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#### Full Length Research Paper

# Dynamics of biotechnology entrepreneurship in South Africa and Brazil

Manessah Alagbaoso\*, Teresa Carmichael and Kerrin Myres

Wits Business School, University of Witwatersrand, Johannesburg, South Africa.

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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 of South Africa and Brazil. This research used a 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. Biotechnology entrepreneurship in Brazil predominantly uses the "system approach" while in South Africa the "individual approach" predominates. The process of biotechnology entrepreneurship in South Africa differs from the process in Brazil due to the differences in the environmental factors that influence biotechnology entrepreneurship, and management strategies, in these two economies.

**Key words:** Biotechnology entrepreneurship, entrepreneurship, biotechnology, management strategies, triple helix, university, industry, government, South Africa, Brazil, qualitative analysis.

#### 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 et al., 2010a; Ahn et al., 2010b; Battelle/Biotechnology Industry Organisation, 2010; Ahn and York, 2011; Ahn et al., 2012; Dunham

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,

\*Corresponding author. E-mail: Manessah.Alagbaoso@standardbank.co.za, manessah@telkomsa.net. (+27) 72 922 0206.

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in order to capitalise on what has been termed the "biocentury" (Battelle/Biotechnology Industry Organisation, 2010).

This study explored 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. Although, this research was based on the organizing framework of the individual-opportunity nexus of entrepreneurship (Shane, 2003), the results the individual-opportunity show that 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 main empirical and theoretical contributions of this research include conducting this research in South Africa and Brazil and the development of a proposed theoretical framework of biotechnology entrepreneurship, respectively.

Methodologically, the use of a qualitative multiple case study approach constitutes a methodological contribution. Current studies in biotechnology entrepreneurship make use of a nomothetic philosophical approach and employs quantitative methods within one developing economy context. 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.

#### Assumption 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. 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 et al., 2010). In addition, they have fairly developed economy, institutions, educational government 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 and 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: Margues and Goncalves Neto, 2007: Bound, 2008; Technology Innovation Agency, 2010; Ernst and Young, 2010b).

#### LITERATURE REVIEW

The literature on general entrepreneurship recognises the role of the individual in the process of entrepreneurship (Kenney, 1986) 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, selfefficacy, 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; Acs 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 been seen 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, Rickne and Bengtsson, 2010) highlights four factors: the perceived role of the university, supportive infrastructure, industrial actor set-up, and networks. The details of these factors include university culture, university infrastructure such as the technology transfer office (TTO), national infrastructure for commercialisation of research, large companies that have receiver capabilities, and

collaboration among key stakeholders. Another 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.

#### 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 products" useful (Biotechnology Organisation, 2008). 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 and Herstatt, 2004; Ahn and Meeks, 2007; Ahn et al., 2010a; Ahn et al., 2012).

### Biotechnology entrepreneurship in 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 and 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, and an Asian country such as Japan, 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 current impact. 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 "innovationdriven" as shown in Table 1. 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) such 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. 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 selfemployment in their lifetime (Acs and Audretsch, 2003:5). The result of this is that an estimated 761,000 new corporations, the number of which 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).

Table 1. 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

Table 2. 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 micro-economic factors aimed at providing incentives for entrepreneurial action

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, Venkataraman and Velamuri, 2008) are shown in Table 2. 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). As might be expected, 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.

## Biotechnology entrepreneurship in emerging 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 (Fontes 2001). The GEM report (Kelley, Singer and Herrington, 2012) classifies South Africa and Brazil as efficiency-driven and as such the key focus is on the efficiency enhancers such as higher education and training, goods market efficiency, labour market efficiency, financial market sophistication, technological readiness, market size. While, these efficiency enhancers are fundamental to the development of entrepreneurial culture in general, the developing economies still need to develop the entrepreneurial conditions necessary for an innovation-driven industry such as biotechnology (Herrington et al., 2008; Bosma and Levie, 2010).

The global issues of 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

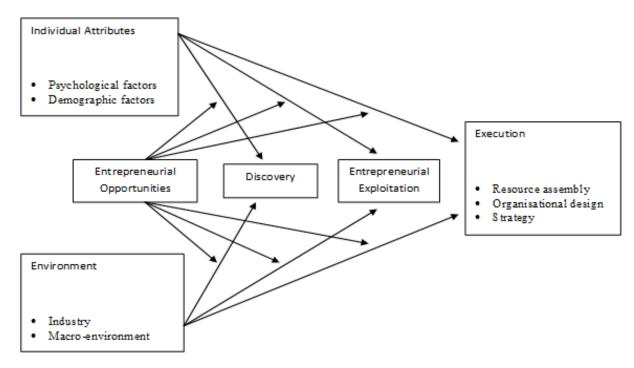


Figure 1. The individual-opportunity nexus framework (Shane, 2003:11).

global competitiveness. These issues highlight the importance of understanding and developing entrepreneurship in general, and specifically biotechnology entrepreneurship, in the emerging economies.

#### Research question

The research question explored in this study is:

#### **Question 1**

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

#### Organising framework

The individual-opportunity nexus framework of entrepreneurship (Shane, 2003:11) (Figure 1) was used as the organising framework for this research, which guided the exploration of the dynamics of biotechnology entrepreneurship in the developing economies of South Africa and Brazil. 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 levels and favourable for productive advanced 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 (2003) individual-opportunity nexus framework for entrepreneurship is able to explain the process of biotechnology entrepreneurship as the literature on biotechnology entrepreneurship aligns to the components of the individual-opportunity nexus framework (Pisano 1990; 1991). This makes this framework useful for understanding the process of biotechnology entrepreneurship 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.

#### RESEARCH METHODOLOGY

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

#### 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, 2007; 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).

#### **FINDINGS AND DISCUSSION**

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. The patterns identified from the within-case analyses of South Africa and Brazil are presented in Table 3 below. The patterns that emerged from within the case analyses of South Africa and Brazil (Table 3) 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 which 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.

#### Theme 1

"There is a dual approach to the practice of biotechnology entrepreneurship, which can be seen as a 'system' or as an 'individual'"

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. 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.

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 upskilled in commercialisation through practical experience. The "individual" approach entails bioscientists acquiring the entrepreneurial and commercialisation skills that enable them to manage the commercialisation of research successfully. 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

Table 3. 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
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 their 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 products	The lack of developed markets for biotechnology products is consistently deemed to be a constraint by most of the respondents	The local market for biotechnology products is 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 and D is the defining step in biotechnology entrepreneurship in South Africa and Brazil	The discovery of these bioentrepreneurial opportunities requires R&D. The intensity and the R&D spend in South Africa are deemed to be below the levels of the developed economies	The intensity and the R&D 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
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

Table 3. Contd.

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 respondents to be an important consideration for biotechnology entrepreneurship in South Africa	Global competitiveness is a key factor in the approach to biotechnology 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 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 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

approach the process in their individual capacity as is often the case in general entrepreneurship. 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), Management Advancement Programme (MAP), and entrepreneurial skills development programme run by some of the stakeholders and sponsored by the government.

#### Theme 2

"Biotechnology opportunities occur in the form of problem, efficiency, and innovation opportunities"

Most of the respondents in South Africa see bioentrepre-

neurial 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 The biodiversity highlighted by the synthesis). 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 South Africa 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 populations energy sufficiency healthier and (Biotechnology Industry Organisation, 2008).

In Brazil, the bioentrepreneurial opportunities are

mostly aligned to efficiency and innovation opportunities and a component of problem opportunities. 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. The innovation opportunities are manifested in the areas of bioenergy; genomics; vaccines; antibiotics; and the use of indigenous knowledge and biodiversity. 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).

The entrepreneurial opportunities in biotechnology 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 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, Oliver, Zucker and Brewer, 1996; Audretsch and Stephan, 1998; Agrawal, 2001; Shane, 2003; Müller et al., 2004; Rothaermel and Deeds, 2004; Powell, White, Koput and Owen-Smith, 2005; Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

#### Theme 3

"Regulation is a critical factor in biotechnology entrepreneurship 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. This regulatory challenge was also recognised in the new bio-economy strategy to be implemented by the government of South Africa.

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. 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. Hence, the regulatory environment is important for general entrepreneurship (Shane and Venkataraman, 2000; Eckhardt and Shane, 2003; Shane, 2003; Lingelbach, De La Vina and Asel, 2005; Phan, Venkataraman and Velamuri, 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 and 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 innovationdriven countries (Kelley et al., 2012) in relation to the effectiveness of the process of entrepreneurship. 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).

#### Theme 4

"An overall conducive environment is necessary for the effective development of biotechnology entrepreneurship in South Africa and Brazil"

The overall environment of biotechnology entrepreneurship in South Africa presents many challenges according to the respondents. 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. 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.

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. 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.

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. 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 Herrington et al. (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 and D transfer, commercial and legal infrastructure for entrepreneurship, internal market openness, physical infrastructure for entrepreneurship, and cultural and social norms.

#### Theme 5

"Research and development is the defining step in bio-

technology entrepreneurship in South Africa and Brazil"

According to the OECD (2009), the primary requirements for R and 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 and D to be inadequate and see it as a gap in the effort to develop the biotechnology industry in South Africa.

By contrast, R and 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 and 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.

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 and D.

R and 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. Given that the discovery of biotechnological opportunities requires R and D, it simply follows that the direct consequence of low R and D spend and activities in developing economies is low levels of biotechnological activities.

#### Theme 6

"There are four types of skills required in biotechnology entrepreneurship in South Africa and Brazil, namely: research, scientific, entrepreneurial, and commercialisation skills"

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. 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.

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 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 and research skills for science biotechnology entrepreneurship in South Africa.

There have 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 and 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).

#### Theme 7

"Effective collaboration among key stakeholders is important to the development of biotechnology entrepreneurship 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.

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.

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 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) leading to a quadruple helix. The quadruple helix is context-specific and in the case of the developing economies the socioeconomic 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.

#### Theme 8

"The government plays an important role in biotechnology entrepreneurship in South Africa and Brazil"

In Brazil, where government leadership and direction were deemed to be effective there have been notable

successes in biotechnology entrepreneurship. 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.

The role of the government in biotechnology entrepreneurship is to provide an enabling regulatory environment and act as a facilitator (Fontes, 2001; 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 bioeconomy 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 purposefully orchestrated non-accidental and 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).

#### Theme 9

"Funding is a critical factor in biotechnology entrepreneurship in South Africa and Brazil"

The funding environment for biotechnology entrepreneurship in South Africa was deemed unfavourable by the respondents. 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.

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.

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).

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.

#### Theme 10

"The local market for biotechnology products is a critical factor in biotechnology entrepreneurship 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. 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.

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. By contrast, the respondents believe that the Brazilian market for biotechnology products is developed. 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.

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 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 (Zylberberg et al., 2012).

## The proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil

The organising framework that guided this research framework (Shane. 2003) is а for general entrepreneurship and is 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 et al. (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 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 2006; Organisation for Economic Young, Cooperation and Development, 2009; Ernst and Young, 2010a; 2010b; Organisation for Economic Cooperation and Development, 2013b; 2013a). No current empirical or industry study has addressed the process 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 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 has characteristics that differentiate the process of biotechnology entrepreneurship from the process articulated in the organising framework of the individualopportunity 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 nonpsychological 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. 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 and D. R and 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

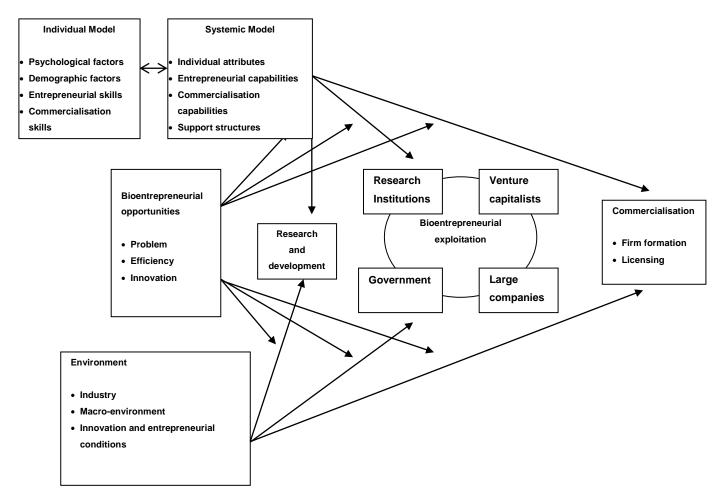


Figure 2. A proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil (adapted from Shane, 2003:11)

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; Ahn and Meeks, 2007; Ahn et al., 2010a; Afonso et al., 2010; Marcovich and Shinn, 2011; Afonso et al., 2012; Leydesdorff, 2012) 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 2. The proposed theoretical framework of biotechnology entrepreneurship in South Africa and Brazil (Figure 2) 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.

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 the problems of the country. 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 and D in the next step. R and 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 and D. R and D spend and intensity are often used as measures to determine how committed countries are to researchintensive industries such as biotechnology, and often determine the output.

In South Africa and Brazil, the abundance of genetic materials as raw materials for R and D, through the biodiversity, is considered a competitive advantage. Only successful outcomes at the R and D stage lead to the exploitation of bioentrepreneurial opportunities. Although, alliances needed to strategic exploit bioentrepreneurial opportunities is the next step, the R and D step often requires funding from multiple stakeholders who will eventually participate in the exploitation of the successful output of the R and 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 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 2 shows that the individual attributes, the bioentrepreneurial opportunities and the environment are deemed to affect all the stages of biotechnology entrepreneurship entrepreneurial exploitation to 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., Ahn and Meeks, 2007; Sytch and Bubenzer, 2008).

## The management strategies adopted by the bioentrepreneurs in response to the environmental variables in South Africa and Brazil

The environmental variables in South Africa and Brazil resulted in different management strategies adopted by the bioentrepreneurs as summarised in Tables 4 and 5. The business management strategies adopted by bioentrepreneurs in emerging market biotechnology entrepreneurship can be broadly categorised into a system approach and an individual approach to business management, as articulated under theme 1.

#### **CONCLUSION AND IMPLICATIONS**

The methodological approach for this research was designed to achieve an in-depth understanding of the process of biotechnology entrepreneurship in South

Table 4. The strategies adopted by the bioentrepreneurs in response to the environmental variables in South Africa.

No.	Environmental variable	Strategy adopted by bioentrepreneurs
i.	Lack of direction and leadership from the government	Most of the respondents avoid interaction with the government agencies at all cost. This impacts the university, industry, government relationships negatively
ii.	Lack of appropriate funding	Bootstrap funding is prevalent and some of the respondents seek funding abroad through donor agencies, venture capitalists and equity investors.  The choice of areas of biotechnology to focus on tends to be areas with lower overall cost and shorter timeframe such as diagnostics.  Most of the bioentrepreneurs try to get to a later stage of development before seeking government funding as this gives them a better chance of securing funding from the government
iii.	Lack of skills	The bioentrepreneurs in South Africa tend to manage all aspects of the business from the core research responsibilities to the entrepreneurial and commercialisation responsibilities, and auxiliary services
iv.	Lack of a developed market for biotechnology products and solution	Most bioentrepreneurs compete in the international market with particular focus on Africa and other developing economies due to their focus on mostly problem opportunities
V.	Lack of infrastructure and support structures	Bioentrepreneurs employ similar strategy to iii above
vi.	An inclination by the universities to prioritise research publication over commercialisation	This leads to most of the bioentrepreneurs operating outside of the university as private entities which further strains the triple helix of university, industry, government relationship
vii.	The loss of skills through the brain drain	Bioentrepreneurs employ similar strategy to iii above
viii.	Low levels of commercialisation of research	The unfavourable environmental variables leads to limited capacity by the bioentrepreneurs to increase the commercialisation activities
ix.	Unfavourable policy and regulatory environment	Bioentrepreneurs employ similar strategy to i above
X.	Poor implementation of policies	Bioentrepreneurs employ similar strategy to i above
xi.	Lack of some of the stakeholders involved in biotechnology entrepreneurship	Bioentrepreneurs employ similar strategy to iii above
xii.	Low levels of R&D spend	Bioentrepreneurs employ similar strategy to viii above

Africa and Brazil in their original contexts. The empirical, methodological and theoretical contributions, as well as the implications for the different stakeholders are articulated below.

#### **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. Few empirical research studies are specific to biotechnology entrepreneurship (Schoemaker and Schoemaker, 1998; Müller et al., 2004; Audretsch et al., 2008; Carsrud et al., 2008; Oliver, 2008; Gunn et al., 2013). Furthermore, 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 addressed.

#### 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

Table 5. The strategies adopted by the bioentrepreneurs in response to the environmental variables in Brazil.

No.	Environmental variable	Strategy adopted by bioentrepreneurs
i.	Effective direction and leadership from the government	Most of the respondents in Brazil work very closely with the government agencies and often work for the government at the same time as they are working for the university or the industry. This has a very positive impact on the university, industry, government relationships and has resulted in the successful completion of many internationally-acclaimed collaborative projects
ii.	Availability of appropriate funding from different sources	Bioentrepreneurs in Brazil are not constrained by a lack of appropriate funding and hence concentrate efforts on getting to results that help solve the national problems and areas of focus, given that government plays a big role in providing appropriate funding
iii.	Lack of aggregate skills	There is a high level of local and international collaboration to alleviate the effect of aggregate skills shortage. The bioentrepreneurs in Brazil also help drive skills exchange programmes that helps build sustainable capacity for the future
iv.	Availability of developed market for biotechnology products and solution	The bioentrepreneurs in Brazil focus primarily on the areas of biotechnology entrepreneurship prioritised by the government in the biotechnology development policy of Brazil. This creates an alignment that caters for national imperatives as well as make Brazil more competitive in the international market
V.	Availability of infrastructure and support structures	Bioentrepreneurs concentrate efforts on getting to results that help solve the national problems and areas of focus; as well as position the country competitively in the international market
vi.	A national culture that considers entrepreneurship to be impure	Bioentrepreneurs tend to work at the university, government and the industry at the same time in order not be seen as being after getting rich
vii.	High cost of funding	Bioentrepreneurs are very cautious about setting up their own biotechnology companies. The tendency is to allow the big biotechnology companies to cushion the funding cost in a collaborative set-up
viii.	Bureaucratic and inefficient processes by government agencies	Bioentrepreneurs in Brazil seek services like patent registration abroad due to the length of time it takes to do this in Brazil
ix.	Unfavourable policy and regulatory environment	The bioentrepreneurs use the good triple helix relationships to effect changes in the policy and regulatory environment of biotechnology entrepreneurship in Brazil
X.	Availability of all the stakeholders involved in biotechnology entrepreneurship	Bioentrepreneurs in Brazil utilise the contributions of the different stakeholders to optimise the outcome of collaborative projects
xi.	High level of R&D funding relative to other emerging economies; but low in comparison to OECD countries	Bioentrepreneurs in Brazil employ similar strategies to ii, iv and v above

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).

#### 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 (Figure 2). 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 The within-case analysis of each case incorporated the lived experiences of the bioscientists, bioentrepreneurs, and subject matter experts 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. 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.

#### Policy and other implications for the government

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.

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 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.

Furthermore, 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. The facilitation role of the government includes the provision leadership, infrastructure. capacity. 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 and 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.

#### 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 and 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 and 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.

#### Conflict of Interests

The author(s) have not declared any conflict of interests.

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