the term “Entrepreneurial Orientation” (EO) has been mostly used to describe an entrepreneurial firm’s strategic orientation, capturing particular entrepreneurial expression in the decision-making styles, methods, and practices (Lumpkin and Dess, 1996). In general, these researchers commonly view EO as the combination of three particular dimensions<sup>1</sup>: innovativeness, proactiveness, and risk-taking. *Innovativeness* is the tendency to engage in and support new ideas, experimentations and creative processes, thus adapting new viewpoints and shifting from existing practices (Guth and Ginsberg, 1990; Lumpkin and Dess, 1996). *Proactiveness* refers to the anticipation of actions within the market, that lead to a first-mover advantage (Miller, 1983; Lumpkin and Dess, 1996). By adopting such a looking-forward perspective, proactive organizations are usually the first to benefit from new emerging opportunities. Lastly, *risk-taking* involves the willingness to invest significant resources to exploit or explore highly uncertain opportunities (Miller, 1983; Morris,

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<sup>1</sup> These dimensions find their roots in the earlier works of Miller and Friesen (1982) and Khandwalla (1977)

1998; Keh et al., 2002). Lumpkin and Dess (1996) suggest two other slightly related dimensions: *autonomy*, described as the independence in implementing new ideas and businesses and *competitive aggressiveness*, as a challenging posture with regard to competitors that wish to enter the market or advance their position.

In general, entrepreneurial process includes the set of activities necessary to identify an opportunity, define a business concept, assess the needed resources, and manage and harvest the business (Ardichvili et al., 2005). Business “opportunity” is a broad term, that may relates to customers, partners, products, markets and any potential situation that may create some kind of future value for the firm (Casson, 1982; Timmons, 2000; Singh, 2000; Sarasvathy et al., 2003).

Since Shane and Venkataraman (2000) suggested that entrepreneurship concerns the discovery and exploitation of profitable opportunities, the study of opportunity has become the cornerstone of entrepreneurship literature, which has intensively grown and flourished in recent years (Venkataraman 1997; Shane and Venkataraman 2000).

In conclusion, entrepreneurial firms tend to pursue innovative projects through the identification of always new opportunities scouted in the environment, with reward expectations that involve calculated, but significant risks. On the contrary, non-entrepreneurial firms have the tendency to adopt a passive, and risk-averse attitude, which basically induce them to follow or imitate competitors. As suggested by Barringer and Bluedorn (1999), firms that lack entrepreneurial orientation adopt a “wait and see” posture.

### **2.5.1 Entrepreneurship and opportunities: an individual-level**

Opportunity Identification has always been recognized as one of the most important abilities of successful entrepreneurs (Shane and Venkataraman, 2000; Ardichvili et al., 2003), and consequently has become an important element in scholarly studies on entrepreneurship. Gaglio and Katz (2001)

sustain that “understanding the opportunity identification process represents one of the core intellectual questions for the domain of entrepreneurship.” The research of Alvarez and Busenitz (2001) on entrepreneurship and resource-based theory has extended its boundaries to include Opportunity Identification as a resource that, through the process of exploitation, can lead to competitive advantage (Shepherd and DeTienne 2005).

In his attempt to define the entrepreneurship construct, Venkataraman (1997) stressed the need for a deeper understanding of entrepreneurial opportunities and their sources.

Shane and Venkataraman (2000, p. 218), further defined the scope of entrepreneurship as including "the study of sources of opportunities, the processes of discovery, evaluation and exploitation of opportunities, and the set of individuals who discover, evaluate, and exploit them."

So, the concept of opportunity plays a central role in entrepreneurship research. However, the notion of "opportunity" describes a wide range of phenomena that can initially appear indistinct, but become shaped through the time (Ardichvili et al., 2003).

Opportunities may emerge as undefined market needs, or "under-employed" resources and capabilities (Kirzner, 1997). In other words, an opportunity can be viewed as the chance to meet a market need through an original combination of resources that generates a higher value (Schumpeter, 1934 Kirzner, 1978; Casson, 1982). Venkataraman (1997) assumed that a business opportunity consists essentially of a series of ideas, attitudes and actions that lead to new products/services creation. Eckhardt and Shane (2003) described entrepreneurial opportunities as "situations in which new goods, services, raw materials, markets and organizing methods can be introduced through the formation of new means, ends, or means-ends relationships "(Eckhardt and Shane, 2003, p. 336).

Drawing upon a literature review of 25 leading academic journals and conference proceedings in a wide range of organizational and business-related disciplines, Ardichvili et al. (2003) describe three



related concepts, which correspond to the principal activities that take place before a deal is closed: opportunity recognition, opportunity evaluation and opportunity development. This thesis adopts the latter view, acknowledging the fact that, although characterized by different levels of formalization (Davis and Sun, 2006; Kind and Zenger, 2007), previous literature on Business Development agrees on the “processual” nature of the BD phenomenon.

Besides shedding light on the concept of opportunity per se, entrepreneurship literature developed three main theoretical perspectives that have deeply influenced the scope and legitimacy of the research stream itself (Stevenson and Sahlman, 1989). Although the three perspectives rest upon a diverse theoretical base, they should not be considered as mutually exclusive. In fact, their interaction may offer complementary views for the study of Opportunity Identification. The “*functional perspective*” focuses on the entrepreneur’s interaction with the economic environment (Casson, 1982; Hebert and Link, 1988). According to this neoclassical view of entrepreneurship, opportunities are considered as independent variables, available to everyone, not only to entrepreneurs (Shane, 2000). Entrepreneurship here is driven by incentives and by the willingness to pay for relevant information (Casson, 1998), given the heterogeneous distribution of knowledge in the economic environment (Hayek, 1945). In their attempt to study how economic actors identify opportunities, Amit et al. (1993) and Bull and Willard (1993) described a situation where different costs and different incentives and rewards were the main drivers of Opportunity Identification (Casson, 1995). More recent literature on Opportunity Identification has shifted the focus from the “functional approach”, considering individuals’ unique personality as the key driving force of the entrepreneurial activity. The aim guiding the “*personality perspective*” is to shed light on the specific individual traits that delineate the profile of successful entrepreneurs (McClelland, 1961; Timmons, 2000). In particular, two factors appear to better foresee the ability to identify new business opportunities: entrepreneurial alertness (Kirzner, 1973) and prior knowledge and experience (Venkataraman, 1997; Shane, 2000). Personality perspective is greatly

based on psychological theories. Many authors distinguish entrepreneurs from other individuals by looking for particular cognitive traits, such as risk propensity, need for achievement, and self-confidence (McClelland, 1961; Brockhaus, 1980; Begley and Boyd, 1987; Shaver and Scott, 1991; Forlani and Mullins, 2000). However, since empirical studies on the topic didn't produced convincing results (Brockhaus and Horowitz, 1986; Low and MacMillan, 1988), researchers have moved the focus from cognitive traits to cognitive processes and mechanisms that entrepreneurs use for collecting, selecting and processing information to identify opportunities in the external environment (Baron, 1998; Nicholls- Nixon et al., 2000; Shane and Venkataraman, 2000). Although this perspective has shed light on new and subjective factors influencing entrepreneurial behaviors, it has received many criticisms for being too static (Gartner, 1988; Shaver, 1995). In this sense, the "*behavioural perspective*" has made an effort in order to explain entrepreneurship from a more dynamic and integrative viewpoint. Lee and Venkataraman (2006) pointed out the importance of the position in social networks as a key structural parameter for studying the opportunity identification process. Early research also assumes that entrepreneurship theory focus should be individual's behaviors (which depend also upon personality) rather than merely personality traits, i.e. what entrepreneurs do rather than who they are (Gartner, 1988).

**Table 2.2: Theoretical perspectives on opportunity identification and their main focus.**

| <b>Opportunity identification approach</b> | <b>Theoretical focus</b>   |
|--|--|
| Functional perspective                     | Entrepreneur's interaction with the economic environment                                       |
| Personality perspective                    | Personality traits of the individual entrepreneur and their link to opportunity identification |
| Behavioural perspective                    | Individual entrepreneur's activity   |

*Source: author's elaboration*

Based on different and often conflicting assumptions underlying these approaches, various models of opportunity identification explain Opportunity Identification process through diverse and specific driving factors (Bhave, 1994; Schwartz and Teach, 1999; Singh et al., 1999, De Koning, 1999). Most of these integrative models depict Opportunity Identification as a staged process (Christensen et al, 1990; Bhave, 1994) pointing out several variables as antecedents to the process itself. One of the most comprehensive models of Opportunity Identification was introduced by Ardichvili and colleagues (2003). They see “entrepreneurial alertness” as a precondition for Opportunity Identification and define the three central factors that determine it: 1) personality traits, 2) prior knowledge and experience, and 3) social networks. A more creativity-based framework of Opportunity Identification is proposed by Hills et al. (1999) who identifies two distinctive phases i.e. opportunity discovery and opportunity formation, and focuses on the social study network context. Also Sigrist (1999) and Shane propose models of opportunity identification, analyzing, respectively, the cognitive processes involved in and the prior knowledge and experience necessary for successful opportunity recognition.

While the above mentioned research attempts to provide a model of Opportunity Identification have certainly contributed to gather important insights on the opportunity identification construct, they do not provide an holistic view of the process for two main reasons. First, authors on entrepreneurship

literature focus only on some peculiar elements of the Opportunity Identification process, depending on the theoretical approach followed (Ardichvili et al., 2003). Second, existing models tend to consider Opportunity Identification as an entrepreneur's point of view, rather than as a firm-level phenomenon, failing to provide the basis for the development of a Opportunity Identification capability .

## **2.6 Markets for Technology, entrepreneurship and marketing**

The discussion above is particularly relevant in the biotechnology industry contest, given the profound and persistent environmental uncertainty, the need to integrate the different disciplines involved in R&D and the tacit nature of the majority of knowledge (Pisano, 2006) In such a context, the managerial approach of classical marketing activities has not been widely adopted. Markets for Technology, in fact, follow different rules compared to traditional industries, since technological innovations create products and markets that change the competitive environment quite often (Moriarty and Kosnik, 1989). As I explained in Section 2.4, the “focus swift” in marketing research mostly derive from the emergence of new organizational forms (Webster, 1992), such as strategic partnerships and networks, that substituted traditional market-based transactions and bureaucratic hierarchical organizations.

When talking about entrepreneurial biotechnology companies and their business operations, several authors suggest that this industry poor commercial performance could greatly be explained by the lack of marketing capabilities (Costa et al., 2004). In addition, they sustain that the great difficulties in setting up marketing strategies for firms competing in such peculiar markets are caused by the lack of market-orientation, along with weak commercial skills needed to lead the company towards the market. However, recent studies have also introduced the idea that, because of biotechnology business specific characteristics, marketing here might be different from what is considered marketing in prior research and common industrial knowledge (Renko, 2006). This raises a fundamental doubt, that this PhD thesis

aims to clarify: biotechnology firms' marketing performance is poor not because of deficiencies in the way it is carried out, but because its nature has not been completely explored.

In his recent works, Rajamäki (2008) very likely explains how biotechnology industry opts for marketing practices which follow different paths compared to other industries: firstly, he recognizes the uncertainty related to R&D which is endogenous to the biotechnology science, secondly, he accounts for the life cycle of a biotechnology product which is exposed to premature failure: the high rate of new products introduction within the market, and the limited duration and extension patents increase the risks associated to obsolescence. Moreover, the length and the costs associated with product development processes, reflect the continuous need of financial resources in order to sustain innovation. These challenges make it difficult to estimate the size of the potential market in biotechnology.

When she explored the market-orientation of entrepreneurial biotechnology companies through qualitative data, Renko (2006) further found that, although biotechnology firms may also show market-oriented behaviors, these were highly related to entrepreneurial orientation, making the identification of the two distinct concepts difficult to define.

In line with that, the association of marketing and entrepreneurship have been increasingly studied in recent years. An example of a relevant issue in this area is a stream of literature exploring the relationship between the MO and the EO of a firm. Hills et al., (1997) and Shaw (2004) explain that organizations are more productive in finding and exploiting new market opportunities if marketing and entrepreneurial activities are merged into one. In recent years, a new concept of marketing, known as entrepreneurial marketing, focuses exactly on the interface between the two disciplines, providing an ideal base to the study of Business Development in the biotechnology industry.

As proposed by Slater and Narver (1995, p.68): “Coupling a market orientation with entrepreneurial values provides the necessary focus for the firm’s information processing efforts, while it also encourages frame breaking action, thus greatly increasing the prospects for generative learning.” Previous literature has consistently revealed a significant positive correlation between MO and EO, and between each orientation and firm performance (Davis et al. 1991; Miles and Arnold, 1991; Jaworski and Kohli, 1993). One possible explanation of these outcomes is that the two orientations might be more than related: they could be part of a distinct, dominant firm-level phenomenon. Thus, in line with the heterogeneous nature of BD as emerged in Section 2.2, combined customer focus, continuous innovation, and proactivity rather than delay in facing the market, are interdependent elements that could work together (Deshpande et al., 1993).

## **2.7 Entrepreneurship/marketing interface and Business Development**

Bjerke and Hultman (2002) suggest that, given the increasing technological and social change that characterize today’s world, firm may be able to conquer and sustain competitive advantages by adopting an Entrepreneurial Marketing approach.

The term “Entrepreneurial Marketing” (EM) was coined by Morris and colleagues in the last decade (2002). Their purpose was to get nearer the border between two disciplines that, until recently, were considered distinct, if not opposite. According to Morris et al. (2002) EM can be conceptualized as “the proactive identification and exploitation of opportunities for acquiring and retaining profitable customers through innovative approaches to risk management, resource leveraging and value creation.” (p. 5). As such, EM adopts an opportunistic standpoint, expressed through a hybrid organizational function that is not simply responsible and focused on communication and customers needs; it is also looking into a continuous discovery of new sources firm improvement through innovation and substantial risk taking.

In particular, according to Hamel and Prahalad (1994), the entrepreneurial approach to marketing emerged as “a mechanism to mediate the tyranny of the served market” (p. 83). In support of this proposition, Atuahene-Gima (1996) discovered that a higher focus on customers (i.e. the classical milestone of market-orientation), corresponded to a lower focus on product innovation. Other scholars found that a “too close” relationship with customers would block firm’s ability to engage in disruptive innovation, which constitute the main cornerstone of future competitive advantage (Christensen and Bower, 1996; Christensen, 2001). Therefore, while serving current customers is a necessary condition to create competitive advantage, it is not sufficient for the firm to sustain or renew competitive advantage in high-velocity, dynamic markets (Davis and Sun, 2006; Uittenbogaard et al., 2005). By contrast, the EM perspective applies to firms that leverage incremental innovation and creativity to serve existing customers (Collingson and Shaw, 2001), while harnessing radical innovation to create and serve new product-market spaces. This is line with the idea of Business Development as a key function in charge of finding new knowledge that can be integrated within the firm and developed/co-developed in order to pursue innovations thus commercializing the same innovative products stemming from R&D activities. In addition, in Markets for Technology, a continuous long-term relationship is more likely to evolve compared to discrete exchanges based upon a single transaction, since mutually beneficial outcomes may accrue over time (Houston and Gassenheimer, 1987; Gummesson, 1991, 1998, 2002; Gronroos, 1994). As I will further explain later, firms in the biotechnology industry wishing to sustain their competitive advantage, must establish and renew their long-term relationships with customers and partners, regardless of their seize. According to previous literature on the topic, this can be achieved through an effective organization and management of the Business Development process, which also generates reciprocally advantageous long-term relationships between the company and its customers (Kind and Zu Knyphausen-Aufseß, 2007; Davis and Sun, 2006; Austin, 2008;).

In what is likely the most comprehensive debate on EM to date, Morris and colleagues (2002) suggest that EM constitutes a proactive organizational convergence towards customer satisfaction, led by innovative value creation. Consistent with the discussion on Business Development earlier in this paper, Morris et al.'s (2002) core elements of EM effectively capture aspects of market and entrepreneurial orientation. In particular, customer intensity and value creation are at the heart of marketing theories (Berthon et al., 1999; Kotler, 2003; Keefe, 2004). Other elements of EM, such as risk management and organizational propensity to proactive behavior, better reflect a more entrepreneurial approach to management (Miller, 1983; Covin and Slevin, 1989; Lumpkin and Dess, 1996). This suggests that innovation from an EM perspective must encompass both radical and incremental product advancements, which not only creates and renews competitive advantage but also serves current profitable markets.

In summary, EM is increasingly proposed as an integrative base to conceptualize marketing in an historical moment characterized by information overload and continuous environmental change. By merging aspects of entrepreneurship and marketing, EM construct has proven to provide a valid alternative in exploring market orientation of entrepreneurial technological firms (Jones et al., 2013).

Given these premises, and in line with the above mentioned debate on the heterogeneous nature of BD activities, *this thesis adopts a EM perspective, considering Business Development as an interface between entrepreneurship and marketing.*



## **CHAPTER 3**

### **OVERVIEW ON CAPABILITY DEVELOPMENT: TOWARD A MODEL TO STUDY BD**

#### **3.1 Introduction**

A number of theoretical perspectives offer insights on how firms might develop organizational capabilities. These primarily include perspectives from 1. resource-based view (Wernerfelt, 1984; Barney, 1991), 2. dynamic capabilities approach (Teece et al., 1997), and 3. knowledge-based view (Grant, 1996; Decarolis and Deeds, 1999).

An important theory on Capability Development is organizational learning (Conner and Prahalad, 1996), which adopts a learning perspective and argues that firm capabilities are developed on the basis of incremental learning and fine tuning of relevant day-to-day activities (Singh and Zollo, 1998; Kale and Singh, 2002). Although the latter approach is particularly appreciated in the strategic management literature, the aim of this work is not to understand learning mechanisms leading to the development of a BD capability, but to provide conceptualizations of the different dimensions underlying firm Business Development capability. In order to do so, I will firstly confront the Capability Development approaches examined above, in order to identify the ones most appropriate for our aim.

Guided by the Dynamic Capability approach, I will then elaborate a model to study BD capability and its relation to competitive advantage.

### **3.2 Capability development: exploring different approaches**

For two decades, many researchers have tried to conceptualize new ways to describe a firm's resources; moreover, they have often labeled their work as a "new" theory of persistent superior performance or competitive advantage (Barney and Clark, 2007). Thus, the literature currently has proponents of "resource-based" (Wernerfelt, 1984; Barney, 1991), "dynamic capability" (Teece et al., 1997), "competences" (Foss, 1996) and "knowledge-based" (Grant, 1996; Decarolis and Deeds, 1999) theories of superior performance (Barney and Clark 2007). While each of these theories has a slightly different way of characterizing firm resources, they share the same underlying theoretical structure. All focus on similar kinds of firm attributes as critical independent variables, debating on the conditions under which these firm attributes will generate persistent superior performance and will lead to largely interchangeably empirically testable assertions.

Table 3.1 below offers a summary of the main promoters, precursors, followers and scholars that have written on each theory i.e. Resource Based View, Dynamic Capabilities View and Knowledge Based View.

**Table 3.1: Main contributors to the different theoretical perspectives**

| <b>THEORETICAL PERSPECTIVE</b> | <b>PRECURSORS</b>   | <b>PROMOTERS</b>   | <b>FOLLOWERS</b>   | <b>AGAINST THE THEORY</b>   |
|--------------------------------|---|--|--|---|
| <b>RBV</b>                     | <ul style="list-style-type: none"> <li>• Penrose (1959)</li> <li>• Learned (1969)</li> <li>• Rumelt (1984)</li> </ul>   | <ul style="list-style-type: none"> <li>• Wernerfelt (1984)</li> <li>• Barney (1986), Teece (1980, 1982)</li> </ul>   | <ul style="list-style-type: none"> <li>• Prahalad &amp; Hamel (1990)</li> <li>• Grant (1991)</li> <li>• Nelson (1991)</li> <li>• Milgrom, Qian &amp; Roberts (1991)</li> <li>• Mahoney &amp; Pandian (1992)</li> <li>• Peteraf (1993)</li> <li>• Amit &amp; Shoemaker (1993)</li> <li>• Henderson &amp; Cockburn (1994)</li> <li>• Teece &amp; Pisano (1994)</li> <li>• Wernerfelt (1995)</li> <li>• Collis &amp; Montgomery (1995)</li> <li>• Conner &amp; Prahalad (1996)</li> <li>• Porter (1996)</li> <li>• Teece, Pisano &amp; Shuen (1997)</li> <li>• Makadok (2001)</li> <li>• Barney (2001)</li> </ul> | <ul style="list-style-type: none"> <li>• D’Aveni (1994)</li> <li>• Foss, Knudsen &amp; Montgomery (1995)</li> <li>• Grant (1996)</li> <li>• Mosakowski &amp; Mc Kelvey (1997)</li> <li>• Williamson (1999)</li> <li>• Priem &amp; Butler (2000, 2001)</li> <li>• Bromiley &amp; Fleming (2002)</li> <li>• Hoopes, Madsen &amp; Walker (2003)</li> </ul> |
| <b>DCV</b>                     | <ul style="list-style-type: none"> <li>• Hayes, Wheelwright &amp; Clark (1988)</li> <li>• Eisenhardt (1989)</li> <li>• North (1990)</li> <li>• Clark &amp; Fujimoto (1991)</li> <li>• Judge &amp; Miller (1991)</li> <li>• Kogut &amp; Zander (1992)</li> <li>• Burgelman (1994)</li> </ul> | <ul style="list-style-type: none"> <li>• Teece, Pisano (1994)</li> <li>• Martin, Dosi &amp; Marengo (1994)</li> <li>• Teece, Pisano &amp; Shuen (1997)</li> <li>• Eisenhardt &amp; Martin, 2000</li> </ul> | <ul style="list-style-type: none"> <li>• Powell (1996)</li> <li>• Magretta (1998)</li> <li>• Zollo (1998)</li> <li>• Lane &amp; Lubaktin (1998)</li> <li>• Dougherty (1992)</li> <li>• Sull (1999)</li> <li>• Gulati (1999)</li> <li>• Larrson &amp; Finkelstein (1999)</li> <li>• Helfat &amp; Raubitschen (2000)</li> <li>• Wetlaufer (2000)</li> <li>• Graebner (2000)</li> <li>• Eisenhardt &amp; Martin (2000)</li> </ul>   | <ul style="list-style-type: none"> <li>• Mosakowski &amp; Mc Kelvey (1997)</li> <li>• Williamson (1999)</li> <li>• Priem &amp; Butler (2000)</li> </ul>   |
| <b>KBV</b>                     | <ul style="list-style-type: none"> <li>• Nonaka and Takeuchi, 1995</li> <li>• Polanyi, 1962</li> </ul>  | <ul style="list-style-type: none"> <li>• Kogut and Zander, 1992</li> <li>• Grant, 1996</li> <li>• Decarolis and Deeds, 1999</li> </ul>   | <ul style="list-style-type: none"> <li>• Blackler, 1993</li> <li>• Weick and Roberts, 1993</li> <li>• Blackler, 1995</li> <li>• Spender, 1996</li> <li>• Cook and Brown, 1999</li> <li>• Patriotta and Pettigrew, 1999</li> </ul>  | <ul style="list-style-type: none"> <li>• Spender, 1996</li> <li>• Cook and Brown, 1999</li> <li>• Patriotta and Pettigrew, 1999</li> <li>• Blackler, 1995</li> <li>• Chacar and Coff, 2000</li> </ul>   |

Source: author’s elaboration

Since an entrepreneurship resource-based approach basically can be considered as a process of identification, acquisition and accumulation of resources to take advantage of perceived opportunities (Bergmann-Lichtenstein and Brush, 2001), I will start the analysis of capability development theories from that.

### **3.2.1 The Resource Based View**

RBV approach was first formulated by Rumelt (1984), Wernerfelt (1984) and Barney (1986). The RBV has its roots in the seminal work of Penrose (1959), who first shifted the firm strategic management point of view from production to resources. Besides looking “inside” a firm to analyze its ability to growth, Penrose (1959) made several other contributions to what became the resource based theory (Barney and Clark, 2007). First, her work looks at the firm as a “bundle of productive resources” that must be coordinated (Penrose, 1959); i.e. the firm develops and differs from other firms because of its own – tangible and intangible - resources, that make it unique. Thus the focus is on the firm capability to manage its competence portfolio to achieve advantages deriving from an efficient differentiation and exploitation of resources. Second, the author adopted a very broad definition of what may be considered a productive resource. While traditional economists like Ricardo converged on only a few resources that might be inelastic in supply (land, etc), Penrose was the first to analyze the competitive implications of other inelastic resources such as managerial groups and entrepreneurial skills. Finally, Penrose recognized that, even within this extended typology of productive resources, there might still be additional sources of firm heterogeneity.

Since then, the Resource Based Approach has grown rapidly until it became one of the most influential streams in Strategic Management (Mahoney and Panclian, 1992) and recognized as “an influential theoretical framework for understanding how competitive advantage within firms is achieved and how that advantage might be sustained over time” (Eisenhardt and Martin 2000). The

RBV perspective focuses mainly on the internal organization of firms, and on the “soft and intangible variables” (culture, learning, development, etc.) in order to explain the firm performance. In particular, it is possible to draw RBV essential postulates as follows:

- Firms are systems combining material and immaterial productive resources that are subjective, individualized and strategic, because they allow to achieve extra profits;
- thus, firms are heterogeneous both for the nature of their stocks of resources and internal capabilities, and for their exploitation;
- with regard to the available resources and their use, firms realize rents representative of various levels of extra profits.

With the term “resources” the RBV involves those tangible and intangible assets that can be estimated and exchanged to create, produce and offer goods in the market (Barney and Clark, 2007). In addition, a firm is strengthened by the presence of “competences”, that are those abilities in managing and exploiting resources, allowing the development of the resources themselves, that is important to achieve the real firms’ goal of competitive advantage. The right combination of resources and competences can lead to the competitive advantage, if it corresponds to the VRIN conditions<sup>2</sup> (Barney, 1991). According to Barney (1991) a firm resource must possess four attributes in order to have this potential: it must be valuable, in the sense that it exploits opportunities and/or neutralizes threats in a firm’s environment; it must be rare among a firm’s current and potential competition; it must be imperfectly imitable; and it must be able to be exploited by a firm’s organizational processes.

So three RBV fundamental linked concepts explain the ties between resources, competitive advantage and governance:

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<sup>2</sup> More information about the VRIN conditions can be found in Bowman and Ambrosini (2003), while the Hoopes et al. (2003) critic them hardly.

- Resources and competences are the fundamental basis of firms;
- These elements are source of competitive advantage and guarantee a rent;
- The RB perspective contributes to the firm management through good governance.

Two conclusions can be drawn from these premises. First, resources which are rare and valuable can induce a competitive advantage. Second, resources which are additionally not imitable, not replaceable, and not transferable can induce a sustainable competitive advantage. However, the connection between specific resources and performance of a corporation is still not clear (Priem and Butler, 2001: 25). Moreover, RBV is considered not suitable for high velocity environments (Bourgeois and Eisenhardt, 1988), because it focuses on resource accumulation. In high tech industry, for example, the continuous change of resources and knowledge is considered to be a key factor for improving firm's performance (Song et al., 2005; Ambrosini and Bowman, 2009). Table 3.2 presents an analysis that summarizes the principal RBV characteristics, strengths and weaknesses.

**Table 3.2: RBV summary**

|                   | <b>RBV</b>  |
|-------------------|---|
| <b>Features</b>   | <ul style="list-style-type: none"> <li>• It is a strategic theory, because it uses differentiated resources according to the specific goal to achieve.</li> <li>• It transforms the B-C-P paradigm into a new one, the P-C-B.</li> <li>• The firm value depends on the services it can offer, linked to scarce strategic resources.</li> <li>• Resources and competences must be simultaneously Valuable, Rare, Inimitable and Non-substitutable (VRIN conditions).</li> </ul>  |
| <b>Focus</b>      | <ul style="list-style-type: none"> <li>• It focuses on strategic internal factors such as resources and capabilities; their mix determines the firm performance.</li> <li>• It tries to understand why firms belonging to the same industry have very different performance: it is because of their heterogeneity in terms of their specific resources, their accumulation and their use.</li> <li>• It focuses on internal resources, their accumulation, development and exploitation.</li> <li>• It opens the door to analysis on ex ante/ex post mechanisms that maintain and strengthen firm heterogeneity.</li> </ul>   |
| <b>Strengths</b>  | <ul style="list-style-type: none"> <li>• It recognizes that firms differ in terms of heterogeneous internal resources and competences, so that their performance are different even if firms belong to the same industry.</li> <li>• It considers strategic resources scarce, not negotiable, inimitable, irreplaceable.</li> <li>• According to this theory, firms are allowed to achieve long-lived rents.</li> <li>• This framework encourages a dialogue between scholars from a variety of perspectives and emphasizes the importance of organization in business research</li> </ul>  |
| <b>Weaknesses</b> | <ul style="list-style-type: none"> <li>• It is considered “static” with respect to new theories because it considers resources at one point in time, without thinking about their evolution.</li> <li>• In changing environments, it lacks of dynamic aspects.</li> <li>• It is not able to operationalize its concepts consistently across firms.</li> <li>• It does not explain why certain firms have competitive advantage in situations of rapid and unpredictable change.</li> <li>• It has three general isolating mechanisms to prevent the imitation of resources and competences (property rights, learning and development costs, causal ambiguity) but they are not the only existing, there are many other mechanisms that do not depend on a firm’s resources or competences.</li> <li>• It has been called conceptually vague and tautological, with inattention to the mechanisms by which resources actually contribute to competitive advantage.</li> </ul> |

*Source: author’s elaboration*

Thus, the practical implications of the resource-based view on management are limited. A specific issue of many RBV related studies is their static view: there is no time series included and, specifically, path dependencies are often not considered. An additional problem is that often researches on particular

resources forget the processes within the organization, which are instead important in gaining competitive advantages. Many research describe the internal environment and processes of corporations as a 'black box'. Both problems - static view and 'black box' - are partly solved by adopting a Dynamic Capability View.

### **3.2.2 Dynamic Capabilities View**

The dynamic capabilities View gathers long term thoughts and proposes a new approach which integrates RBV and focuses attention on the firm's ability to renew its resources in line with changes in its environment. Thus the dynamic capabilities view (DCV) gives emphasis on the firm's reactivity in complex contexts.

As Teece et al. (1997) explain, "the global competitive battles in high-technology industries have demonstrated the need for an expanded paradigm to understand how competitive advantage is achieved. [...]" (p. 515). Winners in the global marketplace have been firms that can demonstrate timely responsiveness and rapid and flexible production innovation, coupled with the management capability to effectively coordinate and redeploy internal and external competences" (Teece et al., 1997). So they refer to this ability to achieve new forms of competitive advantage as "dynamic capabilities" in order to emphasizes the firm's ability to involve adaptation and change.

In order to avoid misunderstandings, Table 3.3 summarizes some definitions of dynamic capabilities that have followed one another in recent years, thanks to the contributions of many scholars that have applied DC framework to their studies.



**Table 3.3: Definitions of Dynamic Capabilities**

| AUTHORS                               | DEFINITION OF DYNAMIC CAPABILITIES  |
|---------------------------------------|---|
| Teece, et al. (1997: p. 516)          | ‘the firm’s ability to integrate, build, and reconfigure internal and external competences to address rapidly changing environments.’   |
| Eisenhardt and Martin (2000: p. 1107) | ‘the firm’s processes that use resources - specifically the processes to integrate, reconfigure, gain and release resources – to match and even create market change. dynamic capabilities thus are the organizational and strategic routines by which firms achieve new resource configurations as markets emerge, collide, split, evolve, and die.’ |
| (Zollo and Winter 2002: p. 340)       | A dynamic capability is a learned and stable pattern of collective activity through which the organization systematically generates and modifies its operating routines in pursuit of improved effectiveness.’  |
| (Winter 2003: p. 991).                | ‘those that operate to extend, modify or create ordinary capabilities.’   |
| (Zahra et al. 2006: p. 918).          | ‘the abilities to reconfigure a firm's resources and routines in the manner envisioned and deemed appropriate by its principal decision-maker.’   |
| Wang and Ahmed (2007: p. 35)          | ‘a firm's behavioural orientation constantly to integrate, reconfigure, renew and recreate its resources and capabilities and, most importantly, upgrade and reconstruct its core capabilities in response to the changing environment to attain and sustain competitive advantage.’  |
| Helfat et al. (2007: p. 1)            | ‘the capacity of an organization to purposefully create, extend or modify its resource base.’   |

*Source: author’s elaboration*

Listing these definitions highlights the general consensus about the Dynamic Capability construct. These definitions reflect that dynamic capabilities are organizational processes in the most general sense and that their role is to change the firm's resource base. The literature also explains that dynamic capabilities are developed rather than acquired from the market (Makadok 2001), are path dependent (Zollo and Winter 2002) and are embedded in the firm (Eisenhardt and Martin 2000). These definitions also show what dynamic capabilities are *not*. First, Winter (2003), Helfat et al. (2007) and Schreyögg and Kliesch-Eberl (2007) emphasize that Dynamic Capability is not an ad hoc problem-solving event or an unplanned reaction. It must contain some patterned element, i.e. it must be repeatable. Zollo and Winter (2002, pp. 340) also suggest that dynamic capabilities are persistent and that “an organization

that adapts in a creative but disjointed way to a succession of crises is not exercising a Dynamic Capability”. Secondly, Zahra et al. (2006) and Helfat et al. (2007) highlight that the use of dynamic capabilities is intentional, deliberate and cannot be associated with random “good luck”. Lastly, the definitions show that, while dynamic capabilities are concerned with strategic change, they are not a synonym for it. In summary, all the previously cited definitions clarified the intentional effort to change the firm's resource base that stands behind the Dynamic Capability construct.

dynamic capabilities include the abilities to learn, to solve and prevent problems and to accumulate relevant new competences and knowledge, that make the firm able to respond to market changes.

According to the DCV, the strategic dimensions of a firm that lead to a competitive advantage are:

- the position on the market, which is determined by its learning processes, by the coherence of its internal/external processes and by its specific assets (technological and knowledge assets, reputational and relational assets, etc.);
- organizational and managerial processes, which structure the activities of a corporation. Very important processes are the learning-related processes including the accumulation of experiences or articulation and codification of knowledge (Zollo and Winter 2002)
- path dependencies, that concern previous decisions. Processes and positions of a corporation are results of historical events, hence, current decisions have to pay attention to this finding (Kogut *et al.*, 1992). Moreover, corporate experiences and knowledge influence the path of a corporation by learning processes.

DCV is thus a system of shared values, management routines (in decision making, adoption of rules, tacit knowledge) that reveal its importance in being difficult to imitate, because dynamic capabilities are built within the firm rather than bought in the market. But capabilities that are hard to imitate, are

also hard to develop and transfer internally, even if codified. Although it places emphasis on the internal processes that a firm utilizes, some scholars are skeptical about the existence and the application of dynamic capabilities.

However, DCV suffers from terminological ambiguity, in particular about its key concepts of competence, capability and routine. It emphasizes dynamic efficiency but does not propose feasible criteria for evaluating it. DCV is also difficult to be measured and put into effect with the standard tools of industrial economics.

**Table 3.4 DCV summary**

|                   | <b>DCV</b>  |
|-------------------|---|
| <b>Features</b>   | <ul style="list-style-type: none"> <li>• It integrates RBV adding the dynamic components it lacks.</li> <li>• Building firm specific (or “idiosyncratic”, in the RBV terminology) capabilities is a slow and gradual process, based on collective learning, that is never automatic.</li> <li>• It indicates not only how the firm plays the game, but also how it has to play it in relation to other assets, to understand how they need to be deployed and redeployed in a changing market.</li> <li>• DC are built inside the firm rather than bought in the market and they are likely to be path dependent routines.</li> <li>• DC are embedded in their organization so that they are hard to be imitated by rival corporations.</li> <li>• A firm can be able to achieve and sustain a competitive advantage analyzing three classes of factors: processes (technological, organizational, managerial), positions and path dependencies.</li> </ul> |
| <b>Focuses</b>    | <ul style="list-style-type: none"> <li>• It underlines the capacity an organization facing a rapidly changing environment has to create new resources, to renew or alter its resource mix.</li> <li>• It focuses on resources and capabilities birth, development, integration, recombination, reconfiguration.</li> </ul>  |
| <b>Strengths</b>  | <ul style="list-style-type: none"> <li>• It places emphasis on the internal processes that a firm utilizes, as well as how they are deployed and how they will evolve.</li> <li>• It focuses on dynamic environments, that were not considered in the RBV</li> </ul>  |
| <b>Weaknesses</b> | <ul style="list-style-type: none"> <li>• It suffer from ambiguity about its terminology, in particular about its key concepts of competence, capability and routine.</li> <li>• It emphasizes dynamic efficiency but a feasible criterion for judging it still has not been proposed.</li> <li>• Some scholars are sceptical about the real DC existence and application.</li> <li>• Dynamic capabilities are necessary, but not sufficient, conditions for competitive advantage: they are, however, used to build new resource configurations in the pursuit of temporary advantages (in a logic of opportunity exploitation).</li> <li>• DCV is a good explanation of firm performance, but it suffers from problems of measurement and operationalization with the standard tools of industrial economics.</li> </ul>   |

*Source: Author’s elaboration*

### **3.2.3 Knowledge Based View**

The recognition that knowledge is the main driver of sustainable competitive and collaborative advantage has been a major breakthrough in management thinking (Sousa 2008). Organizations in knowledge intensive industries, such as IT and biotechnology, have understood that, in order to

prosper, they must find new ways of acquiring the knowledge they need exactly when they need it, so as to adapt to a rapidly changing and increasingly complicated environment.

The approach of “knowledge as resource” has become the dominant perspective of Knowledge Based View (KBV) in strategy (Grant, 1996). In fact, the dominant KBV considers the latter as a development of the resource-based thinking, where the concept of resources is extended to include intangible assets and, specifically, knowledge-based resources (Grant, 1996; Decarolis and Deeds, 1999). According to the Knowledge Based View “the competitive advantage of corporations is caused by the knowledge management” (Kogut and Zander, 1992). In particular, Grant (1996) argues that what determines firms’ competitive advantage in dynamic environments is tacit individual knowledge; its value, in fact, does not suffer from erosion due to obsolescence and imitation, because it is both unique and relatively immobile. In order to overcome the subsequent issue of integrating specialized and tacit knowledge of individuals, Grant identifies three characteristics which increase knowledge’s strategic value: 1. efficiency, 2. scope and 3. flexibility of integration. The former depends upon common knowledge, frequency and variability of tasks, and a structure that economizes on communication (Eisenhardt and Santos, 2002). A broader scope of integration facilitates instead the creation and conservation of competitive advantage. The flexibility of integration refers to the inclusion of new knowledge and the reconfiguration of existing one. In addition, Grant, along with other authors (Kogut and Zander, 1996; Kogut, 2000), supports that knowledge can also be integrated externally through relational networks that span organizational boundaries (Eisenhardt and Santos, 2002). These networks act as effective systems to access and integrate new knowledge, especially in high-velocity environments, where the speed and scope of knowledge combination play a key role in sustaining competitive advantage (Bourgeois and Eisenhardt, 1988).

Another central theme of KBV is that knowledge detained at both individual and firm level enhance the development of firm-level capabilities that may lead to competitive advantages (Grant, 1996).

According to Leonard-Barton (1992) a core capability is the knowledge set which distinguishes and provides a competitive advantage to an organization and describes four dimensions underlying this knowledge set: employees skills and knowledge, technical systems, managerial systems and values and norms associated with the knowledge itself (Leonard-Barton, 1992). Thus, according to KBV, organizational capabilities develop as a result of recombining and/or integrating knowledge inside and outside the firm.

Within KBV, knowledge is also related to innovation. Many studies on knowledge sourcing suggest that external linkages are important for a variety of innovation-related outcomes such as patents, patent citations, speed of product development, quality of the product pipeline, and introduction of new products (Allen, 1977; Katz and Tushman, 1981; Brown and Eisenhardt, 1998; McEvily and Zaheer, 1999). External network seems to support managers in the identification of new technical knowledge and understanding trends of their industry's trajectories. Thus, in dynamic environments, searching for, identifying, accessing, and sharing new knowledge are important activities for innovative performance.

**Table 3.5: KBV summary**

|                   | <b>KBV</b>   |
|-------------------|--|
| <b>Features</b>   | <ul style="list-style-type: none"> <li>• Knowledge is the most important resource of the firm</li> <li>• knowledge is held by individuals (know-what and know-how), and yet it is also embedded in the organizing principles by which people voluntarily cooperate in an organizational context</li> <li>• firms are able to grow and deter competitive imitation only by continuously recombining their knowledge and applying it to new market opportunities</li> </ul>  |
| <b>Focuses</b>    | <ul style="list-style-type: none"> <li>• The KBV focusing on intangible resources, rather than on physical assets. In this perspective, knowledge is the most important resource, and heterogeneous knowledge bases across firms are the main determinants of performance differences (DeCarolis &amp; Deeds, 1999).</li> </ul>  |
| <b>Strengths</b>  | <ul style="list-style-type: none"> <li>• The theme of knowledge is highly related to both innovation and networking</li> <li>• It is suitable for dynamic environment</li> <li>• justifies the existence of differences in performance between organizations as a consequence of knowledge asymmetries</li> </ul>  |
| <b>Weaknesses</b> | <ul style="list-style-type: none"> <li>• The basic tenets of KBV have not received much empirical examination</li> <li>• The theory has not been tested with regard to the nature of competitive advantage (temporary vs. sustained) or the source of that advantage (knowledge vs. knowledge processes).</li> <li>• the normative implications of the theory have received little empirical examination</li> <li>• Measures used for performance (speed of knowledge transfer, patents, learning) are not actually measures of performance that can yield insights into the nature of competitive advantage, the source of that advantage, or whether that advantage exists at all</li> <li>• there appears to be little, if any, empirical evidence that this assumption is true.</li> <li>• the strategic logic is simply an extension of the resource-based view of strategy in general</li> </ul> |

*Source: author's elaboration*

### **3.3 Discussing the different approaches**

The discussion above provides a comprehensive overview of the four main theories on capability development. They are all valid and consolidated frameworks, although each of them has peculiarities that makes them better applicable to different contexts.

The objective of this thesis is, among others, to study how firms develop a Business Development capability (BDC) in the biotechnology industry. As extensively explained in Chapter 2 (Section 2.2),

BDC in high tech industries concerns the identification of new business opportunities that create value for the firm (Davis and Sun, 2006).

While Resource Based View and Capabilities Based View focus on resources and capabilities that are stable and enduring sources of competitive advantage, Business Development is a future-oriented practice that aims at developing the existent business through the identification of new external opportunities which are expected to create a certain degree of change within the company's stock of resources (included the customer base) and competences (Murray, 2012).

The knowledge based view has been very much applied to high tech and knowledge intensive contexts, such as the biotechnology industry, also because of its ability to detect innovative behaviors. However, its empirical application is still extensively criticized due to the lack of solidity in the "knowledge" construct itself.

Wondering if it is even possible to sustain competitive advantage in high-velocity environments, some other authors (Eisenhardt, 1989; D'Aveni, 1994; Eisenhardt and Martin, 2000) focus on the capacity to change, rather than to possess and use knowledge or other types of resources, "as the central driver of a flow of temporary advantages that leads to superior performance in such environments" (Eisenhardt and Santos, 2002, p. 145). This Dynamic Capability perspective (Teece et al., 1997), has been criticized mainly because of the difficulty in interpreting the two distinct terms "dynamic" and "capability" as one single word.

According to an in depth analysis of seminal articles on the topic (see Section 3.2.2) a Dynamic Capability should not to be intended as a capability in the RBV sense; in fact, it is not a resource.

More specifically, the RBV sees capabilities as either processes that firms deploy to utilize resources (Amit and Shoemaker 1993) or a type of resources (Barney,1991). A valuable resource base grants a



firm the substantive capabilities to get enough earnings to survive in the present (Zahra *et al.*'s, 2006); in other words, it grants operating capabilities (Winter, 2003). Dynamic capabilities, instead, are processes *that impacts upon resources*, that lead to the development of a most satisfactory resource base (Eisenhardt and Martin, 2000; Teece, 2007). Dynamic capabilities are “future oriented”, while capabilities refer to something the firm needs for competing today; thus “static”, if dynamic capabilities are not developed and applied to change them.

In addition, it is unclear to what the adjective “dynamic” refers to. According to Eisenhardt and Martin (2000), dynamic capabilities can be deployed also in relatively stable environments, thus excluding the reference to environmental dynamism. It may also be possible that the capability itself is dynamic, i.e. it changes overtime; but this is also incorrect because, according to Eisenhardt and Martin (2000), dynamic capabilities consist of *repeated processes*, suggesting that we are dealing with quite stable phenomena. Thus, according to my interpretation of the phenomenon, the term “dynamic” refers to *how the resource base is changed* in dynamic environments *through the deployment of dynamic capabilities*. In other words, the dynamism relates to the interplay between the dynamic capability and the resource base, which leads to the modification of the latter.

Accordingly, this thesis adopts such interpretation of dynamic capability, proposing a new framework for capturing Business Development dynamic capability.

### **3.4 Toward a model to study Dynamic Capabilities in Markets for Technology**

The Dynamic Capability View argues that competitive advantage does not necessarily stems from scarce, difficult to imitate and firm-specific resources, but from how they are configured by managers. Indeed, Teece (2007) describes dynamic capabilities as a set of specific, but hard to identify, processes,

procedures, systems, and structures. Otherwise, “sustainable competitive advantage would erode with the effective communication and application of Dynamic Capability concepts” (Teece, 2007:1321).

Besides shedding light on the dimensions underpinning Business Development, the goal of this thesis is to explore the managerial and organizational antecedents, i.e. the microfoundations, that are capable of explaining a superior BD capability. Drawing from Teece et al. (1997), I argue that such capability is dynamic in nature since it is designed to effect organizational change and to allow a firm “to integrate, build and reconfigure internal and external competences to address rapidly changing environments” (Teece et al., 1997, p. 516).

A Dynamic Capability approach has been adopted in the literature to look into a number of phenomena similar to BD, e.g. new product development (Deeds et al., 1997), alliance formation (Rothaermel and Deeds, 2006), innovation (Jantunen, 2005) and external knowledge acquisition (Zahra and George, 2002).

In the biotech industry, there are many variable that intervene between BD and growth. As I will explain later, the uncertainty of R&D is the big driver of growth volatility (Pisano, 2006). In this sense, it would be very difficult to support a direct link between BD and performance. What is possible, instead, is to suggest that BD is what allow firms to exploit and recombine its resource base through the identification and acquisition of new external opportunities. Such opportunities (the resulting deals) will be impacting on the rate of new product development of the firm, a fairly used expression of performance in the biotechnology industry (Stalk and Hout 1990).

Consistently with this reasoning, I advance that Dynamic Capability constitute an ideal approach to study a specific organizational phenomenon, Business Development, through which resources and competences can be exploited, integrated and reconfigured.

For the purpose of the thesis, I developed a framework in order to combine the different variables mentioned above. The framework encompasses four major building blocks:

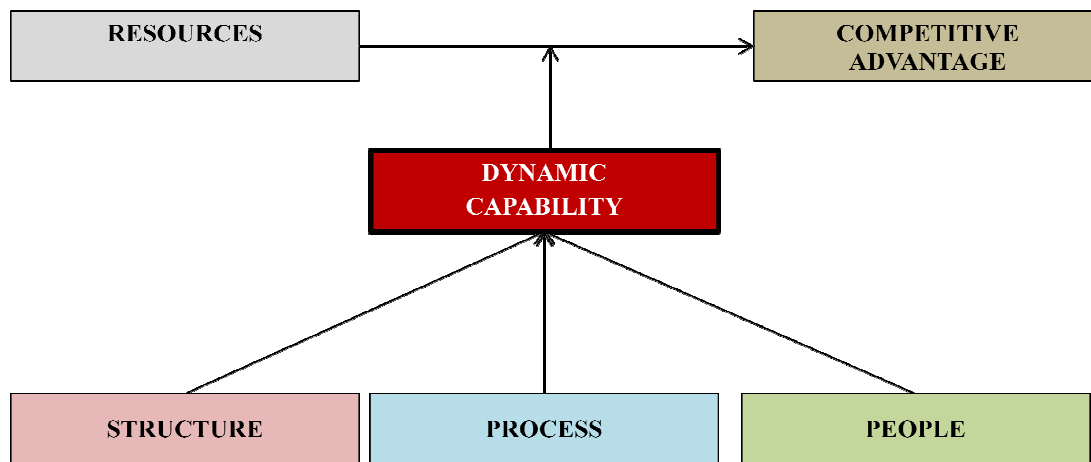
(1) Resources, represent both tangible and intangible firm assets (i.e. resources and competences);

(2) Firm competitive advantage, conceptualizes the extent to which a firm is able to maintain a competitive leadership in specific market segments;

(3) A BD dynamic capability results in the integration and reconfiguration of the firm's knowledge base to address rapidly changing environments. With the purpose of capturing such phenomenon, I draw from Teece's work (2007), who suggests that dynamic capabilities posse two critical functions: sensing and seizing new business opportunities;

(4) Microfoundations include the organizational and managerial antecedents of a dynamic capability. In particular, Teece (2007) defines microfoundations as the distinct "processes, procedures, organizational structures, decision rules and skills that lie behind dynamic capabilities. Thus, in line with Bianchi et al. (2009), I propose a distinction among three microfoundation blocks: (1) process; (2) structure; (3) people.

**Figure 3.1: Theoretical framework proposed for studying BD capability**



*Source: author's elaboration*

### **3.5 Rationale of the Model**

The underlying principle of the theoretical framework proposed above is that, particularly in high tech industries, resources<sup>3</sup> alone do not explain competitive advantage, because specific dynamic capabilities are needed in order to deploy and recombine resources so as to achieve sustainable competitive advantage (Teece et al, 1997; Eisenhardt and Martin, 2000).

In a Market for Technology, a primary expression of enterprise competitive advantage is the rate at which the firm develops new products and exploit their market potential (Stalk and Hout 1990). Such ability is important in order to get early cash flows for greater financial independence, external visibility and legitimacy, early market share, and to increase the likelihood of survival (Schoonhoven et al., 1990). In addition, firms that develop new products and bring them to market faster than competitors, have a higher probability to gain first-mover advantages. This is particularly evident in the

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<sup>3</sup> From now on, when I will use the term “resources” as a term that includes assets, capabilities, processes, attributes, information, knowledge, etc. controlled by the firms (Barney, 1991)

biopharmaceutical industry, where restrictions on patent protection leads to “market races” where “the winner takes it all” (Gilbert and Newbery 1982; Tirole 1988). However, even in more “low tech” industries, the advantages of being first, in terms of market supremacy, reputation effects, experience curve effects, and the like, can still be of great importance (Lieberman and Montgomery 1988).

Let us consider a firm that has been able to develop commercial opportunities from its technological know-how. To convert this know-how into a viable product, the firm has to bring together a set of assets that usually include complementary technological know-how, manufacturing know-how, market know-how, and, of course, financing (Teece 1988). The importance of complementary technological know-how reside in the increasing interdisciplinarity of new product development, that calls for the integration of know-how from different areas (Dosi, 1982; Mowery and Rosenberg 1989; Rosenberg, 1982). Marketing know-how may also be relevant: in order for new products to succeed, they have to be designed to best satisfy customer needs (Ruekert and Walker, 1987). Firms need manufacturing know-how to understand how to efficiently manufacture a new product while minimizing its time to market (Stalk and Hout 1990). Finally, access to financial resources is important, because without funds many entrepreneurial firms will be unable to further advance their technological know-how into a commercial product.

Theoretically, given time and initial financial resources, a firm can develop internally the complementary technological, manufacturing, and marketing assets needed to transform new knowledge into a commercially viable product, the commercialization of which will then provide enough resources to further invest in the above mentioned assets.

Given that, firm resources influence performance, a key tenet of the Resource Based View of the firm: the more the resources of the firm, the greater their expected value (Barney, 1991).

However, in high tech markets, where environmental change is extremely high, firms may have lost the ability to capture any first-mover advantages to faster competitors by the time resources have been achieved. When minimizing time to market is an important competitive requirement, as is often the case (Stalk and Hout 1990), firms source complementary technological, marketing, and manufacturing know-how, as well as financial resources, outside the firm boundaries (Hamel et al., 1989; Mitchell and Singh 1992; Shan 1990; Pisano 1990).

Thus, in line with this reasoning, I argue that the relationship between resources and competitive advantage is mediated by the development of a Business Development (dynamic) capability. Such capability is expected to quickly integrate and recombine the extant resource base through the proactive identification and capture of external business opportunities (Teece, 2007). Such continuous dynamicity in the resource base is expected to reduce the time it takes to develop new products and bring them to market, thereby increasing their probability of survival and/or capturing first-mover advantages. In summary, firms with a Business Development capability are expected to manage their resources better than competitors.

As suggested by Bianchi et al. (2009), when dynamic capabilities (DC) exist, the relationship between resources and competitive advantage occurs; otherwise, “the relationship does not occur, is weaker, or is not sustainable over time” (Bianchi et al., 2009, pp. 42). This explain why some companies are not able to fully realize their resources potential (Ray et al., 2004).

In line with the authors, my framework suggests that a BD capability is built and shaped by managerial decisions on the process, the organizational structure and the people that involved in BD. That is to say that the main drivers of superior sensing and seizing of BD opportunities are particular organizational and managerial systems that firms voluntarily develop and implement. I will thoroughly explain such microfoundation in the following paragraphs.

### **3.5.1 Microfoundations: Structure**

According to the evolutionary economics theory (Nelson and Winter, 1982), firms will likely be more effective at capability development when they build up procedures, or “routines” that are purposefully designed to gather, integrate, and disseminate relevant organizational knowledge acquired through individual and organizational experience (Kale et al., 2002). Expanding on the foundations of evolutionary economics, Zollo (1998) and Kale and Singh (1999) argue that firm capabilities are developed through incremental learning and fine-tuning of relevant daily activities in the firm. Other scholars have argued that organizational capabilities could also be developed by substituting or complementing incremental learning from daily activities (Zollo, 1998; Kale and Singh, 1999) with organizing rules through which individual and group knowledge is configured and managed within the company. Such “architectural competence” (Henderson and Cockburn, 1994), basically encompass organizational processes that are applied to integrate and coordinate information and actions among various people and sub-groups within the firm. These integrative mechanisms constitute a significant locus of firm learning, by facilitating generation of feedbacks from past and ongoing experiences in different parts of the company (Pisano, 1994). For this purpose, Grant (1996) suggested the adoption of hierarchical structures, teams and rules.

Along with some other authors (Harbison and Pekar, 1998; Mitchell, 2000), Kale et al. (2002) suggested that centralized coordination of this kind is equally important in the alliance context. In particular, they sustained that an alliance capability would rest upon how effectively the firm is able to capture, share, and disseminate the alliance management know-how associated with prior experience with regard to every aspect of an alliance, from formation to termination. To the extent that firms engage in these activities in the form of a fairly stable and repetitive pattern, these activities can be

viewed as the knowledge management routines that form the basis for a capability. (Kale et al, 2002, p. 750).

### **3.5.2 Microfoundations: Process**

While some professionals in the firm may possess the necessary cognitive and creative skills, the more desirable approach is to embed scanning, evaluation, negotiation and alliance management activities within the firm itself. The company is in fact exposed to more risks if such activities are left to the cognitive traits of a few individuals: if, for example, they left for pursuing new job opportunities, their competences and knowledge would also be lost. Thus, dynamic capabilities are impacted by the organizational processes that the enterprise has created to manage its business in the past (Teece et al., 1997, Teece, 2007).

The scouting activities that are relevant to “sensing” consist of information about the business ecosystem scenario. With respect to technologies, R&D activity can itself be thought of as a form of “search” for new products and processes. However, R&D is too often usually a manifestation of “local”, internal search, which is only one component of relevant search. In fast-paced environments, with a large percentage of new product introductions coming from external sources, exploration activities should not just be local. Firms’ search must, in fact, embrace potential collaborators – i.e. customers, suppliers, co-operators - that are active in complementary innovative activity (Teece, 2007).

Opportunity creation and/or discovery by individuals require both access to information and the ability to recognize, sense, and shape knowledge. As in the case of R&D, BD processes can be put in place inside the enterprise to obtain new technical information, to monitor customer needs and competitor activity, and to shape new products and processes opportunities. In addition, the way information and resources are shared within the company is also a fundamental element of innovative



behaviour (Kanter, 1984; Pinchot, 1985). Communication, classified by its amount and quality, has proven to be a pivotal element of the success of entrepreneurial initiative in large organizations (Peters and Waterman, 1982; Zahra, 1991). Because of the problem of information decay as information moves through a hierarchy, firms must create systems and practices to retain knowledge within the firm.

Information must be sorted out, and must reach those individuals or groups capable of making sense of it. If companies fail to engage in such activities, they won't be able to assess market and technological developments and spot opportunities. As a consequence, they will likely miss opportunities available to others.

In their work on dynamic capabilities, Zollo and Winter (2002) propose that deliberate efforts to articulate and codify collective knowledge relevant to carry out complex organizational tasks, act as a basis for improving a firm's ability to manage those tasks more effectively. According to the authors, such efforts may be especially important in the context of building capabilities to manage tasks or activities that occur repetitively. It is thus important to understand how the BD process is carried out and which are the practices and tools that mostly sustain and guide the effective identification and management of new business opportunities.

### **3.5.3 Microfoundations: People**

Dynamic capabilities reside in large measure with the enterprise's top management team (Tece, 2007). Maintaining dynamic capabilities thus requires entrepreneurial capacities. Entrepreneurship as intended here is different but related to other managerial activity; in fact, entrepreneurial management is about recognizing and comprehending opportunities, getting things started, and uncovering innovative and improved systems of putting things together. It is also about creatively coordinating the

aggregation of diverse elements, getting authorizations for activities that are “out of the ordinary”, and sensing business opportunities. Entrepreneurial management has little to do with analyzing and optimizing. It is more about sensing, seizing and figuring out the next big opportunity and how to address it (Teece, 2007).

Literature has come to associate the entrepreneur with the individual who starts a new business offering a new or improved product or service. Such achievement is clearly entrepreneurial, but an entrepreneurial management function embedded in dynamic capabilities is not confined to startup or new ventures activities and to individual actors. It involves recognizing problems and trends. Success involve the exploration of all the new opportunities open to the company, and decisions on which business model is the most appropriate to exploit them. Entrepreneurial managers can thus sense and even help shaping the future, release the enterprise from the past, and stay ahead by increasing knowledge assets, protecting them with intellectual property rights, establishing new value enhancing asset combinations, and transforming organizational structures.

Understanding the personal peculiarities that characterizes the ability of such individuals to sense and seize new opportunities is one of the objective of this thesis.

## CHAPTER FOUR

### THE BIOTECHNOLOGY INDUSTRY

#### 4.1 Introduction

Today few leaders in the biotechnology and life sciences industry can feel secure or confident that their company has what it takes to succeed in an increasingly turbulent environment. The day-to-day work is focused on managing projects and people, being concerned about costs, fund raising, producing results, and so on.

In this scenario, it is a must to spend some time looking at the overall strategic picture. Being aware of the extremely competitive landscape in which their companies compete, is a pivotal necessity for any manager and entrepreneur, particularly in such a fast paced sector as biotechnology<sup>4</sup> The next pages provide an detailed overview of this industry, with a specific focus on life sciences.

#### 4.2 Markets for Technology

High tech industries are populated by firms that specialize in the creation of new technologies. Today, this represents an increasingly explored topic, where scholars in economic disciplines address the nature and dynamics of Markets for Technology, (Serrano 2010, Lamoreaux and Sokoloff 2003), and where firms basically exchange IP rights in order to develop and grow (Gambardella et al., 2006). As reported by Gambardella and colleagues (2006), small and large firms are responsible for, respectively, 25% and 9% of the patents licensed in Europe (Gambardella et al., 2006).

Markets for Technology are usually characterized by a dense network of companies specialized in single stages of the R&D pipeline. Given the high risks and costs of innovation, such firms prefer in

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<sup>4</sup>Murray, Michael and Michael Hopkins (2012). *A Biotech Manager's Handbook*. Publishing Series in Biomedicine

fact to buy, sell or co-develop technologies rather than to invest in upstream or downstream assets (Gambardella et al. 2006; Arora et al., 2001). Despite the increasing relevance of Markets for Technology, *there is still a lack of advices from management literature on how managers should act in Markets for Technology* (Arora et al., 2001). The present PhD thesis wishes to narrow this research gap, taking as study context the biotechnology industry, a widely adopted example of the functioning of Markets for Technology (Arora et al., 2001)

Arora et al. (2001, pp. 3-5), provide one of the best overview on the scope surrounding Markets for Technology. Consistently with their definition:

1. *Technology* is defined as useful *knowledge* originating and being rooted mostly in the engineering and scientific fields;

2. The main *motivation that drives commercialization* is the knowledge held within physical assets , rather than the assets themselves;

3. Sometime knowledge can be embodied in physical artifacts (e.g. a method for rapidly screening biological compounds may be embodied in the chip that performs the screening). In such a case the cost of developing the knowledge embodied in the artifact significantly exceeds the cost of creating the artifact;

4. Technology may be tangible and accessible or still under development;

5. In the denomination “Market for Technology”, “market” is used in a broad sense . In fact, while in the consumer market transactions involve the exchange of products/services for money, in Markets for Technology firms usually exchange IP rights, regulated by rigorous contracts and embedded in some sort of collaborative agreement.

Market for Technology consists of transactions of intellectual property and (not necessarily patented) know how, as well as patent licensing (Arora et al. 2001). For the aim of the thesis, I want to

emphasize two features of this particular type of markets that, for their part, justify the relevance of investigating further market orientation in this context. The first feature is about the sources of new product ideas, and the second is about the nature and scope of demand.

*Identification of new product ideas.* The generation of innovative ideas is frequently considered a critical activity for the development of new products. Gagliano (1985) suggested that idea generation brainstorming should not aim at identifying “the” best way, but should instead aim at discover the greatest possible number of new ways. In support of this principle, other scholars demonstrated that the percentage of new product ideas generated in a firm has a very high correlation to performance measurements (For a review, see Troy et al., 2001). Greater amounts of market information, as well as the key organizational structure and managerial choices of a firm, contribute to enhance idea generation (Troy et al. 2001). In other words, one of the reasons for companies to be market oriented is that this orientation helps them to create new, more successful ideas for future products.

In order to clarify the nature of the contest, it is important to specify that in Markets for Technology, ideas for new products and technologies originate from basic science and research, not from customer needs. Business in such markets is about searching for uses and commercial possibilities for technologies ideas. Consequently, the marketing effort is viewed as a necessary consequence of the product or technology, and not vice versa as it “should be” (Levitt 1960, pp. 8).

*Demand conditions.* The second point I wish to make here is about the nature and scope of demand. Most businesses today face a highly competitive market situation. End-user demand is declining in many sectors and companies are struggling with restricting markets. End-users simply do not need and/or cannot afford all the goods available to them, so customers are selective in what they buy.

Often, the demand side of Markets for Technology is somewhat different. New technologies and solutions that stem from science and research rather than customers’ wishes have a potential to create new markets. Let us consider an extreme example: there is a large number of medical conditions and

illnesses for which there are no cures today. These unmet medical needs do not constitute markets as for today, because there are no suppliers in the markets, hence no exchange. However, if a new product is commercialized which addresses such unmet medical need, it has for a while “all the demand in the world” , thanks to patent protection.

Even though this example of unmet medical needs is an extreme one, there is no doubt that technology markets have been filled, in the past, with products and concepts that have created totally new and profitable markets upon their introduction.

The field of biotechnology is a prime example of the functioning of Markets for Technology, and it is also the context of the empirical study in this thesis. Due to strong contact with professionals like medical doctors and customers, market leaders in biotechnology often utilize their superior position to collect leading information on the market and technology (Takayama et al., 2002). However, young, small, science-driven organizations, mainly in biotechnology, are not “naturally” exposed to market knowledge. For these firms, the network of existing customers is often nonexistent; a large number of small innovative firms operate totally in the field of R&D and have no products on the markets for the time being. This is why being market oriented is especially challenging for these young, small organizations.

In summary, Markets for Technology have distinctive features that make sources of new product ideas, demand conditions and the resulting competition different from other more traditional markets.

### 4.3 Biotechnology as a Science-Based Business

For a better understanding of what biotechnology stands for, we first need to define which technologies can be characterized as science-based, since the categorization of a specific technology as science-based is not unanimously accepted.

Meyer-Krahmer and Schmoch (1998) define “*science-based technology*” as a field with frequent references to scientific publications, whose major interest is the observation of science. In general, compared to others, science-based business entails unique challenges that require different kinds of organizational and institutional arrangements and different management approaches.

Gary Pisano (2006), more precisely, points out what is distinctive about science-based business. Many firms use scientific knowledge to create innovative products and solutions. But the use of science in itself does not characterize a science-based business. The author defines as science-based companies those who attempt to both create science and capture value from it. That is, science-based business, actively participates in the process of advancing and creating science and, in this sense, biotechnology falls within this category (Pisano, 2006).

As discussed before, biotechnology is an interdisciplinary field built on the interaction between different areas, such as biology and engineering. It draws upon a wide array of scientific fields, such as microbiology, biochemistry, molecular biology, cell biology, immunology, protein engineering and the full range of bioprocess technologies. Over the past decades, a hallmark of such *knowledge-intensive* industries has been the hiring of a relatively high percentage of people with advanced education, training, and experience. A longitudinal analysis conducted over more than 300 US biotechnology firms by Powell et al. (2009), has shown that about one-third of the employed personnel held a Ph.D. or M.D. degree.

Furthermore, in accordance with Niosi (2003), biotechnology is a science-based activity since it is highly *research-intensive*, and since research is not only performed internally in the R&D department of the firms, but also carried out in partnerships with universities, research centers and other companies. From 1999 up to now, the pharmaceutical industry has noticeably increased the amount of R&D partnerships, due to the high costs of clinical trials and the high risk profile of the R&D activities. R&D in biotechnology is based on the development of scientific activities in universities and in public laboratories, with whom these firms entertain dense collaborations. In fact, as a science-based technology, biotechnology is especially dependent on the cooperation and interaction with academic institutions, governmental and/or industrial, since, in its sector, academic knowledge needs to be transferred to the industry at an early stage (Giesecke, 2000).

#### **4.4 Biotechnology Industry Structure**

The biotechnology industry predominantly consists of companies that use at least one biotechnology technique to produce goods and service or to perform biotechnology R&D. These companies have been historically differentiated from the mainstream pharmaceutical industry which includes traditional pharmaceutical companies which base their approach to drug development more on chemistry than on genetics. Over time, this distinction has become more and more slim, as the business models of companies operating in the industry have continued to evolve. Nowadays, as we discussed in Chapter 1.3, biotech firms can often afford to move their drug production further along the clinical phases, thus maintaining more control on the revenue, and adopting multiple alliances strategies, to outsource the regulatory, marketing and distribution activities that the big pharmaceutical companies are usually better equipped to handle.



The OECD Biotechnology Statistics Database shows that currently<sup>5</sup> Europe had the largest number of biotechnology firms (6,500+ firms), while the United States, with a slightly smaller number of companies than Europe, currently leads the world in the area of biotechnology because its patent law and legislation - such as the Bayh-Dole Act (1980) - provide favorable incentives to mitigate the high risks associated to this business<sup>6</sup>. In their research, Zucker, Darby and Brewer (2002) show that the American biotechnology industry was essentially nonexistent in 1975 and has grown to seven hundred active firms in only 15 years( Zucker et al., 2002). In their study, the authors suggest the existence of a tight connection between the intellectual capital created by frontier research and the creation of firms in the industry, claiming that the presence of intellectual capital was the main driver for the growth of the industry itself.

Compared to Europe, the US biotech industry has the largest and most successful companies, which benefit from a greater availability of venture capital, invests three times more on R&D and generates twice as much revenue in total<sup>7</sup>. The US leading position is also due to a greater entrepreneurial culture, a greater mobility of research scientists and a strength in information technologies critical for life sciences research. Moreover, the development of the US biotech industry has largely been financed in the initial stages by venture capital firms, while the European venture capital market is still fragmented and not sufficiently structured to support the biopharmaceutical sector<sup>8</sup>. As reported by OECD, about two thirds of the 2012 total venture capital in the US is invested in life sciences, compared to only 20% in the European Union.

Biotech companies range in size from small start-ups to multi-billion dollar firms, but most of them are still not yet cash-flow positive and are burning investors' capital on research and development. In

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<sup>5</sup> [www.oecd.org](http://www.oecd.org). Data presented here refer to 2011. Please consider that different sources provide significantly different data since different methodologies and definitions are used.

<sup>6</sup> [www.bio.org](http://www.bio.org)

<sup>7</sup> <http://www.oecd.org>

<sup>8</sup> [www.ec.europa.eu/cip](http://www.ec.europa.eu/cip)

Europe biotech companies are mainly research-intensive small and medium enterprises that generate very limited revenue<sup>9</sup>.

In analyzing the biotechnology field, six dominant, interdependent categories have to be taken into consideration: pharmaceuticals, medicine, agriculture, biomaterials, computing, and military applications. The common thread that runs through these categories is dependence on the function of genes at the molecular level (Bergeron & Chan 2004). This study, however, focuses on pharmaceuticals, medicine and the application of biomaterials for medical purposes.

#### **4.5 The Biopharmaceutical Sector**

Pharmaceutical industry experienced a structural break in terms of performance in the mid-eighties after the introduction of the first successful biotechnology drug, i.e. human insulin, launched in 1982. The emergence of biotechnology has not led to the decay of the existing pharmaceutical companies (Rothaermel, 2001). Rather, the traditional pharmaceutical industry has looked with favour into the biopharmaceutical industry, leading to a cooperation between traditional pharmaceutical firms, like Merck or Pfizer, and new biotechnology firms, such as Biogen or Immunex. Sharp (1999) identifies three main historical phases in the relationship between established firms and biotechnology companies.

The initial phase, regarding the initial stage of biotechnology industry formation, was mainly characterized by uncertainty and skepticism by most established companies which distanced themselves from the new-born biotechnology industry. They also invested in sufficient scientific expertise to keep abreast of developments and monitor the industry.

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<sup>9</sup>EuropaBio 2006

At a second phase , the established pharmaceutical companies recognized the valuable market potential of biotechnology and began to invest into it, either through acquisitions/alliances of biotechnology firms or the development of in-house competences.

The last, more recent, phase involves the commercialization of biotechnology products: the large pharmaceutical companies procure themselves the products developed by biotechnology companies and evolved them into large-scale marketed products (Sharp, 1999).

Biopharmaceutical clusters typically arised in close proximity to academic medical centers, universities and nonprofit research institutions with strong biomedical R&D bases, with most opportunities for collaboration and public/private partnerships (PhRMA, 2010). As mentioned earlier, the interconnection among these key figures is critical and crucial. No wonder if biotechnology is the industry with the highest absolute number of strategic alliances (Hagedoorn, 1993). Biotech research is a field where the growth of strategic alliances has been really remarkable from inception, with an annual average growth rate of 25% (Audretsch, Feldman, 2003). Furthermore, biopharmaceutical companies are increasingly forming partnerships with the public sector, in particular universities and academic medical centers, to generate breakthroughs in basic research that may result into clinical development opportunities. In the vertical alliance chain, typical of this sector, many young biotechnology firms act as intermediaries: they enter early partnerships with public sector research institutions and universities and - later on - build downstream commercialization alliances with incumbent firms (Stuart et al., 2007). A possible explanation is that biotech development requires complementary and heterogeneous assets that often reside in different types of organizations. Established large companies have usually experience in large scale production, marketing and distribution and, most of all, they have the resources required to brings products to the market. On the

other hand, new biotech startups are very specialized and better able to deal with innovative setups and technologies<sup>10</sup>.

Therefore, strategic alliances between large and small firms are often formed to bring these complementary competencies together and are hugely widespread in the biotechnology industry. In fact, they do not only allow firms to leverage their competitive assets, but also to benefit of larger scale economics and productivity for both the companies involved, especially in terms of product development and go-to-market (Audretsch, Feldman, 2003). Stuart, Ozdemir and Ding (2007) emphasize that the enormously costly process for commercializing biotechnologies distinguishes biotechnologies from many other university-originated technologies. Early stage biotechnology firms cannot raise sufficient capital to directly market its products, and hence depend on downstream alliances. The substantial financial and capability-based requirements for commercializing biomedical technologies entails that early stage companies partner with established organizations.

In line with this concept, Rothaermel (2001) describes the new biopharmaceutical industry as the result of extensive interfirm cooperation between established pharmaceutical firms and new biotech firms. According to the author, that happens because pharmaceutical firms face severe difficulties in adapting to radical technological change, while new biotechnology firms lack the necessary competences and scale to commercialize the outputs of their drug discovery and development research, and also the capital to fund them. Therefore they succeed in accessing mutually complementary value chain activities through extensive interfirm cooperation.

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<sup>10</sup> It is useful to refer to the large literature about the "attacker's advantage" and the "resistance" to innovate by incumbent companies. Cfr. Foster R. (1986), *Innovation: The Attackers Advantage*, Summit Books, New York NY. Beinhocker E. D. (1999), "Robust adaptive strategies", *Sloan Management Review*, 40(3), pp.83-94; Snull D.N. (1999), "Why good companies go bad", *Harvard Business Review*, 77(4), pp. 42-52; Englehardt C. e Simmons P. (2002), "Creating an Organizational Space for Learning", *The Learning Organization. An International Journal*, 9(1), pp. 39-47

#### 4.5.1 Main Players in the Value Creation Process

What stands out about the biopharmaceutical industry is that it takes many partners to create economic value. To go from new ideas to new innovative treatments calls for a wide range of collaborations with university scientists and physicians (PHARMA, 2010). The biotechnology industry depends heavily on public science, defined as knowledge that originates from universities, research institutions and government laboratories (G.S. McMillan, , F. Narin, D. L. Deeds, 2000). Unlike many other sectors, in which there is a clear distinction between the basic research performed in universities and public sector R&D institutions and the applied research and development undertaken by private enterprises, in biotechnology sector basic and applied research are often deeply interconnected<sup>11</sup>. The history of the biotechnology industry can be viewed as a series of licensing and collaborative relationships, from universities to biotech firms and, ultimately, to large pharmaceutical companies.

Universities, as well as research institutes, are the source of basic scientific knowledge and new breakthroughs and represent an input to innovation, playing a key role in the process of patenting innovations. In particular, the approval of the Bayh-Dole Act in 1980 has created a uniform patent policy among the many federal agencies that fund research, enabling universities to retain title to inventions made under federally-funded research programs. In recent times, however, universities have assumed a more active role in the commercialization of scientific ideas through patenting and the establishment of technology licensing as part of their academic life. Many universities grant licenses to biotechnology companies, usually through various economic provisions, like licensing fees, milestone payments and royalty schemes (Edwards, Murray and Yu, 2003). The importance of academic research to successful commercialization of scientific discoveries is confirmed by Di Gregorio and Shane

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<sup>11</sup> [www.wipo.int](http://www.wipo.int)

(2000). Jensen and Thursby (2001) confirm that active, self-interested participation of university professors is an essential condition for successful commercial licensing of university inventions.

The traditional pharmaceutical companies, often referred to as Big Pharma, encompass some of the world's largest and most profitable firms (like Johnson and Johnson, Roche, GlaxoSmithKline, Merck, Sanofi Aventis, Novartis, Astra Zeneca, Abbott, Bristol-Myers Squibb and Eli Lilly) whose main focus is to identify promising discoveries and then take these onto the market. The Big Pharma firms have the critical resources and capabilities necessary to the commercialization process, for example internal laboratories and experience in managing the FDA approval procedures, but also the ability to screen and understand potential commercial breakthroughs, often made in research-intensive companies like biotech firms or universities and research institutes (K. Haanes, Ø. Fjeldstad, 2000). During the start-up phase of biotech industry development, US biotech companies were particularly interested in forming strategic alliances with domestic pharmaceutical companies, since they needed strong partners with established distribution networks to conquer the US market (Forrest and Martin, 1992).

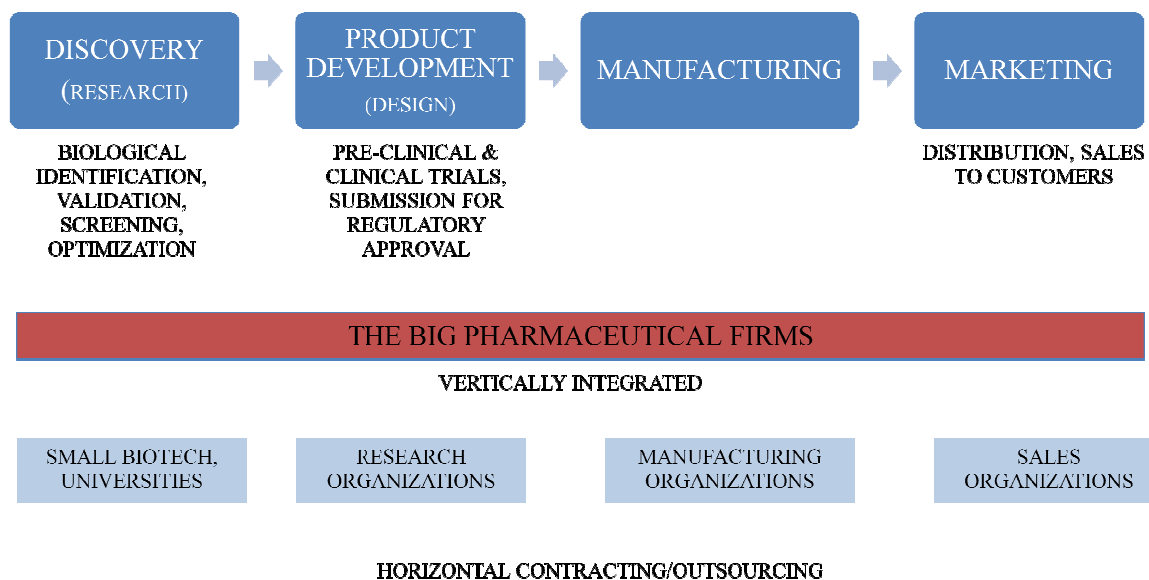
As Howe (2003) points out, historically, large pharmaceutical houses have been understandably proud of their own research discovery capabilities, which they housed internally, and tried to manufacture their own products and develop huge sales and distribution forces. In the last decade, pharmaceutical innovation has been particularly challenging (Fernandez et al., 2012), with the failure rates of R&D projects escalating, the costs of R&D expanding, and the time taken to move from drug patent to market launch increasing (Pammolli et al., 2011). Even in this climate, the importance of in-licensing is increasing (Huggett et al., 2011; Wood Mackenzie, 2003; Booth and Zimmel, 2004; Featherstone and Renfrey, 2004) as established pharmaceutical companies continue to sign large numbers of deals to access promising drugs from younger, smaller biotech firms (Munos, 2009; Kneller, 2010; O'Neill and Hopkins, 2012, Hopkins et al., 2013). This trend is driven by the higher

success of externally sourced molecules compared to internally generated ones (Danzon et al., 2005) and emphasize the negative consequences of missing the markets for technologies (Arora et al., 2001).

Thus, although still maintaining a minimum degree of basic and preclinical research activities, Big Pharma companies are better at drug refinement (From Clinical Development, onward) than at drug discovery and they are superior at bringing a drug through the intricate phases of testing, manufacturing and marketing. Whereas most of the resources allocated by large, established firms are devoted to downstream activities, upstart biotechnology firms and universities generally dedicate their resources to the upstream segments of the value chain, as shown in Figure 4.1 (Stuart et al., 2000).

However, all these entities are strongly interdependent and interconnected by extensive cooperative arrangements (Arora and Gambardella, 1990; Powell, 1996).

**Figure 4.1: The value chain of the biopharmaceutical industry**



Source: Authors' elaboration from <https://web.duke.edu/soc142/team2/images/mychain2.jpg>

#### 4.5.2 The Product Development Process

During the last 10-15 years, the biopharmaceutical sector has become one of the most research-intensive sectors and a key part of the knowledge based economy. Also compared to other major industries - such as the chemical industry - that rely on research and development (R&D), biotech companies generally invest a significantly higher proportion of their revenues in R&D, often between 40% and 50%<sup>12</sup>.

Economic analyzes of the R&D process in the pharmaceutical sector indicate that it is high-risk, even for large established firms. The main reasons for that are the following:

- the drug development is extremely capital intensive, costing an estimated \$300 to \$600 million dollars and taking 12 to 15 years to get from preclinical to market<sup>13</sup>;
- most of the new drug candidates fail to reach the market;
- the process of bringing a new compound to the market takes a long time the ability of revenue generation of marketed products is highly skewed;
- the biopharmaceutical approval process is rigorous and complex, since biotechnology companies must comply with the standards of the Food & Drug Administration (FDA) that regulates the introduction of new drugs or the US Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) that both impose safety/performance standards on the development of pesticides, herbicides and genetically altered crops.

The discovering and developing process of new therapeutics consists of different phases:

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<sup>12</sup> [www.wipo.int](http://www.wipo.int)

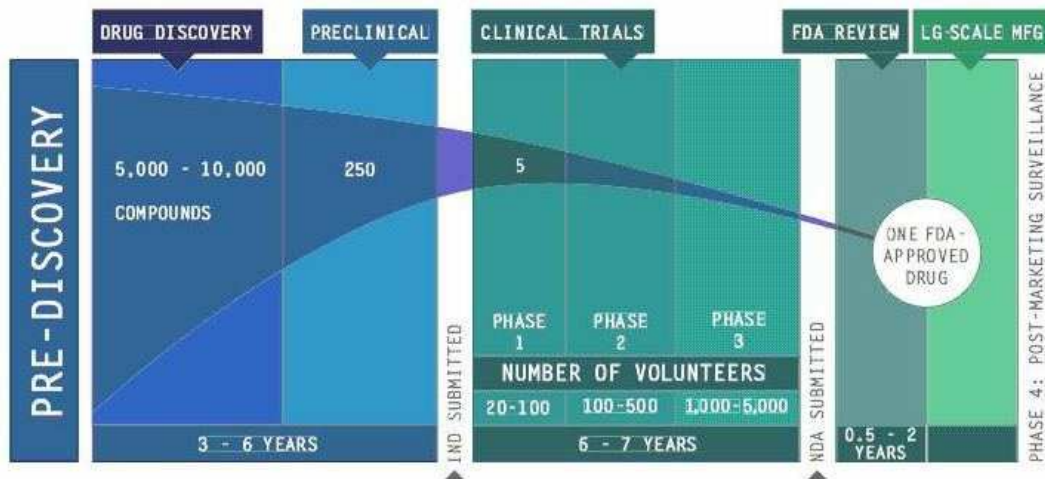
<sup>13</sup> <http://www.oecd.org>



- Discovery and early research;
- Pre-clinical testing;
- Clinical trials (Phase I, II and III);
- Phase IV, Post approval and marketing testing.

The timeframe of the biotechnology drug discovery and development process is described in Figure 4.2. Below.

**Figure 4.2: Timeframe of the Biotechnology Drug Discovery and Development Process**



Source: [http://www.innovation.org/drug\\_discovery/objects/images/chart\\_print.gif](http://www.innovation.org/drug_discovery/objects/images/chart_print.gif)

In the following paragraphs I will briefly explain the different steps required to bring a new compound to the market.

#### *Early Discovery and Preclinical Development*

*Preclinical* testing analyzes the bioactivity, safety, and efficacy of the formulated drug product. These testing activities are critical to the drug's eventual success and, as such, is scrutinized by many regulatory entities. The preclinical stage of drug development requires the application of rigorous

scientific standards and expertise to effectively advance drug candidates from the laboratory to clinical trials. During this phase, plans for clinical trials and an Investigative New Drug (IND) application are prepared.

### *Clinical Trials*

*Clinical* trials are aimed at proving the safety and efficacy of the new drug candidate for humans. Clinical activity is articulated in four subsequent phases.

#### *Phase 1: Clinical Development - Human Pharmacology*

Thirty days after the IND application has been filed, the biopharmaceutical company may begin a small-scale *Phase 1* clinical trial unless the FDA places the study on hold. Phase 1 studies are used to evaluate pharmacokinetic parameters and tolerance, generally in healthy volunteers. These studies include initial single-dose studies, dose escalation and short-term repeated-dose studies.

#### *Phase 2: Clinical Development - Therapeutic Exploratory*

*Phase 2* clinical studies are small-scale trials to evaluate a drug's preliminary efficacy and side-effect profile in a small group of patients (typically ranging from 100 to 250). The participants studied in this phase are usually patients who suffer diseases that the experimental medicine is intended to treat. They are usually identified by physicians in multiple sites (research centers, clinics, and hospitals) all over the world. Additional safety and clinical pharmacology studies are also included in this category.

#### *Phase 3: Clinical Development - Therapeutic Confirmatory*

*Phase 3* studies are large-scale clinical trials for safety and efficacy in large patient populations. These trials generally provide the primary basis for the benefit-risk assessment for the new medicine and much of the core information about the drug that is analyzed to be included in the future label of the medicine.

While Phase 3 studies are in progress, preparations are made for submitting the Biologics License Application (BLA) or the New Drug Application (NDA). NDAs are reviewed by the Center for Drug Evaluation and Research (CDER). This application, which includes reams of data from all stages of testing, is a requirement for FDA approval to market the new medicine.

Sometimes, when side effects come to light, the FDA may require additional studies (Phase 4) to evaluate long-term effects.

#### *Phase 4: Post approval marketing testing*

The final post marketing phase of drug testing is becoming more and more important to explore the safety in larger number of patients after longer-term treatment (IRS, 2013). In fact, through such trials, researchers collect additional information about long-term risks, benefits, and optimal use. These trials often involve thousands of subjects and may continue for several years.

Finally, once the new drug receives the FDA approval, it has to be manufactured and sold.

The development times are similar between the US and Europe and also have not changed much over the past decades. Not only is the time required by new drug development very long, but attrition rates are also really high. According to PHARMA, for every 10,000 compounds synthesized, only one will be approved by the FDA (Alexander and Salazar, 2009). Failure can result from toxicity, manufacturing difficulties, inadequate efficacy, economic and competitive factors, and various other problems. A successful drug can be very profitable. If companies do manage to make a safe and effective treatment for a major disease<sup>14</sup> (such as lung cancer or a burdensome disease such as senile

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<sup>14</sup> Data from O'Neil and Hopkins (2012) reveal that there are several million people worldwide affected by diseases that are not treated with adequate intensity. Due to the high costs related to R&D, pharmaceutical companies typically concentrate their pipeline investments in drugs that promise huge returns. This is the cause of the still too limited attention to illnesses such as tropical disease that, although represent a large diffusion at a global level, are not widespread in the developed countries. On the other hand, diseases affecting the prosperous, developed world, whereas patients and governments are willing and have funds to pay for treatments, feature much more prominently in drug development projects.

dementia) and get the drug onto the market, the rewards can be enormous (the so called "*blockbuster drugs*")<sup>15</sup>.

#### **4.5.3 Alternatives to develop the business.**

Profitability and revenue growth is not easy to achieve in general, and - for technology-based companies - it is an even greater challenge. For technology-based businesses, such as biopharmaceuticals, the *value chain* is particularly complex and then difficult to develop and manage.

In a competitive market, characterized by rapid change and uncertainty, many interconnected factors influence the success of a firm.

Several cross-industry studies have shown how *patents* are crucial for biotech companies since, as in any research-based industry, the protection of research results is a key determinant for the firm growth. Regulatory and patent issues can still hamper and distort trade flows. For example, the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPs) establishes certain minimum protections for intellectual property. Also, it is necessary to consider that biotechnology industry has relatively low imitation costs and patents are a fundamental condition for future exclusive products (Niosi, 2003). In addition, *collaborations* are viewed as increasingly important to make significant progress, improve productivity and increase biotech firms efficiency. Many companies expand R&D collaboration vertically with grants, licensing, and acquisitions, as well as horizontally with private/public partnerships and pre-competitive collaborations. Many theories put the accent on external factors to explain growth in biotechnology firms, considering strategic alliances to be the major determinant, since firms must keep contact with the sources of constantly evolving knowledge to succeed (Niosi, 1995, Powell et al., 1996 Gambardella, 1995). Therefore, both internal activities and strategies, such as the product area and protection of intellectual property through patents, as well as

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<sup>15</sup> More than 120 drugs earned more than \$1 billion in revenues in 2009 (O'Neil and Hopkins, 2012).

external factors, such as venture capital financing and strategic alliances, have an impact on rapid growth in the biopharmaceutical sector.

Besides being science-driven, the majority of firms operating in the biopharmaceutical industry are very small and they may adopt different commercialization routes for their innovations: either take their technology direct to the market as a final product or channel it through large established companies that will then apply their know-how and resources to commercialize it. Some firms follow a hybrid model and combine research services and licensing with research for their own product development in order to survive while aiming for an integrated activity in the future (Pfirrmann 1999; Costa et al. 2004). The deals between smaller, upstream inventors and larger, downstream marketers are often structured as licensing agreements, and functional complementarity is the driving force behind such alliances. It is not surprising that the motivations for alliances differ significantly between licensors and licensees (McCutchen & Swamidass 2004).

The two notable and widely researched characteristics of the field of biotechnology are the dominance of small firms and the dense interorganizational networks within the small firm community as well as between small and larger firms (Barley et al., 1992). Organization level ties among new biotechnology firms have been studied by Barley et al. (1992), Kogut et al. (1992), Powell, Koput & Smith-Doerr (1996), and Shan (1990). Relationships between biotechnology firms and large pharmaceutical firms have been covered by Pisano (1990), Arora & Gambardella (1990), and McCutchen & Swamidass (2004). Liebeskind et al. (1996) looked at scientific knowledge transfer through individual-level ties, and Oliver & Liebeskind (1998) combined the individual and organizational network levels. The overall contribution from all these studies seems to be that the embeddedness of biotechnology firms in collaborative inter-firm networks is essential for the development of competitive advantages.

## **CHAPTER FIVE**

### **RESEARCH DESIGN AND METHODOLOGY**

#### **5.1 Introduction**

This chapter presents the research methodology used in this study to explore the theme of Business Development. The guiding methodological principle adopted is the achievement of consistency between the philosophical stance behind the research and its key objectives (Easterby-Smith et al, 1991), already identified in previous chapters (Chapter three and Chapter four).

The present chapter structure is the following: Section 5.2 analyzes general research philosophy issues, discussing the positivist and constructivist paradigms suitability regarding the debate on induction vs deduction and regarding the choice between qualitative or quantitative research approach. Furthermore, it is discussed the philosophical viewpoint adopted by the present study, also providing a brief research process overview. Sections 5.3 and 5.4 present the qualitative analysis and its related process, justifying the exploratory case study method choice and providing a detailed explanation of the rationale behind cases selection. Finally, Section 5.5 describes the qualitative analysis in details, providing a sample description and a case study summary.

#### **5.2 Research Philosophy**

This part of the thesis elaborates on the philosophical standpoint of the research. Easterby-Smith et al (1991) suggest three motivations underlying the necessity of exploring the research methodology: In primis, the researcher clarifies his/her research strategy by redefining and specifying the research method. This comprises the variety of evidence collected and its origin, how such evidence is, the way in which evidence is decoded, and how it facilitates the research question answering. Secondly, the understanding of the research philosophy allows the evaluation of different research methods and their

pros and cons at the project early-stages , in order to avoid unnecessary and inappropriate work. Thirdly, the enhancement of the author creativity in either the selection or the adaptation of different research approaches. The present chapter will explain the philosophical stance behind the present research, the theoretical orientation followed, along with the choice reasons for a qualitative versus a quantitative approach.

### **5.2.1 Positivism versus constructivism**

When explaining the research philosophy of a particular study, it is always fundamental to point out the appropriate theoretical paradigm the author used to conduct the scientific investigation. As suggested by Bogdan and Biklan (1982, p. 30) a theoretical paradigm represent “a loose collection of logically held together assumptions, concepts, and propositions that orientates thinking and research.” The research philosophy comprises three main conceptual units: ontology, epistemology and methodology. Ontology refers to the main assumptions the researcher made on reality, epistemology analyzes the nature of knowledge (i.e. the relations occurring between the researcher and the reality), and methodology refers to how the researcher explore the reality (Guba and Lincoln, 1994; Parkhe, 1993).

*Positivism*<sup>16</sup> sustains that objective reality is granted , and just found in the reality out there; epistemologically, this goal can be achieved with clear degrees of certainty using objective scientific methodologies (Jean Lee, 1992; Carson et al., 2001). Such reality is populated by discrete elements with recognizable and classifiable features (Cohen, 1994; Guba and Lincoln, 1994; Hirschman, 1986; Nancarrow et al., 2001). Thus, the classical inquiry technique of positivism is deduction through theory testing (Layder, 1993). Using the hypothetico-deductive method allows the researcher to run statistical

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<sup>16</sup> Positivism is the traditional approach of the physical sciences, while it is also dominant in established social sciences disciplines, such as psychology and economics (Gabriel, 1990; Kidd, 2002).

tests and generalize results (Guba and Lincoln, 1994). Examples of typical data collection approaches of this kind include quantitative surveys and database analyzes. Finally, during the data collection process, the researcher is generally far from the investigated phenomena (Anderson, 1986).

On the other hand, the *constructivist approach* aims at “constructing” reality by investigating the standpoints of individual respondents rather than given, fixed observations (Hunt, 1991). This approach has a relativist ontology, since it assumes the subjectivity of reality (Carson et al., 2001; Roy, 2001; Jean Lee, 1992;). Epistemologically, objectivity is rejected by principle, while the interest is on understanding a particular point of view (Morgan and Smircich, 1980); in this case, perception and reality are two different things<sup>17</sup>. The main focus is then on the values behind perceptions, and on which values, among others, emerge to surface the underlying perceptions and on which one come to surface the inductive process. Opposite from the positivist paradigm, the theory-building approach typical of constructivism calls for an active relationship between respondent and researcher (Guba and Lincoln, 1994; Anderson, 1986) the latter required to develop subjective opinions about what discussed during the interaction (Anderson, 1986, Guba and Lincoln, 1994).

### **5.2.2 Qualitative versus quantitative methods**

The issue now is to understand which of the previously described philosophical stances is the more appropriate. While pros and cons have been associated to each method (Table 5.1), the answer lies in the specific research goal. The in-depth and detailed exploration of the qualitative approach is particularly useful when the objective is to study a new, unexplored or emerging topic. While the quantitative approach is used to determine specific facts or the correlation between two or more facts. Also, while quantitative analysis is based on models that simplify reality, qualitative methodologies

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<sup>17</sup> Perceptions are important because they assist in examining a complex reality, but perceptions or multiple realities cannot be the focus of constructivist research. Constructivism is interested in the values lying beneath perceptions.



automatically reflects the reality. The former is specifically adapted for broad scale researches, providing reliable statistically tested results that can be generalized to other contexts; on the other hand, the detailed picture that qualitative analyzes provides of a specific phenomenon, goes to the detriment of its generalized qualitative analysis.

**Table 5.1: Qualitative versus Quantitative Research Methods**

| Criteria   | Qualitative Method  | Quantitative Method   |
|--|---|---|
| <b>Basic beliefs about the nature of reality</b> | <ul style="list-style-type: none"> <li>• There is one objective reality that is not dependent on human interpretation</li> </ul>  | <ul style="list-style-type: none"> <li>• There are multiple realities; reality is not purely objective, and does not exist independent of the humans who interpret it</li> </ul>  |
| <b>Main paradigm types</b>                       | <ul style="list-style-type: none"> <li>• Positivism</li> </ul>  | <ul style="list-style-type: none"> <li>• Constructivism</li> </ul>  |
| <b>Common research methods</b>                   | <ul style="list-style-type: none"> <li>• Experiment</li> <li>• Survey</li> </ul>  | <ul style="list-style-type: none"> <li>• Grounded theory</li> <li>• Action research</li> <li>• Ethnography</li> <li>• Case study</li> </ul>   |
| <b>Quality assurance</b>                         | <ul style="list-style-type: none"> <li>• Reliability: internal and external</li> <li>• Validity: construct, context</li> <li>• Sampling: random and deliberate</li> </ul> | <ul style="list-style-type: none"> <li>• Construct validity, confirmability, internal validity/credibility, external validity/transferenceability, reliability/dependability</li> <li>• Sampling: purposeful</li> </ul> |
| <b>Key differentiating characteristics</b>       | <ul style="list-style-type: none"> <li>• Primarily deductive process used to test pre-specified concepts, constructs, and hypotheses that make up a theory</li> </ul>     | <ul style="list-style-type: none"> <li>• Primarily inductive process used to formulate theory</li> </ul>  |
|  | <ul style="list-style-type: none"> <li>• More objective: provides observed effects (interpreted by researchers) of a problem or condition</li> </ul>                      | <ul style="list-style-type: none"> <li>• More subjective: describes a problem or condition from the point of view of those experiencing it</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Number-based</li> </ul>  | <ul style="list-style-type: none"> <li>• Text-based</li> </ul>  |
|  | <ul style="list-style-type: none"> <li>• Less in-depth but more breadth of information across a large number of cases</li> </ul>  | <ul style="list-style-type: none"> <li>• More in-depth information on a few cases</li> </ul>  |
|  | <ul style="list-style-type: none"> <li>• Fixed response options</li> </ul>  | <ul style="list-style-type: none"> <li>• Unstructured or semi-structured response options</li> </ul>  |
|  | <ul style="list-style-type: none"> <li>• Statistical tests are used for analysis</li> </ul>   | <ul style="list-style-type: none"> <li>• No statistical tests</li> </ul>  |
|  | <ul style="list-style-type: none"> <li>• Can be valid and reliable: largely depends on the measurement device or instrument used</li> </ul>                               | <ul style="list-style-type: none"> <li>• Can be valid and reliable: largely depends on skill and rigour of the researcher</li> </ul>  |
|  | <ul style="list-style-type: none"> <li>• More generalizable</li> </ul>  | <ul style="list-style-type: none"> <li>▪ Less generalizable</li> </ul>  |

Source: author's elaboration from Liouka (2006)

Summarizing , both qualitative and quantitative methodologies can offers critical contributions in the scientific research. Hence, they should be regarded as complementary, not competing methods, and should be chosen depending on which method is more likely to provide a more comprehensive, clearer, more complete and above all the more descriptive answer to the research question.

However, given the type of research this thesis is pursuing, and the relative limited time at disposal, it has been decided to select the qualitative approach. The following section will explain why the methodological choice is the most appropriate for this thesis research objectives. .

### **5.3 Philosophical posture of the thesis**

This thesis aim to explore the phenomenon of Business Development. Given the scarcity of previous academic work on the topic, a qualitative point of view has been adopted to confront the phenomenon, calling for a theory-building approach as a first step. The latter offers significant insights on the nature of Business Development, as well as on its antecedents. Moreover, many researches that studies similar heterogeneous phenomena recommend the use of qualitative methodologies as well (Gungaphul and Boolaky, 2009; Gartner and Birley, 2002; Fillis et al., 2004; Eckhardt and Shane, 2003; Miles and Darroch, 2004; Gaglio and Katz, 2001).

It is now important to explain and clarify the use of previous theories in the qualitative analysis of the present study. The main issue related to the pure deductions achieved through a qualitative method is that they might overlook results and concerns raised in previous theoretical works. However, the present study aligns with the idea that the consideration of the existent body of literature is central for the qualitative study design and data analysis (Miles and Huberman, 1994; Yin, 1993; Perry and Coote, 1994; Neuman, 1994). In addition, some authors stressed the importance of the “enquiring” qualitative analysis techniques (Savage and Black, 1995; Miles and Covin, 2002), especially when dealing with research territories characterized by a very blurred body of knowledge. This assumption is in line with

the specific need of the present thesis, given that the emerging topic of Business Development still lies at an early stage of investigation.

#### **5.4 Selection of particular research methods**

After explaining why a qualitative approach is essential for addressing present study goals, I now clarify the motivations behind the choice of the particular qualitative method. The choice is based on a critical analysis of the pros and cons associated with the method, and in relation with the study context. The key element that drive the selection of the case study approach has been to achieve the optimal fit between research goal and methodological strategy (Patton, 1990; Bryman, 1992). However, I considered also other parameters, such as external limitation (cost and time), as well as my own capabilities (Ghauri and Grønhaug, 2002). Table 5.2 provides a general outlook of the basic research methods considered, while the following paragraphs justify the particular choice of the case-study method and the survey research most appropriate method to address present study goals.

**Table 5.2: Evaluating different research methods**

| Research Methods       | Pros  | Cons   |
|------------------------|---|--|
| <b>Survey</b>          | <ul style="list-style-type: none"> <li>• Generalisability of findings (large samples can be tested)</li> <li>• Particularly useful for hypotheses testing</li> <li>• Easy and inexpensive to administer</li> <li>• Offers anonymity</li> </ul>  | <ul style="list-style-type: none"> <li>• Not in-depth, hence not useful for studying complex or conceptual issues (limited information captured)</li> <li>• Responses may be biased by the questions</li> <li>• Statistical validity and reliability concerns</li> <li>• Problems with low-response rates</li> </ul>   |
| <b>Experiment</b>      | <ul style="list-style-type: none"> <li>• Robust control of variables possible</li> <li>• Causality can be established</li> </ul>  | <ul style="list-style-type: none"> <li>• High cost in terms of time and money</li> <li>• Legal and ethical constraints</li> <li>• Recruiting subjects is not easy</li> <li>• Artificial</li> </ul>   |
| <b>Grounded Theory</b> | <ul style="list-style-type: none"> <li>• Systematic generation of new theory from data (interactive nature between data collection and analysis)</li> <li>• Analyse experiences from the standpoint of those who live it</li> <li>• Context-based and process-oriented</li> </ul>   | <ul style="list-style-type: none"> <li>• Perspective-based methodology (perceptions vary)</li> <li>• Difficult when conceptualising complex phenomena, requires strong research capabilities</li> <li>• Not recommended for description</li> <li>• Subject to researcher bias (requires ability to maintain analytic distance)</li> <li>• Generalisability questionable</li> </ul> |
| <b>Case Study</b>      | <ul style="list-style-type: none"> <li>• Provides in-depth and holistic perspective</li> <li>• Multi-faced; can show different perspectives</li> <li>• Can show how processes work over time and give insight into cause and effect</li> <li>• Can serve both exploratory, descriptive and explanatory purposes</li> <li>• Can supplement statistics or survey results</li> </ul> | <ul style="list-style-type: none"> <li>• Limited generalisability; not representative of entire populations</li> <li>• Time-consuming and expensive to administered</li> <li>• Subjective</li> <li>• Data analysis depends heavily on the analytical skills of the researcher</li> <li>• Particularly difficult when dealing with rich and complex data</li> </ul>                 |
| <b>Ethnography</b>     | <ul style="list-style-type: none"> <li>• In-depth and holistic description</li> <li>• Can identify causalities</li> </ul>   | <ul style="list-style-type: none"> <li>• Bias of the researcher (liable to subjective interpretation towards perspectives of the researcher's own culture)</li> <li>• Requires strong research capabilities</li> <li>• Time-demanding</li> </ul>   |
| <b>Action Research</b> | <ul style="list-style-type: none"> <li>• Findings have perfectly practical implications</li> <li>• Provides unique insights</li> </ul>  | <ul style="list-style-type: none"> <li>• Requires full access to the organization (difficult to achieve)</li> <li>• Perceived as improving mainly practitioner and not academic knowledge</li> <li>• Time-demanding</li> </ul>   |

*Source: author's elaboration from Liouka (2006)*

### 5.4.1 The case study method

In terms of qualitative research, the case study method was chosen as most appropriate to address the research purposes of this study mainly for three reasons:

Firstly, the case study research implies the exploration of a phenomenon in its natural setting (Eisenhardt, 1989). Hence, it is particularly suitable for research in new or emerging topics, where the focus is to investigate a new research theme concerning a contemporary set of events (Yin, 2003). Given the lack of research in the particular subject of Business Development, the exploratory case study approach was regarded as most appropriate. This particular research perspective is thus expected to facilitate the immersion in the organizational context of the investigated firms and the collection of rich data from multiple sources of evidence. Under this light, the case study method provides a systematic and holistic view of the nature and managerial factors associated with Business development (Bonoma, 1985; Carson et al., 2001; Ghauri and Grønhaug, 2002).

Secondly, since the exploratory case study approach primarily aims at theory building rather than hypotheses testing (Eisenhardt, 1989), it appears most appropriate to address the major exploratory purposes of this thesis. In particular, the exploratory case study approach seems particularly effective in providing useful insights relevant to the under-investigated theme Business Development (Eisenhardt, 1989; Gummesson, 2005) and may greatly assist in the development and refinement of the conceptual model presented in Section 3 (Figure 3.2).

Thirdly, the case study method is generally considered well suited for global markets researches, where data are collected from cross-border and cross-cultural settings (Marschan- Piekkari and Welch, 2004). Considering that this research focuses on firms of different countries of origin, the use of case study research is considered most appropriate for dealing with cross-national differences.

## 5.5 Qualitative Research

Given the nature of this thesis, exploratory case studies were preferred over the two possible alternatives (descriptive and explanatory<sup>18</sup>), given the scarcity of relevant literature in the fields of Business Development. In addition, exploratory studies are particularly useful when little extant knowledge exists and there is limited empirical data to form a sound basis for making predictions (Bryman and Burgess, 1995; Easterby-Smith et al, 2001; Ghauri and Grønhaug, 2002).

Based on the research objectives and on a review of relevant literature, I later developed a semi-structured interview guide. As previously explained (Section 5.2.4), some earlier theories were taken into consideration prior to conducting qualitative researches and during the analysis of qualitative data. Indeed, conducting case study research with a strong methodological base, requires an initial identification of previous theories in the area of research (Lincoln and Guba, 1985, Miles and Huberman, 1994; Neuman, 1994; Perry and Coote, 1994; Yin, 2003). Early theory can thus be viewed as supplementary evidence that can be used to triangulate data gained from the external reality of the case studies.

Therefore, although the interviews began with unstructured questions, some explorative questions were also integrated in the interview guide. That ensured that interviewees' perceptions about critical issues identified in prior theory were raised (Section 5.3.2). The qualitative data examination itself was also based considerably on prior theoretical considerations that have been raised in Chapters 2.

After the interview has been developed, I conducted in-depth face-to-face interviews with senior manager, Business Development managers and CEOs. Then I analyzed data both at a single-case and – subsequently - at a cross-case level (Miles and Huberman, 1994; Patton, 1990).

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<sup>18</sup> A descriptive approach is suitable for providing an accurate account of events and situations, while an explanatory approach is used to establish causal relationships between variables (Bryman and Burgess, 1995; Easterby-Smith et al, 2001; Ghauri and Grønhaug, 2002; Yin, 2003).

### **5.5.1 The selection of cases**

The study focus on firms which develop biopharmaceutical products and technologies. As explained in Chapter 4, there are many definitions of “biopharmaceuticals” and this causes some difficulties in defining and identifying biopharmaceutical enterprises (Rader, 2005). As the study only focuses on biotech for human healthcare (“red biotech”), I will use the OECD definition of biotechnology enterprises, namely “a firm engaged in key biotechnology activities such as the application of at least one biotechnology technique to produce goods or services and/or the performance of biotechnology R&D”. However, firms specialized only in one specific activity (e.g. bio-manufacturing firms, service providers, consultancy companies, etc) were excluded.

As specified in the previous Section 4, the challenge in the biopharmaceutical industry is to develop new products/technologies based on new scientific knowledge and research results. Biopharmaceutical firms typically develop new medicines based on a technology platform. This technology platform corresponds to scientific knowledge and tools for drug development. The main challenge for many drug-discovery companies is to move from the early stage in the value chain and reach the market with new products. On the other hand, larger firms such as pharmaceutical companies need to fill their pipeline with new projects to develop, in order to leverage their “core” resources and capabilities in the clinical development, manufacturing and commercialization phases. In order to provide evidence on Business development covering the whole biopharmaceutical value chain, this study considers both small and large enterprises focused on discovery and development of biopharmaceutical products for human healthcare, modern technology tools and approaches. Enterprises which have actually managed to introduce a product on the market, may also be part of the target group if they are currently involved in biopharmaceutical R&D.

The underlying deciding principle in selecting case study firms has been to choose “information rich cases”, namely multinational firms, worthy of in-depth investigation as suggested by Patton, (1990) and Yin (1994). According to their advices, “multiple cases” should be regarded as “multiple experiments” and not “multiple respondents in a survey”, hence replication logic and not sampling logic should be used for multiple-case studies. Other researchers support this method of case selection and endorse the inappropriateness of random sampling. As example, Eisenhardt (1989, p. 537) states that the “random selection of cases is neither necessary, nor even preferable”.

In particular, the present study cases selection was based on the following three criteria:

1. The selected firms had to exhibit a declared Business Development function
2. Firms had to consider Business Development as a key process for gaining competitive advantage on competitors, sustained over time
3. Firms selection was based on their considerable variety in terms of value adding activity, industry and country of origin. This criterion was adopted in order to allow wide generality and entirety in the findings.

Regarding the number of cases to be included in a multiple case-study analysis, Eisenhardt (1989) recommends that cases should be added until “theoretical saturation” is reached. In other words, the addition of new case studies should stop when theoretical saturation is reached. In a similar vein, Lincoln and Guba (1985, p. 204) recommend to proceed with sampling selection “to the point of redundancy”. Similarly, Patton (1990) does not provide an exact number or range of cases that could serve as guidelines for researchers, claiming that “there are no rules” for sample size in qualitative research (Patton, 1990, p. 181). Nonetheless, Eisenhardt (1989) recommends studies to be between four and ten cases.



In line with the above , ten cases were included in this study, following the logic of maximum variety (Cook and Campbell, 1979), including firms operating in different countries (U.S., Italy, Germany, etc.) and of different size (ranging from 8 to 86.000 employees), active in diversified sectors (cancer, diabetes, vaccines, neurology, etc) and involved in various value-adding activities (research, development, pre-clinical. commercialization, marketing, etc). This aspect of the case study design facilitated the generality of the findings in a wide spectrum of firms.

### 5.5.2 Data collection

All but two companies accepted to be identified through their real names. The case in which the interviewees refused to disclose the company’s identity is referred to as “Bionium Pharmaceuticals” and “Intracare”. Table 5.3 presents basic information about the case companies.

**Table 5.3: Overview of the case study companies**

| Company’s Name                 | Home country | Employees | Turnover (\$) |
|--------------------------------|--------------|-----------|---------------|
| <b>Dompé</b>                   | Italy        | 700       | 550 mln       |
| <b>Nicox</b>                   | France       | 43        | 6.8 mln       |
| <b>Bionium Pharmaceuticals</b> | Us           | 1300      | 872 mln       |
| <b>Shire Plc</b>               | Ireland      | 5000      | 4,3 bln       |
| <b>Merck</b>                   | Us           | 86000     | 48 bln        |
| <b>Janssen – Cilag</b>         | Germany      | 700       | 537 mln       |
| <b>Genextra</b>                | Italy        | 19        | 499 thousand  |
| <b>Crown bioscience</b>        | Us           | 520       | 210 mln       |
| <b>Intracare</b>               | Us           | 25        | 2.44 mln      |
| <b>Quipu</b>                   | Italy        | 8         | 1.12 mln      |

*Source: author’s elaboration*

The empirical data were collected from 2009 to 2012. The main source of data was collected face-to-face and by telephone interviews with key company decision makers (CEOs, top management representatives, BD vice presidents, BD managers). All of them can be considered as key informants,

because their competence reflected the corporate strategy, as fundamental decision makers. The average interviews' time has been about one hour, with some interviews lasting as long as three hours.

During the interviews it has been utilized a semi-structured interview guide with thirteen open-ended questions. All respondents agreed to talk about particular episodes and experiences related to the company's life and behavior, which increased the validity of the research. The questions covered different topics, such as business development practices, strategic company orientation and decision making processes. Interviewees have authorized recordings of the interviews, which were conducted in English, except for Dompé, Genextra and Quipu, which were conducted in Italian. Data obtained were analyzed in several phases (Yin, 2003) beginning with recordings transcription followed by within-case analysis of each company (Eisenhardt, 1989).

In order to increase the reliability and validity of the study, I triangulated interviews data with additional primary and secondary information such as consulting and financial reports, press releases, trade journals articles, industry reports, process documentation and others. . As suggested by various authors (Eisenhardt, 1989, Miles and Huberman, 1994, Strauss and Corbin, 1998, Yin, 1994), for each case it was developed a brief description , which was then turned into a full description of the whole case (Yin, 1994). Critical event analysis was utilized to describe the way opportunities were identified and managed, along with the consequent examinations on the relationship between specific aspects of BD and BD effectiveness.

### **5.5.3 Case study summaries**

The following paragraphs provide a short review of each case study firm, with a focus on Business Development activities.

Dompé. Dompé is one of Italy's leading biopharmaceutical companies, with a solid history of innovative drugs development mainly regarding high social impact illnesses. The company focuses its

offer on Primary Care in orphan diseases areas. Business Development activities at Dompé respond directly to the R&D department and are carried out by a group of 4 people. The Senior Manager has a degree in organic chemistry and, since 2006, she gradually abandoned lab activities for more managerial roles. Above all, Dompé considers the ability to put together and coordinate a team as the most important skill of a Business Developer. People who are “called” to join the team from other organizational functions, need to deserve high consideration from the BD manager, who must take into account their daily commitments; at the same time, they also must be stimulated to take their responsibility. The BD process starts with systematic opportunity-searching activities supported by different knowledge sources. Beyond that, keeping in mind the CEO’s strategic directions and recommendations . The role of BD manager is the identification of the company most profitable opportunities ,the putting together of a team with the appropriate competencies and t the coordination and the evaluation of the negotiation phases. During the entire BD process, the most important and strategic information is shared with the CEO through regular contacts. In cases where the BD manager supports the pursuit of an opportunity that is in contrast with top management ’s strategic guidelines, she should challenge the management. This is a good practice at Dompé and contributes to increase the renewal and alignment of strategies within market environment. In order to detect knowledge on new business opportunities, the BD manager looks at industry specific databases and reports, goes to conferences and meetings and, sometimes, is helped by specialized consultants. The BD manager also uses her personal business network in order to access more sensitive information on interesting facts and trends. Making the BD manager responsible of her actions and decision is a very important aspect for Dompé, since there is a specific evaluation system for her function, which include two different dimensions: a quantitative one, which varies with the number of opportunities that reach the evaluation phase and the number of closed deals, and a qualitative one, related to the ability to efficiently manage the team.

Nicox. Nicox S.A. is a French pharmaceutical company that was conceived in Italy (Milan) in 1996, by an Italian-American team with strong technical background and prior experience in the pharmaceutical industry. The company was build around its owner's nitric oxide (NO)-donating research platform. Nicox developed naproxcinod, a CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate for the signs and symptoms of osteoarthritis relief, from preclinical to regulatory submission. In line with its strategic re-positioning in the ophthalmic space, Nicox's research platform is now focused on ocular diseases where NO has shown to play an important role.

The BD manager at Nicox is a member of the Board of Management (Executive Vice president), has a PhD in Chemistry and also a very rich experience in various management roles within the company . The BD manager must be able to understand science without necessarily being an expert in the opportunity sector related to a specific therapeutic field; he or she must instead be able to cooperate and coordinate with experts inside the company at the right moment of the opportunity management process, i.e. evaluation and due diligence. At Nicox, the BD function provides the Board of Management, with two important types of information: first, the necessary data to evaluate the market, the competition, and the new emerging trends and second, the quantitative and qualitative data on the probability of success of a new idea, project, venture, in line with the corporate strategy. This information becomes available through a systematic process of market scouting and analysis, which is made effective by the capability of identifying appropriate business opportunities. The evaluation of information, resources and competences within and outside the firm may influence the BD manager in choosing one or another opportunity. In order to transfer the BD-related knowledge from the individual to the firm level, three important procedures are followed: constant relation, direct contact, and information sharing. An efficient way to evaluate the BD manager is to link his pay to the number of deals he closes and to the value of those deals. In this way, the Business Development manager is

motivated to pursue the most profitable opportunities for the firm, that indirectly becomes the most profitable opportunities for himself. Overall, BD at Nicox has a very important and strategic role not only for opportunity identification processes but also for strategy formation. The information that the BD manager gets from the market is in fact precious factors in the definition of the overall strategy.

*Bionium.* Bionium is a biotechnology subsidiary of a Japanese pharmaceutical company. The most important cancer drug produced by the company is approved as a treatment for blood cancer and diaphragm lymphoma. Bionium has more than a dozen other drug candidates in the pipeline, most of them cancer related. At Bionium, the best BD people do not have necessarily a specific knowledge, but have instead general knowledge in the field in which the company operates (e.g. oncology), and other business skills such as in sales management, negotiation, and interpersonal communication. The head of the BD process has the “seeker” function. A typical seeker profile is a researcher with some managerial skills, wanting to become more operative. Seekers scout the market in search of opportunities, and make early evaluations. In addition, they must have the competence to strategically understand what the company needs; in order to do so they need to regularly attend conferences while looking for opportunities that fit company strategic needs. When seekers find particularly interesting opportunities, they bring them to the company, and a committee with BD management is formed. If the opportunity passes this stage, scientific specialists will be increasingly involved, and some specific and detailed scientific meeting may be set up. The following phase is the due diligence, where the opportunity is discussed in depth from all possible points of view. If the opportunity is convincing, the negotiators/transactions team begins to discuss the Term Sheet with the counterpart, where legal and commercial issues (such as the type of payments, amount of royalties, milestones, etc.) are discussed. Since this phase is very complex and delicate ( such as in cases requiring an acquisition, or a big co-development deal) top management is usually involved. If the agreement is signed, BD still has to put efforts in making it work well and manage the relationship through the Alliance management function.

By Bionium experience, occasionally things went wrong after the deal was done, because of biases in communication between companies.

Shire Plc. Shire is a global specialty biopharmaceutical company with its major operations in the US, UK, and Switzerland. The company operates in 29 countries and is organized into three divisions: Specialty Pharmaceuticals division, Human Genetic Therapies (HGT) business, and Shire Regenerative Medicine. Business Development at Shire is headed by a vice president who reports directly to the CEO and has three senior vice presidents reporting to him. Each of the vice-presidents is responsible for one division. In general, one of the most strategic tasks of BD is to constantly monitor new technologies and products in the company's therapeutic areas of current interest and identify new areas for business models expansion. "If developing new drugs is about Research and Development, finding new business opportunities for Shire is about Search and Development" (VP). In order to do so, all people in charge of BD activities at Shire operates an extensive network and generally posses large experience in Business Development acquired in other companies. Usually this means ten years for the new acquisitions and up to more than twenty five years for the most experienced people. BD responsables are also involved in an internal industrial organization called the "Licensing Executive Society" (LES) and interact with other companies BD counterparts at conferences like Pennsylvania Bio, California Bio, the JP Morgan Conference. BD people have to be aligned with company objectives s and to know what the company is going to commercialize , to develop and to develop and/or sell company products. Internal communication practices are the biggest issue, since they must ensure that Business Development and the Commercial and the R&D departments are aligned. Complex communication rules are followed: this is a good way to control the BD outputs, to make sure that what they select and put forward in the BD process is a profitable opportunity for the company itself; not only a way to get larger bonuses at the end of the year. This contributes to explain the managers need of having a scientific and not just a business background. The BD team benefits of direct access to

internal expertise across the full range of functions, from initial scientific review through full commercial evaluation.

Merck&Co. Merck is one of the largest global health care company. Its operations are principally managed on a products basis and consist of four sectors : Pharmaceutical, Animal Health, Consumer Care and Alliances . The BD department at Merck is divided into two main functions: one deals with product licensing , and the other one is responsible for commercial partnerships. In general, BD is on the lookout for new opportunities, wich may include in- and out-licensing, collaborative research, co-development, and co-promotion agreements. BD also formally reviews and responds for every opportunity that might complement company programs or might help to increase the competitiveness of the firm. The partnership process is particularly efficient: for each opportunity the company pursues, BD assigns an experts team to support negotiations, alliance structure and alliance management. One of the first steps involves connections: worldwide scouts are in charge of building relationships and seeking for opportunities by relating with companies, going to conferences, looking on secondary data. After an opportunity is identified, the opportunity needs to be understood more in depth, through an initial non-confidential review of the counterpart by the Review and Licensing Committee and internal face-to-face scientific meetings. If this phase is passed, the BD function starts the due diligence and the term sheet negotiations. Finally - excluding cases of mergers and acquisitions – an alliance management unit is appointed to monitor progress throughout the agreement and ensure good implementation of the collaboration.

Janssen-Cilag GmbH. Janssen-Cilag is a pharmaceutical company based in Germany which focuses on the research, development and manufacture of drugs. The company has expertise in various therapeutic areas and it operates through four divisions according to their applications: 1. Internal Medicine, 2. Central Nervous System, 3. Biotechnology and 4. Virology. The formal BD department at Janssen-Cilag is headed by a BD manager supported by three other people. The BD manager responds

directly to a Board member, namely the head of marketing and sales. In the BD unit it is important to have both scientists and business people, so that they can compensate one another lack of knowledge, although , everyone has in general some experience in both fields . In order to be able to properly carry out the BD function, BD people have also access to other functional experts inside the company. In such a case, the coordination of the team becomes increasingly delicate because more flexibility and respect of other colleagues' priorities are requested. The BD process at Janssen-Cilag starts with a strategic gap analysis: according to the overall strategy that the Board regularly communicates, the BD manager identifies the major strategic gaps to fill and the strategic timetable to be followed. Afterwards, the team proceeds with the screening of existing and emerging business opportunities through internet, open source databases or with the help of consultants, depending on the quantity and type of information needed. This phase produces an opportunities "short list" and, after going through some strategy fixed criteria, BD people contact the most interesting potential partners to evaluate more in depth potential opportunities. If all the requirements are met, deal management phase follows, involving due diligence and negotiations. The alliance function is separated from the formal BD Unit, and it is dedicated to global deals; whereas small alliances/deals alliance management practices are dealt within the BD department.

Genextra. Genextra is a holding firm created in 2004 by a group of Italian entrepreneurs and financial institutions in partnership with leading scientists from the European Institute of Oncology (IEO). Its main goal is to identify innovative researches in life science and to develop new therapies and tools by creating performing business initiatives. Genextra develops its products through four companies which maintain flexibility within their individual organizations, but share with Genextra common strategic guidelines and pivotal resources. For Genextra, BD activities are the heart of the firm, along with R&D. The company has one corporate BD manager, who is responsible for new opportunities identification with regard to three out of four companies of the Holding. Intercept



Pharmaceutical, a US based firm, is the only exception: here the role of BD is still covered by the CEO, mainly because there are many people in the Board who have worked in BD roles. In this case, BD is not a formalized function, but a role implicitly carried out by the entire Board. The BD process initiates researches, including scouting, analysis and evaluation of projects of interest to be acquired within the holding structure. In a second phase, once a project – or part of it - is selected and acquired, the BD manager starts scanning the environment again, to identify new opportunities that help develop the project itself. The final goal is to make it reach a level of maturity such that it can then be licensed-out or sold. The BD manager, who had both business and scientific/technical background, dedicated a lot of his time to attend conferences and industry specific events in different countries, where he could get updated information on the market and maintain/create business contacts. At Genextra BD role is considered of high responsibility, since BD managers operate a first selection of possible strategic guidelines the group may follow. The evaluation of BD deals is based on both quantitative and qualitative criteria. The quality of a deal is reflected by the quality – in terms of market power and share - of the partner. With regard to compensations, BD managers receives bonuses according to the number and the condition of deal closed.

Crown Bioscience. Founded in 2006, Crown Bioscience is a premier drug discovery company providing cutting-edge translational platforms and cost-effective drug discovery solutions for its biotech and pharmaceutical partners in dedicated therapeutic areas: Oncology and Metabolic Disease. The BD function is carried out by four people, each assigned to a particular geographical area (Europe, China, Japan and USA). They are all relatively at senior level and respond to the CSO (Chief Scientific Officer). All of them have both knowledge of science and management. When more specific knowledge support is needed, BD involves colleagues from the R&D or any other particular company function. In the past, the BD and the R&D departments have had some major misunderstanding, mostly because of discontinuous communications and poor alignment on each other goals and priorities. That

is why Crown Bioscience is setting up very specific coordination mechanisms, such as shared online blogs, through which each part keeps track on a regular basis of the most important activities. BD at Crown Bioscience may involve identification of different kind of business opportunities, that may turn into technology licensing deals, collaboration deals, partnerships with local companies to increase the local presence and M&A activities. Before starting the opportunity management process, these growth options are presented to CSO for approval; then the BD proceeds with the evaluation, due diligence, and final negotiation phase. Furthermore, BD goal is to provide to CSO any relevant market info that the CEO and the Board may need for company growth. The evaluation of BD performance is based partly on quantitative evaluation of the deals closed, and partly on measurement of deals maintained over time. This practice relates to whether BD is purely a prospective functionality that looks for opportunities and brings opportunities in, or it is also responsible for the maintenance of relationships and of collaborations. Overall, BD people at Crown Bioscience have a high level of autonomy within each geographical area, and very good communication between each other. When the opportunity entails the acquisition of another company, the Board is fully involved.

*Quiipu*. is a spin-off company of the Italian National Research Council (CNR) and of the University of Pisa. The company's IP is based on patent technology from the Italian National Research Council. Quiipu mission is to provide products and services in the high-tech diagnostic and preventive medicine field. Specifically, the core business includes systems and techniques to assess early markers of cardiovascular risk by image/signal processing. The Company is located in the Research Area of Pisa (Tuscany, Italy) and the team is composed of 4 people, supported by 3 scientific advisors. Quiipu management team is composed of four persons, most of whom have both scientific and business background and experience. In particular, Quiipu CEO/founder has a MSc degree in electronic engineering and a Master Executive Degree in High-Tech Entrepreneurship. The knowledge gained from his previous experiences allowed him to start this new venture, aiming to become global since its

inception. BD is a consolidated set of activities performed since Quipu inception with the aim to actively integrate company products and services in the high-tech diagnostic and preventive medicine markets. At the beginning, BD leader role at Quipu was held by the founder, who concentrated his efforts on finding partners that could support the company's software development and the validation of the methodology through epidemiological studies. In 2011, collaborations with institutions and universities in UK, US and France allowed Quipu to be ready for commercializing its technology. In 2012, a dedicated BD manager was hired and BD became a staff function on the Board. This was because the company started to deal with different and parallel projects and the CEO's time constraints did not allow him to follow all the BD processes. Since then, however, the CEO meets with the BD manager monthly or weekly depending upon the volume of activities. Such alignment meetings are highly functional to both the CEO and the BD manager. The CEO is kept posted with market/environmental information on the evolution of each single opportunity, and the BD manager is updated on the company's strategic outlooks in order to be aware of any firm good opportunity at any precise point in time. Operating full time, the BD manager supports the executive team in three main ways. Firstly, it constantly informs the organization on available partnering opportunities, providing quantitative and qualitative data on the probability of success of the most interesting collaborations (both with customers and R&D partners). This information becomes available through a systematic process of market scouting and analysis, which is made effective by the manager's capability to identify appropriate business opportunities. Secondly, after the opportunity is selected together with the CEO for further analysis, the BD proceeds with the R&D colleagues in discussing further details with potential partners (evaluation phase). Thirdly, BD manager guides the negotiation phase, with the aim of closing the deal at the most favourable conditions for the company. Presently, Quipu BD manager is evaluating partnerships with ultrasound equipments producers, in order to explore new potential markets and product applications. In addition, he is looking for the extension of Quipu's sales network

– which accounts already of distributors in 12 European countries - to the US, through a sales agreement with a local hardware producer.

Intracare. Intracare is a biopharmaceutical company focused on the development and commercialization of new therapeutic products to treat chronic liver diseases, such as primary biliary cirrhosis, utilizing its expertise in bile acid chemistry. Company's product candidates have potential to treat orphan and more prevalent liver diseases for which currently exist limited therapeutic solutions. Founded in 2002 and based in New York, Intracare team counts 25 employees; the management team is composed of five members, all with international experience and technical background. All members of the team have worked within the industry for many years and had leading positions in high tech companies operating worldwide. For Intracare, BD activities are the heart of the firm, along with R&D. BD is responsible, since inception, for research, scouting, analysis and evaluation of projects of interest to be acquired within the holding structure. In a second phase, once a selected project is acquired, the BD starts scanning the environment to identify new opportunities which help developing the project itself, making it reach a level of maturity to be licensed or sold-out. Also in such a case, the BD manager is the person who searches for the ideal business opportunities.

The centrality of these activities is very well expressed by the words of the Managing Director: "...Without a strong BD capability the company business model would have been incomplete". The BD process, clearly defined since the beginning, were initially managed and coordinated by the CEO. He dedicated much of his time to attending conferences and industrial specific events in different countries, where he could get updated information on the market (technologies, trends, competitors, new companies, etc) as well as maintain/create business contacts. Through these systematic activities, the firm has been able to effectively identify new opportunities, such as recent research, development, license and commercialization agreements with a Research Institution in France and a licensing

agreement with a Japanese Pharmaceutical firm. The great amount of deal closed in the past 10 years is also due to the appointment of a dedicated BD manager right after the inception, as CEO support. He has a significant business network derived from previous experiences along with a biotechnology and management background. His main task is to guide the firm in the identification and evaluation of the best global opportunities which may enhance the value of company's resources, ultimately negotiating the best contractual terms to exploit external assets. As an example, Intracare is actively collaborating with different Institutions in the UK, Switzerland, Israel and Austria. In addition, it has entered distribution agreements with companies in Japan and Turkey. Given the high risks and responsibility associated with the selection and evaluation of opportunities, BD manager variable pay and recognitions are quite high; this has a positive impact on the perception of the job and increases the level of perceived personal responsibility. BD function at Intracare is a staff function, in order to grant constant communication and a reasonable alignment on the strategic objectives between the CEO and the BD manager; the horizontal nature of the function facilitates also the interaction with other organizational functions. In fact, in order to evaluate opportunities and negotiate contract terms, BD integrates knowledge from the R&D department as from the legal and IP staff.

#### **5.5.4 Integrity of the case study research**

In dealing with Positivism's criticisms about the lack of methodological rigor and the probability of bias (Patton, 1990; Yin, 1989), case study researchers have matured many different approaches for incrementing the integrity of qualitative research (Riege and Nair, 1996). In order to achieve integrity in the case study research and authenticate the empirical quality of the case study evidence this thesis applies some of the numerous techniques recommended by the literature (Miles and Huberman, 1994; Yin, 2003). Furthermore, during the evaluation of the case study results, data- and between method-triangulation were applied by gathering and comparing insights from multiple respondents (within some of the firms) and using diverse methods (interviews, data from observations and archival data)

(Denzin, 1989). In particular, company documents and records were used either to confirm or to challenge the information collected from interviews and field notes. I established the reliability of the analysis by creating a retrievable case study database (Yin, 1989), and by developing of a case study protocol, which included the use of “table shells” to record data (Miles and Huberman, 1994). These procedures ensured the focus of data collection on Business Development concepts, verifying that the same information was collected for all cases, and completed through proper data analysis.

Internal and external validity were established through a pattern matching logic (Miles and Huberman, 1994; Yin, 1994): pattern models that emerged from single cases were compared to each other (literal and theoretical replication across cases) and also to pattern models emerged from previous literature (i.e. analytical generalization). This process was determinant for the generalizability of the findings. In addition, explanation building allowed interpretation and sequential inclusion of cases in order to establish causal relationships.

Finally, the process of content analysis was discussed with knowledgeable scholars (Yin, 1989). In particular, I requested advice from three academics<sup>19</sup> in order to gain additional insights on the key issues/concepts that had emerged and also to avoid researcher subjectivity concerns.

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<sup>19</sup> During the case-study analysis, valuable advice was provided by Prof. Michael Hopkins, Senior Lecturer at the University of Sussex (SPRU), Prof. Antonella Zucchella and Stefano Denicolai, respectively Professor and Lecturer at the University of Pavia (Department of Economics and Management), who took the time to review the interview transcripts and discuss with the researcher the key themes that had emerged.

## CHAPTER 6

### RESULTS AND DISCUSSION

#### 6.1 Introduction

As seen above, ten case-studies, all of them concerning firms operating in the biotech industry, have been investigated to shed light on specific Business Development features.

As illustrated in Chapter 1, the purpose of this research has been twofolded. Further to provide an updated definition of Business Development, first goal has been to reveal the constitutive dimensions characterizing the BD phenomenon, by drawing from both marketing and entrepreneurship literature. The research on entrepreneurship/marketing interfaces has experienced a great development in the last decade, and, thanks to the outcomes provided by previous literature, BD appears the most apt approach to study the theoretical dimensions that characterize the phenomenon. But this thesis goes beyond that, and aims at studying the managerial and organizational antecedents of a BD capability. Many authors clearly define capabilities as processes that can be found across companies (Eisenhardt and Martin, 2008), and investigate the managerial processes, skills, procedures and values that lead to capability building (Keil, 2004; Teece, 2007; Leonard-Burton 1992). In fact, an analytical and empirical understanding of these aspects is needed to exploit sources of competitive advantages deriving from capabilities (Keil, 2004). Given the importance of capabilities for the success and growth of firms (Chandler, 1992, Barney, 1992; Teece et al., 1994; Lado and Wilson, 1994), this thesis aims at exploring the microfoundations that support the creation of a firm-level BD capability. In order to do so, it has been adopted a dynamic capability approach and considered Dynamic Capability as

comprising three building blocks: 1. the characteristics of people that perform BD functions, 2. the organizational structure, and 3. the best practices and tools related to the BD process (Teece, 2007).

## **6.2 How do the investigated firms define Business Development?**

The present research examines the broader aspect of Business Development. As thoroughly explained in Chapter 2 (BD literature), the concept of BD is still recent in its emergence and evolution and its distinctive character has not yet been well defined. Furthermore, BD does not have a shared language that describes it and its role (Gigliano et al., 2011). Moreover, the few existing contributions that studies on Business Development draw from different literature background, fail to provide a shared definition of the phenomenon. After an in-depth analysis of these contributions, the *fil rouge* that emerges is the association between Business Development and new business opportunities, whose identification seems to be the purpose of BD itself. In fact BD has been defined as “routines and skills that serves to enable growth by identifying opportunities..” (Davis and Sun, 2006), “a set of tasks and processes concerning analytical preparation of potential growth opportunities..” (Sørensen, 2012), “an activity (...) intended to find and develop new revenue opportunities...” (Gigliano et al, 2011).

Consequently, a more holistic and comprehensive examination of the phenomenon of Business Development is necessary (Davis and Sun, 2006; Gigliano et al., 2011). To this end, the early objective of case study research is to clarify BD definition using the lenses of corporate management, namely: what does Business Development actually mean to the individual firm?

The exploratory cross-case study helped to uncover this question. Management of the ten investigated firms was specifically asked to define Business Development within their organization, and to provide illustrative examples of BD activities undertaken at the firm level. Table 6.1 indicates



the terms, themes and ways used by the interviewees to explain “BD” meaning providing examples of what they consider to be the main BD outcomes.

**Table 6.1: Business Development definitions and outcomes**

| COMPANY        | DEFINITION OF BUSINESS DEVELOPMENT   | BUSINESS DEVELOPMENT OUTPUTS (Deals closed) |  |                             |      |
|----------------|--|---|--|-----------------------------|------|
|                |  | Object of the deal                          | Direction of the resource flows (Company VS 3rd party) | Third party involved        | Year |
| <b>Dompe</b>   | For us, BD is a process that aims at strengthen our research pipeline through the capture, analysis and management of new business opportunities.  | Company shares                              | IN   | AAA                         | 2011 |
|                |  | Company shares (acquisition)                | IN   | Anabasis                    | 2011 |
|                |  | Commercialization rights                    | IN   | Dyax Corporation            | 2008 |
|                |  | Manufacturing rights                        | IN   | Protox Therapeutics         | 2007 |
|                |  | Distribution rights                         | IN   | Altarex Medical Corporation | 2005 |
| <b>Nicox</b>   | In our company, BD act as a “scouting function” for new potential clients, new partners and every new potential opportunity that can enhance firm’s growth   | Commercialization rights                    | IN   | RPS                         | 2012 |
|                |  | Marketing rights                            | IN   | Immco Diagnostics           | 2013 |
|                |  | Commercialization rights                    | OUT  | Bausch& Lomb                | 2010 |
|                |  | Development agreement                       | JOINT  | Merck                       | 2010 |
|                |  | Development agreement                       | JOINT  | TOPIGEN                     | 2005 |
| <b>Merck</b>   | BD at Merck actively seeks business opportunities to complement and enhance the company’s original research and product portfolio. In particular, it pursues discovery and development collaborations and look for jointly delivering products with partners.  | Co-development agreement                    | JOINT  | Abide Therapeutics          | 2013 |
|                |  | Development agreement                       | JOINT  | Bristol-Myers Squibb        | 2013 |
|                |  | Development agreement                       | IN   | Cerecor                     | 2013 |
|                |  | Commercialization rights                    | OUT  | Adcock Ingram               | 2011 |
|                |  | Development agreement                       | IN   | Depomed                     | 2009 |
| <b>Bionium</b> | Although the type of opportunities may vary across firms, BD regards the systematic analyses of the market, which allow the company to detect new interesting and profitable opportunity that are evaluated in order to determine their fit with the overall strategic objectives of the firm. Then BD manages the most promising opportunities and look for turning them into valuable deals. | Distribution rights                         | IN   | Atossa Genetics             | 2013 |
|                |  | Promotion rights                            | JOINT  | Janssen                     | 2010 |
|                |  | Research agreement                          | JOINT  | UC San Diego                | 2010 |
|                |  | Distribution rights                         | IN   | Golden helix                | 2010 |
|                |  | Development agreement                       | IN   | Trigen                      | 2007 |
| <b>Crown</b>   | Business Development means identify, evaluate and close any deal that helps the company to grow. This concern the identification of and involvement in licensing deals, collaboration deals, partnerships with local companies that may support your presence in particular countries, M&A activities and so on.   | Research agreement                          | JOINT  | Beijing Purunao Biotech     | 2012 |
|                |  | Research agreement                          | JOINT  | Jiangsu Hengrui Medicine    | 2012 |
|                |  | Research agreement                          | OUT  | Jasco Pharmaceuticals       | 2010 |
|                |  | Research agreement                          | JOINT  | Pfizer                      | 2009 |

| COMPANY        | DEFINITION OF BUSINESS DEVELOPMENT   | BUSINESS DEVELOPMENT OUTPUTS (Deals closed) |  |                             |      |
|----------------|--|---|--|-----------------------------|------|
|                |  | Object of the deal                          | Direction of the resource flows (Company VS 3rd party) | Third party involved        | Year |
| <b>Dompe</b>   | For us, BD is a process that aims at strengthen our research pipeline through the capture, analysis and management of new business opportunities.  | Company shares                              | IN   | AAA                         | 2011 |
|                |  | Company shares (acquisition)                | IN   | Anabasis                    | 2011 |
|                |  | Commercialization rights                    | IN   | Dyax Corporation            | 2008 |
|                |  | Manufacturing rights                        | IN   | Protox Therapeutics         | 2007 |
|                |  | Distribution rights                         | IN   | Altarex Medical Corporation | 2005 |
| <b>Nicox</b>   | In our company, BD act as a "scouting function" for new potential clients, new partners and every new potential opportunity that can enhance firm's growth   | Commercialization rights                    | IN   | RPS                         | 2012 |
|                |  | Marketing rights                            | IN   | Inmco Diagnostics           | 2013 |
|                |  | Commercialization rights                    | OUT  | Bausch& Lomb                | 2010 |
|                |  | Development agreement                       | JOINT  | Merck                       | 2010 |
|                |  | Development agreement                       | JOINT  | TOPIGEN                     | 2005 |
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|                |  | Development agreement                       | JOINT  | Bristol-Myers Squibb        | 2013 |
|                |  | Development agreement                       | IN   | Cerecor                     | 2013 |
|                |  | Commercialization rights                    | OUT  | Adcock Ingram               | 2011 |
|                |  | Development agreement                       | IN   | Depomed                     | 2009 |
| <b>Bionium</b> | Although the type of opportunities may vary across firms, BD regards the systematic analyses of the market, which allow the company to detect new interesting and profitable opportunity that are evaluated in order to determine their fit with the overall strategic objectives of the firm. Then BD manages the most promising opportunities and look for turning them into valuable deals. | Distribution rights                         | IN   | Atossa Genetics             | 2013 |
|                |  | Promotion rights                            | JOINT  | Janssen                     | 2010 |
|                |  | Research agreement                          | JOINT  | UC San Diego                | 2010 |
|                |  | Distribution rights                         | IN   | Golden helix                | 2010 |
|                |  | Development agreement                       | IN   | Trigen                      | 2007 |
| <b>Crown</b>   | Business Development means identify, evaluate and close any deal that helps the company to grow. This concern the identification of and involvement in licensing deals, collaboration deals, partnerships with local companies that may support your presence in particular countries, M&A activities and so on.   | Research agreement                          | JOINT  | Beijing Purunao Biotech     | 2012 |
|                |  | Research agreement                          | JOINT  | Jiangsu Hengrui Medicine    | 2012 |
|                |  | Research agreement                          | OUT  | Jasco Pharmaceuticals       | 2010 |
|                |  | Research agreement                          | JOINT  | Pfizer                      | 2009 |

Source: author's elaboration

The majority of BD related researches take a specific perspectives with regard to BD tasks and scopes, such as commercialization of innovative products/technologies (Gigliano et al, 2010; Davis and Sun, 2006; Bianchi et al., 2009; Murray, 2012) or alliance management (Kale et al., 2006). On the contrary, the firm case studies analyzed clarified that BD focus is not limited to particular types of deals. Instead, its aim is to explore any potentially interesting opportunity and “*decide which business model is the most appropriate to exploit it*” (Shire).

The findings of the cross-case analysis prove that, while Business Development encompasses different types of initiatives (Kind and Zu Knyphausen-Aufseß, 2007), it is essentially a broader concept that relates to the sensing and seizing of opportunities (Teece, 2007). More specifically, BD process aim is to (1) identify external business opportunities (i.e. partners) that may enhance the firm’s resource base, (2) evaluate such opportunities, (3) negotiate the best possible contract terms in order to effectively exploit them and (4) manage the relationship with partners.

According to the interviews, Business Development is an extremely relevant activity as shown by all the case study firms, because BD coordinates and guides the effective management of the firm’s inflow and outflow of products and technologies with external partners. The ultimate aim is to create conditions in order to quickly manage the rapidly changing and risky environment and achieve a competitive advantage in the market.

Given the previous literature contribution and the testimonies from *the ability to proactively identify and capture external business opportunities that integrate and recombine the firm resource base in order to manage continuous environmental changes and expand business into new market spaces*. the case study firms, I suggest a more accurate definition of BD in the biotech industry as *the ability to proactively identify and capture external business opportunities that integrate and recombine the firm resource base in order to manage continuous environmental changes and expand business into new*

*market spaces*. So defined, BD represents an *opportunistic perspective*, with BD managers continually discovering new opportunities and sources of value for the firm. Although mergers and acquisitions are excluded from the Markets for Technology (Arora et al., 2002), Business Development may also be in charge of managing such kind of deals as confirmed by Dompé, Shire, Bionium, Genextra and Merck executives.

### **6.3 Core dimensions of Business Development**

The notion of "opportunity", thus, describes a wide range of phenomena which can initially appear indistinct, but which become shaped and seized throughout the BD process. In particular, as explained in Chapter 2, the notion of BD is likely to lie at the interface between entrepreneurship and marketing.

Previous works (Kind and Zu Knyphausen-Aufseß, 2007; Austin, 2008) suggest that BD ultimately manages in-licensing, joint development and out-licensing deals. In particular, the pursuit of such development alternatives calls for high level of innovation and risk management (Murray, 2012; Austin, 2008), since BD have to identify, among others, resources and competences that will contribute to advance the R&D pipeline and, as such, suffer from uncertainty by definition. They also involve a high market focusing, since the ultimate goal of BD is to create value: directly, monetizing firm's investments in R&D through the commercialization/out-licensing of products and technologies; and indirectly, by finding complementary resources that increase the firm's product development potential (Davis and Sun, 2006; Giglierano et al., 2011).

As suggested in Chapter 2, *this thesis adopts a EM perspective*, considering the Business Development phenomenon as an heterogeneous construct that calls for the integration of marketing and entrepreneurship practices. In line with the approach followed by Morris et al (2002), I explore the BD phenomenon in order to define and explore the constitutive BD dimensions.

By following the approach adopted by Morris et al. (2002) to explain entrepreneurial marketing, my aim is the identification of theoretical dimensions that underlie Business Development in the biotechnology industry, thus providing a compact explanation of the phenomenon.

In order to address this research gap, managers were asked to elaborate on Business Development activities, responsibilities and goals, and to relate BD with the main themes and activities characterizing marketing and entrepreneurship (Miles and Darroch, 2004). Afterwards, interview transcripts were analyzed (as explained in Chapter 5) following the “constant comparative analysis” method (Glaser and Strauss, 1967), constantly comparing interview contents to prior theory and available data, in order to produce valid dimensions of the Business Development construct .

As illustrated in the following sections, BD role within the firm is designed around seven key dimensions.

### **6.3.1 Opportunity focus**

As emerged from case studies and from previous literature (Davis and Sun, 2006; Sørensen, 2012), the main BD activity is to look for external business opportunities that can meet and enhance corporate strategy. So if the strategic goal is to sell or out-license products/technologies to monetarize internal assets, or to move away from a market no more in line with corporate long term objectives, then BD must search for partners that may be interested to adopt their assets (Kind and Zu Knyphausen-Aufseß, 2007). If the goal is in-licensing/acquiring a product technology in order to enrich the pipeline and consolidate/enlarge firm’s presence within a certain market, then BD must search for partners that may possess that asset and wish to out-license it. Finally, if the goal is to bring a product/technology to a further developmental stage, but the firm lacks the willingness (e.g. because of the high risk or the newness of the market) or the necessary resources or the competences to do it alone, BD would look

for a partner disposed to jointly develop the product/technology. The focus on external opportunities allow firms in the biopharmaceutical industry to develop their business without sustaining higher levels of risks and uncertainty that comes with solo internal R&D. Variety of opportunities — e.g a partner in a target market or a company with complementary assets — are sensed by individuals with particular characteristics and not others. *“You must be able to see opportunities outside, in the market. This is not an easy task, since you must have an heterogeneous background in terms of previous knowledge. But also creativity”* (Shire) Creativity is particularly important to expand the opportunity horizon dictated by market boundaries and to explore new alternatives. *“We weren’t thinking about it, but since our BD manager suggested that Big Pharma would have been interested in buying our compound, then we explored that option. We weren’t involved in that particular therapeutic area anymore and, in addition, the economic counter value was extremely interesting”* (Merck).

It may also happen that particularly perceptive individuals may sense opportunities continuously in any environment in which they find themselves (Endsley, 1995). *“Too much creativity lead to dispersion. This is why it is important for BD to maintain alignment with the corporate strategy”* (Bionium). Sensing opportunities is complex; sensing the right opportunities, is even more challenging. Moreover, in the case of BD, *“the focus on opportunity is maintained all along the opportunity “life cycle””* (Dompé). In fact, BD managers must evaluate and discuss the opportunity which, in time, become a more elaborate concept (Koning and Muzyka, 1999).

In line with that, Entrepreneurship literature commonly regards opportunity development as a continuous and proactive process necessary for the development of the business (Ardichvili et al., 2003); it is very important for the firm to evaluate opportunity at each stage of their development, although the evaluation may be informal or even unarticulated (Timmons, Muzyka, Stevenson and Bygrave, 1987). Once an opportunity has been recognized as strategically important for the firm, a

preliminary evaluation activity begins. In the case of high tech industries, such as biopharmaceutical, the first step may involve a feasibility analysis or business plan, that ensure whether the opportunity is in line with the strategic firms objectives and whether the proposed resource combination can, in fact, deliver specified value (Ardichvili et al., 2003). This activity may be very useful also for assessing whether the value deliverable from a specific mix of resources and competences can be actually translated into growth. In addition, a business plan usually implies the existence of a business concept, namely the “form” the opportunity will take form once it will be practically implemented (i.e. joint venture, outsourcing, acquisition, corporate VC, collaboration, licensing agreement, etc).

If this is not the case, the evaluation process can specify the business concept that would be feasible. Once a preliminary business plan for a new collaborative opportunity or for acquiring and restructuring an existing business is completed, some cases require an additional due diligence phase. *“This second and more in-depth evaluation step, usually involves both internal and external counterparts; it is very long and complicated”* (Bionium). This phase is necessary to “scan” the counterpart and assert the integrity of both the opportunity per se, particularly when the partner is not well known, and the potential deal have a particularly important impact on the strategy or on the budget (e.g. acquisition of a company, out-licensing deal with a Big Pharma).

Whether or not an opportunity will pass through this process, highly depends on a number of constraints or limitations such as strategic objectives, risk propensity, financial resources, individual responsibilities, and so on. An “opportunity” that does not successfully pass through the evaluation stage may be revised or even aborted. A careful assessment of resources and markets of both firms and an in depth examination of the counterpart involved in the deal, often lead to useful revisions of business concepts (Ardichvili et al., 2003). This means that an opportunity may start with the idea of



becoming, for example, a R&D contract, while, after a proper internal and external evaluation of key factors, it ends to become a more suitable acquisition.

### **6.3.2 Innovation drive**

Innovation is a key word utilized by all ten investigated companies. In particular, most of them tend to use the term “innovative” when describing the opportunities that are identified and pursued through BD. Essentially, they describe innovation as covering the entire sphere of business activity. For example, BD may detect innovative ideas about a potential market or technology to exploit, may identify an innovative product to buy may find an innovative research project to pursue, or may pinpoint an innovative academic research to finance. This means that BD function is valuable until it increases the innovative activity of the firms. Indeed, the notion of “innovation” has been strongly linked to the concept of entrepreneurship in literature (Drucker, 1985; Lumpkin and Dess, 1996). “We are always looking for opportunities that increase the innovativeness of the firm, either in terms of markets or products” (Janssen Cilag). For example, Quipu is looking for new opportunities in the US, trying to detect suitable companies available to enter into distribution agreements. In this case, Business Development activities will allow Quipu to enlarge its presence in a new and very profitable market. In other cases, product innovation is what drives BD managers to search for partners available to jointly develop a particular compound. While the BD manager at Dompé searches the market for new opportunities, she has innovative ideas, identifying opportunities that allow the company to do things better and differently from the past. *“My job is also to propose and discuss with the CEO innovative business solutions to pursue, given the fresh and updated information I gather everyday out in the market”* (Dompé). During the interviews, all respondents emphasized the importance of BD as a “supplier” of innovative scenarios, contributing to the renewal of corporate strategy and the maintenance of a culture of continuous innovation.

In other words, since promoting a culture of innovation is critical for idea generation and OI, these ideas and opportunities actually form the basis of the firm's innovation culture. A typical observation has been that of Shire: *“Creating opportunities requires a specific kind of innovative mindset, an innovative environment on site that we try to build and sustain.”*

### **6.3.3 Risk attitude**

Literature has identified a risk-taking attitude as an important element of a firm's entrepreneurial orientation (Covin and Slevin, 1991; Lumpkin and Dess, 1996). As defined in Chapter 2, risk-taking refers to the extent to which an organization is willing to undertake significant and risky resource commitments and actions with uncertain outcomes (Miller and Friesen, 1978; Keh et al., 2002). The results of the cross-case research corroborate the relevance of risk-taking within the Business Development function. In particular, Genextra, Dompé, Shire and Bionium acknowledge the importance of promoting an internal “calculated risk-taking culture”. Management in these firms explains how they constantly need to assess the level of risk that they are prepared to take while evaluating business opportunities.

The following interviewees quotes are indicative of such a risk-taking standing:

*“Uncertainty and risk are intrinsic to the industry and BD knows that on 1000 promising molecules, only 5 will arrive at the end and will be commercialized. This means that risk management is one of the key components of the BD job. And BD managers must be good enough to understand if an identified opportunity will lead to a success or a failure.”* (Genextra).

*“In general, every single opportunity that BD evaluate is risky. This is due to the fact that you will never know exactly what happens when molecules and organisms interact, although the interaction has*

*an high probability to be successful. This is why a BD manager must have a scientific background: it wouldn't be possible to evaluate risk otherwise.” (Crown Biosciences).*

*“Risk-taking is a central part of the BD. For us, it is important to evaluate potential customers in order to be sure we can effectively provide our services for an interesting period of time. If you are overloaded with small customers you may lose the chance to get “the big one.” (Nicox).*

From the above quotes , it is evident that Business Development entails risk-taking decisions mostly because of the nature of the biopharmaceutical industry itself. This is probably one of the reasons why BD functions flourished the most in high tech industries (Davis and Sun, 2006), mainly to support management in risk-taking decisions that directly impact on the overall firm's strategy.

#### **6.3.4 Proactive orientation**

During the interviews, management further explained how important entrepreneurial opportunities had emerged within the subsidiary boundaries through a continuous process of systematic and proactive market scouting. Literature has defined such attitude as an internal “proactive posture” (Lumpkin and Dess, 1996). Proactiveness is viewed by management as the winning approach to gather superior market- and industry- specific knowledge. In other words, competitors superior knowledge , potential partners and emerging technological discoveries are considered central in a truly proactive culture. Accordingly, Bartlett and Ghoshal (1998) have asserted the organizational learning relevance in developing internal capability of sensing and rapidly responding to change. This is evident in the following quotes:

*“Knowledge of our pipeline and industry dynamics is extremely useful for Business Development since it allows to be ahead of most companies in their thinking and in their practice implementation.” (Merck).*

Consequently, a proactive posture seems to be important to identify market opportunities prior to competitors. In fact, as sustained by Nordman and Mèlèn (2006), windows of opportunities in high tech environments rapidly open and close, requiring firms to be proactive in their scouting activities. This notion is in line with the logic of “demand bubbles” (Corniani, 2002) which arise from a specific company-driven stimulus able to pool a number of potential stakeholders that are homogeneous in their interest regarding the company’s offering. Once the product or service has been bought, the bubble tends to disappear. In line with that, the completion of second Phase 3 trial of DX-88 - a Dyax Corporation proprietary technology - attracted the attention of a pool of companies that aimed at developing or consolidating their expertise in the area of rare diseases. However, thanks to its proactive search and monitoring, Dompé was the only one to succeed , grating exclusive commercialization rights on angioedema technological development. Other case study firms explained how their willingness to be ahead of the market and industry developments requires an increased alertness to new opportunities, as these arise. Management quotes:

*“It’s extremely important to continuously scan the market because opportunities are not available forever. if you miss one, it can be gone forever.” (Janssen).*

*“We have to be ahead of what’s actually happening, market developments or industry developments; this allows us to proactively look for opportunities.” (Bionium).*

### **6.3.5 Resource leverage**

Markets for Technology enlarge the strategy space: firms can choose to license-in technologies instead of developing them in-house; they can also chose to license-out the technology, instead of (or in addition to) investing in the downstream assets needed to manufacture and commercialize the goods (Arora and Gambardella, 2001). The concept of resource combination reflect the idea that, in a global

competitive environment, with a risky R&D process, firms need to organize their business model in order to do “more” with “less”. Thus, for example, Intracare has been able to concentrate on developing its technology rather than on its application, by relying on licensing and other arrangements to boost returns on its innovative effort. In line with that, BD at Intracare ensured, among others, integrative resources and competences to carry out certain preclinical experiments and tests, gaining royalties from commercial agreements to finance further technological development. The fact that firms value their resources while exploring and capturing new opportunities facilitate the emergence of new ways to use the same resources. For example, Quipu is evaluating partnerships with ultrasound equipments producers, in order to explore new product applications, thus stretching the use of available resources.

BD, in fact, is not only about exploring the outside. BD is directly responsible to find external business opportunities that can optimize and enhance the exploitation of internal assets; at the same time, every single deal that BD closes results in a new combination of the available resources.

BD managers in the case study companies have shown the the capacity to see the interactions between internal and external resources and pursue their combination in order to create a higher value. Leveraging resources is not an automatic and easy task. It is more a creative rather than mechanical activity. This ability to recognize resources that are not fully exploited and see how they could be used in new, unconventional ways requires lot of experience, technical and business skills and entrepreneurial perspective. For example, Bionium have renewed and recombined its tangible and intangible asset base through more than twenty major partnerships since its inception; these include in- and out-licensing, collaborative research, co-development, and co-promotion agreements. Today, their late-stage development superior capability in oncology encompass both small molecule and antibody drugs; here Business Development works systematically to find the most appropriate candidates that

can be explored, leveraging resources and capabilities on a constant base. By leveraging on the company's unique models, molecular profiling, and data analysis capabilities, Crown's BD manager signed a co-development agreement with Jasco Pharmaceuticals, providing the partner company the "boost" they needed for the development of a novel small molecule.

### **6.3.6 Network focus**

Although assessment of customer needs is the cornerstone in market orientation, the word "customers" has been rarely mentioned by managers of the case study firms. The early stage of exploration and exploitation of the biotechnological platform implies that knowledge bases are still heterogeneously dispersed among diverse organizations (Malerba and Orsenigo, 2001; Pisano, 2007) spread all over the world. This obliges firms to continuously enter transactions for the use, diffusion and creation of technologies. This may involve full technology packages patents and other IP know how and patent licensing. It also includes transactions involving knowledge that is not patentable or not patented (Arora and Gambardella, 2001). Such market structure and the complexity of the exchanged technologies explains the importance of maintaining good relationships with counterparts in the long run, since their fundamental contribution is usually required after the deal is signed. For all the case study firms, a partner can be the licensor or the licensee of the firms' innovations or even a co-developer (joint R&D, manufacturing, marketing, sales, etc); in general, all the actors involved in the industry can be firms' potential partners: research laboratories, hospitals, other firms, or health management organizations, depending upon the type and pipeline position of the object of the deal. As sustained by Dompé and Genextra's representatives, the nature of the industry itself is probably the main reason that explains the consolidation of Business Development functions and departments within the majority of firms operating in the field. BD has no mean to exist if the company develops primarily through internal operations. *"In more traditional industries, such as food and automobile, the company*

*doesn't need BD. It needs marketing and sales.*" (Crown); "... *Although it may seem like sales, BD is about partners, NOT one-shot customers. Also in cases when you are "selling" or licensing out your technology to another company, the relationship you enter brings you more than pure economic value*" (Shire). Beyond conventional perspectives on market orientation and customer centrality, Business Development entails long term relationships with partners because the assets they exchange are complex and call for a continuing interaction.

### **6.3.7 Value creation**

In August 2011, Intracare entered into a research, development, license and commercialization agreement, granting a French organization the exclusive license to research, develop and commercialize a novel product used for several treatments in all countries other than the United States and Japan. In return, the licensee granted Intracare an exclusive royalty-free license to research and develop various products used in the treatment of diabetes, obesity, atherosclerosis and reperfusion injury in the United States and Japan. Often Business Development creates value in forms that go beyond cash returns. This explains the difficulties in evaluating BD performance. Every firms use different criteria given the specificity BD goals.

The case study firms associate good Business Development with higher profitability, enhanced revenues and assets growth. In addition, BD value can be categorized as financial or non-financial, intermediate or final, and short or long term.

Crown and Bionium long term value is associated to higher rates of new product, service, and process introduction while for Merck long term means great generation of new and value-enhanced resources. All companies agree on the fact that well managed and effective BD functions reflect more productive external alliances and networks. Short term values may refer to financial resources that flow

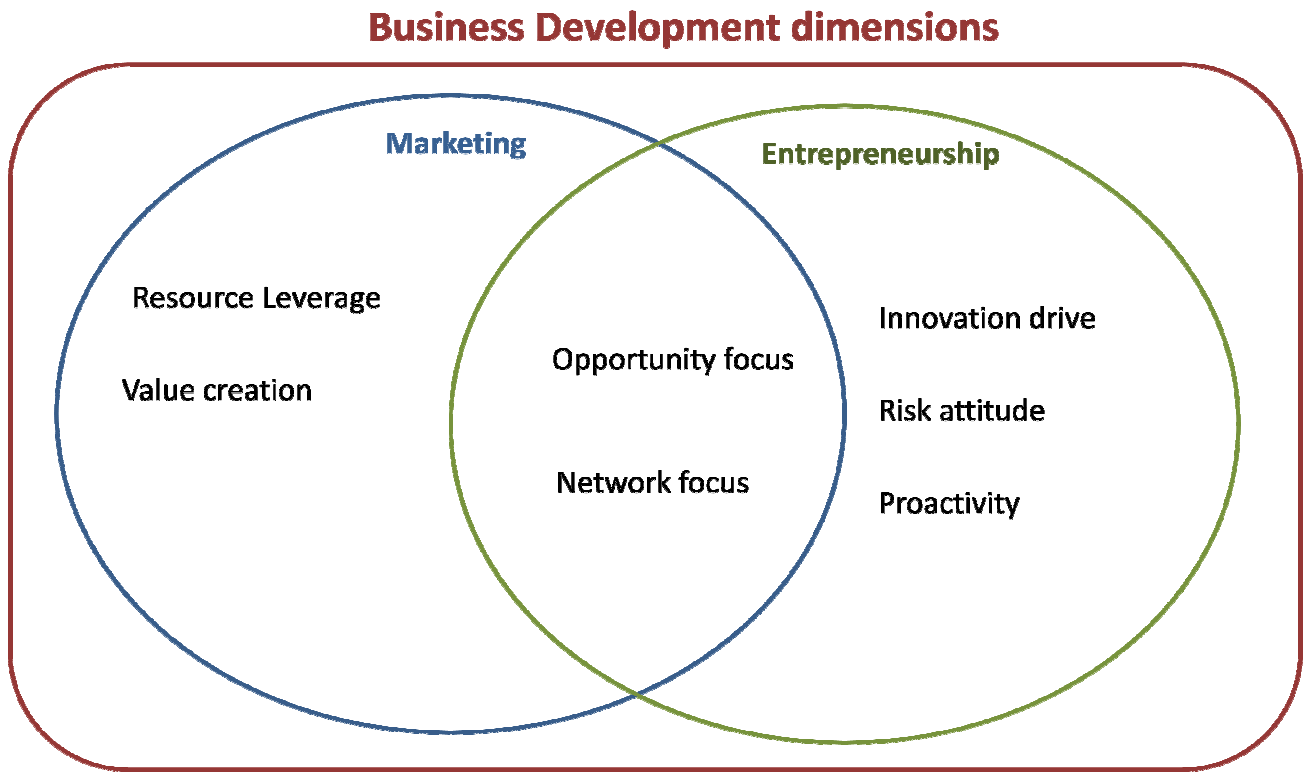
into the company after commercialization or out-licensing agreements (upfront payments), and to the stock market gains following alliances announcements (in line with Kale et al., 2002). Long term financial outcomes include the increasing profits from co-marketing agreements, distribution agreements in new territories, and so on. .

#### **6.4 The interaction among dimensions**

The seven dimensions that emerge from the case studies reflect the hybrid nature of BD as a phenomenon at the interface between entrepreneurship and marketing. In particular, *proactiveness*, *risk management*, *innovation focus*, as explained in Chapter 2 (Section 2.5), derive from the literature on entrepreneurial orientation (Miller and Freisen, 1983; Covin and Slevin, 1994; Morris and Sexton, 1996; Zahra and Garvis, 2000). *Resource leverage* and *value creation*, on the other hand, are among the most emphasized elements in the recent marketing literature (Carson and Gilmore, 2001; Gaddefors and Anderson, 2008; Morris et al., 2002), also in the light of the specific characteristics of the Market for Technology (Arora et al., 2001). Besides being the central focus of entrepreneurship study (Shane and Venkataraman, 2000; Ardichvili et al., 2003), *opportunity focus* is also very important to the market-driven approach to marketing, which implies opportunity seeking to be one of the core distinctive elements (Schindehutte et al., 2008; Hills and Sarin, 2003). Finally, as explained in Chapter 2 (Section 2.4 and Section 2.5.1), the theme of *networking* is central to entrepreneurship (Burt, 1992; Starr and MacMillan, 1990; Borch, 1994; Burt, 1997; Nahapiet and Goshal, 1998; Lin, 2001; Adler and Kwon, 2002; Powell et al., 1996; Singh et al., 1999; Singh, 2000; Aldrich and Wiedenmayer, 1993) and to the recent literature on relationship marketing (Achrol and Kotler, 1999; Gummesson, 2008; Hunt et al., 2006; Morgan and Berton, 2008; Palmatier et al., 2006).



**Figure 6.1: Dimensions of Business Development in Markets for Technology**



*Source: author's elaboration*

It is important to underlie that the theoretical dimensions described as the core of Business Development interact among each other. Risks, for example, may be mitigated through resource leveraging in the form of collaboration, which in turn results in increasing innovation levels stemmed from joined experiments on a compound. In addition, although they are all part of the same recipe, not all of the dimensions need to be operating at the same time for Business Development to occur. For example, while innovation drive is higher in in-licensing and co-development deals, it is less important when the goal is to commercialize a product or out-license IP rights. In essence, according to this approach, *the competitive advantage of biotech firms stems from the ability to identify entrepreneurial*

*opportunities through exploratory marketing activities and capturing them into value creating deals.*

As such, the focus of opportunities lies at the heart of Business Development.

When facing conditions of dynamism, change and complexity, companies are pushed to adopt proactive and changing orientations, as well as pursuing higher levels of innovation. Under these conditions, there is no guarantee that a sustainable competitive advantage can be achieved through traditional, reactive, risk-averse management (Johnston, Lee, Saini, and Grohmann 2003; Slater and Narver 1995). Market instability rises uncertainty and doubts among all the actors operating in the environment, but it also pushes companies to take decisions quicker, opening a greater variety and number of business opportunities. Here, marketing activities are particularly central. In entrepreneurial marketing, for example, marketing efforts become more personalized and unique, with more choices for different clients in different market segments (Deshpande 1999; Sanchez 1999). Business Development, on the other hand, concentrate on gathering information from all third parties that are related to the firms (past and present partners) and to its representatives (personal business network). In the latter case, the systematic assessment of information through networking to identify new business opportunities becomes paramount. Table 6.2 show the main similarities and differences among marketing, entrepreneurial marketing and business development, as resulting from the literature review and the case study analysis.

**Table 6.2: Differences between Marketing, Entrepreneurial marketing and Business Development**

| Conventional Marketing   | Entrepreneurial Marketing (EM)  | Business Development (BD)  |
|--|---|--|
| <ul style="list-style-type: none"> <li>• An essentially reactive stance with respect to the external environment</li> </ul>                      | <ul style="list-style-type: none"> <li>• The firm attempts to influence or redefine aspects of the external environment</li> </ul>  | <ul style="list-style-type: none"> <li>• The firms aim at redefine its resource base in order to proactively shape external environment</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Strives to follow customers</li> </ul>  | <ul style="list-style-type: none"> <li>• Strives to lead customers</li> </ul>   | <ul style="list-style-type: none"> <li>• Strives to lead partners</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Serving existing markets</li> </ul>   | <ul style="list-style-type: none"> <li>• Creating new markets</li> </ul>  | <ul style="list-style-type: none"> <li>• Serving existing markets more and/or better and creating new ones</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Focal point is efficient management of the marketing mix</li> </ul>                                     | <ul style="list-style-type: none"> <li>• Focal point is new value creation for the customer through relationships, alliances, resource management approaches, and the marketing mix</li> </ul>      | <ul style="list-style-type: none"> <li>• Focal point is new value creation for the firm and its partners through relationships, alliances, resource management approaches and the marketing mix</li> </ul> |
| <ul style="list-style-type: none"> <li>• Risk is to be minimized</li> </ul>  | <ul style="list-style-type: none"> <li>• Risk is necessary and EM's job is to manage the firm's risk profile in a calculated fashion</li> </ul>   | <ul style="list-style-type: none"> <li>• Risk is endogenous and BD is responsible for managing it in line with corporate guidelines</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Marketing as an objective, dispassionate science</li> </ul>   | <ul style="list-style-type: none"> <li>• While acknowledging value of science and learning, recognition is given to the roles of passion, zeal, and commitment in successful EM programs</li> </ul> | <ul style="list-style-type: none"> <li>• BD is a high status position that create the conditions for the firm to implement its startegy.</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Reliance on proven formulas and established rules of thumb</li> </ul>                                   | <ul style="list-style-type: none"> <li>• Psychology of challenging commonly shared assumptions</li> </ul>   | <ul style="list-style-type: none"> <li>• Psychology of challenging commonly shared assumptions</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Supports the innovation efforts of other functional areas of the firm, most notably R&amp;D</li> </ul>  | <ul style="list-style-type: none"> <li>• The home of the entrepreneurial process in the organization</li> </ul>   | <ul style="list-style-type: none"> <li>• Marketing and entrepreneurship converge in the BD function</li> </ul>   |
| <ul style="list-style-type: none"> <li>• A functional silo</li> </ul>  | <ul style="list-style-type: none"> <li>• A cross-disciplinary and inter-functional pursuit</li> </ul>   | <ul style="list-style-type: none"> <li>• BD as a cross-disciplinary and inter-functional pursuit</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Promotion and customer communication receive the greatest amount of attention from marketers</li> </ul> | <ul style="list-style-type: none"> <li>• The relative investment or resources in different areas of the marketing mix is context specific</li> </ul>  | <ul style="list-style-type: none"> <li>• Partners communication receive the greatest amount of attention from BD</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Scarcity mentality, zero-sum game perspective on resources</li> </ul>                                   | <ul style="list-style-type: none"> <li>• Opportunity is pursued regardless or resource controlled; philosophy of resource leveraging is paramount</li> </ul>  | <ul style="list-style-type: none"> <li>• Opportunity is pursued regardless or resource controlled; philosophy of resource leveraging is paramount</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Heavy dependency on survey research</li> </ul>  | <ul style="list-style-type: none"> <li>• Skeptical use of conventional research; employment of alternative methods (e.g., lead user research, 'backward' research)</li> </ul>                       | <ul style="list-style-type: none"> <li>• Mixed used of conventional intelligence and networking, with a prevalence of the latter over the former</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Facilitates transactions and control</li> </ul>   | <ul style="list-style-type: none"> <li>• Facilitates speed, change, adaptability, agility</li> </ul>  | <ul style="list-style-type: none"> <li>• Facilitate speed, change and proactivity</li> </ul>   |

*Source: author's elaboration from Morris et al. (2001)*

## 6.5 Business Development Capability

The above analysis makes a step forward Business Development literature by identifying the theoretical dimensions behind the phenomenon. BD represents a different vision of the business itself and its relationship with the marketplace and it constitute an hybrid managerial phenomenon which incorporates both marketing and entrepreneurial aspects particularly useful in a Market for Technology. Moreover, this thesis aims at capturing the microfoundations behind a BD dynamic capability. Testimonies from the 10 case study firms allows to apply the theoretical framework presented in chapter 3 to the BD study.

The framework posits that resources influence competitive advantage: the greater the firm's tangible and intangible assets, the greater are the expected value firms can extract from them. As suggested the BD manages:

*“If Crown tomorrow cuts its BD function, completely, it wouldn't be impacting the company until few months. BD responsibility would in fact be assigned to some other function (probably R&D or the CEO) which should however dedicate part of its time to manage the BD process and related activities.”* (Crown).

*“Without BD, the stock of firm resources at a given time period will allow the firm to maintain a certain degree of product development.”* (Genextra).

The theoretical framework also posits that the influence of resources on performance is mediated by the development of an BD Dynamic Capability.

*“... But without a BD function, the company development would be too slow and, also if BD responsibility would be assigned to some other function part-time, that wouldn't be enough in the long-run.” (Janssen)*

*“If we do not close a constant number of deals, i.e. grasp a constant number of opportunities that inject new and complementary resources into the pipeline, the company would be stuck very soon.” (Shire).*

*“You need time – a lot of time, dedicated time! - to carry out the process properly, going to conferences, maintain your network of existing and potential partners; you need a budget. Otherwise Janssen would never be this competitive.” (Janssen).*

The analysis of the case studies may suggest that firms has developed over time a dynamic capability to successfully recombine and exploit resources. First, the dynamic character of such capability allowed firms to adapt and reconfigure resources and management systems to match the requirements of a changing environment. At the end of the 1990s, changes in the competitive scenario brought Dompé to a significant variation in its corporate strategy, shifting from “primary care” to “specialities” market. At the firm level, this moved the focus from commercialization to R&D in emerging biotechnology medicine, which called for integrative resources and competences that could be synergically integrated with the existing ones. Since then, all technology exchanges (in- and out-licensing, acquisitions, BD) and throughput deals constituted the fuel that allow the company to develop in this new competitive environment. Consistently with the registration of its first product application, Quipu appointed a full time BD manager, who substituted the CEO (previously in charge of BD but only on a part time and ad hoc basis), and consolidated the flow of activities necessary to carry out BD. When Intracare started its activity, the CEO was the responsible for finding new opportunities that could enhance and integrate the few but valuable internal resources; no systematic

process for BD existed. But right after the announcement that their lead compound was able to reverse liver fibrosis, a BD function was formally established. This in order to systematically exploit the potential value of the technology by further advancing its development through complementary external competences.

As hypothesized by Teece (2007), BD capability allows the case study firms to accomplish two fundamental functions:

- (1) To sense BD opportunities when they are still in an early stage.
- (2) To seize the most promising BD opportunities.

According to the testimonies of the case study companies, the collection of valuable market knowledge from external sources, keeping in mind a resource leveraging logic, is central for the BD aim of timely identifying and seizing growth opportunities. From the analysis of internal reports, it emerges that in 2012 around twelve business opportunities were identified and evaluated by Crown's BD manager. Seven of which actually become valuable deals. In general, around 50% of opportunities that have been identified by the case study firms are then seized in contractual agreements. This reveals the importance of effective identification, since more identified opportunities correspond to more deals closed (Merck).

Equally important is the effective selection of best opportunities that will create the highest value. Shire representative also acknowledges the importance of seizing, i.e. the ability to quickly address opportunities by negotiating the best contractual terms to extract the most possible value from the opportunity. Efficient seizing of promising opportunities allowed Dompé to rapidly develop its capabilities in oncology by investing in 2 firms, Filogen and AAA. "Accurately *evaluating*

*opportunities and promptly transform them in exploitable assets is absolutely fundamental to increase the rate of success.” (Dompé).*

In the light of this, we posit the following proposition:

***P1. Dynamic Capability in BD mediates the relationship between resources and competitive advantage. Firms with superior sensing and seizing of opportunities will manage their pipeline better than competitors through integration and recombination of internal and external resources.***

The theoretical framework also posits that specific organizational and managerial mechanisms (microfoundations) underlie the development and the strengthening of Dynamic Capability in BD. From the case study it emerges that superior sensing and seizing of BD opportunities were achieved through key managerial solutions adopted by Chemfirm in the past years. Relevant aspects will be discussed in more details hereinafter.

### **6.5.1 Microfoundations: BD Structure**

BD structure in the case study firms is characterized by a separate dedicated function, that take different names according to the company (e.g. Business Development, Corporate Development, Licensing and External Scientific Affairs); this means having at least one full time person charged with the responsibility of pursuing new business opportunities and transforming them into valuable deals. The structural separation is necessary given the *“time consuming activities that BD implies”* (Genextra). Dompé, Prentos and Crown suggested that a structural separation from other functions allow BD to have a more comprehensive overview of both the internal and external environments. According to Shire, Bionium and Merck, a dedicate BD function represents the interface between the market and the company. Thus, enhance external visibility and contribute to promote firm credibility. This is confirmed by the fact that all the BD representatives in the case study firms have contacted or

have been contacted from other companies' BD managers in order to discuss technology exchange-related interests.

Consistently with Kale et al. (2002), which find that in the context of alliance-making firms with a dedicated alliance function show higher level of alliance capability, we posit the following proposition:

***P2a. A dedicated function responsible for BD, result in superior sensing and seizing of BD opportunities.***

In addition, a dedicated BD function must be put in a position that allow cross functional communication and management. “*BD is an independent staff function that must be able to move freely across the company in order to monitor and coordinate – when necessary – the resources needed for evaluate and close a deal.*” (Intracare). This is in line with a market-driven logic, which calls for the involvement of all company functions in the management and elaboration of market knowledge (Day 2000/2001). That also justify the shared choice not to place the BD function within another particular division. “*Ideally, BD is the kind of activity the CEO should do. But as the company begin to populate its pipeline, such function must be done by a dedicated staff, with similar powers.*” (Genextra). The legitimacy to request part-time resources across divisions and high decisional autonomy to employ resources within its own budget guaranteed rapid seizing, as demonstrated by the high level of deals closed by the case study firms. Moreover, firms representatives agreed on the idea that appointing BD to a staff function that reports directly to the CEO increases the visibility and authority of the role, facilitating the coordination of different, cross-functional resources toward the achievement of common goals.

***P2b. A BD function positioned as a staff function to the CEO, result in superior sensing and seizing of BD opportunities.***



Finally, companies set up particular incentive mechanisms, that help to ensure the bond between what the BD considers to be strategic for the firm and what is effectively the best opportunity for the firm. These mechanisms are usually in both qualitative and quantitative forms, in order to direct the motivation towards the pursuit of firm's objectives (Venkataraman, 1997) and not only personal returns. In order to maintain a high entrepreneurial alertness, BD managers need to be sufficiently rewarded for their ability to manage risk and develop business opportunities. This is usually translated in a higher average pay, which may always rise thanks to a percentage variable pay based on results. Such mechanisms represent key incentives to pursue an excellent personal performance, which automatically corresponds to an excellent performance for the firm, as reported by the majority of the interviewees. At Crown and Merck, for example, the fact that BD people feel that their activities and knowledge greatly influence the overall performance of the firm, constitutes a powerful motivation to work as if the company belonged to them.

***P2c: A BD function driven by incentive mechanism result in superior sensing and seizing of BD opportunities.***

Being in close contact with strategic decision makers such as the CEO or members of the Board, also influences positively the motivation of BD managers, because it becomes an automatic sign of high status. At Shire and Bionium the will of BD managers to maintain such a status becomes one of the strongest motivation to carry out their activities in a very accurate and productive fashion. As shown in the further supporting evidence in Table 6.3 They feel their contribution is extremely important for the decision making process and this encourages them to think entrepreneurial and operate accordingly. Table 5 shows the evidence of factors characterizing the values dimension.

Because BD play an increasingly important role in overall corporate strategy, the person in charge of BD should participate in the strategy-making processes at the highest level of the company. In fact,

all the case study companies appoint a vice president or director of BD at the top management level. This is in line with Kohli and Jaworski (1990, p. 7) which suggest that “the commitment of top managers is an essential prerequisite to a market orientation”

*P2d: BD function tightly integrated at the top management level, result in superior sensing and seizing of BD opportunities.*

**Table 6.3: Supporting evidence regarding BD Structure**

| <b>Company</b>                 | <b>Evidence</b>   |
|--------------------------------|---|
| <i>Dompé</i>                   | <i>BD is a very rich, difficult and sophisticated job, that is respected at all Company's levels.</i>   |
| <i>Nicox</i>                   | <i>BD does not create the strategy, but it does influence it and makes sure that the strategy is a realistic one.</i>   |
| <i>Bionium Pharmaceuticals</i> | <i>BD manager is more similar to the CEO than any other member of the board, because he has the responsibility to bring to the company's attention a potentially interesting opportunity or not. In this sense, he has something in common with an entrepreneur.</i>  |
| <i>Shire Plc</i>               | <i>Business Development is an horizontal function that helps Shire realize its goals by supporting continuous growth and evolution;<br/>We try to stimulate their ability by making them feel their contribution is extremely important for decisions we take about strategy.</i>   |
| <i>Merck</i>                   | <i>BD is not only about finding the best promising molecule; BD is about strategically where the company wants to be in a few years from now. That's why our BD people may be assimilate to some extent to entrepreneurs.</i>   |
| <i>Janssen – Cilag</i>         | <i>BD is a key function for the company because it gets an updated overview of the market, providing valuable and rare information to strategic decision makers.</i>  |
| <i>Genextra</i>                | <i>Without the BD the Company's business model would be incomplete.</i>   |
| <i>Intracare</i>               | <i>Our BD manager is part of the management team and has full responsibility on good and bad deals</i>  |
| <i>Crown bioscience</i>        | <i>We have a great autonomy in the opportunity management process. For example, if I see an opportunity for a collaboration for a co-marketing agreement or a licensing deal, it is basically left entirely after me to evaluate and negotiate the deal in the my territories. That's why I feel my work is extremely valuable for the company's future strategic choices;<br/>Usually, the greater the variable pay of the BD managers, the more effective the contribution of BD to the firm.</i> |
| <i>Quipu</i>                   | <i>Our Business Development manager is a fundamental figure in the organization since he coordinates our efforts whenever a new opportunity is up to be pursued</i>   |

*Source: author's elaboration*

### 6.5.2 Microfoundations: BD Process

According to Davis and Sun (2006), the capability to “enable growth by identifying opportunities and guiding the deployment of resources” is mostly expressed through highly unstructured routines, which may cause a decrease in the effectiveness of the capability itself (Davis and Sun, 2006). On the contrary, our case studies show that firms develop mechanisms or routines that are purposefully designed to manage and control relevant organizational knowledge.

In big companies such as Shire, Merck and Bionium, the BD department may be divided into functions, where BD people have specialized skills, according to the different tasks. Also in this case, a BD manager is always in charge for coordinating the process. In the case of smaller companies, such as Quipu, Genextra, and Intracare, the BD manager puts together a team picking up people with the needed skills from other departments. In the identification phase, *“the “seekers” go out and seek the opportunities. In addition, they make a first “informal” evaluation when they identify opportunities to bring at the company’s attention.”* (Shire). Here BD people must understand strategically what the company needs; they go to conferences and use their network in order to find opportunities that fit those strategic needs. When they find an opportunity, they discuss about it within an internal committee of other functional managers and – in particularly important cases – senior management. In the interviewed big pharma companies these meetings are typically due every month; which reflects the importance of maintaining everybody updated on what is happening outside the company, in order to maintain strategic alignment and providing senior management with updated market information. The following evaluation phase (or “due diligence”) consists in a more in-depth screening of the opportunity and the partner. In pharmaceutical companies, which evaluate many opportunities at a time, this phase can be very long. Here the deal/opportunity is discussed in details with the committee and involve also IP and R&D representatives. The Negotiators/transactions team is the one responsible

for the “commercial” part of the process: the term sheet. People working in it becomes involved around the end of due diligence. Commercial terms usually regard 3 main areas

- upfront payments (immediate payments);
- milestones (payments along the way);
- royalties (payments once the products is on the market).

*“During the negotiation phase, top management is usually more involved because it is a very delicate phase.”* (Merck). If the negotiation phase becomes too long or difficult to conclude, *“it is better to step back and go through additional evaluation”* (Nicox). In fact, since a contract is something defined and that, in many cases, will regulate relationships for long periods of time, it is best for both parts to evaluate all the possible alternatives to end in a win-win situation.

If the agreement is signed, the company still have to put efforts in making it work well. Alliance management, the last phase of the BD process, is quite a new function, that emerged in the last decade, once everybody started recognizing the importance of relationships with the partners. This is something common among the case study companies:

*“Signing the agreement is not enough. You have to manage the relationship.”* (Dompé).

*“If things go wrong after the deal is done, it is usually because of biases in communication between companies.”* (Bionium).

In general, as emerged by the analyses above, companies outlined the central role of an open communication and knowledge exchange from and towards the BD process. As suggested by Janssen BD manager , *“it is very important to facilitate an open communication between BD and other functions. The R&D manager, legal office and IP people must be constantly updated on what we are*

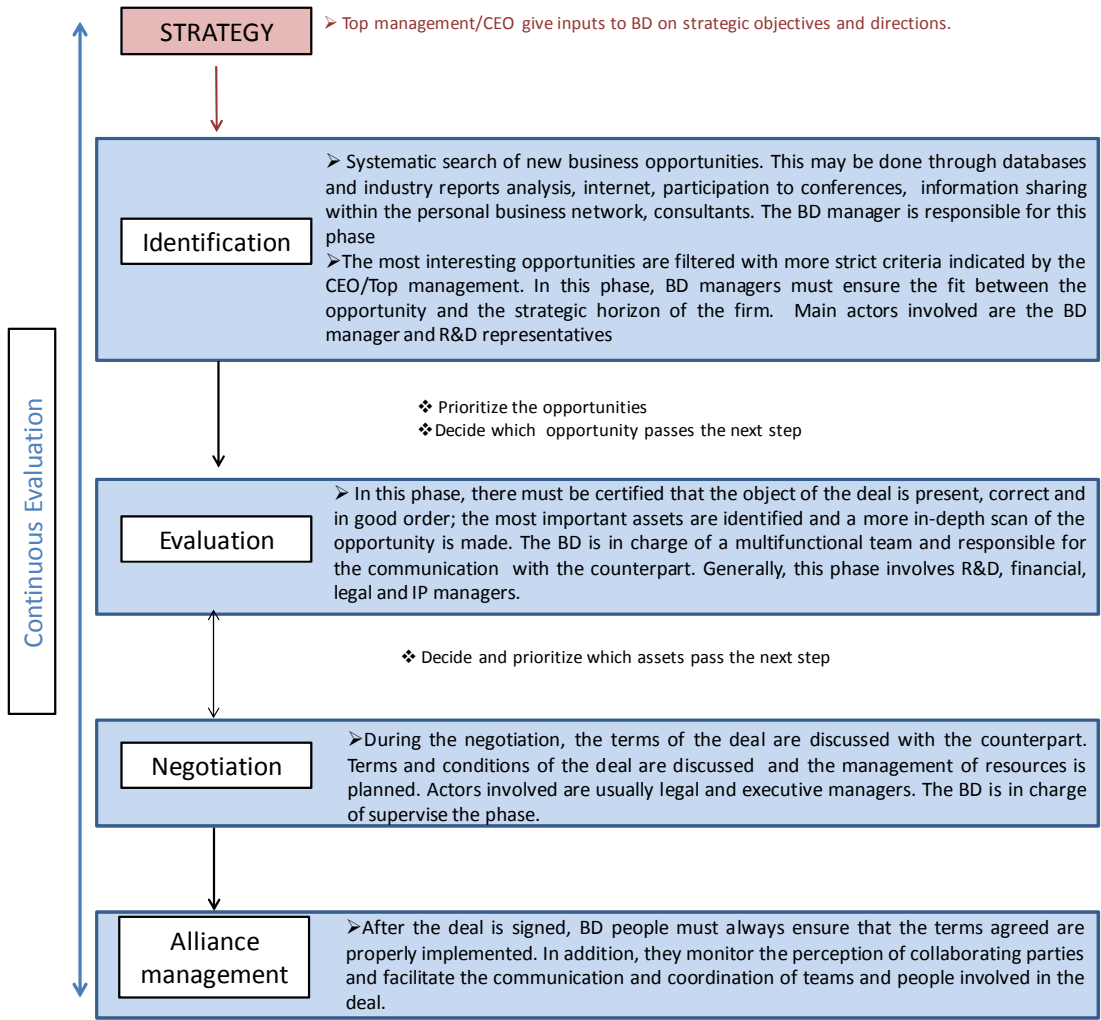
*doing, since their contribution is pivotal in getting the best possible deal. The communication with the top management is particularly critical to ensure alignment between the strategy and the market”.*

During the entire BD process, the most important and strategic information is shared with the CEO through regular contacts. In cases where the BD manager supports the pursuit of an opportunity that is in contrast with top management’s strategic guidelines, he or she should challenge the management. This is a good practice at Dompé and contributes to increase the renewal and alignment of strategy with market environment. As suggested by recent seminal works on capability development (Teece, 2007; Kale and Singh, 2007), implementing processes is fundamental for learning and accumulate skills and best practices by carefully capturing, codifying, sharing, and internalizing relevant know-how. Accordingly, I posit the following propositions:

***P3a: A clearly defined BD process helps companies to accomplish superior sensing and seizing of opportunities.***

***P3b: Open communication with internal stakeholders helps the company to accomplish superior sensing and seizing of opportunities.***

**Figure 6.2: The BD process**



Source: Author's elaboration

Moreover, high proficiency in executing tasks along the BD process helped all the case study firms to identify new opportunities and effectively to organize and efficiently to embrace them (Teece et al., 1997). In order to detect new business opportunities in Dynamic Markets - in which windows of opportunity rapidly open and close (Nordman and Mélen, 2008) - a good BD function should, *in primis*, systematically screening business domains in line with the corporate strategy. “If the search activity would stop until a deal is closed, then we would be in great trouble right now. The “gestation”

*of an opportunity is far from being a rapid process. I mean, Shire is very good at it, so we are efficient compared to others. But still, from the moment you make the first contact with a partner, you won't close a deal before 8-10 months!"* (Shire). *"Opportunities rise and disappeared very quickly, and you must be there in order to catch them at the right moment. This is way BD need to systematically and proactively search, seek, sense what's outside there."* (Crown).

The case studies analyzed suggest that an effective professional network management plays an important role in the scouting phase, compared to intermediaries (Bidault and Fischer, 1994). The challenge here is to create search and communication structures that enhance systematic knowledge exchange without creating information overload. Among the intermediaries, (companies mentioned industry specific databases, participation to conferences and meetings, access to information on the internet, and use of external consultants), the most commonly used are conferences and partnering meetings. Such intermediaries provide a large number of information and are good mechanisms to gather a great amount of data in a small period of time.

*"Thinking about conferences, you usually go there for meeting small biotechs that wish to out-license their products. You can have access to 15-20 different opportunities at one time, and this is good because both parts have interest in telling and listening to each other."* (Merck).

According to Bionium, Shire, and Merck, conferences and partnership events in general are very good in providing an overview of the most *"obvious alternatives to pursue for developing your pipeline."* (Bionium).

*"At the very beginning we hired a BD consultant because we didn't have the competences and the time to do it internally. That was useful, because he was able to identify 2 collaborators that contributed to the development of one of our lead compounds; and also helped us understand the importance of such function."* (Intracare).



However, the most effective procedure for gathering sensible information on opportunities is social networking, particularly powerful and pivotal for reducing the costs of resources necessary for sensing opportunities (Cromie, Birley, & Callaghan, 1994; Portes, 1998; Lin, Ensel, & Vaughn, 1981). Quipu and Genextra's managers point out that the company is particularly proficient in the scouting activities especially because of their professional network management. Merck, Bionium, Nicox and Shire consider their professional network of contacts as the most valuable source of information. In 2011 past knowledge and good business relations enabled Dompé to acquire Anabasis, a biopharmaceutical company dedicated to the development of innovative therapies for the eye. In addition, many companies suggested that a balanced mix of personal network and intermediaries is necessary for two main reasons. First, information you find on databases, conferences and on the internet, is mainly driven by the market, provides a "snapshot" of a particular situation at a certain time", and, most importantly, does not (or it does very partially , in the case of conference) allow probing and brainstorming with the "source"; in addition, conferences themselves are a very good ground for networking. *"At partnership events, nothing happens besides networking."* (Bionium); *"It is difficult to find the "right one" during conferences. Most of the time, they (Big Pharma) listen to you just to explore. However, some of them may call you back after few months to see how is your development going."* (Intracare).

Information through personal network involves interaction, in-depth, constantly updated, and – in many cases - "hot" information about potential opportunities. Thus, personal relationships and intermediaries provide heterogeneous and sensible information, help mitigating information asymmetries (Lichtenthaler, 2013) and facilitate the matching between supply and demand of technologies (Bidault and Fischer, 1994).

*"Our BD managers are very skeptical of most forms of traditional marketing research, like commercial database, internet or consultants. They are useful, but less effective than networking. All*

*the good stuff happens through networking! Both with existing partners or through the personal network of the BD managers or the board.”*

In line with a market driven-approach (Day, 1994) which underlies the importance of systematicity and proactiveness in gathering, interpreting, and using market information, we posit the following proposition:

***P3c. A systematic market scouting activity, relying on an intense use of network over market intermediaries, helps firms accomplish superior sensing of opportunities.***

The case study firms also highlights the importance of partners selection when seizing BD opportunities. In the case of in-licensing and acquisitions, Shire, Genextra, Merck and Bionium demonstrated a very proficient evaluation mechanism. Two clear criteria are taken into account when selecting the most suitable projects: the contribution, in terms of assets, that the “acquiring” companies need to invest in each opportunity and the existence of a strong mutual advantage. Primarily, the partner has to be leader in those assets that the company lacks and that are needed for advancing a compound in the pipeline. Secondly, and more obviously, everybody agreed on that the negotiation phase could only be successful when both part have a strong interest in closing the deal.

*“The choice of the partner makes ninety per cent of BD success”(Shire).*

The fact that these companies are now established players in their own market spaces provides evidence of the effectiveness of the partners’ evaluation mechanisms developed by the case study firms. In the light of their experience, I suggest that:

***P3d. Accurate selection of partners based on the quality of complementary assets and on the existence of a mutual advantage helps firms accomplish superior seizing of opportunities.***

**Table 6.4: Supporting evidence regarding the BD Process**

| Company                        | Evidence  |
|--------------------------------|---|
| <b>Dompé</b>                   | <p><i>In order to detect knowledge on new business opportunities, the BD manager looks at industry specific databases and reports, goes to conferences and meetings and, sometimes, is helped by specialized consultants;</i></p> <p><i>During the entire BD process the most important and strategic information are shared with CEO, through meetings, phone calls, or emails.</i></p>        |
| <b>Nicox</b>                   | <p><i>Sensible information must be constantly transferred to the CEO and other members of the Board, if involved in the particular opportunity.</i></p>   |
| <b>Bionium Pharmaceuticals</b> | <p><i>There are formal channels where companies have to disclose all the information and typically companies these days advertise their pipeline because that accounts a lot for the share price, but as I said there are also informal channels where you get to know other companies.... It has become like speed-dating!</i></p>   |
| <b>Shire Plc</b>               | <p><i>BD constantly monitors new technologies and products in our therapeutic areas of current interest and identifies new areas for expansion of the Shire business model. Monitoring procedures have been improved during the years thanks to the systematic reporting from and to all the members of BD team</i></p>   |
| <b>Merck</b>                   | <p><i>We spend a lot of time in getting to know other scientists and doctors, because all companies have to work with them. Contacts with Star scientists are particularly important for the company; in fact, a doctor may provide some interesting and rare information;</i></p> <p><i>Then you go to big conferences and accumulate other knowledge on what is going on in research.</i></p> |
| <b>Janssen – Cilag</b>         | <p><i>The network is the most important means to share and create new knowledge for the company. It is very important to communicate both formally and informally, with external business contacts and partners and internally.</i></p>   |
| <b>Intracare</b>               | <p><i>If the Business Developer is able to raise the interest and close the deal with a big multinational company like Pfizer or Novartis, he demonstrates his talent and will be proportionally remunerated.</i></p>   |
| <b>Crown bioscience</b>        | <p><i>The most effective way for a BD manager to get new and sensible knowledge on emerging opportunities and market trends is to develop business networks with other Business developers, opinion leaders and star scientists.</i></p>  |

Source: author's elaboration

### **6.5.3 Microfoundation: BD People**

Successful BD is accomplished through the work of individuals.

In the case study firms people in charge of BD are employees or managers who possess multiple skills that enable them to detect the best opportunities emerging from the market. These skills primarily relate to prior knowledge and experience, and personality. According to Venkataraman (1997) and Shane (2000), prior knowledge refers to an individual's distinctive information about a particular subject matter and provides him or her with the capacity to identify certain opportunities.

For all the case study firms, individuals' prior knowledge and experience is considered as a key driver of opportunity value recognition, learning and application to new profitable ends, since the value of new information often calls for integration with prior knowledge in order to be identified (Shane and Venkataraman, 2000). In particular, all the interviewees agreed that it is very important for a BD person to have a background in both business and science.

In line with that, Levinson (1987) sustained that managers with high levels of marketing education and training are usually more alert to market instability and evolution; as well as more creative in resource leveraging, in order to take advantage of changes. Moreover, technical/scientific and product development knowledge is essential for BD managers in order to understand the mechanisms of the industry and the strategic importance of the assets involved in BD deals.

As suggested by the evidence in Table 6.5, this may include graduate degree, PhD, MBA, industry specific courses. Prior knowledge deriving from education smoothes the process of new knowledge accumulation and absorption, and thus enlarges the amount of available opportunities. This is in line with many entrepreneurship research on the topic, that demonstrated that individuals are more likely to detect information and identify opportunities related to their existing knowledge (Von Hippel, 1994; Fiet, 1996; Venkataraman, 1997; Shane, 1999, 2000).

Besides education, prior knowledge may be the outcome of work experience. Theories of human capital (Becker 1964) suggest that, among others, individuals retain two types of knowledge from their employer firm: technological capital, i.e. scientific knowledge; and social capital, i.e. personal contacts and network ties (Yli-Renko, Autio & Sapienza 2001). Accordingly, Shire representative sustain that individuals with experience in different companies tend to have access to a broader set of opportunities and opportunity sources, such as wider business networks. In particular, prior knowledge of markets, such as knowledge about competitors, products, existing and emerging technologies, can improve existing ways of organizing and benefiting from innovation (Shane, 2000). On the same line, the integration between knowledge related to individual's domain (e.g. pharmaceutical, IT, chemicals, BD.) and different knowledge accumulated over the years – usually through interaction - leads to a more effective opportunity detection. The integration of different sources of expertise, often cited as a critical success factor in new product development, is beneficial especially in the context of BD, which is a knowledge intensive activity that requires the execution of heterogeneous tasks, ranging from technical to marketing and legal. Since multidisciplinary skills appear to be distinguishing characteristics of BD people, we posit the following proposition:

***P4a. BD professionals combining technical and market knowledge help firms accomplish superior sensing and seizing of opportunities.***

Besides increasing market and technical knowledge, previous work experience is associated with a greater personal network. Interpersonal relationships in social networks can provide access to information and know-how (Burt, 1997; Nahapiet and Goshal, 1998; Lin, 2001; Adler and Kwon, 2002), and are relevant to entrepreneurial phenomena. In particular, scholarly contribution to the topic focuses on the importance of entrepreneurs' social networks with respect to innovation (Powell et al., 1996), opportunity identification (Singh et al., 1999; Singh, 2000), and opportunity exploitation (Aldrich and Wiedenmayer, 1993).

***P4b. BD professionals with a wide business network help firms accomplish superior sensing of opportunities***

Another very important aspect of the BD manager is related to personality traits. According to Shire, Dompé and Janssen, there are two very important aspects that increase the effectiveness of BD: strategic thinking and entrepreneurial thinking. Strategic thinking is needed to ensure the focus on firm competitiveness, while entrepreneurial thinking is associated with propensity towards innovative solutions, risk taking and proactiveness in capturing opportunities. They are two faces of the same coin, and are related to the ability of sensing the best opportunities (matched to their resources and with the highest potential returns) and then seizing them through strategic business planning. *“The goal of BD is to provide the firms the necessary resources to create competitive advantages. In order to do so, BD manager should be able to tolerate and manage risk in order to deal with high degree of uncertainty typical of BD initiatives; to act proactively by driving innovative solutions; and to shape opportunities around the firm’s strategy.”* (Dompé).

In the same way, Jaworski and Kohli (1993) sustain that company growth in dynamic markets always involves some degrees of risk and, if top management rejects these risks, it is unlikely that the company will be able to effectively respond to environmental changes.

In this sense, a strategic entrepreneurial mindset call for an integration of entrepreneurial (opportunity seeking actions) and strategic (advantage seeking actions) perspectives to design and implement entrepreneurial strategies that create wealth (Sathe, 2003; Dhliwayo and Van Vuuren, 2007).

***P4c: BD managers with a strategic entrepreneurial attitude help firms accomplish superior sensing and seizing of opportunities.***

As mentioned before, BD is a staff function, because it must be able to integrate knowledge and specific skills from different functions, such as R&D, legal and IP department, CEO. Thus, a BD manager must be able to coordinate a team. BD work involves the setting up of a team of complementary people with different skills and objectives. For example, Dompè previous BD manager had a perfect background, though she wasn't able to manage the coordination with other functions nor "negotiate" on their priorities: *"In this work you need diplomacy. You must be able to understand other people's work, balance everyone's efforts and coordinate the whole thing properly in order to get your colleagues to work with you and be committed."* (Dompé). This caused several problems in BD effectiveness, like slowdowns in the opportunities management process on account of sporadic intra-team communications and unclear responsibilities along the process. Today, the tact and skill new BD managers have in dealing with people, leads to increased efficiency of the overall BD process.

***P4d: Coordination capability of the BD manager helps a better seizing of business opportunities***

**Table 6.5: Evidence regarding Microfoundations: People**

| <b>Company</b>                 | <b>Evidence</b>   |
|--------------------------------|---|
| <b>Dompé</b>                   | <p><i>When you are not able to anticipate the needs, to involve and make people in the group feel important, you will lose them and won't be able to effectively carry on the BD process;</i></p> <p><i>Our BD manager has a degree in organic chemistry. She has always worked in pharmaceutical firms' R&amp;D laboratories until 2006. After some experience in managerial roles, she is now ready for a Business Development position.</i></p>  |
| <b>Nicox</b>                   | <p><i>Our BD manager has a Degree in Medical Chemistry and an experience of more than 30 years in the pharmaceutical industry. He covered managerial positions in many multinational companies such as Boehringer Mannheim and Roche, and mid-size international companies such as Recordati and Poli (Licensing).</i></p> <p><i>If the opportunity turns out to be bad, your career will be limited. So the BD manager is evaluated not only on the number of opportunities he identifies, but also on the quality of each deal. On the other side, if the project is good, BD is proportionally rewarded;</i></p> |
| <b>Bionium Pharmaceuticals</b> | <p><i>The BD team must be heterogeneous in order to have different experts for different situations.</i></p>  |
| <b>Shire Plc</b>               | <p><i>Everyone comes with a lot of experience in Business Development from other companies: 10 years for the newest persons up to 25+ years for the people with the most experience. They all possess both science- and market-based knowledge.</i></p>   |
| <b>Merck</b>                   | <p><i>Aside from their knowledge of technologies, markets and industries, deal structuring and partnering, BD managers need to have a great team coordination capability.</i></p>   |
| <b>Janssen – Cilag</b>         | <p><i>In our case, my background is more of a business background, but it is of course also important to have scientists in the group that can compensate the knowledge one doesn't have;</i></p>   |
| <b>Genextra</b>                | <p><i>The capacity of coordinating a team is a very important skill that enable the BD manager to easily manage shared responsibilities.</i></p>  |
| <b>Quipu</b>                   | <p><i>Due to his international profile and professional experiences, our BD manager is familiar with the requirements of this sector and represents the approach pursued by Quipu: to actively integrate its products and services in the high-tech diagnostic and preventive medicine markets</i></p>  |
| <b>Crown bioscience</b>        | <p><i>Science only doesn't grow the business. It may be the sexiest molecule on the planet, but it doesn't automatically lead to growth. That's why BD managers must have also some business knowledge.</i></p>   |

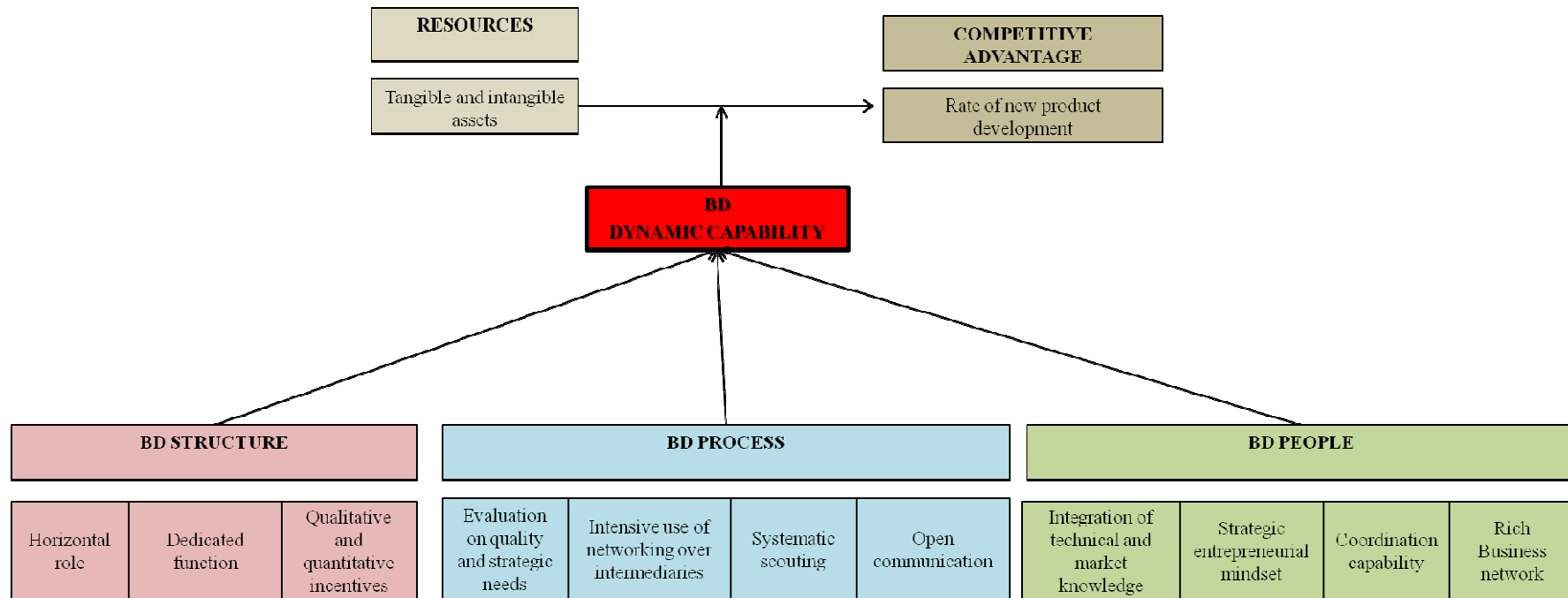
Source: author's elaboration



## **6.6 The refined model**

Figure 6.3 shows the results from the case study analyses with reference to Business Development Dynamic Capability. According to this framework, a BD Dynamic Capability emerges as a multi-factorial phenomenon, which allows firms operating in the biotechnology industry to integrate and recombine internal and external resources. In particular, BD capability do not originates only from highly skilled and open-minded individual within the organization, but stems from the combination of the latter with specific structures, processes and practices at the firm-level. These ensure a constant and controlled knowledge flow of external information within the firm, support the activity and consolidate the role of BD managers and speed the rate at which opportunities are explored and seized.

Figure 6.3: Refined model explaining Business Development capability



Source: author's elaboration

## CHAPTER 7

### CONCLUSIONS AND EMERGING ISSUES

#### 7.1 Result summary

This PhD thesis represent one of the first empirical efforts towards the understanding of Business Development in the biotechnology industry. In particular, the work was designed to answer three critical questions about the nature of Business Development.

- What is Business Development in the biotechnology industry?
- What are the core dimensions characterizing the Business Development phenomenon?
- What are the microfoundations underpinning a Business Development capability?

These questions have now been addressed by drawing from literature in different fields of studies, i.e. marketing, entrepreneurship, technology management and strategic management. Also, in-depth case studies of multiple biotechnology firms operating in Europe and US have been supportive in the process of answering the questions. The aim of this last chapter is to discuss the main findings of the thesis and clear out the deriving theoretical and managerial contributions. Let us start by summarizing the answers to the three research questions, then by discussing the contributions, limitation and future research outlooks opened by this study.

In order to provide a precise and clear definition of Business Development (BD) in the biotechnology industry, I first reviewed some previous literature which analyzes the phenomenon, as well as works concerning related topics concepts. This helped to better understand the function, role,

tasks of BD, and the people involved in it. Different contributions are based on different theoretical backgrounds, thus providing definitions partially driven by specific point of view adopted (i.e. market orientation vs entrepreneurial orientation). The analysis of the above mentioned research gave an understanding of BD as an heterogeneous phenomenon that presents aspects related to both marketing and entrepreneurship literature. While previous studies have adopted either marketing or entrepreneurship as theoretical frame, thus failing to capture the heterogeneous nature of BD, I decided to adopt both concepts jointly, following the path of emerging studies on entrepreneurial/marketing interfaces.

The increasing scholarly attention to the interface between marketing and entrepreneurship has provided several contribution on the role of marketing in innovative entrepreneurial ventures, focusing much less on how entrepreneurship can contribute to the marketing practice. Nonetheless, are becoming increasingly evident the difficulty of classical marketing approaches in addressing the needs of firms operating in highly changing and competitive environments (Morris et al., 2002; Hultman and Hillis, 2011; Miles et al., 2011; Hillis and Hultman, 2003). In Market for Consumers, firms have adopted a number of different approaches such as disruptive marketing, guerrilla marketing, expeditionary marketing and radical marketing that scholars have recently attempted to integrate under the unifying framework of “entrepreneurial marketing (Morris et al., 2002). This thesis adopt a similar point of view to explore the set of activities that practitioners calls “Business Development” to capture an entrepreneurial way to carry out marketing activities in Markets for Technology.

A qualitative research approach made it possible to explore the nature of Business Development, uncovering different fundamental aspects necessary to enrich the understanding of this business practice. In order to fill this research gap, managers of 10 small and large biotech firms operating in

Europe and UE were asked to provide a definition of BD and to elaborate on the pivotal elements behind the phenomenon.

According to their testimonies, BD can be conceptualized as the *ability to proactively identify and capture new external business opportunities which integrate and recombine the resource base of the firm in order to manage continuous environmental changes and expand business into new market spaces*. Such definition highlights the opportunistic nature of Business Development as seen from the perspective of practitioners in the field.

In particular, in order to profit from investments in innovation, i.e. commercialize (sell/out-license) products/technologies resulting from internal R&D, BD must focus on partners' needs to identify high potential sales leads and to plan the marketing strategy accordingly. On the other hand, despite environmental dynamism, BD must constantly ensure the company with fresh complementary resources (in-licensing of innovative compounds to exploit; partners with integrative capability to jointly develop an innovative technology, etc) that enhance the firm's competitive advantage. This well reflects the seven theoretical dimensions that the managers' interviews highlighted as underpinning the phenomenon in Markets for Technology; i.e. resource leveraging, opportunity focus, partner intensity, innovation drive, risk attitude, proactive orientation and value creation.

In examining the notion of Business Development, the present study drew on relevant recommendations either from entrepreneurship literature (Amabile, 1990; Shane, 2000; Fiet, 2002; Shepherd and DeTienne, 2005) or from marketing literature (Kohli and Jaworsky, 1990; Narver and Slater, 1990; Morris et al., 2002), to investigate the managerial and organizational foundations that underlie the ability to identify and capture business opportunities in order to sustain competitive advantages.

I addressed such research question by adopting a Dynamic Capability perspective (Eisenhardt and Martin, 2000), which has been successfully applied to interpret phenomena similar to BD, such as absorptive capacity and new product development. In chapter 3, using research into Dynamic Capabilities and literature about BD, a theoretical framework was developed to illustrates the microfoundations of BD dynamic capability, i.e. the managerial and organizational variables from which the ability to identify and capture new external business opportunities originates.

In particular, the case studies show in a real context how Dynamic Capability in BD is able to integrate and recombine firm resource base and ensure sustainable competitive advantages, by implementing specific actions regarding BD structural organization, BD process practices and BD personnel. The analysis of the case studies helped to develop a variety of related research propositions, as summarized in Table 7.1.

**Table 7.1: Research propositions summary**

|   |
|---|
| <i>P1. Dynamic Capability in BD mediates the relationship between resources and competitive advantage. Firms with superior sensing and seizing of opportunities will manage their pipeline faster and better than competitors through integration and recombination of internal and external resources.</i> |
| <i>P2a. A dedicated function responsible for BD, result in superior sensing and seizing of BD opportunities.</i>  |
| <i>P2b. A BD function positioned as a staff function to the CEO, result in superior sensing and seizing of BD opportunities.</i>  |
| <i>P2c: A BD function driven by incentive mechanism result in superior sensing and seizing of BD opportunities.</i>   |
| <i>P2d: BD function tightly integrated at the top management level, result in superior sensing and seizing of BD opportunities.</i>   |
| <i>P3a: A clearly defined BD process helps companies to accomplish superior sensing and seizing of opportunities.</i>   |
| <i>P3b: Open communication with internal stakeholders helps the company to accomplish superior sensing and seizing of opportunities.</i>  |
| <i>P3c. A systematic market scouting activity, relying on an intense use of network over market intermediaries, helps firms accomplish superior sensing of opportunities</i>  |
| <i>P3d. Accurate selection of partners based on the quality of complementary assets and on the existence of a mutual advantage helps firms accomplish superior seizing of opportunities.</i>  |
| <i>P4a. BD professionals combining technical and market knowledge help firms accomplish superior sensing and seizing of opportunities.</i>  |
| <i>P4b. BD professionals with a wide business network help firms accomplish superior sensing of opportunities.</i>  |
| <i>P4c: BD managers with a strategic entrepreneurial attitude help firms accomplish superior sensing and seizing of opportunities.</i>  |
| <i>P4d: Coordination capability of the BD manager helps a better seizing of business opportunities.</i>   |

*Source: author's elaboration*

## **7.2 Theoretical implication**

This work may provide support and inspiration to scholars in entrepreneurship and marketing management. It suggests in fact new interpretative frameworks that shed light on the nature of Business Development, also deeply analyzing the heterogeneous emerging phenomenon that lies at the interface between marketing and entrepreneurship.

In particular, the theoretical foundation underlying BD highlights the need for marketing practices, which engage in an ongoing process concerning identification of entrepreneurial opportunities, thus leading to changes inside and outside the organization, in line with a Dynamic Capability overview of the firm. In fact, while marketing has always been viewed as responsible for promoting and selling firm's products, Business Development stressed the need of an essential opportunity centered function, guided by networking activities different from the classical market intelligence. This is in line with Bonoma (1986), who predicted that marketing will increasingly be seen as a boundary function, responsible for interacting with key potential elements of the market environment on a regular, "proactive", base. He sustained that, as much as those elements become more complex and dynamic, boundary functions should become more flexible and opportunity driven. Since marketing is historically the custodian of customers, competitors and products related knowledge, it is consequent for this function to embrace entrepreneurial processes, translating its observations into the redesign of corporate resource base and product/market mix (Murray, 1981).

In fact, many research has confirmed the importance of opportunity identification as an emerging study theme within the field of marketing (Morris et al., 2002; Morrish, 2011; Morris et al., 2011; Gonzales-Benito et al., 2007; Miles et al., 2011). In particular, Gonzales-Benito et al. (2007, p. 501) recently posited that "Market orientation refers to the persistent search for market opportunities".

Accordingly, there is a recent growing evidence showing the need for the use of more innovative and opportunity-driven approaches to marketing (Levinson, 1993; Clancy and Kreig, 2000; Rosen, 2000); such approaches, like guerrilla marketing, disruptive marketing or innovative marketing has been primarily observed in Markets for Consumers, and studied in the literature under the integrative name of Entrepreneurial Marketing (EM). However, even in analyzing entrepreneurial technology firms operating in high tech industries (Jones et al., 2013), previous studies on EM focused only on



consumer markets, where firms actions are driven by the willingness to satisfy final consumers needs (Gaddefors and Anderson, 2008; Hills and Hultman, 2006; Jones and Rowley, 2011; Jones et al., 2013). Conversely, the particular characteristics of Markets for Technology call for a different type of approach, i.e. Business Development, which is driven by innovation, centered on opportunities and focused on partners.

In particular, interviewees in the empirical studies carried out, rarely talked about “customers”, but mainly about “partners”; which - in line with an inductive approach - have encouraged the integration of a variety of new elements in the domain of market orientation: co-developer, buyers, sellers, hospitals, research institutes, investors, etc. So, compared to EM, BD goes one step further and shifts the focus from customers to any third-party which may represent a valuable ally for pipeline renovation. Given that, the query is now how far is possible to extend marketing and market related orientation boundaries. In line with Renko (2008), this qualitative investigation shows that firms in Markets for Technology do show signs of market-oriented behaviors: they look for market information, thus sharing it internally and leveraging the acquired knowledge to capture opportunities. However, the way firms carry out such activities is quite different from market-oriented behaviors reported in previous researches. For example, proactive marketing intelligence is often channeled within a firm as a consequence of technological collaboration; this is because such particular collaboration becomes part of the firm’ network, leveraged by BD managers during their opportunity search activities. Firms also acquire information about their customers, as potential licensors, in scientific conventions like conferences, partnering events, or through research discoveries reported in scientific journals. These particular source of market knowledge and information have never been considered as sources of market-related knowledge in the traditional marketing literature. This brings us back to the interface between entrepreneurship and marketing.

If we accept the following statements, as suggested by our case study interviewees: as

*“Business development managers of our firm periodically participate to conferences and partnerships events.”* (Dompé), or

*“We collaborate with a variety of technology partners with whom we build a relationship also in order to learn about future market trends and competition.”* (Bionium),

then we widen the sphere from market oriented paradigms to entrepreneurship and entrepreneurial orientation. In fact the case study results confirm that Business Development managers, similarly to entrepreneurs (Read et al., 2009), are skeptical of most forms of traditional marketing research, (database, internet, consultants) and instead tend to prefer strategies based on networking and co-creation with partners when attempting to identify innovative products or other business opportunities. The implication is that *firms are not constrained by the resources they currently control* or have at their disposal. As we have seen in chapter seven, firms are able to leverage resources in a number of different ways; for example, technical resources can be out-licensed in order to get financial resources to fund new products development or to invest in marketing rights for the commercialization of a particular technology; in addition, technical resources such as the competence to develop a certain type of product can be leveraged by in-licensing new compounds which need to be further developed; financial resources can be leveraged to buy a new company and so on.

On the other hand, this study has furthermore proved the importance of BD to *enhance entrepreneurial activities at the firm level*, suggesting that companies should focus on exploring risky and innovative opportunities, being able, at the same time, of leveraging their resources in order to capture value from those opportunities, mainly through specific managerial and organizational mechanisms. Thus, not relying only on the talent of specific individuals.

While the topic of Business Development merits further research attention, previous literature has acknowledged that BD essentially “enable growth by identifying opportunities” (Davis and Sun, 2006:146). Literature on entrepreneurship agrees on the fact that the notion of Opportunity Identification (OI) constitutes the heart of entrepreneurial activity (Shane and Venkataraman, 2000). Regardless of its criticality, the study of Opportunity Identification is still at its early stage. In fact, the majority of research contributions on the topic tend to adopt an individual-level viewpoint, rather than considering OI as a firm-level phenomenon.

Thus, since identification of new external opportunities is a fundamental aspect of Business Development, the present study contributes to the understanding of diverse managerial organizational factors that influence the effectiveness of OI. This is in line with the call from entrepreneurship scholars to explore more holistic and integrative framework for the study of OI processes within firms (Liouka, 2006), particularly within the context of Market for Technology.

Moreover, a framework which explains BD microfoundations might be able to clarify different levels of competitive advantage, thus representing a promising base for future empirical studies. In line with Covin and Slevin (1989), microfoundations enrich the micro-domain of entrepreneurship studies by providing valuable advices on how entrepreneurs discover, assess and exploit opportunities.

In addition, it demonstrate that dynamic capability approach offers a good perspective to explore BD. In fact, while the focus on serving current customers, typical of marketing, is a necessary condition for creating a competitive advantage, marketing by itself will not allow the firm to sustain or renew competitive advantages in high-velocity, dynamic markets. By contrast, a Business Development capability implies that firms proactively explore new business opportunities by identifying external

partners that can contribute to the recombination and integration of resources to create and serve new product-market spaces.

### **7.3 Managerial contribution**

The managerial advices which derive from the present research apply to both small and large firms operating in the biotechnology industry, but can also be extended to firms competing in other Markets for Technology. Essentially, the study shows that in order to maintain a competitive advantage, firms operating in Markets for Technology must integrate marketing and entrepreneurial practices under a unique business function, i.e. Business Development. In their efforts towards growth, it is not enough for firms operating in Markets for Technology to commercialize their products and reinvesting the deriving financial resources in internal development. If so, they would only need marketing and/or sales functions to find the best partners willing to acquire the company's product.

On the other hand, firm-level entrepreneurship, i.e. proactive search of innovative and risky opportunities, is not enough to ensure performance. If so, firms would lack the market prospective - i.e. the sensible information from customers, partners, sellers, and any third party involved in the environment in which the venture operates - which allows to evaluate opportunity feasibility and potential values , even in the light of tangible and intangible resources possessed.

In order to merge this two perspectives, firms need to develop a Business Development capability.

The experience of the case study firms as interpreted through the theoretical framework proposed in Chapter 6 (Section 6.6), offers stimulating insights on how to organize and manage Business Development in order to achieve a sustainable competitive advantage.

*Firstly*, companies should identify one or more managers:

- who possess both business and scientific background
- with a rich business network to be leveraged to systematically identify new business opportunities ;
- with a strategic entrepreneurial attitude;
- with the ability to coordinate teams of heterogeneous resources.

Although these personal-specific factors may contribute to identify opportunities, additional firm-level practices are needed to develop a BD capability and capture the value of such opportunities.

A *second* advice to firms who want capture, integrate, and expand Business Development know-how, as indicated by many researches (Kaleet al.,2002), is to create a separate, dedicated organizational unit (or at least appoint one dedicated person) charged with the responsibility to retain prior BD experience at the firm-level. In fact, given the proactive nature of the searching process, Business Development activity is very time consuming , and producing great amount of information.

In addition, BD managers must be felt entrusted and listened in the key strategic decision processes of the company, because the information provided is uniquely updated, sensitive, and useful for strategy formation. For these reasons, companies should structure BD as a staff function to the CEO, or directly appoint a member of the board with BD responsibilities.

*Thirdly*, the BD process must be clearly defined in all its diverse phases. A systematic scanning process is particularly central to detect unstable windows of opportunities and evaluate the external environment. In a dynamic and science based industry like biotechnology, investments in the development of market knowledge base are often forgotten (Costa et al., 2004). This is why many

small biotech firms have a poor commercial success. In order to overcome this shortcoming , it is important to systematically gather information from the market, through the use of intermediaries (consultants, database, etc) and, primarily, by utilizing business networks and through personal contacts of BD managers and other members of the organization, along with various collaborators and partners. In addition, BD managers must keep frequent contacts with internal personnel (top mgmt and functional mgmt) in order to ensure the alignment between strategy, opportunities, and their feasibility.

The framework presented in this PhD thesis, and particularly the rich and heterogeneously empirical basic matters it discusses, provide managers in biotech industry with a wide set of insights deriving from an open approach toward innovation and Business Development in general.

All these points could profitably be taken into account by firms willing to set up their own BD units or who need to make changes in poorly performing situations. . Such indications should be considered as general advices or starting points to be evaluated according to company needs and resources , rather than best practices or “how-to” plans for success.

#### **7.4 Limitations and future research**

The study has a number of limitations . The outcomes and their interpretation are based on qualitative case studies conducted in Europe and in the US, following the principle of analytical, not statistical, generalization. Scholars abiding to positivist and post-positivist philosophy of research would consider this as a limitation. For this reason, it is worth to assess the validity of the research results by conducting a more extensive quantitative study in order to test the suggested propositions.

The thesis represents the first exploratory phase of a larger research project, which aims exactly at exploring the outcomes of Business Development in order to identify some common and effective

performance measurements. How do firms measure BD contribution? Should it be valued only by the number of deals closed, or there is something more? In addition, it is clear that different BD outcomes (i.e. in-license, out-license, co-development, acquisition, etc) have different impacts on competitive advantage (performance, rate of new product development, rate of market share, etc). Progress in these areas will help to consolidate Business Development as a business practice per se.

Future researches should aim at exploring more in depth relationships between Business Development and competitive advantage throughout empirical studies on a large scale. To do so, a central point should be to track how firms develop Business Development capability over time; in line with Teece et al. (1997), the most suitable approach could be integrating the “path” dimension of dynamic capability to the proposed framework. This would open some interesting research avenues on the origin of Dynamic Capability understanding how they develop and evolve over time. The learning processes needed to consolidate DC, would be the perfect objectives of longitudinal studies, aiming at the provision of sensible, rich and precious information that other type of research approaches rarely obtain.

In addition, more exploratory researches need to be done in order to consolidate Business Development construct. For instance, deeper insights on the relationship that bonds BD core dimensions would be useful to clarify potential conflicts among them, along with the formalization of specific hypothesis regarding the overall construct. Lastly, as suggested by Morris et al (2002), it would be interesting to explore the existence of different levels of BD within firms (e.g. BD as a tactic, BD as a strategy, BD as a culture).

As a final analysis, Business Development holds much potential in harmonizing the interactions between marketing and entrepreneurial logics, and mainly , in making it a driving force towards the achievement of a sustainable competitive advantage.



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