

3. SOUTH AFRICAN POLICY AND LEGISLATIVE ENVIRONMENT

3.1. LEGISLATION

South Africa has been a WTO member since 1995 and is a signatory to the TRIPS Agreement that resulted in expanded commitments to internationally binding guarantees of corporate 'intellectual property rights' over science and technology, production processes and products, such as pharmaceutical drugs⁵⁰. South Africa, like many developing countries significantly responded to the TRIPS Agreement by tightening IPR protection regimes⁵¹. The empirical evidence (notably changes to the TradeMark Act) suggests that the TRIPS Agreement has been successful in coercing South Africa and WTO member countries to strengthen domestic protection of IPR.

Furthermore, there are more than 30 pieces of legislation in South Africa that directly impact on the NSI, the Report only elaborate on the most recent legislation in South Africa in respect of the innovation landscape, i.e.

- Biodiversity Act
- Intellectual Property Rights from Publicly Financed R&D Act
- R&D Tax Incentives

Intellectual Property Rights from Publicly Financed R&D Act

The specific object of this legislation is that intellectual property emanating from publicly financed research and development should be commercialised for the benefit of all South Africans, and protected from appropriation. The IPR Act further provides for an enabling environment for intellectual property -

- creation,
- protection,
- management and
- commercialisation and utilisation.

Because this IPR Act impacts on all future EU collaboration agreements a recommendation is made to develop guidelines for the interpretation of the Act by EU partners.

Biodiversity Act

The National Environmental Management: Biodiversity Act builds on the White Paper on the Conservation

⁵⁰ Dot Keet, South Africa's official position and role in promoting the WTO

⁵¹ Ryan Cardwell, The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights, ITJ

and Sustainable Use of South Africa's Biological Diversity, which was published in 1997. The Biodiversity Act is of particular importance to the EU because many collaboration partnerships are based on the transfer of sensitive biological material from South Africa to EU partners by means of Material Transfer Agreements (MTA).

Among other the Act provides for bioprospecting, access and benefit sharing, the establishment of a Bioprospecting Trust Fund into which all moneys arising from material transfer and benefit-sharing agreements must be paid.

A recommendation to harmonise Material Transfer Agreements is made.

Pharmaceuticals and the Patent Act

There is currently a fierce, on-going debate in South Africa on the alleged impact that the Patent Act has on access to free medicine for the poor. This Report does not contain any reference to any formal or informal position of Government, stakeholders or lobby groups on the subject matter, mainly because the debate is at a very early stage. It is, however, one of the recommendations that the envisaged workshop will provide for a session on "Access to medicine, the Patent Act and Innovation in south Africa". This topic will be of interest to may EU partners who sponsor clinical trials at South African Institutions.

R&D Tax Incentives

The tax incentive (up to 150% of R&D expenditure) is aimed at encouraging businesses to undertake and invest in R&D in South Africa. The objective is to help companies build capabilities to create new products, processes, devices and techniques, and /or significantly improve existing ones. This incentive is part of a package of measures that the government of South Africa has introduced to support R&D led innovation, industrial development and competitiveness.

A recommendation is made to investigate how this incentive can directly or indirectly benefit EU-collaborators on SA research projects.

The table below represents the most important legislation in South Africa that impacts on the innovation landscape. The paragraphs listed in the right column link to the relevant paragraph in this document.

- Biodiversity Act
- IPR from Publicly Financed R&D Act
- Taxation Laws Amendment Act 2011 (Section 11D)

LEGISLATION	RELEVANT AGENCY	PAGE
Accreditation Act	SANAS	74
Agricultural Research	ARC	85
ASSAf Act	ASSAf	50
Astronomy Geographic Advantage Act		134
Biodiversity Act	DEAT	88
Biodiversity	SANBI	88
Companies Act	CIPC	73
Copyright Act	CIPC	73
Designs Act	CIPC	73
GMO Act	BIOSAFETY	86
Higher Education Act	CHE	79
Human Sciences Research Council Act	HSRC	49
IPR from Publicly Financed R&D Act	NIPMO	59
Medical Research Council	MRC	91
National Advisory Council on Innovation Act	NACI	60

National Empowerment Fund Act	NEF	<u>75</u>
National Health Laboratory Service Act	NHLS	<u>92</u>
National Research Foundation Act	NRF	<u>60</u>
Natural Scientific Professions Act	DST	<u>40</u>
National Small Business Act	SEDA	<u>78</u>
National Youth Development Act	NYDA	<u>98</u>
Nuclear Energy Act	NECSA	<u>84</u>
Patents Act	CIPC	<u>73</u>
Plant Breeders' Right Act	DAFF	<u>85</u>
Scientific Research Council Act	CSIR	<u>52</u>
Standards Act	SABS	<u>74</u>
South African National Space Agency Act	SANSA	<u>52</u>
Taxation Laws Amendment Act 2011	DST	<u>40</u>
Technology Innovation Agency Act	TIA	<u>46</u>

Trade Marks Act	CIPC	<u>73</u>
Water Research Act	WRC	<u>93</u>

3.1.1. BIODIVERSITY ACT

The National Environmental Management: Biodiversity Act No. 10 of 2004 was passed in September 2004. This legislation builds on the White Paper on the Conservation and Sustainable Use of South Africa’s Biological Diversity, which was published in 1997. In the “way forward” of this Policy, it was envisaged that a priority action of this policy will be to draft an action plan through which detailed implementation strategies can be developed. This forms an essential component of the National Environmental Strategic Action Plan (National Biodiversity Strategy and Action Plan). The development and implementation of the National Biodiversity Strategy and Action Plan (NBSAP) is an ongoing and iterative process. The NBSAP and the National Biodiversity Framework (NBF) must be seen as a continual cycle of implementation, monitoring, review and revision.

Bioprospecting (§0 Chapter 6 of the Act provides for bioprospecting, access and benefit sharing the establishment of a Bioprospecting Trust Fund.

Refer to §0 More details.

3.1.2. TAXATION LAWS - SECTION 11D (§0

The Taxation Laws Amendment Act 2011 introduced specific enhancements to the existing scientific and or technological research and development (R&D) tax incentive provided under Section 11D of the Income Tax Act. These changes are effective from 1 October 2012.

A company undertaking R&D in the Republic of South Africa qualifies for a 150% tax deduction of its operational R&D expenditure. This incentive is available to businesses of all sizes in all sectors of the economy that are registered in South Africa.

All the eligible R&D expenditure will qualify for an automatic 100% tax deduction. An additional 50% uplift applies to expenditures on R&D activities that have been approved by the Minister of Science and Technology, based on the provisions of Section 11D of the Income Tax Act.

The incentive is aimed at encouraging businesses to undertake and invest in R&D in South Africa. The objective is to help companies build capabilities to create new products, processes, devices and techniques, and /or significantly improve existing ones. This incentive is part of a package of measures that the

government of South Africa has introduced to support R&D led innovation, industrial development and competitiveness.

Refer to S0 for more detail.

3.1.3. THE INTELLECTUAL PROPERTY RIGHTS FROM PUBLICLY FINANCED RESEARCH AND DEVELOPMENT ACT 51 OF 2008 (IPR Act)

OVERVIEW

1. Objective of the IPR Act

The specific object of the legislation is that intellectual property (IP) emanating from publicly financed research and development (R&D) should be identified, protected (where applicable), utilised and commercialised for the benefit of all South Africans.

2. What kind of Intellectual Property (IP) is involved?

Section 1 of the IPR Act defines IP as

„any creation of the mind that is capable of being protected by law from use by any other person, whether in terms of South African law or foreign intellectual property law, and includes any rights in such creation, but excludes copyrighted works such as a thesis, dissertation, article, handbook or publication which, in the ordinary course of business, is associated with conventional academic work.“

Thus all forms of IP and any associated rights (IPR) fall within the scope of IP as defined in the IPR Act.

This includes the IPRs such as patents, plant breeders' rights, registered designs rights, trade marks and copyright all of which emanate from a research and development activity.

3. Guidelines

NIPMO has issues various Guidelines, Practices Notes and interpretation notes that covers topics such as IP ownership, reporting and approval requirements etc.

These documents can be obtained from the Department of Science and Technology website (www.dst.gov.za) under the NIPMO tab.

4. Ownership of IP

The IPR Act governs the ownership and utilisation of IP which flows from publicly financed R&D⁵². The IPR Act provides for three possible IP ownership options namely (a) the default position, (b) the co-ownership provision, and (c) the full cost arrangement in which IP ownership may be negotiated.

4.1 Default position

The default position on IP ownership, emanating from publicly financed R&D according to the IPR Act, is stipulated in Section 4(1) which states: "*Subject to section 15(2), intellectual property emanating from publicly financed research and development **shall be owned by the recipient***".

A "recipient" is defined as "*any person, juristic or non-juristic, that undertakes research and development using funding from a funding agency and includes an institution*". A "funding agency" is further defined as the "*State or an organ of state or a state agency that funds research and development*".

Thus the default position on IP ownership in terms of the IPR Act is that (if the requirements for co-ownership are not met) the recipient that undertakes R&D using funding received from a funding agency will be the owner of any IP that emanates from that R&D.

4.2 Co-Ownership provision

Section 4(1) is subject to Section 15(2), which deals with joint ownership of IP in all such cases where the IPR Act applies (i.e. where research projects are NOT being undertaken on a full cost basis). In all such cases a private entity or organisation may at most become a joint owner of IP emanating from publicly financed R&D if four requirements are met.

Section 15(2) provides that:

"A private entity or organisation may become a co-owner of the intellectual property emanating from publicly financed research and development undertaken at an institution if –

- a) there has been a contribution of resources, which may include relevant background intellectual property by the private entity or organisation;*
- b) there is joint intellectual property creatorship;*
- c) appropriate arrangements are made for benefit-sharing for intellectual property creators at the institution; and*

⁵² Section 1 of the IPR Act: "publicly financed research and development" means research and development undertaken using any funds allocated by a funding agency but excludes funds allocated for scholarships and bursaries

d) *the institution and the private entity or organisation conclude an agreement for the commercialisation of the intellectual property.*

4.3 Full cost arrangement

Section 15(4)⁵³ of the IPR Act provides for a private entity or organisation⁵⁴ to pay the full cost of R&D undertaken at an institution, such that the R&D is deemed not to be publicly financed and the provisions of the IPR Act do not apply.

It should, however, be noted that the IP ownership does not automatically belong to the full cost funder (i.e. private entity or organisation). As the IPR Act does not apply, IP ownership will be determined in terms of applicable IP statutes and contractual arrangements. In the case where the IP belongs to the institution, the institution has the discretion to make the IP available by assigning or licensing the IP, at no further cost, to the private entity or organisation. Alternatively, the parties may negotiate a further margin for the transfer of (assignment) or access to (licence) the IP.

5. Commercialisation Rights

5.1 Private Entity as Exclusive Licensee

Section 15(1) of the IPR Act provides that

“A private entity or organisation may become an exclusive licensee of intellectual property emanating from publicly financed research and development undertaken at an institution if such private entity or organisation has the capacity to manage and commercialise the intellectual property in a manner that benefits the Republic.”

Section 11 of the IPR Act further prescribes that such exclusive IP transaction must also include certain commercial benefits. For example Section 11(1)(d) of the IPR Act provides that

(d) exclusive licence holders must undertake, where feasible, to manufacture, process and otherwise commercialise within the Republic;

No approval is required for a local exclusive licence, however in terms of Section 12⁵⁵, NIPMO approval is

⁵³ Section 15(4) of the IPR Act: (a) Any research and development undertaken at an institution and funded by a private entity or organisation on a full cost basis shall not be deemed to be publicly financed research and development and the provisions of this Act shall not apply thereto. (b) For the purposes of paragraph (a) “full cost” means the full cost of undertaking research and development as determined in accordance with international financial reporting standards, and includes all applicable direct and indirect cost as may be prescribed.

⁵⁴ Section 15(5) of the IPR Act: (5) For the purposes of this section, private entity or organisation includes a private sector company, a public entity, an international research organisation, an educational institution or an international funding or donor organisation.

⁵⁵ Section 12 of the IPR Act: (1) Offshore intellectual property transactions are subject to the following conditions: A recipient must advise NIPMO of its intention to conclude an intellectual property transaction offshore; subject to paragraph (c), offshore intellectual property transactions may occur only in accordance with prescribed regulations and any guidelines contemplated in section 9(4)(e); and any intellectual property transaction which does not comply with the regulations and guidelines requires prior approval of NIPMO. (2) A recipient wishing to undertake an intellectual property transaction offshore in the form of an assignment or exclusive licence must satisfy NIPMO that: there is insufficient capacity

required for an offshore exclusive licence. Regulation 12(7)⁵⁶ of the IPR Act further states that the recipient (typically a Higher Education Institution or Science Council) must lodge an application on a prescribed form and provide proof to satisfy NIPMO that there is (a) insufficient capacity in the Republic to develop or commercialise the IP locally, (b) that the Republic will benefit from such offshore transaction⁵⁷ and (c) that the prospective licensee will ensure that the benefits of the IP are accessible to the Republic on reasonable terms⁵⁸.

5.2 Private Entity as Non-Exclusive Licensee

Regulations 12(1)⁵⁹ and 12(2)⁶⁰ state that the recipient may determine the terms and conditions for any non-exclusive licence outside of South Africa to IP fully owned or co-owned by the recipient and determined on an arms-length basis. No NIPMO approval is required for non-exclusive royalty-bearing IP transactions.

Section 12(1)(c) of the IPR Act further states that “any intellectual property transaction which does not comply with the regulations and guidelines requires prior approval of NIPMO.”

6. General

6.1 The State retains, in terms of the IPR Act, certain access to IP which emanated from publicly financed R&D for health, security and emergency needs of the Republic. A proclamation by the President, pursuant to a determination by Parliament, must be made before the State may exercise its rights only until such time as the emergency needs have been alleviated.

6.2 In summary, NIPMO approval must be obtained for all offshore assignments, offshore exclusive licences (as set out above) and all royalty-free transactions. A response must be received from NIPMO within 30 days from submission of a complete application by NIPMO, failing which the IP transaction will be deemed to be approved by NIPMO.

EU partners

in the Republic to develop or commercialise the intellectual property locally; and the Republic will benefit from such offshore transaction.

56 Regulation 12(7) of the IPR Act: A recipient must lodge an application in prescribed Form IP5 or IP6 with NIPMO for approval of an assignment of intellectual property offshore or grant of an exclusive licence, respectively, in terms of section 12(2) of the Act in compliance with the following conditions - (a) the application must detail compliance with section 12(2) of the Act and this sub-regulation (6); and (b) the recipient clearly articulates the benefits of the intellectual property to the Republic.

57 Section 12(2) of the IPR Act: A recipient wishing to undertake an intellectual property transaction offshore in the form of an assignment or exclusive licence must satisfy NIPMO that— (a) there is insufficient capacity in the Republic to develop or commercialise the intellectual property locally; and (b) the Republic will benefit from such offshore transaction.

58 Regulation 12(6) of the IPR Act: An exclusive licence agreement must in addition to the statement in sub-regulation (4) include appropriate terms and conditions, in particular - require that commercialisation of the intellectual property by a prospective licensee must ensure that the benefits of the intellectual property are accessible to the Republic on reasonable terms; an irrevocable and royalty-free right of the State to use or have the intellectual property used on behalf of the Republic, for the health, security and emergency needs of the Republic in terms of the Act; and NIPMO's rights in terms of section 14(4) of the Act, if the intellectual property is not commercialised within the reasonable period set out in the exclusive licence agreement.

59 Regulation 12(1) of the IPR Act: A recipient may, subject to section 11 of the Act, and sub regulations (2), (3) and (4) determine the terms and conditions for any nonexclusive licence to intellectual property governed by the Act that is fully owned by the recipient, outside the Republic or with an off-shore entity or person, or on an arms-length basis or for the purposes of promoting or facilitating the recipient's research and development activities.

60 Regulation 12(2) of the IPR Act: Subject to the written consent of co-owner(s) of intellectual property co-owned by a recipient with co-owner(s), which may not be unreasonably withheld, a recipient may determine the terms and conditions for any non-exclusive licence outside the Republic or with an off-shore entity or person, to such co-owned intellectual property, on an arms-length basis.

A) The term private entity or organisation

The IPR Act⁶¹ defines in Section 15(5) a “private entity or organisation” as a private sector company, a public entity, an international research organisation, an educational institution, or an international funding or donor organisation.

In terms of Section 15(5) EU partners will fall within the definition of “private entity or organisation” as either a private sector company or an international research organisation.

Public Entities: Treasury provides a list of public entities and a regular basis. The latest list was published on 15 March 2013 (<http://www.treasury.gov.za/legislation/pfma/public%20entities/default.aspx>)

3.2. INNOVATION RELATED POLICIES

The Department of Science and Technology’s policy landscape is as follows:

1996	White Paper on Science and Technology
2009-2014	Government Medium Term Strategic Framework
2001	National Biotechnology Strategy
2002	National Research and Development Strategy
2003	Advanced manufacturing Technology Strategy
2004	New Strategic Management Model for South Africa's science and technology system
2005	National Nanotechnology Strategy
2010	National Space Strategy
2007	The South African Earth Observation Strategy
2007	OECD review of Innovation Policies in SA
2008-2018	Ten-Year Innovation Plan
2009	National Energy Efficiency Strategy
2010	Nanoscience and nanotechnology 10-year research plan
2011	A Beneficiation Strategy for the Minerals Industry of South Africa
2011-2016	DST Strategic plan
2012-2017	National Department of Health Strategic Plan
2014-2015	Industrial Policy Action Plan
2030	National Development Plan, Vision for 2030

61 Section 15(5) of the IPR Act

