BIOTECHNOLOGY SECOND PAPER

Policy Recommendations and Interventions

ACCESS MARKET INTERNATIONAL (PTY) LTD
SOUTH AFRICA

Liandi Blom

Robert Mulder

EXECUTIVE SUMMARY

SUMMARY OF THE BIOTECHNOLOGY SECTOR REPORT

As concluded from the Western Cape MEDS Biotechnology Research Study Report, the biotechnology sector of the Western Cape has, since the inception of the Cape Biotech Initiative in December 2001, grown through amongst other initiatives, the creation of the Cape Biotech Trust (CBT) and currently represents a small but promising building block towards regional competitiveness. Although the CBT focus area is more towards human health biotechnology solutions, as a result of its mandate from the Department of Science and Technology (DST), the Western Cape has specific requirements in the area of plant biotechnology to support its agricultural and natural environment. Through a good working relationship with PlantBio, based in the KwaZulu-Natal with representation in the Western Cape, local institutions and companies benefit from the support and funding of government.

The MEDS Study has shown that the sector has a well-developed university education and research system producing highly skilled labour and suppliers of equipment and consumables are well supported. Supporting industries including, commercialisation support from incubators, manufacturing support and financial services including venture capital are also well represented. Government has created several national programmes that support the development of the biotechnology industry and the regional infrastructure in the Western Cape is regarded as being adequate. The biotechnology sector however is slow to commercialise the ideas developed within the university and science council environment.

Despite some 400 research groups, the sector comprises of only 15 core biotechnology companies according to the EgoliBio National Biotechnology Survey conducted in 2003. The majority of the Western Cape biotechnology companies are heavily reliant on donor funding, the reasons for this are numerous, the most apparent are that this nascent industry is capital intensive, requires highly skilled and specialised staff, has long lead times for ideas to mature into revenue generating products or services and is highly risky. Setup costs can run into several millions of Rands and ongoing operational costs can easily match this. Even assuming the start-up company is able to raise finance, the cost of regulatory, tax and administrative compliance is substantial for the small companies. Given the substantial investment in education and training required by most employees, the remuneration offered is low compared to other industries and many potential contributors to the sector find it preferable to move into other less risky and more remunerative areas of business. Many biotechnology innovations require considerable lead time due to proof of concept research, field/clinical trials and registration processes and thus consume start-up capital for several

years before any return is possible. Given the basic level of South Africa's social safety net, the cost of failure to entrepreneurs is high and actively discourages entrepreneurs from leaving the refuge of the university environment. A lack of business to science crossover skills has also been raised as a barrier to the commercialisation of biotechnology innovation.

According to the MEDS Study, these challenges are not insurmountable. Biotechnology is a high-risk, high-return sector which, with appropriate funding, government support and strong industry body participation, can grow. Significantly more funds need to be made available to registered companies who are able to prove they have a viable business model supported by independently audited science. Government needs to raise the profile of the industry through facilitation of the efforts of the commercial entities in the industry rather that acting as the face of the industry. The Cape Biotech Trust and Plant Bio related initiatives in the Western Cape needs to be supported in its initiatives by business, government and academia if a coherent sector growth plan is to be realised.

POLICY RECOMMENDATIONS

Based upon the analysis in the previous sections of the report relating to the policy environment, the impact of the various policies on the biotechnology sector in the Western Cape, the issues identified within a recommended policy framework, various policy and strategy recommendations are made. These recommendations address the leverage economic growth in the biotechnology sector, including its competitiveness and performance.

Recommendation 1 – Identify and confirm which priority sectors in the Western Cape have critical needs that can be enhanced by supporting biotechnology initiatives, which are most likely to stimulate economic growth or satisfy social requirements indirectly. This needs to be ascertained prior to the Province supporting an agreed set of biotechnology programmes and projects.

The Western Cape Province should, through the MEDS process, be selective in providing support for sectors underpinned by biotechnology, which will be able to play a role in satisfying the provinces economic growth and job creation needs. The Province should not just invest in biotechnology because it is a National Government initiative, but should directly influence the course of the CBT and PlantBio activities based on the provinces economic and social development needs. This would ensure that the funding being utilised, part of which is

sourced from National Government, is channelled into meeting provincial requirements thus ensuring that a return is realised through support sector economic growth and job creation.

The recommendation is substantiated by the fact that despite the CBT having undertaken stakeholder assessments of the Provinces' needs in the formulation of the current strategy, it has been reported as not yet being fully endorsed by the sector players in the Province as mentioned in the Biotechnology Sector Report.

The consequences of the recommendation would be the support provided by biotechnology initiatives in delivering on the objectives of other sector development plans, which would further contribute to economic development and job creation In the Western Cape.

Recommendation 2 – The Province needs to facilitate and support the raising of funds to support biotechnology development in line with those sectors, underpinned by biotechnology that will contribute to Western Cape economic growth and job creation strategy. This includes the involvement and collaboration with neighbouring provinces within the broader region.

Funding is the vital to the source of all biotechnology developments, as illustrated in the numerous international investigations on the significant amounts of funding that have been put into the development of biotechnology clusters.

The recommendation is substantiated by the fact that the biotechnology instruments in the Western Cape have identified additional non-Government funding from a range of organisations. Once the biotechnology interventions within the selected growth sectors have been identified by the MEDS programme, the Province would be in an even stronger position to substantiate and raise funding for the identified needs within the sectors they wish to promote.

The consequence the Province not being involved in fund raising would be that the growth of the biotechnology sector in South Africa might largely ignore provincial needs. If relevant Provincial departments were to get involved to raise and provide funding, steer research, the benefit would be to the benefit of the Provinces' economic development and job creation programme. The timing for this recommendation should commence in the 2006/7 budget year once the provincial priorities have been established and the relevant biotechnology support for the appropriate sectors has been identified.

Recommendation 3 – Research undertaken in the Western Cape must be focused, through a series of interventions involving the 400 biotechnology research groups, to ensure that utilisation of research undertaken is improved and economic benefits are derived.

Once the biotechnology strategy for the Western Cape becomes focused in terms of what the desired sectoral outputs are, and a monitoring system is in place, so biotechnology research conducted in the Western Cape will need to be further focussed. This needs to be undertaken to produce utilisable research outputs to increase the extent to which current research is utilised far beyond the current 55% level estimated by the National Council for Innovation (NACI). Justified research requests need be channelled through the CBT and PlantBio through to the research institutions, possible tax incentives provided on eligible research, which will enable significantly more research to be focused through the implementation of NACI's proposed R&D Charter, towards the Provinces' needs where economic benefit will be derived.

National and Provincial Government could establish a tax incentive scheme to encourage businesses to undertake eligible R&D, which meets national and provincial needs and imperatives. The scheme must guarantee quick and consistent delivery of incentives, in the form of tax credits or cash, to companies that qualify, similar to the one operating successfully under Canada.

Research utilisation, measured by NACI, is particularly low in South Africa. It was reported in the Biotechnology Sector Report that the Western Cape biotech R&D spend rates are considerably below the lowest rating and are reported to be in the region of 0.0975%. This is extremely low compared to national targets that have been established between 4 to 5%.

This recommendation needs to be applied to all research institutions, such as universities and science councils, but more so the academic research institutions. The recommendation should be passed on the Western Cape Department of Education and monitored through the DEDT, with strong involvement through the biotechnology instruments operating in the region, namely CBT and PlantBio. The consequences of more focused research are a greater flow of potential outcomes into the biotechnology industry and therefore those selected sectors which biotechnology supports.

Recommendation 4 – Develop measures of strategic performance for the Western Cape

biotechnology sector that aggregate all sub-sector biotechnology activities that contribute to the Provincial economy and thereafter establish targets for effective monitoring and evaluation.

It is of fundamental importance that the Province drives what is important to enable it to achieve its economic growth targets, though the definition of measurable objectives, validation through research, execution and tracking through measurement towards set goals.

The broad objectives for the development of the biotechnology sector in the Western Cape therefore needs to be measured and monitored at Provincial level rather than at the innovation centre (BRIC) level. The role of biotechnology, as a cross-cutting sector, must contribute in a measurable way towards stimulating the growth of appropriate sectors such as agriculture, food, healthcare products and services as well as utilities such as water provision and purification.

From the analysis of the policies and the CBT and PlantBio strategic plans and inputs from the Department of Science and Technology's KPI's, a number of performance measures have been suggested, which measure, funding provision, relevant R&D output, measures of commercialisation success and employment creation.

These measures should be elevated to provincial level and made relevant to the Western Cape's needs. The recommendation is substantiated by the fact that currently the CBT and PlantBio's strategic performance is measured in terms of a set of KPA's, developed by the Department of Science and Technology, the achievement of which will impact on the Province, but only within the scope of activity that the innovation centres cover. This clearly does not indicate what contribution is being made to the Western Cape Province.

It is important that baseline targets are also set for each of the performance measures that are finally decided upon. Clear milestones or due dates should be defined for the achievement of specific levels of performance against these measures. A dedicated communication and follow-up plan to track performance against the measures regularly should be put in place in order to focus stakeholders as to imminent objectives and goals.

The consequences of not adopting this recommendation will be that biotechnology in the Western Cape could become to nationally focused, or to opportunistic in nature and not

contribute to the economic growth of the Western Cape through the sectors which it supports.

Due to the fact that the biotechnology sector is a cross-cutting sector and currently relatively narrowly focused in the Western Cape Province, the range of policies relevant to the industry is narrow. Another reason is that the sector is primarily in the research and development lifecycle and has not yet progressed to a mature manufacturing sector, which would still take some time to develop.

Although a number of policies from the different government departments can be said to have, to a certain degree, an impact on biotechnology, none of them currently significantly contribute to the economic restructuring of the sector.

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1 THE BIOTECHNOLOGY SECTOR POLICY ENVIRONMENT

Due to vast amount of research and development that has taken place in the field of biotechnology in various sub-sector applications such as human health, plant and animal health and feeds, the subject matter of biotechnology has defined itself as an area that needs to be closely monitored and controlled. As described in the biotechnology sector overview report there are various concerns and issues about the introduction of biotechnology related research and commercialisation. During its emergence a number of international policies and protocols have emerged, due the nature of the research and commercialisation that has evolved in the industry. As more sensitive interventions and products emerge so international protocols have emerged, which gave structure and direction to the national strategies and policies. The various international and local policies applicable to the biotechnology sector in the Western Cape include:

International Sector Policies

- OECD policies, decisions and recommendations by the council
- UN Biosafety Protocol/Cartagena Protocol on Biosafety
- WTO agreements and decisions

National Sector Polices

- National R and D Strategy (NRDS)
- National Biotechnology Strategy (NBS)
- Advanced Manufacturing Strategy (AMTS)
- Integrated Manufacturing Strategy (IMS)
- The Technology and Human Resources for Industry Programme (THRIPS)
- The Support Programme for Industrial Innovation (SPII)
- Health Research Policy in South Africa 2001
- HIV/Aids/STD Strategic Plan For South Africa 2000 – 2005
- Genetically Modified Organisms Act, 1997

- The Human Tissue Act (Act 65 of 1983)
- The Foodstuffs, Cosmetics And Disinfectants Act (Act 54 of 1972)
- The Animal Improvements Act (Act 62 of 1998)
- The Plant Breeders Act (Act 15 of 1976)
- The Agricultural Pest Act
- The National Environmental Management Act (NEMA) 1998
- Biodiversity Act of 2004
- The Patents Act (Act 57 of 1978)

2 INTERNATIONAL SECTOR POLICIES IMPACTING ON THE BIOTECHNOLOGY SECTOR

The following international policies have played a significant role in shaping the industry since 1994. All of the international policies impacting on the biotechnology in South Africa have been considered by industry experts both at government level as well as at regional level and have, where relevant, been incorporated in the National Biotechnology Strategy (NBS) as well as considered by the Cape Biotechnology Trust (CBT) strategy. For the reasons mentioned these international policies will only be mentioned and not discussed in full detail.

2.1 THE ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD) POLICIES, DECISIONS AND RECOMMENDATIONS

Numerous recommendations impacting on the environment have been made by the OECD Council since the year 2000, of which the most recent have been listed, relevant to biotechnology

Recommendation of the OECD Council on the Use of Economic Instruments in Promoting the Conservation and Sustainable use of Biodiversity April 2004[1]

The Environment Policy Committee recommends that "member countries establish and apply a policy framework aimed at ensuring the efficient long-term conservation and sustainable use of biodiversity and its related resources. It suggests to members to make greater and more consistent use of domestic economic instruments in the application of their biodiversity policy frameworks, while attempting to reach further agreement at the international level on the use of economic-based policy instruments with respect to biodiversity conservation and management. The policy further recommends that market and non-market instruments be integrated into an effective and efficient mix of policies and recommends that biodiversity policy objectives be integrated in a cost-effective manner into government sectoral policies."

Environmental Strategy for the First Decade of the 21st Century May 2001[1]

The Council calls for "significant reductions in threats to ecosystems and their species from habitat loss and fragmentation, changes in land use patterns, pollution, introduction of invasive species, and over-exploitation or extinction of wild species. OECD Environment Ministers agreed in the same Strategy that "….countries should apply precaution as appropriate in situations where there is a lack of scientific certainty".

2.2 UNITED NATIONS (UN) BIOSAFETY PROTOCOL / CARTAGENA PROTOCOL IN BIOSAFETY

The UN -sponsored convention on Biological Diversity negotiated a biosafety protocol to regulate the international movement of gene-spliced organisms. It is based on the precautionary principle which dictates that "every new product or technology including, in this case, an improvement over less-precise technologies, must be proven completely safe before it can be used". The Cartagena Protocol on Biosafety came into effect on 11 September 2003.

This protocol requires that governments of the signatory nations be informed of any potential living GMO entering into a signatory country with the intention of introducing this GMO into the environment. South Africa signed this Protocol in October 2003.[2]

[1] www.oecd.org

2.3 WORLD TRADE ORGANISATION (WTO) AGREEMENTS AND DECISIONS

WTO Agreement on Subsidies[3]

The agreement recognizes that subsidies may play an important role in economic development programmes of developing countries, and in the transformation of centrally-planned economies to market economies.

WTO TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement[3]

The agreement recognises that "widely varying standards in the protection and enforcement of intellectual property rights and the lack of a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods. These have been a growing source of tension in international economic relations and as a result rules and disciplines were needed to cope with these tensions. To that end, the agreement addresses the applicability of basic GATT principles and those of relevant international intellectual property agreements; the provision of adequate intellectual property rights; the provision of effective enforcement measures for those rights; multilateral dispute settlement; and transitional arrangements.

With respect to the implementation of the agreement, it envisages a one-year transition period for developed countries to bring their legislation and practices into conformity. Developing countries and countries in the process of transformation, from a centrally-planned into a market economy, would have a 5-year transition period and least-developed countries 11 years. Developing countries which do not at present provide product patent protection in an area of technology would have up to 10 years to introduce such protection. However, in the case of pharmaceutical and agricultural chemical products, they must accept the filing of patent applications from the beginning of the transitional period. Though the patent need not be granted until the end of this period, the novelty of the invention is preserved as of the date of filing the application. If authorization for the marketing of the relevant pharmaceutical or agricultural chemical is obtained during the transitional period, the developing country

[2] www.africabio.com

[3] www.wto.org

concerned must offer an exclusive marketing right for the product for five years, or until a product patent is granted, whichever is shorter. "

3 NATIONAL SECTOR POLICIES IMPACTING ON THE BIOTECHNOLOGY SECTOR

In South Africa the main national policies impacting the biotechnology sector have been developed in the Department of Science and Technology (DST) which was the Department of Arts, Culture, Science and Technology (DACST) prior to 1994. In 2003 it was separated from the Arts and Culture component and now focuses wholly on science and technology policy implementation.

3.1 DEPARTMENT OF SCIENCE AND TECHNOLOGY

DACST commissioned the Technology Foresight Studies in 1999 which concluded that biotechnology should be one of the focus technologies for South Africa to pursue. Based upon this recommendation a number of initiatives, policies and strategies were launched relevant to the decision that biotechnology would be one of the selected technology missions. DST has written several national policies as well as strategies to provide guidance to decision making. It is apparent that many of the strategy documents produced are to a greater extent more policy orientated documents that provide guidelines for the execution of relevant strategy. Strategy documents, such as the National Biotechnology Strategy omits the specifics that a strategy document should contain, such as specific measurable objectives with targets and a set of supporting initiatives to ensure that the objectives are attainable.

3.1.1 National R & D Strategy - Policy Overview

The White Paper on Science and Technology resulted in the National R & D Strategy [NRDS] for South Africa in a bid to close the chasm that exists between science and technology and economic development in South Africa.

In terms of the R&D Strategy the following points are pertinent to the biotechnology sector and form the basis for this development. The content has been drawn extensively from the NRDS.

It is interesting to note that the National R&D Strategy was in fact published after the National Biotechnology Strategy which should have informed the same. It was however well known at the time that the national imperatives as stated in the White Paper largely frame the National R&D Policy, so although the publication sequence was reversed the content of the NBS flows logically.

The National R&D Strategy has a number of key components and their relative impact on the biotechnology sector both national and regional is discussed hereafter in the appropriate level of detail.

The intention of the National R&D Strategy (NRDS) is to develop a strategic view of all actors, stakeholders and participants in the National System of Innovation, through a single responsible department, namely DST. This will allow better governance, more effective resource allocation and better outcomes in the short, medium and long term.

The three operational strategic objectives in the NRDS are:

1. Innovation must be facilitated through the technology missions, one of which is biotechnology

2. Human capital development and transformation must be an outcome

3. Creating an effective government science and technology system (alignment and delivery)

   The following measures of strategic performance are stated as being required by the strategy:

   - UNDP technology achievement index
   - R&D intensity
   - High and medium technology exports
   - Economic growth attributable to technical progress

   Baseline targets have been set in 2002 and targets have been set for 2012

4. The following strategic initiatives are stated as being critical to the execution of the policy

    - The establishment of a mission coordinating agency
    - The alignment of funding instruments
    - Provincial / regional coordination

The innovation "pillar" involves the establishment and funding of a range of technology missions, one of which is biotechnology, that are critical for promoting economic and social development.

The key objective of technology and innovation missions, mentioned in the policy, are the acceleration of economic growth and the creation of wealth on a sustainable basis, and the improvement of the quality of life of all South Africans. Such missions are established to create conditions for accelerated innovation based on technology. Not all technology and innovation missions do this in the same way. In some cases, the technologies already exist and the focus is on cost-reduction, demonstration and enhanced adoption in new settings. In other cases, the technologies are new or undergoing intense change, and technological mastery by industry and academia becomes crucial to innovation. Different missions therefore have different mixes of activity to achieve their objectives. In the post-Cold War era, successful economic strategies are closely aligned with government investment in innovation.

Innovation requires targeting and resources. The later stages of innovation (scale-up, product introduction, process engineering, and new plant trials) are expensive and remain technologically risky. The rewards for the successful nations are significant.

Innovation missions have an impact on human resource development but, increasingly, innovation missions assume that the necessary human resource skills and competencies are being produced by the higher education system. The focus is on key technological innovation, demonstration of technology, incubation of new businesses and enhanced networks of knowledge workers, and firms involved in technological innovation.

South African organisations currently have little opportunity or resources for quantum innovation. There is however evidence of a number of emerging technologies that are lost or

not commercialised because of a lack of innovation resources. In addition, there is a need for an enhanced role for the social sciences in understanding and providing strategies to enhance the rate of innovation.

The success of the technology and innovation missions is dependent on the achievement of the following outcomes:

- Improvement in quality of life through enhanced adoption of positive innovations.
- The ability to generate wealth and employment based on enhanced adoption of imported know-how, an increased rate of innovation and improvement, and the incubation and establishment of new enterprises.
- An increase in technological support to existing firms in the target domain.
- Increases in the number of science, engineering and technology human resources.
- Levels of, and increases in, foreign direct investment.
- Real increases in private sector R&D spending.
- South African controlled global intellectual property licenses.

It is important that the National R&D Strategy requires that regional / provincial coordination should be undertaken.

3.1.2 National Biotechnology Strategy - Policy Overview

The National Biotechnology Strategy [NBS] was published in 2001, and was largely informed from the White Paper on Science and Technology and the constructs of the NRDS issued in 2002.

The NBS has framed the way forward for the development of the biotechnology industry in South Africa. The document although named a strategy document, is to a large extent a policy document as few measurable objectives appear to be present. The document, to a large extent, creates the operating framework within which specific strategy must be

formulated

The NBS states that the following needs to clearly address the stated national imperatives:

- To improve access and affordability to healthcare
- To provide sufficient nutrition at low cost
- Create jobs particularly in manufacturing
- To protect and cherish our rich environment
- Reducing the impact of HIV / AIDS
- Rural development
- Urban renewal
- Crime prevention
- Human resource development

The strategy reemphasises the NRDS wherein it states that regional needs identification and integration must be considered. It states that there must be an emphasis on linking knowledge to applications and aligned to this effective and aligned IP creation and management.

The following are important statements from the NBS that need to be considered at the provincial and regional level with respect to strategy implementation:

- Biotechnology research in SA is leading edge but lacks focus
- Knowledge is produced in the context of application
- High expectation research must lead to economic and social benefit
- Interdisciplinary teams work on trans-disciplinary research activities

- Diversity of participating organisations
- Greater international linkages

In conclusion the NBS is also seen as per the R&D strategy to be more of a policy document providing direction for the development of the sector from a national perspective. The NBS needs to be reviewed from a national point of view and more specific objectives created at two levels, those that are applicable nationally and that can be acted upon at a national level and those that can be affected at a regional level.

3.1.3 Advanced Manufacturing Strategy (AMTS) - Policy Overview

The National Advisory Council on Innovation (NACI) advises the Minister of Science and Technology on strategies for the promotion of technology innovation; international scientific liaison; science and technology policy and the co-ordination and stimulation of the National System of Innovation.

In May 2002, NACI identified the need for developing a National Advanced Manufacturing Technology Strategy (AMTS) for South Africa.

The stated goals and objectives of the National Advanced Manufacturing Technology Strategy are to:

- Develop a vision of the technological profile of the industrial sector in the year 2014
- Identify priority sectors which have the greatest potential for supporting relevant goals contained in the IMS and the NRDS. These goals include national and social goals such as job creation and equity
- Stimulate technological upgrading in industry
- Facilitate the flow of technological resources to industry through new knowledge networks to foster innovation
- Facilitate the building of an environment conducive to innovation, particularly through

the supply of skilled manpower, technology infrastructure and funds

It is stated that the implementation of the strategy will be achieved through a combination of Centres of Innovation, Innovation Networks and specific initiatives or projects. Specific programmes such as focused human resource development will be driven through tertiary education institutions. The need to ensure provincial and metropolitan council alignment and support for initiatives is an essential part of implementation.

The AMTS does not specifically address the biotechnology sector as part of its scope, probably due to the fact that the development of the sector is still in its infancy from a manufacturing as well the fact that it is also a cross-cutting industry. Due to the fact that the biotechnology sector has significant potential to grow its manufacturing base, cognisence should be taken of the AMTS requirements for the future development of the industry.

3.2 DEPARTMENT OF TRADE AND INDUSTRY

The following strategy from the Department of Trade and Industry (*the dti*) is applicable to the biotechnology sector in the Western Cape.

3.2.1 Integrated Manufacturing Strategy - Policy Overview

the dti issued an Integrated Manufacturing Strategy to stimulate the manufacturing sector from an industry viewpoint. The strategy document, from which extracts have been taken, is summarized below.

The Integrated Manufacturing Strategy was released in 2002 by *the dti*. The integrated manufacturing strategy (IMS) is a strategy for all processes that transform natural products into manufactured products, and all associated processes, thus extending beyond the boundaries of what were traditionally considered to be industrial processes, to include various related activities and services. These include the extraction of raw materials and procurement of inputs, the production of intermediate goods and final products, packaging, marketing, distribution and retail.

The IMS can be understood as the integration of interventions related to competitiveness. These interventions include:

- market access
- beneficiation and value addition
- regional production
- equity and economic participation
- knowledge-intensity and services integration
- development of integrated value matrices

Essentially, it is the integration of these six approaches that drives the IMS.

3.2.2 The Technology and Human Resources For Industry Programme (THRIP) - Programme Overview

This initiative, driven by *the dti* is a partnership programme established in 1991, designed and managed by the National Research Foundation (NRF) and *the dti*. The aims of THRIP are to provide South African industry with the means to obtain specific responses to its technology needs to provide a flow of highly skilled researchers and technology managers who understand research, technology development and the diffusion of technology. The programme takes into account the viewpoints of both industry and academia; and aims to provide a new and enhanced educational experience within the context of technology development and/or diffusion through customised participation by students in collaborative projects.

The programme has an important role to play in the development of the biotechnology sector in the Western Cape. Use of the programme is reported to be not as optimally integrated into the instrument sectors strategies as what could be leveraged.

3.2.3 The Support Programme for Industrial Innovation (SPII) - Programme Overview

the dti introduced the Innovation Support for Electronics Scheme (ISE) in October 1989 to promote the local design and manufacture of innovative electronic products. Due to the need

to offer a wider support structure, this programme was replaced by the Support Programme for Industrial Innovation (SPII) on April 1st 1993. SPII is designed to promote technology development in all manufacturing industries in South Africa through support for innovation of competitive products and/or processes.

The programme is utilised by biotechnology researchers, but is not well integrated into the strategies of the biotechnology instruments operating in the Western Cape, as stated by CBT.

3.3 THE DEPARTMENT OF HEALTH

Policies in the Department of Health that are relevant to the biotechnology industry would mainly revolve around healthcare and the treatment of diseases that are problematic on the African continent. As far as the Western Cape is concerned any diseases that are being investigated by researchers in the Province or any specific diseases found in the province would be important from a policy perspective.

3.3.1 Health Research Policy in South Africa 2001 - Policy Overview[4]

The policy aims to create a framework and environment for healthcare and disease research to contribute effectively to health development and is envisaged as an integral part of long-term health development aimed at improving the health and quality of life of all South Africans and reduces inequalities within the system.

This policy:

- "Creates clear mechanisms for the re-allocation of government spending according to the health sector research priorities and needs.
- Establishes channels for capacity building and redressing of inequities in health research. Introduces a long-term perspective for health sector research needs to introduce new management approaches to health research in South Africa.

[4] Department of Health; www.doh.gov.za

The policy articulates a number of goals to fulfil its mission of promoting research that contributes towards the improvement of human health and welfare in South Africa:

- To develop a national health research system that contributes to equitable health development
- To promote innovation in health and health related service delivery
- Through research advance knowledge that underpins health and equitable, quality health care
- To develop a co-coordinated, well funded agenda for research
- To nurture talent and develop capacity to conduct research and utilise its findings
- To encourage uptake of research-based knowledge into the health care system"

"The single most important determinant of an effective health research system is the issue of governance and leadership. Governance within the context of the health research policy relates to the means and actions by which the broad research community organises itself in the pursuance of its mission of promoting research that has the potential to improve human health and welfare. Weak inter-sectoral links between the health sector and others such as environmental affairs, education and finance, is another major hindrance to effective health research. In addition the burgeoning number of actors and initiatives within health research must be moderated by enhanced co-ordination and collective decision-making and action."

Currently, healthcare research is conducted managed and financed by a diverse number of organisations with very little co-ordination, accountability and impact analysis of the research on the critical health needs of South Africa. A need exists for a coordinating structure within health research.

The national leadership and coordination structures should be an inclusive body representing all members of the broad research community. It should champion health research for equity and social justice. The leadership should provide advice on the research agenda and the financing of that agenda to the various funding institutions and departments. The national body should receive information on the quality and impact of the research and the national

priorities and goals should become an integral part of the international research agenda.

3.3.2 HIV/AIDS/STD Strategic Plan for South Africa 2000 – 2005 - Strategic Plan Overview[4]

This document is a "broad strategic plan designed to guide the country's response as a whole to the epidemic. It is not a plan for the health sector specifically, but a statement of intent for the country as a whole, both within and outside government. It is recognised that no single sector, ministry, department or organization is by itself responsible for the addressing the HIV epidemic. It is envisaged that all government departments, organizations and stakeholders will use the plan as the basis to develop their own strategic and operational plans so that all our initiatives as a country as a whole can be harmonised to maximize efficiency and effectiveness."

"It is envisaged that each government ministry has a focal person and team whose responsibility will be to plan, budget, implement and monitor HIV/AIDS interventions." It is also recommended that all other sectors including parastatals, NGOs, the private sector, faith-based organisations, youth, and women will also have dedicated HIV/AIDS representatives to assist in addressing the problem.

The general strategies of the plan are to increase access and acceptability to Voluntary HIV Counselling and Testing, improve STD management and the treatment of opportunistic infections and promote increased condom use to reduce STD and HIV transmission, to improve the care and treatment of HIV positive persons and persons living with AIDS to promote a better quality of life and limit the need for hospital care.

The following bodies or structures on national and provincial level are involved in assisting in achieving the goals and strategies above:

- The Cabinet
- The South African National Aids Council
- Interdepartmental Committee on Aids (IDC)
- MINMEC

- Provincial Health Restructuring Committee (PHRC)
- Director-Generals Form
- HIV/AIDS and STD Directorate of the Department of Health.

By contributing to medical research through already existing institutions such as South African Aids Vaccine Institute (SAAVI), the biotechnology sector supports the HIV/AIDS/STD strategy of improving the care and treatment of HIV positive persons and persons living with AIDS to promote a better quality of life and limit the need for hospital care.

The SAAVI public-private partnership was established to co-ordinate the research, development and testing of HIV/AIDS vaccines in South Africa. SAAVI is based at the MRC and is working with key national and international partners to produce an affordable, effective and locally relevant HIV/AIDS vaccine in as short a time as possible. SAAVI brings together researchers from the universities of Cape Town and Stellenbosch, the National Institute of Communicable Diseases, the Medical Research Council, AlphaVax, the University of North Carolina, the division of AIDS at the National Institute of Allergy and Infectious Diseases, the HIV Vaccine Trial Network and the International AIDS Vaccine Initiative.

3.3.3 The Human Tissue Act (ACT 65 OF 1983) – Purpose of Act[5]

This Act makes provision for "the use of tissue, blood and gametes, which are removed or excised from a living donor, to be used only for medical and dental purposes. This includes the transplantation of tissue, the production of a therapeutic, diagnostic or prophylactic substance, blood transfusion, the production of a blood product and, in the case of a gamete, artificial insemination". Note that there is no reference in the Act to purely scientific investigations and experimentation and it is doubtful if these activities can be described as `medical'. It is a criminal offence for anyone to obtain tissue, blood or a gamete for any other purpose than that stipulated by the Act.

[5] Medical Research Council of South Africa; www.mrc.ac.za

3.3.4 The Foodstuffs, Cosmetics and Disinfectants Act (ACT 54 OF 1972) - Purpose of Act[4]

The main purpose of the Act is to control the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants; and to provide for incidental matters.

3.4 NATIONAL DEPARTMENT OF AGRICULTURE

The Department of Agriculture and the Agriculture Research Council's are together the most relevant to the plant biotech industry. All of the applicable acts and policies have been covered in the PlantBio strategy which considered the requirements from a national point of view through a series of interviews and analysis of all published documents.

PlantBio has successfully translated the requirements into a strategy document which addressed both national and regions imperatives. One act that does have significant bearing on the biotechnology industry is the Genetically Modified Organisms Act of 1997, which is summarised below.

3.4.1 Genetically Modified Organisms ACT, 1997 - Overview of Act[6]

The Act provides for measures to "promote the responsible development, production, use and application of genetically modified organisms (GMO's); to ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequence to the environment." The Act also pays attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for risk assessments and to establish a council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith.

[6] South African Government Information; www.info.gov.za

The objectives of the Council are "to advise the Minister on all aspects concerning the development, production, use or application of genetically modified organisms and to ensure that all activities with the regard to the development, production, use, application and release of such organisms are performed in accordance with the provisions of this Act."

The use of genetically modified foods is still largely problematic and world renowned nutritionist authors are still extremely skeptical about the use of GM foods and continue to state that the long term effects of GM crop usage for food is largely unknown.

3.4.2 The Animal Improvements Act (ACT 62 OF 1998) – Overview of Act[7]

Genetic resources are a key component of animal improvement. It's through a combination of genetic resources and other factors, that animal production and performance can be improved.

The informed, orderly and responsible use of genetically superior animals to improve the efficiency of these resources is the basis of animal improvement.

The objectives of the policy are to:

- "Facilitate poverty alleviation through the sustainable utilisation of animal genetic resources
- Promote and support the identification, evaluation, breeding and use of genetically superior animals to improve the production and performance of animals used for food, agriculture, sport and recreation.
- Promote the sustainable use of Animal Genetic resources (AnGR) as a major contributor to National food security.
- Facilitate the conservation of animal genetic resources for food and agriculture.
- Facilitate reduction in the risk of disease transmission through animal improvement.

[7] National Department of Agriculture; www.nda.agric.za

- Strive for a competitive animal production sector."

3.4.3 The Plant Breeders Act (ACT 15 OF 1976) - Overview of Act[7]

A plant breeder's right is a form of "Intellectual Property Right providing for the acquisition of legal rights, in order to obtain royalties as remuneration for efforts made during the breeding of a new variety of a plant." The act therefore provides the owner of a variety the opportunity to obtain financial reward for his/her efforts, as the breeding and development of a new variety is expensive and time consuming. The act states that it is important to obtain new and improved plant varieties as there is a constant demand for better quality, higher yields, better processing properties and increased disease resistance.

"The Plant Breeders Act provides for a system where under plant breeders' rights relating to varieties of certain kinds of plants may be granted and registered; for the requirements which have to be complied with for the grant of such rights; for the protection of such rights and the grant of licenses in respect of the exercise thereof and to provide for incidental matters. "

Other agricultural policies relating to and impacting on biotechnology are the Agricultural Pest Act and the Plant Improvement Act (Act 54 Of 1976).

3.5 DEPARTMENT OF ENVIRONMENTAL AFFAIRS AND TOURISM

The main Acts of the Department of Environmental Affairs and Tourism impacting on biotechnology are:

3.5.1 The National Environmental Management Act (NEMA) 1998 – Purpose of Act[8]

The above Act provides for "cooperative environmental governance by establishing principles for decision-making on matters affecting the environment, institutions that will promote cooperative governance and procedures for coordinating environmental functions exercised by organs of state; and to provide for matters connected therewith. "

[8] www.polity.org.za

3.5.2 Biodiversity ACT OF 2004 – Purpose of Act[8]

Due to the potential risks and effects of biotechnology on South Africa's biodiversity, policies such as the Biodiversity Act of 2004 serves as a platform to provide for the efficient management, control and conservation of the diversity of the Republic's biological resources.

The stated objectives of the Biodiversity Act are to, within the framework of the National Environmental Management Act, provide for the management and conservation of biological diversity within the Republic and of the components of such biological diversity, to provide for the use of indigenous biological resources in a sustainable manner as well as the fair and equitable sharing among stakeholders of benefits arising from biosprospecting involving indigenous biological resources.

The Act attempts to give effect to ratified international agreements relating to biodiversity which are binding on the Republic and to provide for co-operative governance in biodiversity management and conservation. It also provides for a South African National Biodiversity Institute to assist in achieving the objectives of this Act.

The Act provides for integrated and co-ordinated biodiversity planning; monitoring the conservation status of various components of South Africa's biodiversity and promote biodiversity research.

The Act also provides for the protection of ecosystems that are threatened or in need of protection to ensure the maintenance of their ecological integrity, for the protection of species that are threatened or in need of protection to ensure their survival in the wild.

The Act attempts to prevent the unauthorized introduction and spread of alien species and invasive species to ecosystems and habitats where they do not naturally occur; to manage and control alien species and invasive species to prevent or minimize harm to the environment and to biodiversity in particular; to eradicate alien species and invasive species from ecosystems and habitats where they may harm such ecosystems or habitats and to ensure the environmental assessments for purposes of permits in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), are conducted in appropriate cases in accordance with Chapter 5 of the National Environmental Management Act.

The Act provides procedures to regulate bioprospecting involving indigenous biological

resources, to regulate the export from the Republic of indigenous biological resources for the purpose of bioprospecting or any kind of research and to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The Act also provides structures for the regulation of the issuing of permits, the administration process and describes the circumstances under which offences are committed and penalties should be given.

Within the Biotechnology sector, it is important to take note of the following functions of the South African National Biodiversity Institute that may impact on the sector:

The South African National Biodiversity Institute established in this Act have the responsibility of monitoring and reporting regularly to the Minister on the status of the Republic's Biodiversity, the conservation status of all listed threatened or protected species and listed ecosystems as well as the status of all listed invasive species.

The Institute is assigned the task of monitoring and reporting regularly to the Minister on the impacts of any genetically modified organism that has been released into the environment, including the impact on non-target organisms and ecological processes, indigenous biological resources and the biological diversity of species used for agriculture.

The Institute shall act as a consultative body on matters relating to biodiversity to organs of state and other biodiversity stakeholders.

3.6 OTHER DEPARTMENT POLICIES, STRATEGIES AND ACTS

Given the stage that the biotechnology industry is in, the numerous policies that might well affect the industry in future are not really applicable at this stage except for the Patents Act (Act 57 of 1978) which is of importance to new innovations within the biotechnology sector. The Act basically provides for the legislation and granting of patents for inventions and for matters connected therewith.

There are other policies emanating from the following departments which will not be discussed here due to its general nature and applicability to all sectors.

- Department of Labour
- Department of Education
- Department of Finance / SARS / treasury

This concludes the description of the policy environment surrounding the biotechnology sector impacting on the Western Cape. In the forthcoming chapter the policies and strategies relavant to the biotechnology industry will be further analysed and their impact in the sector assessed in the context of industry issues.

4 BIOTECHNOLOGY SECTOR POLICY ANALYSIS AND IMPACT

Based on the various policies reviewed in the previous chapter, the specific impact of these policies on the biotechnology sector needs to be considered to evaluate their relevance in identifying potential areas, where policy may be influenced or specific policy recommendations made, to leverage the development of the sector in the Western Cape. This policy analysis and impact section describes how the main policies most relevant to biotechnology industry support each other, considers policy overlaps or contradictions as well as the extent to which policies are coordinated by different Government departments. An evaluation of collaboration and communication amongst existing industry bodies and companies also provides an overview of the issues around the biotechnology industry policy environment.

4.1 ANALYSIS OF THE BIOTECHNOLOGY POLICY ENVIRONMENT

The three main strategies that impact on the biotechnology sector at this stage are the:

- National R&D Strategy (NRDS)
- National Biotechnology Strategy (NBS)
- Advanced Manufacturing Technology Strategy (AMTS)

There are several common themes that flow through these policies that are largely being followed by the biotechnology sector in the Western Cape.

From a national biotechnology perspective, biotechnology is managed through the Biotechnology Unit of the Department of Science and Technology. As mentioned in the sector report, the CBT also has a comprehensive strategy of its own for directing the chosen five focus areas of biotechnology, which are predominantly in the human health domain. PlantBio also has a national strategy which has some focus areas in the Western Cape. Both the above biotechnology instruments, as they are referred to by DST, are innovation centres which have been formed to enable the regional biotechnology industry to develop to its full potential and impact on the growth of the Western Cape Province.

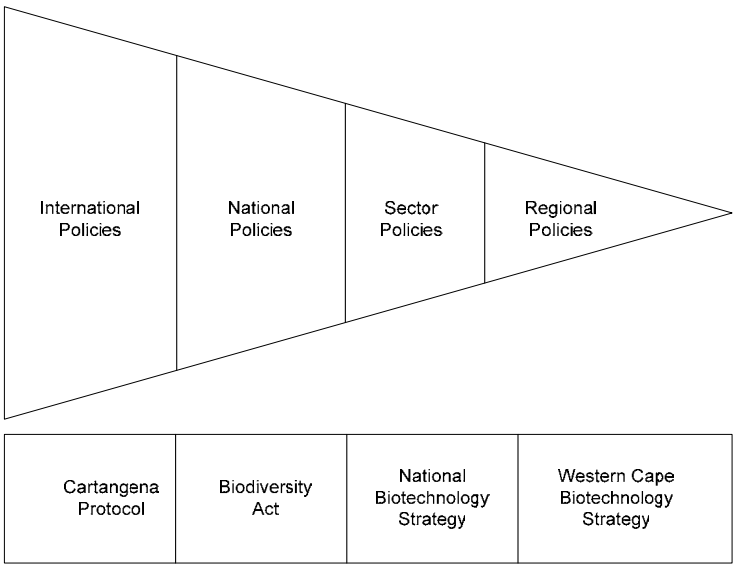
Although the National Biotechnology Network (NBN), another instrument within the National Biotechnology Unit, acts as an innovation network across the biotechnology sector, it largely operates on a national basis and covers all provinces thus negating the necessity of establishing a similar facility in the Western Cape. The NBN could however be more extensively utilised to the advantage of the biotechnology initiatives within the Province. Currently greater involvement and interaction with NBN could be established to promote the biotechnology IP and access to international knowledge bases to benefit numerous local players in the industry.

The Western Cape also has the Acorn incubation facility in place for commercialisation of biotechnology.

4.2 POLICY IMPACT ON THE BIOTECHNOLOGY SECTOR

The three main biotechnology sector strategies mentioned all support each other, mainly due to the fact that they are formulated from the within the Department of Science and Technology. The IMS was a forerunner to the AMTS and therefore adopts similar requirements.

Figure 1: Four levels of policy influencing sector



Although the various aforementioned strategies are related to one another they are not necessarily dependent upon each other for successful implementation. This is a positive aspect, considering that the alignment of concepts and objectives. There are however policy / strategy statement overlaps between the three major strategies cited, due to a similar approach to innovation being adopted across all three strategies.

It is apparent that there is coordination between *the dti* and the DST in their approach to stimulating growth in the biotechnology sector. The illustration of this is that the contributors (authors and reviewers mentioned in the policy documents) to the development of the strategies are stakeholders in both departments and are also well represented in terms of their involvement in the industry. It can be concluded that these policies therefore have more of a technology and industry development focus, but are not comprehensive in terms of addressing skills and education issues. Representation of other Government departments that are directly impacted, such as the Department of Labour and the Department of Education, appear to be far less evident.

4.3 ISSUES RELATED TO THE POLICY ENVIRONMENT WITHIN THE SECTOR

In analysing the various policies pertaining to the biotechnology sector and taking into account the current state of the sector in the Western Cape Province, as described in the sector overview report, a number of pertinent issues were identified, which are described below.

Lack of Clear Provincial Objectives and Measurement Criteria

There are no national and provincial biotechnology policies that exist. In the Western Cape Province the CBT strategy has been derived from the three national strategies, namely the National R&D Strategy, the National Biotechnology Strategy and the relevant concepts within the Advanced Manufacturing Technology Strategy. All three strategies have been thoroughly interpreted at the sector level by the biotechnology industry players, CBT and PlantBio, in the Western Cape, but further clarity is often sought in terms of more specifically stated objectives, especially at national level which can in turn be translated to provincial government level. Related to this is the measurement of success within the biotechnology sector especially at the provincial level.

The choice of which biotechnology products the Western Cape should specifically pursue, to meet its own needs in is not at all clear at this stage and no particular research project of product stands out at this stage. The DST is however undertaking an analysis of all major biotechnology projects being undertaken nationally by all BRICs' and PlantBio to ascertain the extent to which they are linked to national imperatives. This exercise could also be linked to provincial requirements as well. This selection of project and specific that need to be pursued at province level should be demand driven, in that the need should be derived from those sectors which biotechnology can have a significant impact.

Unfocussed Research

Biotechnology research in South Africa is stated, in the NBS, as being leading edge but lacks focus. A review is currently underway of all biotechnology instruments from a national Government viewpoint. Although a significant effort has been made to focus efforts in relation to funding provided, R&D projects being pursued still appear to be extremely diverse, due mainly to the way in which they have been selected through comprehensive analyses conducted by CBT and PlantBio, largely in isolation of national governments direct

involvement. There is a realisation that more focus is required, especially in terms of addressing the national, regional and provincial imperatives, which the biotechnology sector will need to take cognisence of.

The NBS states that knowledge must be produced in the context of application. This is still deemed to be a major issue and demands more focus from a research output point of view.

Knowledge outputs need to be significantly more focused towards application, as is reported in a study by NACI on The Utilisation of Research in South Africa. The Western Cape's 400 research groups appear to be producing significant amount of research and opinions are that some research projects need to be more focused towards the biotechnology priorities of the province, while it is obviously still important to address national, regional and global research problems. The 50 strategic recommendations developed on improving research utilisation have set out to address this issue, but to date they have not yet been promulgated.

The NBS states that biotechnology research must lead to economic and social benefit. Most of the social benefit derived from biotechnology research will result from addressing the national imperatives, such as food security and disease prevention and cure. The growth of CBT's envisaged biotechnology cluster in the Western Cape from the currently low manufacturing base will eventually create economic benefit for those sectors which it supports, such as Agriculture, Health Care and utilities such as water.

Low Level of Collaboration

A further requirement of the NBS is that interdisciplinary teams should work on trans-disciplinary research activities. It appears, from interviewee opinion, that this is an area that still needs to be addressed by the biotechnology sector BRIC in the Western Cape as well as PlantBio. Coordination and synergy between researchers will enable outputs to be achieved in a more effective manner.

Diversity of participating organisations working on biotechnology projects is deemed to be important within an effective National System of Innovation (NSI). One of the concerns of the Biotechnology Unit of the Department of Science and Technology is that there is not enough coordination amongst the numerous different organisations operating in the biotechnology sector. One challenge is that coordination and cooperation in developing biotechnology

cannot occur in isolation in one region, such as the Western Cape, but will need to be coordinated externally to the province to ensure an appropriate contribution to the countries national imperatives. There therefore appears to be a significant amount of work to be done to achieve higher levels of cooperation both inside the Western Cape and with other BRIC's located in other regions.

Greater international linkages are encouraged by the NBS and it appears that this is an area that is well addressed. The cost of international liaison is expensive and justifications need to be put into place for liaison to be effective.

Lack of Business Science Cross-Over Skills

A range of skills and a competent workforce are essential for the development of any industry cluster ranging from research, to commercial and management skills. Mention was repeatedly made of research- business cross-over skills to enable the transition from research to commercial viability of many of the research and incubated projects to proceed with minimal risk.

Low Levels of Remuneration in the Industry

The distinct lack of skills is to a large extent driven by the low levels of remuneration evident in the biotechnology industry. Graduates do not remain in the industry due to low levels of remuneration on entering the job market as well as a low propensity to earn a more market related remuneration over the short term to medium term. In meeting equity targets, the retention of black graduates in the biotechnology sector is even more problematic, as they seek more profitable less risky opportunities in other related and unrelated industry sectors.

Intellectual Capital

The management of intellectual capital and related licensing of technologies are long standing issues impacting on the development of the biotechnology industry. It is well known and repeatedly stated that the issues surrounding the management of intellectual capital are matter for national government of resolve.

These above explored issues are the main issues highlighted as a result of the research undertaken in the biotechnology sector of the Western Cape.

4.4 POLICY FRAMEWORK FOR ECONOMIC GROWTH

New policy for the biotechnology sector at National Government level is deemed not to be an important requirement at this stage. However at provincial level the required focus for the biotechnology sector in the Western Cape needs to be formulated into both policy and strategy. A comprehensive assessment of provincial needs was considered in the formulation if the CBT Strategy[9] but a novel look at policy and strategy must help drive what areas of biotechnology the Western Cape Province needs to focus on.

There are various ways within which a sector's growth can be promoted. These ways include a variety of policy levers, strategies and interventions from government at national, provincial and local or municipality levels. Successful interventions of biotechnology successes, such as in British Columbia in Canada in FDI, technology transfer and domestic resource allocation is

not a matter of whether or not a government should intervene, but rather how it should become involved.

By studying the various types of interventions and areas requiring support, four focus areas of intervention are recommended. These four areas can also be regarded as *perspectives* for policy or strategy formulation. These areas include *market*, *technology*, *skills* and *institutional arrangements*. The four focus areas are not mutually exclusive but rather complementary to each other and together, through cause and effect relationships, promote a common goal of economic growth and competitiveness enhancement. The typical types of interventions can be grouped in each of these focus areas to provide a clear structure for analyzing the type of support that is required by the biotechnology sector in the Western Cape Province. Each of the focus areas are generically described below and thereafter analysed in the context of the emerging biotechnology sector and envisaged cluster in the Western Cape.

Table 1: Government policy levers

Skills	**Institutional**
▪ Lower labour living costs	▪ Institutional participation in sectoral councils
▪ Ensure/ promote attractive living conditions for management	▪ Cluster/learning network support
▪ Skills development for labour and lower management - SETAS	▪ Enabling framework
	▪ Influence central statistics for provincial sectoral data
	▪ Lobbying
	▪ Profile image building and projection
Market	**Technology**
▪ Dissemination sector/ trade intelligence information	▪ R&D / Innovation Support
▪ Export Information	▪ Create sector support centers of excellence
▪ Service provider directory	
▪ Supply Side Policy (e.g. competitiveness fund)	
▪ Analyze global sector trends	
▪ Import export complementation ▪ Import Credit Certification Scheme ▪ Duty Credit Certificate Scheme ▪ Import Rebate Credit Certificate	
▪ Inward trade missions to province	

Skills

The importance of human capital can not be underestimated and has long been recognised as an important catalyst for successful economic growth. The overall returns, for example, for an additional year of education has been estimated at 24 percent for primary education in Sub-Saharan Africa. A similar multiplier is also relevant to a specific industry's development. Although unskilled labour influences the production cost competitiveness, the picture is different for high-technology industries, where production techniques have advanced and have grown more capital intensive. The high international rate of development and competitiveness requires that the minimum "entry" skill levels and competence requirements are much higher than originally deemed necessary when the South-Asian low labour rates dominated the markets. In order to enter the highly competitive markets niche competencies

in higher-technology fields are a key requirement, making specialised education more important. Competitive wage rates, specifically for unskilled labour, will always be a critical requirement, although specialised skills are more sought after in the new economies.

In terms of the Western Cape biotechnology sector, a high level of research skills exists in the Province with some 400 research groups currently active. The skills primarily service the innovation stage of biotechnology, with relatively low rates being paid. Skill requirements for the commercial market are readily available, but with the relatively low labour rates, many experienced graduates do not remain in the industry. The industry is also largely reliant on a combination of technical and commercial skills for its success.

Institutional Support and Arrangements

The level of institutional support for companies operating in a sector is a further critical component in promoting the competitiveness of a sector. Institutional support for high-technology sectors such as biotechnology, based on knowledge intensive activities is crucial in competing in cutting edge markets. The types of support activities that can be leveraged from an institutional perspective include research and development of new technologies, productivity in the manufacturing environment through capacity optimization and leveraging, economic research and market intelligence provision.

These activities are not only fostered through the interaction with tertiary education facilities but also the support from provincial governments to set up *centres of excellence* to promote research and development and technical skill promotion.

The concept of establishing Regional Biotechnology Innovation Centres (BRIC's), meets the suggestion of the *center of excellence* approach. Support originally from the Cape Biotech Initiative (CBI) and the subsequently the Cape Biotech Trust (CBT) has largely fulfilled this role. National support is evident through funding and guidance though the policies impacting on the sector as reported in a previous section.

As manufacturing is currently in its infancy in the biotechnology sector, little support is required at this stage in terms of productivity enhancement, capacity enhancement and leveraging.

Technology

The improvement in technology applied in an environment, country or sector, is probably the primary driver for economic growth. Solow (1957) attributed that 87.5 percent of the increase in output per man-hour between 1909 and 1949 to technical change[10]. While formulating a successful technology policy "is an art rather than a science", as stated by Lall and Teubal (1998), one cannot omit the importance of including it as a critical component in formulating growth strategies.

For South African biotechnology innovators, the access to new technologies is crucial. The key components include research and development, accessing skills to apply technologies effectively and initiating intelligent international partnerships to source and transfer technology.

There is international evidence that research and development can be incentivised successfully as has been demonstrated in Canada. The Canadian Government has established a tax incentive scheme to encourage Canadian businesses to undertake R&D that will lead to more technologically advanced products and processes. The scheme is the largest single source of government support for eligible industrial R&D and guarantee quick and consistent delivery of incentives, in the form of tax credits or cash, to companies that qualify under the scheme. Exclusions are what are deemed to be non value-adding from a technology perspective such as social research and market research.

While there are a variety of ways to access research and development, a choice has to be made as to the optimal vehicle or source of the necessary information[11].

The US has established successful industry-university relationships to form an important source of new technology. The Bayh-Dole Act promoted "marketable" technology development with federal funding

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[10] More Instruments and Broader goals: Moving toward the Post-Washington consensus, J. Stiglitz

[11] Creating Value in a Digital Era, J. Zysman

Focused technology research initiatives through start-up or spin-off programmes from established larger corporations

Cluster research projects formed between a combination of companies to promote a common goal

Major companies will set-up technology development outposts to monitor developments and tap into distinctive pools of talent and technology around the world

Country focused research and development through public laboratories and in support of industrial laboratories.

The National System of Innovation addresses this perspective adequately in terms of existing policies, strategies and the supporting funding that accompanies these levers. The development of the CBT strategy, the idea of developing a biocluster, has to some extent been formulated with the priorities of the Western Cape Province in mind. The challenge now is to ensure that the strategy remains focused and delivers on both national and provincial imperatives. The management of intellectual capital and the transfer of technologies through partnership development have also been adequately addressed by CBT.

Market

Equally important to the other three areas, but probably one of the most complex focus areas, includes the policy levers to promote growth through addressing trade and market forces. Firstly several international agreements have to be considered such as the Washington Consensus which advocated the use of instruments such as macroeconomic stability, liberalised trade and privatisation to promote economic growth.

For the South African and Western Cape biotechnology sector this should be seen in the context that the country has achieved macroeconomic stability, through a variety of Free Trade Agreements that has resulted in a liberal trade environment. On the third point there is specific intent for subsidised biotechnology start-up companies to be commercialised as soon as possible to ensure that they can either provide products to satisfy the social needs of the country or province or compete in the open market.

The Washington consensus was based on a rejection of the state's activist role and the

promotion of a minimalist, non interventionist state, which is contrary to the role played by governments in the establishment of numerous biotech clusters internationally. The approach to growing the biotechnology cluster in the Western Cape is in line with other international start-ups.

While Foreign Direct Investment (FDI) is one of the most sought after vehicles to promote economic growth, it is an instrument that could be equally applied in each of the four focus areas. Where it is most appropriately applied in the Western province biotechnology sector is dependant on the level of need in other sectors, which have a propensity to grow the local economy.

The transformation of the biotechnology sector in the Western Cape is largely nationally driven at this stage, the DST being the provider of funds although there is guidance by the CBT. The CBT is managed by a local board with involvement from the Western Cape Province. The Provinces' broader needs could be more effectively communicated through policy and strategy to further focus on all the branches of biotechnology including plant and human health, in the Western Cape.

5 BIOTECHNOLOGY SECTOR POLICY AND STRATEGY RECOMMENDATIONS

Based upon the analysis in the previous sections of the report relating to the policy environment, the impact of the various policies on the biotechnology sector in the Western Cape, the issues identified within a recommended policy framework, various policy and strategy recommendations are made. These recommendations address the leverage economic growth in the biotechnology sector, including its competitiveness and performance.

It is a fact that the biotechnology sector in the Western Cape Province is already established, albeit in its infancy, and that it is largely in the research and development stage with very little commercial contribution to the Western Cape economy being evident at this stage. A consideration from the Provincial Government's point of view could be whether to leave the biotechnology industry to grow at its own pace through the CBT and PlantBio initiatives, without any intervention, or whether to play and active role in providing some direction to the sectors growth. The key challenges and success factors impacting on the development of the biotechnology industry have largely been addressed by the aforementioned organisations. Issues such as appropriate skill development and for example, the need for science cross-over skills which are imperative for biotechnology commercialisation, are mentioned on numerous occasions by interviewees. Another issue that is a high priority in the biotechnology industry is the management of intellectual property and revenues that may flow from the sales of the same. The resolution of many of these issues has therefore not been addressed in the recommendations to the Province, as they are adequately addressed in the CBT and PlantBio strategies.

Given the fact that MEDS process is yet to establish the sector priorities for the Province, which would in turn inform the above, it is suggested that the biotechnology sector does warrant attention due to the cross-cutting nature of the industry. Its ability to have some influence on the growth trajectory of other sectors, as well as to solve a range of socio-economic problems that impact not only at provincial level but at national level as well, warrants that the sector be considered in the light of the Western Cape's Micro-economic Development Strategy.

It is within this context that the following recommendations can be made regarding the

biotechnology sector in the Western Cape Province.

5.1 POLICY RECOMMENDATIONS

The following is a list of recommendations regarding policy in the biotechnology sector in the Western Cape:

Recommendation 1:

Identify and confirm which priority sectors in the Western Cape, have critical needs that can be enhanced by supporting biotechnology initiatives, that are most likely to stimulate economic growth or satisfy social requirements indirectly. This needs to be ascertained prior to the Province supporting an agreed set of biotechnology programmes and projects.

The Western Cape Province should, through the MEDS process, be selective in providing support for sectors underpinned by biotechnology, which will be able to play a role in satisfying the provinces economic growth and job creation needs. The Province should not just invest in biotechnology because it is a National Government initiative, but should directly influence the course of the CBT and PlantBio activities based on the provinces economic and social development needs. CBT's focus areas are currently on food and beverage, healthcare, agriculture and industrial utilities such as water. Further attention should be given to focus projects in these sectors as well as in other sectors such as energy, where biotechnology could play a role. This would ensure that the funding being utilised, part of which is sourced from National Government, is channelled into meeting provincial requirements thus ensuring that a return is realised through support sector economic growth and job creation.

It is acknowledged that some provincial needs have been taken into account in the development of the CBT strategy, but as the Provinces needs are further refined through the MEDS process, the CBT and PlantBio should be encouraged to further focus on projects that will impact significantly on the development of the biotechnology sector. This must be done through a comprehensive sector analysis, after the MEDS sector selection process has been completed, to assess where biotechnology can incrementally stimulate those sectors within the provincial economy that have the propensity to deliver economic growth and jobs to the

Western Cape. The analysis must be undertaken by CBT in conjunction with PlantBio with the necessary provincial guidance and support. The outputs of this process will provide guidance on which biotechnology projects should be focused on to promote sector growth.

The recommendation is substantiated by the fact that despite the CBT having undertaken stakeholder assessments of the Provinces' needs in the formulation of the current strategy, it has been reported as not yet being fully endorsed by the sector players in the Province as mentioned in the Biotechnology Sector Report. The 5 CBT areas of focus mentioned in the Biotechnology Sector Report therefore need to be considered in terms of provincial priorities as well. Further to this the sector report stated that, the alignment of biotechnology initiatives to related sector needs, that are able to be impacted by biotechnologies at the Provincial level, does not appear to be clear.

Further justification is that the National Biotechnology Strategy states that regional biotechnology strategies must be established, which has in fact been done, but as mentioned, in the absence of a clearly defined Provincial strategy and supporting policies.

This recommendation is therefore highly appropriate for the Western Cape Province due to the fact that because biotechnology is a cross-cutting sector, it is able to influence growth in other sectors though technology and innovation as is advocated by the National Research & Development Strategy.

For the recommendation to be promulgated, representatives from CBT, PlantBio their support organisations the National Biotechnology Network (NBN) and the PUB (known as Public Understanding of Biotechnology) and DEDT representatives with sector representatives need to consider and agree the Province priorities that might be influenced by biotechnology initiatives. The competencies required for this recommendation to be considered and executed, is that of a stakeholder in the Provincial Government, who would be able to achieve consensus, without being bias on the Provinces' strategic issues at stake. The suggested timing for this would be in the latter part of 2005, prior to the forthcoming budget year and funding cycle.

The consequences of the recommendation would be the support provided by biotechnology initiatives in delivering on the objectives of other sector development plans, which would further contribute to economic development and job creation. The execution of this is

however conditional upon constant monitoring of the agreed outcomes going forward, which is the topic of a further recommendation.

Recommendation 2:

The Province needs to facilitate and support the raising of funds to support biotechnology development in line with those sectors, underpinned by biotechnology that will contribute to Western Cape economic growth and job creation strategy. This includes the involvement and collaboration with neighbouring provinces within the broader region.

Funding is the vital to the source of all biotechnology developments, as illustrated in the numerous international investigations on the significant amounts of funding that have been put into the development of biotechnology clusters. South Africa's experience in the ease with which funding can be accessed is about 25% less than in other developed countries[12] Biotechnology research is highly dependant on significant amounts of funding, and currently the two biotechnology instruments CBT and PlantBio have both developed funding plans based on their own identified needs. The support of these funding plans, and participation in raising additional funding by the Province could further bolster the attainment of Provincial needs and even regional needs, especially where needs, such as in agriculture, go beyond the Western Cape Province. Surrounding provinces may well have similar needs in terms of meeting national imperatives or provincial development objectives. This consideration of biotechnology needs across provinces could well create the opportunity for greater fund raising and sharing to sustain biotechnology development projects that are of common interest. For the identified priorities in the Province or region to be targeted, it is therefore essential that joint funding support be provided. A further reason for securing more substantial funding would be to assist with the development and retention of skills, which are imperative for the development of a bio-cluster. Market related remuneration needs to be considered in developing funding proposals, and this is more easily done when adequate amounts of funding are available.

The recommendation is substantiated by the fact that the biotechnology instruments in the Western Cape have identified additional non-Government funding from a range of organisations. They have already been successful in raising numerous funding tranches from

[12] World Competitiveness Report 2003

a wide variety of organisations. Other research institutions, such as the universities and science councils also raise funds for research projects they undertake. It was however reported by CBT and PlantBio that the process of raising funds in time-consuming, long and onerous, especially when applied for at the BRIC level and that the impact on development of the BRIC was significant. CBT also reported that there was insufficient grant funding for R&D in commercial organisations operating in the Western Cape. The Provinces more direct involvement might well circumvent some of these problems.

Once the biotechnology interventions within the selected growth sectors have been identified by the MEDS programme, the Province would be in an even stronger position to substantiate and raise funding for the identified needs within the sectors they wish to promote.

The institutional framework for seeking the required levels of funding is tripartite in nature, with the DEDT and relevant Department, representing the sector and the relevant biotechnology BRIC all playing a role. This would be essential for two reasons. Firstly that any applications for funding are undertaken in a coordinated manner and secondly, that the usage and application of the funding is agreed by all parties. Members of the tripartite organisation would all be well versed with the needs clearly identified and the justification for the funding application. Knowledge of international donor organisations would obviously be essential and the ability to develop convincing funding applications, and to negotiate the same, is essential.

The consequence the Province not being involved in fund raising would be that the growth of the biotechnology sector in South Africa might largely ignore provincial needs. If relevant Provincial departments were to get involved to raise and provide funding, steer research, the benefit would be to the benefit of the Provinces' economic development and job creation programme.

The conditions in the Western Cape Province are currently favourable to pursue this recommendation, due to the fact that the biotechnology instruments have been established and are currently operating by catering for a broad range of national, regional and commercial needs. The timing for this recommendation should commence in the 2006/7 budget year once the provincial priorities have been established and the relevant biotechnology support for the appropriate sectors has been identified.

Recommendation 3:

Research undertaken in the Western Cape must be focused, through a series of interventions involving the 400 biotechnology research groups, to ensure that utilisation of research undertaken is improved and economic benefits are derived.

Once the biotechnology strategy for the Western Cape becomes focused in terms of what the desired sectoral outputs are, and a monitoring system is in place, so biotechnology research conducted in the Western Cape will need to be further focussed. This needs to be undertaken to produce utilisable research outputs to increase the extent to which current research is utilised far beyond the current 55% level estimated by the National Council for Innovation (NACI). There are undoubtedly numerous research problems that need to be investigated within the selected sectors of the Western Cape in which biotechnology plays a role. From the first recommendation, where the sectoral focus of biotechnology has been suggested as being identified, justified research requests need be channelled through the CBT and Plantbio through to the research institutions. This will enable significantly more research to be focused towards provincial needs where economic benefit will be derived.

The interventions to focus research in the Western Cape and increased collaboration between universities and commercial organisations in the biotechnology sector must be supported to promote idea generation and sharing within the industry. NACI is considering the launch of an R&D Charter to bridge this gap which, will go along way to overcoming the problem of insufficient collaboration among scientists and institutions, as reported by the CBT. This charter needs to be adopted by research institutions in the Province.

National and Provincial Government could establish a tax incentive scheme to encourage businesses to undertake eligible R&D, which meets national and provincial needs and imperatives. The scheme must guarantee quick and consistent delivery of incentives, in the form of tax credits or cash, to companies that qualify, similar to the one operating successfully under Canada.

An example of biotechnology issues that can be researched is the production and promotion of genetically modified (GM) foods. The Western Cape is the hub of retail in South Africa. Research undertaken to date is reported to be unrepresentative and poorly designed, the results of which have been criticised. The retail industry needs far more convincing and persuasion regarding the consumption of GM foods, if they are ever to become a reality. Retailers are likely to have access to international networks of experts that consider issues

regarding GM food consumption and the trends in buying behaviour. A further example would be to undertake consumer behaviour research sooner than later to ascertain opinions regarding the retailing of GM foodstuffs in the South African market. These are examples whereby potential markets could be comprehensively researched before resources and funding are committed to research and development. It is essential that the concerns surrounding GM foods be addressed to ensure the realisation of the full economic potential of modern biotechnology.

Research utilisation, measured by NACI, is particularly low in South Africa. It was reported in the Biotechnology Sector Report the Western Cape biotech R&D spend rates are considerably below the lowest rating and are reported to be in the region of 0.0975%. This is extremely low compared to national targets that have been established between 4 to 5%.

In the research utilisation survey conducted in 2003 by NACI, only 54% of fundamental research, much of which is individually selected according to HSRC research, and between 60 to 69% percent of strategic research, was being utilised at the time of the survey. It can be concluded that this in all likelihood applies to the Western Cape Province which also formed part of the survey. The fact that research utilisation in terms of the practical usage of research sits at some 55% in South Africa means that a significant amount of research in biotechnology is not undertaken for the purpose of effective utilisation of the output. The fact that the National Research Foundation (NRF) reported that the Western Cape is home to 41% of South Africa's leading and internationally acclaimed researchers and that 27% of these are involved in biotechnology does not say much for utilisable research being conducted in the sector.

CBT also states that researchers spent a significant amount of time on teaching rather than research and as a result the Western Cape has too few world class scientists, the main reason being that they are evaluated on publications rather than the commercialisation of their outputs. This is also borne out by the fact that limited funding has also impacted on the number of patents and scientific articles published by South African scientists.

Provincial priorities in biotechnology should be communicated to the CBT and PlantBio biotechnology instruments operating within the province and to achieve this, specific funding should be assigned and channelled for research to be undertaken to meet provincial needs, as highlighted in CBTs strategic analysis. Significantly more focus on value-added research

is required in the biotechnology industry in the Western Cape, a further criticism levelled by CBT as a result of the competitiveness survey conducted. The development of a strong science base is an imperative for biotechnology cluster development, as stated by research conducted by the Department of Trade and Industry in the UK.

This recommendation needs to be applied to all research institutions, such as universities and science councils, but more so the academic research institutions. The recommendation should be passed on the Western Cape Department of Education and monitored through the DEDT, with strong involvement through the biotechnology instruments operating in the region, namely CBT and PlantBio. Involvement with the NACI's anticipated establishment and implementation of a Research Charter is also essential. The competencies required for effectively monitoring what type research needs to be undertaken, should be undertaken by biotechnology research associations; the biotechnology instruments and the two Provincial department's mentioned.

The consequences of more focused research are a greater flow of potential outcomes into the biotechnology industry and therefore those selected sectors which biotechnology supports. This in turn should result in the relevant sectors of the Western Cape benefiting significantly in the long term. The consequences of not undertaking this intervention to focus research, will result in a further wastage of research effort which will only be of benefit to the researcher, rather than the economy.

Recommendation 4:

Develop measures of strategic performance for the Western Cape biotechnology sector that aggregate all sub-sector biotechnology activities that contribute to the Provincial economy and thereafter establish targets for effective monitoring and evaluation.

It is of fundamental importance that the Province drives what is important to enable it to achieve its economic growth targets, though the definition of measurable objectives, validation through research, execution and tracking through measurement towards set goals.

Given that the National Government is providing funding for the development of biotechnology in the region, which includes both the Western and Northern Cape, it would be prudent to ensure that this funding benefits not only the region as a whole, but the Western Cape in particular, as it is the dominant economy in the region. The Province has had to put its

support behind the CBT strategic plan, buy its representation on the CBT Board, and because of this has influence over the development of the biotechnology industry. Given that the same influence should be exercised over PlantBio for the region, the broad objectives for developing the biotechnology sector in the Western Cape therefore needs to be measured and monitored at Provincial level rather than at the BRIC / innovation centre level. The reason for this that the role of biotechnology, as a cross-cutting sector, must contribute to stimulating the growth of appropriate sectors such as agriculture, food, healthcare products and services as well as utilities such as water provision and purification.

Measures mentioned in the National R&D Strategy and the National Biotechnology Strategy as well as the Key Performance Indicators (KPI's) currently utilised for the BRIC's must be considered for determining appropriate measures of strategic performance that impact on the Province as a whole. These will need to be finalised and consensus reached by key stakeholders before being put into effect. From the analysis of the policies and the CBT and PlantBio strategic plans and inputs from the Department of Science and Technology's KPI's, the following are some suggested performance measures that should be considered, as biotechnology products and services emerge from the developing bio-cluster in the Western Cape and become commercialised:

- Number of patents generated in the Western Cape and revenues derived there from
- Number of new companies operating, aggregated revenues / sales output per year and year on year aggregated growth
- Average measures of profitability and survival rate of established companies.
- Number of people employed in the biotechnology sector across different stages of the value chain
- Annual non- government funds raised and year on year increments and return on funding, specified as a ratio

This recommendation is substantiated by the fact that the CBT's strategic performance is measured in terms of a set of KPA's, developed by the Department of Science and Technology, the achievement of which will impact on the Province, but only within the scope of activity that CBT covers. This clearly does not indicate what contribution is being made to

the Western Cape Province. Other areas which it is covering might influence South Africa or perhaps even Africa with its unique set of heath and agricultural problems, which might not be of particular concern to the Province. PlantBio is measured by similar criteria. These measures can be elevated to provincial level and made relevant to Western Cape's needs. Unless a strategy is reduced to strategic objectives that are measurable, and targets established are unlikely to be effectively executed[13]. It is important that some kind of return on funding investment is considered, the current funding of approximately R120 million having being incurred to date as stated in the sector report. The fact that the Cape Biotechnology Trust has estimated that there are more than 1 100 people employed in the sector, with approximately 350 people involved in core biotechnology, is a good measure of sector growth and could well be used to track employment in the sector as it moves more and more from a research focus into commercialisation.

The NRDS strategy requires that regional and provincial coordination must occur in the biotechnology sector. Appropriate measurements at the provincial measure should result in a more coordinated national provincial effort being achieved. Most of the DST NRDS strategic objectives have taken cognisence by the players in the biotechnology sector in the Western Cape, through the formation of the CBT BRIC and PlantBio's initiatives. There is however an initiative underway to better align the national and regional objectives.

It is important that baseline targets are also set for each of the performance measures that are finally decided upon. Clear milestones or due dates should be defined for the achievement of specific levels of performance against these measures. A dedicated communication and follow-up plan to track performance against the measures regularly should be put in place in order to focus stakeholders as to imminent objectives and goals.

In the application of the recommendation the Western Cape, the institutional structure that would be relevant would be DEDT, who would have to set up a Provincial board to develop and monitor the strategy from a Provincial perspective. Competencies for effective monitoring are believed to have been placed at DEDT to fulfil this role.

[13] Norton, D. P. and Kaplan, R.S.; The Balanced Scorecard - Measures that Drive Performance, Harvard Business Review, 1992

The consequences of not adopting this recommendation will be that biotechnology in the Western Cape could become to nationally focused, or to opportunistic in nature and not contribute to the economic growth of the Western Cape through the sectors which it supports.

Due to the fact that the biotechnology sector is a cross-cutting sector and currently relatively narrowly focused in the Western Cape Province, the range of policies relevant to the industry is narrow. Another reason is the sector in research and development lifecycle and has not yet progressed to a mature manufacturing sector, which would still take some time to develop.

Although a number of policies from the different government departments can be said to have, to a certain degree, an impact on biotechnology, none of them currently significantly contribute to the economic restructuring of the sector.

5.2 CONCLUDING REMARK

Due to the fact that the biotechnology sector is a cross-cutting sector and currently relatively narrowly focused in the Western Cape Province, the range of policies relevant to the industry is narrow. Another reason is the sector in research and development lifecycle and has not yet progressed to a mature manufacturing sector, which would still take some time to develop.

Although a number of policies from the different government departments can be said to have, to a certain degree, an impact on biotechnology, none of them currently significantly contribute to the economic restructuring of the sector.