INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK

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Division: International Trade and Economic Development
Contact email: ipframework@thedti.gov.za

the dti
Department:
Trade and Industry
REPUBLIC OF SOUTH AFRICA

Intellectual Property Consultative Framework

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1. Purpose

i. The National Development Plan (NDP) calls for greater emphasis on innovation, improved productivity, more intensive pursuit of a knowledge economy and 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), industrial development and more broadly - economic growth.

ii. Government's experience to date has shown that IP is a vast, interdisciplinary field that implicates a broad range of government departments and agencies. Therefore, it is impossible for one Ministry, absent extensive inter-governmental consultation and collaboration to present a broadly representative governmental perspective. The same can be said of the numerous sectors of society that are affected by IP.

iii. The purpose of this document is not to prescribe South Africa's IP policy position, but to put forward the perspective of **the dti** in a consultative instrument to facilitate what will be continuous engagement with governmental partners and society at large. This in our view is the best way to render the formulation of South Africa's IP policy a joint project that adopts a coordinated approach.

iv. The extent of public engagement; the internal capacity of governments on IP matters; and the degree of government co-ordination are key factors in national IP policy formulation and law reform.[1] **the dti** aims to ensure that the development of South Africa's IP policy takes into account these fundamental principles. The IP Consultative Framework will serve as a tool in pursuing this approach.

v. South Africa requires a coordinated and balanced approach to IP that provides effective protection of IP rights (IPRs) and responds to South Africa's unique innovation and development dynamics. South Africa's IP Policy must engender the ethos of the Constitution and complement the country's industrial policy and broader socio-economic development objectives. Hence, the IP Policy must be informed *inter alia* by the Constitution, NDP, the National Industrial Policy Framework (NIPF) and the various iterations of the Industrial Policy Action Plan (IPAP). It should also be aligned to the country's objectives of promoting local manufacturing, competitiveness and transformation of industry in South Africa.

vi. Increasingly, IP is discussed in various international forums such as the World Intellectual Property Organization (WIPO), The World Trade Organization (WTO), the Group of Twenty (G20), the Organization for Economic Co-operation and Development (OECD) and in engagements with trade partners. This requires a coordinated South African approach to IP matters informed by South Africa's development imperatives.

vii. The South African Constitution guarantees the right to property and that no law may permit arbitrary deprivation of property.[2] In terms of the Constitution, property is not

[1] Deere (2009) 'The Politics of Intellectual Property Reform in Developing Countries' in *Property And Sustainable Development: Development Agendas In A Changing World*, Pedro Roffe, ed., Edward Elgar Press: Oxford: Oxford University Press, at p 113.
[2] Section 25 of the Constitution of the Republic of South Africa 1996.

limited to land and would by implication include IP. This interpretation is consistent with Constitutional Court jurisprudence.[3] In addition, the Constitution provides a balanced approach to property rights by also taking into account public interest. In this regard, public interest includes the nation's commitment to bring about reforms that promote equitable access. A balanced approach will be taken in the development of the IP policy in line with the Constitution.

viii. As stated in paragraph 7 of the African Group's proposal for the establishment of a Development Agenda for WIPO:

> *"IP is just one mechanism among many for bringing about development. It should be used to support and enhance the legitimate economic aspirations of all developing countries including LDCs, especially in the development of their productive forces, comprising of both human and natural resources. IP should therefore, be complementary and not detrimental to individual national efforts at development, by becoming a veritable tool for economic growth".*

ix. This document raises discussion points and proposes a way forward for South Africa to ensure a development-oriented IP policy which is cognizant of the international, regional and domestic context. As such, it proceeds from the basis that the IP policy should advance the following objectives:

a. Engender the ethos of the Constitution.
b. Align the country's IP regime to its NDP and industrial policy.
c. Develop a co-ordinated intergovernmental approach to IP.
d. Strike a balance between the creators and users of IP.
e. Stimulate innovation.
f. Facilitate the development of key industries while striking a balance with the public interest.
g. Contribute to the attraction of foreign direct investment and technology transfer.
h. Adopt a coordinated approach to IP in sub-regional, regional and international forums.
i. Promote public health.

2. <u>Strategy</u>

i. The IP policy is eagerly awaited in view of the important issues and interests that it will affect. Hence, there is a need to assure the public that government recognizes the urgency and importance of reform in key areas. On the other hand, urgency cannot be a reason to sacrifice the requisite depth of analysis in what are highly technical, important and contentious issues.

ii. As a means of striking a balance between the need for urgent action in some areas and further in depth study in others, it is suggested that the issues be categorized as immediate, medium term and monitoring and evaluation.

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[3] *Re Certification of the Constitution of the RSA,* 1996 (4) SA 744 (CC) and *Laugh it Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International* 2006(1) SA 144 (CC).

iii. The immediate issues will be analyzed and in depth, tangible reforms suggested in consultation with intergovernmental partners and external stakeholders. Finite timelines would be attached to these.

iv. The medium term issues form part of the in-built agenda. These are key areas that require further in-depth study. This should be done in accordance with international best practices such as WIPO methodologies and informed by domestic priorities. More flexible timelines would apply to these.

v. The monitoring and evaluation of existing initiatives would be undertaken with the view to undertaking impact assessment and alignment with the broader IP Policy where necessary. Flexible timelines would be applicable.

vi. It is proposed therefore that in light of the urgency, importance, high public profile as well as the strong institutional capacity and experience possessed by government on the intersection between IP and public health which covers among others medicines, vaccines and diagnostics, this area together with its multiplicity of sub-issues should be the immediate priority. It is also important to pursue areas where South Africa has international commitments such as geographical indications (GIs) to comply with and take advantage of opportunities contained in international agreements.

vii. Prioritizing these issues affords an opportunity to establish public confidence in the process being undertaken by government. This will serve us well going forward as we pursue the broader in-built agenda once the immediate issues have been addressed.

3. Inter-Ministerial Committee (IMC) on IP

i. Given the cross cutting nature of IP, ensuring inter-governmental coordination is key. While **the dti** may lead on IP, only a collaborative effort can harness the collective resources in government to the benefit of the people of South Africa

ii. The committee must be comprised of government officials responsible for implementing programs that either affect or are affected by IP.

iii. In the immediate term, the IMC would serve as a consultative forum aimed at achieving a coordinated approach to the IP policy formulation process. This function would continue as we pursue the broader in – built agenda. Thereafter, the committee would ensure implementation of the IP policy in government programs.

iv. Another key function that the committee would serve is to ensure a consistent and coherent government approach to multilateral IP forums. To achieve this end, the IMC should work closely with government officials representing South Africa at multilateral forums to ensure harmonized negotiating positions.

v. The establishment of the committee is an urgent priority.

4. Immediate issues

Overview

Immediate domestic review – sub-issues include:

- Local manufacture and export in line with industrial policy,
- Patents – substantive search and examination,
- Patent opposition,
- Patentability criteria,
- Disclosure requirements,
- Parallel importation,
- Exceptions,
- Compulsory licenses,
- IP & competition law.

International best practice – a Brazil Russia India China South Africa (BRICS) perspective.

International commitments – including GIs.

4.1 Immediate domestic review

i. The South African government has a proud history of robustly engaging with issues that concern the intersection between IP and public health. Indeed the government's stance in *PMA v the President of the Republic of South Africa* was a key factor leading to global dialogue around the potentially negative impact of IPRs on public health,[4] culminating in the Doha Declaration on TRIPS and Public Health.[5]

ii. South Africa has been a key player in the global recognition that the duty owed by States to safeguard public health is not inconsistent with their concomitant responsibility to honor 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."*

iii. Having said this, the South African government has to date not made full use of the flexibility within international law through the pursuit of appropriate 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.[6] Indeed, this Constitutional imperative is reflected in government policies such as the NDP and the National Drug Policy for South Africa.[7] It is apt that the IP Policy should support these instruments.

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[4] Case 4183/98.
[5] WT/MIN(01)/DEC/2, 20 November 2001.
[6] Section 27 of the Constitution of the Republic of South Africa, 1996.
[7] The NDP seeks *inter alia* to increase male and female life expectancy to 70 and to prevent and reduce the disease burden while the National Drug Policy aims to ensure the availability and accessibility of essential

iv. 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, innovation and ensuring equitable access to medicines. This will require development of an appropriate framework for granting patents. A number of interventions as outlined below will be explored.

4.1.1 *Local manufacture and export in line with industrial policy*

i. The Pharmaceuticals industry is one of the priority sectors identified by IPAP. The contribution of manufacturing in this industry to South Africa's GDP has declined from 1.6-1.1% over the past 6 years. Having said this, the sector provides direct employment to approximately 10,000 people and the downstream segment provides approximately 25,000 jobs.[8]

ii. 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. According to the National Association, the country spent 8.7% of its GDP on healthcare in 2014 passing the 5% recommended by WHO.

iii. Despite these figures, 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.[9] There is tremendous potential for this sector to grow and contribute further jobs to the South African economy.

iv. Growth of the domestic pharmaceutical industry will contribute to sustainability of supply and allow the country to fulfill key health objectives of the National Drug Policy, in particular, to ensure the availability and accessibility of essential drugs.[10] It is estimated that 65% of domestic demand is met by imports and that medical products are the 5th largest contributor to South Africa's trade deficit.[11] While imports are an important source of medicines, increasing domestic capacity by promoting beneficiation and localization will ensure 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.[12]

v. Project Ketlaphela is a government driven initiative aimed at establishing a fully integrated pharmaceutical company. The entity will engage in the manufacture of APIs and in the short-medium term, tablet formulation targeting the burden of diseases initially for South Africa and subsequently expanding into the Southern African Development Community (SADC). This will be key to increasing the domestic component of the supply of generic antiretrovirals (ARVs) and improving security of supply both domestically and sub-regionally. South Africa's IP regime should complement the country's industrial development ambitions as they pertain to key sectors such as pharmaceuticals.

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drugs. NDP, p. 71-72 and National Drug Policy for South Africa, p. 3. While the latter instrument predates the Constitution, it is reflective of the ethos of Section 27 of the Bill of Rights.

[8] IPAP 2013/14-2015/16, p. 97.

[9] *Ibid*.

[10] National Drug Policy for South Africa, p. 3.

[11] Abbott, Correa and Drahos (2013), Emerging Markets and the World Patent Order, at p. 270.

[12] For example, Emtricitabine is frequently used in South Africa whereas globally lamivudine is more prevalent.

4.1.2 *Substantive Search and Examination*

i. It is a matter of much debate that South Africa does not conduct substantive search and examination (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 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. 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 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 that render it crucial to work toward the adoption of SSE.

ii. The underlying policy rationale of patents is to serve as an incentive to stimulate innovation. In adopting SSE, the challenge will be to ensure that patentability criteria are observed while at the same time avoiding backlogs. This will require judicious and efficient use of limited State resources.[13] Several models are being considered, including the introduction of online patent searches and substantive examination that combines partial recognition of searches and examination reports conducted in foreign offices, with full substantive examination in certain fields pursuant to the country's development and public interest considerations. Whichever model is adopted, the rolling out of SSE must be done in a manner consistent with the non-discrimination requirements in Article 27.1 of the TRIPS Agreement.

iii. Fundamentally, adopting a SSE approach which takes into consideration a nation's capacity constraints and legitimate public health interest by prioritizing certain sectors would not conflict with the TRIPS Agreement. The interpretation of Article 27.1 of the TRIPS Agreement must be conducted in accordance with the Vienna Convention on the Law of the Treaties. The said Article 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 complaint where the examination of patents (a hypothesis not covered in Article 27.1) is introduced for a particular field of technologies since the patents would still be available and the scope and content of the patent rights would not be affected.[14]

iv. We are conscious that the implementation of SSE like any new administrative procedure may have teething problems. For this reason, CIPC is considering entering into outsourcing arrangements with certain patent offices that are known to be highly efficient. This would be a contingency against the accumulation of inordinate backlogs.

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[13] CIPC is in the process of recruiting an initial 20 Patent examiners who will undergo intensive training.

[14] In addition, a WTO Panel has already pronounced that differentiation – a legitimate practice – must be distinguished from discrimination. See Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R.

4.1.3 *Patent Opposition*

i. Affording third parties an opportunity to bring their resources to bear and present relevant information to patent examiners in an opposition process can augment the capacity of CIPC to conduct SSE.

ii. Revocation proceedings entail the prohibitive costs and risks of litigation. South Africa should consider the most efficient ways of utilizing opposition procedures in line with international best practice and pursuant to stakeholder input.

4.1.4 *Patentability Criteria*

i. Article 1 of the TRIPS Agreement read with Articles 7 and 8 give WTO members the flexibility to implement and interpret the TRIPS patentability requirements in a manner consistent with *inter alia*, their public health concerns.[15] The absence of SSE in South Africa renders government unable to use this flexibility in the grant of patents.

ii. International best practice from a broad range of sources should be considered in order to develop an appropriate approach for South Africa.

4.1.5 *Disclosure Requirements*

i. In terms of Article 29 of TRIPS, members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This policy instrument can be used to augment the capacity of CIPC to conduct SSE in a timely fashion. Moreover, it can be used to facilitate technology transfer which is of key importance if South Africa is to reap the benefits of IP and is accordingly one of the key objectives of the TRIPS Agreement.[16]

ii. The use of disclosure requirements in a manner that utilises the flexibility in the TRIPS Agreement should be considered.

4.1.6 *Parallel Importation*

i. Article 6 read together with footnote 6 to the TRIPS Agreement gives members the flexibility to determine their own regimes for the exhaustion of IPRs.

ii. In South Africa, parallel importation is governed by 1997 amendments to the Medicines and Related Substances Act 101 of 1965 (Medicines Act),[17] which legislation is administered by the Department of Health (DOH). The relevant provision applies notwithstanding any rights conferred in terms of the Patents Act.[18] This would suggest that the lack of utilization of this provision does not relate directly to IPRs. Having said this, explicitly incorporating total international exhaustion into the Patents Act would clarify matters.[19]

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[15] Novelty, involving an inventive step/ non obviousness and being capable of industrial applicability constitute the patentability criteria set out in Article 27 of TRIPS.
[16] Article 7 of the TRIPS Agreement.
[17] Section 15C of the Medicines Act.
[18] *Ibid*.
[19] 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.

iii. Communication and information sharing between **the dti** and DOH would be important in addressing any antagonism between relevant provisions, particularly as DOH works toward implementation of the recently proposed amendments to the Medicines Act.[20]

4.1.7 *Exceptions*

i. As a means of striking a balance between the rights of creators and users of IPRs, Article 30 of the TRIPS Agreement allows members to provide limited exceptions to patent rights.

ii. South Africa incorporated the early working/ "Bolar" exception in a 2002 amendment to the Patents Act.[21] This is an important tool to assist generic producers to enter the market as soon as possible once the patentee's exclusive rights cease.

iii. **the dti** should engage the DOH, generic producers and other relevant stakeholders to ascertain the effectiveness of this provision. Further exceptions could be considered if it is deemed that they could contribute to the furtherance of the objectives of the IP policy to the benefit of South Africa. The World Health Organization (WHO) for instance 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.[22]

4.1.8 *Voluntary Licenses*

A voluntary license can generally be described as an agreement between an IPR holder and another party. In the South African public health context, the other party has tended to be a generic producer. Voluntary licensing has contributed to generic competition particularly where ARVs used in the treatment of HIV/AIDS are concerned. Having said this, voluntary licenses may not always provide the requisite level of access in other disease areas. Hence, government requires a mix of policy options for instances where voluntary mechanisms prove inadequate.

4.1.9 *Compulsory Licenses*

i. This policy instrument is regarded as one of the most important tools to ensure that IPRs do not unduly restrict access to essential innovations. Its use in the context of the intersection between patents and public health has provoked entire libraries of academic work, volumes of policy discourse and some of the most intense treaty negotiations of our time.

ii. The TRIPS Agreement sets conditions for the use of compulsory licenses.[23] Provided that these are complied with, it is now a matter of course that States have the right to determine the grounds upon which they issue compulsory licenses.[24]

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[20] Medicines and Related Substances Amendment Bill 2014.
[21] Section 69A(1) of the Patents Act.
[22] Global Strategy & Plan of Action on Public Health, Innovation & Intellectual Property (GSPA-PHI), Element 2.4 (e).
[23] Article 31 of the TRIPS Agreement.
[24] Paragraph 5 of the Doha Declaration of TRIPS and Public Health.

iii. Voluntary licensing arrangements such as the Medicines Patent Pool (MPP) are crucial to the South African government's efforts to provide access to affordable medicines and we will continue to engage in them. Having said this, in order to promote sustainability of supply, it is important to ensure that a workable compulsory licensing system is in place to increase affordability and restrain anti-competitive practices where the need arises.

iv. It is important to acknowledge that IPRs cannot be seen as the sole impediment to effective utilization of compulsory licensing as a policy instrument. South Africa is yet to issue a compulsory license despite the Patents Act providing for it.[25] The current tendering system is one example of a non-IP related impediment to the use of compulsory licensing. Measures to facilitate contracts that allow tender recipients to maximize economies of scale should be considered. In this regard, the WHO has recommended that ccountries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.[26]

v. In addition, it is important to ensure that the compulsory licensing procedure provided in our legislation does not result in unnecessary delays or undue obstacles. Various means of streamlining the compulsory licensing processes should be considered in accordance with international best practice and in consultation with stakeholders. The following observations pertaining to the Patents Act warrant consideration:

4.1.9.1 Judicial process

i. All applications for compulsory licenses in South Africa are subject to a judicial process before the Commissioner of Patents.[27] The grant of a compulsory license is therefore subject to the timeframes and expenses that apply to litigation. This can be exacerbated and access further delayed in the event that the decision of the Commissioner to grant a license is appealed.[28]

ii. The TRIPS Agreement does not require the grant of compulsory licenses to be made subject to a judicial process. A more streamlined and accessible administrative process should be considered.

4.1.9.2 Adequate remuneration

i. One of the TRIPS conditions for the grant of compulsory licenses is that the IPR holder must be paid an adequate remuneration.[29] The Patents Act does not contain guidelines on how to ascertain what would constitute adequate remuneration other than providing a non-exhaustive list of factors that may be relevant.[30] The provision of guidelines can assist parties to achieve timely conclusion of the voluntary license negotiations that are mandatory in certain

[25] Section 56 of the Patents Act.
[26] Global Strategy & Plan of Action on Public Health, Innovation & Intellectual Property (GSPA-PHI), para 24.
[27] Sections 8 and 19 of the Patents Act.
[28] Section 76 of the Patents Act.
[29] Article 31(h).
[30] Section 56(7) of the Patents Act.

cases.[31] This would prevent undue delay in the voluntary license negotiation process. One precedent is the Canada Access to Medicines Regime (CAMR).

ii. Guidelines for determining adequate remuneration should be explored as a means to streamline the compulsory licensing process.

4.1.9.3 Government use

i. The TRIPS Agreement explicitly states that public non-commercial use of patented subject matter is not subject to the requirement of negotiating with an IPR holder.[32] The South African Patents Act goes beyond what is provided for in TRIPS by requiring Ministers of State to enter into such negotiations before an application to the Commissioner of Patents can be made.[33]

ii. The inclusion of this requirement may cause unwarranted delays and should be reviewed.

4.1.9.4 Compulsory licenses for export

In terms of compulsory licensing for export, South Africa played an important role in raising the profile of the IP and public heath debate at the WTO and has joined the growing body of WTO members that have adopted the Paragraph 6 mechanism through ratification.[34] The paragraph 6 mechanism has however been the subject of various criticisms.[35] The South African government is cognizant of the stated limitations and will engage stakeholders to find ways of ensuring that our implementation is as simplified as possible. In addition, we will engage constructively within the WTO structures to find ways of streamlining the Paragraph 6 mechanism.

4.1.9.5 Compulsory licenses to remedy anti-competitive practices

i. Article 31(k) allows members to use compulsory licensing as a remedy to anti-competitive practices. Such licenses can be issued without complying with a number of TRIPS conditions, most notably: prior negotiation with patent holders, being limited to the purpose for which it was authorized, and the requirement of being predominantly for domestic use.

ii. As mentioned above, the licensing provisions in the Patents Act do not take full advantage of TRIPS flexibilities. The judicial process provided by the Patents Act is in general, more cumbersome than required in TRIPS. This is particularly true of Article 31(k).

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[31] Article 31(b) of the TRIPS Agreement requires the grant of compulsory licenses to be preceded by voluntary license negotiations except in circumstances of national emergency or public health crises, public non-commercial use, and to remedy anti-competitive practices.
[32] *Ibid*.
[33] Section 4 of the Patents Act.
[34] Both Houses of Parliament ratified the Paragraph 6 mechanism in terms of section 231 of the Constitution in November 2015, and the instrument of acceptance has been deposited at the WTO Secretariat.
[35] Joint NGO Statement on TRIPS and Public Health: WTO Deal on Medicines – A Gift Bound in Red Tape. September 10, 2003.

iii. A more streamlined administrative process for the issuance of compulsory licenses should be considered. In addition, it is suggested that guidance be introduced as to which practices would be considered anti-competitive. This could be done by way of an amendment to the Patents Act,[36] alternatively guidelines could be issued. Either route must be pursued in consultation with relevant government institutions and stakeholders.

4.1.10 *IP and Competition*

i. In theory, the development of new medicines involves high costs and risks, and for this reason IP protection is considered an instrument that allows innovators to recoup investment. Without adequate IP protection, the theory posits, these investments simply would not be made. Currently, a global debate, led by the WHO, is underway around incentive models in the context of medicines.[37]

ii. Competition regulation has a role in ensuring that patents are not used as platforms for illegitimately extending the market power. Markets for many pharmaceuticals are inelastic. Furthermore, there are aspects of the South African markets for pharmaceuticals that increase the opportunities for anti-competitive practices such as their small and concentrated nature. Finally, it should be noted that from a public interest perspective, purchasers of essential medicines are not ordinary consumers in that their demand is inelastic. There is great public interest in ensuring access to medicines. The South African competition law was developed as a transformational device in the early days of post-apartheid South Africa. It should therefore be able to accommodate these special features of medicine consumers.

iii. In addressing the interface between IP and competition, the TRIPS Agreement gives members 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 empowers WTO members to take measures aimed at restraining anti-competitive practices.

iv. Article 31(k) of TRIPS concerns compulsory licenses to remedy anti-competitive practices while Article 40 empowers members to prohibit anti-competitive licensing practices and provides a large degree of discretion in defining the prohibited practices.

v. The Competition Act 89 of 1998 (Competition Act) and the Patents Act can be used to action the competition related TRIPS flexibilities and advance consumer welfare. Chapter 2 of the Competition Act and various licensing provisions in the Patents Act are most pertinent.[38]

vi. Chapter 2 of the Competition Act covers practices such as horizontal restrictions, vertical restrictions and abuse of dominance.

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[36] A 2013 UNDP Study suggests that expressly stating that the section 56 grounds constitute anti-competitive practices. While this suggestion has merit, further consultative deliberation would be required given the complex legal and economic issues at play.
[37] Section 4.3(vii) below.
[38] Sections 56-57 and 90 of the Patents Act.

vii. The famous *Hazel Tau* case, which was spearheaded by civil society, is a pertinent matter.[39] Although it was resolved before the Tribunal could consider the substantive merits; the case was a watershed as it clarified that competition law is an important instrument to achieve an appropriate balance between the interests of the creators and users of IP.

viii. Few parties have sought to use the provisions of the Competition Act to alleviate adverse impacts of exclusive IPRs on consumer welfare and by extension, public health. One factor is the relative smallness of the South African pharmaceutical market. This serves as a disincentive to generic companies incurring the cost of litigation. Another factor is the highly technical nature of the requisite analysis. Interested parties are likely to face such difficulties going forward given the complexity of the legal and economic considerations involved as well as the relative dearth of jurisprudential succor.

ix. Guidelines on IP and competition could be developed in line with international best practice and in consultation with relevant government departments and stakeholders.

4.2 International best practice – a BRICS perspective

i. In developing the appropriate approach to the issues raised above (4.1) due regard will be given to international best practice, including the experience of countries in similar levels of development such as BRICS. It will be important to study how these countries have utilized the TRIPS flexibilities to respond to their specific needs.

ii. The South African government through **the dti** in particular participates in the recently established BRICS IPR Cooperation Mechanism (IPRCM). The said institution will serve as an important information sharing forum that can augment the collective information and human capital resources of policy makers and implementation agencies in BRICS countries as well as deepen mutual cooperation.

iii. Having said this, South Africa's unique dynamics must inform the approach to the country's IP policy.

4.3 International commitments

i. South Africa is party to the following multilateral treaties in 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.

[39] *Hazel Tau et al. v. GlaxoSmithKline, Boehringer Ingelheim, et al. & AIDS Healthcare Foundation et al v. GlaxoSmithKline, Boehringer Ingelheim, et al.* Case Numbers: 2002sep226 & 2002jan357.

ii. With the exception of TRIPS these treaties are all administered by WIPO while the WTO administered TRIPS incorporates the substantive provisions of the Paris and Berne Conventions.

iii. South Africa has been party to the TRIPS Agreement since inception and is an active, influential participant in the TRIPS Council. TRIPS has become a fundamental aspect of the international IP regime and South Africa has played an important role in safeguarding the flexibilities available to members. Having adopted the 2030 Agenda for Sustainable Development, and in particular, Sustainable Development Goal 3, it is incumbent on South Africa to continue playing this role.

iv. WIPO members have concluded numerous treaties to which South Africa is not party. It is important for countries to safeguard their policy space and not assume obligations that would not be in the national interest. On the other hand, treaties are aimed at dealing with important global challenges that cannot be addressed through domestic instruments due to their extra-territorial nature. In addition, certain treaties can assist countries to advance their offensive interests thereby increasing gross national income (GNI).

v. In light of the principals established in the IP policy, South Africa should analyze WIPO treaties to which we are not party in order to determine whether they present opportunities that could benefit the country which we are currently not utilizing.

vi. Aside from the above mentioned IP treaties, South Africa is party to several other international arrangements that are implicated by IP such as WHO. That organization's Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health".[40] To give effect to this mandate, WHO plays a strategic and central role in the relationship between public health, innovation and IP.[41]

vii. WHO has been engaged in efforts to address identified weaknesses in the global R&D system which is 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 research efforts, and overuse of medicines such as antibiotics.[42] De-linkage of the market price from R&D costs, use of open knowledge innovation, and use of licensing conditions to favour access, are regarded as core principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG).[43] 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, these include rapid diagnostic tests and R&D for new antibiotics and anti TB medicines.

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[40] Article 1 of the Constitution of the World Health Organization.

[41] Global Strategy & Plan of Action on Public Health, Innovation & Intellectual Property (GSPA-PHI), para 15.

[42] 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.

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

viii. South Africa must 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 an IMC on IP will ensure a coordinated approach.

ix. In terms of regional and bilateral arrangements, a trend has emerged in terms of which standards of IP protection that go beyond what is required by TRIPS are being promoted.[44] South Africa and other developing countries worked extremely hard at 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.

x. An IMC on IP should examine any treaties under negotiation which contain IP provisions to ensure that they comply with the principles of the IP Policy.

4.3.1 *Geographical Indications (GIs)*

i. South African does not have a statute dealing specifically with GIs, and also does not have a *sui generis* registration system for GIs in respect of all kinds of products, however this position may change given certain legislative initiatives underway. The following statutes contain references to GIs or deal with indications of the geographical origin of goods or services:

ii. Trade Marks Act no. 194 of 1993; Agricultural Products Standards Act no. 119 of 1990; Liquor Products Act 60 of 1989; and Merchandise Marks Act 17 of 1941.

iii. The Department of Agriculture Forestry and Fisheries (DAFF) has published draft regulations on GIs which were open for public comment. Continued inter-Ministerial engagement is encouraged.

iv. At multilateral level there are several developments that have a bearing on the protection of GIs. TRIPS provides for the protection of GIs through Articles 22, 23 and 24. A debate which has stalled at this point is how Members will agree to set up a multilateral system for notification and registration of wines and spirits GIs.

v. South Africa has agreed to conclude a bilateral GI Protocol with the EU that goes beyond wines and spirits. 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.

vi. WIPO's Lisbon System for the International Registration of Appellations of Origin offers a means of obtaining protection for an appellation of origin in the contracting parties to the Lisbon Agreement. The Lisbon System should be considered by an IMC on IP.

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[44] Roffe 'Intellectual Property Bilateral Agreements and Sustainable Development: The Challenge of Implementation' (2007) Jan Intellectual Property Bilateral Agreements and Sustainable Development- Series: 1 at http://www.ciel.org/wp-content/uploads/2015/03/FTA_ImplementationPub_Jan07.pdf. Valdés and Tavengwa, WTO, Economic Research and Statistics Division, Staff working Paper ERSD-2012-21, 31 October 2012, p. 40. WTO, WIPO, WHO, "Promoting Access to Medical Technologies and Innovation – Intersections Between Public Health, Intellectual Property and Trade", 2012, p. 84.

5. In-Built Agenda

5.1 Medium term

i. This section proposes substantive issues that should be addressed once policy formulation on the immediate issues has been secured. It also sets out recent developments in terms of international best practice in IP policy formulation and suggests ways in which South Africa can implement these.

ii. 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".*

iii. 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)".

iv. Development Agenda Project DA_10_05 was conducted from 2009-2012 and served as a pilot project with the aim of developing tools for IP policy formulation. Algeria (which joined the project in 2011) Dominican Republic, Mongolia, Moldova, Tanzania and Mali participated.

v. The project resulted in the successful development and publication of a comprehensive methodology toolkit for the formulation of National IP Strategies.

vi. Development Agenda Project DA_10_05 and the resulting toolkit were subject to an external review which found the methodology to be sufficiently consultative and responsive to the needs of member States. The review also found that the toolkit is both replicable and adaptable. This outcome is supported by the toolkit's use by at least 10 other countries. Indeed, of the 29 countries that have recently concluded or are in the process of formulating their IP policies, many are doing so with the assistance of WIPO.

vii. WIPO technical assistance has in the past been criticized for placing too much emphasis on compliance with international IP standards, which were generally seen as favoring multinational corporations from developed countries without due regard for a demand-driven approach that takes into consideration the economic nuances and development objectives of countries receiving the technical assistance. Having said this, since the adoption of the 45 recommendations of the development agenda, WIPO has taken significant steps to remedy such concerns and its input into the formulation of national IP policies in developing countries is evidence of this evolution. A strong case in point is the Rwanda IP Policy of 2009 which is largely regarded as a progressive and sound instrument.

viii. It is suggested that South Africa follows an approach that is in line with WIPO-established methodologies but tailored to South Africa's specific dynamics. Here, a broadly constituted IMC on IP could work together with the WIPO Secretariat. As a member of WIPO, the vast resources of this institution are available to South Africa and government would be remiss in not bringing them to bear.

ix. The following substantive issues are proposed as working areas for the IMC to develop in collaboration with WIPO and other expert institutions:

- IPRs in agriculture;
- IPRs and biotechnology/ genetic resources;
- IPRs and the environment/ climate change/ green technologies;
- IPRs and the informal sector;
- Branding of South African goods and services (collective marks, certification marks and GIs);
- Safeguarding South African emblems and national icons;
- IPRs and the government;
- Commercialization of IPRs;
- IPRs and localization and beneficiation;
- Policymaking in the international arena;
- IPR awareness & capacity building; and
- Enforcement.

x. This list is indicative and not exhaustive. It will be refined in accordance with intergovernmental and stakeholder consultations.

5.2 Monitoring and evaluation

i. Several legislative initiatives have commenced or been concluded prior to the formulation of the National 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. This allows the finalization of existing initiatives – to which significant resources have already been committed - while ensuring an opportunity for alignment with the broader IP Policy.

ii. The following themes are covered in the existing initiatives:

a. 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

b. Traditional knowledge (TK)/ indigenous knowledge.