



Companies and Intellectual
Property Commission
a member of **the dti** group

SUBMISSION BY SOUTH AFRICA

Exceptions and Limitations

OCTOBER 9, 2017

ISO 9001: 2008 Certified

The dtiCampus (Block F - Entfufukweni), 77 Meintjies Street, Sunnyside, Pretoria | P O Box 429, Pretoria, 0001

Tel: +27 12 394 5378 | Fax: +27 12 394 6378 | Call Centre: 086 100 2472

Email: ALudin@cipc.co.za | Website: www.cipc.co.za

Table of Contents

1. Introduction and background	3
2. Exceptions and Limitations to Patent Rights in South Africa.....	4
2.1. Compulsory licences:.....	5
2.2. Compulsory licence on a dependent patent	6
2.3. Compulsory licence in the case of abuse.....	7
2.4. Patentable subject matter (Article 27).....	11
2.5. Exhaustion of rights (parallel importation) (Article 6).....	13
2.6. Regulatory (bolar) exception (Article 30).....	15
3. Competition law (Article 40)	16
4. South Africa's IP Policy.....	16
4.1. Establishment of SSE.....	18
4.2. Licences to access medicines.....	19
4.3. Parallel importation	19
4.4. Bolar Exceptions.....	19
5. Conclusion	20

1. Introduction and background

South Africa welcomes the opportunity to make submissions on the topic of exceptions and limitations. South Africa recognizes the role that Intellectual Property (IP) and Intellectual Property Rights (IPRs) play in the global context of advancing innovation, the dissemination of knowledge, the creation of thriving industries and its contribution to the global economy.

We have also noted with concern the detrimental effect that the creation of monopolies can have on public health and advancing inequalities between developed and developing economies. It highlights therefore the importance of striking a balance between preserving the rights of creators of IP on the one hand, by providing incentives for their creativity and ingenuity, but equally important, providing access to knowledge, technology transfer and safe affordable medicines for the benefit of all.

South African law reflects the principles embodied in the Trade Related Aspects of Intellectual Property Laws (TRIPS), and the Doha Declaration in particular with regards to the measures that member states may implement in local legislation to protect the public against the abuse of patent rights and monopolies. However the practical implementation of the provisions that give effect to the TRIPS, have not been effective in protecting the public against patent monopolies and ensuring that the public has access to essential medicines, at an affordable price.

In the light of the above, South Africa has consulted extensively with a number of intergovernmental organisations, government departments and organs of state, Non-Government Organisations (NGOs), activist groups and industry bodies and all relevant stakeholder in formulating a national IP policy that is cognisant of the rights of IP creators and simultaneously, is sensible to the needs of the public, in particular from a public health perspective.

These efforts culminated in the Draft National Policy on Intellectual Property (DNPIP)¹ which was published in 2013. The DNPIP was government's directive to address issues of fragmentation in the IP laws, and to provide a clear policy on the administration of IP laws in South Africa.

¹ <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf>

The DNPIP was followed by and replaced by the Intellectual Property Consultative Framework (IPCF)² which was published in July 2016. The IPCF sets out a phased approach to formulating a national IP Policy for South Africa and established an Inter-Ministerial Committee on Intellectual Property (IMCIP), which comprises Ministers from various government departments that administer IP laws in South Africa, for inter-governmental co-ordination of the policy formulation processes and implementation.

The IPCF sets out a two phased approach to formulating a national IP Policy. Phase 1 will deal with two aspects, namely Patents and Public Health and International IP Cooperations. Phase 2 will deal with developmental goals and needs of South Africa which are medium term goals.

On 7 August 2017, the South African Government, through the Department of Trade and Industry (Dti), published the Draft IP Policy of South Africa (Phase 1) (DIPP)³ which is open for public consultation for a period of sixty days. Further details of the DIPP are contained in this report.

What follows below is a summary on the current IP law regime in South Africa and its shortcomings in addressing the substantive on public health and other developmental goals of South Africa and how the policy formulation process and the structural reforms of the IP laws aims to address these shortcomings.

2. Exceptions and Limitations to Patent Rights in South Africa

As a member of WTO and signatory to the TRIPS agreement South Africa has committed to having certain patent laws in the country and to protect the rights of IP creators by providing incentives for their creations and ingenuity. Over the years however, the TRIPS agreement has been criticised regarding the increasing levels of patent protection and the effect that the increased levels of protection have on the prices of medicines. TRIPS was amended to include provisions to remedy the negative effects of patent protection or patent abuse, in practice however, it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to access to medicine⁴.

The Doha Declaration, which was instituted to remedy these shortcoming in TRIPS sought to provide governments with the sovereign right to take measures to protect public health, thus giving primacy to public health over private intellectual property⁵.

² <http://www.thedti.gov.za/news2016/IPConsultativeFramework.pdf>

³ <http://pmg-assets.s3-website-eu-west-1.amazonaws.com/170825intellrctualpropertypolicy-draft.pdf>

⁴Hoen. TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond, p 41.

⁵ibis

South Africa has enacted within its local legislation, provisions that seek to safeguard the rights of the public to safe affordable medicines. South Africa has however experienced a number of challenges implementing the legislation to give effect to the Doha declaration. Below follows a synopsis of the current legislation in so far as it deals with patents and public health, and its shortcomings in addressing issues of public health concerns.

2.1. Compulsory licences:

South Africa has made provision for compulsory licences under Section 55 and 56 of the Patents Act no. 57 of 1978 ('Patents Act'). Compulsory licensing, although new to South Africa in 1997, is not foreign to the developed world, almost all of the member of the EU provide for compulsory licensing in their legislation⁶.

Governments can use compulsory licences in public health to address amongst others high prices of medicines; anti-competitive practices by pharmaceutical companies; failure by pharmaceutical patent holders to sufficiently supply the market with needed medicines; and in emergency public health situations. In practical terms compulsory licensing can be used to bring down the prices of medicines and to ensure a sufficient supply of medicines in the market in cases where the patent holder cannot, or will not, provide sufficient supplies at the right price. It is also a critical tool in emergency situations where the patent holder cannot respond to an urgent situation⁶.

The Patents Act provides for a judicial process for the determination and issue of compulsory licences i.e. applications for compulsory licences are determined by the Commissioner of Patents. In practice, the Commissioner of Patents is a judge of the High Court, appointed by the Judge President of the relevant Regional Court to preside over matters pertaining to IP. Often, a number of judges are appointed for this purpose and typically with no or little experience in dealing with IP matters.

⁶<http://blogs.sun.ac.za/iplaw/2014/01/24/public-health-sector-and-the-south-african-national-policy-on-intellectual-property/>

An applicant/patentee who wishes to obtain a compulsory licence can approach the court for an order to grant a compulsory licence, in the case of a dependent patent (Section 55), or in the case of an abuse of the patent rights by a patentee. The Commissioner of Patents will hear evidence in support and against the grant of the compulsory licences and make such order as appropriate.

2.2. Compulsory licence on a dependent patent

Section 55 of the Patents Act deals with dependent patents wherein the working of a patent is dependent on another patent and the patentee and would be licensee cannot agree on the terms of licensing of the patent. Section 55 of the Patents Act provides as follows:

“Where the working of a patent (hereinafter referred to as a dependent patent) without infringement of a prior patent is dependent upon the obtaining of a licence under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the commissioner for a licence under the prior patent, and the commissioner may grant such a licence on such conditions as he may impose, but including a condition that such licence shall be used only for the purpose of permitting the dependent patent to be worked and for no other purpose: Provided that the commissioner shall not grant such a licence unless –

- (a) the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the prior patent;*
- (b) the proprietor of the dependent patent granted the proprietor of the prior patent on reasonable terms a cross-licence to use the invention claimed in the dependent patent; and*
- (c) the use authorised in respect of the prior patent is not assignable except with the assignment of the dependent patent.”*

This section was inserted in the Patents Act in 1997. To date there has been only one compulsory licence case in South Africa in respect of a dependent patent in the matter between *Atomic Energy Corporation of SA Ltd v The Du Pont Merck Pharmaceutical Co 1997 BIP 90 (CP) at 93H*, where the court held that the applicant must show that the dependent patent is valid, and that the royalty he suggests is reasonable.



2.3. Compulsory licence in the case of abuse

Section 56 of the Patents Act provides for a compulsory licence in the case of abuse of patent rights by a patentee. Section 56 of the Patents Act provides as follows:

“(1) Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.

(2) The rights in a patent shall be deemed to be abused if –

(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;

(c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or

(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.

(3) The patentee or any other person appearing from the register to be interested in the patent may in the prescribed manner oppose the application.

(4)

(a) The commissioner shall consider the application on its merits and may order the grant to the applicant of a licence on such conditions as he or she may deem fit, including a condition precluding the licensee from

importing into the Republic any patented articles. (b) If the commissioner is of the opinion that an order directing the grant of a licence is not justified, he may refuse the application.

(c) A licence granted under this section shall include a provision that, subject to adequate protection of the legitimate interests of the licensee, the licence shall, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the commissioner, are unlikely to recur.

(5) Any licence granted under this section shall be non-exclusive and shall not be transferable except to a person to whom the business or part of the business in connection with which the rights under the licence were exercised has been transferred.

(7) In determining the conditions on which any licence is granted the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.

(7A) The commissioner may order that a licence granted in terms of this section shall be deemed to have been granted on the date on which the application has been received by the registrar.

(8) Any order of the commissioner under this section shall be made with a view to avoiding the abuse found by the commissioner to have been established.

(9) The commissioner may amend or revoke any licence granted under this section.

(10) Subject to the conditions that may be attached to the licence, a licensee under this section shall have the same rights and obligations as any other licensee under a patent.

(13)

(a) The commissioner may, when ordering the grant of a licence under subsection (4)(a), award costs against the applicant or patentee concerned or any person opposing the relevant application.

(b) In so awarding costs, the commissioner shall inter alia have regard to - (i) the nature and extent of the abuse found by him to have been established; and (ii) whether the application for a licence under this section might have been avoided by the grant, by the patentee concerned to the applicant, of a voluntary licence on reasonable terms.

(14) For the purposes of this section the expression "patented article" includes any composition of matter or any product of a patented process or method or any product produced by a patented machine."



Since the introduction of the above section in 1997, there have been five applications for compulsory licences that have come before our courts and the courts have yet to grant a compulsory licence. Below follows a summary of cases that have proceeded before our courts.

COMPULSORY LICENCES – BRIEF DETAILS OF CASES

1. Sanachem (Pty) Ltd v British Technology Group PLC 1992 BP 276 (CC)
 - Patent covered agricultural chemicals including permethrin.
 - All five grounds of abuse (as there then were) were raised.
 - The application was unsuccessful – no licence granted.
2. Afritra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd 1992 BP 331 (CC)
 - Patent covered diapers.
 - The application was unsuccessful – no licence granted.
3. Circuit Breaker Industries Ltd v Barker and Nelson (Pty) Ltd 1993 BP 431 (CC)
 - Patent covered a circuit breaker mounting kit.
 - No licence granted.
4. Syntheta (Pty) Ltd (previously Delta G Scientific (Pty) Ltd) v Janssen Pharmaceutica NV and Another 1998 BIP 264 (AD)
 - Patent covered agricultural chemicals.
 - Applicant for licence wanted to manufacture in South Africa solely for export.
 - The application was unsuccessful – no licence granted.
5. Atomic Energy Corporation of South Africa Ltd v The Du Pont Merck Pharmaceutical Company 1997 BIP 90 (CC)
 - Patent covered a diagnostic agent.
 - It was not an abuse of rights case but a dependent patent licence case.
 - The application was unsuccessful – no licence granted.

In many instances, the high cost of litigation and the timeframes to reach finality on matters relating to compulsory licences remains a deterrent to making use of this flexibility afforded in the TRIPS agreement and the DOHA Declaration. It is therefore an ineffective means of addressing the key challenge of providing access to safe affordable medicines in the case of abuse of patent rights. Many South Africans who require access to medicines subject to patent rights are unable to afford these medicines let alone approach a court to grant an order for a compulsory licence. As a result, millions of people are currently denied lifesaving health services or are plunged into poverty because they are forced to pay unfordable fees for their care.

Typically cases for compulsory licenses are settled out of court due to pressure from activist groups or government interventions. South Africa has a proud history of robustly engaging with issues that concern intersection between Intellectual Property (IP) rights and public health. Indeed the South African government's stance in the case between the Pharmaceutical Manufacturers Association versus the President of South Africa (the late President Nelson Mandela) in 1998, was a key factor leading to global dialogue around the potential negative impacts of intellectual property rights on public health, culminating in the Doha declaration on TRIPS and Public Health.

In the late nineties, for countries such as South Africa, the affordability of antiretroviral medicines was the main barrier to them being listed as essential medicines, and provided to patients. In 1998 the National Essential Medicines Lists Committee recommended to the Minister of Health that antiretroviral therapy (ART) be approved for provision to persons living with HIV/AIDS, provided that the price of the medicine could be reduced. It was within this context that the interpretation of TRIPS and IP protection and their impact on pricing and affordability of medicines became salient.

Since 2001 many Generic manufactures have secured voluntary licenses to produce medicines in South Africa, including over 20 licenses for medicines in the antiretroviral category. The increase in voluntary licensing (VL) agreements for ARV drugs was often a result of civil society pressure, and the use of competition law. For example, in 2002 activist initiatives of the Anti-Retroviral Therapy (ART) treatment campaign, resulted in some multinational companies being found guilty of excessive pricing by the South African Competition Commission. At this time the prices of patent holders were between 3 and 10 times higher than the least expensive generic version of the same medicines.

In 2004, the prices of ARV dropped to a level where the South African department of health introduced them as essential medicines. However, prices remained relatively high and there were concerns regarding financial sustainability. Over time, however, often as a result of ongoing civil society pressure, increasing numbers of voluntary licenses were issued, resulting in steady price decreases. In one example, in 2006 a license for the drug tenofovir (TDF), was granted to a generic manufacture and as a result the price for the drug decreased by 64%.

Similarly in 2007, activist pressure resulted in complaints to the Competition Commission regarding more multinational companies for excessive pricing. As a result, these companies issued voluntary licenses, after which competition increased and prices for the medicines concerned decreased in state tendering processes. Licenses for generic manufacturing of APIs in other parts of the world have also contributed to cheaper APIs, and thus cheaper medicine formulation since APIs accounts for approximately 70% of the cost of manufacturing for ARVs.



Companies and Intellectual
Property Commission
a member of **the dti** group

The current activist initiative 'Fix the Patent Laws' has resulted in a number of media battles and ongoing pressure towards multinational pharmaceutical companies regarding pricing and affordability for patented medicines. This activist campaign aims to strengthen Intellectual Property laws in South Africa in the interests of stimulating medicine price competition. This is an ongoing process with multiple stakeholder involvement including the Department of Trade and Industry, the Department of Health and the Department of Science and Technology.

2.4. Patentable subject matter (Article 27)

The three criteria for patentability (novelty, inventive step and industrial application) are not defined under TRIPS. Each member state is free to interpret their meanings, which can determine what is patentable under local law. In addition, governments can refuse to grant patents for three reasons that may relate to public health, including inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27.2); diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27.3a); and certain plant and animal inventions (Article 27.3b).

South Africa has a depository system for the registration for patents, meaning that patent applications are examined only as to formalities and are not examined substantively. Accordingly, South Africa has accordingly not benefited from the abovementioned exemption and limitation; and will only be able to do so once the substantive examination of patent application has been implemented.

South Africa defines Patentable inventions under Section 25(1) of the Patents Act as: *... any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.*

ISO 9001: 2008 Certified

The dtiCampus (Block F - Entfufukweni), 77 Meintjies Street, Sunnyside, Pretoria | P O Box 429, Pretoria, 0001

Tel: +27 12 394 5378 | Fax: +27 12 394 6378 | Call Centre: 086 100 2472

Email: ALudin@cipc.co.za | Website: www.cipc.co.za

Exceptions to patent rights are provided in Section 25 and 36 of the Patents Act which provide:

Section 25(2): *“Anything which consists of - (a) a discovery; (b) a scientific theory; (c) a mathematical method; (d) a literary, dramatic, musical or artistic work or any other aesthetic creation; (e) a scheme, rule or method for performing a mental act, playing a game or doing business; (f) a program for a computer; or (g) the presentation of information, shall not be an invention for the purposes of this Act.”*

Section 25(3): *“The provisions of subsection (2) shall prevent, only to the extent to which a patent or an application for a patent relates to that thing as such, anything from being treated as an invention for the purposes of this Act.”*

Section 25(4): *A patent shall not be granted - (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro- biological process or the product of such a process.”*

Section 25(11): *“An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry.”*

Section 25(12): *“Subsection (11) shall not prevent a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method.”*

Section 36: *“(1) If in the case of any application it appears to the registrar - (a) that the application is frivolous on the ground that it claims as an invention anything obviously contrary to well established natural laws; or (b) that the use of the invention to which the application relates would be generally expected to encourage offensive or immoral behaviour, he shall refuse the application.*

(2) If it appears to the registrar that any invention in respect of which an application for a patent is made might be used in any manner contrary to law, he may refuse the application unless the specification is amended by the addition of such disclaimer in respect of that invention, or such other reference to the illegality thereof, as the registrar may think fit.”

Thus, making such inventions not patentable. The key impact of this flexibility is that countries can ensure that only true inventions are patented⁷. South Africa as a non-examining country has not made use of this exception as the patentee is only required to comply with the formal requirements. As a result South Africa has one of the highest grant rates in the world. Patents which do not meet the substantive requirements for patentability are granted with broad invalid claims. The issues of novelty, inventive step, industrial applicability, clarity, sufficiency of disclosure can only be determined by the courts. It is therefore only a handful of patents that are challenged in court on the substantive issues of patentability as the cost of litigation remains an insurmountable barrier to most applicants.

The implementation of substantive search and examination (SSE) would mean that the rampant practise of 'ever-greening' in the pharmaceutical industry would be curbed and the number of invalid patents on the Register of patents will be reduced. It is envisaged that this will lead to a greater number of medicines being made available in generic forms in a competitive market, which would have a positive impact on prices⁶.

Accordingly, in order to address to give full effect to the provisions of Article 27 of TRIPS, South Africa will in the near future embark on the SSE of patent applications. The Department of Trade and Industry has already taken steps to implement SSE by hiring examiners who are currently being trained to examine patent applications while the legislative processes to implement SSE of patent applications are being concluded.

2.5. Exhaustion of rights (parallel importation) (Article 6)

Exhaustion of rights under IP theory refers to the point at which the right holder loses legal control over a protected product by virtue of selling or otherwise releasing it into the channels of commerce. Provisions for parallel importation would then allow the same article to be imported from a different country at a lower price than it is being sold in its domestic market by the patent holder or the licensee⁶.

⁷http://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA%2B10TRIPS_en_0.pdf

Exhaustion of rights is provided for in the Patents Act in Section 45 (2),

“the disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article.”

Even though the South African Patents Act recognises the doctrine of exhaustion of rights, uncertainty remains as to whether it applies nationally or internationally. This remains to be tested in a court of law.

Additionally, South Africa has made provision for this flexibility as it relates to Public Health under Section 15C, of the Medicines and Related Substances Control Amendment Act No. 90 of 1997 ('Medicines Control Act'), which allows the Minister of Health to:

“..prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;”

This provision allows for the generic substitution of off-patent drugs whilst Section 22F provides that the patients be informed of the availability of generic medicines as opposed to branded products. The objective of this legislation is to increase the access to medication as generic forms are often cheaper and thus more affordable to the public.

The implementation of Section 15C did not come without its challenges. The pharmaceutical industry, backed by some governments, vigorously opposed the enactment of Section 15C, arguing that it was tantamount to a complete annulment of patent rights and that it violated the TRIPS agreement. In spite of vociferous opposition, Section 15C was signed into law by the late President Nelson Mandela on 12 December 1997.

In an attempt to block the implementation of Section 15C, over 40 of the World's largest and most powerful pharmaceutical companies initiated a court action, challenging the constitutionality of Section 15C before the High Court of South Africa in February 1998. Section 15C was also put on the agenda for high-level bilateral trade discussions between South Africa and some countries which resulted in South Africa being placed on a special 'watch list' in 1998 and 1999 relating to international trade relations.

These tensions escalated, and ultimately created significant public awareness and controversy regarding the conflict between the pharmaceutical industry and developing countries. As this pressure increased the narrative emerged that pharmaceutical companies were putting 'profit before the people'. The lawsuit against the South African government was ultimately withdrawn unconditionally in May of 2001, with costs. Civil society treatment access activists cite the successful media campaigns as central to achieving this victory.

2.6. Regulatory (bolar) exception (Article 30)

This exception allows a potential competitor to use an invention to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term without the authorization of the patent holder. This exception is provided in the Patents Act under Section 69A (Acts of non-infringement) which provides as follows:

(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

Section 69A provides that it shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of, or import a patented invention on a non-commercial scale and solely for the purposes reasonably related to obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product. This provision is meant to allow for more rapid introduction of generics into the market which leads to more rapid competition and lowering of prices.

Although Section 69A allows for rapid introduction of generic medicines on the market, the generic manufacturer is however not permitted to use the patented invention other than for the purposes of obtaining regulatory approval. Furthermore, it is not permitted for a generic manufacturer to stockpile a product prior to the expiry date of the relevant patent with a view to commercial sales immediately the patent expires. Furthermore, Section 69A does not make provision for research exceptions. The DIPP

aims to provide exceptions for research and experimental activities with broader application than IP and the associated rights when developed using public funds.

3. Competition law (Article 40)

Article 40 of the TRIPS Agreement, it is recognized that licensing practices or conditions pertaining to IP rights that restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. Consequently, the TRIPS Agreement allows WTO members to specify in their legislation the specific licensing practices or conditions that may constitute an abuse of IP and have an adverse effect on competition in the relevant market⁶.

With regards to competition law, South Africa passed the Competition Act No 89 of 1998, accompanied by the Competition Commission (the Commission). The commission is empowered to investigate, control and evaluate restrictive business practises, abuse of dominant positions and mergers in order to achieve equity and efficiency in the South African economy. The objective of this legislation is to ensure adequate and healthy competition in the pharmaceutical market, improving pricing and availability of needed products.

The Medicines Control Act further allows for price transparency (Section 22G Pricing Committee):(2) *“The Minister may, on the recommendation of the pricing committee, make regulations-(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic, which should in theory lead to more competitive pricing in the industry.”* However in practice this has not been the case as prices for medicines remains relatively high and unaffordable to many South Africans.

4. South Africa’s IP Policy

The South African IP landscape is characterised by a number of IP legislations under the administration of various government departments and organs of state. Each department and/or organs of state administers its own piece of legislation with limited engagement with other government departments. This resulted in policy incoherence and the ineffective administration of IP laws in South Africa. To address this issue, the South African government, through the Department of Trade and Industry (Dti) published the DNPIP in 2013.



Companies and Intellectual
Property Commission
a member of **the dti** group

The objective of the DNPIP was to provide a national IP System that is informed by other national priorities that seeks to address other national objectives; and a co-ordinated approach on IP matters by government departments and other organs of state. The DNPIP was however heavily criticised by stakeholders at large for being incoherent, containing unsubstantiated statements, and also containing incorrect statements on the law.

As a way forward, in July 2016, the South African cabinet approved a new IPCF, which as a consultative approach that sought to include all relevant stakeholders, which includes government, the pharmaceutical industry, NGOs and the general public in formulating a new IP Policy for South Africa. The IPCF considered a two phased approach tackling issues of IP. Phase 1 will have two main focus areas, namely:

Patents and public health: *Local manufacture and export in line with industrial policy, Patent–substantive search and examination Patent opposition, Patentability criteria, Disclosure requirements, Parallel importation, Exceptions Voluntary licensing, Compulsory licences and IP & competition law.*

International IP Cooperation: *coordination in international forums, and the implementation of commitments undertaken in international agreements.*

Phase 2 will focus on mainly developmental goals for South Africa and considering international best practices, in consultation with intergovernmental organizations who have expertise in this area. Thus, the focus in Phase 2 of the IP policy will be on *inter alia: 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, Commercialization of IP, Enforcement, IP and localisation and beneficiation, IP awareness & capacity building, IPRs and the environment/climate change/green technologies, IP in agriculture; IP and biotechnology, genetic resources, and genomic sovereignty.*

The IPCF also provided for the formation of an Inter-Ministerial Committee on Intellectual Property (IMCIP), to strengthen national level policy and institutional coherence between trade and intellectual property, and promote the right to health and public health objectives. The IMCIP is tasked with coordinating laws, policies and practices that may impact on health technology innovation and access. The draft IP policy (Phase 1) emanating from the IPCF was published on 8 August 2017, which is open to public comments for a period of sixty days. The draft IP policy (Phase 1) provides governments'

ISO 9001: 2008 Certified

The dtiCampus (Block F - Entfufukweni), 77 Meintjies Street, Sunnyside, Pretoria | P O Box 429, Pretoria, 0001

Tel: +27 12 394 5378 | Fax: +27 12 394 6378 | Call Centre: 086 100 2472

Email: ALudin@cipc.co.za | Website: www.cipc.co.za

thinking on the key issues related to patents and public health and makes provision for structural reforms of South African IP law.

4.1. Establishment of SSE

The IPCF and the DIPP make provision for the introduction of SSE for patent applications. The current depository system is deemed to be inappropriate for advancing the objectives of a knowledge economy and striking the appropriate balance between public health and the grant of patent rights. Since applications are not examined for patentability, invalid patents, with a broad scope of claims are allowed to remain on the Patent Register, and the challenge the validity of such patents requires a judicial process that is expensive and time consuming.

Initially focussing examination in the health sphere and progressively expanding the examination scope to cover other technology areas. In addition, recommendations are made for the establishment of a third party observation systems and a post-grant opposition system. The draft IP Policy also makes provision for a pre-grant opposition system once sufficient capacity has been developed and subject to availability of resources.

The introduction of SSE aims to ensure that South Africa grants quality patents and provides a level of certainty to applicants that their granted patents are enforceable rights. By examining applications for patents to determine novelty, inventive step, industrial applicability, clarity and sufficiency of disclosure, only patents that are deserving can be granted. Patentability can be determined in line with national priorities and in a manner that seeks to advance public health and the creation and dissemination of knowledge.

It also aims to provide mechanisms for challenging the validity of the grant of a patent and lowering the burden on applicants who may wish to challenge validity of the grant of a patent, by proving administrative processes such as third party observations and opposition systems as opposed to a purely judicial process.



Companies and Intellectual
Property Commission
a member of **the dti** group

4.2. Licences to access medicines

The DIPP makes provision for an administrative process for the determination of compulsory licences as opposed to the current judicial process. The judicial process has its shortcomings in that it involves the costs and timeframes of litigation. This process is therefore inaccessible to persons who require access to medicines. The exact manner in which the administrative process will be implemented is yet to be determined.

The DIPP also proposes voluntary licensing as a means of addressing public health issues in particular in instances where such medicines are derived from publicly financed research and development activities.

4.3. Parallel importation

The interpretation of the Patents Act and the Medicines and Related Substances Act 101 of 1965 (Medicines Act) appears to suggest the local exhaustion of rights which limits the scope of parallel importation. The DIPP makes provision for a broader interpretation which includes international exhaustion of rights.

4.4. Bolar Exceptions

South Africa inserted Section 69A into the Patents Act to provide for rapid introduction of generic drugs into the market after the patent to which a drug relates expires. However, this exception does not provide for research and experimental use. The DIPP will consider manners in which effect can be given to this research exception in consultation with relevant stakeholders.

ISO 9001: 2008 Certified

The dtiCampus (Block F - Entfufukweni), 77 Meintjies Street, Sunnyside, Pretoria | P O Box 429, Pretoria, 0001

Tel: +27 12 394 5378 | Fax: +27 12 394 6378 | Call Centre: 086 100 2472

Email: ALudin@cipc.co.za | Website: www.cipc.co.za

5. Conclusion

South Africa is embarking on a consultative and inclusive process to address issues of IP rights and access to essential medicines. We recognize the importance of striking a balance between the needs of indigent people who require access to medicines but because of their status are unable to afford and access essential medicines and on the other hand, the need to incentivize pharmaceutical companies to continue in investing in research and development of new medicines to address future needs.

In all these efforts, we would want to be in a position to continue to call on WIPO and all intergovernmental organisations, to support us to craft IP policies that support our objectives of balancing the rights of innovations and needs of the public.