# THE DEVELOPMENT OF THE HEALTH BIOTECHNOLOGY SECTOR IN SOUTH AFRICA.

by

Marion Nyaboke Motari

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Graduate Department of Institute of Medical Sciences/Joint Centre for Bioethics
University of Toronto

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## *Abstract*

*This is a qualitative study of the South African health biotechnology sector. This study uses the National System of Innovation (NSI) framework as a conceptual tool to identify and analyze the factors that encourage and/or hinder the development of the health biotechnology in South Africa. This study aims at gaining an insight of how the sector has developed within the NSI framework and provide lessons for other developing countries on how to develop a local capacity and effectively harness health biotechnology innovations to improve health. This study identifies the main themes that have arguably influenced the development of the health biotechnology in the country. These themes include, the exploitation of indigenous knowledge together with science based innovations, the importance of adopting a biotechnology strategy that identifies new opportunities and a competitive edge, the importance of knowledge networks and mission oriented strategies that target local health needs.*

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**List of Abbreviations**

| | |
|---|---|
| AIDS | Acquired Immune Deficiency Syndrome |
| BAC | Biotechnology Advisory Committee |
| BRICs | Biotechnology Regional Innovation Centres |
| CBD | Convention on Biological Diversity |
| CIPRO | Companies and Intellectual Property Registration Office |
| CSIR | Council for Scientific and Industrial Research |
| DoE | Department of Education |
| DoH | Department of Health |
| DST | Department of Science and Technology |
| DTI | Department of Trade and Industry |
| FDA | Food and Drugs Administration |
| GDP | Gross Domestic Product |
| GMO | Genetically Modified Organisms |
| GODISA | Range of programmes jointly funded by the EU and the Department of Science and Technology to facilitate technology transfer and incubation in SMMEs |
| HIVAC | HIV Advisory Committee |
| IP | Intellectual Property |
| IPR | Intellectual Property Rights |
| IPTT | Initiative for Pharmaceutical Technology Transfer |
| MCC | Medical Control Council |
| MEDUNSA | Medical University of South Africa |
| MITI | Ministry of International Trade and Industry |
| MNC | Multi National Companies |
| MRC | Medical Research Council |
| NACI | National Advisory Committee on Innovation |
| NEPAD | New Partnership for Africa's Development |
| NRF | National Research Foundation |
| NSI | National Systems of Innovation |
| OECD | Organization of Economic Co-operation and Development |
| R&D | Research and Development |
| S&T | Science and Technology |
| SAAVI | South Africa AIDS Vaccine Initiative |
| SACRO | South African Companies Registration Office |
| SAIMR | South African Institute for Medical Research |
| SANBI | South African Institute of Bioinformatics |
| SAPTO | South African Patent and Trademark Office |
| SETIs | Science, engineering & Technology Institutions |
| SMME | Small Medium and Micro Enterprises |
| THRIP | Technology and Human Resource for Industry Programme |
| TRIPS | Agreement on Trade Related Aspects of Intellectual Property rights |
| UCT | University of Cape Town |
| USA | United States of America |
| UWC | University of Western Cape |
| VC | Venture Capital |
| WHO | World Health Organization |
| WP | White Paper |

| | |
|---|---|
| ZAR | South African Rand |

**List of Statutes**

Aliens Control Act No. 96 of 1991

Genetically Modified Organisms Act No. 15 of 1997

Medicines and Related Substances Control Act No. 101 of 1965

Patents Act No. 57 of 1978

Universities Extension Act, 1959

Witchcraft Suppression Act No. 3 of 1957

## Chapter 1.0

## Introduction

South Africa is the most developed country on the African continent with a per capita income of US$3000.[1] The country has developed a very strong scientific and technological base in the mining and arms industries. These technological advancements are a result of the political history of South Africa, which led to the country's isolation from the global community. As a matter of necessity, the country had to develop its own technological infrastructure.[2] The apartheid regime developed policies to strengthen its technological infrastructure in the arms industry, textile, and mining and allocated resources to implement these policies but very little focus was placed on developing health technology in the country.

However, in 2000, the South African government begun focusing its research support to biotechnology. This has led to the adoption of a National Biotechnology Strategy, which creates incentives for the development of the biotechnology industry. The Department of Science and Technology (DST) administers the national strategy. The development of health biotechnology is recognized within the broader biotechnology framework as potentially contributing to the national priorities, which include access, and affordability to healthcare, food security, job creation and environmental protection.

### 1.1 The Case Study

This is a qualitative study[3] using grounded theory techniques to analyze data collected from interviews with experts in the biotechnology sector in South Africa, documents and observations. I use the National Systems of Innovation (NSI) framework to identify and

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[1] Department of Trade & Industry, http://www.dti.gov.za

[2] See South Africa study in Mani, S. (2002) Government, Innovation and Technology Policy: An International Comparative Analysis. Edward Elgar, Inc.

[3] Further details in the Methods section (Chapter 3)

analyze factors that have encouraged and/or hindered the development of a successful biotechnology sector in South Africa.

**Objectives of the study**:

- Identify and analyze factors that encourage and /or hinder the development of a successful health biotechnology sector in South Africa
- Gain an insight of how this sector has developed within the context of South Africa's nation system of innovation
- Draw recommendations on how to develop a local capacity to harness health biotechnology innovations to improve health in developing countries.
- A contribution to the available body of knowledge on the applicability of the NSI conceptual framework to developing countries.

The NSI conceptual framework, which is also the framework adopted for South Africa's science and technology (S&T) policy analysis[4], is used in this study as an analytical tool to identify and better understand the actors in the development of the South African health biotechnology sector. Chris Freeman[5] defines the NSI[6] conceptual framework as "a network of institutions in public and private sectors whose activities and interactions initiate, import, modify and diffuse technologies."

This study defines biotechnology by adopting the Organization for Economic Co-operation and Development (OECD) definition of 1998, which defines biotechnology as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services." For the purpose of this study, I also include genome-related technologies and tools such as proteomics and bioinformatics. The study also recognizes the importance of the use of indigenous plants and traditional knowledge, and includes the study of indigenous plants and their products.

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[4] South Africa's White Paper on Science and Technology (1996) adopts a concept of "South African national system of innovation"

[5] In Edquist, C. (ed.) (1997) Systems of Innovation. Technologies, Institutions and Organizations. London Pinter Press

[6] In-depth discussions of NSI in Chapter 2

## 1.2 Rationale of Study

Rapid development in genomics and health biotechnology promise to revolutionize and improve the way diseases are identified, prevented, diagnosed, treated and modulated.[7] Unfortunately most of these developments are taking place in the developed countries, and with very little attention to health biotechnology research focusing on diseases prevalent in developing countries.[8] It is feared that this may lead to a "genomics divide", similar to the digital divide between developed and developing countries.[9]

Technological advances such as the use of molecular diagnostics, recombinant technologies to develop vaccines and the use of genome related technologies such as proteomics, pharmacogenomics and bioinformatics offer various options for addressing public health issues facing developing countries.[10] These technologies have not been fully exploited in developing countries. For instance, South Africa established its first medical research council (MRC) bioinformatics centre, the South African Bioinformatics Institute (SANBI), just two years ago. It is believed that recombinant vaccines have the potential to offer affordable protection against disease for which effective drugs do not yet exist.[11] South Africa is actively exploiting the vaccines avenue, through the South African AIDS Vaccine Initiative (SAAVI).

If these technologies are not adequately harnessed, diseases such as HIV/AIDS, tuberculosis, and malaria will continue claiming lives in South Africa and indeed the rest of Sub-Saharan Africa. It was estimated in 2001 that 2.65 million women and 2.09 million men between the ages of 15-49 were living with HIV. It was also estimated that

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[7] R. Porter, (1997) The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present. London: HarperCollins
[8] S.R. Benatar, A. Daar & P.A. Singer, (2003) Global Health Ethics: the Rationale for Caring, *International Affairs Journal,* 79, 1 (107-138)
[9] Singer P.A. & A.S Daar (2001) Harnessing Genomics and Health Biotechnology to Improve Global Health Equity. *Science* 294 (5540) 87-89
[10] Daar, AS, *et al* (2002) Top 10 Biotechnologies for Improving Health in Developing Countries *Nature Genetics* 32(2): 229-232
[11] Daar, AS, *et al (2002) ibid.*

there were approximately 83,581 babies who had become infected through mother to child (MTC) transmission.[12] The reality this statistics express have a huge impact on South Africa's social fabric and work force, which in turn affects the South African economy.

### 1.3 The South African Biotechnology Sector at a Glance

This is a quick overview of the previous work and publications of the biotechnology sector, highlighting what has already been studied and thus creating a basis for this study. South Africa has made huge strides in the development of the agricultural biotechnology sector and most of data published is on the agricultural sector.[13] It is the first African country to commercialize genetically modified foods. To that effect the government has put in place the Genetically Modified Act (GMO Act-1997) to regulate agricultural biotechnology. While it is noted that having legislation in place is not the only mark of the existence of a robust technology sector, it is worth noting that South Africa does not have any legislation directly addressing health biotechnology.

In the area of health biotechnology there are lots of research activities taking place within various research institutions and universities. The government has three main research institutions doing biotechnology R&D, the Agricultural Research Council, the Council for Scientific and Industrial Research, and the Medical Research Council. Of particular interest is the MRC, which specifically targets health research for disease prevalent in the country. The academic institutions with robust medical and life sciences research include the Universities of Cape Town, Pretoria, Freestate, Natal and Stellenbosch.

There are a number of vaccine development initiatives in the areas of HIV/AIDS, TB, malaria and other non-infectious diseases prevalent in South Africa. South Africa is a country with a rich biodiversity, which has been exploited for years by traditional healers.

[12] Department of Health. (2001) National HIV & Syphilis Seroprevalence Survey of Women Attending Public Antenatal Clinics in South Africa.
[13] See generally Country profile by Koch, M. & Webster, J. in Tzotzos, G.T & Skryabin, K.G (Ed) (2000) Biotechnology in the Developing World and Countries in Economic Transition, CABI Publishing

The government and the MRC have initiated programmes for the development of local indigenous knowledge of medicinal substances. These initiatives have a huge potential impact on the development of the health biotechnology sector.

Despite the very robust R&D environment in South Africa, there are various challenges facing the development of the health biotechnology sector in South Africa. Top on the list is the lack of an adequate critical mass[14], which is partly attributed to the migration of scientists from the country in search of greener pastures and partly due to the apartheid regime, which secluded the disadvantaged communities from good quality education. Other challenges include the lack of adequate funds for research, lack of entrepreneurial qualities among researchers and "the absence of a development oriented research culture."[15] Public perceptions may also stifle the development of biotechnology as aptly put by one South African scientist, "Public perception is the most likely factor to stall further development of biotechnology."[16]

It is argued here that the available literature does not examine the South African health biotechnology sector, but rather emphasizes agricultural biotechnology. The literature does not address the specific roles played by the different actors/stakeholders in the health biotechnology sector and how it influences the development of the sector. It does not examine the existence and extend of collaboration between the different actors and therefore fails to highlight the importance of linkages in the creation of a robust sector.

This study will fill in the gap by identifying the different actors and their specific roles and also examine the different levels of linkages and the nature of linkages. Another novel contribution of this study to the body of existing knowledge is the examination of public perceptions as relating to health biotechnology specifically, which will be a major step towards ensuring that new health technologies are effectively introduced into the healthcare system. This study will also serve as an example of the applicability of the NSI

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[14] Muffy & Webster *ibid.*

[15] Burton, S.G &Cowan,(2001) D.A The Development of Biotechnology in South Africa" EJB, Vol.5 Issue 1

framework, which is largely developed with a backdrop of developed countries, to a developing country.

## 1.4 Organization of Study

The study will be presented in five chapters. Chapter 2 describes the NSI conceptual framework, which has been used for this study. This chapter defines the basic concepts of a NSI. And provides an in-depth analysis of available literature on NSI. The chapter lays a basis for this study by identifying the major institutions that constitute a NSI.

Chapter 3 describes the research methods, including the description of methods of data collection and analysis and the steps taken to enhance the validity of the analysis.

Chapter 4 contains the results of the study. This is an analysis of all the data collected describing the development of South Africa's health biotechnology sector.

The discussions of the themes emerging from the results are contained in Chapter 5. This chapter identifies the successes of the South African health biotechnology innovation system and highlights the lessons that can be learnt from the South African experience and their applicability to other developing countries.

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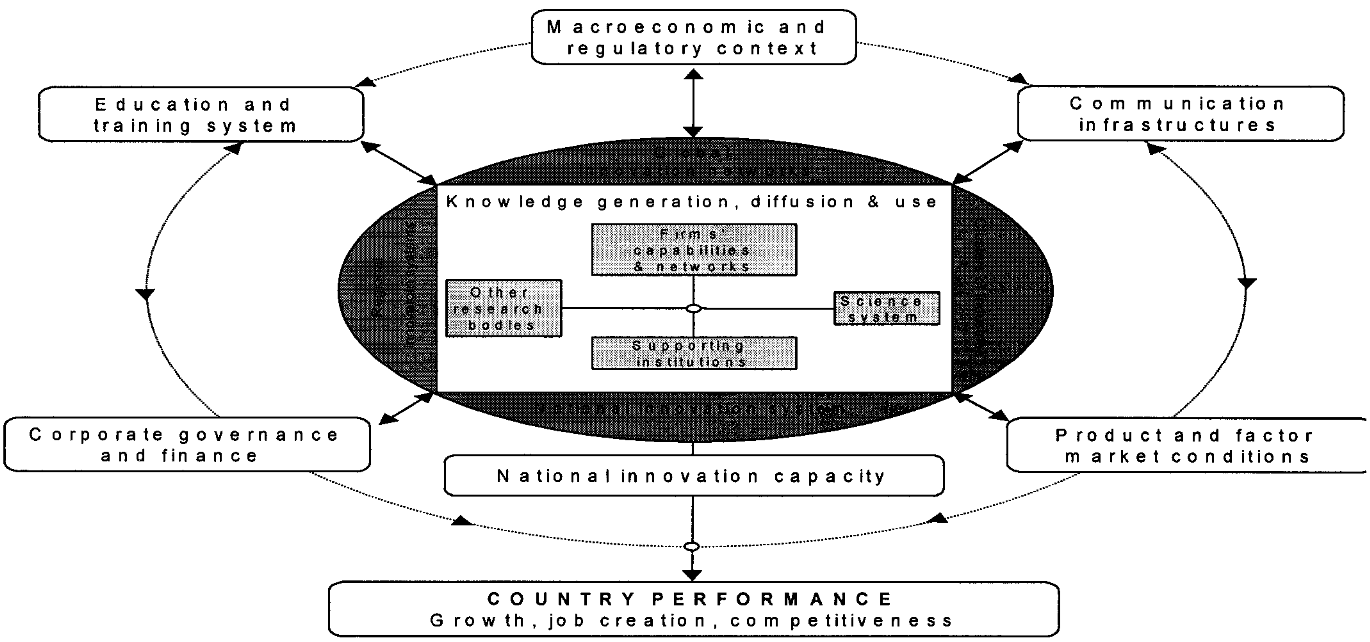
[16] http://www/africabio.addr.com/status/statusf.htm South Africa Status and future Prospects of Biotechnology

## Chapter 2.0 Conceptual framework

### Introduction

This chapter discusses the National Systems of Innovation (NSI) framework. It begins with a section that defines the framework and concepts such as 'innovation', 'learning', 'system' and 'nation' that constitute the basic concepts of the framework. This is followed by a section that identifies and describes the main elements of a NSI. The diagram below represents the institutions that are identified in this chapter as critical and also laying a basis for the study of the South African health biotechnology innovation system. The chapter ends with a critique of the applicability of the NSI framework in developing countries.




<u>*Diagram 2. 1: Institutions within national systems of innovation*</u>

### 2.1 The National Systems of Innovation Conceptual Framework

The concept of NSI is increasingly being used by policymakers as a framework for the analysis and evaluation of different economies and as a suitable framework for understanding various ways to support technological change and innovation. The notion of NSI is a relatively recent development, with its emergence being traced back to 1988.[17] The NSI denotes a system of interconnected institutions involved in the creation, storage and transfer of knowledge and skills, which define new technologies. In the oft cited definition, Metcalfe [18] defines NSI as a,

> "...set of distinct institutions which jointly or individually contribute to the development and diffusion of new technologies and which provide the framework which governments form and implement policies to influence the innovation process."

The definition makes explicit reference to institutions, governments and innovation policies and presupposes the existence of links between the different actors. Edquist,[19] refers to the NSI concept as a 'conceptual framework or an approach, which scholars and policy makers find useful for the analysis of innovation." He draws a distinction between formal theory and a conceptual framework, the difference being that the former denotes theories, which have been proven and not disputed, while the later are useful for the generation of hypotheses and empirical generalizations. This therefore means that the NSI framework is still very conceptually ambiguous, and that any institution could generally fall within the NSI, or could very well be excluded depending on its relevance to technological development.

## 2.2 Definition of Concepts

The conceptual basis of the NSI framework rests on a broadly shared definition of the basic concepts, which are

- Innovation
- Learning
- System

[17] According to Freeman, C. (1995): Bengt Ake Lundvall was the first person to use the expression 'National Systems of Innovation' back in 1988.

[18] Metcalfe, S. (1995) "The Economic Foundations of Technology Policy: Equilibrium and Evolutionary Perspectives." In Stoneman P. (ed.), Handbook of the Economics of Innovation and Technological Change, Oxford, pp. 409-512."

[19] In Edquist, C. (1997) 'Systems of Innovation Approaches: Their emergence and Characteristics' in Edquist, C. (ed.) (1997) Systems of Innovation: Technologies, Institutions and Organizations. London Pinter Press

- Nation

### 2.2.a Innovation

Innovation can be broadly defined to include, technical innovations, organizational, institutional and even social innovations. Nelson & Rosenberg[20] define innovations as the process by which firms get into practice product design and manufacturing processes that are new to them, if not the universe or even to the nation. This definition by Nelson & Rosenberg refers to the processes of technological change that lead to the introduction, production and commercialization of new products and processes. This definition does not just stop at the production of the new products and processes but also includes the diffusion of the products or processes into the market.

Lundvall[21] defines innovation as the outcome of learning processes through which economically useful knowledge is accumulated. In this definition Lundvall suggests that innovation and learning are inseparable, leading to the assumption that innovation is not uni-directional. It is as a result of networking between activities, institutions and agents.

Innovation does not have to be the production of a completely new product or process, in a strict sense. It can be the re-organizing and recombining of already existing ideas or knowledge, into new and novel ways to create new products and/or new processes. This creates the distinction between radical innovations and incremental innovations.

### 2.2.b Learning

Learning and knowledge are closely intertwined. Daniel Bell[22] has ably defined knowledge as " a set of organized statements of facts or ideas, presenting a reasoned judgment or an experimental result, which is transmitted to others through some

[20]Nelson, R. R. & Rosenberg, N. (1993) Technical Innovation and National Systems. In R.R. Nelson (ed.) (1993) National Systems of Innovation: A Comparative Study. Oxford: Oxford University Press
[21] Lundvall, B.-A. (ed.) (1992) National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning. London Pinter Press

communication in some systematic form". Learning is the process by which innovative knowledge is imparted in others. This can be either through the education and training system, apprenticeship, or within the innovative firms in activities embedded within daily routine.

Lundvall[23]defines learning as a complex process that involves the acquisition of new knowledge as well as new combinations of already existing knowledge. As earlier mentioned, innovation cannot be treated as separate from learning, which therefore means that innovation cannot be understood if it is treated as learning that takes place in a vacuum; It is to be viewed as an interactive and cumulative process. Knowledge could be in the form of data, information, codified knowledge or tacit knowledge.

According to Lundvall, knowledge is the most fundamental process in the modern economy and it follows therefore that the most important process is learning. It becomes vital therefore from the viewpoint of encouraging economic growth and employment to analyze the knowledge and learning aspects of systems of innovation. This includes, though not exclusively, the formal research and development system, education and training system, and learning within the firm. Knowledge networks are also important in this regard because not only is the creation of knowledge important but also its accessibility.

Traditional/indigenous knowledge is increasingly becoming important when studying innovation systems in developing countries. Indigenous knowledge is critical in developing countries and less so in developed countries, which rely heavily on science based, research intensive innovations.[24] It is therefore important to integrate aspects of local and traditional knowledge into the economies of developing countries through a broad-based innovation system approach. The concept of using a broad based -approach

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[22] In Castells, M. The Rise of the Network Society: The Information Age Vol. 1 pp. 17
[23] Lundvall, B.-A. (ed.) (1992) *Supra.*
[24] Lundvall, B.-A. et al. (2002) National Systems of Production, Innovation and Competence Building. *Research Policy* 31:213-231

to analyzing innovation systems is relatively new[25] and aims at considering all peculiarities (including knowledge systems) of the innovation system in study.

Learning can either occur at the production level (learning by doing), whereby knowledge production is as a by product of production leading to better and improved production process, or at the consumption level (learning by using), where the feedback from consumers is used to improve the products.

Lundvall identifies different types of learning and classifies them thus:

- Learning by searching, through more institutionalized activity like what happens in an R&D lab.
- Learning by exploring which includes activities within academic institutions and other research institutions.

**2.2.c System**

A system refers to complexes of elements or components, which mutually condition or constrain each other, so that the whole complex works together, with some reasonably defined overall function.[26]

The interactive learning process that characterizes innovations needs to be addressed within a systems approach.[27] The systems approach assumes that the overall performance of a cluster of elements depends not only on the characteristics of single elements, but on how elements mutually constrain and influence each other. In order to describe a system of innovation it is not sufficient to specify its elements or constituent parts. The emphasis should be placed on the relationships between these elements and their interdependence in influencing innovation.[28]

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[25] See generally Lundvall, B.-A.(2002) *ibid.*

[26] Fleck, J. (1992) Configurations: Crystallizing Contingency. *The International Journal of Human Factors in Manufacturing.* Autumn

[27] Lundvall, B. -A. (ed.) (1992) *Supra.*

[28] Marsili, O. (1999) National Systems of Innovation: Survey of the Literature Review for European Biotechnology Innovation System. SPRU:University of Sussex

Nelson & Rosenberg[29] see the innovation system as a concept, which consists of a set of institutions whose interactions determine the innovative performance of national firms. The system concept encompasses a set of institutional actors that together play different but important roles in influencing innovative performance in a country. These institutions include more than just the formal R&D sector.

### 2.2.d Nation

A nation state defines the boundaries, not only in geographic terms but also for relatively homogenous patterns of social and cultural values shaping the institutional set up of a system of innovation.[30] Different experiences, economic, political, historical and/or even cultural, within a country, may influence the pattern and rate of innovation within a country.

National boundaries are important in studying a NSI because different states may adopt different policies or legislation that may affect innovation systems in different ways. This is reflected in the way different countries that though in the same "economic or even political zone", may be at different levels of technology advancement. A good example is a country like South Africa, which is relatively technologically advanced especially as far as biotechnology is concerned, unlike its neighbors like Zimbabwe and Botswana. This difference can be probably attributed to the fact that during the apartheid period in South Africa, which led to political and economic seclusion of South Africa from the rest of the world. This unfortunate experience created a need for self-sufficiency within South Africa and thus an incentive for innovation.

The other reason why nation states are important for NIS is the fact that most trade and commercial policies are shaped and implemented at the national level, and thus

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[29] Nelson, R. R. & Rosenberg, N. (1993) *Supra.*
[30] Lundvall, B. -A. (ed.) (1992) *ibid.*

consequently interpreted by the actions of public institutions in fostering these national policies. Edquist[31] rightly observes that "most public policies influencing the innovation system or the economy as a whole are still designed and implemented at the national level."

The concept of "national systems of innovation" has been criticized as not being very credible in the era of the new economy, which is characterized with efforts towards regionalization, and globalization of trade. To this end, it would be very difficult to precisely measure other external influences on national innovation systems, say, the effect of multi national companies. Lundvall[32] is very critical of this fact and observes that using a nation as a unit of analysis may be inappropriate because a nation may not be characterized by homogeneity of social and cultural values that the NSI approach presupposes.

Many writers on NSI have posited different and various definitions of the concepts underlying the NSI framework, thus leaving the framework conceptually ambiguous. Different studies reveal the fact that there is also not any widely accepted approach to reviewing a NSI. This can be attributed to the fact that different national systems of innovation should be considered in their peculiarity and diversity. Factors such as, which country is being studied, which technology is in question and the period of study can influence the elements that may be taken as relevant for the study. This brings us to the next section of this paper, which analyses the different elements of a NSI.

### 2.3 Elements of a NSI

Lundvall[33] identifies two key elements of a NSI. These are the structure of the production system and the institutional set up.

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[31] Edquist, C. (ed.) (1997) *Supra.*
[32] Lundvall, B. -A. (ed.) (1992) *Supra.*

### i. Structure of the Production System

The structure of the production system is important in a NSI study because it influences the pattern of learning within the firm. The specialization pattern that arises from learning by doing, in the production process also influences the innovation system. The learning process in the production line is important especially if it influences the process of incremental innovations.

### ii. Institutions Within a NSI

Different authors have advanced different definitions of what is meant by 'institutions'. Some authors go as far as to create a distinction between institutions and institutional actors. For instance Edquist and Johnson[34] argue that institutions represent forms of behavioral regularities in society, whereby these regularities are intended as habits of individuals. This definition brings in the distinction created between formal and informal institutions.

It is argued that both types of institutions, formal and informal, have a role to play in the process of technological innovations.[35] Some authors do not create the distinction between formal and informal institutions. This failure to create a clear distinction often leads to the creation of a very narrow taxonomy for the analysis of a NSI.[36] Lundvall[37] suggests that to remedy the ambiguity, consideration must be to "...which sub-system and social institutions should be included, or excluded, in the analysis of the system in a task involving historical analysis as well as theoretical considerations...a definition of the systems of innovation must be kept open and flexible regarding which subsystem should be included and which processes should be studied."

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[33] Lundvall, B. -A. (ed.) (1992) *Ibid.*
[34] Edquist, C. & Johnson B. (1997) 'Institutions and Organizations in Systems of Innovation.' In Edquist, C. (ed.) (1997) Systems of Innovation, Technologies, Institutions and Organizations, Pinter
[35] Schoser, C.(1999) Institutions Defining National Systems of Innovation, Discussion Paper
[36] Schoser, C. (1999) *Ibid.*
[37] Lundvall, B. -A. (ed.) (1992) *Supra.*

Carlsson and Stankiewicz[38] argue that "institutions are the normative structures which promote stable patterns of social interactions/transactions necessary for the performance of vital social functions...by institutional infrastructure of technological system we mean a set of institutional arrangements (both regimes and organizations). Which directly or indirectly support, stimulate, or regulate the process of innovation and diffusion of technology. The range of institutions involved is very wide. The political system, education system (including universities) patent legislation and institutions regulating labor relations, are among many arrangements which can influence the generation, development, transfer and utilization of technologies."

The Carlsson and Stankiewicz concept of institutions seems to be quiet heterogeneous and very complex. It includes 'normative structures', 'regimes' as well as 'organizations of various kinds. They also include laws and regulations determining behavior and organizational structures.

Institutions serve a very pivotal role in technological innovations. They are ones responsible for the facilitation and creation of an interactive learning process, which is very central for the innovation process. Johnson[39] identifies some of these functions as:

- They act as a conflict resolution mechanism
- Are informational devices to reduce uncertainty and ambiguity
- Co-ordinate the production and use of knowledge
- Provide incentives to enable the interactive learning
- Govern cognitive processes and help individuals to form a common conceptual basis and language to understand and communicate and acquire knowledge in an interactive learning process.

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[38] Carlsson, B. & Stankiewicz, R. (1995) On the Nature, Function and Composition of Technological Systems. In B. Carlsson. (ed.) (1995) *Technological Systems and Economic Performance: The Case of Factory Automation.* Dordrecht: Kluwer
[39] Johnson, B. (1992) 'Institutional Learning' in B.- A. Lundvall (ed.)

### 2.3.a Formal Institutions

Formal institutions are basically codified behavioral patterns leading to the creation of a specific organization. Such informal institutions have clearly fixed rules of operation that are explicitly outlined. Most formal institutions posses a kind of "physical existence". This category of institutions includes the innovative firms and companies, research institutions (both public and private), and technology transfer agencies. Technology policies, laws and regulations also fall within the category of formal institutions.

Institutions serve as a very important function in the process of technology transfer and technology change. This is especially so because of the interactive nature of the learning process that brings about innovation. The 1999 OECD report[40] clearly illustrates the importance of institutions, thus,

> "…new technologies are less and less the result of isolated efforts by the lone inventor or the individual firm. They are increasingly created, developed, brought to the market and subsequently diffused through complex mechanisms built on inter-organizational relationships and linkages."

The interaction between institutions creates what may loosely be termed as an "innovative network". The degree of interaction between constituents of the network can be measured indicators such as collaborative R&D initiatives, number of co-authored scientific articles, ownership of patents and citations.

The education system in a country also influences the innovativeness of the people going through the system. It is critical to analyze how the system encourages technological innovations. Universities and research institutions work closely with companies and contribute to the creation and application of new technological knowledge. Factor such as the easy flow of personnel and consequently knowledge (both codified and tacit), between educational institutions and research institutions, or the creation of university spin-off firms can be factors that stimulate innovation.

In the category of formal institutions in a NSI, this study will discuss the different roles of the following institutions in encouraging a robust and innovative national system:[41]

- The role of the government
- The education and training system
- The research and development sector
- The role of firms

### 2.3.b Informal Institutions

Increasingly there has been a realization that informal institutions such as behavioral patterns and social norms and values do greatly influence the general state of innovation within a country. To this end Metcalfe[42] states,

> "In recent years increased emphasize has been devoted to the various informal networks which provide the connections within national systems...such informal networks are important routes for technology transfer and for transfer of more tacit knowledge."

Informal institutions create the social base that facilitates technological innovations. The analysis of informal networks emphasizes the qualitative aspects of cooperation and interaction between producers (suppliers) and consumers. Emphasis here is on the relationship between the firm and producers with consumers, with the aim of establishing the degree of cooperation between the two parties and the existence of communication links that facilitate learning. Most importantly, informal institutions may influence public policy for instance for technology programmes, because in most cases it depends on how much the stakeholders lobby.[43]

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[40] Organization for Economic Co-operation and Development (OECD) (1999) The National Innovation Systems Project

[41] Refer to Diagram No.1 above

[42] Metcalfe, S. (1995) "The Economic Foundations of Technology Policy: Equilibrium and Evolutionary Perspectives." In Stoneman P. (ed.), Handbook of the Economics of Innovation and Technological Change, Oxford, pp. 409-512."

### 2.4 Roles of Different Institutions in a NSI

#### 2.4.a The Role of Government

The government plays important roles in relation to the process of technological innovation and innovation change. In this process, the government plays multiple roles, namely, as a user of innovations, producer of R&D and as a regulator of the process. The diverse roles played by the government are reflected by the public policies designed and implemented by the government. These can be in the form of technology policies designed and implemented by the government, laws and regulations such as intellectual property regimes, financial and tax systems and funding of R& D activities.

Historical evidence shows that the state has a very influential role in facilitating the creation of a robust and successful technology sector in a given country. Classical examples of state driven success and or failure are Japan and China respectively. In the instance of Japan, the country's success in becoming one of the world leaders in information technologies was as a result of strategic guidance from the state.[44] In the same breadth the failure and retardation of the Chinese technological innovations can be blamed on the lack of the states interest in technology and change to state policy during the reign of Ming and Qing dynasties. [45]

This section will analyze the major roles played by government in a NSI. The analysis will be clustered as:

- Technology policies
- Intellectual property regimes
- Financial and tax systems
- Funding research activities

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[43] Diagram 2.1 above illustrates the interaction of social acceptance and market demand
[44] Georgette Wang, (ed.), Treading Different Paths: Informatization in Asian Nations, Norwood, NJ: Ablex pp. 68-97

*Technology Policies*

In general terms, a policy is an official statement with a specific purpose, a set of objectives, defined goals and outcomes, and a set of criteria for choosing among competing alternatives. A policy can be explicit or implicit. An explicit technology policy is desirable in most instances because it induces a direct effect to achieve a specific goal, which in most instances is to spur growth and development in a given area of technology.

The rise of Japan as a leading economic and technological power is a good example of the importance of a nation having an explicit technology policy. Senker, J. *et al.*[46] observe that, "industrial exploitation does not depend on only the amount of money invested by governments or other investors. Associated policies for technology innovation and transfer play a crucial role." Indeed it is now widely argued that a nation will fall progressively behind if it does not have an explicit technology policy.[47]

A technology policy is a set of policy actions to raise the quantity and efficiency of innovative activities. Science and Technology (S&T) policies within a country play a significant role in the development and production of innovations. A government policy often reflects the government's commitment (or lack of it) to advancing technological advancements. Policies promote the formation of new technology firms, as they act as an incentive to invest. Depending on how the policy is formulated and drafted it can promote interaction between academic and industrial researchers.

The presence of an S&T policy provides a framework within which different actors within the innovation system can be technologically involved. It also provides a mechanism for government funding of R&D initiatives.

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[45] These leaders are said to have lost interest in technological innovations and were interested to please the social elite whose interest was in the arts and humanities

[46] Senker, J. *et al.* (2000) European Exploitation and Biotechnology-do Government Policies Help?, *Nature* June, Vol. 18 pp605-608

[47] Nelson, R. R. & Rosenberg, N. (1993) *Supra*

However it must be noted that the mere presence of a technology policy does not provide a blue print for technological innovation. The policy must be supportive of innovation and must identify new opportunities that contribute to technology development in the country.[48] Policies must be appropriate to the country's conditions and needs and must be able to reinforce a country's competitive edge.[49] This is clearly reflected in the different technology policy approaches adopted by countries such the United States, which radically differs from that taken by Japan, and further differing from that taken by say Germany.

Inappropriate policies may stifle technological innovations. This has mainly been the case in African countries, for instance the biosafety policy framework adopted by Kenya has been blamed for the slow development of agricultural biotechnology in Kenya.[50]

Technology has a generally crosscutting nature affecting many other disciplines or aspects of life. A challenge for developing countries in policy formulation and administration is to be very careful not to take a piecemeal approach. Technology policy must take a systemic view, in the sense that different policy actions should not contradict each other. Technology innovation policies should be able to interact with other policies without conflicts or contradictions. Efforts directed towards policy coordination can be extremely valuable for developing countries.

There has been a lot of discourse for and against globalization of developing countries. It would be foolhardy for developing countries to ignore the effects of globalization to their own systems of technological innovation and technology transfer into the different specific countries. Globalization may affect the process of knowledge acquisition by use of patents and copy rights, and most times may be used to exploit poor countries, as was

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[48] Carlsson, B. & S. Jacobson (1997) 'Diversity Creation and Technological Systems: A Technology Policy Perspective.' in Edquist, C. (ed.) (1997) *Supra.*

[49] Allansdottir, A. *et al* (2002) Innovation and Competitiveness in European Biotechnology. *Enterprise Papers No. 7,* Enterprise Directorate-General European Commission

[50] Paarlberg, R. (2000) Governing the GM Crop Revolution, Policy Choices for Developing Countries. *Food Agriculture and the Environment Discussion Paper 33.* International Food Policy Research Institute

recently evidenced in South Africa where pharmaceutical companies denied cheap access of anti-retrovirals for the treatment of HIV/AIDS, claiming patent protection.[51]

In light of the globalization debate and the increased convergence in the economies of most countries (especially those of industrialized nations), is it really relevant to have a national technology policy? It has been increasingly argued especially in developed countries, that national technology policies, designed to give national firms a competitive edge are now obsolete in a world where trade, finance and technology cross national borders. [52] The approach taken by Japan illustrates that national technology policies are not necessarily obsolete despite the world becoming a global village. The Japanese Ministry of International Trade and Industry (MITI), under whose portfolio science and technology is, has adopted a number of strategies within its national technology policy to both support national technological innovations, while at the same time "achieve harmonious international relations."[53] This has been achieved by allowing and indeed encouraging foreign companies to be actively involved in otherwise national R&D programmes.

*Intellectual Property Rights (IPR)*

Intellectual property rights are essentially established to perform two functions namely to create incentives for innovative behavior and to help diffuse knowledge. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)[54] states that the objective for IPR protection should be to,

> "...to contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and a balance of rights and obligations."

[51] 39 pharmaceutical companies sued the South African government in 1998 objecting the government's bid to provide cheap generic drugs to 4.7 million people living with HIV/AIDS
[52] Fransman, M. (1995) Is National Technology Policy Obsolete in a Globalized World? The Japanese Response. *Cambridge Journal of Economics*, 19 (1) 5-24
[53] Fransman, M. (1995) *ibid.*
[54] TRIPS Agreement constitutes Annex 1C to the Marrakesh Agreement establishing the World Trade Organization (the WTO Agreement)

IPRs through patent systems make it possible for innovative firms to appropriate the benefits of their innovative activity. However, IPRs are not the only appropriation method available to firms, other methods such as secrecy, lead-time advantages and technological complexity can be used. It therefore becomes a policy question to ensure that a country adopts an optimal IPR regime. An optimal IPR regime in this case would be one that achieves both goals of encouraging innovative activity and also knowledge dissemination without breeding an unhealthy monopoly that interferes with the diffusion of new innovations.

Of most relevance to biotechnology innovations are patents. A patent is a legal property right over an invention, which is granted by the national patent office. A patent provides its owner a monopoly (with limited duration) for exploiting the patented invention as an incentive for disclosure. Patent systems are very efficient as a tool for information dissemination especially in technologies that are rapidly evolving such as biotechnology.

Patents provide a vehicle through which inventors can gain a means of appropriating their ideas generated to society and at the same time can create monopolies, which may interfere with the diffusion of the new inventions. Patents should ideally stimulate inventive activity and at the same time should discourage the inventor from "hoarding" useful knowledge by disclosing it through patent process. This places a very onerous task to policy makers, the task of ensuring that the patent system rewards inventors and at the same time does not impose impossible royalties on users, to the extent that it reduces the usage of the invention to a sub-optimal level.

A country may choose to adopt a "strict" patent regime, where innovative firms get full patent protection for their inventions, as is the case with the US owned genetically modified seed companies, or a less strict regime. What may be termed as "less strict" regimes have been found to work best for innovative activities in most countries, especially developing countries. For instance, the IPR regime in Brazil does not offer significant patent protection in areas of chemicals, pharmaceuticals, metal alloys and mixtures. One of the principle rationales of the Brazilian property rights system is to protect the local firms from potential exploitation by foreign producers and to reduce the costs of appropriating relevant foreign technology and using it for their own local context as a means of technology transfer.

However, countries, especially developing countries should be very cautious when adopting a “less strict” approach because it has its down sides. For instance such a regime could possibly deter foreign firms from transferring or using locally their most advanced and up to date technology. The balance, I would think, created by introducing other incentives such as conducive FDI policies and tax regimes and subsidies may offset the disincentive created by a less strict regime.

The presence of a patent system and a patent office in a country is not in itself enough for the diffusion of knowledge. Firms within the industrial sector have to use patents as a source of technological knowledge. It would be important therefore to maintain a patent database within a country and make it as widely accessible as possible. This is one challenge that faces developing countries. Most developing countries hardly maintain any patent databases. It therefore becomes a daunting task to try and assess the impact of patent systems to knowledge distribution within an industry.

Small innovative firms may be discouraged from patenting their innovations by the high costs that accompany the whole process of patenting a product. The patenting procedure in most countries is complex and time consuming and requires the hiring of legal expertise, which small firms are unwilling to do. The cost of obtaining, maintaining and enforcing patent rights may be so high as to discourage small firms from seeking patent protection. It is therefore important to study the patent system in a NSI survey to establish the implications of the IPR regime and its effects to the innovative capability of firms.

Another very important aspect to consider in an IPR system would be the method of appropriation for university research, either contract research or otherwise. Universities, especially public universities, are ideally the powerhouses of new knowledge and a means through which scientific and technological networks are formed. A system that allows universities and other public research institutions to restrict free access to research information may stifle innovation rather than encourage innovation especially in developing countries where scarce financial and human resources must be shared among institutions.

*Financial and Tax Systems*

A successful innovation system can be built around a variety of financial structures. The two most common are the bank-based system, or the stock exchange-based system. Different countries have different systems of financing S& T initiatives, and are mostly influenced by social and cultural factors that are country specific. For instance a venture capital is very important for the US innovation system, while it is almost of no importance to Japan.[55]

Investment in technological innovations is characterized by a high degree of uncertainty. Just by the nature of technological innovations, it may take a very long time before an innovative firm can realize any returns or real profits from such an investment. In addition to this, at the time of setting up most technology firms, most of them do not have much in the form of tangible assets to attract any substantial start up capital. All they might have is the knowledge and skills of the founder members. This makes it very difficult to assess the market value of the firms and at times may discourage risk averse investors from investing in such technological ventures and consequently it becomes very hard to attract funds especially in a bank-based system.

The financial structure within a country has an impact on the innovative capabilities of firms and indeed can be a bottleneck for the development of new technologies if financial institutions allow short-term profit objectives to over-ride the long-term objectives of an innovative firm.

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[55] Robin, C. & G. Paal (2000) Innovation Policy in a Knowledge-Based Economy. *MERIT Study*. Publication No. EUR 17023

Governments in developing countries would do well to provide financial incentives to small firms as an encouragement, especially in instances where such small firms are competing with established multi-national corporations. Such financial incentives that would prevent small firms from being choked out of business by multi-national corporations would be for instance the provision of tax breaks/holidays. Another way that would encourage R&D would be to treat money spent on R&D as tax exempt expenses.

*Funding Basic Research Activities*

Basic research has all the characteristics that tend to lead investors to under invest in it. These factors include large investment costs, uncertainty of the outcome and the potential inappropriability of rewards. This therefore makes direct government involvement in basic research justifiable and even encouraged. Government funding could either be directed to university basic research activities or industrial research activities. The best funding model would be one that encourages collaboration between the two, to avoid duplication and unnecessary expenses of already scarce public funds.

Public funding for basic research, especially in developing countries can be in the form of human resource creation through programmes for financial aid in higher education and graduate fellowships. Such funds may also be used to support the acquisition of the physical equipment essential to research by providing expensive scientific equipment and well-equipped laboratories. Such funds may also be used for hiring highly qualified personnel who may demand very competitive salaries. The provision of competitive salaries in public research institutions may also help to curb brain drain from developing countries to developed countries.

The US innovation system has government funding for basic research in universities as one of its strengths. A study carried out by Mowery & Rosenberg[56] illustrate the

[56] Mowery, D.C & Rosenberg, N. (1993) The U.S National Innovation System. In Nelson, R.R. (ed.) (1993) *Supra*

following points on the importance of government funding for basic research especially in universities:

- It strengthens university commitment to basic research and builds up a strong knowledge base for innovation
- It reinforces the links between research and teaching activities (which is an important aspect of a NIS as discussed later)
- It helps to relate more effectively basic research and industrial application

### 2.4.b The Role of Education and the Training System

The education and training system is generally considered as a fundamental dimension of a NSI.[57] It is composed of schools, polytechnics, colleges and universities. The education and training system of a country is important because innovative activities of firms and other research institutions depend on the support of a "growing supply of qualified people from the education system and a thorough industrial training system for a variety of craft and technical skills."[58]

It is argued that the education and training system is important for innovation for two main reasons, it determines the supply of skills in scientific, engineering and technical fields of knowledge and influences the attitude of workers towards new technological innovations and technological change.

Universities represent the main institutional actor of the higher education system though it may be unfair to say that other educational institutions do not make any contribution to the innovation system. For universities to make meaningful contributions to an innovation system, it is not only the general level of teaching that is important, but also the ability of the education system "to adapt with speed and flexibility to new

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[57] Lundvall, B. -A. (ed.) (1992) *Supra.*
[58] Freeman, C. (1992) The Economics of Hope: Essays of Technical Change, Economic Growth and the Environment. London and New York: Pinter

developments in science and technology".[59] To be able to achieve this degree of flexibility, the higher education system needs to combine different areas of knowledge in more creative and non-traditional ways. This flexibility goes hand in hand with the multi-disciplinary character of developments in science and technology.[60]

Important also is the ability of universities to establish links between industry and higher education. Such links could be created through various ways. One way would be the integration within the courses of an internship programme where students do practical work in a real industry situation. This helps to expose the students to real problems and gives them an opportunity to practice what they have learnt theoretically in class. It is also acts as "filters" for hiring personnel into the firms from the universities.[61]

The German Innovation System emphasizes the importance of apprenticeship, and learning through experience. The creation of a liaison between universities and research institutions and with industry serves the important function of binding the scientific and technological communities and industry, thus providing an opportunity for students to learn by doing.

Education and training systems in schools and other training institutions reflect social and cultural values of the country. These social and cultural values may influence the content of the education system especially in terms of integration of diverse fields of knowledge.[62] In examining the nature of education and training systems in a country some of the pointers to look for are whether the education system over specializes in certain fields. For example most education systems in Africa over emphasize white-collar careers due to the creation of a huge working class population during the colonial era. The effects of such emphasize to the innovation system cannot be gainsaid.

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[59] Nelson, R.R (ed.) (1993) National Systems of Innovation: A Comparative Study. Oxford: Oxford University Press

[60]Keck, O. (1993), The National Systems of Technical Innovation in Germany', in Nelson, R. R. (ed.) National Systems of Innovation. A Comparative Analysis, Oxford University Press.

[61] Mowery & Rosenberg (1993) The U.S National Innovation System in Nelson R.R. (ed.) *Ibid.*

Marsili[63] argues that an education system that overspecializes in certain fields diminishes the absorptive capacity of the students in the sense that graduates will have difficulty absorbing knowledge from outside their domains. This would be a major flaw given that innovation requires a certain degree of dynamism. The education system should be broadly based and forward-looking.

The broadening of knowledge bases and the need to be flexible at the firm level implies a need for broadly educated and trained personnel simply so as to remain competitive through innovation. The broader the education the more flexible the worker is in transferring from job to job and thus technology transfer and dissemination of tacit knowledge. Knowledge mobility is encouraged for a successful NSI.

With respect to learning at the firm level, in-house education, on job training and rotational schemes for workers within a firm may facilitate the introduction of new products and processes. The training and education system implemented by a firm not only increases workers' skills, but also their flexibility to adapt to changes in the working environment. Such changes may occur as a consequence of technological innovation. The training and education system is an important source of variety of skills and can reduce the strength of inertial forces within the firm.[64]

### 2.4.c The Role of the Firm

The bulk of the effort to innovate must certainly come from the firms, and this makes them the most important element in an NSI.[65] Firms are important in a NSI for their coordinative role in organizing search and innovative processes. An industrial firm is defined ' with reference to its administrative framework, within which industrial activities

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[62] Marsili, O. (1999) National Systems of Innovation: Survey of the Literature Review for European Biotechnology Innovation System. SPRU: University of Sussex.
[63] Marsili, O (1999) *Ibid.*
[64] Odagiri, H. & Goto, A. (1993) The Japanese System of Innovation: Past, Present and Future. In Nelson R.R. (ed.) *Ibid.*
[65] Schoser, C. (1999) Institutions Defining National Systems of Innovation: A New Taxonomy to Analyze the Impact of Globalization. *University of Freiburg Discussion Paper No. 20.* See also Schumpeter, J. (1912) generally

are co-ordinated.[66] By the fact that firms have access to and can develop technical novelty and market selection, they play the important role of organizing and directing innovation.

Firms may be in the form of large multi-national companies (MNCs) or small and medium sized companies (SMCs). For these companies to remain competitive they must attain a certain level of competence, which is embedded within the personnel within the firm.

It is imperative to understand what characteristics make a firm more or less innovative and how innovation is generated within a firm. Though generally, it may be said that the propensity of a firm to innovate depends on technological opportunities it faces, it is not always true for all firms. Technological capability of a firm and its behavior is shaped by other institutions that constitute constraints and incentives for innovation such as laws, health regulations, social rules and technical standards.[67]

The innovative success of a firm also depends to a large part on the presence of skilled labor force and other characteristics of the firm in terms of the financial structure, strategy on markets, alliances with other firms and universities. The presence of alliances with other firms and universities is very important since as Freeman[68] observes, "networking is now becoming of critical importance for effective innovation." It is important to establish both trade networks and knowledge networks between these firms.

### 2.4.d The Role of Research Institutions and the R&D Sector

Those institutions directly involved in the production and diffusion of new scientific and technological knowledge characterize a country's R&D system.[69] The R&D system comprises of both the public and private institutions, such as university laboratories,

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[66] Definition by Penrose in Edquist, C. (ed.) (1997) Systems of Innovation, Technologies, Institutions and Organizations, Pinter

[67] Edquist, C. (ed.) (1997) *Supra.*

[68] Freeman, C. (1992) *Supra.*

national research institutes and industry. The relationship between all actors in the R&D system is important in terms of contributions made towards research.

The government plays a huge part in influencing innovation by funding R&D activities within its interest areas. For instance a country may make a policy decision to fund health biotechnology research in line with its national priority to alleviate and eradicate disease and poverty. Therefore in a way the R&D sector within a country can be used to identify the areas of priority within a country. For instance national security is of prime importance for the US as a result of terrorist attacks, most federal funds are expected to go towards R& D related to security and warfare.

### 2.5 The Existence of Networks and Linkages

Having discussed the roles of different institutions in an NSI, it is important to stress the importance of the relationships that exist between these different institutions. Given the fact that in a NSI, innovation is not only determined by the actors, but also by the relationship between them, it becomes imperative to analyze the relationship between them. In pursuit of innovation, firms interact with other organizations to gain, develop, and exchange various kinds of knowledge, information or even gain other type of support such as financial or human resource.

Innovation is a result of complex interactions between and among different institutions and other external conditions, it is therefore important to have a very cohesive network between the different actors in a NSI.

### 2.6 A Critique of the NSI Approach

The NSI concept is ridden with numerous conceptual ambiguities. The NSI approach is based on concepts such as "innovation" and "institutions", which do not have a widely accepted definition. This lack of clear a definition makes it very hard to create an

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[69] Freeman, C. (1992) *Ibid.*

applicable taxonomy of what constitutes a NSI. The introduction of the Oslo Manual in 1996 by the OECD was an attempt to create a common taxonomy for innovation systems surveys. However the taxonomy has been criticized as falling short of creating an applicable taxonomy not only for the developing countries but also for the developed countries.

The lack of a common applicable taxonomy for NSI surveys makes it very hard to define the limits of what should be included in a system of innovation. However this is not entirely a weakness as this absence of a clear demarcation of what does and does not constitute a system of innovation could be used to enable the policy makers to identify the core players of the NSI in question and therefore include circumstances only peculiar to the country in study.

Having said that, is the NSI approach relevant for developing countries? The relevance of the NSI approach to developing countries greatly depends on how it is applied. It would not be right to assume that similar circumstances prevail in developing countries as those in developed countries. That would also mean that developing countries are faced with other challenges that greatly influence the government's commitment to innovation. For developing countries, innovation must be relevant to the national priorities, which in most cases are food and nutrition, provision of basic health and poverty eradication.

It is also important to consider the fact that globalization has affected the developing world in a totally different way from how it has affected the developed world. To some extent it is justified to say that globalization has exposed developing countries to exploitation and unfair trade practices. Therefore when analyzing a system of innovation in a developing country, it is important to study the effects of MNCs to the country's innovative capability.

On the other hand, the NSI approach is a very useful tool for measuring economic development and identifying areas that require policy attention. It would therefore not be wise to totally ignore the approach and dismiss it as inapplicable for developing countries. It is also a useful tool for identifying a country's competitive edge and thus enabling the government to create policies that further enhance this competitive edge as against other countries.

**Summary**

This chapter on the NSI conceptual framework introduces the reader to the definition of the framework and lays the groundwork for the analysis of the South African health biotechnology innovation system. The definition of basic concepts such as 'innovation', 'learning', 'system' and nation enable the reader to understand the underpinnings of the framework and is thus able to identify the institutions that characterize a national innovation system. It is reiterated here that the most important aspect of an innovation system is not only the institutions but also the presence, nature and extent of the existing linkages and knowledge networks between these institutions.

The following chapter discusses the methodology used for this study. The chapter details the processes and methods for collecting data on the development of the South African health biotechnology innovation system and how the data was analyzed and validated.

## Chapter 3.0 Methodology

This is a chapter on the methodology used for this study. Although not a grounded theory study, the data for this study was analyzed using grounded theory techniques. In this chapter I give a detailed account of the processes and methods used for data collection and data analysis, and the methods used for data validation and enhancing data integrity. The chapter begins with a brief definition of the NSI conceptual framework and identifying the main themes that form the basis for the data collection process. The chapter ends with a section that identifies the methodological weaknesses of this study and a small section on research ethics processes undertaken for this study.

### 3.1 Methods

#### 3.1.a Research Design

This was a case study of the development of the health biotechnology innovations system in South Africa. A case study is an empirical inquiry that investigates a contemporary phenomenon within its real life context.[70] This case study used the National System of Innovation (NSI) conceptual framework.[71] The case study method is preferred for this study since NSI processes require complex interactions through linkages, are country specific and therefore very context specific and involve social processes.

### 3.2 Conceptual Framework

The NSI conceptual framework was used as an analytical tool to identify and analyze the factors, which have encouraged a successful development of health biotechnology in South Africa. The themes emerging from the NSI conceptual framework are used to evaluate the description of the South African health biotechnology innovation sector. The NSI framework denotes a system of interconnected institutions involved in the creation,

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[70] Yin, R.K (1994) Case Study Research: Design and Methods. Thousand Oaks, CA: Sage Publications, Inc.

storage and transfer of knowledge and skills, which define new technologies. The framework was used as an analytical tool for identifying the different aspects of what comprises an innovation system. The framework also provided a lens through which the different roles played by the actors in the innovation system are analyzed. The questions asked in the interviews were structured in a way that elicited answers that provided more information on these aspects.

### 3.2.a Main Actors

As mentioned in chapter two the NSI framework has been defined as "a set of distinct institutions which jointly or individually contribute to the development and diffusion of new technologies and which provide the framework which governments form and implement policies to influence the innovation process." This definition assumes the presence of different institutions in an innovation system (herein refereed to as actors) working together with government to develop the innovation system.

I was therefore interested in finding out who the main actors are in South Africa's health biotechnology innovation system are and what their specific roles are in the development of the same. I explicitly asked the interviewees this question: *"Who are the main actors in the health biotechnology sector in South Africa."* This question anticipated that the interviewees would identify the different actors, after which a further question would be asked on what their specific role is, such as "*Could you please describe the role of each of them.*"

The main themes emerging from the NSI conceptual framework that guided the data collection process included,

- The role of government:

The government influences the development of an innovation system through the institutional and policy infrastructure set up to support health biotechnology development

[71] See Chapter 2 on conceptual framework for detailed discussion of NSI

in the country. The government also influences biotechnology innovation through legal and regulatory frameworks such as intellectual property protection regulations and tax and financial systems. The information gathered in the interviews and from documents identifies how the South African government participates in the health biotechnology sector.

- The role of the education sector

The education sector supports the supply of skilled human labor into the health biotechnology innovation system. I was interested in understanding the particular role played by the education system in South Africa towards supporting the growth and development of health biotechnology in South Africa. The contributions of the education sector to health biotechnology development could be in the form of education and training. It could also be in conducting basic research and translating it into applied research that consequently supports industry by creation of spin off companies. I was interested to find out to what extent the South African education sector does that.

- The role of the private sector

Firms have been identified as the most important element of a NSI[72] as the bulk of the effort to innovate comes from them. I was interested in collecting data that provides information on the size and characteristics of the private sector firms in South Africa. The contribution of both local and multinational firms towards health biotechnology development is of interest to this study.

- The role of the R&D sector

The R&D sector provides the scientific and technological base for the country and is constituted by different research institutions. I was interested in identifying the main health biotechnology research institutions in South Africa and what their specific roles in the development of health biotechnology are. Of particular interest was identifying what

[72] Schoser, C. (1999) Institutions Defining National Systems of Innovation. A Taxonomy to Analyze the Impact of Globalization. *University of Freiburg Discussion Paper* No. 20

their specific research activities/programmes are, and why these programmes are identified as priority areas for research.

### 3.2.b Linkages

The NSI conceptual framework emphasizes the presence of linkages and networks between the different actors. These linkages may be in the form of collaborative research, provision of research funds, have an administrative purpose, education and training, and commercialization of health biotechnology products. I was also interested in finding out the nature of the linkages that exist between the different actors and whether people preferred formal or informal linkages and the reasons for their preference. Accordingly, this study examines the extent and patterns of linkages between the different actors within the innovation system and the extent and patterns of international linkages. I was also interested in finding out what the advantages and/ or challenges are in maintaining the linkages between the different actors.

### 3.2.c Market Demand and Social Acceptability

This study identifies the main health biotechnology products and services in the innovation system. I was interested in finding out what factors contributed to the development of the particular product and therefore explore the extent to which production is influenced by the domestic market needs *vis-a vis* the export market.

The social acceptance of health biotechnology product influenced by the level of understanding and knowledge of the risks and benefits of biotechnology largely influences the success rate of a new technology especially in developing countries. I was interested in finding out what the public perceptions of health biotechnology are in South Africa and how receptive the public is to health biotechnology services and products.

### 3.3 Setting

This study was conducted in four major cities of South Africa namely, Pretoria, Johannesburg, Durban and Cape Town. The choice of these cities was influenced by the focus of the study, which is to identify the main factors contributing to successful health biotechnology development in South Africa. These cities were identified after compiling the list of potential informants and then finding out in which cities they were located in. These cities were identified as having large presence of public research institutions, universities, relevant government offices and private firms, within the cities or in nearby cities.

### 3.4. Identification of Key Informants

The themes identified above guided the scope of the data collection process. Before beginning the data collection exercise, I conducted a search and "recruited" key informants. The criteria used for identifying the key informants/participants is that they are either current or former employees of the major institutions involved in the development of health biotechnology in South Africa. I also examined background documents describing the biotechnology development in South Africa and where possible I conducted Internet searches on institutions and of the people I wanted to interview.

I also relied on recommendations sought from people knowledgeable in this field such as from staff in the New Partnership for Africa's Development (NEPAD) and the World Health Organization (WHO). The basis for the selection of the informants is their expertise on health biotechnology development in South Africa.

I contacted the identified experts by e-mail. The initial email introduced them to the study and I explained to them what the study was about and describing to them what the aims and purposes of the study were. I informed them how long the intended interview would last (60-90 minutes), and asked whether they were willing to participate. All the people contacted were willing to participate. I then proceeded to contact them either by email or telephone to set up an interview appointment. Some of the key informants identified other potential informants, a technique known as snowballing sampling. I then contacted them using the same process described above. The following section describes the data collection process.

### 3.5. Data Collection

I collected the data in the months of July and August 2002. The main sources of information for this study are semi-structured interviews of key informants, sampled documents and observations. The key informants are identified using the process described above, as people whose daily work affects the South African health biotechnology innovation system. The people identified included high level executives and distinguished researchers within their respective areas of work. There was a representation of both genders, with 9 females and 19 males interviewed. All the key informants have at least a university first degree, and are considered as influential in their areas of work.[73]

The study uses the theoretical sampling method to sample key informants and documents. This is the concept of "sampling on the basis of emerging concepts" to determine which are "key".[74] For instance if a person was mentioned as influential in an aspect of health biotechnology development in South Africa, either on a document or by another person, I would seek to interview that person. The same applies to documents that are mentioned as important.

[73] The key informants consisted of medical doctors, virologists, government bureaucrats, university professors, policy specialists, business managers and private entrepreneurs.
[74] Strauss, A.L., & Corbin, J.M., (1990) Basics of Qualitative Research: Grounded Theory Procedures and Techniques. Newbury Park, CA: Sage Publications. Page 176

### 3.5.a. Key informant Interviews

An interview guide was prepared before conducting the interviews.[75] The interview guide was developed based on relevant literature on NSI and previous research. It was developed through a consultative process with a multi-disciplinary research team. This consultative process enhanced the focus of the research and further sharpened the underlying themes for this study. The interview guide was then circulated to external experts who have conducted similar studies in Europe for comments and advice.

Key informants were interviewed in a face-to-face setting. In three instances I also used group interview settings, where I interviewed informants from the same institution at the same time. The group interview settings were particularly useful because they allowed for deliberation and debate among the informants, which in itself was a confirmatory process of the data being collected.

The key informants were first asked open-ended questions, such as "*Who are the main actors in the health biotechnology sector in South Africa*?" Such open-ended questions were then followed with more specific question such as "*How would you describe the role of public research institutions in supporting health biotechnology in South Africa?*" The specific questions were asked especially if the respondent/interviewee did not mention the issue in question. I will use the following excerpt from one of the transcripts to illustrate the interview process.

| |
|---|
| *Interviewer:* *Who are the main actors in the health biotechnology sector in South Africa?* |
| *Respondent:* *That I don't think I'm going to be able to give you information on. If we look at it from a research perspective, then we would say it is both our researchers in our statutory institutions, it is also the high education sector where much of this research work on the biotechnology front happens. Our Medical Research Council has limited operational research activities at the MRC. It is has it more in what you can call research nodes, at a hospital, at a higher education sector, clinics and so forth. So you find they are also stakeholders in this because they are engaged in this research field on* |

[75] Interview Guide attached as Appendix 1

*the health front. Then we can't really at this stage speak of pharmaceutical base here in South Africa. In fact it's part of our strategy that we would develop a pharmaceutical base. The argument I made earlier about saying we have lost biodiverse resources here. South Africa holds about one tenth of the world's biodiversity and the contributions we can make in terms of pharmaceutical products is a lot that we haven't actually explored. So let's call it the future pharmaceutical industry, is an important stakeholder/role player. So we look at what there is. We look at potential, whether it's a new core that we are going to pull out of graduates and so on, from the universities and so forth. And of course, we have government itself as an important stakeholder because government always has that responsibility for addressing health needs of a nation. And government itself designs instruments and so forth to deal with that. And so they have a stake in, how we are approaching the whole biotechnology front, what can it do [i.e. biotechnology] what are the risks involved. Is that answering your question?*

From this broadly open-ended question, I was able to identify distinct actors involved in developing health biotechnology in South Africa. These actors include the statutory research institutions, of which the MRC is one. The next is government and then the high education sector (universities) and hospitals. From this answer I was able to identify that the MRC has research nodes at universities and hospitals and that pointed towards the presence of research linkages. This answer also claims that South Africa has no pharmaceutical base, though it is anticipated that it will grow based on the exploitation of biodiversity in the country. This answer did not talk about the particular roles the different actors played, so I went on to ask the same informant a structural question[76], aimed at focusing further the roles of the different actors.

Interviewer: *Just to expound on the different stakeholders that you have mentioned, you began saying the role of government in the development of instruments...could you just tell me the role of each of these. You mentioned the researchers, how do they contribute. The high education sector, how does it contribute, the MRC and how do you see the pharmaceutical in future contributing and the government?*

The informant then went ahead to clarify the different roles played by the different actors towards developing health biotechnology. In instances where the informant did not clearly identify the specific roles, I followed them with verification questions. The same was done for all interviews. For instance for the same sample interview used above I specifically asked,

> *<u>Interviewer</u>: has the government put in place things like tax incentives to act as incentives for investors in the health biotechnology industry?*
> *<u>Respondent</u>: No, no tax incentives...in fact as a country we have been steering away for quite sometime from indirect incentives. We do have a few special levies and tax incentives in terms of industry development and also just one broad based tax incentive in terms of R&D being given expensing treatment when looking at tax requirements from companies. So instead of treating R&D as an investment it's deductible as an expense. And other than that, we really support biotechnology engagement through direct incentives. So in effect we have special programs like one that's called the National Innovation fund which has a window there dedicated to biotechnology...I could just site one or two of them for you.*

The interviews lasted approximately 60-90 minutes. They were all audiotaped and transcribed. The sample size of the individuals to be interviewed was not predetermined before the interview exercise. However there was a conscious effort made towards ensuring an adequate representation of academia, public research institutions, government policy makers and private firms. This study however, lacks an adequate representation of civil society. I was not able to interview representatives from non-governmental organizations (NGO), lobby groups, or traditional healers' representatives. This can be partially explained by the fact that unlike agricultural biotechnology, health biotechnology has not evoked the same public reactions and as such there is no active civil society constituency for health biotechnology in South Africa.

In total there were 22 interviews with a total of 28 people interviewed.[77] Table 1 below, represents the number of people interviewed from the different sectors.

| **Sector** | **No. of People Interviewed** |
|---|---|
| Government Policy | 5 |
| Academia | 9 |

[76] Defined as questions that function to focus further the researcher's enquiry by expanding and enhancing the description of a particular area of research interest. See Crabtree, B.E. & Myer, W.J., (1992) Doing Qualitative Research. Newbury Park, CA: Sage Publications

[77] Out of the 22 interviews there were three group interviews; two of which had 3 people and one had 2 people

| | |
|---|---|
| Research Institutions | 9 |
| Private Firms | 5 |
| **Total** | **28** |

*Table 3.1: The number of people interviewed from different sectors*

Sampling decisions were made concurrently with data analysis until theoretical saturation was reached. Theoretical saturation was attained when no new concepts emerged during the analysis of successive interviews. Information that was not anticipated by the interview guide is also captured and analyzed. For instance it was not anticipated that there would be a mention of the effects of apartheid on the development of human resource for biotechnology. Apartheid was mentioned as causing the South African scientists to start thinking innovatively about research that would benefit the country and therefore led to expansion of the science and technology (S&T) base in South Africa.

### 3.5.b Document Sampling

The documents sampled in this study include relevant published information, governmental reports and other government documentation such as policy briefs and descriptions of legal and regulatory frameworks. Key documents were obtained as hard copies from South Africa or electronically where possible. Examples of documents that were sampled include among others[78]:

1. White Paper on Science and Technology (1996)
2. National Biotechnology Strategy (2001)
3. National Strategy for Mathematics, Science &Technology (2001)
4. Health Research Policy in South Africa (2001)

### 3.5.c Observations

The interviews took place at the institutions of the informants and thus made it possible to take additional notes on observations. For example I was able to make tours in the labs and took notes of what I saw. These observations are corroborated with the audiotaped interviews. For instance, I toured the Diarrhoeal Pathogens Research Unit at the Medical University of South Africa (MEDUNSA). In this lab I was able to verify some of the things that the informant had mentioned such as shortage of staff, and also the presence of Elisa tests that had been developed in the lab for internal use.

### 3.6 Data Analysis

This study takes a non-statistical approach to analyze the information from data gathered from multiple sources. Although not a grounded theory study, the data was analyzed using grounded theory techniques.[79] The data analysis was organized in 2 phases open and axial coding.

In open coding, the data is read and then fractured by identifying the chunks of data that relate to a theme, concept or idea. I used codes that emerge from the NSI conceptual framework, as well as from the data. For example all the information that related to the role of government was identified and grouped together. I will use the following excerpt from a group interview to illustrate how I did the open coding.

<u>Interviewer</u>: *I notice that there has not been explicit mention of the role of government; does the government play any role in supporting the growth of the sector?*
<u>Respondent 1</u>: *Well it is the government that funds the MRC, so we would say that government provide funds.*
<u>Respondent 2</u>: *The CSIR gets parliamentary grants, for example when we were initiating the rational molecule design programme...h h through the national system of innovation we have a number of funding streams which benefit the CSIR, Universities, MRC and private industry.*
<u>Interviewer</u>: *Can you give me an example of funding streams?*
<u>Respondent 1</u>: *For example we have the innovation fund, which has a biotechnology focus, another area of focus is ICT.*
<u>Interviewer</u>: *Are there other roles apart from funding that the government plays?*
<u>Respondent 2</u>: *We have the national biotechnology strategy coordinated by DACST [now DST]*

[78] A full list of references is provided at the end of every chapter
[79] Strauss, A., & Corbin, J., in N. K. Denzin &Y. S. Lincoln (Eds.) (1994) Handbook of Qualitative Research. Thousand Oaks: Sage Publications, Inc.

*Respondent 1: We can call that policy formulation. Oh! There are other ways through which the government funds biotechnology, through giving universities funds for students, this is administered by the National Research Foundation.*
*Respondent 2: We also have the THRIP, which has a condition for matching funds. We also have the GODISA programme route of DACST. It has financed one of our incubator programmes*

All the information in the excerpt above relates to the various roles played by the government. From this information I was able to identify 2 broad roles of government as follows. The same was done for all interviews.

Role of government

1) Funding

- Funds MRC
- Through Parliamentary grants
- Has funding streams

    -Innovation Fund

    -National Research Foundation (NRF)

    -THRIP

    -GODISA

2) Policy formulation

- National biotechnology strategy

In axial coding, similar themes emerging from open coding were organized into conceptual categories. These conceptual categories are then compared with each other to eliminate redundancy and ensure that the categories are comprehensive. The NSI conceptual framework had already identified some of the core conceptual categories (usually identified through selective coding),[80] while others emerged from the interview data. To use the example of the role of government again, all the information that talked about government under open coding was further analyzed to identify emerging concepts, such as government funding, development of a biotechnology policy and regulatory frameworks. To this extent, the fact that I was not using grounded theory affected the

[80] Selective coding is the process of identifying core concepts emerging from axial coding

way I analyzed the data given that I had already preconceived conceptual categories that I was searching for in the data.

### 3.7 Validation of Data

The findings were validated in 4 ways.[81] Data validity in qualitative studies has been defined as when a second person finds a similar story as the one told in the analysis.[82] The following is a description of all the 4 validation steps taken for this study.

- **Member check**

I sent a draft of the results to the key informants for their comments and for confirmation that the story line in the analysis is reflective of the real situation of the health biotechnology sector in South Africa. Six informants responded out of all the 28 contacted, verifying the accuracy of the results and making further suggestions. The comments of the key informants are then taken into account and analyzed to adjust any discrepancies in the descriptive results of the case study.

- **Sampling of Key Informants**

The sampling process of the key informants ensured up to the extent to which it was possible, a mixed representation of views. Ensuring that people from different sectors of the South African innovation system were interviewed enhanced the variety of views that were brought into the interviews.

- **Triangulation method**

Triangulation compares data from different sources of information and looks for a pattern of convergence to develop or corroborate an overall interpretation.[83] I triangulated the data from the different sources to maximize comprehension (corroboration and evidentiary based) and also to include diversity. I used multiple sources of data namely

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[81] Altheide, D.L. & Johnson J.M. Criteria for Assessing Interpretive Validity in Qualitative Research. In Denzin N.K. & Lincoln Y.S., (Eds.) (1994) Handbook of Qualitative Research. Thousand Oaks: Sage Publications Inc.
[82] Crabtree, B.E. & W.J. Myer (1992) *Ibid.*
[83] Mays, N. & Pope, C. (2000) Qualitative Research in Health Care: Assessing Quality in Qualitative Research. *British Medical Journal* 320: 50-2

key informant interviews, sampled documents and observations. However I must acknowledge here that though observations are part of the methods, they do not constitute a major part and therefor this research does not rely heavily on observations. For example the information from documents was used to support or refute any interview findings, and vice versa. For example all informant said that the government has not put in place any tax incentives to encourage firms to invest in health biotechnology. This claim was confirmed by the biotechnology strategy[84] document.

- **Reflexivity**

To enhance reflexivity, members of the thesis supervisory committee oversaw the data collection and analysis process. Along with my own data analysis and coding of the raw data, the supervisory committee became familiar with the data and participated in the data analysis. This reduced chances of personal biases in the study. My thesis supervisory committee is composed of an interdisciplinary research team of scholars and professionals from different disciplines and backgrounds. Interdisciplinary research can help develop connections between discipline specific theories, and lead to shared conceptual frameworks that transcends traditional disciplinary boundaries.[85]

Though I collected and analyzed the data the consultative process with the supervisory committee enhances the objectivity of the data. All research activities are rigorously documented to permit a critical appraisal of the methods.[86] This included keeping a detailed journal of all interviews, communications and conceptual processes for this study.

## 3.8 Identified Methodological Weaknesses

The fact that this study relies heavily on grounded theory techniques for data analysis while itself not a grounded theory study could be construed as a misnomer. This is

[84] National Biotechnology Strategy for South Africa, 2001 (Page 57)
[85] Khan, R.L. (1993) The MacArthur Foundation Program in Mental Health and Human Development: An Experiment in Scientific Organization. Chicago: MacArthur Foundation
[86] Mays, N. & Pope, C. (1995) Rigour and Qualitative Research. *British Medical Journal* 311: 109-12

because this study does not allow the data to independently define the conceptual categories through the process of selective coding. Another methodological weakness is the fact that data collection phase preceded the actual field research. This was occasioned by logistical constraints such as time and money.

The number of responses elicited through the member-check process is less than satisfactory. There were 6 responses out of the possible 28, which are far from representative of all the sectors represented in this study. Though not an inherent problem of the methodological approach to this study, the poor response rate from the key informants denies this study the intended purpose of member checks and thus is identified as a weakness of this study.

Another weakness is the failure in some instances to verify some of the issues that were raised by the key informant member check. For instance one interviewee mentioned Highveld Biologicals as a health biotechnology company dealing with "*tissue culture mediums*." A further search on this company was not fruitful and thus this company was not included in the analysis of this study.

### 3.9 Research Ethics

The University of Toronto's Ethics Review Committee approved this study. The nature of the study being that involving a public policy issue, did not require further ethics approval in South Africa. All the interviewees were asked to give verbal informed consent for their participation in the study. The informed consent was obtained at the start of the interview after giving the details of the study and the nature of their participation[87]. The free and informed consent was audiotaped in all instances.

Verbal consent was preferred for this study instead of written consent. Audiotaping the consent process is a better documentation of the legitimacy of the process as it captures the whole process, unlike written consent. The research poses minimal risks to the

[87] See Appendix 2

participants and verbal consent did not adversely affect the rights and welfare of the informants. All the raw data will be protected as confidential and is only available to the research team. No individual will be identified in dissemination without his/her explicit agreement. The research findings will be freely disseminated to the participants of this study. This brings us to the next chapter, which is on the results of the collected and analyzed data.

## Chapter 4.0 Results

### Introduction

This chapter presents the results of data collected on the development of the health biotechnology sector in South Africa. As earlier mentioned this study relies on three main sources of data namely semi-structured interviews of key informants,[88] documents[89], and observations. The chapter is organized in themes emerging from the National Systems of Innovation (NSI) conceptual framework[90] and those emerging from the interview data.

The chapter begins with an overview of the health biotechnology sector in South Africa and the perceived role of health biotechnology in the national economy and its contributions to the healthcare system. This will be followed by a section that examines the status of the health biotechnology sector, highlighting its perceived successes and/or failures and an analysis of the prospects of growth in the next 5-10 years.

Having established the status of health biotechnology in South Africa, I will then endeavor to identify the different actors in developing health biotechnology with specific reference to their different roles within the innovation system. A section follows this on the role of linkages between the different actors and the presence of clusters as a source of innovative ideas and expertise for biotechnology development. The perceived benefits and challenges of the linkages will also be examined.

The public perception of new technologies is an important aspect influencing the successful adoption of technology and its implementation. The last section in this chapter will be on the findings of what the South African public perceives health biotechnology to be and how receptive they are to new health technologies.

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[88] Direct quotations are in italics and are as close as possible to the exact wording of the interview
[89] Documents include relevant published information, governmental reports, policy briefs and documents describing legal frameworks and regulatory processes
[90] A detailed analysis of the NSI is found in Chapter 2

## 4.1 South Africa's Health Biotechnology Sector

### 4.1.a Health Biotechnology Products

I explicitly asked all the informants/participants of the study whether they knew any South African health biotechnology products in the market. The table below represents those products that were mentioned in the interview.[91]

| Products[92] | Producer | Patent | In the Market |
|---|---|---|---|
| Colorectal Cancer detection device | Human Genetics Research Unit at University of Cape Town(UCT) | No | No |
| Elisa tests | Diarrhoeal Pathogens Research Unit at Medical University of South Africa (MEDUNSA) | No | No |
| Gene set sequences (STACKdb & STACK_PACK | Electric Genetics (PTY) Ltd. | Yes | Yes[93] |
| Monoclonal Antibody for cancer detection | Medical Research Council (MRC) | Yes | No[94] |
| Repotin | Bioclones (PTY) Ltd. | Yes | Yes |
| Traditional Medicine with anti-malaria activity | UCT/MRC | Provisional patent | No |
| Traditional medicine with immune boosters[95] | MRC/traditional healer | No | No |
| Traditional medicine with TB activity | University of Pretoria/MRC | Patent application in process | No |

*Table 4.1: A list of Biotechnology Products in South Africa*

Most of the people interviewed felt that there had to be products in the market, though they could not readily name them. The majority would use a general term like

[91] There could be more products in South Africa, other than those mentioned at the interviews. A further Internet search indicates for example the companies mentioned here have other products than those mentioned in this table and are discussed further under the section of the role of private firms.
[92] Arranged in alphabetical order
[93] Has never been used in South Africa, even though available
[94] A problem with the international partner was cited as the reason for the delay in introducing the product into the market
[95] Conducting safety studies at the time of data collection

"*diagnostics*" to describe what they thought was in the market. Others said that there are some products in the pipeline and it would be very early to talk about products being in the market.

The reasons cited for lack of awareness of the health biotechnology products existing in South Africa included the fact that there was lack of a coordinated approach to research such that most of the work that is done never gets to the public. Another reason is what was termed as the "*apartheid mentality*". This is a mentality that causes people not to share information freely even among researchers. However it was felt that this was changing because of the new research collaborations encouraged by funding agencies.

The researchers, who had products (Table 4.1), that were not yet in the market, cited various reasons for that. Some said they simply did not have time to follow the new inventions. One researcher with a patentable product said, "*I don't have time to follow up things…I just don't have extra time for that.*" Others said that they were producing things for internal use within their labs/work and were not thinking of patenting them, while others said that they did not know how to go about patenting their products and others did not know the potential of patenting their products.

**4.1.b Status of Health Biotechnology in South Africa: Too Early to Tell.**

The experts interviewed perceive the components of a successful health biotechnology sector as:

1. One that recognizes the health priorities in the country,
2. Good implementation of technology with 100% technology transfer
3. Government support
4. Presence of investors
5. Presence of partnerships (both local and international)
6. Is manifested by economic success

I asked the experts whether they thought that the South African health biotechnology sector was successful or not. This question elicited different answers. The majority of the experts felt that it was still too early to gauge the success. A few others felt that it was successful and others felt that it was not successful. It must be noted however that all the interviewees expressed optimism about the growth of health biotechnology in the country.[96]

Those who felt that health biotechnology was successful, cited the fact that the government had put in place programmes through agencies such as the National Research Foundation (NRF) and the Medical Research Council (MRC) that encourage collaborative research. These collaborative research ventures were viewed as successes since they create avenues that enable previously disadvantaged communities to do research. For instance, historically black universities did not have strong research components and were historically not involved in cutting edge research[97] and institutions like the MRC did not recruit black scientists[98]. Through collaborative research the black communities can now be involved in defining the research agenda and also be actively involved in the actual research activities.

Another mark of success was the fact that the government has placed a lot of emphasis on research that is relevant to the South African context. This has made research more product oriented and with an emphasis to bridge basic research to applied research. A good example is the SAAVI project, which is directed towards producing a vaccine against AIDS for the virus prevalent in the region. Together with this South Africa prides itself of having top-notch scientists, whose expertise can be harnessed towards developing biotechnology. One of the most cited personality during the interviews was Mark Shuttleworth, who at the time of the interviews had just returned from his space tour. The scientists in South Africa are abreast with international scientific developments and this was cited as a mark of success.

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[96] All interviewees were explicitly asked whether they were optimistic or pessimistic of the development of health biotechnology in the country

[97] Cherry, M. (2002) The Rainbow Academic Nation. *Nature* 417(23) 377-378

[98] Information from interview

Those who felt that the South African health biotechnology sector was not successful justified this by saying that they "*could not even quote any single product*," coming out of the system. It was also felt that genomics was still a very new area and that the country does not yet have an adequate level of expertise in the subject. The lack of critical mass coupled with the fact that there is not enough collaboration between the existing expertise was cited as affecting research. It was felt that there was not a genuine motive for collaboration in research. Some of those interviewed felt that the fact that some funding agencies require researchers to have partners may lead to situations where collaboration is driven by the need to meet the funding criteria and thus affecting the level of knowledge sharing.

Biotechnology R&D is an area that requires huge investments. Lack of adequate funding to support the growth of the sector causes people to concentrate on doing basic research. The lack of a large and supportive market also causes industry to shy away from investing in health biotechnology. One researcher expressed his frustration in trying to persuade large pharmaceutical companies to invest in health biotechnology R&D:

> *"There are no people to invest in health biotechnology because the people who need the solutions are poor people...the fact that most diseases affect the poor, black women affects the level of investment in health...if this problem [of AIDS] was affecting mainly white middle class men we would have a lot of industries trying to look for solutions."*

Other reasons cited for the lack of success included the fact that the previous regime did not invest in biotechnology infrastructure as compared to investments in arms manufacture and mining. As such, there is lack of adequate biotechnology infrastructure. Low education was also identified as a reason for lack of success and a cause to the slow implementation of technologies generally. It was also felt that the focus on deliverables was very recent and for a long time, this had been a problem. As a result no real innovations came through the health sector. One scientist said, "*we are now moving beyond peer reviewed publications and conferences, and now looking for commercialization for the first time.*"

It was felt that for a long time there was no emphasis placed on the development of health biotechnology as a component of health delivery, though this is now changing. In the past there was little government investment in terms of national budget in stimulating biotechnology, but it was hoped that this would change with the implementation of the biotechnology strategy. One expert felt that the formulation of the biotechnology strategy was a first step towards creating success in health biotechnology.

Some interviewees expressed some skepticism though on how much should be expected from the government. Since the government is faced with other burdens-as a result of the country's political past- biotechnology development is unlikely to be first priority.

Among those who felt that it was still too early to gauge the level of success, it was felt that there was a good amount of research taking place. There is a huge potential of success of health biotechnology since South Africa is endowed with a rich combination of biodiversity and indigenous knowledge. As one expert said, "*there is real excitement in health biotechnology.*" The reasons that were cited for lack of a local health biotechnology product were that most of the research was done in a fragmented way with no collaboration, lack of investment in taking research to viability and lack of entrepreneurial skills among academics. It was felt that more time was needed before making an assessment of the health biotechnology sector as things were beginning to change.

### 4.1.c Potential Impacts of Health Biotechnology in South Africa: Economic Development and Disease Alleviation

It was not disputed that health biotechnology has a role to play in the development of South Africa's economy and that this technology would directly impact on the country's GDP. One policy maker had this to say,

> *"if there are some innovative technologies that could be employed to address some basic priorities, then I think there is a big potential, otherwise if it is something expensive and nice to have but not essential to have, I don't see a huge market right now...biotechnology must have a role to play in alleviating disease,*

*but my impression is that because it's usually an expensive and sophisticated intervention, its applicability for developing countries is limited...but cheaper interventions would definitely have a huge impact"*

The development of a strong health biotechnology industry in South Africa would have tremendous impacts on the economy if it is applied to come up with sustainable solutions to local health problems. This would ease the disease burden in the country especially HIV and related diseases. One scientist however said that if biotechnology was to become a success, especially in the eradication of HIV/AIDS, a holistic approach had to be taken. He said,

*"While there is a role for health biotechnology, there's so much basic educational issues that need to be resolved, and societal issues that need to be resolved, that would be able to benefit from biotechnology. For example if we have a simple diagnostic technique for HIV patients we might be able to prevent MTC (Mother to Child Transmission), but experience is that less than 20% are interested in taking the test. Diagnostics for TB would be great, but there is a huge compliance problem."*

The HIV/AIDS epidemic is a huge economic problem with the bulk of the infections in South Africa being among people within the most economically productive ages of 15-49.[99] HIV/AIDS research consumes the greatest percentage of government funded health related research[100]. If a lasting solution is found for HIV/AIDS and related infections, there will be an increased life span with a better quality of life, which in turn will enhance productivity. Consequently, a remedy to the HIV problem will free up governmental funds that are currently going into vaccine and drug R&D and the money can be used to address other developmental imperatives such as access to education, poverty eradication and combating crime.

There is a potential that the development of local health biotechnology companies would be an economic boost in terms of wealth and job creation. Nevertheless, one expert was quick to say,

*"...however biotechnology might not be the sole answer to job creation per se because of the presence of unskilled labor."*

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[99] UNAIDS (2002)Report on the Global HIV/AIDS Epidemic
[100] News section: Nature (1999) vol.402. 23/30December

The production of drugs locally would be cheaper and will consequently contribute to disease eradication and alleviation, which in turn would increase production within the work force. A local industry will also reduce the reliance on international pharmaceutical companies for drugs and vaccines, who in the past have been "*profit driven.*" Through the Initiative for Pharmaceutical Technology Transfer (IPTT)[101] it is hoped that South Africa will start producing its own generic drugs and thus establish local pharmaceutical and vaccines industries. South Africa intends to take a leadership role in the African continent through initiatives such as the New Partnership for Africa's Development (NEPAD)[102] and will use such regional initiatives to start exporting health biotechnology products to neighboring countries.

South Africa is richly endowed with natural resources, which have not been fully exploited for economic gain. Exploitation of South Africa's biodiversity and indigenous knowledge through biotechnology platforms will both benefit the local communities as well as the country at large. Indeed in one group interview it was said that,

> *"For the purpose of developing our economy in biotechnology I see the indigenous knowledge dominating as opposed to the pure science route."*

Health biotechnology is also perceived to be fundamental for disease management and therefore as potentially having an impact on the hospital system. The only caveat however to this is that the impact will only be felt if it is affordable and simple enough to be used even in rural areas.

Health biotechnology will definitely increase efficiency within the healthcare system. The main impact, as articulated in the interviews, is its contribution to preventative medicine, which is "*less strenuous for the healthcare budget.*" Biotechnology is important in identifying populations that are more predisposed to developing certain

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[101] This is an initiative that has been formed to exploit the Doha Declaration whereby countries in the north undertake to assist countries in the South in technology transfer.
[102] South Africa is the host country to the NEPAD secretariat and is taking an active leadership role through President Thabo Mbeki.

disorders through the use of preventative medicine, manage those individuals in an appropriate way. Further impact within the hospital systems would be in providing local diagnostic, vaccines and affordable drugs.

### 4.1.d Prospects of Health Biotechnology in 5-10 years: The Future Looks Exciting

I asked the interviewees what their thoughts were on the prospects of health biotechnology in the next 5-10 years in South Africa. All but 3 people felt that the prospects were "*very good.*" and that, "*the future looks really exciting.*" One of those who did not think much is going to change in the next 10 years said,

*" it is going to take longer than that because of social, educational and health delays."*

The prospects look good because South African scientists are well trained and capable of developing technologies. South Africa has in effect developed a strong knowledge base around some diseases and around health trends. It is expected that a number of world class biotechnology companies will start developing in South Africa. For example some of the interviewees noted that "*Shimoda*[103] *and SANBI*[104] *are on the right track*"

It is expected that there will be growth since there is enormous potential in the country. There is going to be vast improvement in biotechnology R&D because of the tremendous amount of government support in terms of funding and policy formulation. The political will and support at the cabinet level and the fact that the government's Department of Science and Technology (DST) is championing the biotechnology agenda is likely to yield real growth and economic gains from health biotechnology. That being the case, one policy maker however said,

*"the downside is the over-optimism in biotechnology, in that it gets all the money and ignore all other economic aspects of the country."*

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103 Is a South African biopharmaceutical discovery company, further discussion under role of private firms

104 South African National Bioinformatics Institute (SANBI) analyzes genomes relevant to South African health research and biotechnology. The institute aims to bring genome information, computational biology, and analytical tools to the South African research community. Further discussion under the role of MRC

It is also encouraging that previously disadvantaged communities are beginning to be engaged. It was generally felt that a lot of innovations will definitely yield benefits in 10 years time. There is a certain level of expectation for the South African AIDS Vaccine Initiative (SAAVI) to yield a HIV vaccine. It was felt that in 10 years time "...[we] *will see a HIV vaccine and TB vaccine come out of South Africa."* The reasons given for that level of optimism were that there is enough research going on in these areas.

In addition to these purely scientific initiatives there are new programmes put in place to look at claims from traditional healers and users of medicinal herbs for any medicinal activity[105]. It is expected that in the next 10 years South Africa should have a service industry supporting a local biotechnology industry.

The level of optimism expressed by the people interviewed is a strong indicator that there is a lot of activity going on in developing the health biotechnology sector and R&D to support it. I therefore inquired who the main actors were in developing the sector and what their specific involvement was. The following is an examination of different actors as identified in the interviews and their different contributions to the biotechnology innovation system in South Africa.

### 4.2 Main Actors

Main actors/players in the South African health biotechnology sector identified broadly as:

1. Government[106]
2. Education and Universities
3. Innovative Firms
4. Public Research Institutions

[105] Details later on the Indigenous knowledge systems programme at the MRC
[106] The government has cross cutting roles, affecting all other actors

### 4.2.1 The Role of Government

The role of government in developing a robust health biotechnology sector in South Africa is multi-faceted. The interviewees unanimously felt that it was the role of government to raise the quality of life of the South African people by developing new interventions to deal with health problems. It was also felt that it was the government's duty to provide intelligence information, such as morbidity rates of the South African population.

Until recently (2000) the South African government was not actively involved in biotechnology development. There is a general feeling that this is now changing. The government is working closely through DST and the science councils to radically expand the biotechnology R&D base, through offering policy infrastructure and funding support. The expansion of biotechnology in South Africa was interpreted by some of those interviewed as having lots of support even from the president's office. The government has been involved in various areas such as:

- Policy formulation
- Creating a regulatory framework
- Intellectual Property protection and regulation
- Funding research
- Financial and tax system

#### 4.2.1.a Policy Formulation

The South African government is involved in defining the R&D agenda by way of policy formulation. The development of the biotechnology sector is addressed within the broad science and technology (S&T) agenda. The South African government developed a White Paper on Science and Technology in 1996. However, some of the interviewees felt that the government did not go into actual formulation of strategy and implementation of the S &T White paper. The White Paper was criticized as suffering "*profound vagueness.*"

To address the gap of the implementation of the S&T White paper, the government commissioned the Minister in charge of the S&T portfolio in 2002, to produce a national research strategy.[107] The same ministry produced a National Biotechnology Strategy in 2001. The following is a discussion of the implications of these two major strategic papers on the development of the health biotechnology sector in South Africa.

### *White Paper on Science and Technology (1996)*

The White Paper on Science and Technology (WP on S&T) is the official government innovation policy document. The WP adopts a concept of a "South African national system of innovation"[108] as the framework for S&T policy analysis. The S&T policy paper provides a framework within which technological advancements can take place in a problem solving approach as well as with a view to meet the demands of the global economy in terms of increased competitiveness.

Science and technology are seen as central to the creation of wealth and improving the quality of life in contemporary society. The WP stresses the role of technology in meeting the basic needs of the South African population. Healthcare provision broadly falls within these basic needs. Recommendations with a direct implication to the development of the health biotechnology sector include:

- Increase technology investment
- Investment in the South African labor force at all skill levels
- Encourage learning of science and mathematics in the education and training system
- Encourages the government to make policy choices about investing in infrastructure, R&D, and education and training[109]

[107] At the time of data collection, the strategy was only in draft but has since been approved by cabinet. The strategy proposes to utilize existing institutions to enhance IT and biotechnology development. It proposes the creation of a Foundation for Technological Innovation as a knowledge-based funding agency.
[108] DACST, (1996) White Paper on Science & Technology: Preparing for the 21$^{st}$ Century. Pg. 17
[109] This recommendation seems to have been implemented, at the time of data collection there was a mechanism in place to establish a national R&D policy and there exists a White Paper in Education and Training which emphasizes the learning of sciences and mathematics

Public investment in R&D is encouraged. There is a clear shift from the traditional way of government support of activities within the government's owns facilities towards a more comprehensive support of R&D executed in the private sector. The Innovation Fund and the National Research Foundation (NRF) were created for this purpose. The government is encouraged to take lead in funding basic research activities and those areas, such as health biotechnology, whose entry costs are prohibitive.

South Africa maintains a good record of quality basic research. The WP reiterates the importance of knowledge generation for technological innovation. Both basic and applied research are encouraged in tertiary education institutions. The WP proposes a framework that promotes closer linkages between universities, science, engineering and technology institutions (SETIs) and the private sector, with the view of sharing risks, resources and knowledge.

The National Advisory Committee on Innovation (NACI) is a relatively new institutional arrangement arising as a result of the S&T white paper. It consists of different stakeholders drawn from the national system of innovation and with the function of carrying out enquiries, studies and consultations with respect to the functioning of the innovation system.

Operationalizing the WP in terms of biotechnology development was followed by the formulation of a national biotechnology strategy.

***National Biotechnology Strategy (2001)***

The formulation of the biotechnology strategy was hailed as one of the major steps towards developing the biotechnology sector in the interviews. The Department of Science and Technology (DST) coordinates the strategy. The following is a brief analysis of the biotechnology strategy with a very specific reference to health biotechnology.

South Africa does not have a large enough local industry tapping into the benefits of the recent biotechnological advancements in genetics and genomics,[110] therefore the biotechnology strategy is aimed at "developing a viable and sustainable biotechnology industry."[111] Health biotechnology is one of the areas identified by the strategy as potentially contributing to the national priorities, which include access, and affordability to healthcare, food security, job creation and environmental protection.

The strategy encourages the use of biotechnology applications as a means of stimulating innovation and providing a competitive edge for industry. A lot of emphasis is placed on the use of health biotechnology applications that address the country's problems and areas that are of national economic priority. For instance, a lot of government effort is targeted towards the development of the HIV vaccine.[112] Specific areas identified for health biotechnology development by the strategy are:

- Development of cheap and easy to use diagnostic kits for early detection and management of infectious diseases
- Development of affordable and safe vaccines for TB, cholera, malaria, human papilloma virus
- Development of drugs for diseases prevalent in the country such as hypertension, cancer, malaria, TB
- Mapping and identifying of gene profile of the South African population to better understand the molecular basis of diseases prevalent in South Africa and further develop technological remedies for diseases
- Creation of a database identifying all the components required for the commercialization of biopharmaceuticals.
- The establishment of a state-supported facility for scaling up and contract manufacture of generic biopharmaceuticals. [113]

[110] Executive Summary, National Biotechnology Strategy, 2001
[111] National Biotechnology Strategy, 2001, page 37
[112] The UNAIDS/WHO AIDS Epidemic Update (2002) estimated that about 4.7 million South African adults lived with HIV/AIDS in 2001
[113] Refer to page 46 of the National Biotechnology Strategy

The strategy identifies a gap between research endeavors in academic and other public research institutions and turning the ideas into commercializable products. It also encourages the creation of public-private partnerships with industry as a way of bridging the gap between research and commercialization. Public awareness will also go along way in creating a local market demand for health biotechnology products.

Creation of human capital and the coordination of already existing human capital is identified as one of the challenges facing the government. The strategy proposes the creation of linkages between different institutions in knowledge sharing, joint research and intellectual property ownership by establishing 3 Biotechnology Regional Innovation Centres (BRICs)[114].

The Cape Biotechnology Initiative in Cape Town focuses on health biotechnology. The BRICs will provide technological platforms for different biotechnology focus areas and will bring capital equipment and specialized expertise from different disciplines together. The BRICs are required to link with a biotechnology incubator, which will in turn be linked into a spin off company thus ensuring that R&D outcomes turn into commercializable products. This will also act as a means of creating knowledge networks and linkages that are a necessary ingredient of a national system of innovation.

For adequate diffusion of new technologies in the market, it is important that the public be well informed and also be engaged in the entire process. The strategy notes that "…it is important to continuously engage with and inform public understanding of the work of biotechnologies, in order to avoid misunderstanding and to ensure public support."[115] If this is achieved in the implementation of the strategy, the people will much more readily use health biotechnology products within the health care system. The Department of Health (DoH) is encouraged to leverage its buying power as a user of health products to stimulate investment in health biotechnology.

[114] In March 2003 the 3 BRICs were launched namely Biopad in Johannesburg, EcoBio in Durban and the Cape Biotechnology Initiative in Cape Town.

Of critical emphasis in the biotechnology strategy is the need for a governmental agency to champion the biotechnology agenda. The strategy proposes the creation of a Biotechnology Advisory Committee (BAC), as the national champion of the biotechnology strategy both in identifying the national priorities and implementing the strategy. The committee is also supposed to constantly monitor the impact of biotechnology expenditure in terms of "new companies, creation of employment and improvement of life." It is curious that the strategy does not mention the introduction of new biotechnology products in the market as a measure of impact.

The effect of the biotechnology strategy has been to create awareness, mainly at institutional level among those working on biotechnology projects. The main thrust of the biotechnology strategy is to use the current research infrastructure to identify 3 BRICs that will bring a range of all players into a kind of innovation hub that will support small businesses emanating from research. It is largely to be translated as an attempt to bring products into the market. Through the biotechnology strategy, this is the first time the South African government is committed to substantial funding to try and develop commercial exploitation of R&D in various research institutions, universities and science councils.

One of the interviewees criticized the biotechnology strategy as not having achievable goals. She said:

> *"...It has no tangible ideas aimed at tangible products...it emphasizes on the creation of BRICs and government pouring money into them, without a prioritization exercise...there's clearly a lack of thought and proper coordination of BRICs."*

### 4.2.1.b Regulatory Framework

Scientists described the research environment as "*a good and supportive research environment...with no stringent regulations.*" They felt that there was nothing put in place to impede research. One scientist said, "*you could pretty much do anything you like.*" Researchers are mainly regulated by institutions where they work. In terms of

[115] National Biotechnology Strategy page 4

government legislation on biotechnology, South Africa has no legislation dealing directly with health biotechnology. One person working in a policy agency said that the probable reason why there is no regulation specifically made for health biotechnology is because South Africa has not developed a critical mass and that not much has happened in this field to necessitate having a regulatory framework.

The main legislation dealing with biotechnology issues in South Africa is the Genetically Modified Organisms Act.[116] This Act focuses mainly on agricultural biotechnology. The Health Research Policy regulates health research,[117] though the policy document does not make explicit reference to health biotechnology research. Intellectual property ownership is regulated by the Patent Act.[118] One expert felt that health biotechnology regulation would be best at institutional level than at the national level.

It was generally felt that the use of indigenous knowledge has not been adequately regulated since there have been instances in the past where communities did not benefit from the exploitation of their knowledge. A good example is the bitter hoodia plant, which the San community chews when going on long hunting trips. In 1996 scientists from the Council for Scientific and Industrial Research (CSIR) isolated P57 as the hunger-suppressing chemical from this plant and patented it. CSIR later licensed a UK-based firm Phytopharm to further develop and commercialize the P57 component. Phytopharm then licensed Pfizer to develop and commercialize P57.[119] This has been a source of conflict between the South African San Council and the CSIR, but the two parties signed an agreement in March 2004, relating to the sharing of benefits that could arise from the potential commercial success of P57.

Some people felt that the lack of a regulatory framework is the reason for what was described as "*instances where biodiversity and biological material jump out of the country.*" It is hoped that this situation will change because the government is in the

[116] Act 15 of 1997
[117] Department of Health, 2001
[118] Act 57 of 1978
[119] http://www.corpwatch.org/news/PND.jsp?articleid=6210

process of enacting laws that will protect biodiversity and use of indigenous knowledge in research. Others felt that ethical concerns such as cloning and stem cell research were not appropriately covered in the current regulatory framework and therefore the government needs to do something.

The Medicines Control Council (MCC) is the statutory body that regulates all clinical trials conducted on human subjects. It is also the body that regulates the manufacture, distribution, sale and marketing of drugs and vaccines into South Africa. The operations of MCC are governed by the Medicines & Related Substances Control Act.[120] The MCC operates through external experts to evaluate data sets submitted to the council by pharmaceutical industries for purposes of registration[121].

Most researchers, especially those involved in clinical trials felt that this council worked well and has developed a good regulatory environment. The fact that the MCC has FDA accepted standards enables scientists to do internationally accepted work, which is a major boost for the researchers.

All researchers had no problem with complying with documentation requirements for clinical trials, though in one instance there was a case where "*3 researchers left a research project because of documentation requirements.*" The majority felt that rigorous documentation did not deter them since they conduct their trials with "*an eye on the FDA.*" South Africa is generally good ground for clinical trials because of disease burden, good infrastructure, good medical schools, good laboratories and a regulatory environment that is respected by the FDA.

### 4.2.1.c Intellectual Property Regulation

The biotechnology strategy proposes the revision of the current regulatory environment to target local and international market. This includes the revision of intellectual property

[120] Act 101 of 1965
[121] http://www.mccza.com

laws to be compliant to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)[122] and other international regulations with potential implications to health biotechnology research and innovation[123]. The South African Patent and Trademark Office (SAPTO)[124] was at the time of this study undergoing some structural changes to make it a search and examining office[125]. This is a clear indication of targeting both the local market and at the same time seeking to satisfy international standards.

A minority of the total of interviewees[126] felt that the Intellectual Property Rights (IPR) system in South Africa worked very well. The system is strong enough since " *all things were given due considerations*."[127] They asserted that they had never experienced any IP problems. One of them in fact said that the good IP system is the reason why South Africa cannot manufacture cheap generic drugs. This was evidenced in 1998 when 39 pharmaceutical companies filed a class action lawsuit against the South African government to prevent parallel importing and or compulsory licensing of cheaper AIDS drugs[128]. The 39 companies later dropped the suit as a result of international public pressure.

On the other hand the majority of the interviewees felt that the IPR system in the country needed to be improved. They felt that the current infrastructure was "*not sophisticated as desired*" and as one requiring procedural and technical changes.

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122 TRIPS Agreement constitutes Annex 1C to the Marrakech Agreement establishing the World Trade Organization (the WTO Agreement)

123 Such as the Convention on Biological Diversity (CBD) which addresses aspects such as equity of benefit sharing and technology transfer, and the Cartagena Protocol on Biosafety, to which South Africa is now a signatory.

124 Which has since merged with the South African Companies Registration Office (SACRO) to form the Companies and Intellectual Property Registration Office (CIPRO)

125 A search and examining patent office has the ability to determine whether patent application is in conflict with, or in duplication of an existing patent and goes beyond a mere ability to find a previously filed patent by searchable index fields.

126 4 out of the total 28

127 A direct quotation form one of the interviewees

128 Parallel importing would allow South Africa to import patented drugs at a cheaper price from other countries without permission from the manufacturer while compulsory licensing would allow them to manufacture such drugs locally. However the South African government has resisted exercising its option of declaring HIV/AIDS as a national emergency that would allow it to under the WTO Agreement to allow compulsory licenses to local manufacturers.

Researchers, especially those within academic circles were accused of neglecting IP issues in the past. However, it was felt that the situation was improving tremendously since the government has now taken an output approach towards financing biotechnology initiatives. This means that researchers with potentially patentable products stand a higher chance of getting government funding for biotechnology research. Patent applications are now regarded as highly as scientific publications by government funding agencies. In the past scientists did not care what happened to their research outputs and viewed publishing in reputable journals as the only reward for research. This was largely attributed to the lack of sensitization among scientists of the need to patent their research products.

In the past South Africa has lost a significant amount of its IP in indigenous knowledge to foreigners. The government is working to reverse this trend, and a lot of awareness has been created among scientists. The awareness level was however described as "*not sufficient.*" Most scientists felt that they did not know enough about IP, while others were simply not interested in patenting their research products. One scientist who works in vaccine development had this to say about patenting vaccines,

> *"I really passionately believe that we need to have vaccines available for Africa. I don't have to make money. Its really to have products out there in the public domain that people can use...but obviously I would be upset if the idea was taken by a big industry and developed and made millions for somebody else. I would rather donate the vaccine to WHO rather than trying to make money out of it."*

Only those who work closely with IP issues or those who have had legal training fully understand about patent protection. This was illustrated during the interviews as most of the interviewees said that they did not understand the technicalities involved in the patenting process. At the time of data collection, the government was in the process of formulating a national policy on indigenous knowledge systems and had 2 draft bills[129] for IP protection in indigenous knowledge.

The Interviewees felt that it was not easy for researchers to get patents for their work since the process is complex, rigorous and expensive and requiring legal expertise. Other

[129] Bill on Recognition, Promotion, Development and Protection of Indigenous Knowledge Systems and the National Biodiversity Bill

reasons cited included lack of legal expertise in the area of biotechnology and that scientists were not very willing to give away their IP due to what was called the "*competition culture*." This culture encourages unhealthy competition among scientists, whereby they guard their knowledge for the fear of being out-done by their colleagues.

As mentioned above, South Africa is currently going through a process of revising its patent laws to be TRIPS compliant. This is deemed necessary if South Africa is to remain competitive in global trade. Despite the optimism expressed by majority of the interviewees on revising the law to the level of TRIPS some felt that it was not worth the cost of restructuring the whole patenting system by for instance, making the patent office a full examining office. South Africa and indeed most developing countries lack the capacity to run such an office. Others felt that there was still a possibility of disputes similar to those with anti-retroviral drugs[130] in genetic and genome technologies since most of these technologies are developed in industrial countries.

Most research institutions, including universities, have their own patent protection policies. For instance, the people interviewed at the Medical Research Council (MRC) said that MRC has recently recognized IPR as a priority. MRC scientists are well informed of their responsibility to recognize and identify potential products from research and register them with the MRC business office, which in turn ensures that any products that need protection are duly protected. At the time of data collection MRC was setting up a register of projects and evaluating IP issues in all their projects. This was seen as a way of stimulating research and channeling research into business ventures. Through patent protection, MRC aims to control pricing for drugs and thus make them available to the public.

The increased awareness surrounding IP issues is largely attributed to the increased exposure of South Africa to the international community and also by the fact that there is more involvement of South African scientists in the production of health technologies.

[130] In 2000, multinational drug companies refused cheap access to antiretrovirals to the estimated 5million HIV/AIDS sufferers on the basis of patent protection

One example of South Africa's participation in the production of health related technologies is seen in the South African AIDS Vaccine Initiative (SAAVI). The IP protection agreement in the AIDS vaccine venture includes a cost control clause and an access clause. The cost control clause controls any future attempts of unfair profiteering in developing countries, while the access clause ensures that if the vaccine proves to be effective, companies will be prohibited from refusing to produce the vaccine on the basis of lack of profit.

Different government agencies have different IP protection policies and this was seen as a hindrance to collaborative research between different government agencies. The different IP protection systems in the different government agencies was also seen as causing some mistrust between universities, funding agencies and the MRC. The MRC requires that patents acquired from any research funded by the council be co-owned with the researchers. Some scientists described the MRC research contracts as "*very restrictive.*" The joint ownership clause was said to "*impede development of IP*". This clause was described as "*too complex and discouraging to pharmaceutical companies who would otherwise buy the IP*". To avoid IP disagreements with MRC, some scientists use the MRC funding for support services and not for research. One researcher felt that,

> *"These funding agencies demand recognition for more than they have put in. If am getting a tenth of my funding from a funding agency, as far as am concerned they should receive a tenth recognition. But they want recognition for the whole thing.*

Most universities are still very young in terms of IP management and development. Majority of them are just beginning to put in place a system for dealing with IP within the university. Universities do not have experience in licensing and as a result, for a long time the university researchers have just been doing their own thing. The lack of a university patenting infrastructure and sensitization among university researchers was blamed for most of the biological material and IP lost from the country. One policy maker said, "*many of our ideas [as a result] have become major products overseas and have evolved into major profit making companies.*"[131]

The universities rely on people being ethical and expecting researchers to notify them of any potentially patentable products. One of the university researchers interviewed felt that this does not work because there are many companies operating within university campuses without the knowledge of the university administration. Most of this is because the university professors are underpaid and have to supplement their salaries with some other sources of income. Some people felt that an attempt to change the status quo would be met with a lot of resistance, unless the salaries for the university researchers are improved. It is hoped that this situation will change as universities are increasingly being pressured to set up IP infrastructure and regulations.

#### 4.2.1.d Funding Research

I was unable to get any reliable information reflecting the exact amount of government funding that goes into biotechnology R&D. This was also supported by the interviews, since it was generally felt that it is very hard to quantify the exact amount of government funding that goes into biotechnology. However, it was felt that the government has increased its funding into biotechnology research. For instance one interviewee said, "*the government had doubled the MRC budget in just 3 years from ZAR75million [US$9.9m] to ZAR150million [US$19.8m].*" However some scientists felt that the funding they get from government is not adequate to run a whole research project and is seed funding to be used as leverage for more funding from international sources.

The total government expenditure in health research is approximately 3.5 billion rand, which is about 50% of the total science expenditure in South Africa. It is approximated

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[131] One scientist gave me this example of how he and his lab had been working for the last 10years with a group of families with a hereditary disease and had mapped the family gene and were at the verge of coming up with some breakthrough discoveries. A scientist came in from an American university, and collected the same biological material from the same families without permission and shipped it to the US. This is still a contentious matter between those concerned and further identities are concealed for confidentiality purposes.

that the South African government spends less than point five percent (0.5%), of the GDP on health research. Government funding in S&T is tied down to national priorities. These priorities are enumerated in the S&T White paper as:

- Promoting competitiveness and employment creation
- Enhancing quality of life
- Developing human resources
- Working towards environmental sustainability
- Promoting an information society

All the people interviewed were asked an explicit question as to the sufficiency of funds for health biotechnology research. This question depending on who was asked elicited different answers. Those who were already "*entrenched*" in the research network said that funding was sufficient since they always get funding. Majority of the interviewees felt that the available funding from government was not adequate.

The government funds health research through a number of agencies. Some people felt that there was quite an overlap since these agencies are somewhat under the same umbrella (namely DST), therefore it is hard to tell who is funding who/what. One prominent way through which government funding can be procured is by tendering a research grant on competitive basis. This type of funding was said to be too "*trivial*" as it amounted to US$10,000. Other ways through which government funded biotechnology research include the use of education grants that go into university research.

The government uses various agencies to fund biotechnology initiatives, namely:

- **Technology and Human Resource for Industry Programme (THRIP)**

THRIP is managed by the National Research foundation (NRF) and the Department of Trade and Industry (DTI). It is estimated that THRIP spends ZAR13m (US$1.7m) on biotechnology R&D[132]. THRIP provides funds for scientific research and activities related to technology development and diffusion, with a condition of matching grants from industry. It is designed to foster collaboration among industry, government research institutions and academia. The academic link is fostered by the requirement that at least one registered South Africa student be involved in and trained in the research. As such it has a role in enhancing the quality and quantity of skilled personnel in South Africa. Currently THRIP is funding two research activities related to health technology.[133]

- **National Research Foundation (NRF)**

NRF funds technology related research. It started out with a focus on industrial research but the interviews show that it has increasingly become accessible to medical sciences. Interview responses show that it is usually more focused on basic research and core science funding. The NRF has a list of criteria of what they consider as important, therefore grant applications have to fall within that general area. This fund also encourages people to apply for training in indigenous knowledge systems.

- **Innovation Fund**

The Innovation Fund is a government agency mandated to support research capacity development. The fund provides grants for end-stage research processes where knowledge can be translated into new and improved processes or services. The Innovation Fund spends approximately ZAR20m (US$3.7m) on biotechnology R&D.[134] It funds biotechnology projects and encourages research in indigenous plants and the exploitation of traditional knowledge on biotechnology platforms. The Fund works by funding consortiums and thus encourages collaboration between industry, academia and the science councils.

- **GODISA**

This is a South African initiative with a series of activities/programmes jointly funded by the EU and DST to facilitate technology transfer and incubation in small, medium and

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[132] Estimated in the National Biotechnology Strategy, pg. 24
[133] http://www.nrf.ac.za/thrip/AnnualReport2002/beyers.htm
[134] Estimates from the biotechnology strategy

micro-enterprises (SMME). Among other technology-related initiatives GODISA is currently funding two health biotechnology initiatives.[135]

One incubator funded by GODISA is Acorn Technologies (Pty) Ltd. This is an incubator assisting entrepreneurs with innovative life sciences technologies in establishing successful and profitable business by bridging the gap between innovation and commercialization. Acorn was founded by a consortium consisting of:

- Catalyst Innovation Incubator (Pty) Ltd (Catalyst) - an early stage Venture Capital Fund
- The University of Cape Town (UCT) Medical School's Faculty of Health Sciences
- The University of Stellenbosch's Office for Intellectual Property (US), and
- The Biomedical Engineering Corporation (Pty) Ltd. (BEC) - a company developing and manufacturing minimally invasive medical implants

- **Science Councils through a parliamentary grant.**

Two science councils were identified as funding health biotechnology research. The 2 councils are:

1. Medical Research Council (MRC)[136] - This is a funding agent for medical research. It provides seed funding for projects that address national priorities.
2. Council for Scientific and Industrial Research (CSIR)- It funds and heads the drug discovery programme and bioprospecting in indigenous plants.

#### 4.2.1.e Financial System

##### i. Tax Incentives

When asked whether the South African government had put in place any tax incentives for potential investors in biotechnology, the interviewees said that there were no tax incentives. One of the scientists said, "*this is a shortcoming that does not encourage the participation of industry.*" The issue of introducing tax breaks was said to be quite

[135] http://www.godisa.net/default.asp
[136] An in-depth discussion of the role of MRC in health biotechnology development follows.

controversial and has been brought up for discussion at government level a number of times. One government official said, "*...the country has been steering away from direct incentives.*"

Introduction of tax allowances has largely been refused on the basis of lack of appropriate skill at the South Africa Revenue Authority, as this will require additional tax experts at the revenue office. The national Biotechnology Strategy notes that, "such allowances have been discussed previously with the National Treasury, and have largely been refused, on the basis that it would be yet another means of undermining tax collection."[137]

**ii. Venture Capital**

It is doubtful whether there is any engagement with angel investors due to the risky nature of biotechnology investments. There is an emergence of venture capitalism in health biotechnology, though this is still very young.

Some of the people interviewed said unequivocally that there existed no venture capital (VC) industry in South Africa, while others felt that though it existed there was not much to talk about. However further research indicated that indeed South Africa does have a VC industry, but with only one firm, known as Bioventures, funding biotechnology firms. It has an approximated ZAR80million (US$10.5m) fund and was at the time of data collection funding three biotechnology companies, one of which is Shimoda biotech and is directly related to health biotechnology. Shimoda biotech.[138] is a South African start up biotechnology company specializing in the production of innovative drug delivery systems using biotechnology platforms.

One of the persons interviewed who works very closely with the VC industry said that the South African VC industry was faced with a number of challenges. These challenges include factors such as under capitalization of VC firms. Due to lack of adequate

[137] Page 57 of the National Biotechnology Strategy
[138] further details discussed under role of private firms

education, investors do not understand the nature of the industry and coupled with the fact that investors are risk averse, there is a gap between research and commercialization. Nobody is willing to fund small start-up firms without a promise of profit.

Other challenges cited in the interview include a shortage of skills and the lack of flexibility among accountants, which was a problem identified as "*rigidity of accountants*." South Africa does not have a history of pension funds investing in private equity and this was identified as a major problem characterized with resistance in changing the trend. Biotechnology is also viewed as very controversial and marred by misconceptions such as GMOs and cloning, therefore most investors would be wary of investing in biotechnology due to ethical implications.

In summary the South African government is actively involved in developing health biotechnology through funding research, through policy formulation and through the creation of legal and regulatory frameworks. The following section outlines the role of the Medical Research Council (MRC) in developing health biotechnology in South Africa.

### 4.3 Role of Medical Research Council (MRC)

The MRC is a statutory council charged with the task of conducting health research. Sixty percent of the MRC budget comes from the government, through the government science vote administered by the Department of Science and Technology (DST). The remaining 40% comes from private sector and international agencies.

The primary mission of the MRC is to build a healthy nation through relevant and excellent health, based on equity, with the aim of improving the health status and quality of life of South Africans. One of the principle goals of the MRC is to develop a local capacity and training black scientists. Most of the funding that goes into health research projects throughout the country is channeled from government through the MRC.

The MRC was described as being a "*fairly conservative institution for many years.*" Up until the mid 1980's the MRC was not accessible to black scientists who as result were not involved in any health research. However, this trend is being reversed and collaborative research is encouraged by MRC. There is now a more integrated approach to research with more collaboration between the previously disadvantaged communities/research institutions with the previously advantaged communities/research institutions. The MRC is currently involved in many research activities through various research units/nodes spread in different parts of the country. The following is a summary of those research projects that were prominently mentioned in the interviews. [139]

### 4.3.a The South African AIDS Vaccine Initiative (SAAVI)

One area in which South Africa is doing cutting edge biotechnology is in the development of an AIDS vaccine. MRC is the lead agency for SAAVI, which is an initiative employing about 120 scientists, both local and from the USA[140]. SAAVI receives up to approximately ZAR75million (approx. US$10m) every year.

SAAVI has a defined portfolio that covers the basic science of vaccine development, vaccine reaction and immunological monitoring of vaccine reactions. It also has a set of ethical guidelines and principles guiding their research in humans.

SAAVI aims to develop a vaccine against the sub-type C virus which is common in South Africa, while also taking advantage of international developments that are useful for the country through linkages with the international community. This is a novel idea to bring the best South African brains to work together and to develop an affordable and accessible vaccine for South Africa and South Africans.

[139] This is not a representation of all the MRC research programmes
[140] Most of them working with Alphavax, a vaccine development company

SAAVI now has about 10 candidate vaccines, one of which should go into phase one trials.[141] The South African HIV Advisory and Community group (HIVAC) deals with sensitizing and making people aware of their rights and consequences of participating in trials and raise issues that come from the community with the scientists.

### 4.3.b The South African Bioinformatics Institute (SANBI)

SANBI is situated at the University of Western Cape (UWC) and also has within it an MRC research unit. Bioinformatics has been strategically targeted as an area of focus within the country and as such the institute is one recipient among several others throughout the country sharing a research grant from DST of about ZAR45million (approx. US$6m) until 2006. SANBI share of the DST grant is ZAR2.1million (approx. US$269,850) per year for 3 years. The institute already has a 10-year plan with assured funding. The strategic focus on bioinformatics is because bioinformatics is viewed as improving biotechnology research within the country and also as being an area with rapid high returns.

Together with conducting research, the institute develops bioinformatics capacity by training students, most of who are later employed within the biotechnology sector, in companies such as Electric Genetics, a university spin-off. SANBI works very closely with Electric Genetics[142] as the academic partner. SANBI plans to start doing surveys of the genetic make up of the diverse South African population, among other things to determine the genetic base to the HIV virus. One of the scientists at SANBI said that it is apparent that there is a genetic-based resistance to the HIV virus, which is a very interesting research area for the SANBI scientists.

[141] predicted at time of data collection
[142] More details under role of private firms

### 4.3.c Indigenous Knowledge Systems for Health

South Africa has about 750 species of medicinal plants, on which 80% of the population relies for medication.[143] There is a high level of optimism of the potential of harnessing these medicinal plants into new, safe, effective and affordable drugs using a biotechnology platform. To this effect, the indigenous knowledge systems for health programme at the MRC was formed in 1997. The programme focuses on doing systems R&D in traditional medicine focusing on diseases affecting the South African population. The main focus so far has been in malaria, TB and recently they have started looking at immune boosters for HIV/AIDS and diabetes. The indigenous knowledge system programme is placed within the business and development directorate as a strategic move towards developing new drugs from traditional medicines. They hope to patent the drugs and license them out in collaboration with the indigenous people.

The MRC, through this programme is actively trying to redress policies of the past where traditional practices were regarded as bad, dangerous and were destroyed. All traditional practices were considered to be repugnant and hence discouraged through the Witchcraft Suppression Act. The MRC has a policy for sharing profits accruing from traditional medicine and indigenous knowledge with the communities concerned. If any traditional medicine product eventually gets into the market, the MRC is committed to sharing benefits and royalties with the local communities from whom the knowledge is acquired. If the products are not commercializable the MRC acknowledges the source of information and source of genetic material.

Various MRC research units have been formed in universities. For instance at the University of Cape Town, there is a the South African Traditional Medicine Research Group, which does research in traditional medicine and attracts young scientists to conduct academic research and also to develop new medicines through knowledge from indigenous people and innovate that knowledge into commercializable products. Other

[143] Information from interview

universities with similar programmes are University of Western Cape and University of the North.

This programme works very closely with traditional healers through educational programmes to raise awareness among them and to regulate the use and access to genetic material and of the knowledge. In the past, this knowledge has been exploited without sharing benefits with the local communities.[144]

In summary the MRC identifies niche areas for health biotechnology development and focuses research effort and funding in these areas. The 3 identified programmes above are involved in cutting edge research that is expected to potentially address South Africa's disease burden, and specifically the HIV/AIDS epidemic.[145]

### 4.4 Role of Universities and other Academic Institutions.

The contribution of universities to the development of biotechnology can be described pre 1994' and post 1994'. Before 1994, one scientist described the research done in most universities and other academic institutions as "*strategic research*". The strategic research was only to serve the interests of the apartheid government. Only a few institutions were actively involved in research activities for instance the University of Cape Town and Witswatersrand University, which were traditionally white universities.[146] Those perceived to be "traditional Afrikaner" universities were described by an expert as " *less productive*." Though University of Pretoria, which falls in the later category is now leading in agricultural biotechnology.

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[144] Pfizer developed an appetite suppressant from a plant that the Khoisan people chew when hunting. This plant causes the Khoisan people to go for days without food. Nothing was given to the Khoisan people as royalty. This issue was hotly contested and as a result an agreement has been entered between the CSIR and the San Council to pay the San community 6% royalties when the drug reaches the market

[145] The UNAIDS Report on Global HIV/AIDS Epidemics, 2002, estimates that by the end of 2001, 5 million adults and children were living with HIV/AIDS in South Africa.

[146] These 2 universities have very good and productive research units investigating infectious diseases, cancer, cardiovascular research and sports medicine

After 1994, things begun changing and a lot of awareness was created, with the aim of including those previously excluded institutions in research initiatives. One such previously excluded university is the Medical University of South Africa (MEDUNSA), which now has a very robust diarrhoeal pathogens research unit, among others, and provides facilities for vaccine clinical trials.

The main role of universities is in training students and providing a constant supply of skilled labor into the workforce. The universities also provided a very supportive role to other research institutions. This support is in the form of providing research personnel and infrastructure. For instance one scientist working for SAAVI approximated that "*approximately 100 scientists out of the 120 scientists who work for SAAVI are drawn from South African Universities.*"

It was generally felt that there is research going on in universities and especially medical schools that could directly impact on the development of health biotechnology. A major concern that was raised is the fact that a lot of research activities were going on and with enormous potential and not much was being done to commercialize these products/ideas. This was identified as a major challenge that needed to be addressed within the national biotechnology strategy.

Some of the reasons advanced for the lack of commercialization of products within the university system was that "*academics feel that they have been trained to do research and not business.*" One researcher from University of Natal said that in their medical school they had devised new ways of doing things, out of need and necessity and went on to say,

"*they are not patented or anything. But they have potential...some of these things have potential.*"

Most universities do not have commercialization departments. The main reason given for this was that most of the research that is going on is at early stages, mainly as ideas or concepts and had not gotten to the level requiring commercialization. Most scientists felt that there was a need to introduce a legal and business course within the science curriculum to create awareness among future researchers.

Interestingly most of the people (even those who worked at universities) interviewed could not name exact research programmes. At best they described it as "*...there is a lot of research going on in our universities.*" The universities that were explicitly mentioned as having research programmes in health biotechnology are:

- **University of Cape Town (UCT)**

UCT is reputed for conducting cutting edge human health research. It is affiliated with two major hospitals, Groote Schuur and the Red Cross Children's hospitals. Its faculty of health sciences houses various MRC research units for instance, the human genetics research unit and the immunology and infectious diseases unit. It also has divisions conducting research in medical microbiology and virology.[147]

- **Stellenbosch University**

Stellenbosch University houses an MRC centre for molecular and cellular biology. This department is involved in various research projects. The TB research group focuses on the molecular epidemiology of M. tuberculosis in a local community, the genetics and spread of drug resistance, the host immune response, host genetic susceptibility, the search for surrogate markers for disease prognosis and the pharmacology of drugs used in the treatment of the disease. Other research projects include the investigation of genetics of cardiac diseases such as hypertrophic cardiomyopathy and progressive familial heartblock type II, the genetics of polycystic kidney disease, esophageal cancer and obsessive compulsive disorder. [148]

- **University of Natal/Durban**

The University of Natal has a very robust HIV/AIDS research programme, which has been described as one of the country's premier research centre for HIV/AIDS. It has a

[147] http://www.uct.ac.za

very comprehensive research programme that examines various aspects of HIV/AIDS infection. It research programme pools together eminent scientists involved in vaccine development and clinical trials.[149]

- **Witswatersrand University**

The Witswatersrand University is affiliated with the South African Institute for Medical Research (SAIMR) and has a strong human genetics department. This department researches on various aspects of human genetic disorders and offers genetic services.

- **University of Pretoria**

The University of Pretoria was often times mentioned with regard to agricultural biotechnology. However, the university has a laboratory working on familial breast cancer, which identifies mutations of breast cancer genes in the South African population.

- **University of Western Cape**

The University of Western Cape (UWC) houses the South African National Bioinformatics Institute (SANBI)[150], which in turn houses an MRC research unit. UWC was mentioned by the interviewees only with regard to SANBI.

### 4.4.1. The Education and Training System

The biggest item on South Africa's national budget is education, with approximately 21% of the national budget going into the education system[151]. As a result of apartheid, the education system is fragmented between the previously disadvantaged and advantaged institutions of learning. The institutions of higher learning were governed by the Universities Extensions Act, 1959, which restricted access to education on race and ethnic lines. The historically white institutions served educational and ideological needs

[148] http://www.sun.ac.za/Internet/Academic/Health/schools/Basic_appl_health/med_physbio/med_biochem/index.htm
[149] http://www.nu.ac.za/research/extra.asp?id=20&dept=RESEARCH
[150] Discussed under the Role of the MRC
[151] Information from interview

of the white South Africa, while the black institutions served to produce a "*subservient class of black people to serve the interests of apartheid.*"[152]

The experts interviewed averred that rural schools have a poorer educational infrastructure, with no books and sometimes, buildings. One expert said,

> *"...in black community schools, teachers were not trained to teach mathematics and sciences and were sometimes miseducated to ensure that the level of education remained vastly inferior."*

As a result of apartheid the overall education and training system in South Africa is not doing too well as it is characterized by disparities between blacks and whites in the development of human potential.[153] The country is currently going through a restructuring process of the education system with the aim to provide equitable access to schooling for children.[154] The proposal made by the department of education report is for the merger of historically black institutions with historically white institutions. It is hoped that by merging these institutions, problems such as the inability to attract and retain good staff and the lack of a research culture in the "black" institutions will be addressed.[155]

The primary and secondary education systems are accused of not doing enough to develop good scientists. The table below illustrates the poor output of mathematics and science subjects in the standard and higher grades. The table shows that the number of students taking mathematics and physical sciences is considerably lower in the higher grade (HG) than in secondary grade (SG) and the percentage of students who successfully pass is even smaller.

| Total No. of candidates (x1000) | Grade | 1997<br>559.0 | 1998<br>552.0 | 1999<br>511.0 | 2000<br>489.9 |
|---|---|---|---|---|---|

[152] Ministry of Education (2002) Transformation and Restructuring : A New Institutional Landscape for Higher Education
[153] Department of Education (2001)National Strategy for Mathematics, Science and Technology Education
[154] The department of education released a report in July 2002, on the transformation and restructuring of higher education in the country. This report is yet to be implemented.
[155] Cherry, M. (2002) The rainbow academic nation, *Nature* 417(23) 377-378

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mathematics | HG | Wrote<br>68.5 | Pass<br>22.8 | %<br>4.1 | Wrote<br>60.3 | Pass<br>20.3 | %<br>3.7 | Wrote<br>50.1 | Pass<br>19.9 | %<br>3.9 | Wrote<br>38.5 | Pass<br>19.3 | %<br>3.9 |
| Mathematics | SG | 184.2 | 66.9 | 12 | 219.4 | 68.6 | 12.4 | 231.2 | 72.2 | 14.1 | 254.5 | 79.6 | 16.2 |
| Physical Science | HG | 76.1 | 27.0 | 4.8 | 73.3 | 26.7 | 4.8 | 66.5 | 24.2 | 4.7 | 55.7 | 23.3 | 4.7 |
| Physical Science | SG | 65.2 | 35.2 | 6.3 | 83.8 | 43.2 | 7.8 | 93.5 | 44.0 | 8.6 | 125.1 | 55 | 11.2 |

*Table 4.2: Pass % in physical sciences and mathematics higher grade and secondary grade, 1997-2000.*
*Source: National Strategy for Mathematics, Science and Technology Education, 2001*

Another major constraint to the education system is the fact that most young people are not interested in the sciences because science careers are not well paying. Most of those who are interested in the sciences want to be medical doctors. The government is trying to sensitize people on the need to study sciences in the hope that they will eventually get into science-oriented careers. Mark Shuttleworth's trip to outer space served to illustrate that science can be fun and to encourage young people. The Shuttleworth Foundation is working hard to provide IT infrastructure into schools and hence create some excitement towards technology.

The tertiary education system was described as excellent and as offering good basic training. Biotechnology education mainly starts at the tertiary level. In some instances funding may be tied to educational activities. For instance the NRF provides research grants to support research in academic institutions and funding agencies such as THRIP require that a student be involved in a research initiative funded by them. Some scientists were concerned because there is no major university programme/degree course in biotechnology. Biotechnology is offered in most universities as a small component within other courses. Some expressed the need to introduce health biotechnology education to children earlier in their schooling since they are most impressionable then and thus develop a culture of thinking around biotechnology issues.

### 4.5 Role of Private Firms

#### 4.5.1 Local Firms

I explicitly asked the interviewees whether they knew of any South African health biotechnology private firms. The following is a brief discussion of the local health biotechnology firms that were mentioned by the interviewees.

- **Shimoda biotech.[156]**

Shimoda biotech. is a South African-based biotechnology company focusing on drug development and researching on novel drug delivery technologies. Greg Gilbert founded it in 1995 with an initial focus of conducting R&D on cancer therapeutics. Initial funding for Shimoda came from private investors. They have since expanded their research focus and have developed novel drug delivery systems that enhance drug molecules, proteins and/or genes to be delivered in selected sites within the human body effectively and efficiently. They have successfully developed cyclodextrin based drug delivery systems for which they have a patent and vesicle-based targeted delivery systems. In April 2002, the received venture capital funding from Bioventures.[157]

- **Bioclones (Pty) Ltd.[158]**

Bioclones is the largest dedicated biotechnology R&D company in South Africa. Cyril Donninger founded it in 1982 and is wholly South African owned. They have developed monoclonal antibodies for use in diagnostics and immunohistology. Bioclone holds patents for these products and exports mouse monoclonal peroxidase antiperxidase (PAP) to Europe. Bioclone is also involved in modern biotechnology R&D and they have developed a recombinant human erythropoietin REPOTIN®, for which they hold a patent. They work closely with local education institutions especially through Ribotech[159], which is one of its subsidiaries. Through these collaborations they are able to conduct clinical trials for their products.

[156] http://www.shimoda-biotech.com
[157] mention above under financial and tax systems
[158] http://bioclones.co.za
[159] Ribotech produces ssRNA and operates as a subsidiary of Bioclones (Pty) Ltd.

- **Electric Genetics**[160]

Electric Genetics is a bioinformatics company based at University of Western Cape (UWC), South Africa. It makes software for gene sequencing that enables pharmaceutical and biotechnology companies to accelerate DNA research by use of computer-based research rather than manual experimentation in the labs. They provide genomic data analysis systems and validate drug targets for pharmaceutical, biotechnology and genomic markets. It has 4 products, STACKdb, STACK_PACK, Evoke and ADAPT. Electric Genetics works in partnership with the South African National Bioinformatics Institute (SANBI)[161]at UWC. UWC is a 1% shareholder in Electric Genetic. In June 2003, Electric Genetic received VC funding from Bioventures.

Most of the people interviewed did not know of any local health biotechnology firm in South Africa. Some people said that there had to be some companies though they could not readily mention their names. It was felt that there needs to be a central database for information of what people are doing. One person said that the types of companies involved are "*...the small type that never hit the newspapers.*" It was felt that there were some small companies being formed by people leaving academia and there was an emergence of small companies setting up, though not very much publicized.

There are very few local biotechnology firms in South Africa due to lack of financial incentives for people to set up. This is a major cause of concern as "*most of the local innovations always tend to get a home offshore*." The reasons that were elicited for lack of a local biotechnology industry included the fact that health biotechnology is still a very young field and the nuances a bit complex for a small economy as South Africa's. Therefore South Africa does not have adequate infrastructure and resources to support a local industry. There also exists a gap between research and commercialization of products.

[160] http://www.egenetics.com
[161] Discussed under role of  the Medical Research Centre

The pre 1994 research focus was driven by the needs of a very small segment of the population and therefore there was no need to develop a huge S&T base. The previous regime was interested in building a military base and food security and mostly ignored biotechnology development. However the same scientific base and personnel that was created by this regime is the same base being exploited for biotechnology R&D.

Economic reasons were also cited for lack of local health biotechnology companies. Due to the high costs of labor and production most local firms are not able to run sustainably and as a result most otherwise viable local companies are bought out by large multinational companies (MNCs). One interviewee said *"the presence of large pharmaceutical companies intimidates local companies by dominating the market or by unfair competition."*

### 4.5.2 International Firms

There is a huge presence of multi-national companies in South Africa. It was generally felt that they only get involved at clinical trials and never get involved in funding research activities in South Africa. It was felt that they are mainly profit driven with very little interest in developing research capacity in the country. There is a feeling that international pharmaceutical companies are exploitative and therefore there is a need for South Africa to develop a local industry. The international companies were accused of having skewed interests, which do not exactly match with the local needs. This is the main reason why South Africa is trying to be self sufficient in vaccine production. One scientist said,

> *"...we have somehow to have our own vaccines...we have started our own industry ...that we can afford to do and maintain."*

The commonly mentioned international firms who are involved in developing South Africa's health biotechnology sector were:

- **Bristol Myers Squibb**

Bristol Myers Squibb works in collaboration with the South African government within the South African Partnership Against AIDS in developing solutions to address the HIV/AIDS epidemic. This public-private partnership works through the SECURE THE FUTURE programme, which has the following aims:

1. Preventing HIV transmission
2. Reducing the impact of HIV/AIDS by supporting community based care
3. Supporting public health initiatives to expand access to HIV/AIDS- related treatment.

- **Glaxosmithkline**

Glaxosmithkline works together with MRC in the Action TB Programme. Action TB is an initiative that was developed and funded by Glaxosmithkline in 1993. It is an international coordinated research programme, which funds research for TB in South Africa. This international research programme aims to develop new targets for anti-TB drugs, and help promote a better understanding of the disease. Action TB is an open research collaboration that encourages discussion between research groups and rapid publication of findings for the benefit of the wider research community. Eighty scientists are employed in South Africa from academic institutions and the commercial sector. It is the largest research programme of its kind in Southern Africa.

***Summary***

In summary the interviews identified a variety of actors in the development of the health biotechnology innovation system in South Africa. The main actors include the government working through the DST, the public research institutions specifically the MRC, universities, and private firms. Some interviewees did also mention that there was a certain category of scientists/individuals who were doing some cutting edge research in health biotechnology. These individuals were described as,

> *"...they really know about health biotechnology and some of them are not interested in the biotechnology strategy...they don't need it. They are highly*

*successful and do not need projects to get on with their work. They do their work and have international collaboration...and make money overseas."*

The World Health Organization (WHO) was identified too as having a limited role in the development of health biotechnology in South Africa. This influence is remotely felt through the interaction with the national Department of Health (DoH) and the MRC. Within the DoH it was felt that since WHO wrote a document on genomics and health, developing countries would start taking biotechnology more seriously. At the time of data collection, South Africa had not done anything about the WHO report at policy level.[162]

Other influences of the WHO that were mentioned include the creation of opportunities for international forums which enhance interaction with other professionals and access to knowledge networks, and consequently impacting on learning and personal development and to some extent support capacity development in the policy arena.

South Africa's biotechnology development strategy is through the formation of clusters and creation of linkages. This is evidenced by the creation of innovation centres, known as Biotechnology Regional Innovation Centres (BRICs), that provide a technological arena for different biotechnology focus areas. These centres act as linkages between different institutions and encourages knowledge sharing, joint research ventures and joint IP ownership. The biotechnology strategy also emphasizes the need for international networks for an improved and efficient innovation system.[163] The following section is an analysis of how these linkages and clusters are exploited to develop health biotechnology in South Africa.

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[162] However South Africa held a conference in March 2003 where the WHO Report on "Genomics and World Health" was adopted.

### 4.6 Developing South Africa's Health Biotechnology Sector through Linkages and Clusters.

#### 4.6.1 Linkages as a Source of Innovative Ideas

The isolation of South Africa from the international community in the 1980's created a situation where South Africa had to find solutions to its own problems. From the early 1960's to the early 1990's South Africa was subjected to various forms of boycotts from the international community. This included trade and academic sanctions. One of the impacts of the international sanctions was the increased need for South Africans to address their local needs and a greater need to rely on their own expertise.[164] This ironically created a strong basic research base within the academic institutions, which would later boost the development of the biotechnology sector in the country.

The scientists in this study were explicitly asked where they got their innovative ideas from and most cited the need to be self-sufficient as part of the reasons for innovation. Some attributed the innovations to lateral thinking coming from experience from research on local problems and talking with other researchers in developing countries who are faced with similar problems and issues and thus working together to come up with alternatives for their problems.

Exposure to the international community enhances innovation as this enables scientists to interact with other experts and share ideas at the global level. Every individual interviewed alluded to be involved in a collaborative research activity with other people or institutions. This emphasized the need for networking and creation of linkages for health biotechnology development.

Some scientists felt that most of their research ideas came from interacting with the local communities and as a result being aware of the problems facing these communities and

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[163] page 53 National Biotechnology Strategy

therefore devising ways to help the communities. To some extent this could be interpreted to be market demand. Other sources of innovative ideas include, continued schooling for researchers, workshops, scientific meetings, in-house research seminars, journal clubs and articles in journals. Easy access to biological material and good research facilities for experimentation were also cited as sources for innovative ideas.

The national health agenda to some extent also dictates the direction of innovation. The government has identified TB, malaria and HIV/AIDS as the 3 main focal areas for health research. Funding agencies provide a broad framework for research areas with an impact on developmental imperatives and this encourages researchers to think within the broad funding framework. Some scientists simply said that they are just interested in doing creative things and do things out of personal research interests and curiosity.

### 4.6.2 Linkages as a Source of Expertise

South Africa's top researchers are predominantly white and aging. South Africa faces a crisis of lack of adequately skilled personnel in biotechnology. This is compounded by the fact that the sciences are not attracting new interests characterized by a drop in the number of students enrolling for mathematics and physical sciences in the education system.[165] Based on a study reported by the Department of Education (DoE), student enrolment into mathematics and science subjects has progressively dropped in the period between 1997-2000, as illustrated by the graph below. This has had a negative effect on the supply of a skilled scientific labor force.

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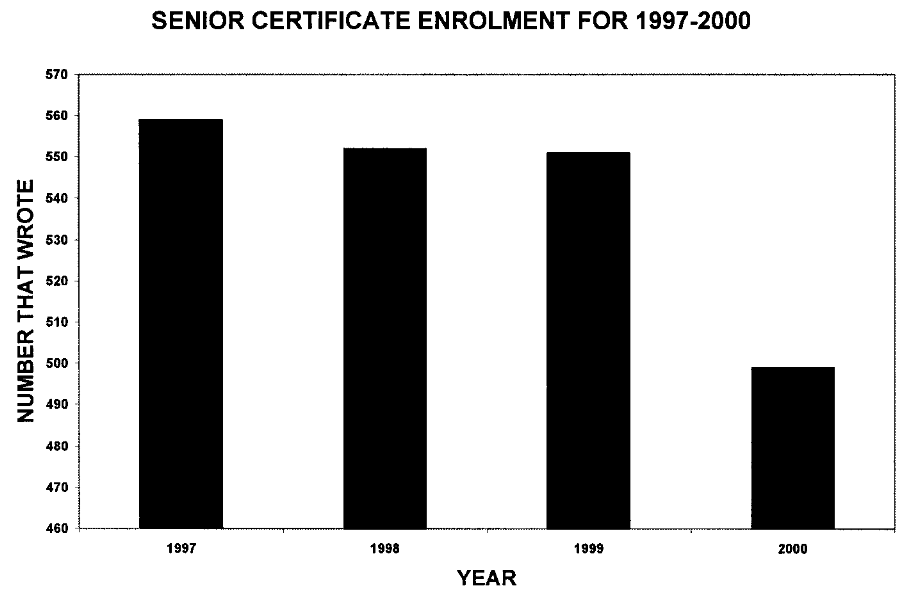
[164] Lancaster, F.W. & Haricombe, L. (1995) The Academic Boycott of South Africa: Symbolic Gesture or Effective Agent of Change. *Perspectives on the Profession. Vol.* 15(1) Fall

[165] Department of Education. (2001) National Strategy for Mathematics, Science and Technology Education, 2001




Graph 4.1: Senior Certificate Enrolments 1997-2000

*Source: DoE, National Strategy for Mathematics, Science and Technology Education, 2001*

Another factor affecting the availability of skilled personnel in biotechnology is the fact that most of the highly trained South African scientists are leaving the country for greener pastures abroad. It is estimated that a total of 233,609 South Africans emigrated in the period of 1989-1997, to the United Kingdom, United States of America, Australia, Canada, and New Zealand.[166] The highest percentage of the South African emigrants falls within the category of professionals or with high level technical skills.[167] One interviewee said that countries like Canada were attracting most of the scientists who *"...prefer to work in rural areas of Canada and get paid 6-7000 in salary...we call that poaching but Canada calls it global community."*[168]

166 Kaplan, D. *et al* (2000) Brain Drain: New Data, New Options, South Africa Network of Skills Abroad. (SANSA)
http://www.uct.ac.za/org/sansa

167 SANSA report (2000) *ibid.*

168 In 1998 the provincial government of Alberta, Canada developed a strategy to deal with the shortage of family doctors in rural communities of the province by recruiting South African doctors. See Bundred, P. & Levitt, C., Medical Migration: Who Are the Real Losers? *Lancet* 356 (2000) 245-6

Most of the research institutions and university departments in South Africa are under staffed. Under staffing is caused due to lack of sufficient money to employ permanent staff, or due to lack of replacements for retiring staff and as earlier mentioned, brain drain. It is no doubt most of the scientists are trained locally and are very competitive on the global landscape. The level of skill and competence of South African scientists is evidenced by the rapid absorption of South African migrants into the international job market.[169]

Most research institutions source their research personnel from universities. For instance the MRC relies heavily on university scientists and draws it research expertise from university research units. This is because MRC is "*a small organization with a small in-house component.*" The small scientific pool within the country was cited as one of the reasons why there "*specific people running the show with no new faces coming in.*"

Funding agencies are increasingly encouraging collaborative research as a requirement to fund any research activity. This is also the idea behind the formation of BRICs under the national biotechnology strategy. Through the linkages created in the BRICs it is hoped that South Africa will be able to adequately tap into the existing few experts and research infrastructure. One university professor who also works with SAAVI as well as several other research initiatives said that it was "*hard to tell when one is doing what for who*", because sometimes one person may have too many assignments.

Having established that most of the biotechnology R&D in South Africa takes place within the context of linkages and collaboration, we shall now examine the nature of the linkages by describing how they are formed, followed by the benefits and challenges of forming linkages.

[169] South African Migration Project (SAMP). (2002) Gender and Brain Drain from South Africa, *Migration Policy Series No.23*

### 4.6.3 Nature of Linkages

All the people interviewed said that they have formal linkages with various working partners. A few of the people said that together with the formal linkages they also have informal linkages. Most people said that they preferred formal linkages to avoid intellectual property ownership squabbles. Others said that formal linkages were important in laying out the "*rules of the game*", since South African researchers are no longer keen to be used for "*shipping biological material abroad.*" Formal linkages were preferred generally.

Both formal and informal linkages evolve in the same type of progression. These relationships emerge mostly from personal contacts and friends in a very ad hoc manner. These contacts are made either in university (where people studied together), or by meeting people in meetings or conferences, both locally and globally. Access to Internet and email facilities were cited as a major boost for follow-up, after conferences and meetings. Some researchers said that they started being contacted for projects after publishing in journals, other said that their reputation preceded them in most cases (headhunting for people based on reputation), while others simply felt that they were attracted to work with people with similar research interests.

Informal linkages always come into play when dealing with colleagues or members of same profession. They involve the exchange of techniques, skills and access to labs. These linkages come about as a result of using same research facilities/labs, same funding or having the same employer. Sometimes this relationship only involves a casual exchange of information "*over coffee.*" Sometimes it involves collaborative research. One scientist said that he favors this type of agreements because they are more relaxed and trust based, while another said he had experienced some authorship problems with informal linkages[170].

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[170] This researcher felt that his colleague had done a substandard job because no agreement or expected standards bound him.

### 4.6.4.a Benefits of Local Linkages

The government through the funding agencies and public research institutions is actively encouraging research collaboration. The education sector is also encouraging research collaboration between universities as evidenced in the transformation and restructuring policy of the education sector.[171] This is especially to facilitate dialogue between researchers from historically disadvantaged and advantaged communities. However one scientists from a previously disadvantaged institution felt that sometimes this kind of collaboration was mistakenly perceived as "*senior partner and junior partner*," and that there is an "*unnecessary scrutiny*" of grant applications from historically disadvantaged universities. While it was generally thought to be advantageous to have research collaborations, some people said that these linkages could sometimes be abused. One person said,

> *"Some of the local linkages can be abused since some partners may only be interested in one partner providing for instance specimen, and just being used on paper as a partner for funding, and without benefit at all."*

One of the benefits for local linkages is the ability to access and use the available experts in the country, whose skill and knowledge is otherwise unavailable in-house. Such networks enhance the scientific and technological support for research projects.

The nature of biotechnology is dynamic and multi-disciplinary. Therefore the exploitation of diverse local expertise leads to better research results/products and may also be an opportunity to share resources to avoid duplication. Large multi-faceted research ventures tend to attract more financial support and therefore, linkages can be used as a leverage for funding. In fact most funding agencies require collaboration as a condition for funding. It is also cost effective to generate IP in a partnership.

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[171] Ministry of Education (2002) Transformation and Restructuring : A New Institutional Landscape for Higher Education

In most instances it is advantageous for researchers working in vaccine and drug development to have research collaboration with university departments that are associated with hospitals. This is because through the universities (medical schools) researchers get access to patients and research tissue. These types of collaborations make it easier and cheaper to conduct drugs and vaccine trials. Most people also felt that biotechnology innovations take place within university research departments and therefore it is important to maintain links with them.

Collaborative research also contributes to capacity building within and without universities. For instance, SAAVI was said to contribute immensely in training the researchers in various aspects of biotechnology and vaccine development. Through SAAVI researchers get the opportunity to learn new trends of the basic science of vaccine development, and latest discoveries and techniques associated to vaccine reactions and immunology monitoring. An initiative as big as SAAVI also serves to train those involved through learning by doing, how to run a large multi-centre/multi-national biotechnology initiative.

Linkages also serve as a source of information of what is happening and the potential opportunities available. It creates possibilities for joint research activities, which are a career boost for most people especially if working with people with good academic reputation. All in all these avenues for information exchange create career improvement opportunities.

Most funding agencies prefer collaborative research as this serves as a quality control mechanism. They mostly prefer formal linkages as this eliminates business management problems, IP and ethical problems. These types of linkages are also useful because clear goals and milestones are set out and therefore enhance research performance.

#### 4.6.4.b Challenges in Local Linkages

It was generally felt that there is a very small skill base in the country, which leads to "fierce" competition for very limited skills. This sometimes causes the scientists to be thinly spread over many research projects. This usually affects their level of commitment and sometimes their performance. Lack of adequate skilled personnel is attributed to a historically segregated education system, brain drain, lack of incentives for scientists and a problem with permanence of staff. The fact that genomics and other biotechnology-related subjects are new is another reason for lack of adequate skill.

There is tension between the previously disadvantaged institutions and advantaged institutions. This leads to a situation where collaborations are not maximally used. Academic challenges were also cited among the disadvantaged communities, which creates an enormous vacuum between upcoming scientists and the already existing scientists. Inter-lab jealousies and morbid competition among colleagues is another very common challenge to productive linkages.

Political challenges were commonly cited by most researchers as a major obstacle to their work. Some felt that the position taken by the government on HIV/AIDS creates a huge amount of psychological despondency and therefore prohibiting easy access to patients to conduct vaccine and drug trials.[172] Those who work closely to the DoH felt that the department does not always work to enhance and support development.

Another challenge is that there is a very low number of post-doctoral fellows in the country. The university infrastructure, with the exception of UWC[173], does not allow for research scientists to work in the universities without taking a teaching position. There are no scientist positions in the university system and this was cited as a challenge in the interviews. The effect of this is that the universities do not employ research scientists to

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[172] President Mbeki has always stated that he maintains an open mind on whether HIV is the cause of AIDS, which has caused a lot of controversy among the South African scientists. In 2000 a presidential advisory panel was constituted to consider the causes of the immune deficiency leading to AIDS.

[173] Information from interview

do research within the university without necessarily having a teaching position. It is reported that post-doctoral bursaries amount to 40% of the amount that most post -docs earn abroad.[174] As a result universities and other research institutions are likely to lose highly skilled biotechnologists.

### 4.6.5.a Benefits of International Linkages

It was unanimously expressed that although it is important to engage with international collaborators, the research agenda has to be oriented to the needs of the South African community. One scientist said,

> *"I am not here to be a pair of hands for international research...am here to do the research that we as a country want to do and is relevant to us."*

One of the benefits of international linkages is the exposure it gives the South African scientists. International exposure enables the South African scientists to know the recent biotechnology trends and therefore keep them well informed. Another practical level of exposure is offering training opportunities abroad. This exposes them to different research approaches and methodology and to different scientific environments. Training abroad and student exchange programmes are mostly useful for courses and curriculum not offered at the local universities.

International collaborations also enable academic institutions to have access to senior academic staff from abroad who are willing to spend some time at their local universities and also play a mentoring and supervisory role to South African students. This is particularly beneficial to the grossly understaffed institutions. One university researcher interviewed in this study had this to say,

> *"...one of the big issues that we have is mentoring. We don't have enough...I'm mentoring 8 masters students and 4 Ph.Ds and am alone...So a direct benefit will be that senior academics from Norway [University of Bergen] will come and spend time and actually share that mentoring load and give support to the students and to the academic staff."*

[174] Page 24 of the National Biotechnology strategy

Another benefit of international linkages includes getting access to international research grants. These are particularly useful because they tend to be in huge amounts. Others are access to technology and skills that facilitate technology transfer, and access to markets and networks that are vital. Another benefit of international linkage especially among developing-country-partners is to provide complementary services between them and creation of a research consortia with developing country scientists for, "*academic thinking and research in biotechnology products that are beneficial, affordable, accessible and acceptable to the local communities.*"

International linkages create networking opportunities with eminent researchers who sometimes may be brought into research projects if their type of expertise is unavailable locally. These types of networking also provide opportunities for South African researchers to go abroad and do research in their collaborators' labs, which are better equipped. For instance one researcher who was interviewed in this study stated that he has a collaborator at the Harvard University with whom they work in a research project for genetic diseases.

The South African scientists stated that the advantage in this collaboration is the fact that he has access to the Harvard labs, "*...which are bigger and better equipped.*" Just like local linkages, international linkages are also a source of information for what is happening and the type of career development opportunities available.

#### 4.6.5.b Challenges for International Linkages

Most of the people interviewed said that the major challenge with international partnerships was that most of the international partners have "*their own*" agendas that don't match the local research agenda. They said that they had to very alert and aware of the conditions of partnerships. For example, an organization like MRC is only interested in research that would meet the national health imperatives and directly benefit the local people, so it would be very hard to get into a partnership with anyone who does not match that requirement.[175]

Another challenge is that South African scientists find it really hard to build and penetrate these networks. One expert felt that "*it's very hard for a small organization sitting at the tip of Africa to be taken seriously.*" Others said that they had experienced hardship in trying to bring international experts due to the immigration laws that make it extremely hard to bring in skilled professionals. Immigration in South Africa is governed by the Aliens Control Act of 1991. The immigration law has been criticized as being "archaic and having cumbersome procedures"[176] that make it difficult for even skilled people to come into the country. Logistical challenges such as distance and language barriers were also cited as challenges to optimal international linkages.

### 4.7 The Presence of Health Biotechnology Clusters in South Africa.

This study defines clusters as "geographic concentrations of interconnected companies suppliers, service providers, firms in related industries and associated institutions (e.g. universities, standards agencies and trade associations) in particular fields that compete and also co-operate."[177] The people interviewed in this study were explicitly asked whether they thought there was an emergence of a health biotechnology cluster in South Africa. Coincidentally, at the time of data collection, DST had put out a request for proposals for BRICs. The national biotechnology strategy proposes the formation of BRICs, as an attempt to form biotechnology clusters within different regions around the country.

The response was that there are no biotechnology clusters in South Africa. The DST strategy was perceived as a move to encourage the formation of clusters. The BRICs idea

[175] In one instance MRC was approached to evaluate a new agent for TB that was extremely expensive, it cost US$500 for each inhalation and patients were had to inhale 3 time a week. That was not applicable to the poor South African community, and the company was turned down.
[176] Crush, J. (2002) The Global Raiders: Nationalism, Globalization and the South African Brain Drain. *Journal of International Affairs.* Vol. 56(1)148-171
[177] Michael Porter in Porter, M. (1990) Competitive Advantage of Nations. London: Macmillan

is putting people together and pooling resources to stimulate biotechnology development. It is hoped that the BRICs will bridge the gap that exists. Some optimism was expressed about the formation of a health biotechnology cluster around the Cape Town region because "*there are 2 mighty universities, MRC, 2 large hospitals and technikons*[178]."[179] It was also felt that there might be an agricultural biotechnology cluster around the University of Pretoria.

Some people felt that South Africa does not have what it takes to have clusters. The reasons given for this kind of skepticism were that the technology is still at very early stages, lack of critical mass to form a cluster, insufficient engagement with the VC industry and a deficiency in business expertise in this area. There is not enough money in the country to take ideas from research to commercialization.

Despite the effort made by DST to create clusters, it was still felt that this might not be sufficient to spur the development of biotechnology clusters. It was felt that there is no team promotion among the scientists. Also it was felt that the black community is not adequately represented because the research scene is "*constantly dominated by the same faces and race groups.*" People invite others to their research ventures depending on how much they can trust them. One person said,

> *"People try to do research together but I don't think that is fundamentally working...you just get more funding if you are in a cluster with industry or with another academic partner. There are small groups of people working together but couldn't be termed as a cluster."*

Generally, it was felt that there are no clusters, though most people alluded to a fair amount of interaction and networking with other institutions. What really exists is a team of consortia in different parts of the country doing collaborative research and most times people just do their own research, or individuals try to promote their work.

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[178] Technikons are the equivalent of what are known as polytechniquesin other countries.
[179] The 2 universities referred to here are University of Cape Town and the University of Western Cape and the 2 hospitals are Groote Schuur and the Red Cross Children's' hospital.

A very important aspect of successful technology is its implementation and application by communities. I went ahead to find out how receptive the South African community was to biotechnology and how knowledgeable the communities are of the benefits and risks associated to biotechnology. I asked all the interviewees to tell me what their thoughts were on how people felt about health biotechnology and biotechnology products. This brings us to the next section on public perceptions towards biotechnology.

### 4.8 Public Perceptions towards Biotechnology.

South Africa is a country in transition and faces significant historically based challenges. The majority of the people interviewed felt that biotechnology did not rank very high in the national priorities since the government has other imperatives to deal with such as political problems, poverty among the rural communities and crime. It was therefore felt that most people, especially the rural people did not concern themselves with biotechnology as they are faced with more pressing needs.

On a general assessment, there is a very low level of knowledge of biotechnology and the potential risks and benefits. This was mainly attributed to the prevailing low levels of education among the people. There is however, a very small portion of the population that is very well informed of all biotechnology trends. Majority of the people think that biotechnology is synonymous to genetically modified organisms. These misperceptions, which have largely led people to think that biotechnology (read GMOs) is dangerous, are mainly perpetuated by popular media and what was termed as the "*hit and run attitude by foreigners*". One expert described the hit and run attitude as when foreigners,

> *"...bring in products and say, "well, I think this is what you need, " without addressing issues such as affordability and safety."*

Statements and attitudes of high-level government officials play a major role in influencing the public perceptions toward biotechnology. For instance it was said that there has been a lot of confusion and damage caused by public confrontations between some scientists and government officials to the communities about HIV/AIDS. One scientist said, "*it is likely to cause problems when the technology is eventually introduced.*" It is felt that the government needs to improve the way it presents some of the issues to the public. On a positive note however, these confrontations about HIV/AIDS have caused a certain level of awareness (whether appropriate or inappropriate) and there is now a huge interest in what is happening in the development of the HIV vaccine by SAAVI.

Another facet of public perceptions, is that health biotechnology or health related solutions, are not met with resistance as agricultural biotechnology. People would for instance, happily take a medication if it promises to make them feel better or a vaccine if it promises to prevent them from getting sick. Only the affluent people can afford to be choosy, a luxury the poor and sickly cannot afford. Sometimes people are either too hungry or too sick to be bothered about biotechnology.

The scientific and research community is very positive and enthusiastic about biotechnology development. It was felt that a "*strong caution and ethical approach to things is very important to avoid indoctrinating society about biotechnology, but present a fair view of both negative and positive aspects.*" The public should be given enough information to be able to clearly understand the meaning of biotechnology. One person said that majority of the South Africans "*need to engage first with the definition of biotechnology...before asking them to use it.*"

Lack of sufficient knowledge about the benefits of biotechnology was cited as the reason why there is a lot of pessimism among the South African community and also extending to the business community. Lack of knowledge was cited as part of the reason why there is no VC industry in South Africa actively involved in biotechnology.

I explicitly asked whether there is any awareness creation programme initiated by institutions or government. Awareness creation is mainly at institutional level and did not go far enough to the community. However some government institutions, DST, DoH, MRC, are beginning to put in place awareness creation programmes aimed at educating and informing the communities about various aspects of biotechnology.

Most people acknowledge the efforts made by DST to spearhead the development of biotechnology in the country. The success of health biotechnology in South Africa depends on how a number of the aforementioned challenges are addressed. The following is a discussion of these results and their implications to the development of the health biotechnology sector in South Africa. It will identify main themes emerging on the steps taken by South Africa towards creating a robust health biotechnology sector.

## Chapter 5.0 Discussions

### Introduction

This final chapter sums up and analyses the different themes emerging from the synthesis of the data collected on the development of the South African health biotechnology innovation system. The themes presented here are those that have been identified as crucial in influencing the development of health biotechnology in the country. The results as presented in the previous chapter reveal a progressive strategy identified by South Africa in identifying their competitive edge in health biotechnology development and exploiting it to meet healthcare needs, wealth creation and economic progress. The factors influencing the development of health biotechnology in South Africa as discussed hereunder are:

1. Government fostered development
2. Focus on HIV and Local Health care needs
3. Exploitation of traditional medicine and Indigenous knowledge
4. Apartheid and the legacy of the past

This chapter identifies the major successes of the South African health biotechnology innovation system and provides possible lessons for other developing countries. The major challenges facing the sector are also identified. At the end of the chapter, I revisit the objectives that were laid out in the introduction chapter and analyze how this study has met those objectives and identify the major contributions to the existing body of knowledge.

### 5.1 Government Directed Development

The South African government has been instrumental in fostering the development of health biotechnology through the creation of policy frameworks and investment in biotechnology R&D. Post 1994 the South African government has focused on stimulating

S&T policies that encourage industrial competitiveness through technological development. Health biotechnology falls within the broad S&T framework envisioned by these policies. The government has also been instrumental by working with the research community to identify niche areas that the country can strategically exploit.

The leadership role played by the South African government structure in fostering health biotechnology development is discussed here with specific reference to how this has impacted on health biotechnology development. The future of health biotechnology innovations looks very promising as it is supported by a strong political will with a focus on products. The South African government provides a good example to other developing-country governments to provide leadership and support for health biotechnology development. The section on government fostered development will focus on policy formulation, investment in biotechnology R&D and the creation of linkages. The diagram below illustrates the different ways in which the South African government is fostering health biotechnology development.

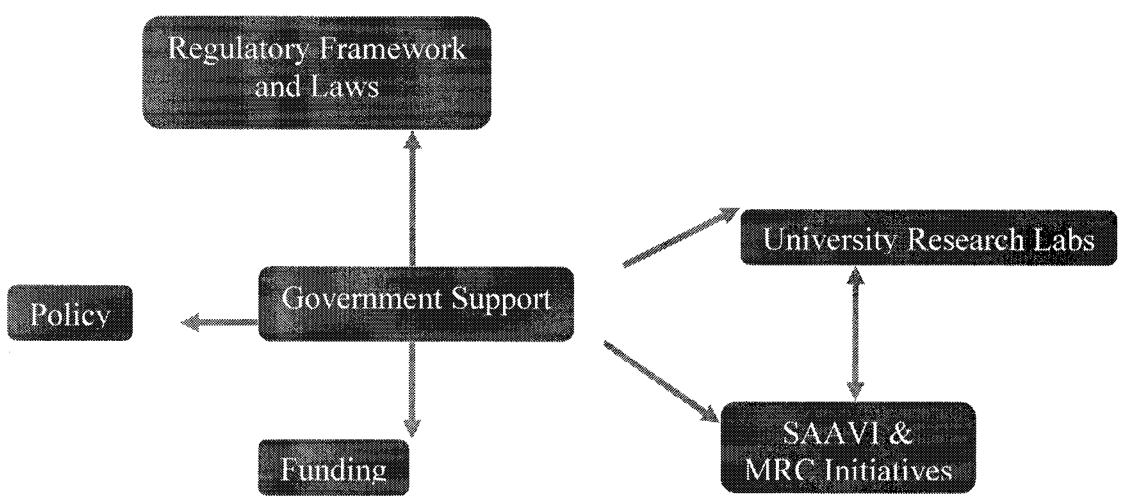


Diagram 5.1: Government Support to Health Biotechnology Development

***Policy Formulation***

The South African S&T policy process shows a tremendous shift from vague policies to more action-oriented policy plans. This trend can be traced back to 1993[180], when the country took its first major restructuring step of the S&T infrastructure. This led to a national science and technology foresight exercise formally known as the National Research and Technology Foresight Project.[181] Among other areas, health technologies were identified as potentially contributing to significant improvements in the quality of life of South Africans in the next 10 years.

The White Paper on Science and Technology was formulated in 1996 and provided a broad S&T policy that did not address specific issues of biotechnology development. The National Biotechnology Strategy (2001) was developed to fill in the gaps of the WP. The biotechnology strategy aims to develop a viable and sustainable biotechnology industry and identifies health biotechnology as one of the areas that R&D investment should focus on. The strategy puts emphasis on an approach that uses health biotechnology applications to address the country's health needs and areas that are of national priority. For instance government effort is targeted towards the development of a HIV vaccine through the South African AIDS Vaccine Initiative (SAAVI) and a TB vaccine initiative through the TB LEAD Programme.[182]

The formulation of the White Paper on Science and Technology in 1996, led to the creation of agencies such as the Innovation Fund and the National Research Foundation (NRF), which are major funding bodies for biotechnology generally and health biotechnology specifically.

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[180] In 1993, The African National Congress (ANC) commissioned the International Development Research Centre (IDRC) to write a report on the country's S&T infrastructure. The report was titled, "Towards Science and Technology Policy for a Democratic South Africa."
[181] http://www.dacst.gov.za/science_technology/foresight/index/htm
[182] LEAD Programmes are those considered to be of national priority. They focus on HIV/AIDS, TB, Malaria, Genetics & Genomics and Crime & Violence.

Critical aspects of success of the biotechnology strategy include the creation of the Biotechnology Advisory Council (BAC) within the Department of Science and Technology (DST), which acts as a national champion for biotechnology development. As a national champion, they play the role of coordinating biotechnology policy, research strategies and funding. The creation of Biotechnology Regional Innovation Centres (BRICs)[183] as regional clusters of biotechnology innovations, and specifically the creation of Cape Biotechnology Initiative, which focuses on health biotechnology is clearly a shift from vague policies to tangible action plans.

***Government Investment in Biotechnology R&D***

As was discussed in the previous chapter the South African government has created a number of funding agencies to fund biotechnology R&D. These funding agencies include, the NRF, the Innovation Fund, the Technology and Human Resource for Industry programme (THRIP) and GODISA[184]. While it is argued that increased funding does not necessarily result into increased innovation[185], the increase in government funding for biotechnology R&D in South Africa has served to create awareness and to encourage research in biotechnology.

The government uses these funding agencies to enhance the development of a robust mission driven innovation system. For instance, government funding is tied to funding research that addresses national priorities. Focusing on national priorities such as disease alleviation can have a cascading effect that is eventually reflected in economic growth.

Government funding is also used to leverage funds from industry and in turn creating a bridge between research and commercialization. For example THRIP funding has a condition for a matching grant from industry. Together with bridging the gap between

[183] BRICs provide technological platforms for different biotechnology focus areas and acts as a focal point that brings in specialized experts and capital equipment
[184] GODISA is a South African initiative with a series of activities/programmes jointly funded by the EU and DST to facilitate technology transfer and incubation in small, medium and micro-enterprises (SMME).
[185] Mani, S., (2001) Government and Innovation Policy: An Analysis of the South African Experience since 1994. *UNU/INTECH Discussion Paper* No. 2001-2

research and commercialization this can be seen as a strategy towards building a biotechnology industry within the country.

Some funding agencies require that a research project must include a training component and essentially create an academic linkage. THRIP funding is a good example of this type of arrangement. Biotechnology innovations are based on learning and the exchange of knowledge, the requirement for an academic partner creates an easy flow of knowledge between academic institutions, research institutions and then to industry. This is a way of ensuring that what is learnt is also put into practice- a strategy that has been applied in the German innovation system.[186] The consequence of this strategy is ensuring a continued supply of skilled labor into the field of biotechnology.

Government funding for biotechnology is also used to enhance research in what may be termed as the country's niche areas. The exploitation of traditional knowledge and indigenous plants is identified in the biotechnology strategy as one area that South Africa has a competitive edge. Funding agencies such as the NRF and the Innovation Fund target research for indigenous knowledge and also offer educational grants in this field.

***Fostering of Research Linkages and Knowledge Sharing***

The creation of linkages and research networks closely overlaps with the issue of government funding. The South African government has put in place various mechanisms to ensure collaborative research and knowledge sharing. This is important in the South African research policy framework due to the historical divisions that existed between the black and white communities in the apartheid period.

One way in which the South African government is fostering the creation of research linkages is by restructuring the education and training system. The department of

[186] The German Innovation system relies heavily on the practice of apprenticeship to pass on knowledge and skills. Refer to Keck, O. (1993) The National Systems of Technical Innovation in Germany, in Nelson R.R. (ed.) National Systems of Innovation: A Comparative Analysis. Oxford University Press.

Education (DoE) released a report in 2002[187] that proposes the merger of historically black institutions with historically white institutions. This is a move towards encouraging a research culture in previously disadvantaged universities and consequently enhancing scientific innovations.

The creation of BRICs as biotechnology focal points is one way that the government attempts to foster the creation of linkages for biotechnology development. The Cape Biotechnology Initiative in Cape Town is supported by academic institutions (University of Cape Town & University of Western Cape and University of Stellenbosch) the Medical Research Centre (MRC), and 2 large hospitals (Groote Schuur and the Red Cross Children's' Hospital). The strategy also requires that the BRICs be linked to a biotechnology incubator, which will in turn be linked to a spin off company. Shimoda biotech[188], which is a biotechnology company, works within this cluster. This is a clear attempt of bringing all the actors of the health biotechnology innovation system together through a research network.

### 5.2 Focus on HIV/AIDS and Local Health Needs

Another theme emerging from the study as a factor influencing the development of health biotechnology in South Africa is the problem posed by the HIV/AIDS epidemic. The advent of HIV has been a powerful catalyst for health biotechnology development in the country. The need for South Africa to find a solution to this epidemic that is estimated to have claimed 360,000 lives in 2001 alone[189], has encouraged research in various aspects of vaccine and drug development for the HIV virus and also for opportunistic infections. As a result R&D for TB in South Africa has being strengthened, the net effect being the development of health biotechnology in the country.

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[187] Ministry of Education (2002) Transformation and Restructuring : A New Institutional Landscape for Higher Education
[188] See details in previous chapter
[189] UNAIDS/WHO (2002) Epidemiological Fact Sheet on HIV/AIDS and Sexually Transmitted Infections

The South African healthcare system is crumbling under the effects of this epidemic at a time when it is going through reconstruction after the apartheid era that was characterized with wide disparities in health and access to healthcare.[190] The HIV/AIDS problem presents various challenges to the South African policy-makers, medical personnel and research communities that have caused them to take a radical shift in research and funding research so as to focus on combating this problem.

Considerable research is taking place in the country, the most prominent being the South African AIDS Vaccine Initiative (SAAVI). It is argued here that it is the need for an urgent solution to the AIDS menace that has spurred biomedical research and biotechnology development in this subject matter. The AIDS problem in South Africa is multi-faceted as discussed herein and affecting various aspects of life, therefore calling for remedial steps.

***Availability and Access to HIV Drugs.***

The healthcare system in South Africa is faced with the problem of lack of access to cheap HIV drugs. Given the magnitude of the HIV crisis in South Africa, they cannot continue to rely on multi-national pharmaceutical companies to provide drugs. The drugs from these companies are expensive and not accessible to majority of the poor South African population, who are ironically the most affected by the AIDS pandemic[191].

Pharmaceutical companies have also expressed a continued apathy and lack of interest in investing in R&D for diseases such as malaria and tuberculosis that cause considerable mortality and morbidity in South Africa.[192] It is estimated that approximately 28 million of the 45 million people living with HIV/AIDS live in Sub-Saharan Africa. This is largely a poor population that cannot be expected to provide a huge profit margin for

[190] Benatar, S.R. (2001) South Africa's Transition in a Globalizing World: HIV/AIDS as a Window and Mirror, *International Affairs* 77, (2) 347-375

[191] One research scientist working with a vaccine initiative in South Africa said, "I really passionately believe that we need to have vaccines available for Africa. I don't have to make money. It's really to have the products out there in the public domain that people can use."

[192] Benatar, SR. (2001) *supra*

multinational companies. It might be speculative to say that if left alone, pharmaceutical companies, are likely to withdraw from providing AIDS drugs if the market proves not to be profitable.

In the face of all these realities, the South African government together with the Medial Research Council, other public research and academic institutions have come together under SAAVI to develop a South African AIDS vaccine which is a remarkable step towards addressing the HIV crisis in South Africa.

The Indigenous Knowledge Systems programme at the MRC, which is an effort towards clinically proving the efficacy of traditional medicines that are said to have immune boosters, used by local communities is also one way of trying to find a remedy for the HIV epidemic. The integrated approach that includes the use of indigenous knowledge[193] towards finding a cure is a clear unique and innovative way of a South African effort in addressing local health needs.

***The Social-Economic Impacts of HIV/AIDS***

Together with being a health concern, HIV/AIDS poses serious social-economic problems that could be addressed if there were a cure for AIDS. The social-economic impacts of AIDS contribute to the need for research and consequently contributing towards health biotechnology development.

The UNAIDS report (2002) estimates that majority of the infected adults are within the ages 15-49. This is usually the most productive period in one's life and therefore means a decline in human resources. It is expected that over the next 10 years the number of employees lost to AIDS in South Africa could be equivalent to 40-50% of the current workforce.[194] It is estimated that a quarter of South African miners are HIV-positive

[193] See table 1 of chapter 4
[194] Love Life Report (2000) The Impending Catastrophe: A Resource Book on the Emerging HIV/AIDS Epidemic in South Africa. http://www.lovelife.org.za

along with almost a fifth of workers of construction.[195] Consequently if South Africa does not address the HIV/AIDS crisis, the country's sustained progress and economic growth is threatened by the HIV epidemic.

### *The African Virus*

The HIV virus that is prevalent in the southern African region is not the same as the one found in western countries. The HIV-1 subtype characterizes the southern African epidemic, while HIV-2 subtypes characterize AIDS in western countries. This therefore implies that most of the research carried out in western countries is specific to the virus most prevalent in the region.

SAAVI focuses on developing a vaccine against the HIV-1 subtype. Studies show that there are major differences between HIV-1 and HIV-2 that require further study.[196] HIV-2 is less transmittable and its infection is compatible with a normal life span in majority of the infected people, while the HIV-1 subtype is more virulent.[197] This is a clear example of a need driven R&D initiative where South Africa is doing research relevant to the country's health needs and consequently impacting on the development of health biotechnology. This fact comes out clearly from the interviews conducted whereby the researchers said that they were mainly motivated to do research that enables them to find solutions for the problems they encounter with the communities.

## 5.3 Exploitation of Traditional Medicine and Indigenous Knowledge

Another theme emerging from the data collected and is identified as strongly influencing the development of health biotechnology in South Africa is the exploitation of the rich biodiversity and natural resource base in the country. This factor combined with the use

[195] The Economist (US) (2001) "The Worst Way to lose Talent; Business and AIDS; South African Firms and AIDS. February 10 pg. 7
[196] Popper, S.J. (1999) Journal for Infectious Diseases
[197] Kaul, R. *et al* (2000) Nature Immunology

of indigenous knowledge to exploit medicinal herbs is strongly coming into play as a factor towards health biotechnology development.

It is estimated that there are 250,000-300,000 traditional healers in South Africa.[198] During the apartheid period traditional medicine practices were shunned and forbidden[199]and therefore the use of indigenous knowledge for economic gain was never addressed at policy level. However post 1994, the South African government through various agencies has began appreciating the potential of using indigenous knowledge to address health needs within the country and also for economic growth to the local communities as well as to the country.

A successful innovation system works through the introduction of new knowledge into the economy[200]. For a developing country like South Africa it is important to integrate aspects of local and traditional knowledge into the economy through a broad-based innovation systems approach.[201] The results of this study indicate that South Africa has adopted this type of innovation strategy that takes into account of the vast natural resources in the country and local knowledge that have been used for years for medical purposes by traditional healers. Exploiting this knowledge through a biotechnology platform and putting in place a regulatory framework is an attempt to harness the knowledge in a sustainable way for economic development.

The MRC Indigenous Knowledge System (IKS) is one such example where there is an attempt towards institutional change that brings in the participation of traditional healers. IKS does this by conducting health research studies in indigenous knowledge and creating new opportunities within medical research to benefit the local communities that are "keepers" of this knowledge and ultimately the country. One good example where

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[198] Fako, T.T, *et al* (2000) 'Transferring Health Technology to South Africa: The Importance of Traditional African Culture.' *Journal of Technology Transfer* (25) 299-305
[199] Fako T.T *Ibid*
[200] Lundvall, B.-A. *et al* (2002) 'National Systems of Production, Innovation and Competence Building.' *Research Policy* 31: 213-231
[201] This is an approach that considers the peculiarities of the innovation system in study and has been used to study the Danish System of Innovation. See Lundvall, B. -A., (2001) Innovation Growth and Social Cohesion: The Danish Model. Edward Elgar, London.

indigenous knowledge contributes to health biotechnology development is the scientific testing and further development of medicinal plants, which are said to have immune boosters. This project is currently undergoing clinical trials[202].

The evidence gathered from the data collected in the interview shows that intellectual property in indigenous knowledge has been lost from South Africa over the years, for example the San bitter hoodia that was developed by Pfizer into an appetite suppressant pill. However the recent years in South Africa have been characterized by an awareness of the need to protect this intellectual property through the creation of relevant polices and legislation. The Department of Science & Technology (DST) is currently in the process of formulating a national policy for the management of indigenous knowledge and has drafted two bills[203] for IP protection in indigenous knowledge.

There are various linkages and networks formed for knowledge sharing in indigenous knowledge research. There are also indigenous knowledge research units within universities such as the University of Cape Town (UCT) and the University of Western Cape (UWC), whereby through scientific research there is a concerted effort to add value to traditional knowledge. The presence of linkages is an important ingredient for an innovation system. The MRC-led 'Antimalaria medicines from medicinal plants of Southern Africa' initiative is a good example. It comprises of a consortium of a team from University of Cape Town, Council for Scientific and Industrial research (CSIR), National Botanical Institute and University of Pretoria. This is clearly a lesson that can be borrowed by other developing countries within the region to tap into indigenous knowledge for biotechnology development and will be discussed later in this chapter.

### 5.4 Apartheid and the Legacy of the Past

Apartheid in South Africa and the consequential isolation from the international community emerges as a theme contributing to the factors influencing the development of

[202] Information from interviews

health biotechnology in South Africa. The interview data suggests that due to the isolation South Africa could not import necessary products and therefore started focusing on research that would address their local needs. This led to the development of a strong scientific base for the mining and arms industries. South Africa is a leader in some technologies such as deep mining, armament and food processing.

The development of the mining industry can be traced back to the last part of the 19th century when gold and diamond were discovered in the country. The country developed vertical and integrated mining combines to harness these precious metals. This structure was supported by a rapid growth of apartheid labor relations. The country became self-sufficient and by the time of the World War 1 (WW1) the country served as a source of supply to the allied war efforts. Subsequently an industrial base was set up and a set of science research councils and produce research agencies established to support the mining industry. The scientific infrastructure set up to support this industry was later to be used to develop biotechnology in the country.

The militarization of the South African economy after 1948 when apartheid was formalized in South Africa caused the need for the country to be self sufficient in supplying energy and weaponry. State research institutions concentrated on R&D for weapons and as a result South Africa now has a very advanced nuclear weapons program. This scientific expertise and other research infrastructure that was developed has contributed in enhancing the development of S&T in South Africa and has had a spillover effect to the development of biotechnology.

The international boycott imposed on South Africa in the mid 1980's and other sanctions caused the country to develop their own technological base to address her needs. A number of statutory scientific councils were established to develop human resources and research capacity. Other aims for the science councils included to fund and carry out research, to provide standards and testing facilities and to develop and transfer various

[203] Bill on recognition, Promotion, Development and Protection of Indigenous Knowledge Systems and the National Biodiversity Bill.

technologies Such councils include the Council for Mineral Technology (MINTEK), Council for Scientific and Industrial Research (CSIR) and the Human Sciences Research Council (HSRC). These science councils now operate with a more inclusive research agenda and are contributing to the development of biotechnology generally and health biotechnology specifically.

The academic boycott prevented many South African academics from attending overseas conferences and from having their research published in international journals.[204] Despite the sanctions against South Africa, 46 years of apartheid in South Africa produced the most advanced economy in Africa.[205]

The success in these two industries created a level of confidence among the South African scientists and started spilling over to veterinary sciences. This cultivated a culture for research that was aimed at local needs. The isolation of South Africa from international interactions and the apartheid legacy in a way causes South African scientists to endeavor to research new and innovative ways that specifically target local needs and therefore boost the local biotechnology innovation system.

## 5.5 Major Challenges Facing the Health Biotechnology Sector in South Africa

The development of health biotechnology in South Africa is also faced with some challenges. The following is a discussion on the challenges that were identified during the interview process as affecting the success of the creation of a robust South African health biotechnology innovation system.

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[204] Linda, V., (1991) Commonwealth Nations Agree to End Academic Boycott of South Africa. *The Chronicle of Higher Education* International News: 30th October

[205] Johns, D., (2001) Health and Development in South Africa: From Principles to Practice. *The Society for International Development* 44:1; 122-128 SAGE Publications

## a) Education and Human Capacity

South Africa has a small percentage of well-educated people. Among these educated people there is an even smaller scientific base attributed to a huge backlog in the education system. Statistics from the 1997/8 National R&D Survey shows that there are 7 researchers per 10000 labor force[206]. The country has very few people trained in specialized areas such as genetics and informatics. As a result of an insufficient supply of skilled personnel, scientists are burdened with extra tasks of writing grants and doing administrative work. Scientists also end up spending a lot of time serving in so many committees.

Another problem affecting the South African labor force is the migration of professionals and skilled personnel to other countries. It is estimated that a total of 233,609 South Africans emigrated to North America and European countries[207]. The education system is also not producing enough science graduates to fill the gap left by the emigrants.[208]

The low salaries paid to researchers and academicians serve as a disincentive to young life sciences graduates who prefer to leave the country to explore other job markets. The government funding agencies do not encourage competition or entry of new faces into the field as "*they continually fund the same people*."

Another level of education would be to educate the scientists or to sensitize them of the importance of IP protection. The scientists also need to be made aware of the existing markets for their products.

[206] Reported in the National Biotechnology Strategy, page 23
[207] Kaplan, D. et al (2000) Brain Drain: New Data, New Options, South Africa Network of Skills Abroad. (SANSA) http://www.uct.ac.za/org.sansa
[208] DoE, (2001) National Strategy for Mathematics, Science and Technology Education

**b) IP Protection for Indigenous Knowledge**

A significant portion of the research conducted in South Africa does not benefit the South African researchers or the communities (in the case of indigenous knowledge). Most of the groundwork is conducted in South Africa but products end up being produced in other countries.[209] This is attributed partly to the fact that traditional knowledge and medicinal plants are not fully covered under the existing legal framework.

One legal expert indicated that IP protection for indigenous knowledge still remains a complex issue in South Africa, and the challenge still remains in identifying a suitable model for protection. While this needs to be addressed in the long run, other short term challenges include addressing inadequate or unfair contractual arrangements-such as what was experienced in the hoodia case[210]- and what was termed by the expert as "*unrealistic expectations of the communities.*"

**c) Funding Health Biotechnology[211]**

Biotechnology initiatives are under-funded since the funding made available for biotechnology R&D is not sufficient. At present, it is not easy to judge the effectiveness of the money put into the biotechnology regional innovation centres (BRICs)[212] as they have just started. The level of venture capital engagement in biotechnology initiatives is not sufficient. The presence of local industry in biotechnology is not adequate to support government funding. This creates a real problem in bridging the gap between research ideas and commercialization. Industrial funding comes mainly from international companies who are accused in most cases of being interested only in gaining access to

[209]A good example is where Pfizer developed an appetite suppressant from a plant that the Khoisan people chew when hunting. This plant causes the Khoisan people to go for days without food.
[210] See discussion in Chapter 4 on results, which highlights the problem between the Council for Scientific and Industrial Research (CSIR) and the Khoisan Community.
[211] One of the challenges experienced in conducting this study is the inability to get reliable sources of exact estimates of government funding going into health biotechnology research
[212] BRICs use the existing research infrastructure in the country to bring a range of regional players into clusters or innovation hub through research linkages that will support businesses emanating from research.

local "*DNA and biological material*", which in most cases may translate into unequal partnerships.

The tendencies for funding agencies to continually fund the same people is a challenge because sometimes the best "bidders" do not always get the funding.

**d) Government and government policy**

The basic health infrastructure in South Africa is poor with most people not having access to basic healthcare. The general population especially those in rural areas are faced with other major problems of acquiring food, shelter, water, sanitation and security. Biotechnology does not rank very high in the list of priorities. However, the government acknowledges the potential role of biotechnology in addressing some of these problems and also for economic growth, hence the biotechnology strategy.

However there is a need for clear prioritization of biotechnology, with a sharper focus on viable initiatives which promise results.

**e) Historical/Political Challenges**

As a result of apartheid, South Africa has two economies in one. This creates a skewed analysis of the potential for biotechnology development in the country. The country is still in transition from the apartheid regime and is faced with significant historically base challenges, such as poverty among rural communities and the provision of basic amenities, crime and political problems. These historically based challenges are likely to push the biotechnology agenda back as the government tries to address other more pressing needs.

**f) Research Institutions and Linkages**

Subtle mistrust exists between most institutions and is aggravated by MRC IP policy, which requires joint ownership between the researcher and MRC for research IP. In some cases the joint IP ownership does not act as an incentive for research. Different research institutions and universities have different regulations governing IP appropriation. The lack of a harmonized IP regulation was perceived as potentially problematic.

The linkages that exist within the country are not optimally used as they are sometimes characterized with mistrust. Research between previously advantaged institutions and previously disadvantaged institutions are sometimes wrongly perceived as "*senior and junior partner*" respectively, which affects the level of information sharing. There is some unused capacity within the country because the majority of the scientists do not share ideas. The following diagram illustrates how the current research networks and linkages are not optimally exploited within the innovation system. If networks were optimal the arrows would show more interaction between the different actors.

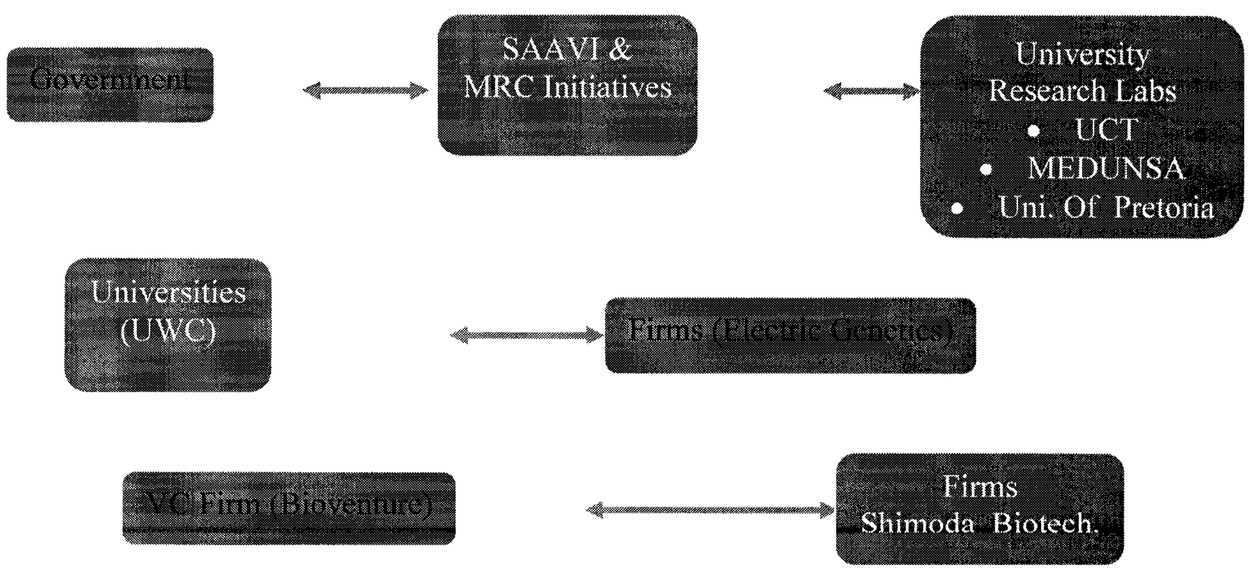


Diagram 5.2: Presence of Non-Optimal Linkages and Networks

**g) Public Perceptions**

The knowledge level of biotechnology is generally low among the communities. There are insufficient public awareness programmes in health biotechnology, causing most people to equate biotechnology to GMOs. Most people do not understand the potential benefits/risks of biotechnology. Communication between scientists and the local community needs to be enhanced and simplified. The government needs to send appropriate messages to the communities to avoid misconceptions. The role of government and top policy makers is critical especially for the introduction of a HIV vaccine into the South African market.[213]

**h) Commercialization of Products**

There is a lot of research going on in labs but with very little being converted into products. There is no system put in place that taps into the available knowledge and using it for commercial benefit and thus economic growth. There needs to be a fundamental shift among the scientists, especially those working in academic institutions, who perceive their work as purely for training purposes. Most scientists do not know how to go about commercializing their products. The biotechnology strategy was criticized by one of the interviewees as *"lacking a fundamental plank in the support structure to commercialize products."*

In summary, the challenges facing the South African health biotechnology innovation system though considerable have not hindered the general development of health biotechnology in the country. It is expected that some of these challenges will be addressed soon with the implementation of the biotechnology strategy. However the issue affecting human capital may linger on for a longer time as the country undergoes the restructuring of the education and training system.

[213] President Thabo Mbeki has always stated that he maintains an open mind on whether HIV is the cause of AIDS. This has caused public confrontations between some scientists and government, causing confusion to the communities about HIV/AIDS. One scientist said, *"it is likely to cause problems when the technology is eventually introduced."*

## 5.6 Lessons Learned from the South African Experience

The study on the South African health biotechnology innovation system provides lessons that can be learned by other developing countries on how to develop health biotechnology and how harness biotechnological innovations to address local health needs. These lessons are considered to be what South Africa has done successfully and can be used as pointers for other developing countries towards successful health biotechnology development.

### Lesson No. 1: Combined exploitation of both indigenous knowledge innovations and science-based innovations

Innovation systems are very knowledge intensive.[214] The South African health biotechnology innovation system adopts what Lundvall and his colleagues[215] call the broad concept of innovation systems. The broad concept of innovation systems is a departure from the traditional NSI concept, which mainly focuses on the role of science and science-based activities. The broad concept seeks to deepen the NSI concept by making it more dynamic and accommodative to other aspects that influence learning and competence building. The broad approach seeks to include those aspects influencing innovation, such as indigenous knowledge for developing countries, that may not have been captured in the existing literature that mainly consists of those elements influencing innovation in developed countries alone.

Such an innovation system does not focus on high tech R&D systems alone, but also takes into account traditional knowledge and seeks to add value to this knowledge by complementing it with scientific knowledge. The South African health biotechnology innovation system recognizes the need to exploit local and traditional knowledge to

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[214] Saviotti, P.P., (1997) Innovation Systems and Evolutionary Theories in Edquist, C. (ed.) Systems of Innovation, Technologies, Institutions and Organizations. Pinter

[215] Lundvall, B. -A. *et al.* (2002) 'National Systems of Production, Innovation and Competence Building.' *Research Policy* 31: 213-231

address health needs in the country. This type of knowledge is more useful in developing countries and is easily lost or de-learnt[216] if not well protected.

South Africa includes traditional knowledge as an area requiring IP protection and regulated exploitation. The realization of the need to expand IP protection to traditional knowledge is to be interpreted as a move towards creating incentives for innovation based on indigenous knowledge and at the same time encouraging knowledge diffusion into the system. Establishing legal frameworks for traditional knowledge IP protection is an attempt to capture tacit knowledge that can otherwise only be acquired experimentally and by demonstration and converting it into codified knowledge. By codification, knowledge acquires more properties of a commodity and can then be used for economic gain.[217]

Other southern countries, equally endowed with rich biodiversity and indigenous knowledge of the use of these natural resources can borrow a leaf from South Africa. Other developing countries can adopt the broad concept of innovation systems which includes traditional knowledge systems as a complementing system to the purely science based innovation system. This will enable these countries to commercially exploit the use of traditional knowledge and harness it to address some of the local health needs.

**Lesson No.2 Importance of a Biotechnology Strategy that Identifies Strategic Action Steps**

The National Biotechnology Strategy identifies new opportunities that can contribute to biotechnology development in the country[218]. Those identified include the development of a safe and efficient HIV vaccine by the South African AIDS Vaccine Initiative and other vaccines, development of cheap diagnostics, drug development for diseases prevalent in the country and bioinformatics.

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[216] Lundvall, B.-A. *et al. ibid.*
[217] Foray, D. (1997) Generation and Distribution of Technological Knowledge: Incentives, Norms and Institutions in Edquist, C. (ed.) *ibid.*

The South African biotechnology strategy also tries to reinforce what South Africa considers to be its competitive edge by exploitation of indigenous knowledge. It is argued that technology policies that reinforce the country's competitive edge are more successful. This argument is illustrated by technology policies in countries such as Sweden and Denmark. The Swedish technology policy promotes process innovation, while the Danish one promotes incremental innovation. The focus on both countries was to reinforce their competitive edge[219].

When making recommendations to other developing countries it is also important to keep in mind that S&T policies tend to be country specific[220] and are greatly influenced by institutional measures in the countries and the policy measures suitable for the peculiarities of the countries. The South African Biotechnology strategy can however be used as a lesson to other developing countries to the extent that it identifies new opportunities to exploit biotechnology and identifies a competitive edge in indigenous knowledge, with the aim of addressing local needs, in this case disease alleviation and eradication.

**Lesson No.3 Creation of Networks and Linkages**

Health biotechnology innovation and indeed any biotechnology innovation is understood as a system or a network. [221] Innovations of this nature are as a result of a collaborative basis of research and the ability of actors to exploit new knowledge and reach out and exploit collaboration among agents and across stages of product development, scientific disciplines and industry frontiers.[222] The complex process through which technological

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[218] Bo Carlson and Staffan Jacobson in Lundvall (ed.) *ibid.* Identify this as a fundamental task for a technology policy.

[219] Edquist, C., &Lundvall, B. -A., (1993) Comparing the Danish and Swedish Systems of Innovation. In: Nelson, R.R (ed.) National Innovation Systems: A Comparative Analysis. Oxford University Press, Oxford

[220] Shulin, G (1999) Implications of National Innovation Systems for Developing Countries: Managing Change and Complexity in Economic Development. *UNU/INTECH Discussion Paper Series* No. 9903

[221] Allansdottir, A., *et al* (2002) Innovation and Competitiveness in European Biotechnology. *Enterprise Papers* No. 7

[222] Refer to Chapter 2 on NSI Conceptual Framework

innovations emerge demands the emergence and diffusion of knowledge elements as well as the translation of this knowledge into new products and production processes[223]. A knowledge system in this regard is to be seen as a network of actors or entities that assume specific functions for the generation, transformation, transmission and storing of knowledge.[224] The actors that create a knowledge system include innovative firms, academic institutions, legal and regulatory infrastructures, policy makers and research institutions; and what really matters is the degree of cohesiveness and the frequency of knowledge interactions among these actors.

The new technological advances taking place in the field of health biotechnology and life sciences generally such as bioinformatics, genomics, pharmaco-genomics and proteomics are very rapid and are very research-intensive. Knowledge in these areas is still very fragmented and dispersed. No single institute is able to generate and develop all the necessary ingredients for discovery and bringing new products to the marketplace.[225] This calls for a very cohesive knowledge system that encourages knowledge sharing and learning to enhance innovations.

The presence of networks and research linkages in an innovation system is an aspect that is emphasized when defining an NSI. The definition of an NSI[226] implies that innovative performance of any system depends on how the different elements/actors within the system interact with each other as a collective system of knowledge creation and knowledge use. The South African health biotechnology innovation system shows a concerted effort towards the creation of networks and research linkages. This is seen in especially through funding agencies' policies that require the formation of research consortia.

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[223] Edquist, C. (ed.) (1997) Systems of Innovation, Technologies, Institutions and Organizations. Pinter

[224] Foray, D. (1997) in Edquist, C. (ed.) *ibid.*

[225] Powell W.W. *et al.* (1996) Inter-organizational Collaboration and the Locus of Innovation; Networks of Learning in Biotechnology. *Administrative Science Quarterly* 41, pp. 116-145

[226] As was discussed in chapter 2 NSI is defined as a "set of distinct institutions which jointly and individually contribute to the development and diffusion of new technologies and which provide a framework which governments form and implement policies to influence the innovative process."

For instance THRIP funding requires for that a research institution must have an industrial partner. There are also efforts to include the learning process within academic institutions into the NSI mainstream. This is seen again, through THRIP funding, which has a training component to research grants. The creation of regional biotechnology innovation centres, where multidisciplinary research is encouraged in consortia of different institutions is likely to yield more health biotechnology innovations. Through the biotechnology strategy, South Africa has now formed three innovation centres, with the Cape Biotechnology Initiative in Cape Town specifically targeting health biotechnology R&D. The other two innovation centres are Biopad in Johannesburg and EcoBio in Durban.

The lack of a collaborative approach to research and the alienation of some communities from the research agenda during the apartheid era, may have been a weakness to the South African innovations system. However the South African government has put in place initiatives to remedy this. Examples of such initiatives include the move to restructure the education system and create mergers between traditionally black universities with traditionally white universities. There is also a move towards increasing the number of black scientists in public research councils, for example the MRC records an increase in the number of black professionals and senior managers between the period of 1997-2001.[227] The inclusion of a traditional knowledge systems programme in the MRC research agenda is also another move towards including previously alienated communities into research activities. Indeed the inclusion of traditional knowledge systems into health research is likely to raise the social value of knowledge by lowering the chance that it will reside with persons or groups who lack the resources and ability to exploit it.[228]

[227] Medical Research Council. Annual Report 2000-2001, page 9
[228] Foray, D. (1997) in Edquist, C. (ed.) (1997) *Supra*

**Lesson 4. A Lesson from the Apartheid and Isolation Experience**

The isolation of South Africa from the international community caused South Africa to look inward and start developing its own research capacity to address its needs at the time. It is clear from this study that the research infrastructure that was developed for research during that time is now being exploited for the development of biotechnology.

While I would not advise any country to adopt apartheid policies, developing countries are encouraged to develop their local research infrastructure with specific research targets as the South African example illustrates. In the case of health biotechnology, a good example would be to identify a problematic disease prevalent in the community and a technology that addresses it, and then develop an infrastructure to support R&D in the area. This is useful for addressing urgent local needs and at the same expanding the local science base that can be exploited to harness economic gain in the knowledge economy.

## 5.7 Filling in the Knowledge Gaps.

The objectives of this study were identified in the introduction chapter as:

1. Identifying and analyzing the factors that encourage and/or hinder the development of a successful health biotechnology sector in South Africa.
2. Gain an insight of how the sector has developed within the context of the South African innovation system.
3. Draw recommendations on how to develop a local capacity to harness health biotechnology innovations to improve health in developing countries.
4. To make a contribution to the available body of knowledge on the applicability of the NSI conceptual framework to developing countries.

The first objective of the study which is to identify factors influencing biotechnology development in South Africa has been successfully met by identifying the 4 major themes discussed above as being the major factors that have facilitated the growth of the health biotechnology in South Africa. In summary these factors are, government push, the need to address local health priorities, the exploitation of indigenous knowledge for economic gain and to address local health needs and lastly the apartheid legacy. The challenges facing the health biotechnology sector are outlined in the section above.

The second objective is addressed by the study by identifying the specific actors involved in health biotechnology development and outlining their specific roles. Previous studies on biotechnology development in South Africa have mainly focused on agricultural biotechnology.[229] This is the first study that identifies the specific actors in health biotechnology development in South Africa using the NSI framework[230]

The third objective, which is to make recommendations on how to harness health biotechnology innovations in developing countries, based on lessons learnt from the South African experience has also been successfully met. The lessons as discussed above are in summary,

- adopting a broad concept of innovation systems which includes the exploitation of indigenous knowledge together with science-based innovations,
- the importance of a biotechnology strategy that identifies new opportunities and a competitive edge,
- the importance of knowledge networks and
- mission-oriented R&D strategies, targeting local health needs

The last objective of this study was to make a contribution to the development of the national systems of innovation (NSI) conceptual framework and particularly its application in developing countries. This is a relevant aspect of the study since the NSI framework was developed with a backdrop of developed countries. Indeed most innovation systems studies have been of the US, UK, France and Scandinavian countries and generally of industrially advanced countries.[231] The practicality and applicability of the NSI framework has continuously been questioned in the face of globalization, which

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[229] See generally Country profile by Koch, M. & Webster, J. in Tzotzos, G.T., & Skryabin, K.G (ed.) (2000) Biotechnology in the Developing World and Countries in Economic Transition, CABI Publishing
[230] As far as published data goes.

as ushered in an era of international trade and an increased interdependence of economies.[232]

The study of the South African health biotechnology innovation system supports previous assertions that national systems are important for assessing innovation systems.[233] The South Africa illustrates that the nation as an entity of study is still relevant and important for health biotechnology innovations. This is illustrated by the fact that at the national level, South Africa is able to determine areas of interests and therefore design an R&D agenda to address those areas. A good example in the South African innovation system is the effort towards exploiting indigenous knowledge for innovations targeted towards addressing health needs. Different innovation systems are faced with different peculiarities and as such the national level provides an optimal study entity especially as far as policy formulation is concerned. This supports the assertion that "as long as nation states exist as political entities with their own research agendas related to innovation, it is useful to work with national systems as analytical objects."[234]

The interview data also suggest that the MNCs present in South Africa are not so actively involved in shaping health biotechnology innovations in the country. In the case of South Africa, health biotechnology R&D and innovations have a locally based origin and directed towards national needs. This is an illustration of the propriety of using a national system as a unit of study.

This study illustrates that the absence of clear definitions of concepts[235] and the heavy reliance on very unclearly defined and broad concepts such as such as "innovation[236]" and

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[231] Lundvall, B.- A. *et al* (2002) National Systems of Production, Innovation and Competence Building. *Research Policy* 31 (2002) 213-231

[232] Castells, M. (2000) The Rise of the Network Society: The Information Age Vol. 1 pg. 114-115

[233] Archibugi, D. & Michie, J. (1995) The Globalization of Technology: A New Taxonomy. *Cambridge Journal of Economics* 19 (1)

[234] Lundvall, B. -A. *et al* (2002) National system of Production, Innovation and Competence Building. *Research Policy* 31 pg. 215

[235] Charles Edquist gives an in-depth discussion of the conceptual ambiguity of the framework in Edquist, C. (ed.) (1997) Systems of Innovation, Technologies, Institutions and Organizations. Pinter

[236] Innovations are defined as new creations of economic significance, which may be brand new and/or new combinations of existing elements. Innovation can be of various kinds, i.e. Technological or organizational

"institutions[237]" is not necessarily a flaw in the framework. This should be seen as an opportunity to broaden the NSI concept to accommodate all aspects relevant to and peculiar to country's innovation system. This is particularly important to developing countries whose innovation systems are uniquely different from those of developed countries. Lundvall and his colleagues support this argument by stating that, " A narrow focus on the role of science and science-based activities is not what is needed. We need a concept that covers all aspects of competence building in socio-economic activities."[238] This study provides an empirical analysis that illustrates that the traditional understanding of innovation within the NSI literature is being refined to accommodate the special circumstances prevalent in developing countries and thus supports the assertion that the NSI conceptual framework can be applied for assessing innovation in developing countries.

The South African study does this by clearly illustrating the importance of traditional knowledge and the use of indigenous plants to develop the health biotechnology sector. The South African innovation system takes into account of local and traditional knowledge, which is not necessarily considered in innovation systems studies of developed countries. South Africa takes a broad concept of innovation systems by trying to integrate traditional knowledge and science-based R&D in ways that complement each other.

## 5.8 Limitations of this Study and Future Directions

This study sets the stage for an initial understanding of the South Africa's health biotechnology innovation system. However it does not adequately address various issues such as the impact of the formation of biotechnology "clusters" in Cape Town, Durban and Johannesburg. Future studies on the economic effects of such clusters could be very useful in illustrating the usefulness of adopting a biotechnology strategy that "forces" the

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[237] Institutions as used in NSI literature comes from diverse theoretical angles and is very broad as to include organizations, markets, routines, habits and laws. See Edquist, C. & Bjorn, J (1997)'Institutions and Organizations in Systems of Innovation' in Edquist, C (ed.) *ibid.*

[238] Lundvall, B.A *et al. ibid*

formation of these regional clusters as against allowing the natural formation of these clusters. Monitoring the successes of these clusters is an interesting point and would take the present one step further from mere assertion of the presence of the clusters to the actual role played by them.

This study provides sufficient indication that South Africa as a country is beginning to integrate aspects of indigenous knowledge to its system of innovation. It would be interesting for future studies of the South African innovation system to analyze whether or not the integration has been successful. If successful, how and why. This could provide useful pointers to other developing countries that do not yet have any infrastructure in place to harness and protect indigenous knowledge.

This study also provides useful information that can be used in the future for a comparative study or analysis with other developing countries. It is hoped that the information provided by this study will be used by the Canadian Programme on Genomics and Global Health (CPGGH), at the Joint Centre for Bioethics will draw a comparative analysis of the South African health biotechnology innovation system with those of countries such as India, China, Egypt and Brazil to illustrate how developing countries can harness technological advancements in addressing local health needs.

### 5.9 Conclusion

In summary, the study of the South African health biotechnology innovation system indicates that it is still too early to fully assess the success of health biotechnology development since this is a very recent focus area in terms of research and government support. However it is not disputed that health biotechnology has a huge potential impact on the country's economic development and in the health care system, especially so far as preventative medicine is concerned. The future of the health biotechnology sector looks exciting and very promising since there are already a number of initiatives put in place such as SAAVI, SANBI and Shimoda biotech. just to mention but a few, that are involved in cutting edge research. There are also early examples of health biotechnology products, some of which are already being commercialized as illustrated by table 4.1 in the previous chapter. The South African health biotechnology sector is likely to yield very exciting results in the future.

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*Appendix 1*

## INTERVIEW GUIDE

### The Development of Genomics/Health Biotechnology in South Africa

The objective of this study is to gain insight into how the health biotechnology sector has developed in your country and to identify and analyze the factors that have encouraged and/or hindered its development.

We define biotechnology as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services" (OECD, 1998). For the purpose of this study we include genome-related technologies and tools, for example, bioinformatics, proteomics etc. In addition we would include the study of indigenous plants and the development of their products.

*Read consent information to participants and seek his/her consent*

*Probe all responses for clarity and explore all conceptually interesting information. Ask questions such as 'Why do you think that?' and 'Can you tell me more about that?'*

### Roles of Main Actors

**1.0 Please describe what your role has been in the development of health biotechnology in your country?**

**2.0 Who are the main actors in the health biotechnology sector in your country? Could you please expand and describe the role of each of them?**

*[Follow up questions if these actors haven't been mentioned]*

**2.1** What has been the government's role in the health biotechnology sector? (e.g. in specific policy making – pertaining to local health needs & coordinating with other related policies, funding, tax incentives, etc.)? or

**2.2** What has been the role of private firms in building up health biotechnology in your country ? (e.g. in commercialization of health biotech products, who are they & are they large/small in size, domestic or subsidiaries of multinationals). or

**2.3** How would you describe the role of public research institutions/ education system/hospital system in supporting health biotechnology in your country?
(e.g. in research, education & training, generation of spin-offs companies, in providing facilities for clinical trials etc.)

**2.4** Please describe if and how the WHO has encouraged development of the local health biotechnology sector?

*If no mention has been made of the role of the regulatory environment please probe and ask*

**2.5** What are the effects of the regulatory environment. Does it encourage or impede the development of health biotechnology?

*If no mention has been made of intellectual property rights please ask:*

**2.5a** What has been the role of intellectual property rights in the health biotechnology development in [name of country]? (incentives, barriers, influence on research prioritization etc.)

*If no mention has been made of needs for documentation in clinical trials please ask*

**2.5b** What has been to effects of the needs for documentation in clinical trials in the development of health biotechnology?

**2.6** Who funds biotechnology R&D/commercialization initiatives? (e.g. main sources of capital, accessibility of loans, presence of angel investors/venture capital firms, tax incentives by government)

*To follow up: has the funding been easily available and sufficient?*

*The information we like to have emerged is:*

*Who have been the main actors in the health biotechnology sector and how have they influenced the development of the sector?*
*When did the health biotechnology sector begin to emerge in [name of country]?*
*What events/conditions/factors have encouraged its development?*
*Have there been any constraints to the development of the sector?*

**Linkages**

**Do the actors in the health biotechnology sector in your country form a health biotech cluster(s)?** If yes please expand and explain if and how the cluster(s) has(/have) benefited health biotech development in your country?

***Our definition of clusters is the following:***

*Clusters are a "Geographic concentrations of interconnected companies, specialized suppliers, service providers, firms in related industries, and associated institutions (for example, universities, standards agencies, and trade associations) in particular fields that compete but also co-operate"*

**4. Could you please tell me if and how your institution/firm is linked with other institutions and firms in the biotechnology sector? If so, to which institutions?**

**4.1** What is the main reason(s) for the linkages?

**4.2** What do you think are the major benefits of these linkages?

*Probe further, if necessary, on :*

*-whether the linkages are mainly in terms of research, commercialization, education, training or participation in governing?*
*-whether they are formal or informal?*
*-the history of the linkages?(People / policies)*
*-were there some challenges in establishing/maintaining the linkages?*
*-whether the nature and extent of your institution's partnerships have changed over time?*

**5. Please tell me if and how your institution/firm is linked with institutions and firms in the biotechnology sector in other countries or with international organizations? If so, to which institutions?**

**5.1 What is the main reason(s) for your international linkages?**

**5.2 What do you think are the major benefits of these linkages?**

*Please probe further, if necessary:*

*-whether the linkages are mainly in terms of research, commercialization, education, training or participation in governing?*
*-whether they are formal or informal?*
*-the history of the linkages?(People / policies)*
*-were there some challenges in establishing/maintaining the linkages?*
*-whether the nature and extent of your institution's partnerships have changed over time?*

**6. What are the main sources of innovative ideas and necessary expertise for your work?** *e.g. in house R&D, through links with other local actors, if so which ones, through consultations with users, international sources, etc?*

**Market Demand**

**7. Could you tell me about some examples of successful health biotechnology products and services from your country?**

*Please probe further, if necessary, on:*
*-whether they are currently in the market?*
*- if there are any exciting ones in the pipeline?*
*-how were they developed?*

**8.Please describe what factors have influenced their development of the products and services from your country**

*Please probe further, if necessary, on:*

*- whether local demand has influenced the development, if so from whom and how?*

*- whether the products have been mainly aimed at export market etc*

**Social Acceptance**

**9. How receptive or positive would you say the public in [name of country] is towards biotechnology in general?**

*Probe further, if necessary, on the reason(s) and ask for examples?*

**10. How knowledgeable would you say the public in [name of country] is about biotechnology? How knowledgeable are they about the risks and benefits of biotechnology?**

*Probe further, if necessary, on the reason(s) and ask for examples?*

**11. Has your company/the government/other institution developed an information program on biotechnology aimed at the public?**

*Probe further, if necessary, on:*

-when was this developed?

-the effects of the program?

-importance of public engagement?

**12. Do you know about some study / report on the public's perception towards biotechnology conducted in your country?**

*Probe further, if necessary, on:*

-what were the main results?

-a contact person for getting details on the study/report?

**Evaluation**

**13. Do you think health biotechnology development has been successful in [name of country] and why? Please give examples.**

13.1. If successful - What do you think are the crucial elements, which have contributed to the success of the health biotechnology system?

13.2 If not successful - what are the major barriers impeding the development of the health biotechnology system?

**14. What do you see as the role of health biotechnology in your country both in the context of health delivery and public health?** (health delivery e.g. more appropriate diagnostics – public health e.g. higher life expectancy)

**15. What do you see as the role of health biotechnology in your country in the context of the wider national economy?**

**16. How would you improve the situation in your country to encourage health biotechnology development further?**

**17. What do you think about the prospects of the health biotechnology sector in your country? Are you optimistic or pessimistic? Where will it be in 5 to 10 years?**

*Appendix 2*

**Consent Information Communicated to Participants in Research**

- My name is Marion Motari. This research is coordinated by the University of Toronto Joint Centre for Bioethics and is supported by a grant from genome Canada
- The purpose of this study is to identify and analyze the factors which have encouraged successful development of health biotechnology in South Africa
- Your participation will consist of an interview, of approximately 60-90minutes, during which you will be asked your views about the development of health biotechnology in South Africa
- You are free to participate or not. Your participation in this study will only be made known if you provide your permission
- In public presentation of the research (in any form), your name will only be associated with any quotes or opinions after obtaining your permission
- The interview will be audiotaped and transcribed. All data, including audiotapes, will be secured in a locked cabinet and only researchers will have access. All audiotapes will be destroyed in seven years.
- You will not benefit directly from participating. The primary benefit of this study will be its contribution to knowledge regarding successful development of health biotechnology in developing countries.
- There are no known risks associated with participating in this study.
- You will have free access to publications or other research reports based on this research.
- If you have any concerns or questions about the research please feel free to contact me or Dr. Peter A. Singer, University of Toronto Joint Centre for Bioethics, 1 416 978 4756
- Will you consent to this study?