Dynamics of biotechnology entrepreneurship in South Africa and Brazil

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ABSTRACT

Biotechnology entrepreneurship is a relatively new and distinct field of entrepreneurship. Most current empirical research is conducted in the developed economies and cannot be directly extrapolated to the developing economies. The paucity of empirical research and the lack of a conceptual framework for biotechnology entrepreneurship constitute gaps that this research addressed through the development of a proposed theoretical framework of biotechnology entrepreneurship based on empirical research conducted within the context of the developing economies of South Africa and Brazil.

The current methodological approaches to research in biotechnology entrepreneurship predominantly make use of a nomothetic philosophical approach and employs quantitative methods. Current research is also often based on surveys conducted within one developing economy context. Consequently, few studies in biotechnology entrepreneurship use the qualitative multiple case study approach.
This methodological gap is addressed in this research through the use of qualitative multiple case studies, in the idiographic philosophical tradition, in two developing economies; South Africa and Brazil. The data collection process included in-depth interviews, documents review and observations, which improved the quality of the research through data triangulation.

Ten themes were identified, which formed the basis for developing the proposed theoretical framework. In addition, seven factors that influence the process of biotechnology entrepreneurship in South Africa and Brazil were identified as regulation; funding; infrastructure; skills; entrepreneurial and commercialisation capabilities; market for biotechnology products; and social development.

This research shows that the individual-opportunity nexus of entrepreneurship does not entirely hold for biotechnology entrepreneurship in South Africa and Brazil. Instead, there is a nexus of research and development; and a government-incentivised environment that is conducive for biotechnology entrepreneurship.

The policy implications of these dynamics in South Africa and Brazil; as well as implications for the other stakeholders in the biotechnology industry are articulated as being linked to the control of the factors that influence biotechnology entrepreneurship by the various stakeholders. Hence, the implications for government are predominantly linked to regulation and infrastructure; and the implications for the other stakeholders are predominantly linked to funding and skills.

Keywords: Biotechnology entrepreneurship, entrepreneurship, biotechnology, triple helix, university, industry, government, South Africa, Brazil, qualitative analysis

DECLARATION

I, ______________________________________, declare that this research report is my own work except as indicated in the references and acknowledgements. It is submitted in fulfilment of the requirements for the degree of Doctor of Philosophy in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other university.

Manessah Obinali Alagbaoso

Signed at Johannesburg, on the 6th day of June 2014

DEDICATION

To all those who believe in the unlimited capacity of humans to achieve

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PART I: FOUNDATION FOR THE RESEARCH

Chapter 1: Introduction

The introduction of the first biotechnology drug, recombinant insulin, in 1982 marked the turning point in the commercial viability of biotechnology innovation, and its potential to address some of the major global problems of healthcare, food security, energy sufficiency, renewable resources and environmental sustainability (Ahn and Meeks, 2007; Ahn, Meeks, Bednarek, Ross and Dalziel, 2010a; Ahn, Meeks, Davenport and Bednarek, 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn, Hajela and Akbar, 2012; Dunham, Ahn and York, 2012). Within the context of entrepreneurship, biotechnology entrepreneurship is relatively new (Meyers, 2012), research-driven and requires the collaboration of human talent, capital and institutions to achieve economic and social development, job creation, poverty alleviation, skills development and technology transfer. These benefits have captured the interest of the developed and developing economies in programmes and activities aimed at promoting biotechnology entrepreneurship, in order to capitalise on what has been termed the “biocentury” (Battelle/Biotechnology Industry Organisation, 2010).

However, the biotechnology industry is currently dominated by the developed economies, which are innovation-driven (Kelley, Singer and Herrington, 2012). Consequently, most of the benefits outlined above also accrue to the developed economies. The efforts of the developing economies, which are either factor or efficiency-driven (Kelley et al., 2012), to develop the biotechnology industry are impeded by the lack of entrepreneurial conditions (Herrington, Kew and Kew, 2008; Bosma and Levie, 2010; Herrington, Kew and Kew, 2010; Kelley et al., 2012) and the paucity of critical mass of empirical research aimed at understanding the industry in the context of developing economies. Ironically, the global problems of healthcare, food security, renewable resources and environmental sustainability are more pertinent in the developing than the developed economies. In addition, the developing economies still grapple with high levels of unemployment, social inequalities, low levels of entrepreneurship and entrepreneurial culture, acute poverty and skills shortages (Kelley et al., 2012).

There is an abundance of empirical research on biotechnology entrepreneurship by several scholars (Dibner, 1986; Bud, 1991; Gittelman, 1999; Kettler and Casper, 2001; Nilsson, 2001; Kivinen and Varelius, 2003; Müller, Fujiwara and Herstatt, 2004; Ahn and Meeks, 2007; Ahn et al., 2010a; Ahn et al., 2010b; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012) and organisations (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010; Ernst & Young, 2010b; Organisation for Economic Cooperation and Development, 2013d, 2013b, 2013c, 2013a) related to the developed economies, where relevant information exists to differentiate between small and entrepreneurial businesses, and the economic contribution of entrepreneurship can be quantified systematically.

Previous studies on biotechnology in South Africa (Department of Science and Technology, 2001; Department of Science and Technology and eGoli Bio, 2003; Cloete, Nel and Theron, 2006; Ernst & Young, 2006; Department of Science and Technology, 2007; Gastrow, 2008) outline the structures put in place by the government to create an environment that is conducive for biotechnology and provide quantitative information on the state of the industry in South Africa. There have been other studies carried out on biotechnology entrepreneurship in developing economies such as China, Brazil and India (Herrington et al., 2008; Phan, Venkataraman and Velamuri, 2008; Herrington et al., 2010; Ernst & Young, 2010b). The outcome of these studies consistently indicates that there is little understanding of biotechnology entrepreneurship in developing economies even though the industry holds great promise for developing economies.

Apart from the annual Global Entrepreneurship Monitor (GEM) report, which South Africa joined in 2001, very few frameworks exist to provide a comparative basis for evaluating entrepreneurship in the developing economies relative to the developed economies. Fewer frameworks exist that are specific to biotechnology entrepreneurship in developing economies.

Given the importance of entrepreneurship in general, and specifically biotechnology entrepreneurship, to the economic and social imperatives of the developing economies, it would have been expected that this industry would command a great deal of empirical research interest and support from government, universities and the private sector. The scarcity of research impedes policy directions, institutional development, regulatory decisions, technology transfer strategy, national competitiveness, investments in innovation and skills development.

This study explores the dynamics of biotechnology entrepreneurship in the developing economies of South Africa and Brazil with the aim of understanding the practical realities of biotechnology entrepreneurship in these economies.

1.1 Significance of the study

The importance of entrepreneurship to the economic development of any economy has been established through several empirical research studies (Schumpeter, 1934; Wennekers and Thurik, 1999; Thurik and Wennekers, 2004; Stel, Carree and Thurik, 2005; Wennekers, Van Wennekers, Thurik and Reynolds, 2005; Herrington et al., 2008; Bosma and Levie, 2010; Carree and Thurik, 2010; Kelley et al., 2012).

Biotechnology is an industry that is based on scientific innovation and entrepreneurship, and it has been frequently described as the economic growth engine of the 21st century (Thurik and Wennekers, 2004; Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010; Ernst & Young, 2010a). While much interest has been generated globally by the potential of biotechnology, very little is known about the industry in the developing economies despite the fact that biotechnology is seen as the driver of economic growth, competitiveness and job creation (Thurik and Wennekers, 2004) in the current globalised knowledge-based economy. There is also an expectation for the emergence of the bio-economy, which is driven by biotechnology entrepreneurship (Organisation for Economic Cooperation and Development, 2013a), and to which South Africa has aligned its national policy on biotechnology entrepreneurship.

It has been shown that there are differences in the entrepreneurial process between the developed and developing economies (Lingelbach, De La Vina and Asel, 2005). The current discourse on the process of biotechnology entrepreneurship in developing economies is based on empirical research carried out in developed economies. This lack of empirical research on biotechnology entrepreneurship in developing economies represents a gap, which this study seeks to address.

In addition to bridging the gap in literature, this study is significant to government policy-making related to biotechnology, skills development, economic development, technology transfer, job creation and legislation, which improve the environment for entrepreneurial activities. The outcome of this research is expected to inform the improvement of government policies such as the National Bio-economy Strategy in South Africa, the Biotechnology Development Policy in Brazil, and specific policies related to the development of bioentrepreneurship in other developing economies.

Other stakeholders that will benefit from this study include research institutions, universities, large companies and venture capitalists. The understanding of the dynamics of biotechnology entrepreneurship in developing economies aids decision making related to strategic alliances, and the commercialisation of intellectual property by the various stakeholders.

1.2 Problem statement

The biotechnology industry is currently dominated by the United States of America (USA) and to a lesser extent by the other developed economies, and most of the empirical research on biotechnology entrepreneurship relates to the developed economies.

Specifically in South Africa and Brazil there is a paucity of empirical research on biotechnology entrepreneurship (Cloete et al., 2006; Gastrow, 2008; Natesh and Bhan, 2009; Ernst & Young, 2010b; Ahn and York, 2011; Meyers and Pruthi, 2011; Ahn et al., 2012; Battelle/Biotechnology Industry Organisation, 2012; Organisation for Economic Cooperation and Development, 2013a). Most studies in these two developing economies are conducted as either market research by consultants in the biotechnology industry (Cloete et al., 2006; Gastrow, 2008; Natesh and Bhan, 2009; Ernst & Young, 2010b; Ahn and York, 2011; Meyers and Pruthi, 2011; Ahn et al., 2012; Battelle/Biotechnology Industry Organisation, 2012; Organisation for Economic Cooperation and Development, 2013a), or empirical research on general entrepreneurship not specific to biotechnology entrepreneurship (Baumol, 1993; Ács and Audretsch, 2003; Shane, 2003; Lingelbach et al., 2005; Audretsch and Lehmann, 2005a; Alvarez and Barney, 2007; Lingelbach, Murray and Gilbert, 2008; Acs, 2010; Lingelbach, Murray and Gilbert, 2013).

Methodologically, the few research studies on biotechnology entrepreneurship, in developing economies, employ mostly the survey or single case study methodologies within one developing economy. These studies cannot be directly extrapolated to developing economies generally due to differences at individual, institutional and environmental levels among developing economies (Lingelbach et al., 2005).

Theoretically, at the time of this research there is no known conceptual framework of biotechnology entrepreneurship, especially in a developing economies context.

This research is aimed at making contributions that address the empirical, methodological and theoretical gaps identified above.

South Africa and Brazil have well-developed first and second-generation biotechnology (Department of Science and Technology, 2001) and have made good progress in developing third-generation biotechnology (Cloete et al., 2006). However, third-generation biotechnology and biotechnology entrepreneurship in South Africa and Brazil still lag far behind the level attained in developed economies across many dimensions (Organisation for Economic Cooperation and Development, 2013d, 2013b, 2013c).
The understanding of the dynamics of biotechnology entrepreneurship in these two developing economies, within its original context, contributes significantly to the knowledge of this field in the developing economies and addresses the identified empirical, methodological and theoretical gaps.

1.3 Purpose statement

The purpose of this study is to explore the dynamics of biotechnology entrepreneurship in South Africa and Brazil.

1.4 Assumptions underpinning the research

There is one assumption that underpins the proposed research. In spite of the difficulties of measuring entrepreneurship in a cross-national context (Carree and Thurik, 1998), it is assumed that the developing economies of South Africa and Brazil are good candidates for the study of biotechnology entrepreneurship in developing economies.

1.5 Structure of the thesis

This study is written up in a thesis that is divided into five parts.

Part I

Part I contains the foundation for the research and include chapters 1 to 4.
Chapter 1 provides the introduction to the study. It also describes the significance of the study, and delineates the problem and purpose statements and assumptions of this study.

Chapter 2 presents a detailed review of the literature on entrepreneurship and biotechnology. Literature on general, academic and technical entrepreneurship, as well as intrapreneurship and entrepreneurial orientation from developed and emerging economies was reviewed in order to gain a broad context in which to position biotechnology entrepreneurship as a specific form of entrepreneurship. From this theoretical basis, specific literature on biotechnology entrepreneurship was reviewed further as the focus of this study was on understanding the extent of empirical research already carried out on this form of entrepreneurship, and the extent to which this is applicable to developing economies.

Chapter 3 contains the research questions that emanated from the literature reviewed, as well as the organising frameworks of entrepreneurship and the triple helix of university, industry, government relations.

Chapter 4 provides a detailed description of the research design and methodology for the study.

Part II

Part II contains the case narratives and includes chapters 5 to 6. Chapter 5 contains the case narrative for South Africa. Chapter 6 contains the case narrative for Brazil.

Part III

Part III contains the case analyses and includes Chapters 7 and 8. Chapter 7 contains the case analysis for South Africa. Chapter 8 contains the case analysis for Brazil.

Part IV

Part IV contains the cross-case analysis, discussion and theory development; and includes Chapter 9.

Part V

Part V contains the conclusions and includes Chapter 10. Chapter 10 contains the conclusions to the research, and articulates the methodological, empirical and theoretical contributions of the research. In addition, this chapter contains policy implications and suggestions for future research.

Chapter 2: Literature Review

The purpose of Chapter 2 is to present a review of literature relevant to the understanding of biotechnology entrepreneurship in developing economies. The scope of the review includes literature from developed economies as this establishes the context for comparison with developing economies and aids the formulation of a relevant theoretical framework and research questions for this study.

2.1 Introduction

The review of literature for this research was based, on literature on general, academic, and technology entrepreneurship, and on Intrapreneurship and Entrepreneurial Orientation (EO) in order to establish the relevant conceptual and theoretical frameworks for entrepreneurship, within which to locate biotechnology entrepreneurship as a specific form of entrepreneurship.

From this theoretical basis, research focused on biotechnology entrepreneurship was reviewed further to gain a deeper understanding of the focus of this study. Furthermore, the review sought to establish the extent of empirical research already carried out on this form of entrepreneurship; the extent to which this empirical research is applicable to developing economies; the gaps in empirical, methodological and theoretical knowledge; and the relevant research questions to be developed.

In fulfilling the above aims, the literature review was structured in terms of the sub-sections shown in the literature review mind map presented in Figure 2.1 below.

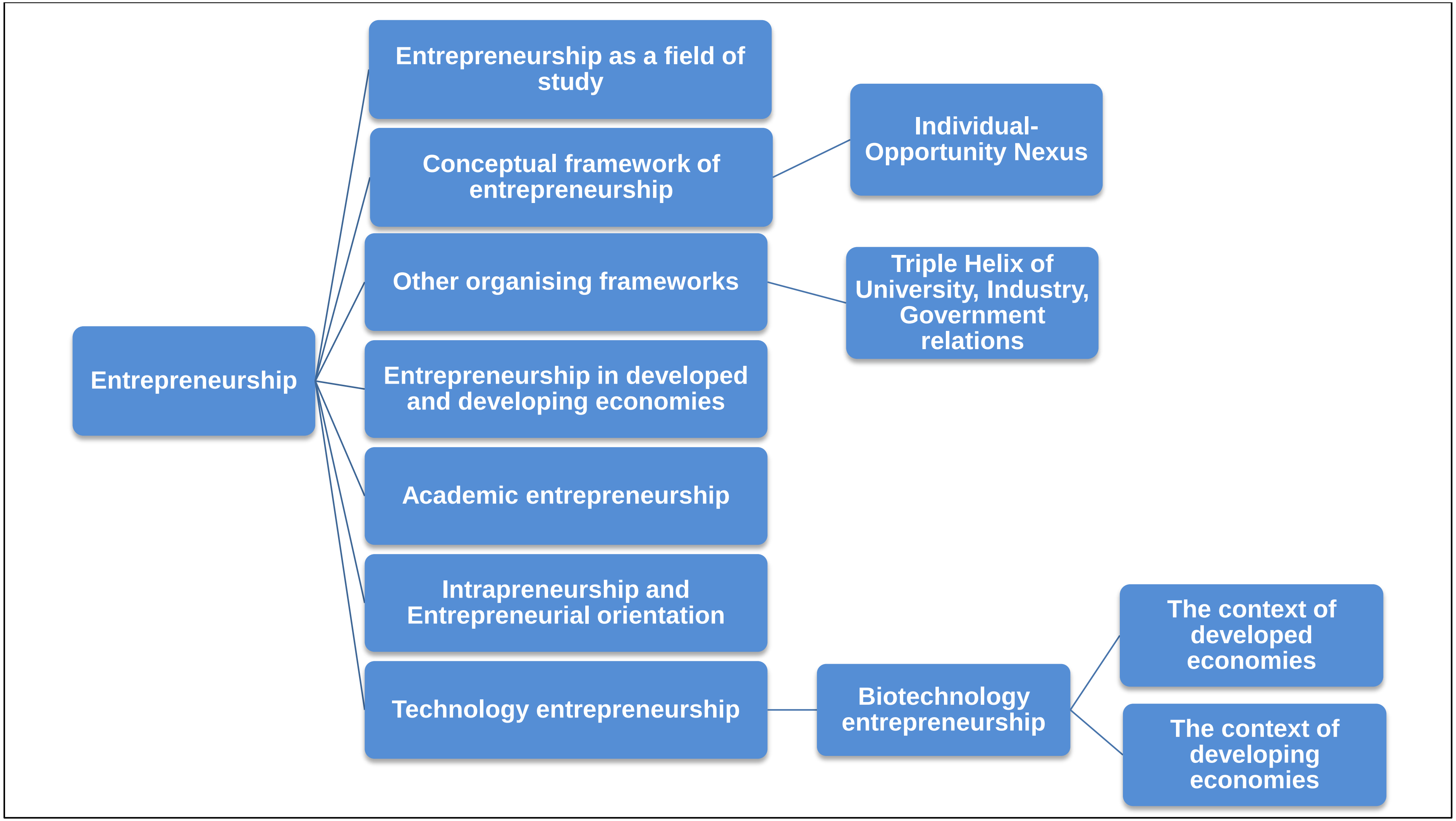


Figure 2.1: A mind map of the literature review headings and sub-headings

2.2 Entrepreneurship

Entrepreneurship is an interdisciplinary field with links to psychology, economics, organisational theory, finance, strategy, technology management and public policy (Shane and Venkataraman, 2000). Much prior research on entrepreneurship has been driven by a researcher's field of affiliation. This constraint has contributed to the lack of a coherent or over-arching conceptual framework for the field of entrepreneurship (Shane, 2003), in spite of wide interest in the field from business, government and academics.

The many definitions of entrepreneurship emanating from these fields and schools of thought incorporate common elements such as the individual, environment, opportunity, innovation, risk, action and new business creation, to varying degrees (Schumpeter, 1934; Gartner, 1988; Venkataraman, 1997; Shane and Venkataraman, 2000). While these definitions cover relevant aspects of entrepreneurship that range from firm creation to self-employment, the definition which is most closely aligned to the objectives of this study is that of Venkataraman (1997) and Shane and Venkataraman (2000), which is based on the conceptual framework of "the individual-opportunity nexus".

> Entrepreneurship is an activity that involves the discovery, evaluation and exploitation of opportunities to introduce new goods and services, ways of organising, markets, processes, and raw materials through organising efforts that previously had not existed. (Shane, 2003:4)

The integration of the individual, environmental and entrepreneurial opportunities (Cunningham and Lischeron, 1991; Shane and Venkataraman, 2000) in exploring the dynamics of biotechnology entrepreneurship has the potential to provide an in-depth understanding of the key aspects of this field in the chosen developing economies. Entrepreneurship is critical to the economic development (Baumol, 1989) of these developing economies, especially in the areas of employment creation and poverty alleviation (Thurik and Wennekers, 2004; Stel et al., 2005; Wennekers et al., 2005; Herrington et al., 2010).

The review of the literature for this study encompassed the two dominant entrepreneurial schools of thought: “focus on the individual” (McClelland, 1961; Kihlstrom and Laffont, 1979; Schere, 1982; Gartner, 1990) and “focus on external forces” (Tushman and Anderson, 1986; Hannan and Freeman, 1987; Ács and Audretsch, 2003). Other schools of thought such as “great person”, “psychological characteristics”, “classical”, “management”, “leadership”, and “Intrapreneurship” (Cunningham and Lischeron, 1991) can be explained in the context of either the individual or the external environment in which opportunities exist (Shane and Venkataraman, 2000). However, “Intrapreneurship”, or corporate entrepreneurship, relates specifically to entrepreneurial activities carried out in an organisational setting (Miller, 1983; Covin and Slevin, 1989) which involves entrepreneurial actions and decision making on the part of senior management and the leadership of the organisation (Covin and Slevin, 1989; Lumpkin and Dess, 1996; Covin and Wales, 2011).

Intrapreneurship, or corporate entrepreneurship, while it is discussed in Section 2.2.5 to provide a context for the study, is outside the scope of this study. Furthermore, this research does not focus on any particular theoretical construct underlying entrepreneurship, but approaches the study from an interdisciplinary perspective, which underlies the individual-opportunity nexus framework of entrpreneurship (Venkataraman, 1997; Shane and Venkataraman, 2000; Eckhardt and Shane, 2003).

An interdisciplinary approach to entrepreneurial research is advocated by researchers such as Shane (2003) and Murphy, Liao and Welsch (2006). The multidisciplinary approach is aligned with the researcher’s interest in gaining a holistic understanding of the field of biotechnology entrepreneurship in the chosen developing economies by drawing on literature from multiple fields and of how bioentrepreneurship contributes to the economic and social development of these economies, job creation, poverty alleviation and innovation (Kelley et al., 2012).

In addition, recent efforts have been made by entrepreneurship scholars to define theoretical foundations for creating a field of entrepreneurial research drawing on disciplines such as economics, management, geography, finance, strategy, organisation theory, technology management, public policy, psychology and sociology (Shane and Venkataraman, 2000; Ács and Audretsch, 2003:3-4).

2.2.1 Entrepreneurship as a field of study

Recent developments in entrepreneurial research are focused on integrating the different approaches to research in the field into a coherent conceptual and theoretical framework (Shane and Venkataraman, 2000; Ács and Audretsch, 2003; Phan, 2004), which bridges the gap between theoretical and practical research (Casson, 2005).

Some of the key areas most discussed in recent literature are: the multidisciplinary approach to research (Ács and Audretsch, 2003; Shane, 2003; Murphy et al., 2006); a common purpose to forge unity among researchers (Low and MacMillan, 1988; Shane and Venkataraman, 2000); alternative theories of entrepreneurial action (Alvarez and Barney, 2007); opportunity-based theories (Eckhardt and Shane, 2003; Murphy and Welsch, 2010); a multidimensional view of entrepreneurial discovery (Murphy and Welsch, 2010); and employment of multiple levels of analysis in entrepreneurship research (Davidsson and Wiklund, 2007). This is by no means an exhaustive list of most recent areas of emphasis in entrepreneurship research, but serves the purpose of highlighting some of the key discourses shaping the future of entrepreneurship research.

This recent trend in entrepreneurship research has several positive implications for biotechnology entrepreneurship.

First, the contemporary nature of recombinant DNA-based biotechnology (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012) lends itself to the application of contemporary approaches in entrepreneurship research. The multidisciplinary approach (Ács and Audretsch, 2003; Shane, 2003; Murphy et al., 2006) is suited to the multifaceted nature of biotechnology (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Biotechnology Industry Organisation, 2008; Battelle/Biotechnology

Industry Organisation, 2012). Biotechnology is plagued by the same crisis of definitional identity (Bud, 1991) as entrepreneurship (Cunningham and Lischeron, 1991) and will benefit from a unified research approach, as proposed by Low and MacMillan (1988).

Secondly, the distinct nature of bioentrepreneurial opportunities, which requires the application of research and development (R&D) in order to be exploited, defies the one-dimensional model of opportunity discovery (Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003) and discovery or creation as proposed by Alvarez and Barney (2007). Bioentrepreneurial opportunities straddle the continuum between discovery and creation (Audretsch, Taylor Aldridge and Perry, 2008), hence falling on a continuum between the Kirznerian (Kirzner, 1978) and Schumpeterian (Schumpeter, 1934) views of sources of entrepreneurial opportunities. Bioentrepreneurial opportunities are better explained by the multidimensional model proposed by Murphy and Welsch (2010), in which there is high serendipity and high deliberation, which Murphy and Welsch termed "Eureka". This terminology is apt for biotechnology entrepreneurship as some of the exploited opportunities in biotechnology have resulted in significant advancement in healthcare (Ahn and Meeks, 2007). In addition future opportunity exploitation in biotechnology is expected to contribute significantly to solutions to the global problems of poverty, healthcare, energy and environment (Biotechnology Industry Organisation, 2008).

Thirdly, the pervasive nature of biotechnology entrepreneurship (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Biotechnology Industry Organisation, 2008) and the involvement of multiple stakeholders at micro and aggregate levels require the employment of multiple levels of analysis in bioentrepreneurship research (Davidsson and Wiklund, 2007; Prodan, 2007) in order to articulate the role of bioentrepreneurship in economic development fully (Low and MacMillan, 1988). However, due to the centrality of the bioscientist in the biotechnology entrepreneurship process (Audretsch et al., 2008), many researchers have focused their studies on the individual unit of analysis (Zucker, Darby and Brewer, 1999; Thursby, Jensen and Thursby, 2001; Bercovitz and Feldman, 2004). In the study carried out by Zucker, Darby and Armstrong (2002) on the role of scientific talent in the creation of university start-ups, the authors found that firms founded by star scientists perform better than others even when the effects of external factors such as location and amount of venture capital financing are accounted for. The implications of this study for levels of analysis in biotechnology entrepreneurship are that interconnectedness occurs between levels of analysis in biotechnology entrepreneurship (Davidsson and Wiklund, 2007) and the individual unit of analysis can explain firm performance (Zucker et al., 2002).

Studies at the organisational unit of analysis (Nerkar and Shane, 2003; Audretsch and Lehmann, 2005b) provide the organisational context such as strategic alliances, funding sources and organisational performance (Audretsch et al., 2008). Other aggregate levels of analysis, such as the country level of analysis (Di Gregorio and Shane, 2003; Lockett and Wright, 2005), provide the institutional context.

As the field of entrepreneurship research develops and matures, the trend is moving towards unification of concepts and approaches towards common goals, explanation of causal relationships and exploration of implications for practice (Low and MacMillan, 1988). These contemporary approaches by entrepreneurship scholars (Low and MacMillan, 1988; Venkataraman, 1997; Shane and Venkataraman, 2000; Shane, 2003; Murphy et al., 2006; Alvarez and Barney, 2007; Davidsson and Wiklund, 2007; Murphy and Welsch, 2010; Wiklund, Davidsson, Audretsch and Karlsson, 2011) provide a better alignment with bioentrepreneurship research than previous approaches based either on the characteristics of the individual entrepreneur (McClelland, 1961; Kihlstrom and Laffont, 1979; Schere, 1982; Gartner, 1990) or on the environment (Tushman and Anderson, 1986; Hannan and Freeman, 1987; Ács and Audretsch, 2003).

Multidisciplinary approach

In order to develop a meaningful approach to entrepreneurial studies, the divergent views of scholars in the different fields underlying entrepreneurship need to be integrated into a coherent framework that provides a basis for the development of the field of entrepreneurship. Murphy, Liao and Welsch (2006) provide an illustrated conceptual history of entrepreneurial thought, which tracks the historical development of entrepreneurial thought from “prehistoric bases” to “multidisciplinary bases”.

The illustration by Murphy et al. (2006) shows that during the “prehistoric bases” entrepreneurship was synonymous with activities such as farming, engineering, architecture and military warfare. Followers of the “economic bases” school thought of entrepreneurship as a new combination of existing resources, explained by psychological factors and dependent on knowledge. The “multidisciplinary bases” are underpinned by the opportunity view of entrepreneurship, in which innovation is considered to be constructive (Murphy et al., 2006).

“The prehistoric bases” are mainly characterised by social controls, regulations and institutions, which place more emphasis on environmental variables as determinants of entrepreneurial activity. In contrast, the economics-based approaches to describing entrepreneurship in the “economic bases” are mainly characterised by innovation, coordination, risk-bearing, and national-level comparative advantages, which emphasise the cognitive and non-psychological aspects of the individual, as well as economic aspects of entrepreneurial activity. Hence, the “economic bases” marked the beginning of the shift towards the realisation that human and environmental factors are relevant in describing entrepreneurial activities, in addition to economic factors (Murphy et al., 2006). The shift of emphasis to the convergence of individual (McClelland, 1961) and environmental factors (Gnyawali and Fogel, 1994) gave rise to the “multidisciplinary bases”, which have opportunity discovery and exploitation (Shane and Venkataraman, 2000; Shane, 2003; Murphy et al., 2006) as the central tenet.

The opportunity view of entrepreneurship is the core of Shane’s (2003) individual-opportunity nexus conceptual framework, which is discussed in the next section.

2.2.2 Conceptual frameworks of entrepreneurship

Although there is no generally accepted conceptual framework for entrepreneurship, recent effort towards the formulation of a conceptual framework for the field of entrepreneurship is gathering momentum. At the forefront of this endeavour is Shane's (2003) proposed individual-opportunity nexus framework, which is based on an interdisciplinary approach to entrepreneurship.

Another important framework that informs the approach to this study is the Triple Helix of University, Industry, Government relations (Etzkowitz and Leydesdorff, 1997; Etzkowitz, 1998; Leydesdorff and Etzkowitz, 1998; Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2001; Leydesdorff and Etzkowitz, 2001).

Individual-opportunity nexus framework

Shane's (2003) individual-opportunity nexus framework (see Figure 2.2) seeks to integrate entrepreneurial research with opportunities, their discovery and exploitation; the enterprising individuals that discover and exploit these opportunities; and the environment in which the entrepreneurial activities occur.

There has been growing support for this approach (Ács and Audretsch, 2003; Murphy et al., 2006; Murphy and Welsch, 2010) owing to its promise to provide the basis for the emergence of entrepreneurship as a distinct field of research.

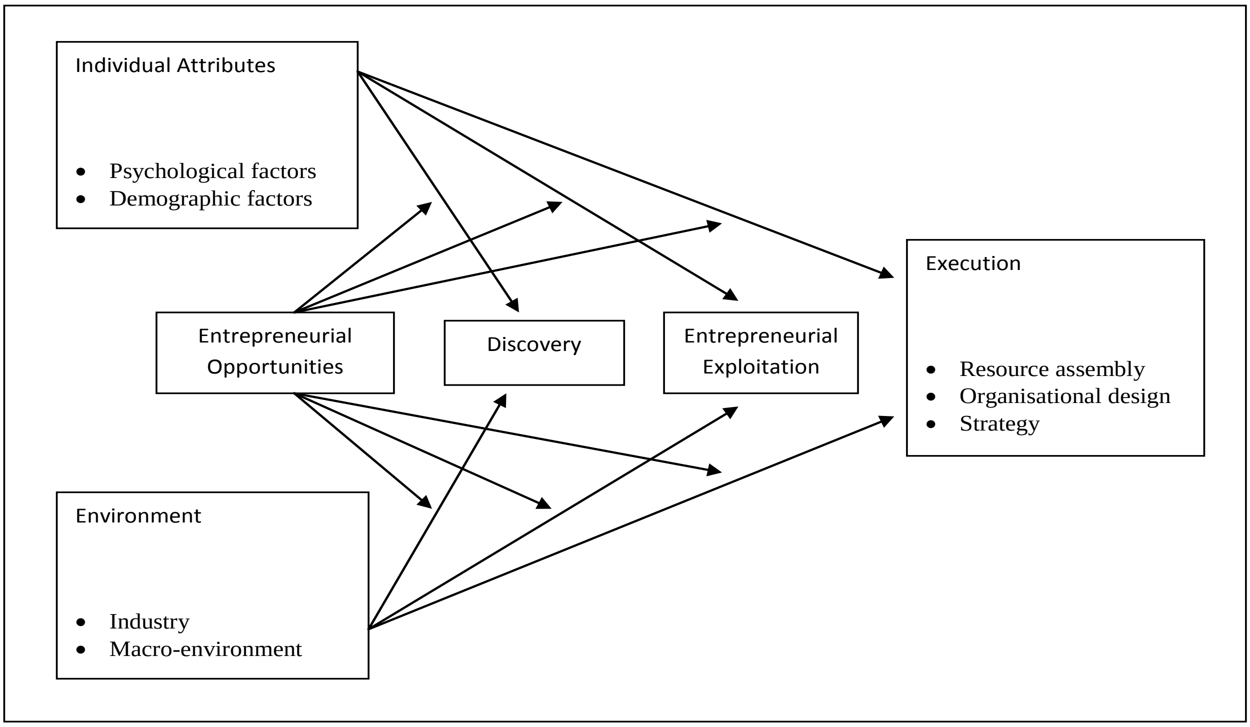


Figure 2.2: The individual-opportunity nexus framework (Shane, 2003:11)

Shane's (2003) framework considers the existence of entrepreneurial opportunities as independent of the actors and as needing to be discovered by enterprising individuals. The individual attributes needed to exploit these opportunities effectively include psychological factors, such as cognition and motivation and non-psychological factors such as education and career experience.

In the environment of entrepreneurship, the three categories of factors believed to influence productive entrepreneurial activity are the economic, political and cultural environments (Shane, 2003). There are marked differences between the developed and developing countries in all three categories of environmental factors. While the four aspects of the economic environment: wealth, economic stability, capital availability and taxation, are all at advanced levels and favourable for productive entrepreneurship in the developed economies, the developing economies face issues of poverty, economic instability, lack of capital and restrictive tax laws (Herrington et al., 2008; Bosma and Levie, 2010). Similarly, political instability in developing economies and low levels of a national culture of innovation and entrepreneurship hamper productive entrepreneurial activity (Herrington et al., 2010).

Shane's (2003) individual-opportunity nexus framework for entrepreneurship is able to explain the process of biotechnology entrepreneurship. This makes this framework useful for understanding the process of biotechnology entrepreneurship in South Africa and Brazil.

Triple Helix Approach (University-Industry-Government relations)

The relevance of the interactions among the university, industry and government, in transforming academic research into societal and economic capital, is demonstrated in the field of biotechnology (Liebeskind, Oliver, Zucker and Brewer, 1996; Agrawal, 2001; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell, White, Koput and Owen-Smith, 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008). Here collaboration between participants has evolved into what is termed: "inter-organisational relationships" (Powell, Koput and Smith-Doerr, 1996), "collaborative networks" (Etzkowitz and Leydesdorff, 1997; Powell et al., 2005), "innovation systems" (Etzkowitz and Leydesdorff, 1997), and more recently "triple helix of university, industry, government relations” (Etzkowitz and Leydesdorff, 1997; Leydesdorff and Etzkowitz, 1998, 2001).

The concept of “capitalised knowledge” in a knowledge-based economy represents a transformation of the traditional role of universities from the provider of basic knowledge, in the form of teaching and research (Etzkowitz, 1998; Leydesdorff and Etzkowitz, 2001), to a key player in the economic development of regions and nations through the commercialisation of academic research (Etzkowitz, 2001). Biotechnology entrepreneurship is at the forefront of this collaboration across universities, government, and industry through the dense network of collaboration and alliances (Oliver, 2008) that characterise the process of exploitation of bioentrepreneurial opportunities (Müller et al., 2004; Rothaermel and Deeds, 2004; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

The study on the “dynamics of innovation” (Etzkowitz and Leydesdorff, 2000) traces the emergence of Triple Helix III from Triple Helices I and II. Triple Helix I represents a configuration in which the government encompasses both industry and university and directs the interaction and relations between them (Etzkowitz and Leydesdorff, 2000). There is a strong possibility that the development of biotechnology entrepreneurship can be differentiated between the developed and developing economies on the basis of the innovation system that predominates (Etzkowitz and Leydesdorff, 2000).

Triple Helix II represents a configuration in which the three institutional spheres are separate with strong borders dividing them and restricted relations (Etzkowitz and Leydesdorff, 2000). Triple Helices I and II are expected to be the predominant form of university-industry-government relations in the developing economies for historical reasons that influence the rate of institutional change and economic growth (Sokoloff and Engerman, 2000; Oyelaran Oyeyinka and Barclay, 2004; Engerman and Sokoloff, 2005; Oyelaran-Oyeyinka, 2006; Engerman and Sokoloff, 2008). Here the transition from Triple Helix I to Triple Helix II is aimed at reducing the influence of government in the university, industry, government relationships (Etzkowitz and Leydesdorff, 2000).

In Triple Helix III, as shown in Figure 2.3, overlapping institutional spheres generate a knowledge infrastructure, with overlapping roles and hybrid organisations emerging at the interfaces (Etzkowitz and Leydesdorff, 2000).

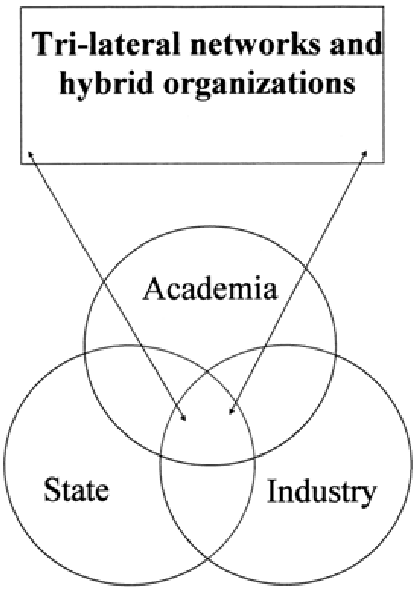


Figure 2.3: The Triple Helix Model of University-Industry-Government Relations (Etzkowitz and Leydesdorff, 2000)

The Triple Helix III configuration aims to create an innovation environment that supports knowledge-based economic development in which collaborations and alliances are aimed at creating, reinforcing and sustaining the knowledge infrastructure (Etzkowitz and Leydesdorff, 2000) without direct control by any of the institutions. The type of triple helix and the extent to which it operates in most developing countries can only be determined anecdotally, as current discussions and studies on the triple helix are focused on developed economies (Leydesdorff and Etzkowitz, 1998; Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2001; Leydesdorff and Etzkowitz, 2001).

Some scholars have criticised the Triple Helix approach as being too abstract and emphasising the consensus aspects of relationships among distinctive epistemic communities (Cooke, 2005); ignoring the entrepreneur (Brannback, Carsrud, Krueger Jr and Elfving, 2008); failing to recognise the role of social movements

(Chataway, Tait and Wield, 2004) and failing to traverse boundaries among epistemic communities successfully (Haas, 1992). In addition, studies by Jensen and Tragardh (2004) and Gunasekara (2006) on the validity of Triple Helix Approach in Sweden and Australia respectively did not yield similar results to that of the Massachusetts Institute of Technology (Cooke, 2005). However, despite these criticisms there is acknowledgment that the abstract principles of the Triple Helix Approach may hold in general (Haas, 1992).

It is also expected that different regions and locations would have different outcomes in applying the Triple Helix Approach due to the different dynamics inherent in the epistemic communities (Haas, 1992; Cooke, 2005). While this may not support generalisation, it may be important to understanding the critical differences between regions in successfully implementing a deliberate strategy for enhancing university, industry, and government relations.

The dynamics of the university, industry, and government relations highlight the need for a multilevel approach to biotechnology entrepreneurship research (Davidsson and Wiklund, 2007; Prodan, 2007). However, this is appropriate in the context of the developed economies where extant literature on single-level analysis (individual, organisation, and regional) readily exists (Davidsson and Wiklund, 2007). For the developing economies, there is a dearth of empirical research on biotechnology entrepreneurship at any level of analysis. This requires a concerted effort from researchers for further research at a multilevel analysis that explains the dynamics of biotechnology entrepreneurship across the innovation network (Etzkowitz, 2001).

2.2.3 Entrepreneurship in developed and developing economies

Entrepreneurship in developed economies has been shown to be different from developing economies because of differences in individual, institutional and environmental factors (Lingelbach et al., 2005; Kelley et al., 2012). These differences, as shown in Table 2.1, make it imperative for more empirical research on entrepreneurship to be conducted in developing economies, rather than draw conclusions based on research conducted in developed economies.

Table 2.1: Distinctive features of entrepreneurship in developed and developing economies (adapted from (Lingelbach et al., 2005)

Measure	Developed economies	Developing economies
Opportunities	Less pervasive and specialised	Broader in scope and pervasive
Locus of operation	Operates at the fringes of the economy	Operates closer to the core of the economy
Markets	Stable, matured markets with proven consistency	Lacks matured markets
Competition	Heightened competition from established incumbents	Reduced direct competitive threats
Risk	Mostly business and market risks	Mostly economic, political and regulatory risks; in addition to higher levels of business and market risks
Strategy	Specialised and concentrated	Portfolio approach to mitigate higher levels of business and market risks
Information flow	Advanced information flow allowing access to upstream and downstream businesses	Limited information flow
Capital availability	Developed venture capital industry and other sources of financing	Lack of alternative sources of financing; prevalence of bootstrap financing
Skills	Access to broader pool of skills and resources	Inadequate availability of skills and resources
Distribution	Advanced distribution network and access to end customers	Lack of access to end customers forces entrepreneurs to start downstream businesses

Table 2.1 shows that the entrepreneurial process in developing economies tends to be different from that of the developed economies across many dimensions (Lingelbach et al., 2005). A key individual factor such as skills availability differs markedly between the developed and developing economies. Biotechnology

entrepreneurship specifically requires the availability of a pool of human talent skilled in bioscience. The extent to which this is available determines to a large extent the success of developing biotechnology entrepreneurship.

Institutional factors such as government, infrastructure, markets, regulation, competition, risk, information flow, capital availability and distribution have also been shown to be different across the developed and developing economies (Kelley et al., 2012).

Furthermore, environmental factors such as opportunities, which are central to the entrepreneurial process, and strategies employed to exploit such opportunities have been shown to be different across the developed and developing economies (Lingelbach et al., 2005). Hence, entrepreneurship as a field of study is significantly enhanced when studied in the contexts of both the developed and developing economies, especially the latter given the paucity of empirical research currently available.

The Global Entrepreneurship Monitor (GEM) model discussed in the next section shows the link among individual entrepreneurial attitudes, activities and aspirations, and national economic growth; and how entrepreneurial activities can be compared across the developed and developing economies and different levels of national conditions.

Global Entrepreneurship Monitor

The GEM conceptual model provides a credible basis for the comparison of entrepreneurial activities across the developed and developing economies, based on their level of economic development (Herrington et al., 2008; Bosma and Levie, 2010; Herrington et al., 2010). Three categories of countries' economies, factor-driven, efficiency-driven and innovation-driven economies, are measured across 12 national conditions aligned to the 12 pillars of global competitiveness (Schwab, Sala-i-Martin, Blanke, Hanouz, Mia and Geiger, 2009; Kelley et al., 2012).

One of the key measures of the GEM model is Total Early-stage Entrepreneurial Activity (TEA), which measures the level of dynamic entrepreneurial activity in a country (Herrington et al., 2008; Bosma and Levie, 2010; Herrington et al., 2010; Kelley et al., 2012). The national conditions are key determinants of the TEA rates across nations. The developed economies have a lower average TEA rate than developing economies, which points to the pervasiveness of opportunities in developing economies and more matured and competitive markets in developed economies (Lingelbach et al., 2005). The differences in national conditions influence the nature and extent of entrepreneurship across different countries.

The GEM model starts off with national conditions within the social, cultural and political context. Most developing economies are still driven by the primary economy owing to their national conditions falling under basic requirements and efficiency enhancers. On the other hand, the national conditions for the developed economies fall under innovation and entrepreneurship, and entrepreneurship makes a greater contribution towards the output of the model, which is national economic growth.

The nature of opportunities also tends to differ between the developing and the developed economies. While there is a predominance of necessity-driven opportunities in the developing economies, the developed economies have a predominance of improvement-driven opportunities (Kelley et al., 2012).

The efficiency-driven countries display marked differences from the innovation-driven countries across factors such as R&D transfer, commercial and services infrastructure, internal market dynamics, internal market openness, physical infrastructure, and cultural and social norms (Kelley et al., 2012). In addition to these differences, there are also differences in factors like finance, general policy, regulatory policy, government programmes, and education (Kelley et al., 2012).

2.2.4 Academic entrepreneurship

Academic entrepreneurship encompasses all research activities that scientists engage in, which lead to the exploitation of opportunities through the start-up of a new firm or licensing of the intellectual property (Audretsch and Stephan, 1998; Mowery and Shane, 2002; Shane, 2004a; Audretsch and Lehmann, 2005a; Audretsch et al., 2008). In the late 20th century and the 21st century most of the emphasis on academic entrepreneurship has been on biotechnology entrepreneurship (Louis, Blumenthal, Gluck and Stoto, 1989; Mowery and Shane, 2002; Audretsch et al., 2008). In addition to commercialisation and licensing, Louis et al., (1989) identified three other forms of academic entrepreneurship that bioscientists engage in: engaging in large-scale science (externally funded research); earning supplemental income; and gaining industry support for university research.

In explaining the role of entrepreneurship in biotechnology, and how scientists engaged in biotechnology research at universities become entrepreneurs, Audretsch, Aldridge and Perry (2008) comment that the “exact role of entrepreneurship in industries such as biotechnology has generally eluded the analytical lens of scholars” (Audretsch et al., 2008). In the same article, Audretsch et al. (2008) offer a quote from *Jurassic Park* as follows: “the late twentieth century has witnessed a scientific gold rush of astonishing proportions: the headlong and furious haste to commercialise genetic engineering. This enterprise has proceeded so rapidly – with so little outside commentary – that its dimensions and implications are hardly understood at all” (Audretsch et al., 2008:179).

Studies that focus on the technology transfer offices (TTOs) of universities (Markman, Espina and Phan, 2004a; Markman, Gianiodis, Phan and Balkin, 2004b; Lockett and Wright, 2005; Markman, Gianiodis, Phan and Balkin, 2005; Wolson, 2007; Oliver, 2008) have explored the link between the activities of the TTOs and the scientist’s entrepreneurial activities in the form of university spin-offs.

The importance of the bioscientist to the process of academic entrepreneurship makes it imperative that analysis at the level of the bioscientist is well understood in developing economies where empirical research has been limited (Lingelbach et al., 2005) across all levels of analysis. A similar view has been put forward by Audretsch et al. (2008) who advocated direct interaction with the bioscientist to create comprehensive and systematic new sources of measurement to assess the extent, nature, determinants and impact of scientific commercialisation of research (Audretsch et al., 2008). Part of this call by Audretsch et al., (2008) has been heeded in the study conducted by Nilsson, Rickne and Bengtsson (2010b) in which four determinants of commercialisation of research were identified: perceived role of the university, supportive infrastructure, industrial actor set-up and networks.

Some of the studies at an individual level of analysis considered the differences across individual cognitive processes (McClelland, 1961; Stevenson and Jarillo, 2007) and their link to opportunity identification and the exploitation of such opportunities (Krueger, 2005). Other studies identified individual attributes such as self-efficacy, collective efficacy, social norms, willingness to incur risk, preference for autonomy and self-direction, and differential access to scarce and expensive resources (Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003). While these studies of individual cognitive processes and characteristics are perfectly applicable to general entrepreneurship, they do not fully explain the role of the bioscientist, which transcends organisational, regional and national levels of analysis.

The study conducted by Zucker et al. (2002) focused on this pivotal role of the bioscientist in influencing firm performance. This is an area that requires further research as the role of the bioscientist is expected to influence not only firm performance but also the process of strategic alliances and government policies on biotechnology. This transcending of levels of analysis is similar to the call by Audretsch et al. (2008) for comprehensive and systematic new sources of measurement, through direct interaction with scientists, to gauge the extent, nature, determinants, and impact of scientist commercialisation of research (Audretsch et al., 2008).

2.2.5 Intrapreneurship and entrepreneurial orientation

The review of the literature on Intrapreneurship and EO is aimed at providing a context in which the design of this empirical study and the appropriateness of the utilisation of different theories can be assessed (Davidsson and Wiklund, 2007).

Intrapreneurship and EO are concepts that represent corporate entrepreneurship (Miller, 1983; Covin and Slevin, 1989; Covin and Wales, 2011) and the degree to which organisations are predisposed to entrepreneurial activities (Miller, 1983; Lumpkin and Dess, 1996). Lumpkin and Dess (1996) differentiate Intrapreneurship from EO. They see Intrapreneurship as the “new entry”, which represents the launch of a new venture, while EO is the processes, practices, and decision-making activities that lead to the “new entry” (Lumpkin and Dess, 1996).

From the earlier formulation of the EO construct as comprising of “innovativeness”, “risk taking” and “proactiveness” (Miller, 1983), which must positively covary, to the later expansion of the construct by Lumpkin and Dess (1996) as multidimensional and including the dimensions of “autonomy”, “competitive aggressiveness”, “innovativeness”, “risk taking” and “proactiveness”, which independently and collectively define the domain of EO, it has been applicable to firm-level analysis and is seen as an organisational-level strategy-making process (Dess and Lumpkin, 2001).

The application of EO at the individual level of analysis is deemed inappropriate as this is a firm-level construct (Khandwalla, 1977; Miller and Friesen, 1982; Lumpkin and Dess, 1996; Dess and Lumpkin, 2001; Basso, Fayolle and Bouchard, 2009). As noted by Urban (2008) in the study of the “prevalence of EO in a developing country”, the representation of the firm by surveys of individuals contributes to the confusion about the level of operationalisation of EO.

Measurement of the link between EO and firm success and performance in the context of developed economies (Zahra, 1991; Zahra and Covin, 1995; Lumpkin and Dess, 1996; Zahra, 1999; Lee and Peterson, 2000; Lyon, Lumpkin and Dess, 2000; Kuratko, Ireland and Hornsby, 2001) and developing economies (Urban, 2008, 2010) has established positive associations within the context of the environment being studied. This may provide a basis of comparability for the entrepreneurial disposition of organisations across the developed and developing economies divide, taking the environmental and organisational factors into consideration (Lumpkin and Dess, 1996).

Having reviewed the literature on the concept of EO (Khandwalla, 1977; Miller and Friesen, 1982; Miller, 1983; Covin and Slevin, 1989; Lumpkin and Dess, 1996; Dess and Lumpkin, 2001; Urban, 2008; Basso et al., 2009; Urban, 2010; Covin and Wales, 2011) and the link between EO and firm success and performance (Zahra, 1991; Zahra and Covin, 1995; Lumpkin and Dess, 1996; Zahra, 1999; Lee and Peterson, 2000; Lyon et al., 2000; Kuratko et al., 2001), it is evident that it is a firm-level construct that is widely researched, contextualised and accepted as a stable construct that explains the process of corporate strategy (Basso et al., 2009). However, its applicability to the study of biotechnology entrepreneurship at organisational level may not yield similar results for the reasons set out below.

First, the very nature of biotechnology entrepreneurship means that EO is a given for situations where a bioscientist follows through on the process of commercialisation of biotechnological research (Audretsch et al., 2008). Hence, research that evaluates the degree of EO in a biotechnology firm set up by an entrepreneurial bioscientist may not yield appropriate results. Even in situations where biotechnology firms are set up by larger organisations as a sub-unit, the very basis of setting up the firm has to be entrepreneurial and innovation-inclined in order to fit into the definition of bioentrepreneurship. Hence, EO is also a given in this situation.

Secondly, the entrepreneurial activities of individuals in biotechnology entrepreneurship do not explicitly require organisational structures, activities and decision making (Lumpkin and Dess, 1996). While EO is more aligned to strategic management and decision making, biotechnology entrepreneurship is dependent on research as a necessary condition and the activities of the individual bioscientists (Zucker et al., 2002).

Thirdly, the activities of the individual in entrepreneurship can often be explained through the individual level of analysis (McClelland, 1961; Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003; Stevenson and Jarillo, 2007) and can be bounded from the organisational level of analysis. However, in bioentrepreneurship the activities of the individual may span multiple levels of analysis (Zucker et al., 2002) and consequently the use of EO will only partially capture the dynamics of the process.

In addition, while opportunity discovery (Alvarez and Barney, 2007) is prevalent in entrepreneurship (including Intrapreneurship), a combination of opportunity discovery and opportunity creation (Alvarez and Barney, 2007) is applicable to bioentrepreneurship (Murphy and Welsch, 2010). Opportunity creation is prevalent as research is a prerequisite (Shane, 2004b; Audretsch et al., 2008).

Thus, while EO is less applicable to individual-level analysis, it may equally not be applicable to firm level analysis in biotechnology entrepreneurship because of possible partial representation, or misrepresentation, of the dynamics of biotechnology entrepreneurship. The dynamics of biotechnology entrepreneurship are expected to be better represented, at a firm-level, through the use of the Triple Helix approach (Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2001), which captures the university, industry, government relations. The sub-dynamics of the Triple Helix approach can be studied as a build-up to the university, industry, government relations dynamics. Hence, the university component of the Triple Helix can be studied in the context of TTOs (Markman et al., 2004a; Markman et al., 2004b; Lockett and Wright, 2005; Markman et al., 2005; Wolson, 2007; Oliver, 2008); the institutional and cultural contexts of the university (Di Gregorio and Shane, 2003; Lockett and Wright, 2005); the new firm started by the scientist (Nerkar and Shane, 2003; Audretsch and Lehmann, 2005b); and the individual bioscientist (Shane, 2004b; Lockett, Siegel, Wright and Ensley, 2005).

2.2.6 Technology entrepreneurship

Technology entrepreneurship comprises mostly Information and Computer Technology (ICT), Engineering Technology and Biotechnology (Eisenhardt and Forbes, 1984). While ICT was the predominant technology of interest in the 20th century (Cooke, 2008), the 21st century area of interest is on biotechnology (Battelle/Biotechnology Industry Organisation, 2010). In the next section, the review of the literature on technology entrepreneurship is focused on biotechnology entrepreneurship.

2.3 Biotechnology entrepreneurship

Biotechnology is situated at the boundary of the fields of biology and engineering. It is a combination of science (medical science, biochemistry, molecular biology, cell biology) and industrial production (medical, food, forest industries) (Kivinen and Varelius, 2003). Hence, similar to entrepreneurship, biotechnology has been defined differently by scholars affiliated to either of the underlying fields (Bud, 1991). This contributes to the confusion about what a single unifying definition for the field in the early stages of development should be. However, 21st century biotechnology has been defined as “the use of cellular and biomolecular processes to solve problems or make useful products” (Biotechnology Industry Organisation, 2008:1).

20th century biotechnology evolved from an emphasis on population problems and agriculture to a focus on areas such as pharmaceuticals, agricultural chemicals, food production, waste disposal and chemical manufacture (Bud, 1991).

In the 21st century, biotechnology has assumed global importance in the areas of healthcare, environmental protection, agriculture, chemistry, and material science (Biotechnology Industry Organisation, 2008), with significant commercial potential (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Ahn et al., 2010a; Ahn et al., 2012), as shown in Figure 2.4.

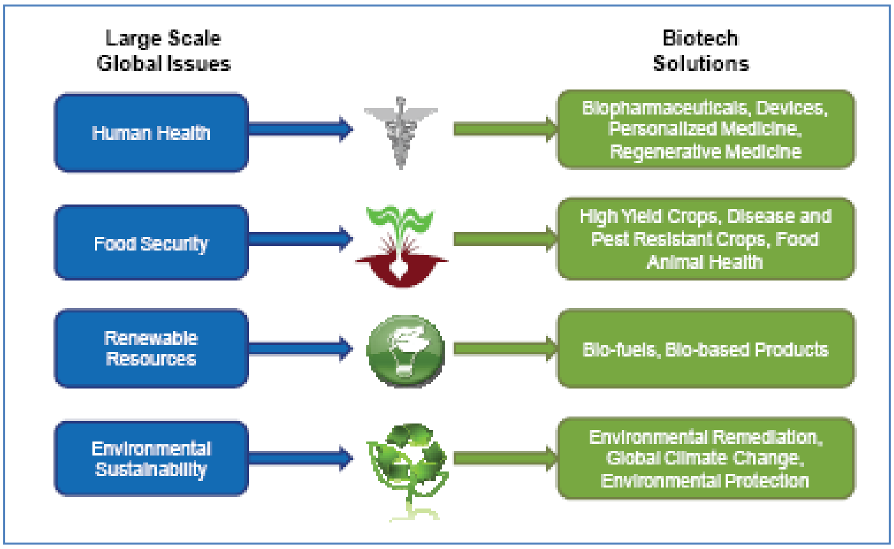


Figure 2.4: Biotechnology solutions to global issues (Battelle/Biotechnology Industry Organisation, 2010)

The large-scale global issues as depicted in Figure 2.4 include human health, food security, renewable resources and environmental sustainability. Biotechnology currently holds the best prospect of providing solutions to these global issues, which are more prevalent in the developing economies. Much progress has been made in terms of solutions across these four global issues, as highlighted in Figure 2.4 (Biotechnology Industry Organisation, 2008), and these solutions are expected to be accelerated in the 21st century; hence, the 21st century has been termed the "biocentury" (Battelle/Biotechnology Industry Organisation, 2010).

In order for the expected benefits of the "biocentury" to be applicable to the developing economies, biotechnology entrepreneurship needs to be well understood in the context of the developing economies, and sustainably developed to boost the competitiveness of these economies.

Within the context of this research, "biotechnology entrepreneurship" and "bioentrepreneurship" refer to activities that involve the discovery, evaluation and exploitation of biotechnological opportunities, through the use of cellular and biomolecular processes, to introduce new goods and services, ways of organising, markets, processes, and raw materials through organising efforts that previously had not existed (Shane and Venkataraman, 2000).

Biotechnology entrepreneurship is synonymous with innovation, as the whole concept is dependent on innovative new solutions driven through entrepreneurial efforts, the commercialisation of which often leads to collaboration between the public and private sectors (Etzkowitz and Leydesdorff, 1997; Leydesdorff and Etzkowitz, 1998; Gittelman, 1999; Kettler and Casper, 2001; Gittelman, 2006).

The importance of biotechnology entrepreneurship extends to technology transfer and technological innovation (Shan, Walker and Kogut, 1994; Leydesdorff and Etzkowitz, 1998), in addition to economic development and job creation (Jones-Evans, 1996; Stringer, 2000). These are areas that are vital to the sustainable economic and social development of both South Africa and Brazil.

2.3.1 The context of developed economies

In developed economies, the United States (US) leads the chart in biotechnology. The US has more companies, employs more people, invests more in research and development, and earns more than all of Europe combined (Kettler and Casper, 2001). This may be as a result of the early-mover advantage which the US gained by embracing biotechnology and actively encouraging the development of the industry decades before Europe took the same route.

In 2010, the bioscience industry was estimated to have directly created 1.6 million jobs in the US and to be indirectly responsible for about 3.4 million jobs in total (Battelle/Biotechnology Industry Organisation, 2012), with a net income of $3.7 billion for publicly traded biotech companies in 2009 (Ernst & Young, 2010b).

Owing to globalisation and through international collaboration, there is extensive interaction between the American and European biotechnology industry through the big multinational biotechnology corporations (Dibner, 1986) and research scientist networks. At a governmental level, many European countries implement similar policy initiatives to America in order to fast-track their biotechnology industries. The existence of similar policy initiatives to those of America has been confirmed in the biotechnology industries of Finland (Kivinen and Varelius, 2003); the United Kingdom, Germany and Japan (Dibner, 1986; Müller, 2002; Muller and Fujiwara, 2002; Müller et al., 2004); and Sweden (Nilsson, 2001).

The combination of American and European biotechnology industries, under the banner of developed economies, constitutes a near total domination of the entirety of the global biotechnology industry, with the developing economies having very little or no impact currently.

It is difficult to make a direct comparison between the biotechnology industry in the developed and developing economies, except in cases such as the biofuel industry in Brazil, owing to the general lack of empirical research and data, and the undeveloped nature of the industry in most developing economies. However, the GEM report provides a basis of comparison for general entrepreneurial activities across these two types of economies (Herrington et al., 2008; Bosma and Levie, 2010), which is assumed to provide a similar comparative basis for biotechnology entrepreneurship.

The GEM report has categorised the national conditions of the developed economies under “innovation-driven” as shown in Table 2.2.

Table 2.2: Importance of different types of national conditions for economic development (Bosma and Levie, 2010)

	Basic requirements	**Efficiency enhancers**	**Entrepreneurial conditions**
Factor-driven economies	Key focus	Develop	Start enabling
Efficiency-driven economies	Maintain	Key focus	Develop
Innovation-driven economies	Maintain	Maintain	Key focus

For developed economies, the basic requirements (institutions, infrastructure, macroeconomic stability, health and primary education) and efficiency enhancers (higher education and training, goods market efficiency, labour market efficiency, financial market sophistication, technological readiness and market size) are in place and are maintained. Nevertheless, the key focus is on the entrepreneurial conditions (Bosma and Levie, 2010) listed below:

i. Entrepreneurial finance
ii. Government policies
iii. Government entrepreneurship programmes
iv. Entrepreneurship education
v. R&D transfer
vi. Commercial and legal infrastructure for entrepreneurship
vii. Internal market openness
viii. Physical infrastructure for entrepreneurship
ix. Cultural and social norms

The prevalence of entrepreneurial activities in the US attests to the availability of basic requirements and efficiency enhancers. About 4% to 6% of America's working population take action to start a new business annually, and about 40% experience bouts of self-employment in their lifetime (Ács and Audretsch, 2003:5). The result of this is that an estimated 761,000 new corporations, the number of which number increases to 4.5 million with the inclusion of all forms of business, are started per year in America as at 1998 (Ács and Audretsch, 2003:28). The trend for the rest of the developed economies is expected to be similar to America, although not to the same magnitude.

Some of the differences linked to the national conditions for the developed and developing economies (Phan et al., 2008) are shown in Table 2.3.

Table 2.3: Differences in national conditions for developed and emerging economies (Adapted from (Phan et al., 2008)

Measure	Developed economies	Emerging economies
Competitiveness	High competitive intensity	Vagaries of policy making and not much competition
Socio-economic linkages	These issues are usually hidden or taken for granted in extant literature	Link between economic development, social welfare and entrepreneurial action
Inputs	Availability of critical mass of inputs required to ignite entrepreneurial action	Lacks the critical mass of inputs (capital, human talent, technology) required to ignite entrepreneurial action
Nature of entrepreneurial action	May be accidental and spontaneous as the necessary conditions already exist	Non-accidental and purposefully orchestrated by government, providing resource endowments, institutions and markets. Government provide both macro- and microeconomic factors aimed at providing incentives for entrepreneurial action

Biotechnology entrepreneurship activities are currently entrenched in the developed economies, and are continually being improved as biotechnology is expected to be the economic growth engine of the 21st century (Battelle/Biotechnology Industry Organisation, 2010). Expectedly, most of the published literature on biotechnology entrepreneurship is based in the developed economies, where industry statistics have been tracked for decades.

The empirical studies on biotechnology entrepreneurship for the developing economies are still at the exploratory stage and the industry has not developed to a stage where statistics are readily available and tracked.

2.3.2 The context of developing economies

In developing economies, biotechnology entrepreneurship holds the tantalising prospect of significantly contributing to food security, improved agricultural output, sustainable environmental development practices, improved healthcare, job creation, poverty alleviation and economic development (Clarke, 2002). The achievement of all, or any, of these benefits depends on the national conditions that exist in the developing economies. The “bigger” economies of the developing world, such as BRIC (Brazil, Russia, India and China), South Africa and possibly Nigeria (Department of Science and Technology, 2001), may be in a better position to exploit the benefits of biotechnology in a globalised world, whether through technology transfer, innovative development of the industry, development of particular niches within the biotechnology industry or a combination of these and other options. These bigger economies represent a vital link between the developing and the developed economies as the basic requirements already exist in these economies.

The GEM report classifies the developing economies used in this study as efficiency-driven (refer to Table 2.2) and as such the key focus is on the efficiency enhancers shown below:

i. Higher education and training
ii. Goods market efficiency
iii. Labour market efficiency
iv. Financial market sophistication
v. Technological readiness
vi. Market size

While these efficiency enhancers are critical to the development of entrepreneurial culture in general, the developing economies still need to develop the entrepreneurial conditions (entrepreneurial finance, government policies, government entrepreneurship programmes, entrepreneurship education, R&D transfer, commercial and legal infrastructure for entrepreneurship, internal market openness, physical infrastructure for entrepreneurship, and cultural and social norms) necessary for an innovation-driven industry such as biotechnology (Herrington et al., 2008; Bosma and Levie, 2010).

The global issues (human health, food security, renewable resources and environmental sustainability) (Battelle/Biotechnology Industry Organisation, 2010) that are addressed by biotechnological solutions are more prevalent in developing economies as are the issues of economic and social development, unemployment and global competitiveness. These issues highlight the importance of understanding and developing entrepreneurship in general, and specifically bioentrepreneurship, in the developing economies.

2.4 Conclusion

In recent times, there has been growing support for a multidisciplinary approach to entrepreneurship research (Thornton, 1999; Ács and Audretsch, 2003; Shane, 2003; Murphy et al., 2006; Murphy and Welsch, 2010). The interdisciplinary approach used in this study supports Shane's (2003) individual-opportunity nexus conceptual framework, which has opportunity discovery and exploitation as its central premise and the Triple Helix of university, industry, government relations (Leydesdorff and Etzkowitz, 1998, 2001), which points to the collaboration-intensive nature of biotechnology entrepreneurship.

The literature on biotechnology entrepreneurship aligns to the components of the individual-opportunity nexus framework (Pisano, 1990, 1991; Gittelman, 1999; Feldman and Ronzio, 2001; Kettler and Casper, 2001; Müller et al., 2004; Rothaermel and Deeds, 2004; Ahn and Meeks, 2007; Bagchi-Sen, 2007). At the same time it highlights the uniqueness of biotechnology entrepreneurship in terms of R&D; alliances between multiple stakeholders, which are aligned to the Triple Helix of university, industry, government relations approach (Leydesdorff and Etzkowitz, 1998, 2001); and the commercialisation of intellectual property.

These unique features of biotechnology entrepreneurship are the basis for the development of the proposed theoretical framework for biotechnology entrepreneurship.

Biotechnology is poised to provide answers to most of the global issues and national imperatives in the 21st century. Hence, the development of the industry ranks high on the list of priorities for many countries, both developed and developing. However, the unique set of requirements for making a success of biotechnology entrepreneurship, such as bioscience skills, capital, technology and an accommodating political, social and economic environment, tilts the odds in favour of developed economies (Lingelbach et al., 2005).

The developed economies dominate the biotechnology industry, with the US leading the charge. This is confirmed in the literature, which shows that across many dimensions such as the following, the developed economies are far ahead of the developing economies:

i. Research publication (Gastrow, 2008)
ii. Patent application (Gastrow, 2008)
iii. Number of biotechnology companies (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010; Ernst & Young, 2010b; Battelle/Biotechnology Industry Organisation, 2012)
iv. R&D spend (Organisation for Economic Cooperation and Development, 2013b)
v. R&D intensity (Organisation for Economic Cooperation and Development, 2013c)
vi. Revenue generated (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010; Ernst & Young, 2010b)
vii. Employment generated (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010, 2012)
viii. Biotechnology products in the pipeline and
ix. Approved biotechnology products in the market (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010, 2012)

The developing economies ranked as efficiency-driven in the GEM report (Herrington et al., 2008; Bosma and Levie, 2010; Kelley et al., 2012) may be proficient in first-generation biotechnology as in the case of South Africa, but not in the recombinant DNA-driven third-generation biotechnology. In developing countries where third-generation biotechnology seems to be relatively developed, such as Brazil, it is concentrated in the agricultural biotechnology sector.

These differences (Lingelbach et al., 2005), gaps and preferences for a particular type of biotechnology entrepreneurship were taken into account in developing the research questions for this study, which are presented in the next chapter.

Research questions were chosen instead of propositions firstly because of the exploratory nature of this study; secondly, because very little empirical research exists for developing economies; and, thirdly, because of the need for an in-depth understanding of biotechnological entrepreneurship in developing economies within its real-life context.

Chapter 3: Research Questions and Organising Frameworks

3.1 Research questions

This section outlines the research questions explored in this study to achieve the purpose of the study, which is to explore the dynamics of biotechnology entrepreneurship in the developing economies of South Africa and Brazil.

Question 1
How do bioscientists carry out biotechnology entrepreneurship in the developing economies of South Africa and Brazil?

Question 2
How is biotechnology entrepreneurship conducted by bioscientists in developing economies similar to the process defined in the literature for developed economies?

Question 3
How is biotechnology entrepreneurship conducted by bioscientists in developing economies different from the process defined in the literature for developed economies?

Question 4
What are the factors that influence biotechnology entrepreneurship in developing economies, and how do they exert their influence?

Question 5
What Triple Helix of university, industry, government relations are experienced by the stakeholders in the biotechnology industry of South Africa and Brazil?

3.2 Organising frameworks

This section outlines the organising frameworks for this research, which guided the exploration of the dynamics of biotechnology entrepreneurship in the developing economies of South Africa and Brazil. These are the individual-opportunity nexus framework of entrepreneurship as shown in Figure 2.2 on page 16 (Shane, 2003:11), and the triple helix model of university, industry, government relations as shown in Figure 2.3 on page 19 (Etzkowitz and Leydesdorff, 2000).

The individual-opportunity nexus framework was used to explore how biotechnology entrepreneurship is carried out in South Africa and Brazil. The process of biotechnology entrepreneurship in South Africa and Brazil is then compared to the literature on the process of biotechnology entrepreneurship in developed economies, in order to identify similarities and differences.

The triple helix approach was used to explore what relationships are experienced by the stakeholders in the biotechnology industries of South Africa and Brazil across the university, industry, and government spheres.

Given the paucity of empirical research on biotechnology entrepreneurship in the context of the developing economies, these organising frameworks linked the literature on entrepreneurship to the data from this research. In this way, the researcher was able to develop an understanding of biotechnology entrepreneurship in the developing economies of South Africa and Brazil.

Chapter 4: Research Methodology

The purpose of Chapter 4 is to describe the philosophical foundations of this research and the strategies of inquiry underpinning it, and to articulate the rationale for choosing the methodological approach described in this chapter. The chapter also describes the research design, the case-selection criteria, data-collection and analysis processes, the steps taken to ensure the validity and reliability of this research, and finally the limitations and delimitations of the research.

4.1 The philosophical foundations of this research

The philosophical foundation of entrepreneurship is not easily defined because entrepreneurship as a field of study has been characterised by multiple underlying disciplines, which influence the approaches used in empirical research. Scholars have tended to support either the individual view (McClelland, 1961; Kihlstrom and Laffont, 1979; Schere, 1982; Gartner, 1990; Bouchikhi, 1993) or the environmental view of entrepreneurship (Tushman and Anderson, 1986; Hannan and Freeman, 1987; Bouchikhi, 1993; Ács and Audretsch, 2003), with each camp defending its philosophical position. Consequently, no consensus has been achieved on the appropriate unit of analysis or design processes, or appropriate data-collection and analysis techniques (Brazeal and Herbert, 1999).

Current empirical studies are dominated by a nomothetic, as opposed to an idiographic, philosophical approach. Biotechnology entrepreneurship is a relatively new field within entrepreneurship (Meyers, 2012) and consequently suffers the same methodological bias. The nomothetic approach is based on objective inquiry and requires the verification of facts through mostly quantitative methods (Guba and Lincoln, 1994). Hence, the predominant school of thought in the field of entrepreneurship, which determines the predominant methodology employed in entrepreneurship research, is positivism (Guba and Lincoln, 1994; Onwuegbuzie, 2002; Onwuegbuzie and Leech, 2005; Neuman, 2006). This fact is supported by the prevalence of quantitative over qualitative methods in the decade ending 2001 (Chandler and Lyon, 2001), in which only 18% of studies used qualitative methods.

In the idiographic philosophical tradition, which is based on the subjective relationship between the researcher and the participants and the co-creation of meaning, the verification of facts is through mostly qualitative methods (Guba and Lincoln, 1994). Hence, the predominant school of thought is interpretive social science (Neuman, 2006; Creswell, 2009).

Despite the low levels of application of the idiographic philosophical tradition, and hence qualitative approaches, in entrepreneurship studies, there has been increasing recognition of the usefulness of a convergence of quantitative and qualitative approaches, or mixed methods, in empirical research. This is aligned to efforts to encourage multidisciplinary approaches to the field of entrepreneurship (Shane and Venkataraman, 2000; Shane, 2003; Murphy et al., 2006; Murphy and Welsch, 2010), which extends to the broadening of the strategies of inquiry (Creswell, 2009).

Some of the reasons for the support of the convergence of quantitative and qualitative approaches in empirical research include:

i. Criticism of the supposed superiority of quantitative methods (Guba and Lincoln, 1994; Long, White, Friedman and Brazeal, 2000; Mir and Watson, 2000; Onwuegbuzie, 2002; Onwuegbuzie and Leech, 2005)
ii. Use of qualitative and quantitative methods for theory generation and theory testing respectively (Long et al., 2000)
iii. The need for practical research and results dissemination in lay language
iv. Generation of possible outcomes of corroboration, elaboration, complementarity and contradiction
v. Provision of a holistic framework for understanding meanings and actions (Brannen, 2005)
vi. Lack of one-to-one correspondence between paradigm and method
vii. The re-conceptualisation of qualitative and quantitative paradigms to lie on an epistemological continuum (Onwuegbuzie, 2002)

The approach taken for this research is guided by Creswell's (2009) framework for design, the interconnection of worldviews, strategies of inquiry and research methods, as shown in Figure 4.1. The philosophical worldviews determine the selected strategies of inquiry, which in turn determine the research methods. The social construction world view or philosophical approach was employed for this research.

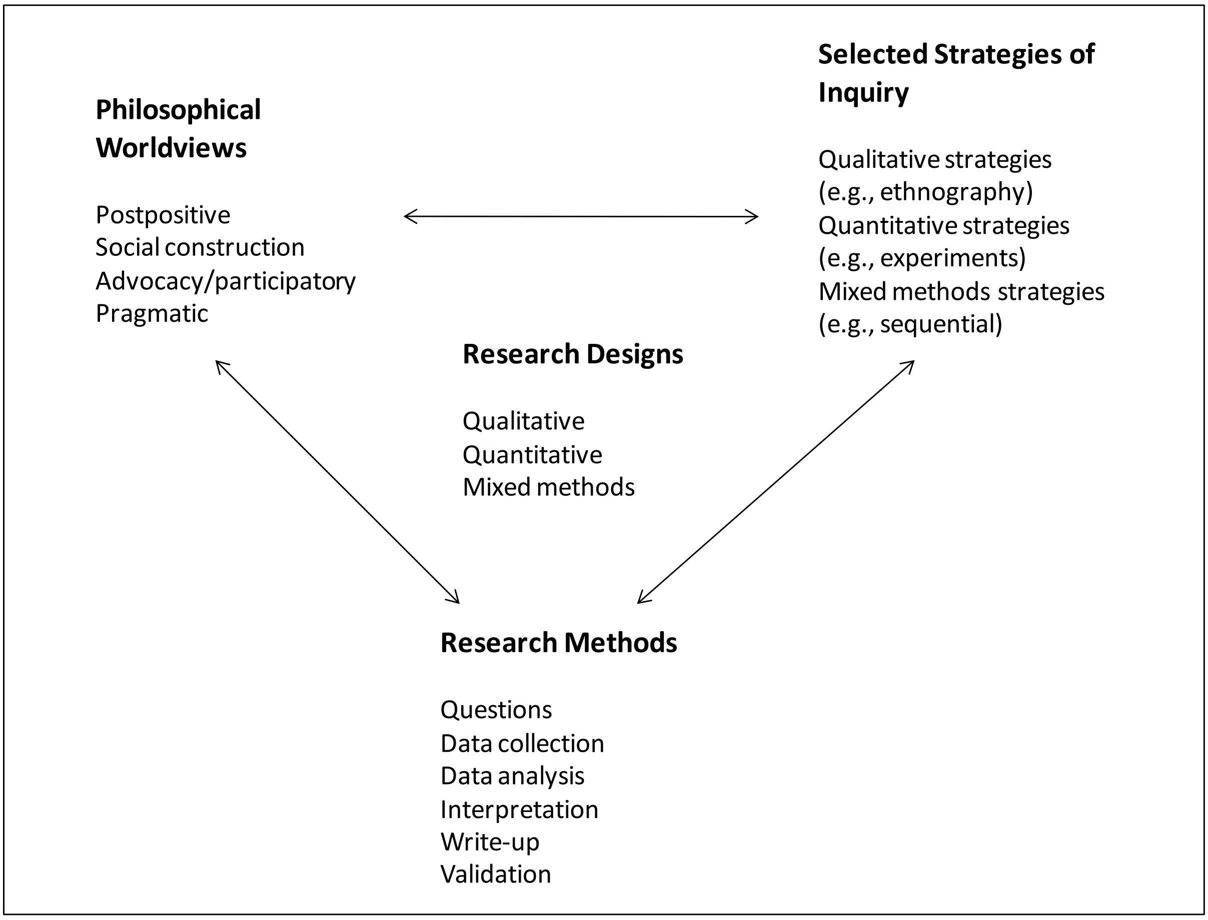


Figure 4.1: Creswell's (2009:5) framework for design – the interconnection of worldviews, strategies of inquiry and research methods

For the social construction worldview, the strategies of inquiry include phenomenology, grounded theory, ethnography, case study and narrative (Creswell, 2009).

The suggested methods to be employed for these strategies of inquiry include emerging methods; open-ended questions; interview data, observation data, document data, and audio-visual data; text and image analysis; and interpretation of themes and patterns (Creswell, 2009). The researcher's practices of research include: positioning themselves, collecting participants' meanings, focusing on a single concept or phenomenon, bringing personal values into the study, studying the context or setting of participants, validating the accuracy of findings, making interpretations of the data, creating an agenda for change or reform, and collaborating with the participants (Creswell, 2009).

Creswell (2009) also advocates a pragmatic approach to research, which removes emphasis from the defence of individual philosophical positions and rather concentrates on the context of the problem and the need for a solution.

The rationale for using an idiographic philosophical tradition for this study is the complex nature of the social interactions involved at the individual, organisational, institutional and national levels which underlie the dynamics of bioentrepreneurship. These interactions are non-linear and have multiple overlapping meanings, and are suitably studied through the case study method.

4.2 Strategies of inquiry underpinning this research

The strategy of inquiry used for this research is the case study.

Yin (2009) defines a case study as an empirical enquiry that:

> investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident (Yin, 2009:18).

The study of the dynamics of biotechnology entrepreneurship in South Africa and Brazil is exploratory. Most of the current empirical research is carried out in developed economies and cannot be directly extrapolated to developing economies owing to differences at individual, institutional and environmental levels between the developed and developing economies (Lingelbach et al., 2005). In addition, biotechnology entrepreneurship is a contemporary phenomenon (Yin, 2009) that needs to be investigated in depth and within its real-life context (Creswell, 2009). The "how" and "why" questions needed to explore and understand how biotechnology entrepreneurship is practised in developing economies also lend themselves to the use of the case study strategy of inquiry (Yin, 2009).

4.3 Research design

The design of this research is informed by the context of biotechnology entrepreneurship in developing economies. This context includes:

i. The nature of the research problem and the research questions to be answered, as detailed in Chapter 3
ii. The fact that current empirical research on this topic is based on developed economies, and very little empirical research exists for developing economies (Lingelbach et al., 2005)
iii. The possibility that entrepreneurship, and hence biotechnology entrepreneurship, is different across the developed and developing economies
iv. The move towards multidisciplinary approaches to entrepreneurship research (Shane, 2003; Murphy et al., 2006; Murphy and Welsch, 2010)
v. The need for methodological expansion in entrepreneurial research (Hindle, 2004)
vi. The need to achieve an in-depth understanding of the phenomenon of biotechnology entrepreneurship in developing economies through qualitative methods of inquiry in the idiographic philosophical tradition

Primary data from a case study design was used for this study. Multiple cases, comprising South Africa and Brazil, were investigated in order to achieve literal and theoretical replication (Eisenhardt, 1989, 1991; Yin, 2009). The individual cases were holistic within the multiple-case study. The case study was carried out at country level of analysis with interviews conducted with individuals associated with the biotechnology industry in various capacities. Environmental and institutional factors have key influences on the dynamics of biotechnology entrepreneurship at a country level. The use of a country level of analysis was expected to embody these environmental factors and be broad enough to provide a true understanding of the dynamics of biotechnology entrepreneurship in the developing economy context. In addition, conducting interviews with individuals within the biotechnology industry ensured that the lived dynamics of biotechnology entrepreneurship within its original context were adequately captured (Creswell, 2009; Yin, 2009).

The research design process followed was Yin's (2009) case study method as shown in Figure 4.2. There are three broad phases: define and design; prepare, collect and analyse; and analyse and conclude, which in total contain five steps.

Steps one and two fall under the "define and design" phase; steps three and four fall under the "prepare, collect and analyse" phase; and step five falls under the "analyse and conclude" phase.

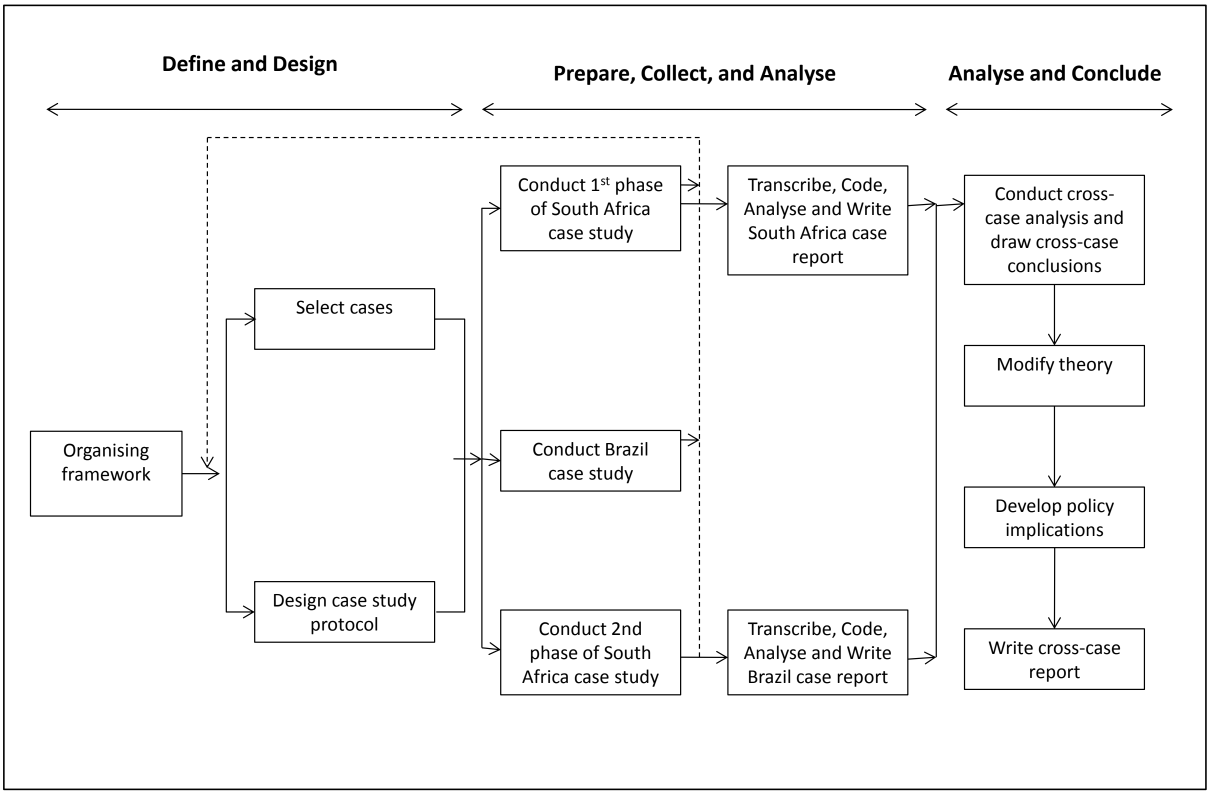


Figure 4.2: Case study method (adapted from (Yin, 2009)

The process started with an organising framework, based on the individual-opportunity nexus framework of entrepreneurship, which guided the definition of appropriate research design and data collection, and the analytical generalisation of the results of the case study (Yin, 2009).

Step two involved the design of a data-collection protocol and the selection of cases. The case selection criteria are outlined in Section 4.4.

Step three involved the conducting of interviews for the case studies in South Africa, and Brazil. The conducting of these interviews was expected to be sequential; hence, the completion of interviews in South Africa was to be followed immediately by interviews in Brazil. However, the initial interviews for South Africa were conducted; then followed by interviews in Brazil; before completing the rest of the South African interviews. The challenges of conducting research in multiple countries were highlighted in this study through the difficulty of securing appointments with key respondents within the same timeframe.

Step three led to the refinement of the organising framework; a review of the selected cases; and a review of the design of the data-collection protocol. The details of the data-collection technique are given in Section 4.5.

Step four involved the writing up of the individual case reports. This included the case narratives, case analysis, the discussion of the outcome of the analysis, and theory development.

Step five is the last step in this design model and in this study comprised the concluding activities of the study such as: drawing cross-case conclusions; modifying theory; developing policy implications; and articulating the methodological, empirical and theoretical contributions of the research.

4.4 The case selection

The focus of this study on a specific type of entrepreneurship, biotechnology entrepreneurship, limited the respondents to bioscientists who had started biotechnology companies or had utilised licensing to commercialise their intellectual property; and subject matter experts involved in biotechnology entrepreneurship through the university, industry or government. Hence, cases were selected purposively. In addition, industry documents were selected purposively to enable data triangulation and enhance the reliability of the research.

The use of homogeneous purposive sampling is aligned to the nature of the respondents for this study, who were expected to be hard to reach (Guest, Bunce and Johnson, 2006), especially considering that the study was conducted across two countries. The sampling methodology also supports the fact that the focus of this study was not on statistical generalisability (Miles and Huberman, 1999; Bowen, 2008) but on the understanding of the dynamics of biotechnology entrepreneurship in South Africa and Brazil within its original context (Yin, 2009).

4.4.1 Rationale for selecting cases

In the context of developing economies, there are other countries that could easily be considered for inclusion into this research, such as Malaysia and Indonesia. However, within the context of biotechnology entrepreneurship there are clear similarities that make Brazil and South Africa good candidates for this research.

Both countries are classified as efficiency-driven economies in the GEM study (Bosma and Levie, 2010; Kelley et al., 2012) and are seen as ideal emerging market partners for biotechnology alliances with developed economies (Veilleux, Haskell and Béliveau, 2010). In addition, they have fairly developed economy, government institutions, educational institutions, regulatory environment and markets according to the standard of developing countries (Veilleux et al., 2010).

On the basis of patent publication, both have fairly good representation of patent publications according to the standard of developing economies (Bound, 2008; United States Patent and Trademark Office, 2009) and are often included in the Organisation for Cooperation and Development (OECD) analysis and reports on biotechnology (Organisation for Economic Cooperation and Development, 2013d).

On the basis of the stage of their biotechnology industry, both have abundant biodiversity and advanced agricultural biotechnology (Cloete et al., 2006; Bound, 2008) and are considered as viable partners for direct foreign investment in biotechnology (Ernst & Young, 2010b).

In terms of government policy on biotechnology entrepreneurship, both have high level of government involvement and clearly defined policies on biotechnology development (Department of Science and Technology, 2001; da Silveira and de Carvalho Borges, 2005; Marques and Gonçalves Neto, 2007; Bound, 2008; Technology Innovation Agency, 2010; Ernst & Young, 2010b).

4.4.2 Rationale for selecting respondents

The purposive samples were made up of individuals with a high degree of knowledge and competence in the research topic (Romney, Weller and Batchelder, 1986; Bowen, 2008) and had either commercialised a biotechnological innovation through firm formation or licensing or were subject matter experts in the area of biotechnology entrepreneurship. The purposive selection of 12 respondents in South Africa and 5 respondents in Brazil, supported by 16 industry documents, rendered an accurate reflection of the dynamics of biotechnology entrepreneurship in South Africa and Brazil respectively (Romney et al., 1986; Guest et al., 2006).

Emphasis was placed on selecting respondents that were relevant to the phenomenon being studied, provided diversity across contexts, provided opportunities to learn about complexities and contexts (Stake, 2006), and explicitly supported literal and theoretical replication, in this way enhancing analytic generalisation of the outcome of the case study (Eisenhardt, 1989, 1991; Yin, 2009). With this in mind, the selection criteria included the following conditions:

i. All respondents were either bioscientists who started biotechnology companies, or utilised licensing, to commercialise their intellectual property or subject matter experts involved with biotechnology entrepreneurship at a university, or in industry or government
ii. The respondents worked in one of the areas of biotechnology entrepreneurship that are prioritised by the governments of South Africa and Brazil, which are industrial, health and agricultural biotechnology
iii. All bioscientists in the sample should have gone through the stages of the organising framework from bioentrepreneurial (entrepreneurial) opportunities to commercialisation of intellectual property (execution). Thus, they should have products that were already in the market or ready to be marketed
iv. All respondents should have engaged or should currently engage in varying degrees of collaboration with other biotechnology stakeholders

Access to the respondents was facilitated through the networks of the researcher's academic supervisors. In addition, the researcher established links to academic networks in Brazil through the biotechnology unit of Ernst & Young, respondents in South Africa after the first interviews, and online internet searches. Links were also established with the Biotechnology Unit of the Department of Science and Technology in South Africa, and similar links were established with other bodies directly or indirectly responsible for biotechnology policy development in South Africa and Brazil.

The profile of the respondents is attached in Tables 7.1 on page 152 and 8.1 on page 206.

4.4.3 Rationale for selecting documents

The documents reviewed and coded for this research were intended to augment the in-depth interviews in providing a complete and triangulated view of the dynamics of biotechnology entrepreneurship in South Africa and Brazil from multiple sources. The documents included in this research fall under the broad categories of policy documents and industry research documents from credible organisations such as the OECD, Ernst & Young, Biotechnology Industry Organisation (BIO), and Battelle.

The policy documents included legislated national policy documents on biotechnology, regional funding policy documents on biotechnology entrepreneurship, university intellectual property policy documents, and the policy document for the government innovation agency. The industry research documents included innovation policy reviews, science and technology industry outlook, agricultural innovation systems, industrial biotechnology, bio-economy, and the general biotechnology industry documents.

These documents were deemed to be credible, reliable, and provided information that enriched the understanding of biotechnology entrepreneurship in general and the context in developing economies in particular.

The documents included for the research in South Africa are:

i. National Bio-economy Strategy 2013
ii. Technology Innovation Agency (TIA) Act 2008
iii. OECD Reviews of Innovation Policy
iv. OECD Science, Technology and Industry Outlook 2010
v. WITS University Intellectual Property Policy 2012

The documents included for the research in Brazil are:

i. National Biotechnology Development Policy
ii. OECD Boosting Innovation Performance in Brazil
iii. FAPESP Creation and Structure Document
iv. FAPESP Co-ordination Document
v. OECD Science, Technology and Industry Outlook 2008
vi. OECD Managing Relations with Industry: The Case of Brazilian Universities

The industry documents that are applicable to South Africa, Brazil, and the developed economies are:

i. Ernst & Young Beyond Borders 2013
ii. OECD Agricultural Innovation Systems - A framework for analysing the role of the Government
iii. OECD Future prospects for industrial biotechnology
iv. OECD Bioeconomy 2030
v. Battelle/BIO 2012 State Bioscience Industry Development

The graphical depiction of the cases, respondents and documents selection aligned to the case study protocol is shown in Figure 4.3.

Under each of the cases, South Africa and Brazil, there are 3 groups of respondents, namely: bioentrepreneurs, subject matter experts and respondents that are both bioentrepreneur and subject matter expert. The subject matter expert group is further sub-divided into those respondents affiliated to university, industry or government.
There is a certain degree of overlap within the subject matter experts group, in which a respondent can be affiliated to more than one entity, such as university and government.

The fourth grouping under each case is documents. This comprises of industry and policy documents related to biotechnology entrepreneurship in this specific case.

The fifth grouping under the hermeneutic unit contains documents related to biotechnology entrepreneurship in general, which includes both cases as well as other developing and developed economies.

Note: The numbering of the respondents in South Africa is aligned to the sequence in which the transcripts were coded. Hence the first 5 interviews are numbered 1 – 5; then the next 7 interviews were numbered 11 – 17; and between these are the interviews conducted in Brazil, which are numbered 6 – 10.
Hence, there are a total of 12 respondents in South Africa and 5 respondents in Brazil.

Format for numbering respondents and documents

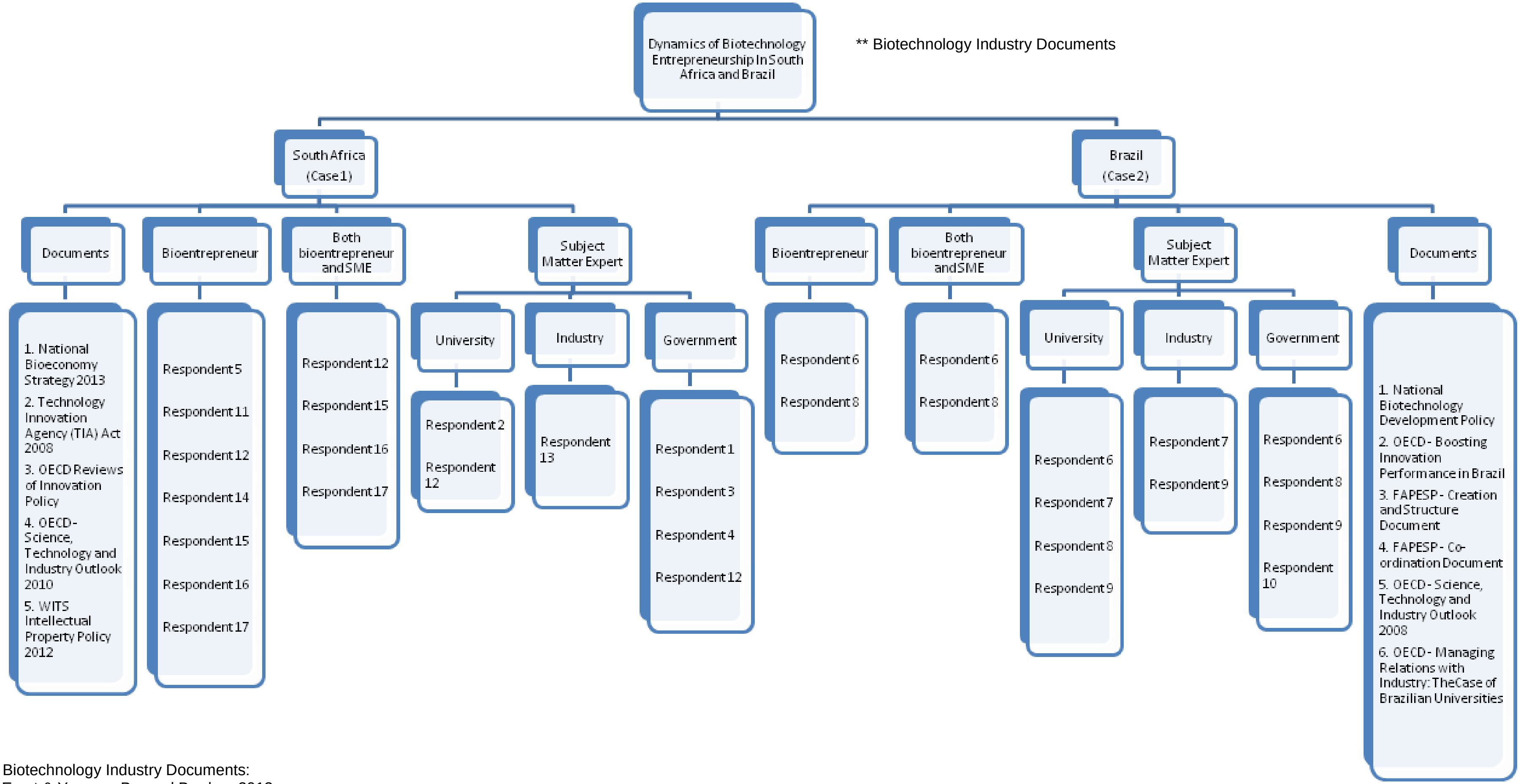
The numbering of respondents, and referencing of verbatim quotes, in the document was dictated by the Atlas.ti CAQDAS used for the data analysis, which analysed the transcripts sequentially and assigned primary document number. Hence, *(Respondent 11 6:46)* refers to interview number 11; primary document 6; transcript line 46.

Table 4.1 illustrates the format for numbering of respondents and referencing the transcript verbatim quotes from Atlas.ti..

Table 4.1: Format for naming respondents and referencing transcript verbatim quotes

Atlas.ti Primary document number	Interview number	Respondent	Case
PD 1	1	1	South Africa
PD 2	2	2	South Africa
PD 3	3	3	South Africa
PD 4	4	4	South Africa
PD 5	5	5	South Africa
PD 6	11	6	South Africa
PD 7	12	7	South Africa
PD 8	13	8	South Africa
PD 9	14	9	South Africa
PD 10	15	10	South Africa
PD 11	16	11	South Africa
PD 12	17	12	South Africa
PD 18	6	1	Brazil
PD 19	7	2	Brazil
PD 20	8	3	Brazil
PD 21	9	4	Brazil
PD 22	10	5	Brazil

The PD ranges P13 – P17 refer to the industry documents for South Africa; P23 - P25, and P32 – P34 refer to the industry documents for Brazil; and the range P27 – P31 refer to the industry document for the overall biotechnology industry (cross-case).



** Biotechnology Industry Documents:
1. Ernst & Young – Beyond Borders 2013
2. OECD - Agricultural Innovation Systems - A framework for analysing the role of the Government
3. OECD - Future prospects for industrial biotechnology
4. OECD Bioeconomy 2030
5. Battelle/BIO 2012 State Bioscience Industry Development

Figure 4.3: A graphical depiction of the case, respondents and documents selection for the research

4.5 Data collection

The process of data collection illustrated in Figure 4.4 was guided by the case study protocol (see Appendix C).

4.5.1 Development of data-collection instrument

The case study protocol was developed after the literature on biotechnology entrepreneurship was reviewed and subsequently the researcher chose two organising frameworks for the research. The data-collection process included multiple sources of evidence: in-depth interviews, documents and observations. This triangulation of data sources improves the quality of the research, as well as addressing validity and reliability issues (Creswell, 2000; Onwuegbuzie, Johnson and Collins, 2011).

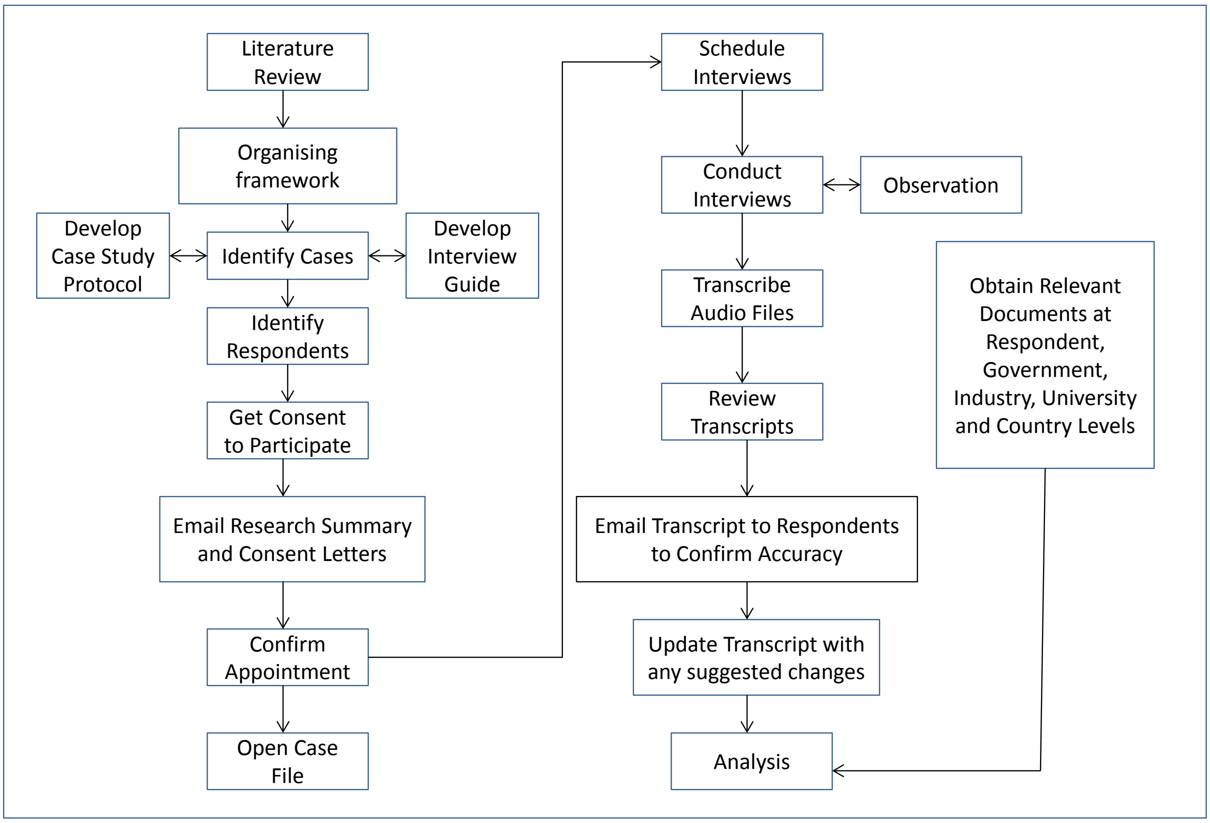


Figure 4.4: A graphical depiction of the data collection process

The case study protocol was developed concurrently with the interview guide and at this stage the two cases, South Africa and Brazil, were also identified.

The next step was the identification of appropriate respondents who fit into the category of respondents required for the research: bioentrepreneurs and subject matter experts in the biotechnology industry affiliated to university, industry or government. Some of the respondents were expected to be both bioentrepreneurs and subject matter experts.

Having identified appropriate respondents, the consent of the respondents to participate in the interviews was sought via email. Of the 12 respondents identified in South Africa, five responded positively. These five were included in the first phase of the case study in South Africa. Subsequently, another eight respondents were identified in South Africa and seven of whom agreed to participate in the research. This brought the total number of respondents in South Africa to 12.

Of the eight respondents identified in Brazil, five responded positively while the remaining three could not participate in the study because of their unavailability at the time the researcher conducted fieldwork in Brazil.

The next step involved sending the respondents the research summary and the consent letters for participation in the study and for the interview to be recorded. This was followed by the researcher's confirmation of the appointment and scheduling of the interview. This stage was performed concurrently with gathering the relevant documents for the research. With all the respondents confirmed and the relevant documents gathered, the case file was opened. Documents included formal prior studies of the same cases, university and government policy documents, and industry documents. This source of evidence yielded background information in the form of written evidence and descriptive statistics that were used to corroborate the other sources of evidence.

4.5.2 Observing the respondents

Observations require the researcher to be present in the real-life environment of the cases to record observed conditions (Creswell, 2009; Yin, 2009; Qu and Dumay, 2011; Klonoski, 2013). Observation as a source of evidence provided real-time information as it occurred and information that was not shared in the interview by the respondent. (A sample observational form is provided in Appendix G).

Observation includes the environment in which the bioentrepreneur or subject matter expert operates; the disposition of the respondent; the respondent's reactions to interview questions; and the attitude of the respondent. These were captured in the field notes by the researcher.

4.5.3 Conducting the interviews

Semi-structured interviews were conducted with the bioscientists and subject matter experts using the earlier-developed interview guide (see Appendices E and F) and the case study protocol (see Appendix D). The development of the interview guide was guided by a review of the literature, the research questions, and the organising frameworks.

The interview guide gave a general outline of the type of interview questions needed to cover all the relevant aspects of the study (Yin, 2009). Given that this was a semi-structured interview, the exact questions posed during the interview differed slightly on occasions but conveyed the same meaning and understanding. There was also scope to probe deeper, where necessary, in order to clarify the respondents' points of view.

The purpose of the protocol is to guide the operational conduct of the data-collection procedure by the investigator in a single case, which forms part of the multiple cases. The protocol is a standardised agenda for the investigator's line of inquiry (Yin, 2009). The effective use of the protocol for each case in a multiple case study guarantees uniformity of data collection aligned to the research questions, theoretical framework and propositions. This is expected to enhance the reliability of the research (Creswell, 2000; Onwuegbuzie et al., 2011).

Fifteen of the interviews were conducted at the respondents' offices. The location of the offices varied from universities, to a business park, a mall, government offices and business premises. Two of the interviews in Brazil were conducted at the respondents' homes because one respondent was on leave at the time and the other undergoing medical treatment.

Conducting the interviews at a time and place convenient to the respondents ensured that the respondents were relaxed and comfortable with accommodating the time needed for the interview, which was one to two hours in most cases. The interviews started with a detailed explanation of the research topic, with the researcher clarifying any question the respondent had from the research summary sent earlier. The respondents were then requested to sign the letters of consent to participate in the research and to have the interview tape-recorded.

The first interview in South Africa was used as a pilot interview to ensure that questions covered during the interview would provide answers to the research questions. This interview was transcribed and reviewed by the researcher's academic supervisor, and her recommendations were used to refine the interview guide for the interviews that followed. Subsequently each interview was reviewed to ensure alignment to the case study protocol, and to identify improvements that were needed for the remaining interviews.

All interviews were tape-recorded and transcribed and the transcripts confirmed as accurate by the respondents before being analysed by the researcher. In addition to the transcripts, the researcher maintained field notes to capture thoughts, observations and reflections on the research.

The transcripts (see Appendix H), documents and the researcher's field notes were the source of the data for the data analysis.

4.6 Data analysis

The qualitative data analysis for this research was conducted in the tradition of building theory from case studies in order to understand the "how" and "why" of contemporary events (Eisenhardt and Graebner, 2007b; Yin, 2009:8; Klonoski, 2013). The dynamics of biotechnology entrepreneurship in South Africa and Brazil were examined in detail to generate theoretical insights (Welch, Piekkari, Plakoyiannaki and Paavilainen-mäntymäki, 2011), understand their peculiarities (Stake, 2006), and the structures and contexts (Klonoski, 2013) in which observed behaviours were analysed.

A Computer Aided Qualitative Data Analysis Software (CAQDAS) package called Atlas.ti version 7.1.6 was used for the data analysis. The use of Atlas.ti was meant to aid rapid, consistent and rigorous qualitative data analysis (Weitzman, 1999; Rambaree, 2007; Hwang, 2008), and extended the researcher's ability to organise, remember and be systematic (Zdenek, 2008).

There were eight steps in the data analysis stage (see in Figure 4.5):

i. Deductive development of the codebook
ii. Preparation of transcripts and documents for coding
iii. Selection of data to code
iv. Coding of the primary documents and the generation of inductive codes and memos
v. Case narratives based on the outcome of the coding exercise
vi. Within-case analysis of cases 1 and 2
vii. Cross-case analysis
viii. Theory development

4.6.1 Deductive development of the codebook

The first step of the data analysis was the deductive development of the codebook (see Appendix I). Guided by the available literature, the proposed conceptual frameworks and the case study protocol, the codebook comprised 176 codes and 21 categories. The deductive codes developed in this step were appropriately described and formed the basis of the coding that occurred in step 3.

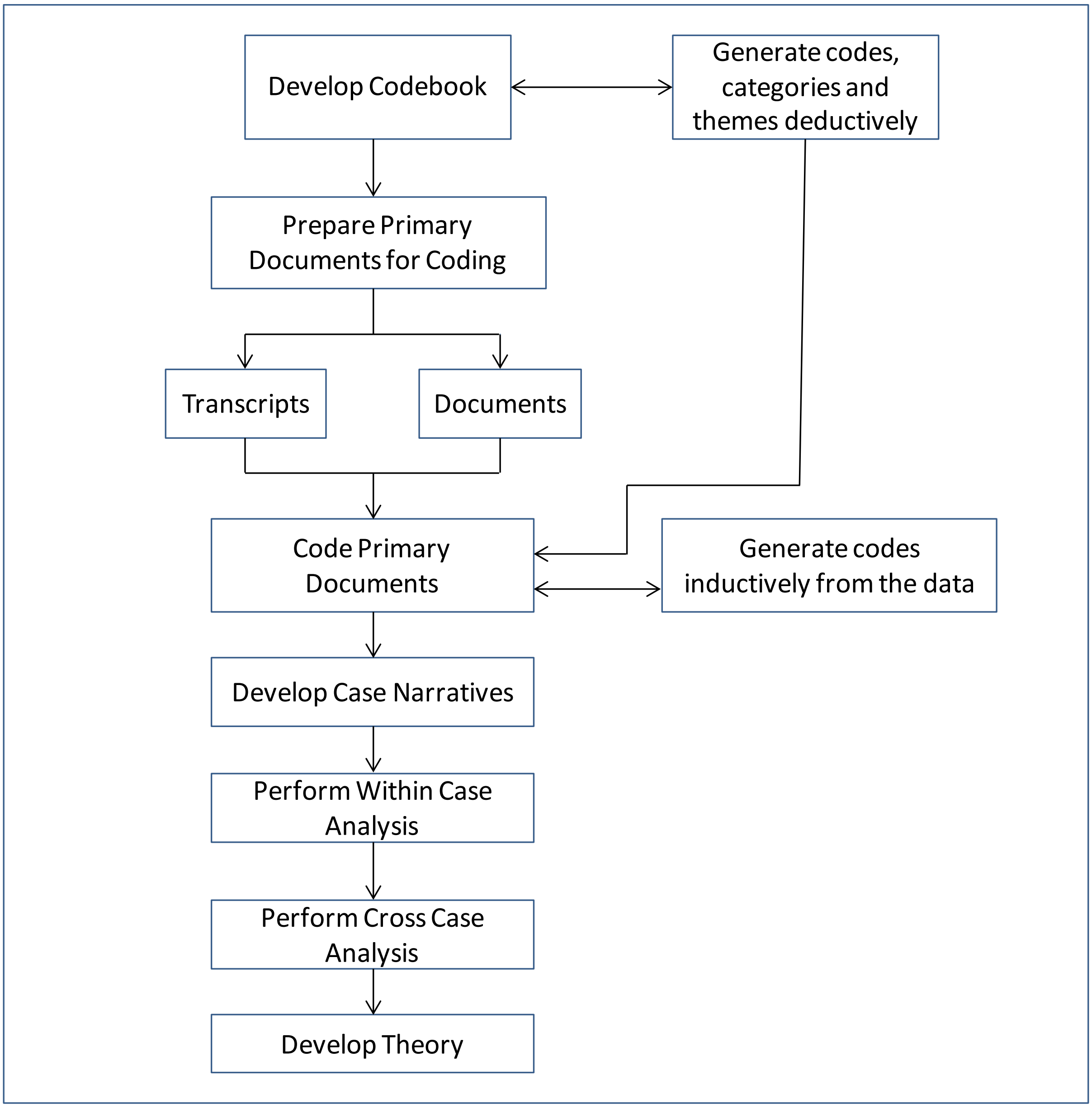


Figure 4.5: A graphical depiction of the data analysis process

4.6.2 Preparation of transcripts and documents for coding

The use of Atlas.ti required that the transcripts and documents, referred to as “primary documents”, be appropriately formatted for use in Atlas.ti (Hwang, 2008). The primary documents were saved as either MS Word or PDF documents prior to being loaded into the personal library created within the hermeneutic unit for the project. The hermeneutic unit is the container for the project and holds all the documents and resources necessary for the project. A total of 33 primary documents were loaded into the personal library comprising 17 interview transcripts and 16 policy and industry documents.

Prior to commencing with coding, the primary documents were grouped into primary document families, representing the units of analysis for the research at country and individual levels. This was an aggregation of the code families and categories into super families (Hwang, 2008; Zdenek, 2008). The super families were: “All respondents” (which represented a country level of analysis); “bioentrepreneurs”, “both bioentrepreneur and subject matter expert”, and “subject matter experts” (which represented an individual level of analysis); and documents (which represented an industry level of analysis). These were created at the level of individual cases and at a cross-case level to enable the within-case and cross-case analysis (Stake, 2006; Yin, 2009) later on.

In addition to preparing the primary documents and creating the primary document families, the deductive codes were manually transferred into Atlas.ti and appropriately described. The codes were also grouped into code families, which represented the categories. The completion of this step was the prerequisite for carrying out the actual coding in the next step.

4.6.3 Selection of data to code

The selection of data for coding was driven by the need to embed the outcome of the coding process in the data, to understand the exact meaning of what the respondents were saying within the context of the research, and to reflect the reality being portrayed in the data segment or quotation accurately (Corbin and Strauss, 2008). Hence, data segments were carefully chosen either to validate the deductive codes or to lead to the generation of inductive codes as a starting point to the development of theory (Charmaz, 2003).

4.6.4 Coding of the primary documents

The primary documents consisted of 402 pages of interview transcripts, 423 pages of documents related to the two cases at country level, and 817 pages of industry documents. This made up a total of 1,642 pages. Most of the industry documents were from credible organisations such as the OECD and Ernst & Young. In addition to the primary documents, 73 memos were created during the course of the coding exercise.

The sequence of the coding was a complete coding of all primary documents related to case 1 in the order in which the interviews were conducted, followed by the coding of all primary documents related to case 2 in the order in which the interviews were conducted.

The primary documents were coded line-by-line to ensure intimacy with the data and accurate understanding of the meaning (Corbin and Strauss, 2008). The deductive codes were assigned to quotations where appropriate and inductive codes (see Appendix J) were created whenever new insights emerged. A total of 170 inductive codes were created in the coding process. This, combined with the 176 deductive codes, resulted in a total of 346 code, which was further rationalised to 335 codes. One new category was also created through the inductive process thereby increasing the number of categories to 22.

This study does not qualify as pure grounded theory (Corbin and Strauss, 2008) as it used both deductive and inductive coding, and involved theory testing and theory development (Lillis, 1999; Miles and Huberman, 1999). However, it can be noted that the number of inductive codes was higher than deductive codes post rationalisation. Furthermore, 29 of the 165 deductive codes were redundant and did not appear in any of the quotations.

Demonstrating data saturation

Data saturation was demonstrated for both cases (Figures 4.6 and 4.7) using Atlas.ti CAQDAS. The definition of saturation in this context is the point where little or no new codes (insights) are generated from additional respondents or documents (Morse, Barrett, Mayan, Olson and Spiers, 2002; Guest et al., 2006).

Figure 4.6 shows that 43% of all the unique codes were generated from the first respondent; 84% by the 12th respondent; and 100% of all the unique codes for case 1 generated by the 16th respondent (document). Hence, no new additional insights were generated from the last respondent (document).

The spikes at "P5: Interview 5" and "P13: Bioeconomy Strategy_Dev2" mark the first transcript of a bioentrepreneur after four subject matter experts (SMEs) and the first coded document after transcripts of SMEs and bioentrepreneurs respectively.

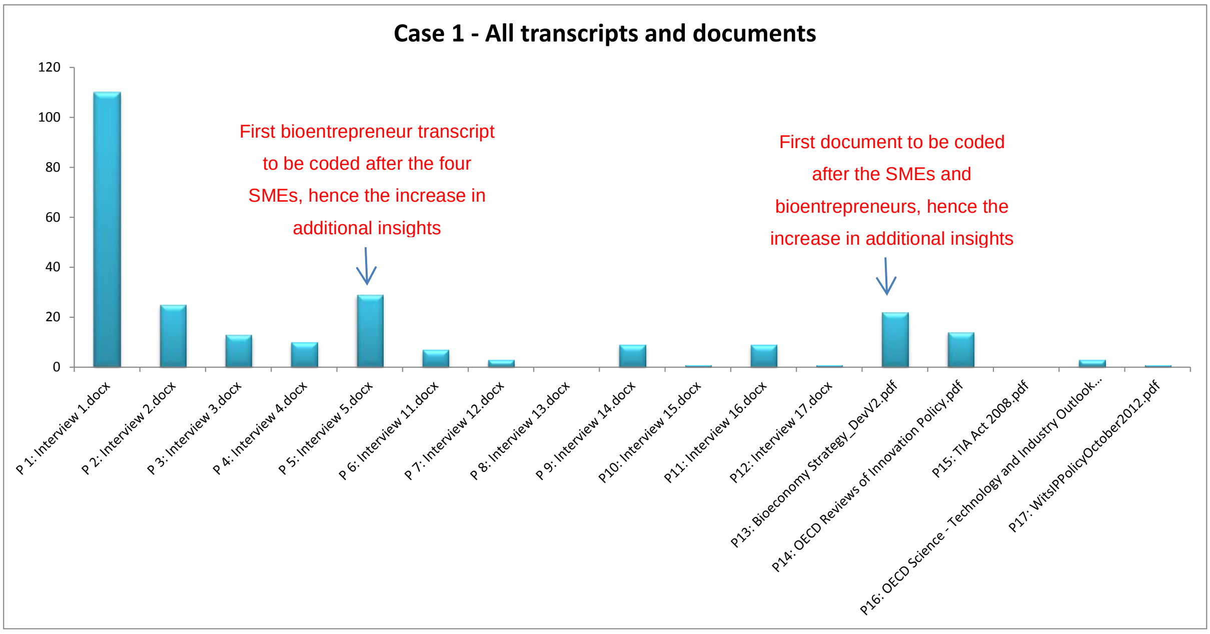


Figure 4.6: Demonstration of data saturation for South Africa

Figure 4.7 shows that 44% of all the unique codes were generated from the first respondent; 77% by the fifth respondent; and 93% of all the unique codes for case 2 generated by the sixth respondent (document). Hence, very little new additional insights were generated from the seventh respondent (document).

The spike at "P34: National Biotechnology Development Policy" marks the first coded document after transcripts of SMEs and bioentrepreneurs.

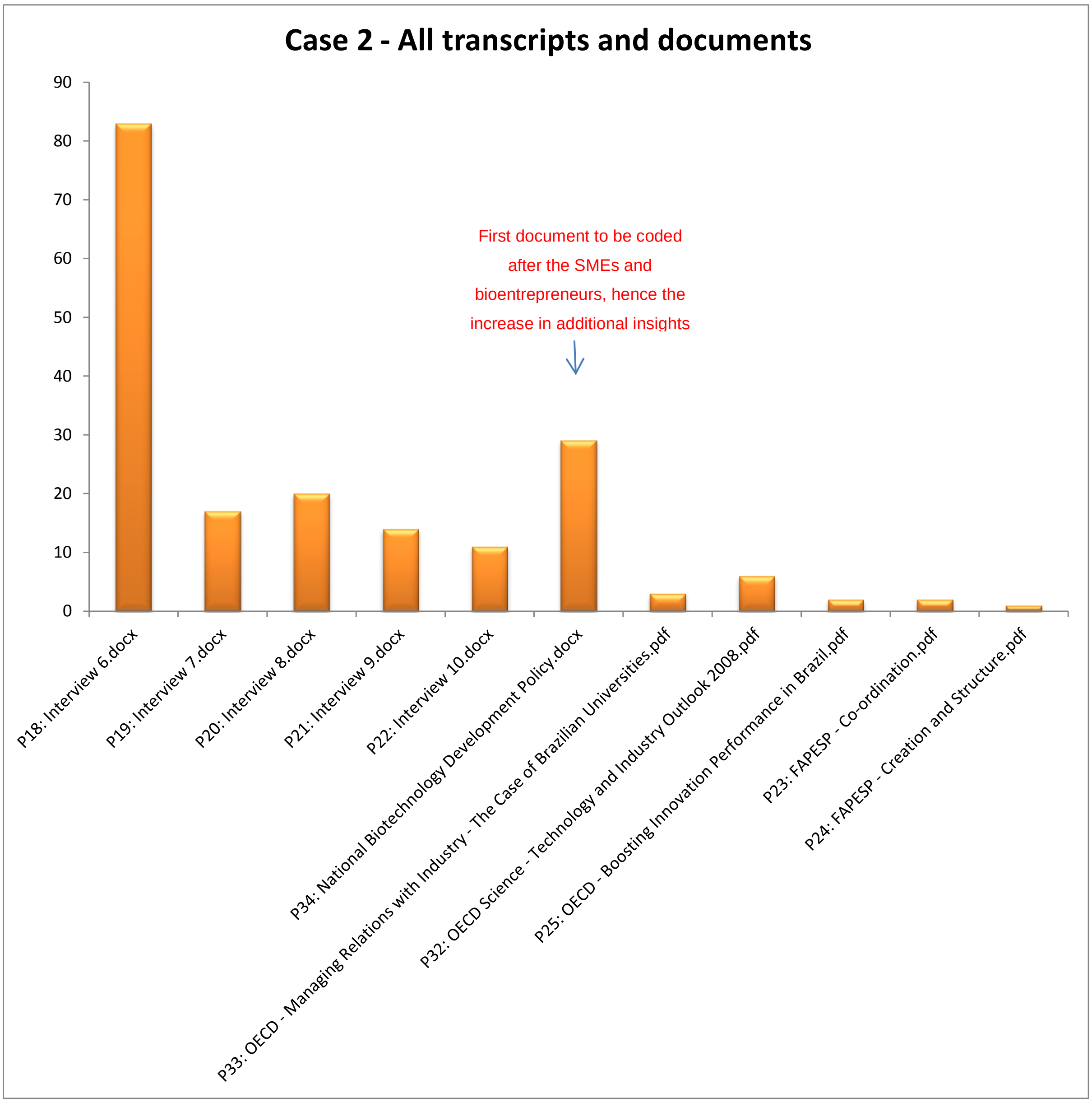


Figure 4.7: Demonstration of data saturation for Brazil

4.6.5 Case narratives

The case narratives tested the alignment of the data to the organising frameworks of the individual-opportunity nexus (Shane, 2003) and the triple helix of university, industry, government relations (Etzkowitz and Leydesdorff, 2000). The case narration was carried out for each case under the headings of "individual level influences”; “business level influences”; “macro-environment influences”; “triple helix relationships”; and “similarities and differences between South Africa or Brazil and the developed economies”.

The personal views of the researcher were captured under the “observations” sub-heading and were intended to enrich the discourse within objective parameters (Eisenhardt and Graebner, 2007b). However, since these observations are not part of the case study data, they have been limited to the case narratives section of the research. The personal views of the researcher contributed to the “thick” description of what was observed during the interview process.

The verbatim quotes enabled the grounding in data of the patterns that eventually emerged in the within-case analysis stage. The aggregated responses of the respondents captured the predominant insights as well as divergences from the predominant view where such divergences were material to a deeper understanding of the real-life experiences of the respondents.

The case narratives provided a rich, “thick” description of the experiences of the respondents within a real-life context (Eisenhardt and Graebner, 2007b; Yin, 2009) of biotechnology entrepreneurship, which guided the identification of patterns; as well as theory development (Carroll and Swatman, 2000; Eisenhardt and Graebner, 2007b; Welch et al., 2011; Klonoski, 2013).

4.6.6 Within-case analysis

The detailed within-case analyses integrated the deep interrogation of the current empirical and market research studies on biotechnology entrepreneurship in South Africa and Brazil; interview transcripts; the output of Atlas.ti CAQDAS; and documents. This was done to get to a consistent and rigorous analytical view (Weitzman, 1999; Rambaree, 2007; Hwang, 2008) of the dynamics of biotechnology entrepreneurship in South Africa and Brazil within its original context (Eisenhardt and Graebner, 2007b; Klonoski, 2013). The patterns identified represented a further aggregation of data to a higher level of abstraction towards theory building (Lillis, 1999; Miles and Huberman, 1999; Eisenhardt and Graebner, 2007b; Klonoski, 2013).

The organising frameworks of the individual-opportunity nexus (Shane, 2003), and the triple helix of university, industry, government relations (Etzkowitz and Leydesdorff, 2000) were utilised to analyse how biotechnology entrepreneurship is carried out in South Africa and Brazil; establish the similarities and differences between this process and the process in the developed economies based on the literature reviewed; and examine the experience of the triple helix relations among the university, industry and government in South Africa and Brazil.

The outcome of the within-case analyses showed the process of biotechnology entrepreneurship as experienced by the respondents in this research. The analysis revealed similarities and differences between South Africa and Brazil; as well as between these two developing economies and the developed economies based on the literature reviewed. Most of these differences were in the environment of biotechnology entrepreneurship, especially related to policy and regulation, funding, aggregate skills, the role of government, the size of the market, and university culture. Differences also related to the nature of bioentrepreneurial opportunities; the scale of R&D; infrastructure and support availability; and the strategic alliances necessary to exploit bioentrepreneurial opportunities.

The similarities were mostly in the psychological and non-psychological attributes of the individual bioscientists and the abundant biodiversity that was considered a competitive advantage for South Africa and Brazil, but not the developed economies.

The triple helix of university, industry, government relations as experienced by the respondents is different from what is achivable in the developed economies as revealed by the empirical research reviewed (Etzkowitz and Leydesdorff, 2000). Both South Africa and Brazil have a hybrid type of triple helix relations that bypasses the sequential progression from triple helix I, to triple helix II, to triple helix III and is characterised by the strong influence of the government.

4.6.7 Cross-case analysis

The cross-case analysis of the combined cases yielded themes, which acted as the building blocks to the proposed theoretical framework of biotechnology entrepreneurship and were compared to the literature in order to deepen interpretation and understanding, as well as enhance generalisability (Eisenhardt and Graebner, 2007b; Welch et al., 2011; Klonoski, 2013). The themes identified in the cross-case analysis stage were used to explore the "how" and "why" (Yin, 2009) of the dynamics of biotechnology entrepreneurship in South Africa and Brazil in the theory development phase.

4.6.8 Theory development

The final step in the data analysis section is the development of theory based on the identified themes in the cross-case analysis stage. This step involved the interrogation of the themes to provide explanations and develop the theory of the dynamics of biotechnology entrepreneurship in South Africa and Brazil. This process enhances the internal validity, generalisability and the theoretical contribution of the research to the extant literature (Eisenhardt and Graebner, 2007b; Yin, 2009; Welch et al., 2011; Klonoski, 2013).

The process of building theory from case study research described by Eisenhardt (1989) goes through eight stages:

i. Getting started, in which the research questions are defined
ii. Selecting cases appropriate to the context being studied
iii. Crafting instruments and protocols for multiple data collection
iv. Entering the field
v. Analysing the data using within-case analysis and cross-case pattern search
vi. Shaping hypothesis using iteration, replication and search for the evidence of "how" and "why" behind relationships
vii. Unfolding literature compared with existing conflicting and similar literature
viii. Reaching closure through theoretical saturation

These steps are similar to the case study method suggested by Yin (2009) (see Figure 4.2), which was followed by the researcher. Yin's (2009) method has three stages:

i. Define and design (develop theory, select cases, design case study protocol)
ii. Prepare, collect, and analyse (conduct case studies, transcribe, code, conduct within-case analysis)
iii. Analyse and conclude (conduct cross-case analysis, draw cross-case conclusions, modify theory)

The difference between the method followed for this study and that proposed by Eisenhardt (1989) is that this research started with an organising framework of entrepreneurship. The other steps are the same as that proposed by Eisenhardt (1989). This means that there is a combination of a deductive and inductive approach to theory building (Lillis, 1999; Miles and Huberman, 1999; Carlile, 2004).

This approach was chosen because of the relative abundance of empirical literature on entrepreneurship but very few studies, which are specifically related to biotechnology entrepreneurship in the developing economies context. Hence, the proposed conceptual framework was based on Shane's (2003) individual-opportunity nexus framework of entrepreneurship from which the conceptual framework of biotechnology entrepreneurship was adapted.

The proposed theoretical framework that emerged from this research showed the dynamics of biotechnology entrepreneurship in South Africa and Brazil. The comparison of this proposed theoretical framework to the organising frameworks that guided the research clearly demonstrated the theoretical contribution of this research to the body of knowledge on the process of biotechnology entrepreneurship in South Africa and Brazil.

4.7 Validity

This section outlines the steps taken to ensure that construct and external validity is enhanced. Although this research is exploratory, inferences made in the conducting of the study were based on the convergence of evidence from multiple sources, which led to triangulation, with rival explanations and possibilities considered (Miles and Huberman, 1999; Yin, 2009). This enhances internal validity.

Construct validity was enhanced by following clearly specified operational procedures which are aligned to the steps in the proposed organising framework of entrepreneurship (see Figure 2.2 on page 16). Multiple sources of evidence, and the review of draft transcripts by respondents were also used to enhance the construct validity of this study (Stake, 2006; Yin, 2009).

External validity was enhanced by the use of literal and theoretical replication logic (Yin, 2009) in the multiple case design. The case-selection criteria (Section 4.4) were designed to ensure that the external validity of the study was enhanced.

Although purposive sampling was employed, this may not have reduced the theoretical generalisation of this study because this generalisation is confined to the dynamics of biotechnology entrepreneurship in the developing economies of South Africa and Brazil. Generalisation to all developing economies may be hampered by differences in individual, institutional and environmental contexts. However, the fact that this is an exploratory study lends itself to improvements of external validity through further research.

4.8 Reliability

Reliability for this study was enhanced through the development of a research design that integrates different aspects of the study, such as the research problem, literature review, research questions, theoretical framework, and data-collection and analysis methods, in a logical manner (Miles and Huberman, 1999). Reliability was further enhanced by the use of an interview guide (Bell, 2005; Leedy and Ormrod, 2005); the use of a case study protocol; and the development of a case study database (Yin, 2009).

In addition, at the level of data collection, the triangulation of data sources at multiple levels was aimed at enhancing the trustworthiness of the outcome of this research (Bowen, 2008).

At the level of interview transcription, each transcript was reviewed by the researcher and validated by the respondent as an accurate reflection of the interview before being included in the data analysis.

At the level of data analysis, data saturation was demonstrated across all super families. Furthermore, the coding process was iterative to capture the underlying meaning expressed by the respondents accurately. Where this could not be captured by the deductive codes, inductive codes were developed.

At the level of reporting, thick descriptions were provided in the case narratives in order to answer the "how" and "why" questions related to the dynamics of biotechnology entrepreneurship in South Africa and Brazil (Yin, 2009). This was supported by verbatim quotations from the interview transcripts.

Finally the conclusions drawn from the research and the theory developed were informed by the literature on biotechnology entrepreneurship, the data and the rigorous application of the principles for qualitative inquiry and multiple case study methodology (Lincoln and Guba, 1986; Eisenhardt, 1989, 1991; Guba and Lincoln, 1994; Miles and Huberman, 1999; Creswell, 2000; Denzin and Lincoln, 2000b, 2000a; Lincoln and Guba, 2000; Stake, 2006; Eisenhardt and Graebner, 2007b; Corbin and Strauss, 2008; Creswell, 2009; Yin, 2009; Klonoski, 2013).

4.9 Limitations of the study

i. This study may have been limited by the chosen sampling procedure, which was purposive and not random. An attempt was made to achieve analytic generalisation, rather than statistical generalisation (Yin, 2009)
ii. The inability of the researcher to speak or understand Portuguese may have limited the range of literature that could have been reviewed for this research in Brazil.

4.10 Delimitations of the study

I. This study includes only entrepreneurial bioscientists who started biotechnology companies, or utilise licensing, to commercialise their intellectual property and biotechnology entrepreneurship subject matter experts
II. The proposed theoretical framework from this study is based on Shane's (2003) individual-opportunity nexus conceptual framework of entrepreneurial process.

4.11 Ethical considerations

The design of this study takes into account important ethical issues related to the respondents, such as fair and professional treatment of respondents; satisfactory steps taken to guarantee anonymity; full and complete disclosure of the purpose of the study (see Appendix A); obtaining respondents' consent to participate in the study willingly (see Appendix B); and verification of the accuracy of transcripts by the respondents before being taken as the final version.

PART II: CASE NARRATIVES

Part II consists of chapters 5 and 6.

Chapter 5 is a narrative summary of the transcripts of the interviews conducted in South Africa.

Chapter 6 is a narrative summary of the transcripts of the interviews conducted in Brazil.

Each summary narrative describes the experience of the process of biotechnology entrepreneurship by the respondents, using the verbatim quotes expressed during the interviews.

Chapter 5: Case Narrative – South Africa

The narrative summary of the transcripts of the interviews conducted in South Africa is provided in this chapter. The interview guide was used to organise the narratives according to categories identified from the literature reviewed, as shown below:

i. Individual level influences
ii. Business level influences
iii. Macro-environment influences
iv. Triple helix relationships
v. Similarities and differences between South Africa and the developed economies

The case narrative describes the experience of the process of biotechnology entrepreneurship by the respondents in South Africa, using the verbatim quotes expressed by these respondents during their interviews.

5.1 Individual level influences

The category individual level influences considered the dynamics that exist at individual level across the respondents in South Africa. There is a relatively low level of inter-connectedness across the university, industry, and government spheres by both the bioentrepreneurs and the subject matter experts in this study. Most of the respondents operate in academia, industry or government but not across these entities.

> *I am not a biotechnologist by training, but I am a biologist. I have a research management background, and when the strategy was introduced they were looking for someone who could actually implement it and I seemed to have the right credentials for that. (Respondent 1 1:143)*

> *I have to provide basically a scientific innovation environment, focussed on applying their skills to some of our unique resources, particularly our*

biological resources and genetic resources in South Africa. (Respondent 4 4:1-2)

The lack of experience of working across multiple entities by the respondents in South Africa results in individualism, self-preservation and the tendency to employ the “individual” approach to biotechnology entrepreneurship. This also encourages unhealthy competition instead of collaboration.

> *I would like to say that I am truly committed to creating techno entrepreneurs, which I am, as long as it is not competing with me.*
> *There is an element of caution. I do not want to create competition to my entity, so it is a little bit ironical because I am a bioentrepreneur but at the same time, my immediate staff I do not want to create a potential threat to my organisation through a discovery that can commercially turn over my company. Because to be an entrepreneur in the first place you have to be tenacious, aggressive, protective, competitive and anti-competitive – you do not want competition. So I do not support competition to me. (Respondent 5 5:70-72)*

The language of the bioentrepreneurs in South Africa was devoid of terms that related to collaboration and instead portrayed an inclination to demonstrate personal achievement rather than develop an industry.

> *I imported some products, so I acquired some market share and generated some cash and used that cash to set up my own manufacturing facility. (Respondent 11 6:10)*

On the few occasions where the respondents worked for more than one of the university, industry, or government entities they worked in an advisory capacity for the development of the bioeconomy strategy; and not in a collaborative project or in a permanent position in these entities.

> *Although I have never been employed by government I have worked a lot for government on various things in the Department of Health and Science*

and Technology. So I have been involved in drafting legislation and policy in both departments for many years. And I have seen the bioeconomy strategy because I have been working on it now with the people at DST (Department of Science and Technology) for several years in one way or another. (Respondent 12 7:4,38)

The lack of inter-connectedness among the respondents in South Africa meant that the individual influences were very personal and shaped by the individual bioscientist's personal circumstances. This may explain why there were no known successful collaborative projects carried out in the biotechnology industry in South Africa; a lack of effective collaboration among the key stakeholders; internal competition among the stakeholders; and a lack of trust.

These individual influences were also observed during the field work and articulated in the Section 5.1.1 below.

5.1.1 Observations during fieldwork

Some of the interesting observations during fieldwork that are worthy of inclusion in this report relate to the magnitude of gaps highlighted by the respondents in South Africa; the role of apartheid in creating mistrust among the stakeholders in the biotechnology industry; and the differences between individual and official views of the stakeholders affiliated to the government.

It was observed that the predominant experience of the respondents was more negative than positive from the numerous challenges raised by the respondents. While some expressed their frustration in a more subtle way, others had an extremely negative view of a lack of prospects for biotechnology entrepreneurship in South Africa.

But you know it is an industry that sort of showed promise, there was a little spark but it is, in my view it is died. That spark has died. (Respondent 13 8:20)

The second noteworthy observation relates to the racial dynamics in South Africa, which were caused by apartheid. The role of apartheid in the level of trust between the stakeholders in the industry was highlighted as a constraint.

> *But I think we still carry the burden of apartheid with us. Where there is still a lot of mistrust, there is still a lot of people not wanting to relinquish power, and I say that in inverted commas, or responsibility to people who would actually be more competent in them because they do not want to end up in the same situation that they were in many years ago. (Respondent 12 7:44)*

This race-based social dynamic is further highlighted in the South African government's affirmative action policies aimed at redressing the consequences of apartheid.

> *Then I am not black enough but I still have to pay tax, I am white enough to pay tax and I am white enough to employ people, that I am white enough to do. (Respondent 17 12:40)*

The third interesting observation relates to the conflict between the personal and official views of the subject matter experts affiliated to the government on biotechnology entrepreneurship in South Africa.

> *But then you must take it as my opinion as opposed to what is in the government policy. (Respondent 1 1:150)*

> *Although I work for the government, the view may not be representative of what the agency feels on biotechnology, so as I say it is my personal view based on my experience in the area. (Respondent 3 3:1)*

These respondents were tasked with implementing the policies related to biotechnology entrepreneurship in South Africa, even though they did not agree with the approach taken by government in implementing these policies.

5.2 Business level influences

The environment in which biotechnology entrepreneurship takes place in South Africa includes economic, regulatory, policy, social, cultural and political environments. The extent to which this environment is conducive to the development of biotechnology entrepreneurship determines the success or failure of strategies and initiatives aimed at improving the biotechnology industry in South Africa.

According to the respondents, the dynamics of biotechnology entrepreneurship in South Africa face many challenges among which are lack of direction and leadership from the government; lack of appropriate funding; lack of aggregate skills; lack of a developed market for biotechnology products and solutions; lack of infrastructure and support structures; low level of research and development spend; an inclination by the universities to prioritise research publication over commercialisation; the loss of skills through the brain drain; and the low level of commercialisation of research.

> *But I think one of the biggest caveats is that that environment, that nurturing environment is not there, either virtually or physically. (Respondent 14 9:65)*

> *There is a tremendous amount of entrepreneurial spirit. There is a strong desire for people to get involved; there are a lot of creative ideas but there are significant obstacles to people realising those goals. (Respondent 12 7:18)*

> *And I do not think we have a biotech industry so to say in South Africa. (Respondent 3 3:53)*

Lack of direction and leadership from the government

The role of the government as a facilitator in the development of biotechnology entrepreneurship in South Africa entails setting the direction, and providing the leadership needed for the effective development of the biotechnology industry. Some of these functions are fulfilled through the government agencies tasked with these responsibilities, such as the Department of Science and Technology (DST) and the Technology Innovation Agency (TIA). While the role of the government is known and acknowledged, the experience of the respondents did not show that the government had effectively carried out this role.

> *Government has to take the lead and drive the development of the sector, which means that government leadership in South Africa, in our context is more important than perhaps in developed economies where their systems are operating. (Respondent 1 1:21)*

> *Government needs to carefully consider the regulations in this area, and the policies. They also need to provide a bit more guidance on what the needs really are. Where are the priority areas in government?*
> *So I think from government's side they need to provide more guidance in these areas. And more emphasis to the scientists, to the researchers involved in these areas. We need to move away from bureaucracy. (Respondent 4 4:51-55)*

> *So that is why we need a development strategy that says, here and here is going to be the focus around development, and for that we need strong universities, we need lots of ideas that are coming out of that space. We need ways to ensure that those ideas are commercialised, so that we kick-start this ball rolling. (Respondent 2 2:139)*

The establishment of TIA was meant to improve the ability of the government to fulfil its role of providing direction and leadership effectively. However, the challenges experienced by the respondents in this research meant that TIA had not achieved this objective yet.

> *TIA is not functioning optimally yet. What TIA should be doing, but it's not yet doing properly, is stimulating the bio-economy. It should be creating critical mass in certain areas. (Respondent 1 1:118-120)*

I think the biggest disappointment that many of us in the field have had over the last 2 or 3 years is that the instrument that TIA was meant to represent has not, has not come to the party, has not come to the fore and the delays that people are experiencing with TIA at the moment have actually meant that in several cases, businesses have had to close down and that is an absolute tragedy in a country where there is such a strong will to grow biotechnology but there was this major obstacle. (Respondent 12 7:20)

Well I do not know what TIA is doing you know. By the time I pulled out of this sector I was so the hell-in with the BRICS and TIA and what I had seen with the inability to move forward. You know I had problems with the way the BRICS were doing things but then when TIA was on the cards, basically the whole sector froze and nobody was willing to make decisions or move forward because no one knew what was happening and what TIA was doing and how much money there would be. So for 2 or 3 years there was just no money. And I just saw biotech companies fall by the wayside. Just literally dropping like flies because there was nobody to fund them. And I saw a bunch of technology move offshore. The government has no idea it is gone. So if you want to develop your local sector government has to come to the party. (Respondent 13 8:30-32)

TIA in particular but also some of the other institutions that I am aware of. As institutions they fail, they fail to establish what they have been mandated to do. With TIA there is a history of failure, failure to deliver, failure to be on time with payments, failure to be responsible with tax payers' money, failure to be responsible in the projects that they run with, it is just complete failure. In general people talk about them as a technology incompetent agency and not an innovation agency. (Respondent 17 12:13-15)

In contrast to the experience of the respondents regarding TIA, at least two respondents experienced effective fulfilment of the government's role by agencies such as the DST and the Department of Trade and Industry (DTI).

I have been quietly impressed, particularly with our two departments which are involved in this, the Department of Science and Technology and the Department and Trade and Industry. I think they have got a number of very good programmes in place of which my company has been a beneficiary and so was the University. (Respondent 15 10:35)

The Department of Science and Technology have been phenomenal in their support of this sector but none of the other ministries have bought into it. DTI has not bought into it, Treasury has not bought into it, and more importantly Department of Health and Agriculture had not bought into it. (Respondent 13 8:52)

The contradictory experience mentioned above may point to the veracity of the expressed lack of government direction and of leadership being localised to a particular agency and not generalised.

Another area of government's failure to provide leadership was deemed to be its inability to curb bureaucracy and provide efficient services and processes.

You will just be astounded at some of the bureaucratic obstacles to commercialisation. It is not that it can't be done but it certainly seems as though South Africa is not making it easy to commercialise a product. (Respondent 1 1:83-84)

Given the role of the government as facilitator in the development of biotechnology entrepreneurship in South Africa its inability to provide effective leadership and direction to the biotechnology industry hampers the development of the industry.

Lack of appropriate funding

The lack of appropriate funding for the development of biotechnology entrepreneurship in South Africa is another gap identified by most of the respondents in the environment of biotechnology entrepreneurship in South Africa.

> *It is financial, a very big component. But it is the right kind of financial. So it is not just a case of like earmark more money. (Respondent 13 8:49-50)*

> *The next challenge is the funding gap, but that money is not prepared to take the risks. So the issue is, how do you de-risk the opportunities and then the money will flow. (Respondent 2 2:85-86)*

> *In South Africa we have a low risk appetite for entrepreneurs in general and the funding of entrepreneurs. (Respondent 3 3:5)*

The lack of appropriate funding in South Africa resulted in some of the respondents meeting their funding needs overseas.

> *If you got a really big idea then you should probably look for your funding overseas that is what I like to do now, I am raising ten million dollars and no South African bank or investor can even come close to the funding.*
> *I think they are more advanced in accepting the opportunities for new ideas, and I think the funds are more readily available. (Respondent 15 10:24-25)*

> *So I think that one of the things to get right is the finance. (Respondent 15 10:32)*

> *We have got a foreign balance sheet, we have establish everything from foreign balance sheet, we have funding from BioVentures and industrial development corporation (IDC) they are also a shareholder, but largely we put in a foreign balance sheet. (Respondent 16 11:34)*

A key component of the funding mechanism for the biotechnology industry in South Africa that was deemed by the respondents to be lacking is the venture capital industry.

> *The other thing obviously that is not working properly here is the venture capital sector. (Respondent 14 9:45)*

> *We have got non-existent venture capital when it comes to biotechnology. (Respondent 16 11:26)*

> *In countries with a smaller and less mature bio-economy, such as South Africa, state intervention is imperative to bolster business activities in the absence of large private sector players and readily available venture capital. To date, the government has played a key role in promoting market success in strategic biosectors through its policy instruments and by enlisting public research institutions. However, there remains much work to be done. (Documents Case 1 13:72)*

The experience of the respondents who received adequate funding from the government was positive compared to those who deemed the funding from the government to be inadequate or inappropriate.

> *I found my experience in South Africa with the government funding agencies absolutely fantastic.*
> *They understand the dynamic, there is a dynamic there of competitiveness. (Respondent 5 5:43-44)*

> *I think from a governmental perspective, from a funding perspective, it is good enough. (Respondent 11 6:31)*

The fact that the government was able to provide appropriate funding on certain occasions was explored further to understand the possible factors responsible for this contradiction. The data showed that on the two occasions where the respondents deemed the government funding to be appropriate, both spent their own money to get their products to the stage of proof of concept: hence, government funding was deployed at a late stage. It can be inferred from the data that the government may prefer funding late-stage projects because of the higher chances of success.

> *I started my own laboratory, private laboratory with private funding, and this laboratory is called Altis Biologics. Subsequently, I registered the IP in my personal name and gave Bone SA the rights to commercialise the IP in the territory of South Africa.*
> *And once I put my application in a second time to the Innovation Fund after 3 years, a number of things had changed. Number 1, there was new IP, number 2, it had been filed for PCT giving access to big markets, number 3, I had proof of concept in small animals like rats, number 4, I had proof of concept in a completed human study in humans, from a tissue coming from humans. Therefore I was able to reduce the risk having used private money to do it, reduce the risk of sample technology, new technology risk. New technology is risky at early stage, you do not know if it is going to work, it is just an idea; you need proof of concept, principles. (Respondent 5 5:22-24)*

> *I imported some products, so I acquired some market share and generated some cash and used that cash to set up my own manufacturing facility. (Respondent 11 6:10)*
> *Being a bioentrepreneur you have to spend a lot of money upfront. (Respondent 11 6:17)*

The challenge regarding appropriate funding for biotechnology entrepreneurship in South Africa is a gap that has resulted in high failure rates of biotechnology companies in the past and may severely hamper the future development of the biotechnology industry in South Africa.

Lack of skills

Another key resource requirement is the availability of research, entrepreneurial and commercialisation skills and capacity to develop the biotechnology industry in South Africa effectively. In the experience of the respondents, although the individual bioscientists have the appropriate research and scientific skills, the entrepreneurial and commercialisation skills are lacking. In addition, there is a shortage of the aggregate skills required to ensure the effective development of the biotechnology industry.

> *So one of the things that we really need to continue and expand is the development of bio-entrepreneurship skills. (Respondent 1 1:139)*

> *I think that the universities in general lack capacity to translate their basic research findings into products and services and that may be in part because there is a lack of adequate technology transfer knowledge. (Respondent 12 7:65)*

> *On top of that you get inventors who think they can be entrepreneurs and CEOs and then you also have a problem because they do not know what they are doing. (Respondent 2 2:39)*

> *It is just that most academics are not very entrepreneurial. (Respondent 2 2:42)*

> *But then somebody in there needs to understand how a business works and those fundamentals of a business and often they do not. (Respondent 13 8:58)*

> *There are not enough people that you can gather together, companies to put up this science park. You need a critical mass for this science park to work and we do not have that. (Respondent 16 11:40)*

Some of the respondents believed that the problem of lack of skills goes further back in the educational system, which has not produced enough science and mathematics skills to ensure the development of science and technology-based industries in South Africa.

> *Global Competitive Index which is put out by the World Economic Forum, as you know, we sit second from the bottom in terms of competency in science and mathematics. (Respondent 12 7:27)*

> *But again it does not help spending 50 million rand setting up a facility if you do not have the people who can use the facility. So we are evolving the two in parallel. We are training the people. (Respondent 12 7:53)*

The challenge of the lack of entrepreneurial skills highlights the differences between a bioscientist and a bioentrepreneur. According to the literature on biotechnology entrepreneurship in the developed economies, the availability of a critical mass of inputs and support structures may mask the fact that the bioscientist, or star scientist according to some literature, does not have entrepreneurial skills. However, the lack of a critical mass of input in South Africa often means that the bioscientist also needs to acquire entrepreneurial skills to make the transition to a bioentrepreneur.

> *Very often we find that if the researcher is the one that runs the company as well, and they do not have the entrepreneurial capability and the business passion to take that project forward and that is a challenge that we often come across. (Respondent 3 3:40)*

> *Doing my MBA at Wits university was a key step to empower myself with sufficient knowledge capital to better understand the business of science. How to do financial models, how to calculate net present values, how to understand strategies and scenario planning. (Respondent 5 5:12-13)*

The lack of entrepreneurial and commercialisation skills in South Africa and the lack of a system to provide these skills together form a notable gap in the biotechnology industry in South Africa. This gap was often closed by the bioentrepreneurs, effectively or otherwise, in an effort to give their firm a chance to succeed.

Lack of a developed market for biotechnology products and solutions

Another key consideration for the development of biotechnology entrepreneurship in South Africa is the size and efficiency of the market for biotechnology products and solutions. The "size of the market" is often used interchangeably with the "size of the biotechnology industry", and both the market and industry were deemed small and under-developed by the respondents.

> *Our industry is so small; it does not yet have clear vision, direction and knowledge of markets and so on. (Respondent 1 1:27)*

> *However, the biggest challenge that is faced in South Africa is that the South African market itself with its biotechnological innovations are too small, the market is too small. (Respondent 4 4:6)*

> *But so I would say that biotechnology in South Africa is nascent. (Respondent 12 7:30)*

> *I mean the market is not here and that is one of the problems, you know the local pharmaceutical industry is focussed on generic manufacturing, they are not focussed on new drug development so any of the pharmaceutical stuff, even the medical device stuff, are all offshore sales. (Respondent 13 8:10)*

> *Bioentrepreneurship in South Africa is still fairly new. Probably being around 20 to 30 years and it is getting momentum all the time, but in terms of the big picture it is a very small part of the business activity in this country, for sure. (Respondent 15 10:3)*

> *We could not survive in South African market because we were not selling enough systems. (Respondent 15 10:7)*

The views on the size of the market in South Africa were not consistent across all the respondents. From a medical diagnostics point of view, there seems to be a developed market in South Africa. This may be due to the nature of the products and the target market.

> *First the market, do we have a direct market for products in South Africa? I believe we do. I think we are far along enough to be able to procure products for biotechnology companies in South Africa; we have the infrastructure to do that. (Respondent 11 6:95-96)*

The government was seen as the biggest buyer of biotechnology products in South Africa, and hence as influencing the size of the market. However, the government as a buyer is often caught between balancing the need to provide service to as many of the populace as possible at an affordable price and the need to protect and promote the local industry. Hence, there were instances where local companies lost out on tenders to foreign companies due to price. If the local biotechnology companies cannot win the competition in their local market, the odds are heavily against them making inroads in the international market with competitors with a far better operational environment than in South Africa.

> *I would say from the government in assisting, in procuring products, it is not good enough. (Respondent 11 6:33)*

> *The tender process here is totally, totally, totally not in our favour, there is a ninety point system in my industry where sixty points they award toward price, thirty points they award toward local content, BEE and others.*
> *We are competing against first world countries like China where they have tech parks, science parks where they don't have to import components.*
> *So when they come to our country and tender obviously it is cheaper for them, so now governments are awarding tenders to the Chinese and to other Asian countries based on price.*
> *They should actually award more points to local content to promote companies growing here and government buying from us. (Respondent 11 6:36-39)*

If you cannot win your own tender in your own country you are just never going to be able to commercialise and right now you cannot because government is buying the cheapest stuff they can find in China or you know whatever the story is. It is the policies and stuff that make business work in the country. (Respondent 13 8:61-63)

Given the pervasiveness and global nature of biotechnology, South Africa can always compete globally. However, this is dependent on how developed and efficient the biotechnology industry in South Africa is and its global competitiveness across the dimensions that best define the industry best in biotechnology.

The challenge with the international markets is it is highly competitive. And I am not sure whether South Africa has that competitive edge to compete in that market. There is a lot of biotechnology that happens within the pharmaceuticals industry. They have huge amounts of resources and funding to fund the biotechnology research within the pharmaceutical industry and we cannot compete. (Respondent 4 4:7-10)

It can be concluded from the above verbatim quotes that although one respondent believed that the market for biotechnology products is adequate in South Africa, the majority of the respondents were of the opinion that the market for biotechnology products is under-developed in South Africa.

Lack of infrastructure and support structures

The resource and infrastructural support to biotechnology entrepreneurship in South Africa is deemed inadequate to the development of the industry, especially in the area of dedicated research institutes and the availability of biotechnology parks and auxiliary services to the industry.

Africa is lacking capacity and infrastructure. But there is not enough depth of capacity to do anything properly. (Respondent 1 1:126-127)

You get a great biotechnologist there and there just is not the support, even in the academic side, there is not the support available to him or her, but there are real opportunities. (Respondent 1 1:128)

But what we are lacking are a set of institutes that have a specific focus. (Respondent 1 1:103)

In my view and it is a resource issue, putting the resources together to create a dedicated institute that focuses on certain areas. It is just a better environment for commercialisation than an academic setting. (Respondent 1 1:114-115)

I think the BRICS also did not have enough resources to nurture some of those businesses, because entrepreneurs sometimes they are not just looking for money, sometimes they are also just looking for business support and I think that was lacking as well. (Respondent 3 3:94)

I need to compete against China but there is no support companies in South Africa where I can buy from, so that is why I export a lot, my biggest sales are export. (Respondent 11 6:41)

Like I said we need, we seriously need a science park in this country where we look at the high impacting biotech businesses, and we look at their needs. (Respondent 11 6:55)

Like a CFO, a really good Chartered Accountant that can do people's finances and report the way investors want reported. No small biotech company needs a full time CFO. One CFO can work across four companies easily so put that person in and there they have got four companies they are working with that is great. (Respondent 13 8:66)

The infrastructural deficiencies in South Africa may have contributed to the tendency of the bioentrepreneurs to approach the process of biotechnology entrepreneurship as individuals rather than being a part of a system of support that provides the necessary requirements for effective bioentrepreneurial activities.

An inclination by the universities to prioritise research publication over commercialisation

The universities are seen to be misaligned to the requirements of biotechnology entrepreneurship in their approach to the management of the need for publication and the economic importance of their innovation.

> *Researchers are under pressure to publish, but at the same time if they publish they lose their intellectual property unless they publish after they have registered their IP or their patent for example. So that is another challenge that I think we definitely face. (Respondent 3 3:77)*

> *So the primary focus of universities is to train students, publish scientific awareness, that is the primary objective. (Respondent 4 4:17)*

> *And I believe a vast majority of researchers are academic researchers that enjoy basic research for their core competency, for their core passion, which is to uncover knowledge. It does not matter if it is linked to dollars, they do not care, they want to know how life works, and they wanted to know how water is transported into a cell. Because it is curiosity and it is research, and it is very, very good and it has to be done. (Respondent 5 5:57)*

> *Secondly, we have got still an academic culture and their incentives at this stage are to publish and to train students. So we have just introduced our IP Act [Intellectual property Act] which says before you publish first check to see if you've got some IP there and if so register this with our national IP management office. (Respondent 1 1:138)*

The need for publication at the universities may be driven by several other factors that are not covered in this research. However, it is apparent that the prioritisation of publication over the commercialisation of research, for whatever reason, does not help the development of biotechnology entrepreneurship in South Africa.

The loss of skills through the brain drain

The consequence of the war for talent and the unfavourable environment for the development of biotechnology entrepreneurship in South Africa is the migration of skills to other locations with a more favourable environment.

> *That is very important and it all starts with the scarce skills. Our scarce skills are leaving South Africa; they are going overseas because the environment is not right here. (Respondent 11 6:72)*

> *I mean by poaching that core, by going to countries like South Africa where there are good researchers and stealing our researchers effectively. (Respondent 13 8:42)*

> *Look we have skills in terms of knowledge but it is diminishing. Many of the top people have left the country. (Respondent 17 12:22-23)*

Relevant skills are being lost through the brain drain not only internationally to biotechnology industry in other countries but also locally to other industries owing to the lack of opportunities in academia and the industry not being developed enough to absorb new entrants.

> *But because there was a lack of opportunities in the academic sphere many of them have been absorbed by insurance companies or that kind of thing, so they are all gone. (Respondent 14 9:66)*

In additional to the challenges mentioned in the sections above, other challenges were mentioned by some of the respondents such as a national culture that does not support the development of biotechnology entrepreneurship; the evidence of corruption in the industry; and the stigmatisation of, and inability to accommodate, failure as a part of the process of biotechnology entrepreneurship. These challenges were not elaborated on as they did not constitute the experiences of the majority of the respondents.

Low level of commercialisation of research

The eventual outcome of biotechnological entrepreneurship is the commercialisation of the intellectual property either through the formation of a new company or through licensing of the innovation to more established companies.

> *It is because we realised if we want to improve the impact of biotechnology in South Africa, we cannot focus on technology and the science, and we must focus on the end point, the economy and the market. (Respondent 1 1:16)*

> *A key criterion for evaluating a proposal was the team, and what the BRICS often did was they required a company to be formed in order to commercialise the product. That immediately put into perspective that this is not an academic exercise, this is a commercial exercise. There are failings with this approach as well but the one positive is it made it very clear, this is not an academic with a pet idea that is just tinkering along, this is a commercial enterprise. (Respondent 1 1:57)*

> *If we say biodiversity, we have to say, right the point here is we want to create an industry out of biodiversity; and we are going to create that industry off the back of our own IP so that it is competitive.*
> *So that means you have to have a whole value chain from universities to companies, including regulations and have all those things working seamlessly. (Respondent 2 2:145-147)*

The experience of the respondents on the commercialisation of research in South Africa was deemed to be below the levels obtainable in the developed economies and some other developing economies such as China.

To commercialise ideas coming out of universities, in the past that has not really happened. (Respondent 2 2:132)

We're used to doing basic research and that is it, and not have that commercial mind-set. (Respondent 3 3:46)
And in terms of projects which can actually be taken to market, there are very few out there. (Respondent 3 3:15)

The problem is we have people that are good at science but they are very bad at pushing these things through into the real world. (Respondent 2 2:103)

The other reason is lack of funding for commercialisation. You can fund 20 R&D projects and probably three serious commercialisation attempts. Secondly, to commercialise globally is a big challenge, both in terms of people, partners and money. (Respondent 2 2:28-30)

I think personally in South Africa, the universities lack certain things in terms of commercialisation. They do the research and they do the training of the students but to complete that innovation chasm, they do not do that.
No, they do not have the skills and the capacity to do that, they are not setup to do that. (Respondent 4 4:21-22)

Yes, we lack in commercialisation, we are doing brilliant research, we are publishing the research and I promise you the Chinese and the European, they are probably downloading our own papers here and making a product out of it, where we lack. (Respondent 11 6:47)

The commercialisation of research in South Africa is deemed to be sub-optimal by the respondents for the reasons given above. It is expected that being at the end of the value chain of biotechnology entrepreneurship, inefficiencies in the stages of opportunity identification, R&D, and opportunity exploitation will negatively affect the efficiency of commercialisation of research.

Owing to these challenges, licensing was seen as an easier means of commercialising research than company formation in addition to improving efficiencies.

> *Licensing could be the easiest way to go, it is an easy way to commercialise. (Respondent 3 3:91)*

> *We are looking at that now, we are looking at licensing companies in Nigeria because it makes sense from a distribution perspective and to also take a load off of us, to licence to a company in Nigeria and they can distribute to the surrounding areas of West Africa, and obviously for the malaria product. (Respondent 11 6:86-87)*

Social linkages

The social linkages to biotechnology entrepreneurship in South Africa was highlighted by more than half of the respondents, which makes it prudent to include the details of the quotes from the respondents in this narrative. This enriches the understanding of the context of biotechnology entrepreneurship in South Africa.

Biotechnology entrepreneurship in South Africa cannot be absolved from the social dynamics of the country. Hence, most of the respondents highlighted the social linkages, which pointed to the unique circumstances of South Africa and the expectations from biotechnology entrepreneurship.

> *We have got huge social issues that need to be resolved in South Africa because of our apartheid past, so that is a high priority and education is a top priority in South Africa. (Respondent 1 1:37)*

> *Obviously if you are developing biotechnology there is a social responsibility. (Respondent 1 1:39)*

The other thing is, there is a community called South Africa, it is everybody and there can be ways to say right, in this region, the benefits from what is exploited out of this region have to go into this region's schools, hospitals, roads, police stations, these are all community benefits. (Respondent 2 2:128)

I do foresee greater pressure from the public in terms of ethical issues surrounding GMOs [Genetically Modified Organisms] and that may impact our regulatory environment and I do see that outcome having an impact on the type of research we do in that particular space.
I feel there would be more public pressure due to environmental factors. So I think that could kick in and could impact on our policy regarding biotechnology, especially that particular area of biotech, agro biotech, where we are looking at genetically trying to modify crops so it suits our environmental conditions in South Africa or the rest of Africa. I am not sure where it is going but I do see greater regulatory hurdles moving forward. (Respondent 3 3:24)

I think there will be a strong focus on ensuring that that kind of research yields some kind of commercial benefit, economic and even social benefit. (Respondent 3 3:69)

The social side, our social impact that we have, that is the reason why we would prefer to not sell our business and to stay in South Africa. (Respondent 11 6:44)

I go a lot to schools, speak to matriculates, I present at universities and I try to get the mind-sets of the students as well. (Respondent 11 6:69)

I think the problem in South Africa is that we are dealing with so many other issues related to our past, related to our huge burden of disease and possibly related to our economy, although our economy, I think, is not the problem here.

But I think we still carry the burden of apartheid with us. (Respondent 12 7:44)

Talk about biotech and all of that, it is not going to employ millions of people; it is going to employ tens of thousands of people. That is certainly an issue. (Respondent 14 9:89)

I just want to do the business and make people happy; you know what I mean, and help poverty and diseases and help people get out of their misery and make a bit of money on the side. (Respondent 17 12:87)

The bio-economy in South Africa should address the country's socio-economic development goals of poverty reduction and improved quality of life, while ensuring continued economic growth. (Documents Case 1 13:36)

South Africa remains a country of extreme inequality. People living at one end of the spectrum enjoy some of the highest living standards in the world, while those at the other end lack access to basic amenities, suffer from food insecurity and are highly susceptible to major diseases such as HIV and tuberculosis. (Documents Case 1 13:55)

The importance of society in the development of biotechnology entrepreneurship in South Africa prompted the government to consider a quadruple helix model that includes the society in health biotechnology.

South Africa will build its health innovation system using the "quadruple helix" model to integrate existing role players – the government, academia, industry and civil society – into a unified and coordinated system. According to the model, industry operates as the seat of production, government provides the framework for secure contractual relationships, and universities provide new knowledge, innovation and technology, while civil society will provide inputs as users of the innovations, holders of *traditional knowledge and co-innovators through consultation. (Documents Case 1 13:104)*

The summary of the business level influences show that there were challenges highlighted by the respondents. The role of the stakeholders - government, venture capitalists, research institutions, and large companies - featured in the challenges to the development of biotechnology entrepreneurship in South Africa.

5.3 Macro-environment influences

The macro-environment influences experienced by the respondents in South Africa include the policy and regulatory environment; the stakeholders involved in biotechnology entrepreneurship; and the research and development dynamics in South Africa.

Unfavourable policy and regulatory environment

The policy and regulatory environment was one of the areas identified by the respondents as important to the development of biotechnology entrepreneurship in South Africa, but with gaps in the current environment.

> *One of the reasons is that we have a very tough regulatory environment, extremely tough. It is a fact that the policies around this and all the regulations and legislations are just coming out and the world has moved so far ahead. (Respondent 4 4:17, 19)*

> *So regulations have been very tricky, bio-prospecting regulations have been so very onerous. So there are lots of policy issues that we need to sort out. (Respondent 1 1:81 - 82)*

> *We have got to change the policies and regulations to allow bio-entrepreneurship to develop much more easily. (Respondent 1 1:143)*

> *The IPR Act has now put a spanner in the works; although that can be negotiated so it is not an absolute thing. (Respondent 12 7:72)*

Challenges related to the policy and regulatory environment were highlighted by almost all of the respondents interviewed, making it an important aspect of biotechnology entrepreneurship in South Africa to be explored further.

Poor implementation of policies and strategies

Another gap identified by the respondents in the environment of biotechnology entrepreneurship in South Africa was the implementation gap. Although policies and strategies may be at the right level, it was deemed that the challenge was being able to implement these in an effective manner.

> *I think our problem as South Africans have been more about the efficient and effective implementation than about developing the right policy or strategy, in short. (Respondent 2 2:21)*

> *So this is implementation issues, nothing to do with the concept or anything like that. (Respondent 2 2:46)*

> *It is 80% implementation challenge and 20% policy challenge. (Respondent 2 2:48-49)*

> *So the policy is one thing, the implementation challenges are much bigger. (Respondent 2 2:68)*

> *The rest of the world is going down one route and government is going down another route, and what they are doing in practise is not that, they are making it more complicated. So again, the implementation challenge is significant. (Respondent 2 2:129)*

> *These failures in implementation appear to involve significant missed opportunities to use research and innovation to support central social and economic development objectives of the new government. (Documents Case 1 14:75)*

The implementation gap is seen by the respondents as a much bigger challenge than the policy gap, and this is linked to the lack of skills and capacity at both the government and industry levels.

> *The execution risk is a problem because there are not enough people that have got the right skills and experience. So I did see a lot of problems on the system, which means you have got serious gaps in capacity at government level or whatever, because they just do not know what they are looking at. (Respondent 2 2:157-158)*

The stakeholders involved in biotechnology entrepreneurship

The key stakeholders in biotechnology entrepreneurship are the government, research institutions, venture capitalists, large biotechnology companies, and civil society. The government provides an enabling regulatory environment and acts as facilitator; the research institutions provide talent and technology transfer capabilities; the venture capitalists provide capital; the large companies act as cooperation partners, customer and competitor (Ahn and Meeks, 2007); and civil society are the users of the biotechnology products. In the case of South Africa, the government's facilitation role includes funding and providing the market for the biotechnology products.

Given that the government, and civil society will normally be default stakeholders; the venture capitalists, research institutions and the large biotechnology companies are the key determinants of whether South Africa has a full complement of the stakeholders required for biotechnology entrepreneurship or not.
Two of these stakeholders, the venture capitalists and the large biotechnology companies are not present in South Africa. This may have contributed to the

challenges experienced by the respondents in the biotechnology industry in South Africa.

> *We have got non-existent venture capital when it comes to biotechnology. (Respondent 16 11:26)*

> *I consider government my number one customer if you like or a stakeholder. (Respondent 14 9:21)*

> *The other thing obviously that is not working properly here is the venture capital sector. (Respondent 14 9:45)*

> *Our fund and everything we did was private sector driven.*
> *It was not about building an industry or any other things, or securing technology in South Africa. It was about investing and making as much return for the investors as possible. (Respondent 13 8:2, 4)*

> *In countries with a smaller and less mature bio-economy, such as South Africa, state intervention is imperative to bolster business activities in the absence of large private sector players and readily available venture capital. To date, the government has played a key role in promoting market success in strategic biosectors through its policy instruments and by enlisting public research institutions. However, there remains much work to be done. (Documents Case 1 13:72)*

The absence of these two key players meant that the government tried to close the gap by assuming the responsibility for funding and R&D spend.

Low level of research and development spend

R&D is a key step in the discovery of bioentrepreneurial opportunities. This is a critical differentiator between biotechnology entrepreneurship and general entrepreneurship, and the R&D spend has become one of the key statistics of measuring the commitment of countries to the development of biotechnology entrepreneurship.

> *The new approach is then going to look at the entire value chain and then research and development becomes much more important than it was in the earlier stage. (Respondent 1 1:53)*

The current level of R&D spend in South Africa is below the average for the OECD countries. This view is corroborated by the respondents in this research.

> *So at the moment we are just less than 1% GDP being spent on R&D. (Respondent 1 1:35)*

> *We have set a target for 1.4 % of GDP by 2014 which we are now on the verge of saying let's put that back to 2016, and then 2% by...it was going to be 2018. (Respondent 1 1:38)*

> *If 2.5 % GDP is the R&D budget, and we are only at 1%, there is a significant difference. (Respondent 1 1:105)*

> *Formal R&D is 0.87% of GDP, and the government's target is to raise this to 1% by 2012, quite an ambitious goal, given the industrial structure. (Documents Case 1 14:9)*

> *So there is a systemic problem where there is a shortage of R&D funding within the system. (Respondent 2 2:40)*

> *We need to look at the level of GDP funding, percentage of GDP.*
> *I unfortunately do not know a lot about Cuba and Brazil biotechnology, I have read about them. But I find similarities because our level of funding is very small. (Respondent 5 5:90)*

> *The lack of major R&D taking place here and the lack of capital are the two major constraints. (Respondent 16 11:47)*

The absence of the large, established biotechnology companies in South Africa was also highlighted as one of the reasons for the low level of R&D in the biotechnology industry in South Africa.

> *Biotechnology in South Africa is dominated by research projects, science councils and small biotechnology firms. There are no large, integrated biotechnology firms to speak of that are indigenously South African. Multinational corporations have a presence, albeit mostly through their distribution and marketing partners. Their research and technology development are usually conducted elsewhere. (Documents Case 1 13:59)*

> *In my view what South Africa needs to be doing is encouraging these big multinational, big biotech companies to establish a branch in South Africa. Not just a distribution branch, but an R&D branch, and hopefully we will be pushing that into the strategy, pushing some kind of approach to provide incentives to companies to create a branch here, which will then assist in our biotech pipeline. (Respondent 1 1:75)*

There is a linkage between R&D spend and intensity. These may also be affected by the availability of skills, infrastructure and capacity, all of which are deemed to be sub-optimal by the respondents. The critical nature of R&D in opportunity discovery and/or creation in bioentrepreneurship means that a shortage of funding will invariably hamper the development of biotechnology entrepreneurship in South Africa.

In concluding this section, it can be said that macro-environmental influences in South Africa have unfavourable components according to the respondents in this research. The policy and regulatory environment was also deemed unfavourable due to difficulties with policy on intellectual property ownership; and policy on technology transfer.

Two of the stakeholders required for the efficient development of the biotechnology industry in South Africa are not available. Hence, this can be regarded as unfavourable component of the macro-environmental influences. Lastly, the R&D

dynamics show that, relative to the developing economies, South Africa is doing well on both R&D spend and intensity. However, it lags behind the OECD countries in terms of both R&D spend and intensity.

5.4 Triple helix of university, industry, and government relationships

Stakeholder collaboration in biotechnology entrepreneurship is a key feature that involves the university, industry and government in a triple helix relationship.

> *The role players within the bio-economy will have to collaborate effectively if the bio-economy is to succeed. These role players include industry, academia, science councils, non-governmental organisations, community-based organisations, not-for-profit companies and the government. (Documents Case 1 13:45-46)*

> *Biotech stakeholders include government departments, industry and academia. (Respondent 1 1:6)*

The triple helix relationship in South Africa is controlled by the government, instead of the emergence of a knowledge infrastructure generated by overlapping institutional spheres. Hence, the government is expected to provide the leadership required to develop an environment that enables effective collaboration among the key stakeholders in the biotechnology industry in South Africa.

> *Government really has a role in defining priorities, initiatives, actions and stimulating an enabling environment. But also doing much more than that; pushing in a particular direction. Without government leadership we are not going to be achieving much. (Respondent 1 1:28 - 29)*

> *I am referring to this triple helix approach. It is not that DST is going to decide what is going to be done; DST is going to show the leadership which is to get the industry and academia input and debate and then provide a way forward. But unless somebody is actually doing that driving*

role, which is government's role I believe in South Africa, we are not going to achieve all that much. (Respondent 1 1:32 - 33)

However, instead of an effective collaboration among the key stakeholders, it does appear that there is misalignment of objectives between government and the other stakeholders.

I come back to the fact that biotech takes a long time and to some extent government wants quicker results. Biotech has got enormous potential and I think that is recognised, but what is not appreciated in government sufficiently well, is that biotech takes time. (Respondent 1 1:152)

This misalignment is not restricted to external stakeholders in the biotechnology industry, but also seems to occur within the government departments tasked with the effective implementation of policies and strategies related to biotechnology entrepreneurship.

Together with academia, science councils and other institutions, we have the collective expertise to drive innovation for South Africa's benefit. However, this expertise is still largely fragmented – conflicted by competition and not aligned in a common purpose. (Documents Case 1 13:5-6)

Secondly you have got DST and you have got DTI, and the bridge between the two is very difficult. So you are damned if you do and you are damned if you do not. (Respondent 2 2:104-105)

There is a lot of competition among the universities, and as I have said I have not explored it but it would be interesting to see in Brazil if there is a collaborative type of effort. (Respondent 3 3:55)

Yes, science councils and universities have become competitors rather than partners. (Respondent 4 4:23)

The experience of the effectiveness of the collaboration among key stakeholders by the respondents in this research was not positive. The quotes below are representative of the practical experience of the triple helix relations by the respondents.

> *So it is sad that the collaborating is not there and I would like to see a change, but at this stage of the game we are not going to have it.*
> *It is just sad that if I have to become involved in sitting on a committee involving government and the industry I would slit my wrist. (Respondent 16 11:52-55)*

> *I think the fact that government is involved has been a very bad thing for us. It is like running the 100m with a ball and chain to your leg, it has not at all been a help, and in fact it is fairly detrimental to the business. (Respondent 17 12:7)*

> *We are doing it in a sense but I often find that this is certainly an issue here; the inability of people here to work together. It is a big problem. It is like everybody is doing a bit somewhere and they are not teaming up, they are not coming together which is a huge detriment. (Respondent 14 9:74-75)*

> *So I was interested to commercialise this technology and I had to do it with the University of Witwatersrand. It was not well received by the university, my attempts, at all. (Respondent 5 5:20-21)*

> *This is a dynamic to be included in your research. This dynamic is called the dynamic of strife, the dynamic of war. And this war dynamic I studied using the principles of Sun Tzu.*
> *The art of war, to sharpen both sides of my blades and decapitate the large university which birthed me, cut his head off and bleed him to death so that my little company can survive. A David and Goliath principle, little Altis, a one man show to bring down a large institution to his knees and cut*

his head off, so that was successfully accomplished. (Respondent 5 5:25-26)

So in my own experience in human health research I can give you examples where the university is interacting with government, or where the university is interacting with industry but I cannot think of many situations in which the three come together.

Even in these circumstances, it is apparent that there are limited but fairly productive levels of collaboration between industry and the university, in particular, with the aim of hiring skilled individuals.

The links to academia are very helpful to us to find high quality graduates. (Respondent 16 11:28)

I think the universities work pretty well with one another. There was of course times that there was some friction between the universities, some competitiveness, some jealousy whatever; and I think similarly between companies. (Respondent 15 10:39-41)

The dynamics of the triple helix relations in South Africa appear to be at the level of triple helix I with the government controlling the relations between the entities. This is different from the developed economies, as shown in the literature reviewed for this study, which are at the level of triple helix III.

5.5 The key similarities and differences between South Africa and the developed economies as experienced by the respondents

This section articulates the key similarities and differences between South Africa and the developed economies, which were highlighted by the respondents.

Similarities

The key similarities highlighted by the respondents in South Africa were intellectual ability and research institutions; implementation challenges; and areas of focus for biotechnology entrepreneurship.

Intellectual ability and research institutions

The intellectual ability of the respondents in South Africa was deemed to be similar to the bioscientists in the developed economies.

> *We here have got as much chance of coming up with clever ideas as some guy sitting anywhere else. We must never think that we cannot compete, we can compete, and that ability to think is a competitive advantage that no one can take away from you (Respondent 2 2:159-160)*

> *And I would say the best South African students is competing with the best anywhere in the world. (Respondent 15 10:18)*

This intellectual ability is not restricted to research and development but extends to the quality of publications produced by the bioscientist in South Africa.

> *I think our innovation, the ability in developing methods and intellectual property, that is on par, and that is at university level; our research is top class, the University of the Western Cape is one of the best biotechnology departments, the publications are world renowned for what they are doing. (Respondent 11 6:45)*

The academic and research institutions were deemed to be similar to those in the developed economies in terms of quality of research and publication.

> *We have good academic institutions and we definitely have a good population with good entrepreneurial drive. (Respondent 16 11:24-25)*

Another valuable national asset is a too small but good collection of established universities and a research institute (science council) system with core areas of considerable strength and experience. Centres of academic research excellence, mainly located in a nucleus of long-established universities, achieve high quality in several areas of research, as reflected in the presence of South African publications among the top 1% of internationally cited publications in several fields and in some cases in the higher quartiles of that group. (Documents Case 1 14:16)

This similarity meant that the bioscientists and research institutions in South Africa compare favourably with their peers in the developed economies.

Implementation challenges

According to the South Africa respondents, the successes associated with the developed economies may not be as widespread as previously thought. The implementation challenges experienced in South Africa are also deemed to be applicable in parts of the developed economies.

Those EU rules are what drive what these agencies do. It is not what works, or what the best is, it is what those EU rules allow them to do. They also have execution type problems. (Respondent 2 2:164-165)

So it has been a difficult thing not just in developing countries but also if you look at Europe, many European companies have not managed to get their biotech industries going. Germany was looking good at one point but it really has not taken off. Countries like Scotland or areas like Scotland within the UK have had a number of success stories but no sustainability. You know those companies were sold off or, in the long term, they are going nowhere. (Respondent 13 8:17)

Similarity of implementation challenges does not necessarily mean that these challenges have the same underlying causes in the developed and developing economies. The context of the implementation challenges in South Africa stemmed from the government agencies who have the responsibility for the implementation of policies and strategies for biotechnology entrepreneurship in South Africa.

Areas of focus

Some areas of focus for biotechnology entrepreneurship were deemed to be similar in South Africa, Brazil, and the developed economies. Environmental biotechnology was highlighted as one area that is focused on by South Africa and the developed economies.

> *Similar to the Brazilians looking at environmental biotechnology, so it is the same drive in South Africa and the same drive internationally and that is where the similarities are. (Respondent 4 4:40)*

The focus on environmental biotechnology is primarily driven by the global need for environmental sustainability.

In summary, the individual skills of the bioscientists in South Africa are as good as any in the developed economies; the universities are as good and the quality of the research output of the universities are on par with the developed economies.
Other areas of similarity highlighted by the respondents are the implementation challenges that are not deemed to be unique to South Africa; and the similar focus on environmental biotechnology by South Africa and the developed economies.

Differences

The differences highlighted by the respondents are in the areas of the lack of aggregate skills and resources; the lack of entrepreneurial skills; the lack of scientific literacy; a lack of support mechanisms; implementation challenges; the lack of appropriate funding; low levels of commercialisation of research; the small size of the biotechnology market in South Africa; the difference in scale; the stigmatisation of failure; the high level of risk; the low level of patency; the lack of effective collaboration; and the failure to attract foreign skills.

Lack of aggregate skills and resources

The aggregate skills needed to boost the development and sustainability of the biotechnology industry in South Africa is deemed by the respondents to be inadequate, and hence different from the developed economies. While the individual bioscientists are on par with their peers in the developed economies, the aggregate skill is not enough to sustain the industry in the future.

> *No we will never be competitive, not as it is at the moment because we simply do not have critical mass; we do not have the resources; we do not have the people and those three things together will not drive us to be a force that can ever compete with the likes of Brazil and with China and with Europe. I mean it is impossible; it is not going to happen. (Respondent 17 12:73-75)*

> *We realise that scientific literacy is very low in South Africa. (Respondent 1 1:40)*

> *Human resource shortages at all levels in mathematics, science and technology. (Documents Case 1 14:15)*

The resources needed for the effective development of the biotechnology industry were also deemed to be lacking in South Africa as opposed to these resources being available in the developed economies.

> *I think what I would say about the developing world is there are not enough resources available, but every country is different. I have not picked up the common thread. (Respondent 1 1:130)*

> *Generally speaking equipment is 40% more expensive here than what it is in Europe and also takes two to three times longer to get here. (Respondent 16 11:44)*

The challenge with the aggregate skills is a systemic problem in South Africa that is driven by the approach to the study of mathematics and sciences at the high school and university levels.

Lack of entrepreneurial skills

The entrepreneurial skills in South Africa are deemed to be lower from the developed economies. Given the fact that most bioscientists are not necessarily entrepreneurs, and that there is a lack of a system of biotechnology entrepreneurship to close the gap, it is up to the bioscientists to close this skill gap in their personal capacity. The fact that this is highlighted as different from the developed economies means that it remains a challenge.

> *What we have identified as a gap in South Africa is the entrepreneurship skills. We are saying we are short of bio-entrepreneurship. (Respondent 1 1:58-59)*

> *So in South Africa there is a shortage of entrepreneurs. There is a shortage of money. There is a lack of ability to structure deals that take into account the global competitive nature and the time to market issues. (Respondent 2 2:31-33)*

> *Only 1.3% of South Africans own and manage an established business that has survived for more than three-and-a-half years, compared to more than 10% of adults in Brazil, Thailand, Greece, New Zealand and China. South African firms also have a poor success rate in comparison with most other developing countries. (Documents Case 1 14:38)*

Lack of support mechanism

The support mechanisms needed to ensure efficient conduct of biotechnology entrepreneurship in South Africa was deemed not to be at an adequate level in comparison to the developed economies.

> *These developed world countries; you notice immediately that the opportunities are far greater. If the scientist/entrepreneur wants to commercialise, there are support mechanisms. There are funding opportunities. There are support opportunities; they can get a leave of absence. I think France does two or two-and-a-half years where an academic will be guaranteed his position if he wants to come back. There are all these kinds of support mechanisms that are much more easily available.*
> *There are charitable foundations, there is philanthropic funding, and there are other opportunities. (Respondent 1 1:107-111)*

> *We still have wide and far and we lack interconnectivity between institutions. We should list our human capital assets on large databases. There is no database in South Africa that lists any doctors or researchers that do virus elimination work, it does not exist. (Respondent 5 5:85-87)*

> *And we do not necessarily have very good reward systems to push us to excellence much higher; combined with the fact that we are disparate from one another, our centres of excellence, the lack of technology parks. (Respondent 5 5:94, 96)*

The support mechanisms highlighted by the respondents in South Africa which are different from the developed economies included different sources of funding opportunities; the availability of a leave of absence for bioscientists; interconnectivity between institutions; scientific databases; the reward system; and biotechnology parks.

Implementation challenges

The lack of effective implementation of biotechnology policies was highlighted by the respondents as being different from the developed economies, as well as developing economies such as Brazil, China and India. These developing economies were considered to have better implementation than South Africa.

> *Whereas in Brazil, and I know a little bit about Brazil but not so much on the biotech side, I sort of suspect that they have been a lot more effective at actually implementing even on a framework type of thing. (Respondent 2 2:22)*

> *Brazil has got the rainfall, they make use of their resources and that is what they did, apply biotechnology to their resources. South Africa in my opinion does not make enough use of it is resources, genetic resources, they are not making enough use of these resources. (Respondent 4 4:15-16)*

Other implementation challenges highlighted by the respondents were the bureaucratic processes at the government agencies responsible for implementing the policies and strategies for biotechnology entrepreneurship and the inability to effectively implement the legislated strategy for biotechnology in South Africa.

> *There is too much red tape and the system is not efficient enough to be able to make decisions quicker. DTI are stranding small businesses at the moment. (Respondent 11 6:91-92)*

> *We developed a biotechnology strategy before India and China developed their biotechnology strategy, South Africa was ahead of all those things. Government started putting money in before the Indian government and the Chinese government woke up to biotechnology. But now we are way behind. (Respondent 13 8:68)*

The respondents believed that the biotechnology policies and strategies in South

Africa are not flawed, but needed to be implemented effectively in order to realise the objectives of the policy and strategies.

Lack of appropriate funding

The lack of appropriate funding was highlighted as one of the key differences between South Africa and the developed economies, with specific comparison to the developing economy of Brazil.

> *So in South Africa again, we have to bootstrap ourselves or as any African country. (Respondent 2 2:136)*

> *The big difference of course is they have huge amounts of funding for it, but not in South Africa. (Respondent 4 4:29)*

> *In Brazil money was put into it. Then I think key drivers were identified and funded and they started to work on it and that is why they have been so successful. (Respondent 12 7:76)*

The funding gap in South Africa was not seen to be only related to government funding but also related to the absence of a developed venture capital industry, and large established biotechnology companies.

Low levels of commercialisation of research

The ability to commercialise the research from the universities effectively was deemed by the respondents to be different among South Africa and the developed economies.

> *The unfortunate part is the value of taking that and making a product out of it and industrialising some of the components, that is where the Chinese and Europe are above us. (Respondent 11 6:46)*

I think commercialisation is below the standard. (Respondent 11 6:89)

This difference was thought to be as a result of the lack of entrepreneurial and commercialisation skills highlighted by the respondents; as well as the challenges in the earlier parts of the value chain of biotechnology entrepreneurship in South Africa.

Small size of the biotechnology market in South Africa

The size of the market for biotechnology products in South Africa was deemed to be different from the developed economies, with emphasis on the small and under-developed nature of the market in South Africa.

Secondly, the market for high tech goods in South Africa is modest, and that comes with all its own challenges. (Respondent 2 2:66-67)

The European market is more open, you get your CE mark you get to sell it in 27 countries, that is a big plus. (Respondent 15 10:28)

So that is the difference between us and Brazil; it is a huge market so it is a disposable income in a way far better than South Africa. When the Department of Agriculture tests the product on some cows in Limpopo Province they test about 20,000 cows at a time. In Brazil you are talking about one or two million at a time. (Respondent 17 12:45-47)

There was also a reference to the openness and efficiency of the European market in comparison to the market in South Africa.

The difference in scale

The scale of biotechnology entrepreneurship in South Africa is deemed to be different from the developed economies by being relatively smaller in scale.

To develop this product we have used only 3.5 million dollars, so the big dissimilarity is the quantum of numbers. USA you spend 600 million dollars to develop recombinant BMP [Bone Morphology Protein], we spent 3.5; the scale is enormously different. (Respondent 5 5:90-91)

She set up a venture capital fund in Brazil to the order of, I think, 150 million dollars. They have got a development bank over there, with billions of dollars as far as I know. I do think that they are on a different scale than what we are. (Respondent 14 9:70)

The scale was also deemed to be different between South Africa and the developing economy of Brazil, with Brazil seen to operate on a larger scale than South Africa.

The other areas of differences highlighted by a few of the respondents, but which was not elaborated on, include the stigmatisation of failure (Respondent 2 2:82); the relative low level of risk management skills in South Africa (Respondent 2 2:88-89); the low level of patenting (Respondent 3 3:83); the lack of effective collaboration among the key stakeholders (Respondent 4 4:31); and the inability to attract foreign skills (Respondent 4 4:38 – 39, 61).

The differences highlighted by the respondents are similar to most of the areas of challenges highlighted in the “business level influences” and the “macro-environmental influences” sections. The differences relate to the developed economies; with some respondents referring to the developing economies of Brazil, India and China.

Chapter 6: Case Narrative – Brazil

The narrative summary of the transcripts of the interviews conducted in Brazil is provided in this chapter. The interview guide was used to organise the narratives according to the categories identified from the literature reviewed, as shown below:

i. Individual level influences
ii. Business level influences
iii. Macro-environment influences
iv. Triple helix relationships
v. Similarities and differences between Brazil and the developed economies

The case narrative describes the experience of the process of biotechnology entrepreneurship by the respondents in Brazil, using the verbatim quotes expressed by these respondents during their interviews.

6.1 Individual level influences

The category individual level influences considered the dynamics that exist at an individual level across the respondents in Brazil. There is a high level of inter-connectedness across the university, industry, and government spheres by both the bioentrepreneurs and the subject matter experts in this study. Most of the respondents have either worked with academia, industry or government; or are currently working across these entities.

> *I started in academia and then we moved to the companies. When we created these two companies, I changed my time at the university. I continued to work there part-time and part-time in the company. (Respondent 8 20:17)*

> *But this was my experience as a scientist and academia and entrepreneur. (Respondent 8 20:27)*

This is basically what I do, I work for EMBRAPA [Brazilian Corporation for Farming and Livestock Research], I work very closely with companies, but it is different than having your own company, because you have very different experiences. By having and running your own company you learn a lot on how real life actually works, as far as employing people, dealing with clients and so on. (Respondent 6 18:15)

I was able to finance a lot of operations between the academic sector and the industry, I had the money, and I had a budget of 90 million dollars a year. Then the Catholic University of Brasilia invited me to set up a graduate programme. Then with Dario Grattapaglia and one of his friends, we set up this programme called Genomics Science and Biotechnology. (Respondent 9 21:8, 10)

I used to be in academia but before I came back to Brazil, and since I came back I am working in government agencies that finance development, research, and technology in general. (Respondent 10 22:1)

The linkages between the respondents in Brazil may have helped in fostering the conditions that made it possible to have the successful collaborative projects; effective collaboration among the stakeholders; an understanding of the common objective of biotechnology entrepreneurship in Brazil; and a consistent understanding of the strengths and challenges of the biotechnology industry by all the respondents.

These individual influences were also observed during the field work and are discussed in the following section.

6.1.1 Observations during fieldwork

Some of the interesting observations noted by the researcher during field work for the study that are worthy of inclusion in this report relate to the positive attitude of the respondents in Brazil; the desire to solve the country's problems; and the uniformity of their experience of the biotechnology industry.

The respondents in Brazil are very positive about the biotechnology industry. Even when challenges are expressed, there is a recognition of the need to be a part of solving these challenges in order to achieve the desired objectives.

> *But our country is doing well and as I told you, it is not a problem for funding, we have a lot of money for basic research at the university, and we have money available for venture capital investment. (Respondent 8 20:72)*

The golden thread among the respondents in Brazil is the desire to solve the country's problems and get the country to compete internationally. All the respondents see the biotechnology industry as a system to which all the stakeholders need to contribute to make it succeed. There was almost no expression of individualism, except where it contributed to the common goal.

> *For example, we have done several tens of thousands of human paternity tests, which are not cutting edge technology, it is a very routine type thing, but you solve problems. So every time you deliver a report you know you are changing the life of some people, so I think that is very motivating for me. (Respondent 6 18:19)*

> *My interest is only in the area of trying to help them to build up their capacity, hiring people, educating people and things like that. (Respondent 8 20:50-52)*

> *Yes, but one thing that is important that I always tell my students, is first do a good job, do good science and try to link with real problems when you are working. Real problems are practical issues that are important for your country, help people or help an area that is important for the country, I say that all the time. (Respondent 8 20:58)*

There is a consistent understanding of the industry and the areas designated as challenges or strengths among all the respondents. The respondents know almost every other stakeholder that is active in the biotechnology industry in person, hence pointing to a very high degree of collaboration in the industry in Brazil.

6.2 Business level influences

The business level influences in the environment of biotechnology entrepreneurship in Brazil include the economic, social, cultural and political environments. The extent to which these environments are conducive to the development of biotechnology entrepreneurship determines the success or failure of strategies and initiatives aimed at improving the biotechnology industry in Brazil.

The business level influences considered to be favourable to the development of biotechnology entrepreneurship in Brazil include: the direction and leadership provided by the government; the availability of appropriate funding from different sources; the developed market for biotechnology products; and the availability of infrastructure.

The other positive business level influences mentioned by one respondent, such as a favourable university culture; availability of capacity; and effective international collaboration are not be elaborated on as they may not be representative of the biotechnology industry in Brazil as a whole.

Government leadership and direction

The government is deemed to have done a good job of providing leadership and direction for the development of biotechnology entrepreneurship in Brazil.

> *The government is very important as a ruler, as giving the institutional and regulatory context to this, but I think that is a part of what society is asking for the government to do. (Respondent 7 19:56)*

So they created Biominas foundation, which was a support institution to create new companies in Brazil. They decided to create this structure because there were huge obstacles to start a business like that in Brazil because there was no funding at all, there was no venture capital, nothing, nothing, nothing. (Respondent 7 19:4-5)

There is clear evidence of the Brazilian government's support of biotechnology entrepreneurship in Brazil. The government has enacted laws and policies and followed through with implementation; provided infrastructure; provided various types of funding to address the various needs of the industry; provided an environment that attracts foreign skills and large companies; and promoted the collaboration between the universities, government agencies and industry.

Because innovation is now on the agenda of all federal government and the state government, all the politicians, they are talking innovation all the time. This is good because there is a possibility of changing the laws, this is the only way of solving this problem, because we have people and talent is a question of numbers. If you have a large number of students a portion of them will be, like any other areas, so we need to take advantage of having this system. (Respondent 8 20:43-44)

Also, in some areas, the government, not all areas, the Minister of Science and Technology and the Minister of Education has agents linked to our graduate programmes. All those agents are trying to find ways of supporting biotechnology in Brazil. (Respondent 9 21:104)

The facilitation role of the government and the multiple aspects of that role, in the development of biotechnology entrepreneurship in Brazil, made it imperative that the government carried out its function effectively. Any failure by the government ultimately impacts on the effectiveness of biotechnology entrepreneurship in Brazil.

Most of the challenges identified by the respondents in Brazil have to do with where government has failed in these roles, such as an unfavourable policy and regulatory environment; high interest rate; bureaucracy; politics; and corruption.

Availability of appropriate funding from different sources

Appropriate funding was deemed by the respondents to be available in the biotechnology industry in Brazil through the government, venture capitalists, and the private sector. This is one of the key factors for the effective development of biotechnology entrepreneurship and may partly account for the success that Brazil has enjoyed in biotechnology entrepreneurship.

> *Well, it is growing over the last five or six years it is growing, there is more and more money available, different organisations that are now putting money.*
> *I think money is not a problem in Brazil, venture capital, it is not a problem at all, the problem is how to get as much as possible, young pupils, students to get involved in this process, how to handle this problem of collaboration with the universities. (Respondent 8 20:61, 64)*

> *Oh, yes, I think the federal government, the state government, all of them. I used to go and talk with the people in government institutions and everybody knows that we need to invest a lot in innovation in biotechnology. I think that it is well supported but laws must change. (Respondent 8 20:89-90)*

> *FAPESP [Foundation for Research Support of the State of Sao Paulo] has a programme that is called, "Research in Small Innovation Companies". And, in this programme, what we do is we give money, for example, to small companies that want to invest in research to do innovation, to improve the production of their products. We give money for a PhD student who's just finished his PhD and wants to create a start-up company, we give money. We have a whole system for selecting and controlling this money, but we do money without asking anything of them. (Respondent 8 20:47)*

The funding for the development of the biotechnology industry in Brazil did not emanate from government sources only, but also from large biotechnology companies and venture capitalists.

> *Then Votorantim Group created a branch dedicated to venture capital, and they created a company called Votorantim New Business. New business means investment in start-up companies involved in biotechnology and communication technology or information technology. (Respondent 8 20:8)*

The long timeframe of biotechnology entrepreneurship, the high risk and the uncertainty of the outcome of R&D means that the traditional form of funding is not suitable to biotechnology entrepreneurship. This accounts for why the funding mechanism for biotechnology entrepreneurship is specialised, whether through the government, private sector, or venture capitalists.

Developed market for biotechnology products

It is the belief of the respondents that the Brazilian market for biotechnology products is developed. The emphasis on national priorities and solving the problems of the country has meant that the areas of focus, such as agriculture, environment, industry, and healthcare, are aligned to the needs of the country. Hence, the local demand creates a local market for the biotechnology products.

> *The positive factor is the Brazilian market, a very good market in terms of maturity and size. (Respondent 9 21:101-102)*

> *So, first is the market, and, secondly, a lot of researchers now in the biotechnology area. But in molecular biology, biochemistry, biophysics and nanotechnology, they are really willing to overcome all the difficulties in Brazil to set up their business. We do believe that the biotechnology industry is going to make a big change in our industry and it will generate more wealth, we do believe this. There is a big desire to move forward in*

spite all the difficulties, we have a dream, as Martin Luther King said, "We have a dream." (Respondent 9 21:102-103)

Despite having a developed market for biotechnology products, the need to compete internationally was expressed by the respondents as one of the factors necessary for the development of the industry in Brazil. Hence, the general environment for biotechnology entrepreneurship needs to be favourable for the bioentrepreneurs to compete favourably; and for Brazil to compete with the developed economies.

Availability of infrastructure

The respondents highlighted the importance of having the necessary infrastructure in the value chain of biotechnology entrepreneurship.

And in biotechnology you need to be careful because you need to plan very well the activities. It is not the kind of business where you can put small amount of money, it is not like that because if you do not have the capacity, if you do not have the laboratories and the equipment and the entire infrastructure necessary to grow as fast as possible, you do not have the result; and if you do not have a result you have nothing. So it is the kind of investment that you need to plan very well. (Respondent 8 20:53)

Most mention of the need for infrastructure pertained to the biotechnology parks, which are important to support the system approach to biotechnology entrepreneurship.

In 1984, the CNPq [National Council for Scientific and Technological Development] launched a programme of support for the creation of technology parks in Brazil. The goal had been to foster the creation of research spin-offs – an acknowledgement of the role of innovative small businesses. (Documents Case 2 33:25)

We created a kind of technology park, where you can bring your start-up companies, they are private, they can hire students in a way that all the inventions that they do in the company belongs to them and not to the university. We are not interested in getting money from the innovation that is done by this company, we are interested that this company grows, develops and makes a lot of money and pays the taxes. That is a priority in the university. This is how we need to do it, it is not simple, but it is the way that we are trying to do it. (Respondent 8 20:40-42)

In addition to the biotechnology parks, the government has also introduced support services that improve the chances of success for start-up businesses in the biotechnology sector in Brazil.

There is one service, they call SEBRAE [Brazilian Service for Small Business]. SEBRAE has a service that helps people to structure small business, their own business, they give money to support it; is this idea commercially viable or not? What would be the pay back if they borrow money? They help you to do all this and they finance the incubator at a university level to help your professor and your students to put your business plan together and that is a big help from the private sector. (Respondent 9 21:61)

Furthermore, there is private sector involvement in providing the infrastructure that supports the biotechnology industry in Brazil.

The Federal university of Santa Catarina has a big incubator infrastructure. That is another process we established in Brazil, financing the incubation system. We have an incubator that can incubate a small company. It is financing the incubation of a small business, either start up or a spin off. This is funded by the private sector in Brazil, the National Industrial Confederation of Industry (CNI). (Respondent 9 21:60)

These favourable business level influences have been instrumental in the successes achieved by Brazil in biotechnology entrepreneurship thus far.

On the other hand, the business level environment of biotechnology entrepreneurship in Brazil was also deemed to have a few key challenges among which are lack of aggregate skills; a national culture that considers entrepreneurship to be impure; high cost of funding; and bureaucratic and inefficient processes by government agencies.

The other challenges mentioned by one respondent, such as the negative impact of politics and corruption are not elaborated on as they may not be representative of Brazil as a whole.

Lack of aggregate skills

The requirement to have individuals with the right psychological, demographic, educational and career background for the development of biotechnology entrepreneurship in Brazil was corroborated by the respondents and documents reviewed for this research.

> *To be successful in boosting business innovation, these policies will need to be complemented by measures aimed at tackling the shortage of skills in the labour force; this shortage is among the most important deterrents to innovation in Brazil, particularly against the backdrop of a widening gap in tertiary educational attainment with respect to the OECD area. (Documents Case 2 25:1)*

The emphasis on the development of human resources is aimed at developing the right bioscientific and entrepreneurial skills needed to sustain the gains made in the development of biotechnology entrepreneurship in Brazil. However, the respondents deemed the aggregate level of skills required for the effective development of the biotechnology industry in Brazil to be inadequate.

Ok, I am going to stimulate the bio-industry and then I need technical people, and where are they? I am talking about a lack of engineers in Brazil; we are importing engineers from abroad, from Europe, where there are no jobs, so we are importing engineers from Spain, from Portugal, from Italy, from Germany. (Respondent 6 18:123)

The dependency of biotechnology entrepreneurship on skilled individuals makes the development of aggregate level of skills important if the successes achieved so far are to be sustained and extended. The government of Brazil has several programmes of skills development in this respect, which involve both local skills development and international exchange programmes.

A national culture that considers entrepreneurship to be impure

The culture of suspicion between business and academics was highlighted by the respondents as a challenge to the development of biotechnology entrepreneurship in Brazil. A career in academics is seen as pure and mixing this with business is seen as being driven by improper motives.

This seems to be an entrenched national culture given that all the respondents highlighted it.

All the scientists that were trying to do this were seen under suspicion by the university colleagues, they thought they wanted money, that they were greedy and things like that, but they were trying to do business as well. (Respondent 7 19:19)

Unfortunately it is not very amenable or conducive to business because I think we have a very Latin and Catholic inheritance in the way that things are done, very different from Anglo-Saxonic, protestant more open and with higher value to entrepreneurship and that it is okay to make money.
For example, the one thing we have suffered in a way is when a scientist decides to set up a business in a Latin/Catholic country, a lot of people

say, oh he is going to get rich, he will not do research anymore, he is selling his soul.

So there is this very wrong view of entrepreneurship, that setting up a company it is not "pure", you have to stay pure in academia, that sort of stuff. So the big challenge for me is to stay as a very productive scientist, publishing good stuff, having lots of students, and all at the same time so that nobody could say anything, and that is a challenge because as I say again, these are long days. (Respondent 6 18:23-27)

This may explain why the bioentrepreneurs in this study were all attached to the university at the same time that they were involved in entrepreneurial activities. Leaving the academic career entirely to focus on bioentrepreneurial activities would have confirmed the views that it was driven by the quest to get rich.

High cost of funding

The high interest rate and taxation are deemed to contribute to the differences in cost of doing business between Brazil and the US. This comparison was in the context of the fact that the bioentrepreneurs in Brazil consider themselves to be competing with the developed economies.

But now the cost, if you buy a reagent in the United States it costs 100 dollars, if you buy it from a company here, the company has to pay all the import tax. So if you are doing sequencing or DNA here it is much more expensive than in the United States, despite the fact that the labour is cheaper. (Respondent 9 21:99)

The funding initiatives of the government at favourable terms, and sometimes designated as "free to operate" (FTO) in which case the recipient is not required to repay the grant, alleviate the challenge of the high interest rate experienced by the respondents.

Bureaucratic and inefficient processes by government agencies

The role of government in promoting and developing biotechnology entrepreneurship in Brazil was acknowledged by the respondents. However, there have been challenges with the efficiency of government agencies to dispense their duties without undue bureaucracy.

> *For us to operate, we had to buy used equipment, and it took me almost a year to do all the bureaucratic paper work to be able to buy used equipment. (Respondent 6 18:41)*

> *For example we have the National Sanitary Agency that gives a very hard time for doing lots of things. For importing reagents you have to explain why you are doing this, what are you going to use it for and it takes forever. Then you have an import licence by the revenue service and it takes a month for them to allow you to import something. (Respondent 6 18:110)*

> *We have some universities like Unicamp and companies like Petrobras and Embraer, they patent, but the whole process is quite slow. The thing is the owner of the patent must pay the fees and maintain the patent and this is not something that is made easy here. (Respondent 10 22:55)*

These inefficiencies result in the lack of competitiveness of the local bioentrepreneurs and have forced some to seek the required services from the international market rather than the local. An example was the tendency to register patents overseas to avoid the bureaucratic delays experienced at home.

Social linkages

The social linkages to biotechnology entrepreneurship in Brazil were highlighted by less than half of the respondents. However, this category is included in the narrative for the business influence of Brazil in order to enrich the understanding of the context of biotechnology entrepreneurship in Brazil.

> *Yes, but one thing that is important that I always tell my students, is first do a good job, do good science and try to link with real problems when you are working. Real problems are practical issues that are important for your country, help people or help an area that is important for the country, I say that all the time. (Respondent 8 20:58)*

> *So when I talk about social issues I talk basically education. A serious investment in high quality education for the next 50 to 100 years, this is what we need. We need solid education for the new generation, so that we break this vicious cycle. Because that impacts the family structure, in Brazil a quarter of the kids that are born do not have a father on their birth certificate, and that is a problem. That means that the family structure which is the nucleus of a successful life of a kid, it is still lacking. (Respondent 6 18:117-118)*

The display of nationalistic tendencies was a common trend among the respondents. It is all about the country, all about solving their problems, and all about helping their fellow citizens through their research activities. This disposition is complemented by the government through policies aimed at solving social problems.

> *The Brazilian federal policy on biodiesel is aimed at alleviating rural poverty (stimulating rural activities to increase employment in rural areas). It is an interesting historical note that energy security was the main driver at the time of the launch of the PróÁlcool programme. At the time climate change had only just started to emerge as a global concern. However, GHG emissions savings has become an additional driver for bioethanol production in Brazil. (Documents Cross-Case 30:28)*

In summary of the business level influences show that there were favourable influences, as well as challenges highlighted by the respondents. The role of the government featured in both the favourable influences, and the challenges, while the role of the other stakeholders such as venture capitalists, large companies and research institutions was deemed to impact favourably on the development of biotechnology entrepreneurship in Brazil.

6.3 Macro-environment influences

The macro-environment influences experienced by the respondents in Brazil include the policy and regulatory environment; the stakeholders involved in biotechnology entrepreneurship; and the research and development dynamics in Brazil.

Unfavourable policy and regulatory environment

The policy environment in Brazil is considered unfavourable to the development of biotechnology entrepreneurship. Although the national biotechnology development policy seemed to be well implemented, the specific policies related to intellectual property ownership and technology transfer from the university to the industry were deemed unfavourable by the respondents.

> *There are some legal difficulties for example, a university professor in Brazil, a federal university or state university professor. Most of them or I would say 95% of them have a contract called, Exclusive Dedication. By exclusive dedication it means that you cannot have a business, or maybe better said, you can own a business, but you cannot run the business.*
> *So that also inhibits many scientists to go out and try something because they are worried there will be a conflict of interests. (Respondent 6 18:90-91)*

> *For example, if you are a company investing in research here at the university, it is fine but if I discover something interesting or important and I want to file a patent on that invention, I cannot license it through the company that invested in that research. And this is one of the most important problems related to technology transfer and development inside*

the universities here in Brazil, because all of them are state and public universities. And of course if you were a company you will not be interested in investing in research and that patent for that invention that was discovered during the research because it can go to your competitor. (Respondent 8 20:31-33)

We do not have a legal framework well organised, well structured, this is inhibiting a lot. (Respondent 9 21:106)

The difficulty of technology transfer from the university to the industry by the researchers, owing to legal restrictions, is one of the gaps in commercialising research in Brazil. This stemmed from the era when academics were seen as purists and kept as far away from business as possible. However, the requirements of biotechnology entrepreneurship in Brazil have necessitated university-industry technology transfer and the legal environment in Brazil has not kept up with this requirement.

The regulatory environment is mostly related to taxation and labour laws, which are also considered unfavourable and inhibitory to the development of biotechnology entrepreneurship by the respondents in Brazil.

In any case, a company would still have to operate in this very difficult business environment. For a number of reasons, interest rates, cost of personnel, taxation for import and general tax structure which is a complex system of several taxes in cascade. The government knows that, the law makers know that, but it is difficult to change things, it takes a while because of course the states and federal governments depend on those taxes. (Respondent 6 18:51-53)

Then of course you have import taxation on reagents and equipment.
At the same time a company in Miami, a company in Beijing will buy that equipment not for $300 000, not for $650 000, but for $250 000 or even lease the machine for $100 000 and pay during the same time I will be paying back my investment, and they will compete with me in the

> *globalised service market of DNA genotyping and sequencing, so make your calculation. (Respondent 6 18:37-39)*

The policy and regulatory environment for biotechnology entrepreneurship in Brazil was considered to be unfavourable by all the respondents in Brazil. Given the fact that the policy and regulatory environment was seen as an important determinant of the success of the biotechnology industry, the challenges identified with intellectual property ownership; technology transfer; labour laws; taxation; and high interest rates inhibit the ability of Brazil to compete effectively with the developed economies in biotechnology entrepreneurship.

The stakeholders involved in biotechnology entrepreneurship

The key stakeholders in biotechnology entrepreneurship are the government, research institutions, venture capitalists, large biotechnology companies, and the civil society. The government provides an enabling regulatory environment and acts as facilitator; the research institutions provide talent and technology transfer capabilities; the venture capitalists provide capital; the large companies act as cooperation partners, customer and competitor (Ahn and Meeks, 2007); and the civil society comprises the users of the biotechnology products. In the case of Brazil, the government's facilitation role includes funding and providing the market for the biotechnology products.

Given that the government and the civil society will normally be default stakeholders, the venture capitalists, research institutions and the large biotechnology companies are the key determinants of whether Brazil has a full complement of the stakeholders required for biotechnology entrepreneurship or not. These stakeholders are actively involved in biotechnology entrepreneurship in Brazil and contribute to the successes attributed to Brazil in the biotechnology industry.

> *FINEP [Research and Projects Financing] was a government funding institution that started a venture capital programme as well, a very huge programme.*

> *And BNDES, the national bank of social development, that also now has a huge fund for biotechnology. (Respondent 7 19:17-18)*

> *The BAT Group, the British American Tobacco Group, has had a lot of Agro business in Brazil, in tobacco, and the paper industry. (Respondent 9 21:2)*

> *Most of the investment was done by Votorantim New Business, but we got some investment from the Federal Institution, from the agency called FINEP. FINEP provide money for innovation in industry. So we got some money from them but most of the money, 90% of it for these two companies came from Votorantim New Business. (Respondent 8 20:35-36)*

> *We have quite a few nice universities, not only here in the state of São Paulo, but also in Rio de Janeiro, Minas Gerais, and other states, very, very well established universities. (Respondent 8 20:80)*

The facilitation role of the government provided the environment necessary to attract the large biotechnology companies, most of whom are not native Brazilian companies. The venture capitalists for biotechnology are equally attracted to environments that are conducive to the development of biotechnology entrepreneurship. Furthermore, most of the research in Brazil is conducted through the public universities, which is also the responsibility of the government. Hence, the government is an important stakeholder in the biotechnology industry in Brazil.

The research and development dynamics in Brazil

Although the R&D spend in Brazil is considered low in comparison to the OECD countries, the research activities at public research institutions are believed to be higher than in most developing economies.

At 1% of GDP, R&D spending (both public and private) is comparatively low by OECD standards and is carried out predominantly by the government. (Documents Case 2 24:3)

I would say it is general and in a way that is unfortunate because innovation type research has not received any preferential treatment, so that is also a problem. (Respondent 6 18:35)

The efforts by the government, at national and state levels, to improve the environment for research and its funding led to the establishment of various successful funding agencies for biotechnology entrepreneurship in Brazil.

In its 41 years of operation, FAPESP has awarded more than 45 thousand fellowships and 35 thousand financial awards to research. The balance of these years of continuous investment clearly show that the Foundation has made a decisive contribution to the expansion and strengthening of scientific and technological research in the State of São Paulo, with considerable impact on its economic, social and cultural development. (Documents Case 2 24:2-6)

These efforts by the government have improved the research intensity in specific areas of biotechnology, such as bioenergy and genomics.

We have a lot of research and development being done in this area of sugar cane and this will be good for the country because of the investment in research. (Respondent 8 20:26)

EMBRAPA has collaborative projects with the pulp and paper business to develop methods, genomic based methods of phenotype predictions. So basically you use DNA analysis to predict outcomes of phenotypes of trees, so you can save time, increase precision and for selecting trees that are more drought-tolerant, cold-tolerant, disease-resistant, and more productive. (Respondent 6 18:87)

The research funding agencies such as FAPESP have a mandate to boost innovation in the country and they do have funding arrangements where the recipient does not need to pay back the grant. The genome projects in Brazil exemplify effective exploitation of opportunities through research, stakeholder collaboration, appropriate funding, and commercialisation.

In summary, the macro-environmental influences in Brazil have a mix of favourable and unfavourable components according to the respondents in this research. The policy and regulatory environment was deemed unfavourable due to difficulties with taxation laws, labour laws, policy on intellectual property ownership and policy on technology transfer.

The stakeholders required for the efficient development of the biotechnology industry in Brazil are all available. Hence, this can be regarded as a favourable component of the macro-environmental influences.

Lastly, the R&D dynamics show that relative to the developing economies Brazil is doing well on both R&D spend and intensity. However, it lags behind the OECD countries in terms of both these factors. There are efforts aimed at improving this situation at national and state levels through the funding agencies of government and through the private sector.

6.4 Triple helix of university, industry, government relationships

The respondents in Brazil have a practical experience of effective collaboration among the university, industry and government. Most of the respondents effectively work for all three spheres, which places them in a position where they can collaborate to deliver on the common objectives of the government, industry and the university. *(Respondent 6 18:87)*

The epitome of a demonstrable effective triple helix relationship and collaboration in the biotechnology industry in Brazil is the genome projects, which involved collaboration among hundreds of stakeholders spanning government agencies, universities, research institutions and industry. The results of this collaboration elevated Brazil to the status of a global leader in certain areas of biotechnology such as genomics and bioenergy.

> *I had a very interesting and rewarding experience when I set up what we called the Genolyptus project, which was a Brazilian network of Eucalyptus genome research. I started this project in 2001 and it went on for 7 years and it is actually still going on but in a different format. (Respondent 6 18:59-60)*

Some of these collaborations resulted in firm formation and one of the most successful biotechnology companies to originate from Brazil was formed as a result of the collaboration between university, industry, and government.

> *Then we created Alellyx, and we put together all the expertise that we developed over a long time together with friends from the University of São Paulo and the University of the State of São Paulo and the University of Campinas and we created a company. (Respondent 8 20:9)*

The triple helix relations were supported by the government through initiatives aimed at creating a favourable environment for the stakeholders to interact productively. The leadership provided by the government and effective implementation of the initiatives through its role as facilitator resulted in the successful collaboration that currently exists across university, industry, and government.

> *The measures announced by the federal government include several that affect universities and their dealings with industry. Examples include the development of targeted research, the promotion of local production and innovation systems, support for the introduction of innovative measures in small and medium-sized enterprises, and an Innovation Act. The process, begun in the 1990s by universities and aimed at speeding up and organising interaction with business, has thus reached a new level. (Documents Case 2 33:16)*

The university, industry, and government stakeholders share a common purpose that has enabled them to collaborate on projects that have practical significance for the imperatives of the country. These projects have often been aligned to the focus areas of human health, agricultural biotechnology, industrial biotechnology, and environmental biotechnology.

> *They had to find an alternative to the antibiotics that were used, we have to sit together and find one. So then we sat together, they had a problem and we had expertise and we then sat together since the beginning, this was in 2004 and we have worked together for eight years. We set up our research strategy and some of the work is done here and some of the work is done in the industry. And now we have several antibiotics that are patented worldwide in the industry. (Respondent 9 21:16)*

There was no explicit reference to quadruple helix in Brazil, even though the references to social linkages imply a consideration for the society and their needs.

It can also be observed that the triple helix dynamics in Brazil constitutes a hybrid of Triple Helix I and Triple Helix III in which the government exerts control in an environment that enables knowledge infrastructure to flourish.

6.5 The key similarities and differences between Brazil and the developed economies as experienced by the respondents

This section discusses the key similarities and differences between Brazil and the developed economies, which were highlighted by the respondents.

Similarities

The respondents saw the similarities in biotechnology entrepreneurship between Brazil and the developed economies in the areas of support for innovation and entrepreneurship; a developed venture capital market; and government leadership.

Quality of bioscientists and universities

The individual skills of the bioscientists are deemed to be on par with the bioscientists in the developed economies. In addition, the universities and quality of research were deemed by the respondents to be of comparable quality to that of the developed economies.

> *I think that we have a very good basic science in this country. Here in Brazil we have agricultural companies, like the state company that is called EMBRAPA, that is got very well trained people and that is one of the good things, but you cannot compare with the US. (Respondent 8 20:70-71)*

> *We have a very well established training for young students, undergraduates and graduates. We have quite a few nice universities, not only here in the state of São Paulo, but also in Rio de Janeiro, Minas Gerais, and other states, very, very well established universities. So when you talk about a country you need to think of big numbers, big numbers means that undergraduate and graduate students, we have a reasonable number and this is positive. The universities are good and the training is good and this is positive. (Respondent 8 20:80)*

> *I think we have good training and I guess the scientific procedure is similar. (Respondent 10 22:47)*

This similarity has meant that the bioscientists in this research compare favourably with their peers in the developed economies and some of them have been recognised internationally for the quality of their research.

Support for innovation and entrepreneurship

Brazil supports innovation and entrepreneurship through various programmes and initiatives aimed at creating a sustained improvement in Brazilian innovation and entrepreneurship in the area of biotechnology.

> *I was in India for a year and Taiwan and the United States. First of all the similarities, with the United States, support for small business, both countries do have programmes for supporting small business. We have money here for supporting start-up companies, incubators within the university departments. In the United States they have several programmes for supporting small business. (Respondent 9 21:89)*

> *Now, as far as common things, overall I think Brazil is a country where people are willing to try. Brazil is a country where people are willing to open up businesses and be their own bosses, it is a very clear trend, the statistics show this, but not in high-risk type investments like we are talking about here. (Respondent 6 18:104-105)*

The respondents mostly compared Brazil to the US and commonly benchmarked Brazil against the US.

Developed venture capital market

The venture capital market in Brazil was seen as one of the most important factors contributing to the development of biotechnology entrepreneurship, similar to the US.

> *The boom of the biotechnology in the US is mainly driven by the venture capital. There is no question about it, if you have a good idea somebody is willing to put up the money, is willing to risk the money and make a lot of money or not. (Respondent 9 21:90)*

The ability of the environment of biotechnology entrepreneurship in Brazil to attract venture capitalists attests to the environment being deemed favourable by the stakeholders in the biotechnology industry.

Government leadership and direction

The important role of government in the development of biotechnology entrepreneurship is seen to be the same in Brazil as it is in some of the other developing economies, such as India.

> *And also another similarity between Brazil and India, the government has a lot to say about the development of the country. In India you have private investors but the government has a big role, as well as in Brazil. Brazil's government also plays a big role in biotech developing in Brazil. (Respondent 9 21:93)*

This leadership role is aligned to the facilitation role of the government in biotechnology entrepreneurship in Brazil, which the government was deemed to have performed effectively.

Differences

The differences highlighted by the respondents were in the areas of regulation, government inefficiencies, the scale difference between US and Brazil, and the cost of doing business.

Regulatory framework

In comparison to the developed economies, the regulatory framework in Brazil is seen as lagging behind and inhibitory to the development of biotechnology entrepreneurship in Brazil.

When you go over there the rules are extremely established, in Brazil the rules are still loose. You never know when to put the ends together. At the government level you do not have a rational legal framework; Korea has a beautiful legal framework. That is the reason why a lot of venture capital are moving to Singapore, they have a very good legal framework. (Respondent 9 21:92)

The challenges with the regulatory environment were deemed by the respondents to be one of the key challenges facing the development and sustainability of biotechnology entrepreneurship in Brazil.

Bureaucracy

The level of bureaucracy in Brazil was consistently highlighted as a challenge for the development of biotechnology entrepreneurship. This was seen to be worse in Brazil than the countries the respondents compared Brazil to, specifically the US.

And also the bureaucratic difficulties between a country like Brazil and a country like the US, those I would say are the two main differences that inhibit in a way, hinder entrepreneurship in life science. (Respondent 6 18:103)

The bureaucratic processes and inefficiencies associated with government agencies in Brazil negate the efforts of the government to drive the development of the biotechnology industry. In specific examples, such as patenting, the respondents resorted to filing their patents overseas in order to avoid the inefficiencies and delays in Brazil.

Resource availability

The level of resource availability in US was contrasted with the scale in Brazil, and lack of resource availability in Brazil was seen as posing a challenge to the productivity of the researchers in the biotechnology industry in Brazil.

In the United States if we are doing the research here right now and you come up with a new idea and you need a new reagent for tomorrow, you just go to the internet and the next morning it is delivered, here it takes four to six months. (Respondent 9 21:98)

The difference in resource availability was not deemed to be a consequence of the distance between Brazil and Europe, but a consequence of the low level of production capability of the required resources in Brazil, and the inefficient tax laws in Brazil.

Innovation culture

The other difference highlighted between Brazil and the developed economies was in the area of innovativeness. Brazilians are deemed to be less innovative than the developed economies.

First of all the culture of innovation in a country like the US or Europe, or many countries in Europe, not all but several, it is still something that does not exist, we are still learning, I think that is a major difference.
It is a system in place that allows for more innovation to happen, even though venture capital sometimes invests in 10 different small start-ups, nine fail and one pays for the failure of the other nine, we do not have that culture yet. (Respondent 6 18:100-101)

The lack of a culture of innovativeness in Brazil may be linked to the preference for an academic career instead of entrepreneurship; and the view of entrepreneurship as being impure and the quest for wealth.

Preference for academic career

The respondents in Brazil believe that most bioscientists are more inclined to be in academics rather than commercialise research due to society’s perception of academics as pure.

In Brazil the stimulus is mostly to go towards academia, seen as a pure, removed from the real life of business. Although this is changing but it is still very strongly felt in academia. (Respondent 6 18:106)

This difference was believed to be changing as Brazil becomes more globalised and the researchers are able to link their research to solutions to national priorities.

Scale

Another difference highlighted by the respondents was in relation to the difference in scale between the biotechnology industry in the US and Brazil.

Yes, completely different, and everything is built to promote and to get there as fast as possible and this is something that is very difficult to compare. (Respondent 8 20:70-71)

One thing that is very, very, very important and that is we need to focus on a small number of projects in areas that are important for the country in order to build up the capacity to compete with them. We cannot do it like they do, they invest in most things, in all areas, we cannot do this, and we need to find a way to focus on a few projects for innovation. Basic science is okay, but for innovation we need to focus on a few areas. (Respondent 8 20:74)

You cannot compare any country with the United States, the amount of money they invest in biotechnology is so big and the infrastructure they have for research in biotechnology is so big, you cannot compare, not even in Europe, or maybe in Japan or in China, it is huge. Not only in terms of infrastructure but in terms of the very well-trained people, of course we are interested in some areas that the US are interested in. But they have all the facilities, but it is not only the facilities, they have *companies that produce all the reagents and the equipment and all the things that you need to do the research, they have all the companies. They work at a velocity that you cannot follow, for example, all the reagents and the equipment that you need to do research with, we import mostly from the US, and this importation process takes months and in the US they can do this in a day, they can ask and have all things in a day, so you cannot compare, it is so huge, it is a very different environment. (Respondent 8 20:68-69)*

In concluding this section, the areas of similarities and differences are linked to the favourable factors and challenges in the development of biotechnology entrepreneurship in Brazil respectively.

This is an important observation that may mean that the process of biotechnology entrepreneurship in Brazil is expected by the respondents to be the same as the process in the developed economies. Hence, the similarities with the developed economies are in the same areas that are considered to be favourable in the environment of biotechnology entrepreneurship in Brazil.

On the other hand, the differences with the developed economies are in the same areas that are highlighted as challenges in the environment of biotechnology entrepreneurship in Brazil.

PART III: CASE ANALYSES

Part III consists of chapters 7 and 8.

Chapter 7 presents a detailed analysis of case 1.
Chapter 8 presents a detailed analysis of case 2.

The case analyses consider how biotechnology entrepreneurship is carried out in South Africa and Brazil using the organising framework of the individual-opportunity nexus framework of entrepreneurship (Shane, 2003). The nature of the relationship across university, industry, and government in both countries is explored using the organising framework of the Triple Helix of university, industry, government relations (Etzkowitz and Leydesdorff, 1997; Etzkowitz, 1998; Leydesdorff and Etzkowitz, 1998; Etzkowitz and Leydesdorff, 2000; Etzkowitz, 2001; Leydesdorff and Etzkowitz, 2001).

Chapter 7: Case Analysis – South Africa

The detailed analysis of case 1 integrates the deep interrogation of the current empirical and market research studies on biotechnology entrepreneurship in South Africa with interview transcripts, the output of Atlas.ti CAQDAS, and documents, to get to a consistent and rigorous analytical view (Weitzman, 1999; Rambaree, 2007; Hwang, 2008) of the dynamics of biotechnology entrepreneurship in South Africa within its original context (Eisenhardt and Graebner, 2007b; Klonoski, 2013).

7.1 Background to biotechnology entrepreneurship in South Africa

Very few empirical studies on the South African biotechnology industry exist (Cloete et al., 2006; Gastrow, 2008). To articulate the current state of biotechnology in South Africa, the national strategy documents (Department of Science and Technology, 2001) were used, in addition to industry research conducted by organisations such as the OECD (Organisation for Economic Cooperation and Development, 2013d, 2013b, 2013c, 2013a), and Ernst & Young (Ernst & Young, 2006, 2010a, 2010b).

The national biotechnology strategy was scheduled to be updated in 2008 but was not completed until 2013. The updated version of the national biotechnology strategy, renamed “the bio-economy strategy” is not publicly available yet and was included in the policy documents used in this research.

South Africa has traditionally been strong in first-generation biotechnology, given its beer and wine industry (Cloete et al., 2006). However, the third-generation biotechnology industry in South Africa is very small relative to this industry in the developed economies (see Figure 7.1).

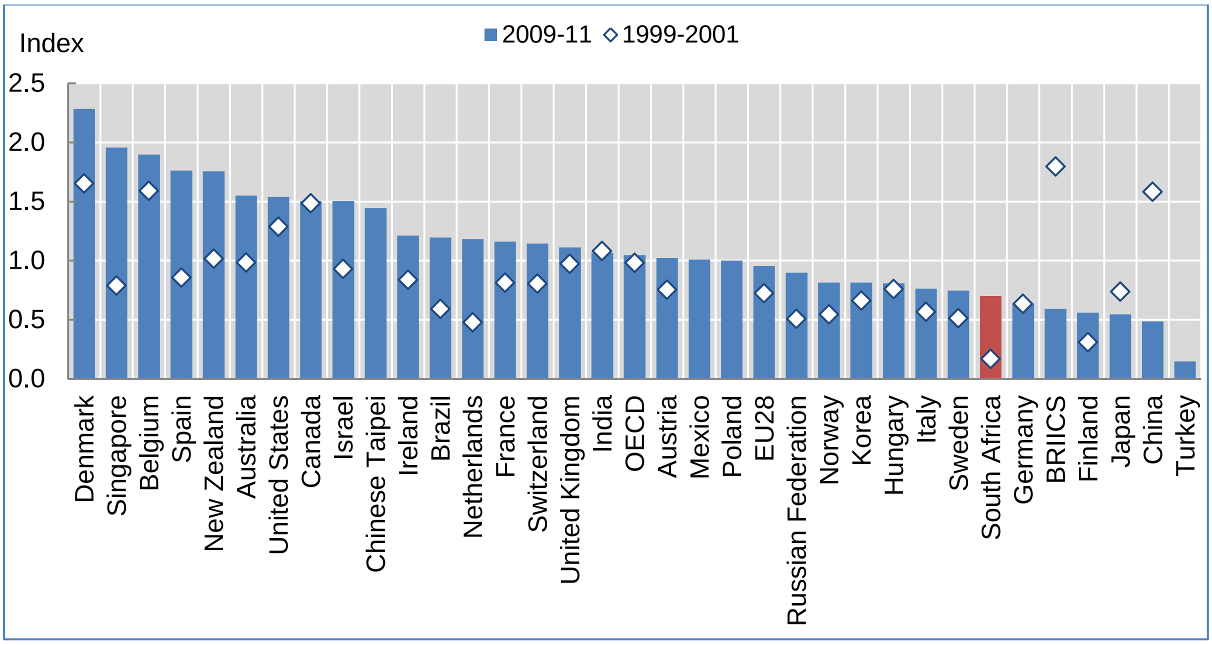


Figure 7.1: Revealed technological advantage in biotechnologies, 1999-2001 and 2009-11 (OECD Patent Database, October 2013) (Organisation for Economic Cooperation and Development, 2013d)

(Note: The bar highlighted in red is the value for South Africa. BRIICS stands for Brazil, Russia, India, Indonesia, China and South Africa)

The relative paucity of empirical research on biotechnology entrepreneurship in South Africa may have contributed to the low position occupied by South Africa on revealed technological advantage in biotechnologies (see Figure 7.1).

7.1.1 National biotechnology strategy

Emphasis on biotechnology in South Africa culminated in the national biotechnology strategy of 2001 (Department of Science and Technology, 2001), which aims to develop a viable and sustainable biotechnology industry.

The guiding principles for the conception and implementation of the strategy include:

i. The need to meet the national imperatives of job creation, rural development, crime prevention, human resource development, the addressing of HIV/AIDS and economic growth
ii. Focus on areas of likely comparative advantage in biotechnology

iii. Development of new programmes that harness existing national scientific and technological competencies
iv. Addressing issues of biosafety
v. Review of the strategy in light of national priorities and international trends in biotechnology development

The adoption of this policy framework led to the establishment of four Biotechnology Regional Innovation Centres (BRICS), the National Bioinformatics Network (NBN), biotechnology incubators and Bioventures (a biotechnology venture capital fund). Various government agencies, research institutions and universities were tasked with the implementation of the strategy, with the Department of Science and Technology having the responsibility of administering the strategy (Cloete et al., 2006).

7.1.2 Creation of the Technology Innovation Agency

In 2010, a new public entity was established, which is known as the TIA. The TIA replaced the BRICS, the Innovation Fund, Advanced Manufacturing Technology Strategy (AMTS) and Tshumisano Trust. The aim of TIA is to stimulate and intensify innovation leading to the development of technology based products and services, by the public and private sector technology based enterprises, and to create an enabling environment in which these could be commercialised (Technology Innovation Agency, 2010)

TIA (2010) provides and mobilises financial and non-financial support across broad technology areas in various sectors of the economy through:

i. Appropriately structured financial and non-financial interventions for the commercialisation of R&D results
ii. The development and maintenance of advanced human capacity for innovation as opposed to just R&D human capital
iii. Building a culture of innovation in the South African economy
iv. Leveraging local and international partnerships in order to facilitate in-bound technology transfer, build local technological competencies, and encourage

foreign direct investment for the commercialisation of technologies in South Africa (Technology Innovation Agency, 2010)

Areas of success are predominantly in agricultural biotechnology and vaccine production. However, these successes pale when compared to those of the developed economies (see Figure 7.1). The role of TIA as articulated in the section above has not been effectively carried out as evidenced by the experience of the respondents who participated in this research.

> *I think the biggest disappointment that many of us in the field have had over the last two or three years is that the instrument that TIA was meant to represent has not, has not come to the party, has not come to the fore and the delays that people are experiencing with TIA at the moment have actually meant that in several cases, businesses have had to close down and that is an absolute tragedy in a country where there is such a strong will to grow biotechnology but there was this major obstacle. (Respondent 12 7:20)*

7.1.3 Constraints

The constraints to the development of biotechnology entrepreneurship in South Africa include:

i. Shortage of bioscience skills (Lingelbach et al., 2005; Cloete et al., 2006)
ii. Shortage of research and publications related to biotechnology (Cloete et al., 2006; Gastrow, 2008)
iii. Low levels of patent application (Gastrow, 2008; United States Patent and Trademark Office, 2009)
iv. Low levels of commercialised biotechnology products (Cloete et al., 2006)
v. Low levels of R&D spend relative to the developed economies (Gastrow, 2008)

vi. Lack of sustained emphasis on biotechnology. The update of the national biotechnology strategy scheduled for 2008 was not effected until 2013 (Department of Science and Technology, 2001)
vii. Lack of performance on mathematics and science in the national curriculum
viii. Lack of a developed venture capital industry (Lingelbach et al., 2005; Lingelbach et al., 2008; Lingelbach et al., 2013)
ix. Lack of entrepreneurial culture at universities (Mitchell, 2006; Kabongo and Okpara, 2010; Chimucheka, 2014)
x. Low level of private sector involvement in biotechnology (Cloete et al., 2006)

These constraints impact on the speed and scale of development of biotechnology entrepreneurship in South Africa. Literature (Müller et al., 2004; Ahn and Meeks, 2007) on developed economies shows that the resolution of these constraints is the necessary condition for creating an environment that is conducive for the development of biotechnology entrepreneurship in South Africa.

7.2 How biotechnology entrepreneurship is carried out in South Africa

The analysis of the process of biotechnology entrepreneurship in South Africa is facilitated through the use of the individual-opportunity nexus framework of entrepreneurship discussed in Chapter 3, as an organising framework. Hence, the components include:

i. Individual attributes
ii. Environment
iii. Entrepreneurial opportunities
iv. Discovery
v. Entrepreneurial exploitation
vi. Execution

7.2.1 Individual attributes

There were 12 respondents in South Africa of which seven were designated as bioentrepreneurs and five were subject matter experts (SME) across university, industry, and government. Among these 12 there were four overlaps, which were designated as both bioentrepreneur and subject matter expert.

In choosing the respondents for the research in South Africa, care was taken to ensure that the purposive sampling was representative of individuals with a high degree of knowledge and competence in the research topic (Romney et al., 1986; Guest et al., 2006; Stake, 2006; Bowen, 2008) and hence, with good insights into the dynamics of biotechnology entrepreneurship in South Africa.

A summary of the characteristics of the respondents for case 1 is presented in Table 7.1.

Table 7.1: Summary of characteristics of respondents for South Africa

Respondent	Position	Qualification	Area of expertise
1	Director at a government agency	M.Sc. in Environmental Biology	Biotechnology policy development and implementation
2	Director at the university	B.Engr.; CFA; MBA	TTO and commercialisation of research
3	Researcher at a government agency	B.Sc. (Honours); MBA; PhD in Biochemistry	Implementation of the biotechnology strategy
4	Chief scientist at a government agency	B.Sc.; M.Sc.; PhD in Chemistry; Associate Professor	Bio-prospecting and the effective use of South Africa's biodiversity
5	Founder of a biotechnology company	M.Sc. MBA; PhD in Biotechnology	Bioentrepreneur in the area of human health specialising in the research and development of osteogenic biomaterials for use in skeletal regeneration therapies in humans
6	Founder of a biotechnology	Biotechnologist; Management	Bioentrepreneur in the area of human health specialising in the production

Respondent	Position	Qualification	Area of expertise
	company	advancement Programme (MAP)	of high quality lateral flow rapid diagnostic test kits
7	Director at the university	Medical doctor; PhD; Professor of Immunology	An ex-bioentrepreneur and closely involved in academics and government initiatives on biotechnology
8	Ex-director of a Venture Capital Fund	MBA; PhD in Cell Biology	Instrumental in setting up and raising South Africa's first venture capital fund for biotechnology.
9	Managing director of a specialist not-for-profit contract research organisation	PhD in Molecular Biology	Combines state-of-the-art information rich genomic and proteomic technologies with bio-computational pipelines to create unique solutions for biological problems in the human health and the agricultural biotechnology sectors
10	Founder of a biotechnology company	B.Sc. in Applied Mathematics and Physics; PhD in musculoskeletal biomechanics; and a DSc (Med) in biomedical engineering	Medical bioengineering specialising in the design and manufacture of medical imaging systems for the diagnosis of breast cancer
11	Co-founder of a biotechnology company	Medical doctor; Pharmacologist	Conducts leading-edge biotechnology research and related bioservices to the biotechnology industry
12	Founder of a biotechnology company	M.Sc. in Physiology, Pathology and Related Sciences	Specialises in the manufacture of wide range of both urinalysis and lateral flow diagnostics products for government, NGO procurement and for private use

In addition to the psychological attributes, the respondents in South Africa possessed the requisite non-psychological factors, such as education and career experience (Barro and Lee, 2000), for biotechnology entrepreneurship. The education factor in biotechnology entrepreneurship is a critical requirement functioning as a bioentrepreneur.

The bioentrepreneurs interviewed in South Africa either already had successful products in the local and international markets or were at an advanced stage of product development.

> *An entrepreneur wants to be independent.*
> *He wants to start something from scratch and build into something substantial, and he likes the insecurity of not having a salary at the end of the month because it drives him to try and make some money.*
> *It is such a great feeling of accomplishment. (Respondent 5 5:62-65)*

> *We export our malaria kits to countries like Papua New Guinea, Pakistan, some African countries via a distributor. And we sell most of our HIV tests, pregnancy tests, drug abuse tests in South Africa to pharmaceutical wholesalers, Department of Health, Department of Education, some other governmental departments and some private companies. (Respondent 11 6:11-12)*

These bioentrepreneurs exhibited individual psychological attributes such as a higher level of cognitive functioning, motivation, leadership qualities, propensity to take risks, action-oriented, self-efficacy, preference for autonomy, self-direction, and differential access to scarce and expensive resources (Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003).

> *And I want to make the first recombinant bone complex in the world, that is my next dream. In 2022, I would like to launch the first recombinant complex, and I would like to have an interview with you again at that time. We meet here in 10 years' time to see what is happening and how we have achieved that. (Respondent 5 5:81-82)*

> *I had customers before I produced. And that of course is important in your way of thinking as well; profiling, building a company, building a brand, building a profile for yourself as an individual. (Respondent 11 6:26-27)*

However, these bioentrepreneurs did not believe that their entrepreneurial skills were inherited. Most of the respondents designated as bioentrepreneurs believed that they were bioscientists who had acquired the business management skills through training to qualify as bioentrepreneurs. *(Respondent 11 6:7)*

Of all respondents designated as bioentrepreneurs in South Africa, only one believed that his entrepreneurial qualities were inherited, and, hence, he would have been an entrepreneur in any field he chose *(Respondent 5 5:55-56)*.

The respondents in South Africa had the necessary bioscientific educational training and were highly qualified academically, as shown in the characteristics listed in Table 7.1. They were also inclined to acquire business management skills, which enabled them to manage the firms set up to commercialise their biotechnological innovations.

> *Doing my MBA at Wits university was a key step to empower myself with sufficient knowledge capital to better understand the business of science. How to do financial models, how to calculate net present values, how to understand strategies and scenario planning. (Respondent 5 5:12-13)*

> *I also attended a programme hosted by Wits University, called the management advancement programme. (Respondent 11 6:7)*
> *It opened up my eyes to think more like a business person than a scientist. Scientists tend to think of the publications we can get, let me do my research, I want to publish this paper. (Respondent 11 6:22)*

This combination of bioscientific and business management skills predisposed them to the “individual” approach to biotechnology entrepreneurship where the scientific and entrepreneurial functions reside in one individual; rather than a “system” approach where the bioscientist does not necessarily have the responsibility for the entrepreneurial or business management side of the running the firm set up to exploit the biotechnological innovation. The system approach is obtainable in biotechnology clusters (Ahn and Meeks, 2007) as seen in the developed economies. The biotechnology clusters in South Africa are underdeveloped and that may be a contributing factor to the tendency for the respondents to adopt the individual approach.

Although the lack of entrepreneurial skills is often cited as one of the constraints facing biotechnology entrepreneurship in South Africa (Cloete et al., 2006; Gastrow, 2008; Ernst & Young, 2010b; Organisation for Economic Cooperation and Development, 2013a), this is at an aggregate and not at an individual level. The skills of the individual bioscientists are deemed to be on par with those elsewhere in the world.

> *Centres of academic research excellence, mainly located in a nucleus of long-established universities, achieve high quality in several areas of research, as reflected in the presence of South African publications among the top 1% of internationally cited publications in several fields and in some cases in the higher quartiles of that group. (Documents Case 1 14:16)*

It can be concluded from the analysis above that the psychological and non-psychological individual attributes for entrepreneurship highlighted in the literature on entrepreneurship are possessed by the respondents in South Africa. In addition, they display the tendency to obtain business management training to enable them to manage their firms effectively as an individual rather than rely on a support system that does not exist in South Africa.

In carrying out the entrepreneurial activities required for the management of their firms, the respondents mostly believe that their entrepreneurial ability is learned and not inherited.

7.2.2 Environment

The environment of biotechnology entrepreneurship in South Africa is fraught with challenges according to the respondents (see Table 7.2 below). In addition, the document analysis highlighted key areas of challenge for biotechnology entrepreneurship in South Africa as human capital (skills), knowledge exploitation, market development (market size) and governance (government direction).

> *This strategy is based on the assumption that the issues facing South Africa's bio-economy – including human capital development, knowledge exploitation, market development and governance – cannot be addressed in isolation, but need to be solved in an integrated, holistic fashion to yield coordinated, systemic interventions. (Documents Case 1 13:68)*

Table 7.2 shows the areas highlighted by the respondents as affecting the environment of biotechnology entrepreneurship in South Africa. Most of these are designated as challenges. Of the nineteen (19) areas highlighted only one was mostly seen as not a challenge while the remaining eighteen areas were seen as challenges by most of the respondents.

The one area that was not seen as a challenge by just over half of the respondents was infrastructure. A careful examination of the verbatim comments on this point showed that the respondents referred to general infrastructure such as roads and electricity; as well as research-oriented infrastructure such as universities and research institutions. However, the infrastructure that was mentioned most often was the biotechnology park. There was a general acknowledgement of the lack of biotechnology parks but about half of the respondents believed that the support structures within the park are more important to the development of biotechnology entrepreneurship than the bricks and mortar.

> *Like I said we need, we seriously need a science park in this country where we look at the high impacting biotech businesses, and we look at their needs. (Respondent 11 6:55)*

So I have never seen infrastructure as being a problem. We have got fantastic roads, we have got great telecommunication. Our basic infrastructure is in place. We have got fantastic universities that are very well equipped. Again it is not through the creation of a biopark that you are going to have a successful biotech industry. (Respondent 12 7:47, 48, 50)

Table 7.2: Points highlighted by South African respondents as affecting the environment of biotechnology entrepreneurship

Point mentioned	This point is mostly considered a gap	This point is mostly not considered a gap
Policy and regulation	√	X
Funding	√	X
University culture	√	X
Government direction	√	X
Skills	√	X
Market size	√	X
Infrastructure	X	√
Brain drain	√	X
Support	√	X
Capacity	√	X
National culture	√	X
Bureaucracy	√	X
Failure	√	X
Corruption	√	X
Politics	√	X
Implementation	√	X
Large biotechnology companies	√	X
Stakeholder conflict	√	X
Problematic exit	√	X

The narrative points were collated by manually going through the narrative summary of the verbatim quotes by the respondents in South Africa, and highlighting the areas mentioned as impacting on the environment of biotechnology entrepreneurship in South Africa.

The outcomes of data analysis using Atlas.ti CAQDAS for the codes that have the most occurrences, but not necessarily in most of the transcripts (vertical occurrence), are shown in Table 7.3. These codes were compared to the narrative points in Table 7.2;and the codes mentioned by most respondents (horizontal occurrence) (see Table 7.4) to establish a pattern.

Table 7.3: The table of codes that were mentioned the most (vertical occurrence)

Number	Codes that occur the most (vertical occurrence)
1	Need for effective collaboration among key stakeholders
2	Lack of appropriate funding
3	Lack of developed markets for biotechnology products
4	Lack of collaboration among key stakeholders
5	Lack of government direction
6	Emphasis on country competitiveness
7	Under-developed venture capital industry
8	Commercialisation of research
9	Evidence of collaboration among key stakeholders
10	Bureaucratic processes
11	Emphasis on national priorities
12	Lack of entrepreneurship skills
13	The academic-bioentrepreneur disconnect
14	Abundant biodiversity
15	Lack of commercialisation skills
16	Obvious socio-economic linkages
17	Pervasive opportunities
18	Availability of skills
19	Lack of conducive environment for biotechnology development
20	Need for direction or leadership
21	Non-conducive regulatory environment
22	University policy on IP ownership
23	Lack of capacity
24	University policy on commercialisation
25	Good support infrastructure
26	Government is seen as a hindrance by other stakeholders
27	Lack of critical mass of input
28	Lack of entrepreneurial culture
29	Obstacles to commercialisation
30	Problem opportunity

Number	Codes that occur the most (vertical occurrence)
31	Economic value
32	Need to develop innovation skills
33	Strategic alliances
34	University publication-commercialisation disconnect

The codes that have the most occurrences in most of the transcripts (horizontal occurrence) are in shown in Table 7.4.

Table 7.4: The table of codes that occurred across most of the respondents (horizontal occurrence)

Number	Codes that appear in most transcripts (horizontal occurrence)
1	Evidence of collaboration among key stakeholders
2	Availability of skills
3	Lack of appropriate funding
4	Lack of developed markets for biotechnology products
5	Under-developed venture capital industry
6	Abundant biodiversity
7	Commercialisation of research
8	Lack of collaboration among key stakeholders
9	Emphasis on country competitiveness
10	Lack of government direction
11	Need for effective collaboration among key stakeholders
12	Non-conducive regulatory environment
13	Obstacles to commercialisation
14	The academic-bioentrepreneur disconnect
15	Biotechnology timeframe
16	Bureaucratic processes
17	Innovation cluster/hub/park
18	Pervasive opportunities
19	Problem opportunity
20	Support for licensing
21	University publication-commercialisation disconnect
22	University spin-off/start-ups
23	Business strategy
24	Conducive environment for biotechnology development
25	Failure to commercialise biotehnology projects
26	Good universities

Number	Codes that appear in most transcripts (horizontal occurrence)
27	Government-incentivised entrepreneurial action
28	Government is seen as a hindrance by other stakeholders
29	Higher levels of business and market risks
30	Lack of capacity
31	Lack of commercialisation skills
32	Lack of competitiveness
33	Lack of conducive environment for biotechnology development
34	Lack of entrepreneurial culture

These are outputs of the Atlas.ti CAQDAS that enabled an in-depth analysis of the code patterns in different dimensions (Weitzman, 1999; Rambaree, 2007; Hwang, 2008).

The reason for analysing the codes in different dimensions is because a particular point may be mentioned many times in the transcript, but may be the experience of one or a few respondents. Hence, it is also important to analyse the codes horizontally to determine the occurrence of particular codes across most or all of the transcripts.
The codes that have most mention within (vertical) and across (horizontal) the transcripts are deemed to be important in identifying the patterns in the data that improve the understanding of the process of biotechnology entrepreneurship in South Africa.

The identified patterns in the environment of biotechnology entrepreneurship in South Africa are summarised below:

i. Most of the respondents believe that there is a lack of collaboration among key stakeholders in biotechnology entrepreneurship in South Africa. Although most of the respondents experience evidence of collaboration with key stakeholders, they agree that there is a need for effective collaboration among key stakeholders

ii. Although most of the respondents believe that the scientific and research skills needed for biotechnology entrepreneurship are available in South Africa, they also deem the entrepreneurial and commercialisation skills to be lacking
iii. The lack of appropriate funding is consistently deemed to be a constraint by most of the respondents
iv. The lack of developed markets for biotechnology products is consistently deemed to be a constraint by most of the respondents
v. The venture capital industry is consistently deemed to be underdeveloped in South Africa
vi. The lack of direction from the government, through its implementation agencies, is consistently deemed to be a constraint by most of the respondents and the activities deemed to be hindering the development of the biotechnology industry
vii. The emphasis on country competitiveness is consistently deemed by most of the respondents to be an important consideration for biotechnology entrepreneurship in South Africa
viii. The regulatory environment is consistently deemed to be a constraint by most of the respondents
ix. Most of the respondents agree that there is a misalignment between the requirements for being an academic and for being an entrepreneur. In addition, the university culture is deemed mostly to prioritise publication over commercialisation
x. The abundance of biodiversity is deemed to be a positive factor by most of the respondents in the development of biotechnology entrepreneurship in South Africa
xi. The general environment for the development of biotechnology entrepreneurship in South Africa is deemed by most of the respondents to be unfavourable

The points that were mentioned the most by the respondents as impacting on the environment of biotechnology entrepreneurship in South Africa are analysed further in the following sections for deeper meaning and explanation (Eisenhardt and Graebner, 2007a). These points are:

i. Lack of, and the need for, collaboration among the key stakeholders
ii. Policy and regulation
iii. Funding
iv. An inclination to prioritise publication over commercialisation by the universities
v. Government direction
vi. Skills
vii. Market size

The lack of collaboration among the key stakeholders

The experience of the collaboration among the key stakeholders in the biotechnology industry in South Africa is covered in detail in Section 7.4.

Policy and regulation

(Represented as “non-conducive regulatory environment” in Tables 7.3 and 7.4)

The policy and regulatory environment of biotechnology entrepreneurship in South Africa includes specific policies that impact on biotechnology entrepreneurship such as intellectual property policy, policies related to R&D activities, policies that govern public universities and research institutions, innovation policies, technology transfer policies, policies related to immigration of foreign skills, labour laws, policies related to ethics in biotechnology and taxation laws related to research.

The policy and regulatory environment of biotechnology entrepreneurship in South Africa appeared as “non-conducive regulatory environment” in the vertical and horizontal code occurrences (see Tables 7.3 and 7.4). This policy gap is recognised in the new bio-economy strategy to be implemented by the government of South Africa *(Documents Case 1 14:68)*.

Although emphasis is being placed on the intellectual property policies, the experience of the overall policy and regulatory environment by the respondents in

South Africa is unfavourable and supports the assertion that the policy and regulatory environment is not enabling.

> *Well I mean South Africa has a number of problems for entrepreneurship that are unique to South Africa like our labour laws, like the difficulty of setting up a business, and then more recently the IP legislation if you have got any government funding. (Respondent 13 8:18)*

> *A lack of delivery of biotechnology strategy largely hinges, not entirely, but largely hinges on the policy environment. They are contradictory and unaligned challenging policy regulatory environment. So there are lots of things that need to be sorted out, and it's one of the things we hope to address through the bio-economy strategy. (Respondent 1 1:77)*

> *And there are a lot of things in our legislation which unfortunately are restrictive to biotechnology emerging as a key driver of the economy.*
> *The first, as I said, is funding, the second is legislation. (Respondent 12 7:24-25)*

In comparison to general entrepreneurship, the policy and regulatory environment plays a bigger role in biotechnology entrepreneurship in South Africa due to the multifaceted nature of biotechnology (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012). Biotechnology impacts on critical areas of society such as food security, human health, environmental sustainability and energy sufficiency (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012).

Funding

(Represented as “lack of appropriate funding” in Tables 7.3 and 7.4)

The funding environment for biotechnology entrepreneurship in South Africa is characterised by the code “lack of appropriate funding”, which occurred many times within and across the transcripts, as shown in Tables 7.3 and 7.4.

The availability of capital (Shane, 2003) is an important factor in any entrepreneurial activity and biotechnology entrepreneurship is often associated with both government and venture capital funding sources (Audretsch et al., 2008).

The experience of the bioentrepreneurs in South Africa is restricted to the government source of funding because of the lack of a developed venture capital industry for biotechnology (Audretsch et al., 2008). This situation may be unique to the South African biotechnology industry as venture capital funding is a core component of biotechnology entrepreneurship in developed economies (Ahn and Meeks, 2007; Ahn et al., 2010a).

> *Funding is very important, an important obstacle and that is at the moment mainly provided by government. (Respondent 12 7:17)*

> *And quite frankly you cannot develop anything in the country without government funding because it is the only source of funding so you are hamstrung from the start. (Respondent 13 8:19)*

In addition to having government as the only source of funding for biotechnology entrepreneurship in South Africa, there is another challenge that the funding from the government is often not appropriate for the nature of the biotechnology industry in terms of risk profile and timeframe.

> *The problem with the government money was that it came with all sorts of strings attached which were not necessarily in line with what our mandate was which was to make as much money as possible.*

They put in loans. I mean these were companies that do not make any money, how on earth are you supposed to pay a loan back or pay interest. (Respondent 13 8:8-9)

An inclination to prioritise publication over commercialisation by the universities

(Represented as "university publication-commercialisation disconnect" in Tables 7.3 and 7.4)

The university culture, which was highlighted as a challenge in the environment of biotechnology entrepreneurship in South Africa is characterised by the code "university publication-commercialisation disconnect" in Tables 7.3 and 7.4. The tendency of the universities to prioritise journal publication over the commercialisation of intellectual property means that the economic benefits associated with the commercialisation of these intellectual properties do not accrue to the university or government.

That is definitely an element. Our universities do focus on publication rather than on commercialisation. (Respondent 12 7:66)

Okay now think about what you are doing in the context of translating this into a useful product. So we are not taught, in the universities to think about what we are doing in terms of the market. We just think about it in terms of research and in terms of the fact that we need publications in order to be able to advance. (Respondent 12 7:68-70)

Researchers are under pressure to publish, but at the same time if they publish they lose their intellectual property unless they publish after they have registered their IP or their patent, for example. So that is another challenge that I think we definitely face. (Respondent 3 3:77)

The rate of scientific publication is often used as a measure for the status of the individual scientist within the university as well as the strength of the scientific credentials of the university and the country (Organisation for Economic Cooperation and Development, 2013e, 2013b, 2013c). Some of the policy actions that the government has taken in South Africa to benefit from both publication and commercialisation of intellectual property encourage a cultural change towards "commercialise first-publish later" among the universities and research institutions.

> *We have got still an academic culture and their incentives at this stage are to publish and to train students. So we have just introduced our IP Act which says before you publish first check to see if you've got some IP there and if so register this with our national IP management office. (Respondent 1 1:138)*

> *Never underestimate the value of good patent; it is possible to be both publishing as well as be taking out a patent. The key thing is to make sure you register the patent first and then you publish. (Respondent 15 10:22-23)*

Government direction

(Represented as "lack of government direction" in Tables 7.3 and 7.4)

The agencies of government that are mostly involved with the development of biotechnology entrepreneurship in South Africa are the DST and TIA. While the DST is responsible for policy and strategy development, TIA is responsible for implementing those policies and strategies (Department of Science and Technology, 2001; Department of Science and Technology and eGoli Bio, 2003; Cloete et al., 2006; Ernst & Young, 2006; Department of Science and Technology, 2007; Gastrow, 2008; Technology Innovation Agency, 2010).

The experience of the respondents interviewed for this research highlighted a lack of effective leadership and direction from the government, and the activities of these government agencies were deemed to be hindering the development of biotechnology entrepreneurship rather than promoting it.

Government needs to carefully consider the regulations in this area, and the policies. They also need to provide a bit more guidance on what the needs really are. Where are the priority areas in government?
So I think from government's side they need to provide more guidance in these areas. And more emphasis to the scientists, to the researchers involved in these areas. We need to move away from bureaucracy. (Respondent 4 4:51-55)

TIA is not functioning optimally yet. What TIA should be doing, but it's not yet doing properly, is stimulating the bio-economy. It should be creating critical mass in certain areas. (Respondent 1 1:118-120)

Yes, but the rest of the world is going down one route and government is going down another route, and what they are doing in practice is not that, they are making it more complicated. So again, the implementation challenge is significant. (Respondent 2 2:129)

Some of the inefficiencies experienced by the respondents with the government agencies are attributed to bureaucracy within the agencies.

I think the Technology Innovation Agency [TIA] plays a big role although there is red tape. Without TIA being there, there would be nothing. (Respondent 11 6:110)

It is bureaucracy in the worst instance and it is so bad that many times we decided to pack up and move elsewhere. (Respondent 17 12:17)

In at least two instances, the experience of the bioentrepreneurs with the government agencies was very positive and contradicted the general experience of most of the respondents. This contradiction points to the possibility that the general lack of direction portrayed by most of the respondents in this research may not be representative of the reality of government activities in the development of biotechnology entrepreneurship in South Africa.

I found my experience in South Africa with the government funding agencies absolutely fantastic. They understand the dynamic, there is a dynamic there of competitiveness. (Respondent 5 5:43-44)
I have been quietly impressed, particularly with our two departments which are involved in this, the Department of Science and Technology and the Department and Trade and Industry. I think they have got a number of very good programmes in place of which my company has been a beneficiary and so was the University. (Respondent 15 10:35)

Skills

(Represented as "availability of skills"; "lack of entrepreneurship skills"; and "lack of commercialisation skills" in Tables 7.3 and 7.4)

The importance of skills (Department of Science and Technology, 2001; Lingelbach et al., 2005; Ahn and Meeks, 2007; Department of Science and Technology, 2007; Phan et al., 2008; Ahn et al., 2010a; Ahn et al., 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012; Kelley et al., 2012) to the development of biotechnology entrepreneurship in South Africa was highlighted by most of the respondents.

In analysing the experience of the respondents regarding the skills landscape, four broad categories of skills were highlighted by the respondents: scientific, research, entrepreneurial, and commercialisation skills. While most of the respondents believed that there was an availability of scientific and research skills in South Africa, the entrepreneurial and commercialisation skills were deemed to be lacking.

So one of the things that we really need to continue and expand is the development of bio-entrepreneurship skills. (Respondent 1 1:139)

So universities and science councils do not want to commercialise.
They would like to commercialise but that is not their passion and they do not have the necessary skills and abilities. (Respondent 2 2:35-36)

A part of the problem identified by the respondents to be contributing to the lack of entrepreneurial and commercialisation skills is the phenomenon of the brain drain where talented individuals are lured away to foreign countries with favourable conditions for biotechnology entrepreneurship.

> *That is very important and it all starts with the scarce skills. Our scarce skills are leaving South Africa; they are going overseas because the environment is not right here. (Respondent 11 6:72)*

The lack of entrepreneurial and commercialisation skills were identified in prior studies on biotechnology industry in South Africa in the form of a lack of skills (Lingelbach et al., 2005), and low levels of commercialisation of biotechnology products (Cloete et al., 2006). This distinction between the types of skills that are lacking is important given the general discourse on the low level of mathematics and science education in South Africa (Department of Science and Technology, 2001; Department of Science and Technology, 2007), which can easily be wrongly interpreted to mean a lack of science and research skills for biotechnology entrepreneurship in South Africa.

Market size

(Represented as "lack of developed markets for biotechnology products" in Tables 7.3 and 7.4)

The lack of developed markets for biotechnology products in South Africa was deemed to be a constraint by most of the respondents. The size of the market was invariably linked to the size of the industry itself, by most of the respondents.

> *However the biggest challenge that is faced in South Africa is that the South African market itself with its biotechnological innovations are too small, the market is too small. (Respondent 4 4:6)*

The general opinion and the general word when you talk to everyone, is that biotechnology industry in South Africa is quite small, that is the general opinion of everyone. (Respondent 4 4:13)

There is no market, it does not exist.
Let us just look from a point of view, our client base is people developing drugs, I do not know one single company developing drugs in South Africa; none of the pharmaceutical companies, in fact there is no prime pharmaceutical development taking place in South Africa. (Respondent 16 11:7-9)

Amid a consensus about the small size and lack of developed markets for biotechnology products among the respondents, there was at least one respondent with a contradictory view on the experience of the market in South Africa.

First the market, do we have a direct market for products in South Africa? I believe we do. I think we are far along enough to be able to procure products for biotechnology companies in South Africa; we have the infrastructure to do that. (Respondent 11 6:95-96)

Although the products and solutions developed by these bioentrepreneurs address the needs of the government to improve human health; crop yield and food security; environmental sustainability; and energy sufficiency; (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012) they still face global competition from other biotechnology and non-biotechnology solutions.
The need for the government to reach as many recipients of this solution as possible often leads to price being the primary consideration for buying either locally or from foreign competitors. An example of this scenario is the roll-out of the HIV/AIDS anti-retroviral treatment in South Africa (*Respondent 13 8:27).*

The tender process here is totally, totally, totally not in our favour, there is a 90-point system in my industry where 60 points they award toward price, 30 points they award toward local content, BEE and others.

We are competing against first world countries like China where they have tech parks, science parks where they don't have to import components. So when they come to our country and tender obviously it is cheaper for them, so now governments are awarding tenders to the Chinese and to other Asian countries based on price. They should actually award more points to local content to promote companies growing here and government buying from us. (Respondent 11 6:36-39)

The lack of a developed market for the biotechnology products and solutions results in the bioentrepreneurs having to compete in international markets.

We could not survive in South African market because we were not selling enough systems. (Respondent 15 10:7)

In concluding this sub-section, there are some differences between the areas highlighted as impacting on the environment of biotechnology entrepreneurship in prior studies (Cloete et al., 2006; Gastrow, 2008) and the areas identified by the respondents. These areas are the policy and regulatory environment; the university culture that leads to the low level of commercialisation; the lack of government leadership and direction; and the small size of the South African market for biotechnology.

The other areas of the environment were mentioned by two or more respondents and that are worth emphasising are the lack of support structures; the lack of capacity; a national culture that does not support bioentrepreneurship; bureaucracy; the stigmatisation of failure; and corruption. These areas were not mentioned by most of the respondents. However, those who mentioned these areas saw them as challenges to the development of biotechnology entrepreneurship in South Africa.

The overall experience of the environment of biotechnology entrepreneurship in South Africa, by the respondents in this research, was unfavourable. However, there were areas that were contradicted by some respondents. Hence, while a deeper understanding (Eisenhardt and Graebner, 2007b) of the environment of biotechnology entrepreneurship is possible from this analysis; it cannot be taken as a conclusive view of the environment of biotechnology entrepreneurship in South Africa.

7.2.3 Entrepreneurial opportunities

The entrepreneurial opportunities in biotechnology seem to be different from the entrepreneurial opportunities in general entrepreneurship in some key aspects.

While the general entrepreneurial opportunities are not known in advance and require enterprising individuals with special psychological attributes (McClelland, 1961; Kihlstrom and Laffont, 1979; Schere, 1982; Gartner, 1990) to uncover them the bioentrepreneurial opportunities are mostly known in advance and require bioscientific skills to get to a solution (Müller et al., 2004).

The discovery of general entrepreneurial opportunities requires the individual entrepreneur to apply their business management capability towards profit making or other forms of positive outcome (Shane, 2003). However, the discovery of bioentrepreneurial opportunities involves a process of R&D to get to the desired outcome, and is more of a “creation” (Audretsch et al., 2008) than a “discovery” (Alvarez and Barney, 2007).

The exploitation of general entrepreneurial opportunities is also mostly dependent on the individual entrepreneur and their organising abilities (Shane, 2003). However, the exploitation of bioentrepreneurial opportunities mostly requires a strategic alliance involving government, large established companies, venture capitalists and research institutions (Müller et al., 2004; Rothaermel and Deeds, 2004; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

Most of the respondents in South Africa see bioentrepreneurial opportunities in the areas of biodiversity and problems related to food security and disease control. These types of opportunities, linked to problems of diseases, food security, the environment and energy are designated as “problem opportunities” (researcher’s synthesis).

The problem opportunities are in the areas of diseases such as HIV, tuberculosis, malaria, and typhoid fever; infertility; crime; road accidents due to drunk-driving; paternity verification; food shortages; low agricultural yields; unsustainable environmental practices; and high energy costs. These problem opportunities are not unique to South Africa or to developing economies (Brännback, Carsrud and Renko, 2007; Battelle/Biotechnology Industry Organisation, 2012) but are predominant in these economies in comparison to the developed economies.

> *We have got huge burden of disease, we have got poverty, and we have got unemployment, really important things from a government perspective. (Respondent 1 1:86)*

> *My personal view is that because of our rich biodiversity, we as a country have a lot to offer in terms of indigenous knowledge and also utilising the biodiversity we have in terms of generating biotechnology products. (Respondent 3 3:73)*

> *So being situated in South Africa makes sense for us because we are diagnostics and your biggest disease and illness and epidemics are in Africa. (Respondent 11 6:43)*

> *Health is a big problem, government is spending in excess of R100 million every two years for HIV tests alone. (Respondent 11 6:60)*

The second form of bioentrepreneurial opportunities identified by the respondents is designated as “efficiency opportunities” and is mostly in the areas of bioprocessing and biomanufacturing. While the efficiency opportunities may not be as ubiquitous as problem opportunities in case 1 because of the low level of industrialisation, the realised efficiencies do provide the opportunity to solve some of the problems of food security, environmental sustainability, healthier populations and energy sufficiency (Biotechnology Industry Organisation, 2008).

> *I think that there is unlimited potential in human health, agricultural biotechnology and industrial biotechnology. (Respondent 12 7:31-34)*

There are few instances in South Africa where the exploitation of “problem opportunities” led to “efficiency and innovation opportunities”. Innovation opportunities are those opportunities that lead to the creation of new innovative products and services not previously in existence. The innovation opportunities are minimal in South Africa and were not mentioned by most of the respondents, as the emphasis was on the problem opportunities, followed by the efficiency opportunities.

> *It came about because De Beers had been suspicious that their workers were stealing their diamonds, so they developed a technique for scanning, taking a whole body x-ray, to find a diamond.*
> *I said this technology has got great opportunity for imaging the breast so we had another project going on in that direction.*
> *And we are developing a very innovative product that is taking x-rays and ultrasounds into one product; nobody else has done that anywhere else in the world. (Respondent 15 10:45-46, 48)*

Bioentrepreneurial opportunities in South Africa take the form of “problem opportunities” in which problems related to health, food security, the environment and energy create bioentrepreneurial opportunities and “efficiency opportunities” in which new means of improving existing products and services, such as bioprocessing and biomanufacturing, are created.

7.2.4 Discovery

Opportunity discovery in general entrepreneurship is different from opportunity discovery in biotechnology entrepreneurship. Opportunity discovery in biotechnology entrepreneurship is more of a “creation” (Audretsch et. al., 2008) than a “discovery” (Alvarez and Barney, 2007) as the solution to the opportunities is created or discovered through R&D.

R&D is a key step that differentiates biotechnology entrepreneurship from general entrepreneurship. This is also the key step that contributes to the predominance of non-psychological factors such as education and career experience (Barro and Lee, 2000) in biotechnology entrepreneurship.

According to the OECD (2009), the primary requirements for R&D to be effective include research universities, other research institutions, a developed scientific educational curriculum, a national culture that supports scientific endeavour, a favourable regulatory environment and talented individuals.

Some of these conditions were recognised as gaps by the respondents in South Africa, and hence they believed that R&D was not well supported in South Africa. The R&D spend in South Africa is low in comparison to other developing economies such as Brazil; or the developed economies (Organisation for Economic Cooperation and Development, 2013b, 2013c).

> *The new approach is then going to look at the entire value chain and then research and development becomes much more important than it was in the earlier stage. (Respondent 1 1:53)*

> *If 2.5 % GDP is the R&D budget, and we are only at 1%, there is a significant difference. (Respondent 1 1:105)*

> *So there is a systemic problem where there is a shortage of R&D funding within the system. (Respondent 2 2:40)*

In addition to the expenditures undertaken by the government, large companies in biotechnology undertake major research and development as well. However, the lack of these large biotechnological companies that undertake major research and development projects was highlighted as a gap.

> *The lack of major R&D taking place here and the lack of capital are the two major constraints. (Respondent 16 11:47)*

The R&D step in biotechnology entrepreneurship is the step that introduces the most risk in the process of biotechnology entrepreneurship as the timeframe can be indeterminable *(Respondent 15 10:9)* and there is no guarantee that the R&D will result in the expected outcome.

> *However, the unfortunate part is being a bio-entrepreneur because it is high-risk, you need to do research and you are not guaranteed a product at the end of the day. (Respondent 11 6:20)*

> *We stimulate publications, high quality work which can then further lead to patents and new products and services.*
> *The cost of research is a huge barrier to bioeconomic development. (Respondent 14 9:17-18)*

The ability to act on bioentrepreneurial opportunities (Shane, 2003) is research-driven. This makes R&D in biotechnology entrepreneurship a critical determinant of the output.

The respondents in South Africa believe that the inadequate level of R&D funding poses a risk to the development of biotechnology entrepreneurship in South Africa, irrespective of the level of other enabling conditions that exist.

> *If you have R1 then you will have R1 output. Even if you have Albert Einstein out there if you give him R1 he cannot build an accelerator, it is impossible. At some point the graph will flatten, here is some knowledge okay that will bring you somewhere and then it flattens off because he cannot do an experiment and that is exactly what is happening here.*
> *It is in every single aspect of this country and it is very unfortunate because there is so much potential but there is no political will. (Respondent 17 12:81-83)*

In terms of the organising framework of individual-opportunity nexus (Shane, 2003), this sub-section highlights a key difference between “opportunity discovery” in general entrepreneurship and “research and development” in biotechnology entrepreneurship. Most of the respondents in South Africa deem the funding for research and development to be inadequate and see it as a gap in the effort to develop the biotechnology industry in South Africa.

7.2.5 Entrepreneurial exploitation

"Entrepreneurial exploitation" (Shane and Venkataraman, 2000; Shane, 2003; Murphy et al., 2006) as depicted in the individual-opportunity nexus framework refers to the stage of general entrepreneurship in which the discovered opportunity is exploited to produce economic value. This exploitation is often an individual undertaking in general entrepreneurship in which new markets, new ways of organising, new products or new firms can be created by the entrepreneur (Shane and Venkataraman, 2000; Shane, 2003). However, the process of exploiting bioentrepreneurial opportunities is not an individual undertaking, and involves an alliance of stakeholders in the biotechnology industry. The strategic alliance needed for effective exploitation of bioentrepreneurial opportunities includes research institutions, venture capitalists, large organisations and government (Müller et al., 2004).

The rationale for these alliances is to fulfil the respective stakeholder roles that enable the efficient exploitation of opportunities. The research institutions provide talent and technology transfer capabilities; the venture capitalists provide capital; the large companies act as cooperation partners, customer and competitor; and the government provides an enabling regulatory environment and acts as facilitator (Ahn and Meeks, 2007).

The experience of this process in South Africa is deemed to be inadequate due to the lack of a developed venture capital industry. The lack of a developed venture capital industry in the process of entrepreneurial exploitation was unanimously highlighted by the respondents as a key impediment to the development of biotechnology entrepreneurship in South Africa.

We have got non-existent venture capital when it comes to biotechnology. (Respondent 16 11:26)

This situation forces the government into a position of trying to fulfil the funding needs of the biotechnology industry in South Africa. This role was highlighted by the respondents as a gap in the form of a lack of adequate and appropriate funding by the government.

The other roles the government plays in the strategic alliance are the provision of a favourable regulatory environment and facilitation (Ahn et al., 2012). In addition, the government also acts as a buyer of the biotechnology products and solutions. All of these roles were highlighted as gaps in the development of biotechnology entrepreneurship in South Africa by most of the respondents. However, there were at least two instances where the government was deemed to have fulfilled these roles successfully.

So government supplied the funds, supplied support structures, helped me administer the grant money, supplied external experts and reviewers, advice, they did a great job.
The result is we have the first biotechnology product from inception into commercialisation. In January this year we received the first revenue from sales of this product. (Respondent 5 5:47-49)

I think from a governmental perspective, from a funding perspective, it is good enough. (Respondent 11 6:31)

The fact that the government was able to provide appropriate funding on certain occasions was explored further to understand the possible factors responsible for this contradiction. The data showed that on the two occasions where the respondents deemed the government funding to be appropriate, both had spent their own money to get their products to the stage of proof of concept; hence, the product had reached a late stage, before the government funding was deployed. It can be inferred from the data that the government may prefer funding late stage projects owing to higher chances of success.

I started my own laboratory, private laboratory with private funding, and this laboratory is called Altis Biologics. Subsequently, I registered the IP in my personal name and gave Bone SA the rights to commercialise the IP in the territory of South Africa.

And once I put my application in a second time to the Innovation Fund after 3 years, a number of things had changed. Number 1, there was new IP; number 2, it had been filed for PCT giving access to big markets; number 3, I had proof of concept in small animals like rats; number 4, I had proof of concept in a completed human study in humans, from a tissue coming from humans. Therefore I was able to reduce the risk having used private money to do it, reduce the risk of sample technology, new technology risk. New technology is risky at early stage, you do not know if it is going to work, it is just an idea; you need proof of concept, principles. (Respondent 5 5:22-24)

I imported some products, so I acquired some market share and generated some cash and used that cash to set up my own manufacturing facility. (Respondent 11 6:10)

Being a bioentrepreneur you have to spend a lot of money upfront. (Respondent 11 6:17)

Another key component of the strategic alliance for the exploitation of bioentrepreneurial opportunities is the presence of large biotechnological companies. The absence of these large companies was also highlighted as a gap in South Africa.

The key thing is that there are these big companies that have deep pockets that can buy out ideas; in South Africa we don't have these big companies. (Respondent 1 1:72)

It can be concluded that the process of entrepreneurial exploitation in general entrepreneurship is different from bioentrepreneurial exploitation because of the requirement for a strategic alliance between key stakeholders of the latter: venture capitalists, large established companies, research institutions and government.

The absence of two key stakeholders in the form of venture capitalists and large established companies in the strategic alliances necessary for bioentrepreneurial exploitation represents a gap which the government has been trying to close. While most respondents saw the government efforts as inadequate, there was at least one example of where the government had successfully fulfilled these roles.

7.2.6 Execution

The end point of the individual-opportunity nexus framework for entrepreneurship is execution, in which value is created for the entrepreneur and the economy (Shane, 2003). The predominant way of doing this in general entrepreneurship is through the creation of a new firm as a vehicle to introduce new goods and services, ways of organising, markets, processes, and raw materials through organising efforts that previously had not existed (Shane, 2003:4).

However, in biotechnology entrepreneurship, the execution can be effected through a new firm formation or through licensing the biotechnological innovation to another entity (Audretsch and Stephan, 1998; Mowery and Shane, 2002; Shane, 2004a; Audretsch and Lehmann, 2005a; Audretsch et al., 2008). The process of execution in biotechnology entrepreneurship is often referred to as "commercialisation of research", or as "commercialisation of intellectual property" (Müller et al., 2004).

Commercialisation of research is at the end of the value chain of biotechnology entrepreneurship (Gittelman, 1999; Feldman and Ronzio, 2001; Kettler and Casper, 2001). The effective strategic alliance required for the exploitation of bioentrepreneurial opportunities ultimately results in the effective commercialisation of research (Ahn et al., 2010a; Ahn et al., 2010b; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012).

The bioentrepreneurs in South Africa practise the process of execution through both firm formation and licensing.

> *You had a lot of companies emanating from research. With research coming out of the universities people were able to start up various biotech businesses. (Respondent 3 3:6)*

> *I think we have to become much better at licensing especially at universities. It is not that a university should not create spinouts or things like that. Should be able to license and do lots of licensing. (Respondent 2 2:73-75)*

> *Develop the IP and then try license it out because we don't have a local presence and a big firm or a big biotech. (Respondent 1 1:73)*

Although this process does take place in South Africa, challenges were identified by the respondents in the areas of commercialisation skills and funding for commercialisation.

> *I think personally in South Africa, the universities lack certain things in terms of commercialisation. They do the research and they do the training of the students but to complete that innovation chasm, they do not do that. No, they do not have the skills and the capacity to do that, they are not setup to do that. (Respondent 4 4:21-22)*

> *The other reason is lack of funding for commercialisation. You can fund 20 R&D projects and probably three serious commercialisation attempts. Secondly, to commercialise globally is a big challenge, both in terms of people, partners and money. (Respondent 2 2:28-30)*

In addition, the challenges with the environment of biotechnology entrepreneurship, the inadequate funding of R&D, and the inadequate exploitation of bioentrepreneurial opportunities in the earlier part of the value chain negatively impact on commercialisation of research in South Africa.

Another challenge highlighted by the respondents in relation to the commercialisation of research is the culture in the universities that make the researchers more inclined to publish instead of commercialise.

> *Yes, we lack in commercialisation, we are doing brilliant research, we are publishing the research and I promise you the Chinese and the European, they are probably downloading our own papers here and making a product out of it, where we lack. (Respondent 11 6:47)*

All these challenges experienced by the respondents at the stage of commercialisation, and at the earlier stages of the value chain, contributed to the limited success with commercialisation of research in South Africa (Cloete et al., 2006) whether through firm formation or licensing.

7.3 Similarities and differences between the process of biotechnology entrepreneurship in South Africa and the developed economies

In order to understand how the process of biotechnology entrepreneurship in South Africa compares to the developed economies, the practical experiences articulated in Section 7.3 using the organising framework of the individual-opportunity nexus is compared to the literature on the process of biotechnology entrepreneurship in the developed economies.

Table 7.5 summarises the key similarities and differences between the process of biotechnology entrepreneurship in South Africa and the developed economies as exemplified by the individual-opportunity nexus framework (Shane, 2003).

Table 7.5: Summary of key similarities and differences between the process of biotechnology entrepreneurship in South Africa and the developed economies

Measure	Literature on developed economies	Insights from this research on South Africa	Some supporting data from respondents
Individual attributes	Higher levels of non-psychological attributes measured by research output and patent applications in addition to psychological attributes. The bioscientists are supported by a system of other capabilities required for effective business management and commercialisation of research, which is often available within biotechnology and innovation parks (Ahn and Meeks, 2007; Ahn et al., 2010a; Ahn et al., 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012)	Non-psychological and psychological and attributes are thought to be on par with the developed economies at individual bioscientist level. However, the aggregate level of skills lags that of the developed economies hence the lower levels of research output and patent applications. The bioscientists in South Africa do not have the support system that provides other capabilities needed for effective business management and commercialisation of research. This forces the bioscientists to try to acquire these skills and in the process their approach to biotechnology entrepreneurship is “individual” as opposed to “system”.	*“Centres of academic research excellence, mainly located in a nucleus of long-established universities, achieve high quality in several areas of research, as reflected in the presence of South African publications among the top 1% of internationally cited publications in several fields and in some cases in the higher quartiles of that group.” (Documents Case 1 14:16)* *“Doing my MBA at Wits university was a key step to empower myself with sufficient knowledge capital to better understand the business of science.* *How to do financial models, how to calculate net present values, how to understand strategies and scenario planning.” (Respondent 5 5:12-13)*

Measure	Literature on developed economies	Insights from this research on South Africa	Some supporting data from respondents
Environment	Favourable economic, political and cultural factors. In addition the support structure, infrastructure, and critical mass of input are all available in the environment of biotechnology entrepreneurship in the developed economies (Lingelbach et al., 2005; Kelley et al., 2012; Urban, 2013)	The environment of biotechnology entrepreneurship in South Africa has many challenges among which are unfavourable policy and regulatory environment; lack of appropriate funding; lack of government direction; an unfavourable university culture; lack of aggregate skills and capacity; and a lack of developed market for biotechnology products. Other necessary support structure and infrastructure, such as biotechnology parks, are also lacking in South Africa	*"Well I mean South Africa has a number of problems for entrepreneurship that are unique to South Africa like our labour laws, like the difficulty of setting up a business, and then more recently the IP legislation if you have got any government funding." (Respondent 13 8:18)* *"This strategy is based on the assumption that the issues facing South Africa's bio-economy – including human capital development, knowledge exploitation, market development and governance – cannot be addressed in isolation, but need to be solved in an integrated, holistic fashion to yield coordinated, systemic interventions." (Documents Case 1 13:68)*
Entrepreneurial opportunities	Prevalence of efficiency and innovation opportunities aimed at improving existing industrial processes or bringing new innovative products and solutions to the market especially in the areas of pharmaceuticals, personalised medicine, cure for rare and lifestyle diseases, and industrial biotechnology	Prevalence of problem opportunities aimed at addressing diseases such as malaria, HIV/AIDS, tuberculosis, and other human health conditions; food security; and improvement in agricultural yield. There were opportunities for efficiency and innovation identified but these were	*"We have got huge burden of disease, we have got poverty, and we have got unemployment, really important things from a government perspective." (Respondent 1 1:86)* *"My personal view is that because of our rich biodiversity, we as a country have a lot to offer in terms of indigenous knowledge and also utilising the biodiversity we have in terms of generating biotechnology products."*

Measure	Literature on developed economies	Insights from this research on South Africa	Some supporting data from respondents
	(Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010)	small in comparison to the problem opportunities. Biodiversity was deemed to be another key bioentrepreneurial opportunity in South Africa	*(Respondent 3 3:73)* *"Being situated in South Africa makes sense for us because we are diagnostics and your biggest disease and illness and epidemics are in Africa. (Respondent 11 6:43)* *Health is a big problem, government is spending in excess of R100 million every two years for HIV tests alone." (Respondent 11 6:60)*
Opportunity discovery	Intense R&D with a high level of R&D spend as a percentage of the GDP on the part of the government; and the presence of large companies that undertake major R&D activities (Gastrow, 2008; Organisation for Economic Cooperation and Development, 2009, 2013b, 2013c)	The R&D spend and intensity are below the average for the developed economies and hence constitute a gap. This is both as a percentage of GDP and also due to the absence of large companies that undertake major R&D activities	*"If 2.5 % GDP is the R&D budget, and we are only at 1%, there is a significant difference." (Respondent 1 1:105)* *"So there is a systemic problem where there is a shortage of R&D funding within the system." (Respondent 2 2:40)* *"The lack of major R&D taking place here and the lack of capital are the two major constraints." (Respondent 16 11:47)*
Opportunity exploitation	The necessary conditions required for effective exploitation of bioentrepreneurial	Constrained by the lack of all necessary conditions for effective exploitation of	*"We have got non-existent venture capital when it comes to biotechnology." (Respondent 16 11:26)*

Measure	Literature on developed economies	Insights from this research on South Africa	Some supporting data from respondents
	opportunities are in place. These include enabling regulatory environment, a developed venture capital industry, large established companies, research institutions, government support and economies of scale (Lingelbach et al., 2005; Phan et al., 2008)	bioentrepreneurial opportunities. These include an unfavourable regulatory environment, under-developed markets, lack of a venture capital industry, lack of commercialisation and entrepreneurial skills, and low levels of aggregate skills and capacity. The lack of a venture capital industry in South Africa forces the government to fulfil the role that would have been undertaken by venture capitalists; in addition to its primary role as a funder and facilitator	*"So government supplied the funds, supplied support structures, helped me administer the grant money, supplied external experts and reviewers, advice, they did a great job.* *The result is we have the first biotechnology product from inception into commercialisation. In January this year we received the first revenue from sales of this product." (Respondent 5 5:47-49)*
Execution	Efficient because of the necessary technology transfer infrastructure being in place. In addition, the conditions for the earlier stages of the value chain such as environment, R&D and opportunity exploitation are favourable (Lingelbach et al., 2005; Phan et al.,	Inefficient because of the lack of necessary technology transfer infrastructure being in place. In addition, there were challenges identified with the earlier stages of the value chain such as unfavourable environment; low levels of R&D spend; and intensity; and lack of some of the necessary stakeholders	*"I think personally in South Africa, the universities lack certain things in terms of commercialisation. They do the research and they do the training of the students but to complete that innovation chasm, they do not do that.* *No, they do not have the skills and the capacity to do that, they are not setup to do that." (Respondent 4 4:21-22)*

Measure	Literature on developed economies	Insights from this research on South Africa	Some supporting data from respondents
	2008; Nilsson, Rickne and Bengtsson, 2010a)	required for effective exploitation of bioentrepreneurial opportunities, such as venture capitalists and large companies Other factors highlighted as contributing to the inefficient commercialisation of research in developing economies are the lack of commercialisation and entrepreneurial skills and the university culture of prioritising publication over commercialisation	*"The other reason is lack of funding for commercialisation. You can fund 20 R&D projects and probably three serious commercialisation attempts.* *Secondly, to commercialise globally is a big challenge, both in terms of people, partners and money." (Respondent 2 2:28-30)* *"Yes, we lack in commercialisation, we are doing brilliant research, we are publishing the research and I promise you the Chinese and the European, they are probably downloading our own papers here and making a product out of it, where we lack." (Respondent 11 6:47)*

From the comparisons in Table 7.5, it can be concluded that:

i. The psychological and non-psychological attributes of the bioentrepreneurs in South Africa are similar to those of the bioentrepreneurs in the developed economies. The differences in skills and capacity are at an aggregate level rather than an individual level
ii. There are marked differences in the environment of biotechnology entrepreneurship between South Africa and the developed economies. While the environment in the developed economies can be summed up as favourable across many dimensions the environment in South Africa can be summed up as unfavourable across many dimensions
iii. The bioentrepreneurial opportunities in South Africa are mostly different from those of the developed economies, with a small overlap in the area of innovation opportunities. The bioentrepreneurial opportunities are designated as mostly problem opportunities, followed by efficiency opportunities and a very small component of innovation opportunities. The developed economies exhibit the reverse of this order, leading with innovation opportunities, efficiency opportunities, and problem opportunities related to human health. South Africa also has opportunities associated with biodiversity which is not present in the developed economies
iv. The process of opportunity discovery in biotechnology is through R&D. This process in South Africa is different from the developed economies in terms of R&D spend, and the intensity of R&D
v. Opportunity exploitation in South Africa is inefficient due to the lack of the key stakeholders required at this stage of the biotechnology value chain, such as venture capitalists and large biotechnology companies. This process in the developed economies has all the necessary conditions and hence is effective
vi. Execution or commercialisation of research goes through the same process of firm formation or licensing in South Africa as it does in the developed economies. However, the lack of entrepreneurial and commercialisation skills, coupled with inefficiencies in the earlier parts of the biotechnology value chain makes this process less efficient in South Africa than in the developed economies

The result of the efficiencies in the developed economies is that the output of biotechnology entrepreneurship is much more rapid, visible and on a much higher scale than in South Africa (Biotechnology Industry Organisation, 2008; Gastrow, 2008; Organisation for Economic Cooperation and Development, 2009; Battelle/Biotechnology Industry Organisation, 2010; Organisation for Economic Cooperation and Development, 2013b, 2013c).

7.4 The nature of the relationship across the university, industry, and government

The relevance of the interactions across the university, industry and government, in transferring academic research into societal and economic capital, is evidently demonstrated in the field of biotechnology (Liebeskind et al., 1996; Agrawal, 2001; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008). The collaboration among these three stakeholders (Etzkowitz and Leydesdorff, 1997; Leydesdorff and Etzkowitz, 1998, 2001) has recently been considered to involve a fourth stakeholder (Afonso, Monteiro and Thompson, 2010; Marcovich and Shinn, 2011; Afonso, Monteiro and Thompson, 2012; Leydesdorff, 2012). The fourth stakeholder in the quadruple helix is context-specific and in the case of South Africa this has been designated as society.

> *South Africa will build its health innovation system using the “quadruple helix” model to integrate existing role players – the government, academia, industry and civil society – into a unified and coordinated system. (Documents Case 1 13:104)*

Most of the respondents in South Africa believe that the relations across university, industry and government in the biotechnology industry in are ineffective, and negatively impact on the development of biotechnology entrepreneurship in South Africa.

So in my own experience in human health research I can give you examples where the University is interacting with government, or where the University is interacting with industry but I cannot think of many situations in which the 3 come together. (Respondent 12 7:74)

We are doing it in a sense but I often find that this is certainly an issue here; the inability of people here to work together.
It is a big problem. It is like everybody is doing a bit somewhere and they are not teaming up, they are not coming together which is a huge detriment. (Respondent 14 9:74-75)

Although the relationship among the university, industry, and government is deemed to be inefficient at an overall level, there are instances where the respondents believe that there is a very productive and efficient relationship among the stakeholders.

The links to academia are very helpful to us to find high quality graduates. (Respondent 16 11:28)

So I think that is also a real plus and I think you just need more companies like mine who have had a positive experience both with government and with the university to say yes this really is working and can continue to work and expand. (Respondent 15 10:37)

Although there are few collaborative projects in biotechnology that have been successfully concluded in South Africa (Cloete et. al., 2006), the mixed experiences of the respondents in South Africa have meant that although most believe that the relationship within the triple helix is inefficient there are pockets of success that point to the possibility of making the relationship more efficient in future.

Given that the “need for collaboration among key stakeholders” is among the codes that has the most mentioned by the respondents, it is acknowledged that without effective implementation the bio-economy of South Africa stands very little chance of success.

The role players within the bio-economy will have to collaborate effectively if the bio-economy is to succeed. These role players include industry, academia, science councils, non-governmental organisations, community-based organisations, not-for-profit companies and the government. (Documents Case 1 13:45-46)

In addition to the lack of collaboration across the three stakeholders of the triple helix, there is also a lack of collaboration within some of the stakeholder groups. Hence, the government agencies do not have effective collaboration; likewise the universities and industry.

I know from speaking to the DST these guys hardly ever talk to the DTI, and that is certainly an issue. (Respondent 14 9:92)

There is a lot of competition amongst the universities, and as I have said I have not explored it but it would be interesting to see in Brazil if there is a collaborative type of effort. (Respondent 3 3:55)

Yes, science councils and universities have become competitors rather than partners (Respondent 4 4:23)

The government controls the relationship with the university and the industry, from a policy, regulation and funding point of view. It is very apparent that the triple helix relationship in South Africa is at what is described by Etzkowitz and Leydesdorff (2000) as triple helix I, which represents a configuration in which the government encompasses both industry and university and directs the interaction and relations between them.

The literature suggests that as countries progress towards a knowledge economy there is a transition from triple helix I, to triple helix II, and then to triple helix III in which the government influence is sequentially diminished and overlapping institutional spheres generate a knowledge infrastructure, with overlapping roles and hybrid organisations emerging at the interfaces (Etzkowitz and Leydesdorff, 2000).

However, with South Africa being at the triple helix I stage, with government influence unlikely to diminish, a high level of socio-economic linkages, and the government considering implementing a Quadruple Helix approach, the path of the triple helix in South Africa is expected to bypass the sequential progression to triple helix II and III and go to what can be termed the "Quadruple Helix of government-controlled university, industry, society relations".

In concluding this sub-section, effective collaboration across the university, industry, and government (Etzkowitz and Leydesdorff, 2000) is acknowledged to be important to the development of the biotechnology industry in South Africa. The current experience of the respondents is such that most deem the relationship to be inefficient. There are instances of competition within the stakeholder groups, instead of the expected collaboration within and between the stakeholders.

The model of Triple Helix experience in South Africa is Triple Helix I (Etzkowitz and Leydesdorff, 2000) and there is an indication from this research that South Africa will not go through a sequential progression to triple helix II and III but may progress to a form of a Quadruple Helix that includes the society as a fourth stakeholder (Afonso et al., 2010; Marcovich and Shinn, 2011; Afonso et al., 2012; Leydesdorff, 2012).

7.5 Summary of within-case analysis of South Africa

The process of biotechnology entrepreneurship in South Africa starts with bioscientists who have the necessary research and scientific skills to carry out biotechnological R&D. Owing to the lack of an adequate support system for providing the entrepreneurial and commercialisation skills needed to commercialise their research, these bioscientists are often forced to acquire entrepreneurial and commercialisation skills to commercialise their research effectively. Consequently, their practice of biotechnology entrepreneurship is as individuals rather than as a part of a system.

The environment under which biotechnology entrepreneurship is practised in South Africa has many challenges across the economic, political and cultural environments (Shane, 2003) key among which are unfavourable policy and regulatory environment; lack of appropriate funding; lack of government direction; an unfavourable university culture; lack of aggregate skills and capacity; and a lack of a developed market for biotechnology products.

The bioentrepreneurial opportunities were identified predominantly in the area of problem opportunities, followed by efficiency opportunities and a small instance of innovation opportunities. In addition, abundant biodiversity is seen as a competitive source of bioentrepreneurial opportunities in South Africa.

The discovery of these bioentrepreneurial opportunities requires research and development. The intensity and the R&D spend in South Africa is deemed to be below the levels of the developed economies, thereby negatively impacting on the effectiveness of the development of the biotechnology industry.

The exploitation of these bioentrepreneurial opportunities requires a strategic alliance of research institutions, venture capitalists, large established biotechnology companies and government. However, this process in South Africa lacks the key stakeholders of venture capitalists and large established biotechnology companies. This forces the government into other roles, which are usually performed by these absent stakeholders in the developed economies.

The execution step of the process of biotechnology entrepreneurship involves the commercialisation of research. The commercialisation of research in South Africa utilises both firm formation and licensing and is deemed to be inefficient due to a lack of entrepreneurial and commercialisation skills. In addition, the challenges with the environment and inefficiencies in the stages of R&D and opportunity exploitation impact on the effectiveness of commercialisation of research.

The diagrammatic representation of the process of biotechnology entrepreneurship, as experienced by the respondents in this research, is shown in Figure 7.2.

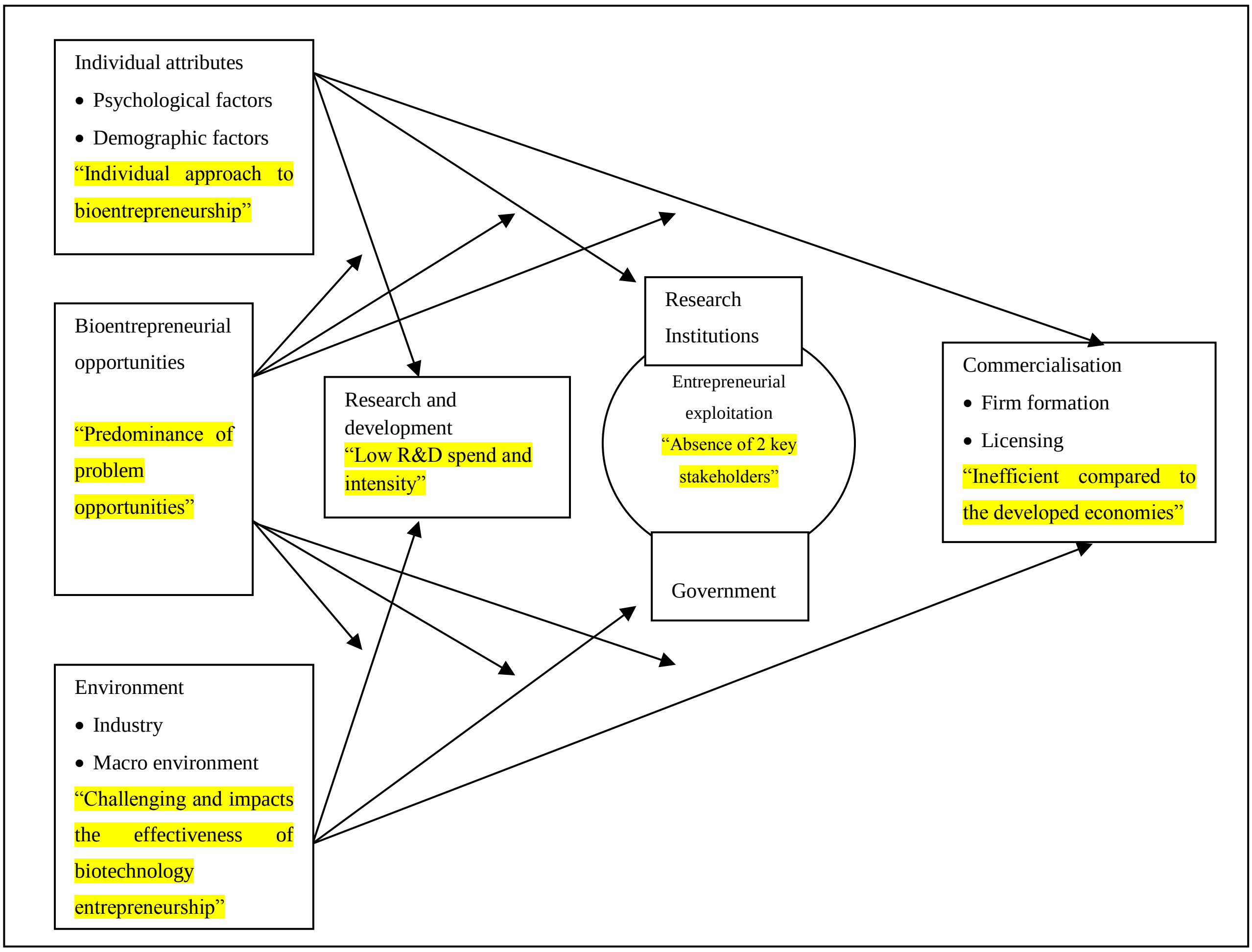


Figure 7.2: A graphical depiction of the process of biotechnology entrepreneurship in South Africa

The direction of the arrows in Figure 7.2 shows that the individual attributes, the bioentrepreneurial opportunities and the environment are deemed to affect all the stages of biotechnology entrepreneurship from R&D to entrepreneurial exploitation and commercialisation of research. While this does not prove causality, the importance of the individual attributes, entrepreneurial opportunities and the environment to entrepreneurship is supported by previous studies (Liebeskind et al., 1996; Audretsch and Stephan, 1998; Agrawal, 2001; Shane, 2003; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

This research extends this knowledge by clearly identifying the type of bioentrepreneurial opportunities that are predominant in the biotechnology industry of South Africa; the environmental conditions in which the process of exploiting these opportunities takes place; and the individual attributes that are used in carrying out this process in South Africa.

Chapter 8: Case Analysis – Brazil

The detailed analysis of case 2 integrates the deep interrogation of the current empirical and market research studies on biotechnology entrepreneurship in Brazil with interview transcripts, the output of Atlas.ti CAQDAS, and documents, to get to a consistent and rigorous analytical view (Weitzman, 1999; Rambaree, 2007; Hwang, 2008) of the dynamics of biotechnology entrepreneurship in Brazil within its original context (Eisenhardt and Graebner, 2007b; Klonoski, 2013).

8.1 Background to biotechnology entrepreneurship in Brazil

Brazil is currently among the developing economies that are recognised as making significant progress in biotechnology. Some of the notable successes include a pioneer status in biofuels, leadership in agricultural biotechnology, being the world's second-largest user of genetically modified (GM) crops, and the formation of innovation-focused biotechnology companies (Ernst & Young, 2010b). The unveiling of the world's first commercially produced aircraft to operate solely on biofuel in 2005, by Empresa Brasileira de Aeronáutica (EMBRAER), marked the recognition of Brazil as a leader in biofuel technology (Bound, 2008). This achievement was acknowledged by *Scientific American* as one of the most important of the year, and Brazil accounts for about 43% of the global supply of ethanol (Bound, 2008).

The classification of Brazil as an efficiency-driven economy (Herrington et al., 2008; Bosma and Levie, 2010; Herrington et al., 2010) may seem at odds with the requirements to be an effective player in bioentrepreneurship, which is innovation driven (Bosma and Levie, 2010). However, given the pervasiveness of biotechnology, Brazil has already achieved a leadership position in biofuels (Ernst & Young, 2010b). In addition, the benefits of biotechnology entrepreneurship align to the development imperatives of Brazil.

The biotechnology industry in Brazil is estimated to be worth $2.6 billion in annual turnover in 2012; it employs 28,000 people and has great potential for growth (Zylberberg, Zylberberg and Oner, 2012). Brazil is among the top countries in revealed technological advantage in biotechnologies in the OECD studies that comprise both developed and developing economies (Organisation for Economic Cooperation and Development, 2013c) (see Figure 8.1).

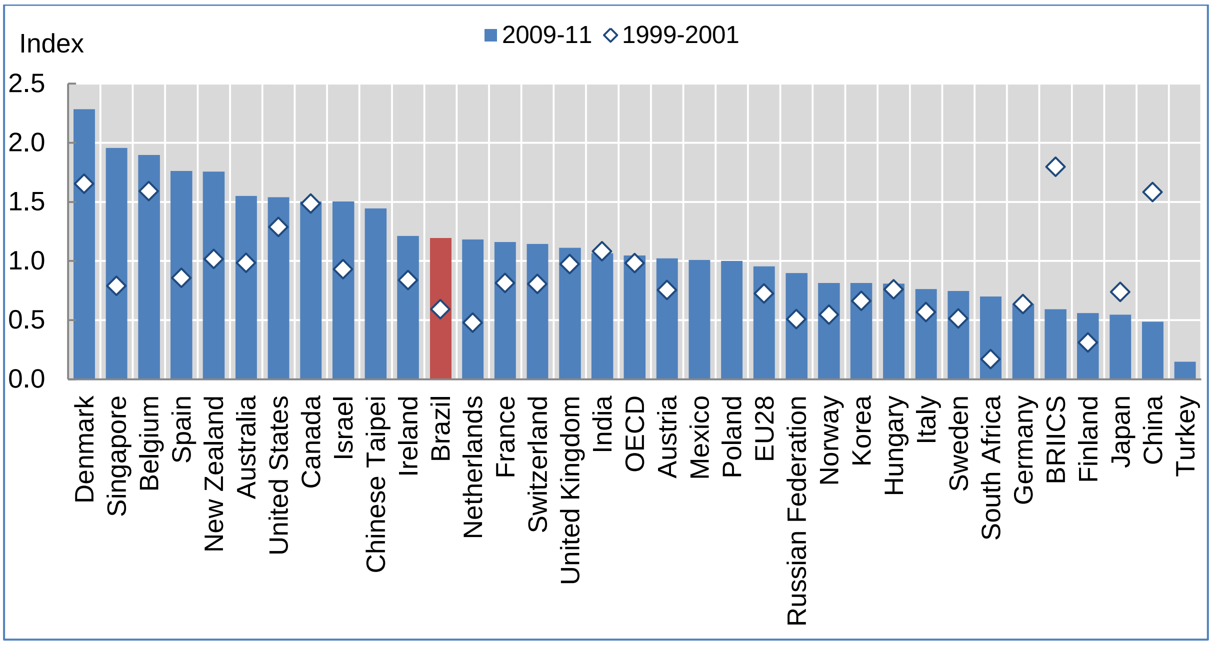


Figure 8.1: Revealed technological advantage in biotechnologies, 1999-2001 and 2009-11 (OECD Patent Database, October 2013) (Organisation for Economic Cooperation and Development, 2013d)

(Note: The bar highlighted in red is the value for Brazil. BRIICS stands for Brazil, Russia, India, Indonesia, China and South Africa)

Other achievements that have set Brazil apart in technology entrepreneurship are:

i. About a ten-fold increase in the number of postgraduates enrolled in universities in the decades from 1985 to 2005
ii. 12% annual growth in the number of science PhDs from 1995 to 2009 (see Figure 8.2)
iii. One of the fastest growing countries in the world in terms of scientific publications in the 21st century
iv. One of the most productive agricultural nations in the world, and the enactment of the Biosafety law in 2005
v. R&D spend of 1% of GDP in 2005 and projected to increase to 1.5% of GDP in 2010

vi. Abundance of natural resources, endowments and assets that has earned it the term “natural knowledge economy”. An example of Brazil’s natural resources is the Amazon rainforest, which holds a third of all plant species (da Silveira and de Carvalho Borges, 2005; Marques and Gonçalves Neto, 2007; Bound, 2008; Zylberberg et al., 2012)

Of particular interest is Brazil’s emphasis on the development of the higher level skills required for the development of the biotechnology industry, as shown in Figures 8.2 and 8.3.

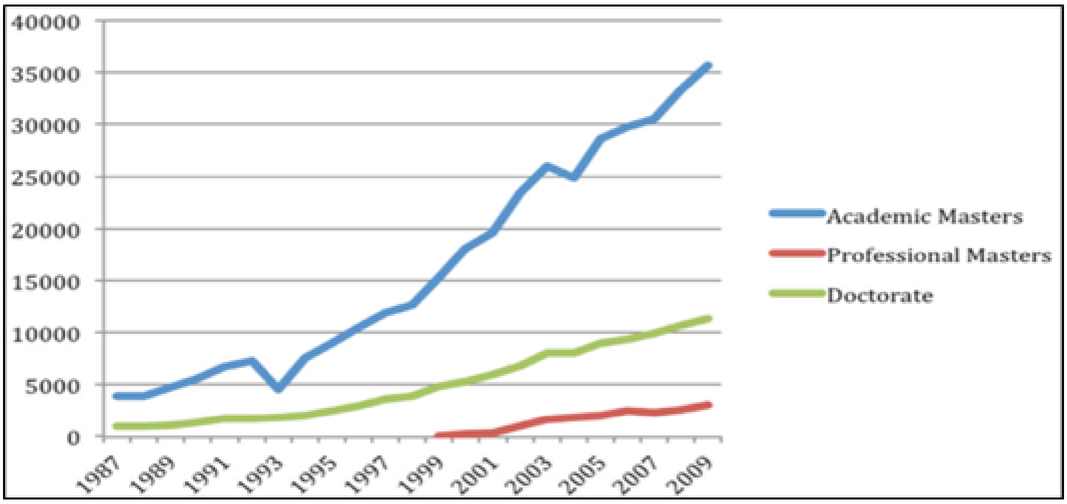


Figure 8.2: Masters and doctoral degrees granted annually in Brazil (Zylberberg et al., 2012)

The growth in the number of postgraduates translates into skills employed in the biotechnology industry, as shown in Figure 8.3 (BRBIOTEC Brasil and CEBRAP, 2011). The presence of employees with postgraduate qualifications is evident in small and medium enterprises, as well as large businesses with more than 100 employees (BRBIOTEC Brasil and CEBRAP, 2011).

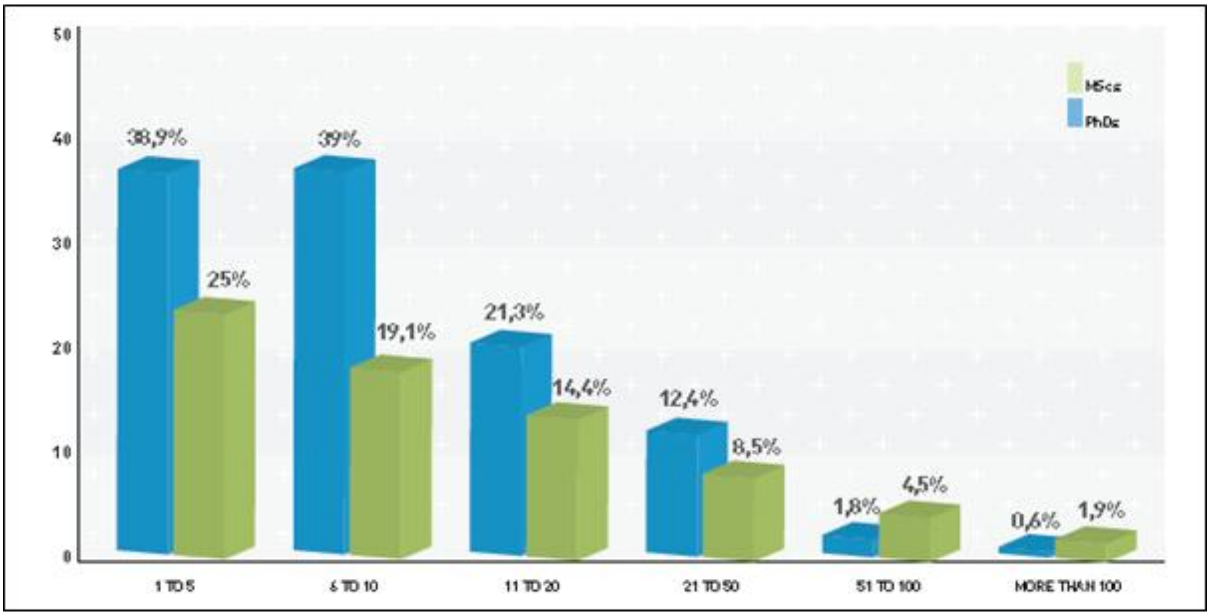


Figure 8.3: Percentage of MScs and PhDs in companies of different sizes.

8.1.1 The national biotechnology development policy

The national biotechnology policy of Brazil was developed in February 2007 as the official legislated policy for the development of biotechnology entrepreneurship in Brazil. The purpose of the national biotechnology development policy, as articulated in the policy document, is given below:

> *The overall objective of the Biotechnology Development Policy is to promote and perform actions with a view to establishing appropriate environment for the development of innovative biotechnological products and processes, encourage increased efficiency of the national productive structure, the innovative capacity of Brazilian companies, absorption technologies, business generation and export expansion.*

The focus areas of biotechnology development in the policy are human health, agricultural biotechnology, industrial biotechnology, and environmental biotechnology. These are outlined below.

Human Health

The emphasis on this area of biotechnology is aimed at domestic production of strategic products for human health through biotechnological means, and within the bounds of the national health policy. It also focuses on the competitive positioning of the Brazilian biotechnology industry in the area of biomanufacturing, with the potential to generate new business, expand its exports, integrate up the value chain and stimulate new demand for innovative products and processes.

Agricultural biotechnology

The emphasis on agricultural biotechnology is aimed at stimulating the generation of strategic agricultural products to boost Brazilian global competitiveness, and achieve food security locally through biotechnology-driven product differentiation.

Industrial biotechnology

The emphasis on industrial biotechnology is aimed at stimulating domestic production of strategic industrial products for biomanufacturing with the potential to expand Brazilian exports, achieve global competitiveness and stimulate demand for new products and processes.

Environmental biotechnology

The emphasis on environmental biotechnology is aimed at stimulating the generation of strategic products in environmental management in order to achieve new levels of environmental quality and competitiveness; conservation and sustainable use of biodiversity; social inclusion; and development of clean technologies.

The government body set up to implement the national biotechnology development policy is the National Biotechnology Committee, with responsibilities for the following:

i. Coordinate the implementation of the biotechnology development policy, promoting the necessary improvements to its full implementation

ii. Conduct its activities in a coordinated and integrated manner to define and implement actions and programmes related to the implementation of the biotechnology development policy
iii. Set up working groups on specific topics that require technical expertise to support the activities of the Committee
iv. Harmonize the biotechnology development policy with the other existing related policies
v. Invite professionals and renowned experts in the field or from other agencies or entities and society to advise on their activities
vi. Propose to update the policy development of biotechnology

Evidently the implementation of the national biotechnology policy of Brazil has been relatively successful given the successes achieved so far and the positioning of Brazil in the global biotechnology industry. Some of the government initiatives that were instrumental to the achievement of these successes, and the collaborative projects are articulated in the sections below.

8.1.2 Government initiatives

Government initiatives in support of biotechnology include the biotechnology development policy and a 10-year US$4.0 billion biotechnology development programme (Ernst & Young, 2010b). In addition, the Ministry of Science and Technology (MCT) coordinates the national science and technology policy, which brings together key players in the biotechnology sector such as the National Council for Scientific and Technological Development (CNPq), Research and Projects Financing (FINEP) and Brazilian Corporation for Farming and Livestock Research (EMBRAPA); policies and regulations such as Innovation Law of 2004, which was designed to strengthen the university-industry research relationship; Good Law of 2005, which was meant to encourage private R&D investment and employment of post graduates in the sector; Programme of Accelerated Growth in Science, Technology and Innovation of 2007, which was meant to raise the level of R&D expenditure as a percentage of GDP from 1% to 1.5%; and Productive Development Policy of 2007, which provides spending targets and tax breaks for key sectors like biotechnology with the aim of increasing high technology exports (da Silveira and de Carvalho Borges, 2005; Marques and Gonçalves Neto, 2007; Bound, 2008).

Figure 8.4 shows the result of the sustained increase in R&D spend in Brazil, which supports the increased relevance of Brazil in the 21st century knowledge economy. Although Brazil still lags behind the developed economies in R&D spend, like other developing economies, it is among the top countries in Latin America.

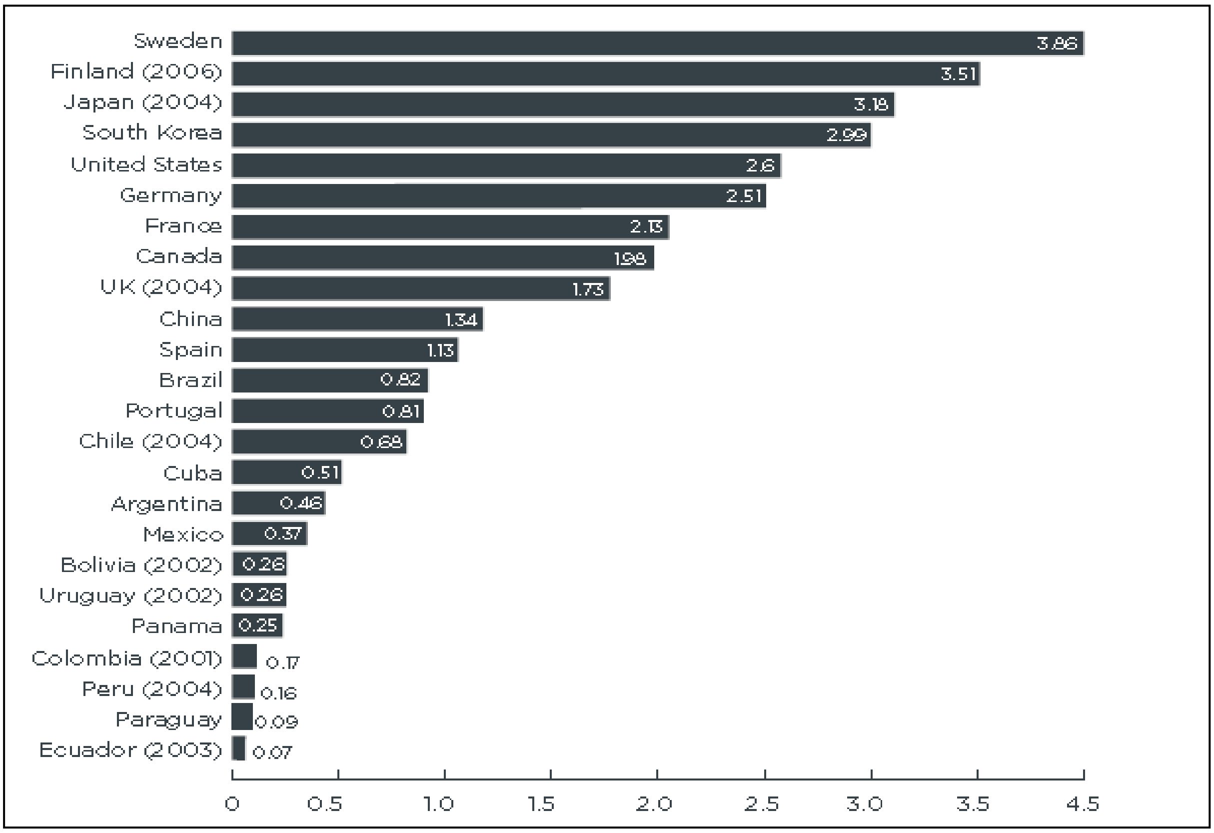


Figure 8.4: R&D intensity, Brazil and selected OECD and Latin American comparison countries, 2005 (Bound, 2008)

Note: R&D Expenditure as % of GDP, 2005 unless otherwise stated

8.1.3 Collaborative projects

One of the key strengths of Brazil in the area of genome sequencing is the formation of collaborative networks (Camargo and Simpson, 2003; Júdice and Vedovello, 2007; BRBIOTEC Brasil and CEBRAP, 2011). This is one of the examples of effective collaboration among key stakeholders in the Brazil biotechnology industry as shown in Figures 8.5 and 8.6.

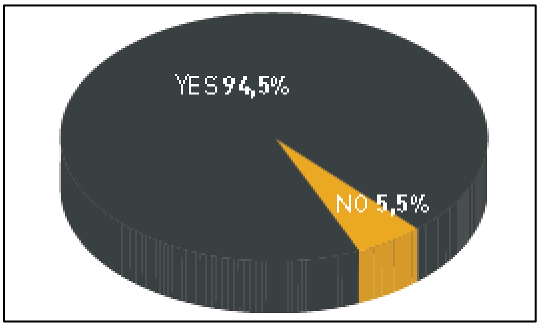


Figure 8.5: Does the company have a relationship with universities or research institutes? (BRBIOTEC Brasil and CEBRAP, 2011)

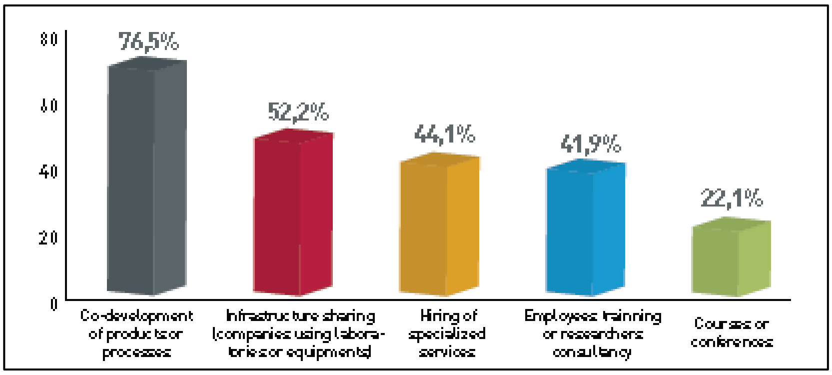


Figure 8.6: What is the aim of this partnership? (BRBIOTEC Brasil and CEBRAP, 2011)

Some of the notable genome sequencing collaborative projects include:

i. The Eucalyptus genome project, in which four paper companies collaborated with research institutions (Camargo and Simpson, 2003; Júdice and Vedovello, 2007)
ii. The coffee genome project with a collaboration of 700 researchers and 40 institutions (Camargo and Simpson, 2003; Júdice and Vedovello, 2007)
iii. The *xylella fastidiosa* project in which 65 laboratories, 75 research groups and 450 researches collaborated. This included international institutions (Camargo and Simpson, 2003; Júdice and Vedovello, 2007)
iv. The sugar cane genome project (Camargo and Simpson, 2003; Júdice and Vedovello, 2007)
v. The *chromobacterium violaceum* project (Camargo and Simpson, 2003; Júdice and Vedovello, 2007)

In addition to collaboration among researches and institutions, there is also a close collaboration among key government institutions such as the MCT, the Ministry of Development, Industry and Foreign Trade (MDIC), Ministry of Agriculture, Stockbreeding and Supply (MAPA) and the Ministry of Education (MEC) among other institutions (Zylberberg et al., 2012).

8.1.4 Constraints

Some of the constraints of biotechnology entrepreneurship in Brazil relate to infrastructure, capital, regulatory challenges, competition, inequality and environmental sustainability (Zylberberg et al., 2012).

8.2 How biotechnology entrepreneurship is carried out in Brazil

The analysis of the process of biotechnology entrepreneurship in Brazil is facilitated through the use of the individual-opportunity nexus framework of entrepreneurship discussed in Chapter 3, as an organising framework. Hence, the components include:

i. Individual attributes
ii. Environment
iii. Entrepreneurial opportunities
iv. Discovery
v. Entrepreneurial exploitation
vi. Execution

8.2.1 Individual attributes

There were five respondents in Brazil, of which two were designated as bioentrepreneurs and three were SMEs across university, industry, and government for the purposes of this research. Among these five there were two overlaps, where respondents were designated as both bioentrepreneur and SME.

In choosing the respondents for the research in Brazil, care was taken to ensure that the purposive sampling was representative of individuals with a high degree of knowledge and competence in the research topic (Romney et al., 1986; Guest et al., 2006; Stake, 2006; Bowen, 2008); and hence with good insights into the dynamics of biotechnology entrepreneurship in Brazil.

A summary of the characteristics of the respondents for Brazil is provided in Table 8.1.

Table 8.1: Summary of characteristics of respondents for Brazil

Respondent	Position	Qualification	Area of expertise
1	Co-founder of a biotechnology company; lecturer; research scientist	Forest Engineer; PhD in Genetics; Professor	Bioentrepreneur in Bioservices; Research scientist at a government institution; Lecturer in Biotechnology and Genomic Sciences
2	Lecturer, researcher and advisor for graduate programme in Biotechnology	PhD in Science and Technology Policy Studies; Adjunct Professor	Specialises in science and technology policy research
3	Founder of a biotechnology company; lecturer; head of Centre for Molecular Biology and Genetic Engineering	PhD in Molecular Biology; Professor	Specialises in molecular biology, genetics, gene cloning, sequencing and genomics
4	Director of graduate programme in Genomic Science and Biotechnology; former director of the National Research Council	Agronomic Engineer; Masters in Mineral Nutrition of Plants; PhD in Plant Biochemistry and Tissue Culture; Professor	Lecturing and research in biochemistry, with emphasis on enzymology and cellular metabolism; policy formulation and implementing strategic programmes aimed at university-industry collaboration in biotechnology
5	Area director for a government research funding agency; licensed researcher	PhD in Policy Studies in Science and Technology	Specialises in the economics of production engineering with emphasis on technological innovation

In addition to the psychological attributes, the respondents in Brazil possessed the requisite non-psychological factors, such as education and career experience (Barro and Lee, 2000), for biotechnology entrepreneurship. All the respondents had a minimum qualification of a PhD in biosciences and related fields; and were all professors in their fields, with the exception of one respondent. The education factor in biotechnology entrepreneurship is a critical requirement for functioning as a bioentrepreneur.

The respondents were highly qualified, experienced and experts in the field of biotechnology entrepreneurship. Some had won national and international awards in their personal capacity for their contribution to the development of biotechnology entrepreneurship in Brazil.

The bioentrepreneurs in Brazil operated within the "system" of biotechnology entrepreneurship and were involved in shaping the policies related to the efficient development of the biotechnology industry in Brazil. The "system" model of biotechnology entrepreneurship in Brazil is driven by the integration between the biotechnology parks and the universities.

> *A majority of Brazil's incubators and technology parks are affiliated with institutions of higher education. In 2003, there were 207 incubators and 10 technology parks operating in Brazil. Of the 207 incubators, 107 were technology-based, and of those 80% had formal ties with universities. All ten of the technology parks had formal and informal ties with universities. (Documents Case 2 33:27)*

The emphasis is on being able to contribute to solving the problems of the country rather than being seen as an excellent entrepreneur. On one instance, the bioentrepreneur returned to a full professorship at the university after managing one of the most celebrated biotechnology entrepreneurship successes in Brazil.

> *Yes, I used to be a bioentrepreneur. I am a professor at the University of Campinas since 1975, which is a long time. And I have been working in*

plant molecular biology for a while. I did my PhD here at university of Campinas, and then I work at post doctorate in England.
Then I returned to Brazil and I started this centre for Molecular Biology.

In another instance, the bioentrepreneur was driven by the need to solve the national problems; and although he owned his own biotechnology company, he also worked for the government's agricultural agency as well as being a professor and researcher at one of the universities tasked with developing young skills for the biotechnology industry.

But there are some people like myself that enjoy more seeing science being applied towards solving a problem, so I think that is the basic thing, internal motivation. (Respondent 6 18:13)

I was working for the government as a research scientist.
In '96, myself and a colleague of mine, we decided to set up a DNA analysis laboratory to use the technologies that we commonly used in our everyday research. It is a private company, called Hereditas DNA Technologies, it was founded in June 1996 and since then, so it is 16 years now, we have been working with DNA genotyping of humans and plants. (Respondent 6 18:2-3)

None of the two bioentrepreneurs considered themselves to be born with entrepreneurial skills or have familial inclination to one. Their training and experience obtained from practical application of research to real-life problems qualified them as bioentrepreneurs and all their activities were geared towards developing the system of bioentrepreneurship in Brazil, rather than developing individual bioentrepreneurs.

No, I do not have any history of entrepreneurship in my family, as far as I know. (Respondent 8 20:57)

In this company I was responsible for the science programme and also for intellectual property. It was very interesting and a very, very nice experience for me because we did not have any experience in intellectual

> *property in academia because we do not play well with intellectual property in academia here in Brazil because it is a little difficult for people to clearly understand how to manage intellectual property.*
> *But working in the company it was very interesting because I learnt a lot from other people and other companies and this was very interesting. (Respondent 8 20:28-29)*

> *First I think was my early experience out of undergraduate, working at a private company, and I think I enjoyed it very much, I learned a lot. I was a good student and everybody wanted me to go and get a Masters right away and I said no. So they offered me this job and I went to work and it was a five-year learning experience on how to actually put in practice what you do in the laboratory. And I think that always motivated me a lot, so to try and see some problem being solved. (Respondent 6 18:11)*

In conclusion, the analysis on the individual attributes of the respondents in Brazil shows that they had the necessary psychological and non-psychological attributes to function effectively as bioentrepreneurs.

Their business management skills were learned from practical experience rather than formal training in business management and there was reliance on the “system” of biotechnology entrepreneurship (Ahn and Meeks, 2007) in Brazil rather than on the “individual”. Hence, the respondents commit time and effort in developing this “system” for the effective development of the biotechnology industry in Brazil, by being involved with government, industry, and the university irrespective of their primary areas of responsibility.

8.2.2 Environment

The environment of biotechnology entrepreneurship in Brazil, as experienced by the respondents, is mixed with an equal occurrence of key challenges and areas considered not to represent gaps in the development of biotechnology entrepreneurship in Brazil.

The challenges include the regulatory environment, especially related to taxation; shortage of aggregate skills; national culture of seeing entrepreneurship as impure; high interest rate, which results in a high cost of funds; bureaucracy; corruption and politics.

> *Then you have the general business environment of a country, and for Brazil it is not well ranked, and we know that. (Respondent 6 18:28)*

> *In any case, a company would still have to operate in this very difficult business environment. For a number of reasons, interest rates, cost of personnel, taxation for import and general tax structure which is a complex system of several taxes in cascade. (Respondent 6 18:51-52)*

> *Because innovation is now on the agenda of all federal government and the state government, all the politicians, they are talking innovation all the time. This is good because there is a possibility of changing the laws, this is the only way of solving this problem, because we have people and talent is a question of numbers. If you have a large number of students a portion of them will be, like any other areas, so we need to take advantage of having this system. (Respondent 8 20:43-44)*

On the other hand, the areas considered not to represent challenges are the provision of direction and leadership by the government; availability of appropriate funding; the size of the market for biotechnology products in Brazil; availability of relevant infrastructure; a university culture that is conducive to the development of biotechnology entrepreneurship; availability of adequate capacity for biotechnology entrepreneurship; and good scope for international collaboration.

> *Moreover, the success that the country has achieved with the results of their research in biotechnology has greatly influenced the demand for cooperation bilateral and/or multilateral agreements with other countries in biotechnology, which can boost its international relations, attracting international capital flows and interest in pursuing new business*

arrangements that enhance the competitiveness of domestic industries. (Documents Case 2 34:33)

Table 8.2 shows the areas highlighted by the respondents that affect the environment of biotechnology entrepreneurship in Brazil. There is an equal split between the factors designated as favourable and those seen as challenges. Of the 14 areas highlighted seven were highlighted as gaps, and seven, not as gaps.

Table 8.2: Points highlighted by Brazilian respondents as affecting the environment of biotechnology entrepreneurship

Point mentioned	This point is mostly considered a gap	This point is mostly not considered a gap
Policy and regulation	√	
Government direction		√
Funding		√
Skills	√	
National culture	√	
High interest rate	√	
Bureaucracy	√	
Market size		√
Infrastructure		√
University culture		√
Capacity		√
International collaboration		√
Corruption	√	
Politics	√	

The narrative points were collated by manually going through the narrative summary of the verbatim quotes by the respondents in Brazil, and highlighting the areas mentioned as impacting on the environment of biotechnology entrepreneurship in Brazil.

The outcomes of data analysis using Atlas.ti CAQDAS for the codes that have the most occurrences, but do not necessarily occur in most of the transcripts (vertical occurrence), are shown in Table 8.3. These codes were compared to the narrative points listed in Table 8.2; and the codes mentioned by most respondents (horizontal occurrence) (see Table 8.4) to establish a pattern.

Table 8.3: The table of codes that were mentioned the most (vertical occurrence)

Number	Codes that occur the most (vertical occurrence)
1	Government-incentivised entrepreneurial action
2	Evidence of collaboration among key stakeholders
3	Non-conducive regulatory environment
4	Need for effective collaboration among key stakeholders
5	The need to compete globally
6	Need to increase the capacity for innovation
7	Conducive environment for biotechnology development
8	High cost of funding
9	Availability of appropriate funding
10	Government inefficiencies
11	Obvious socio-economic linkages
12	Developed venture capital industry
13	Emphasis on country competitiveness
14	Emphasis on national priorities
15	Abundant biodiversity
16	Emphasis on solving problems
17	Bureaucratic processes
18	Positive future outlook
19	Emphasis on skills development
20	Availability of local market for biotechnology products
21	Good support infrastructure
22	Evidence of social and cultural challenges
23	Improved agricultural output
24	Personal motivation
25	Political-industry disconnect
26	Availability of skills
27	Eagerness to contribute to the development of the biotechnology industry
28	High inflation
29	Need for favourable tax laws
30	Need to increase research and development spend
31	New markets
32	Skills development through collaboration
33	Ability to attract foreign skills and expertise
34	Good universities

The codes that have the most occurrences in most of the transcripts (horizontal occurrence) are as shown in Table 8.4.

Table 8.4: The table of codes that occurred across most of the respondents (horizontal occurrence)

Number	Codes that appear in most transcripts (horizontal occurrence)
1	Abundant biodiversity
2	Evidence of collaboration among key stakeholders
3	Good universities
4	Government-incentivised entrepreneurial action
5	Need for effective collaboration among key stakeholders
6	Non-conducive regulatory environment
7	Political-industry disconnect
8	Availability of appropriate funding
9	Availability of local market for biotechnology products
10	Availability of skills
11	Career
12	Conducive environment for biotechnology development
13	Emphasis on country competitiveness
14	Emphasis on national priorities
15	Emphasis on solving problems
16	Evidence of social and cultural challenges
17	Good research facilities
18	Good support infrastructure
19	Government inefficiencies
20	Government policy on innovation
21	High inflation
22	Higher levels of business and market risks
23	Negative view of entrepreneurship
24	Support for patenting
25	The need to compete globally
26	Academic background
27	Agricultural biotechnology
28	Availability of good quality bioscientists
29	Biofuels
30	Bureaucratic processes
31	Developed venture capital industry
32	Eagerness to contribute to the development of the biotechnology industry
33	Emphasis on skills development
34	High cost of funding

These are outputs of the Atlas.ti CAQDAS that enabled an in-depth analysis of the code patterns in different dimensions (Weitzman, 1999; Rambaree, 2007; Hwang, 2008).

The reason for analysing the codes in different dimensions is that a particular point may be mentioned many times in the transcript, but may be the experience of one or a few respondents. Hence, it is important also also analyse the codes horizontally to determine the occurrence of particular codes across most or all of the transcripts.
The codes that have most mention within (vertical) and across (horizontal) the transcripts are deemed to be important in identifying the patterns in the data that improve the understanding of the process of biotechnology entrepreneurship in Brazil.

The identified patterns in the environment of biotechnology entrepreneurship in Brazil are summarised below:

i. There is collaboration among the key stakeholders and this collaboration is acknowledged to be important to the effective development of biotechnology entrepreneurship in Brazil
ii. The government plays an important role in incentivising bioentrepreneurial activities in Brazil
iii. The regulatory environment for biotechnology entrepreneurship in Brazil is deemed to be unfavourable
iv. Appropriate funding is available for the development of biotechnology entrepreneurship in Brazil
v. The high cost of funding in Brazil constrains the development of the biotechnology industry
vi. The abundant biodiversity constitutes a source of competitive advantage for the development of the biotechnology industry in Brazil
vii. The universities in Brazil are good at conducting the research required for the development of biotechnology entrepreneurship in Brazil
viii. The politicians do not have a full understanding of the requirements of the biotechnology industry
ix. The local market for biotechnology products is considered developed

x. The research and scientific skills necessary for the development of biotechnology entrepreneurship are available. The entrepreneurial and commercialisation skills are available through the system of biotechnology entrepreneurship in Brazil
xi. Global competitiveness is a key factor in the approach to biotechnology entrepreneurship in Brazil
xii. The aggregate capacity for innovation needs to be improved
xiii. The inefficiencies of the government and its agencies affect the effectiveness of the development of biotechnology entrepreneurship in Brazil
xiv. There is an overall enabling environment for the development of biotechnology entrepreneurship in Brazil

The areas that were mentioned the most by the respondents in the narrative analysis; and the areas that were mentioned the most within (vertical) and across (horizontal) the transcripts are explored further in the following sections.

The top seven areas highlighted in the environment of biotechnology entrepreneurship in Brazil are:

i. The importance of collaboration among the key stakeholders
ii. Policy and regulation
iii. Government direction
iv. Funding
v. Skills
vi. High interest rate
vii. Bureaucracy

The importance of collaboration among the key stakeholders

The experience of the collaboration among the key stakeholders in the biotechnology industry in Brazil is covered in details in Section 8.4.

Policy and regulation

(Represented as “non-conducive regulatory environment” in Tables 8.3 and 8.4)

The experience of challenges with the policy and regulatory environment for biotechnology entrepreneurship in Brazil was unanimous across all the respondents. The specific areas that were highlighted as challenges were policies related to intellectual property ownership; policies related to technology transfer from the university to the industry; taxation laws; and labour laws.

> *They have to charge more and more taxes to be able to operate. So you have a very complex system of taxation with state taxes, federal taxes and all kinds of different constantly changing taxation systems. So that also scares a lot of people, you hear a lot of difficult stories of people that set up business and just went down because they just could not deal with all the complex taxation systems. (Respondent 6 18:33)*

> *Yes, policies and because of the law. Most of the research universities in Brazil that do almost 100% or 95% of their research in this country are public universities. Public universities mean that they are regulated by law, the state laws because it is very difficult for intellectual property and technology transfer. It still exists, and this is a major problem, we need to change this. This is one of the most important points for technology transfer in this country. (Respondent 8 20:30, 34)*

> *There are several legal obstacles that prevent public universities in Brazil from negotiating with enterprises in a flexible and “fluid” manner, and the foundations were designed to help universities overcome these obstacles. (Documents Case 2 33:20)*

> *There are some legal difficulties, for example, a university professor in Brazil, a federal university or state university professor. Most of them or I would say 95% of them have a contract called, Exclusive Dedication. By exclusive dedication it means that you cannot have a business, or maybe better said, you can own a business, but you cannot run the business.*

So that also inhibits many scientists to go out and try something because they are worried there will be a conflict of interests. (Respondent 6 18:90-91)

I say that the biotechnology in Brazil is not developed a lot, there are several variables, but the biggest variable is that we do not have legal safety. The rules are not well established, when the rules are not well established, they are not well carried out. (Respondent 9 21:79)

And government is investing a lot but their restrictions are very tough.
Yes, do not forget that Brazil is a country where everybody is guilty until proven innocent. Then they put money in all of them, lots of money, but the law is not good enough. (Respondent 10 22:11-13)

On the other hand, the patent law was deemed to be well established but plagued by implementation challenges due to bureaucracy.

The patent laws in Brazil are fairly well established from my point of view because I make a lot of patents and I have applied in Brazil and outside the country. The problem is, the structure for approving patents takes three or four years to get your patent registered, and when you apply for it you are protected. (Respondent 9 21:80)

The challenges in the policy and regulatory environment highlighted by the respondents discourage an individual approach to biotechnology entrepreneurship and further entrench the system approach to biotechnology entrepreneurship in Brazil.

Government direction

(Represented as “government-incentivised entrepreneurial action” in Tables 8.3 and 8.4)

The experience of the respondents in Brazil in relation to the leadership and setting of direction from the government was positive. The respondents acknowledged the role of the government in establishing the policy framework for the development of the biotechnology industry; the infrastructure and support structures; the funding agencies at national and state levels; the platforms for collaborative projects; and the involvement of stakeholders such as industry and academia in decision making.

> *Then the government in all levels are implementing several kinds of programmes to stimulate innovation and entrepreneurship, but the results are very small. (Respondent 10 22:14)*

> *But innovation became an obsession in Brazil. (Respondent 10 22:45)*

> *Government was mainly the driving force, because a lot of us that somehow had the experience outside of academia went to the government, to be in the government. We knew that we had to change the way we are working in science and technology in Brazil. We had to support the industrial sector but the government has been the big driving force I would say. And now the market is where it is internationally competitive. (Respondent 9 21:57)*

> *The government is very important as a ruler, as giving the institutional and regulatory context to this, but I think that is a part of what society is asking for the government to do. (Respondent 7 19:56)*

> *If you look at bioentrepreneurship around the world, the government has always had and still has an important role. (Respondent 6 18:121)*

The national funding agency, FINEP and the state funding agencies such as FAPESP play a very important role in funding research and development in Brazil.

In its 41 years of operation, FAPESP has awarded more than 45 thousand fellowships and 35 thousand financial awards to research. The balance of these years of continuous investment clearly show that the Foundation has made a decisive contribution to the expansion and strengthening of scientific and technological research in the State of São Paulo, with considerable impact on its economic, social and cultural development. (Documents Case 2 24:2-6)

FINEP is an organisation of the Brazilian federal government under the MCT, which is devoted to funding of science and technology in the country. FAPESP is a public foundation with the aim of providing grants, funds and programmes to support research, education and innovation of private and public institutions and companies in the state of São Paulo.

Funding

(Represented as “availability of appropriate funding” in Tables 8.3 and 8.4)

The availability of capital (Shane, 2003) is an important factor in any entrepreneurial activity and biotechnology entrepreneurship is often associated with both government and venture capital funding sources (Audretsch et al., 2008).

The respondents to this research were of the opinion that appropriate funding is available for the biotechnology industry in Brazil. The sources of this funding are primarily the government through its national and state funding agencies; the private sector; and venture capitalists (Audretsch et al., 2008). The availability of appropriate funding in Brazil through these sources is similar to the process of biotechnology entrepreneurship in developed economies (Ahn and Meeks, 2007; Ahn et al., 2010a).

I think we have 100 funds active in Brazil. It can be seed money, mezzanine money or equity in this 100. The Brazilian government puts a lot of money in biotechnology; it is called a special programme, a strategic programme. So I believe it is the government, but I am not sure of the numbers. (Respondent 7 19:47-48)

There is a lot of interest not only from capitalists in Brazil, but outside Brazil that are interested in investing in the country. This has been done in the last five or six years in the area of bioenergy for example. People investing, big multinational companies, merging with Brazilian companies and setting up big sugar cane deals and this is important and this is positive and there is a lot of money available. (Respondent 8 20:83)

FAPESP also has specific programmes to support small businesses. (Respondent 10 22:20)

Basically this programme gives you money for you to go from your research findings to your product. They give you money for researchers, for the goods you need for getting your process moving on. (Respondent 9 21:48)

A key component of the funding adequacy in Brazil is the role played by the venture capitalists in the strategic alliance required to exploit bioentrepreneurial opportunities (Ahn and Meeks, 2007).

Skills

(Represented as "availability of skills" in Tables 8.3 and 8.4)

The respondents in Brazil believed that the research and scientific skills are available at individual levels for the development of biotechnology entrepreneurship in the country. However, the aggregate skills were deemed to be inadequate and as having a negative impact on the speed and scale of the development of the industry.

In the state of São Paulo we have three big universities, Unicamp, the University of São Paulo and the University of the State of São Paulo. All together graduate and undergraduate students, we used to have something like 300,000 students and of course a portion of these students are very talented people. There are people with entrepreneurship skills *and talented people who could be used in the innovation system. (Respondent 8 20:38)*

Now it is amazing, when I arrived here in the 90s, I do not think there were many, there were just a few. There are lots of people that are coming from PhDs; there is a huge programme of doctor formation in Brazil, which is mostly funded by the government. (Respondent 7 19:31-32)

Do we have manpower for this industry? Do we have qualified people? Well, not really and why? (Respondent 6 18:126)

Human resources are a key challenge. Currently there are only 1.48 researchers per 1000 total employment (2006) and only 10.7% of all university graduates have degrees in science and engineering. (Documents Case 2 32:3)

The basic difference I guess is education; they are very good in mathematics. We do not have very good talent for exact sciences. (Respondent 10 22:51-52)

We have lots of jobs for qualified people and at the same time we have unemployment, which means we have a lot of people that did not have the opportunity to actually go to a decent school, could not learn anything. They are barely literate I would say and are looking for jobs, and the jobs that are out there in bioentrepreneurship, the jobs that we would be creating are qualified jobs. I am not talking about PhD, I am talking about just good high school graduates, good technical, we lack those people but at the same time we have unemployment. (Respondent 6 18:116)

When the skills gap did appear, international collaboration and the attraction of foreign skills were used to fill the gaps. That this went on smoothly points to the fact that Brazil has an environment that is conducive for biotechnology entrepreneurship development that attracts foreign skills.

We hired people with PhD here in Brazil or in other countries, mostly the United States. We invested in post doctorates with experience abroad. But we train people also, we used to train people, to send people for training and we did that for intellectual property, we sent people for training in the United States. One important thing is we maintained this since the beginning, very close collaboration with scientists in the US and Europe. We used to have a kind of scientific counselling with very important scientists from Europe and from the US, and this was very important. (Respondent 8 20:21)

And to do this you need the expertise and sometimes we have the expertise here in Brazil, but sometimes we do not have the expertise. So we used to bring people with the strongest experience in biotechnology in the industry in creating our start-up companies and this was very useful for us to do that. (Respondent 8 20:22)

The entrepreneurial and commercialisation skills were not identified as challenges by the respondents in Brazil, which supports the view that the process of biotechnology entrepreneurship in Brazil utilises the "system" approach rather than the "individual" approach. The system provides the commercialisation and entrepreneurial capabilities necessary for the successful exploitation of bioentrepreneurial opportunities.

High interest rate

(Represented as "high cost of funding" in Tables 8.3 and 8.4)

The recent past of very high inflation in Brazil may be over, but the respondents deem the interest rate on funding to be high, in this way contributing to an environment with a high cost of doing business.

In the past, if you borrow money from the bank, it is suicide.

Then the industrial sector of Brazil, because of the high inflation rate, they are not willing to invest in any R&D effort that has high risk. They prefer to buy technology outside of Brazil. (Respondent 9 21:43-45)
Although we do not have high inflation like we had the previous time, but it still costs a lot of money if you borrow money. (Respondent 9 21:107)

Before that we had inflation until 1994, between 1980 and 1994 there was almost 15 years of very high inflation, where it was difficult to think of investing because it was hard to plan anything. (Respondent 6 18:31)

The challenge provided by the high interest rate is alleviated by the funding initiatives of the government at favourable terms and sometimes designated as “free to operate” (FTO), in which case the recipient is not required to repay the grant.

So the money is free, it is FTO, so they have all the freedom to operate.
I think this is a very nice programme, we invested last year about 50 million dollars in different projects. I think this is one of the most important programmes in Brazil, trying to stimulate the creation of start-up companies in all areas. (Respondent 8 20:47)

Other factors that address the high interest rate challenge are the fact that most research in Brazil is conducted through the public universities, which means that the funding for the research is from the government and not the individuals and most bioentrepreneurial activities involve large established companies.

Bureaucracy

(Represented as “bureaucratic processes”; and “government inefficiencies” in Tables 8.3 and 8.4)

The bureaucracy and inefficiencies experienced in government processes were highlighted as challenges to the development of biotechnology entrepreneurship in Brazil.

But if you see how the agencies work, you see a high level of bureaucracy. (Respondent 10 22:8)

In Brazil, the system that controls the private investment is so bureaucratic they do not want to see the results; they want to see the process. If all the people are put in the right order, fine, but it does not matter if you make good use of the money or not, if you got a good result. (Respondent 9 21:94)

For us to operate, we had to buy used equipment, and it took me almost a year to do all the bureaucratic paper work to be able to buy used equipment. (Respondent 6 18:41)

Talking about patents, the national institute of intellectual property in Brazil, for us to register the brand of our company, it took 10 years, a name, a brand, 10 years. (Respondent 6 18:99)

In concluding the section on the environment of biotechnology entrepreneurship in Brazil, it is worth noting that the constraints in the development of the biotechnology industry in Brazil identified by Zylberberg et al. (2012) include infrastructure, capital, regulatory challenges, competition, inequality and environmental sustainability. However, only one of these constraints, regulatory challenges, was highlighted by the respondents in this research as a challenge. The infrastructure and support structures were deemed to be available and adequate; the capital was deemed to be appropriate and sufficient; competition was seen as a positive motive for the development of the biotechnology industry, and not a constraint; inequality was highlighted as a social linkage and not directly a constraint of biotechnology entrepreneurship; and environmental sustainability was seen as one of the areas of emphasis and not as a constraint.

One other area of the environment, which was mentioned by two or more respondents, that is worth emphasising is the national culture of seeing entrepreneurship as “impure” in comparison to academics.

8.2.3 Entrepreneurial opportunities

The bioentrepreneurial opportunities are mostly aligned to the Brazilian biodiversity; efficiency and innovation opportunities; and a component of problem opportunities.

> *I would say that the opportunities in life science are very wide, many areas. Brazil is a big agricultural country, certainly a power house in that area. Then there is an area of service in biotechnology that is difficult because again the competition with the cost structure of a company abroad. It is difficult for us because our cost structure is complex.*
> *Then you have an area of generating products, bioproducts. You develop or you discover a molecule in some biodiversity source. I think that is an area where Brazil has the best opportunity to evolve. (Respondent 6 18:74-79)*

The problem opportunities are in the areas of diseases such as lifestyle diseases; infertility; paternity verification; and food shortages. These problem opportunities are not unique to Brazil or to developing economies in general (Brännback et al., 2007; Battelle/Biotechnology Industry Organisation, 2012) but are predominant in comparison to the developed economies.

> *For example, we have done several tens of thousands of human paternity tests, which are not cutting edge technology, it is a very routine type thing, but you solve problems. So every time you deliver a report you know you are changing the life of some people, so I think that is very motivating for me. (Respondent 6 18:19)*

> *We need to improve yield, we need to fight against the diseases and biotechnology can help a lot to do this and this is why I believe that the world, and not only the countries, all the world needs to invest heavily in biotechnology. (Respondent 8 20:54)*

The efficiency opportunities are mostly in the areas of bioenergy; genomics; pharmaceuticals; bioprocessing and biomanufacturing. The realised efficiencies provide the opportunity to solve some of the problems of food security, and environmental sustainability, promote healthier populations and contribute to energy conservation.

> *As Brazil is very rich in natural resources the agenda has always been connected with the exploration of these resources. (Respondent 10 22:2)*

> *Another competitive advantage of Brazil for the development of biotechnology is its remarkable biodiversity. There are about 200,000 species of plants, animals and microorganisms that have already been registered and it is estimated that this number could reach one million eight hundred thousand species. It is almost a fifth of all global biodiversity distributed in six biomes (Amazon, Cerrado, Caatinga, Atlantic Forest, Pantanal and Pampa), plus the coastal and marine zone. (Documents Case 2 34:36)*

> *All the biotechnology companies today, they have two words, food and fuel, because plants can supply both, fuel and food. When we are talking about fuel, sugar cane is a premium crop to produce bioenergy, and all of those companies elected sugar cane as a big bioenergy crop to invest in. (Respondent 8 20:24)*

> *We are a tropical country with a lot of sun and water and a lot of land available and a good temperature. So we need to invest in Agro industry. We need to invest in agriculture to improve our crop yield and we need to invest in for example, bioenergy and to try and develop all the needs from bioenergy crops and develop industries around this area. I think this is something we can do here, we have a competitive advantage. (Respondent 8 20:75)*

> *I think Brazilian is more focussed on natural resources, biodiversity and biofuels. Also if you see the agricultural side it is also based on the most important Brazilian products, there are more products and they do research on them because we are the biggest producer of oranges in the*

world. The first genome programme was in oranges. (Respondent 7 19:49-51)

The innovation opportunities are in the areas of bioenergy; genomics; vaccines; antibiotics; and the use of indigenous knowledge and biodiversity.

The government is trying to propose to the university, to researchers to work and try to solve the problems we have in Brazil. Because of the high cost in Brazil, the Federal government, several decades ago, set up the foundation for developing a vaccine in biopharmaceutical that they use on a large scale in Brazil. The big pharmaceutical companies, they are not going to produce for example products for controlling childhood disease, childhood disease is only for Africa and Latin America.
Another big force is the potential of biodiversity; we have been exploring the potential biodiversity in Brazil. Personally we do have a lot of potential exploring biodiversity in Brazil, every time somebody uses a plant for curing a tumour and you go deeply, you find chemical principles involved in controlling tumours. One of the plants in Brazil now, there is already a product going to market for curing cancer, from one of the plants in Brazil. (Respondent 9 21:105)

Develop and promote the sustainable use of Brazilian biodiversity with a view to economic and social development of the country, particularly for the competitiveness of Brazilian biomanufacturing, respecting the rights and obligations arising from activities access to genetic resources and associated traditional knowledge. (Documents Case 2 34:12)

This characteristic of the bioentrepreneurial opportunities in Brazil means that it straddles the opportunity continuum between the developing and developed economies, with problem and efficiency opportunities aligning it to the characteristics of developing economies and innovation opportunities aligning it to the characteristics of developed economies.

8.2.4 Discovery

According to the OECD (2009), the primary requirements for R&D to be effective include research universities, other research institutions, a developed scientific educational curriculum, a national culture that supports scientific endeavour, a favourable regulatory environment and talented individuals.

> *So it is an easy equation, you know there is a certain demand and it is just a matter of doing it right, which is not necessarily easy. Especially with recombinant DNA molecules, doing it in the laboratory is one thing, expressing it into small scale; another thing is producing a product that will pass through all the clinical trials. (Respondent 6 18:85)*

R&D in Brazil is well supported and funded through the national and state government agencies; private sector initiatives; international collaboration; and large biotechnological companies. In spite of this, the R&D spend still falls below the OECD average and the respondents believed that more needs to be done to sustain the level of research intensity in the industry. However, there are initiatives by the government to increase the R&D spend (Bound, 2008).

> *At 1% of GDP, R&D spending (both public and private) is comparatively low by OECD standards and is carried out predominantly by the government. (Documents Case 2 24:3)*

> *So unless there is like a full tax exemption for R&D in life science for 20 years in Brazil, there is no way we can really build strong biotech/life science innovation industry, there is no way. (Respondent 6 18:44)*

The discovery of, or ability to act on (Shane, 2003), bioentrepreneurial opportunities is research-driven. This makes R&D in biotechnology entrepreneurship important.

8.2.5 Entrepreneurial exploitation

The strategic alliance needed for effective exploitation of bioentrepreneurial opportunities includes the research institutions, venture capitalists, large organisations and government (Müller et al., 2004).

> *So it is an alliance between my employer which is EMBRAPA and the companies. The companies will not do it themselves; they will count on the support of the governmental research agency. (Respondent 6 18:88)*

All these stakeholders are present in the biotechnology sector in Brazil and this has resulted in the successful exploitation of opportunities.

> *He got support from the government national agency called FINEP that finances industrial development. Then he got money for doing the R&D work from FINEP. He got from our developing bank; he got financing to build an industrial park. He also got money from our National Research Council for doing the R&D work. (Respondent 9 21:31)*

> *Well, it is growing over the last five or six years it is growing, there is more and more money available, different organisations that are now putting money.*
> *I think money is not a problem in Brazil, venture capital, it is not a problem at all, the problem is how to get as much as possible, young pupils, students to get involved in this process, how to handle this problem of collaboration with the universities. (Respondent 8 20:61, 64)*
> *Then Votorantim Group created a branch dedicated to venture capital, and they created a company called Votorantim New Business. New business means investment in start-up companies involved in biotechnology and communication technology or information technology. (Respondent 8 20:8)*

The other roles the government plays in the strategic alliance are the provision of a favourable regulatory environment and facilitation (Ahn et al., 2012). In the case of Brazil, the government also acts as a buyer of the biotechnology products and solutions. Among these government roles, the regulatory environment and bureaucratic processes were highlighted as gaps in the development of biotechnology entrepreneurship in Brazil.

8.2.6 Execution

Commercialisation of research is at the end of the value chain of biotechnology entrepreneurship (Gittelman, 1999; Feldman and Ronzio, 2001; Kettler and Casper, 2001). The effective strategic alliance required for the exploitation of bioentrepreneurial opportunities ultimately results in the effective commercialisation of research (Ahn et al., 2010a; Ahn et al., 2010b; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012).

> *Then the company became important, not only nationally but internationally, and then we started receiving contracts with the big players in the agricultural biotechnology market. Then, in December 2008, our companies were bought by Monsanto. Monsanto is one of the largest agricultural biotechnology companies in the world. (Respondent 8 20:13-15)*

> *All the research from industry came here to the laboratory at the University of Brasilia and it was good research and then they made it the first insulin produced worldwide. They produced the first commercially viable insulin in ‘84 or ’85. (Respondent 9 21:25)*

The low number of challenges in the individual context, the environment of biotechnology entrepreneurship, research and development, and the exploitation of bioentrepreneurial opportunities in the earlier part of the value chain positively impacts on commercialisation of research in Brazil. However, the level of commercialisation of research in Brazil is still deemed to be below the level for the developed economies.

I think we still miss this scaling up of knowledge, we still miss that. (Respondent 6 18:86)

Despite academic excellence in many niche areas, including photonics, materials science, biotechnology and tropical agriculture, other indicators point to the need for improvement, particularly in terms of converting knowledge into productivity gains in the business sector. (Documents Case 2 24:7)

8.3 Similarities and differences between the process of biotechnology entrepreneurship in Brazil and the developed economies

In order to understand how the process of biotechnology entrepreneurship in Brazil compares to the developed economies, the practical experiences reported in Section 8.2 using the organising framework of the individual-opportunity nexus are compared to the literature on the process of biotechnology entrepreneurship in the developed economies.

Table 8.5 summarises the key similarities and differences between the process of biotechnology entrepreneurship in Brazil and the developed economies as exemplified by the individual-opportunity nexus framework (Shane, 2003).

Table 8.5: Summary of key similarities and differences between the process of biotechnology entrepreneurship in Brazil and the developed economies

Measure	Literature on developed economies	Insights from this research on Brazil	Some supporting data from respondents
Individual attributes	Higher levels of non-psychological attributes measured by research output and patent applications in addition to psychological attributes. The bioscientists are supported by a system of other capabilities required for effective business management and commercialisation of research, which is often available within biotechnology and innovation parks. (Ahn and Meeks, 2007; Ahn et al., 2010a; Ahn et al., 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012)	Non-psychological and psychological attributes are thought to be on par with the developed economies at individual bioscientist level. However, the aggregate level of skills lags that of the developed economies hence the lower levels of research output and patent applications. The bioscientists in Brazil have the support system that provides other capabilities needed for effective business management and commercialisation of research. This makes them inclined to the "system" approach to biotechnology entrepreneurship.	*"We ran these companies for six-and-a-half years and we developed a lot of technologies. You know that biotechnology is heavily dependent on intellectual property. And this is the most important part of biotechnology because it takes a long time to have a product so you need to start at the beginning, having intellectual property and you create intellectual property, patent families in order to protect the technology that you are investing in." (Respondent 8 20:11)* *"So I am a forest engineer by training in undergraduate and then I did my PHD in Genetics." (Respondent 6 18:1)* *"My background is in Agronomic engineering, I am an Agronomist. Then I moved to the University of São Paulo where I did work with biochemists of a plant virus. Later I went to Ohio State in Columbus to get my PhD in enzymology, to work with enzymes* *I work mainly from fungus enzymes from the*

Measure	Literature on developed economies	Insights from this research on Brazil	Some supporting data from respondents
			Amazon basin, from hot spots in Brazil." (Respondent 9 21:1)
Environment	Favourable economic, political and cultural factors. In addition the support structure, infrastructure and critical mass of input are all available in the environment of biotechnology entrepreneurship in the developed economies. (Lingelbach et al., 2005; Kelley et al., 2012; Urban, 2013)	The environment of biotechnology entrepreneurship in Brazil has some challenges among which are unfavourable policy and regulatory environment; lack of aggregate skills and capacity; high cost of doing business; and bureaucracy. The funding for research is adequate and the government provides effective direction and leadership.	*"In my research laboratory in EMBRAPA, I buy equipment and reagents with tax exemptions because it is government, although it is not totally exempt, I still pay about 15% on top of the FOB cost of the equipment. If I am in a company, my tax cost on top of the FOB is about 110%." (Respondent 6 18:37)* *"And this is one of the most important problems related to technology transfer and development inside the universities here in Brazil, because all of them are state and public universities." (Respondent 8 20:33)* *"But unfortunately I can say that there is this sense that academia is far removed from society, it is an elitist view of the universe, and this is very damaging I would say to the possibility of entrepreneurship." (Respondent 6 18:27)* *"For a patent to be analysed in Brazil, what I know from colleagues of mine that have submitted patents, it takes at least five to seven*

Measure	Literature on developed economies	Insights from this research on Brazil	Some supporting data from respondents
			years to get a patent analysed, not approved." (Respondent 6 18:99)
Entrepreneurial opportunities	Prevalence of efficiency and innovation opportunities aimed at improving existing industrial processes or bringing new innovative products and solutions to the market; especially in the areas of pharmaceuticals, personalised medicine, cures for rare and lifestyle diseases, and industrial biotechnology. (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2010)	Prevalence of efficiency and innovation opportunities aimed at improvement in agricultural yield; efficiencies in biomanufacturing; and innovation in bioenergy. There were problems identified but these were small in comparison to the efficiency and innovation opportunities. Biodiversity was deemed to be another key bioentrepreneurial opportunity in Brazil	*"Another competitive advantage of Brazil for the development of biotechnology is its remarkable biodiversity. There are about 200,000 species of plants, animals and microorganisms that have already been registered and it is estimated that this number could reach 1,800,000 species. It is almost a fifth of all global biodiversity distributed in six biomes (Amazon, Cerrado, Caatinga, Atlantic Forest, Pantanal and Pampa), plus the coastal and marine zone." (Documents Case 2 34:36)* *"We have areas where we are leading, this business of bioenergy." (Respondent 8 20:80-82)* *"Then they set up one of the first biotechnology centres in Brazil for bioplant and I was the R&D director in this bioplant and therefore I worked with a private business for several years trying to develop biotechnology applied to plant systems and we worked in different lines at that time." (Respondent 9 21:3)*

Measure	Literature on developed economies	Insights from this research on Brazil	Some supporting data from respondents
Opportunity discovery	Intense R&D with a high level of R&D spend as a percentage of the GDP on the part of the government; and the presence of large companies that undertake major R&D activities. (Gastrow, 2008; Organisation for Economic Cooperation and Development, 2009, 2013b, 2013c)	The R&D spend and intensity are below the average for the developed economies and hence constitutes a gap. However, they are improving and there are large companies that undertake major R&D activities.	*"We have to have an incentive, like entrepreneurship is an area that is much incentivised in Brazil. We have an institution that is working exclusively on this in Brazil; it is called SEBRAE (Brazilian Service for Small Business)." (Respondent 7 19:55)* *"In 1998 we started a very big project on genomics and this project was financed by FAPESP, which is the research funding agency of the state of São Paulo." (Respondent 8 20:4)*
Opportunity exploitation	The necessary conditions required for effective exploitation of bioentrepreneurial opportunities are in place. These include an enabling regulatory environment, developed venture capital industry, large established companies, research institutions, government support and economies of scale. (Lingelbach et al., 2005; Phan et al., 2008)	Most of the necessary conditions required for effective exploitation of bioentrepreneurial opportunities are in place. These include developed a venture capital industry, large established companies, research institutions, and government support.	*"Then in 2002, we created a start-up company called Alellyx Applied Genomics, and we created this company with investment from the Votorantim Group, Votorantim is one of the large industrial corporations in Brazil." (Respondent 8 20:7)* *"In the last five years we have had a relatively large contract with the Brazilian government, so we are the reference laboratory for doing all the fingerprinting for all protected varieties of crop plants in Brazil." (Respondent 6 18:9)* *"FINEP was a government funding institution that started a venture capital programme as well,*

Measure	Literature on developed economies	Insights from this research on Brazil	Some supporting data from respondents
			a very huge programme. *And BNDES, the national bank of social development, that also now has a huge fund for biotechnology." (Respondent 7 19:17-18)*
Execution	Efficient because of the necessary technology transfer infrastructure being in place. In addition, the conditions for the earlier stages of the value chain such as environment, R&D and opportunity exploitation are favourable. (Lingelbach et al., 2005; Phan et al., 2008; Nilsson et al., 2010a)	Mostly efficient because of the necessary technology transfer infrastructure being in place. In addition, the conditions for the earlier stages of the value chain such as environment, R&D and opportunity exploitation are mostly favourable.	*"At the same time, the second company CanaVialis developed a huge sugar cane germoplast bank, and then started to make contracts with a sugar cane mill. In 2008, we had about 25% of the market contracted with our companies." (Respondent 8 20:13)* *"They had to go through all the process of authorisation, doing all the red tape and then 10 years later it was being marketed in Brazil.* *Producing 80% of the national needs for insulin and exporting the crystals to Europe and Russia." (Respondent 9 21:28)* *"So either you sell the company to a bigger stakeholder or you license it, which is right, there is nothing wrong." (Respondent 9 21:70)*

From the comparisons in Table 8.5, it can be concluded that:

i. The psychological and non-psychological attributes of the bioentrepreneurs in Brazil are similar to those of the bioentrepreneurs in the developed economies. The differences in skills and capacity are at an aggregate level rather than an individual level

ii. There are similarities and differences in the environment of biotechnology entrepreneurship between Brazil and the developed economies. While the environment in the developed economies can be summed up as favourable across many dimensions the environment in Brazil can be summed up as mostly favourable, and unfavourable across few dimensions

iii. The bioentrepreneurial opportunities in Brazil are similar to those of the developed economies, being predominantly efficiency and innovation opportunities. The bioentrepreneurial opportunities are designated as mostly efficiency opportunities, followed by innovation opportunities and a very small component of problem opportunities. The developed economies exhibit a slightly different trend, leading with innovation opportunities, efficiency opportunities, and problem opportunities related to human health. Brazil also has opportunities associated with biodiversity, which category is not present in the developed economies

iv. The process of opportunity discovery in biotechnology is through R&D. This process in Brazil is different from the developed economies in terms of R&D spend, and the intensity of R&D but better than most developing economies

v. Opportunity exploitation in Brazil is mostly efficient due to the availability of key stakeholders required at this stage of the biotechnology value chain, such as venture capitalists and large biotechnology companies. This process in the developed economies has all the necessary conditions and hence is effective

vi. Execution or commercialisation of research goes through the same process of firm formation or licensing in Brazil as it does in the developed economies. In addition, the “system” approach to biotechnology entrepreneurship is similar to the approach as adopted in the developed economies.

Although Brazil has been recognised for its leadership position in some areas of biotechnology, the result of the efficiencies in the developed economies is that the output of biotechnology entrepreneurship is much more rapid, visible and at a much higher scale in these economies than it is in Brazil (Biotechnology Industry Organisation, 2008; Gastrow, 2008; Organisation for Economic Cooperation and Development, 2009; Battelle/Biotechnology Industry Organisation, 2012; Organisation for Economic Cooperation and Development, 2013b, 2013c).

8.4 The nature of the relationship across the university, industry, and government

The relevance of the interactions among the university, industry and government, in transforming academic research into societal and economic capital, is evidently demonstrated in the field of biotechnology (Liebeskind et al., 1996; Agrawal, 2001; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008). The collaboration among these three stakeholders (Etzkowitz and Leydesdorff, 1997; Leydesdorff and Etzkowitz, 1998, 2001) has recently been considered to involve a fourth stakeholder (Afonso et al., 2010; Marcovich and Shinn, 2011; Afonso et al., 2012; Leydesdorff, 2012). The quadruple helix is context-specific and in the case of Brazil the socio-economic linkages may point to the possibility of the fourth stakeholder being the society.

> *Article 2 shall put in place the process of communication and participation for the Brazilian society.*
> *Article 3 should ensure that biotechnology and economic and technological cooperation are accessible to the whole society, to ensure added value to products and promote social inclusion and quality of life throughout the production process. (Documents Case 2 34:14-15)*

The triple helix relationship across the university, industry and government in Brazil functions effectively. Although the respondents believe that there is room for improvement, there have been collaborative projects in Brazil that are internationally acclaimed, such as the genome projects.

A growing scientific community has allowed for the development of collaborative research programmes that require a large number of researchers. Recent experience in this area is promising and has the potential for engaging the business sector in commercially-oriented research. For example, the Genome Project, set up in São Paulo in partnership with the Citrus Producers Association (Fundecitrus), resulted in the DNA sequencing of a phyto-pathogenic bacterium, the Xylella Fastidiosa, which allowed Fundecitrus researchers to devise ways to protect orange trees from a disease (citrus variegated chlorosis, CVC) that had been associated with considerable economic loss in the past. The joint venture also generated at least two spin-off companies in the field of genomics and bioinformatics. Another example is the Biota Research Programme, a conservation and sustainable development-oriented biodiversity research effort to study and map biodiversity in the state of São Paulo. (Documents Case 2 25:24)

Government leadership has also prioritised the collaboration between the stakeholders to the extent that this has been fairly institutionalised in the industry and has become the way of doing business. The effectiveness of this collaboration in Brazil has helped the country become a leader in bioenergy.

Since the beginning we said we have to establish a relationship with industry, otherwise we are doing biotechnology fiction. I went to the minister of Science and Technology and almost forced them to invest in this agreement between industry, academia and government. (Respondent 9 21:11-12)

Also I think other important landmarks are the genomics in Brazil, you know this story as well. This is São Paulo's part because São Paulo was the leader in this process, all the genomic research was done by networks in Brazil and this trained a lot of scientists in doing this because you cannot do this in small laboratories, you have to do it in huge laboratories, so it was a process of learning. (Respondent 7 19:29)

The respondents in Brazil have a very positive view of the collaboration among the university, industry and government. This collaboration has resulted in some major collaborative projects and outcomes that exploit the efficiency and innovation opportunities.

> *I had a very interesting and rewarding experience when I set up what we called the Genolyptus project, which was a Brazilian network of Eucalyptus genome research. I started this project in 2001 and it went on for seven years and it is actually still going on but in a different format. We got matching funds from industry, from a pool of industries, pulp and paper and energy industry that plant forests. The government put some money and we developed a long and complex project to develop some genomic resources, some experimental resources, some field experiments and also to enhance the understanding of this interaction of genomics into plant breeding for trees. (Respondent 6 18:59)*

Government controls the relationship with the university and the industry, from a policy, regulation, and funding point of view. It is very apparent that the triple helix relation in Brazil is a hybrid of what is described by Etzkowitz and Leydesdorff (2000) as triple helix I, which represents a configuration in which the government encompasses both industry and university and directs the interaction and relations between them and triple helix III, in which overlapping institutional spheres generate a knowledge infrastructure, with overlapping roles and hybrid organisations emerging at the interfaces. This configuration aims to create an innovation environment that supports knowledge-based economic development in which collaborations and alliances are aimed at creating, reinforcing and sustaining the knowledge infrastructure (Etzkowitz and Leydesdorff, 2000) without direct control by any of the institutions.

The unique dynamic in Brazil is that triple helix III characteristics are exhibited but with a direct control from the government, which is a characteristic of triple helix I. With every indication of a continued government control, improvement of the environment in which triple helix III flourishes, and strong social linkages, it is possible that the evolution of the triple helix in Brazil will go the route of a “Quadruple Helix of government-controlled university, industry, society relations”.

8.5 Summary of within-case analysis of Brazil

Biotechnology entrepreneurship in Brazil is conducted by bioscientists who have the necessary research and scientific skills to carry out biotechnological R&D. The availability of infrastructure and support structures, which provides the entrepreneurial and commercialisation skills, enables the bioscientists to employ the system approach to biotechnology entrepreneurship.

Biotechnology entrepreneurship in Brazil faces certain challenges across the economic, political and cultural environments in which it operates (Shane, 2003). Key among these are unfavourable policy and regulatory environment; lack of aggregate skills and capacity; and bureaucratic and inefficient government processes.

On the other hand, there were noted positives in the environment of biotechnology entrepreneurship in Brazil, such as the availability of appropriate funding, government-incentivised entrepreneurial activities, availability of large established biotechnology companies, availability of venture capital companies and effective collaboration among the key stakeholders.

The bioentrepreneurial opportunities were identified predominantly in the area of efficiency opportunities, followed by innovation opportunities and a small instance of problem opportunities. In addition, abundant biodiversity is seen as a competitive source of bioentrepreneurial opportunities in Brazil.

The discovery of these bioentrepreneurial opportunities requires R&D. The R&D intensity and spend in Brazil are deemed to be adequate and are being improved by the government and the private sector. However, they are below the levels of the developed economies.

The exploitation of these bioentrepreneurial opportunities requires a strategic alliance of research institutions, venture capitalists, large established biotechnology companies and government. This process in Brazil employs all the key stakeholders: venture capitalists, research institutions, government and large established biotechnology companies. This is similar to the process of exploiting bioentrepreneurial opportunities in the developed economies.

The execution step of the process of biotechnology entrepreneurship involves the commercialisation of research. The commercialisation of research in Brazil utilises both firm formation and licensing and is deemed to be efficient due to the efficiencies in the earlier parts of the biotechnology value chain and the availability of the system to enable the commercialisation of research. A diagrammatic representation of the process of biotechnology entrepreneurship, as experienced by the respondents in Brazil, is shown in Figure 8.7.

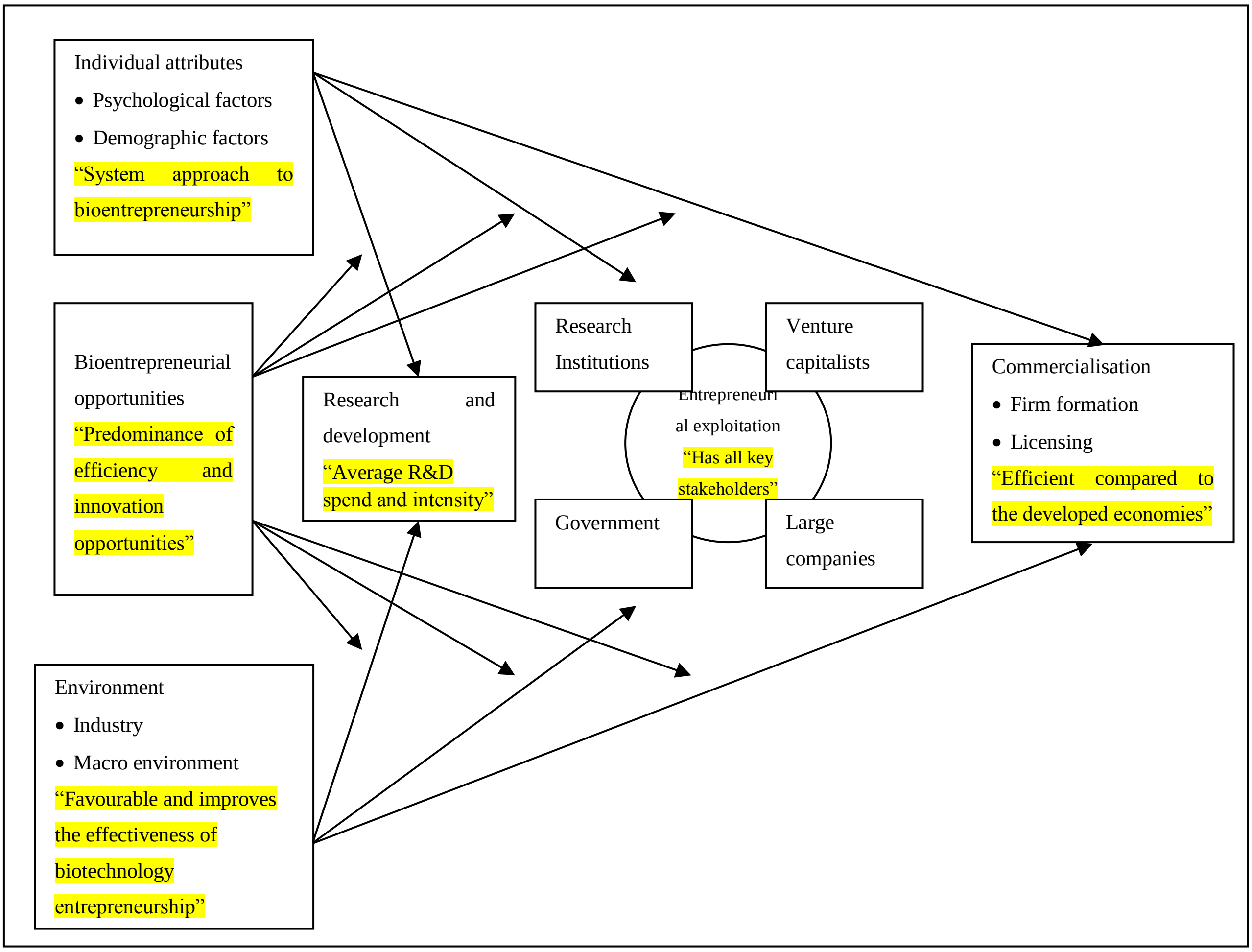


Figure 8.7: A graphical depiction of the process of biotechnology entrepreneurship in Brazil

The direction of the arrows in Figure 8.7 shows that the individual attributes, the bioentrepreneurial opportunities and the environment are deemed to affect all the stages of biotechnology entrepreneurship, from R&D, to entrepreneurial exploitation and commercialisation of research. While this does not prove causality, the importance of the individual attributes, entrepreneurial opportunities and the environment to entrepreneurship is supported by previous studies (Liebeskind et al., 1996; Audretsch and Stephan, 1998; Agrawal, 2001; Shane, 2003; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

This research extends this knowledge by clearly identifying the type of bioentrepreneurial opportunities that are predominant in the biotechnology industry of Brazil the environmental conditions under which the process of exploiting these opportunities takes place and the individual attributes that are used in carrying out this process in Brazil.

PART IV: CROSS-CASE ANALYSIS, DISCUSSION AND THEORY DEVELOPMENT

Part IV consists of Chapter 9.

Chapter 9 presents a cross-case analysis of South Africa and Brazil, a discussion of the results of the analysis, and theory development.

The sub-sections include:

i. Patterns identified from within-case analysis of South Africa and Brazil
ii. Themes identified from the patterns
iii. The proposed theoretical framework of biotechnology entrepreneurship
iv. Summary of the cross-case analysis of South Africa and Brazil

Chapter 9: Cross-Case Analysis

The cross-case analysis is an aggregate view (Stake, 2006) of the research on the dynamics of biotechnology entrepreneurship in South Africa and Brazil. The patterns that emerged from the peculiarities of the individual case studies are aggregated to themes and contrasted with the literature on biotechnology entrepreneurship to enable an accurate interpretation towards developing theory.

9.1 Patterns identified from within-case analyses of South Africa and Brazil

The patterns identified from the within-case analyses of South Africa and Brazil are presented in Table 9.1 below.

Table 9.1: Patterns from within-case analyses of South Africa and Brazil

Emerging themes	Patterns in South Africa	Patterns in Brazil
Individual versus system approach	Owing to lack of adequate support system to provide the entrepreneurial and commercialisation skills needed to commercialise their research, these bioscientists are often forced to acquire entrepreneurial and commercialisation skills to commercialise their research effectively. Consequently, their practice of biotechnology entrepreneurship is as individuals	The availability of infrastructure and support structures, which provides the entrepreneurial and commercialisation skills, enables the bioscientists to employ the system approach to biotechnology entrepreneurship

Emerging themes	Patterns in South Africa	Patterns in Brazil
Collaboration	Most of the respondents believe that there is a lack of collaboration among key stakeholders in biotechnology entrepreneurship in South Africa. Although most of the respondents experience evidence of collaboration with key stakeholders, they agree that a need exists for effective collaboration among key stakeholders	There is collaboration among the key stakeholders and this collaboration is acknowledged to be important to the effective development of biotechnology entrepreneurship in Brazil
The role of government	The lack of direction from the government, through its implementation agencies, is consistently deemed to be a constraint by most of the respondents and the activities deemed to be hindering the development of the biotechnology industry	The government plays an important role in incentivising bioentrepreneurial activities in Brazil
Regulation	The regulatory environment is consistently deemed to be a constraint by most of the respondents	The regulatory environment for biotechnology entrepreneurship in Brazil is deemed to be unfavourable
Funding	The lack of appropriate funding is consistently deemed to be a constraint by most of the respondents	There is availability of appropriate funding for the development of biotechnology entrepreneurship in Brazil
Markets for biotechnology	The lack of developed markets for biotechnology products is	The local market for biotechnology products is

Emerging themes	Patterns in South Africa	Patterns in Brazil
products	consistently deemed to be a constraint by most of the respondents	considered developed
The skills required for biotechnology entrepreneurship	Although most of the respondents believe that the scientific and research skills needed for biotechnology entrepreneurship are available in South Africa, they also deem the entrepreneurial and commercialisation skills to be lacking	There is an availability of the research and scientific skills necessary for the development of biotechnology entrepreneurship. The entrepreneurial and commercialisation skills are available through the system of biotechnology entrepreneurship in Brazil
Nature of bioentrepreneurial opportunities	The bioentrepreneurial opportunities were identified predominantly in the area of problem opportunities, followed by efficiency opportunities and a small instance of innovation opportunities	The bioentrepreneurial opportunities were identified predominantly in the area of efficiency opportunities, followed by innovation opportunities and a small instance of problem opportunities
Biodiversity	The abundance of biodiversity is deemed to be a positive factor by most of the respondents in the development of biotechnology entrepreneurship in South Africa	The abundant biodiversity constitutes a source of competitive advantage for the development of the biotechnology industry in Brazil
R&D is the defining step in biotechnology	The discovery of these bioentrepreneurial opportunities requires R&D.	The intensity and the R&D spend in Brazil are deemed to be adequate and are being

Emerging themes	Patterns in South Africa	Patterns in Brazil
entrepreneurship in South Africa and Brazil	The intensity and the R&D spend in South Africa are deemed to be below the levels of the developed economies	improved by the government and the private sector. However, they are below the levels of the developed economies
Exploitation of bioentrepreneurial opportunities effected through collaboration	The exploitation of these bioentrepreneurial opportunities requires a strategic alliance of research institutions, venture capitalists, large established biotechnology companies, and government. This process in South Africa lacks the key stakeholders: venture capitalists and large established biotechnology companies	This process in Brazil has all the key stakeholders: venture capitalists, research institutions, government and large established biotechnology companies
Commercialisation of research is determined by the dynamics of the earlier steps in the process of biotechnology entrepreneurship	The commercialisation of research in South Africa utilises both firm formation and licensing and is deemed to be inefficient due to a lack of entrepreneurial and commercialisation skills	The commercialisation of research in Brazil utilises both firm formation and licensing and is deemed to be efficient due to the efficiencies in the earlier parts of the biotechnology value chain, and the availability of the system to enable the commercialisation of research
Country competitiveness	The emphasis on country competitiveness is consistently deemed by most of the	Global competitiveness is a key factor in the approach to biotechnology

Emerging themes	Patterns in South Africa	Patterns in Brazil
	respondents to be an important consideration for biotechnology entrepreneurship in South Africa	entrepreneurship in Brazil
Environment of biotechnology entrepreneurship	The general environment for the development of biotechnology entrepreneurship in South Africa is deemed by most of the respondents to be unfavourable	There is an overall conducive environment for the development of biotechnology entrepreneurship in Brazil
	Most of the respondents agree that there is a misalignment between the requirements for being an academic and being an entrepreneur. In addition, the university culture is deemed to be mostly prioritise publication over commercialisation	
	The venture capital industry is consistently deemed to be underdeveloped in South Africa	
		The high cost of funding in Brazil constrains the development of the biotechnology industry
		The universities in Brazil are

Emerging themes	Patterns in South Africa	Patterns in Brazil
		good at conducting the necessary research required for the development of biotechnology entrepreneurship in Brazil
		The politicians do not have a full understanding of the requirements of the biotechnology industry
		The aggregate capacity for innovation needs to be improved
		The inefficiencies of the government and its agencies affect the effectiveness of the development of biotechnology entrepreneurship in Brazil

The patterns that emerged from the within case analyses of South Africa and Brazil (see Table 9.1) resulted in 14 areas of alignment between South Africa and Brazil, from which the emerging themes were derived. The patterns referred to the same concept but not necessarily with the same experience or outcome. Hence, there were instances of positive versus negative experiences across the patterns.

The patterns that were a function of the other patterns; and the patterns that appeared in only one of the cases were not considered for inclusion as themes.

9.2 Themes identified from the patterns

Based on the patterns identified from the within-case analyses of South Africa and Brazil the following themes were derived.

1. There is a dual approach to the practice of biotechnology entrepreneurship, which can be seen as a “system” or as an “individual”
2. Biotechnology opportunities occur in the form of problem, efficiency, and innovation opportunities
3. Regulation is a critical factor in biotechnology entrepreneurship in South Africa and Brazil
4. An overall conducive environment is necessary for the effective development of biotechnology entrepreneurship in South Africa and Brazil
5. R&D is the defining step in biotechnology entrepreneurship in South Africa and Brazil
6. There are four types of skills required in biotechnology entrepreneurship in South Africa and Brazil: research, scientific, entrepreneurial and commercialisation skills
7. Effective collaboration among key stakeholders is important to the development of biotechnology entrepreneurship in South Africa and Brazil
8. The government plays an important role in biotechnology entrepreneurship in South Africa and Brazil
9. Funding is a critical factor in biotechnology entrepreneurship in South Africa and Brazil
10. The local market for biotechnology products is a critical factor in biotechnology entrepreneurship in South Africa and Brazil

The details of these cross-case themes are discussed in the following sub-sections.

9.2.1 Theme 1

"There is a dual approach to the practice of biotechnology entrepreneurship, which can be seen as a 'system' or as an 'individual'"

Meaning of theme 1 in the context of this research

The system approach to biotechnology entrepreneurship is applicable when the skills and capabilities required for effective commercialisation of research do not rest in a single individual. The individual bioscientist brings to the process the scientific and research skills; and the other stakeholders bring entrepreneurial and commercialisation capabilities, and other support structures. The effective collaboration between the bioscientist and the other stakeholders results in a system of biotechnology entrepreneurship that has all the necessary requirements for the effective commercialisation of research.

The individual approach to biotechnology entrepreneurship is applicable when the skills and capabilities required for effective commercialisation of research rest in a single individual. In addition to having the scientific and research skills, the individual is required to have the necessary entrepreneurial and commercialisation capabilities. In this approach the other support structures may or may not be available in which case it may be the responsibility of the individual to provide the support structures. This approach leaves little room for collaboration, encourages competition, and is similar to the role of the individual entrepreneur in general entrepreneurship.

> *Biotechnology as an industrial activity is still very highly research-dependent. Often the organisation that generates an idea does not have all the skills necessary to take that idea to eventual product roll-out. This is one reason why clustering became an important feature of the development of biotechnology. (Documents Cross-Case 30:35)*

Manifestation of theme 1 in South Africa and Brazil

The manifestation of theme 1 resulted in dual approaches to the process of biotechnology entrepreneurship in South Africa and Brazil. With the availability of infrastructure and support structures, as experienced by the respondents in Brazil, the “system” approach to biotechnology entrepreneurship was adopted. On the other hand, the lack of infrastructure and support structures, as experienced by the respondents in South Africa, manifested in the adoption of the “individual” approach to biotechnology entrepreneurship.

In the “system” approach to biotechnology entrepreneurship, a bioscientist may not necessarily need to acquire the entrepreneurial and business management skills necessary to manage the commercialisation of research successfully. The “system” delivers the entrepreneurial and commercialisation resources required for effectively carrying out biotechnology entrepreneurship, through the government, venture capitalists, large biotechnology companies, or a combination of these.

This form of biotechnology entrepreneurship is manifested in Brazil through the commercialisation of research that involved the provision of the entrepreneurial and commercialisation resources by large biotechnology companies and government.

> *Then in 2002, we created a start-up company called Alellyx Applied Genomics, and we created this company with investment from the Votorantim Group, Votorantim is one of the large industrial corporations in Brazil. (Respondent 8 20:7)*

This is further manifested in the availability of incubators and technology parks and the effective collaboration that provides the other support structures needed for the effective commercialisation of research.

> *A majority of Brazil’s incubators and technology parks are affiliated with institutions of higher education. In 2003, there were 207 incubators and 10 technology parks operating in Brazil. Of the 207 incubators, 107 were technology-based, and of those 80% had formal ties with universities. All*

> *ten of the technology parks had formal and informal ties with universities. (Documents Case 2 33:27)*

The bioscientists who participated in this research in Brazil did not need to go through formal training to acquire the entrepreneurial and commercialisation skills necessary for the commercialisation of their research. The system delivered this capability and they were up-skilled in commercialisation through practical experience *(Respondent 6 18:11; Respondent 8 20:28-29).*

The "individual" approach entails bioscientists acquiring the entrepreneurial and commercialisation skills that enable them to manage the commercialisation of research successfully *(Respondent 5 5:12-13; Respondent 11 6:7; Respondent 11 6:22)*. This form of biotechnology entrepreneurship develops as a result of the lack of the support structures and infrastructure to provide the entrepreneurial and commercialising resources.

This form of biotechnology entrepreneurship is manifested in South Africa due to the lack of a developed venture capital industry, the large established biotechnology companies and other critical infrastructure and support structures. The bioscientists acquire the necessary entrepreneurial and commercialisation skills through formal training and approach the process in their individual capacity as is often the case in general entrepreneurship.

> *I imported some products, so I acquired some market share and generated some cash and used that cash to set up my own manufacturing facility. (Respondent 11 6:10)*

The bioscientists who participated in this research in South Africa needed formal training in business management to acquire the entrepreneurial and commercialisation skills needed for effective commercialisation of their research. This training took the form of a Master of Business Administration (MBA) *(Respondent 5 5:12-13)*; Management Advancement Programme (MAP)

(Respondent 11 6:7); and entrepreneurial skills development programme run by some of the stakeholders and sponsored by the government *(Respondent 12 7:7-9)*.

Comparison with the literature

The literature on general entrepreneurship recognises the role of the individual in the process of entrepreneurship in developed and developing economies. The psychological attributes necessary for the individual to function effectively as an entrepreneur include higher levels of cognitive functioning, motivation, leadership qualities, propensity to take risk, action-orientation, self-efficacy, preference for autonomy, self-direction, and differential access to scarce and expensive resources (Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003).

In addition to the psychological attributes, the requisite non-psychological factors such as education and career experience (Barro and Lee, 2000) are necessary for biotechnology entrepreneurship.

Studies also recognise the role of the environment or “external forces” (Tushman and Anderson, 1986; Hannan and Freeman, 1987; Ács and Audretsch, 2003) in the process of entrepreneurship in developed and developing economies. In addition, the process of biotechnology entrepreneurship in the developed economies has ben een to be driven primarily through collaboration of stakeholders (Müller et al., 2004;), which is similar to having a system of biotechnology entrepreneurship.

The literature on the determinants for researchers' choice to engage in commercialisation (Nilsson et al., 2010a) highlights four factors: the perceived role of the university, supportive infrastructure, industrial actor set-up, and networks. The details of these factors include the university culture, university infrastructure such as the TTO, national infrastructure for commercialisation of research, large companies that have receiver capabilities, and collaboration among key stakeholders.

A third component of the literature is the addition of the role of entrepreneurial opportunities (Shane and Venkataraman, 2000). The integration of the individual, environmental and entrepreneurial opportunities (Cunningham and Lischeron, 1991; Shane and Venkataraman, 2000) in exploring the dynamics of biotechnology entrepreneurship has the prospect of providing an in-depth understanding of the key aspects of biotechnology entrepreneurship in South Africa and Brazil. This informed the decision to use the individual-opportunity nexus framework of entrepreneurship (Shane, 2003) as an organising framework for this research.

This research confirms and extends the existing literature in a number of ways. There was a confirmation of the importance of the roles played by the individual and the environment. The psychological and non-psychological individual attributes are critical to the success of biotechnology entrepreneurship in South Africa and Brazil. Similarly, the environment in which biotechnology entrepreneurship is conducted constitutes the biggest difference between the developing and developed economies; and within the cases in this study the environment of biotechnology entrepreneurship constitutes the biggest difference between South Africa and Brazil.

The existing literature was extended by articulating the impact of the environment on the approach to biotechnology entrepreneurship in South Africa and Brazil. The individual and system approaches, applicable to South Africa and Brazil respectively, showed that different approaches are employed in different contexts based on the environmental dynamics of each context.

9.2.2 Theme 2

"Biotechnology opportunities occur in the form of problem, efficiency, and innovation opportunities"

Meaning of theme 2 in the context of this research

Bioentrepreneurial opportunities pre-exist and do not require the special psychological attributes possessed by a few individuals to be discovered. However, these opportunities require R&D to be exploited.

> *For all of these examples, the problems that need to be solved are known in advance. These include the problem diseases, the types of crop traits that would improve agricultural output, and the types of industrial products that can be replaced with biomass. In addition, the size of the potential market for products such as biofuels or anti-cancer drugs can be estimated with a reasonable degree of accuracy. (Documents Cross-Case 31:25)*

Bioentrepreneurial opportunities take the form of "problem opportunities", in which problems related to diseases, human health, food security, the environment and energy create bioentrepreneurial opportunities; "efficiency opportunities", in which new means of improving existing products and services, such as bioprocessing and biomanufacturing, are created; and "innovation opportunities", in which new innovative products and services, not previously in existence, are created.

Manifestation of theme 2 in South Africa and Brazil

Most of the respondents in South Africa see bioentrepreneurial opportunities in the areas of biodiversity and problems related to diseases and food security. These types of opportunities, linked to problems of diseases, food security, the environment and energy are designated as "problem opportunities" (researcher's synthesis).

The biodiversity highlighted by the respondents falls within the second category of opportunities. The second form of bioentrepreneurial opportunities identified by the respondents is designated as "efficiency opportunities", which mostly occur in the areas of bioprocessing and biomanufacturing. While the efficiency opportunities may not be as ubiquitous as problem opportunities in case 1 due to the low level of industrialisation, the realised efficiencies do provide the opportunity to solve some of the problems of food security and environmental sustainability, and create healthier populations and energy sufficiency (Biotechnology Industry Organisation, 2008).

There are few instances in South Africa where the exploitation of the “problem opportunities” has led to “efficiency and innovation opportunities”. The innovation opportunities are minimal in South Africa and were not mentioned by most of the respondents, as the emphasis was on the problem opportunities, followed by the efficiency opportunities *(Respondent 15 10:45-46, 48)*. The manifestation of problem and efficiency opportunities was highlighted by the respondents in South Africa *(Respondent 1 1:86; Respondent 3 3:73; Respondent 12 7:31-34).* Hence, bioentrepreneurial opportunities in South Africa take the form of “problem opportunities” and “efficiency opportunities”.

In Brazil, the bioentrepreneurial opportunities are mostly aligned to efficiency and innovation opportunities and a component of problem opportunities *(Respondent 6 18:74-79)*.

The efficiency opportunities are manifested mostly in the areas of biodiversity; bioenergy; genomics; pharmaceuticals; bioprocessing and biomanufacturing. The realised efficiencies do provide the opportunity to solve some of the problems of food security and environmental sustainability, and achieve healthier populations and energy conservation (*Respondent 10 22:2; Documents Case 2 34:36; Respondent 8 20:24; Respondent 8 20:75; Respondent 7 19:49-51).*

> *Another competitive advantage of Brazil for the development of biotechnology is its remarkable biodiversity. There are about 200,000 species of plants, animals and microorganisms that have already been registered and it is estimated that this number could reach 1,800,000 species. It is almost a fifth of all global biodiversity distributed in six biomes (Amazon, Cerrado, Caatinga, Atlantic Forest, Pantanal and Pampa), plus the coastal and marine zone. (Documents Case 2 34:36)*

The innovation opportunities are manifested in the areas of bioenergy; genomics; vaccines; antibiotics; and the use of indigenous knowledge and biodiversity *(Respondent 9 21:105; Documents Case 2 34:12)*.

The nature of the bioentrepreneurial opportunities in Brazil means that it straddles the opportunity continuum between the developing and developed economies, with problem and efficiency opportunities aligning it to the characteristics of developing economies; and innovation opportunities aligning it to the characteristics of developed economies. Hence, the different types of bioentrepreneurial opportunities are designated as problem, efficiency, and innovation opportunities (researcher’s synthesis).

Comparison with the literature

The entrepreneurial opportunities in biotechnology seem to be different from the entrepreneurial opportunities in general entrepreneurship in some key aspects. While general entrepreneurial opportunities are not known in advance and require enterprising individuals with special psychological attributes (McClelland, 1961; Kihlstrom and Laffont, 1979; Schere, 1982; Gartner, 1990) to uncover them bioentrepreneurial opportunities are mostly known in advance and require bioscientific skills to obtain a solution (Müller et al., 2004).

The discovery of general entrepreneurial opportunities requires the individual entrepreneur to apply their business management capability towards profit making or other forms of positive outcome (Shane, 2003). However, the discovery of bioentrepreneurial opportunities involves a process of R&D to get to the desired outcome, and is more of a “creation” (Audretsch et. al, 2008) than a “discovery” (Alvarez and Barney, 2007).

The exploitation of general entrepreneurial opportunities is also mostly dependent on the individual entrepreneurs and their organising abilities (Shane, 2003). However, the exploitation of bioentrepreneurial opportunities mostly requires a strategic alliance involving government, large established companies, venture capitalists, and research institutions (Liebeskind et al., 1996; Audretsch and Stephan, 1998; Agrawal, 2001; Shane, 2003; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

This research extends the existing literature by providing a differentiation of the types of bioentrepreneurial opportunities that exist in South Africa and Brazil. By comparison to existing literature, the three types of bioentrepreneurial opportunities that form a continuum of opportunities in the developed and developing economies are problem, efficiency, and innovation opportunities. These types of opportunities are linked to the needs and priorities of the different contexts.

9.2.3 Theme 3

"Regulation is a critical factor in biotechnology entrepreneurship in South Africa and Brazil"

Meaning of theme 3 in the context of this research

The regulatory environment of biotechnology entrepreneurship in South Africa and Brazil includes specific policies that impact on biotechnology entrepreneurship such as the national bio-economy strategy of South Africa; the national biotechnology development policy of Brazil; the intellectual property policy; policies related to R&D activities; policies that govern public universities and research institutions; innovation policies; technology transfer policies; policies related to immigration of foreign skills; labour laws; policies related to ethics in biotechnology; and taxation laws related to research.

> *The regulatory environment affects innovation in many ways. It influences the size and behaviour of firms, as well as input and output markets. The government plays an important role in setting standards and decreasing administrative burden. Regulations aim to respond to market failures and improve welfare. Regulations are inherently linked to reducing risks for economic agents and the environment, while innovation is about taking risks. To balance risk and innovation, governments should promote innovation through market incentives and goal-based approaches when developing good regulation. (Documents Cross-Case 29:29)*

The development and implementation of these policies and regulations by the government impact on the degree of effectiveness of biotechnology entrepreneurship in South Africa and Brazil.

Manifestation of theme 3 in South Africa and Brazil

The regulatory environment of biotechnology entrepreneurship in South Africa was deemed to be non-conducive for biotechnology entrepreneurship by the respondents *(Respondent 13 8:18; Respondent 12 7:24-25)*. This regulatory challenge was also recognised in the new bio-economy strategy to be implemented by the government of South Africa *(Documents Case 1 14:68)*.

> *A lack of delivery of biotechnology strategy largely hinges, not entirely, but largely hinges on the policy environment. They are contradictory and unaligned challenging policy regulatory environment. So there are lots of things that need to be sorted out, and it's one of the things we hope to address through the bio-economy strategy. (Respondent 1 1:77)*

Similarly, the experience of challenges with the regulatory environment for biotechnology entrepreneurship in Brazil was unanimous across all the transcripts. The specific areas that were highlighted as challenges are policies related to intellectual property ownership; policies related to technology transfer from the university to the industry; taxation laws; and labour laws *(Respondent 8 20:30,34; Documents Case 2 33:20; Respondent 6 18:90-91; Respondent 9 21:79; Respondent 10 22:11-13)*

> *They have to charge more and more taxes to be able to operate. So you have a very complex system of taxation with state taxes, federal taxes and all kinds of different constantly changing taxation systems. So that also scares a lot of people, you hear a lot of difficult stories of people that set up business and just went down because they just could not deal with all the complex taxation systems. (Respondent 6 18:33)*

The regulatory environment of biotechnology entrepreneurship in South Africa and Brazil defines the existence of the industry, the rules of engagement among the stakeholders and the general environment in which the industry operates.

Comparison with the literature

The regulatory environment is important for general entrepreneurship (Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003; Lingelbach et al., 2005; Phan et al., 2008) and determines the effectiveness of the process of entrepreneurship to some extent.

The regulatory environment is also considered to be one of the primary requirements for effective R&D, in addition to research universities, other research institutions, a developed scientific educational curriculum, a national culture that supports scientific endeavour, and talented individuals (Organisation for Economic Cooperation and Development, 2009). The GEM also highlights the regulatory environment as one of the differentiators of the efficiency-driven and innovation-driven countries (Kelley et al., 2012) in relation to the effectiveness of the process of entrepreneurship.

Specifically in biotechnology entrepreneurship, the role of the government includes the provision of a favourable regulatory environment (Müller et al., 2004; Nilsson et al., 2010).

In comparison to general entrepreneurship, the policy and regulatory environment plays a bigger role in biotechnology entrepreneurship in South Africa and Brazil due to the multifaceted nature of biotechnology (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012). Biotechnology impacts on critical areas of the society such as food security, human health, environmental sustainability and energy sufficiency (Dibner, 1986; Muller and Fujiwara, 2002; Müller et al., 2004; Ahn and Meeks, 2007; Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012).

This research confirms the views of existing literature on the critical importance of a favourable regulatory environment to the process of biotechnology entrepreneurship.

9.2.4 Theme 4

"An overall conducive environment is necessary for the effective development of biotechnology entrepreneurship in South Africa and Brazil"

Meaning of theme 4 in the context of this research

The overall environment of biotechnology entrepreneurship in South Africa and Brazil includes the regulatory environment; political environment; economic environment; cultural environment; social environment; innovation and entrepreneurial environment; available pool of skills; governance (government leadership); funding; infrastructure; and the size of the market for biotechnology products.

The experience of the respondents in South Africa and Brazil was set within the context of these environments, with the regulatory environment being the dominant environment.

Manifestation of theme 4 in South Africa and Brazil

The overall environment of biotechnology entrepreneurship in South Africa presents many challenges according to the respondents (see Table 7.2 on page 158). The challenges highlighted by most of the respondents include a policy and regulatory environment that is not conducive to entrepreneurship; lack of appropriate funding; an inclination by the universities to prioritise publication over commercialisation of research; lack of government leadership and direction; lack of aggregate skills, as well as entrepreneurial and commercialisation skills; and lack of a developed market for biotechnology products. These challenges were corroborated by the document analysis, which highlighted areas of challenge such as human capital, knowledge exploitation, market development and governance *(Documents Case 1 13:68)*.

> *But I think one of the biggest caveats is that that environment, that nurturing environment is not there, either virtually or physically. (Respondent 14 9:65)*

Of the 19 areas highlighted only one was mostly seen as not a challenge while the remaining 18 areas were seen as challenges by most of the respondents (see Table 7.2 on page 158).

In relation to Brazil, the environment of biotechnology entrepreneurship, as experienced by the respondents, is mixed with an equal occurrence of key challenges and areas considered not to represent gaps in the development of biotechnology entrepreneurship in Brazil. Table 8.2 (see Table 8.2 on page 211) shows the areas highlighted by the respondents as affecting the environment of biotechnology entrepreneurship in Brazil. There is an equal split between the factors designated as favourable and those seen as challenges. Of the 14 areas highlighted seven, were highlighted as gaps, and seven, not as gaps.

The challenges include the regulatory environment, especially related to taxation; shortage of aggregate skills; national culture of seeing entrepreneurship as impure; high interest rate, which results in high cost of funds; bureaucracy; corruption and politics *(Respondent 6 18:51-52; Respondent 8 20:43-44).*

On the other hand, the areas considered not to represent challenges are the provision of direction and leadership by the government; availability of appropriate funding; the size of the market for biotechnology products in Brazil; availability of relevant infrastructure; a university culture that is conducive to the development of biotechnology entrepreneurship; availability of adequate capacity for biotechnology entrepreneurship; and good scope for international collaboration *(Documents Case 2 34:33)*.

The overall environment was deemed unconducive for the development of biotechnology entrepreneurship in South Africa by the respondents. In contrast, the respondents in Brazil believed that the overall environment in Brazil was conducive for the development of biotechnology entrepreneurship.

Comparison with the literature

The institutional environment needed for supporting the development of entrepreneurship in general (Kelley et al., 2012; Urban, 2013) is also applicable to biotechnology entrepreneurship. The three categories of factors believed to influence productive entrepreneurial activity are the economic, political and cultural environments (Shane, 2003).

However, the overall environment for the development of biotechnology entrepreneurship in South Africa and Brazil includes regulatory and social environments. The regulatory environment is particularly important in the environment of biotechnology entrepreneurship (Müller et al., 2004; Ahn and Meeks, 2007). Also the innovation and entrepreneurial environment proposed by Kelley, Singer and Herrington (2012) contains key elements that are important to the development of biotechnology entrepreneurship, such as entrepreneurial finance, government policies, government entrepreneurship programmes, entrepreneurship education, R&D transfer, commercial and legal infrastructure for entrepreneurship, internal market openness, physical infrastructure for entrepreneurship, and cultural and social norms.

There are marked differences between the developed and developing countries in all three categories of environmental factors (Shane, 2003). While the four aspects of the economic environment: wealth, economic stability, capital availability and taxation, are all at advanced levels and favourable for productive entrepreneurship in the developed economies, the developing economies face issues of poverty, economic instability, lack of capital and restrictive tax laws (Herrington et al., 2008; Bosma and Levie, 2010). Similarly, political instability in developing economies and low levels of a national culture of innovation and entrepreneurship hamper productive entrepreneurial activity (Herrington et al., 2010).

This research confirms the existing literature on the importance of an overall environment that is conducive to the development of biotechnology entrepreneurship in South Africa and Brazil. While the literature reviewed was on general entrepreneurship or bioentrepreneurship in the developed economies, its applicability to biotechnology entrepreneurship in South Africa and Brazil was confirmed in this research.

9.2.5 Theme 5

"Research and development is the defining step in biotechnology entrepreneurship in South Africa and Brazil"

Meaning of theme 5 in the context of this research

The ability to act on bioentrepreneurial opportunities is research-driven. This makes R&D in biotechnology entrepreneurship a critical determinant of the output.

To exploit the opportunities in biotechnology, individuals with the research and scientific skills have to go through a process of R&D. These opportunities are known in advance and fall within the categories of problem, efficiency and innovation opportunities. An example of a problem opportunity in South Africa is a cure for HIV/AIDS. The opportunity for a cure for HIV/AIDS can only be attained through R&D, and subsequently using the entrepreneurial and commercialisation capabilities to commercialise the research.

The R&D step in biotechnology entrepreneurship is the step that introduces the most risk in the process of biotechnology entrepreneurship, as the timeframe and cost can be indeterminable and there is no guarantee that the R&D will result in the expected outcome.

R&D in the context of this research refers to all R&D activities that the bioscientists undertake in order to get to a desired solution or product that addresses a problem, improves existing processes, or introduces new innovative products and solutions. It also includes the environment of R&D in South Africa and Brazil in terms of R&D spend and intensity.

Manifestation of theme 5 in South Africa and Brazil

According to the OECD (2009), the primary requirements for R&D to be effective include research universities, other research institutions, a developed scientific educational curriculum, a national culture that supports scientific endeavour, a favourable regulatory environment and talented individuals.

Most of the respondents in South Africa deem the funding for R&D to be inadequate and see it as a gap in the effort to develop the biotechnology industry in South Africa. The R&D spend in South Africa is low in comparison to other developing economies such as Brazil or the developed economies *(Respondent 1 1:105; Respondent 2 2:40)*.

In addition to the expenditures undertaken by the government, large companies in biotechnology undertake major R&D. The lack of these large biotechnological companies that undertake major R&D projects was highlighted as a gap by the respondents in South Africa *(Respondent 16 11:47)*.

> *So there is a systemic problem where there is a shortage of R&D funding within the system. (Respondent 2 2:40)*

> *The lack of major R&D taking place here and the lack of capital are the two major constraints. (Respondent 16 11:47)*

By contrast, R&D in Brazil is well supported and funded through the national and state government agencies; private sector initiatives; international collaboration; and large biotechnological companies. In spite of this, the R&D spend still falls below the

OECD average and the respondents believed that more needed to be done to sustain the level of research intensity in the industry *(Documents Case 2 24:3; Respondent 6 18:44)*.

> *At 1% of GDP, R&D spending (both public and private) is comparatively low by OECD standards and is carried out predominantly by the government. (Documents Case 2 24:3)*

The experience of the respondents in South Africa and Brazil was that the level of R&D spend lags behind the developed economies. Although the respondents in Brazil highlighted the availability of different sources of funding for research, they believed that more needed to be done for them to compete with the developed economies. The level of R&D spend, as a percentage of GDP, is still not on par with that obtainable in most of the developed economies, and the OECD countries (Organisation for Economic Cooperation and Development, 2013b).

Comparison with the literature

Opportunity discovery in general entrepreneurship is different from opportunity discovery in biotechnology entrepreneurship. Opportunity discovery in biotechnology entrepreneurship is more of a “creation” (Audretsch et. al., 2008) than a “discovery” (Alvarez and Barney, 2007) as the solution to exploit the opportunities is created or discovered through R&D.

R&D is a key step that differentiates biotechnology entrepreneurship from general entrepreneurship. This is also the key step that contributes to the predominance of non-psychological factors such as education and career experience (Barro and Lee, 2000) in biotechnology entrepreneurship.

Historically, developed economies are more R&D intensive than developing economies are. Consequently, R&D-driven technologies and industries, such as biotechnology, are more prevalent in the developed than the developing economies.

The US leads the R&D expenditure chart (Organisation for Economic Cooperation and Development, 2013b), followed by the rest of the developed countries. South Africa's R&D expenditure is assumed to depict the level of R&D expenditure by developing economies, given the fact that South Africa is ranked among the efficiency-driven economies in the GEM research (Herrington et al., 2008; Bosma and Levie, 2010; Herrington et al., 2010). Although Brazil is not included in the OECD biotechnology statistics, the level of total R&D expenditure in Brazil is among the highest in Latin America as shown in Figure 8.4 on page 203.

The intensity of biotechnology R&D as a percentage of industry value added is also highest in the US, with South Africa coming in ahead of Russian Federation in last position among all the countries included in the survey (Organisation for Economic Cooperation and Development, 2009).

Given that the discovery of biotechnological opportunities requires R&D, it simply follows that the direct consequence of low R&D spend and activities in developing economies is low levels of biotechnological activities. This research therefore supports the existing literature regarding the importance of R&D to the development of biotechnology entrepreneurship in the developed economies and finds it to be equally applicable to South Africa and Brazil.

9.2.6 Theme 6

"There are four types of skills required in biotechnology entrepreneurship in South Africa and Brazil, namely: research, scientific, entrepreneurial, and commercialisation skills"

Meaning of theme 6 in the context of this research

In the context of this research "skills" refers to all the identified skills necessary for the effective commercialisation of research in South Africa and Brazil. These skills are research, scientific, entrepreneurial, and commercialisation skills.

The “research skill” refers to the ability of a bioscientist to conduct scientific research with the rigour and thoroughness that leads to a desirable outcome. The “scientific skill” refers to the ability of the bioscientist to understand and apply accepted scientific methods and standards towards scientific activities like research, publication, and dissemination of knowledge. The “entrepreneurial skill” refers to the business management acumen necessary to manage a firm effectively to achieve the desired socio-economic and financial performance. The “commercialisation skill” refers to the capabilities needed to convert laboratory research successfully into economic and social value.

Manifestation of theme 6 in South Africa and Brazil

The importance of skills to the development of biotechnology entrepreneurship in South Africa was highlighted by most of the respondents. In analysing the experience of the respondents regarding the skills landscape, the four broad categories of skills highlighted by the respondents were scientific, research, entrepreneurial, and commercialisation skills.

While most of the respondents believed that scientific and research skills are available in South Africa, the entrepreneurial and commercialisation skills were deemed to be lacking (*Respondent 2 2:35-36)*.

> *So one of the things that we really need to continue and expand is the development of bio-entrepreneurship skills. (Respondent 1 1:139)*

The respondents in Brazil believed that the research and scientific skills are available at individual levels for the development of biotechnology entrepreneurship in the country. However, the aggregate skills were deemed to be inadequate and as negatively impacting on the speed and scale of the development of the industry *(Respondent 8 20:38; Respondent 6 18:126; Respondent 6 18:116)*.

> *Human resources are a key challenge. Currently there are only 1.48 researchers per 1000 total employment (2006) and only 10.7% of all*

university graduates have degrees in science and engineering. (Documents Case 2 32:3)

The entrepreneurial and commercialisation skills were not identified as challenges by the respondents in Brazil, which supports the view that the process of biotechnology entrepreneurship in Brazil utilises the "system" approach rather than the "individual" approach. The system provides the commercialisation and entrepreneurial capabilities necessary for the successful exploitation of bioentrepreneurial opportunities.

The different levels of availability of all the identified skills in South Africa and Brazil may contribute to the differences in success of commercialisation of research in the two countries. While Brazil has all the identified capabilities within the system of biotechnology entrepreneurship; South Africa tries to get all the necessary skills within the individuals; and the scale of successes has been in favour of Brazil.

Comparison with the literature

The lack of entrepreneurial and commercialisation skills was identified in prior studies on the biotechnology industry in South Africa in the form of a lack of skills (Lingelbach et al., 2005), and low levels of commercialisation of biotechnology products (Cloete et al., 2006). This distinction between the types of skills that are lacking is important given the general discourse on the low level of mathematics and science education in South Africa (Department of Science and Technology, 2001; Department of Science and Technology, 2007), which can easily be wrongly interpreted to mean a lack of science and research skills for biotechnology entrepreneurship in South Africa.

There has also been much emphasis on the importance of skills in biotechnology entrepreneurship across industry research; empirical research on developed economies; and empirical research on developing economies. (Department of Science and Technology, 2001; Lingelbach et al., 2005; Ahn and Meeks, 2007; Department of Science and Technology, 2007; Phan et al., 2008; Ahn et al., 2010a;

Ahn et al., 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012; Kelley et al., 2012).

In contrast to general entrepreneurship, the research and scientific skills are must-haves for participation in biotechnology entrepreneurship, as R&D is used to discover or create opportunities in biotechnology entrepreneurship (Ahn and Meeks, 2007; Phan et al., 2008; Ahn et al., 2010a; Ahn et al., 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn et al., 2012; Dunham et al., 2012).

This research confirms the critical importance of skills in biotechnology entrepreneurship in South Africa and Brazil. It also extends the existing literature in understanding the different skills required for biotechnology entrepreneurship in South Africa and Brazil; and how the availability of these four skills in South Africa and Brazil influences the model of biotechnology entrepreneurship practised in South Africa and Brazil.

9.2.7 Theme 7

"Effective collaboration among key stakeholders is important to the development of biotechnology entrepreneurship in South Africa and Brazil"

Meaning of theme 7 in the context of this research

The stakeholders in biotechnology entrepreneurship in South Africa and Brazil are the government, research institutions, venture capitalists, large biotechnology companies, and society (*Documents Cross-Case 30:36)*.

These stakeholders are aligned to the triple helix of university, industry, government relations model. In this model, the government represents the government sphere of the model; the research institutions represent the university sphere; and the venture capitalists and large biotechnology companies represent the industry sphere. The society stakeholder is a fairly recent addition to the academic discourse on the triple helix model, which has led to proposals for a quadruple helix with society as the fourth sphere.

The determination of these stakeholders was informed by the literature on biotechnology and entrepreneurship; the analysis of the transcripts of the interviews; and the organising framework of the triple helix of university, industry, government relations model.

> *The role players within the bio-economy will have to collaborate effectively if the bio-economy is to succeed. These role players include industry, academia, science councils, non-governmental organisations, community-based organisations, not-for-profit companies and the government. (Documents Case 1 13:45-46)*

The stakeholders contribute different requirements to the process of biotechnology entrepreneurship in South Africa and Brazil. In addition, they have different needs.

The research institutions provide talent and technology transfer capabilities; the venture capitalists provide capital; the large companies act as cooperation partners, customer and competitor; and the government provides an enabling regulatory environment and acts as facilitator. The needs of the stakeholders vary between economic development, financial return and commercialisation of research.

> *This rise of convergence, in turn, reinforces the importance of strategic collaborations. With convergence, there is a strong need for a "bigger bench" of scientists - both within academia and industry - undertaking discovery and development. Convergence will require capabilities not typically possessed in a single organization and so lead to more collaboration and strategic partnering. (Documents Cross-Case 27:21)*

Given the different roles and needs of the stakeholders, it is important that the collaboration among the stakeholders is effective for achieving the goal of the development of biotechnology entrepreneurship in South Africa and Brazil.

Manifestation of theme 7 in South Africa and Brazil

The key manifestation of the importance of effective collaboration among the stakeholders in biotechnology entrepreneurship in South Africa and Brazil relates to collaborative projects, which resulted in positive outcomes in Brazil, where the collaboration among the stakeholders was deemed to be effective. In South Africa, where the collaboration among the stakeholders was deemed to be ineffective, few successful collaborative projects were achieved.

The genome projects defined the success of effective collaboration among key stakeholders in Brazil, and resulted in international recognition for the biotechnology industry in Brazil. Some of the notable genome sequencing collaborative projects in Brazil include: the Eucalyptus genome project, in which four paper companies collaborated with research institutions; the coffee genome project with a collaboration of 700 researchers and 40 institutions; and the *xylella fastidiosa* project in which 65 laboratories, 75 research groups and 450 researches collaborated. This included international institutions; the sugar cane genome project; and the *chromobacterium violaceum* project.

> *A growing scientific community has allowed for the development of collaborative research programmes that require a large number of researchers. Recent experience in this area is promising and has the potential for engaging the business sector in commercially-oriented research. For example, the Genome Project, set up in São Paulo in partnership with the Citrus Producers Association (Fundecitrus), resulted in the DNA sequencing of a phyto-pathogenic bacterium, the Xylella Fastidiosa, which allowed Fundecitrus researchers to devise ways to protect orange trees from a disease (citrus variegated chlorosis, CVC) that had been associated with considerable economic loss in the past. The joint venture also generated at least two spin-off companies in the field of genomics and bioinformatics. Another example is the Biota Research Programme, a conservation and sustainable development-oriented biodiversity research effort to study and map biodiversity in the state of São Paulo. (Documents Case 2 25:24)*

The personal experience of one of the pioneers of the collaborative genome projects in Brazil was described as rewarding *(Respondent 6 18:59)*.

There was no successful collaborative research project in South Africa highlighted by the South African respondents; and a few successful collaborative research projects in South Africa were highlighted in the literature on South Africa (Cloete et al., 2006). This may be as a result of the ineffective collaboration among the key stakeholders.

> *We are doing it in a sense but I often find that this is certainly an issue here; the inability of people here to work together. It is a big problem. It is like everybody is doing a bit somewhere and they are not teaming up, they are not coming together which is a huge detriment. (Respondent 14 9:74-75)*

However, there was an acknowledgement of the importance of effective collaboration among the stakeholders in biotechnology entrepreneurship by some of the respondents in South Africa; despite the fact that there were no successful collaborative projects similar to those in Brazil *(Respondent 15 10:37)*.

Further indication of the importance of effective collaboration among the key stakeholders in the biotechnology industry was the emphasis which the respondents placed on it in this research. Effective collaboration was highlighted as one of the top codes, in terms of frequency of occurrence within and across the transcripts, in both South Africa and Brazil.

The importance of effective collaboration among the key stakeholders in the biotechnology industry was also demonstrated by the governments' prioritising of the collaboration between the stakeholders as a necessary condition to the development of biotechnology entrepreneurship in South Africa and Brazil. This collaboration, which is often takes the form of a triple helix of university, industry, government relations, is legislated in the national biotechnology policy documents for both South Africa and Brazil.

Comparison with the literature

The relevance of the interactions among the university, industry and government, in transforming academic research into societal and economic capital, is demonstrated in the field of biotechnology (Liebeskind et al., 1996; Agrawal, 2001; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

The collaboration among these three stakeholders (Etzkowitz and Leydesdorff, 1997; Leydesdorff and Etzkowitz, 1998, 2001) has recently been considered to involve a fourth stakeholder (Afonso et al., 2010; Marcovich and Shinn, 2011; Afonso et al., 2012; Leydesdorff, 2012) leading to a quadruple helix. The quadruple helix is context-specific and in the case of the developing economies the socio-economic linkages may point to the possibility of the fourth stakeholder being the society.

The triple helix relations in South Africa and Brazil, based on the experience of the respondents in this research, do not follow a sequence of triple helix I, II and III as postulated by Etzkowitz and Leydesdorff (2000). In the model, in the progression from triple helix I to III the influence and control of the government is diminished. However, it is envisaged that the influence and control of the government will not diminish in the biotechnology industry in South Africa and Brazil.

This leads to a scenario where there is a possibility of a hybrid model of Triple Helix I, which represents a configuration in which the government encompasses both industry and university and directs the interaction and relations between them; and Triple Helix III, in which overlapping institutional spheres generate a knowledge infrastructure, with overlapping roles and hybrid organisations emerging at the interfaces (Etzkowitz and Leydesdorff, 2000) without direct control by any of the institutions.

The uniqueness of this hybrid model is that the gains of Triple Helix III will be appropriated in an environment where the government maintains the influence and control over the interactions of the stakeholders. It is also noteworthy that this bypasses the Triple Helix II, in which the three institutional spheres are separate with strong borders dividing them and restricted relations (Etzkowitz and Leydesdorff, 2000). In support of this assertion is that there is little chance of separation from the government, given its importance and the needs of the industry.

This research confirms and extends the existing literature in a number of ways. The stakeholders of biotechnology entrepreneurship are confirmed as being the government, research institutions, venture capitalists, large biotechnology companies, and society. In addition, effective collaboration among the stakeholders is confirmed as being important for biotechnology entrepreneurship.

The existing literature is extended by highlighting the role played by stakeholder collaboration in the dual approach to biotechnology entrepreneurship. The “system” approach is predominant in an environment of effective collaboration among the key stakeholders while the “individual” approach is predominant in an environment of ineffective collaboration among the key stakeholders.

Another extension to existing literature is the articulation of the nature of triple helix relations that are practised in the biotechnology industry of South Africa and Brazil, based on the experience of the respondents to this research. The hybrid model is a combination of triple helix I and III; bypasses triple helix II; and maintains government control.

9.2.8 Theme 8

"The government plays an important role in biotechnology entrepreneurship in South Africa and Brazil”

Meaning of theme 8 in the context of this research

The roles of the government in biotechnology entrepreneurship in South Africa and Brazil include provider of a favourable regulatory environment, facilitator, and funder of R&D, buyer of biotechnology products, and establisher and maintainer of public research institutions.

Of the five roles highlighted above, the roles of providing a favourable regulatory environment and facilitation were highlighted in existing literature. In addition, the role of the establishment and maintenance of public research institutions is a known responsibility of government.

However, the roles of government as funder of R&D and buyer of biotechnology products, as experienced by the respondents in South Africa and Brazil, extend the responsibility of the government and hence its importance in the development of biotechnology entrepreneurship in South Africa and Brazil.

Manifestation of theme 8 in South Africa and Brazil

The terms of reference for engaging in biotechnology entrepreneurship in South Africa and Brazil are legislated by the governments in the national policies related to the biotechnology strategy of both countries. The national bio-economy strategy of South Africa and the national biotechnology development policy of Brazil are the policy bases for the practice of biotechnology entrepreneurship in South Africa and Brazil respectively.

In Brazil, where government leadership and direction were deemed to be effective there have been notable successes in biotechnology entrepreneurship.

> *Government was mainly the driving force, because a lot of us that somehow had the experience outside of academia went to the government, to be in the government. We knew that we had to change the way we are working in science and technology in Brazil. We had to support the industrial sector but the government has been the big driving force I would say. And now the market is where it is internationally competitive. (Respondent 9 21:57)*

> *Moreover, the success that the country has achieved with the results of their research in biotechnology has greatly influenced the demand for cooperation bilateral and/or multilateral agreements with other countries in*

biotechnology, which can boost its international relations, attracting international capital flows and interest in pursuing new business arrangements that enhance the competitiveness of domestic industries. (Documents Case 2 34:33)

The challenges to biotechnology entrepreneurship in Brazil identified by most of the respondents were also mostly in areas of government responsibility such as the policy and regulatory environment; bureaucracy and inefficiencies of the government agencies; high cost of funding; lack of aggregate skills; politics; and corruption.

By contrast, the respondents in South Africa highlighted the lack of government leadership and direction as one of the challenges in the environment of biotechnology entrepreneurship. The government agencies tasked with the implementation of the policies and strategies for biotechnology entrepreneurship were deemed to be ineffective by most of the respondents. Hence, all but one of the 19 areas highlighted by the respondents as impacting on the environment of biotechnology entrepreneurship in South Africa were designated as challenges.

Yes, but the rest of the world is going down one route and government is going down another route, and what they are doing in practice is not that, they are making it more complicated. So again, the implementation challenge is significant. (Respondent 2 2:129)

Theme 8 is further revealed in the codes, with most occurrences within and across the transcripts in South Africa and Brazil. These include policy and regulation; government-incentivised entrepreneurial action; government direction and leadership; bureaucratic processes associated with the government agencies; government inefficiencies; funding; and skills development.

Comparison with the literature

The role of the government in biotechnology entrepreneurship is to provide an enabling regulatory environment and act as a facilitator (Müller et al., 2004; Ahn and Meeks, 2007; Nilsson et al., 2010).

The regulatory environment includes the policies and laws that impact on biotechnology entrepreneurship in South Africa and Brazil, such as the national bio-economy strategy of South Africa; the national biotechnology development policy of Brazil; the intellectual property policy; the technology transfer policy; the taxation laws; and labour laws. The role of the government as a facilitator includes creating a favourable environment for biotechnology entrepreneurship and providing grants and incentives (Müller et al., 2004).

These roles as articulated in the literature relate to the developed economies, and specifically to Germany and Japan (Müller et al., 2004). This is corroborated by the role of the government in the biotechnology industry of the US (Ahn and Meeks, 2007) and the rest of the developed economies.

Few studies on the role of the government in biotechnology entrepreneurship are specific to the developing economies. However, from a general entrepreneurship point of view, the nature of entrepreneurial action in the developing economies is non-accidental and purposefully orchestrated by government, providing resource endowments, institutions and markets. Government provides both macro- and microeconomic factors aimed at providing incentives for entrepreneurial action (Phan et al., 2008) (see Table 2.3).

This research extends the existing literature on the role of government in biotechnology entrepreneurship in a number of ways. The respondents in South Africa and Brazil highlighted the role of the government in funding research and development through dedicated funding agencies. This extends the earlier role of facilitator, which includes grants and incentives (Müller et al., 2004), to the role of the government as a funder of R&D in the biotechnology industry of South Africa and Brazil.

This research highlights an additional role of the government as a buyer of biotechnology products. The prevalence of problem opportunities in South Africa, driven by diseases such as HIV/AIDS and tuberculosis, makes the government the biggest buyer of biotechnology solutions to these diseases for its citizens. Similarly, the prevalence of efficiency opportunities in Brazil, driven by the need to improve agricultural crop yields and biomanufacturing, makes the government the facilitator and buyer of the products to meet the needs of its citizens.

The role of the government as a buyer of biotechnology products influences the size of the market for biotechnology products in South Africa and Brazil.

9.2.9 Theme 9

"Funding is a critical factor in biotechnology entrepreneurship in South Africa and Brazil"

Meaning of theme 9 in the context of this research

"Funding" in the context of this research refers to the funding of R&D; the funding for infrastructure development; the funding of capacity-building activities; the funding of support structures and activities; the funding of opportunity exploitation activities; and the funding of commercialisation of research.

These different types of funding are provided by different sources such as the government, venture capitalists, large organisations and other private sector entities. Where these sources exist and the funding is adequate and appropriate, the funding environment was deemed to be favourable. On the other hand, where these sources of funding do not exist or funding is inadequate or inappropriate for the needs of biotechnology entrepreneurship, the funding environment was deemed to be unfavourable.

Manifestation of theme 9 in South Africa and Brazil

The funding environment for biotechnology entrepreneurship in South Africa was deemed unfavourable by the respondents *(Respondent 12 7:17; Respondent 13 8:19)*. The lack of a developed venture capital industry and large biotechnology companies meant that the government was deemed to be the only source of funding for biotechnology entrepreneurship in South Africa. This presented another challenge in that the funding from the government is often not appropriate for the nature of the biotechnology industry in terms of risk profile and timeframe *(Respondent 13 8:8-9).*

By contrast, the respondents in Brazil were of the opinion that appropriate funding was available in the biotechnology industry in Brazil. The sources of this funding are primarily the government through its national and state funding agencies; the private sector; and venture capitalists *(Respondent 7 19:47-48; Respondent 10 22:20; Respondent 9 21:48).*

> *There is a lot of interest not only from capitalists in Brazil, but outside Brazil, that are interested in investing in the country. This has been done in the last five or six years in the area of bioenergy, for example. People investing, big multinational companies, merging with Brazilian companies and setting up big sugar cane deals and this is important and this is positive and there is a lot of money available. (Respondent 8 20:83)*

The contrasting scenarios in South Africa and Brazil in terms of the availability of appropriate funding may play a key role in the performance of the biotechnology industry in both countries. Given the research-intensive nature of discovering or creating biotechnology opportunities, the high risk associated with the industry, and the timeframe from research to commercialisation, the emphasis of the respondents on funding as either a challenge or an enabler points to the importance of funding in the process of biotechnology entrepreneurship.

In the experiences of the respondents in South Africa, those who had appropriate funding from the government were not as critical of the funder role of government in biotechnology entrepreneurship. On the contrary, those who had not received appropriate funding from the government were very critical of government's funder role. In other instances, the lack of appropriate funding was held responsible for the collapse of biotechnology companies in South Africa *(Respondent 13 8:30-32).*

Comparison with the literature

The availability of capital (Shane, 2003) is an important factor in any entrepreneurial activity and biotechnology entrepreneurship is often associated with both government and venture capital funding sources (Audretsch, Taylor Aldridge and Perry, 2008).

> *Financing mechanisms are increasingly used to focus research on priorities. A challenge for governments is to find a balance between funds for basic research and funds for output-driven research, and between stable, institutional funding and project or programme-based funding tied to specific objectives and missions.*
> *Institutional funding, including for infrastructure, is critical for long-term research capacity while project-based funding is used to promote competition within the research system. (Documents Cross-Case 29:46)*

The experience of the bioentrepreneurs in South Africa was mostly restricted to the government source of funding, owing to the lack of a developed venture capital industry for biotechnology (Audretsch et al., 2008). This situation may be unique to the South African biotechnology industry, as venture capital funding is a core component of biotechnology entrepreneurship in developed economies (Ahn and Meeks, 2007; Ahn et al., 2010a). The availability of appropriate funding in Brazil through these sources is similar to the process of biotechnology entrepreneurship in developed economies (Ahn and Meeks, 2007; Ahn et al., 2010a), where the government plays a big role despite the availability of other sources of funding.

> *The US industrial biotechnology drive has been led centrally, initiated by government and/or the administration, with massive public research funding. (Documents Cross-Case 30:18)*

This research confirms the existing literature on the critical importance of funding to the process of biotechnology entrepreneurship.

9.2.10 Theme 10

"The local market for biotechnology products is a critical factor in biotechnology entrepreneurship in South Africa and Brazil"

Meaning of theme 10 in the context of this research

The areas of emphasis for the bioentrepreneurs in South Africa and Brazil are primarily driven by the needs of the local market. While in South Africa the predominance of problem opportunities influences emphasis on diseases, in Brazil the predominance of efficiency opportunities influences emphasis on improvements to agriculture, healthcare, the environment, and industrial processes. Hence, the local market is a critical factor in biotechnology entrepreneurship in South Africa and Brazil.

Of the bioentrepreneurs who participated in this research, all had access to other markets besides their home markets, for their biotechnology products and services. For those that predominantly exploited problem opportunities, their accessible markets were predominantly in the developing economies. Conversely, for those who rendered bioservices and exploited efficiency and innovation opportunities, their markets were predominantly in the developed economies. The same is applicable to biotechnology companies outside of South Africa and Brazil, which have access to the South African and Brazilian markets, depending on their area of focus and the nature of the bioentrepreneurial opportunity being exploited. Hence, the size of the local market is an important factor in the dynamics of biotechnology entrepreneurship.

Manifestation of theme 10 in South Africa and Brazil

The size of the market for biotechnology products in South Africa and Brazil was seen as a critical factor in biotechnology entrepreneurship. In South Africa, the size of the market was deemed small and underdeveloped by most of the respondents *(Respondent 1 1:27; Respondent 12 7:30; Respondent 13 8:10; Respondent 15 10:7).*

> *However the biggest challenge that is faced in South Africa is that the South African market itself with its biotechnological innovations are too small, the market is too small. (Respondent 4 4:6)*

From a medical diagnostics point of view, there seems to be an adequate market in South Africa. This may be due to the nature of the products and the target market (*Respondent 11 6:95-96)*.

The government was seen as the biggest buyer of biotechnology products in South Africa and, hence, influences the size of the market. The ability of the local companies to sell to the government determines their success in the local market. If the local biotechnology companies cannot win the competition in their local market, the odds are heavily against them making inroads in the international market with competitors with a far better operational environment than in South Africa *(Respondent 13 8:61-63)*.

By contrast, the respondents believe that the Brazilian market for biotechnology products is developed *(Respondent 9 21:102-103)*. The emphasis on national priorities and solving the problems of the country means that the areas of focus, such as agriculture, environment, industry and healthcare, are aligned to the needs of the country. Hence, the local demand creates a local market for the biotechnology products.

> *The positive factor is the Brazilian market, a very good market in terms of maturity and size. (Respondent 9 21:101-102)*

Despite having a developed market for biotechnology products, the need to compete internationally was expressed by the respondents as one of the factors necessary for the development of the industry in Brazil. The competitive pressure highlighted by the respondents in their local market was from biotechnology companies outside the borders of their local market, in both developing and developed economies. Hence, biotechnology entrepreneurship is global; the choice of market is mostly determined by the type of bioentrepreneurial opportunity that is being exploited by the bioentrepreneur; and a developed local market may be a factor in favourably positioning the bioentrepreneur to compete globally.

Comparison with the literature

The empirical research on biotechnology in South Africa (Gastrow, 2008) did not address the relevance of the local market for biotechnology products. The importance of the local market in Brazil was alluded to in the study carried out by Zylberberg, Zylberberg and Oner (2012). There may have been more empirical research to this effect in Brazil, but these studies would most likely have been written in Portuguese. This limitation has been accounted for in the section on the limitations of this study.

According to industry research, biotechnology has assumed global importance in the areas of healthcare, environmental protection, agriculture, chemistry and material science (Biotechnology Industry Organisation, 2008; Battelle/Biotechnology Industry Organisation, 2012) in the 21st century. This is in response to the large-scale global issues such as human health, food security, renewable resources and environmental sustainability.

The areas highlighted as the focus areas by the respondents, such as human health, agriculture, industrial biotechnology and environmental biotechnology in the local market are aligned to the areas of global emphasis in the literature. This research extends the existing literature on the critical importance of the local market for biotechnology products in South Africa and Brazil.

9.3 The proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil

The organising frameworks that guided this research, the individual-opportunity nexus framework of entrepreneurship (Shane, 2003) and the triple helix of university, industry, government relations (Etzkowitz and Leydesdorff, 2000), are frameworks for general entrepreneurship and are not specific to biotechnology entrepreneurship.

The existing literature on biotechnology entrepreneurship that has a framework related to the process of biotechnology entrepreneurship is that of Müller, Fujiwara and Herstatt (2004), on the study of sources of bioentrepreneurship in Germany and Japan. However, the model by Müller et al. (2004) is restricted to the stakeholders needed for the exploitation of bioentrepreneurship opportunities.

Two previous empirical studies on biotechnology in South Africa (Gastrow, 2008) addressed the quantitative profile of biotechnology research and development in South Africa and the state of biotechnology in South Africa, with emphasis on the national biotechnology strategy and its implementation respectively. Other industry studies on the biotechnology industry in South Africa have concentrated on the key initiatives driven by the government and the performance of the industry (Ernst & Young, 2006; Organisation for Economic Cooperation and Development, 2009; Ernst & Young, 2010a, 2010b; Organisation for Economic Cooperation and Development, 2013b, 2013a).

No current empirical or industry study has addressed the process of biotechnology entrepreneurship in South Africa by the bioentrepreneurs and stakeholders engaged in the process.

Previous studies on biotechnology entrepreneurship in Brazil have been more extensive in addressing the biotechnology industry holistically (Zylberberg et al., 2012). However, a language limitation prevented the researcher from being able to review studies in Brazil that were published in Portuguese.

There is no existing theoretical framework of biotechnology entrepreneurship that enables the study and understanding of the process of biotechnology entrepreneurship in different contexts, whether in the developed or developing economies.

The themes identified in the cross-case analysis of South Africa and Brazil have characteristics that differentiate the process of biotechnology entrepreneurship from the process articulated in the organising framework of the individual-opportunity nexus of entrepreneurship.

At the level of individual attributes, the process of biotechnology entrepreneurship utilises two models, the individual model and the systemic model. The individual model is based on the psychological and non-psychological attributes of the individual and the acquisition of entrepreneurial and commercialisation skills. The systemic model is based on the psychological and non-psychological attributes of the individual, in addition to a system of biotechnology entrepreneurship that provides entrepreneurial capabilities, commercialisation capabilities and support structures. Both models are driven by the environmental conditions that exist in the context of the study. Hence, while the individual model is practised in South Africa, the systemic model is practised in Brazil and the developed economies.

The individual attributes for general entrepreneurship, based on the organising framework of the individual-opportunity nexus of entrepreneurship, are concerned with the individual only.

At the level of entrepreneurial opportunities, the bioentrepreneurial opportunities are known in advance and differ in different contexts. Hence, while problem opportunities predominate in South Africa, efficiency opportunities predominate in Brazil. The entrepreneurial opportunities in the organising framework are not specific to the context and their discovery is dependent on the enterprising individual.

At the level of environment for entrepreneurship, the themes related to the overall environment for biotechnology entrepreneurship, regulatory environment, funding, skills, and size of local market show that there are differences in the environment of entrepreneurship in the organising framework and the experience of the respondents in this research.

While the environment in the organising framework includes industry and the macro-environment, the environment for biotechnology entrepreneurship is broader and includes innovation and entrepreneurial conditions, in addition to industry and the macro-environment.

At the level of discovery, opportunity discovery in general entrepreneurship is dependent on the enterprising individual. However, this process in biotechnology entrepreneurship is dependent on R&D. R&D, in turn, is dependent on skills, infrastructure and funding, all of which are part of the innovation and entrepreneurial conditions.

At the level of opportunity exploitation, this stage in general entrepreneurship is dependent on the individual entrepreneur. In contrast, the theme from this research shows that this stage in biotechnology entrepreneurship in South Africa and Brazil is dependent on effective collaboration among the key stakeholders. The existing literature (Müller et al., 2004) on the exploitation of bioentrepreneurial opportunties shows that this requires a strategic alliance of government, research institutions, venture capitalists and large biotechnology companies.

At the level of execution, the individual entrepreneur engages in resource assembly, organisational design and strategy (Shane, 2003) to create commercial value. In the process for biotechnology entrepreneurship, the collaboration among key stakeholders enables the efficient commercialisation of research through firm formation or licensing.

Furthermore, while the outcome of execution in general entrepreneurship satisifies the value creation need of the individual entrepreneur, the outcome of commercialisation of research in biotechnology entrepreneurship satisfies the need of multiple stakeholders in the form of economic development, financial return, and commercialisation (Ahn and Meeks, 2007), as well as social benefit.

Gaps exist in current empirical literature and industry research related to the process of biotechnology entrepreneurship in South Africa and Brazil. In addition, there are differences between the process of general entrepreneurship, based on the organising framework of individual-opportunity nexus, and the process of biotechnology entrepreneurship in South Africa, based on the cross-case themes for this research.

To address these gaps and differences, a theoretical framework of biotechnology entrepreneurship in South Africa and Brazil is proposed as shown in Figure 9.1.

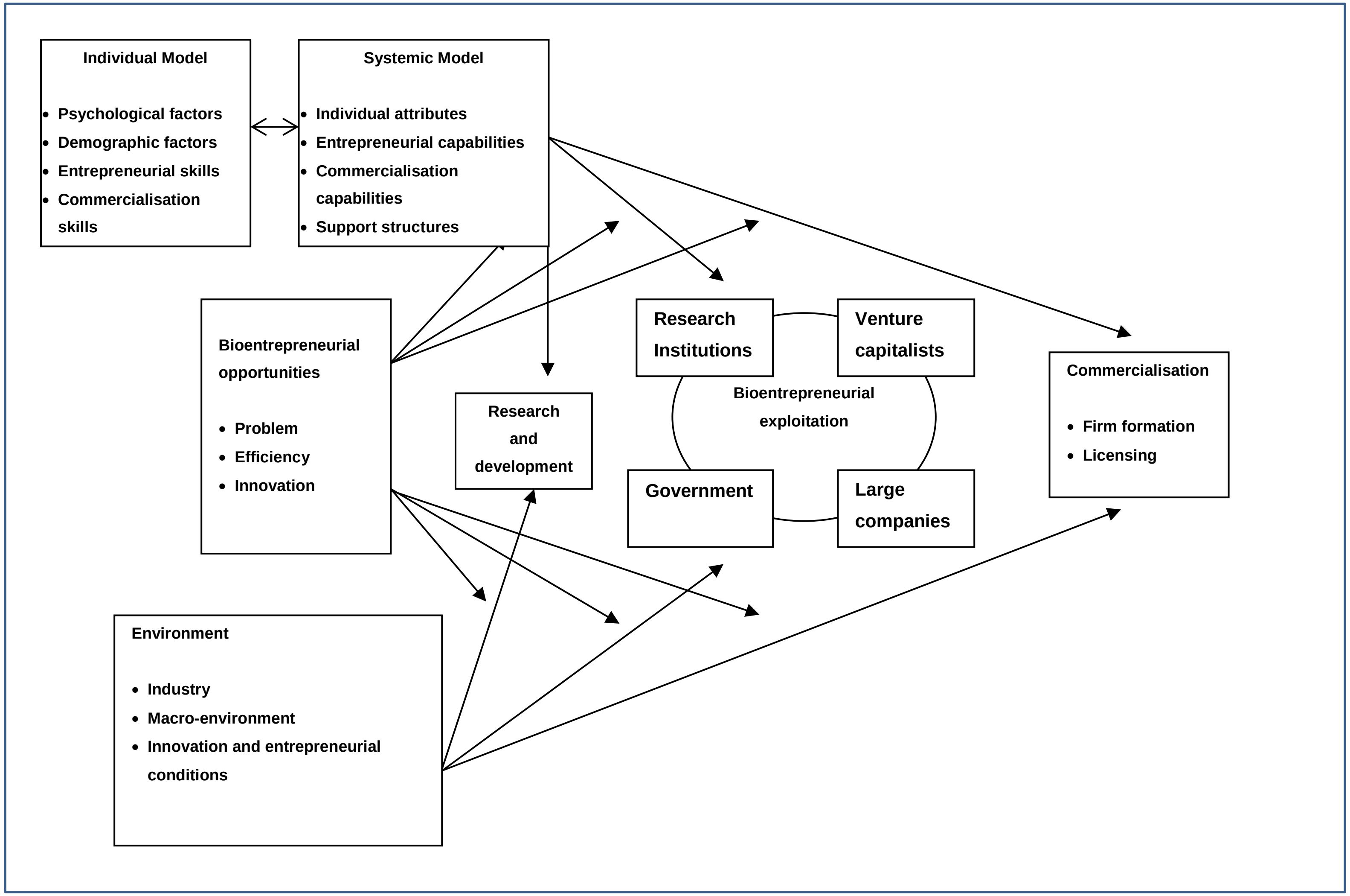


Figure 9.1: A proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil (adapted from Shane, 2003:11)

The proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil (see Figure 9.1) captures the process of biotechnology entrepreneurship in the developing economies of South Africa and Brazil.

The individual and systemic models of biotechnology entrepreneurship are driven by environmental conditions. Given that the systemic model is operational in developed economies, it may mean that favourable environmental conditions support the emergence of the systemic model, while unfavourable environmental conditions support the emergence of the individual model.

Emphasis at this stage should be on providing the capabilities and support structures for developing a system rather than training individuals to operate in the individual model.

The bioentrepreneurial opportunities are known in advance and are often informed by the needs and priorities of the country, which are both social and economic. The approach in choosing which bioentrepreneurial opportunities to focus on should be informed by the areas that would make the biggest impact on solving the problems of the country. Another consideration would be areas of competitive advantage such as biodiversity in South Africa and Brazil.

The environment is where most of the differences occur between different contexts. This is because most of the factors are environmental factors and the extent to which the environment is conducive to bioentrepreneurial development determines to a large extent the ability to attract foreign skills, other sources of funding and large biotechnological companies and the ability to develop entrepreneurial and commercialisation capabilities within the system, and ultimately the success of biotechnology entrepreneurship. The government often plays a big role in determining the effectiveness of the environmental factors.

The individual attributes and the environment determine the effectiveness of R&D in the next step.

R&D is dependent on skills, infrastructure and funding. This is the defining point of biotechnology entrepreneurship, as the timeframe, outcome and cost can all be indeterminate, with no guaranteed outcome. Most of the costs incurred in biotechnology entrepreneurship occur at this stage; hence, multiple funding sources are often required to drive R&D. R&D spend and intensity are often used as measures to determine how committed countries are to research-intensive industries such as biotechnology, and often determine the output.

In South Africa and Brazil, the abundance of genetic materials as raw materials for R&D, through the biodiversity, is considered a competitive advantage. Only successful outcomes at the R&D stage lead to the exploitation of bioentrepreneurial opportunities. Although the strategic alliances needed to exploit the bioentrepreneurial opportunities is the next step, the R&D step often requires funding from multiple stakeholders who will eventually participate in the exploitation of the successful output of the R&D.

The exploitation of bioentrepreneurial opportunities requires effective collaboration among the key stakeholders, specifically a strategic alliance of government, research institutions, venture capitalists and large companies. At this stage considerable resources are needed to go from the laboratory to the market and this works better in a systemic model than in an individual model, as the capabilities required are often beyond an individual. The availability of all these stakeholders defines the process of biotechnology entrepreneurship in the developed economies. In this study, Brazil has an availability of stakeholders while South Africa does not. That may explain the different approaches in these two developing economies in terms of adopting the individual or systemic approach. The stage of bioentrepreneurial exploitation leads to commercialisation of research, which is the final stage in the model.

The success of the stage of commercialisation of research is dependent on the success of the preceding stages in the framework. This is achieved either through firm formation or licensing. The different stakeholders have different needs, which are realised through successful commercialisation of the research.

The government is involved in most of the stages of the framework in South Africa and Brazil, through multiple roles such as facilitator, funder and buyer of biotechnology products. The extent of government involvement is determined by the specific context of each country.

The triple helix of university, industry, government relations plays a key part in biotechnology entrepreneurship because of the high level of collaboration required. In this study, the triple helix of university, industry, government relations is controlled by the government, which creates a hybrid of triple helix I and III in Brazil while South Africa implements a triple helix I model.

The direction of the arrows in Figure 9.1 shows that the individual attributes, the bioentrepreneurial opportunities and the environment are deemed to affect all the stages of biotechnology entrepreneurship from R&D to entrepreneurial exploitation and commercialisation of research. While this does not prove causality, the importance of the individual attributes, entrepreneurial opportunities and the environment to entrepreneurship is supported by previous studies (Liebeskind et al., 1996; Audretsch and Stephan, 1998; Agrawal, 2001; Shane, 2003; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell et al., 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

9.4 Summary of Chapter 9

The cross-case analysis of South Africa and Brazil aims to aggregate the data for the individual cases into a higher level abstract that aids generalisation from data to theoretical proposition (Eisenhardt, 1989, 1991; Yin, 2009).

The cross-case analysis resulted in ten themes derived from the patterns identified in the within-case analyses of South Africa and Brazil.

The comparison of the themes to existing literature shows that there were instances of confirmation of the existing literature and instances of extension of the literature.

The confirmation of existing literature lends credence to the use of organising frameworks of general entrepreneurship to study biotechnology entrepreneurship.

The extension of existing literature represents an addition to the body of knowledge on biotechnology entrepreneurship in South Africa and Brazil. Furthermore, this provides an understanding of the process of biotechnology entrepreneurship in South Africa and Brazil, which is neither extrapolated from the developed economies nor inferred from general entrepreneurship.

The exploratory nature of this research because of a paucity of empirical research on biotechnology entrepreneurship in South Africa and Brazil meant that existing literature was not contradicted. Instead, insights that were different from the existing literature on general entrepreneurship were designated as extension rather than contradiction since they could not be directly compared.

These themes form the basis of understanding the dynamics of biotechnology entrepreneurship in South Africa and Brazil and the development of the proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil.

PART V: CONCLUSIONS AND IMPLICATIONS

Part V consists of Chapter 10.

Chapter 10 contains the conclusions relative to the research questions, contributions made by this research, implications for stakeholders and recommendations for future research.

Chapter 10: Conclusions and implications

This chapter concludes the thesis entitled "Dynamics of biotechnology entrepreneurship in South Africa and Brazil".

The sub-sections of this chapter present conclusions relative to research questions; the empirical contribution of this study to the literature; its methodological contribution to the literature; and theoretical contribution to the literature; policy and other implications for the government; implications for the other stakeholders; and recommendations for future research.

10.1 Conclusions relative to research questions

This section articulates how the research questions for this study were addressed by the outcome of the research.

The methodological approach for this research was designed to achieve an in-depth understanding of the process of biotechnology entrepreneurship in South Africa and Brazil in their original contexts. The within-case analysis of each individual case, and the cross-case analysis of South Africa and Brazil; provide the themes that address the research questions.

Research Question 1

How do bioscientists carry out biotechnology entrepreneurship in the developing economies of South Africa and Brazil?

The process of biotechnology entrepreneurship in South Africa and Brazil starts with bioscientists who have the necessary research and scientific skills to carry out bioscientific research. Given that the bioentrepreneurial opportunities are known in advance to be predominantly in the categories of problem and efficiency opportunities, the environment in which the process of biotechnology entrepreneurship takes place plays a key role in determining the approach to the process.

Where a system provides the support structures and entrepreneurial and commercialisation capabilities needed to commercialise research, the bioscientists adopt the systemic approach to the process of biotechnology entrepreneurship. The systemic approach is the approach that is practised in Brazil.

On the other hand, where a system that provides the support structures and entrepreneurial and commercialisation capabilities needed to commercialise research is lacking, the bioscientists are forced to acquire entrepreneurial and commercialisation skills to commercialise their research effectively. Consequently, their practice of biotechnology entrepreneurship follows the individual approach. The individual approach is the approach that is practised in South Africa.

The environment in which biotechnology entrepreneurship is practised in South Africa presents many challenges across the economic, political and cultural environments (Shane, 2003). Key among these challenges are an unfavourable policy and regulatory environment; lack of appropriate funding; lack of government direction; an unfavourable university culture; lack of aggregate skills and capacity; and a lack of a developed market for biotechnology products.

By contrast, the environment in which biotechnology entrepreneurship is practised in Brazil presents challenges and positives. The challenges are across the economic, political and cultural environments (Shane, 2003). Key among them are an unfavourable policy and regulatory environment; lack of aggregate skills and capacity; and bureaucratic and inefficient government processes.

On the other hand, the positives include the availability of appropriate funding, government-incentivised entrepreneurial activities, availability of large established biotechnology companies, availability of venture capital companies, and effective collaboration among the key stakeholders.
The bioscientists in South Africa and Brazil operate in these environments to exploit bioentrepreneurial opportunities identified predominantly in the area of problem and

efficiency opportunities and occasionally innovation opportunities. In addition, abundant biodiversity is seen as a competitive source of bioentrepreneurial opportunities in South Africa and Brazil.

The discovery of these bioentrepreneurial opportunities requires R&D. The intensity and the R&D spend in South Africa and Brazil are deemed to be below the levels of the developed economies, in this way negatively impacting on the effectiveness of the development of the biotechnology industry.

The exploitation of these bioentrepreneurial opportunities requires effective collaboration of the stakeholders, specifically a strategic alliance of research institutions, venture capitalists, large established biotechnology companies and government. However, South Africa lacks the key stakeholders of venture capitalists and large established biotechnology companies. This forces the government into roles that are performed by these absent stakeholders in the developed economies. In Brazil all the key stakeholders are available, which makes the process of exploiting bioentrepreneurial opportunities similar to the process followed in the developed economies.

The execution step of the process of biotechnology entrepreneurship involves the commercialisation of research. The commercialisation of research in South Africa and Brazil utilises both firm formation and licensing. In South Africa the process is deemed to be inefficient because of a lack of entrepreneurial and commercialisation skills. In addition, the challenges presented by the environment and inefficiencies in the stages of R&D and opportunity exploitation impact the effectiveness of the commercialisation of research. The commercialisation of research in Brazil is deemed to be efficient because of the efficiencies in the earlier parts of the biotechnology value chain and the availability of the system to enable the commercialisation of research.

Research Question 2

How is biotechnology entrepreneurship conducted by bioscientists in developing economies similar to the process defined in the literature for developed economies?

The similarities between the processes of biotechnology entrepreneurship in the developing economies and the process defined in the literature for developed economies are defined at two levels: the theoretical and the thematic levels.

At a theoretical level, using the proposed theoretical framework for biotechnology entrepreneurship, the process of biotechnology entrepreneurship in South Africa and Brazil is similar to the process defined in the literature for developed economies. Hence, the process incorporates individual attributes, either as an individual model or systemic model; utilises bioentrepreneurial opportunities; engages in R&D; operates within an environment of industry, macroeconomic, and innovation and entrepreneurial conditions; exploits bioentrepreneurial opportunities through a strategic alliance of the biotechnology stakeholders; and commercialises research through firm formation or licensing.

However, at the thematic level the similarities are restricted to certain components of the process. There are no thematic similarities between South Africa and the developed economies in the process of biotechnology entrepreneurship. In Brazil, these similarities include predominance of the systemic model to biotechnology entrepreneurship; a favourable overall environment for the development of biotechnology entrepreneurship; availability of entrepreneurial and commercialisation capabilities; effective collaboration among the stakeholders; effective government leadership and direction; availability of appropriate funding; and a developed market for biotechnology products.

Research Question 3

How is biotechnology entrepreneurship conducted by bioscientists in developing economies different from the process defined in the literature for developed economies?

The differences in the process of biotechnology entrepreneurship between the developing and developed economies are more defined at the thematic level.

The thematic differences in the process of biotechnology entrepreneurship between South Africa and the developed economies include the predominance of the individual model to biotechnology entrepreneurship; the predominance of problem opportunities; the non-conducive regulatory environment; unfavourable overall environment for the development of biotechnology entrepreneurship; the low level of R&D spend; lack of an aggregate level of skills; lack of entrepreneurial and commercialisation skills; lack of effective collaboration among the stakeholders; lack of government leadership and direction; lack of appropriate funding; and an underdeveloped market for biotechnology products in South Africa.

The thematic differences in the process of biotechnology entrepreneurship between Brazil and the developed economies include the predominance of efficiency opportunities; the non-conducive regulatory environment; the low level of R&D spend; and lack of an aggregate level of skills in Brazil.

Research Question 4

What are the factors that influence biotechnology entrepreneurship in developing economies, and how do they exert their influence?

The factors that influence biotechnology entrepreneurship in South Africa and Brazil are determined as the means through which the stakeholders influence the theoretical framework of biotechnology entrepreneurship towards an outcome. Hence, the stakeholders control the factors, which in turn influence the theoretical framework, which results in an outcome. The diagrammatical representation of this relationship is shown in Figure 10.1.

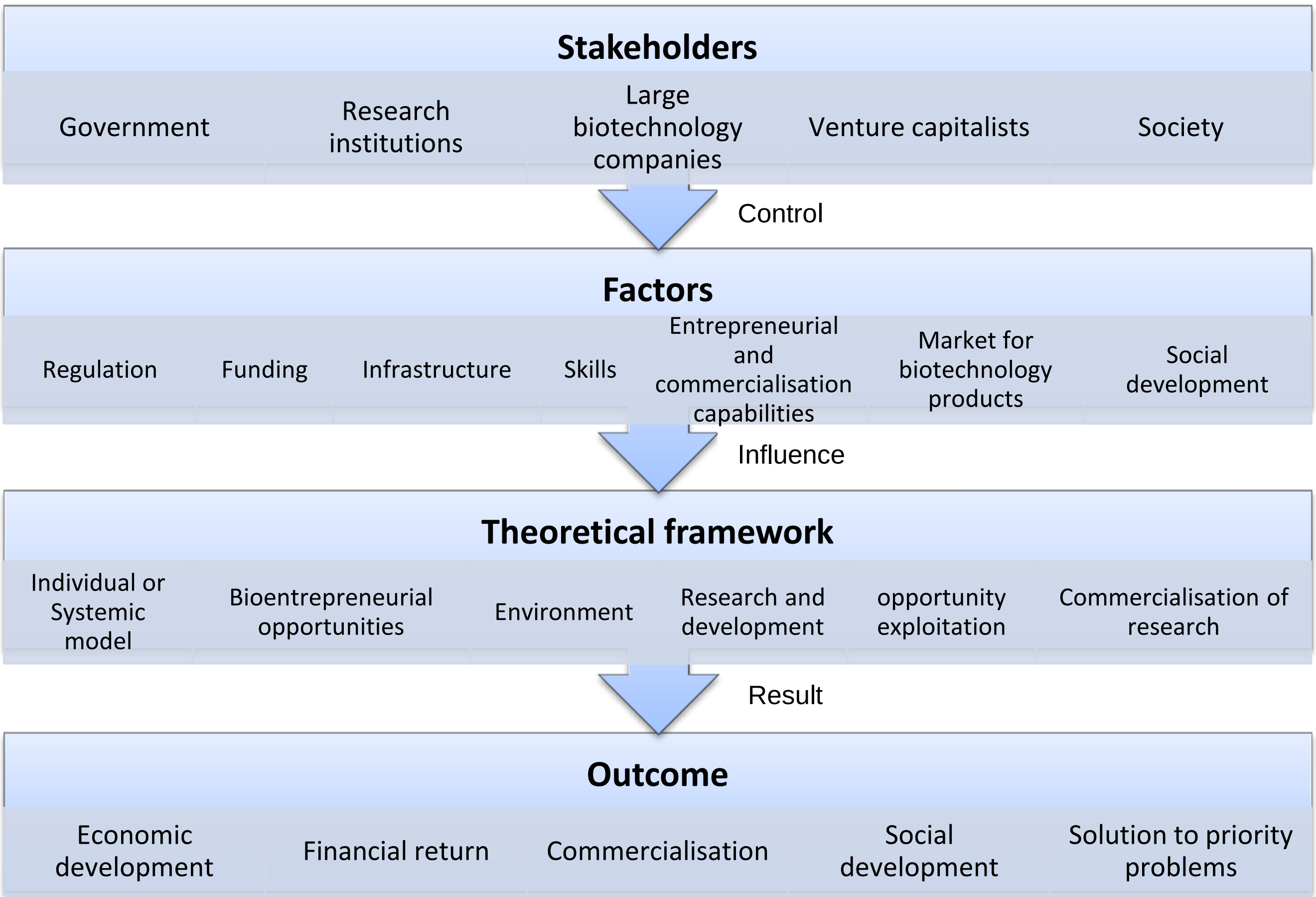


Figure 10.1: Factors that influence the process of biotechnology entrepreneurship in South Africa and Brazil

As shown in Figure 10.1, the government controls the factors of regulation, funding, infrastructure and market for biotechnology products; the research institutions control the factor of skills; the large biotechnology companies control the factors of funding, entrepreneurial and commercialisation capabilities, and market for biotechnology products; the venture capitalists control the factors of funding, and entrepreneurial and commercialisation capabilities; and the society controls the factor of social development.

The factors that influence the process of biotechnology entrepreneurship in South Africa and Brazil are regulation; funding; infrastructure; skills; entrepreneurial and commercialisation capabilities; market for biotechnology products; and social development.

Regulation has the highest influence on the theoretical framework because it influences all the stages of the theoretical framework.

In the experience of the respondents in South Africa and Brazil, the unconducive regulatory environment for biotechnology entrepreneurship impacted on intellectual property ownership (opportunity exploitation); technology transfer from the university to the industry (commercialisation of research); cost of doing business through taxation (environment); and availability of skills through labour laws (individual attributes and R&D).

Funding, infrastructure and skills primarily influence R&D as well as opportunity exploitation, commercialisation of research, and the environment for the development of biotechnology entrepreneurship in South Africa and Brazil.

In the experience of the respondents in South Africa and Brazil, the lack of these factors in South Africa influenced the framework items negatively and this was highlighted as a challenge. The reverse was true in Brazil, where these factors were available and were not highlighted as challenges. In both South Africa and Brazil, skills at individual level were deemed available, but the aggregate skills were deemed lacking.

Entrepreneurial and commercialisation capabilities influence the exploitation of bioentrepreneurial opportunities and the commercialisation of research.

In the experience of the respondents, these capabilities were lacking in South Africa and hence the exploitation of bioentrepreneurial opportunities and commercialisation of research were deemed ineffective. The lack of these capabilities may stem from the lack of the stakeholders that control these capabilities, namely large biotechnology companies and venture capitalists, in South Africa. These capabilities were present in Brazil and hence the experience of the respondents regarding opportunity exploitation and commercialisation of research was positive.

Markets for biotechnology products influence R&D; opportunity exploitation; and the commercialisation of research.

In the experience of the respondents in South Africa and Brazil, the market for biotechnology products was deemed underdeveloped in South Africa and developed in Brazil. Consequently, the impacted framework items were deemed challenges in South Africa but not challenges in Brazil.

Social development influences the environment for biotechnology development in South Africa and Brazil.

In the experience of the respondents in South Africa and Brazil, the social linkages to biotechnology entrepreneurship were highlighted. However, social development was expressed as a need rather than a factor and hence there was not sufficient data in this research to designate social development as a challenge or not a challenge.

Research Question 5

What triple helix of university, industry, government relations are experienced by the stakeholders in the biotechnology industry of South Africa and Brazil?

In the experience of the respondents in South Africa and Brazil, the government controls the relationship with the university and the industry, through the factors of regulation, funding, infrastructure and market for biotechnology products.

The factors within government's control allow it to influence the overall environment of biotechnology entrepreneurship in South Africa and Brazil, in which the university and industry participate as stakeholders.

In the South African biotechnology industry, the government has a near monopoly of the factors. For this reason the triple helix relation in South Africa is at what is described by Etzkowitz and Leydesdorff (2000) as Triple Helix I, which represents a configuration in which the government encompasses both industry and university and directs the interaction and relations between them.

The experience of the triple helix relations by the respondents in South Africa was deemed inefficient and instances of competition within the stakeholder groups were mentioned, instead of the expected collaboration within and among the stakeholders.

There is an indication from this research that South Africa will not go through a sequential progression to Triple Helix II and III, but may progress to a form of a Quadruple Helix that includes the society as a fourth stakeholder (Afonso et al., 2010; Marcovich and Shinn, 2011; Afonso et al., 2012; Leydesdorff, 2012).

In the Brazilian biotechnology industry, the government does not have a monopoly of the factors; hence, the triple helix relation in Brazil is a hybrid of what is described by Etzkowitz and Leydesdorff (2000) as Triple Helix I, which represents a configuration in which the government encompasses both industry and university and directs the interaction and relations between them, and Triple Helix III, in which overlapping institutional spheres generate a knowledge infrastructure, with overlapping roles and hybrid organisations emerging at the interfaces.

The unique dynamic in Brazil is that Triple Helix III characteristics are exhibited but with a direct control from the government, which is a characteristic of Triple Helix I. With every indication of a continued government control, improvement of the environment for Triple Helix III to flourish and strong social linkages, there may be a possibility that the evolution of the Triple Helix in Brazil will go the route of the "Quadruple Helix of government-controlled university, industry, society relations".

In light of the above, it can be concluded that the triple helix of university, industry, government relations experienced by the stakeholders in the biotechnology industry of South Africa and Brazil is a hybrid of the existing triple helix models, with a strong possibility of progressing to a quadruple helix that includes the society as a fourth stakeholder.

10.2 Empirical contributions to the literature

The main empirical contribution of this research to the literature is the contribution to the body of knowledge, which addresses the gap created by the paucity of empirical research on biotechnology entrepreneurship in the context of developing economies. Most of the current empirical research is carried out in developed economies, as single case studies using a nomothetic philosophical approach (Guba and Lincoln, 1994; Chandler and Lyon, 2001), and cannot be directly extrapolated to developing economies because of differences at individual, institutional and environmental levels between the developed and developing economies (Lingelbach et al., 2005).

Most research related to biotechnology entrepreneurship is conducted as either empirical general entrepreneurship research (Baumol, 1993; Ács and Audretsch, 2003; Shane, 2003; Lingelbach et al., 2005; Audretsch and Lehmann, 2005a; Alvarez and Barney, 2007; Lingelbach et al., 2008; Acs, 2010; Lingelbach et al., 2013) or biotechnology industry research (Cloete et al., 2006; Gastrow, 2008; Natesh and Bhan, 2009; Ernst & Young, 2010b; Ahn and York, 2011; Meyers and Pruthi, 2011; Ahn et al., 2012; Battelle/Biotechnology Industry Organisation, 2012; Organisation for Economic Cooperation and Development, 2013a), as the field of biotechnology entrepreneurship is relatively new (Meyers, 2012).

Few empirical research studies are specific to biotechnology entrepreneurship (Schoemaker and Schoemaker, 1998; Müller et al., 2004; Audretsch et al., 2008; Carsrud, Brännback and Renko, 2008; Oliver, 2008; Gunn, Dever, Tzagarakis-Foster, Lorton Jr, Kane and Masterson, 2013).

Furthermore, of the empirical research that is specific to biotechnology entrepreneurship, most studies are specific to the developed economies and few are specific to the developing economies (Onyeka, 2011). The paucity of empirical research on biotechnology entrepreneurship in the developing economies' context creates a gap that this research seeks to address.

In the words of Audretsch et al. (2008):

> *The exact role of entrepreneurship in industries such as biotechnology has generally eluded the analytical lens of scholars. (Audretsch et al., 2008)*
>
> *The late twentieth century has witnessed a scientific gold rush of astonishing proportions: the headlong and furious haste to commercialise genetic engineering. This enterprise has proceeded so rapidly – with so little outside commentary – that its dimensions and implications are hardly understood at all. (Audretsch et al., 2008:179)*

In contributing to addressing the gap created by the paucity of literature on biotechnology entrepreneurship in South Africa and Brazil, an in-depth understanding of the process of biotechnology entrepreneurship in these two countries was achieved.

The process of biotechnology entrepreneurship in South Africa utilises the individual model of biotechnology entrepreneurship due to the challenges presented by the environment. While the process of biotechnology entrepreneurship in South Africa is theoretically similar to the developed economies, it is thematically different to the developed economies and this contributed to the observed differences between the output of biotechnology entrepreneurship in South Africa and the developed economies.

The process of biotechnology entrepreneurship in Brazil utilises the systemic model of biotechnology entrepreneurship due to the overall conducive environment for biotechnology entrepreneurship. The process of biotechnology entrepreneurship in Brazil is theoretically similar to the developed economies and also thematically similar to the developed economies in certain areas. This may have contributed to the observed successes of biotechnology entrepreneurship in Brazil.

Another empirical contribution of this research is the identification of the thematic similarities and differences between South Africa and Brazil and the developed economies, based on the experience of the respondents for this research.

The thematic differences of the process of biotechnology entrepreneurship between South Africa and the developed economies provide a deeper understanding of the observed differences between the biotechnology industry in South Africa and the developed economies.

On the other hand, the thematic similarities of the process of biotechnology entrepreneurship between Brazil and the developed economies provide a deeper understanding of the observed similarities between the biotechnology industry in Brazil and the developed economies.

Another empirical contribution of this research is the identification of the factors that influence biotechnology entrepreneurship in South Africa and Brazil, and how these factors exert their influence. A framework (see Figure 10.1) for the relationship across stakeholders, the factors, the proposed theoretical framework, and the outcome of biotechnology entrepreneurship guided the identification of the factors.

These seven factors: regulation, funding, infrastructure, skills, entrepreneurial and commercialisation capabilities, market for biotechnology products, and social development, exert their respective influences on different components of the theoretical framework and are controlled by the stakeholders, who are: government, research institutions, large biotechnology companies, venture capitalists and society.

A further empirical contribution of this study is the articulation of the nature of the triple helix relations experienced by the respondents in South Africa and Brazil. The respondents in South Africa experienced a lack of effective collaboration among the key stakeholders in biotechnology entrepreneurship. Consequently, a triple helix I model is practised in South Africa, in which the government controls the relationship between the university and industry. However, the inclusion of the society in a quadruple helix will see South Africa go from triple helix 1 to a quadruple helix without going sequentially through triple helix II and III as advocated in the literature (Etzkowitz and Leydesdorff, 2000).

The respondents in Brazil experienced effective collaboration among the key stakeholders in biotechnology entrepreneurship. A hybrid model of triple helix I and

III is practised in Brazil, in which government control, characteristic of triple helix I, is combined with the generation of knowledge infrastructure, characteristic of triple helix III. Similarly, triple helix II is bypassed and a possibility exists of implementing a quadruple helix that includes the society due to the strong social linkages.

10.3 Methodological contributions to the literature

The few studies on biotechnology entrepreneurship, in developing economies, employ mostly survey methodology and single case studies within one developing economy. The use of qualitative multiple case studies, in the idiographic philosophical tradition, in two developing economies, is deemed to enrich the discourse in biotechnology entrepreneurship and hence make a contribution to the knowledge of biotechnology entrepreneurship in developing economies.

A qualitative multiple case study method was used for this study, at a country level of analysis. The use of a holistic multiple case study approach provided the opportunity for literal and theoretical replication (Yin, 2009). The case selection was purposefully aimed at good candidates for biotechnology entrepreneurship in the developing economies with sufficient similarity, and variability, to provide a suitable context for this research (Yin, 2009).

Within the cases, the selection of the respondents was based on individuals with a high degree of knowledge on and competence in the research topic (Romney et al., 1986; Bowen, 2008) and who have either commercialised a biotechnological innovation through firm formation or licensing or are SMEs in the area of biotechnology entrepreneurship affiliated to the university, industry or government. In addition, industry policy and research documents from credible organisations such as the OECD, Ernst & Young, BIO, and Battelle were reviewed and coded for this research to augment the in-depth interviews in providing a complete and triangulated view of the dynamics of biotechnology entrepreneurship in South Africa and Brazil from multiple sources.

Semi-structured in-depth interviews were conducted with the bioscientists and SMEs using the earlier developed interview guide (see Appendices E and F) and the case study protocol (see Appendix D). The development of the interview guide was guided by the literature review, the research questions and the organising frameworks for this research.

A CAQDAS called Atlas.ti version 7.1.6 was used for the data analysis. The use of Atlas.ti aided rapid, consistent and rigorous qualitative data analysis (Weitzman, 1999; Rambaree, 2007; Hwang, 2008), and extended the researcher's ability to organise, remember and be systematic (Zdenek, 2008).

Another methodological contribution of this research was the use of Atlas.ti CAQDAS to demonstrate data saturation for both cases (see Figures 4.6 and 4.7 respectively). The definition of saturation in this context is the point where few or no new codes (insights) are generated from additional respondents or documents (Morse et al., 2002; Guest et al., 2006). The literature on how to demonstrate saturation is sparse, even though it is considered to be a desirable feature of good qualitative research (Guest et al., 2006).

The case narratives provided a rich, "thick" description of the experiences of the respondents within a real-life context (Eisenhardt and Graebner, 2007b; Yin, 2009) of biotechnology entrepreneurship, which guided the identification of patterns and themes towards theory development (Carroll and Swatman, 2000; Eisenhardt and Graebner, 2007b; Welch et al., 2011; Klonoski, 2013).

The framework for presenting the case narratives and analyses was derived from literature and guided by the interview guide and case study protocol, as well as the organising frameworks of the individual-opportunity nexus framework of entrepreneurship and the triple helix of university, industry, government relations. The within-case analysis was conducted for each of the two cases to identify the emerging patterns. This represented a further aggregation of data to a higher level of abstraction towards theory building (Lillis, 1999; Miles and Huberman, 1999; Eisenhardt and Graebner, 2007b; Klonoski, 2013).

The cross-case analysis of the combined cases yielded themes that were compared to the literature to deepen interpretation and understanding, as well as enhance generalisability (Eisenhardt and Graebner, 2007b; Welch et al., 2011; Klonoski, 2013). The themes formed the basis of the proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil.

10.4 Theoretical contributions to the literature

The main theoretical contribution of this research is the development of a theoretical framework of biotechnology entrepreneurship, which defines the dynamics of biotechnology entrepreneurship in South Africa and Brazil.

The research followed the idiographic tradition, defining themes that are tested against literature. The proposed theoretical framework of biotechnology entrepreneurship is based on the themes that emerged from the cross-case analysis of the process of biotechnology entrepreneurship in South Africa and Brazil. The within-case analysis of each case incorporated the lived experiences of the bioscientists, bioentrepreneurs, and SMEs in biotechnology entrepreneurship in South Africa and Brazil.

At the time of this research, there is no known theoretical framework of biotechnology entrepreneurship, especially from a developing economies' context.

The theoretical framework incorporates the individual attributes that define the psychological and non-psychological orientations of the bioscientists involved in biotechnology entrepreneurship. In addition to cognition and motivation, education and experience in the field of bioscience are necessary individual attributes. The process of biotechnology entrepreneurship in South Africa and Brazil was shown to work according to an individual model and systemic model respectively.

The theoretical framework also defines the bioentrepreneurial opportunities as pre-existing in one of the three areas of problem, efficiency or innovation opportunities, with problem and efficiency opportunities predominating in South Africa and Brazil respectively.

The environmental context of the theoretical framework consists of industry and the macroeconomic environment, as well as innovation and entrepreneurial conditions. Regulation, funding, infrastructure, skills, entrepreneurial and commercialisation capabilities, market for biotechnology products, and social development are the key factors that impact on the environmental context of biotechnology entrepreneurship in South Africa and Brazil.

R&D is defined in the theoretical framework as a unique form of opportunity discovery or creation in biotechnology entrepreneurship. In South Africa and Brazil, the abundance of genetic materials as raw materials for R&D, through the biodiversity, is considered a competitive advantage.

The exploitation of bioentrepreneurial opportunities, in the theoretical framework, requires effective collaboration among the key stakeholders, consisting of government, research institutions, venture capitalists and large companies. According to the respondents for this study, all the stakeholders are present in Brazil, while South Africa lacks the venture capitalists and large biotechnology companies.

The theoretical framework defines the commercialisation of research as the culmination of the process of biotechnology entrepreneurship. This is achieved either through firm formation or licensing. The effective collaboration required throughout the framework also plays a part in effective commercialisation of research.

Although this theoretical framework cannot be generalised to all developing economies, it provides the means to study the process of biotechnology entrepreneurship in other developing and developed economies. The in-depth understanding of the process of biotechnology entrepreneurship in South Africa and Brazil informs policy recommendation for the government and recommendations for other industry stakeholders.

10.5 Policy and other implications for the government

The theoretical contribution of this research has policy implications for the government as a policymaker and government agencies responsible for formulating and implementing policies related to biotechnology entrepreneurship.

One of the themes identified through the cross-case analysis is “the government plays an important role in biotechnology entrepreneurship in South Africa and Brazil”. In addition, the policy and regulatory environment was among the top challenges identified for the development of biotechnology entrepreneurship in the developing economies that provided the focus of this research.

The role of government in providing a favourable environment for the development of biotechnology entrepreneurship includes legislation on the national biotechnology strategy, policies on public research institutions, policies related to research funding, intellectual property policies, regulations on university-industry technology transfer, regulations on taxation, labour laws, policies on the acquisition of scarce skills, policies on science and mathematics in the education curriculum, and policies related to regional and international collaboration on biotechnology entrepreneurship.

The government also controls most of the factors that influence the process of biotechnology entrepreneurship in South Africa and Brazil, and hence should utilise this leverage to foster an environment that is conducive for the development of biotechnology entrepreneurship.

The availability of the relevant policies and regulations; the effectiveness of implementing these policies by the government agencies; and the leadership and direction provided by government were highlighted as some of the differences between the developed and developing economies.

The governments of South Africa and Brazil should endeavour to review the policies and regulations related to biotechnology entrepreneurship regularly to ensure that they are aligned to the needs of the industry. They should ensure the effective implementation of such policies and regulations through appropriate resourcing and mandates and continuously monitor the experience of the stakeholders in the industry to assess the relevance of the policies and regulations.

The empirical contributions of this research have other implications for the government. The government plays the roles of facilitator, buyer of biotechnology products and solutions, and funder, in addition to the role of providing a favourable policy and regulatory environment. This makes it an important component of the value chain.

The facilitation role of the government includes the provision of leadership, infrastructure, capacity, research institutions and platforms for local and international collaborations among key stakeholders. The role of government as a buyer is necessitated by the social obligation of government to provide improved healthcare, food security, energy sufficiency and sustainable environmental practices. The role of the government as a funder includes the funding of R&D, infrastructure funding and project funding.

It is recommended that the government of South Africa, in particular, find effective ways of delivering on these roles to create a conducive environment for the development of biotechnology entrepreneurship.

The empirical and theoretical contributions of this research are expected to inform government policy formulation and implementation related to the development of biotechnology entrepreneurship in South Africa and Brazil.

10.6 Implications for the other stakeholders

The empirical contribution of this research has implications for the other stakeholders involved in the biotechnology industry, such as the research institutions, venture capitalists, large biotechnology companies and bioentrepreneurs.

A clearer understanding of the dynamics of biotechnology entrepreneurship in developing economies is expected to aid decision making related to the biotechnology entrepreneurship by these stakeholders. There are multiple points of stakeholder collaboration and strategic alliances in the proposed theoretical framework for biotechnology entrepreneurship. These are in the environment for biotechnology entrepreneurship; R&D; opportunity exploitation; and commercialisation of research.

The research institutions need to review their policies on intellectual property and the transfer of technology from the university to the industry, in alignment with similar policies by the government. This was highlighted as one of the gaps in the development of biotechnology entrepreneurship in these developing economies. Furthermore, the culture of the universities and research institutions needs to be changed from prioritising publication to being focused on commercialisation of research to realise economic and social value.

The understanding of the dynamics of biotechnology entrepreneurship in these developing economies, especially in South Africa where there is a lack of a developed venture capital industry, will aid the venture capitalists in understanding the peculiarities of the environment, the challenges and gaps, the role of the government and the opportunities that can be exploited. Importantly, the lessons from the success of the venture capital market in Brazil can be implemented in South Africa, given an enabling regulatory environment.

The absence of large biotechnology companies was highlighted as one of the gaps in South Africa. Given the involvement of the large biotechnology companies in major R&D; their role as cooperation partners, customer and competitor; and the availability of good research universities and skilled researchers in South Africa, there is an opportunity for the large biotechnology companies to seek out collaboration opportunities in South Africa, provided the enabling environment expected to be provided by the government is in place. Similarly, they can use their expertise in Brazil to enter the South African biotechnology industry.

The seven factors that influence the process of biotechnology entrepreneurship in South Africa and Brazil, identified in this research, are controlled by the stakeholders in various degrees. This provides clarity on the scope of control and influence available to each stakeholder in the biotechnology industry.

10.7 Recommendations for future research

The proposed theoretical framework of biotechnology entrepreneurship should be empirically tested for its applicability to the context of other developing economies apart from those used for this research.

In addition, the proposed theoretical framework of biotechnology entrepreneurship should be empirically tested for its applicability to the context of developed economies, given the global nature of biotechnology entrepreneurship.

Another area of possible future research related to the proposed theoretical framework of biotechnology entrepreneurship is in the evaluation of the relative contribution of the components of the framework to the success of biotechnology entrepreneurship in a particular context.

It is recommended that the factors that influence the process of biotechnology entrepreneurship be tested in different contexts. In addition, further study of the influence of the social development factor is recommended to understand how this influence is exerted.

This research also uncovers possible deviations from the triple helix of university, industry, government relations model (Etzkowitz and Leydesdorff, 2000), which involves a hybrid model that retains government control and influence, while seeking to create a knowledge economy. Another area of possible future research is to study how the triple helix model is applicable to the developing economies.

In addition, the social linkages and the intentions of implementing a quadruple helix of university, industry, government, society relations (Afonso et al., 2010; Marcovich and Shinn, 2011; Afonso et al., 2012; Leydesdorff, 2012) in a developing economy context are recommended for further research.

It is recommended that future research in the field of biotechnology entrepreneurship utilise a qualitative multiple case study approach in order to understand the “how” and “why” of the phenomenon of biotechnology entrepreneurship in its original context (Creswell, 2009; Yin, 2009).

Finally, given the limitations of this study in terms of purposive sampling and the language barrier, it is recommended that future research use a different sampling methodology and conduct the research in the native language of the context in question.

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Appendix A: Participation information sheet

Dear Respondent,

I am a doctoral student at WITS business school, University of Witwatersrand, Johannesburg, South Africa. I am working on a doctoral study titled: “Dynamics of biotechnology entrepreneurship in South Africa and Brazil”. The research proposal for this study was approved by the university panel on the 29th of September 2011, and all academic and ethics requirements needed for the research to proceed have been met.

This exploratory study is expected to lead to a practical understanding of the process of biotechnology entrepreneurship in these two developing economies, which is expected to guide government policy-making and stakeholders involved in biotechnology entrepreneurship towards optimising the potentials of biotechnology in the twenty first century.

Case study method will be used and this requires in-depth interviews of respondents. I have identified you as an ideal candidate for this study and will appreciate it if you accept the invitation to participate in this study. Each interview will last about two hours and will be tape-recorded to ensure accuracy of information when transcribed. There may be more than one interview session, or a need for a follow up. I will also request to have access to recent and archived documents relevant to the study.

Anonymity is guaranteed through coding of interview transcripts and information from other sources. The researcher will also sign a confidentiality and non-disclosure agreement provided by you. In addition, draft write-up of all information and conversation will be verified with you for accuracy before the final version is produced.

Should you require further clarification of any aspect of this study, my contact details are: Cell phone: 072 922 0206; Office: 011 631 2957; Office email: Manessah.Alagbaoso@standardbank.co.za; Home email: manessah@iburst.co.za

My supervisors’ contact details are: Prof. Terri Carmichael – Terri.Carmichael@wits.ac.za and Dr Kerrin Myres – resonate@icon.co.za

I look forward to your participation in this study and do thank you in anticipation.

Yours sincerely,

Alagbaoso Manessah

Appendix B: Letter of acceptance to participate in the study

I ……………………………………………… do accept to participate in the doctoral research titled: “Dynamics of biotechnology entrepreneurship in South Africa and Brazil”, which is being carried out by Manessah Alagbaoso of the Wits Business School, University of Witwatersrand, Johannesburg, South Africa.

I confirm that my participation is voluntary and I will provide information that upholds the integrity and quality of the research outcome.

Appendix C: Letter of consent for interview to be tape-recorded

I ……………………………………………… do consent to the tape-recording of the interview of which I am an interviewee. I understand that the purpose of tape-recording the interview is to ensure an accurate representation of the interview discussion.

In addition, I understand that this interview is necessary for the doctoral research titled: "Dynamics of biotechnology entrepreneurship in South Africa and Brazil", which is being carried out by Manessah Alagbaoso of the Wits Business School, University of Witwatersrand, Johannesburg, South Africa.

I confirm that my participation and my consent for the interview to be tape-recorded are voluntary and I will provide information that upholds the integrity and quality of the research outcome.

Signed: ………………………………   Date: ……………………………………

Appendix D: Case Study Protocol

1. Introduction to the Case study and purpose of the protocol

This case study aims to explore the dynamics of biotechnology entrepreneurship, in its real-life context, in South Africa and Brazil. The in-depth understanding of the process of biotechnology entrepreneurship in these two developing economies will provide a basis for policy and decision-making related to biotechnology entrepreneurship that is specific to the contexts of these developing economies.

The purpose of the protocol is to guide the operational conduct of the data collection procedure by the investigator in a single case, which forms part of the multiple cases.

1.1 Case study questions

Question 1 - relates to the dynamics of biotechnology entrepreneurship in South Africa (if the case in question is in South Africa); and the dynamics of biotechnology entrepreneurship in Brazil (if the case in question is in Brazil)

Question 2 - relates to the similarities between the process of biotechnology entrepreneurship in the developed and developing economies

Question 3 – relates to the differences between the process of biotechnology entrepreneurship in the developed and developing economies

Question 4 - relates to the factors that influence the process of biotechnology entrepreneurship developing economies

Question 5 – relates to the Triple Helix of University, Industry and Government

Note: These questions are aligned to the theoretical framework and propositions; and will be posed at the individual level of analysis.

1.2 Theoretical framework and propositions

The organising frameworks for this case study are the individual-opportunity nexus framework of entrepreneurship; and the triple helix of university, industry, government relations.

The components of the individual-opportunity nexus framework of entrepreneurship are:

i. Individual attributes of the bioscientist
ii. Environment
iii. Entrepreneurial opportunities
iv. Discovery
v. Entrepreneurial exploitation
vi. Execution

The components of the triple helix of university, industry, government relations are:

i. Triple Helix I
ii. Triple Helix II
iii. Triple Helix III

The theoretical propositions based on the literature and organising frameworks are:

Proposition 1 – the case study will show how biotechnology entrepreneurship in developing economies is carried out by the bioscientists

Proposition 2 – the case study will show similarities in the process of biotechnology entrepreneurship between the developed and developing economies

Proposition 3 – the case study will show differences in the process of biotechnology entrepreneurship between the developed and developing economies

Proposition 4 - the case study will show the factors that influence the process of biotechnology entrepreneurship in developing economies

Proposition 5 – the case studies will show the applicable Triple Helix of University, Industry, Government relations that is practiced in South Africa and Brazil as it relates to biotechnology entrepreneurship

Note: that the five case study questions are aligned to these five propositions respectively.

1.3 Role of protocol in guiding the case study investigator

The protocol is a standardised agenda for the investigator's line of inquiry. The effective use of the protocol for each case in the multiple case study guarantees uniformity of data collection aligned to the research questions, theoretical framework and propositions. This is expected to enhance the reliability of the research.

2. Data collection procedures

The details of the data collection procedure are populated in the table below.

2.1 Details of cases to be visited

Country	Interviews Documents	Designation	Date
South Africa	• 5 – Nicholas Duneas • 11 – Ashley Uys • 12 – Michael Pepper • 14 - Reinhard Hiller • 15 – Kit Vaughan • 16 – Justine Devine • 17 - Louis Roux	Bioentrepreneur	2012/2013
	• 2 – Duncan Raftesath	Subject Matter Expert - University	2012
	• 13 – Heather Sherwin	Subject Matter Expert - Industry	
	• 1 – Ben Durham • 3 – Mohammed Sayed • 4 – Vinesh Maharaj	Subject Matter Expert - Government	2011/2012
	• 12 – Michael Pepper • 15 – Kit Vaughan • 16 – Justine Devine • 17 - Louis Roux	Both bioentrepreneur and SME	2013
	• National bio-economy strategy • Technology Innovation Agency	Documents	

Country	Interviews Documents	Designation	Date
	(TIA) Act • WITS University Intellectual Property Policy		
Brazil	• 6 – Dario Grattapaglia • 8 - Paulo Arruda	Bioentrepreneur	2012
	• 6 – Dario Grattapaglia • 7 – Valeria Judice • 8 - Paulo Arruda • 9 – Ruy Caldas	Subject Matter Expert - University	2012
	• 7 – Valeria Judice • 9 – Ruy Caldas	Subject Matter Expert - Industry	2012
	• 6 – Dario Grattapaglia • 8 - Paulo Arruda • 9 – Ruy Caldas • 10 - Conceicao Vedovello	Subject Matter Expert - Government	2012
	• 6 – Dario Grattapaglia • 8 - Paulo Arruda	Both bioentrepreneur and SME	2012
	• National biotechnology development policy • FAPESP creation, structural and co-	Documents	

Country	Interviews Documents	Designation	Date
	ordination • OECD Biotechnology Industry documents		

2.2 Data collection plan

The data collection plan includes multiple sources of evidence as listed:

i. Interviews with the bioscientists and subject matter experts
ii. Documents - formal prior studies of the same case, administrative documents, company reports, and media reports pertaining to the bioscientists
iii. Archival records - records pertaining to the bioscientists
iv. Direct observation - researcher to be present in the real-life environment of the cases where applicable

2.3 Expected preparation prior to site visits

Prior to site visits, the investigator is expected to:

i. Have background knowledge of the bioscientist or subject matter expert, if possible, from electronic sources, published works, previous case studies and information available in the media
ii. Review the case study protocol
iii. Re-confirm the appointment
iv. Ensure that all equipments (laptop, tape recorder) and materials (writing materials) are ready and in good working order

3. Outline of case study report

The outline of the case study report is expected to be as shown below, but the researcher will maintain enough flexibility to review the outline as the case study develops.

i. The dynamics of biotechnology entrepreneurship in developing economies

ii. The similarities between biotechnology entrepreneurship in developed and developing economies
iii. The differences between biotechnology entrepreneurship in developed and developing economies
iv. The factors that influence biotechnology entrepreneurship in developing economies
v. The dynamics of the Triple Helix of University-Industry-Government relations in South Africa and Brazil
vi. Empirical, theoretical and methodological contributions of the study
vii. Policy implications for the government
viii. Decision-making implications for other biotechnology stakeholders
ix. Recommended areas of further research

4. Case study questions

1. The dynamics of biotechnology entrepreneurship in developing economies

i. Describe how the commercialisation of your intellectual property came into being in detail. (For an SME this question is adapted to: What is you're his role in the biotechnology industry in South Africa or Brazil?)
ii. What are your views on the dynamics of biotechnology entrepreneurship in South Africa?
i.
ii. Describe your operations in details. This need to cover the following areas:
    a. Your individual role, at psychological and non-psychological levels
    b. The effect of environmental factors, emphasising the economic, political and cultural environments
    c. The details of bioentrepreneurial opportunities; how they are discovered and why particular opportunities are pursued
    d. The process of research and development
    e. The process of entering into strategic alliances
    f. The process of commercialisation of intellectual property

2. The similarities between the process of biotechnology entrepreneurship in the developed and developing economies.

   i. In what ways is biotechnology entrepreneurship in developing economies similar to the developed economies?

3. The differences between the process of biotechnology entrepreneurship in the developed and developing economies.

   i. In what ways is biotechnology entrepreneurship in developing economies different from the developed economies?

4. The factors that influence biotechnology entrepreneurship in developing economies.

   i. What are the factors that influence biotechnology entrepreneurship in developing economies?

5. The dynamics of the Triple Helix of University-Industry-Government relations in a developing economy context.

   i. From which of the three perspectives, University, Industry, Government, do you operate?
   ii. Do you perceive your role to be fully contained within one perspective or cutting across the different perspectives? If yes, which ones?
   iii. What are the dynamics at play with the relations between these three perspectives?
   iv. What are the sub-dynamics at play within your own perspective and across these three perspectives?
   v. How would you access the efficacy of the current relations between the University, Industry and Government?
   vi. What are the positives of the current relations between the three perspectives?
   vii. What are the constraints of the current relations between the three perspectives?
   viii. What would be ideal relations between the University, Industry and Government, for biotechnology entrepreneurship in a developing economy like South Africa and Brazil?

Appendix E: Interview guide - Bioentrepreneur

The interview guide gives a general outline of the type of interview questions needed to cover all the relevant aspects of the study. Given that this will be semi-structured interview, the exact questions posed during the interview may differ slightly but will convey the same meaning and understanding.

Preliminaries

i. Formal introduction and thank the interviewee for his/her participation
ii. Clarification of the purpose of the interview and the study, and confirmation of the duration of the interview
iii. Indicate that the interview will be tape-recorded and get interviewee consent for that
iv. Give the interviewee opportunity to ask questions before the interview commences

Likely interview questions

1. The dynamics of biotechnology entrepreneurship in developing economies

iii. How did your career as a bioscientist get started?
iv. What skills are required at individual level in order to engage in biotechnology entrepreneurship?
v. Why are these skills important for biotechnology entrepreneurship?
vi. How does the economic environment affect your operations?
vii. How does the political environment affect your operations?
viii. How does the cultural environment affect your operations?
ix. What are the bioentrepreneurial opportunities that you see that exist in this economy?
    a. How are these opportunities discovered?
x. How do you carry out research and development?
xi. How do you engage in strategic alliances?
xii. Why do you engage in strategic alliances?
xiii. What strategy do you employ to commercialise your intellectual property?

xiv. Why do you employ this particular strategy to commercialise your intellectual property?

2. The similarities between the process of biotechnology entrepreneurship in the developed and developing economies.

i. How is your process of biotechnology entrepreneurship similar to bioentrepreneurship in developed economies?

3. The differences between the process of biotechnology entrepreneurship in the developed and developing economies.

i. How is your process of biotechnology entrepreneurship different from bioentrepreneurship in developed economies?

4. Factors that influence biotechnology entrepreneurship in developing economies.

i. What are the factors that influence your process of biotechnology entrepreneurship?

5. The dynamics of the Triple Helix of University-Industry-Government relations in a developing economy context.

ix. From which of the three perspectives, University, Industry, Government, do you operate?

x. Do you perceive your role to be fully contained within one perspective or cutting across the different perspectives? If yes, which ones?

xi. What are the dynamics at play with the relations between these three perspectives?

xii. What are the sub-dynamics at play within your own perspective and across these three perspectives?

xiii. How would you access the efficacy of the current relations between the University, Industry and Government?

xiv. What are the positives of the current relations between the three perspectives?

xv. What are the constraints of the current relations between the three perspectives?

xvi. What would be ideal relations between the University, Industry and Government, for biotechnology entrepreneurship in a developing economy like South Africa and Brazil?

Appendix F: Interview guide – Subject Matter Expert

The interview guide gives a general outline of the type of interview questions needed to cover all the relevant aspects of the study. Given that this will be semi-structured interview, the exact questions posed during the interview may differ slightly but will convey the same meaning and understanding.

Preliminaries

v. Formal introduction and thank the interviewee for his/her participation

vi. Clarification of the purpose of the interview and the study, and confirmation of the duration of the interview

vii. Indicate that the interview will be tape-recorded and get interviewee consent for that

viii. Give the interviewee opportunity to ask questions before the interview commences

Likely interview questions

1. The dynamics of biotechnology entrepreneurship in developing economies

xv. What is your role in the biotechnology industry in South Africa?

xvi. What are your views on the dynamics of biotechnology entrepreneurship in South Africa?

xvii. How does the economic environment affect biotechnology entrepreneurship in South Africa?

xviii. How does the political environment affect biotechnology entrepreneurship in South Africa?

xix. How does the cultural environment affect biotechnology entrepreneurship in South Africa?

xx. What are the bioentrepreneurial opportunities that you see that exist in this economy?

   a. How are these opportunities discovered?

2. The similarities between the process of biotechnology entrepreneurship in the developed and developing economies.

ii. How is your process of biotechnology entrepreneurship similar to bioentrepreneurship in developed economies?

3. The differences between the process of biotechnology entrepreneurship in the developed and developing economies.

ii. How is your process of biotechnology entrepreneurship different from bioentrepreneurship in developed economies?

4. Factors that influence biotechnology entrepreneurship in developing economies.

ii. What are the factors that influence your process of biotechnology entrepreneurship?

5. The dynamics of the Triple Helix of University-Industry-Government relations in a developing economy context.

xvii. From which of the three perspectives, University, Industry, Government, do you operate?

xviii. Do you perceive your role to be fully contained within one perspective or cutting across the different perspectives? If yes, which ones?

xix. What are the dynamics at play with the relations between these three perspectives?

xx. What are the sub-dynamics at play within your own perspective and across these three perspectives?

xxi. How would you access the efficacy of the current relations between the University, Industry and Government?

xxii. What are the positives of the current relations between the three perspectives?

xxiii. What are the constraints of the current relations between the three perspectives?

xxiv. What would be ideal relations between the University, Industry and Government, for biotechnology entrepreneurship in a developing economy like South Africa and Brazil?

Appendix G: Observational form

The attached table shell will be used to record direct observations. The attributes are not exhaustive and will be updated as the research progresses.

Observed attribute	**Comments**
Physical location of the bioscientist	e.g. in an industrial complex, biotechnology park, office blocks etc
Scientific laboratory	e.g. co-located at the company's offices, not co-located at the company's offices
Appearance of scientific laboratory	e.g. spotlessly clean, untidy, unhealthy etc
Access restrictions to scientific laboratory	e.g. staff only access, limited access to non-staff, public access allowed etc
Manufacturing facility	e.g. present or not present
Scale of manufacturing facility	e.g. extensive, small
Attitude of bioscientist	e.g. professional, friendly, hostile
Document management	e.g. fully electronic, combination of electronic and manual, fully manual
Evidence of innovation	e.g. awards, recognition of achievements