INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK
(Department of Trade & Industry, South Africa)

SUBMISSION BY ACADEMICS, EXPERTS, SCHOLARS AND PRO-ACCESS ADVOCATES

30 September 2016

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This document is submitted by a group of experts, scholars and access advocates working in the various areas of intellectual property law and policy, based at or affiliated with South African universities and other institutions, including non-governmental organisations. It does not purport to speak for all experts, scholars and advocates, nor does it reflect the positions of our respective institutions. The contributors and supporters are committed to a pro-public policy perspective on intellectual property matters, and many have regularly contributed to the discourse on improving access to public health, knowledge and other technologies.

Introduction

The Department of Trade and Industry's (the **dti**) Intellectual Property Consultative Framework (the Framework) identifies the intersection between intellectual property (IP) and public health as a priority area that requires immediate domestic review. Thus, the focus of this submission is on this priority area.

In crafting an IP policy framework affecting, among other things, medical technologies, policy and lawmakers must address the tension that exists between the protection of IP rights and human rights – the rights of the public to have access to medicines and other health technologies necessary for their well-being. If there had been any doubt about how to resolve this tension, then the issue must surely have been settled with the release of the Report of the UN Secretary-General's High Level Panel on Access to Medicines on 14 September 2016 (the Panel Report). The Panel Report states:

"Human rights are fundamental, universal entitlements that people inherently acquire by virtue of their birth. In comparison, intellectual property rights are 'one policy tool among many for encouraging innovation and technological research and development.' Intellectual property rights are temporary, revocable, transferable privileges granted by states and can be suspended or revoked under certain conditions laid out in the TRIPS Agreement when it is in the interest of the state or society."

Yet the primacy of the right to health is not obvious from a reading of the Department of Trade and Industry's IP Consultative Framework (the Framework). The Framework recognises the 'intersection between IP and public health' and proposes to prioritise public health measures in implementing the policy. While we welcome this statement of intent and several of the **dti's** positive proposals, it is disconcerting that the Framework fails to reference the human rights paradigm in its approach to policy-making. This is a key theme which recurs in our submission.

The Framework extols IP rights protection as a key driver of innovation, but the evidence for that proposition is less convincing. In addition to the considerable scholarly literature suggesting a thin connection between IP and innovation, the experience of India, and the proposed policies of Brazil, suggest that stringent patent standards better serve the pursuit of innovation than weaker standards, such as they exist in the US and EU. While the latter standards have led to a crisis in pharmaceutical innovation and in pricing of new medicines, rendering essential medicines inaccessible, more stringent patent standards have the potential to rescue pharmaceutical innovation, as well as increase access to medicines. In this regard the Panel Report states in Recommendation 2.6.1(a)

"WTO Members must make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred."

In addressing the requirement that countries adopt stringent patent standards, the Panel Report deliberated on the existing model for financing research and development (R&D) into health technologies namely, rewarding innovative activity with patent monopolies, and concluded that it has produced impediments to access and innovation:

"it also has created important tensions because of high prices, and fuelled policy incoherencies through the application of exclusivity-driven business models. Because this system is predicated on the ability to generate profit, governments and the biomedical industry have often failed to deliver

new health technologies for diseases that do not, and cannot, promise high returns—those that mostly afflict the poor regardless of where they may live."

In general, well-designed IP policies and legislation can be a useful but imperfect policy instrument in promoting innovation, technology transfer, R&D, industrial development and - more broadly - economic growth, but only if anti-competitive risks are avoided and if IP standards, exceptions and exemptions allow for mutual benefits of IP rights holders and users in the public interest.

The correct framing of a well-tailored IP policy does not relate to innovation and development objectives only, as is acknowledged in the Framework. The Constitution and South Africa's accession to various international and regional human rights conventions impose human rights obligations on the state, including the right to access health care and the corresponding right of access to essential medicines. In addition, South Africa's population is entitled, under relevant human rights norms, to share in the benefits of scientific advancement. These human rights principles ought to have been directly addressed in the Framework.

It would be appropriate that the development of IP policy begins with reference to the Bill of Rights, the most relevant and urgent of which are the right to access health care, including medicines, the right to education, including the right to educational materials, and the right to just administrative action.

This framing must inform the objectives of the policy which, we suggest, should seek to: engender the ethos of the Constitution, most particularly human rights obligations pertaining to health; strike a balance between the creators and the users of IP and the public at large; stimulate innovation, including incremental innovation and adaption appropriate to national needs; promote public health and the right to health and of access to medicines more broadly; and promote access to knowledge.

Our approach is thus to engage with the Framework in a sympathetic and constructive yet critical manner. In the following submission we make comments on the provisions of the Framework and, where appropriate, offer recommendations.

In sum, we recommend that:

- The Government should set strict guidelines and time frames for the finalisation of policy in this area and the drafting of relevant implementing legislation.
- In the meantime, the **dti** should initiate regulatory and sub-regulatory reforms, including pharmaceutical patent examination guidelines, that would clarify and tighten patentability criteria for pharmaceuticals, and allow for immediate patent examination in this area of vital national interest.
- The implementation of a substantive search and examination system should be prioritised, and the relevant legislation promulgated to facilitate substantive examination beyond mere formalities. Clarifying this issue would, for example, allow the **dti** to take forward examination of pharmaceutical and other health technology-related patents as a matter of urgency, especially as it has already hired and is training a cadre of patent examiners.

- Legislation should be written incorporating all public health flexibilities, including:
    - The immediate amendment/repeal of Patent Regulations 40 and 41, in order to facilitate substantive examination of patent applications and to fully comply with the intent of section 34 of the Patents Act;

- The introduction of examination guidelines linked to strict patentability standards with proscription on minor modifications to or variations of known substances, new use and new formulation patents to prevent ever-greening;
- Full disclosure in patent applications including their foreign status and, when available, the International Non-proprietary name (INN) of pharmaceutical-related patents;
- Pre- and post-grant opposition procedures, accessible to all interested parties (widely defined);
- Parallel importation under an explicit international exhaustion regime;
- Expansive compulsory licensing and government use provisions, including simplified procedures, expanded (including public health) grounds for grant, and remuneration guidelines for low percentage royalties;
- Compulsory licences to remedy anti-competitive conduct;
- Extensive early working exceptions, as well as other exceptions for educational, scientific and research purposes; and
- Exclusion of diagnostic, therapeutic and surgical methods; plants, animals and genetic material.

We submit that these measures are all compliant with the TRIPS Agreement and, further, have long been proposed by various international expert panels, including the most recent UN Secretary-General's High Level Panel.

The process of reforming South Africa's IP laws has been an inordinately long one. Given the critical public health and public interest issues at stake, we cannot over-emphasise the need to move with utmost urgency to finalise the policy.

The remainder of this document provides detailed comments for many of the sections contained in the IP Consultative Framework document. We will be available to elaborate on our submission if required.

Intellectual Property Consultative Framework – Section-by-Section Review

1. Purpose

	Our comments
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.	IP is one policy instrument, among others, to promote economic and social development. Evidence concerning the impacts of IP on innovation and more particularly on technology transfer, R&D investments, and industrial development and economic growth is contested, especially in low and middle income countries. Well-designed IP policies and legislation can be a useful but still imperfect policy instrument in promoting innovation, technology transfer, research and development (R&D), industrial development and more broadly - economic growth, but only if anti-competitive risks are avoided and if IP standards, exceptions and exemptions allow for mutual benefits of users in the public interest. Innovation is a worthy goal, and a key aspect of the economic growth strategies of other comparable developing countries. In this regard, in addition to the considerable scholarly literature suggesting a thin connection between IP and innovation, it should be noted that the experience of India, and the proposed policies of Brazil, suggest that higher, more stringent patent standards (such as they exist in India, and are proposed in Brazil) better serve the pursuit of innovation over lower, weaker standards, such as they exist in the US and EU. While the latter standards have led to a crisis in pharmaceutical innovation, rendering essential medicines inaccessible, higher, more rigorous patent standards have the potential to rescue pharmaceutical innovation, as well as increase access to medicines. The current formulation places an over-emphasis on economic considerations (such as competitive advantages) over social imperatives (access to knowledge-based goods). It is also disconcerting that the concept of human rights is not mentioned once in the Framework, which is indicative of the conceptual divide in seeking a balance between IP protection and human rights.
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-	Inter-governmental and stakeholder consultation is important, but South Africa's IP policies concerning pharmaceutical patents have been under review for a long time and reforms are urgently needed. The Government of South Africa should set strict guidelines and timelines for the finalisation of policy in this area and the drafting of relevant implementing legislation. In the meantime, the **dti** should initiate regulatory and sub-regulatory reforms, including

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.	pharmaceutical patent examination guidelines, that would clarify and tighten patentability criteria for pharmaceuticals, and allow for immediate patent examination in this area of vital national interest.
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.	This framing that suggests a protracted additional period of consultation with government partners and other stakeholders that could unreasonably delay needed reforms. In just the past five years, it is likely that South Africa has granted over 10,000 pharmaceutical patents, many of which would have been rejected even in the US and Europe.
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. **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.	There has already been an intense multi-year period of public engagement on the pharmaceutical patent-related aspect of South Africa's emergent IP policy. Although this Consultative Framework is perhaps a useful step in finalising the consultative process, **dti** and other relevant ministries must promptly finalise actual policy and then proceed expeditiously to accelerate the resulting legal reforms required. In doing so, the policy needs to focus not only on subjective issues such as capacity constraints, but also an elaboration of the external context such as the developmental challenges facing South Africa that need to drive IP reform, namely the problems of the lack of access to medicines, educational materials and other public goods.
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	The correct framing for a well-tailored IP policy does not relate to innovation and development objectives only, as is acknowledged elsewhere in this framework. The South African Constitution and South Africa's accession to various international and regional human rights conventions imposes human rights obligations on the country, including the right to access health care and the corresponding right of access to essential medicines. In addition, South Africa's population is entitled, under relevant human rights norms, to share in the benefits of scientific advancement. These human rights principles should be directly addressed in this provision.

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.	In addition, the United Nations Secretary-General's High Level Panel on Access to Medicines has just addressed in detail the policy incoherence between IP and trade, human rights, and public health. Furthermore, South Africa is party to various understandings with regional partners, including SADC and the African Union which, among other matters, directly address obligations to act on public health crises, including HIV, tuberculosis, and malaria, and the need to utilise all legally permissible public health flexibilities under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health. Regard must also be had to the Report of the Special Rapporteur in the field of cultural rights: Patent policy and the right to science and culture (Office of the High Commissioner for Human Rights (OHCHR). Human Rights Council 70th Session, 4 August 2015, UN General Assembly, New York). Other major fora of discussion around IPRs are bilateral and regional trade negotiations, where developing and least developed countries are often coerced into agreeing to TRIPS-plus standards of IPR protection. In this context, the statements under **International commitments (4.3** ix) of the Framework are welcomed.
vii. The South African Constitution guarantees the right to property and that no law may permit arbitrary deprivation of property. In terms of the Constitution, property is not limited to land and would by implication include IP. This interpretation is consistent with Constitutional Court	It is appropriate that the development of IP policy begins with reference to the relevant rights in the Bill of Rights, the most relevant and urgent of which are the right to access health care, including medicines, the right to education, including the right to educational materials, and the right to just administrative action. The assertion that the South African Constitution unambiguously guarantees property rights with respect to intellectual property is inaccurate. Section 25, which deals with property, states that no-one may be arbitrarily deprived

jurisprudence. 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.	of property or deprived of property without compensation. This is not equivalent to a constitutional right to property such as is found in the constitutions of some countries. In Certification of the Constitution of the Republic of South Africa, 1996 (CCT 23/96) [1996] ZACC 26 http://www.saflii.org/za/cases/ZACC/1996/26.html, the Constitutional Court considered the claim that IP rights are a "universally accepted fundamental right, freedom and civil liberty", and concluded that such an interpretation "cannot be characterised as a trend which is universally accepted". While it is accurate to say that the Constitution requires a balanced approach to what is properly considered property by taking into account public interest, the Constitution's human rights obligations actually require the Government of South Africa to prioritise the right to health as a primary objective. Despite UN organs such as the Committee on Economic Social & Cultural Rights reporting that Art 15 of the International Covenant on Economic Social and Cultural Rights (ICESCR) should always be interpreted to prioritise human rights over property rights, South African courts have routinely deferred to IPRs in granting interdicts against alleged infringers of patents before a full hearing on revocation proceedings - see *Pfizer v Cipla* (2005) ZACCP; *Aventis v Cipla* (2012) ZASCA. Thus it is imperative that the IP policy provide clarity on the government's position on this issue.
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,*	The assertion that IPR protection enables economic growth is overstated and not supported by evidence. Research indicates that increased IP protection appears to have little effect in the developing country context, and that domestic innovation accelerates in countries with higher levels of economic development, educational attainment and economic freedom. Further, strengthening patent rights results in an increase in filings from foreign applicants, with no effect on filings by local inventors. Finally, the correlation between strong IP protection and foreign direct investment is yet to be established.

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.	This is an important and constructive section, but the right to health and of access to essential medicines needs greater specification and prioritisation, especially since this consultative document is focused on pharmaceutical patents. The stated objectives should be revised as follows: a. Engender the ethos of the Constitution, most particularly human rights obligations pertaining to health. d. Strike a balance between the creators and the users of IP and the public at large. e. Stimulate innovation, including incremental and adaption appropriate to national needs. i. Promote public health and the right to health and of access to medicines more broadly. and j. promote access to knowledge.

2. Strategy

	Our comments
i. The IP policy is eagerly awaited in view of the important issues	We offer no comment at this time.

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.	The phased approach is supported. In addition, there is a need to define more clearly key processes such as: • The immediate amendment/repeal of Patent Regulations 40 and 41, in order to facilitate substantive examination of patent applications; The introduction of examination guidelines linked to strict patentability standards. Such changes would ensure full compliance with section 34 of the Patent Act (the Act) which provides: 'The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it'. The Act requires more than mere compliance with formalities, and envisages substantive examination of the application according to the patentability criteria listed in section 25(1).
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.	It is positive to suggest finite timelines for immediate issues, such as pharmaceutical IP policy, but it should require "finite and expeditious" timelines. In addition to the processes mentioned under our comments to (ii) above, steps must be taken to operationalise opposition procedures, permitted exceptions and other flexibilities.
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.	It is contestable that WIPO methodologies represent international best practices. As South Africa and other developing countries frequently assert, WIPO's development policies are still underdeveloped and under-implemented, and are not properly reflected in its technical assistance and guidance documents. This is particularly true with respect to pharmaceuticals and access concerns.

More flexible timelines would apply to these.	In addition, SA should look to other developing country exemplars in designing its regulatory system, such as Argentina, India and Brazil.
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.	Impact assessments, whether of current or future initiatives, must include human rights impact assessments as recommended in the Report of the Special Rapporteur in the field of cultural rights: Patent policy and the right to science and culture, referred to above.
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.	It is completely appropriate for **dti** to identify this area as one of immediate priority and urgency. The prioritisation of public health and the constitutional ethos/human rights approach to interpreting IP issues in the Framework is welcomed. This principle should inform policy, implementation and ultimately judicial decisions.
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.	We offer no comment at this time.

3. Inter-Ministerial Committee (IMC) on IP

	Our comments
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.	'Inter-Ministerial' appears to be used interchangeably with 'inter-governmental' (the latter is a misnomer here, as it usually means between governments). This committee must be promptly convened and it must finalise the relevant IP policy framework concerning pharmaceuticals and other health technologies as a matter of urgency. It is crucial that this committee comprises high-level decision-makers for the sake of expedition and progress.
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.	This consultative forum should be able to readily feed its inputs in cabinet decision-making processes, for tabling of draft legislation and regulations.
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.	Consistency is best achieved if the IMC is a high-level organ which promotes coherence in policy and negotiations at international and regional levels.

4. Immediate issues

4.1 Immediate domestic review

	Our comments
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, culminating in the Doha Declaration on TRIPS and Public Health.	This is an important point. South Africa needs to continue and, in fact, escalate its role in this regard.
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."*	This is an important point. South Africa needs to continue and, in fact, escalate its role in this regard.
iii. Having said this, the South African government has to date not made full use of the flexibility within international law through	It is extremely important that the Government acknowledges that it has not made full use of allowable flexibilities in international law and that it has a Constitutional imperative to increase, indeed to prioritise,

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. Indeed, this Constitutional imperative is reflected in government policies such as the NDP and the National Drug Policy for South Africa. It is apt that the IP Policy should support these instruments.	access to medicines. In this regard it is also important to note that the UN Secretary General's High Level Panel Final Report on Access to Medicines states that countries must adopt stringent standards of patentability and that they should adopt all other TRIPS-compliant flexibilities. The policy should require, among others: • Strict patenting standards with proscription on new use and new formulation patents to prevent ever-greening; • Full disclosure in patent applications; • Pre- and post-grant opposition procedures; • Parallel importation under an explicit international exhaustion regime; • Expansive compulsory licensing and government use provisions (simplified procedures, expanded grounds for grant, remuneration guidelines with low percentage royalties); • Compulsory licences for anti-competitive conduct; • Extensive early working exceptions, as well as other exceptions for educational, scientific and research purposes; and • Exclusion of diagnostic, therapeutic and surgical methods; plants, animals and genetic material.
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	It is appropriate that the **dti** should seek the input of other relevant governmental partners, but it is vital that the **dti** should do more to assert its opinion on some of the key policy issues identified, most especially patentability criteria. The process risks being further delayed if the **dti**, the department with the most expertise, does not articulate clear positions on certain contested issues and indicate its preferred policy approach as a guide to other government partners' deliberations.

number of interventions as outlined below will be explored.	

4.1.1 Local manufacture and export in line with industrial policy

	Our comments
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.	Industrial policy is an important development goal, to be closely aligned with other equally, if not more, important goals such as the realisation of the universal right to health through enabling access to cheaper generic medicines. South Africa currently sources approximately 38% of its supply from originator companies (MNCs), and approximately 58% from generic firms (predominantly local). In India, the BRICS country where access to medicines is arguably at the highest level, supply from MNCs accounts for approximately 20% of the market, as against approximately 80% which is supplied by generic companies, predominantly local industry. Given South Africa's relatively developed generic drug industry, this would suggest that any sound industrial policy strategy on IP should seek to grow the base of the South African domestic generic drug industry, thus boosting local production, skills, and employment.
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.	It is also a two-tier market in terms of production, as stated above, with 58% of the market held by MNCs and about 38% of the market held by South African generic drug companies.
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. There is tremendous potential for this sector to grow and contribute	South Africa can certainly learn from the experience of India, the developing country which has most successfully created and maintained a pharmaceutical industry, which it did so by instituting high standards for patentability, pre- and post-grant opposition and other pro-access provisions.

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. 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. 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.	Growing a locally owned, domestic pharmaceutical industry will not only contribute to the health and wellbeing of South Africans by increasing access to medicines, but also to promoting the local economy, in terms of employment and contribution to the GDP, and development of skills.
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	South African remains a relatively small market, and the route to developing the industry lies in becoming a supplier to other developing countries, particularly in Southern Africa. The future of the domestic industry does not require patent monopolies, but the freedom to make medicines that can be exported to least developed countries and developing countries, as affirmed in the Doha Declaration. Many access to medicines efforts rely on South Africa's capacity to supply the southern African region and beyond. The licences negotiated with MNCs after the TAC Competition Commission cases in the period 2002-2004 have applied to all SADC countries. While Project Ketlaphela is an important initiative, in addition the enabling framework to access cheaper generic medicines from multiple producers should immediately be put in place.

as they pertain to key sectors such as pharmaceuticals.	

4.1.2 Substantive Search and Examination

	Our comments
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.	The depository system is a relic of the colonial era, during which the colonies were expected to grant blanket approval of all IPRs granted in the metropolis. This system disserved the colonies in the past, and continues to do so as developing and least developed countries struggle to catch up technologically. India serves as a good example of the benefits of fully-capacitated patent-examining office. It is extremely important that this section prioritises the implementation of a substantive search and examination system. It is perhaps important to clarify, however, that the relevant legislation actually allows for substantive examination beyond mere formalities. Clarifying this issue would, for example, allow the **dti** to take forward examination of pharmaceutical and other medical technology related patents as a matter of urgency, especially as it has already hired and is training a relevant cadre. The major beneficiaries of the depository system are patent applicants and their lawyers, not the public which has to contend with unwarranted (pharmaceutical) patents, long undeserved patent terms, and delayed access to cheaper drugs. Regulations 40 and 41 unduly circumscribed the examination function permitted by section 34, and must be repealed.
ii. The underlying policy rationale of patents is to serve as an incentive to stimulate innovation. In adopting SSE, the challenge will	It is appropriate to recognise that South Africa is free to prioritise SSE in the pharmaceutical sector and also that its capacity in this area is weak at present. However, South Africa should exercise great caution in relying, even

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. 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 nondiscrimination requirements in Article 27.1 of the TRIPS Agreement.	partially, on examinations conducted by foreign offices, especially foreign offices that have adopted lower standards of patentability (novelty, inventive step, industrial applicability, and disclosure) than South Africa. For example, many countries, including the United States, countries in Europe, and Japan apply relatively lax standards that allow patenting of minor modifications/variations of known substances, new pharmaceutical formulations/dosages, and new uses of medicines. One of the main objectives of South African patent law reform and SSE should be to weed out undeserving secondary patents in order to prevent the evergreening of periods of patent exclusivity. On the other hand, India provides a model provision on eliminating evergreening. The adoption of SSE will also bring the patent system into alignment with the constitutional imperative in section 33 of fair administrative action, and will additionally need to expand the present narrow standing rules, in line with section 38 of the Constitution, to include a wide definition of an 'interested party' to any proceedings.
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	This clear articulation of TRIPS compliance is correct and it is highly appropriate to emphasise this, given unwarranted claims of discrimination raised by industry stakeholders in the past.

field of technologies since the patents would still be available and the scope and content of the patent rights would not be affected.	
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.	Guarding against backlogs is important but it is even more important that only worthy patents be granted under stringent patentability criteria. Some foreign offices that are "highly efficient" enforce laxer standards than those that South Africa should adopt. Therefore, South Africa should consider reference to or partial reliance on examinations in countries with more stringent standards such as India and Argentina, and should consider having examiners trained by these patent offices, as well as by NGOs offering technical expertise.

4.1.3 Patent Opposition

	Our comments
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.	This is a key principle of a transparent examination system. The policy should spell out the pre- and post-grant opposition procedures, with wide *locus standi* rules, and adequate opportunity for the public to make inputs.
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.	The **dti** should articulate a more complete set of recommendations than this. Opposition procedures should be easy to use, be expeditious, should allow for both the introduction of evidence and argument, and adverse rulings against oppositions should be appealable.

4.1.4 Patentability Criteria

	Our comments
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. The absence of SSE in South Africa renders government unable to use this flexibility in the grant of patents.	Previous iterations of IP policy contained strong language regarding the proscription on evergreening. The strict criteria for patentability should be spelt out in detail, as suggested below.
ii. International best practice from a broad range of sources should be considered in order to develop an appropriate approach for South Africa.	This is an inadequate articulation of the policy issues at stake in terms of patentability criteria and the **dti's** preferences concerning policy choices that should be made. This issue is one of the most important policy reforms under consideration, second only to SSE. South Africa has an opportunity to adopt stringent patentability criteria and disclosure requirements and must do so to fulfil its constitutional and human rights obligations. Lax standards allow patenting of minor modifications/ variations of known substances, of new pharmaceutical formulations/dosages, and of new uses of medicines. Lax standards can also create barriers to incremental innovations and needed adaptations to medical technologies. Lax standards allow additional patent barriers and longer periods of exclusivity that will interfere with South Africa's goal of developing its local production capacity. Therefore, a primary objective of South African patent law reform and SSE should be to adopt stringent standards of patentability (novelty, inventive step, and industrial applicability) to weed out undeserving secondary patents in order to prevent the evergreening of periods of patent exclusivity. In particular, South Africa should consider disallowance of so-called Markush claims and repeated use of divisional patents.

4.1.5 Disclosure Requirements

	Our comments
i. In terms of Article 29 of TRIPS, members shall require that an	In addition to requiring full disclosure of all known methods of working the patent, including identification of

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.	the best known method, and illustrating or exemplifying the invention, South Africa could and should require disclosure of patent status in other countries. Further, South Africa could and should require disclosure of the international nonproprietary name (INN) of pharmaceutical-related patents either at the time of application or thereafter when an INN has been assigned.
ii. The use of disclosure requirements in a manner that utilises the flexibility in the TRIPS Agreement should be considered.	The need to use all legally-permissible and available flexibilities has long been accepted. The policy need not go back to 'should be considered' (here and under following provisions). The UN High Level Panel states unequivocally that all TRIPS flexibilities *must* be adopted.

4.1.6 Parallel Importation

	Our comments
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.	This is indeed the case.
ii. In South Africa, parallel importation is governed by 1997 amendments to the Medicines and Related Substances Act 101 of 1965 (Medicines Act), which legislation is administered by the Department of Health (DOH). The relevant provision applies notwithstanding any rights conferred in terms of the Patents Act. This would suggest that the lack of utilization of this provision does not relate directly to IPRs. Having said this, explicitly incorporating total international	This Framework should acknowledge that the current regulatory regime concerning parallel importation is not working and propose reforms for an effective scheme. For example, aspects of regulation 7 of General Regulations, 2003 impose unrealistic strictures for this flexibility to be effective. **Th dti** should negotiate with the Department of Health to repeal these, while retaining section 15C(b) of the Medicines Act as a provision enabling parallel importation. Parallel importation is also governed by section 45(2) of the Patents Act (as amended in 2002), and is administered by the **dti**. This provision should be clarified to permit parallel importation under the international exhaustion regime, and

exhaustion into the Patents Act would clarify matters.	include both branded and generic products (as is the case in Kenya). There should be proper alignment of these parallel importation provisions emanating from the respective departments.
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.	We offer no comment at this time.

4.1.7 Exceptions

	Our comments
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.	We offer no comment at this time.
ii. South Africa incorporated the early working/ "Bolar" exception in a 2002 amendment to the Patents Act. This is an important tool to assist generic producers to enter the market as soon as possible once the patentee's exclusive rights cease.	This is in fact the case.
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	Article 30 of the TRIPS Agreement permits a research exception allowing both commercial and non-commercial research on and with the patent product or process. In addition, it allows an educational use exception, a prior use exception, and an individual formulation use exception. 'Other relevant stakeholders' should be explicitly defined to include civil society organisations representing people who

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.	need access to medicines, patient groups and persons representing the public interest.

4.1.8 Voluntary Licenses

	Our comments
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.	The government can also regulate voluntary licenses with respect to competition objectives and concerns and should do so. In particular, anti-competitive practices in voluntary licensing must be avoided by, for example, requiring open licences to multiple suppliers, so that voluntary licences do not become the vehicle for protecting exclusive markets for licence holders, thus defeating the aim of increasing access to medicines. Additionally, the Framework should address the issue of market segmentation, from the perspective of enhancing access.

4.1.9 Compulsory Licenses

	Our comments
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	We offer no comment at this time.

discourse and some of the most intense treaty negotiations of our time.	
ii. The TRIPS Agreement sets conditions for the use of compulsory licenses. 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.	This section should state that South Africa's current law does not make full use of this flexibility to describe permissible grounds for compulsory and government use licenses. In addition, consistent with the commitment to foreground public health, the various grounds for compulsory licences and government use based on public health and access considerations should be spelt out. Such grounds include: inadequate supply to the market; desire to make fixed-dose combinations of medicines owned by different right holders; desire to allow commercialisation of a follow-on, dependent patent that is technologically important; desire to have multiple sources of supply to prevent shortfalls of stock; and desire to promote local production where there have been failures in technology transfer from right holders.
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.	This is very important to emphasise, especially because MPP licenses are only in place with respect to HIV and HCV at present.
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. The current tendering system is one example of a non-IP related impediment to	It is not accurate to say that IPRs act as impediments to effective utilisation of compulsory licensing. Instead, the legal Framework for compulsory licence applications is needlessly restrictive and needs to be reformed. Indian legislation provides for mandatory export licenses addressing requests from countries with insufficient manufacturing capacity.

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 countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.	
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:	In addition to streamlining, attention needs to be paid to expanding the grounds for compulsory licenses along the lines suggested under (ii) above.

4.1.9.1 Judicial process

	Our comments
i. All applications for compulsory licenses in South Africa are subject to a judicial process before the Commissioner of Patents. 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.	This is a key impediment to the use of compulsory licences.

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.	The law should be amended to set up an administrative tribunal of appropriately qualified persons with sound understanding of both our constitutional ethos and the technical aspects, to consider compulsory licence applications.

4.1.9.2 Adequate remuneration

	Our comments
i. One of the TRIPS conditions for the grant of compulsory licenses is that the IPR holder must be paid an adequate remuneration. 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. The provision of guidelines can assist parties to achieve timely conclusion of the voluntary license negotiations that are mandatory in certain cases. This would prevent undue delay in the voluntary license negotiation process. One precedent is the Canada Access to Medicines Regime (CAMR).	This is a necessary and important measure to be adopted.
ii. Guidelines for determining adequate remuneration should be explored as a means to streamline the compulsory licensing process.	Clear guidelines need to be developed and, in particular, should require low percentage royalty payments in order not to nullify the price-correcting effects of the licence.

4.1.9.3 Government use

	Our comments
i. The TRIPS Agreement explicitly states that public non-commercial use of patented subject matter is	This is an unnecessary barrier which must be corrected.

not subject to the requirement of negotiating with an IPR holder. 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.	
ii. The inclusion of this requirement may cause unwarranted delays and should be reviewed.	**dti** should recommend that the requirement of negotiations be dropped.

4.1.9.4 Compulsory licenses for export

	Our comments
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. The paragraph 6 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 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.	If the Paragraph 6 option is to be effective, it should be revised in order to enable a swift and expedient export of pharmaceutical products produced under compulsory licence. (as indicated in the Panel Report).

4.1.9.5 Compulsory licenses to remedy anti-competitive practices

	Our comments
i. Article 31(k) allows members to use compulsory licensing as a remedy to anticompetitive 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.	It is not correct that compliance with the requirement that 'the authorisation be limited to the purpose for which it was granted' is dispensed with under this Article. Rather, the Article requires that a competent authority may refuse termination of such authorisation if the conditions which gave rise to the authorisation in the first place are likely to recur.
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).	We offer no comment at this time.
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, alternatively guidelines could be issued. Either route must be pursued in consultation with relevant government institutions and stakeholders.	This is a very constructive idea that should be taken forward. Note, however, that Article 44 of the TRIPS Agreement provides for judicially sanctioned compulsory licenses and South Africa should consider adoption of the same.

4.1.10 IP and Competition

	Our comments
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.	South African has a progressive competition framework, which has been utilised with some success, to enhance access to medicines (as alluded to in the 2 TAC cases mentioned above). In seeking a balance between IP and competition interests, the Competition Commission of South Africa suggests that potential conflicts between intellectual property rights and competition mandates should be resolved according to the extent to which the "long-term pro-competitive benefits" of a practice outweigh its "short-term 'anti-competitive' effects." While the general principle has been articulated, there are no specific guidelines on the application of the Competition Act, 2008 to IP, nor is there an express provision for the issuance of a compulsory licence in the case of a finding of anti-competitive conduct by IP rights holders. For further analysis and recommendations on this topic, see http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.
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	See comments under 4.1.10 i. above.

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.	The provisions of the Competition Act, also administered by the **dti**, should be aligned with the proposed new Patents Act, and further refined to eliminate monopolistic practices such as those sometimes conducted by the innovator pharmaceutical industry.
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.	See comments under 4.1.10 i. above.
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.	See comments under 4.1.10 i. above.
vi. Chapter 2 of the Competition Act covers practices such as horizontal restrictions, vertical restrictions and abuse of dominance.	See comments under 4.1.10 i. above.
vii. The famous *Hazel Tau* case, which was spearheaded by civil society, is a pertinent matter.	See comments under 4.1.10 i. above.

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.	See comments under 4.1.10 i. above.
ix. Guidelines on IP and competition could be developed in line with international best practice and in consultation with relevant government departments and stakeholders.	See comments under 4.1.10 i. above.

4.2 International best practice – a BRICS perspective

	Our comments
i. In developing the appropriate approach to the issues raised	Within the BRICS context, Brazil and India are the most obvious comparators. Together, India, South Africa and

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.	Brazil form the closest comparison group within BRICS – all three countries are diverse, multi-ethnic, relatively new democracies, with strong emerging economies and similar income disparities and public health concerns. India instituted a comprehensive patent reform in 2005 (The Patents Amendment Act 2005), the main features of which are (a) high standards of patentability to boost both innovation in the pharmaceutical industry as well as facilitate access to medicines, (b) due process for pre- and post-grant opposition, (c) a wide variety of measures, including compulsory licensing provisions, to ensure compliance by the pharmaceutical industry with constitutional rights and societal concerns. Though unusual and bold at the outset, Indian patent law has since been validated through numerous judicial outcomes, and is now universally regarded as compatible with the WTO's trade rules, especially TRIPs. In 2013, a bill was introduced in Brazil's House of Representatives, namely, PL 5.402/2013, which sought extensive reform to the country's Industrial Property Law. The bill followed an exhaustive and detailed report from the Center for Strategic Studies & Debates, released in the Brazilian Chamber of Deputies, entitled "Brazil's Patent Reform: Innovation Towards National Competitiveness," and subsequently received support from the Subcommittee for the Industrial Health Complex (CIS) of the House of Representatives. A 2014 report. PL 5.402/2013 and supplemental legislative proposals concerned with expanding access to medicines, together present a strong, evidence-based rationale for utilising TRIPs flexibilities, and closely follow the model of the Indian law as amended in 2005.
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	The BRICS IPRCM should be used to negotiate training and technological transfer agreements with those partners who have adopted measures to improve access to medicines as elaborated above.

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.	We offer no comment at this time.

4.3 International commitments

	Our comments
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.	We offer no comment at this time.
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.	We offer no comment at this time.

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.	South Africa's advocacy role should now be translated into concrete actions, such as domesticating all available flexibilities.
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).	We offer no comment at this time.
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.	We offer no comment at this time.

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". To give effect to this mandate, WHO plays a strategic and central role in the relationship between public health, innovation and IP.	South Africa should give effect to its commitments, especially under the ICESCR, in the formulation of its IP policy.
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. 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). 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	We offer no comment at this time.

include rapid diagnostic tests and R&D for new antibiotics and anti TB medicines.	
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.	South Africa's policy should commit to these laudable principles proposed to reduce the costs of medicines, and should further contribute to the sustainability of alternative models of financing R&D for medicines.
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. 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.	This is an important principle to articulate in the Framework and be guided by in trade negotiations.
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)

	Our comments
i. South African does not have a statute dealing specifically with	We offer no comment at this time.

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.	We offer no comment at this time.
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.	We offer no comment at this time.
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.	We offer no comment at this time.
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.	We offer no comment at this time.

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.	We offer no comment at this time.

5. In-Built Agenda

5.1 Medium term

	Our comments
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.	We offer no comment at this time.
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*	We offer no comment at this time.

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)".	We offer no comment at this time.
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.	We offer no comment at this time.
v. The project resulted in the successful development and publication of a comprehensive methodology toolkit for the formulation of National IP Strategies.	We offer no comment at this time.
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	The toolkit should be critically assessed in light of South Africa's needs with regard to access to essential technologies, and its constitutional obligations. In particular, the toolkit developed for South Africa should include human rights impact assessments of proposed intellectual property policy as recommended by the Report of the Special Rapporteur in the field of cultural rights: Patent policy and the right to science and culture.

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.	The technical assistance provided by WIPO is still often perceived to be pro-IPRs rather than expressly pro-access in the public interest. An example is the Rwandan IP law (which it helped craft). While this law excludes the patenting of pharmaceuticals until 2033 by virtue of its position as an LDC, the WIPO assistance has also promoted unduly strict enforcement and other measures.
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	SA should adopt best practices from countries which have a more pro-access orientation, such as India, Brazil, Argentina; develop its IP policy based on its unique circumstances, and proactively contribute to the development of a reform agenda at WIPO and other fora. There are also other sources of specialised technical assistance on pro-development and balanced IP policies that might be consulted, including South Centre, SARPAM, UNDP, and other independent IP experts.

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.	This list should prioritise the imperatives of a developmental state, and should swiftly progress from the immediate tasks to address these compelling and important medium term issues. It should also prioritise Human Rights in the context of Intellectual Property as there is inadequate understanding of the importance of human rights for intellectual property policy.
x. This list is indicative and not exhaustive. It will be refined in accordance with intergovernmental and stakeholder consultations.	We offer no comment at this time.

5.2 Monitoring and evaluation

	Our comments
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.	Many concerns have been raised about the existing legislative initiatives particularly around copyright and traditional knowledge. The approach proposed for this Framework should be used to review such initiatives, and the **dti** should seek alignment with the broader policy objectives articulated here, such as the primacy of human rights over IP protection.
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)	