

# Framing a National Policy and Legislation for Managing Intellectual Property Rights Resulting from Publicly Financed Research and Development

McLean Sibanda

Senior Patent Attorney – Innovation Fund\*

***World Intellectual Property Organization LIFE Sciences Symposium: Public Sector Intellectual Property Management***

*WIPO, Geneva, Switzerland, 15<sup>th</sup> December 2008*

## **Abstract**

*This paper gives a summary of the development of the South African legislation in respect of intellectual property emanating from publicly financed research and development. Some important lessons are provided in respect of the process followed. Whereas it is important to specifically legislate in terms of ownership of such intellectual property rights, issues of access and availability of products and/or services based on such research can be dealt with in a less prescriptive and yet effective way, firstly by expressing such intent in the objects of the legislation and then ensuring that recipients of public funds structure exploitation agreements with appropriate humanitarian provisions where possible. The paper also deals with reasons for providing the State with residual rights to such intellectual property rights, particularly in the case of non-commercialisation and also in national emergencies and to meet the State's health, security and other priorities.*

## **1. Introduction**

In 2002, the South African government published the National Research and Development Strategy<sup>1</sup> ("**R&D Strategy**"), which amongst other things noted that "*At present, there is little appreciation for the value of intellectual property as an instrument of wealth creation in South Africa.... The rights of government, financing institutions, performing institutions and their staff are not defined. There is an urgent need for the creation of a proper framework and enabling legislation for the management of intellectual property arising from publicly financed research.*" The R&D Strategy also suggested that such a framework had to be legislated, place an obligation on recipients of public funds to protect and ensure commercialisation of intellectual property emanating from publicly financed research and

---

\* PO Box 2600, Pretoria, 0001, South Africa; [mclean@nrf.ac.za](mailto:mclean@nrf.ac.za); The Innovation Fund is an instrument of the Department of Science and Technology of the Government of the Republic of South Africa, managed by the National Research Foundation

<sup>1</sup> [www.pub.ac.za/resources/docs/sa\\_rd\\_strat\\_2002.pdf](http://www.pub.ac.za/resources/docs/sa_rd_strat_2002.pdf)

development and the right of the state to acquire the right to use such intellectual property in the public interest should be established.

In ensuing years, South Africa has through an extensive public consultation process and consultations amongst key government departments, spanning at least four years, developed (i) the Intellectual Property Rights from Publicly Financed Research Policy Framework<sup>2</sup> ("**Policy Framework**"), which was approved by the Cabinet of the Government of the Republic of South Africa in May 2007; and (ii) the Intellectual Property Rights from Publicly Financed Research and Development Legislation ("**PFR-IP Legislation**") which was adopted by the Parliament's National Assembly on 18<sup>th</sup> November 2008.

The Policy Framework was seen as a necessary precursor to legislation that be a catalyst for increasing the social and economic benefits from public research and development funding. More particularly, within a developing country perspective, there is a need to defend public spending on research and development in light of other competing priorities such as eradicating poverty, food and energy security and the like. Within the context of South Africa, some of these competing priorities are based on the emergence of South Africa from the apartheid era, and hence the need to normalize the South African society.

In finalizing the Policy Framework for submission to Cabinet, the Department of Science and Technology ("**DST**") also prepared, for Cabinet's approval, a draft legislation based on the Policy Framework to initiate the legislative process. Although others have argued that there was possibly no need for a legislative framework in light of the fact that the Policy Framework had been approved by Cabinet, it is clear from the R&D Strategy that the framework for managing intellectual property emanating from publicly financed research and development 'should be legislated'. Besides, for any such policy to be enforceable, it has to be given the force of law.

Cabinet approved the draft legislation for public comment in May 2007, after which a period of at least three months was allowed for written public comments. The public comment process was initiated by request for written submissions. A review of the written submissions from public and private sector stakeholders, including other government

---

<sup>2</sup> [www.naci.org.za/OECD/IPR\\_from\\_PRF\\_Policy\\_Framework.pdf](http://www.naci.org.za/OECD/IPR_from_PRF_Policy_Framework.pdf)

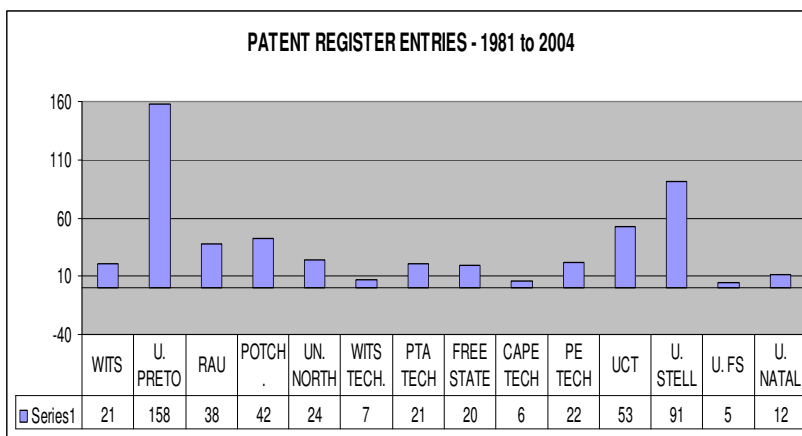
departments, led to a process of rewriting the draft legislation, followed by an extensive public consultation process.

## 2. Intellectual Property Rights from Publicly Financed Research and Development Policy Framework

In designing the Policy Framework, the South African government sought to lay down the broad principles for managing intellectual property emanating from publicly financed research and development. More particularly, the Policy Framework had to ensure that recipients of public funds had to appreciate that intellectual property is an instrument not only for wealth creation but also for socio-economic development. In developing the Policy Framework and ensuing legislation described below, it was important to particularly address a number of issues including the significant number of 'IP leakages' at publicly financed institutions comprising research institutes and higher education institutions, to overseas jurisdictions, with very little to no benefits accruing to the South Africa public which had funded the research leading to such intellectual property.

A review of South Africa's publicly financed research institutions had also revealed discrepancies in respect of ownership of intellectual property, benefit sharing practices, and commercialisation of such intellectual property, and generally low patenting rates.

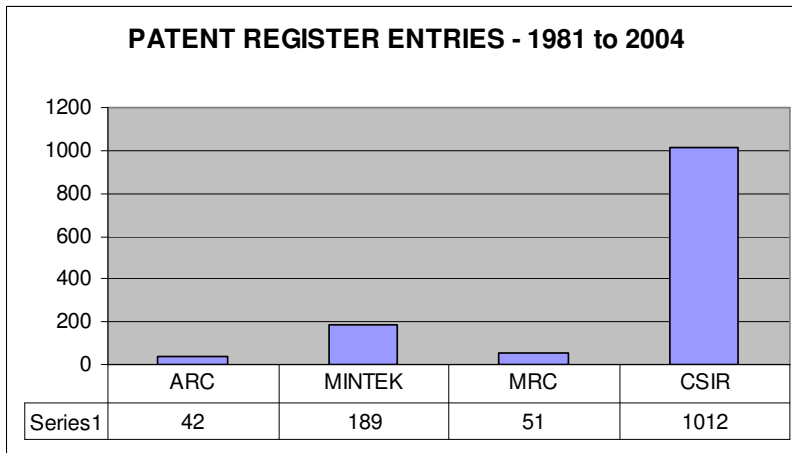
Figure 1: South African Patent Office Patent Register entries citing higher education institutions in the period 1981 to 2004.



Figures 1 and 2 are patent register entries at the South African Patent Office, in respect of higher education institutions and research institutes, respectively. These entries include both provisional and complete

patent applications. At the time, South Africa had over 23 higher education institutions. It is evident from Figure 1, that not all of these had any patent register entries.

Figure 2: South African Patent Office Patent Register entries citing research institutes in the period 1981 to 2004.



The patent register entries generally represented a very low patenting rate in respect of South Africa’s higher education institutions and research institutes in general, the reasons for this included lack of institutional policies in respect of IP

ownership and infrastructure for IP management and commercialisation. Whereas some institutions owned intellectual property developed by their researchers, most either had no policies in this regard, or had policies that granted the researchers the rights to such intellectual property, the so called ‘professor’s privilege’. The Policy Framework was seen as being essential to providing the foundation for establishment of and harmonization of institutional policies. The Policy Framework also recognizes that some institutional arrangements would have to be put in place to institutionalize the principles set out in the Policy Framework and also the provisions of ensuing legislation.

A review of all other existing South African intellectual property related legislation was undertaken to ensure alignment. Furthermore, there was a review of interventions that had been initiated, pursuant to the R&D Strategy. These ranged from the extent of institutional policies and practices in respect of IP ownership, commercialisation and benefit sharing, to financing mechanisms for intellectual property protection and capacity building initiatives in respect of IP management at publicly financed institutions.

International benchmarking suggested that nearly all developed countries with the exception of Canada and Ireland had opted to level the playing field through introduction of legislation to regulate results emanating from publicly financed research and development. This also revealed that developing countries with emerging economies were also adopting a similar approach.

Within the South African context, the key stakeholders that had to be considered in developing the Policy Framework were Government, the inventors, higher education institutions, funding agencies, the private sector and the general South African public.

The Policy Framework recognizes that although research is conducted by individuals, the institutions will be the ones who will always be recipient of public funds. In this regard, the Policy Framework recognizes the need to provide incentives to the individual researchers from successful commercialisation of their research results, through benefit sharing arrangements.

The Policy Framework requires institutions to put in place mechanisms for invention disclosures but also benefit sharing arrangements based on international best practices. Research that is fully financed is not regulated by the Policy Framework, although the institutions are encouraged to negotiate some benefits for their researchers before agreements are concluded.

The Policy Framework implicitly recognizes the challenges and possible conflict with their missions of publicly financed institutions, in respect of direct commercialisation of intellectual property and in this regard, provides preference to licensing as probably the most important mechanisms to transfer intellectual property to industry. However, the creation of start-up companies is recognized, particularly in the case where there is no immediate licensee.

It is in the area of commercializing such intellectual property that specific provisions in respect of accessibility and availability of resulting products can be regulated. Within the South African context, the Policy Framework recognizes that intellectual property should be used as an instrument for socio-economic development and recommends preferences for non-exclusive licensing to ensure wider access to intellectual property developed with public funds. The Policy Framework however recognizes that in certain circumstances, particularly where substantial investment is required to further develop the intellectual property, exclusive licensing may be the preferable. In that case, performance clauses are to be included in the relevant agreements. A mechanism for review of exclusive licence arrangements and where possible, limiting them to specific markets / fields, is proposed to be regulated. The inclusion of humanitarian provisions to protect in advance the possibility of sharing the IP with third parties for the benefit of people in need, is specifically recognized

by the Policy Framework, with recommendations that where possible such beneficiaries should be identified in advance by amongst other factors, field of use, geographic region, market, and income levels. This would be similar to the provisions in the case of golden rice<sup>3</sup>, in which subsistence farmers were exempted from paying royalties. Furthermore, we are of the view that this could be interpreted broadly to include the right of publicly financed institutions to negotiate preferential licensing terms in respect of developing countries or the so-called orphan diseases, and possibly a two tier pricing system in respect of sale of drugs or products covered by the intellectual property developed with public funds. Within the South African context, a specific implementation of these provisions has been used for example in the commercialisation of intellectual property relating to an innovative hydroxyapatite orbital implant<sup>4</sup> ("**Eyeborn**") used to replace the eyeball of a patient who has lost an eye. Eyeborn was developed by a consortium comprising the CSIR, University of the Witwatersrand, Pretoria Eye Institute and funded with public funds through the Innovation Fund. The agreements with the distributors of this implant provide for availability of the implant to public hospitals at a lower price than to private hospitals. Although some could argue that this could be potentially in violation of competition law principles, we are of the view that if the national policies and associated legislation specifically provide and motivate for the existence of such practices, such provisions would be legally enforceable and exempt for competition law violations.

Related to the commercialisation of intellectual property is the right of the State to such intellectual property. The Policy Framework recognizes (i) the obligation to disclose any intellectual property emanating from publicly financed research and development with failure to disclose leading to forfeiture of rights to the undisclosed intellectual property and any benefits accrued or pending; (ii) that with the right to own intellectual property there is an obligation to commercialise such intellectual property and failure to commercialise should result in some 'march-in rights' being exercisable by the State; and (iii) the State should not pay twice to use the intellectual property, particularly for governmental purposes, including national emergencies.

---

<sup>3</sup> Krattiger A and I Potrykus. 2007. Golden Rice: A Product-Development Partnership in Agricultural Biotechnology and Humanitarian Licensing. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A.

<sup>4</sup> <http://researchspace.csir.co.za/dspace/handle/10204/1078>

### **3. Intellectual property Rights from Publicly Financed Research and Development Legislation**

It is important that in establishing such legislation a process of sensitizing various stakeholders is undertaken. More importantly, the stakeholders should have the opportunity to express their views, comment on the various drafts of the legislation, and where possible, propose appropriate provisions that are objectively in the national interest to ensure that the final legislation meets the objectives defined by the guiding policy framework. However, at the end, government needs to decide on the best legislative framework that achieves the desired results, after having considered the views of the stakeholders.

Whereas the national policy could be very detailed, legislation is less detailed and needs to specifically identify issues that must be legislated, with detailed implementation provisions being left to regulations that may be promulgated to support the implementation of the legislation. This is the approach that has been adopted by South Africa.

A review of the South African research conducted at publicly financed institutions revealed that although a substantial amount of R&D was funded by public funds, in certain areas, private sector funded larger portions of R&D. As some government funding programs such as the Technology and Human Resources for Industry Programme<sup>5</sup> (“**THRIP**”) require that private sector provide matching funds, it was important to consult extensively to ensure that the interests of all the parties were considered in finalizing the legislation.

The Policy Framework laid the basis for developing the legislative framework set out in the PFR-IP Legislation, as envisaged in the R&D Strategy. Following the completion of the public consultation process which led to the finalization of the Policy Framework, the first draft of the PFR-IP Legislation<sup>6</sup> was formulated and published for public comment in May 2007. Substantial written comments were received from both public and private sector organizations, giving a summary of concerns, input and recommendations. The first draft of the legislation was very prescriptive but it achieved the purpose of laying a sound foundation for constructive engagement by the South African public with government to ensure that we had an enabling legislation, and this engagement contributed significantly to increasing

---

<sup>5</sup> [www.nrf.ac.za/thrip/](http://www.nrf.ac.za/thrip/)

<sup>6</sup> [www.info.gov.za/view/DownloadFileAction?id=72471](http://www.info.gov.za/view/DownloadFileAction?id=72471)

awareness of intellectual property issues generally. Following review of the written public comments, the following principles guided the redrafting of the draft legislation, namely, that the final legislation must: (i) be based on a consistent approach to ensure protection of IP developed with public financing (ii) be benchmarked against good practice globally and contextualised for national and regional efficacy (iii) identify key functions and responsibilities; (iv) achieve a good balance between incentives and control (v) provide certainty in terms of publicly financed IP and (vi) not hinder private-public collaborations.

In February 2008, with the draft legislation having been extensively revised in light of the written public comments, an international benchmarking exercise was undertaken to clarify certain issues raised in some of the written submissions. The USA owing to the Bayh-Dole Act, provided some useful precedents and lessons, with countries such as Canada where no such legislation exists, also providing good benchmarks. An international review panel comprising intellectual property experts from the USA, India, Canada and South Africa was constituted by the DST to extensively review the draft legislation in light of the provisions of the Policy Framework and also the guiding principles, as well as international best practices. This culminated in an extended stakeholder workshop with the review panel, which resulted in a refined draft legislation which was ready for submission to Cabinet for approval. With the draft legislation approved by Cabinet, a process of public hearings was held by the Portfolio Committee on Science and Technology and the National Council of Provinces, leading up to the adoption by the South African Parliament's National Assembly of the final PFR-IP Legislation on the 18<sup>th</sup> November 2008. At the time of writing of this paper, the PFR-IP Legislation was awaiting assent by the National President, and the draft regulations were being finalised for public comment.

The main objective of the PFR-IP Legislation is that *"intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the Republic, whether it be for a social, economic, military or any other benefit"*. More particularly, the PFR-IP Legislation seeks amongst other matters *to "ensure that (a) a recipient of funding from a funding agency assesses, records and reports on the benefit for society of publicly financed research and development; (b) a recipient protects intellectual property emanating from publicly financed research and development from appropriation and ensures that it is available to the people of the Republic; (c) a recipient identifies commercialisation opportunities for intellectual*



*property emanating from publicly financed research and development; ..... (e) the people of the Republic ... have preferential access to opportunities arising from the production of knowledge from publicly financed research and development and the attendant intellectual property; .... (g) where necessary, the State may use the results of publicly financed research and development and the attendant intellectual property in the interest of the people of the Republic.”*

As can be seen from the object and objectives of the PFR-IP Legislation set out above, the use of broad language is meant to ensure accessibility and availability of products and/or services from results of publicly financed research and development. In this regard, appropriate regulations could be formulated to specifically guide achievement of such objectives.

Table 1: Summary of institutional policies and technology transfer capacity

<b>Institution</b>	<b>IP Policy</b>	<b>Tech. Transfer Capacity (Year Established)</b>	<b>Institution</b>	<b>IP Policy</b>	<b>Tech. Transfer Capacity (Year Established)</b>
University of Cape Town	Yes	Limited (2002)	University of Pretoria	Yes	Limited (1996)
University of Stellenbosch	Yes	Yes (1999)	North West University	Yes	Yes (2003)
Nelson Mandela Metropolitan University	Yes	Limited (2007)	University of the Witwatersrand	Yes	Limited (2003)
Rhodes University	Yes	No	University of Limpopo	No	No
Walter Sisulu Metropolitan University	Yes	No	Mangosuthu University of Technology	No	No
Durban University of Technology	No	No	University of KwaZulu-Natal	No	In process of establishment
University of Fort Hare	No	No	UNISA	No	No
Cape Peninsula University of Technology	No	No	University of Western Cape	No	No
Vaal University of Technology	No	No	CSIR	Yes	Yes (2001)
University of Johannesburg	Yes	Limited (2004)	Water Research Commission (WRC)	Yes	Limited (2003)
Central University of Technology	No	No	University of Zululand	No	No
Vaal University of Technology	No	No	Tshwane University of Technology	Yes	Limited (2005)
Medical Research Council (MRC)	Yes	Yes (2004)	Agricultural Research Council (ARC)	Yes	No
Mintek	Yes	Limited			

The main issues dealt with in the PFR-IP Legislation are the following (i) obligation on recipient of public funds to disclose, protect, and manage intellectual property emanating from publicly financed research; (ii) obligation to ensure that such intellectual property is commercialized in the national interest; (iii) benefit sharing arrangements with intellectual property creators; (iv) establishment of appropriate infrastructure and capacity to effectively manage intellectual property at publicly financed institutions, this is particularly needed in the case of South Africa as can be seen from Table 1 above; (v) process for disposing of intellectual property rights off-shore (vi) establishment of a central agency, the National Intellectual Property Management Office to administer the implementation of the PFR-IP Legislation and provide assistance to recipients in ensuring achievement of objects thereof; (v) regulating IP ownership in case of co-financed research and development; (vi) rights of the State to intellectual property emanating from publicly financed research and development.

The PFR-IP Legislation also establishes an Intellectual Property Fund to support publicly financed institutions to protect their inventions.

Whereas the Policy Framework was specifically directed to publicly financed research institutions, the PFR-IP Legislation is directed to recipients of public funds designated for purposes of research and development. This was based on significant funding for innovation that the South African government has made available to small businesses through instruments such as the Innovation Fund<sup>7</sup> and the Biotechnology Innovation Centres<sup>8</sup>. According to the PFR-IP Legislation, a recipient is any person, juristic or non-juristic, that undertakes research and development using funding from the State or an organ of State or a State agency that funds research and development. Such a recipient owns the intellectual property emanating from such funded research and development, and should they elect not to own it, then they have to give the State an opportunity of assessing whether or not the State would suffer any prejudice if such intellectual property was not statutorily protected.

The recipient has the freedom to determine the nature and conditions of exploitation of intellectual property, with assignment being seen as an exception rather than the norm, and exclusive licenses being subject to recipient determined performance clauses. Government

---

<sup>7</sup> [www.innovationfund.ac.za](http://www.innovationfund.ac.za)

<sup>8</sup> [www.plantbio.org.za](http://www.plantbio.org.za); [www.lifelab.org.za](http://www.lifelab.org.za), [www.capebiotech.co.za](http://www.capebiotech.co.za); [www.biopad.org.za](http://www.biopad.org.za)

does however have the right to review any exclusive licence agreement to ensure that it has performance clauses. Intellectual property transactions with parties outside South Africa's borders ("**off-shore transactions**") are regulated, with the recipient being required to show that such a transaction would benefit South Africa. The draft regulations only regulate exclusive licence arrangements and assignments, with non-exclusive off-shore transactions being unregulated.

Each intellectual property transaction is required to specifically provide the State with "*an irrevocable and royalty-free licence authorizing the State to use or have the intellectual property used throughout the world for the health, security and emergency needs of the Republic*". It is anticipated that government would probably have to declare a state of emergency before making use of this licence, as it is not the intention of government to erode the viability of any businesses based on such intellectual property. The right of the State to intellectual property emanating from publicly financed research and development should not be confused with the rights that any State has in the case of national emergencies to any patents, for example. In the former case, the right arises from the fact that the research that gave rise to such intellectual property was funded with public funds, whereas in the latter case, these rights arise under international treaties.

The right of intellectual property creators at publicly financed institutions to benefit sharing is more clearly defined in respect of the minimum benefits sharing from exploitation of their intellectual property. The institutions may, however through their institutional policies or by agreement with their researchers propose higher amounts. For the first R1,000,000 of gross revenues accruing to the institutions, intellectual property creators are entitled to at least R200,000. Thereafter, a minimum of 30% of nett revenues after considering deductible expenses detailed in regulations must be paid to the intellectual property creators. This entitlement is for as long as revenues are generated from such intellectual property and the right passes to the creator's estate in the event of death.

One of the challenges in implementing the PFR-IP Legislation will be in changing researchers' mindset, particularly those at publicly financed institutions who are often incentivized on the basis of publications and who view intellectual property protection and publication as being mutually exclusive. The other challenge will be in quickly establishing the requisite capacities for managing and commercializing intellectual property. Most of the institutions in Table 1

have either no technology transfer offices or under resourced technology transfer offices, as managing and commercializing intellectual property is a fairly new activity for most of these institutions. What is particularly important is to ensure that specialist skills are developed across technology sectors, as there are nuanced approaches required for each technology sector. In this regard, one of the approaches that South Africa has adopted is to develop specialist intellectual property and commercialisation specialist skills through programs initiated by the Innovation Fund.

#### **4. Conclusions**

In developing the South African legislation in respect of intellectual property from publicly financed research and development, a process was adopted which entailed numerous public consultations, awareness, sensitisation, establishing a national policy framework to start to guide and encourage the right kinds of behaviour.

An enabling legislation which considers the interests of all stakeholders and seeks to justify government funding of research and development in light of all other competing priorities has been developed. Implementation of this legislation will require that publicly financed institutions be sufficiently capacitated to undertake their obligations under the PFR-IP Legislation. Exploitation provisions will have to be customised for each of the technology sectors and aligned with national government strategies. For example, issues of access and availability of products of publicly financed research and development could be adequately dealt with by encouraging appropriate licensing provisions aimed at achieving humanitarian benefits. The approach in South Africa has not been to specifically legislate this but to provide broadly for this in the objects section of the legislation.

The march-in-rights provisions are essential to ensure that government always has a say in the case of non-commercialisation of intellectual property emanating from research funded with public funds, to ensure that the public had prospects of reaping some benefits from such research. Furthermore, provisions granting the State rights in the case of national emergencies and/or for governmental purposes only are also important to ensure that the State does not pay twice and/or spend significant time negotiating licensing terms with recipients in the case of emergencies or strategic use of intellectual property for the country's health, security and other purposes.

Whereas benchmarking is vital, it is important that there be customisation that takes into account local conditions.

We believe that the South African legislation in respect of intellectual property emanating from publicly financed research and development provides clarity in respect of ownership and obligations in respect of such intellectual property. Furthermore, the legislation lays down the principles necessary to ensure accessibility and availability of products and services based on such intellectual property for the benefit of the South African public and others. The legislation also provides the State with rights to ensure that such intellectual property is commercialised, and also that if so required in the case of emergency needs of the Republic, government will be entitled to make use of such intellectual property to address such needs. The extensive public consultation processes have ensured that the PFR-IP Legislation provides a good balance of interests of (i) publicly financed institutions and intellectual property creators, (ii) the State and recipients of public funds, (iii) prospective licencees of such intellectual property and the public as represented by government, and (iv) private sector research funders and collaborators, publicly financed institutions, and the State.

### **Acknowledgements**

This paper was prepared for the WIPO Life Sciences Symposium: Public Sector Intellectual Property Management, held in Geneva, Switzerland on 15<sup>th</sup> December 2008. Both the Policy Framework for Intellectual Property Rights from Publicly Financed Research and the PFR-IP Legislation were championed by the Department of Science and Technology ("DST") of the Government of the Republic of South Africa under the leadership of the Minister of Science and Technology, the Honourable Minister Mosibudi Mangena. The author led the Innovation Fund team that undertook the public consultation process on the development of the Policy Framework for Intellectual Property Rights from Publicly Financed Research, pioneered by Dr Adi Paterson former DST Deputy Director General: Research, Development and Innovation. The author was also involved with the drafting and finalisation of the PFR-IP Legislation on secondment to the DST, under the leadership of Dr Boni Mehlomakulu DST Deputy Director General: Research, Development and Innovation. The author extends his gratitude to both Dr Adi Paterson and Dr Boni Mehlomakulu for their guidance and leadership.