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INTELLECTUAL PROPERTY POLICY OF THE REPUBLIC OF SOUTH AFRICA PHASE I

Division: International Trade and Economic Development

Intellectual Property Policy of The Republic of South Africa Phase I 2018

Contents

1. List of Abbreviations

- ABS Access and Benefit Sharing
- ACIP Australia's Advisory Council on IP
- AMR Antimicrobial resistance
- ARIPO African Regional Intellectual Property Organization
- AU African Union
- BRICS Brazil, Russia, India, China, South Africa
- CBD Convention on Biological Diversity
- CIDP Committee on Development and Intellectual Property
- CIPC Companies and Intellectual Property Commission
- CEDAW Convention on the Elimination of all Forms of Discrimination against Women and Girls
- CEWG Consultative Expert Working Group on Research and Development: Financing and Coordination
- CRC Convention on the Rights of the Child
- CRPD Convention on the Rights of Persons with Disability
- G20 Group of 20
- GI Geographical Indication
- ICESCR International Covenant on Economic, Social and Cultural Rights
- IMCIP Inter-Ministerial Committee on Intellectual Property
- IP Intellectual Property
- IPAP Industrial Policy Action Plan
- IPR Intellectual Property Rights
- LDC Least Developed Countries
- LMMC Like-Minded Mega-Diverse Countries
- NDP National Development Plan
- NGP New Growth Path Framework
- NEDLAC National Economic Development and Labour Council
- NIPF National Industrial Policy Framework
- OAPI Organisation Africaine de la Propriété Intellectuelle
- PAIPO Pan African Intellectual Property Organization
- PCT Patent Cooperation Treaty
- R&D Research and development
- SDG Sustainable Development Goals
- SADC Southern African Development Community
- SAHPRA South African Health Products Regulatory Agency
- SMMEs Small, medium and micro-enterprises
- SSE Substantive Search and Examination
- **the dti** The Department of Trade and Industry
- TRIPS The Agreement on Trade-Related Aspects of Intellectual Property Rights
- UNCTAD United Nations Conference on Trade and Development
- UNDP United Nations Development Programme
- UNHLP United Nations Secretary General's High Level Panel on Access to Medicines
- UPOV International Convention for the Protection of New Varieties of Plants
- WHO World Health Organization
- WIPO World Intellectual Property Organization
- WTO World Trade Organization

2. Introduction

The National Development Plan (NDP) of South Africa calls for a greater emphasis on innovation, improved productivity, an intensive pursuit of a knowledge economy and the better exploitation of comparative and competitive advantages. Intellectual Property (IP) is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), creative expression, consumer protection, industrial development and more broadly, economic growth.

South Africa's economic development strategy aims to accelerate growth along a path that generates sustainable and decent jobs in order to reduce poverty and the extreme inequalities that characterise our society and economy. The National Industrial Policy Framework (NIPF), implemented through the Industrial Policy Action Plan (IPAP), is a central component of our economic development strategy. The NIPF and IPAP seek to encourage and upgrade value-added, labour-absorbing industrial production, and diversify the economy, by moving away from the current over-reliance on commodities and non-tradable services. Knowledge, innovation and technology are increasingly becoming the drivers of progress, growth and wealth.

Therefore, South Africa needs to transition towards a knowledge economy, and away from an over-reliance on natural resources. A specific framework of conditions is necessary to enable South Africa to make this transition, and an IP Policy is one of the core elements required to achieve this objective.

The South African Constitution already protects intellectual property rights (IPR) from arbitrary deprivation and in recent decades, South Africa has made significant strides in the just protection, administration, management, and deployment of IP.

Statutes relating to IP in South Africa include, but are not limited to:

- Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008
- National Environmental Management: Biodiversity Act 10 of 2004
- Patents Act 57 of 1978
- Merchandise Marks Act 17 of 1941
- Copyright Act 98 of 1978
- Designs Act 195 of 1993
- Plant Breeders' Rights Act 15 of 1976
- Trade Marks Act 194 of 1993

Despite attention paid to IP law-making in the country, there is a need for a comprehensive IP Policy that will promote a holistic, balanced and coordinated approach to IP that is mindful of the many obligations mandated under the South African Constitution.

The goals of this comprehensive IP Policy are:

- To consider the development dynamics of South Africa and improve how IP supports small institutions and vulnerable individuals in society, including in the domain of public health
- To nurture and promote a culture of innovation, by enabling creators and inventors to reach their full potential and contribute towards improving the competitiveness of our industries
- To promote South African arts and culture
- To solidify South Africa's various international obligations, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Protocol on ABS), in the service of our genetic resources and traditional knowledge associated with genetic resources

The strategy employed in this comprehensive IP Policy includes:

- Advancing a balanced and coordinated approach to IP that regulates IPRs in line with the South African Constitution
- Introducing key policy reforms that account for the development dynamics of South Africa
- Promoting innovation and a knowledge economy
- Leveraging competitive and comparative advantages to advance the transformation of the South African economy

The overarching objective is to ensure that this comprehensive IP Policy becomes a just, balanced, and integral part of the broader development strategy for South Africa by assisting in transforming the South African economy, and thereby leveraging human resources for the broader economic benefit, increasing local manufacturing, and generating more employment.

The comprehensive IP Policy will be implemented in a phased approach. The current document constitutes the first phase in what will be a comprehensive policy to be developed and updated over the medium term. Phase I covers IP and public health, coordination in international forums, and the implementation of commitments undertaken in international agreements. Phase I priorities have been identified on the basis of South Africa's development objectives, supplemented by research, analysis, and experience, as well as assessments of existing capacity to implement the measures outlined herein.

The comprehensive IP Policy proposes key reforms that are aimed at advancing South Africa's socio-economic development objectives as outlined in key policy documents of the national government, such as the National Development Plan (NDP), the New Growth Path Framework (NGP), National Drug Plan, NIPF and the various iterations of IPAP.

The key reforms include:

- The introduction of substantive search and examination (SSE) for patents, which is a key step towards ensuring that the patent regime fulfils its purpose of stimulating genuine innovation. This will benefit patent holders by granting them rigorously assessed rights, and benefit the public at large by ensuring that market exclusivity is only granted when appropriate. Importantly, SSE will not only apply in the health sphere; it will eventually have much broader application. However, with due regard to capacity constraints and resources, the IMCIP – in consultation with diverse stakeholders – will determine the initial fields in which full SSE will occur. These fields will be progressively expanded, as the capacity of the state increases.

- The leveraging of flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure that South Africa protects IPRs while simultaneously promoting public health, local manufacture, research and development, innovation, food security, environmental considerations, transfer of technology and broad socio-economic development.

- The promotion of regional cooperation and integration in IP.

- A commitment to all relevant international obligations South Africa is party to.

- The promotion of economic empowerment through, among other means, the implementation of the "utility model" to support the registration of patents by resident small, medium and micro-enterprises (SMMEs), historically disadvantaged individuals, and companies who are operating in the informal sector. This entails enacting exclusivity similar to a patent right, granted by a state, to an inventor or the inventor's assignee, for a fixed period of time. However, the terms and conditions for granting a utility model are slightly different from those for ordinary patent, including a shorter term of protection and less stringent patentability requirements. The term "utility model" is sometimes addressed differently in other countries, with the terms "petty patents", "short-term patents" or "innovation patents".

- A coordinated approach to creating awareness about IP among South Africans, so as to protect nationally-owned IP that is related to indigenous resources, traditional innovation and traditional knowledge.

- The creation of a system for protection for traditional knowledge which will guard against misappropriation and exploitation, as well as promote further research and development into products and services based on traditional knowledge.

- The promotion of international best-practices in IP that align with South Africa's development objectives.

The IP Policy is ordered as follows:

- Section 3 contains the problem statement that sets out the need for the IP policy and the key issues it will address.

- Section 4 consists of the purpose of the IP Policy within the context of South Africa's broader development objectives.

- Section 5 contains the strategy which outlines a phased-approach towards the development of a comprehensive IP Policy.

- Section 6 highlights the role of the Inter-Ministerial Committee on IP (IMCIP), whose purpose is to harness the collective resources available within government as a whole, to the benefit of the people of South Africa.

- Section 7 articulates in detail what is entailed under Phase I of the IP Policy.

- Section 8 summarises and outlines the "in-built" agenda, that is, IP issues which will be explored in detail and implemented in the medium term.

- Finally, Section 9 concludes by setting the IMCIP the task of implementing the IP Policy.

3. Problem Statement

Broadly, while South Africa has made significant progress in the deployment of IP within the country, and has ensured that it has a legislative framework that protects IP, the country yet lacks a comprehensive IP Policy that will promote a holistic, balanced and coordinated approach to IP. What is required is a comprehensive IP Policy that will promote and contribute to South Africa's socio-economic development betterment, by promoting local manufacture, preserving and leveraging the country's resources and heritage, encouraging innovation, and empowering domestic industries and individuals who seek to take advantage of the IP system.

Specifically, the intersection of IP and public health has long been an issue of contention within South Africa, and one without resolution to date. Recognition of the problem began as early as 1997, with amendments to the Medicines Act, and the subsequent case, *PMA v the President of the Republic of South Africa*. Thus, it has been twenty years since the problem was identified. As both a constitutionally guaranteed right, as well as a key development goal, the issue of access to health care services – and the role of IP in delivering public health – has been at the forefront of human rights debates in the country.

A substantial part of the problem with optimising the role of IP in public health is that South Africa does not conduct SSE prior to the grant of patents. Our patent laws and implementing regulations are such that the Registrar of Patents, housed within the Companies and Intellectual Property Commission (CIPC), only conducts examination in relation to the formalities of the application. Hence, South Africa employs a so called "depository system" in terms of which the subject of a patent application is *only* examined against the substantive criteria of novelty, inventive step, and industrial applicability *if* the patent is challenged in litigation, such as in relation to infringement or revocation.

A recent comparative study conducted by scholars from Columbia and Harvard Universities reveals that South Africa grants a far higher percentage of patents from all applications filed in the country than virtually any other comparable country.[1] On average, 93% of patents applied for in South Africa were granted, as compared to 61% in the United States of America, 53% in Mexico, 51% in the European Union (51%), and only 29% in Japan. World Intellectual Property Organisation (WIPO) statistics demonstrate that within comparable developing countries, the figures from India and Brazil show even lower rates of granting: in 2015, India approved 19% of all patent applications, while Brazil approved a mere 14%.[2]

Historically, the depository system for patents was instituted in South Africa due to resource constraints. A depository system places the cost of substantive examination on parties that are directly interested in the patent, thereby allowing the state to direct scarce technical skills toward infrastructure and other key developmental areas. Despite this benefit, there

[1] Sampat and Shadlen, The Effects of Restrictions on Secondary Pharmaceutical Patents: Brazil and India in Comparative Perspectivehttp://economics.harvard.edu/files/economics/files/sampat-bhaven_effects_of_restrictions_on_secondary_pharma_patents_brazil_and_india_3-4-16.pdf

[2] http://www.wipo.int/ipstats/en/statistics/country_profile/

are substantial drawbacks for both producers and users of IP. For producers, the lack of examination reduces the security of their patents, since the grant of a patent does not guarantee that the subject of the patent meets patentability criteria in the country, or that it does not contain subject matter excluded by law. Indeed, scholars from a leading South African university conducted a study which found that a significant number of patents granted in South Africa would not pass muster under an examining system.[3]

Users of IP are prejudiced on the other hand because subject matter that should be in the public domain can be unfairly monopolised by exclusive rights. Moreover, the underlying policy rationale of patents is to serve as an incentive to stimulate innovation. Granting an exclusive right in the absence of genuine innovation is anathema to the proverbial bargain that the patent holder is supposed to strike with society, namely, disclosure in return for monopoly protection, resulting in society being short-changed, and overall negative consequences for both access and innovation.

In addition, South Africa's approach to international IP cooperation is currently not optimally coordinated, whether between government departments or even, in some cases, within a single government department. It is not always clear that international positions are taken with a clear understanding of obligations in our Constitution. It is also not clear that we are currently taking full advantage of the opportunities presented by globalisation, as manifested in various international treaties, to uplift vulnerable sections of South African society, and contribute to development on the African continent.

A coordinated South African approach to IP informed by South Africa's development imperatives is sorely missing, and urgently necessary. The IMCIP, a consultative forum and drafting team aimed at achieving a holistic approach to the IP Policy formulation process, is a first step in achieving this coordination, but not an end in itself. What is required is for government officials across departments and functions to be able to take on harmonised negotiating positions at multilateral forums, in order that we may be able to take advantage of every developmental opportunity that serves to boost South African social and economic advancement.

[3] Pouris and Anastassios Pouris, 'Patents and economic development in South Africa: Managing intellectual property rights'. South African Journal of Science. 2011, 107(11/12) Art. #355, available at: http://dx.doi.org/10.4102/sajs.v107i11/12.355

4. Purpose

The National Development Plan (NDP) calls for greater emphasis on innovation, improved productivity, the intensive pursuit of a knowledge economy and better exploitation of comparative and competitive advantages.

Though there is broad agreement at a political level that IP is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), creative expression, consumer protection, industrial development and more broadly, economic growth, the precise contours of IP regulation are contested. Economic literature reveals an inconclusive link between increased IP protection and economic development. For example, in a report on the international patent system, the WIPO secretariat noted that:

> "Inconclusive empirical evidence on the role of the patent system to encourage research and development (R&D) and technology transfer makes it difficult to draw any clear-cut conclusion about the effectiveness of the patent system for economic development".[4]

Leading economists that have applied their minds to the issue have similar views.

In a study published by the National Bureau of Economic Research in the US, Harvard Professor, Josh Lerner surveys data from 72 countries over 150 years and opines that "to date, there is no robust empirical evidence that stronger patent rights indeed stimulate growth".

Nobel Laureate in Economics Professor Joseph Stiglitz recently wrote:

> "The developing country needs to ask, what IPR (or more broadly, innovation system) best advances its own standard of living. Stronger IPR may constitute a barrier to the ability of its firms catching up to the frontier, even if it enhances innovation within the country. Because developing countries are engaged in catching up, the optimal IPR regime for them will in general differ from that for a more advanced economy".[5]

These are but a sample of numerous studies by leading economists that draw similar conclusions.

A comprehensive IP Policy that examines the issue in the context of the South African reality, and optimises its regulation is necessary. Verily, no singular approach can be deemed universally appropriate for heterogeneous territories with varying and dynamic

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[4] SCP/12/3 Rev. Standing committee on the law of patents, Twelfth session, Geneva, June 23 to 27, 2008. Report on the International Patent System. Available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev.pdf

[5] Stiglitz et al, Innovation, Intellectual Property and Development, A Better Set of Approaches for the 21st Century, available at: http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf

levels of development and socio-economic circumstances. Each country must deploy its own intellectual resources to ascertain and effect the appropriate policy, and hence, the importance of this exercise.

South Africa requires a coordinated and balanced approach to IP that provides effective protection of IPR and responds to South Africa's unique innovation and development dynamics. South Africa's IP Policy must first and foremost engender the ethos of the South African Constitution. It must also reflect the country's industrial policy and broader socio-economic development objectives. Hence, the IP Policy must be informed *inter alia* by the Constitution, NDP, NIPF and the various iterations of IPAP. It should also be aligned to the country's objectives of promoting local manufacturing, competitiveness and transformation of industry in South Africa. This must be done within a broader context where the state is bound to respect and implement various international commitments; those pertaining to human rights are of fundamental importance. The policy will also strengthen South Africa's commitments to its international obligations such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access and Benefit Sharing (ABS) as far as IP relating to genetic resources and traditional knowledge associated with genetic resources.

Beyond compliance with international obligations, South Africa must play its part in shaping the global order at various forums where IP is discussed such as WIPO, the World Trade Organisation (WTO), the World Health Organisation (WHO), the Group of Twenty (G20), political formations such as the Brazil, Russia, India, China & South Africa forum (BRICS) and in African regional organisations. This requires a coordinated South African approach to IP that is informed by South Africa's development imperatives. International cooperation must aim to make IP a tool to achieve sustainable development within the country.

The South African Constitution provides a balanced approach to property rights in general by affording protection against arbitrary deprivation of property, while also taking into account the public interest. In this regard, public interest includes the nation's commitment to bring about reforms that promote equitable access to services and products involving IP, such as in the sphere of health.

It should be recalled that IP is an instrument of industrial policy that is tailored by state organs to accomplish development objectives. IP is typically characterized by limitation, such as regarding its duration. The characterization of IP as property should be understood within this context. As nations adjust their industrial policy, including in relation to social policy, so too do they adjust the rights and obligations of IP holders[6]. In line with the South African Constitution, a balanced approach will be taken in the development of the IP Policy.

[6] In the United Sates (US) for instance, judicial decisions regarding the scope of IP subject matter can and do eliminate broad categories of previously patented inventions, invalidating previously granted patents., *See, e.g.*, the decision of the US Supreme Court in *Association for Molecular Pathology v. Myriad Genetics*, 133 S Ct 2107 (2013), in which the Court determined that human genes (and their DNA sequences) as found in nature are not patentable subject matter.

The IP Policy seeks to advance the following objectives:

- Engender the ethos of the Constitution
- Align the country's IP regime to its NDP and broad industrial policy
- Develop a co-ordinated inter-Ministerial approach to IP
- Strike a balance between the owners and users of IP
- Stimulate genuine innovation
- Facilitate the development of key industries while striking a balance with the public interest
- Foster investment and technology diffusion
- Adopt a coordinated approach to IP in sub-regional, regional and international forums
- Promote public health
- Comply with international obligations, in particular those pertaining to human rights.

5. Strategy

The IP Policy is a necessary and eagerly awaited document, in view of the important issues and interests that it will affect. There is a need to urgently address key areas, such as IP and public health, in relation to which significant analysis and consultation have been conducted. Yet, urgency cannot be a reason to sacrifice the requisite depth of analysis required to address highly technical, important, and contentious issues.

As a means of enabling government to pursue urgent action in some areas, conduct further in-depth study and consultation in others, and to respond to a fast-evolving discipline, formulation of the IP Policy will be conducted using a dynamic, phased approach. The issues have been categorized into immediate, medium term, and monitoring &evaluation.

The immediate issues have been analysed and tangible reforms suggested in consultation with inter-Ministerial partners and external stakeholders.

The medium-term issues form part of the in-built agenda. These are key areas that require further in-depth study. Such study will be done with due regard to international best practices from a broad range of sources including *inter alia* industrialised nations and countries with similar developmental and socio-economic considerations, as well as multilateral organizations, such as, but not limited to, the World Health Organization (WHO), WIPO, the United Nations Conference on Trade and Development (UNCTAD), and the United Nations Development Programme (UNDP). Ultimately, however, national considerations and priorities will be paramount.

The monitoring and evaluation of existing initiatives will be undertaken with a view to alignment with the broader IP Policy, where necessary.

Based primarily on institutional capacity within government, as well as public interest considerations, two main themes are addressed substantively in the immediate term. These are the intersection between IP and public health, which covers, among others, medicines, vaccines and diagnostics, as well as South Africa’s approach to international IP cooperation.

6. IMCIP

Given the cross-cutting nature of IP, ensuring inter-departmental coordination is key. While **the dti** may lead on IP, only a collaborative effort can harness the collective resources available within government as a whole, to the benefit of the people of South Africa. For this reason, Cabinet approved the establishment of the Inter-Ministerial Committee on Intellectual Property (IMCIP).The Report of the United Nations Secretary General's High Level Panel on Access to Medicines (UNHLP) states that governments should strengthen national level policy and institutional coherence between trade and intellectual property, and promote the right to health and public health objectives by establishing national inter-ministerial bodies to coordinate laws, policies, and practices that may impact on health technology innovation and access"[7]. The establishment of the IMCIP Is therefore aligned to this recommendation.

The IMCIP is currently comprised of government officials responsible for implementing programs that either affect, or are affected, by IP. The IMCIP is constituted by the Ministries of Trade and Industry, Health, Economic Development, International Relations and Cooperation, Science and Technology, Communications, Telecommunications and Postal Services, Higher Education and Training, Agriculture Forestry and Fisheries, Arts and Culture, Energy and Environmental Affairs.

The IMCIP serves as a consultative forum and drafting team aimed at achieving a coordinated approach to the IP Policy formulation process. This function will continue into the future, with membership being adjusted accordingly as we pursue the broader in-built agenda. In addition, the IMCIP will ensure implementation of the IP Policy in government programs.

Another key function that the IMCIP will serve is to ensure a consistent and coherent government approach at multilateral IP forums. Such an approach must be consistent with the principles of the IP Policy, as well as the country's broader developmental objectives and its human rights framework. To this end, the IMCIP will work closely with government officials representing South Africa at multilateral forums to ensure harmonised negotiating positions. This is congruent with the United Nation's (UN's) 2030 Agenda for Sustainable Development, and, in particular, Sustainable Development Goal (SDG) 17 which seeks to revitalise a global partnership for sustainable development, *inter alia*, by enhancing policy coherence for sustainable development.[8]

[7] UNHLP at page 36

[8] United Nations General Assembly (2015) Transforming our world: The 2030 Agenda for Sustainable Development, A/70/L.1. Available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E

7. Phase I

Phase I will cover the following issues:

IP and public health

Sub-issues include:

- Local manufacture and export in line with industrial policy
- Patent–substantive search and examination
- Patent opposition
- Patentability criteria
- Disclosure requirements
- Parallel importation
- Exceptions
- Voluntary licensing
- Compulsory licences
- IP & competition law
- Rule of law & legal certainty

International IP cooperation

Sub-issues include:

- Multilateral arrangements
- Regional and bilateral arrangements.

7.1 IP and public health

The South African government has a long history of engaging with issues at the intersection of IP and public health. Indeed, the 1999 case, *PMA v the President of the Republic of South Africa* – when a consortium of multinational pharmaceutical companies sought to block amendments to the Medicines Act in 1997 that would expand access to medicines – was a key factor leading to global dialogue around the potentially negative impact of IPRs on public health,[9] culminating in the Doha Declaration on TRIPS and Public Health.[10]

South Africa has been a key driver of the now global recognition that the duty owed by states to safeguard public health is not inconsistent with their concomitant responsibility to honour international treaty obligations. Tellingly, paragraph 4 of the Doha Declaration on TRIPS and Public Health states as follows:

> *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."*

[9] Case 4183/98.
[10] WT/MIN(01)/DEC/2, 20 November 2001.

Having said this, the South African government has to date not made full use of the flexibilities available within international trade rules through the pursuit of appropriate national policy and legislation. This is despite a constitutional imperative to increase access to medicines as a component of the state's obligation to take reasonable measures toward the realization of the right to healthcare services. Indeed, this constitutional imperative is reflected in government policies such as the NDP and the National Drug Policy for South Africa.

Consultations with a leading medical funder in South Africa have revealed that at least 20 pharmaceutical products on the market in South Africa are commercially available at between a 9%-35% cheaper price in jurisdictions where biosimilars are available. These products are still under patent in South Africa, despite their expiry in other jurisdictions due to sub-optimal features of the South African patent system. Further examples of the failures of the current system are documented in studies from civil society, such as the 2016 paper entitled "Patent barriers to medicine access in South Africa: A case for reform".[11]

Government engagements with patient groups over the last two decades have highlighted the dire circumstances that ensue from lack of affordability. The state is obliged to work toward sustainable redress.

In addition to these domestic obligations, the state's duty to progressively realise the right to health is captured in international instruments which South Africa has ratified such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Rights of the Child (CRC), Convention on the Elimination of all Forms of Discrimination against Women and Girls (CEDAW), the Convention on the Rights of Persons with Disability (CRPD), and regional treaties such as the African Charter on Human and Peoples' Rights.

It is therefore fitting that the IP Policy should support these domestic and international instruments pertaining to the right to health.

What follows is a discussion of key areas identified by **the dti** as domains where a more equitable balance could be struck between private and public interest. The purpose of highlighting these issues is to garner the views of governmental partners on how best to achieve an appropriate balance. The aim is to ensure that South Africa protects IPRs and at the same time achieves its objectives of promoting national development imperatives, which include, among others, boosting local manufacturing, promoting innovation and ensuring equitable access to medicines. This will require the development of an appropriate framework for granting patents. A number of interventions, as outlined below, will be explored.

7.1.1 Local manufacture and export in line with industrial policy

Increasing the local production of pharmaceuticals to meet domestic needs, as well as creating export opportunities within the continent and beyond, is an overarching goal of the IP Policy, and in line with the National Development Plan (NDP), as well as the National Industrial Policy Framework (NIPF), implemented through the Industrial Policy Action Plan (IPAP). Substantive policy recommendations that follow in this document, are, each one of them, designed to boost local production and export, though it is recommended that additional policy measures be implemented in order that domestic industry is encouraged to take full advantage of the opportunities offered in the IP Policy.

The pharmaceutical industry is one of the priority sectors identified by IPAP. The contribution of this industry to South Africa's GDP has declined from 1.6% to 1.1% over the past six years. Having said this, the sector provides direct employment to approximately 10,000 people, and the downstream segment provides approximately 25,000 jobs.

The local pharmaceutical market (a two-tier pharmaceutical market, divided into the public and private market) is the largest in Sub-Saharan Africa, and worth a total estimated R40 billion annually. In spite of this, the South African pharmaceuticals sector is still relatively small by international standards, constituting a mere 0.4% and 1% of the global market by value and volume respectively. There is tremendous potential for this sector to grow and contribute value-added jobs to the South African economy. Growth of the domestic pharmaceutical industry will contribute to the sustainability of supply and allow the country to fulfil key health objectives as outlined in the National Drug Policy, in particular, to ensure the availability and accessibility of essential drugs.

It is estimated that 65% of the domestic demand for pharmaceuticals, by value, is met by imports, and that medical products are the fifth largest contributor to South Africa's trade deficit. While imports are an important source of medicines, increasing domestic capacity by promoting localization will ensure our security of supply, given, *inter alia,* that the country's unique disease burden necessitates drugs formulated using specific active pharmaceutical ingredients (APIs) of which global supply is limited. Moreover, a vibrant pharmaceutical production sector is important to developing and maintaining the science and technology community in South Africa, as the availability of employment opportunities is critical to whether a student or researcher channels his or her efforts toward a particular scientific area.

In addition, recent experience in many countries demonstrates that reliance on a limited number of medicines suppliers, including for generic products, may result in substantial price increases because of a lack of competition. One important mechanism for promoting reasonable pricing is to ensure a diversity of supply sources, including through local production.

The WHO recognises that formulating a national IP system that is conducive will go a long way in stimulating the local production of pharmaceuticals. (It also acknowledges that other factors play a part, such as whether local producers have the required technical know-how to manufacture a particular product without the need for technology transfer, the availability of a trained workforce, existing infrastructure, local market conditions and disease burden). Therefore, formulating an appropriate IP Policy and implementing the corresponding legal framework can contribute to significantly strengthening the local industry.

Policy instruments outlined below will be used to promote local manufacture as a means of securing sustainability of supply and reducing the trade deficit, while not unduly restricting access to essential goods in the process.

7.1.2 Substantive Search and Examination

The examination of patent applications within the sovereign territory of South Africa is a key component of an evolved IP ecosystem. This examination, or "substantive search and examination" is of great benefit to holders and users of IP, in that it provides a robust framework for the awarding and management of IP. Capacity constraints in South Africa, however, require a phased, strategic approach in line with national developmental goals. This approach is explicitly encouraged by WIPO and other multilateral bodies engaged in regulating global IP norms.

It is a matter of much debate that South Africa does not conduct SSE prior to the grant of patents. Section 34 of the Patents Act 57 of 1978 (Patents Act) read together with Regulations 40 and 41 of the Patent Regulations, 1978 (Patent Regulations) have the effect that the CIPC only conducts examination in relation to the formalities of the application. Hence, South Africa employs a so-called depository system.

The major benefit of the depository system is that it places the cost of substantive examination on parties that are directly interested in the patent, usually, in the event that the grant of a patent is challenged at the level of the Commissioner of Patents. This allows the state to allocate scarce technical skills toward infrastructure development and other key developmental areas. Despite this benefit, there are major drawbacks for both the producers and users of IP resulting from the depository system which have been canvassed in numerous studies. The introduction of SSE will result in greater legal certainty for patent owners and ensure that the public interest is served by ensuring that the patent system truly promotes innovation. It is crucial to work toward the adoption of SSE. The underlying policy rationale of patents is to serve as an incentive to stimulate innovation, and SSE is a key tool to ensure this objective is met. In principle, therefore, patent applications should always be subjected to substantive examination. In practice, however, countries may not yet have the human and/or financial resources to put into place and properly implement a full system of substantive examination.

In a 2014 *Policy Guide on Alternatives in Patent Search and Examination*,[12] WIPO states that one of the ways to address capacity constraints is by *"limiting substantive examination to certain strategic fields of technology for the country concerned."* It continues to state that: *"Applications relating to other fields of technology may be subject to formality examination only or to outsourcing either within or outside the country."*

Fundamentally, adopting a SSE approach which takes into consideration a nation's capacity constraints and legitimate public interest by prioritising certain sectors would not conflict with the TRIPS Agreement. Any interpretation of Article 27.1 of the TRIPS Agreement must be conducted in accordance with the Vienna Convention on the Law of the Treaties. Article 27.1 of TRIPS only refers to discrimination in respect of three hypotheses (the place of invention, the field of technology and whether products are imported or locally produced) and only in relation to the availability and 'patent rights enjoyable'. Therefore, that provision could not be the basis for a successful complaint where the examination of

[12] At page 8. The policy guide is available online at http://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf

patents (a hypothesis not covered in Article 27.1) is deployed only in certain strategic areas, since patents in other areas would still be upheld, and the scope and content of patent rights would not be affected. Moreover, it has previously been determined in the WTO dispute settlement process that Article 27.1 of the TRIPS Agreement permits differentiation among fields of technology for legitimate reasons, which would naturally include assessing patent applications for different subject matter areas in a manner appropriate to those areas[13]. In addition, phasing-in SSE in a manner that recognizes the importance of assuring adequate technical capacity among patent examiners and efficient organization of the SSE process is without doubt a legitimate basis for differentiating among patent subject matter areas, particularly for developing countries.

Having said this, concerns expressed by some stakeholders that patent applications in only one field of technology (namely pharmaceuticals) will be subject to full substantive examination are misplaced. The intention is to identify a range of strategic sectors for full SSE, including and beyond the health sphere, based on capacity within government, as well as development and public interest considerations. As government's capacity expands, the fields which are subjected to full substantive patent examination will be expanded concomitantly and with on-going consultation. Determination of the fields that will initially be subject to full substantive examination will be done in consultation with a broad range of stakeholders including, among others, the IMCIP, industry and civil society. The SSE Guidelines, to be developed in due course, pursuant to extensive consultations, will detail the precise modalities.

It is important to note that the CIPC has gone to great lengths to capacitate a very able cohort of patent examiners. The examiners are all experts in their respective technical fields, with a significant number holding PhDs. In addition, the examiners have received theoretical and practical training from South African institutions, WIPO, and some of the world's most efficient patent offices. Furthermore, CIPC has been working closely with the European Patent Office (EPO) pursuant to a memorandum of understanding between the two offices.

SSE is by no means unprecedented in Africa, with the Egyptian and Ethiopian offices carrying out SSE at the national level and the African Regional Intellectual Property Office (ARIPO) doing so in accordance with the Harare Protocol. In light of the significant training and international cooperation being brought to bear by CIPC and its partners, it stands to reason that South Africa is at the very least, no less well placed than its continental forebears to evolve from a depository system.

[13] see Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R, para. 7.94. *See* discussion of the US research exemption specifically directed to pharmaceutical patents, *infra* note 43, for example of an exemption limited to a field of technology for legitimate reasons.

7.1.3 Patent Opposition

Patent oppositions afford an opportunity for public intervention in the patent application process, and it is recommended that participation in the process be made open in order to maximally benefit the state and South African industry and society. It is recommended that, eventually, opposition proceedings are enacted in the law both prior to and after the grant of a patent. In the interim, owing to capacity constraints, it is recommended that patent law recognises a third-party submission system or "observation" to stand in for the pre-grant opposition process and for existing provisions in administrative law to be used in lieu of post-grant oppositions.

By their nature, opposition proceedings can achieve a range of policy aims in respect of substantive patent examinations, including:

- Harnessing all available information and expertise relevant to the application for or grant of a patent;
- Encouraging domestic inventors to increase technological expertise by providing an incentive to pay attention to patent applications;
- Providing some degree of certainty regarding the validity of a patent; and
- Limiting the need to engage in time-consuming and expensive patent revocation proceedings.

Most importantly, such proceedings seek to ensure that only those inventions that meet domestic statutory requirements for patentability are granted patent protection. It goes without saying that the enactment of such procedures would necessarily entail the inclusion of safeguards to curtail abuse.

In general, there are three types of opposition proceedings:

- First, a process that permits third-parties to submit information that is relevant to the consideration of an application for a patent, which is sometimes referred to as a third-party observation mechanism;
- Second, a pre-grant procedure in terms of which a third-party may actively oppose the grant of a patent at some point between the submission of the application and the making of a decision on whether a patent should be granted; and
- Third, a post-grant procedure in terms of which a third-party may appeal against or review the grant of a patent, ordinarily within a specified period as determined in domestic law.

From the perspective of the state, the choice of recognising any particular opposition proceeding has implications for human and financial resources. Thus:

- The third-party observation mechanism is the least resource-intensive, as it does not trigger any specific procedure involving the third-party once the relevant information has been submitted.
- Pre-grant opposition proceedings are potentially more resource-intensive as they require the state to put in place an administrative procedure that makes provision for the active participation of applicants and third-parties. That said, by harnessing available information and expertise relevant to the application for or grant of a patent, the state's resources may effectively be supplemented.

- Post-grant opposition procedures may be even more resource-intensive, as they require the state to put a separate structure in place to consider the relevant appeal or review. That said, such proceedings could seek to make use of review mechanisms already recognised in law, even if only on an interim basis pending the development of internal capacity and expertise.

The IP Policy aims to make provision for:

- A third-party observation mechanism in terms of which all self-identified parties are entitled to make written submissions opposing the grant of any particular patent; and
- A post-grant opposition mechanism that would require the development and promulgation of regulations, and makes provision – for as long as the contemplated system of post-grant opposition is not yet in force – for all such oppositions to proceed by way of administrative review in accordance with the provisions of the Promotion of Administrative Justice Act 3 of 2000 ("PAJA").[14]
- In addition, legislative provision should be made to allow for the introduction of pre-grant opposition proceedings once the Minister of Trade and Industry is satisfied that there is sufficient capacity within the substantive examination system to make appropriate use of such proceedings.

In light of the interactions that government has had with some stakeholders, it bears mentioning that there is nothing novel or controversial about the inclusion of opposition procedures in a modern IP system. This is evident form analysing numerous jurisdictions. For instance, the European Patent Convention makes express provision for a post-grant opposition procedure in Articles 99 to 101. In the case of the US, because of the costs, risks, and time associated with seeking to invalidate a patent, US patent law – like its EU counterpart – now makes provision for low cost post-grant review proceedings.[15] The USPTO explains:

> "*Post grant review process begins with a third party filing a petition on or prior to the date that is 9 months after the grant of the patent or issuance of a reissue patent. The patent owner may file a preliminary response to the petition. A post grant review may be instituted upon a showing that, it is more likely than not that at least one claim challenged is unpatentable. If the proceeding is instituted and not dismissed, a final determination by the Board will be issued within 1 year (extendable for good cause by 6 months*)."[16]

As indicated above, the introduction of opposition procedures will entail the inclusion of appropriate safeguards and shall be subject to a robust assessment of available capacity. Neither the rejection of patents nor delayed enjoyment of IPRs are viewed as desirable by the South African government. Rather, the promotion of a system that harnesses all available information to ensure a high level of efficiency and patent

[14] Under PAJA, a review of administrative action must ordinarily be brought within a reasonable period, and no later than 180 days after the decision in question was made (or brought to the attention of the person instituting the review).
[15] 35 U.S.C § 321
[16] https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/post-grant-review

quality is sought. The implementation of SSE and opposition procedures will be guided by, and pursue, these ends.

7.1.4 Patentability Criteria

In line with emerging international best practice, patentability criteria will be developed in order to promote genuine innovation through the patent system in South Africa. Such criteria will be implemented in the process of examination of patent applications and will aim to strike the optimal level of IP protection, promote innovation, and balance the rights of IP holders and users alike. It is recommended that patentability criteria form a part of the Patents Act, as well as any subsequent regulations and guidelines for the examination of applications.

Patent law in South Africa is based on the theory that the "limited statutory monopoly afforded to a patentee is seen as a means of encouraging inventors to put their inventions into practice, because by this means they obtain the financial rewards their inventive gifts warrant."[17] It clearly recognises that "by encouraging inventors to put their inventions to use, the benefit to the public (an essential quid pro quo of the theory) is served."[18] Central to this understanding of the purpose served by patent law is that the grant of market exclusivity, for a defined period, is required to create incentives for innovation.

Article 27.1 of the TRIPS Agreement affords WTO members much flexibility when setting patentability criteria. While it requires that patents be granted for inventions that are new, involve an inventive step, and are capable of industrial application, it does not detail what is meant by these requirements. Instead, the footnote to the provision merely states that "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious and 'useful' respectively."

Article 27.1 is not to be read in isolation, but rather together with provisions such as Article 1.1, which stipulates that WTO members are free to determine the most appropriate method of implementing the TRIPS Agreement. As well as, Article 7, which amongst others, recognises that IP protection "should contribute … to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare"; and Article 8.1, which entitles WTO members to enact patent and other IP laws that protect public health and nutrition.

Read together with these provisions, Article 27.1 gives a country such as South Africa the flexibility to interpret and implement the patentability requirements in a manner consistent with its constitutional obligations, developmental goals, and public policy priorities. Amongst other things, this would include the adoption of patentability criteria that address the country's public health and environmental concerns, as well as industrial policy objectives.

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[17] *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd) v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA) at 88H – J

[18] Ibid

In light of the inherent flexibility afforded to World Trade Organization (WTO) members in implementing patentability criteria, differing approaches can be discerned. Various countries have and continue to periodically review and adapt the application of patentability criteria to achieve appropriate levels of patent quality and advance their policy objectives. One interesting example is Australia, which, in 2012 adopted legislation which upwardly adjusted standards for patentability. A recent report of Australia's Productivity Commission reveals that the 2012 reforms did not adequately "raise the bar" and hence the same jurisdiction is currently considering further changes to the inventiveness test in its patent law.[19] The report, read together with an earlier draft of the same publication, suggest that the changes are informed by the desire to ensure that patents are awarded to inventions that are "socially valuable" and "additional".

While international best practices from a broad range of sources should be considered in developing appropriate legislative language for South Africa, particular attention should be paid to contexts that are relevant to this country. Put simply, international comparisons will only be helpful to the extent that they are able to assist in implementing patentability criteria in a manner consistent with the state's constitutional obligations, developmental goals, and public policy priorities.

As identified by the WHO, appropriate application of patentability criteria plays an important role in the growth of a domestic pharmaceutical industry. Without such criteria, patent law alone may not be descriptive enough to assist examiners in identifying and recognizing genuine innovation.

7.1.5 Disclosure Requirements

In order to gain a full and fair understanding of a patent application, applicants are required to adequately disclose the nature of the invention therein. In order to assist in the process of examination of such applications, in addition to the existing disclosure requirements in the Patents Act, it is recommended that applicants be asked to provide information regarding the status of similar and related applications filed in other international jurisdictions.

In terms of Article 29(1) of TRIPS, members shall require that an applicant for a patent disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. When an invention is not effectively disclosed within the meaning of Article 29(1) of TRIPS or when the application relates to unspecific or speculative embodiments of the invention, the grant of a patent may not only harm innovation and unduly affect competition, it will also constitute a violation of international law. Section 32(3)(b) of the Patents Act complies with this obligation and should be retained.

Article 29(2) of TRIPS provides that members may require a patent applicant to provide information concerning the applicant's corresponding foreign applications and grants. South Africa's patent legislation does not oblige applicants to furnish such information. As we move toward SSE, requiring the provision of pertinent information about corresponding patent applications and grants is recommended.

[19] Intellectual Property Arrangements Productivity Commission Final Report April 2016 (Hereinafter, Australia-Final Report), Page 216.

7.1.6 Parallel Importation

South Africa's unique developmental needs, particularly in public health, require the exploration of every legal opportunity to support the viability and expansion of the public health system, including, in the case of patented products such as medicines, the ability to purchase said medicines from any external territory that is necessary. The implementation of parallel importation will be undertaken in a controlled manner pursuant to consultations with respective stakeholders.

Parallel imports are products legitimately placed on the market in one country, and brought in to another without the consent of the patent holder. It is important to point out that by definition they are not counterfeit products. The World Trade Organization explains:[20]

> *"Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.*
>
> *For example, suppose company A has a drug patented in the Republic of Belladonna and the Kingdom of Calamine, which it sells at a lower price in Calamine. If a second company buys the drug in Calamine and imports it into Belladonna at a price that is lower than company A's price, that would be a parallel or grey import."*

Article 6 read together with footnote 6 to the TRIPS Agreement gives members the autonomy to determine their own regimes for the exhaustion of IPRs and in South Africa, parallel importation of medicines is already expressly permitted. Here it is pertinent to note that the US Supreme Court expressly adopted international exhaustion of patents, thereby authorizing parallel imports of products under U.S. patent.[21]

15C of the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act") provides:

"The Minister [of Health] may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may –

(a) *notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;*

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the

[20] See https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm

[21] *Impression Products, Inc. v. Lexmark International, Inc.*, 581 U.S. 1523 (2017).

Authority in the prescribed manner, may be imported;

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).”

Thus subject to the conditions and procedures as prescribed by the Minister, the Medicines Act authorises *“a person other than … the holder of the registration certificate of the medicine already registered [in South Africa]”*[22] to import the identical medicine, provided it *“originates from any site of manufacture of the original manufacturer as approved by the [South African Health Products Regulatory] Authority”*.[23]

Having said this, a narrow interpretation of section 45(2) of the Patents Act in its current form could potentially give rise to challenges should parallel importation be pursued. Hence, there is a need to clarify in the Patents Act that parallel importation of medicines in the manner prescribed in the Medicines Act does not constitute an infringement of the former legislation.

Should parallel importation be required in sectors other than health, the Ministries responsible for the specific sectors could sanction sector-specific parallel importation in a controlled manner through legislative provisions similar to Section 15C of the Medicines Act after conducting the necessary consultations with relevant stakeholders. This approach strikes a balance between access, on the one hand, and the interests of nascent industries on the other.

Some stakeholders have expressed concern that parallel importation has the potential to lead to counterfeits being introduced to the South African market. Yet perusing the regulatory framework established in terms of section 15C of the Medicines Act, which is set out in regulation 5 of the General Regulations made in terms of section 35 of the Medicines Act,[24] makes it plain that this is not a legitimate concern. Indeed, the South African medicines regulatory system has robust and expressly designed procedures to prevent counterfeits from entering the market through parallel importation.

Amongst other requirements, regulation 5(1) states that the medicine in question must be *“imported from a person licensed by a regulatory authority recognised by the [South African Health Products Regulatory] Authority”*,[25] and that the importer must be *“in*

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[22] Only a locally-based natural or juristic person may register a medicine in South Africa.

[23] In noting these provisions, the IP Policy identifies a potential problem with the use of section 15C(b):

“In South Africa, parallel importation of medicines is governed by the 1997 amendments to the Medicines and Related Substances Act 101 of 1965 (Medicines Act), which legislation is administered by the National Department of Health (DOH). The relevant provision applies notwithstanding any rights conferred in terms of the Patents Act. Having said this, a narrow interpretation of section 45(2) of the Patents Act in its current form could potentially give rise to challenges should parallel importation be pursued.”

With this in mind, the IP Policy continues:

“There is a need to clarify that parallel importation of medicines in the manner prescribed in the Medicines Act does not constitute an infringement of the Patents Act. Beyond health, this would allow Ministries responsible for specific sectors to sanction sector-specific parallel importation in a controlled manner pursuant to consultations with their respective stakeholders: in effect, striking a balance between access, on the one hand, and the interests of nascent industries on the other.”

[24] Government Notice 859, *Government Gazette* No. 41064, 25 August 2017

[25] Regulation 5(1)(b). The South African Health Products Regulatory Authority is South Africa’s medicine and medical device regulator.

possession of a permit issued by the Authority".[26] To obtain such a permit, the importer must satisfy a number of requirements, such as –

- providing documentary proof that the medicine in question *"is registered in its country of export by a regulatory authority recognised by the Authority"*;[27] and
- submitting *"a certified copy of a licence in respect of premises in terms of … section 19 of Customs and Excise Act, 1964 (Act 91 of 1964); and section 22 of the Pharmacy Act [53 of 1974]"*.[28]

Collectively, these (and other) provisions of regulation 5 put in place a tight framework that does not facilitate the market entry of counterfeits.

- Not only must the medicine in question be registered in the country from which it is to be exported, but the medicines regulatory authority in that country must be recognised by its counterpart in South Africa.
- In addition, the person exporting the medicine must be licensed by that country's medicines regulatory authority to do so.
- Moreover, the importer must be licensed to operate both a customs and excise warehouse, as well as a pharmacy.

Thus, the law permitting parallel imports is designed with robust safeguards to prevent the entry of counterfeit medicines into South Africa.

7.1.7 Exceptions

An environment of scientific inquiry and growth can be fostered by allowing researchers in all sectors of the economy to explore and experiment with products protected by patents. With particular patented products, such as medicines, it is furthermore essential to facilitate research, development and testing of IP products in the commercial and industrial sectors prior to the expiry of the patent term, in order that said products might reach the market as soon after the expiration date of the patented period as possible, in order to provide maximum benefit to society.

The TRIPS Agreement explicitly states that the objective of promoting and enforcing IPRs is to contribute to the promotion of technological innovation and to the transfer and dissemination of technology. This is to be done to the mutual advantage of producers and users of technological knowledge alike, and in a manner conducive to social and economic welfare, thus achieving a balance of rights and obligations. As a means of striking a balance between the rights of owners and users of IPRs, Article 30 of the TRIPS Agreement allows members to provide limited exceptions to patent rights. Indeed, exceptions placed on patent rights are an important means of achieving the appropriate set of policies that best foster R&D and technology diffusion.

[26] Regulation 5(1)(c)
[27] Regulation 5(2)(e)(ii)
[28] Regulation 5(2)(d). Section 19 of the Customs and Excise Act deals with the licensing of customs and excise warehouses; section 22 of the Pharmacy Act deals with the licensing of pharmacies.

7.1.7.1 Bolar

South Africa incorporated the early working/ "Bolar" exception in a2002 amendment to the Patents Act. The provision is an important tool to assist generic producers to research, create, and test a patented product before the end of term of the patent, thereby allowing the entry into the market as soon as possible once the patentee's exclusive rights lapse. Consultations with stakeholders have confirmed the importance of this measure in accelerating the entry of generic competition. This will likely be enhanced with the full operationalization of the South African Health Products Regulatory Agency (SAHPRA).

7.1.7.2 Research and experimental use

The patent system aims to promote scientific and technological progress by granting exclusive rights for genuinely new inventions. But the enforcement of these exclusive rights against researchers can sometimes interfere with further progress in the field of the invention. A WTO Panel observed that "a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge, and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public."[29]

While the WHO has recommended that member states should consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with TRIPS, the benefits of incorporating such exceptions extend beyond the public health sphere. Numerous jurisdictions have sought to preserve the scope of researchers to advance the state of knowledge through the use of exceptions for research and experimental activities.

Emerging economies seeking to grow their technological base such as India and Brazil employ such measures. African states and regional norm-setting institutions do the same. In Switzerland, the 2008 amendments to Swiss patent law have also made provision for this.

Provision is made in the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008 (IPR Act) that any recipient of public funds may use IP (fully owned or co-owned with a third party) which is the subject of a commercial transaction for research, development and educational purposes.

The IP Policy outlines an intention to develop a carefully crafted set of exceptions for research and experimental activities with broader application than publicly funded research. This will be done in compliance with TRIPS and in consultation with a diverse range of stakeholders.

[29] Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R, para. 7.94

7.1.8 Voluntary Licences

Voluntary efforts by IP-holders to create fair and beneficial licences in the country are encouraged to the fullest extent, building on South Africa's history of having taken advantage of many such national and international opportunities.

A voluntary licence is where a patent holder offers on his or her own accord a licence to a third party to produce, market and distribute the patented product.[30] In the South African public health context, the third-party has tended to be a domestic generic producer, or the Medicines Patent Pool (MPP), which acts as a public health intermediary to ensure generic producers voluntary licences with access-friendly terms and conditions.

Voluntary licensing has contributed to generic competition, lower prices and accessibility, particularly where antiretroviral drugs (ARVs) used in the treatment of HIV/AIDS are concerned. Industry practice on voluntary licences varies widely in geographical scope, number of licensees, freedom to manufacture active pharmaceutical ingredients (APIs), and other important terms and conditions. This is why increased transparency with respect to the terms and conditions in voluntary licences, such as terms exemplified by MPP licences, should be encouraged, thereby enabling voluntary licences that promote access and innovation, come with effective transfer of technology, and do so in full consistency with existing TRIPS allowances.

It is worth noting that when IP has been created using public funds, the IPR Act prescribes certain preferences for IP transactions. These preferences include non-exclusive licences, and further, that licences are granted to SMMEs and Broad Based Black Economic Empowerment (BBBEE) entities. The IP Policy aims to promote voluntary licences, on fair terms, as a means to effectively transfer technologies and promote access, especially in the area of health.

7.1.9 Compulsory Licences

South Africa's unique challenges, including especially vulnerable populations and urgent development concerns, will require the scope of compulsory licences to be strengthened and clarified in a manner that is fair and compliant in relation to both international obligations and national law. Following due process, guidelines will be introduced, including legal process for government use, and a renewed effort to facilitate the process of exporting IP goods, such as medicines, to the African continent.

Notwithstanding the important role of voluntary licences, they have not always provided the requisite level of access in disease areas other than HIV/AIDS and, to a lesser extent, Hepatitis C (HCV). Therefore, while voluntary arrangements have been, and will continue to be, the first port of call, South Africa requires a broader set of policy options to

[30] WHO (2007), '*Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines*'? Available at: http://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf

address instances where voluntary mechanisms prove insufficient or inadequate. In order to promote the sustainability of supply, it is important to ensure that a workable compulsory licensing system is in place to achieve affordability of essential goods, and restrain anti-competitive practices, as the need arises. One such instrument recognized by international law is compulsory licensing.

The TRIPS Agreement sets specific conditions for the use of compulsory licences. Even so, the Doha Declaration confirmed explicitly that "each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." Almost fifteen years later, the UNHLP reiterated the importance of compulsory licensing and the sovereign right of states to make use of it, including ensuring the expedient use of compulsory licences or government use provisions.

Applications for compulsory licences in South Africa are currently subject to a judicial process before the Commissioner of Patents. The grant of a compulsory licence is therefore subject to the timeframes and expenses that apply to litigation. Furthermore, this process can be exacerbated, and access further delayed, in the event that the decision of the Commissioner to grant a licence is appealed. The present Policy therefore envisages a system of compulsory licences that may be granted in accordance with the TRIPS Agreement to meet the country's development objectives, in a manner that is both more effective and efficient than the status quo currently allows.

7.1.9.1 Government use

Insofar as public non-commercial use of patented subject matter is concerned, which is sometimes referred to as "government use" (though the scope of government use may extend beyond public, non-commercial use), Article 31(b) of the TRIPS Agreement explicitly states that such use is not subject to the requirement of prior negotiations with an IP holder. Precedent for implementation of this policy tool can be found *inter alia* in the US where the law "permits the government to 'use' patents at any time without permission of the patent holder, as long as reasonable compensation is provided." As Brennan *et al* explain in their recent publication in the Yale Journal of Law & Technology:

> *"[28 U.S.C. § 1498] is rooted in the government's sovereign immunity and is regularly used today, for example, in the service of national defense. Where medicines are concerned, it has been invoked only once in recent years. During the anthrax scare in 2001, the government threatened to use § 1498 to buy a generic antibiotic and then quickly cut a deal with the manufacturer for greatly reduced prices. Although this provision has been largely forgotten, in the 1960s and early 1970s, federal agencies relied on the statute to procure generic medicines, and understood it as a critical tool to curb drug prices."*[31]

[31] H Brennan et al, "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health", (2016) 18 Yale J.L & Tech. 260 at 279-280. The empowering provision is 28 U.S.C. § 1498

In South Africa, Section 4 of the Patents Act, which entitles "a Minister of State [to] use an invention for public purposes", requires prior negotiations relating to the conditions of government use (and not the issuing or the licence per se). If agreement is not reached, an application must be made by or on behalf of such Minister, to the Commissioner of Patents, for the determination of the conditions. Not only does this impose a prior negotiation requirement (which is not required by the TRIPS Agreement), but it imposes adversarial litigation proceedings in the event a patentee does not agree to the conditions attached to the licence in question (also not required by the TRIPS agreement).Therefore, keeping in mind that TRIPS does not impose prior negotiation requirements, any proposal for government use in South Africa must also be in line with procedural fairness requirements in South African law.

7.1.9.2 Compulsory licences for export

South Africa played an important role in raising the profile of the IP and public heath debate at the WTO, and was one of the WTO members that ratified the Paragraph 6 system, thereby enabling an amendment of the TRIPS Agreement to facilitate access to medicines in countries that lack pharmaceutical manufacturing capacity. The said mechanism has, however, been the subject of various criticisms. The South African government is cognizant of the stated limitations and will engage stakeholders to find ways of ensuring that implementation is as simplified as possible, and will continue to engage constructively within the WTO structures to find ways of streamlining the Paragraph 6 mechanism.

7.1.10 IP and Competition Law

Competition law and policy have, in the recent past, been applied to cases involving IP and the public interest. Building on this recent history, a joint effort is recommended, along with the Competition Commission, to clarify the remit and scope of the intersection between competition law and IP.

The theoretical underpinning for providing IP protection to medicines is that the development of new medicines involves high costs and risks, and as such, IP protection is considered a legal method by which innovators may recoup these investments. Without adequate IP protection, the theory posits, these investments simply would not be made. Apropos this theory, currently, a global debate is underway, most prominently at the WHO, around incentive models in the context of medicines.

Competition policy in South Africa, as reflected in the preamble to the Competition Act 89 of 1998 (Competition Act) seeks to address, amongst other things, inadequate restraints against anticompetitive trade practices and unjust restrictions on full and free participation in the economy by all South Africans. It thus aims to open up the economy to greater ownership by a larger number of South Africans in order to attain an efficient, competitive, economic environment, one that balances the interests of workers, owners and consumers, and focuses on the development of all South Africans. This is accomplished by preventing cartels aimed at price-fixing, limiting output or otherwise restricting competition, by preventing firms from gaining market power in unjustified

ways, including through anticompetitive mergers, thus raising barriers to market entry by new firms. Competition policy is also concerned with preventing firms with market power from abusing their dominant positions, including by charging excessive prices to the detriment of consumers. The role of competition authorities is therefore to ensure markets function efficiently and to the benefit of both consumers and producers.

Competition regulation has a role in ensuring that patents are not used as platforms for illegitimately extending market power. In addressing the interface between IP and competition, the TRIPS Agreement gives members the scope to use competition policy as an instrument to facilitate access to medicines. Article 8 on its own, and in particular, read through the interpretive lens of the Doha Declaration on TRIPS and Public Health, recognizes the right of WTO members to take measures aimed at restraining anti-competitive practices.

Both competition law and patent law together can be used to implement competition-related TRIPS flexibilities and advance consumer welfare. Chapter 2 of the Competition Act, which covers practices such as horizontal restrictions, vertical restrictions, and abuse of dominance, and various licensing provisions in the Patents Act are pertinent in this regard.[32]

Under provisions of the Competition Act, a party can apply for an exemption from the application of parts of the provisions of the Competition Act, subject to relevant criteria. More specifically, in limited circumstances, section 10(4) of the Competition Act exempts agreements or practices which may relate to the exercise of specific IPRs such as patents, copyright and trademarks. Examples of agreements which may fall within the scope of exemption provisions under the Competition Act include delayed entry agreements, no challenge clauses, market division and allocation, tying, rebates and discounts, exclusive licensing, refusal to licence or supply, price fixing, information sharing and standard setting.

Competition authorities regulate market conduct and intervene in the exercise of IPRs where market distortions are created to the detriment of consumer welfare. The intervention of competition authorities is done on a case-by-case basis, informed by jurisprudence and principles developed over time, comparative analysis, and interaction with other regulators, to ensure that interventions lead to long-term competitive benefits. The application and enforcement of competition law ought to be done in a manner that fosters the protection and enforcement of competition on the merits, while recognizing IPRs and their potential to contribute to technological innovation, the knowledge economy, as well as the transfer and dissemination of technology to society which can advance social and economic welfare. Although South African jurisprudence in relation to the interplay between competition law and IPRs is still in its infancy, there is scope to develop fields of work and guiding principles.

[32] Sections 56-57 and 90 of the Patents Act

7.1.11 Rule of Law, Legal Certainty & Security of Investments

The rule of law in South Africa is sacrosanct. Constitutional guarantees ensure that any exercise of public power must be rational, and adopted following a rational process. Thus, reforms to South Africa's patent system, as contemplated in this Policy, can only be implemented in a lawful, transparent, fair, and open process. Furthermore, the proposed changes increase legal certainty with respect to patents and other forms of intellectual property in South Africa, in comparison to the status quo. Finally, the patent system as envisaged is designed to increase and diversify investment in the country.

The rule of law has always been, and shall always remain sacrosanct in democratic South Africa.

Section 1(c) of South Africa's Constitution states that the rule of law is one of the values upon which the country has been founded as *"one, sovereign, democratic state"*. As an incident of the rule of law, the doctrine of legality makes it clear that the exercise of public power is always subject to certain constraints, regardless of the exact nature of that power. As Justice Goldstone noted almost 20 years ago in the landmark *Fedsure* judgment:[33]

> *"It seems central to the conception of our constitutional order that the Legislature and Executive in every sphere are constrained by the principle that they may exercise no power and perform no function beyond that conferred upon them by law."*

Relying on *Fedsure*, this concept was explained more recently by Justice Navsa in *South African National Roads Agency Ltd v Cape Town City*:[34]

> *"[I]t is now accepted as elementary that the exercise of public power is subject to constitutional control and is clearly constrained by the principle of legality. A repository of power may not exercise any power or perform any function beyond that conferred upon it by law and must not misconstrue the nature and ambit of the power."*

The rule of law requires that any exercise of public power must, in addition, be rational. As Justice Chaskalson explained in the *Pharmaceutical Manufacturers Association* case:[35]

> *"It is a requirement of the rule of law that the exercise of public power by the Executive and other functionaries should not be arbitrary. Decisions must be rationally related to the purpose for which the power was given, otherwise they are in effect arbitrary and inconsistent with this requirement. It follows that in order to pass constitutional scrutiny the exercise of public power by the Executive and other*

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[33] *Fedsure Life Assurance Ltd and Others v Greater Johannesburg Transitional Metropolitan Council and Others* 1999 (1) SA 374 (CC) at para 58

[34] 2017 (1) SA 468 (SCA) at para 75, writing on behalf of a unanimous bench.

[35] *Pharmaceutical Manufacturers Association of SA and Another: In re Ex parte President of the Republic of South Africa and Others* 2000 (2) SA 674 (CC) at para 85 (footnote omitted). At the time, Justice Chaskalson was President of the Constitutional Court. Following a constitutional amendment, he later became Chief Justice.

functionaries must, at least, comply with this requirement. If it does not, it falls short of the standards demanded by our Constitution for such action."

More recently, the requirement of rationality has been extended to cover process in addition to substance. In *Democratic Alliance v President of the Republic of South Africa and Others*,[36] for example, then Acting Deputy Chief Justice Yacoob held that *"both the process by which the decision is made and the decision itself must be rational."*[37]

As already indicated, these safeguards apply to every exercise of public power. Further safeguards apply where a decision also constitutes administrative action, as defined in section 1 of PAJA.

Subject to certain exclusions, administrative action means:

"any decision taken, or any failure to take a decision, by –
(a) an organ of state, when –
(i) exercising a power in terms of the Constitution or a provincial constitution; or
(ii) exercising a public power or performing a public function in terms of any legislation; or
(b) a natural or juristic person, other than an organ of state, when exercising a public power or performing a public function in terms of an empowering provision, which adversely affects the rights of any person and which has a direct, external legal effect".

Amongst others, the additional safeguards introduced by PAJA include requirements of procedural fairness and reasonableness. While it is not necessary to consider the nature and extent of these grounds of review here, it is important to note that these additional safeguards make it easier to have administrative decisions reviewed and set aside.[38]

So what does this all mean for this Policy, as well as any amendments to the Patents Act 57 of 1978 ("the Patents Act") that may be made following its adoption and promulgation? There are at least two significant implications:

(i) First, this Policy must be lawful and substantively rational, and adopted following a procedurally rational process.[39] Given the clear need for this Policy, as well as its purpose and goals, the relatively low threshold set by the principle of legality has been met. Moreover, **the dti** has repeatedly gone to great lengths to solicit, and consider, the views of all key stakeholders, and has involved leading global institutions and thought leaders in the formulation of the policy. The consultation process was thus both rational and fair.

[36] 2013 (1) SA 248 (CC) at para 34
[37] See also *Albutt v Centre for the Study of Violence and Reconciliation, and Others* 2010 (3) SA 293 (CC) at para 51
[38] While a rational process may not necessarily be procedurally fair, the converse doesn't hold true. Similarly, while a rational decision may not necessarily be reasonable, a reasonable decision will always be rational.
[39] The adoption of this Policy is unlikely to constitute administrative action.

(ii) Second, any decision taken in terms legislative amendments (to give effect to this Policy) must satisfy the requirements of lawful administrative action, as set out in PAJA, as well as the principle of legality. The following examples are instructive:

- Given that PAJA defines administrative action to include a failure to take a decision, an applicant for a patent would be acting well within his or her rights when challenging any failure to complete the contemplated substantive examination process timeously. In such circumstances, a court may direct that the process be completed within a specified time.

- In the event a patent application is denied on the basis that the invention is not novel, does not involve an inventive step, or otherwise fails to satisfy any other patentability criterion, an applicant for a patent could take that decision on review. In so doing, the applicant could submit that irrelevant considerations were taken into account in reaching that decision, or that relevant considerations (such as the grant of the patent in comparable jurisdictions) were not taken into account.

- Should a compulsory licence be granted without the relevant statutory requirements being met, a patentee could apply for the decision to grant the licence to be reviewed and set aside on the basis that the decision-maker did not have the legal authority to grant the licence.

In each case, the High Court would have to consider the relevant facts in light of the provisions of PAJA, and our well-developed jurisprudence on administrative law. Should any party be unhappy with the decision of the High Court, leave to appeal to another court – be it the full bench of the High Court, the Supreme Court of Appeal, or the Constitutional Court – could be sought.[40]

When considered collectively, the legal mechanisms available to interested parties to ensure that the rule of law is respected make it plain that the much-needed reforms to South Africa's patent system, as contemplated in this Policy, can only be implemented in a lawful, transparent, fair, and open process. Should parties feel aggrieved by any aspect of this process, or its outcome (including the manner in which the new rules are implemented), they would have at their disposal various options to resolve their disputes.[41]

Finally, the IP Policy is designed to stimulate investment in the South African economy. As stated at the outset, this Policy is congruent with the NIPF and IPAP, both of which form central components of our economic development strategy, as encapsulated under the NDP. This Policy is designed to increase and invite investment in the country in two

[40] While there is a right to seek leave to appeal, there is no right to an appeal per se.
[41] This is guaranteed by section 34 of the Constitution, which reads as follows:
"Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum."

important ways:

(i) First, this Policy increases legal certainty in respect of IP, particularly with respect to patents. A significant consequence of the depository system, as currently employed, is that the lack of substantive patent examination results in deferring the validity and strength of patents granted in the country to courts, usually through time-consuming and expensive litigation. This Policy aims to rectify this situation by providing all patent applicants much greater assurance on the merits of their applications, right at the outset of the process of obtaining a patent in South Africa.

(ii) Second, by taking into account the socio-economic challenges facing the country, this Policy is designed to create an equitable system of IP management which will be attractive to a substantially greater number, and variety, of IP industries:

- With respect to the pharmaceutical industry, for example, this Policy is designed to invite investment from a range of manufacturing countries across the world. Not only are the countries of North America and Europe in its sights, but so too are emerging economies such as Brazil, Israel and India, across the categories of originator and generic manufacturers.

- Furthermore, and with respect to the same industry, this Policy is also designed to stimulate internal investment through the expansion and growth of existing pharmaceutical manufacturers within the country, who form an important section of the national economy.

Furthermore, all of this should be read within the context of the numerous incentives that the South African government has made available to investors such as, among others, the allowance in terms of Section 12I of the Income Tax Act; the Critical Infrastructure Programme (CIP); the Support Programme for Industrial Innovation (SPII); the Strategic Partnership Programme (SPP); and a suite of benefits associated with investing in a Special Economic Zone (SEZ) such as preferential corporate tax, building allowance, and employment tax incentive.

7.2 International IP Cooperation

In the international arena, multiple overlapping opportunities will be evaluated, including updating compliance with existing signed treaties and conventions, identifying treaty opportunities to help South African society – such as small businesses with the Madrid Protocol, and visually impaired citizens with the Marrakesh Protocol – as well as protecting traditional knowledge, and fostering continental and international cooperation in IP.

Joseph Stiglitz, the Nobel Prize winner in economics, notes that "IP has become one of the major issues of our global society. Globalization is one of the most important issues of the day, and IP is one of the most important aspects of globalization, especially as the world moves toward a knowledge economy. How we regulate and manage the production of

knowledge and the right of access to knowledge is at the centre of how well this new economy, the knowledge economy, works and of who benefits."[42]

South Africa must necessarily play a leading role in this global discourse. In doing so, we must be guided by the objectives of the IP Policy.

7.2.1 Multilateral Arrangements

South Africa is party to the following multilateral treaties on IP:

- Berne Convention for the Protection of Literary and Artistic Works (Berne Convention), since October 1928;
- Paris Convention for the Protection of Industrial Property (Paris Convention), since December 1947;
- WIPO Convention, since March 1975;
- TRIPS Agreement, since January 1995;
- Budapest Treaty (Deposit of Micro-organisms), since December 1997;
- Patent Cooperation Treaty (PCT), since March 1999.
- Protocol Amending TRIPS, since February 2016.

The following multilateral agreements are also pertinent:

- International Convention for the Protection of New Varieties of Plants (UPOV Convention), since November 1977;
- Convention on Biological Diversity (CBD), since November 1995 as well as the CBD's Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit Sharing (ABS).

7.2.1.1 World Trade Organization

South Africa has been party to the WTO and therefore the TRIPS Agreement since inception. TRIPS has become a fundamental aspect of the international IP regime and South Africa has played an important role in safeguarding, clarifying and expanding the flexibilities available to members. South Africa is an active, influential participant in the TRIPS Council, where we have consistently adopted progressive positions in pursuit of the Doha development agenda. As a developing country and having adopted the 2030 Agenda for Sustainable Development, in particular, SDG17, it is incumbent on South Africa to continue playing this role.

7.2.1.2 World Intellectual Property Organization

South Africa is a respected member of WIPO and plays an active role in the African Group along with partners in the African continent. South Africa was also one of the countries that supported and pushed for the adoption of the WIPO Development Agenda in 2007, which seeks to re-orient the thrust of WIPO's work to take into consideration the concerns and aspirations of developing countries.

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[42] Stiglitz (2008) at page 1695.

While South Africa follows all WIPO committees, it pays special attention to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC); the Standing Committee on Copyright and Related Rights (SCCR); the Standing Committee on the Law of Patents (SCP); the Committee on Development and Intellectual Property (CDIP); the Advisory Committee on Enforcement (ACE) and the Programme and Budget Committee (PBC).

Several WIPO-administered treaties to which South Africa is not party have been the subject of discussion for some years. These include:

- Locarno Agreement Establishing an International Classification for Industrial Designs (1968);
- Strasbourg Agreement Concerning the International Patent Classification (1971);
- Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks (1973);
- Nice Agreement Concerning the International Classification of Goods and Services for Marks (1979);
- Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989);
- Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled (2013).

Through the IMCIP, South Africa will explore legal instruments and international treaties that are critical to advance the objectives of the IP Policy. This will include the Madrid Protocol, which is a system whereby business owners in any signatory country can file for a trademark in their local office, which, after consultation with WIPO, can translate into global trademark protection across all 100+ signatory countries.

This will also include the Marrakesh Treaty which entered into force on 30 September 2016. The Treaty helps to implement the CRPD; thereby serving as an important instrument toward realizing the fundamental right of one of the most marginalized populations to access knowledge. This is crucial as realization of the said fundamental right contributes to poverty reduction and inclusive development.

Specifically, the goal of the Marrakesh Treaty is to end the 'book famine' – the fact that only about 7% of published books are made available globally in accessible formats, such as Braille, audio and large print, and DAISY digital formats. In the developing world, the figure is less than 1% and in South Africa, the figure is said to be 0.5%. Copyright law barriers are contributory factors that that the Marrakesh Treaty seeks to address. In doing so it supports implementation of the Sustainable Development Goals (SDGs) 1, 4, 8, 10, 11 and 16 which provide specific recognition for disability and promote the social, economic and political inclusion of all.

South Africa has ratified the Convention on the Rights of Persons with Disability (CRPD) and contributed positively to the conclusion of the Marrakesh Agreement individually and within the auspices of the African Group. It is imperative that South

Africa translates these international efforts to domestic action by ratifying and implementing the Marrakesh Agreement. This will make accessible formats available to South African visually impaired persons and contribute to the universal adoption of a historic and laudable legal instrument.

The aim will be to safeguard policy space and refrain from assuming obligations that would not be in the national interest. On the other hand, it must be understood that international treaties are, by their very nature, aimed at addressing important global challenges that cannot be solved through domestic instruments alone, due to the international nature of the problem. It is therefore possible that certain treaties can assist countries in advancing their own national interests. In this regard, the IMCIP will analyse WIPO treaties to which South Africa is not currently party in order to determine whether they present opportunities that could benefit the country, including as they relate to both vulnerable populations and economically productive sections of society.

7.2.1.3 Convention on Biological Diversity (CBD)

South Africa is considered to be the third most diverse country on the planet, boasting a significant biological diversity, housing 10% of the world's plants, 7% of the world's reptiles, birds and mammals, 15% of known coastal marine species, and one entire floral kingdom within its borders. To preserve this diversity, the Department of Environmental Affairs (DEA) promulgated and administers the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) (NEMBA or Biodiversity Act) and the Bioprospecting, Access and Benefit Sharing (BABS) Amendment Regulations of 2015.

The objectives of the Act include, among other measures, conservation of South Africa's biodiversity within the framework of the National Environmental Management Act, 1998; the protection of species and ecosystems that warrant National protection; the sustainable use of indigenous biological resources; and the fair and equitable sharing of benefits arising from bioprospecting involving indigenous biological resources.

The Act also seeks to give effect to the ratified international agreements relating to biodiversity which are binding on the Republic, such as the CBD and its two protocols, i.e., the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit Sharing as well as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The Biodiversity Act regulates bioprospecting involving indigenous biological resources and the export from the Republic of indigenous biological resources for the purpose of bioprospecting or any other kind of research. The Act also provides for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The Nagoya Protocol on ABS provides a legal framework for the effective implementation of one of the three objectives of the CBD, namely, the fair and

equitable sharing of benefits arising out of the utilization of genetic resources and traditional knowledge associated with genetic resources.[43]

Furthermore, the Nagoya Protocol on ABS represents an important tool for greater legal certainty and transparency for both providers and users of genetic resources, and for strengthening the ability of indigenous and local communities to benefit from the use of their traditional knowledge, innovations, and practices associated with genetic resources. The Nagoya Protocol on ABS came into force on 12 October 2014 and South Africa has been a contracting party since its entry into force.

South Africa is a respected party to the CBD and its protocols, and plays an active role in the African Group, and also in the Like-Minded Mega-Diverse Countries (LMMC). South Africa was one of the countries that supported and pushed for the adoption of the Nagoya Protocol on ABS in 2010, and consequently became one of the first 10 countries to deposit instruments of ratification as a sign of its commitment to the objectives of this protocol.

South Africa pays special attention to the following committees under the CBD and its protocols: the Ad-hoc Working Group on Article 8(j) and related provisions;the Subsidiary Body on Scientific, Technical and Technological Advice; the Subsidiary Body on the Implementation; the Compliance Committee on the Nagoya Protocol on ABS; the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources; and the discussion on the need and modalities of Global Multilateral Benefit Sharing Mechanism under the Nagoya Protocol on ABS.

South Africa will therefore continue to implement the CBD and its protocols and will continue to engage positively in the Conference of the Parties (COP) as well as the Conference of the Parties serving as Meeting of the Parties (COP-MOP).

7.2.1.4 World Health Organization (WHO)

Aside from the above-mentioned treaties, South Africa is party to several other international arrangements that are implicated by IP such as those at the WHO. The objective of the WHO is the attainment by all peoples of the highest possible level of health. To give effect to this mandate, WHO plays a strategic and central role in the relationship between public health, innovation, and IP.

WHO has been engaged in efforts to address identified weaknesses in the global R&D system, which is currently reliant on market-based incentives such as patents. The current R&D regime has stimulated significant innovations and will continue to do so, but it has not been able to address issues such as lack of affordability, limited research where market returns are small or uncertain (including the 'neglected diseases' that predominantly affect the world's poorest), inefficient overlap of

43 See https://www.cbd.int/abs/about/

research efforts, and overuse of medicines such as antibiotics.[44]De-linkage of the market price from R&D costs, the use of open knowledge innovation, and the use of licensing conditions to favour access, are all regarded as core principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG).[45]Antimicrobial resistance (AMR) is considered a global public health threat. Lack of new tuberculosis (TB) medicines is also a public health imperative. A number of strategies to address AMR have recently been reported, including rapid diagnostic tests, and R&D for new antibiotics and anti-TB medicines.

South Africa will continue to participate in R&D initiatives and multilateral IP forums in a coordinated fashion ensuring that the positions adopted are consistent. Formulating governmental positions under the auspices of the IMCIP will ensure a coordinated approach.

7.2.1.5 Political Formations such as BRICS

Science, technology and innovation play a central role in promoting an inclusive macroeconomic environment characterized by inclusive growth and sustainability. BRICS should harness bilateral synergies to accelerate sustainable development of the five member countries.

The central modalities of this cooperation should be sharing and exchanging information on science, technology and innovation policies and strategies; leveraging contacts and programmes aimed at enhancing collaborative innovation projects among BRICS countries; and the formulation of joint long-term problem-focused cooperation programmes. Their cooperation should be based on the principles of voluntary participation, equality, mutual benefit, reciprocity and subject to the availability of resources for collaboration by each country, keeping in mind the variable geometry of the research and development systems of the BRICS member countries.

BRICS scientific, technological and innovative cooperation will be carried out as per the provisions of the agreed "MoU on Cooperation in Science, Technology and Innovation" and the overarching vision for implementation of this MoU by BRICS Science Technology and Innovation ministerial meetings. Similarly, the IPR Cooperation Mechanism (IPRCM) has relevance in this context.

South Africa will aim to leverage BRICS cooperation to advance its objectives.

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[44] Moon "WHO: Past, Present and Future WHO's Role in The Global Health System: What Can Be Learned from Global R&D Debates"?Public Health. 2014 Feb; 128(2): 167-72. doi: 10.1016/j.puhe.2013.08.014. Epub 2014 Jan 3.

[45] WHO Secretariat, Progress Report on World Health Assembly resolution 66.22 (A/RDMCF/2) April 2016

7.2.2 Regional and Bilateral Arrangements

In terms of regional and bilateral arrangements, a distinct trend has emerged, in terms of which standards of IP protection that go beyond what is required by TRIPS are being promoted around the world. South Africa and other developing countries have worked extremely hard at the multilateral level to ensure that the flexibilities within the TRIPS Agreement were unequivocally recognized as legitimate policy tools, particularly as they pertain to public health. It is crucial that we do not erode the gains made multilaterally by assuming TRIPS "plus" IP obligations in bilateral and regional engagements.

With specific reference to geographical indications (GIs), South Africa has concluded a bilateral GI Protocol with the EU that goes beyond wines and spirits.[46] This, however, does not change South Africa's position at the WTO in respect of the limited and non-binding nature of the establishment of an international wines and spirits GI Register for information purposes only.

Keeping in mind South Africa's official position in international forums in relation to GIs, and subject to extensive consultation with a broad range of stakeholders, South Africa may consider a *sui generis* registration system for GIs in respect of all kinds of products. Such consideration, however, must be congruent with existing legislation.[47]

In recent years, African Union (AU) members have become increasingly interested in IP policy.[48]Adopting a pro-development and balanced approach to IP is crucial in a region exclusively comprised of developing and least developed countries (LDCs).[49]South Africa's engagement on IP issues at various regional forums must contribute to this approach.

Regional IP institutions exist in the form of the African Regional Intellectual Property Organization (ARIPO) and *Organisation Africaine de la Propriété Intellectuelle* (OAPI). Concurrently, the AU is working toward the establishment of a Pan African Intellectual Property Organization (PAIPO). The key challenge for the African continent as we pursue these initiatives is to improve coordination of the different initiatives to promote efficient use of resources and ensure a robust discussion of potentially divergent approaches to IP pursued by the different continental forums. ARIPO and OAPI have recognized the need to align their approaches and have begun working toward integrating their functions into the broader AU vision on IP, and it is essential that we join the dialogue with an evidence-based South African perspective.

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[46] Protocol 3 to the Economic Partnership Agreement (EPA) between the European Union and its Member States, of the one part, and the SADC EPA States, of the other part

[47] Trade Marks Act no. 194 of 1993; Agricultural Products Standards Act no. 119 of 1990 (APS); Liquor Products Act 60 of 1989 (LPA); and Merchandise Marks Act 17 of 1941 (MMA).

[48] 29 AU member states have either concluded or are in the process of formulating their IP policies.

[49] Of AU's 54 member states, 34 are classified as LDCs and 20 as developing countries.

South Africa will work with regional partners to facilitate increased coordination to ensure that regional IP arrangements contribute to a development-focused model of regional economic integration in Africa.

8. In-Built Agenda

8.1 Medium Term

The agenda envisaged in the IP Policy consists of short term (current) and medium term (immediate future) issues. In the medium term, after a consultative process, policy will be drafted covering several remaining core concerns around IP, ranging from developmental and poverty alleviation needs within South Africa, to safeguard the country's cultural, agricultural and biological heritage aimed at among others promoting the development of green technologies.

This section raises substantive thematic areas that will be addressed in the next phase of what is a dynamic and continuous policy development exercise. It also sets out recent developments in terms of international best practice in IP policy formulation, and suggests ways in which South Africa will seek to implement these learnings.

One of the key aspects of the WIPO Development Agenda was for WIPO to place a greater emphasis on demand-side developmental concerns of developing members in its provision of technical assistance. This is aptly captured in Recommendation 10 which mandates WIPO:

> *"To assist member States to develop and improve national intellectual property institutional capacity through further development of infrastructure and other facilities with a view to making national intellectual property institutions more efficient and promote fair balance between intellectual property protection and the public interest. This technical assistance should also be extended to sub-regional and regional organizations dealing with intellectual property".*

To implement this recommendation, WIPO undertook several initiatives such as the formation of the Committee on Development and Intellectual Property (CIDP) and the establishment of a project named: "Improvement of National, Sub Regional and Regional IP Institutional and User Capacity (Development Agenda Project DA_10_05)".The project resulted in the development and publication of a comprehensive methodology toolkit for the formulation of National IP Strategies (hereinafter WIPO toolkit).50

In developing an approach to Phase II, South Africa will leverage the assistance of intergovernmental organizations of which the country is a member, such as WIPO, UNDP and UNCTAD, who have significant expertise on development-centred approaches to IP. South Africa will also continue to play a meaningful role in the CIDP.

Collaboration with inter-governmental organizations and examples from other countries provide important insights. Ultimately, however, South Africa will design and continuously update its IP Policy in line with constitutional imperatives, national objectives and social concerns.

[50] Available at: http://www.wipo.int/edocs/pubdocs/en/wipo_pub_958_1.pdf

The following substantive issues constitute areas for the IMCIP to develop in collaboration with development partners. The thematic areas discussed are indicative and not exhaustive. During Phase II, the discussion will be refined and elaborated in accordance with intra-governmental and stakeholder consultations.

- **IPRs and the informal sector**: The very nature of the informal sector raises the key question: is IP of any relevance? While innovation is not necessarily the preserve of the formal economy, the type of innovation typically seen in the informal sector may not lend itself to formal IP protection. Thus before policy on this issue can be developed, it is important to understand the constraints to IP protection in the informal economy, including the tangible costs and benefits of intellectual property protection in particular in relation to generation of employment. Work in this regard is on-going, under the leadership of WIPO. In Phase II, this policy will explore the best means of using the IP system to empower this sector of the economy by using intangible assets as a veritable tool for the upliftment of economically marginalized communities. Areas to be explored include among others utility models and industrial designs.

- **Branding of South African goods and services (collective marks, certification marks and GIs)**: The Trade Marks Act already makes provision for the registration of both collective and certification marks, and for the application of the provisions of the Trade Marks Act to such marks "in so far as they can be applied". In addition, the LPA provides protection for wine and spirit GIs while the MMA protects broader agricultural GIs as an interim measure pending migration of the protection to the Agricultural Products Standards Act. In Phase II, this policy needs to consider whether the relevant legislation provides sufficient and appropriate brand protection to South African goods and services.

- **Safeguarding South African emblems and National icons**: At the international level, emblems (and other official signs and hallmarks) are protected by Article 6*ter* of the Paris Convention. In order to obtain protection, a party to the Convention must notify all other parties – via WIPO – that it desires protection in respect of identified emblems. Article 6*ter* does not require legislative action to protect a country's emblems domestically; however, legislation must be enacted to protect other countries' emblems. In Phase II, this policy will consider whether legislation is needed to protect South African emblems within the country, and if so, the form it ought to take. Unlike emblems, national icons are not ordinarily the subject of statutory protections. That said, countries have considered whether – and if so to what extent – they should be protected. For example, Australia's Advisory Council on IP (ACIP) was requested "to examine the mechanisms available for the protection of what may be regarded as national icons." Having considered the ACIP's recommendations, the federal government decided against legislating "a specifically designed system for protecting national icons". In Phase II, the issue will be considered, mindful of the constitutional concerns that arise.

- **Commercialization of IP**: The commercialization of IP is the process in terms of which IP-protected products or services are brought to market. Commercialization may be done by the rights holder alone, in partnership with another party, or by another party acting in terms of a licence or an assignment of rights. Innovators of varying scale have expressed frustration in their efforts to commercialize their

products or services. With due regard to policy interventions such as **the dti**'s National Technology Commercialization Strategy, the Department of Science & Technology's (DST's) Innovation White Paper and the Department of Telecommunications and Postal Service's (DTPS) National Integrated Information Communication Technology (ICT) Policy White Paper, Phase II of this policy will explore means of enhancing the role IP can play in bringing goods and services to market.

- **Enforcement**: Here, the state's role is primarily to provide the legal and institutional framework within which rights in IPRs may be enforced. However, to the extent that South Africa is obliged by its international commitments, it may have to play a more active role in the enforcement of certain rights. In providing the requisite legal and institutional framework, the state must take reasonable measures aimed at ensuring that constitutionally protected rights are not infringed. Phase II will analyse the state's current execution of this mandate and propose modifications where necessary.

- **IP and localisation and beneficiation:** With the understanding that IP can be both an opportunity as well as a challenge to South African industry and society, Phase II of this policy will make use of existing scholarly evidence on the current production of IP within South Africa. In doing so, and within the parameters of our international obligations, the state can create a differentiated system of empowerment and beneficiation for local industry groupings and individuals who seek to take advantage of the IP system in myriad ways, thereby contributing to the empowerment of South African persons.

- **IP awareness & capacity building:** In promoting a better understanding of the IP system, it is necessary to first thoroughly study and understand both the opportunities and challenges presented by domestic and international IP policy. To this effect, empowering diverse stakeholders – from different sections of industry, health, civil society, agriculture, arts and other related areas – to gauge the system, and to offer views on ways in which they can use or remake the IP system to best provide for people in South Africa, is essential. Phase II of the policy will seek to scale up the work and coverage of the CIPC so that the state is better able to communicate with stakeholders, particularly the most disadvantaged about the opportunities available through the state's IP architecture to promote domestic social and economic development**.**

- **IPRs and the environment / climate change / green technologies:** The development, deployment and generation of green technologies are key steps in delivering the state's obligations in respect of the environment and climate change. To this effect, adopting comprehensive TRIPS flexibilities will be essential, not only towards the transfer and diffusion of new green technologies, but also to facilitate an environment within which domestic research and generation of such technologies will be possible. Phase II of the policy will therefore consider whether any TRIPS flexibilities can and ought to be implemented in domestic IP law, and if so, will seek to promote the use of such flexibilities in delivering domestic green technology.

- **IP in agriculture; IP and biotechnology, genetic resources, and genomic sovereignty:** The question of how to best apply IP within areas related to agriculture

is an evolving discussion that has parallels in other developing countries with comparable natural heritage, for example, in Asia and Latin America. As such, those tasked with making domestic policy on IP and agriculture will necessarily have to consider international obligations, including applicable conditions within the Paris Convention and the TRIPS Agreement. With due regard to instruments such as the DST Bio-economy Strategy, Phase II of the policy will consider, amongst others, the following four issues:

- How to reconcile provisions mandated by TRIPS and the CBD, especially as it pertains to "access and benefit-sharing" clauses that seek to give control of a region's natural heritage to residents of that region;
- Supporting efforts at developing indigenous and international biotechnology, without endangering access to agricultural products and/or limiting plant variety diversity;
- Ensuring farmers' rights, as well as implementing constitutional obligations to protect genomic sovereignty within the state; and
- Considering other potential protections to boost domestic agricultural production.

8.2 Monitoring & Evaluation

Monitoring and evaluation is an essential part of the IP Policy, and will commence with key existing concerns around the deployment of IP in the country, starting with the protection of traditional knowledge and copyright concerns that relate to access to knowledge.

Several legislative initiatives have commenced or been concluded prior to the formulation of the IP Policy. Indigenous knowledge and copyright-related issues are most pertinent. It is proposed therefore that these constitute the issues that will be subject to monitoring and evaluation.

The following themes are covered in the existing initiatives:

- Copyright and related issues, including:
  - IP & creative industries, access to knowledge – libraries and archives/ disabled persons/ copyright exceptions and limitations/ digital technologies,
  - IPRs in the digital age; and
- Traditional knowledge (TK)/ indigenous knowledge.

The IP Policy aims to strengthen inter-agency cooperation through the IMCIP, monitoring and evaluation will be employed to progressively promote alignment between all the policy instruments and address any issues of concern in what is a dynamic and on-going policy development exercise.

9. Conclusion

The comprehensive IP Policy will be developed through a coordinated process through the IMCIP, informed by South Africa's development imperatives. The IMCIP will continue to be the consultative forum that will oversee the development of the IP Policy, and will promote a balanced and coordinated approach to the IP Policy formulation process. In addition, the IMCIP will determine legislative and regulatory implications with the aim of facilitating the implementation of the IP Policy. Stakeholder engagements will be enhanced to ensure that the IP Policy advances South Africa's national interests and responds to the socio-economic development dynamics of the country.