

G:ENESIS

Assessment of the Regulatory
Proposals on the Intellectual
Property Policy Framework for South
Africa

Prepared by Genesis Analytics for the
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LIST OF ACRONYMS

| | |
|--------|--|
| AIDS | Acquired Immune Deficiency Syndrome |
| ANVISA | Portuguese abbreviation for National Agency for Sanitary Vigilance |
| API | Active Pharmaceutical Ingredients |
| ARIPO | African Regional Intellectual Property Organisation |
| ARV | Antiretroviral |
| BI | Boehringer Ingelheim |
| BMS | Bristol-Myers Squibb |
| BRICS | Brazil, Russia, India, China and South Africa |
| CIPC | Company and Intellectual Property Commission |
| COMED | Co-ordinating Committee for Medical Procurement |
| DALRO | Dramatic, Artistic and literary Rights Organisation |
| DoE | Department of Energy |
| DoH | Department of Health |
| DST | Department of Science & Technology |
| dti | Department of Trade and Industry |
| ECT | Electronic Communications and Transactions |
| ELSEN | Education for Learners with Special Educational Needs |
| EPO | European Patents Office |
| FDI | Foreign Direct Investment |
| GDP | Gross Domestic Product |
| GI | Geographical indication |
| GSK | GlaxoSmithKline |
| HIV | Human Immunodeficiency Virus |
| HR | Human Resources |
| IB | International Bureau of WIPO |
| ICT | Information communications technology |
| IDC | Industrial Development Corporation |
| INPI | Portuguese abbreviation for Brazilian Patent Office |
| IP | Intellectual Property |
| ISA | International Search Authority |
| ISP | Internet Service Providers |
| JPO | Japanese Patent Office |
| KIPI | Kenya Industrial Property Institute |
| MCC | Medicines Control Council |
| MNO | Mobile Network Operator |
| MSF | Medecins Sans Frontieres |
| MVT | Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled |
| NAB | National Association of Broadcasters |
| NCE | New Chemical Entities |
| NIPMO | National Intellectual Property Management Office |
| NPA | National Prosecuting Authority |
| PCT | Patent Cooperation Treaty |
| PPP | Purchasing Power Parity |
| R&D | Research and Development |
| RAM | Random Access Memory |
| RIA | Regulatory Impact Assessment |
| RISA | Record Industry of South Africa |
| SADC | Southern Africa Development Community |
| SAHPRA | South African Health Products Regulatory Agency |
| SAMPRA | South African Music Performance Rights Association |

| | |
|-------|---|
| SAMRO | Southern African Music Rights Organisation |
| SAPS | South African Police Services |
| SEP | Single Exit Price |
| SME | Small and Medium Enterprises |
| SSE | Substantive Search and Examination |
| STD | Sexually Transmitted Disease |
| TAC | Treatment Action Campaign |
| TB | Tuberculosis |
| TPM | Technical Protection Measure |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| UNISA | University of South Africa |
| USPTO | United States Patent and Trademark Office |
| VAT | Value Added Tax |
| VIPs | Visually Impaired and otherwise print disabled |
| WASPs | Wireless Applications Service Providers |
| WCT | WIPO Copyright Treaty |
| WHO | World Health Organisation |
| WIPO | World Intellectual Property Organization |
| WPPT | WIPO Performances and Phonograms Treaty |
| WTO | World Trade Organisation |

EXECUTIVE SUMMARY

Genesis Analytics was contracted by the Department of Trade and Industry (**the dti**) to provide an assessment of the proposed changes to the Intellectual Property (IP) Policy Framework. **The dti** issued the draft national policy on IP ('the Draft Policy') to the public for comment in September 2013. The stated intent of the Draft Policy is to bring South Africa on a par with the IP practices of other developing countries, to foster innovation and economic growth, and to enhance public access to medicine and healthcare by placing reasonable limits on the market exclusivity of pharmaceutical originator drug manufacturers.

The report aims to assess the social and economic impact of the regulatory proposals in **the dti's** draft IP policy and to identify whether each of the proposals is sufficient, efficient and suitably designed to meet its objectives. The three major policy themes within the draft IP policy were reviewed:

- the introduction of a Substantive Search and Examination (SSE)¹ system for patent registration;
- the introduction of TRIPS flexibilities into the Patent Act, these being, a) pre- and post-grant opposition, b) patentability criteria, c) compulsory licensing, and d) parallel importation; and
- the amendment of local legislation to implement the contents of international treaties on a) copyright (Berne Convention, Marrakesh Treaty, WIPO Copyright Treaty, WIPO Performers and Phonograms Treaty, Beijing Treaty on Audio-visual Performances), b) designs (Hague Agreement and Protocol) and c) trademarks (Madrid Agreement and Protocol, Lisbon Agreement).

Affected stakeholders were identified and an extensive consultation process undertaken to provide a situational analysis of the IP regulatory environment and to determine the distributional effects of the selected proposed changes to the IP framework. Where possible, all costs and benefits were quantified in Rand terms; in most cases it was possible to provide a qualitative cost-effectiveness assessment only, which relies on research with industry stakeholders, economic theory and common sense. A framework was developed to evaluate the policy proposals and derive applicable recommendations to maximise the benefits and minimise the costs associated with the policy proposals. Relevant policy alternatives were also identified based on engagement with key stakeholders and consideration of international practice.

The key findings in relation to each of the policy proposals assessed are outlined below.

1. **Proposal to introduce SSE for patent registration:** South Africa currently has a depository system of patent registration. Patent applications must meet certain formality requirements to be granted, but are not examined against the criteria for patentability, namely, novelty, non-obviousness and industrial applicability. Switching to an SSE system will bring South African IP practice in line with that of other developing countries, including Brazil and India.

An SSE system contributes to the strengthening of the quality of the IP system since patents are subjected to a more rigorous application process, and the likelihood of

¹ Also commonly referred to as Search and Substantive Examination.

granting invalid patents is therefore diminished. However, the SSE is complex and costly to implement, both financially and in terms of human resources. It is thus incumbent on government to make a sober assessment of its ability to meet the critical success factors necessary for effective implementation of an SSE system. If effectively implemented, the SSE will reduce the incidence of invalid patents being granted and curb evergreening practices by large multinational pharmaceutical companies. Effective implementation relies on the establishment of efficient systems and processes in the patent office to perform SSE functions, adequately trained resources, and up-skilled legal representation to service any litigation cases that arise. If these measures are put in place, which will take time to see to, the risks of extensive delays, an ineffective patent system and reputational damage to South Africa, can all be mitigated.

Based on the analysis and consultations it is therefore recommended that this policy proposal be implemented subject to adequate measures being taken to mitigate the risks associated with poor implementation. There are several implementation options available for the SSE, which should be properly explored prior to deciding and embarking on the ultimate implementation route, including: conduct a prior-art search only; conduct SSE internally; outsource the examination function and enter into mutual recognition arrangements; conduct SSE for select industries only; or, conduct bifurcated procedure, with delayed deadline for examination.

2. ***Proposal to provide for pre- and post-grant opposition:*** The current IP legislation provides for revocation of a patent through a judicial process. There is no provision for pre- or post-grant opposition. The Draft Policy proposes that legislation be amended to have both pre- and post-grant opposition to effectively foster the spirit of granting stronger patents. There is concern that, if provided for, the opposition proceedings will introduce delays to the system of patent registration and open the system up to potential abuse if third parties attempt to delay registration by lodging frivolous opposition claims. Furthermore, it is suggested that the pre-grant opposition is redundant when a substantive examination is performed and post-grant opposition is not necessary in light of revocation proceedings. However, the introduction of the pre-grant opposition is intended to provide an opportunity for interested parties to challenge and restrict the granting of weak or invalid patents early on in the process, without incurring prohibitive litigation costs. If structured as a simple, administrative, summative process, the opposition proceedings strengthen the patent system by effectively limiting invalid patent grants. Effective implementation relies on the capacitation of resources with technical and legal expertise to adjudicate opposition proceedings, the capacity to manage the increased administrative burden and efficient systems and processes to support opposition proceedings. It is possible in this manner to mitigate the risks of extensive delays and to limit the scope for abusive practices.

The policy review recommendation is to implement this proposal provided that the requisite staff, systems and processes are in place for effective implementation. The detailed structuring of the opposition proceedings needs to be carefully considered with the aim of limiting the burden of the process and any potential for abuse.

3. ***On amending the patentability criteria to exclude the patenting of new uses of known products:*** South African IP legislation currently allows for the patenting of new uses of known products in the pharmaceutical industry. This is subject to abuse by patentees who attempt to extend the term of patent protection through multiple patents on a single known product. Such anti-competitive behaviour can have negative

consequences for public health, in particular, where originator pharmaceutical companies apply for multiple patents (on chemical compounds, new uses, molecular compositions etc.) on a single drug. The Draft Policy aims to introduce stricter patentability criteria to curb this practice, known as ‘evergreening’, as it impedes access to healthcare through high medicine prices. Following the example by Indian Patent law, including a patentability requirement of ‘enhanced efficacy’ may work to curb evergreening, although it is unclear on what implications this may have on other industries. In addition, the extent of evergreening in South Africa is unclear and there is a possible unintended consequence of curbing innovation in the pharmaceutical industry, in particular the field of medical devices.

The policy review recommendation is to adopt the policy proposal with amendments. Careful crafting of the criteria is required to mitigate the risk of unintended consequences. Another more targeted alternative is the SSE system which would effectively examine patents for evergreening, although this has far greater cost implications.

4. ***On aligning compulsory licensing with international treaties:*** The draft IP Policy recommends that compulsory licensing should be introduced in South Africa in line with international treaties. Compulsory licensing is the authorization, by the government, to someone other than the patent holder to produce the patented product without the consent of the patent owner. The policy objective in this case is interpreted to be the advancement of public healthcare. Current legislation does allow for compulsory licensing, although the application process is seen as burdensome and complicated.

It is recommended that South Africa adopt the improvement of compulsory licensing implementation but with revision. It is noted that the main advantage in improving compulsory licensing processes is the increased bargaining power in voluntary licensing negotiations with patentees. However, the actual implementation of a compulsory license may trigger significant risks, such as inability to produce under a license because of insufficient local manufacturing capabilities, adversarial relationships between the private and public sector and decreased trade and / or FDI. Government Use license, a special form of compulsory licensing may instead serve to achieve government’s public health objective without amending the process more generally. It is also recommended that clear guidelines for compulsory license application requirements be published for the public and legal community. Given the importance of a consistent, accurate and timely communication with the public and patentee, government departments should devise a clear strategy in this regard.

5. ***On aligning parallel importation with international treaties:*** As it stands in South Africa, parallel importation is only enabled for medicines and does not more generally apply to all patents. South Africa’s current patent law implies a national exhaustion of rights, which would need to be amended to reflect international exhaustion of rights, thereby allowing for parallel importation. International rights exhaustion is the concept that once a patent holder, or any authorized agent, has sold a patented product anywhere in the world they cannot prohibit the subsequent resale of that product.

The policy review recommendation is that parallel importation should be considered in light of alternative measures. For successful parallel importation to be implemented, the single critical success factor of increased regulatory involvement and quality oversight is unlikely to be secured and severe risks (low potential savings, adversarial relationships between patentees and state and inability of local industries to compete) are very likely to

occur. Alternatively, compulsory licensing may be used to achieve improved access to healthcare, without these associated risks.

6. ***On adopting copyright flexibilities as per the Berne Convention:*** The interpretation of this policy proposal is that South Africa should amend its copyright law to i) enhance access to and use of copyright works and ii) to enhance access to information for the enhancement of education, research and free speech. The Berne Convention flexibilities that are pro-development have not been adopted in South African legislation. The Appendix to the Paris Act of the Berne Convention thus allows a choice between a compulsory license system and the possibility of limiting the right of translation to 10 years. The Berne Convention also provides clarity around the issues of fair dealing (limitations and exceptions on exclusivity rights, such as, research and study) and parallel importation of copyright materials.

Given the increased legal certainty and pro-development approach of access to educational materials afforded by the Berne Convention, the policy review recommendation is to accept the proposal by acceding and amend South Africa's copyright law accordingly.

7. ***On implementation of WIPO Internet Treaties (WCT and WPPT):*** South Africa's Copyright Act and Performers Protection Act do not provide rights holders any digital exploitation rights. South Africa is a signatory but has not yet acceded to the WCT, which deals specifically with copyright protection for the digital platform. Given the increased legal clarity of rights in the ever growing digital era, it is recommended that copyright laws be amended to be in alignment with the WCT. Currently, South Africa has not ratified the WIPO Performers and Phonograms Treaty (WPPT). The WPPT grants performers and producers of phonograms four kinds of economic rights (those of reproduction, distribution, rental, and making available). One risk with the implementation of these rights is a possible imbalance of public/private rights. However, the policy proposal should be implemented since this risk can be mitigated through the careful crafting of fair dealing provisions to ensure users' right to access.

8. ***On Adoption of other International Treaties on IP Rights:*** According to the draft IP policy, Parliament has approved ratification of the Madrid Protocol for the International Registration of Marks and the Hague System on the International Deposit of Designs.

- a. The Madrid Protocol offers several advantages, such as a choice for the applicant, allowing international registrations to be based on national applications and not only on individual applications in each country where protection is sought. Given the advantages of legal certainty, cost-saving of filing in multiple jurisdictions and the ease of access to international markets for generators of IP, the policy recommendation is to implement the policy proposal provided all the necessary legal, administrative, human resources and systems requirements have been complied with.
- b. The Hague Agreement allows multi-jurisdictional registrations through the filing of a single application and enables designers to protect their designs with minimum formalities in multiple countries or regions. A high risk of acceding to this Agreement however is the loss of the ability to protect functional design. Protection of functional designs, as opposed to aesthetic designs, is currently allowed for in South African law to foster low level innovation. This risk may however be mitigated through the introduction of a petty patent system which protects designs that are

not entirely functional or entirely aesthetic. As such the implementation of the policy proposal to align with the Hague System is recommended provided the necessary legal, administrative, human resources and systems requirements have been complied with.

- c. In addition, South Africa became a signatory to the Marrakesh Treaty in July 2013. The Marrakesh Treaty focuses on copyright exceptions to facilitate the creation of accessible versions of books and other copyrighted works, in particular print disabled persons such as the visually impaired. It sets a norm for countries ratifying the Treaty to have a domestic copyright exception covering these activities, and allowing for the import and export of such materials. The adoption of the Marrakesh Treaty and the amendment of the Copyright Act to provide for the exceptions and limitations relating to accessible copies of works are strongly recommended.
- d. The Lisbon Agreement provides for the protection of appellation of origin. Indications of the geographical origin of goods are becoming increasingly important in the trade environment. Geographical Indications (GIs) are protected through a wide variety of different approaches in different countries, and often by a combination of two or more approaches. It is recommended to adopt the Lisbon Agreement, coupled with the development of other legislative instruments to implement the effective protection of appellations of origin and GIs. A system will have to be developed for national as well as international registration, the submission of objections and the enforcement of appellations of origin of member states.
- e. The profound impact of the development and convergence of information and communication technologies on the production and use of audiovisual performances mandated the adoption of new international rules. The Beijing Treaty also provides performers with protection in the digital environment, giving them some measure of control over how and when their works – the films and videos they perform in – are used on the Internet. The underlying objective of this treaty is to develop and maintain the protection of the rights of performers in their audiovisual performances in a manner as effective and uniform as possible. It is recommended that South Africa accedes to the Beijing Treaty.

Based on the methodology outline above, the policy review recommendation for each of the policy proposals assessed is stipulated in the table below.

| Category | Policy proposal | Policy Review Recommendation |
|----------------------------------|--|---|
| Search & Substantive Examination | <ul style="list-style-type: none"> • <i>South Africa should introduce a SSE system for patent registration, to coexist with the depository system, where patent examination implementation will be supported (at least initially) by departments/universities/research institutions.</i> | <ul style="list-style-type: none"> • Recommended that policy proposal be adopted, provided that: <ol style="list-style-type: none"> 1. Efficient systems and processes are put in place to manage the search and examination functions of the patent office; 2. Requisite resources are adequately trained: examiners and search officers; and 3. There is efficient legal representation to lodge patent claims under SSE system and to process litigation cases that arise. |
| Pre- and post-grant opposition | <ul style="list-style-type: none"> • <i>The Patents Act should be amended to have both pre- and post-grant opposition to effectively foster the spirit of granting stronger patents</i> | <ul style="list-style-type: none"> • Policy should be implemented provided that: <ol style="list-style-type: none"> 1. Resources with the technical and legal expertise to adjudicate the opposition proceedings are capacitated 2. Sufficient resources are employed to manage the administrative burden of opposition proceedings 3. Adequate regulatory measures are adopted to ensure that opposition proceedings strengthen the system 4. Systems and procedures in place are well defined and simply structured |
| Patentability criteria | <ul style="list-style-type: none"> • <i>South African legislation should allow strict rules to apply to patenting as competition principles may be undermined. This should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as is the case under the TRIPS Agreement.</i> | <ul style="list-style-type: none"> • Recommended that policy proposal be adopted with revision |
| Compulsory licensing | <ul style="list-style-type: none"> • <i>Compulsory licensing should be introduced in South Africa in line with international treaties, such as the Doha Decision 6 of the WTO negotiations on Trade and Public Health.</i> • <i>Apply investment standards for the protection of IP asset of investment, in particular for a</i> | <ul style="list-style-type: none"> • Recommended that policy proposal be adopted with revision |

| Category | Policy proposal | Policy Review Recommendation |
|--|---|---|
| | <p><i>compulsory licence in determining public purpose;</i></p> <ul style="list-style-type: none"> • <i>South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health.</i> | |
| Parallel importation | <ul style="list-style-type: none"> • <i>South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health.</i> • <i>South Africa should facilitate in its legislation the ability to import patented products if it can get them cheaper in other jurisdictions (parallel importation). Parallel importation of IP can also be made at a regional arrangement and, in this regard, South Africa may wish to influence regional integration for the purpose of access to medicines</i> | <ul style="list-style-type: none"> • Policy proposal should be considered in light of alternative measures |
| Copyright flexibilities - Berne | <ul style="list-style-type: none"> • <i>To enhance access to copyrighted materials and achieve developmental goals for education and knowledge transfer, South Africa must adopt pro-competitive measures under copyright legislation. The legislation must provide the maintenance and adoption of broad exemptions for educational, research and library uses.</i> • <i>The amendment of the Copyright Act to through the adoption of Berne and TRIPS exceptions and limitations for the public benefit.</i> | <ul style="list-style-type: none"> • Policy proposal should be adopted |
| Implementation of WIPO Internet Treaties | <ul style="list-style-type: none"> • <i>The WIPO Internet treaties must be viewed in the context of the country's needs and requirements.</i> • <i>South Africa internet users must be entitled to fair use rights such as making and distributing copies from electronic sources in reasonable numbers for educational and research purposes and using reasonable excerpts in commentary and criticism.</i> • <i>South Africa should consider carefully before acceding to the WIPO Copyright Treaty and should not follow the path of the US Digital Copyright Management Act (DCMA) and EU (database Directive) as these instruments are restrictive and, therefore, bad models for copyright legislation of a developing country like South Africa. The DCMA and EU Directive restrict the number of downloads, whether for commercial or personal/research use...</i> | <ul style="list-style-type: none"> • Policy proposal should be adopted |

| Category | Policy proposal | Policy Review Recommendation |
|---|--|--|
| Adoption of other International Treaties on IP Rights | <ul style="list-style-type: none"> • <i>Parliament has approved ratification of the Madrid Protocol for the International Registration of Marks and the Hague System on the International Deposit of Designs.</i> • <i>South African enterprises should be assisted to register their trademarks nationally and internationally where they have a footprint.</i> | <ul style="list-style-type: none"> • Policy proposal should be adopted, and furthermore South Africa should adopt the Lisbon Treaty and accede to the Beijing Treaty.² |

² No policy proposals on the Lisbon and Beijing treaties were included in the Draft Policy.

1. INTRODUCTION

Genesis Analytics was contracted by the Department of Trade and Industry to provide an assessment of the proposed changes to the Intellectual Property (IP) Policy Framework. **The dti** issued the Draft National Policy on IP (“the Draft Policy”) to the public for comment in September 2013. This assessment focuses on a selection of the policy proposals in the Draft Policy, identifying the critical policy themes as representative of the core policy objectives and a significant change in the IP regulatory landscape and likely to appear in the second drafting of the IP Policy Framework. The major themes included in this assessment include:

- The introduction of a patent SSE system.
- The incorporation of TRIPS flexibilities into the Patents Act.
- The amendment of various local legislation to implement the contents of international treaties on copyright, designs and trademarks.

Further to this, the assessment identifies important proposals missing from the Draft Policy and poorly articulated or evidenced proposals which require attention.

1.1. BACKGROUND

South Africa’s socio-economic challenges often result in competing development imperatives for the government. Initiatives to foster economic growth and provide an enabling environment for the private sector by promoting innovation and technology development must be balanced with the need to provide citizens with affordable access to the innovations and technologies developed. There is in particular a social development objective to enhance public access to health care and medicines in South Africa; an objective for which intellectual property protection is a pertinent concern.

The major challenge with the IP system in South Africa is presumed to be the fragmented nature of the policy framework. Four main challenges with the current system have been proposed by **the dti**:

1. There is a lack of coordination with the various government departments involved in IP related matters.
2. IP law has not taken into account the social and economic concerns of South Africa as a developing country.
3. Regional and international treaties have been adopted without properly assessing the associated costs and benefits.
4. There is no substantive search and examination patent system in South Africa.

1.2. OBJECTIVE OF THE REPORT

A Regulatory Impact Assessment (RIA) is typically conducted early in the regulatory process so as to set out the costs and benefits of policy choices while the policies can still be influenced. Furthermore, a RIA is traditionally performed where the policy proposals are specific, clearly defined and unambiguous. Since this report was contracted after the proposed

amendments to the national IP Framework had been drafted, and many of the policy proposals are broad in nature, it does not constitute a traditional RIA. Rather, it is an independent appraisal of the proposed amendments to the national IP Framework. The report does not itself design or recommend policy but rather aims to assess the impact (economic and social) of selected regulatory proposals in **the dti's** Draft Policy and identify whether each of the proposals is sufficient, efficient and suitably designed to meet its objectives.

The report sets out to achieve the following core objectives:

- Assess the available evidence of innovation and industry stakeholders affected by IP policy in South Africa (limited to desktop review and stakeholder consultations);
- Conduct an independent situational analysis of IP regulatory environment and affected stakeholder groups;
- Assess the problems identified by **the dti**;
- Advise whether the proposed policy changes are relevant and sufficient to solve the identified problems;
- Provide an independent view of the costs and benefits and associated risks with **the dti's** proposals;
 - Highlight the implications of the integration of international treaties into national legislation; and
 - Derive from the analysis of obtained information a set of applicable and implementable recommendations to maximise benefits and minimise costs associated with IP policy framework.

1.3. METHODOLOGY

Given the broad scope of the draft IP Policy, for a more in-depth analysis, the assessment focused on a select number of the policy themes. These were chosen such that:

- The selected policy themes represent the core issues of policy objectives and a significant change in the IP landscape.
- The selected policy themes are relatively clear i.e. specific, well defined and unambiguous.
- The selected policy themes are important enough that it will likely appear in some form in subsequent drafts of the policy document.
- The selected policy themes are not in existing legislative amendment bills (e.g. indigenous knowledge in the Intellectual Property Laws Amendment Bill 2010) that are near to achieving parliamentary approval or is part of a separate review process (e.g. collecting societies in the Copyright review commission).

Table 1 below lists the proposals, as well as the interpretation of the related policy objective, which were considered for assessment.

Table 1. Policies selected for assessment

| Category | Policy proposal | Policy Objective |
|----------------------------------|--|--|
| Search & Substantive Examination | <ul style="list-style-type: none"> South Africa should introduce a SSE system for patent registration, to coexist with the depository system, where patent examination implementation will be supported (at least initially) by departments/universities/research institutions. | <ul style="list-style-type: none"> Curb the incidence of drug evergreening by pharmaceutical companies; and to Reduce the incidence of invalid, trivial patents being granted. |
| Pre- and post-grant opposition | <ul style="list-style-type: none"> The Patents Act should be amended to have both pre- and post-grant opposition to effectively foster the spirit of granting stronger patents | <ul style="list-style-type: none"> Provide opportunity for interested parties to challenge and restrict the granting of weak or invalid patents, without incurring prohibitive costs. |
| Patentability criteria | <ul style="list-style-type: none"> South African legislation should allow strict rules to apply to patenting as competition principles may be undermined. This should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as is the case under the TRIPS Agreement. | <ul style="list-style-type: none"> Curb the incidence of drug evergreening by pharmaceutical companies |
| Compulsory licensing | <ul style="list-style-type: none"> Compulsory licensing should be introduced in South Africa in line with international treaties, such as the Doha Decision 6 of the WTO negotiations on Trade and Public Health. Apply investment standards for the protection of IP asset of investment, in particular for a compulsory licence in determining public purpose; South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health. | <ul style="list-style-type: none"> To improve the application of compulsory licenses, both in terms of process and cost |
| Parallel importation | <ul style="list-style-type: none"> South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health. South Africa should facilitate in its legislation the ability to import patented products if it can get them cheaper in other jurisdictions (parallel importation). Parallel importation of IP can also be made at a regional arrangement and, in this regard, South Africa may wish to influence regional integration for the purpose of access to medicines | <ul style="list-style-type: none"> To make the process more practical through legislative definitions and clarification such that public healthcare is improved |
| Copyright flexibilities - Berne | <ul style="list-style-type: none"> To enhance access to copyrighted materials and achieve developmental goals for education and knowledge transfer, South Africa must adopt pro-competitive measures under copyright legislation. The legislation must provide the maintenance and adoption of broad exemptions for educational, research and library uses. | <ul style="list-style-type: none"> The amendment of the Copyright Act through the adoption of Berne and TRIPS exceptions and limitations for the public benefit. |

| Category | Policy proposal | Policy Objective |
|---|---|---|
| | <ul style="list-style-type: none"> <i>The amendment of the Copyright Act to through the adoption of Berne and TRIPS exceptions and limitations for the public benefit.</i> | |
| Implementation of WIPO Internet Treaties | <ul style="list-style-type: none"> <i>The WIPO Internet treaties must be viewed in the context of the country's needs and requirements.</i> <i>South Africa internet users must be entitled to fair use rights such as making and distributing copies from electronic sources in reasonable numbers for educational and research purposes and using reasonable excerpts in commentary and criticism.</i> <i>South Africa should consider carefully before acceding to the WIPO Copyright Treaty and should not follow the path of the US Digital Copyright Management Act (DCMA) and EU (database Directive) as these instruments are restrictive and, therefore, bad models for copyright legislation of a developing country like South Africa. The DCMA and EU Directive restrict the number of downloads, whether for commercial or personal/research use...</i> | <ul style="list-style-type: none"> The WCT and WPPT should be implemented by the amendment of the Copyright Act and the Performers Protection Act Copyright Act and the Performers Protection Act should be amended so that exceptions and limitations and a general fair dealing provision extend to use of digital works. Anti-circumvention provisions should not prohibit access to works or preclude users from relying on exceptions and limitations to copyright that are otherwise available |
| Adoption of other International Treaties on IP Rights | <ul style="list-style-type: none"> <i>Parliament has approved ratification of the Madrid Protocol for the International Registration of Marks and the Hague System on the International Deposit of Designs.</i> <i>South African enterprises should be assisted to register their trademarks nationally and internationally where they have a footprint.</i> | <ul style="list-style-type: none"> The adoption of the International Treaties to enhance South Africa's IP system including: <ol style="list-style-type: none"> The Marrakesh Treaty The Hague Agreement The Lisbon Agreement The Madrid Protocol The Beijing Treaty |

Information on the selected proposals was gathered through the following methods:

1. Reviewing of all **the dti's** papers and existing research
2. Reviewing of other secondary literature
3. Reviewing of public comment submissions
4. Reviewing of relevant international experience
5. Conducting stakeholder consultation (see Appendix B for detailed list)

The comparative case studies were chosen either because they are high profile examples with particular lessons for the South African context, or have tested a policy proposal discussed to reveal relevant arguments for and / or against the proposal.

As noted in the preceding section, the assessment did not follow the process of a traditional RIA. A more traditional RIA is done ex-post, or before a policy is due to be implemented. In this instance, the option of doing nothing was limited due to the status quo of the legislation – in some cases the policy has already been accepted and in others there are legislative accommodations in place already.

To assess the impact of the selected policy proposals in the Draft Policy, a cost benefit analysis was conducted. After stakeholder groups were identified, the associated economic, distributional and social effects of the selected proposals in the Draft Policy were analysed. Where possible, the costs and benefits have been quantified in Rand terms; in most cases it is possible to provide a qualitative cost-effectiveness assessment that relies on research with industry stakeholders, economic theory and common sense. Relevant alternatives were also identified based on engagement with key stakeholders and consideration of international practice.

Based on the findings of this analysis, a framework was applied to evaluate the policy proposals and determine the appropriate recommendation. The framework is included in Appendix B but the logic in each step is detailed here.

The framework is used to reach a policy conclusion by (i) confirming the policy as a being able to achieve the policy objective and (ii) weighing up the probability of the critical success factors and severe risks.

Step 1: Theoretically, can the policy objective be met through the proposal?

This step is necessary to determine whether the policy proposal alone is sufficient to meet the policy objective as interpreted. In some cases, the proposal may be successfully initiated and implemented but the policy objective may go unmet due to other external factors. These elements are noted where possible.

Step 2: What is the probability of critical success factor being secured?

In this step it is assumed that all prevailing external conditions will remain constant. Those factors which have been identified through a literature review, international case studies, stakeholder interviews and commentary submissions are analysed in this section. Critical success factors are those without which the policy proposal will fail to meet the objective successfully. The probability that each of these factors is able to be guaranteed going forward

is considered to be low, medium or high. Ideally, for a policy to be considered all critical success factors should have a high probability of occurring.

Step 3: What is the probability of severe risks occurring?

Under the same *ceteris parabis* assumption as in Step 2, severe risks are brought into focus in this step. Severe risks are defined as risks with severe, broader, negative impacts that are likely to occur if the proposal is implemented. The probabilities of these occurring are considered to be low, medium or high. Ideally, for a policy to be considered all severe risks should have a low probability of occurring.

Step 4: Can these risks be mitigated?

Where risks in Step 3 are considered medium or high, an attempt has been made to answer whether any mitigation may be carried out. This will inform whether amendments to a policy are required.

Step 5: What is the conclusion on the implementation of the policy?

An overall judgement on the policy proposal in light of the above framework has been with the option to:

- Adopted without changes
- Adopted with revision
- Rejected
- Delayed
- Considered in light of alternative measures

On one end of the spectrum a policy should be rejected if all or most critical success factors are unlikely to be secured and if all or most of the severe risks are very likely to happen. On the other end a policy may be adopted without changes if all or most critical success factors are likely to be secured and if all or most of the severe risks are unlikely to occur. If there are risks which may be mitigated, the policy recommendation may be to adopt with revision or delayed. Alternative measures are considered in light of other proposals and whether there is a possibility of implementing another proposal to achieve the same objective.

It should be noted that the analysis of the focus areas is reflective of the Draft Policy in that an access to healthcare lens is applied. At the same time, the effects of the policy proposals on other industries has been explored and detailed where effects are evident.

The report is structured as follows: Section 2 contextualises the theoretical relationships between IP and economic development, the South African regulatory and governance frameworks; Section 3 assesses each of the selected proposals as per the methodology; and Section 4 briefly examines the inter-relationship between key proposed policies and contains a list of policy issues requiring further attention.

2. CONTEXT

2.1. THEORETICAL FRAMEWORK

The granting of a patent by the state to an IP generator grants the owner the exclusive right to benefit from and commercialise on this innovation. In exchange, the owner fully discloses the novel details of this innovation in the application such that on expiry, it is available for public use. This is the delicate balance of intellectual property between encouraging innovation and promoting access to information.

The definition of a strong IP system framework is defined as one with:

- A high quality of knowledge that can be owned as property,
- Owners that have greater rights relative to users of IP, and
- Lengthy but effective duration of property owners' rights.

In addition, the strength of intellectual property rights depends on three attributes:

- *Duration*: measured in years from the date of the filing of an application
- *Breadth*: this quality is easier to order than measure. For example, a patent covering rain gear is broader and covers more IP than a patent covering umbrellas.
- *Remedy*: acting within the scope of a patent or copyright without a license from the owner infringes it. It is usually the law that provides a remedy for infringement.

Taken together, the duration and breadth of an intellectual property right define the patent scope. An overly protective IP system reduces the ability to disseminate information and limits social gains while an excessively weak system fails to provide adequate returns on the owner's investment and thus reduces innovation.

Relationship between IP and economic development

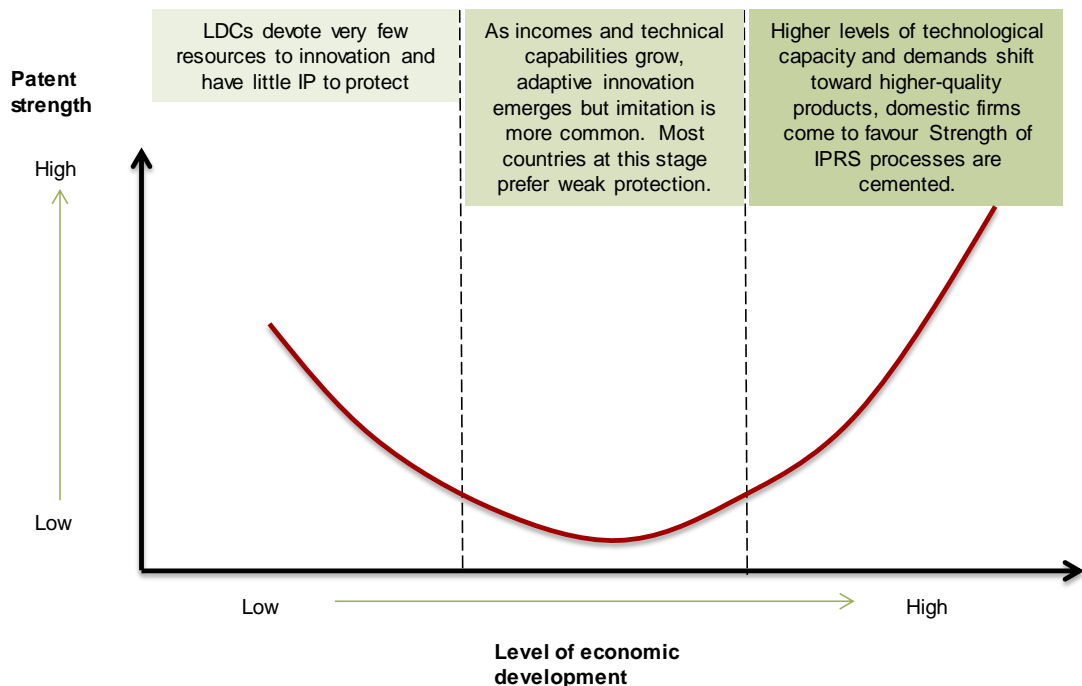
The relationship between the nature of an IP regime and the level of economic development in a country is deemed endogenous by the literature.³ The IP regime of a country, through channels of innovation, productivity, trade, FDI in various sectors, has the power to change in the level of economic growth. The choice of an appropriate national regime of IP protection is also dictated by the level of economic development. The former is the more debatable of the two paths.

When considering how the level of economic development affects the choice of IP regime, the literature states quite clearly that the choice or design of a national IPR regime is not formulaic in terms of a country's level of economic development. It is however stage dependent - at an early stage of development, the country implements weak IPR protection to facilitate imitation while at a later stage of development, the country implements strong IPR protection to encourage domestic innovation. In improving their IPR systems, developing countries may also make use of technical assistance from US government agencies and international organisations such as WTO and WIPO.

³ See Maskus, K.E. (2000), Intellectual property rights and development, "Beyond the Treaties Symposium"

Figure 1 below depicts the converse relationship of how the level of economic development in a country affects the IP regime that is chosen / developed. The strength of patent rights first falls as incomes rise from their lowest levels. With a lack of resources, a lack of innovation and ability to enforce IP laws makes a strong system unnecessary and unattainable. IP strength then reaches a minimum at some intermediate income level and patent laws are strengthened as development proceeds. During this intermediate phase, human capital is also improving, increasing the ability for domestic innovation. The strength of patents then seems to accelerate at high income levels as enforcement become efficient. Also, at this stage innovation results from research rather than imitation, thus requiring higher levels of protection to recoup higher costs of innovation.⁴

Figure 1. Strength of IP regime vs. level of economic development



Source: Chen, Y., T. Puttitanun, *Intellectual property rights and innovation in developing countries*, *Journal of Dev. Econ*, 2005

In comparing developed and developing countries by the industries that contribute the most to GDP the following observations around IP regimes have been made:

- **Agriculture:** agricultural research in developing countries is commonly publicly-funded which decreases the need for a strong IP regime. (Privately-funded research in developed countries requires stringent IP laws for added innovation incentives)
- **Manufacturing:** developing countries often engage in more labour-intensive manufacturing activities which are less in need of innovation than the capital-intensive activities of developed countries.
- **Services:** in most developing countries the access to technology is limited, reducing the need for the strong IP protection. South Africa, India, China and Brazil are notable exceptions with established services sectors.

⁴ Maskus, K.E. (2000), Intellectual property rights and development, "Beyond the Treaties Symposium"

In contrast, the effect of an IP regime on economic development is less clear. The significance of intellectual property rights in economic activity depends on the amount of resources countries devote to creating intellectual assets and the amount of protected knowledge and information used in production and consumption.

In developing an IP system, countries should consider both domestic and international IPR regimes / laws (e.g. TRIPS Agreement). The literature also recommends that some sectors should be focused on given that they are more affected by a national IP regime than others e.g. pharmaceutical, agricultural, services industries

The design and implementation of an IP system in developing countries, in particular, often has the following objectives at their core:

- Development of local innovation
- Increased flows of technology
- Increased trade and FDI
- Promotion of competitive markets
- Enhanced access to health and education

In the Draft IP Policy, **the dti's** position supports a favourable IP system that is able to promote incremental innovation. The policy states that:

- *Intellectual property rights (IPRs) involve **complex incentives and potentially have great social consequences**, especially for developing countries.*
- *Government policies on IPRs are aimed at **overcoming market failures** and, hence, promoting technological development and innovation.*
- *IPRs give innovators the exclusive right to derive material benefits from their creations as a **reward for intellectual effort and research expenses**.*

2.2. REGULATORY FRAMEWORK IN SOUTH AFRICA

South Africa's IP regime shaped by domestic law and set against an international arena of frameworks to which South Africa is signatory.

The **two main components of IP are copyright and industrial property rights regulation**. As such, the domestic legislation currently governing South African IP comprises Copyright law and Industrial property law, which generally include patents, trademarks and designs.

The Cornerstone Acts governing IP law in South Africa include:

- Copyright Act No. 98 of 1978
- Patents Act No. 57 of 1978
- Trade Marks Act No. 194 of 1993
- Designs Act No. 195 of 1993
- Performers Protection Act 1967

- Intellectual Property Laws Amendment Act 28 of 2013
- Counterfeit Goods Act 37 of 1997
- Registration of Copyright in Cinematograph Films Act 62 of 1977
- Merchandise Marks Act, No. 17 Of 1941
- Intellectual Property Rights in Publicly Financed Research and Development Act 51 of 2008

The administration of rights was incorporated in the Companies and Intellectual Property Registration Office (CIPRO), formed in 2002, which has now been incorporated into the Companies and Intellectual Property Commission (CIPC).

Further to the IP legislation outlined above, the South African IP regime is framed by the several policy and strategy documents. These include:

- The proposed IP policy framework put forward by the dti
- South Africa's National Research and Development Strategy (2002)
- The OECD's review of South Africa's innovation policy (2007)
- Report of the Ministerial Review Committee on the Science, Technology and Innovation Landscape (2012)
- South African Innovation Survey (2008) by Human Sciences Research Council and the Department of Science and Technology

In the global context, South Africa is a member of most international IP treaties, including the Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement); Paris Convention for the Protection of Industrial Property; Patent Cooperation Treaty (PCT), and the Budapest Treaty on international recognition agreement of the Deposit of Microorganisms and the Berne Convention for the Protection of Literary and Artistic Works 1886; Marrakesh Treaty; Rome Convention; Madrid Act and Protocol; Hague Agreement; and Beijing Treaty. South Africa has signed but not implemented the WIPO Copyright Treaty and the WIPO Performance and Phonograms Treaty.

2.3. GOVERNANCE BODIES

The effective governance and enforcement of IP regulation in South Africa is overseen by multiple regulatory bodies, given the far-reaching relevance and scope of IP. The major entities in the current South African landscape are listed below:

- Competition Commission
- Competition Tribunal
- National Advisory Council on Innovation (NACI)
- Council for Scientific and Industrial Research (CSIR)
- National Intellectual Property Management office (NIPMO)

- Technology Innovation Agency (TIA)
- Medical Research Council (MRC)
- National Consumer Commission

3. ASSESSMENT OF PROPOSALS

This section assesses the selected proposals from the draft IP policy, outlined in the methodology section above. The draft IP policy is, at times, unclear about the policy objective of stated proposals. In the case of ambiguity, this report provides an interpretation of the policy objective based on consultation with **the dti** and industry stakeholders.

3.1. SUBSTANTIVE SEARCH & EXAMINATION

3.1.1. Policy proposal

The draft IP policy proposes that cabinet approve the establishment of an SSE system for patent registration to coexist with the current depository system of patent registration, in order to have strong technologies.⁵

It is proposed that South Africa adopt a multifaceted approach in as far as registration of patents is concerned; that is, use the depository (registration), SSE and the utility patent systems.

The draft IP policy asserts that Government must co-ordinate departments/ universities/ research institutions that have competencies in evaluating patents and must be involved in kick-starting the patents evaluation process.

A cost and benefit analysis should be conducted through the Regulatory Impact Assessment (RIA) process and benchmarks should be based on similar economies such as India, Brazil and Egypt. In this regard, benefits should not only be calibrated in monetary terms as access to public health does not necessarily translate into monetary value.

3.1.2. Status quo

Depository system:

The South African Patents Office uses a depository patent registration system. A patent is 'examined' by the Registrar for formality requirements only. If the patent application complies with the formalities prescribed in the Patents Act 57 of 1978 it is accepted for registration. The application is filed with the CIPC and a written notice of the acceptance is issued within 18 months from the date of filing. No formal examination takes place to assess whether the technology meets the criteria for patentability, namely, novelty, non-obviousness and industrial applicability. It is presumed that a registered patent is valid.

After a patent is granted, there is a nine-month moratorium during which the patent may not be enforced. At a later date, the patent may be enforced should it be infringed upon. A patent's validity may be challenged. For the patent to be revoked, the onus is on the challenger to prove the allegations of invalidity. The costs associated with determining validity are therefore incurred after the patent is granted, and are borne by the courts, patent holders and third parties.

⁵ The Draft Policy is not clear on the form of implementation of SSE. This report does not specifically investigate the impact of a co-existing depository system and SSE system, as it is understood that the intention of the policy proposal is to shift entirely to the SSE system over time. This report examines the merits and demerits of an SSE system, based on theoretical analysis and drawing on case studies. The effects of implementing an SSE system are analysed in relation to the major affected stakeholders.

In the absence of an SSE system, the patent holder weighs the enforceability of a patent prior to litigation to enforce the patent. Resources are therefore not spent examining a patent of little value (commercial or otherwise), which is unlikely to be enforced.

Until such time as a patent is either enforced or challenged in court, the strength⁶ of the patent is uncertain in the current system. In the absence of SSE of patent applications, 'weaker' or low-quality patents may be granted. Consequently, South Africa also grants a much high proportion of patent applications relative to other developing countries that examine patent applications prior to grant, as shown on the table below.

Table 2. Number of applications per office (2012):

| Country | Total | Total Grants | % |
|--------------|---------|--------------|-----|
| Brazil | 30,116 | 2,830 | 9% |
| China | 652,777 | 217,105 | 33% |
| India | 43,955 | 4,328 | 10% |
| Kenya | 259 | 76 | 29% |
| South Africa | 7,444 | 6,205 | 83% |

Source: WIPO Statistics Database, October 2013

Patent registration is handled by a patent attorney on behalf of the applicant. Only a patent attorney may sign the complete specification of a patent application. This is in an iterative process during which the patent attorney will conduct a search of the prior art and craft the patent application accordingly. The patent holder is responsible for renewing the patent and renewal is subject to annual renewal fees, beginning from the expiry of the third year from the date of filing.

“Indirect/effective” examination:

In terms of section 43(4) and Regulation 46A(3) any third party can request search reports and documents for patents that have been filed and examined internationally after a period of five years from date of application for a patent. This makes South African patents granted vulnerable to claims that are, for instance, too wide in scope in light of examinations in other jurisdictions. South African patent attorneys therefore have an incentive to amend patent filings in South Africa in accordance with the findings of international search and examination procedures. Similarly, the CIPC may delay the acceptance of a patent in South Africa to await the international examination results, thereby fulfilling an indirect examination function. South African applicants may then amend the claims based on this effectively “indirect examination” so that patents granted in South Africa are on par with the protection granted in other jurisdictions.

Filing profile:

- Approximately 7000 patents are filed in South Africa per annum (and an additional 2800 provisional applications are made).⁷
- 8 - 12% of patent applications are filed locally with the CIPC; the balance is filed via the PCT.⁸

⁶ Strength of a patent system refers to the enforceability of a patent when its validity is challenged

⁷ CIPC; A provisional application, describing the invention and informal drawings, may be lodged followed by a complete application 12 months later. If the complete application is not lodged, the provisional application will lapse.

- During 2013, the CIPC granted 54 patents to publicly financed institutions of the 4681 patents granted in total, amounting to 1% of the total patents granted.
- Considering pharmaceutical patents specifically, over 90% of the patent applications filed in South Africa are made through the PCT process.
- There is a high incidence of non-renewal of patents, although this is not uncharacteristic in relation to international norms.⁹

3.1.3. Problem statement and evidence

First, the depository system results in a higher incidence of patents being granted. It follows that low-quality (non-inventive) and invalid patents are being granted since the validity of a patent application is not examined against the patentability criteria. Patents are typically considered the 'currency of technology transfer' since the patenting of an invention necessitates that the particulars of that invention be disclosed, making new knowledge accessible to the public in exchange for the monopoly exploiting the invention related to the disclosed information. However, the patenting of non-inventive technologies will also grant a monopoly to the patentee which may inhibit access to technologies and knowledge that would otherwise be available for public use. The end result is the unfair 'tying up' of non-inventive technologies under patent protection.

Therefore, a high incidence of low-quality and invalid patents may have the consequence of stifling competition in the economy by securing unwarranted market-power to the patent-holder and precluding alternative or new market players from the market.

Evidence:

- **Invalid patents:** 30% of pharmaceutical patents registered in South Africa are found to be invalid in the US and EPO.¹⁰ The effect of registering invalid patents is not clear, as patent registration does not imply that the patent is enforced. But, it is the case that South Africa's patent system contains a sizeable proportion of patents that are not legally enforceable.
- **High incidence of non-renewal of patents:** "A review of renewal patterns of South African patents has revealed that in the 8th year after application only approximately 40% of granted patents are maintained, only 20% by year 15, and less than 10% in the last year."¹¹ On the one hand this statistic may be indicative of the practice of filing multiple patents at the onset of the invention process, as a precautionary and pre-emptive measure, prior to sufficient investigation into the financial (or otherwise) validity of the patent – which if found unviable is reason to let the patent lapse. On the other hand, it may be the result of deliberately filing patents that are not valid and therefore not enforceable, which are hence allowed to lapse when this invalidity becomes obvious.

⁸ "The Patent Cooperation Treaty is a treaty which allows an individual/resident of the member states of that treaty to lodge an application in one office (Receiving Office) and 31 months thereafter the applicant may enter the PCT National Phase in all countries, members of PCT in which he has intention to seek protection. The PCT application is processed through the International Phase and the National or Regional Phase." [Accessed at: http://www.cipc.co.za/Patents_FAQs.aspx]

⁹ Adams & Adams: "A review of renewal patterns of South African patents has revealed that in the 8th year after application only approximately 40% of granted patents are maintained, only 20% by year 15, and less than 10% in the last year."

¹⁰ Sampat et al, 2012, as cited in "The Economic & Social Case for Patent Law Reform in South Africa" by C. Tomlinson & L. Rutter (2014)

¹¹ SAIPL Submission

Second, the depository patent registration system is less effective in preventing drug evergreening practices than a substantive examination patent system. Access to medicine and healthcare in South Africa is a priority concern. Evergreening has the effect of locking up originator drugs under patent protection for an extended period. As a result, generic drug manufacturers are not permitted to enter the market. The extended monopoly rights granted to the originator drug manufacturer means prices remain inflated, since there is no price competition to drive down prices. Access to medicines and healthcare is inhibited in this manner.

Evidence:

- **Incidence of abuse:** See example of evergreening as provided under the “Patentability Criteria” in Section 3.3. It should be noted that patent attorneys argue that there is a low prevalence of evergreening practice in South Africa since the judiciary and court process are proficient in detecting and preventing instances of evergreening. However, the current IP regime has allowed the granting of secondary patents to extend the market exclusivity of multinational medicine patents.¹²
- **Price competition:** South Africa has a relatively well-developed local pharmaceutical industry, comprised predominantly of generic manufacturers. Multinational pharmaceutical companies do not typically manufacture in South Africa. The effect of generic entry to market on the price of originator brand medicine is a lowering of the originator brand medicine price. As the number of generics available on the market increases, the absolute price of originator brand medicines declines.¹³

Third, the draft IP policy asserts that South African patents do not survive the test of *competitiveness throughout the world*.

Evidence:

- This statement is problematic insofar as it stands to justify reforms to the Patent Act. It may hold true that in general South African technologies do not surpass international practice in quality and innovation, but, South Africa has strengths in organic chemistry, engineering (mining), petroleum and biodiversity (plants).¹⁴ It should be noted that stronger patent protection does not ensure that the technology it protects is necessarily of a higher quality or that it provides a significant competitive edge. Nor does the examination of a patent test the economic viability of the patent.¹⁵

3.1.4. Policy objective

The dti asserts that an SSE system would ensure “stronger patents are granted, improving access to health and increasing competitiveness of South African technologies”.

A search report provides the examiner with an initial assessment of whether a technology is absolutely novel, covering all applicable prior art. Search reports also facilitate self-selection of

¹² Business Monitor International South Africa Pharmaceuticals & Healthcare Report - Q2 2014

¹³ van der Merwe Smit, E., & Bredenkamp, J., “Originator and generic medicine: pricing and market share” in *International Journal of Pharmaceutical and Healthcare Marketing* 7.2 (2013): 104-119.

¹⁴ See MacDonald Netshitenzhe: Chief Director: Policy & Legislation, CCRD, the dti “Intellectual Property: Substantive Search and Examination of Patents” presentation at the Intellectual Property Africa 26-27 February 2013, available at http://www.thedti.gov.za/business_regulation/presentations/ip_examination_of_patents.pdf; Notable South African innovations include the CAT scanner, the speed gun, the ‘Kreepy Krawly’, the ‘Dolos’ and ‘Pratley Putty’ are all world-class inventions

¹⁵ UCT submission

applicants out of the patent registration process if they are not certain of the patentability of their invention. A substantive examination scrutinises patent applications against defined criteria, including novelty, inventive step, industrial application, and the disclosure of the best method to implement the invention to ensure that only valid enforceable patents are granted.

Essentially, the intent of the policy proposal is to:

- Curb the incidence of evergreening by pharmaceutical companies; and
- Reduce the incidence of invalid, trivial patents being granted.

With regards to implementation, there is a fair degree of ambiguity around how the SSE will be put in place. Some reference is made to implementation options, including:

- Parallel implementation of the SSE with the depository system;
- Discrimination per sector to phase in the SSE; and
- Making use of human resources from academic and research institutions to create examination capacity.

3.1.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the introduction of the SSE system:

- Generators of IP¹⁶
- Legal system and representatives¹⁷
- Government
- Academia
- Pharmaceutical focus – New Chemical Entities (NCEs or originator drugs) manufacturing pharmaceutical companies
- Pharmaceutical focus – Generic manufacturers
- Pharmaceutical focus – Medical device manufacturers
- Society
- Economy

In addition, the effects have been split between immediate (short and medium term) and broader (long term) effects.

3.1.5.1. Generators of IP: positive if effectively implemented; likely negative.

¹⁶ The draft policy is skewed towards the pharmaceutical industry, but, all industries are affected, including those where South Africa has a competitive advantage and strong local IP content (i.e. in the film and media industry, mining, construction, IT and logistics).

¹⁷ including patent attorneys, judges and the courts

The direction of impact on patent applicants will depend heavily on the outcome of implementation of the proposed SSE. Patent applicants will face higher costs associated with the SSE system than currently faced with a depository system. The SSE provides applicants with greater legal certainty over the validity of patents granted. Even if the SSE is effectively implemented, the more inquisitorial process will extend the time period from the date of lodging an application to it being granted.

If effective implementation is guaranteed the SSE is likely to result in a higher quality patent system, where patents granted will be viewed as strong and are more likely to be found valid if challenged. If poorly implemented, the credibility of the patent system will diminish. The risks of implementing an SSE system without capacity or resources to ensure its efficacy are detailed in the section below on costs.

3.1.5.2. Legal representatives: Likely positive.

The depository system currently places the responsibility on the legal system to determine and enforce the validity of a registered patent. Moreover patent attorneys are required to file claims on behalf of the applicant registering a patent. The introduction of an SSE system will shift the responsibility away from the courts system to that of the examination office. However, patent attorneys will still be involved in the iterative process of patent filing and will interact with examiners through this process. The burden of drafting patent claims is likely to increase as well as the workload but this will raise the commercial gains to legal representatives. Further, disputes that arise in the SSE process may still be escalated to legal proceedings. In order to realise these gains, legal representatives will have to incur the costs relating to the implementation of SSE- specific training.

In broader terms, if the SSE is effectively implemented, the stronger patent system that results will incentivise an increase in patent applications and this will in turn positively affect legal representatives. If, in contrast, the patent system is inadvertently weakened by unforeseen delays to the patent registration process as a result of ineffective implementation, and the credibility of the patent system diminishes such that inventors are disinclined to apply for patents, legal representatives may be negatively affected by a loss of business.

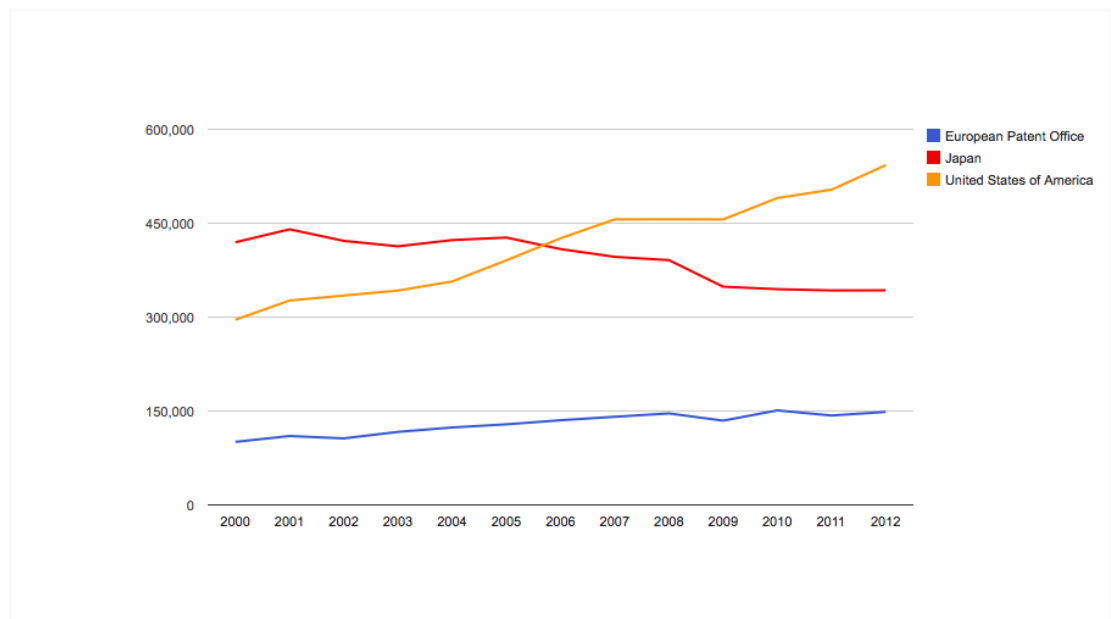
3.1.5.3. Government: likely negative.

The costs of implementation borne by government are high, both in the establishment – which requires the costly development and implementation of systems, and human resource skills development and training – and operation of the examination office. But, if fees are transferred to applicants, the office could be financially self-sustaining. If the SSE is effectively implemented, the examination of a patent application on substantive merits will facilitate the enforcement of high patent standards to reduce the incidence of low-quality patent registrations (that protect inventions of limited inventiveness). A higher quality examination process should deter applicants to apply for the registration of patents for technologies that do not clearly meet the patentability criteria. This will result in fewer applications being lodged.

At the same time, there is an opposing force at work: the enhanced credibility of the patent system is likely to encourage patent applications to be made. Overall, the volume of applications lodged will be determined by whichever of these implications has greatest effect. Empirically, the number of applications lodged has tended to rise in the US and the EU and decline in the case of Japan, but there may be multiple drivers behind these statistics. The

table below shows the total patent application trends for the European Patents Office, and the offices of the United States and Japan.

Graph 1: Total patent applications (direct and PCT national phase entries)



Source: WIPO, 2013

In the longer term, the SSE requires continuous reinvestment in skills and systems, which is costly to government. There is a considerable reputational risk if South Africa fails to implement the SSE effectively. Nonetheless, a number of prominent developing countries have moved towards SSE systems in place of depository systems and South Africa would therefore be on a par in IP protection by introducing an SSE system.

3.1.5.4. Academia: Likely negative

(In the event that academics from existing tertiary education institutions provide examination capacity).

It is not feasible to expect that academics can staff the proposed SSE without there being negative implications for the already under-resourced tertiary institutions in South Africa. Moreover, issues of conflict of interest are certain to arise since academics are not necessarily independent parties, due to the likelihood of the same academics being generators of IP in their own right. Entrusting an academic with examination rights may result in biased, preferential or discriminatory treatment in the granting of patents.

In the longer term, if government seeks to address the shortage of skills by investing in building the requisite skills, academia would benefit from the support and increased demand.

3.1.5.5. Pharmaceutical focus – NCE manufacturers: likely negative.

The effective implementation of an SSE system would result in a higher quality patent system in so far as fewer invalid patents are granted. This enhances the credibility of the system and is likely to encourage innovation, as inventors are incentivised by the security of protection of rights. However, if the SSE implementation results in extensive delays to registration as a result of backlogs in applications' examinations, the period in which an inventor can recover

the costs to the invention – through proprietary sales – is shortened and the incentive to invest in research and development is diminished.

In the long run, if effectively implemented, the SSE provides greater legal certainty to NCE manufacturers and improved business confidence. If, in contrast, the SSE system is poorly implemented, the credibility of the patent system will diminish which may disincentivise innovation.

3.1.5.6. Pharmaceutical focus – Generic manufactures: likely positive.

To the extent that the depository system allows for evergreening practices, more so than an SSE system, the implementation of an SSE system will benefit generic manufacturers by reducing this practice. Implications associated with extensive delays to patent registration will however impact generic manufacturers similarly to originators manufacturers in a negative manner.

3.1.5.7. Pharmaceutical focus – Manufacturers and producers of medical devices: likely negative.

Delays to the patenting process may be greater than the lifespan of the medical device. In the absence of an appropriate regulatory framework (which is unlikely before 2014/15), a more inquisitorial system preceding the granting of patents will jeopardise production and the South African medical device manufacturing industry.

3.1.5.8. Society: positive if effectively implemented; likely negative.

The implications to society will likely be felt in the longer term as the patent system is reformed by through the introduction of an SSE system. Barriers to access of unaffordable medicines will be removed as the SSE system only grants patents that are inventive and novel. This is a positive impact to society. Consumers are also provided with greater product variety at lower prices as a result of increased competition. In contrast, if the SSE is poorly implemented, innovation and competition will be hindered. An important consideration with far-reaching effects is the impact that staffing the SSE with academics from under-resourced academic institutions will have on the education system. The brain drain that results from drawing academics away from posts in academia will compromise the education system.

3.1.5.9. Economy:

Effect of SSE system on Competition: positive if effectively implemented; likely negative.

It is presumed that to the extent that the SSE results in fewer low-quality patents being granted, competition would be positively affected. Access to knowledge / technologies is improved when low-quality (undeserving) patents are limited. Competition between manufacturers of alternative originator companies and between originator and generic companies therefore improves. However, if the SSE is poorly implemented, competition will be thwarted.

Small and medium enterprises may face disproportional costs to patent registration. If the increased costs of an SSE system are transferred to applicants, without preferential pricing options, the majority of South Africans will be precluded from IP protection as a result of prohibitive fees.

Effect on Manufacturing in SA: likely negative.

A stronger patent system will enhance innovation, as is delineated in Section 0 above. The increased innovation will promote South African manufacturing output in industries in which South Africa has (competitive) domestic manufacturing capabilities, for instance in the production of mining equipment. In contrast, if the SSE is poorly implemented, industries in which South Africa already has high levels of production and a competitive advantage will be jeopardised in the long run (as a result of diminished incentive to innovate). In the case of pharmaceuticals, South Africa relies largely on imports to meet local demands for medicines. Aspen Pharmacare and Adcock Ingram are the largest local pharmaceutical manufacturers of generics. Of the international companies, Pfizer, GlaxoSmithKline and Sanofi have local manufacturing facilities.¹⁸ A stronger patent system will not necessarily enhance domestic manufacturing of pharmaceuticals since the IP regime is only one consideration in the strategic decisions of whether to manufacture in South Africa.

Effect on Foreign Direct Investment (FDI) and Trade: likely negative.

FDI and exports will be deterred if the SSE system results in extensive delays, which shorten the time to recover R&D spend. In contrast, South Africa will require fewer imports if the SSE system strengthens the patent system, leading to greater competition and productivity of domestic industry. South Africa is increasingly seen as a platform for entry into other sub-Saharan African markets and therefore an attractive destination for FDI, which would be encouraged by a stronger patent system. If the positive effects on competition are strong enough, South Africa's pharmaceutical trade imbalance will diminish.

3.1.6. Assessing benefits / pros

1. ***Reduction in number of invalid patents and reduced incidence of abuse:*** The SSE system subjects patent applications to an assessment against a set of patentability criteria when the application is made. As a result, the incidence of granting invalid patents is lowered. The potential to register an invalid patent deliberately or to register frivolous claims is reduced since such patents are unlikely to be found eligible for patenting through the substantive examination.
2. ***Enhanced IP protection and innovation:*** In the long term, SSE may be beneficial to South Africa in terms of IP protection and innovation. The SSE system reduces the number of invalid patents granted. A stronger IP regime, defined by a lower incidence of invalid patents granted, may incentivise R&D spend since the patent provides to the patent holder a monopoly over the use of the patented technology and allows for costs to be recovered. Greater R&D spend is typically associated with increased innovation. However, a stronger IP regime does not necessarily ensure that the quality of the technology under patent is superior. There are examples of weak IP regimes associated with high levels of innovation, such as in China. Nor is it necessarily the case that stronger IP protection is enough to incentivise high R&D spend since developing countries like South Africa constitute small markets for profitable drugs/technologies.
3. ***Fewer barriers to access to medicines:*** The barriers to access to medicine extend beyond that of IP protection. However, the strength of an IP regime is one factor that may advance or inhibit access to medicine. If, through strengthening the IP regime –

¹⁸ Business Monitor International South Africa Pharmaceuticals & Healthcare Report - Q2 2014

by raising the standard for innovation – only drugs that are inventive are patented, such that patent protection serves to reward R&D investments only and not to retard competition and obstruct market forces that drive down prices, then access to medicine will be advanced through the implementation of the SSE system.

4. **Reduction in the costs of future litigation:** By ensuring that only valid enforceable patents are granted, the effective implementation of an SSE system results in fewer instances where a patent's validity is necessarily challenged through litigation. In this way, the SSE is associated with fewer litigation costs down the line than is so in a depository system. In the case pharmaceuticals, legal representatives estimate the cost of a litigation case at ZAR 2-3million per case.
5. **Establishment of an International Search Authority (ISA) in South Africa:** There is an opportunity to position South Africa as an international search authority and regional examination hub. South Africa may have enough science and engineering graduates to implement an SSE system but this is not sufficient to become a credible ISA. To improve the technical quality of patents, South Africa would need also to develop regulations and manuals to instruct the manner in which patentability criteria should be applied in different cases internationally.¹⁹

3.1.7. Assessing costs / cons

1. **The efficacy of an SSE system may not be superior to the depository patent registration system:** The Draft Policy does not consider the advantages and disadvantages of the current depository system. The nature of the current system is arguably such that it combines the best of the deposit system and examination system and therefore renders the introduction of merit-based examination unnecessary and an unjustified expense. Examination is currently conducted prior to litigation in large commercial cases so no resources are wasted examining less commercially viable applications. If the practical considerations of implementing an SSE are overlooked, its efficacy will be neither guaranteed nor likely.

In addition, in 1978, it was decided against establishing an SSE in the Patents Act. The reasoning behind this has not been explored or provided in the Draft Policy and should be considered.

2. **If not adequately capacitated the efficiency of the SSE system will be compromised:** Several stakeholders have raised concerns over the likelihood of extensive backlogs for applications that may result from implementing an SSE, particularly if implemented in conjunction with the depository system. The Draft Policy overlooks practical considerations including long delays. The SSE system necessarily increases the time to review and grant a patent application. If the requisite support is not in place to conduct this procedure, backlogs build up, causing extensive delays. For instance, in Brazil the application backlog is about 8 years.²⁰ Delays in the process of examination further complicate the assessment of patent applications against the patentability criteria: when a patent application is examined, the non-obviousness of the patent must be assessed retrospectively for the time at which the patent was filed. The effect may be to snowball delays.

¹⁹ UNCTAD Submission

²⁰ NIPRO submission

Drawing on South African experience, the CIPC has struggled in its endeavour to digitise registrations. Switching from a depository system to an SSE system may face similar challenges resulting in inefficiencies or a non-functioning system.

3. **South Africa has limited capacity for implementation and management of an SSE system:** Introducing a substantive patent examination system requires large investment in human and financial resources. In Brazil, a team of 700 technical staff is used to carry out the search and examination process, and the average period used for the SSE of a patent application is 10 years.²¹ South Africa has a quarter of the number of patent applications than that of Brazil, so an estimated 150 technical people, at least, will be required to implement an SSE in South Africa. It is optimistically held that South Africa has enough science and engineering graduates to implement an SSE.²² But, the substantive examination of patent applications requires highly qualified examiners and their training requires time and financial means. South Africa does not currently have the adequate skills to search beyond the first sub-class of a patent.

Even if South Africa is able to staff the SSE by “buying in” the academics according to demand, there are important concerns over the independence of the examiner. South African universities are highly entrepreneurial and compete in technical fields. Thus, using university resources as examiners may result in conflicts of interests and ethical complications.

Despite the lack of capacity, it is argued that the CIPC has an obligation to examine patent applications for patentability. To this end, an SSE could be implemented in phases but there are risks associated with discriminating against select industries. Discrimination in this regard may be found to contravene the commitments of WIPO and, furthermore, may not be constitutionally permissible in South Africa. An expanded view of the potential to differentiate across technologies is provided below.

4. **The cost of implementation of the SSE system is high and may not offer satisfactory ‘value for money’:** Given the magnitude of patents filed with no economic value, developing countries are cautioned against committing too many resources to ensuring high-quality examination. Rather, it is argued that patent litigation is typically associated with high-value patents and is therefore appropriately dealt with by the courts.

The current depository system has an operating cost of R14 million per annum. The costs of implementing an SSE system in South Africa will be additional to the depository system costs. There are several costs to consider:

- **Operational costs:** A South African examination office will not have the benefit of economies of scale given the relatively small volume of patents filed in South Africa. This means that overtime, South Africa is unlikely to see diminishing operational costs. There is a minimum examination infrastructure that South Africa will need to establish for the SSE system, but the low volume of patent applications will result in a low caseload per examiner, in comparison to examination officers in larger jurisdictions. In addition to the costs of establishing computer systems and infrastructure, there is a cost associated

²¹ SAIPL submission

²² UNCTAS submission

with accessing international databases and scientific journals, amounting to about ZAR 10million per annum. This makes an SSE system in South Africa more costly in comparison to the depository system.

- **Litigation costs:** Although the SSE shifts the responsibility to the examination office and away from the courts to determine patent validity, it is noted that examination often involves a dispute, associated with litigation costs. This is because TRIPS provides for a judicial review if the decision of the examination is to decline a patent.
- **Resource costs:** Training costs and employment costs must be considered when costing resources for an SSE system. It is estimated that the South African Patents Office will require a minimum of 150 examiners, as a proportional estimate based on the Brazilian case. It is possible for a qualified examiner to conduct a search so it is not necessary to employ searchers separately. It costs approximately ZAR 1 million per person per annum to train an examiner. This amounts to a capital outlay of about ZAR 150 million in training costs. The CIPC asserts that it is possible to offset training costs through a free or reduced training fee arrangement with WIPO and several leading international IP offices that provide training programmes for search and examination. Through this arrangement 20 resources can be trained per annum, in situ. It will therefore take close to 8 years to up-skill 150 resources. Additional training costs thereafter will depend on attrition rates and professional development targets. The CIPC expects the number of examiners required to operate the SSE to remain constant for another 50 years.

In the examination office, salaries begin at approximately ZAR 700,000 per annum for a searcher (while gaining seven years' experience) and increase to approximately ZAR 1.5 million per annum for an examiner. If an additional 20 examiners are employed per annum, the annual salary cost will increase by ZAR 30 million. With 150 examiners employed, total salary costs will amount to ZAR 225 million per annum. If resources are too thinly stretched, the quality of patents granted may suffer.

The costs of implementation of the SSE may be reduced by differentiating across technologies. If the SSE is only applied to a selection of technologies and class of invention, then fewer examiners will be required to operate the SSE. Costs will be proportionately less, depending on the number of patent filings in the selected technology and class of invention. The capital lay-out for access to databases will not be affected.

- **Costs to the applicant:** The cost to the applicant of switching from a depository system to an SSE system will depend on whether costs are transferred to the applicant or absorbed by government. South Africa is currently a relatively low cost patent system. Under the current regime, patent applicants incur a fee of about ZAR 600 plus legal fees (approximately ZAR 15 000 according to legal representatives). With an SSE system, the cost to the applicant will depend on how the SSE is structured. If examination is outsourced this will cost about EUR 1000 (ZAR 10,000)²³ per application plus legal fees if any amendment to the application claim is required. In the case of

²³ Based on CIPC estimations

extensive backlogs, applicants bear another cost since uncertainty over the validity of claims takes longer to be resolved and this has cost implications.

- **Value for money:** In so far as a search function is concerned, there is doubt about whether the costs of resources to perform this function are justifiable: of the annual average of 7000 patent applications, 6000 are filed through PCT and therefore undergo some search process already. Introducing an SSE in South Africa would hence ensure that the outstanding 1000 patents undergo a search procedure too, at cost to the government or applicants if the cost is transferred.
5. **Upholding national standards may limit cross-border facilitation:** The outsourcing of SSE functions may not be feasible if standards differ across jurisdictions.²⁴ Mutual recognition arrangements are becoming increasingly popular globally. Offices can share a common search report which identifies relevant prior art, but, the decision on whether to grant a patent will differ according to national law.²⁵
 6. **SSE is not a tool to enhance global competitiveness of South African Technology and may hurt local competition:** With the SSE system in place, patents granted are more likely to be valid and hence less easily challenged. However, patent strength does not translate into higher quality of the technology under patent protection. The global competitiveness of South African technology is not enhanced through patent protection. Locally, there may be a negative effect on competition in the absence of an SSE system as low-quality or invalid patents are granted, making access to technology increasingly difficult. Large organisations that can afford to register and enforce multiple patents exclude parties that cannot afford to challenge the weaker patent or to purchase a license of use from exploiting technology-dependent opportunities.²⁶

Even if an SSE system is implemented, there may be a negative effect on local competition as a result of backlogs to the application grant process. Backlogs may delay or deter other innovators from inventing. Further to this, if product variety is compromised as a result of delays, competitors and consumers may incur increased additional costs.²⁷

7. **The introduction of an SSE system may result in discriminatory practices:** If the SSE system considers and treats technologies from sectors or industries in the economy differently, this may be deemed discriminatory.²⁸ Furthermore, if delays in the patent application grant process affect one sector or industry and not another, this may be viewed as discriminatory. The TRIPS Agreement allows for differentiation in order to enhance access to products however prohibits discrimination across different fields of technology. It may be argued, given that patent protection has different market and socioeconomic implications for different technologies, that treating technologies differently is not tantamount to discrimination. In fact, to prevent discrimination,

²⁴ Third World Network submission

²⁵ Ragavan, S. (0012). *Patent and trade disparities in developing countries*.

²⁶ Stellenbosch commentary

²⁷ Ragavan, S. (0012). *Patent and trade disparities in developing countries*.

²⁸ "The TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability." [Accessed at http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm].

different treatments may be necessary to 'level the actual conditions of competition across all fields of technology'.²⁹

It may therefore be permissible to phase in the implementation of the SSE system per industry. Article 1.1 of the TRIPS Agreement requires members to give effect to the provisions of the TRIPS Agreement. Article 1.1 provides that members shall be free to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice. It is generally understood that the international legal framework leaves countries much room to manoeuvre in introducing any particular approach to prior art search and examination by their patent offices. There are options to construct search and examination systems (such as a depository system only, a depository system combined with a prior art search, or SSE) and various ways to operate search and examination work in patent offices, including search and examination in cooperation with other offices.³⁰ The choice of a search and examination system to be adopted in South Africa should be in line with South Africa's economic, social and public policy objectives and should ideally evolve with time. In this context, the Patents Act should maintain certain operational flexibilities in line with national strategic goals and progressive development policies. In this regard a phased-in approach to search and examination of patent applications would be preferable given South Africa's skills scarcity and national priorities of food security and access to health care.

If pharmaceuticals are considered to have always had a discriminatory limitation of term of protection (related to regulatory approval) there may be grounds to differentiate the pharmaceutical industry from other fields of technology, initially if the search and examination process and the regulatory approval processes are conducted simultaneously. The staggered approach to the implementation of the SSE may result in legal action and objections both nationally and internationally. If found to be unconstitutional or contrary to South Africa's international obligations, discriminatory practices with reference to SSE for specific fields of technology will be disallowed. This will bar the staggered implementation and efficacy of the SSE system. According to our research the staggered implementation of an SSE system is not in breach of article 27.1 of the TRIPS Agreement.

3.1.8. Application of analysis framework

To analyse the aforementioned effects on the various stakeholders, recommendations are formed using the framework described in Section 1.3.

Theoretically, can the policy objective be met through the proposal?

The dti hopes to strengthen the patent system through the introduction of the SSE. It is presumed that stronger patents will be granted, access to health will improve (by curbing the incidence of evergreening practices by pharmaceutical companies) and the competitiveness of South African technologies will increase.

²⁹ Accessed at http://www.ip.mpg.de/files/pdf3/Patent_Declaration_en.pdf

³⁰ CDIP/7/3 "Patent-Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels – Part II", Chapter V
http://www.wipo.int/meetings/en/details.jsp?meeting_id=22102; SCP/20/8 "Work-sharing Programs among Patent Offices and Use of External Information for Search and Examination"
http://www.wipo.int/meetings/en/details.jsp?meeting_id=30925

If the SSE is effectively implemented, with adequate preparation in terms of designing an implementation strategy, formalising the examination guidelines, and ensuring all requisite skills, systems and processes are put in place, the quality of South Africa's patent system will be enhanced.

It is not correct to assume that an effective SSE system will necessarily enhance the public's access to medicine or healthcare, since the patent system is only one component in an ecosystem that determines affordability, availability and accessibility of healthcare and medicines. The SSE system will reduce the probability of evergreening practice. To the extent that this serves as a barrier to access to medicines, the SSE facilitates the removal of barriers.

The quality of the patent system has no direct impact on the quality of technology under patent protection. To this end, the introduction of an SSE system will not ensure an increase in the competitiveness of South African technologies.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|---|------------|---------------|-------------|
| Efficient systems and processes in place to manage the search and examination functions of the patent office | x | | |
| Adequately trained resources: examiners and search officers | x | | |
| Efficient legal representation to lodge patent claims under SSE system and to process litigation cases that arise | | | x |

It is important that prior to introducing the SSE system adequate measures are taken to ensure effective implementation. This requires an upfront capital outlay to build the resourcing capacity, the guiding principles for examination, and all systems and processes to perform SSE functions. It is unlikely that the necessary steps to meet these prerequisites can be taken in the coming months, even if the financial support is made available, since the process of upskilling staff and developing systems is lengthy. Furthermore, the CIPC's recent difficulties in digitising patent applications do not bode well for the implementation of a significantly more complex system, such as SSE.

The legal representation and courts system in South Africa, although under pressure in terms of capacity, is often lauded as effective and fair. It is therefore within reason to assume that the implications of switching from a depository patent registration system to an SSE system will be accounted for and provided for by the legal representation and courts system. Again, the process of building capacity and skills particular to patent litigation is time consuming.

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--|------------|---------------|-------------|
| Extensive delays to the patent registration system | | | x |
| Weaker patent system, with innovators disincentivised from investing in new technologies | | x | |

| High severity risk | Low | Medium | High |
|---|-----|--------|------|
| Reputational harm to South Africa associated with failing to implement the SSE system effectively | | x | |

There are several risks associated with introducing the SSE system without ensuring effective implementation. These are based on the experience of comparator developing countries, and developed countries, which have adopted the SSE system. The risk which is most likely to occur is that of extensive delays to the registration process. The SSE system is a more inquisitorial process relative to the current depository system and therefore requires more time to conduct the SSE functions. Given South Africa’s lack of technical skill and capacity in this regards, a switch to the SSE system will very likely result in extensive delays to patent registration. If this risk is not managed, the patent system’s credibility will be threatened and the entire system could weaken. South Africa identifies the strength of its patent system as a driver of innovation and technology development. A weaker patent system will therefore hurt innovation. A less likely but real possibility is that the SSE system is implemented poorly to the detriment of South Africa’s reputation in IP practice internationally.

Can these risks be mitigated?

It is possible to mitigate the risks mentioned above and allay fears of failure of implementation; however, this is probably not achievable on a short timescale. A rudimentary comparison with Brazil provides an estimate of the number of search officers and examiners required to operate an SSE system in South Africa – about 150 resources. Training these resources requires financial support from government and time. It does not seem feasible that SSE be staffed with academics from higher learning institutions. However, South Africa has enough technically competent graduates to build the resources, although costly to the state.

There are multiple options for the implementation and operation of an SSE available to the patent office. These include (i) conducting the entire SSE process in-house, (ii) making use of external results from other international patent offices, or (iii) seeking external assistance through WIPO’s International Cooperation on the Examination of Patents (ICE) service. The most suitable option will depend on South Africa’s capacity.

Similarly, the development of systems and examination guidelines, prior to implementation, will help to prevent the risks of introducing an SSE system from becoming real issues.

3.1.9. Policy recommendation

Based on the analysis above, it is recommended that the policy be implemented, ***provided*** that adequate measures are taken to mitigate the risks outlined in the section above. Specifically, it is critical that the necessary resources be up-skilled for effective implementation. There are several implementation options available for the SSE, which should be properly explored prior to deciding and embarking on the ultimate implementation route:

- ***Conduct search only:*** Some countries have established a patent office search capability, compiling a search report for each patent granted based on a prior art search. No examination is conducted but third parties have full access to the search

report and can therefore assess the validity of the patent granted.³¹ This search function may also be outsourced.

- **Conduct SSE for all patent applications:** Implementing the SSE for all patent applications will have the highest associated costs, in terms of resources and finances. South Africa will have to build the capacity to perform these functions internally.
- **Conduct SSE for select industries only:** the Draft Policy suggests that the SSE be introduced for select technologies in the interest of promoting access to healthcare and food security. Hence, pharmaceutical patent applications and agricultural industry patent applications pertaining to food production would be subject to the SSE system. The constitutionality of differentiation across different fields of technology should be investigated further so as not to amount to discrimination. While the TRIPS agreement prohibits discrimination across different technologies, Article 27(1) does not prevent countries from differentiating between fields of technology according to the unique characteristics of the technology and the socio-economic priorities of the state (as they pertain to the technology).³²
- **Outsource examination and enter into mutual recognition arrangements:** It is wasteful for the same patent to undergo extensive examination in multiple patent offices. Using information uncovered in one examination office may facilitate the work of examiners in another, especially in identifying prior art.³³ Recent years have seen a large rise in collaboration across the largest patent offices in the world. There has been an increase in the number of national patent offices recognised as International Search Authorities for PCT filings at WIPO and a rise in Patent Prosecution Highways bilateral agreements, whereby the search and examination report of a patent filed at one office are made available to expedite the application process at another office. NIPMO and UNISA Law suggest that a collaborative system be adopted, at least temporarily, with involvement of one or more co-operating examining foreign patent offices. Examination may be outsourced but this increases the risk of loss of secrecy.³⁴ Alternatively, a country may re-register a patent filed in another country, provided the necessary administrative arrangements are established.
- **Conduct bifurcated procedure, with delayed deadline for examination:** The US examination system, which has a full search and examination obligation, is relatively costly. South Africa may consider a cheaper alternative whereby a bifurcated procedure is adopted with a delayed deadline for substantive examination. In some countries, the patent office carries out a substantive examination only on request by the applicant, by a set deadline. This means applicants have more time to assess the financial viability of the patent. This reduces the workload for examination officers.
 - At the EPO 30-40% of applications are withdrawn before an examination is requested.
 - If the period in which an examination can be requested is very lengthy, unexamined applications may block inventions from other firms because they must wait longer to identify proprietary technologies.

³¹ WIPO, CDIP, Seventh Session (2011)

³² Accessed at http://www.ip.mpg.de/files/pdf3/Patent_Declaration_en.pdf

³³ Patent Backlogs and Mutual Recognition. (2010). UKIP.

³⁴ NIPRO submission

Examples of some of the implementing and operation strategies adopted by various countries are detailed in the Country Comparison section below (Section 3.1.11).

3.1.10. Alternative options

The SSE system is not necessarily superior to the depository system in practice. If effectively implemented, the SSE will advance the State's objectives of ensuring stronger patents are granted and access to health is improved. However, the SSE should not be seen as the panacea for issues of patent quality or access to health:

- While there are clearly benefits to government and the South African public to be gained from the establishment of an effective SSE system, it is important to note that the SSE system may not be necessary to achieve the stated policy objectives. There are examples of other countries with effective depository or hybrid systems – France, Belgium, Holland, Switzerland – which suggest that it may not be necessary for South Africa to adopt the SSE system.
- In so far as access to medicines is concerned, IP should not be considered in isolation. The significance of IP needs to be assessed alongside confounding factors that impede access. Delays to registration at the Medicines Control Council (MCC), for instance, take up to 5 years. This is due in part to the lack of resources available to process applications. It is also as a result of generic drug applications flooding the system, driven by profit incentives. The South African Constitution does not allow for restrictions on the submission of dossiers, as is done in Australia. It has been argued that the inhibiting factor to access to medicine in South Africa is not the IP system but the registration of medicines, handled by the MCC. Ultimately there are limitations as to what IP policy can effectively achieve, and which objectives are therefore reasonable.

Furthermore, it is incumbent on government to make a sober assessment of its ability to meet the critical success factors necessary for effective implementation of a comprehensive SSE system. In the event that government determines that it is unlikely to meet the critical success factors, research should be conducted to assess the feasibility of each of the following alternative options to the SSE system. These options are based on the analysis and from consultation with industry stakeholders.

- **Implement hybrid system:** Rather than implementing an SSE, adopt a hybrid system such as that used in France, whereby the examiner may reject the patent if it is not new but not if it is not inventive – since less skill is required to check novelty. The government should benchmark against efficient systems, not similar economies.
- **Oblige mandatory registration of pharmaceutical companies in specified territory abroad:** It is suggested that pharmaceutical companies should be required to register a patent in a specific territory abroad (i.e. UK which has similar laws) as a precursor to filing in South Africa.
- **Assign stronger patentability criteria:** Consider instead redefining the criteria for granting patents to reduce the likelihood of frivolous applications and to limit the potential for abuse such as evergreening practices.
- **Establish an electronic database:** The implementation of a user-friendly electronic database may encourage early entry of generics.

- **Establish a specialised patents court:** The patent system in South Africa is effective but the court system needs improving with regards to costs, delays and quality of judgment; it may be beneficial to establish a specialist court to review patents that are challenged.³⁵ This will have associated costs but could be limited by drawing on existing commissions and legal bodies. The benefit of maintaining a depository registration system with the introduction of a specialised patents court is that the current system is enhanced without an excessive overhaul required to implement the SSE, especially given that there is no guarantee that the SSE system will deliver the objective of establishing a superior quality patent system in South Africa.
- **Use tax incentives to encourage innovation:** IP is only one component that contributes to the level of innovation in an economy. Another driving factor is the business environment and incentives for gain. Tax benefits can be used as a tool to encourage innovative research. It is suggested that an employee's inventions system be introduced in South Africa which offers incentives for employee inventors and employers to invest in R&D by reducing the associated risks with adequately protected by IP.³⁶

3.1.11. Country comparison

3.1.11.1. Patent Application procedures in Africa

The African Regional Intellectual Property Organisation (ARIPO) is an intergovernmental organisation of African states, co-operating in patent and other IP matters. ARIPO comprises of 18 member states and 12 observer states; South Africa is an observer state. The objectives of ARIPO include industrial & economic integration, IP integration, IP protection, capacity building.

Both the depository system of patent registration and SSE system is used in African countries. Examples of countries using the depository system include Malawi, Mozambique, Namibia, Rwanda, Tanzania, Zambia, and Zimbabwe. Kenya (undertaken by KIPI) uses a full substantive examination system. Examples of countries with outsourced patent substantive examination procedures include Botswana, Lesotho, Gambia, Ghana, and Uganda to ARIPO.

In a study of 44 African countries' patent offices, it was found that most national patent offices were not capable of efficiently or effectively performing the task of examining patent applications and collating patent information for public disclosure.³⁷

This has negative implications for technology transfer and domestic industrialisation.

3.1.11.2. Substantive Search and Examination: Kenya

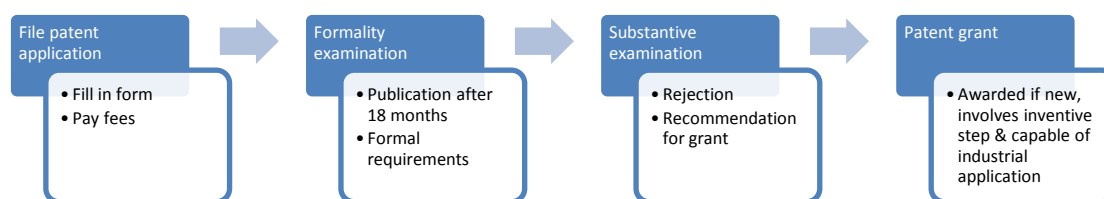
The Kenya Industrial Property Institute (KIPI) was founded in 1990 (originally KIPO, a division of Ministry of Trade & Industry). The main function of KIPI is to assess applications and grant industrial property rights and to promote invention and innovation in Kenya. The diagram below illustrates the procedure for patent registration.

³⁵ Spoor & Fisher submission

³⁶ UNISA submission

³⁷ Mgbeoji, I. (2014). African Patent Offices Not Fit for Purpose. *Innovation & Intellectual Property*, 234.

Figure 2. Procedure for patent registration



Kenya Industrial Property Institute (KIPI) announced in April 2014: “Following a review of the practice in the Institute with regard to the processing of utility model applications, the Institute has decided to discontinue the carrying out of substantive examinations in relation to utility model applications with effect from 1 May 2014 in order to align the practice with the Industrial Property Act, 2001. However, such applications shall continue to be subject to examination for compliance with all the other requirements of the Act and Regulations.” The new rule only applies to utility models. Patent applications continue to be subject to substantive examination.

Kenyan law allows examiners to request any information or documents from applicants to assist examination of patent applications. Patents may not be granted on the basis that they have been granted by other patent offices; however, examiners may refer to other resources such as WIPO-patent scope.

The formal examination process typically takes 90 days (plus 60 days if there is an extension). A further 60 days is taken to respond to substantive examination opinion (90 days extension). The maintenance or renewal of a patent occurs annually, with a grace period of 6 months; restoration must be obtained within 6 months after grace period.

Lessons from KIPI – challenges faced:

- Access to prior art documents is limited;
- The office has inadequate skills to perform SSE functions effectively;
- Mechanisms for information sharing have not been satisfactorily established; and
- Examination facilities are not adequately provided for.

3.1.11.3. Substantive Search and Examination: India

In 2002, India was the largest producer of generic drugs in the world, followed by Brazil. Indian producers have supplied low-cost drugs to domestic and international low- and medium income markets. The Indian Patents Act (1970) explicitly excluded pharmaceutical product patents and only admitted process patents for 7 years.

In March 2005, India passed the third amendment of the Patents Act, which recognises product patents. This was only at the end of the transition period for developing countries to comply with TRIPS. In so doing, India attempted to take advantage of flexibilities in TRIPS so as to protect their supply of generic medicines.

The Indian examination patent system for the registration of pharmaceutical patents involves eleven steps, including pre-grant and post-grant opposition provisions.³⁸ Revered by many developing countries for restricting the potential for abuse and evergreening practices of originator drug manufacturers, the Act prohibits patent protection for variants of existing compounds unless there is proven enhanced efficacy. UNAIDS holds the Indian example as a model for developing countries attempting to use TRIPS flexibilities to promote public health.

Lessons from India - implications:

India's Patents Office is self-funded through the fees it charges. Several other countries have drawn on Indian legislation to draft their own IP protection legislation, heralding the Indian case as a paragon for ensuring access to medicine and healthcare is prioritised. However, the Indian patent system has been criticised for extensive delays and has been challenged by the manufacturers of originator pharmaceuticals.

3.1.11.4. Substantive Search and Examination: Brazil

As a middle-income country, Brazil has an imperative to balance the need to secure returns to R&D investment and distribute benefits from innovation to society. Brazil first amended its patent legislation in 1996, to meet the TRIPS requirements – five years ahead of the deadline for developing countries – and has consistently advocated for the use of TRIPS flexibilities by developing countries.

Local industry suffered as a result, not yet having built up the necessary capacity to benefit from strong IP protection.

The argument in favour of strengthening IP included: that it would be an opportunity to modernise, it would enhance quality and competitive capabilities in the domestic market, and it would encourage technology transfer and foreign investment in R&D.

However, in reality, stronger IP did not promote innovation. Moreover, access to healthcare is said to have suffered.

In 2001, Brazil amended its IP legislation, mandating that any pharmaceutical patent application must be approved by the Brazilian Patent Office (INPI) and ANVISA, the national drug regulatory body. An ANVISA office was set up to re-examine patents that had been approved by INPI. ANVISA raised objections to non-obviousness and second medical use of an invention and overturned patents granted by INPI.

In 2011, ANVISA's role in patent examination was challenged constitutionally and restricted to risks to public health alone.³⁹

The Brazilian government has geared its departments towards promoting incremental innovation. Accordingly, the examination institution grants patents for technologies with little inventiveness.

In October 2013, the Brazilian Centre for Strategic Studies and Debates launched "Brazil's Patent Reform: Innovation Towards National Competitiveness" proposing changes to the

³⁸ Accessed at <http://www.compcom.co.za/assets/Uploads/events/Seventh-Annual-Conference-on-Competition-Law-Economics-Policy/Parallel-3B/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf>

³⁹ "ANVISA" examining patent applications in Brazil (2012) [Accessed at https://www.aippi.org/enews/2012/edition26/Magnus_Aspeby.html]

existing patent legislation to improve the quality of patent examination. The campaign calls for the adoption of pre-grant opposition procedures and asserts that the drug regulatory body should be reinstated as the authority in reviewing pharmaceutical patent applications. The proposals are strongly influenced by the Indian case.

Lessons from Brazil - Implications of the SSE:

The implementation of an SSE can negatively impact a country's patent system. In Brazil, there are delays of between five and ten years in finalising the prosecution of patent applications. Such delays may diminish the value of applying for patent protection and hence reduce the incentive of making knowledge available to the public. Moreover, lengthy pendency rates compromise business interests since delays to the grant or refusal of a patent application have an impact on other business entities which are delayed in their use of the patented technology or their endeavours to patent their own technology.⁴⁰

3.1.11.5. Substantive Search and Examination in Europe, the US and Japan.

There has been a rise in patent filings across the world in the past decade due to higher R&D expenditure, new technologies, globalisation, greater involvement of SMEs and universities, and partnerships between universities and industry. The growing number of applications is associated with higher backlogs in patent examination offices. High backlogs threaten the quality of the patent system as examiners become overloaded with work. As the quality of the patent system diminishes, the number of low-quality applications filed increases further burdening examiners in a "vicious cycle" of degradation.

In particular, the USPTO has been criticised for high backlogs and low levels of rigour in the examination of patents resulting in a weaker quality patent system. The USPTO has grant rates of about 87%, as compared to the EPO and JPO at about 67%. Grant rates and quality are affected by the extent of the backlog in the examination office but also by the operational design of the examination procedure. This is detailed below for each of the EPO, USPTO and JPO.⁴¹

- **EPO:** The EPO has a SSE patent system. In Europe, the examiner must undertake the relevant search report. Search reports are published with the patent application 18 months after their priority date – unless refused by the examiner or withdrawn by the applicant. Patent examination must be specifically requested by the applicant. Examination pendency is about 63 months at the EPO, including 18 months for the search function and 45 months for substantive examination. The long pendency is not due to backlogs but longer time spent on examination for each patent. Relative to Japan and the US, Europe has a costly patent system. The EPO received 148,560 patent applications in 2012 according to WIPO.
- **USPTO:** The USPTO has a SSE system. A comprehensive list of prior art must be submitted by the applicant. Search reports are not made public: applications for the domestic market remain hidden and are only published if enforced. International applications are published 18 months after application. Filing a patent automatically leads to a search and examination. Examination pendency in the US is about 35 months including SSE. This system favours speed but at a higher cost since more low-quality patent applications must be examined. The backlog in the US has been

⁴⁰ Accessed at <http://www.patentlawyermagazine.com/examining-examination-in-a-developing-country/>

⁴¹ van Pottelsberghe de la Potterie (2011). The quality factor in patent systems, in Industrial and Corporate Change.

attributed to very low fees and a less rigorous examination process. Compared to Japan and Europe, the US patent system is the most affordable. In order to encourage small, innovative companies and universities from applying, an SME-specific fee schedule permits discounted rates for these entities of up to 50%. The USPTO received 542,815 applications in 2012 according to WIPO.

- **JPO:** Japanese patents are subject to a SSE. A comprehensive list of prior art must be submitted by the applicant. The JPO outsources the undertaking of search reports to independent organisations in the private sector. Search reports are not made public. Japanese applications are open with file histories made available to the public after an application has been published. All applications are published 18 months after application. Patent examination must be specifically requested by the applicant, within three years of the date of application (previously seven years). Utility patents are examined for compliance with formalities only, not against patentability criteria. The request system results in fewer examinations being performed but may prolong the period during which unexamined requests block other applications. In order to encourage small, innovative companies and universities from applying, an SME-specific fee schedule permits discounted rates for these entities of up to 50%. The JPO received 342,796 applications in 2012 according to WIPO. Applications have decreased since 2006, due in part to declining economic activity and in part to applicants becoming more selective in filing, filing higher quality patents rather than volumes.

3.1.11.6. Substantive Search and Examination in Singapore, Israel and Jordan

There are several options available to countries wishing to implement a substantive examination system for patent registration. An International Patent Office may, for instance, conduct the SSE entirely in-house; or, make use of external results from other IPOs; or, seek external assistance through WIPO's International Cooperation on the Examination of Patents (ICE) service.

Small IPOs lacking examiners with the specific expertise to conduct an SSE in all technology areas may wish to use the external results published from an SSE conducted at other IPOs. It is often possible to make use of external SSE results in developing countries given the high proportion of foreign patent applications filed. Cambodia, Bhutan and Laos are examples of countries with small IPOs.

The national legislation on the use of external results differs across jurisdictions. Some countries make specific allowances for the use of external SSE results. In Israel, if identical patent applications are made at specified IPOs, then the results from the SSE at those IPOs may be used to grant the patent in Israel without conducting a substantive examination.

- **Israel:** Israeli law authorises the examination office to skip substantive examination of a patent application if the application is granted by selected international patent offices, provided the claims are identical. The Israeli examination office may examine the patent application regardless, but, this is not common practice. The list of corresponding international patent offices includes, inter alia, the USPTO, EPO and Denmark.

In other countries, legislation makes more generic provisions for the use of external SSE results.⁴²

- **Singapore:** In Singapore, SSE is done through partnering with international patent offices, including Austria, Denmark and Hungary (for local and mixed routes). Although previously operating under a self-assessment system whereby applicants were responsible for ensuring that claims issued were valid, legislation was amended in February 2014 to move to a positive-grant patent system. All standard patent applications must now be examined by the Intellectual Property Office of Singapore.
- **Jordan:** The patent application process in Jordan has two tracks, the first filing application (local) and second filing application (foreign). Applications are first assessed for all formal requirements. A preliminary substantive examination is then conducted. If complete, a substantive examination is conducted. Jordanian patent regulation permits the registrar to seek assistance from the technical expertise to assess patentability from any authority deemed necessary, i.e. any academic local institution of the World Intellectual Property Organisation. For second filing applications, the Jordanian Patent Office may use the SSE reports from international patent offices.

3.2. PRE- AND POST-GRANT OPPOSITION

3.2.1. Policy proposal

The Patents Act should be amended to have both pre- and post-grant opposition to effectively foster the spirit of granting stronger patents.

3.2.2. Status quo

There is no provision for pre- or post-grant opposition to patent applications or registration of patents in the current IP legislature.⁴³ The system provides for the revocation of a patent, through a judicial process. Any party may challenge the validity of a patent by instituting revocation proceedings before the High Court of South Africa. The system is said to be structured so as to be cost effective, however, revocation proceedings typically involve high litigation costs. In contrast, the cost of pre- and post-grant opposition is covered by the patent office.

The cost of revocation procedures are said to be similar to that of opposition procedures where opposition procedures are escalated to legal proceedings.

Revocation procedures can theoretically take 6 months; 1.5 years at best; and, on average take 3 to 5 years.

3.2.3. Problem statement and evidence

With a depository patent registration system, the validity of a patent is not tested unless the patent is challenged legally. Invalid and frivolous patents are granted without opposition. All

⁴² http://www.wipo.int/edocs/mdocs/mdocs/en/ompi_pi_yao_13/ompi_pi_yao_13_www_228403.pdf

⁴³ There is provision for opposition to the Register's restoration or amendment of a patent, for 2 months after the publication of the Register's intention in the Patent Journal.

weight is thus placed on the judicial system to determine the validity of patents. Judicial proceedings, however, are associated with time delays and high costs.

Revocation proceedings cost between ZAR 40,000 and ZAR 80,000 for a simple case. There are examples of revocation proceedings that have amounted to ZAR12million in legal fees, such as the case of Pharma Dynamics vs. Bayer.

Cases can take up to 5 years to conclude due to delays in hearing dates.

3.2.4. Policy objective

The introduction of the pre-grant opposition is intended to provide an opportunity for interested parties to challenge pending patent applications which would restrict the granting of weak or invalid patents, without incurring prohibitive litigation costs.

The draft IP Policy states: In India, the implementation of pre- and post-grant opposition has resulted in fewer “weaker” patents being granted that do not meet the requirements of "newness", "novelty", "obviousness" and "usefulness for trade/agriculture".

3.2.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the provision for pre- and post-grant opposition:

- Generators of IP
- Legal system and representatives
- Government
- Pharmaceutical focus – New Chemical Entities (NCEs or originator drugs) manufacturing pharmaceutical companies
- Pharmaceutical focus – Generic manufacturers
- Society
- Economy

In addition, the effects have been split between immediate (short and medium term) and broader (long term) effects.

3.2.5.1. Generators of IP: indeterminate

If the provision of pre- and post-grant opposition results in extensive delays to the application grant process, as a consequence of the increased administrative burden, applicants will be disadvantaged. Even longer delays will result if opposition proceedings are open to abuse. If on the other hand the process results in fewer low-quality patents being granted, thereby strengthening the patent system, this will benefit all innovators with valid technologies for patenting by providing increased legal certainty. Provision for pre- and post-grant opposition makes it faster and potentially cheaper for parties to challenge the validity of a patent application or grant, especially benefiting those with limited resources. It is also cheaper for patent-holders to defend a challenge to the validity of their patents.

3.2.5.2. Legal system and representatives: likely positive

To the extent that pre- and post-grant opposition limits the wrongful obtaining of patents, and therefore reduces the number of litigation cases brought against patent-holders, the demand for legal representation will decline and associated commercial gains will suffer. If post-grant opposition proceedings are escalated to litigation, the workload and commercial gains to legal representation will increase.

3.2.5.3. Government: likely negative

Provision for pre- and post-grant opposition necessarily introduces an administrative burden to the patent registration system as a result of document-intensive procedures, since oppositions must be filed, evaluated and documented. The state will incur increased financial costs, both operational and in order to up-skill the office of the Registrar of Patents to effectuate this provision. The state is furthermore at risk of being held liable for legal costs when a decision to grant the opposition to the grant of a patent is overturned, which would have negative financial implications.

In the longer term, the costs to government may be offset by the societal gains since government indirectly bears the burden of providing for society.

3.2.5.4. Pharmaceutical focus – NCE manufacturers: likely negative

If the opposition proceedings introduce delays to the patent application grant process this may have a costly impact on pharmaceutical companies that rely on maximising the period of monopoly protection to amortise R&D investments. If the effect of the opposition proceedings is ultimately to strengthen the quality of the patent system, the credibility of the patent system will increase, encouraging innovation. Pharmaceutical manufacturers will benefit from the certainty of business decisions and legal certainty that results. In other words, as the probability of a patent granted being valid rises, the risk to companies lowers. Pharmaceutical companies engaging in evergreening practices will be disadvantaged by the more stringent process of pre- and post-grant opposition proceedings.

3.2.5.5. Pharmaceutical focus – Generic manufacturers: likely positive

The provision for pre- and post-grant opposition makes it more affordable and easier for a challenger to oppose the validity of a patent. Generic manufacturers enter the market after the expiration of an originators drug manufacturer's patent. The opposition proceedings reduce the likelihood of that initial patent term being extended through the registration of new uses of known substances and therefore benefit generic manufacturers.

3.2.5.6. Society: likely positive

The provision for pre- and post-grant opposition, if adequately staffed and prepared for, will enhance public access to generic, cheaper medicine by enabling a higher quality patent system and reducing the likelihood of invalid patents being granted. If however the opposition proceedings result in extensive backlogs to the registration of patents, this may deter R&D spend which ultimately reduces investment into medicines for developing country diseases, negatively impacting the public.

3.2.5.7. Economy: indeterminate

Effect on Competition.

By providing for early opposition to patents granted, the pre- and post-grant opposition provisions should result in fewer low quality patents being granted. Competition will therefore improve as access to use of technology improves. If however the delays caused by the opposition proceedings become extensive, due to administrative overloads or abuse of the pre-grant opposition to delay registration, competition will be thwarted.

Effect on Foreign Direct Investment (FDI) and Trade.

If delays to patent registration are extensive as a result of pre-grant opposition proceedings, the time to recover R&D spend is shortened and FDI is disincentivised. Contrastingly, the provision for opposition should contribute to a higher quality patent system which will provide innovators with legal certainty and incentivise FDI in South Africa.

3.2.6. Assessing benefits / pros

1. ***Cost effective means of challenging invalid patents:*** Pre-grant opposition is a less costly tool for challenging the validity of a patent early in the process compared to post-grant challenges, which involve high litigation costs. Patent revocation proceedings are costly, estimated at between ZAR 30,000 and ZAR 500,000 by industry stakeholders, and potentially escalating into millions in legal fees. In the case of Pharma Dynamics versus Bayer, Pharma Dynamics reports to have incurred costs in excess of ZAR 12 million while challenging the validity of Bayer's patent.
2. ***Enhanced quality of the patent system:*** The pre- and post-opposition is paid for by the patent office and is thus cheaper for the challenger of the patent. Invalid patents are therefore more likely to be challenged and overturned without having to resort to litigation proceedings. The threat of challenges to invalid patents serves as a deterrent to applicants abusing the patent system.
3. ***Increased certainty for business decisions:*** Pre-grant opposition can increase certainty for business decisions for both innovators and generic manufacturers "by settling contested patent claims much earlier (and less expensively) than post-grant litigation could."⁴⁴ Patent-holders are more certain of the validity of their patents since the rigour of the patent registration system is greater when opposition is provided for.
4. ***Improved regulatory efficiency:*** The process of pre-grant opposition involves collating and presenting prior art. Uncovering prior art can enhance regulatory efficiency as this information facilitates patent examiners in assessing novelty and inventiveness.

3.2.7. Assessing costs / cons

1. ***Potential redundancy:*** The introduction of substantive examination requires that patent applications to be evaluated on the basis of patentability through an extensive investigative process. It is possible as such that providing for pre-grant opposition becomes a redundant process in addition to a substantive search and results in undue costs and delays in the application process.⁴⁵

⁴⁴ Rastogi, P. (2014). "Patent Opposition System In India: An Overview". Mondaq business briefing.

⁴⁵ SAIPL submission

Similar concerns of redundancy have been raised around the introduction of the post-grant opposition given the existing provision for revocation proceedings, which already forms part of the Patents Act.⁴⁶ Both post-grant opposition proceedings and revocation proceedings potentially amount to costly legal contestation.

2. **Potential abuse of opposition provision:** Pre-grant opposition proceedings were originally included in the Patent Act of 1952. However, this was removed from the Patent Act of 1978. Pre-grant opposition was considered open to abuse by patent attorneys and interested parties, who used this as a means of prolonging and delaying the granting of patents. There are however means of mitigating the potential for abuse of pre-grant opposition through the imposition of timelines and cost-shifting mechanisms.⁴⁷

In the case of pre-grant opposition, the challenger may not yet have access to all information necessary to challenge a patent application. The case may therefore be built on ambiguities.⁴⁸ This may result in wasteful expenditure and inefficient use of resources.

3. **Financial cost to the state:** The state will incur costs of pre- and post-opposition. The state bears the cost of publication of all applications for a patent in the pre-grant opposition procedure. If the opposition is challenged legally by the patentee, the state risks being held liable for the legal fees incurred by the patentee.
4. **Financial costs to patentee and opposing third party:** The patentee and opposing third party will incur professional legal fees associated with opposition.
5. **Administratively burdensome and delays to the patent grant process:** The pre- and post-grant opposition proceedings are associated with high volumes of documentation, which require processing and can become burdensome to manage. Pre-grant opposition may lead to substantial delays to the granting of patents – both as a result of procedural delays and deliberate delays if the pre-grant opposition is abused by applicants.

3.2.8. Application of analysis framework

To analyse the aforementioned effects on the various stakeholders, recommendations are formed using the framework described in Section 1.3.

Theoretically, can the policy objective be met through the proposal?

The introduction of the pre-grant opposition is intended to provide an opportunity for interested parties to challenge patent applications early without incurring litigation costs. Opposition proceedings are designed to restrict the granting of weak or invalid patents and to limit frivolous claims. In principle provision for opposition enhances the rigour of the patent application process and increases the likelihood of invalid patents being rejected or overturned. This serves to disincentivise applicants from lodging claims that do not clearly meet the criteria for patentability.

What is the probability of critical success factor being secured?

⁴⁶ Innovation Hub submission

⁴⁷ Rastogi, P. (2014). "Patent Opposition System In India: An Overview". Mondaq business briefing.

⁴⁸ Rastogi, P. (2014). "Patent Opposition System In India: An Overview". Mondaq business briefing.

| Critical success factor | Low | Medium | High |
|---|-----|--------|------|
| Resources with the technical and legal expertise to adjudicate the opposition proceedings | | x | |
| Resources manage the administrative burden of opposition proceedings | | x | |
| Efficient systems and processes to support the opposition proceedings | | x | |

The Draft Policy is silent on the implementation details for the opposition proceedings proposed. In order for the provision of pre- and post-grant opposition to be effective in achieving policy objectives, it is necessary to structure the proceedings as an administrative process with simple procedures that are inexpensive to perform. It has been suggested that a board or panel of experts be established to resource the opposition proceedings. This may require building skills and capacity if the skills cannot be sourced. It is possible to secure these critical success factors, however, adequate time must be allocated to the process prior to effectuating the policy proposal.

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|---|-----|--------|------|
| Extensive delays to the registration of patents as a result of backlogs due to administrative overload | | | x |
| Abuse of pre-grant opposition to delay the registration of patents | | | x |
| Wasteful use of resources if pre-grant opposition proceedings become redundant with SSE | | x | |
| Wasteful use of resources if post-grant opposition proceedings become redundant with revocation proceedings | | x | |

In India, where provision is made for both pre- and post-opposition, sophisticated systems have been developed to manage the opposition proceedings. However, opposition proceedings are document-intensive and there have been delays associated with the heavy load of documentation. The probability of extensive delays to patent registration in South Africa, due to overburdened resources at the patent office or abuse of opposition proceedings, is high. Given that South Africa has in the past experienced abusive practices to delay the patent registration process, it is prudent to take action to prevent this from reoccurring if provision for opposition is reintroduced.

The wasteful use of resources is a serious concern in South Africa where limited resources are thinly stretched. On the one hand the provision for pre-grant opposition could be considered redundant should the SSE system be implemented effectively and on the other hand it could also strengthen the SSE system. The post-grant opposition could be considered redundant given the existing provision for revocation proceedings. However, it is not fair to dismiss the pre- and post-grant opposition proceedings as necessarily redundant since these proceedings are structured to maximise the opportunity to prevent / revoke invalid patents without the

challenging party necessarily incurring high litigation costs. Adequate regulatory measures could be adopted to ensure that opposition proceedings strengthen the system (see Policy recommendations *infra*).

Can these risks be mitigated?

It is possible to reduce the likelihood of extensive delays to patent registration by deterring the filing of frivolous or unfounded opposition. This may be achieved by introducing costs that are affordable to genuine challengers but deter abusive or perverse behaviour. Another approach may be to provide very specific detail on the requirements and documentation necessary for an opposition filing to be considered.

If the systems and procedures in place are well defined and simply structured this will reduce the probability of administrative-related delays to registration. One suggestion is to structure the opposition proceedings as an administrative process, before a tribunal of senior councils, so that costs are limited – this is done in Europe, where it takes about two years to conclude an opposition challenge.

To limit the potential for wasting resources an option may be to provide for either the pre-grant opposition only or the post-grant opposition only. Stakeholders offered divided views as to which opposition provision is preferred should only one be provided for.

3.2.9. Policy recommendations

Based on the analysis above, the policy should be implemented provided that adequate measures are taken to ensure effective implementation. An implementation plan is imperative to design and effectuate all processes, systems and resources required to mitigate the abovementioned risks are provided for, especially if an SSE system is implemented.

- The pre-grant opposition provision is not necessarily redundant in an SSE system. It is argued that the justification for pre-grant opposition is primarily to serve as a substitute for an examination procedure. However, the pre-grant opposition provision extends beyond the function of the SSE by allowing third party involvement. The SSE system may still overlook evidence of the invalidity of a patent. Therefore, provision for pre-grant opposition, provided it is effectively managed, enhances the rigour of the patent application process and therefore the quality of the patent system.
- Similarly, post-grant opposition is sometimes labelled as redundant given the existing provision for revocation proceedings. While post-grant opposition proceedings may escalate to costly litigations, they are structured so as to allow for the early challenge of a patent's validity, to avoid costly litigation.
- It may be cumbersome to have both opposition proceedings. It is important therefore to ensure that a simple summation procedure be designed and practiced.
- It is recommended that a board, panel or tribunal with legal and technical expertise be established to oversee opposition proceedings.

3.2.10. Alternative options

- ***Provide for a defined finite period of post-grant opposition:*** In the nine months moratorium period after granting patent, during which a patent-holder may not take action against an infringement, introduce a post-opposition procedure.

- **Adopt a third party observation procedure:** The European Patent Office uses a similar procedure whereby third parties may draw the attention of an Examiner to pertinent facts or publications which may not have been uncovered in the Search or Examination to date.⁴⁹
- **Introduce an IP tribunal to oversee opposition proceedings:** Use retired Judges or build requisite technical and legal skill to staff a panel or tribunal to encourage quick resolution.

3.2.11. Country comparisons

3.2.11.1. India

Opposition proceedings are structured to restrain invalid patent grants and to limit frivolous claims or patents of minimal invention. The 2005 amendment to the Patent's Act in India introduced a two-stage opposition procedure comprising both pre- and post-grant opposition.

- **Pre-grant Opposition:** India first introduced provisions for pre-grant opposition to pending patent applications under the Patents and Designs Act 1911.50 Section 25(1) of India's Patent (Amendment) Act 2005 makes provision for pre-grant opposition of a patent, whereby any third party may challenge the validity of a patent application, after the application has been published but prior to the patent being granted. There is no fee payable to file a pre-grant representation.⁵¹
- **Post-grant Opposition:** For the period of one year after the publication of the grant of a patent, any 'person interested' may submit an opposition against the patent, as provided for in section 25(2) of India's Patent (Amendment) Act 2005. Since the patent has already been issued, infringement proceedings may be introduced in post-grant opposition. As post-grant opposition is a judicial process, it is more costly than pre-grant opposition and takes longer to resolve. The cost of filing notice of opposition and being heard in post-grant opposition proceedings is approximately US\$220.

In addition to pre- and post-grant opposition, the Indian Patent's Act provides for revocation procedures. This is permitted until the end of the patent term.

3.2.11.2. Opposition in Europe, the US and Japan

Provision for opposition differs across different jurisdictions, with different implications in terms of quality of patent system, cost and timelines. The opposition procedures for the EPO, USPTO and JPO are detailed below.

EPO: The EPO has a low-cost system of post-grant opposition, whereby any person can file an opposition for a European patent within nine months of the publication of the grant.

USPTO: There is no post-grant opposition process in the US, but there are interference and re-examination proceedings, which may result in the cancellation of a patent granted. Any third party may request the re-examination of the validity of a granted patent at any time during the period of enforceability of a patent.

⁴⁹ INTERPRAT commentary

⁵⁰ [Prabodh Malhotra. (October 2010). Impact of TRIPS in India . Retrieved from <http://www.palgraveconnect.com/pc/doi/10.1057/9780230290747>]

⁵¹ Rastogi, P. (2014). "Patent Opposition System In India: An Overview". Mondaq business briefing.

JPO: There is no post-grant opposition process in Japan. The JPO abolished its post-grant opposition procedure in 2003. Third parties may now challenge a granted patent through invalidation proceedings only. Invalidation can be filed by anyone at any time after grant (including after the patent has expired). The number of invalidation request submitted is far fewer than opposition cases filed prior to 2003. Invalidation suits are associated with long delays and high-costs which may explain the reduced incidence. The JPO is looking to review and re-introduce the post-grant opposition in 2014.⁵²

3.3. PATENTABILITY CRITERIA

Article 27 of the TRIPS Agreement stipulates that patentable subject material must satisfy the criteria of novelty, non-obviousness and industrial applicability. A considerable degree of flexibility is imparted to TRIPS members regarding the definition of such key terms. This has led to varied interpretations and treatment of the subject, particularly the patentability of new uses or methods of using existing products.

3.3.1. Policy proposal

The Draft National Policy on Intellectual Property recommends the following changes to patentability criteria:

South African legislation should allow strict rules to apply to patenting as competition principles may be undermined. This should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as is the case under the TRIPS Agreement.

The interpretation of this policy recommendation is that stricter patentability criteria should be formulated, particularly around new uses for known substances.

3.3.2. Status quo

South Africa's current standard for patentability has raised concerns that drug evergreening may occur. While not a formal patent concept, evergreening is the practice of patenting marginal modifications to extend the term of monopoly pricing.⁵³ In South Africa, patents are granted on a product, but with pharmaceutical products various molecules and uses are also patentable. Section 25(9) of the Patents Act states that patents may be granted for inventions of a substance or composition used in treatment, therapy, surgery or diagnosis relating to human or animal bodies, even if the substance / composition forms part of the state of the art immediately before the priority date of the invention, so long as the *use* of the substance or composition does not. In other words – if the substance itself is known, a novel *use* may still be patented. The provision in section 25(9) is deemed to be a TRIPS Plus provision, given that TRIPS does not explicitly require members to provide for the patenting of new uses of a known substance. It is also important to note that it only applies to the pharmaceutical industry.

In reality, pharmaceutical companies patent various elements such as chemical molecules, crystalline forms, salt forms, new compounds, dissolution profiles, formulations, dosing regimens, manufacturing processes and new uses / indications of a single drug, thereby extending the patent term, and consequently monopoly, on the drug. For roughly every 100

⁵² EPO. [Accessed at: <http://www.epo.org/searching/asian/asia-updates/updates-2013/20130516a.html>]

⁵³ Löfgren, H. and Williams, O.D., *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South*, p3

drugs that fail during the Research and Development (R&D) phase, only one drug will be marketed and sold.⁵⁴ Pharmaceutical companies thus have an incentive to protect the monopoly they have on drugs that go to market in order to maximise profitability and recoup their total R&D costs.

It is worth noting that drug evergreening is a disputed concept. Patenting of marginal modifications gives rise to a secondary patent. A secondary patent does not prevent use by competitors of the primary patent once it has expired. Consequently, the 'extension' of a patent through evergreening is not possible. For evergreening to lead to this kind of 'extension' of a patent it must be, incorrectly, assumed that a competitor or generics manufacturer should have access to the improved version of a drug held by the originator rather than produce under the expired patent.

3.3.3. Problem statement and evidence

South Africa explicitly provides for the patenting of new forms, new uses and new formulations of existing medicines. This increases the possibility of the evergreening of drugs.

The following are examples of drug evergreening cases which are present in SA:

Bayer's *Yaz* and *Yasmin* vs. Pharma Dynamics' *Ruby* (contraceptive)

Yasmin, manufactured by Bayer, is the most widely used oral contraceptive in the world. It was first patented in 1990 and the molecular composition expired in 2010. In 2004 Bayer launched *Yaz* which allowed them to patent the dissolution profile and particle size of *Yasmin*, which is valid until 2024. Pharma Dynamics, a generics manufacturer of the drug, is arguing that the 2004 patent is invalid since it is neither unique nor innovative given that *Yaz* is a combination of pre-existing products. Pharma Dynamics is prevented from manufacturing and selling *Ruby*, its generic of *Yasmin*, given that the necessary dissolution profile is now patented through *Yaz*.

In SA, the patent judgment has now been appealed by Pharma Dynamics. The case has been waiting 18 months and may be heard in 2015. The incentive exists for Bayer to protect / prolong its monopoly on the drug given that it generated USD 1.1 billion in sales in 2011⁵⁵ and in 2013 it was the company's 4th best selling product, making up 9.9% of total revenue.⁵⁶

Osaka and Bristol-Myers Squibb *Abilify* (schizophrenia, bipolar disorder or depression)

Aripiprazole, marketed as *Abilify* in South Africa by Bristol-Myers Squibb (BMS) and manufactured by Otsuka. South African price per mg (R3.56/mg) is 20% higher than the Japanese price per mg (R2.84/mg). South African cost per unit for a 10mg tablet is over 35 times higher than the average generic price in India. *Abilify*'s high profitability drives Otsuka's earnings growth⁵⁷, contributing over 30% to the company's total consolidated net sales in 2012. The company has an incentive to maintain market exclusivity through patenting strategies.⁵⁸ In South Africa, a substantial number of patents have been filed on *aripiprazole*, by BMS and Otsuka, as well as by the companies Alkermes and Synthon. Otsuka and BMS

⁵⁴ Interview with IMS

⁵⁵ <http://www.bloomberg.com/news/2012-07-31/bayer-s-yasmin-lawsuit-settlements-rise-to-402-6-million.html>

⁵⁶ Bayer Annual Report, 2013

⁵⁷ Otsuka Annual Report, 2012

⁵⁸ Otsuka Annual Report, 2012: *Any unfavorable ruling, decision or settlement resulting in the launch of generic versions of ABILIFY in the U.S. would likely result in substantial decrease in the sales of ABILIFY in the U.S., which would have a material adverse effect on our financial condition and results of operations.*

have filed applications on various process, method, and formulation patents in 2003, 2005, 2006, and 2010, with two pending applications filed in May 2013 and July 2013. These processes, methods and formulations are all crucial to the manufacturing of Abilify. Securing patents for each separately allows for patent protection to prevail for longer than 20 years on the drug itself. In addition, a high number of pending patent applications can lead to uncertainty for generic competitors, affecting their ability to enter the market.⁵⁹

Novartis' *Imatinib* (cancer medication)

Imatinib mesylate, whose brand names are Gleevec and Glivec, is under patent in South Africa and therefore can only be purchased from the patent holder, Novartis. In South Africa there are a total of seven patents containing the word 'imatinib' whose expiration dates range from 2025 to 2029. This means that if one of these patents applications of a new use of a known drug are granted, Novartis will enjoy patent protection until at least 2025, blocking any entry by a generic company which may reduce prices. Gleevec / Glivec is Novartis' top selling product and makes up 12.5% of pharmaceutical sales in markets outside of the U.S. Novartis sells the drug at R863 per 400 mg tablet while generics in India by Cipla and Natco are priced at R46.20 and R53.18 per 400 mg tablet respectively.⁶⁰ As such a loss in patent protection is expected to impact significantly on the company's operating income⁶¹. The company also admits that while patents in the US and EU are set to expire in the coming few years, 'the product is protected by additional patents claiming innovative features'.⁶² India rejected the patent application on Imatinib mesylate citing that it is a new formulation of an existing molecule.⁶³

AstraZeneca's *Esomeprazole / Nexium* (treatment of various gastric conditions)

Esomeprazole, sold under the brand name Nexium, has been pharmaceutical company AstraZeneca's bestselling product. Esomeprazole is the S-isomer of its predecessor Omeprazole (marketed as Prilosec). The two medicines are different chemical compositions of the same molecule and are used to treat the same conditions. In 2001 AstraZeneca's patent on Omeprazole expired and in response, the company developed and patented the new formulation, Esomeprazole. A quick search of South Africa's Company and Intellectual Property Commission (CIPC) database reveals that 12 substance, formulation and process patents on Esomeprazole or Omeprazole have been granted in South Africa since 2000. In 2006 the European Patents Office (EPO) revoked a substance patent on Esomeprazole, following a challenge by a generic producer, Ratiopharm. In 2011, the EPO revoked a patent on the oral administration of Esomeprazole on the grounds that it lacked inventiveness.⁶⁴ A loss of patent protection or loss of exclusivity on the related product has serious consequences and could lead to a significant decrease in product sales⁶⁵. In 2012, Nexium made up 81% of AstraZeneca's sales in emerging markets.⁶⁶ In the UK where TEVA UK is marketing the

⁵⁹ Adams & Adams presentation to the SA Pharmaceutical Regulatory Affairs Association, *Patent law – What a regulatory pharmacist should know*, 2013, available at <http://www.sapraa.org.za/presentations/Sept2013/Patent%20Law%20-%20What%20a%20Regulatory%20Pharmacist%20Should%20Know%20Sept%202013.pdf>

⁶⁰ Tomlinson, C., *An analysis of cancer medicines: failure to use TRIPS flexibilities means that SA pays far more for cancer medicines than the cost of generics available internationally*, obtained from MSF.

⁶¹ Novartis Annual Report, 2013

⁶² Ibid. 60

⁶³ See Country comparison of India below

⁶⁴ http://www.fixthepatentlaws.org/?p=176#_ftn1

⁶⁵ AstraZeneca Annual Report 2012

⁶⁶ Ibid. 65

generic of Esomeprazole a single 40 mg tablet costs about R6.69 while AstraZeneca supplies Esomeprazole in South Africa at R12.87 per tablet.⁶⁷

The preceding four examples all allude to the incentives for pharmaceutical originator manufacturers to resort to evergreening practices. From this, indicators pointing to possible evergreening practices, which should be considered jointly, are speculated on:

- Prices of the drugs are comparably higher than other developing countries such as India and Brazil or, in some cases, developed countries such as the UK.
- These drugs are substantial contributors to the revenue and sales profiles of original manufacturers.
- Various subsequent patent applications on similar compounds and related processes have been applied for by the manufacturer.

3.3.4. Policy objective

The policy aims to curb drug evergreening practices. This subjects pharmaceutical markets to more competition, which has the ability to drive prices down and hence increase the affordability of certain medicines.

3.3.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's patentability criteria:

- Generators of IP (Generally, and with a focus on the pharmaceutical industry)
- Legal system and representatives
- Government
- Society
- Economy

In addition, the effects have been split between immediate (short and medium term) and broader (long term) effects.

3.3.5.1. Generators of IP: indeterminate

An immediate effect of stricter criteria will be a reduction in patent applications given that frivolous patents are discouraged and have less chance of being granted. On the other hand, those who are granted patents benefit from legal certainty. Patents become better defensible in court with less interpretation required by the courts, and hence decreased uncertainty in legal outcomes. However, with the curbing of frivolous patents and evergreening in the pharmaceutical industry, the risk of restricting legitimate and important incremental innovation in the industry increases. Medical devices, for example, rely heavily on incremental innovation which may be restricted as evergreening is curbed. If stricter patentability criteria are to be applied to a wider range of industries through section 39 of the Patents Act, incremental

⁶⁷ Ibid. 64

innovation in other industries may be necessarily restrained for the sake of curbing evergreening practices in the pharmaceutical industry.

In the longer term, the patent system could experience improved quality of protection, assuming that relevant processes and players become well informed of the changes and their implications over time. For those medical innovators who are rewarded for novelty or inventiveness as measured by the number of patents, decreased patent applications may not be beneficial. Conversely, it may create incentives for generators of medical IP to invest more resources in the development of more innovative inventions that are patentable.

3.3.5.2. Legal system and representatives: likely negative

An immediate effect on the legal system is a reduction in both the number of pharmaceutical applications for the registration of patents and infringement cases given that patent protection is of higher quality and patents are more likely to be defended. Related to this is the fact that a tighter scope of protection by patents means that less information is subject to infringement and, conversely, more is available in the public domain. In addition, the drafting of patent application will be subject to stricter criteria making legal firms more likely to conduct more extensive searches and apply more stringent standards to the applications. Over time, as more interactions occur between the patent office and the legal firms, certain practices will be established as legal firms discover what practices make for successful applications. This will be passed on through the training of candidate patent attorneys.

3.3.5.3. Government: likely positive

As the processors of patent applications, government will be faced with a decreased application burden as frivolous medical patent claims are deterred. In this way, if frivolous patents in the pharmaceutical industry are used to effect evergreening, the government's objective of curbing the practice will be achieved. In the longer term, the government will also be better placed to fulfill its obligation of enabling access to healthcare for citizens.

3.3.5.4. Pharmaceutical focus: likely negative

As mentioned, stricter patentability criteria imply a decreased ability to patent 'frivolous' patents. In the case of original drug manufacturers, new uses / chemical compounds of known drugs will no longer be patentable, by definition. In the case of generic manufacturers, more information is then available to create generic medication and commercialise on. In this way, stricter patentability criteria can be seen as allowing for less valuable information to be 'locked up'. In the short term, pharmaceutical companies that are unable to maintain profitability without the practice of evergreening will likely fail and hence contribute to a decrease in R&D and innovation.

In the longer term, if evergreening is curbed, pharmaceutical originators may be incentivised to redirect efforts into developing new molecules / processes / formulations or legitimately enhancing old ones rather than attempting to patent the new uses of known substances.

3.3.5.5. Society: likely positive

With valuable medical information and technology being less prone to patent protection, increased access by members of the public encourages innovation by providing for the easy use and further development of this knowledge.

Over time, lower prices of medication and other patent protected inventions, such as diagnostic tests and medical devices, are expected. This is as a result of a reduction in the number of frivolous pharmaceutical patents which prevent market entry, and hence, competition. Lower prices are also subject to the effective functioning of other processes forming part of the supply chains of such markets.

3.3.5.6. Economy: indeterminate

International research which uses patents / patent applications as proxies of innovation may classify South Africa as lacking in innovation based on fewer applications. However the strength of the patents which are issued is better than with weaker patentability criteria. In other words, these patents are more easily defended in court by patent holders. As a whole, the quality of the patent system is also improved i.e. there are a fewer number of weak patents that are granted.

3.3.6. Assessing benefits / pros

1. **Stricter criteria create incentives for pharmaceutical companies to invest in new molecular entities and new classes of medicines** rather than attempting to patent new uses of known substances.
2. **With stricter criteria, fewer patents are granted.** More generic manufacturers may enter due to the diminished prospect of infringement. The additional competition from these manufacturers in turn drives prices of medicines lower.
3. **Stricter patentability criteria imply that fewer patent applications** are received and processed by patent office, alleviating administrative and associated cost burdens.
4. **Secondary patents, which secure monopolies for extended periods, are avoided.** The legal and related costs which are associated with defending these patents (that are more likely to be challenged) are also avoided. In the case of Bayer's *Yaz* and *Yasmin* vs. Pharma Dynamics' *Ruby*, Pharma Dynamics has incurred R12 million in litigation costs, R2 million in stock losses and R100 million forgone revenue to date. Time delays have also been incurred as the case has been postponed for 18 months and may only be heard in 2015.

3.3.7. Assessing costs / cons

1. **The restriction on patentability assumes that additional patents associated with a product will be weaker.** However, often incremental innovation is important to advancing medicines. A recent study⁶⁸ finds that 63% of the drugs on the World Health Organization's Essential Drug Lists are 'follow-on' drugs. Some examples of drugs serving developing world diseases using known drugs / substances include:⁶⁹
 - a) AIDS: Atripla, the first-ever single-pill AIDS treatment regimen combining three drugs into one pill, simplifying the dosing regimen and increasing patient compliance.

⁶⁸ Cohen, J. and K. Kaitin. *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, American Journal of Therapeutics, vol.15, 2008, pp.89-91.

⁶⁹ See <http://www.ipwatchdog.com/2013/10/17/the-importance-of-protecting-incremental-improvement-innovation/id=45725/>

- b) Hepatitis C Virus: A modified formulation of interferon alfa improved the positive response rate of patients receiving treatment from 38-43% to 54-56% and drastically simplified dosing regimens improving patient compliance.
- c) Malaria: Improvement innovation led to the development of a new formulation of two anti-malarial drugs, artesunate and amodiaquine, reducing dosing regimens from eight tablets a day to two.
- d) Chagas Disease: Clinical trials are underway to explore the effects of the antifungal medicine ravuconazole against the pathogen that causes Chagas disease, a neglected tropical disease affecting nearly 10 million people.
2. **Stricter patentability criteria imply that fewer patent applications are made.** These are often a proxy for innovation, which may imply that innovation in the country is decreasing. Reports such as the World Economic Forum Global Competitiveness Reports, a well referenced publication, use the number of patent applications to draw conclusions on the level of innovation in a country.⁷⁰
 3. **If the patentability criteria are set too high, less applications will be made and accepted.** This may have negative consequences in the form of less information being disclosed to the state for future use, on expiry, by the public.
 4. **Stricter patentability criteria may disincentivise investment by originators.** This is because frivolous patents (or those used as a means of evergreening) that are challenged are judged by stricter standards and are less likely to be upheld. This would result in higher litigation costs for originators with a smaller chance of a 'weaker' patent being upheld. As a consequence, there is less chance of patent protection to recoup these initial investments.
 5. **Stricter criteria for patentability do not necessarily translate into higher quality technologies.** While the higher bar for granting patents ensures that patents have increased validity, there is no guarantee that the medical technology being patented is of a higher standard internationally. This is because the territorial nature of patents only protects innovation from local competition. In relation to foreign territories patented South African technologies are not necessarily more competitive.
 6. **Drug evergreening in the pharmaceutical industry may be marginally curbed.** However, this is possibly at the cost of other industry innovations which are consequently deterred by stricter criteria. Section 25(9) allows for the patenting of new uses of known substances within the pharmaceutical industry but introducing stricter patentability criteria to curb the abuse of this provision may still curb innovation that is legitimate within the industry, such as those relating to medical devices.
 7. **It is possible that the application of stronger or different patentability criteria specifically to the pharmaceutical industry may be contradictory to TRIPS Art 27.1.**⁷¹ However, the World Health Organisation (WHO) cites the EC-Canada case⁷² in which the panel found that: "Article 27 prohibits only discrimination as the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that

⁷⁰ See http://www3.weforum.org/docs/WEF_GlobalCompetitivenessReport_2013-14.pdf

⁷¹ The Article states that 'patents shall be available for any inventions, whether products or processes, in all fields of technology'.

⁷² See WT/DS114/R, 17 March 2000

may exist only in certain product areas". Furthermore, public health is not seen as a 'field of technology', but rather a problem area that may be addressed with products originating in different technological fields, such as equipment, software, diagnostic kits, medicines, and a large variety of devices used for medical treatment.⁷³ As noted, section 25(9) of the Patents Act is regarded as a TRIPS Plus provision.

3.3.8. Application of analysis framework

To analyse the aforementioned effects on the various stakeholders, recommendations are formed using the framework described in Section 1.3.

Theoretically, can the policy objective be met through the proposal?

It is possible for evergreening practices, particularly in the pharmaceutical industry, to be curbed by introducing stricter patentability criteria. By disallowing the patenting of new uses for known substances, patent applications will more likely be for newly developed innovations with legitimate and novel improvements. As a result frivolous patents for the sake of prolonging patent protection will fall away.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|---|-----|----------|------|
| Efficient court processes and procedures regarding infringement cases for successful implementation ⁷⁴ | | X | |

All things equal⁷⁵, efficient court and judicial processes are a key requirement for ensuring that stricter patentability requirements result in stronger quality patent protection. While the legislative changes can be successfully formulated, implementation through the judicial system is what gives the patentability criteria effect. This is because under the current depository system, the granting of a patent is purely administrative. The strength or quality of a patent is only tested in court under revocation proceedings. It has been argued that in South Africa, revocation procedures are fast and can be cost efficient.⁷⁶ Other stakeholders claim that revocation proceedings can be complex, costly and lengthy.⁷⁷ However this is not an indication of the quality of decisions made. Since the system is currently efficient in some aspect, there is a balanced probability of this success factor being fully secured.

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|---|-----|----------|----------|
| Curbing drug evergreening at the cost of legitimate incremental innovation in the pharmaceutical industry | | X | |
| Fewer patent applications imply less information disclosed for public use at expiry of patent | | | X |

⁷³ <http://apps.who.int/medicinedocs/en/d/Js2301e/13.html>

⁷⁴ Assuming the depository system persists in South Africa

⁷⁵ In particular, this success factor is critical if the depository system remains in place.

⁷⁶ From stakeholder interviews with law firm Adams & Adams

⁷⁷ UNDP (2013), *Using law to accelerate treatment access in South Africa*

Section 25(9) allows for the patenting of new uses of known substances within the pharmaceutical industry but introducing stricter patentability criteria to curb the abuse of this provision may still curb innovation that is legitimate within the industry, such as those relating to medical devices. The restriction on patentability assumes that additional patents associated with a product will be weaker which may in reality be untrue. For this reason a balanced probability of curbing legitimate innovation is assumed. The risk of less information being disclosed for public use at expiry of patent has a higher probability of occurring. This is based on the assumption that increased patentability criteria result in less applications. It should be noted that with a depository system, like South Africa's, all applications are likely to be granted through the administrative process.

Can these risks be mitigated?

The above risks are considered to be medium and high respectively. In the case of curbing drug evergreening at the cost of legitimate innovation in the pharmaceutical industry, mitigation is complicated due to the fact that TRIPS Article 27.1 requires that *'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology...'*. As such, applying stricter patentability criteria in any way that isolates the pharmaceutical industry to curb evergreening may go against this. However, it is often argued that healthcare is a social welfare issue and not a field of technology. A Government of South Africa submission to WTO to discuss and clarify this issue of discrimination / differentiation may be necessary. In addition, if the patentability criteria are carefully crafted, this may limit the negative effects on innovation in other industries. Such as in the India case (see Section 3.3.11), the patentability criteria can include the requirement of enhanced efficiency. This has the ability to curb evergreening while still encouraging innovation in other fields, if either examination is conducted before granting of the patent or efficient court processes are in place for revocation. A second mitigation option may be to remove the provision for patents of new uses of known substances as per section 25(9) of the Patent Act that relates specifically to the pharmaceutical industry. In all likelihood, the industry would then make use of section 39(3) of the Patent Act which makes use of patents of addition. This provision allows for innovation but is difficult to abuse in the same way as evergreening given that the expiry date of the patent does not move out further with a successive patent of addition.

The risk of fewer patent applications implying less information disclosed for public use at expiry of patent is a longer term one. The effects thereof will likely be decreased innovation and knowledge dissemination. This will need to be addressed through more focused interventions that encourage innovation and technology transfer.

3.3.9. Policy recommendation

As a result of the above analysis, policy implementation should be adopted with amendments, considering that the true extent of evergreening in South Africa is unclear. Even if evergreening is shown to be extensive, introducing stricter patentability conditions will not fully eradicate the practice. The additional requirement for a new use of a known substance to also display 'enhanced efficacy' is one way of curbing evergreening while still encouraging innovation in other industries. This has been done in India which is covered in the case study below. There exists a second, more targeted, alternative – the SSE system - which is able to achieve the policy objective of curbing evergreening, without the risks of curbing widespread innovation. However this option comes with its own set of risks (e.g. delays in patent prosecution) and higher costs (e.g. human resources and access to databases). For more see Section 3.1.

3.3.10. Alternative options

To achieve the policy objective of curbing evergreening, the SSE system may be used in place of introducing stricter patentability criteria. The examination process inherent in the SSE system would ensure that patents are granted for innovative improvements. However, it should be noted that the SSE system may not be as cost-effective as amending patentability criteria and has inherent delays due to the examination processes involved. See Section 3.1 for more on this.

3.3.11. Country comparisons

India

India has set the standard for developing countries seeking to curb the patenting of new uses of known substances. It is included here as an example due to the fact that the patentability criteria has been fully and explicitly tested in the following court case. Section 3(d) of the Indian Patents Act states that:

“The following are not inventions within the meaning of this Act... (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy...”

In other words, for a substance to be patentable it should, in addition to the three conventional patentability criteria (i.e. novelty, non-obviousness and industrial applicability), a known substance should also exhibit enhanced efficacy.

The main objective of section 3(d) of the Indian Patents Act is to avoid pharmaceutical companies obtaining patents on old medicines that constitute an incremental or trivial improvement of known substances. It also disallows patents on the discovery of new forms or new uses of old drugs.⁷⁸ The provision has been approved by WHO Public Health⁷⁹ and countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent evergreening patents from being granted.

This provision became the subject of litigation in India and garnered global attention when Novartis challenged a ruling by Indian patent authorities that its leukemia drug *Glivec* was only a slightly modified form of an existing treatment, *Anti Leukaemia*. The company looked to patent Glivec based on the claim it was 30% more soluble than its predecessor but the court questioned the newness of the application.⁸⁰ A High Court ruled that the Patent Office was

⁷⁸ *India: Section 3(D) Of Indian Patents Act 1970: Significance And Interpretation*, Aayush Sharma, Singh & Associates, available at

<http://www.mondaq.com/india/x/295378/Patent/SECTION+3D+OF+INDIAN+PATENTS+ACT+1970+SIGNIFICANCE>

⁷⁹ Innovation and Intellectual Property Rights Report 2006

⁸⁰ http://articles.economicstimes.indiatimes.com/2012-10-31/news/34837228_1_glivec-indian-patents-act-therapeutic-efficacy

justified in its exclusion of a patent application for *Glivec* on the grounds of section 3(d). Novartis appealed this decision to the Madras High Court on the following grounds:

- The criterion of enhanced efficacy is in addition to the TRIPS criteria. While the TRIPS agreement gives WTO members the option of granting patent rights that provide more protection than the basic criteria mandated by TRIPS, it does not allow members to implement stricter requirements for obtaining a patent. As such section 3(d) is unconstitutional because it violates the provision of the TRIPS agreement.⁸¹
- The Indian Patents Act fails to define terms such as ‘efficacy’ and ‘substance’ bestowing ‘unguided power on the Controller’. In turn, the Act is vague and illogical.

In response to each reason for appeal:

- The High Court looked into the conflict between the international law and municipal law and ruled that municipal law prevails in such conflict. Moreover, in India, international treaties are not directly enforceable.
- The court also rejected the second contention since “Efficacy means the ability to produce a desired or intended result. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be therapeutic efficacy.”

Based on this, the Supreme Court, where the matter was finalized, upheld the decision by the Madras High Court and Indian Patent Office and rejected Novartis’ patent application.

This decision will likely have implications on the limits of the new uses exception worldwide, given that it has taken place in the world’s largest generic pharmaceutical manufacturing locale.⁸² The rejection of Novartis’ application opens the doors for a range of generic manufacturers to supply cheaper copies of *Glivec* to poor patients. Notwithstanding the complex channels of public health, the ruling represents a move in the right direction for access to inexpensive medicines in developing countries.

Although it is too soon to determine the effects of the decision, in a 2014 interview Rohit Malpani, director of policy and analysis at *Medecins Sans Frontieres (MSF)* claimed that *‘In the absence of such a system, patented medicines in South Africa, for example, can cost up to 35 times more than in countries like India.’*

Conversely, the ruling may adversely affect investment in the pharmaceutical industry. In reaction to the ruling, Ranjit Shahani, vice chairman and managing director of Novartis India warned that

‘We should be more worried about what impact this will have on patient well-being and the ability to address the challenge of unmet medical needs. Meanwhile, all R&D investments in any case have moved to China with seven global companies having invested billions of dollars

⁸¹ The counter-argument to this is that the ‘enhancement of known efficacy’ is equivalent to the ‘surprising effect’ requirement which is an accepted for the inventive step in many jurisdictions including the European Union (see *India: Section 3(D) Of Indian Patents Act 1970: Significance And Interpretation*, Aayush Sharma, Singh & Associates).

⁸² Development Dimensions of Intellectual Property in Indonesia

after the patent law was promulgated in India. These are Novartis, Roche, Sanofi, Pfizer, GSK, Astra Zeneca and Elli Lilly. Not a single investment came to India.'

Further investment data over the coming years will make it possible to test whether the claim that such investment has indeed been redirected from India due to the strengthening of patentability criteria.

3.4. COMPULSORY LICENSING

Compulsory licensing is the authorisation, by the government, to someone other than the patent holder to produce, import or export the patented product without the consent of the patent owner. In other words, a compulsory license is an involuntary contract between a willing buyer and an unwilling seller which is imposed or enforced by the state.⁸³ Article 31 of the TRIPS Agreement lists several conditions which a compulsory license and its issuance are subject to:

1. the party applying for a compulsory license must have attempted to negotiate a voluntary license with the patent holder on reasonable commercial terms (however in the cases of emergencies, anti-competitive practices and government use this does not hold),
2. the patent holder must be adequately remunerated,
3. the license cannot be given exclusively to the licensee(s), i.e. the patent holder is allowed to continue to produce, and cannot be reassigned,
4. scope and duration is limited for the purpose in which the use was authorised,
5. each case must be considered on its own merits, and
6. a compulsory license should be subject to legal review and appeal in the country of issue.

The flexibility has been present in the TRIPS Agreement since it took effect in 1995. However, since then concerns began to surface around patent rules restricting access to affordable medicines. This proved especially true in developing countries attempting to control diseases of public health importance, including HIV/AIDS, tuberculosis and malaria. In response, World Trade Organisation (WTO) Members adopted a special Ministerial Declaration in Doha to clarify ambiguities arising from governments concurrently applying the principles of public health and the terms of TRIPS.⁸⁴ The 'Doha Declaration'⁸⁵ states that members may stipulate other grounds, such as those related to non-working of patents, public health or public interest under which a compulsory license is issued. As such, the ability to issue a compulsory license is not necessarily limited to an emergency situation.

The Doha Declaration contains a major revision⁸⁶ to paragraph (f) of TRIPS Article 31 which restricted the issuance of compulsory licenses for the purpose of supplying the domestic market. This change allows for the issuance of a compulsory license to produce drugs for

⁸³ Gupta, R., *Compulsory Licensing under TRIPS: How far it addresses public health concerns in developing nations*, August(2010)

⁸⁴ http://www.who.int/medicines/areas/policy/doha_declaration/en/

⁸⁵ This is often referred to as the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, which was adopted by the World Trade Organization's General Council on August 30, 2003.

⁸⁶ The Declaration itself has not yet taken place but members are bound to the Implementation Decision

export to developing countries which can prove insufficient or nonexistent manufacturing capacities in the pharmaceutical capacity.⁸⁷ To effectively use the provision, potential importing and exporting countries may require a change to their local legislation, particularly to the requirement that production under compulsory licensing be predominantly for the domestic market. So far Norway, Canada, India and the EU have formally informed the TRIPS Council that they have changed their legislation in this regard. Article 31 remains the applicable directive when compulsory licenses are issued for purposes other than local domestic supply.

3.4.1. Policy proposal

The Draft Policy recommends that

1. *Compulsory licensing should be introduced in South Africa in line with international treaties, such as the Doha Decision 6 of the WTO negotiations on Trade and Public Health.*
2. *South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health.*

The policy proposal is interpreted to mean that existing legislative provisions for compulsory licensing within the Patents Act should be amended to specifically allow for public health considerations, in line with the Doha Declaration.

3.4.2. Status quo

In South Africa, section 56 of the 1978 Patents Act provides for compulsory licences to be granted when patent rights are being abused⁸⁸ and the patent is to be used for public purposes.

Although a compulsory license has never been formally, publicly issued in the South African context, a few negotiations have reached private settlements in the form of voluntary licenses. The closest documented example remains the Treatment Action Campaign's case against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) in 2002.

In 2001, Indian pharmaceutical manufacturer Cipla formally requested South Africa's dti to issue compulsory licenses for patents relating to the following HIV drugs: nevirapine, lamivudine, zidovudine, stavudine, didanosine, efavirenz, indinavir and abacavir. Cipla was to sell these treatments at approximately R3 000 below the price offered by most multinationals. In essence, Cipla wanted to be granted compulsory licenses to import and market generic ARVs. The request was denied and TAC decided to intervene in the matter in 2002 by filing a complaint with the Competition Commission against GlaxoSmithKline and Boehringer Ingelheim.⁸⁹ TAC, which was eventually joined by 12 other parties, charged these corporations with excessive pricing in respect of ARVs.⁹⁰ The pharmaceuticals were both found to have contravened the Competition Act of 1998, and to have abused their dominant positions in their

⁸⁷ Ibid. 83

⁸⁸ Generally, this is the inadequate use and hence, locking up, of useful information

⁸⁹ Berger, J.M., *Litigation strategies to gain access to treatment for HIV / AIDS: The case of South Africa's Treatment Action Campaign*, Wisconsin International Law Journal, 2002

⁹⁰ Love, J.P., *Recent examples of the use of compulsory licensing on patents*, Knowledge Ecology International, 2007. Available at http://www.keionline.org/misc-docs/recent_cls.pdf

ARV markets. The parties settled privately before the Competition Tribunal could issue a decision. The terms of the final settlement require the firms to:⁹¹

1. extend the voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector;
2. grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare;
3. permit the licensees to export the ARVs to sub-Saharan African countries;
4. permit the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa;
5. permit licensees to combine the relevant ARV with other antiretroviral medicines; and
6. charge royalties of no more than 5% of the net sales of the relevant ARVs.

Given that no public compulsory license has been issued in South Africa, the status quo consists mainly of speculation by stakeholders around the following themes:

Compulsory licensing as a tool for improved access to drugs.

By affecting a compulsory license on a patented drug, the monopoly rights of the patent holder are diminished due to the fact that another party may manufacture the product, thus limiting control over accessibility. As a result, the entry of a generic into the market is facilitated. This results in increased competition to the originator and decreased prices of, often, lifesaving inventions and medicines. In the case of pharmaceuticals, originator companies argue that there are few cases in which the process of compulsory licencing is the best policy option to promote access to medicines. There is a danger that monopoly powers and hence profitability of drugs comes under threat. In this way the investment incentive and innovation in new therapeutic fields and medicines is stifled, particularly by large pharmaceuticals. On the contrary, developing countries such as South Africa form a very small and often less profitable component of these large pharmaceutical companies' revenue portfolio. Patients in industrialised nations often have health insurance which allows health companies to charge higher rates. In addition, in 2009 South Africa made up only 0.4 percent of global pharmaceutical companies' total revenue.⁹² As a result, extremely limited investments are made into developing countries such as South Africa, making the risk of disinvestment less severe.⁹³

A better approach may be to partner with research-based pharmaceutical companies to research innovative pricing approaches such as tiered pricing and income-determined patient access programmes.⁹⁴ Medicine production forms one part of a complex process of healthcare delivery. Without fixing structural, long term issues in the South African health system such as poor systems of accountability, infrastructure and funding constraints and the scarcity of health professionals and managers⁹⁵, compulsory licensing may remain a limited policy option.

⁹¹ <http://www.cptech.org/ip/health/cl/recent-examples.html> (currently Knowledge Ecology International)

⁹² Kudlinski, A., *The South African Pharmaceutical Sector Profile for the Consideration of Designation of Pharmaceutical Products in Terms of the PPPFA*, South African Department of Trade and Industry, 2011

⁹³ Mugambe, L., *The exceptions to patent rights under the WTO-TRIPS Agreement: Where is the right to health guaranteed?*, 2002

⁹⁴ Commentary submission by Pfizer

⁹⁵ Francis, K. and Edemeston, E., *Beyond Band-Aids: Reflections on public and private health care in South Africa*, 2012

Litigation process and associated costs of a compulsory license application.

Several stakeholders have pointed out that the legislation enabling compulsory licensing in the Patent Act of 1978 is subject to lengthy and expensive processes. Any application for a compulsory license must be heard by the Commissioner of Patents in what amounts to a full judicial proceeding. The proceeding is also subject to review in the High Court. This procedure is not a TRIPS requirement. A 2013 UNDP Report⁹⁶ claims that such a procedure may take three or more years to conclude. In addition significant legal and technical costs are incurred through the action, particularly in an unsuccessful application. On the contrary, there are stakeholders who are of the view that further amendments to the current legislation are unnecessary because the Minister of Health is nevertheless able to declare a national health emergency and issue a compulsory license. This is done by exercising the relevant TRIPS provisions.

Section 4 of the Patents Act makes provision for government use licenses, a specific kind of compulsory license. This is a compulsory license which is issued by the state to itself for public non-commercial use. Unlike a normal compulsory license, government use licenses do not require prior notice or negotiation with the patent holder. However, notification and payment of fair compensation is required afterwards.

Negotiating power of compulsory licensing.

Compulsory licenses are seen as a more adversarial means of negotiation with patent holders. While they allow for the use of patented information without the patent holders consent, it does not require the patent holder to transfer technical expertise and institutional knowledge required in the production of the drug / invention. The threat of acquiring a compulsory licence is considered sufficient leverage, against patent holders, to seek a negotiated voluntary license. Unlike a compulsory license, these are able to include terms such as the transfer of other knowledge and skill to the new manufacturer.

Incentives to apply for a compulsory license.

The process of compulsory licensing is usually initiated by an application by a third party. Given the antagonistic nature of this route, it is unlikely that generic manufacturers who have multifaceted commercial relationships with originator drug companies will be eager to make such an application. On the contrary, there are Indian and Chinese generic manufacturers with no ties to these originators that are willing to produce under compulsory licenses. To make use of such generic companies, it may be necessary for government to drive the compulsory licensing process.

From a more practical perspective, if South Africa issues a compulsory license but does not have the pharmaceutical manufacturing capabilities at hand it may import these products under the Doha Declaration. However South Africa is yet to amend local legislation, in line with the Implementation Decision of the Doha Declaration, to provide for the export and import of patented products under a compulsory license.

3.4.3. Problem statement and evidence

Our interpretation of the problem around compulsory licensing in SA is that the current application procedure is subject to long time delays and high costs, which are problematic

⁹⁶ Ibid. 77

insofar as the guiding legislation is open to interpretation, and thus makes the outcome of the judicial process highly uncertain.

The fact that only one compulsory license has been issued in the context of South Africa's healthcare challenges since the introduction of the enabling legislation, and another license under the DOHA regime (Canada-Rwanda), suggests that compulsory licensing is, in one way or another, impeded. An alternative interpretation is that the issuing of voluntary licenses is often due to the threat of a compulsory license, and so the lack of compulsory licenses is not evidence of failure. Interviews with the Department of Health⁹⁷ suggest that generic manufacturing companies such as Aspen Pharmacare frequently negotiate voluntary licenses to produce drugs at cheaper prices. In this way originator companies have more influence (than in the case of compulsory licensing) and can lessen the impact of lower prices on the international benchmarking of their drugs.

The litigation process and associated costs of a compulsory license application, as mentioned in the preceding section, may be one such barrier in applying for a license. A UNDP study estimates that it takes 3 years and R1 million to issue a compulsory license in SA. Other stakeholders⁹⁸ have estimated minimum costs of R200 000 – R300 000 to apply for a license. Given that only one high profile case has run its course, these are best guesses.

Generics manufacturer Cipla claims that it is typically not feasible for generic suppliers to make use of these provisions because burden of proof on an applicant is particularly high. For example, in the case of Syntheta (Pty) Limited (previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and another 1998 BIP 264 (SCA)⁹⁹ the application failed because the applicant failed to prove 'serious jurisdictional facts'. These include the claims that the invention was not being adequately worked, the reasonableness of the terms of previous negotiations and abuse of market dominance in terms of pricing.

3.4.4. Policy objective

Our interpretation of the policy objective underpinning the policy recommendations is to improve the application of compulsory licenses, both in terms of process and cost (however, there is no indication as to what form such changes would take) to advance public health objectives.

3.4.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's compulsory licensing legislation:

- Generators of IP (Generally, and with a focus on the pharmaceutical industry)
- Legal system and representatives
- Government
- Society
- Economy

⁹⁷ Interview with Gavin Steel, Head of procurement at South African Department of Health

⁹⁸ Innovation Hub, Adams & Adams

⁹⁹ See judgement at <http://www.saflii.org/za/cases/ZASCA/1998/74.html>

In addition, the effects have been split between immediate (short and medium term) and broader (long term) effects.

3.4.5.1. Generators of IP: likely negative

Once a compulsory license is effectuated, innovators are more likely to suffer from the partial erosion of IP rights. In the case of a compulsory license being issued, the patent holder is still entitled to remuneration but loses the freedom to negotiate directly with licensing partners. However, issuance of a compulsory license is only possible if voluntary negotiations fail.

3.4.5.2. Legal system and representatives: likely positive

Applications for a compulsory license require extensive proof which results in increased legal participation and hence fees.

Once compulsory license applications become more prevalent, due to easier application costs and processes, the accumulation of legal skill and expertise in such cases should occur.

3.4.5.3. Government: indeterminate

The direct effects to government in terms of effectuating compulsory licensing are substantial. Firstly, the ability to issue such a license increases the state's bargaining power in voluntary negotiations with the patentee. If properly implemented, a compulsory license to a pharmaceutical company can cause a direct decrease in the public health spend of these drugs due to lower prices.

However, it should be kept in mind that there exists a significant burden of proof in the application for a compulsory license. Legally, it must be shown that certain conditions are fulfilled and the issuance of the compulsory license is justified. For example, the *Evidence* write up of this section refers to the judgment in Syntheta (Pty) Limited (previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and another 1998 BIP 264 (SCA).¹⁰⁰ Other requirements include formal notification to the World Trade Organisation (WTO). Once a compulsory license is issued, manufacturing under the compulsory license becomes the applicant's responsibility. If the South African government is the applicant, the risk of implementation is one that must be adequately managed. This may include a co-ordination of members of different industries and government.

If the South African government were to effectuate the Doha Declaration, it would be required to make legislative changes that allow for the import and export of products under a compulsory license as per the Implementation Decision. This would have resourcing effects, as members of the government pass the change through parliament, as well as potential timing delays. If South Africa looks to import products under the Doha Declaration it would also need for the exporting country to have effected this change in their legislation. Given that China and India, our most probable trade partners in APIs and other pharmaceutical products, have made the necessary amendments, amending our own local legislation would allow us to take full advantage of the Doha Declaration.

In the longer term, the effectuation of compulsory licenses may jeopardise on-going relationships with companies for whom a compulsory license is a material threat. Although the product may simply be replaced in the case of a withdrawal of supply by patentees, the

¹⁰⁰ See judgement at <http://www.saflii.org/za/cases/ZASCA/1998/74.html>

government's relationship with these originator companies may be valuable in the future. Characteristics such as location, price or even the specific product (such as second- and third-line drugs) itself make the government, in some ways, reliant on originator manufacturers and unable to substitute away from the original product.

3.4.5.4. **Pharmaceutical focus: indeterminate**

Given that originator pharmaceutical companies invest heavily in R&D patent protection is an important factor in recouping these costs. The output of R&D investment is often lifesaving medication which can prove essential in managing health crises. As such pharmaceutical companies are particularly affected if compulsory licensing is effectuated where the erosion of patent rights needs to be balanced with provision of affordable medical treatment.

If compulsory licensing is a constant, real threat to pharmaceuticals, in the longer term on-going relationships with public sector clients may become adversarial. For generic manufacturers, a compulsory license can increase demand for the drugs in question, as a manufacturer is required to produce the cheaper medication under the compulsory license. If this is a local manufacturer using what is most likely to be developed country technology, the absorption of such expertise can translate into increased productivity as developed country technology is absorbed. This is subject to a concerted effort to effectively transfer such technology and break down other barriers to productivity such as insufficient human capital or weak institutional arrangements.

3.4.5.5. **Society: indeterminate**

As a longer term effect, if relationships between healthcare providers and pharmaceutical manufacturers are harmed, access to health may be inhibited. Due to the fear of a compulsory license being issued, companies may cut R&D investment as reduced patent protection reduces the ability to recoup costs. As such, the R&D into medicines specific to developing countries / regions may suffer, leading to a lower chance of provision of such medicines.

If compulsory licensing is successful and the production under the license occurs efficiently, the applicable inventions should be sold at lower prices. The increased competition by these goods will also introduce a wider range of choice to consumers, which has the potential to lower prices. In the case of medicines, this will contribute to improved access to healthcare.

3.4.5.6. **Economy: indeterminate**

If a compulsory license is used to break up monopoly power or the abuse of a dominant market position by a patentee, this can have the effect of increased competition. The benefits of this include lower prices for consumers and a broader distribution of profits within the industry. The effectuation and issuance of compulsory licenses may lead to South Africa being seen as an investment destination which does not prioritise the protection of IP rights. This could dampen FDI as international companies prefer other territories where patent protection is stronger, affording patentees monopoly power.

3.4.6. **Assessing benefits / pros**

1. ***The option of a compulsory license provides the government with substantial bargaining power both before and, potentially, after issuance.*** In negotiations for a voluntary license stakes are raised given that the next option available to government

is a compulsory license, the conditions of which are not in favour of the patentee. Once a compulsory license is issued, a signal is given to other players in the industry that the government is committed to advancing access to medicines and the compulsory licensing process, ensuring that future negotiations are carried out more conscientiously e.g. Brazil and Malaysia with regards to compulsory licensing in the pharmaceutical industry.¹⁰¹

2. ***The issuance of a compulsory license will include terms and conditions which require the new producer or importer to provide the product at lower prices.*** Alternatively, compulsory licenses allow generic manufacturers to lower marginal costs by expanding the demand pool i.e. selling in countries other than the local market. This has the potential to, through increased competition, decrease price. According to Health Minister Dr. Aaron Motsoaledi¹⁰², the country is a long way off the World Health Organization's (WHO) recommendations on public health spending. South Africa spends about 8.5 percent of GDP, higher than the WHO's recommended five percent and three other BRICS countries. Brazil, with a population nearly four times South Africa's, has an index that is only 0.5 percent higher. If properly implemented, a compulsory license to a pharmaceutical company can cause a direct decrease in the public health spend of these drugs due to lower prices.
3. ***Compulsory licensing has the ability to foster the development of a local industry.*** The up skilling of a local manufacturer not only creates additional employment but also results in the local assimilation of developed country technology.
4. ***Compulsory licenses may lead to a reduction in the unnecessary locking up of useful information or patent abuse.*** If conditions associated with a compulsory license allow for / require technology transfer to local players, this allows for the distribution of useful information that would, under regular patent laws, be considered an infringement.
5. ***Compulsory licenses can be used to break up monopolies and cartels, another abuse of patent rights.*** This can be done by issuing the compulsory license to an outsider to the cartel or industry for increased competition.

3.4.7. Assessing costs / cons

1. ***Generics companies may be unwilling or unable to provide manufacturing services.*** A compulsory license is a last resort once voluntary licensing negotiations have failed. Resorting to the annulment of certain patent rights means that the process is often antagonistic by nature. For this reason it is unlikely that generic manufacturers who have multifaceted commercial relationships with originator drug companies will be eager to make such an application or take part in the manufacturing process. A search for generic manufacturers with no ties to these originators that are willing to provide manufacturing services may be required in this case.
2. ***Decreased investment in drugs for developing country diseases.*** The possibility of compulsory licensing can adversely affect investment by companies given that the exclusivity of a patent is under threat. This creates uncertainty around whether

¹⁰¹ <http://www.kommers.se/Documents/dokumentarkiv/publikationer/2008/rapporter/report-the-wto-decision-on-compulsory-licensing.pdf>

¹⁰² See Focus Report, *South Africa Pharma report*, 2012

research and development costs may be fully recouped, affecting profitability of investments. However, there is evidence to suggest that originator companies do not invest in drugs designed to combat diseases that dominate Sub-Saharan Africa, due to the low spending power of African governments/citizens and hence low profits. Unless the disease also afflicts citizens of developed countries and a combination of adequate incidence and the spending power of developed country governments/health insurance industry/citizens justifies the R&D investment. On the other hand, innovation in drugs for “poor country diseases” is a critical element in tackling public health issues.¹⁰³ As such, any disinvestment by originator companies, and hence no treatment, may be worse than the high prices of drugs that are available.

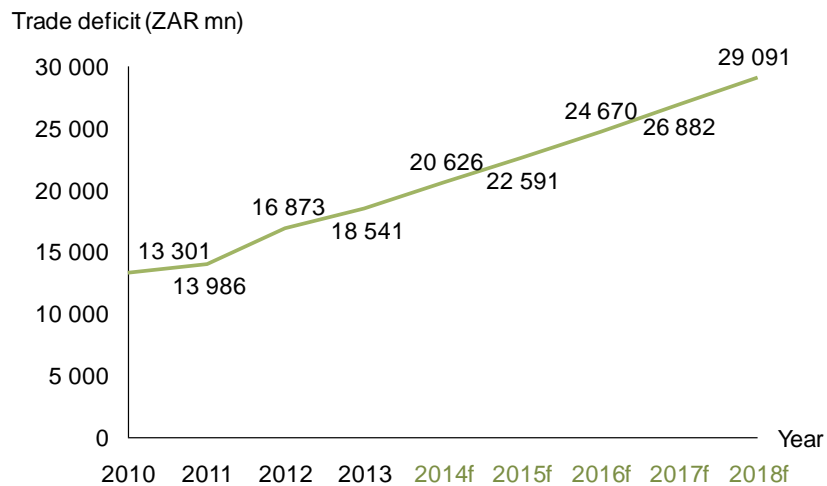
3. ***Another consequence of the antagonistic nature of compulsory licensing is that there is no guaranteed transfer of technical knowledge beyond anything disclosed in the patent application.*** This will require the compulsory license holder to invest in reverse-engineering the patent, which may be expensive and technically complex.
4. ***The burden of proof by the applicant may be considerable.*** Applicants are required to provide proof that previous negotiations have been reasonable, but unsuccessful, is required. In addition, instances of patent abuse must be convincingly proven. In the case of *Syntheta (Pty) Limited (previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and another 1998 BIP 264 (SCA)*, the applicant was unsuccessful because they were unable to provide evidence that i) the decision not to extract full commercial gain from the patent (i.e. patent abuse) was not economically rational, ii) substantial consideration has been made with regards to the public health benefits of the compulsory license (not purely commercial gain), iii) offers in failed negotiations, prior to litigation, were reasonable and iv) pricing was an instance of abuse of market position.¹⁰⁴
5. ***Applicants face the legal costs and time delays.*** Given that the ultimate decision is highly uncertain, the potentially high costs and long time delays acts as a deterrent to applicants.
6. ***If compulsory licensing adversely affects companies closely associated with large trade partners, government will be subject to severe international and local criticism*** as in the case between Brazil and the U.S. (see Brazil case study). The U.S. is South Africa’s 4th largest origin country of import (valued at R1.2bn) and the largest export destination (valued at R75m) of pharmaceutical products.¹⁰⁵ Even excluding APIs, the pharmaceutical sector runs a significant trade deficit which looks set to grow (See Figure 3 below). This dependence on trade to supply pharmaceutical predicts to the local market should not be underestimated.

¹⁰³ Ibid. 93

¹⁰⁴ See *Syntheta (Pty) Limited (previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and another 1998 BIP 264 (SCA)*

¹⁰⁵ Ibid. 92

Figure 3. South Africa Pharmaceutical Trade Data and Forecasts (ZAR million), 2010-2018



Source: BMI report, *South Africa Pharmaceuticals & Health Report, 2014*

7. ***In many developing countries, manufacturing capacity may not be ideally placed to deliver on the actual production under a compulsory license.*** While the Doha Declaration allows for the importation of the product, middle income countries such as South Africa may have some capacity to build on. To ramp up on this research and capacity takes a concerted effort with considerable coordination.¹⁰⁶ While South Africa has a developed pharmaceutical manufacturing base¹⁰⁷ it is somewhat limited with regards to the production of Active Pharmaceutical Ingredients (API).¹⁰⁸ In this regard, South Africa faces stiff competition from India and China.¹⁰⁹ To be able to import medication under the Doha Declaration, not only would South Africa still need to effect the legislative changes that provide for the Doha Implementation Decision but it would need to be confirmed that the related exporting country also has provision to do so. Potential supplier countries such as India, China, and South Korea have all amended local legislative regimes to allow for the export of pharmaceutical drugs to address public health concerns. It should be noted that a highly likely consequence of enabling the Doha Declaration is that of increased dependence on these import countries. Local manufacturing capabilities may remain underdeveloped as they fail to compete with these cheaper imports.

8. ***Costs are not totally eradicated.*** Although the terms of a compulsory license allows for the manufacturing of the product by a third party, the patentee's right to compensation is not wavered. This implies that while costs are lower, they are not entirely removed.

3.4.8. Application of analysis framework

¹⁰⁶ See the case study of Brazil below.

¹⁰⁷ Roche and Fansidar have a malaria manufacturing centre in Cape Town, GSK has a plant for manufacturing its deworming agent, Albendazole, in Cape Town and Sanofi-Aventis has set up a global TB manufacturing hub in South Africa (see Wen, Y, and Matsaneng, T., *Patents, pharmaceuticals and competition: benefiting from an effective patent examination system*, Competition Commission South Africa. Available at: <http://www.compcom.co.za/assets/Uploads/events/Seventh-Annual-Conference-on-Competition-Law-Economics-Policy/Parallel-3B/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf>)

¹⁰⁸ <http://www.who.int/bulletin/volumes/92/3/13-128413/en/>

¹⁰⁹ Stakeholder interview with IPASA

To analyse the aforementioned effects on the various stakeholders, recommendations are formed using the framework described in Section 1.3.

Theoretically, can the policy objective be met through the proposal?

The policy objective of advancing public healthcare can be met through the use of compulsory licensing. However, it should be noted that it is only able to address a singular aspect of access to healthcare, namely, price. Other pillars of public healthcare must be considered separately. A report by **the dti**¹¹⁰ points out critical weaknesses at the provincial level regarding the logistics of medical supplies, stock shrinkage, HR problems and procurement of contractors / agents who add little value at high commissioning rates. These issues affect the achievement of access to healthcare but have little consequence in terms of compulsory licensing.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|--|------------|---------------|-------------|
| Proof of conditions justifying a compulsory license in court | | X | |
| Clear and regular communication regarding the process | | X | |
| Co-ordination of human capital to implement technology transfer arrangements | X | | |
| Legislative amendments to enable use of Doha Declaration | | | X |

While many applications for compulsory licensing have been made in the South African context, none have reached a public, formal conclusion. One of the main reasons is the failure of applicants to provide the court with robust proof that the license is justified. Compulsory licenses can only be issued if, amongst others, it can be shown that voluntary negotiations have been reasonable and unsuccessful, it is economically reasonable for patentees to not exercise a patent and that public welfare is at stake due to the manner of use of a patent.¹¹¹ As such there is an equal probability of securing this success factor as proof will differ on a case-by-case basis.

In the case of Brazil, communication during the process of compulsory licensing was critical to success. This included details of pricing by the different parties during voluntary negotiations. Once a compulsory license was eventually issued, this did not come as a surprise to any party. Communication by the Brazilian government opened dialogue around the process and allowed for trade partners and other organisations to raise objections and warnings. This works towards mitigating the risk of adversarial relationships mentioned below. There is an equal probability of this success factor being secured given that many stakeholders have criticized the IP policy process thus far, finding it non-inclusive and uncoordinated. However, with government aware of the importance of communication this may be addressed in future.

The third critical success factor drawn from the analysis is the co-ordination of human capital to implement technology transfer arrangements. Even if the arrangements and programmes are targeted and well thought out, the capacity for technology transfer remains

¹¹⁰ Ibid. 92

¹¹¹ See Syntheta (Pty) Limited (previously Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and another 1998 BIP 264 (SCA

underdeveloped. The preliminary 2014 National Scarce Skills List¹¹² acknowledges a lack of various engineers, science technicians, medical and agricultural scientists, industrial pharmacists and R&D managers in South Africa. These are assumed to be crucial for technology transfer processes, particularly in the pharmaceutical industry. Securing these skills is, at best, a long term possibility. For this reason there is a low probability of securing this critical success factor.

Although legislative amendments are easy enough to obtain they remain a critical success factor if compulsory licensing is to be implemented, particularly in the face of limited local pharmaceutical manufacturing capabilities. The costs to this are the time and resources required to follow the state process involved in any legislative amendment.

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--|-----|----------|----------|
| Insufficient local manufacturing capabilities to effect compulsory license | | | X |
| Adversarial relationships between private and public sectors | | | X |
| Decreased trade and / or Foreign Direct Investment | | X | |

An insufficient local manufacturing capability to effect compulsory licenses is a severe risk in the South African context. As mentioned, South Africa has a developed pharmaceutical manufacturing base but is somewhat limited with regards to the production of APIs. As such the risk of being unable to manufacture locally under a compulsory license is high. The Brazilian implementation of compulsory licensing was particularly effective given that the country has 300 pharmaceutical companies, including strong state-controlled R&D and manufacturing sector. In particular, companies such as FIOCRUZ and Far-Manguinhos have been vital in reverse-engineering ARV technologies.¹¹³

Compulsory license issuance around the world have shown adversarial relationships developing between private companies, who are usually the patentees, and government, the issuers of compulsory licenses. These relationships may deteriorate during the process given i) the change of the patent protection levels initially depended upon by the patentee and ii) the power of civil society and public outcries to pressure government into issuing a compulsory license. The Brazil case reveals that a consequence of these adverse relationships is that often technology transfer is not included in the disclosure of protected information by the patentee. As a result the risk, upon issuance of a compulsory license, of these relationships deteriorating is very high.

An UNCTAD presentation on experiences of compulsory licensing around the world warns of the reality of possible trade repercussions. In Thailand, as a result of compulsory licenses issued, the U.S. removed three Thai export products from Generalized System of Preferences which reduced trade to the US by USD 380 million. However trade to the rest of the world increased by USD 521 million. The Thai Ministry of Health also claims that these licenses had

¹¹² See the South African Department of Higher Education and Training *Call for comments on the National Scarce Skills List*, published in Government Gazette Notice 380 of 2014

¹¹³ Ibid 92

no effect on the Thai Stock Exchange.¹¹⁴ As such, negative repercussions are more likely to be bigger in larger developing countries. In addition, the more compulsory licenses are issued, the more lessons are learnt and improved on, resulting in these repercussions being minimized. Based on these experiences, the risk of decreased FDI and trade is set at a medium level.

Can these risks be mitigated?

To address the limited manufacturing capabilities of developing countries that are looking to issue compulsory licenses, the Implementation Decision document of the Doha Declaration allows for the import of a drug which is under compulsory license. This is one mechanism which may be used to mitigate the risk of reduced manufacturing capabilities. However this comes with the warning that manufacturing capabilities, in particular of APIs, will likely never be developed in South Africa if patented drugs are imported. This is, in essence, an erosion of technology transfer to local manufacturers. In addition, South Africa will still be required to effect legislative changes for this to be made possible. In particular the South Africa's Patent Act will need to incorporate Article 31f) of the TRIPS Agreement. A decision will have to be made on whether South Africa will implement the Doha Declaration as an exclusive importer or as both exporter and importer. This in turn will require legislative amendments to align with the Doha Declaration's Implementation Decision, justifying the amendments as a critical success factor.

Ability to mitigate the last two risks is somewhat limited. Communication to all stakeholders and trade partners may provide opportunities to mitigate the negative repercussions. However, adopting a generalized mitigation strategy is unwise and each instance would require careful consideration of the factors aggravating relationships.

3.4.9. Policy recommendation

From the analytical discussion above, it is recommended that South Africa adopt the improvement of compulsory licensing implementation but with revision. It should be noted that the main advantage in improving compulsory licensing processes, and hence the *ability* to implement one, is the increased bargaining power in voluntary negotiations with patentees. It is the actual implementation of a compulsory license that triggers the aforementioned high severity risks. If the objective of government is to be able to manufacture a patented invention without permission from the patentee, an alternative to a compulsory license is a Government Use license. This is less arduous and may be used specifically for a state of emergency (for more see Section 3.4.2). A Government Use license focuses any intervention to a particular case where essential public goods are not being delivered due to excessive levels of patent protection. Government Use licenses do not require any amendment to the current legislation but do possess some of the risks applicable to a compulsory license such as relationship management and communication strategies.

In terms of successful implementation, developing technological capabilities for manufacturing under compulsory license is critical. As a secondary measure regarding manufacturing capabilities, legislative provision must be made for South Africa to import and export under the Doha Declaration. Clear guidelines for compulsory license application requirements should be published for the public and legal community. In addition, communication practices by government for use throughout the process of compulsory license issuance should be carefully considered.

¹¹⁴ von Braun, J., *Use of Compulsory Licenses: Selected National Experiences*, UNCTAD, available at: http://www.unctad.org/sections/dite_totip/docs/tot_ip_0018_en.pdf

3.4.10. Alternative options

Given that compulsory licensing is already in effect, alternative options are considered unnecessary.

3.4.11. Country comparisons

Brazil – the role of government in compulsory licensing

South Africa and Brazil are both middle-income countries that have capacity within the healthcare system to treat epidemics such as HIV / AIDS. For example both have high immunization rates against measles and TB¹¹⁵ and significant pharmaceutical manufacturing capacity relative to their region.¹¹⁶ However, a marked departure in the level of government action with regards to compulsory licensing is evident between the two BRICS nations.

In 1996 Brazil passed National Legislation for its Intellectual Property Law, which allows for compulsory licensing. In 2001, the Brazilian government publicly considered issuing a compulsory license for ARV Efavirenz but negotiations with manufacturer Merck & Co. for a price reduction were successful and the issuance was avoided. With the country's AIDS epidemic in a state of continued need¹¹⁷, the government then asked Merck to voluntarily license the generic production of Efavirenz for Brazil's National STD/AIDS Program. Negotiations began but failed in 2007 and the Minister of Health declared compulsory licensing of Efavirenz as acceptable for non-commercial, public interest purposes and as such issued the license.¹¹⁸

The compulsory license comprised a validity period of five years and compensation to Merck of 1.5 percent royalties. In addition, the Brazilian Government ordered Merck to transfer all technical documentation necessary for the production process. In response, the company provided the corresponding patent document only. The disclosure of the patented invention was found to be insufficient and did not enable the local generic company, Farmanguinhos, to produce a generic form of the drug. Farmanguinhos had to perform its own research activities on small, imported quantities of the generic from India. One of the main challenges for Brazil was the development of the local manufacturing processes. In response, an advisory group for the manufacturing processes and related issues was created by the Brazilian government, and a special group to accelerate the production established by the Brazilian regulatory agency.¹¹⁹ Two years later, Farmanguinhos eventually began production.¹²⁰ In the interim the government resorted to the importation of the generic, Stocrin, from India. These measures have resulted in a price reduction of the drug to USD 0.56 per pill from USD 1.56.¹²¹

The decision was not without its criticism, with the Brazilian government defending its position against its largest trading partners. In 2004, the US Trade Representative ranked Brazil among its "Special 301" Report's Priority Watch List countries. It has stated that "The Brazilian Government has at times indicated consideration of the use of compulsory licensing on patented pharmaceutical products". A US Congress member warned that compulsory licensing

¹¹⁵ UNDP, *Human Development Report*, 2001

¹¹⁶ See NEPAD, *Strengthening Pharmaceutical Innovation in Africa*, 2010 and Caliaro, T. and Ruiz, R. M., *Structure and Innovation in Pharmaceutical Industry in Brazil: The Impact of Generic Drugs*, 2010

¹¹⁷ Brazil spent more than R\$960 million on antiretrovirals in 2006, which was close to double the amount spent in 2003

¹¹⁸ Program on Information Justice and Intellectual Property (PIJIP), *Timeline on Brazil's Compulsory Licensing*, 2008

¹¹⁹ <http://www.accessstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/>

¹²⁰ Bond, E. and Saggi, K., *Compulsory licensing, price controls, and access to patented foreign products*, 2012

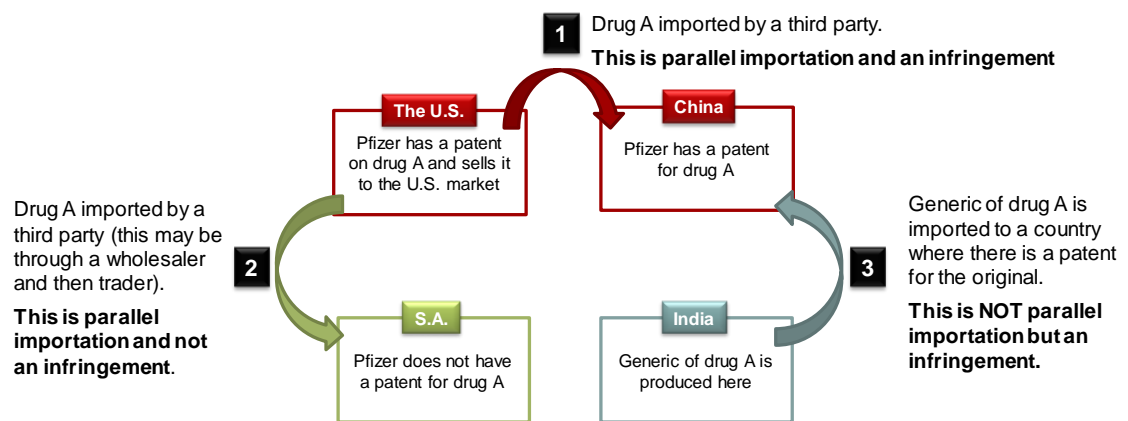
¹²¹ <http://www.aidsmap.com/Brazil-issues-compulsory-license-on-efavirenz/page/1427206/>

would threaten bilateral trade relations between the two countries while other Congress members called for sanctions should the country issue out compulsory licenses. Internal opposition also came in the form of the Brazilian Federation of Pharmaceutical Industry. Despite these challenges, and changes in the Minister of Health, the Brazilian government achieved an increased patient reach of 2.8 percent. With the generic introduction, the drug represents approximately 3.9 percent of the costs of the ARV expenditures of the Brazilian Government, down from 12 percent.¹²²

3.5. PARALLEL IMPORTATION

Parallel imports refer to products that are marketed in one country and imported into another country without the approval of the patent owner. These goods are first put onto the foreign market either by the patent owner or with the patent owner's permission. Parallel imports are not imports of counterfeit products or illegal copies. The following examples illustrate this:

Figure 4. Examples clarifying parallel importation



In the first case, an original drug is patented by a company, say Pfizer, in the U.S. Once the drug is sold and traded by a third party to another country where a patent is active, this is a parallel import. However, it is an infringement in the second country because the patent in China gives Pfizer the exclusive right to sell and import the drug. The second case is one where the receiving country does not have in place this patent protection. In this case the drug is still a parallel import but does not infringe on any patent. The final case is a parallel importation and also an infringement. This is because the generic is not the original drug and hence not a parallel import. It is also an infringement because the patent once again protects Pfizer from third party imports of the same product.

Parallel importation is governed by the principle of *'exhaustion of rights'*. This is the concept that once a patent holder, or any authorised agent, has sold a patented product they cannot prohibit the subsequent resale of that product. This is due to the fact that their rights in respect of that market have been exhausted by the act of selling the product. A *national exhaustion of rights* does not allow the patentee any control of commercial exploitation once the patented product has been legally sold. However, the patent holder may still oppose the importation of original goods marketed abroad based on the right of importation. In the case of *regional exhaustion*, the first sale of the patented product by the patent holder exhausts any patent rights not only domestically, but within the whole region, and parallel imports within the region can no longer be opposed based on the IP right. The *international exhaustion of rights* implies

¹²² Ibid. 119

that patent rights are exhausted once the product has been sold by the patent holder or with his consent in any part of the world.

In Figure 4 above, national exhaustion by China has been assumed in the first case of importation between the U.S. and China. If China decided to enforce an international regime of exhaustion then the importation of a drug would be parallel importation and no longer an infringement.

The TRIPS Agreement allows for countries to determine their own regime of rights exhaustion. Article 6 states that even if a country allows for parallel imports in a way that another country believes is in violation of TRIPS, this cannot be raised as a dispute in the World Trade Organization (WTO) unless fundamental principles of non-discrimination are involved. The Doha Declaration 5(d) confirms that Members may choose how to deal with exhaustion in a way that best fits their domestic policy objectives.¹²³

Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. In this way parallel importing can be used to increase access to affordable medicines. Because there are substantial price differences between the same pharmaceutical product sold in different markets, it would allow for the importation of the same drug at prices lower than those offered in South Africa.¹²⁴

3.5.1. Policy proposal

The Draft Policy states that

1. *South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health.*
2. *South Africa should facilitate in its legislation the ability to import patented products if it can get them cheaper in other jurisdictions (parallel importation). Parallel importation of IP can also be made at a regional arrangement and, in this regard, South Africa may wish to influence regional integration for the purpose of access to medicines.*

The above proposal has been interpreted to mean that existing legislative provisions for parallel importation within in the Medicines and Related Substances Control Act should be amended to align with Doha Decision 6. However, the Doha Declaration merely affirms the ability of a member country to choose its regime of parallel importation. The Patents Act should be amended to provide for parallel importation of patented inventions, by effecting either international or regional exhaustion of patent rights.

With regards to pharmaceutical products, the Medicines and Related Substances Control Act no 101 of 1965 currently allows for parallel importation. As such, the policy analysis looks at the effects of introducing parallel importation (either through a regional or international regime of rights exhaustion) in the Patents Act.

3.5.2. Status quo

According to section 45(1) of the Patents Act:

¹²³ http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm
¹²⁴ http://www.who.int/medicines/areas/policy/doha_declaration/en/

The effect of a patent shall be to grant to the patentee in the Republic, subject to the provisions of this Act, for the duration of the patent, the right to exclude other persons from making, using, exercising, disposing or offering to dispose of, or importing the invention, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention.

The patentee is thus granted the right of exclusively 'importing the invention' but section 45(2) states that:

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.

In other words, once sold by the patentee, the patentee has exhausted his rights due to the territorial nature of patents. This implies that national exhaustion is in effect, limiting the potential for parallel importation. If parallel importation is to be effected, this would have to be explicitly changed to regional or international exhaustion. In the case of pharmaceuticals, a permit granted by the Minister of Health in terms of section 15C(b) of the Medicines and Related Substances Control Act no 101 of 1965 currently allows for the parallel importation of medicines only. As such parallel importation of pharmaceuticals is explicitly allowed for in legislation, subject to the Minister's approval. If parallel importation is to be included in the Patents Act it may not be feasible for Ministers to be consulted for each case. In this way the parallel importation permit process is likely to be administrative than judicial.

3.5.3. Problem statement and evidence

The main gap in the current legislation is the lack of definition of patent exhaustion in section 45(2). In the case of national exhaustion the patent holder may still enforce their rights to import goods and thus contest any application for parallel importation. If a legislative amendment explicitly states that the patentee who sells his product both domestically and internationally gives up these rights, then international exhaustion of rights is in effect and parallel importation is made legal. Given that the Doha Declaration allows for each country to decide on its own regime of exhaustion, this is compliant with the TRIPS Agreement.

Spoor & Fisher add that while 'patentee' is defined to be the proprietor of a patent granted in the Republic, the term 'licensee' is undefined in the Act and could be interpreted to mean a licensee under a corresponding foreign patent which extends the territory of rights exhaustion beyond a national regime.

Also, the process of applying for parallel importation is somewhat onerous with many stakeholders claiming that it is not user friendly.

At present section 15(c) is written into South African law as a judicial process, requiring an applicant to go to court to effectuate parallel importation. The legislation is given effect through regulation 7 of the General Regulations, 2003. To date, no medicines have been imported into South Africa using this legislation. This is possibly due to various provisions in regulation 7 which may unduly burden the parallel importation process.¹²⁵

- Regulation 7(2) requires the submission of extensive documentation to the Minister of Health. However, applicants have found that administrative infrastructure to handle such submissions is absent.

¹²⁵ MSF, TAC and Section 27

- Regulation 7(2)(e)(iv) requires the applicant to provide documentary evidence of the price at which the imported medicine will be sold, even though this may not be known at the time the application is made.
- Regulation 7(3) limits the parallel importation permit to two years but regulation 7(5) requires the applicant to seek full registration of the imported medicine, despite the limited importation permit. In addition, the data required for registration is confidential and is the proprietary property of the patent holder. It would not be in its commercial interests for a patentee to release such information and certification to a parallel importer.¹²⁶

3.5.4. Policy objective

The overall objective of the policy is to make the process more practical through legislative definitions and clarification such that access to public healthcare is improved.

3.5.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's parallel importation legislation:

- Generators of IP (Generally, and with a focus on the pharmaceutical industry)
- Legal system and representatives
- Government
- Society
- Economy

In addition, the effects have been split between immediate (short and medium term) and broader (long term) effects.

3.5.5.1. Generators of IP: likely negative

By explicitly allowing for parallel importation, the rights of patents will no longer be limited to national exhaustion. Depending on the regime chosen this will define the region of exhaustion as being national, regional or international. In other words the geographical market on which the product is placed will determine whether the patent rights in South Africa are still in effect.

3.5.5.2. Legal system and representatives: likely positive

Infringement of patent rights becomes more complicated once the terms for parallel importation are explicit. In response, up skilling within the legal profession will probably occur over time. Clients of lawyer will likely pay the costs of such training and specialised services with increased legal fees for applications and infringement cases relating to parallel importation.

3.5.5.3. Government: indeterminate

¹²⁶ National Association of Pharmaceutical Manufacturers (NAPM)

In the short to medium term, similarly to compulsory licensing, government will be armed with increased bargaining power in negotiations with patentees. As a result the public health budget will benefit from greater value for money and lower medicine prices. Conversely, government will be responsible for establishing the administrative and coordination role to effect parallel importation safely and fairly. Especially in the case of drugs, regulatory control will be essential for the importation of regulated goods. Although there is provision and regulation in the Medicines and Related Substances Control Act for the parallel importation of medicines, a provision in the more general Patent Act will require health and safety regulations to be improved, particularly if the Ministers decision is no longer required for parallel importation to be legal. For other industries, to effectively enforce this regulation, government customs officials and health regulators will need to be up-skilled to ensure parallel importations are of the same quality, efficacy and health and safety standards as the locally patented product. For all industries, regulation will also be required over traders who have the ability to profiteer unduly from the price differentials. In addition, if a system of regional exhaustion is adopted and explicitly indicated, implementation will require a concerted effort of coordination in the SADC region that will, naturally, need to be led by South Africa.

In the longer term, government should be aware that the demand for domestic products could potentially decrease as original products from other jurisdictions are freely imported.

3.5.5.4. Pharmaceutical focus: indeterminate

Parallel importation allows for consumers of patented products to take advantage of price differentiation – the practice by international companies that sell the same product at different prices the world over. This, supported by national patent protection, allows international companies to optimise profits. If parallel importation in South Africa is legally possible in all fields, these patentees will have an increased probability of decreased profitability due to the importation of cheaper products from other jurisdictions. If the Ministers discretion is no longer required and the process more administrative for the pharmaceutical industry, pharmaceutical companies will be particularly vulnerable as large price differentials are required to recoup high R&D costs from different markets.

3.5.5.5. Society: indeterminate

In the short to medium term, parallel importation can lead to lower prices, but the extent to which they are lower depends on the government's ability to regulate profits by traders. The price differential allows for traders to profit but if the purpose of parallel importation is to provide cheaper patented products, this should be monitored. While products may be cheaper, it should be noted that customers are no longer protected by after sales services and warranties from the original manufacturer under parallel importation.

In the longer term, customers benefit from increased choice of a protected product at lower prices. This is subject to the clear legislative definition and effective implementation of parallel importation. Parallel importation can also be used to increase the legal certainty of quality and regulation of imports which may be occurring, illegally, anyway. Due to the threat of parallel importation, companies may cut R&D investment as reduced patent protection reduces the ability to recoup such costs. As such, the R&D into products specifically addressing developing countries' / regions' needs, will lead to a lower chance of provision of such products / treatments. Over time, the presence of parallel imports can lead to decreased technology transfer as inventions are imported rather than developed and produced in South Africa.

3.5.5.6. Economy: indeterminate

The immediate effect to the economy is that traders, legally, have the ability to arbitrage price differentials and thus extract profits from parallel importation. Although a product will not be sold at a price as high as the patented version in South Africa it may, on the other hand, not be sold as cheaply as in the origin country. This gap is the range at which the trader is able to set his margin. As far as these margins are regulated and kept in line, South African consumers can benefit from lower prices of patented products.

South Africa has limited API manufacturing capabilities with a heavy reliance on imported APIs. In conjunction with stiff international competition, this puts the economy at a disadvantage with regards to developing manufacturing capacity. Allowing for a more administrative process to legalise parallel importation will further impede the development of these capabilities the industry.

The legalisation of parallel importation may lead to South Africa being seen as an investment destination which does not prioritise the protection of IP rights. This could dampen FDI as international companies begin to prefer other territories where patent protection, and hence monopoly power, is stronger. Productivity and the ability of the local manufacturing industry to compete may be compromised due to the extreme competition provided by international firms importing.

3.5.6. Assessing benefits / pros

1. **Parallel importation may result in cheaper versions of the patented product.** The rationale behind parallel importation is that if a patented product is available at a lower price elsewhere in the world, this can be provided to the local market at lower costs. Decreased prices of goods that are parallel imported can work to lower the spending by the state on these products e.g. education materials, communication devices and scientific inventions.
2. **Cost inefficiencies in the local industry are eradicated.** A second round effect is that local retailers are forced to drive down the price of patented goods given the increased competition by cheaper parallel imports.
3. **Parallel importation may be used as leverage in price negotiations with patentees.** A resistance to a more administrative parallel importation process, particularly by pharmaceutical companies, may cause extensive reputational damage. In 2001, 39 pharmaceutical companies dropped its legal effort to prevent South Africa from importing cheaper essential drugs. GlaxoSmithKlein's chief executive, J. P. Garnier, said 'We're not insensitive to public opinion. That is a factor in our decision-making.'¹²⁷
4. **Excessively high local prices of essential medicines may result in the illegal importation of counterfeits through the black market.** A more administrative process around parallel importation can provide legal certainty for illegal parallel importation that is already occurring. It provides regulatory processes to ensure the safety and efficacy of the imported product and can contribute to reducing counterfeit products.

¹²⁷ <http://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html>

5. **Parallel importation allows the local market to access and take part in the growing global market.** This has the advantages of increased technology transfer and competition.

3.5.7. Assessing costs / cons

1. **By allowing for easier parallel importation, the benefits of price discrimination by pharmaceuticals in various countries are eroded.** Consumers and governments benefit if the originator companies are more profitable and use this excess to invest more in research and development and ultimately provide new and better medicines.¹²⁸
2. **Conversely, South Africa may be on the wrong end of price discrimination, lowering the effectiveness of parallel importation.** South Africa falls into the lower price ranges for most international pharmaceutical companies, thus making it unlikely that parallel importation will yield cheaper imports of the original drug. International comparisons of drug pricing are notoriously complex and can vary widely depending on which drugs are considered and how different volumes of medicines consumed are accounted for. Although prices may not be low enough to ensure wide spread affordability, through the Co-ordinating Committee for Medical Procurement (COMED) tendering system for drugs, the government has been able to ensure that medicines for the state sector are around 35% lower than the World Health Organisation's (WHO) International Drug Price Indicator Guide.¹²⁹ In particular, Table 1.4.3. in *The South African Pharmaceutical Sector Profile for the Consideration of Designation of Pharmaceutical Products in Terms of the PPPFA* shows a decrease in the price of publicly procured ARVs from 2008 to 2010. The report also states that the government also procures mostly generic medication. Current procurement processes mean that competition is intense - amongst other factors, barriers to entry are low due to zero-rated import duties and widespread use of voluntary licenses for patented medicines. Due to innovative medicines going off-patent and increased generic drug competition, the share of the patented drug market is expected to gradually decline, falling by roughly 10% to 46.8% in 2023. On the other hand, the generic drug sector which accounted for 31.2% of the total value of the drug market in 2013, will rise to 36.5% and 41.7% of total drug spending in 2018 and 2023, respectively. Two drivers behind this trend are i) the public sector Single Exit Price (SEP) pricing system that controls retail mark-ups based on a tiered pricing structure and ii) private sector medical aid schemes which encourage the uptake of generic medicines . A decreased market share of patented drugs means that the benefits of parallel importation are also decreased as only South African patented drugs, which are not subject to competition, can be sold at a higher price in South Africa.
3. **Parallel importation could introduce considerable risk to patients,** if the regulation and control of supplies is amended such that the process is more administrative than judicial. South Africa has a closed register system i.e. to sell a drug it must be registered. This substantial cost burden has, over the years, led to the development of a sizeable counterfeit market, making the dangers of parallel importation even more

¹²⁸ Abbott, F.M., *Parallel Importation: Economic and social welfare dimensions*, prepared for Swiss Agency for Development and Cooperation (SDC), 2007.

¹²⁹ See Free Market Foundation comment on to the Department of Health in response to Government Gazette No 28214 of 11 November 2005 (Notice No 2007 of 2005)

likely.¹³⁰ Although parallel importation is legal for medicines, this is at the discretion of the Minister of Health and a more administrative process of parallel importation may encourage the importation of counterfeit medication. Illegal copying of pharmaceuticals in South Africa remains highly problematic, with an estimated one in five drugs sold on the market believed to be fakes. The majority of fake medicines is exported from India, China and Pakistan and reach pharmacies through corrupt drug wholesalers. The Department of Health (DoH) currently has a four-man team investigating fake medicines. To date there has only been one successful prosecution.¹³¹

4. **Parallel importation often functions on commercial incentives.** If a trader gains access to a cheaper version of the same drug in a different territory (where it is patented), it may not be sold as low as what it is purchased. In this way, pricing is more difficult to regulate directly.
5. **Under parallel importation, local manufacturing capability is not encouraged.** Local industries are less profitable as cheaper drugs are imported, making them unable to compete and hence survive. In the case of pharmaceuticals, 95% of APIs are imported including those for ARVs and antibiotics. In addition, most locally based pharmaceutical formulations are made up of 40 - 70% imported APIs. **The dti**, in partnership with the DoH, the DST and the IDC undertook pre-feasibility studies to investigate the possibility of increasing the manufacturing of APIs and API intermediates. The general conclusion has been that due to the relatively small size of the SA market, competition with low-priced APIs made in China and India and the absence of domestic production of intermediates for synthesis of APIs, local manufacturing of APIs would require price premium of 30% to 50% (compared to imports of the same APIs) to be marginally feasible. More broadly, if industries are not likely to become or remain competitive (even in the absence of parallel importation), parallel importation would result in net gains as price gains from cheaper imports surpass the costs of a weak or non-existent local manufacturing capability.

3.5.8. Application of analysis framework

To analyse the aforementioned effects on the various stakeholders, recommendations are formed using the framework described in Section 1.3.

Theoretically, can the policy objective be met through the proposal?

The overall objective of the policy in terms of parallel importation is to make the process more practical through legislative definitions and clarification such that public healthcare is improved. Similarly to the case of compulsory licensing, it is only able to address a singular aspect of access to healthcare, namely, price. Other pillars including distribution, infrastructure, human capital capacity etc. must be considered separately.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|--|----------|--------|------|
| Increased regulatory involvement and quality oversight | X | | |

¹³⁰ Interview with IPASA

¹³¹ BMI Report, *South Africa Pharmaceuticals & Healthcare Report Q2 2014*, 2014

The most crucial factor in successfully implementing parallel importation is the regulatory role of government. As mentioned, government will be responsible for establishing the administrative and coordination role to effect parallel importation safely and fairly, especially in the case of drugs. To effectively enforce this regulation, government customs officials and health regulators will need to be up-skilled to ensure parallel importations are of same quality, efficacy and health and safety standards as the locally patented product. Regulation will also be required over traders who have the ability to profiteer unduly from the price differentials. (see *Government*, Section 3.5.5.3). The probability of achieving this regulatory oversight is low, particularly in the pharmaceutical space, given the failures of the MCC thus far. Challenges at the MCC include capacity constraints in the form of 24 part time reviewers, the review of sizeable technical reports within limited time periods, a large backlog of 18 000 applications and extensive approval delays.¹³² Although a new council, the South African Health Products Regulatory Agency (SAHPRA), with stronger governance is in the process of being established, parallel importation oversight may be an unwanted additional burden for the institution.

Illegal copying of pharmaceuticals in South Africa remains highly problematic, with an estimated one in five drugs sold on the market believed to be fakes. As such it is unlikely that the DoH will be able to clamp down on counterfeiting activities, a likely possibility under parallel importation regimes.

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--|-----|--------|------|
| Potential savings do not translate into lower prices | | | X |
| Adversarial relationships between private and public sectors | | | X |
| Inability of local industries to compete | | | X |

The risk that potential savings do not translate into lower prices is especially high considering three likely factors – South African medicine prices not being lower than many other countries, decreasing sized of patented drug market and profiteering by traders. As such South Africa is probably placed in the lower end of pricing discrimination by international pharmaceutical companies but it would be impossible to compile a list specifying price differences of drugs compared with their lowest-cost imports.¹³³ In addition, a decreased market share of patented drugs means that the benefits of parallel importation are also decreased as only South African patented drugs, which are not subject to competition, can be sold at a higher price in South Africa for higher profits.

In 2001, 39 drug manufacturers took up legal procedures to prevent South Africa from importing cheaper anti-AIDS drugs and other medicines. After mounting international pressure from AIDS activists, former President Nelson Mandela and former Secretary General Kofi Annan of the United Nations, the companies dropped the law suit. They conceded that the parallel importation law allowing the government to purchase brand-name drugs at the lowest rates available anywhere in the world complied with international trade agreements. However, tensions were heightened during the three year battle, with pharmaceutical companies shutting

¹³² Treatment Action Campaign, *Developing, registering and using medicines*, 2010, available at <http://www.section27.org.za/wp-content/uploads/2010/04/Chapter13.pdf>

¹³³ Kudlinski, A., *The South African Pharmaceutical Sector Profile for the Consideration of Designation of Pharmaceutical Products in Terms of the PPPFA*, South African Department of Trade and Industry, 2011

down factories in South Africa, cancelling investments and claiming that South African health officials were intent on destroying international treaties intended to protect drug patents.¹³⁴ As such the risk of such a situation resurfacing in the face of simplified parallel importation processes is considered high.

Inability of local industries to compete is a highly likely risk. This is due to the fact that while South Africa has manufacturing capabilities these are somewhat limited. The heavy reliance on imported APIs, along with stiff international competition, implies that South Africa is already at a disadvantage with regards to developing manufacturing capacity. Allowing for parallel importation will further impede the development of these capabilities the industry.

Can these risks be mitigated?

The risk which can be mitigated is that traders will erode the gains of parallel importation by including high margins on parallel imported products. For this to be curbed the government would need to set up a regulatory body to monitor prices and to set a cap on the profits which traders are able to make on these goods.

3.5.9. Policy recommendation

Given the fact that in Section 3.5.8 the single critical success factor is unlikely to be secured and that all three severe risks are very likely to occur, parallel importation should be considered in light of alternative options (see below).

3.5.10. Alternative options

Given that the recommendation on compulsory licensing is to accept with revision (See Section 3.5.9), parallel importation legislation need not be included in the Patents Act. Even if the implementation is successful, it is possible for the policy objectives of parallel importation to be met through compulsory licensing. In this way the severe risks which are likely to occur by expanding parallel importation to all patents are also avoided.

For more on how compulsory licensing is able to achieve the objective of advancing public healthcare see Section 3.4.

Another option which may be considered in the place of parallel importation is the development of institutional / legal links between IP and competition law which limit the powers of abuse. To protect local industries which are subject to overwhelming competition through parallel importation, more targeted policies by government aimed at protecting these industries may be considered.

3.5.11. Country comparisons

European Union

The policy proposal suggests that regional exhaustion of rights is a possibility in dealing with parallel importation in South African intellectual property law. For this reason the European Union provides an example of regional exhaustion of rights in terms of parallel importation.

¹³⁴ <http://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html>

For the purposes of setting up a common or single market in the European Union, the European Community (EC) Treaty (Article 3) establishes the principle of free movement of goods within the Union. The basic framework for this principle, including parallel importation, is laid down in Articles 28 and 30 of the EC Treaty. In addition, the European Court of Justice (ECJ) interprets these articles with the view to making the common market a reality and has, as such, developed the doctrine of community-wide exhaustion.

The general rule of community-wide exhaustion is that if a product has been first put on the market in any Member State by the right owner, or with his consent, the intellectual property right is exhausted for all the Member States, and the product can freely circulate through the whole of the common market without any restriction. Community-wide exhaustion doctrine traces back to the mid-1960s when in *Consten and Grundig v. Commission* the ECJ decided that once goods had been placed on the Community market with the consent of the trademark holder, enterprises would lose the right to block movement of these goods among the Member State markets.

In addition, community exhaustion within the EU dictates that a drug approved for human use in one EU member state must be granted authorisation in all other member states unless the concerned member state objects through a formal process. However, drug companies still negotiate with individual countries over pricing and reimbursement. This allows for the price differentials within the EC that make parallel trade a possibility. Parallel trade in the EU is further fuelled by the structure of the distribution chain i.e. the wholesale and retail distribution functions. The large number of players in the pharmaceutical distribution chain prevents total vertical control by any one stakeholder. Parallel distributors who are also wholesalers use parallel importation to maximise profit by acquiring products from low priced countries and selling such goods to retailers in countries with higher drug prices.

Within the EC, various policies to promote parallel importation are also in effect. These are tabled below.

Table 3. Policies to promote the use of parallel imported drugs in key importing countries in the European Union (2004)

| Policy to promote use of parallel imported drugs | Denmark | Germany | Netherlands | Norway | Sweden | United Kingdom |
|---|---------|---------|-------------|--------|--------|----------------|
| Pharmacy required to inform patient of availability of parallel imported products | X | X | | | X | |
| Pharmacy quota on parallel import dispensing rates | | X | | | | |
| Financial incentives for pharmacy to dispense parallel imported drugs | | | X | X | | X |
| Financial incentives for dispensing lower-price drugs in general, | | | | X | X | |

| Policy to promote use of parallel imported drugs | Denmark | Germany | Netherlands | Norway | Sweden | United Kingdom |
|--|---------|---------|-------------|--------|--------|----------------|
| including parallel imported drugs | | | | | | |

Source: Kanavos, P. and Kowal, S., *Does pharmaceutical parallel trade serve the objectives of cost control?* 2008

A 2004 study¹³⁵ suggests that the price of branded pharmaceuticals in the home market falls as the volume of parallel imports rises. A second study¹³⁶ shows that although parallel import penetration is significant in many EU countries, parallel trade generates, at best, moderate savings to health insurance. In addition, it is not necessarily associated with sustainable long-term price competition and can lead to product shortages in exporting countries and, recently, a higher probability of counterfeiting. Parallel distributors emerge as the key beneficiaries from parallel importation. The study also found that high transaction costs associated with parallel trade, the lack of sustainable long-term price competition and the lack of tangible benefits to patients make this practice an inefficient means of containing costs.

3.6. COPYRIGHT FLEXIBILITIES (BERNE CONVENTION)

3.6.1. Policy proposal

The Draft National Policy on Intellectual Property recommends the following changes to South African copyright law:

To enhance access to copyrighted materials and achieve developmental goals for education and knowledge transfer, South Africa must adopt pro-competitive measures under copyright legislation. The legislation must provide the maintenance and adoption of broad exemptions for educational, research and library uses.

The interpretation of these policy recommendations are that South Africa should amend its copyright law to i) enhance access to and use of copyright works and ii) to enhance access to information for the enhancement of education, research and free speech.

3.6.2. Status quo

Members of the TRIPS Agreement (even if they are not bound by the Berne Convention) must comply with the substantive provisions of the 1971 (Paris) Act of the Berne Convention for the Protection of Literary and Artistic Works (1886).

South Africa is a member of the Berne Convention and the WTO/TRIPS. South African copyright law and related rights are regulated by:

- Copyright Act no 98 of 1978
- Copyright Regulations, 1978
- Registration of Copyright in Cinematograph Films Act no 62 of 1977

¹³⁵ Ganslandt, M. and Maskus, K.E., *Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union*, 2004

¹³⁶ Kanavos, P. and Kowal, S., *Does pharmaceutical parallel trade serve the objectives of cost control?*, 2008

- Registration of Copyright in Cinematograph Films Regulations, 1980
- Performers' Protection Act no 11 of 1967.

Fair dealing

The concept of fair dealing is not defined in the Copyright Act of 1978. Section 12 of the Copyright Act lists certain exceptions and limitations applicable in respect of each category of copyright works. The Act also provides for the making of certain reproductions of copyright works to be permitted by way of regulation, in a manner not in conflict with the normal exploitation of the work and not unreasonably prejudicial to the legitimate interests of the copyright owner. The reproductions relate primarily to archival or library conservation or storage, or the making of copies for classroom use for teaching and/or educational purposes.¹³⁷

The Berne Convention, the TRIPS Agreement and the WCT provide that limitations or exceptions to copyright shall:

- a) be confined to certain special cases;
- b) not conflict with a normal exploitation of the work; and
- c) not unreasonably prejudice the legitimate interests of the right holder.

The Copyright Act should be amended to incorporate a general fair use provision so that in an infringement proceeding, a use that is the subject of a complaint becomes subjected to a two-tier examination. If the use falls within one of the specific limitations or exceptions expressly provided for in the Copyright Act, the infringement proceeding would immediately fail. If the use does not fall within the ambit of those specific provisions, the more general fair use provision will be applied. If it fulfils the requirements in the general provision, the use will still be allowed notwithstanding that sections 12 and 13 do not specifically contemplate such use.

Incorporate the maximum flexibilities available in the teaching exception

The following are pro-development measures:

- Allow the utilisation of the whole of a work for teaching – the Berne Convention permits the use of copyright works by way of illustration in publications, broadcasts or sound or visual recordings for the purpose of teaching. It does not prohibit the utilisation of the whole of a work, so long as it is justified by the purpose and is compatible with fair practice.
- Do not limit the types and forms of utilisation for teaching. The teaching exception in the Berne Convention uses the word “utilisation” and the word encompasses several different kinds of rights, such as reproduction right, translation right, adaptation right and possibly even the right of communication to the public.
- Extend the teaching exception to all classes of education, including distance education. The word “teaching” used in the teaching exception in the Berne Convention is not confined to classroom instruction and extends to correspondence courses.

¹³⁷ Adams & Adams Practical Guide to Intellectual Property in Africa at 517-518.

- Do not restrict the number of copies that may be made of illustrations for teaching. The teaching exception in the Berne Convention does not restrict the number of copies of publications or sound or visual recordings that can be made for the purpose of illustrations for teaching.¹¹⁶ The making of multiple copies of such works is thus allowed so long as it is compatible with fair practice. Allow the use of copyright works in broadcasts.

Parallel importation

Copyright is infringed indirectly by the following acts: by any person who, without the authority of the copyright owner, imports, sells, lets, by way of trade offers or exposes for sale or hire, or distributes for purposes of trade, an article in South Africa if he knew that the making of the article constituted an infringement of copyright or would have constituted an infringement if made in South Africa.

Under the exhaustion doctrine, the rights of an intellectual property owner terminate after an exercise of the rights by the owner. The classic example of the exhaustion doctrine is the resale of a book by the authorized purchaser. Such purchaser can resell the book without infringing the distribution rights of the copyright owner.

The exhaustion doctrine is controversial as it imposes a limitation on the intellectual property owner's rights. The exhaustion doctrine can be limited by placing restrictions on the scope of the application of the exhaustion doctrine, what rights are exhausted, what acts by the owner trigger exhaustion, and the geographic scope of exhaustion.

In order to ensure that the Copyright Act incorporates the rule of international exhaustion, national lawmakers should ensure that:

- a) The "right to control importation" of authorised copies of copyright work is not included in the bundle of rights given to copyright owners;
- b) If copyright owners are granted the right to control sale, transfer or other distribution of authorised copies of copyright work, such right should be limited to the control of only the first distribution and not to any subsequent distribution; and
- c) If copyright owners are granted the right to control sale, transfer or other distribution of authorised copies of copyright work, such right should not apply to copies previously circulated in any other part of the world.
- d) International exhaustion should apply to the physical copies of works.
- e) The international exhaustion should not apply to cinematograph films, sound recordings and computer programs.

The Berne Convention does not address the exhaustion of rights.

Access to education

The cost of procuring educational material in South Africa is considered relatively high. The provision of schoolbooks to scholars is a significant factor in the state's education costs and the procurement of books is a significant proportion of the state's expenditure on education (in

2003 it was over R1bn). This is extremely important as textbooks are probably the most important input in promoting learning.¹³⁸

Compulsory licensing

The compulsory licensing provisions in the Appendix to the Paris (1971) Act of the Berne Convention should be adopted. In accordance with the Berne Convention a general fair dealing provision and wide exceptions and limitations to foster teaching should be adopted. Article 40 of the TRIPS Agreement to control anti-competitive licensing should also be adopted. Lastly, section 23(2) of the Copyright Act which prohibits parallel importation should be repealed.

The first flexibility is a compulsory licensing regime that allows governments to grant a licence to make a translation of “works published in printed or analogous forms of reproduction” and publish the translation in “printed and analogous forms of reproduction”. Such licence can only be granted for the purpose of teaching, scholarship or research. The second type of compulsory licensing under the Appendix to the Berne Convention enables governments to grant a licence to reproduce and publish “works published in printed or analogous form of reproduction”. Such licence can only be granted for use in connection with systematic instructional activities.

As far as the exclusive right of translation is concerned, the Berne Convention offers a choice, in that a developing country may, when acceding to the Convention, make a reservation under the so-called “ten-year rule”. This provides for the possibility of reducing the term of protection in respect of the exclusive right of translation; this right, according to the said rule, ceases to exist if the author has not availed himself of it within 10 years from the date of first publication of the original work, by publishing or causing to be published, in one of the member countries, a translation in the language for which protection is claimed.

Anti-competitive practices

Article 40 of the TRIPS Agreement provides that national legislation may adopt measures to control licensing conditions that may constitute an abuse of intellectual property rights. A provision should be adopted in the Copyright Act to provide that licensing conditions that have an adverse impact on competition in the relevant market shall be prohibited as it constitutes an abuse of copyright.

3.6.3. Problem statement and evidence

The Berne Convention flexibilities that are pro-development have not been adopted in South African legislation. The Copyright Act and Copyright Regulations contain some exceptions and limitations to copyright protection, but the full range of possible exceptions that developing countries may adopt in accordance with the Appendix to the Berne Convention has not been adopted.

The Appendix to the Paris (1971) Act of the Berne Convention provides that a compulsory license may be granted in respect of a work for:

- (i) translation for the purpose of teaching, scholarship or research, and

¹³⁸ Department of Education. 2003. Report to the Minister: Review of the Financing, Resourcing and Costs of Education in Public Schools. Pretoria: Government Printers at 7.

- (ii) reproduction for use in connection with systematic instructional activities,

These licenses may be granted, after the expiry of certain time limits¹³⁹ and after compliance with certain procedural steps, by the competent authority of the developing country concerned. They must provide for fair compensation in favour of the owner of the right. In other words the payment to be made by the compulsory licensee must be consistent with standards of royalties normally adopted with respect to licenses freely negotiated between persons in the two countries concerned.

Provision is also required to ensure a correct translation or an accurate reproduction of the work, as the case may be, and to specify the name of the author on all copies of such translations or reproductions. Copies of translations, reproductions and publication under licenses are not, however, allowed to be exported. Since the license is non-exclusive, the copyright owner is entitled to bring out and place on the market his own equivalent copies, upon which the power of the licensee to continue making copies under the license would cease. However, in that event, the compulsory licensee's stock can be exhausted.

The Appendix to the Paris Act of the Berne Convention thus allows a choice between a compulsory license system and the possibility of limiting the right of translation to 10 years as referred to above.

Parallel importation is prohibited by section 23(2). The South African Copyright Act thus adheres to the national exhaustion of rights. The exceptions and limitations are narrowly crafted – discussed below under “evidence”.

Evidence:

Fair dealing

Sections 12 and 13 of the Copyright Act contain the exceptions and limitations to copyright protection. The Regulations have also been criticised as follows:

“A set of regulations providing concessions for libraries and educational institutions, which are ambiguous, contradictory and virtually unworkable in practice, further undermines the effectiveness of the law

...

PASA has long seen the regulations as problematic and has been pressing for their amendment for more than a decade. While it could be argued that they do not in fact, in their strict interpretation, confer the right to cumulative multiple copying, their very ambiguity has undermined the effectiveness of the law. As a result, publishers wishing to take action against infringements in educational institutions or libraries would be faced with lengthy and expensive legal arguments about the interpretation of these regulations.”¹⁴⁰

Parallel importation

Table 4 illustrates how books in South Africa, even of local authors, are priced very high. Among the main reasons for the excessive pricing of books in South Africa is a lack of competition in the market, evidenced in several ways across the spectrum of book publishing.

¹³⁹ For works connected with the natural and physical sciences and with technology (and this includes mathematical works) the period is three years; while for works of fiction, poetry and drama, the period is seven years

¹⁴⁰ Gray, E. and Seeber, M. 2004. Print Industries Cluster Council (PICC) Report on Intellectual Property Rights in the Print Industries Sector. Commissioned by the Department of Arts & Culture, Government of South Africa, p.66, 69.

In the Academic book publishing market (denoting textbooks and reference material primarily for tertiary education), the GPI report notes that three publishers (LexisNexis Butterworths, Pearson and Juta) have a combined market share of 62%. Academic book distribution is even more consolidated, with two firms – Van Schaik and Juta retail – holding close to a 100% market share. In the schoolbooks market (i.e. primary and secondary education), five publishers (Maskew Miller Longman, Macmillan, Nasou, Oxford University Press and Juta) hold a combined market share of 71%.¹⁴¹ It is difficult to explain the price differentiation apart from market and manufacturing inefficiencies.

The national exhaustion of rights has far-reaching effects as it renders parallel imports of copyright works illegal in South Africa. Parallel import can be an important tool for developing countries to gain access to knowledge contained in copyrighted materials.¹⁴²

Parallel importation would allow distributors and booksellers to choose from a range of world markets as opposed to the South African market, which could lead to a more equitable pricing structure. Parallel importation would open access to cheaper copyright works abroad. A relative lack of competition in the marketplace is an important factor. The lack of competition is evident from the sole-supplier situations and the high price of the books.

National copyright legislation should therefore follow the rule of international exhaustion rather than the rule of national exhaustion.

Access to education

Evidence gathered by Consumer International indicates that copyrighted educational materials are indeed prohibitively priced in developing countries and in that manner pose a barrier to access to knowledge. This is evident from the results of a comparative price survey of book prices.¹⁴³

In South Africa, textbooks form the single highest component of student costs. Government is the single largest procurer of textbooks, accounting for over half the publishing industry's turnover.¹⁴⁴ Moreover, the publishing industry relies heavily on the schoolbook market. It is noted:

*“Schoolbooks are the staple of the South African publishing industry. When the schoolbook market falters, as it did in 1997, the ripple effect – downsizing, job losses and demoralisation – affects the whole industry.”*¹⁴⁵

In 2003, the Director General of the DoE highlighted the book-price crisis in a report to the Minister of Education:

“The price of textbooks warrants special attention, partly because textbooks constitute such a large portion of the state’s expenditure on education...”

¹⁴¹ <http://www.iprsonline.org/unctadicts/docs/06%2005%2031%20tralac%20amended-pdf.pdf>

¹⁴² Consumers International Copyright and Access to Knowledge Policy Recommendations on Flexibilities in Copyright (2006) at 24; see Table 1 isupra.

¹⁴³ See Appendix 1 in Consumers International Copyright and Access to Knowledge Policy Recommendations on Flexibilities in Copyright (2006).

¹⁴⁴ Gray, E. and Seeber, M. 2004. Print Industries Cluster Council (PICC) Report on Intellectual Property Rights in the Print Industries Sector. Commissioned by the Department of Arts & Culture, Government of South Africa, p. 12; See Andrew Rens, Achal Prabhala and Dick Kawooya Intellectual Property, Education and Access to Knowledge in Southern Africa (2006) <http://www.iprsonline.org/unctadicts/docs/06%2005%2031%20tralac%20amended-pdf.pdf> at 17.

¹⁴⁵ Gray, E. and Seeber, M. 2004. Print Industries Cluster Council (PICC) Report on Intellectual Property Rights in the Print Industries Sector. Commissioned by the Department of Arts & Culture, Government of South Africa, p61.

*Though there has been no proper study into the matter, some views suggest that the textbook industry may not be sufficiently competitive, and that it is characterized by too many sole-supplier situations to ensure competitive prices. Higher prices could allow producers to make abnormally high profits, or might simply sustain inefficient production processes. Thorough research is required on this subject to inform possible responses by Government to improve the competitiveness of the industry. Such a study might include an assessment of the relative costs of production in South Africa compared to those in other countries.*¹⁴⁶

Several factors apart from copyright law drive the prices of schoolbooks up and inhibit access to education. The cost of textbooks is an important contributory factor to the rising costs of education. Factors such as inadequate competition in the production of textbooks, inappropriately high quality standards, costs relating to inefficient planning and distribution, and poor retrieval rates in schools are cited by Pillay¹⁴⁷ as the reason why schoolbooks cost so much.

The lack of adequate planning and the cycles of redesign of curricula by the Department of Education also contribute to the prohibitive prices of schoolbooks. A Mail and Guardian article has noted that in 2012 procurement processes had been stalled because price negotiations between provinces and publishers were still taking place.¹⁴⁸

Pillay has noted:

“It has also been argued that South Africa has excessively expensive textbooks as a result of the quality of paper used and the binding techniques employed. Many developing countries at levels of economic development similar to South Africa make do with textbooks of much lower quality paper, printing and binding. It has been estimated that the price of textbooks could be lowered by 20% if lower grade paper were used, formats standardised and bigger print runs introduced.

...

The current fragmented approach, whereby nine provinces – and often individual schools – purchase textbooks in an unco-ordinated fashion provides greater variety but fewer economies of scale, and therefore higher prices (DoE, 2003). Moreover, the fragmented way in which demand for textbooks is currently structured is very conducive to monopolistic and sole-supplier situations. The lead time for the production of a textbook is long, a fact that has not been adequately taken into account when the roll-out of new learning programmes takes place. The schooling system pays for ‘tightness of implementation deadlines’ through higher textbook prices (DoE, 2003).

...

There are also significant opportunity costs attached to the inability to recover textbooks adequately. Provincial departments of education spend hundreds of millions of rand each year in replacing textbooks not recovered from learners; indeed, an investigation launched by the national department in 1999 revealed that most provinces lacked effective retrieval systems

¹⁴⁶ Department of Education. 2003. Report to the Minister: Review of the Financing, Resourcing and Costs of Education in Public Schools. Pretoria: Government Printers as cited by Andrew Rens, Achal Prabhala and Dick Kawooya Intellectual Property, Education and Access to Knowledge in Southern Africa (2006) <http://www.iprsonline.org/unctadictsd/docs/06%2005%2031%20tralac%20amended-pdf.pdf> at 17.

¹⁴⁷ PUNDY PILLAY Administered Prices EDUCATION A report for National Treasury <http://www.treasury.gov.za/publications/other/epir/Education.pdf> 10-11.

¹⁴⁸ See Bongani Nkosi “Textbooks crisis: Price talks stall 2013 deliveries” Mail & Guardian 07 Sep 2012 <http://mg.co.za/article/2012-09-07-50-price-talks-stall-delivery-in-provinces>

and that only 40% to 50% of textbooks were recovered in some schools. It was also estimated that only 1% of learners in Limpopo returned textbooks. About 55% of Mpumalanga's books are retrieved, while the Gauteng Education Department had no mechanisms in place in 2001 to recover the 10% of books that had to be replaced (DoE Media Survey).

The supply of textbooks is further affected by corruption and theft, the challenge of tender awards, inefficient procurement and distribution by inexperienced private companies, and by a lack of co-ordination of provinces' dealings with publishers. In rural provinces, distribution is complicated by the fact that many schools lack storage facilities – in 2000/01 the Department of Education and the National Treasury set up a task team to monitor procurement and distribution of textbooks. A Resources and Information Network, costing R2m and funded by the national Department of Education, was piloted in KwaZulu-Natal in 2001 to improve efficiency and cost-effectiveness. According to the director of the Media in Education Trust, the organisation overseeing the project, 'a lot of money is spent in developing learning materials but the majority of it never reaches the schools' (DoE Media Survey, 2003).

Other problems facing the school textbook industry include the cost of paper, numerous mark-ups in the production process, poor local printing quality and tight government deadlines. Printing in the Far East is cheaper and of better quality, but the short notice of requirements given by departments of education eliminates this option.

Beyond the cost of producing the books themselves, the cost of textbooks includes government spending on approving, procuring and distributing them, and managing their retention. Suggestions to improve efficiency and costs in relation to textbooks include making books last longer, encouraging business with other African countries and exchanging material with these countries, and eliminating value-added tax (VAT) on textbooks. The Print Industries Cluster Council, established in 1999 to promote reading and improve access to printed matter, attempts to facilitate dialogue on these matters between government and the industry. According to a facilitator of the council, competition keeps the price of textbooks low and the quality high. He says 'compared with school uniforms, sporting equipment, classrooms or furniture, textbooks are a bargain,' arguing further that zero rating of VAT on books would boost efforts to promote literacy and reduce education costs. (DoE Survey, 2003)"

Although copyright law has not directly contributed to the high prices of educational material, there is a need to introduce provisions within copyright law to promote access to essential learning materials. Compulsory licensing and the introduction of measures to control the abuse of copyright and parallel importation could be utilised where essential learning materials are inaccessibly priced.¹⁴⁹

3.6.4. Policy objective

The Berne Convention flexibilities that are pro-development have not been adopted in South African legislation. South Africa should amend its copyright law to enhance access to and use of copyright works and to enhance access to information for the enhancement of education, research and free speech.

3.6.5. Affected Stakeholders

¹⁴⁹ See Andrew Rens, Achal Prabhala and Dick Kawooya Intellectual Property, Education and Access to Knowledge in Southern Africa (2006) <http://www.iprsonline.org/unctadictsd/docs/06%2005%2031%20tralac%20amended-pdf.pdf> at 13-14.

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's copyright regime:

- Government
- Public (Users of works)
- Copyright owners
- Authors
- Educational institutions
- Libraries
- Societies for collective management of copyright – DALRO; PASA SAMRO; SAMPRA RiSA; NAB
- Broadcasters
- The publishing sector
- Booksellers

Stakeholders in the print industry value chain¹⁵⁰ will also be indirectly affected. These stakeholders include the developers of markets,¹⁵¹ the packagers of content,¹⁵² the deliverers of the packaged product to the consumer,¹⁵³ the suppliers to the sector,¹⁵⁴ the customers of the sector,¹⁵⁵ the employees in the sector¹⁵⁶ and the society within which businesses in the sector operates.

¹⁵⁰ Gray, E. and Seeber, M. 2004. Print Industries Cluster Council (PICC) Report on Intellectual Property Rights in the Print Industries Sector. Commissioned by the Department of Arts & Culture, Government of South Africa, (May 2004)

¹⁵¹ This includes the advertising & marketing agencies, research & development agencies and marketing divisions of downstream companies.

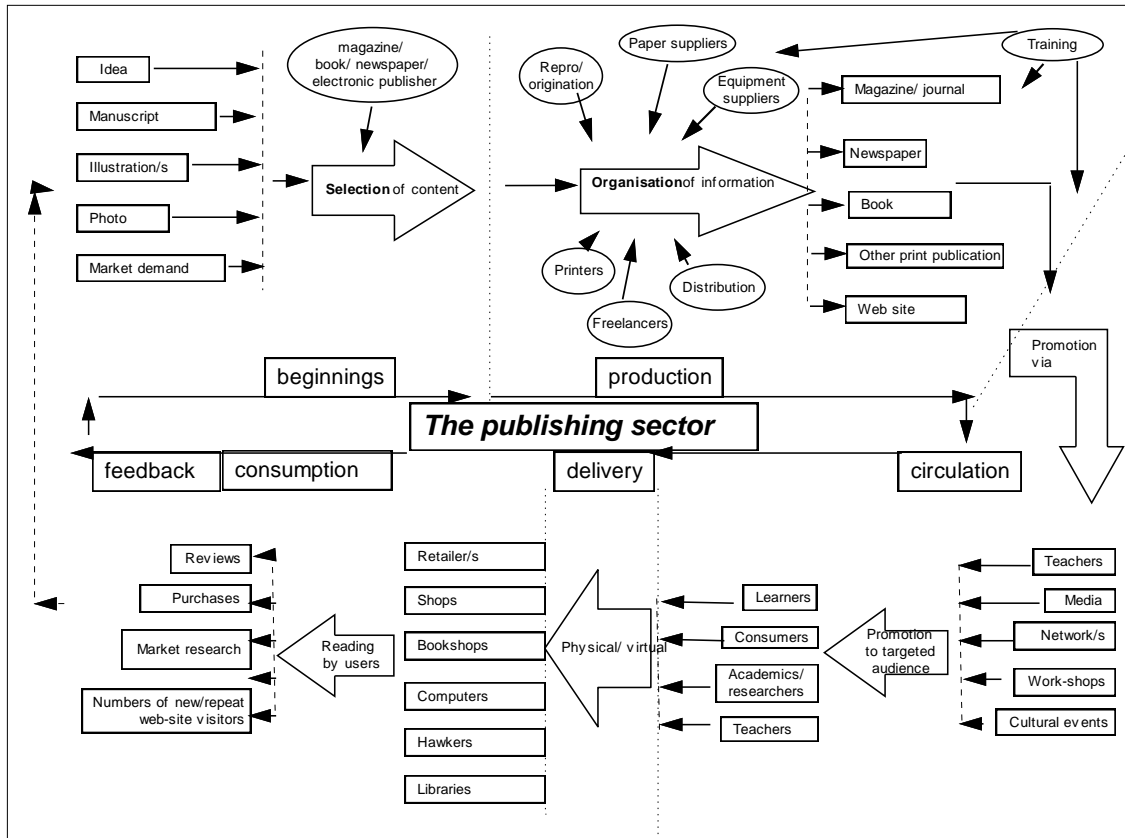
¹⁵² This includes printers and paper-makers.

¹⁵³ This includes distributors and booksellers.

¹⁵⁴ This includes material and equipment suppliers, ITC, HR and Training suppliers.

¹⁵⁵ Readers of books, magazines and newspapers, manufacturers and retailers of product and consumers/purchasers of packaged products.

¹⁵⁶ Workers and their families within sector and related sectors.



Source: Gray, E. and Seeber, M. 2004. Print Industries Cluster Council (PICC) Report on Intellectual Property Rights in the Print Industries Sector. Commissioned by the Department of Arts & Culture, Government of South Africa, Figure 2 page 36.

3.6.5.1. Government: likely positive

In the short term the Government will incur costs to amend the Copyright Act and to draft new Regulations. The state will incur costs for this process as well as for capacity building. The broader and long term effect will be very positive. **The dti's** credibility will be enhanced due to the positive impact of broader exceptions and limitations on society.

The long-term impact will also be positive as the government would have played an active role in supporting the public domain, access to education and consumer access to fairly priced goods. South Africa will play a leading role in adopting a pro-development copyright policy and copyright regime in BRICS and in Africa.

3.6.5.2. Public (Users of works): likely positive

The public will benefit from the adoption of Berne flexibilities both in the short term and in the long term. In the short term the public will benefit due to the pro-competitive prices of copyright works. The public will benefit by an increased freedom to make use of copyright works. This will positively impact on access to information, education and the enrichment of the public domain.

The adoption of wide exceptions and limitations for the public benefit would include the removal of any restrictions on ways in which quotations may be made; and no limit on purpose of quotation. This will stimulate creativity and freedom of expression. The adoption of a

general fair use provision and an explicit Parody exception will have a positive impact as it will foster basic human rights such as access to information and free speech.

The inclusion of a provision on the control of anti-competitive practices will ensure fair consumer practices with accompanying benefits such as fair terms and conditions and affordable copyright works. The adoption of international exhaustion will have a positive impact on the price of copyright works as parallel imports would offer competitive advantages especially a lowering of prices. A negative effect should be flagged in this regard, namely the fact that parallel imports may compromise after sales repairs and warranties.

3.6.5.3. Copyright owners/authors: likely negative

The amendment of the Copyright Act will foster legal certainty as the interpretation of the current exception and limitation provisions are fraught with difficulties. Legal certainty will have a short term positive effect as well as a long term positive effect.

The legal certainty on the scope of the exceptions and limitation will also have a negative financial impact as it will be clear that no remuneration may be levied for minor uses (e.g. the photocopying of portions of a work for teaching or research).

Due to the enhanced permitted use that users may make of a work, it may result in a financial constraint as fewer copies of works may be sold. Permissible uses for research and education will curb remuneration for of reprographic rights. Publishers and authors may lose revenue in the short and long term.

The drop in sales of works could have a negative effect on authors' reputation and goodwill in the market – the reputational loss is a negative long-term effect.

3.6.5.4. Educational institutions/ learners: likely positive

The adoption of wide exceptions and limitations, such as the utilization of whole works for teaching will have a positive impact on educational institutions. The effect is both short and long term. The abolishment of the limit on types and forms of utilization of works for teaching purposes will enhance teaching and learning with an overall positive effect on learners and institutions in the long term. The extension of the exceptions to all forms of teaching, also distance teaching, will have a positive effect on institutions' ability to deliver tuition services at a distance. The inclusion of the right to broadcast works for teaching purposes will enable and enrich multi-media teaching. It will also enrich learners' learning experiences due to enhanced availability of learning materials.

In terms of the proposed policy an unrestricted number of copies may be made for classroom use. As a consequence institutions will pay much less to DALRO for the reprography of literary works and may elect to adopt business models where the current blanket reprographic licenses will become obsolete. In the long term institutions will save on operating costs. These savings will hopefully also benefit learners.

The adoption of an international regime of exhaustion will open the world market to users at competitive prices. Compulsory licenses will enhance local culture and access to knowledge– for example the translation of a foreign text into an indigenous language.

3.6.5.5. **Libraries: likely positive**

The adoption of wide exceptions and limitations will enhance libraries' freedom to operate. A review of the Copyright Act and the adoption of sound pro-access principles will provide legal certainty.

In terms of the proposed policy an unrestricted number of copies may be made by teachers for classroom use. As a consequence institutions will pay much less to DALRO for the reprography of literary works and libraries may elect to adopt business models where the current blanket reprographic licenses will become obsolete. As a consequence libraries will save on operating costs.

The adoption of an international regime of exhaustion will open the world market to libraries and enable libraries to take advantage of competitive prices in procuring collections of material.

3.6.5.6. **Societies for collective management of copyright: likely negative**

The adoption of wide exceptions and limitations and other pro-development measures will provide legal certainty where currently the interpretation of the provisions is problematic and had led to uncertainty. Permissible uses for research and education will curb remuneration. Likewise no remuneration will be payable for minor uses. Both these factors will curb the collecting society's ability to collect royalties for the reproduction of works.

3.6.5.7. **The publishing sector: likely negative**

Parallel importation of books could lower the income of publishers as a substantial part of the trade in the book industry in South Africa pertains to imported books. The loss of right of importation may impact negatively on existing business relationships.

One of the long term effects would be the loss of remuneration especially if a compulsory license is granted to translate works into indigenous languages. This is because over time, reading preferences are able and likely to change, thus negatively affecting the market size for publishers.

3.6.6. **Assessing benefits / pros**

1. **Parallel importation:** An adoption of international exhaustion of rights and the legalization of parallel imports will most probably have a positive impact on the price of consumer goods in South Africa.
2. **Exceptions and limitations:** The amendment of the sections in the Copyright Act dealing with exceptions and limitations will lead to legal certainty. The enhanced limitations and exceptions will strengthen the right of access to works
3. **Compulsory licenses:** Compulsory licenses enhance availability and costs of textbooks for education – a positive impact on Basic Education textbook spending. The publication of local translated editions of educational material at affordable prices will alleviate costs for tertiary research and education and will foster the growth of technical works in indigenous languages.

4. **Clear fair dealing provisions:** Clear limitation of scope of protection, especially the general fair dealing provision based on the three step test of the Berne Convention will enhance fundamental rights especially freedom of expression.

3.6.7. Assessing costs / cons

5. **Quality compromise:** It has been noted that parallel imports may compromise after sales repairs and warranties of products such as computer programs and CDs. However, if these works are excluded from the international exhaustion regime it will not pose a problem. The use of the protection offered by the Consumer Protection Act should suffice.
6. **Loss of revenue:** The publishing industry does not believe that demands for multiple copying for educational use can be met through enacting fair dealing provisions. It is of the opinion that it would cause serious harm to the publishing industry and other copyright industries. It recommends the use of collective licensing agreements, priced to suit local conditions, with regulatory backing to ensure maximum participation. The loser in this case would be the publishing industry.

Fewer copies of locally produced works may be sold and publishers and authors may lose revenue. The parallel importation of books may impact on the stability of the printing industry and the related sectors. Permissible uses for research and education will curb remuneration for of reprographic rights. These royalties are collected by DALRO and distributed to publishers only. As authors do not share in the royalties it will not have a negative effect on the incentive to create works.

3.6.8. Application of analytical framework

Theoretically, can the policy objective be met through the proposal?

The policy objectives are attainable through the amendment of the Copyright Act. In principle the provision of legislative provisions to ease access would be sufficient. However, it is important that awareness is generated amongst users, libraries, academics, scholars and teachers.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|--|-----|--------|------|
| Amendment of the Copyright Act and the drafting of regulations to ensure implementation | | | x |
| Awareness campaign – all stakeholders especially in the educational sector. The attainment of consumer awareness is difficult. | x | | |
| Resources with technical expertise to manage process. Technical skills refer to expert legal knowledge. | | | x |

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|---|-----|--------|------|
| Local publishing industry of educational works for scholars may suffer financial hardships. | | X | |
| Loss of income on the part of publishers | | | x |
| Loss of income on part of authors | x | | |
| Imbalance of public/private rights | x | | |

Can these risks be mitigated?

The risks that the policy intervention poses to the publishing industry are inextricably linked to the prices charged for schoolbooks. The risk factors that can be mitigated through various intervention strategies that reach beyond copyright law. These intervention strategies should address, inter alia, the lack of competition in the production of textbooks (perhaps through tender procurement processes), the lowering of paper and printing quality, mitigation of costs relating to inefficient planning and distribution, and addressing the poor retrieval rates of used schoolbooks by schools.

3.6.9. Policy recommendations

It is recommended that the Copyright Act be amended to adopt the maximum flexibilities as mandated by the Berne Convention and the TRIPS Agreement.

3.6.10. Alternative options

Certain other commercial practices also impinge on the price of books. South Africa is one of the few countries in the world which levies a Value Added Tax (VAT) on books, currently resulting in a 14% increase in retail price. A customs tariff is also levied on imported books as well as freight charges. The new e-VAT to be levied on all digital products (including e-books) will further contribute to the unaffordability of copyright works. Addressing and curbing these forms of levies on access to education would be an alternative option.

The publishing industry made the following suggestion:

*“...while recognising the importance of the availability of information in a society such as South Africa’s, does not believe that it is the role of a private sector industry group to subsidise the education of poorer students by effectively offering them free study material. Nor can it take responsibility for shortcomings in university library budgets. It therefore suggests **exploration of the provision of textbooks to disadvantaged students, including ring-fencing bursary funds for books.***¹⁵⁷

¹⁵⁷ Gray, E. and Seeber, M. 2004. Print Industries Cluster Council (PICC) Report on Intellectual Property Rights in the Print Industries Sector. Commissioned by the Department of Arts & Culture, Government of South Africa, (May 2004) at 60.

3.6.11. Case studies

3.6.11.1. Access to schoolbooks: Nancecol, Johannesburg

Andrew Rens, Achal Prabhala and Dick Kawooya note the following case study on the importance of access to works for education:

“An instructive example of the failure in access to learning materials in secondary school education can be found at Nancecol (formerly, the Nancefield College of Technology), an adult learning centre in South Africa, where 485 students spend half their day completing Grades 9, 10 and 12 of the secondary education system (Grade 11 is conflated into the grade 12 syllabus for adult education). Over the course of field visits conducted by the Access to Learning Materials Project in Southern Africa and the South African Students Congress in 2005, it was observed that not one of the students or teachers at the school owned a single textbook. The school administration itself only owned two copies of textbooks applicable for one subject (out of 12) for one level (Grade 9).

Teachers at the school taught from old books and handwritten notes, while students relied on their class notes for reference. The distribution of textbooks to Nancecol by the provincial DoE had been disrupted, and conversations with the school administration suggested that there were procedural problems in local bureaucracy that needed urgent attention. The administrator hastened to add that even if distribution were to function efficiently, the local education budget allowed for only something like one in five students to have access to textbooks.

Nancecol is located in Klipspruit, a neighbourhood of Soweto, which is among the largest black townships in South Africa, accounting for a third of the city of Johannesburg’s population.”

3.6.11.2. Prices of books: SA and Indonesia

The Comparative Price Study¹⁵⁸ shows that when the price of a book is considered in the context of a country’s GDP per capita (i.e. the average individual income), these books become prohibitively expensive to the average Indonesian and Thai.

When a student in Indonesia is made to pay US\$81.70 for Goodman & Gilman’s *The Pharmacological Basis of Therapeutics*, it is equivalent to a student in the US paying US\$3,170.97 for the same book in GDP per capita terms and US\$913.07 when compared using the GDP per capita calculated at purchasing power parity (PPP) exchange rate.

Below is a table that illustrates the price differentiation in three markets of books published by South African publishers and written by South African authors.

Table 4. Price differential of South African books

| Work | South Africa | USA | UK |
|--|--------------|----------|----------|
| Nelson Mandela <i>Long walk to freedom</i> | \$ 21.70 | \$ 10.15 | \$ 10.15 |
| Oxford English Dictionary | \$ 23.70 | \$ 11.60 | \$ 16.30 |

¹⁵⁸ See Appendix 1 in Consumers International *Copyright and Access to Knowledge Policy Recommendations on Flexibilities in Copyright* (2006).

| Work | South Africa | USA | UK |
|----------------------------|--------------|----------|----------|
| JM Coetzee <i>Disgrace</i> | \$ 44.61 | \$ 20.46 | \$ 24.00 |

Source: Andrew Rens, Achal Prabhala and Dick Kawooya *Intellectual Property, Education and Access to Knowledge in Southern Africa* (2006)

<http://www.iprsonline.org/unctadictsd/docs/06%2005%2031%20tralac%20amended-pdf.pdf>

3.6.11.3. Parallel importation – a comparison¹⁵⁹

Canada

Under section 27(2)(e) of the Copyright Act,

“[i]t is an infringement of copyright for any person to... import... a copy of a work... that the person knows... would infringe copyright if it had been made in Canada by the person who made it.”

This provision governs parallel importation of copyrighted works and imposes a principle of international exhaustion for works made overseas by the copyright owner or its authority.

Section 27.1 of the Canadian Copyright Act expressly prohibits parallel importation of books in cases where (1) the book was made overseas by owner of copyright but imported into Canada without consent of the copyright owner and (2) importer knows or should have known that the book would infringe copyright if the importer made it in Canada.

Canadian copyright law recognized for the first time a general principle of exhaustion in 2012 through the enactment of section 3(1)(j) of the Copyright Act which gives the copyright owner the exclusive right *“in the case of a work that is in the form of a tangible object, to sell or otherwise transfer ownership of the tangible object, as long as that ownership has never previously been transferred in or outside Canada with the authorization of the copyright owner.”*

India

The current copyright act was passed in 1957, ten years after independence. Exhaustion is recognized for literary, dramatic, musical, or artistic works in section 14 of the Copyright Act.

Section 14 does not apply to computer programs, cinematographic works or sound recordings. Consequently, copyright exhaustion does not apply to these last types of works.

Act grants to the copyright owner the exclusive “to sell or give on hire, or offer for sale or hire, any copy of the sound recording regardless of whether such copy has been sold or given on hire on earlier occasions. In addition, separate rental right provisions for software limit copyright exhaustion for computer programs.

Brazil

Brazilian copyright law has roots in a moral rights tradition and has been enforced largely through criminal provisions. Exhaustion is not part of the current Brazilian copyright statute and is not developed in the case law. National exhaustion in the form of a first sale doctrine is part of the proposed copyright reform of 2010.

¹⁵⁹ Based on S Gosh “The Implementation of Exhaustion Policies: Lessons from National Experiences” Issue Paper 40 International Centre for Trade and Sustainable Development).

China

The Chinese Copyright Act, amended in 2010, does not provide for the exhaustion of rights. However, the copyright owner does not enjoy an exclusive right to import the copyright work. Parallel importation is thus possible under Chinese copyright although there is no legislative provision to this effect.

3.6.11.4. Australian provision for access to education:

For one example of a sovereign copyright law that (partially) enables the educational provisions suggested, see Australia - the Copyright Act 1968 (Act No. 63 of June 7, 1968 as amended in 2002):

Section 10(1A). Without limiting the meaning of the expression educational purposes in this Act, a copy of the whole or a part of a work or other subject matter shall be taken, for the purposes of the provision in which the expression appears, to have been made, used or retained, as the case may be, for the educational purposes of an educational institution if:

(a) it is made or retained for use, or is used, in connection with a particular course of instruction provided by the institution; or

(b) it is made or retained for inclusion, or is included, in the collection of a library of the institution.

[and]

Section 40–(1) A fair dealing with a literary, dramatic, musical or artistic work, or with an adaptation of a literary, dramatic or musical work, for the purpose of research or study does not constitute an infringement of the copyright in the work.

(1A) A fair dealing with a literary work (other than lecture notes) does not constitute an infringement of the copyright in the work if it is for the purpose of, or associated with, an approved course of study or research by an enrolled external student of an educational institution.

(1B) In subsection (1A) the expression lecture notes means any literary work produced for the purpose of the course of study or research by a person lecturing or teaching in or in connection with the course of study or research.

(2) For the purposes of this Act, the matters to which regard shall be had, in determining whether a dealing with a literary, dramatic, musical or artistic work or with an adaptation of a literary, dramatic or musical work, being a dealing by way of reproducing the whole or a part of the work or adaptation, constitutes a fair dealing with the work or adaptation for the purpose of research or study include:

(a) the purpose and character of the dealing;

(b) the nature of the work or adaptation;

(c) the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;

(d) the effect of the dealing upon the potential market for, or value of, the work or adaptation; and

(e) in a case where part only of the work or adaptation is reproduced—the amount and substantiality of the part copied taken in relation to the whole work or adaptation.

23 Mirroring a situation generally applicable in the global south, where governments' involvement in curricular development is high in primary and secondary education, and less in tertiary education.

3.7. IMPLEMENTATION OF WCT AND WPPT

3.7.1. Policy proposal

The WIPO Internet treaties must be viewed in the context of the country's needs and requirements.

South Africa should consider carefully before acceding to the WIPO Copyright Treaty (WCT) and should not follow the path of the US Digital Copyright Management Act (DCMA) and EU (database Directive) as these instruments are restrictive and, therefore, bad models for copyright legislation of a developing country like South Africa. The DCMA and EU Directive restrict the number of downloads, whether for commercial or personal/research use.

South Africa internet users must be entitled to fair use rights such as making and distributing copies from electronic sources in reasonable numbers for educational and research purposes and using reasonable excerpts in commentary and criticism.

3.7.2. Status quo

The WCT and the WPPT

The advent of digital communications and its impact on the creation, production (and reproduction) and use of literary and artistic works, performances and recordings, and its potential for undermining the basic tenets of copyright and related rights, led to the adoption by the World Intellectual Property Organisation (WIPO) in December 1996 of two new treaties, the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT), together commonly referred to as the “Internet treaties”.

Key aspects of these international treaties and of the national copyright laws that relate to them include the communication right, the management of rights information and anti-circumvention provisions.

Copyright protection

The Copyright Act does not provide for the fair dealing or exploitation rights in relation to the digital environment. South Africa is a signatory but has not yet acceded to the WCT. The Copyright Act and the Performers Protection Act do not provide rights holders any digital exploitation rights.

The Copyright Act does not provide for any exceptions and limitations in the digital era – such as a private copy exception or a media shifting exception. Furthermore, the viewing of the contents of a website constitutes an unauthorized reproduction of the works displayed.

Performers' protection

South Africa is not a signatory to the Rome Convention and has not ratified the WIPO Performers and Phonograms Treaty (WPPT). The TRIPS Agreement requires its member states to provide protection to performers in respect of their fixed and unfixed performances. The Performers' Protection Act provides such protection, but makes it clear that the rights created under the Act will in no way restrict or affect the rights provided by other laws in regard to copyright in literary, musical or artistic works.

The Performers' Protection Act no 11 of 1967 imposes restrictions on the use of unfixed performances without the consent of the performer, including –

- broadcasting or communicating the performance to the public
- making a fixation of the performance
- making a reproduction of a fixation of the performance.

Where there is a commercial fixation of a performance, the Act restricts the use of such fixation, without payment of a royalty to the performer, by –

- broadcasting the performance
- causing the performance to be transmitted in a diffusion service
- causing any communication of the performance to the public.

The royalty payable is to be determined by agreement between the performer and the broadcaster, or between their collecting societies.

The protection extends from the date on which a performance takes place, for a period of 50 years (calculated from the end of the calendar year). Enforcement can take place by civil proceedings. Certain contraventions constitute offences; the penalty is a fine or imprisonment.

3.7.3. Problem statement and evidence

The WCT (2002) is a special agreement under the Berne Convention. Any contracting party (even if it is not bound by the Berne Convention) must comply with the substantive provisions of the 1971 (Paris) Act of the Berne Convention for the Protection of Literary and Artistic Works (1886). Furthermore, the Treaty mentions two subject matters to be protected by copyright - (i) computer programs, whatever may be the mode or form of their expression, and (ii) compilations of data or other material ("databases"), in any form, which by reason of the selection or arrangement of their contents constitute intellectual creations.

As to the rights of authors, the Treaty deals with three:

- the right of distribution,
- the right of rental, and
- the right of communication to the public.

The right of communication to the public is important as it covers on-demand, interactive communication through the Internet (such as the streaming of works from a web site).

Article 6(2) of the Treaty addresses the issue of the exhaustion of the right of distribution. It does not oblige contracting states to choose a national, regional or international exhaustion regime— of the right of distribution after the first sale or other first transfer of ownership of the original or a copy of the work, with the authorization of the author. Further, the Treaty does not address the regulation of the chosen exhaustion regime.

The WCT requires member states to

“provide adequate legal protection and effective legal remedies against the circumvention of effective technological protection measures that are used by authors in connection with the exercise of their rights and against the removal or altering of (“rights management information”) necessary for the management (e.g., licensing, collecting and distribution of royalties) of their rights.”

In terms of Article 10 of the WCT, contracting parties may carry forward and appropriately extend limitations and exceptions to the digital environment. The Agreed Statement concerning Article 10 of the WCT emphasises the need to maintain a balanced copyright regime:

It is understood that the provisions of Article 10 permit Contracting Parties to carry forward and appropriately extend into the digital environment limitations and exceptions in their national laws which have been considered acceptable under the Berne Convention. Similarly, these provisions should be understood to permit contracting parties to devise new exceptions and limitations that are appropriate in the digital network environment.

It is also understood that Article 10(2) neither reduces nor extends the scope of applicability of the limitations and exceptions permitted by the Berne Convention.

The WPPT (2002) deals with intellectual property rights of two kinds of beneficiaries:

- (i) performers (actors, singers, musicians, etc)
- (ii) producers of phonograms (the persons or legal entities who or which take the initiative and have the responsibility for the fixation of the sounds).

The WPPT grants to performers and producers of phonograms four kinds of economic rights:

- the right of reproduction,
- the right of distribution,
- the right of rental, and
- the right of making available.

The last-mentioned right covers, in particular, on-demand, interactive making available through the Internet.

The WPPT grants three kinds of economic rights to performers in respect of their unfixed (live) performances:

- (i) the right of broadcasting (except in the case of rebroadcasting),
- (ii) the right of communication to the public (except where the performance is a broadcast performance), and

(iii) the right of fixation.”

The WPPT also grants performers moral rights: the paternity and integrity rights. The Treaty obliges the contracting parties to provide legal remedies against the circumvention of technological measures (e.g., encryption) used by performers or phonogram producers in connection with the exercise of their rights and against the removal or altering of (“rights management information”) necessary for the management (e.g., licensing, collecting and distribution of royalties) of their rights.

Evidence:

In South Africa’s efforts to fight cybercrime, the WCT-principles were partially introduced into South African law. Section 86 of the Electronic Communications and Transactions (ECT) Act 25 of 2002 constructs a new cyber offence relating to the unauthorised access to, interception of, or interference with data which is, at its core, an anti-circumvention prohibition. The anti-circumvention prohibition is relevant to all data, namely electronic representations of information in any form. South African consumers have been placed in an unfortunate position as legislation dealing with the circumvention of technological protection measures outside the realm of copyright law is enacted, yet it applies to copyright works. It is irrelevant that the device has any lawful purpose other than the circumvention. Also, to procure or possess such a device with the intent of gaining unauthorised access to data is a criminal offence. The fair dealing defence does not help a consumer, as the anti-circumvention provision is not specifically related to copyright infringement. The ECT Act’s provision on technical protection measures TPMs disturbs the balance of public and private rights.

Evidence:

South African copyright law does not grant copyright owners a communication or making available right. The Performers Protection Act grants performers neither the making available right nor any moral rights. Because South Africa is not a member of the Rome Convention or the WPPT, reciprocal protection does not automatically apply to South African performers. As far as needletime right is concerned protection is conferred on a strictly reciprocal basis.¹⁶⁰ SAMPRA points out in its submission that South African copyright law continues to protect most new foreign recordings by virtue of “first publication” in terms of the Copyright Act.

The result is that recordings by international artists, for example Lady Gaga and Adele, are protected in South Africa - but recordings by local performers Mi Casa and Lira are not widely protected outside South Africa.¹⁶¹

Exceptions and limitations have not been adapted for digital era – e.g. media shifting. The Copyright Act grants the copyright owner of musical work, a literary work and a sound recording the exclusive right to distribute her work by broadcasting it and by transmitting it in a diffusion service. The copyright owners of a sound recording and the performers also have the additional right to communicate the sound recording or the fixed performance to the public.

Broadcasts and programme-carrying signals are technologically specific. Section 1 of the Copyright Act defines a broadcast as

‘a telecommunication service of transmissions consisting of sounds, images, signs or signals which (a) takes place by means of electro-magnetic waves of frequencies of lower than 3 000

¹⁶⁰ See section 5(1)(b) of the Performers Protection Act.

¹⁶¹ See SAMPRA submission under “Internet Treaties”.

GHz transmitted in space without an artificial conductor; and (b) is intended for reception by the public or sections of the public, and includes the emitting of programme-carrying signals to a satellite.'

A programme-carrying signal is defined as

'a signal embodying a program which is emitted and passes through a satellite'.

During the 'up-leg' of a transmission (i.e. whilst it is being sent to a satellite), a programme-carrying signal is a broadcast. Once the broadcast passes through a satellite it is transformed from a broadcast to a programme-carrying signal.

As noted above, South African copyright law does not grant copyright owners a communication or making available right. Mobile-communication protocols, combinations of wired and wireless communication systems and converged communication platforms fall outside of the realm of broadcasts and programme-carrying signals. Webcasting and interactive on-demand systems cannot be characterised as relying on either broadcasts or programme-carrying signals.

3.7.4. Policy objective

The WCT should be implemented by amendment of the Copyright Act and the Performers Protection Act. New exceptions and limitations should be developed as is applicable in the digital environment whilst anti-circumvention provisions should not prohibit access to works or preclude users from relying on exceptions and limitations to copyright that are otherwise available.

The WPPT should be implemented by the amendment of the Copyright Act and the Performers Protection Act

3.7.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's copyright regime:

- Public (Users of works)
- Content providers – media houses and Wireless Applications Service Providers WASPS,
- Rights holders –
 - authors,
 - publishers,
 - broadcasters,
 - producers of sound recordings, and
 - performers
- Educational institutions
- Libraries

- Societies for collective management of copyright –
 - Dramatic, Artistic and literary Rights Organisation (Pty) Ltd (DALRO).
 - Southern African Music Rights Organisation Limited (SAMRO),
 - South African Music Performance Rights Association (SAMPRO),
 - Record Industry of South Africa (RISA)
 - National Association of Broadcasters (NAB)
- Enforcement
 - South African Police Services (SAPS)
 - National Prosecuting Authority (NPA)
 - Judiciary
 - Mobile Network Operator (MNOs) Internet Service Providers (ISPs) and WASPS

3.7.5.1. Public (Users of works): indeterminate, possibly positive

- **New exception:** Every time a user views a web page on the Internet a temporary copy is made in the Random Access Memory (RAM) of the user's device. The adoption of a temporary copy exception will clarify that temporary copies made in the course of viewing files do not constitute copyright infringement. The enactment of this provision will provide legal clarity and certainty.
- **TPMs should not bar access:** Where a user seeks to access a work for fair dealing purposes then TPMs should not bar access.
- **Media shifting:** The amendment of the Copyright Act to authorize media shifting (for example the loading of a private copy of a sound recording on more than one device (computer and iPod)) will enhance legal certainty.
- **TPMs:** Users could be affected negatively as – TPMs could pose technical difficulties in gaining lawful access to a work.

3.7.5.2. Content providers: mostly negative

Content providers will be faced with the responsibility of respecting authors' rights in the online environment. This would entail:

- **Amendment to business models:** Content providers will have to conclude new license agreements with collecting societies and copyright owners – a negative effect.
- **Escalation of costs:** Content providers have to pay for the exploitation of exclusive rights and royalties will be payable to collecting societies – a negative effect.

- **Decrease in revenue:** As content providers have to pay for the exploitation of exclusive rights profit margins will decline. In addition, royalties will be payable for what has been a free use up to now – a negative effect.
- **Increased legal certainty:** The adoption of the WCT and WPPT will provide legal clarity – a positive effect.

3.7.5.3. Rights holders: largely positive

New exclusive rights: Authors will enjoy the right to benefit from the exploitation of works on Internet. This would translate into an increase in revenue base for rights holders – performers and authors alike.

3.7.5.4. Educational institutions: likely positive

Clarity on fair dealing: Educational institutions will enjoy the ability to deliver distance education in an improved manner. The fair dealing as applied to digital copyright works will be clear. Academics will enjoy digital fair use rights and an increase in legal certainty.

3.7.5.5. Libraries: likely positive

Legal certainty: The implementation of the WCT and the WPPT will enable libraries to offer more effective and additional service to users. The digital archiving rights to be exercised by libraries will make a long-term positive impact on the preservation of the South African cultural and historical heritage as well as scarce material.

3.7.5.6. Societies for collective management of copyright: likely positive

Effective collective management of rights: Collection societies will be able to conclude license agreements for the digital exploitation of works. If the WCT and WPT exclusive rights are adopted it will expand the legal base for the collective management of copyright.

One negative aspect in the difficulties collecting societies will experience in providing adequate training and information to their members and users alike.

In the long term the increase in income and the ease of keeping digital records of the use of works will enable collecting societies to manage their members' interests more efficiently. This will in turn result in an enhancement of business environment for the collective management of copyright.

3.7.5.7. Government: mostly positive

Legislative amendment: Government will be burdened by the associated costs involved in the amendment of the Copyright Act in order to implement the WCT and the WPPT. These costs inter alia entail the obtaining expert advice, consulting with stakeholders and costs related to the drafting process, Government will also need to train and up skilling staff to be able to devise policy and public awareness campaigns on digital copyright law and the online protection of consumers.

Government should ensure capacity because if the Internet Treaties are implemented successfully it will have a positive impact on digital economy. Similarly, the implementation of the WCT and the WPPT will also have a positive impact on digital economy.

3.7.6. Assessing benefits / pros

Authors and performers would enjoy the right to benefit from exploitation of works on Internet. Collection societies will be able to conclude license agreements for the digital exploitation of work and online exploitation. This will result in an increase in revenue base for rights holders.

The positive outcome would be the stimulation of South African cultural and creative industries. The adoption of the temporary copy exception to provide legal clarity to users is a positive. TPMs would only be applicable to copyright works. Appropriate exceptions and limitations for digital uses could be adopted. This will result in legal certainty for users on permitted digital uses.

3.7.7. Assessing costs / cons

TPMs could bar access to works unless owners are obliged to provide the key to decrypt. Practical implementation of exceptions and limitations where works are protected by TPMs would be difficult especially in the online environment where reciprocal obligations are not imposed on copyright owners in other countries.

The protection of digital works could result in the diminishing of the public domain. The capacity to enforce the legal provisions is problematic as jurisdictional borders become fused in cyberspace.

3.7.8. Application of analysis framework

Theoretically, can the policy objective be met through the proposal?

The policy objectives are attainable through the amendment of the Copyright Act. In principle the provision of legislative provisions to implement the WCT and the WPPT are imperatives.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|---|-----|--------|------|
| Amendment of the Copyright Act and to implement the WCT and the WPPT and the drafting of regulations. | | | X |
| Amendment of the Performers Protection Act to implement the WPPT and the drafting of regulations. | | | X |
| A government resources with technical expertise to manage process | | | X |

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|---|-----|--------|------|
| Imbalance of public/private rights – TPMs to bar access Although legislative provisions will attempt to address this it may not translate into ease of access for all users. | | x | |

Can these risks be mitigated?

The risks that the mandatory implementation of anti-circumvention provisions and the protection of rights management information may bar access to works in the digital environment may be mitigated through the careful crafting of fair dealing provisions to ensure users' right to access may be enforced. As such, the Copyright Act must not incorporate such anti-circumvention provision without expressly linking the provision to copyright infringement or without the simultaneous inclusion of obligations where a user is entitled to a corresponding limitation to copyright protection. Furthermore, users should be able to access the work for legitimate purposes through the intervention of the copyright owner.

3.7.9. Policy recommendation

It is recommended that the WCT and the WPPT be implemented through legislative amendments. The approach of Luxembourg is exemplary.

The ECT Act should be amended to exclude copyright works from its ambit.

3.7.10. Alternative options

None.

3.7.11. Country comparisons

Below is an extract from the copyright provisions of the US, the EU and Luxembourg. The approach adopted by Luxembourg is preferable.

3.7.11.1. United States

DMCA

In 1998, the United States Congress passed the *Digital Millennium Copyright Act*.¹⁶² The DMCA adds to the minimum level of protection required in the WCT: it strikes at both acts and devices that enable the circumvention of technological protection.¹⁶³ The Act states in section 1201(A)(1)(A) that no person may circumvent a technological measure that effectively controls access to a copyright work. A technological measure, in turn, has been defined as a measure that effectively controls access to a work if the measure, in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the author, to gain access to the work.¹⁶⁴ To circumvent a technological measure means to descramble a work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure without the authority of the author.

3.7.11.2. European Union

Copyright Directive

The European Union adopted the WCT in its Copyright Directive.¹⁶⁵ Member States are obliged to provide adequate legal protection against acts of circumvention. Member States

¹⁶² Digital Millennium Copyright Act of 1998 105 Pub L No 304 112 Stat 2660 (hereafter referred to as 'DMCA).

¹⁶³ Correa CM "Fair use in the digital era" 2002 (33) International Review of Industrial Property and Copyright Law 570-585.

¹⁶⁴ See DMCA § 1203(B). See Albert, GP Intellectual Property Law in Cyberspace (BNA Books Washington DC 1999) 265-271.

¹⁶⁵ 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright law in the information society (Copyright Directive).

must also prohibit the dealing in products or services that are primarily designed for circumvention of technological protection measures or that have limited use other than circumvention.

The Copyright Directive contains one compulsory exception related to temporary copying and a number of prescriptive non-mandatory exceptions.¹⁶⁶ Article 6.4 provides that the governments of Member States may intervene to enable a beneficiary of an exception to benefit. However, where there is an agreement between the parties the governments cannot intervene, which effectively limits this to paper-based works.

3.7.11.3. Luxembourg

Copyright, neighboring rights, database rights and patents Act of 18 April 2004 amending - 1. Law of 18 April 2001 on copyright, neighboring rights and databases, and the two modified 20 July 1992 amending the patent regime of law. invention.

"Section 1 - Technical measures

Art. 71ter. term "technical measure" is referred to any technology, device or component that, in the normal course of its operation, is designed to prevent or restrict acts, in respect of works or services protected acts not authorized by the rightholder a copyright, related right or the sui generis right provided for in Part 6 of this Act.

Technological measures shall be deemed effective where the use of a protected work or service is protected by copyright holders thanks to the application of an access code or process protection, such as encryption, scrambling or other transformation of the work or the provision or mechanism copy that achieved this protection.

Art. 71quater's circumvention of any effective by a person who knows, or has reasonable grounds to know, she is pursuing that objective technical measure is prohibited.

It is also prohibited to manufacture, import, distribute, sell, rent, advertising for sale or lease to own for commercial purposes of devices, products or components, or provide services that are being promoted, advertised or marketed for the purpose of circumventing protection or have only limited commercially significant purpose or use other than limited to circumvent or that are primarily produced, adapted or performed for the purpose of enabling or facilitating the circumvention of any effective technological measure.

Whoever contravenes any prohibition contained in the preceding paragraphs and is not acting only for private purposes shall be punished under Article 83 of this law.

Any interested party, including authorized under this Act to manage or administer copyright or neighboring rights organization, is entitled to ask for termination pursuant to section 81 of this Act, any act in contravention of a prohibition under paragraphs 1 and 2 above.

Art. 71quinquies. Notwithstanding the legal protection of technological measures, rights holders must take the necessary measures, including by contract, to ensure that beneficiaries have legal access to the protected work or service, an exercise without hindrance and under the conditions there, with the following exceptions:

1 illustration of education, referred to in Articles 10, 46 and 2, 9,

¹⁶⁶ See a 5(2)-5(4). These exceptions include (free or paid for) exceptions relating to the photographic reproduction of material, private copying, illustrations for teaching, etc.

2 private reproductions, referred to in Articles 10, 4 and 46, 4,

3 recordings by broadcasting organizations, referred to in Articles 10, 9 and 46, 7,

4 reproductions by libraries, etc.. which question the first part of Article 10, 10,

5 uses for the benefit of people with disabilities who question Article 10, 11,

6 public safety and smooth procedures that referred to in section 10, 12,

7 uses of databases, referred to in Articles 10a and 68.

To the extent that holders of rights still failing to take action under the first paragraph, the predicted exceptions, a professional group or association to represent their interests are entitled to bring an action for an injunction pursuant to Article 81 of this Act in order to stop the implementation of technical measures that impede the exercise of those exceptions.

The technological measures applied voluntarily by rightholders under the first paragraph, including those implemented under voluntary agreements, as well as possibly implemented pursuant to a court decision are protected against circumvention in accordance with Article 71quater above.

The provisions of the first and second paragraphs of this Article shall not apply to works or services which are made available to the public at the request according to the contractual arrangements between the parties so that everyone can have access to the area and at a time individually chosen by them.

Art. 71sexies. provisions of this section do not apply to technical measures used in connection with computer programs.

Section 2 - Information on the copyright regime

Art. 71septies. "Information on the copyright regime" is referred to any information provided by rightholders which identifies the work, performance or database protected under Part 6 of this Act, author or any other rightholder. This concept also refers to information on the terms and conditions of use of the work of the service or the database, and any numbers or codes that represent such information.

The information rights management is provided when any of the information provided by the definition of the first paragraph is attached to a copy or ceremonial in connection with the communication to the public of a work of a service or a database protected under the 6 th of this Act. "

Art. 71octies. prohibited Are

(1) the removal or alteration of any information on rights management in electronic form, or

(2) the distribution, importation for distribution, broadcasting, communication or making available to the public works, services or databases that are protected under this Act and whose data information rights management in electronic form has been removed or altered without authority by a person who is knowingly and without authorization, knowing or having reasonable grounds to believe that, in so doing, it shall lead, enable, facilitate or conceal an infringement of any copyright, related right or right sui generis .

Whoever contravenes the prohibition in the preceding paragraph and who is not acting only for private purposes shall be punished under Article 83 of this law.

Any interested person, including authorized under this Act to manage or administer copyright or neighboring rights organization, is entitled to ask for termination pursuant to section 81 of this Act, the conduct in contravention of the prohibition referred to in paragraph 1 st."

3.8. ADOPTION OF OTHER INTERNATIONAL TREATIES ON IP RIGHTS

3.8.1. Marrakesh Treaty

3.8.1.1. Policy proposal

This issue was not addressed in the Draft National IP Policy.

3.8.1.2. Status quo

The Marrakesh Notification No. 1 from the Republic of India was published on the 30th of June 2014.¹⁶⁷ The Marrakesh Treaty focuses on copyright exceptions to facilitate the creation of accessible versions of books and other copyrighted works. It sets a norm for countries ratifying the Treaty to have a domestic copyright exception covering these activities, and allowing for the import and export of such materials.

The Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled (MVT) was adopted in June 2013.

The MVT places an obligation on Member States to provide for limitations or exceptions to the right of reproduction, the right of distribution, and the right of making available to the visually impaired and otherwise print disabled (VIPs) accessible format copies.

Authorized entities may, on a non-profit basis, make accessible format copies, which can be distributed by non-commercial lending or by electronic communication. This is conditional upon the requirement that:

- a) the entity had lawful access to the work,
- b) introduced only those changes needed to make the work accessible, and
- c) supplied the copies only for use by beneficiary persons.

VIPs may also make a personal use (back-up) copy where they have lawful access to an accessible format copy of a work.

An authorised entity, as defined by the treaty is found in Article 2(c):

“ ‘authorized entity’ means an entity that is authorized or recognized by the government to provide education, instructional training, adaptive reading or information access to beneficiary persons on a non-profit basis. It also includes a government institution or non-profit organization that provides the same services to beneficiary persons as one of its primary activities or institutional obligations.”

¹⁶⁷ http://www.wipo.int/treaties/en/notifications/marrakesh/treaty_marrakesh_1.html.

Authorised entities should also meet several criteria:

“An authorized entity establishes and follows its own practices:

- (i) to establish that the persons it serves are beneficiary persons;*
- (ii) to limit to beneficiary persons and/or authorized entities its distribution and making available of accessible format copies;*
- (iii) to discourage the reproduction, distribution and making available of unauthorized copies; and*
- (iv) to maintain due care in, and records of, its handling of copies of works, while respecting the privacy of beneficiary persons in accordance with Article 8.”*

At the domestic level countries can confine limitations or exceptions to those works that cannot be "obtained commercially under reasonable terms for beneficiary persons in that market." Use of this possibility requires notification to the WIPO Director General.

Contracting Parties must allow the import and export of accessible format copies under certain conditions. Regarding importation, when an accessible format copy can be made pursuant to national law, a copy may also be imported without right holder authorization. With reference to exportation, accessible format copies made under a limitation or exception or other law can be distributed or made available by an authorized entity to a beneficiary person or authorized entity in another Contracting Party for the exclusive use of the works by beneficiary persons. Cross-border transfer by authorized entities is not permitted unless the Contracting Party in which the copy is made is a party to the WIPO Copyright Treaty or otherwise applies the three-step test to limitations and exceptions implementing the MVT.

The MVT leaves Contracting Parties the freedom to implement its provisions taking into account their own legal systems and practices, including determinations on "fair practices, dealings or uses", provided they comply with their three-step test obligations under the Berne Convention.

South Africa has the most limitations and exceptions for education and library purposes in its Copyright legislation if compared to other developing countries.

Yet, South Africa does not address the needs of the people with sensory-disabilities.

Denise Nicholson¹⁶⁸ notes:

“Except for enlargement of printed text by a partially-sighted reader, almost every conversion from print to an alternative form is a transgression of copyright law. Section 13 of the Copyright Regulations has specific exceptions for libraries and educational purposes, which include limited multiple copying for classroom use. People who are deaf or partially-sighted can benefit from photocopied handouts, in normal or enlarged print. However, these exceptions do not extend to persons requiring conversions from print material to alternative formats, or conversions from audiotapes to text, or conversions from text to more visual formats, for deaf

¹⁶⁸ See Denise Nicholson Copyright - Are people with sensory-disabilities getting a fair deal? <http://pcf4.dec.uwi.edu/viewpaper.php?id=379&print=1>

persons. They also do not extend to distance learners or informal literacy learners, many of whom have sensory-disabilities.

...

DALRO offers transactional copyright licences to the educational sector and corporate organizations. It does not clear copyright for any adaptations, translations or conversions to alternative formats, except for Braille conversions, which are covered in its Blanket Licence, which is only available for tertiary institutions.”

In developed countries, barely 5% of all published works are available in formats which are accessible to blind people (large print, audio, braille or DAISY) – in developing countries, this number drops to a mere 0.5%. This estimation made by the World Blind Union (WBU) is the root of the current literary crisis known as the Book Famine!¹⁶⁹

3.8.1.3. Problem statement and evidence

The Marrakesh Treaty is not yet in force. South Africa was one of the 51 countries that signed this treaty when it was adopted.

Evidence:

Catherine Saez¹⁷⁰ has noted that the implementation of the Marrakesh Treaty may be difficult. She noted that the 2013 Marrakesh Treaty has been applauded by beneficiaries throughout the world for answering the need for wider access to special format works for visually impaired people, but a major concern is that fact that that the path to its implementation, even after it is ratified by enough countries, appears to be strewn with difficulties in developing countries.

A number of challenges face authorised entities in providing access to special format works to visually impaired people. Authorised entities need to be able to manage data and master complex technical processes. Authorised entities need:

- to demonstrate that beneficiaries are print disabled.
- to transform those files into the exact format or copy them on the right medium
- be able to convert works in accordance with the Unicode system;
- to manage a fragmented supply chain for product deliveries

Dipendra Manochais quoted in the article by Catherine Saez. He notes that:

“A recent visit to Bangladesh and Sri Lanka, he said, showed that libraries serving the print disabled do not have registries, and no adequate process for registering beneficiaries, he said. Neither are they able to maintain records of transactions showing who received the books and how many copies they received, he said.

...

¹⁶⁹ South African National Council for the Blind

<http://www.eyesite.co.za/General/ArticlesforConsumers/ViewConsumerArticles/tabid/67/smId/399/ArticleID/118/reftab/64/t/ACCESS-FOR-BLIND-VISUALLY-IMPAIRED-AND-OTHER-READING-DISABLED-PERSONS-TVI/Default.aspx>.

¹⁷⁰ Catherine Saez “Developing Countries Lack Capacity To Take Advantage Of Marrakesh Treaty” Intellectual Property Watch (18 December 2013 @ 12:00 am) <http://www.ip-watch.org/2013/12/18/developing-countries-lack-capacity-to-take-advantage-of-marrakesh-treaty/>

Libraries for visually impaired persons in developing countries are often primarily manned by volunteers, he explained.

Missions in Bangladesh, Sri Lanka and Namibia revealed a number of practical challenges, he said, among which is the fact that in most developing countries, publishers and the visually impaired communities do not communicate and publishers are unaware of the needs of blind people.

...

Finally, the affordability of the technology remains a problem for developing country visually impaired users who need special tools, such as DAISY players.”¹⁷¹

3.8.1.4. Policy objective

The Copyright Act should provide Sensory-disabled users permission to transform material into accessible formats or media, unless the rights-holder is providing the appropriate accessible version at the same time and under the same terms as to sighted-persons.

3.8.1.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa’s copyright regime:

- Disabled persons
 - Blind
 - Visually impaired
 - Reading disabled
 - Persons with a physical disability that prevents them from holding and manipulating a book.
- Authorised entities
 - SA Council for the Blind
 - Organisations for Disabled persons
 - Department of Basic Education
 - Special Needs Schools
- Content providers/publishers
- Government

3.8.1.6. Disabled persons: likely positive

¹⁷¹ Catherine Saez “Developing Countries Lack Capacity To Take Advantage Of Marrakesh Treaty” Intellectual Property Watch (18 December 2013 @ 12:00 am) <http://www.ip-watch.org/2013/12/18/developing-countries-lack-capacity-to-take-advantage-of-marrakesh-treaty/>

VIPs will be positively impacted. The MVT will establish new rights to provide VIPs with access to works and ultimately to knowledge and culture. The increase in the number of works in accessible format will enrich and increase access to works. Furthermore, the import/export provisions facilitate cross-border and international co-operation. The only negative aspect is that access may be costly to some VIPs – for example the costs of acquiring a DAISY device.

3.8.1.7. Authorised entities: mostly negative

Authorised entities will gain a host of new responsibilities and will need to ensure that adequate capacity is established. First managerial and administrative functions will have to be performed. Mechanisms will have to be developed to determine the eligibility of beneficiary persons. The authorised entities will also have some copyright and records management responsibilities, namely to discourage the reproduction, distribution and making available of unauthorized copies and to maintain due care in, and records of, its handling of copies of works. Furthermore, authorized entities will have to manage a fragmented supply chain for product deliveries.

It has been noted above that authorized entities must be technologically enabled as they will be responsible for the transformation of accessible files into specified formats (i.e. be able to convert works in accordance with the Unicode system).

Authorised entities will thus have to invest in human capital development and ICT systems. Not all authorised entities (for example some ELSN schools) will be able to fulfil this role.

3.8.1.8. Content providers/ Publishers: mostly negative

Content providers will be required to respect new rights of users and to facilitate VIPs access to works by making works available in accessible formats. This will necessitate an amendment to content providers' business models.

It may also impact on existing contractual obligations. Content providers will have to enter into new license agreements. These new responsibilities imply an escalation of transaction costs. As a result content providers will suffer a decrease in revenue.

3.8.1.9. Government: likely positive

In the short term the Government will incur costs to amend the Copyright Act and to draft new Regulations for the implementation of the new exceptions and limitations, to prevent abuse and to provide for the export of works that fall under the MVT. The state will incur costs for the legislative process, public advocacy and capacity building.

The broader and long term effect will be very positive. This endeavour will enhance and support access to works for the disabled. It has a clear humanitarian and social development dimension and its main goal is to create a set of mandatory limitations and exceptions for the benefit of the VIPs. As noted below, the implications of implementing the Marrakesh Treaty is that South Africa will be seen to be pro-development and for the enablement of the disabled. The Government's credibility will be enhanced due to the positive impact of VIPs access to works.

3.8.1.10. Assessing benefits / pros

Positive impact: It has a clear humanitarian and social development dimension and its main goal is to create a set of mandatory limitations and exceptions for the benefit of the VIPs.

3.8.1.11. Assessing costs / cons

Negligible costs for publishers as far as production of an accessible copy is concerned publishers only need to make books available in an electronic format (accessible format). Possible loss of market share as disabled will no longer purchase works in non-accessible formats.

3.8.1.12. Application of the analysis framework

Theoretically, can the policy objective be met through the proposal?

Yes the proposal is based on the newly formed MVT – it is aligned to international best practices.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|--|-----|--------|------|
| Legislative implementation | | | X |
| Capacity building in government with regards to implementation oversight | | x | |
| Capacity building of authorized entities | | | X |

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--------------------------|-----|--------|------|
| No legislative enactment | x | | |

3.8.1.13. Policy recommendation

The adoption of the Marrakesh Treaty and the amendment of the Copyright Act to provide for the exceptions and limitations relating to accessible copies of works are strongly recommended.

3.8.1.14. Alternative options

None.

3.8.1.15. Country comparisons

3.8.1.15.1. Legislation for the visually-impaired

Several countries, mostly developed countries, have already adopted specific provisions that address exceptions for visually-impaired persons, as follows:¹⁷²

- Australia, Part V Division 3 of the Copyright Act of 1968;
- Canada, Section 32 of the Copyright Act of 1997;
- United States of America, Section 121 (the Chafee Amendment of 1996) of the Copyright law;
- European Union, Article 5(3)(b) of the Directive 2001/29/EC on the harmonization of certain aspects of copyright and related rights in the information society of 2001;
- United Kingdom, the Copyright (Visually Impaired Persons) Act of 2002
- Denmark, Section 17 of the Danish Copyright Act of 2003;
- Japan, Article 33bis of the Copyright Law of 2003;
- Republic of Korea, Article 30 of the Copyright Act of 1995;
- Latin America region:-
 - Brazil, Article 46 of Law 9.610 of 1998
 - Nicaragua, Article 34 of Copyright Law of 1999
 - Paraguay, Article 39 of Law 1328/98 of 1998
 - El Salvador, Article 44 of the Law on Promotion and Protection of Intellectual Property of 1993;
- Panama, Article 17 of Law 15 of 1994;
- Dominican Republic, Article 44 of Law 65 of 2000.

3.8.1.15.2. Filadelfia School for the Blind

In 2005, students at the Filadelfia School for the Blind – in a township called Soshanguve outside Pretoria, South Africa – were compelled to go on strike to protest the unavailability of learning materials in Braille. Text-to-audio and text-to-Braille conversion incur significant process costs, but notwithstanding, licensing factors – whether related to a delay in obtaining formal permission, or the cost of obtaining an adaptation license – remain as barriers.

3.8.2. Madrid Agreement and Protocol

3.8.2.1. Policy proposal

No policy proposal was included in the Draft National IP Policy.

¹⁷² See Denise Nicholson Copyright - Are people with sensory-disabilities getting a fair deal? <http://pcf4.dec.uwi.edu/viewpaper.php?id=379&print=1>

3.8.2.2. Status quo

South Africa is a member of the Paris Convention for the Protection of Industrial Property ("Paris Convention") and the WTO.

South African trade mark law is regulated by:

- Trade Marks Act no 194 of 1993
- Trade Mark Regulations, 1995
- Merchandise Marks Act no 17 of 1941
- Intellectual Property Laws Amendment Act of 2013.

The International Classification of Goods and Services under the Nice Agreement (9th edition) is currently applied to South African trade mark applications, although South Africa has not acceded to the Nice Agreement. A separate trade mark application is required for a trade mark falling within different classes of goods or services.

The Paris Convention provides for the protection of well-known marks (Article 6bis), the protection of trade names (Article 8) and claims deriving from unfair competition (Article 10bis). Any person who has applied for registration of a trade mark in a Paris convention country is entitled to claim priority for the same date as the date of first application in a convention country. The application in South Africa must be filed within six months after the date of first application in a convention country.

Government has expressed its intentions to accede to the Madrid Protocol in the near future.¹⁷³

3.8.2.3. Problem statement and evidence

The "Madrid Agreement concerning the International Registration of Marks" ("Madrid Agreement") was adopted in 1891 and entered into force in 1892 and it has been amended a few times. The Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks was entered into in 1996.¹⁷⁴ The Common Regulations under the Madrid Agreement Concerning the International Registration of Marks and the Protocol Relating to that Agreement¹⁷⁵ also came into force on in 1996, the Agreement and Protocol jointly known as Madrid System.

The system is administered by the International Bureau of WIPO (IB), which maintains the International Register and publishes the WIPO, Gazette of International Marks. The states that are parties to the Agreement and /or the Protocol are collectively referred as contracting parties. The contracting parties together they constitute Madrid Union and every member of the Madrid Union is a member of its Assembly and their major responsibilities are the adoption of the program and budget of the Union and the adoption and modifications of the regulations and fixing of the fees etc.

¹⁷³ Companies and Intellectual Property Commission STRATEGY 2013 – 2018
http://www.cipc.co.za/Publications_files/CIPC_new_strategy_2013.pdf.

¹⁷⁴ As amended on November 12, 2007.

¹⁷⁵ As in force on January 1, 2013.

The office of origin must certify that the mark is the same as that in the basic registration or basic application, that any indications such as description of the mark or a claim to colour as a distinctive feature of the mark are the same as those contained in the basic registration or basic application, and that the goods and services indicated in the international application are covered by the list of goods and services in the basic registration or basic application.¹⁷⁶ It must also certify the date on which it received the request to present the international application and this date will be the date of the international registration, provided that the international application has been received by the IB within a period of two months from that date. If the international application has not been received within that period, the international registration shall bear the date on which the said international application was received by the International Bureau.¹⁷⁷

The IB checks that the international application complies with the requirements of the Agreement or Protocol, goods and services, fees etc. and if they found any irregularities, will be communicated to the Office of origin and the applicants and these must be complied within three months, otherwise the application will be abandoned.¹⁷⁸ Several time periods are applicable to the procedures. If, for example, the IB considers that the requirements of Rule 9(4)(a)(xiii) are not complied with, it shall make a proposal of its own for the classification and grouping and shall send a notification of its proposal to the Office of origin and at the same time inform the applicant together with the amount, if any, of the fees due as a consequence of the proposed classification and grouping.¹⁷⁹ The Office of origin may communicate to the International Bureau an opinion on the proposed classification and grouping within three months from the date of the notification of the proposal.¹⁸⁰ If no opinion has been communicated to the International Bureau under paragraph 12(2), the amount referred to in paragraph 12(1)(b) shall be payable within four months from the date of the notification referred to in paragraph 12(1)(a). If an opinion has been communicated to the International Bureau under paragraph 12(2), the amount referred to in paragraph 12(1)(b) or, where applicable, paragraph 12(5) shall be payable within three months from the date of the communication by the International Bureau of the modification or confirmation of its proposal under paragraph 12(5) or 12(6), as the case may be. If payment is not received within the three or four month period, the international application shall be considered abandoned.¹⁸¹ Once the applicant comply all the requirements, the mark is recorded in the International Register and published in the Gazette.

The IB then notifies each Contracting Party in which protection has been sought.

It is obligatory on the part of designated Contracting Parties to examine the International registration in exactly the same way as an application filed directly. The IB must be notified of the first official action or declaration, namely an acceptance, a provisional acceptance or provisional refusal within the period prescribed by the law applicable to that Office and at the latest, within 12 months.¹⁸² Any Contracting Party may declare that, for international registrations made under the Madrid Protocol, that the aforementioned time limit of one year is replaced by 18 month.¹⁸³ It is not uncommon for parties to adopt the longer time period to examine applications – for example, the United States has opted for the longer 18 months' time period. If no refusal is issued within the 12 or 18 month time period, the mark must be

¹⁷⁶ See article 3(1) of the Protocol.

¹⁷⁷ See article 3(4) of the Protocol.

¹⁷⁸ See paragraph 11(4)(b) of the Rules.

¹⁷⁹ See paragraph 12(1)(a)-(b) of the Rules.

¹⁸⁰ See paragraph 12(2) of the Rules.

¹⁸¹ See paragraph 12(7)(a) of the Rules.

¹⁸² See article 5(2)(a) of the Protocol.

¹⁸³ See article 5(2)(b) of the Protocol.

accepted for protection. Once again several other time limits apply. If the notification of provisional refusal is deemed to be irregular, a rectified notification must be sent within two months¹⁸⁴ from the receipt of the invitation.

The individual countries are permitted to indicate that the refusal is based on an opposition, even if the opposition is not decided until after the twelve or eighteen month period, if WIPO is notified of the possibility of opposition within the required period.¹⁸⁵ It is not necessary that a final decision on the refusal be taken within the applicable time limit and it is sufficient that all grounds for refusal are notified within the time limit. Countries may refuse to protect a mark in their territory, but their refusal may be based solely on the grounds which would apply in the case of a mark filed for national registration.¹⁸⁶

When an Office informs the IB, in connection with a given international registration, of the possibility that opposition may be filed after the expiry of the 18 months period, it must, where the dates on which the opposition period begins and ends are known, indicate them in the communication. If such dates are, at that time, not yet known, they must be communicated to the IB once they become known.¹⁸⁷ The IB will record this information in the international register, transmit it to the holder of the international registration and publish it in the Gazette.

An Office which has sent to the IB a notification of provisional refusal should send a statement, once all procedures before the said Office relating to the protection of the mark have been completed, indicating that the provisional refusal is confirmed or is totally or partially withdrawn and the said statement recorded in the international register and published in the Gazette.

The Protocol offers several advantages and it differs from the Agreement in offering options such as:

- a choice for the applicant, allowing international registrations to be based on national applications and not only on national registrations;
- a period of 18 months, instead of one year, for contracting parties to refuse protection, with the possibility of a longer period in the case of a refusal based on an opposition;
- the possibility for the office of a designated contracting party to receive, instead of a share in the revenue from the standard fees, an “individual fee” whose amount may not be higher than the fees it charges for national or regional registration or renewal, the said amount being diminished by the savings resulting from the international procedure;
- the transformation of an international registration which is no longer protected because the basic mark has ceased to have effect in the country of origin, international or regional applications in some or all of the designated contracting parties, with the filing date, and where applicable the priority date, of the international registration.

The distinct advantages offered by the Madrid Protocol when compared to the Madrid Agreement:

¹⁸⁴ See paragraph 18(1)(iv) of the Rules.

¹⁸⁵ - See more at: <http://corporate.findlaw.com/intellectual-property/international-trademark-registration-the-madrid-protocol-takes.html#sthash.1wcHuFe0.dpuf>

¹⁸⁶ See article 5.

¹⁸⁷ The time period is at least one month from the expiry of the opposition period and, in any case, not later than seven months from the date on which the opposition period begins see article 5(2)(c)(ii) of the Protocol.

| ISSUE | MADRID AGREEMENT | MADRID PROTOCOL |
|---|--------------------------------|--|
| Membership | Members States | States and Organizations |
| Basic mark upon which international registration is based | Basic registration | Basic registration and Application |
| Time period first action/refusal | 12 months | 12 or 18 or 18+ months |
| Dependency | 5 years | 5 years with possible transformation |
| Period of registration | 20 years | 10 years |
| Language | French | French, English and Spanish |
| Fees | Supplementary or Complementary | Supplementary or Complementary or Individual |

Evidence:

Currently a South African trade mark owner may file a trade mark application in a Paris convention country. The only advantage of such an application is the claim to priority for the same date as the date of first application in a convention country. Such a trade mark application must be lodged individually in each convention country. Each application will be subject to each jurisdiction's formalities, language requirements, fees and prosecution.

The Madrid Protocol offers several advantages to South African trade mark owners. An international registration may be obtained by simply filing one application with the International Bureau (through the office of the home country), in one language (English, French or Spanish) and paying one set of fees.

An international application must designate one or more contracting parties (not the contracting party whose Office is the Office of origin) in which the mark is to be protected. Further contracting parties may be designated subsequently. A contracting party may be designated only if that contracting party and the contracting party whose Office is the Office of origin are both party to the same treaty, that is, the Agreement or the Protocol.

Similar advantages exist for maintaining and renewing a registration. Likewise, if the international registration is assigned to a third party, or is otherwise changed, such as a change in name and/or address for service, this may be recorded by means of a single procedural step with effect for all designated contracting parties.

International registration is also to the advantage of the designated Trademark Offices. For example, they neither need to examine the application for compliance with formal requirements, nor classify the goods or services. The designated Trademark Offices is also not responsible for the publication of marks. These functions are fulfilled by the International Bureau. It should be noted that any refusal, withdrawal or cancellation of the basic application or basic registration within five years of the registration date of the international registration will lead to the refusal, withdrawal or cancellation of the international registration.

The individual and other designation fees collected by the International Bureau are transferred to the contracting parties in which protection is sought. Should the International Registration Service close its biennial accounts with a profit, the proceeds are divided amongst the contracting parties.

One of the greatest disadvantages of the Madrid Protocol is article 6(3) of the Madrid Protocol. In terms of this provision an international registration remains dependent on the mark registered or applied for in the office of origin for a period of five years from the date of its registration. The basic registration ceases to have effect, whether through cancellation following a decision of the office of origin or a court, through voluntary cancellation or through non-renewal, within this five year period, the International registration will no longer be protected. Similarly, where the International registration was based on an application in the office of origin, it will be cancelled if, that application is refused or withdrawn within the five year period. Thus, the first five years are crucial for international registrations, whatever happens to the basic application or registration in the office of origin also affect the rest of designations under the international registration.

The article 9quinquies of the Madrid Protocol provides the transformation of an International Registration into National or Regional Application, in the event that the International Registration is cancelled at the request of the Office of origin. The transformed national applications must be filed within three months from the date on which the international registration was cancelled and the goods and services listed in the application must have been covered by the list of goods or services contained in the original International registration. In such circumstances, the applicant has to bear more expenses by paying national fees in each designated countries and one of the advantage of the Madrid Protocol become a disadvantage.

The basis of International registration is the application of the office of origin and any cancellation or deletion of goods or services from the office of origin will also to be deleted from the International registration.

The change in ownership can be recorded only if the transferee is a person who is entitled to file international applications, hence, a transfer of ownership to an entity, which is not a party to the protocol is not possible Another disadvantage of the Madrid Protocol is its limited membership; especially many emerging economies are not yet members of the system. The amendment of mark is not permitted in the Madrid system. The applicant has to file the same mark where he filed in the Office of Origin; even the slight amendment of the mark will not be entertained by the IB.

3.8.2.4. Policy objective

South Africa should accede to the Madrid Protocol to assist South African trade mark owners to expand internationally and to register foreign-owned trade marks in South Africa.

3.8.2.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's trade mark regime:

- Owners of trade marks
- CIPC

- IP attorneys
- Design and advertising community

3.8.2.5.1. Owners of trade marks: likely positive

Owners will enjoy increased certainty of the validity of their marks after 5 years. The Madrid Protocol offers South African trade mark owners ease of access to international markets. Ultimately trade mark owners enjoy savings – the Madrid Protocol offers the possibility to lodge one application for the mark in multiple jurisdictions.

3.8.2.5.2. Government/CIPC: likely negative

Government will incur associated costs for the amendment of the Trade Marks Act. The current back-log is no longer problematic. In accordance with the CIPC's *Service Delivery Standards* a first official action in relation to new trade mark applications is issued 12 months from date of application¹⁸⁸ Interviews with stakeholders have indicated that the time from the application for a trade mark to the receipt of a first official action is down to seven months – four months quicker than the Service Delivery Standards. However, other respondents have cautioned that it would seem as though all efforts have been put into improving the turn-around time to the first official action that other procedures are lagging behind. A case in point is the time it takes the CIPC to issue a registration certificate after acceptance of the mark.

Implementation of the Madrid Protocol in South Africa necessitates the amendment of South African legislation and procedures to provide for the international registrations under the Protocol and to harmonise the way national trademark registrations interact with international applications.¹⁸⁹ In addition to legislative amendments the CIPC will need to implement new trade mark prosecution system which implies budget requirements. These procedures include:

- the procedure for handling applications for international registration of trade marks that are filed with the International Bureau of WIPO
- multi-class applications
- requests to extend the protection that results from international registration of trade marks to South Africa
- the protection given to protected international trade marks in South Africa
- the circumstances in which protection of an international registration ceases and the procedures to be followed when this happens
- the cancellation of an international registration at South Africa's request, and
- the effect of cancelling an international registration.

Other costs are associated with the training and up skilling of staff and ongoing operational costs. CIPC will have to ensure that it has the necessary capacity prior to implementation.

¹⁸⁸ http://www.cipc.co.za/SDS/Service_delivery_Standards_Trade%20marks_13_May_2014.pdf

¹⁸⁹ For the experience in Mexico see Karla Crespi "The Madrid Protocol: what are the benefits to Mexico?" (2012) World Intellectual Property Review <http://www.worldipreview.com/article/the-madrid-protocol-what-are-the-benefits-to-mexico>

If the Madrid Protocol is implemented successfully it will have a positive impact on filings and cost-to-company. It will also have a positive impact on the economy.

Lynelle Tuffery-Huria¹⁹⁰ provides some insights into the number of applications that the CIPC could expect when compared to the growth in international filings in New Zealand:

The Intellectual Property Office of New Zealand (IPONZ) predicted the numbers for Madrid Protocol would be 200– 400 for the first year international applications flowing out of New Zealand (approximately 16–33 each month) and 7,000–9,000 for the first year international applications designating New Zealand (approximately 583–750 each month).

AJ Park obtained some statistics from IPONZ and the World Intellectual Property Office (WIPO) database on international applications. At January 24 this year, the current filing statistics are 33 international applications flowing out of New Zealand and 205 international applications designating New Zealand.

Another author¹⁹¹ noted the experience in New Zealand:

We expect there may be an increase in the number of foreign companies registering their trademarks here, because the marginal cost of ‘adding’ New Zealand to their filing program will be significantly reduced under the Madrid Protocol.

In the past some foreign companies may have chosen not to file here because of the relatively small size of our market and the accompanying costs of filing here. Now, with the reduced costs, those companies might decide to file here. This could mean that, over time, the New Zealand trademark register becomes more ‘cluttered’, particularly with foreign-owned trademarks that are not yet being used here. This may mean New Zealand companies take increased risks if they adopt a new trademark without searching them first.

There would have to be significant adaptations of the expected number of applications in South Africa should the Madrid system be adopted in South Africa.

The current predictions are:¹⁹²

| Date | 2012/13 | 2013/14 | 2014/15 | 2015/16 | 2016/17 | 2017/18 |
|---------------------------------|---------|---------|---------|---------|---------|---------|
| Total Trademark registration | 33,452 | 37,536 | 42,412 | 48,236 | 55,198 | 62,373 |
| Estimated local filings | 19,737 | 23,684 | 28,421 | 34,105 | 40,926 | 47,883 |
| Estimated international filings | 13,715 | 13,852 | 13,991 | 14,131 | 14,272 | 14,414 |

If trade mark prosecution is not up to standard it will result in a reputational loss as international trade mark owners will be hesitant to designate South Africa. An important aspect is thus adequate preparation from a legislative, administrative, systems and human resources perspective. There is currently a Madrid Working Group working under the leadership of Ms Fleurette Coetzee of CIPC. The Madrid Working Group has already drafted an implementation plan that addresses legislative, administrative, systems and human resources requirements for accession to the Madrid Protocol. The documents prepared by the

¹⁹⁰ Lynelle Tuffery-Huria “Madrid Protocol – predictions vs reality” March 6, 2013 Ideology <http://www.idealogue.co.nz/magazine/44/madrid-protocol-predictions-vs-reality>.

¹⁹¹ Kate Beecroft “The Madrid protocol bullfight” 13 March 2012 Ideology <http://www.idealogue.co.nz/magazine/38/madrid-protocol-bullfight>

¹⁹² See CIPC STRATEGY 2013 – 2018 ‘COUR SE CORRECTION AND OPTIMI SAT ION!’ http://www.cipc.co.za/Publications_files/CIPC_new_strategy_2013.pdf

Madrid Working Group¹⁹³ should be studied to gain further insights into the readiness of the CIPC to meet all the challenges posed by the implementation of the Madrid system.

3.8.2.6. IP attorneys: likely positive

Trade mark attorneys will have to implement new forms and procedures in their office management systems. This will be costly and training costs will also be incurred. An increase in international filing may be expected as South Africa becomes a designated country which would translate into an increase in South African IP legal fees. IP attorneys will still be engaged in the filing applications. It is expected that disputes will in some instances escalate to litigation. This will result in legal fees and fees related to services rendered in respect of such litigation.

If trade mark prosecution is not up to standard South Africa will suffer reputational loss and international as well as national clients will loath to file.

3.8.2.7. Assessing benefits / pros

The main advantage of the Madrid Protocol is that it allows trade mark owners to obtain protection in any or all member states by filing one application in one jurisdiction with one set of fees. Joining the Madrid System will bring down the cost of international trade mark registration for South African companies, and this should make it easier for them to compete on the global stage. Another advantage is that the trade mark filing strategy may be adapted as the company's commercial interests grow, allowing the owner to file in one jurisdiction to begin with, and then extend the protection afforded to the international registration to various other jurisdictions as it becomes cost effective to do so.

The advantages of the Madrid Protocol have been noted as follows: "...it'll become significantly cheaper for local companies to expand their IP protection overseas. There will often be no need to appoint local representatives in each country. Companies will be better placed to establish their legal rights overseas earlier, perhaps avoiding unfortunate situations where... companies have previously not filed overseas because of low cash flow, and have had to deal with serious problems downstream when other companies had come into their foreign market with a similar or even identical trademark."¹⁹⁴

South Africa and Brazil are now the only BRICS countries that are not members of Madrid, and Brazil has indicated that it will be joining in the near future.¹⁹⁵

3.8.2.8. Assessing costs / cons

One disadvantage is that the international applications are dependent on the national application or registration. Any refusal, withdrawal or cancellation of the basic application or basic registration within five years of the registration date of the international registration will lead to the refusal, withdrawal or cancellation of the international registration.

A second problem relates to the capacity of the CIPC. It is a requirement under the Madrid Protocol that applications examined within 18 months.¹⁹⁶ In 1998 trade mark applications took

¹⁹³ These documents are of a confidential nature and was not available to Genesis for scrutiny.

¹⁹⁴ Kate Beecroft "The Madrid protocol bullfight" 13 March 2012 Ideology

<http://www.idealogue.co.nz/magazine/38/madrid-protocol-bullfight>.

¹⁹⁵ Andrew John Bellingall "BRAZIL MOVES TOWARDS THE MADRID PROTOCOL"
http://www.country-index.com/articles/article_30.pdf

26 months to be granted¹⁹⁷ and the situation degraded to a period from submission of an application to grant in excess of 36 months. Currently, in accordance with the CIPC's Service Delivery Standards, a first official action in relation to new trade mark applications must be issued 12 months from date of application.¹⁹⁸ This is comfortably within the Madrid requirements of 12 to 18 months. Not all aspects of CIPC's service delivery are these exemplified and all official actions should be brought to an acceptable service delivery level.

Several amendments to the South African Trade Marks Act will also be necessary – as indicated above. For example, the Trade Marks Act will have to be amended to provide for the first official action to be provided within the specified time, provision should be made for multi-class applications, the co-ownership of trade mark applications and a declaration by the applicant that the goods or services that she applies for on the application form fall within the applicant's business activity, to name a few.

3.8.2.9. Application of the framework

Theoretically, can the policy objective be met through the proposal?

The policy objectives are attainable through the adoption of the Madrid Protocol.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|--|-----|--------|------|
| Amendment of the Trade Marks Act and the drafting of regulations to ensure implementation. Internationally many examples exist of implementation models. Technical assistance from WIPO is also readily available, | | | x |
| Maintaining current Service Delivery Standards for first official action | | | x |
| Implementation Service Delivery Standards to adhere to all the time lines of the Madrid system. | | X | |
| Resources with technical expertise to manage process - this expertise already exists in the dti and external stakeholders in the form of the Madrid Working Group. | | | x |

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|---|-----|--------|------|
| Unable to implement effective administrative system | | x | |
| Unable to maintain first official action Service Delivery Standards | x | | |

Can these risks be mitigated?

¹⁹⁶ Andrew John Bellingall "BRAZIL MOVES TOWARDS THE MADRID PROTOCOL"

http://www.country-index.com/articles/article_30.pdf

¹⁹⁷ Owen Dean "The future of South African trade marks" [HTTP://BLOGS.SUN.AC.ZA/IPLAW/FILES/2012/08/THE-FUTURE-OF-SOUTH-AFRICAN-TRADE-MARKS.PDF](http://blogs.sun.ac.za/iplaw/files/2012/08/the-future-of-south-african-trade-marks.pdf).

¹⁹⁸ Stakeholders that were interviewed indicated that the CIPC's Service Delivery Standards are being met. Some indicated that the first official action is usually received within seven months.

The risks can be mitigated depending on the availability of resources to plan, implement and manage the process.

3.8.2.10. Policy recommendations

Accession to the Madrid Protocol to facilitate international applications is recommended.

3.8.2.11. Alternative options

None.

3.8.2.12. Country comparisons

Japan: Measures to adopt the Madrid Protocol

MEASURES TO EXPEDITE EXAMINATION PROCESS

The Japanese Patens Office (JPO) has initiated action to reduce the pendency of period for refusal from 22 Months in the year 1996 to 17 months in the year 1998.¹⁹⁹ They have outsourced the prior searches for figurative marks and the computerization of examination processes also started. At the time of the accession of the Protocol in the year 2000 the period for refusal reduced to 11.1 months.

INSTITUTIONAL STEPS

The amendment of the relevant Japanese law to facilitate the Madrid Protocol applications and some of the important provisions as follows-

- Stipulate the statutory period for examination within 18 months.
- Incorporate the provisions concerning applications for international registration from Japan to WIPO s International Bureau.
- Stipulate special provisions concerning applications for International trademark registration, where Japan as designated country.
- Stipulate special provisions concerning applications for trademark registration in respect of Central attack.
- Improve the provisions concerning the fee structure covering commissions for individual fees set out in the Madrid Protocol.

OPERATIONAL STEPS

- Development of computer systems for administrating the information on applications and registrations under the Madrid Protocol.
- Setting up the International Trademark Application Office and the International Trademark Application Examination Office to which Officers who have completed training programs provided by WIPO s International Bureau are assigned.

¹⁹⁹ See N.BABU EFFECTIVE IMPLEMENTATION OF THE MADRID PROTOCOL WITH A SPECIAL EMPHASIS TO THE ORGANIZATIONAL SET UP IN INDIA http://www.jpo.go.jp/torikumi_e/kokusai_e/pdf/ipcoop_asia-pacific_e/2009wipo_india.pdf

OTHER STEPS

- Training has given to examiners at WIPO and also extensive Training given in Foreign Language
- Enlightenment and publicity for Japanese users by way of seminars and booklets
- Working- level briefing sessions for Intellectual property systems
- Every year, around October, gives lectures regarding the outline of the Madrid system and application procedures in four cities.

India

Various procedures are explicitly explained and forms have been prepared for the implementation of the Madrid Protocol in India - see Guidelines for Functioning under the Madrid Protocol (Trade Marks Registry Mumbai Version- 1) (2013)http://www.ipindia.nic.in/Whats_New/guidelines_MadridProtocol_17December2013.pdf

3.8.3. Hague Agreement and Protocol

3.8.3.1. Policy proposal

No policy proposal was included in the Draft National IP Policy.

3.8.3.2. Status quo

South Africa is a member of the Paris Convention and the WTO/TRIPS. South African design legislation consists of:

- Design Act no 195 of 1993
- Design Regulations, 1999.

Application for a design registration may be made by way of (i) a non-convention national application, or (ii) a convention application claiming priority of the first-filed application in a Paris Convention country. Any person who has filed a first design application in a Paris convention country, is entitled to claim priority from such earlier application, provided the South African application is filed within six months from such earlier application.

It is anticipated that South Africa will accede to the Hague Agreement in the near future.²⁰⁰

3.8.3.3. Problem statement and evidence

Hague Agreement Concerning the International Registration of Industrial Designs was concluded in 1925. The Hague Agreement allows multi-jurisdictional registrations through filing single application. The Hague Agreement enables designers to protect their designs with minimum formalities in multiple countries or regions.

An international deposit does not require any prior national deposit. It is made directly with the International Bureau of WIPO by the depositor or his representative on a form provided free of

²⁰⁰ Companies and Intellectual Property Commission STRATEGY 2013 – 2018
http://www.cipc.co.za/Publications_files/CIPC_new_strategy_2013.pdf.

charge by the International Bureau. It may, however, be made through the national Office of a Contracting State if the law of such State so permits. The law of a Contracting State may also require, in cases where that State is the State of origin that the international deposit be made through the national Office of that State. Non-compliance with this requirement does not prejudice the effects of the international deposit in the other Contracting States.

The owner of an international deposit enjoys the priority right afforded under Article 4 of the Paris Convention for the Protection of Industrial Property if he claims this right and if the international deposit is made within six months of the first national, regional or international deposit made in, or having effect in, a State party to the Paris Convention or a Member of the World Trade Organization.

A single international deposit may comprise several designs, up to a maximum of 100. All the designs in a single deposit must however be in, or be intended for incorporation in articles listed in, the same class of the International Classification (Locarno Classification).

Any Contracting State whose domestic legislation offers the possibility of refusing protection, as the result of an administrative *ex officio* examination or of opposition by a third party, may refuse protection for any industrial design not meeting the requirements of its domestic law. The Geneva Act provides that any designated Contracting Party may refuse, in part or in whole, the industrial designs that are the subject of the industrial design registration "where the conditions for grant of protection under the law of the Contracting Party are not met."¹⁰ However, in light of Article 14(2)(a) of the Geneva Act, if a refusal has not been communicated to WIPO by the Contracting Party prior to expiration of the designated refusal period, the "*international registration shall have the same effect as a grant of protection of the industrial design under the law of the Contracting Party.*"

Refusal of protection may not, however, extend to the formalities and other administrative acts that must be considered by each Contracting State as having been accomplished as of the time the international deposit is recorded at the International Bureau. No Contracting State may require, in particular, publication of the international deposits other than that made by the International Bureau.

Refusal of protection must be notified to the International Bureau within six months of the date on which the national Office received the issue of the Bulletin in which the international deposit concerned was published. The International Bureau transmits a copy of the refusal to the depositor, who has the same remedies against the decision to refuse as he would have had if he had deposited the design or designs concerned with the Office that has taken the decision to refuse. Where no refusal is notified within the period of time referred to above, the protection of the designs included in the international deposit is the same as if the deposit had been entered in the national register of the State concerned.

Evidence:

Where applications are lodged in separate territories the territoriality of rights are applicable.²⁰¹ This will result in design applications that:

- Are filed for each market

²⁰¹ Grégoire Bisson "Hague System for the International Registration of Industrial Designs" paper delivered at the International Symposium on the Protection of Industrial Designs
http://www.wipo.int/edocs/mdocs/hague/en/ompi_di_san_11/ompi_di_san_11_15.pdf

- Are filed in many offices
- Are filed in many languages
- Have to comply with many formalities
- Have to be paid in many currencies
- Result in many registrations to manage
- Are cumbersome, and
- Are expensive.

The main aim of the international deposit of industrial designs is to enable protection to be obtained for one or more industrial designs in a number of States through a single deposit filed with the International Bureau of WIPO. Under the Hague Agreement, any person entitled to effect an international deposit has the possibility of obtaining, by means of a single deposit made with the International Bureau of WIPO, protection for his industrial designs in Contracting States of the Agreement with a minimum of formalities and expense.

The applicant is thus relieved of the need to make a separate national deposit in each of the States in which he requires protection, thus avoiding the inherent complication of procedures that vary from one State to another.

The Offices of the Contracting States have no specific tasks in the implementation of the Hague Agreement, except in those cases where the domestic or regional legislation of the State permits or requires the international deposit to be effected through them or lays down a novelty examination for deposited designs.

The system is cost-effective and efficient, thereby creating opportunities that would not otherwise exist for any enterprise with a limited IP budget. It is a flexible system affording right holders great flexibility in targeting national, regional or global markets for particular products.²⁰²

3.8.3.4. Policy objective

The implementation of the WCT and WPPT to enhance access and the growth of authors' remuneration rights in the digital environment.

3.8.3.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's design regime:

- CIPC
- SABS
- Designers

²⁰² Grégoire Bisson "Hague System for the International Registration of Industrial Designs" paper delivered at the International Symposium on the Protection of Industrial Designs
http://www.wipo.int/edocs/mdocs/hague/en/ompi_di_san_11/ompi_di_san_11_15.pdf

- Owners of designs - businesses

3.8.3.5.1. Designers

Designers will enjoy increased opportunity to register aesthetic designs in the international market. The Hague Agreement Protocol offers South African designers ease of access to international markets. Ultimately designers enjoy savings –and the possibility to market their designs in multiple jurisdictions.

3.8.3.5.2. CIPC

- Normal work is reduced
- Office relieved from formal examination
- Office gets a « clean file » on which to base its substantive examination, if any
- Sovereignty on substantive issues is preserved:
- same regime as for national filings

3.8.3.5.3. IP Attorneys

- Design-related work as a new business line
- More registrations in general mean more business:
- license and contract work
- enforcement or litigation work

3.8.3.6. Assessing benefits / pros

Positive impact and benefits for users are evident at a glance.

| National/Regional Route | International (Hague) Route |
|---|--------------------------------|
| many Offices for filing | one Office for filing |
| many languages | one language |
| many currencies | one currency |
| many registrations | one international registration |
| many renewals | one renewal |
| many modifications | one modification |
| foreign attorney or agent foreign attorney or (first needed at filing) | agent (needed only if refused) |

3.8.3.7. Assessing costs / cons

The 1993 Designs Act creates a two-part register: part A for aesthetic designs, and part F for functional designs. The policy reason for this distinction is that Parliament recognised that

functional-design registrations may have a far more serious impact on industry than aesthetic-design registrations.

The term "aesthetic design" is defined in section 1(1) as

“any design applied to any article, whether for the pattern or the shape or the configuration or the ornamentation thereof, or for any two or more of those purposes, and by whatever means it is applied, having features which appeal to and are judged solely by the eye, irrespective of the aesthetic quality thereof.”

An aesthetic design which is new, original, and intended to be multiplied by an industrial process can be registered.²⁰³ A design is deemed to be new if it is different from or if it does not form part of the state of the art immediately before the priority date (sect 14(2)). The concept of "state of the art" is defined in a manner similar to the definition of this term in section 25(6) and (7) of the Patents Act 57 of 1978. For designs, the concept comprises all matter which has been made available to the public (whether in the Republic or elsewhere) by written description, by use or in any other way, and all matter contained in earlier co-pending applications (sect 14(3)).

No feature of an article in so far as it is necessitated solely by the function which the article is to perform, and no method or principle of construction shall give the registered proprietor of an aesthetic design any rights under the Act in respect such feature, method, or principle (sect 14(5)).

The term "functional design" is defined in section 1(1) of the 1993 Designs Act to connote

“any design applied to any article, whether for the pattern or the shape or the configuration thereof, or for any two or more of those purposes, and by whatever means it is applied, having features which are necessitated by the function which the article to which the design is applied, is to perform, and includes an integrated circuit topography, a mask work and a series of mask works.”

A functional design can be registered if it is new, not commonplace in the art in question, and intended to be multiplied by an industrial process.²⁰⁴

The duration of the registration of a functional design is ten years from its date of registration or its release date, whichever is the earlier.²⁰⁵ The registration of functional designs is unique to the South African legal system. In the rest of the world only recognize aesthetic designs and specifically excluded functional designs from registration. Accession to the Hague Agreement will necessitate the repeal of the functional designs as such designs are not registrable internationally.

3.8.3.8. Application of the framework

Theoretically, can the policy objective be met through the proposal?

Yes.

²⁰³ See sect 14(1)(a) read with sect 14(4).

²⁰⁴ See sect 14(1)(b) read with sect 14(4).

²⁰⁵ See sect 22(1)(b).

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|---|-----|--------|------|
| Amendment of the Designs Act and the drafting of regulations to ensure implementation | | | x |
| Resources with technical expertise to manage process | | | x |

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--|-----|--------|------|
| Loss of ability to protect low-level technologies (functional designs) | | | x |

Can these risks be mitigated?

The risk that the policy intervention poses to the designer of functional designs may be mitigated by the introduction of a petty patent system.

3.8.3.9. Recommendations

Accede to the Hague Agreement and amend the Designs Act and Regulations.

3.8.3.10. Alternative options

Implement a petty patent system in addition to the accession to the Hague Agreement.

3.8.3.11. Country comparison

United States

The Patent Law Treaties Implementation Act of 2012 signed by President Obama on December 18, 2012 implements the Hague Agreement in the United States. It is intended to provide industrial designs with protection in states and governmental organizations parties to this arrangement through a single international application effected at the WIPO. Before the Hague Agreement, an application had to be filed in every country where protection was desired, resulting in several applications being filed for a single design patent. Under the Hague agreement a single application can provide protection in multiple countries.

An international application under the Hague Agreement does not require a prior national deposit, and can be filed either at the WIPO or at the national office. The application may be in English, French or Spanish.

When filing an application under the Hague Agreement, one must either be a citizen of a Contracting Party or a Member State of an international organization that is a Contracting Party. Alternatively, one must have either a residence or an habitual residence on the territory of a Contracting Party, and one must have an effective industrial or commercial establishment on the territory of a Contracting Party.

The Hague Agreement consists of three International Treaties, but since 2010 only two of them are still enforced: The Geneva Act (1999) and The Hague Act (1960). (The London Act of 1934 was frozen in 2012).

The Geneva Act and the Hague Act are independent from each other, such that one country can join one or both. Accordingly, when asking for protection under the Hague Agreement in several countries, it is crucial to confirm that those countries are parties to the same Act. The United States are party to the Geneva Act but not the Hague Act. Consequently, the United States can ask protection in countries party to the same act (the Geneva Act) but cannot ask for protection in a country which is party only to the Hague act.

The Hague Agreement increases the protection duration for design patents in the US from 14 years to 15 years. This increase in protection duration is based on an initial 5 year protection which may be renewed for an additional 5 years, every 5 years until the total protection is reached, in countries where protection is desired. The total duration of design patent protection may vary according to each country's rules.

Under the Hague agreement, an international application may contain a maximum of 100 Designs. All designs must belong to the same Locarno classification, which is an International Classification for Industrial Designs. Application costs are expected to increase with the number of designs claimed.

Under the Hague Agreement, publication takes place six months after the date of the international registration. However, an applicant may request immediate publication or request a deferment of publication.²⁰⁶

3.8.4. Lisbon Agreement

3.8.4.1. Policy proposal

No policy proposal was included in the Draft National IP Policy.

3.8.4.2. Status quo

As a member of TRIPS Agreement, the use of GI's must accordingly be protected under South African law. GI specific statutory protection exists in South Africa. In addition, a variety of statutes deal with related legal matter. In addition, the common law can be used to address conduct that is by way of unlawful competition.

A distinction must be drawn between protection that involves the conferring of rights and protection that forbids certain forms of conduct.

The Merchandise Marks Act²⁰⁷ amongst others makes it an offence to apply a false trade description to goods.²⁰⁸ A trade description is amongst others defined as an indication as to place or country of manufacturing or production of goods. It includes any mark or the like that according to custom in trade is taken to serve as indication of place of manufacturing or production of goods.²⁰⁹ The term "mark" is defined broadly and includes a word and any graphical representation.²¹⁰ Persons that are liable under such conduct are amongst others those that knowingly participated therein or had reason to suspect that a trade description so used was not genuine.²¹¹ The protection corresponds with the protection of indication of source

²⁰⁶ Guest blog <http://www.protectingdesigns.com/blog/tag/hague-agreement>

²⁰⁷ Merchandise Marks Act 17 of 1941, as amended (The Merchandise Marks Act).

²⁰⁸ Art. 6 of the Merchandise Marks Act.

²⁰⁹ Art. 1 of the Merchandise Marks Act.

²¹⁰ Art. 1 of the Merchandise Marks Act; "mark".

²¹¹ Art. 6 of the Merchandise Marks Act.

under the Paris Convention,²¹² as referred to above. Being broader than pure GI protection, protection under the Merchandise Marks Act will comply with the requirement to prevent the abuse of a GI as required by the TRIPS Agreement.

A right conferring protection for GI's under South African law must be obtained under the Trademarks Act. Marks that exclusively consist of signs that may serve in trade to designate amongst others the geographical origin of goods can, however, not be registered as trademarks. Provision is furthermore made for the registration of certification marks and collective marks. Certification and collective marks are similar to collective and certification marks in other jurisdictions. Collective marks are useful for obtaining rights to a GI under South African law. Such marks, in so far as distinctive, are available for the goods of persons that are members of an association for distinguishing it from similar goods of persons that are not members of such association.

The face of SA IP law has changed drastically, with the adoption of the Intellectual Property Laws Amendment Act, 2013.²¹³ Specific provision is made for the amendment of the Trade Marks Act. A traditional term or expression may be registered as a geographical indication or a certification trade mark or a collective trade mark.²¹⁴ A geographical indication may also be registered as a certification trade mark or a collective trade mark.²¹⁵ A geographical indication is defined insofar as it relates to indigenous cultural expressions or knowledge as an indication that identifies goods or services as originating from the territory of the Republic or a locality on that territory, where the particular quality, reputation or other characteristics of the goods or services is attributable to the geographic origin of the goods or services, including natural or human factors.

Geographical indications that are traditional terms or expressions are only registrable if they are derivative geographical indications created after commencement of the Intellectual Property Laws Amendment Act, 2013 and it must have originated from an indigenous community.²¹⁶ Alternatively, the term must also have been passed down from a previous generation.²¹⁷ The provisions of section 43(B)(8)(a) will not readily find application as geographical indications usually develop over generations.

The Counterfeit Goods Act²¹⁸ prohibits amongst others the use of mark involving intellectual property rights in relation to goods without the authority of the owner of the rights. A mark in the case of not being a trademark or otherwise qualifying for copyright protection is only regarded as an intellectual property right where it has been positively dealt with under the Merchandise Marks Act.²¹⁹ GI protection under the Counterfeit Goods Act will consequently require such positive notification.

Under the Agricultural Product Standards Act, as amended,²²⁰ the use of a mark, in whichever way set out, in connection with the sale of an agricultural product, that conveys or creates a false or misleading impression as to, amongst others, the quality or place of production of such

²¹² Art 1(2) of the Paris Convention.

²¹³ The Amendment Act has not yet taken effect.

²¹⁴ See section 43B(2) of the Trade Marks Act.

²¹⁵ See section 43B(4)-(5) of the Trade Marks Act.

²¹⁶ See section 43B(8)(a) of the Trade Marks Act.

²¹⁷ See section 43B(8)(b) of the Trade Marks Act.

²¹⁸ Counterfeit Goods Act 37 of 1997 (The Counterfeit Goods Act).

²¹⁹ Art. 1 of the Counterfeit Goods Act; the terms "counterfeiting" and "intellectual property right" taken in conjunction with art. 15 of the Merchandise Marks Act that gives authority for prohibiting the use of any mark or the like.

²²⁰ The Agricultural Products Standards Act 119 of 1990 (The Agricultural Product Standards Act) as amended by the Agricultural Products Standards Amendment Act 63 of 1998.

product is prohibited.²²¹ A specific prohibition can be declared in connection with geographical and other names including any use in conjunction with words such as "kind", "type" or the like.²²² While protection under this statute is not absolute as it requires the sale of a product, it is at any rate clear that the value of a GI in fact lies in its commercialization.

In relation to alcoholic products the Liquor Products Act,²²³ amongst others, prohibits the use of the name of any country or word or expression containing such name in relation to the sale of liquor product except for product originating from that specific country.²²⁴

Under South African common law misleading or deceiving of the public in respect of own performance inclusive of as to the origin of goods has been ruled as an act of unlawful competition. The legal object in such case is, however, not something akin to a mark but rather the right to attract custom that ties in with the goodwill of an enterprise.²²⁵

While it appears as though most circumstances that regulate the use of GI's are covered under the various statutes briefly referred to above, a definite prohibition is often required under these statutes.

3.8.4.3. Problem statement and evidence

The geographical names, for which systems of protection have been introduced, both nationally and internationally, fall into three categories: indications of origin, geographical indications and appellations of origin.

Paris Convention

The early protection of geographical indications referred to this form of protection either as "indications of source" or "appellations of origin". Under the Paris Convention,²²⁶ indications of source and appellations of origin are included as matter that qualifies for protection. Article 1(2) stipulates that "*The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition*". Article 10(1) prohibits the "*direct or indirect use of a false indication of the source of the goods*".

It should be noted that only false indications are covered by Article 10. No protection is provided for cases when the indication is used in translated form or accompanied by terms such as "kind", or "type", or when it is deceptive, i.e. likely to mislead the consumer.

Madrid Agreement 1891

The 1891 Madrid Agreement for the "Repression of False or Deceptive Indications of Source on Goods" provides for the imposition of penalties for the false and deceptive indications of

²²¹ Art. 6 of the Agricultural Products Standards Act.

²²² Art 6A of the Agricultural Product Standards Act. Article 6A relates to TRIPS Agreement article 23.

²²³ Liquor Products Act 60 of 1989 (The Liquor Products Act).

²²⁴ Article 11 of the Liquor Products Act. Section 12(1) provides that "no person shall use any name, word, expression, reference, particulars or indication in any manner either by itself or in coherence with any other verbal, written, printed, illustrated or visual material in connection with the sale of a liquor product in a manner that conveys or creates or is likely to convey or create a false or misleading impression as to the nature, substance, quality, composition or other properties, or the class, cultivar, origin, age, identity, or manner or place of production, of the liquor product." The "false or misleading" standard means that a geographic indication need not be misleading in order to be prohibited. In fact, even a statement that provides the true origin of the product may be unlawful under this provision.

²²⁵ See for example *William Grant & Sons Ltd and Another v Cape Wine and Distillers Ltd and Others* 1990 (3) 897

(C).

²²⁶ Article 1(2) of the Paris Convention 1967 available at www.wipo.int/treaties/en/ip/paris.

sources of goods. The Agreement addresses cases where consumers are defrauded or where confusion is caused in the mind of the consumer. The Agreement has 36 members.

Lisbon Agreement 1958

Under the 1958 Lisbon Agreement for the Protection of Appellations of Origin and their International Registration contains the first international definition of appellations of origin and introduces a mechanism that affords international protection for appellations of origin and is independent of domestic legislation. The Lisbon Agreement was concluded in response to the need for an international system that would facilitate the protection of a special category of such geographical indications, i.e. “appellations of origin”, in countries other than the country of origin, by means of their registration at the International Bureau of WIPO

It provides for the international registration of appellations of origin, and at the same time the Contracting Parties undertake *“to protect on their territories, in accordance with the terms of this Agreement, the appellations of origin of products of the other countries of the Special Union, recognised and protected as such in the country of origin”*²²⁷

As long as an appellation is protected in the country of origin, it cannot be deemed to have become generic in another country of the Special Union. This agreement currently has 28 Members.

An appellation of origin is the geographical name of a country, region, or locality, which serves to designate a product originating therein, the quality and characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors. Appellations of origin are also geographical indications, but the term “appellation” is understood as narrower than the concept “indication” as used in the Paris Convention since 1925, and are defined in the 1958 Lisbon Agreement as the geographical name of a country, region, or locality, which designates a product originating therein, the quality or characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors.

Article 1(2) of the Lisbon Agreement lays down that, in order to qualify for registration at the International Bureau of WIPO, an “appellation of origin” must be “recognized” and “protected” in the “country of origin”. Article 2(1) elaborates on this by defining “appellation of origin” and Article 2(2) by defining “country of origin”.

The appellation of origin must be “recognised” and “protected” in the country of origin means that the appellation of origin (country, region or locality) recognized as serving to designate a product that originates therein and meets certain qualifications. Such recognition of the denomination must be based on the reputation of the product and protection of the appellation of origin must have been formalized by means of legislative provisions, administrative provisions, a judicial decision or any form of registration. The manner in which recognition takes place is determined by the domestic legislation of the country of origin.

The Lisbon system facilitates the registration of appellations of origin on an international level on the basis of provisions laying down the procedural rules governing the international registration procedure and lays down a number of provisions for the protection to be accorded to internationally registered appellations of origin. Article 3 requires Member States to protect appellations of origin registered at the IB against any usurpation or imitation of the appellation

²²⁷ See article 1/2..

of origin, even if the true origin of the product is stated or if the appellation is used in translated form or accompanied by terms such as “kind,” “type,” “make,” “imitation” or the like.

The registration of appellations of origin shall be affected with the IB, at the request of the Authorities of the countries of the Special Union, in the name of any natural persons or legal entities, public or private, having, according to their national legislation, the right to use such appellations.²²⁸ An objection may be raised against the registration of an appellation of origin within one year of its registration²²⁹ and third parties that make use of such a registered appellation of origin have two years to terminate such use, on condition that the Authority advise the International Bureau accordingly during the three months following the expiration of the period of one year provided for in paragraph 5(3).

Registered appellations of origin need not be renewed. Registrations are published in the official Bulletin and can be searched through the Lisbon Express database.

TRIPS Agreement

The TRIPS Agreement²³⁰ in particular uses the term a "geographical indication of origin" (GI). The concept is described as a linkage between goods and a geographical area for quality, reputation or other characteristic that is attributable to such area as geographical origin. Article 22, paragraph 1, reads: "*Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin*". While the definition of a GI is broader than that of an appellation of origin the latter is also covered by it. The TRIPS Agreement requires that its members must provide legal means to prevent the misleading use of GI's as well as their protection under conditions of unfair (unlawful) competition.²³¹

All products are covered by Article 22, which requires members to protect geographical indications in order to avoid misleading the public and to prevent unfair competition. Article 23 provides a higher or enhanced level of protection for geographical indications for wines and spirits: subject to a number of exceptions, they have to be protected even if misuse would not cause the public to be misled. In some cases, an exception exists to the protection of geographical indications. Among the exceptions that the TRIPS Agreement allows are: when a name has become the common (or “generic”) term (for example, “cheddar” now refers to a particular type of cheese not necessarily made in Cheddar, in the UK), and when a term has already been registered as a trademark.²³²

To accommodate previous use in a jurisdiction of a term or the like other than that where it has developed as GI, the TRIPS Agreement provides in article 24(6) that an indication which is identical to a term that is customary in the common language as common name for the same goods or services will not be affected. While any kind of goods can become involved in such GI linkage, particular provision is made for wines and spirits.²³³ The addition of words such as "kind" or "type" cannot serve as distinguishing feature as regards an established GI.²³⁴ A multilateral system for notification and registration is also envisaged.

²²⁸ Article 5(1) of the Lisbon Agreement.

²²⁹ Article 5(3) of the Lisbon Agreement.

²³⁰ TRIPS Agreement art. 22(1).

²³¹ TRIPS Agreement art. 22(2).

²³² See Article 24 and also http://trade.wtosh.com/english/tratop_e/TRIPS_e/gi_background_e.html.

²³³ TRIPS Agreement art. 2.

²³⁴ TRIPS Agreement art. 23(1).

In addition to particular provision for wines and spirits TRIPS Agreement also gives particular exceptions in case of such goods. Previous use of a wine or spirit-related GI²³⁵ in a jurisdiction other than that where it has developed as GI, is accommodated by the TRIPS Agreement. It is accordingly specified that an indication which is identical with the customary name of a grape variety that existed in the territory of a jurisdiction as of the date of entry into force of the World Trade Organization Agreement will not be affected.²³⁶ In addition, GI's that have been used for the same or related goods by nationals of a member other than that where the GI has become established for a period of more than ten years prior to 15th April 1994 or in good faith prior to this date, are also permitted to continue with such use except if otherwise negotiated between specific members.²³⁷ In such a case, the GI is said to have become generic. The first paragraph of Article 24 of TRIPS Agreement stipulates that Member states agree to enter into negotiations aimed at increasing the protection of individual geographical indications under Article 23.

Evidence:

The basic concept underlying geographical indication (GI) is delightfully simple, and is familiar to any shopper who chooses Roquefort over blue cheese or Basmati rice over boil-in-the-bag. However, the author cautioned that when it comes to their legal protection, the picture becomes complex.

Geographical indications are place names (in some countries also words associated with a place) used to identify products that come from these places and have these characteristics (for example, "Champagne" for the vineyards of Champagne in France are on the northern limits of the latitudes at which grapes are usually grown in the South of France, the latitude lines for the Agave growing regions in Mexico (five Mexican states) for "Tequila" or "Roquefort", made in the caves at Roquefort-sur-Soulzon, France).

Further evidence:

The Rooibos saga is closer to home – i.e. what is the best way to protect a geographical indication. Rooibos plants grow exclusively in certain arid areas of western South Africa in very particular soil conditions. Rooibos tea has many health properties and advantages and has been produced in South Africa since 1930. In 1992 a South African company, *Forever Young*, registered Rooibos as a trademark in the U.S. for use on skincare products. When the company's owner retired in 2001, she sold the trademark for ten dollars to her American business partner, *Burke International*.²³⁸ While the major Rooibos processor in South Africa, *Rooibos Ltd.*, had started procedures to get the trademark cancelled soon after its registration, the US owner demanded royalties from South African companies for using the term Rooibos in the U.S.²³⁹

This Rooibos saga was partially responsible for the bold step the South Africans government has taken in proposing the protection of traditional knowledge through the amendment of the

²³⁵ Product of the vine.

²³⁶ TRIPS Agreement art. 24(6).

²³⁷ TRIPS Agreement art. 24(4) read in conjunction with art. 24(1).

²³⁸ Elizabeth March "...And a Tea..." Sept (2007) *WIPO Magazine*
http://www.kit.nl/net/KIT_Publicaties_output/showfile.aspx?e=921

²³⁹ March op cit.

Patents Act of 1978, the Designs Act of 1993, the Copyright Act of 1978, the Trade Marks Act of 1993, the Performers Protection Act of 1967. Its outcome is described as follows:²⁴⁰

“One of the results that came out of this whole case is the establishment of the South African Rooibos Council (SARC). Although it is still in its infancy, it represents the whole industry (small and commercial producers, labour, processors, etc.) and is an ideal vehicle for collective action. Another result is that, since this case reached the headlines, various government institutions (Department of Trade and Industry, National Agricultural Marketing Council) started showing interest in the problematique surrounding this case. At the same time, and providing a link between policy development and research, a number of research projects surrounding Geographical Indicators were launched. These included a collaborative project between four of the nine Provinces, the multi-stakeholder (Universities, Research Institutions, Government Departments) and multi-country (South Africa, Namibia, France) Duras Project as well as the Biodivalloc project. “

"It will be the rooibos tea manufacturers of South Africa which will have ownership of that particular name and that term will be applicable only to products that come from and are approved by us," he said.

The minister said the designation was significant, given the popularity Rooibos had acquired in Europe in recent years. In 2013, the South African Rooibos Council scrambled to stop an attempt by a French company -- the Compagnie de Trucy -- to trade mark Rooibos in France.

In July 2014, 105 South African names secured GI status in terms of a trade agreement between the Southern African nations and the European Union. Protected GIs include:

- rooibos
- honeybush,
- Karoo lamb

and several wine-growing regions such as Robertson. These names secured geographic indicator status in the long-awaited economic partnership agreement between southern African nations and the European Union, Trade and Industry Minister Rob Davies said on 21 July 2014.²⁴¹ Currently in South Africa no GI protection may be attained (apart from the special provision for wines). The bi-lateral recognition gained as a result of the economic partnership agreement will not be applicable to parties outside the agreement.

3.8.4.4. Policy objective

South Africa should develop a framework to effectively identify, protect and exploit its geographical indications, including appellations of origin.

3.8.4.5. Affected stakeholders

The following stakeholder groups have been considered as affected parties regarding the proposed changes to South Africa's regime for the protection of geographical indications:

²⁴⁰ See Troskie "Geographical Indications at the National Level: A Variety of Approaches and Institutional Aspects" paper delivered at the 2007 International Symposium on Geographical Indications held in Beijing, China 26-28th June 2008 at 5.

²⁴¹ <http://www.moneyweb.co.za/moneyweb-south-africa/rooibos-protected-in-eu-trade-pact>.

- Producers and trade organisations
- Government/CIPC
- Consumers
- IP attorneys

3.8.4.5.1. Producers and trade organisations: mostly positive

From a producer’s perspective, producers located in the region of origin where the GI-certified good is produced would expand their markets. They would also be able to use the GI name when selling their GI produce and the potential income stream associated with the GI name. The latter also gain from a price premium attached to the GI-certified good. Market exclusivity will also be gained as producers in other regions that would no longer be permitted to produce the GI good if they are not located in the region for which the GI has been registered.

It is clear that the registration of GIs lead to economic welfare for the producers. In one study it has been noted that:

- Guatemalan coffees fetch a price premium of about 95%;
- Honduran and Bolivian coffees receive a price premium of 77%;
- Toscano olive oil a premium of 20%; and
- wines labelled “Napa Valley” had prices 61% higher than wines labelled “California”.²⁴²

As far as market exclusivity is concerned: *In South Africa, if we consider a case where beef biltong (the dried, raw meat product) were to receive GI protection, cattle farmers in Australia would no longer be allowed to describe any produce as biltong when exporting to the South African market but would have to find an alternative name. Australian farmers would then have to remarket their produce and familiarise consumers in South Africa with the new brand name.*²⁴³

3.8.4.5.2. Government/CIPC: mostly negative

As noted under status quo above, disparate pieces of legislation provide protection to GIs. If the Lisbon Agreement is adopted a proper framework should be developed for the protection of appellations of origin. A system will have to be developed for national as well as international registration, the submission of objections and the enforcement of appellations of origin of member states.

The limitation of appellation of origin is that it can only pertain to geographical names – in this case Karoo lamb would for example be registrable. The protection would extend to all 28 members of the Lisbon Agreement without the necessity to negotiate protection in terms of trade agreements.

A traditional term or expression may be registered as a geographical indication or a certification trade mark or a collective trade mark. The Intellectual Property Amendment Act

²⁴² Dinga Fatman “Policy considerations of adopting Geographical Indication protection in South Africa” Trade and Industrial Policy Strategies at 2.

²⁴³ Dinga Fatman “Policy considerations of adopting Geographical Indication protection in South Africa” Trade and Industrial Policy Strategies at 2.

has not yet entered into force, but regulatory mechanisms, administrative systems and human resources must be developed to implement the protection of traditional terms or expressions that are geographical indications.

3.8.4.5.3. Consumers: Mostly positive

Consumers will benefit due to the consistent availability of genuine goods. The protection of geographical indications will protect consumers against misleading trade practices related to the origin of goods and services.

A possible negative effect could be the price premium which develops following GI status as indicated above.

3.8.4.5.4. IP Attorneys: Mostly positive

Traditional terms and expressions and the general protection of GIs may attain higher prominence. This could lead to more registrations in general which would translate into increased revenues. Additional work would Also emanate from license and contract work, enforcement or litigation work

3.8.4.6. Assessing benefits / pros

Trade: Indications of the geographical origin of goods are becoming increasingly important in the trade environment. This is especially the case where the association between goods and its origin carries a connotation of some or other uniqueness such as quality or other characteristics. Protection under such indication of geographical origin is found in the benefit that producers of associated goods can prevent producers of similar goods from outside the region from identifying their goods with the region via such indication.

A product's quality, reputation or other characteristics can be determined by where it comes from. The protection of geographical indications is bolstered in trade agreements. Even in the pre-TRIPS Agreement era the South African authorities concluded a bilateral agreement with the French authorities in respect of, amongst others, the GI's "Champagne" and "Burgundy". South Africa and the EU negotiated a trade agreement with South Africa dealing with aspects of science and technology, fisheries and wines and spirits. The agreement also included the aspect of free trade between South Africa and the countries of the EU. Conclusion of the agreement was amongst others coupled to acceptance on the part of the South African negotiators that the names "port", "sherry", "grappa" and "ouzo", as protected as GI's in the countries of the EU under a regulation of the European Commission, should also be accepted as such in the South African market.

Van de Kop et al notes as follows:

“Origin-based labels are the opposite of global brands, though their existence is based on the same principle of helping consumers with their choice by guaranteeing a set of key predictable quality characteristics. But the process to establish trust with the buyers is different. Whereas the production process of global brands is uniform across locations, origin-based labels can be produced only within a given geographical area. That particular area contributes something to the end product that is unique and makes a recognizable difference. The French concept of terroir best defines what is meant by area in this respect. A terroir is a historically developed interaction between (a) the product's biophysical properties that result from a specific geographical entity, and (b) the local community's practices and culture.

Origin-based labelling recognizes that the products of a terroir have additional value as compared to global brands. This value belongs to the community that developed those products over many, many years. Origin-based products are by definition sustainable and beneficial to a local community.”

In this regard if South Africa adopts the Lisbon Agreement then it could obtain international protection for its appellations of origin. This would greatly enhance trade.

3.8.4.7. Assessing costs / cons

Anti-competitive impact: From the cross border perspective, we have seen how the use of geographical denominations may give rise to disputes that could impede trade flows.²⁴⁴ While there is a risk that they impede market entry, it is not unlike the risk stemming from the best known trademarks. A number of additional anti-competitive practices can be identified. Three main types of risks from the standpoint of free competition and market rules: monopolistic cartels, obstacles to new market entrants, and over administration and over-regulation.

While coordination in a food chain under appellation of origin is recognised to be important, there is still a risk that coordinating channels, and the agreements that result, will impede proper market operation. There is a danger that producers will push market prices up by cutting the volume of total supply.

Quotas: Starting from a given reference year, total supply is allocated among producers on the basis of that year’s quotas. Unless production quotas are allocated on grounds of relative efficiency, consumers are likely to pay more because supply is held down and at the same time forgo the benefits that enhanced productivity would bring. Producers, compelled to stay within their quotas, lack the incentive to operate more efficiently. There may be an impact on the quality of the end product as well. It should be noted that with some exceptions, goods of designated origin are usually produced on a small scale and hold only a small share of the market.²⁴⁵

3.8.4.8. Application of the framework

Theoretically, can the policy objective be met through the proposal?

Yes.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|---|-----|--------|------|
| Legislative amendments | | | x |
| Development of a national registration system of GIs and appellations of origin | | | x |
| Cohesion amongst producers to maintain high quality | | | x |
| Consumer education | | x | |
| Resources with technical expertise to manage process | | | x |

²⁴⁴ Working Party on Agricultural Policies and Markets of the Committee for Agriculture, Joint Working Party of the Committee for Agriculture and the Trade Committee Appellations of origin and geographical indications in OECD member countries: economic and legal implications COM/AGR/APM/TD/WP(2000)15/FINAL (OECD) (2000)

²⁴⁵ Ibid.

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--|-----|--------|------|
| Prices may increase for local GIs | | | x |
| Certain local producers may be excluded if not from specific region – loss of income | | | x |
| Anti-competitive effects | | x | |
| GIs or appellations of origin to loose distinctiveness | x | | |

Can these risks be mitigated?

The risk that the policy intervention poses to producers that are not from the designated regions may be mitigated by the other policy interventions. The risks of increases in prices may be mitigated by inflow of foreign currency and local subsidies. Local GIs may retain distinctiveness if trade organisations, regional organization and producers develop mechanisms to guard against such eventuality. International best practices should be secured from other jurisdictions.

3.8.4.9. Recommendation

Adopt the Lisbon Agreement. Develop other legislative instruments to implement the effective protection of appellations of origin and GIs.

3.8.4.10. Alternative options

Protect only GIs through trade agreements.

3.8.4.11. Country comparison

Geographical indications are protected through a wide variety of different approaches in different countries, and often by a combination of two or more approaches. These include unfair competition laws (passing off), consumer protection acts, and agricultural quality control regimes, laws governing trademarks as collective marks and certification marks, and registration under specific, sui generis GI laws. There is no agreement as to the “best” methods to promote and protect GIs, and WIPO supports individual Member States in whatever national system they adopt, within the applicable international legal framework.

European Union

The European Union protects two denominations, which relate to two different levels of link between product and geographical origin. For the designation of origin the link is essential, and the entire production process must take place in the defined geographical area, but for the geographical indication the link is not so strong since it is sufficient that either production, processing or preparation take place in the area specified. The reputation element is found only in the definition of geographical indication.

Other jurisdictions

Elsewhere, especially in common law countries, we find systems of protection for geographical indications embodied in existing laws on trademarks, unfair trade practices and consumer protection. Australia, Canada and the United States are in this group, together with the United Kingdom, although the latter is a special case.

In these countries, protection for geographical indications is covered by trademark law. As a rule, a geographical indication cannot be registered as a trademark, but it can be registered as a certification mark. In that case certification may apply to materials, methods of manufacture, quality, or geographical origin. Registration as a certification mark entails presenting user regulations. It cannot be used and marketed by its owner. Accordingly, producers form groups and the group itself becomes the owner of the certification mark, which is then used and marketed by the producers themselves.

Among the countries giving special protection to appellations of origin, some refer back to a lengthy tradition. This is the case with some European Union countries, in particular France, Italy, Portugal and Spain. On the other hand, Korea has just recently adopted a special system to protect geographical names which bears a close resemblance to the systems covering appellations of origin.

Coffee: Ethiopia and Columbia

Coffee is the second most traded commodity in the world after oil. Altogether, we drink over 400 billion cups each year. To retailers in wealthy countries, coffee means consumers willing to pay \$4 for a cappuccino. To many farmers in developing countries, it means hard toil to earn less than a dollar a day. Seeking to narrow this gap, growers and governments in coffee producing countries are using a range of intellectual property rights to differentiate their coffee in the market place and so achieve higher returns.

Representatives from two of the world's great coffee-producing nations, Ethiopia and Colombia, told their stories at WIPO's 2007 International Symposium on Geographical Indications in June.

Ethiopia

The story began in 2004, when the EIPO began working with partners to identify a mechanism which would lead to a greater share for Ethiopia's coffee growers of the high retail prices fetched by their Harrar, Sidamo and Yirgacheffe coffees. Following extensive studies and consultations, a project proposal was developed to capture the intangible value of selected fine coffees. A consortium of stakeholders led by Mr. Mengistie was formed, including representatives of farmers' cooperatives, coffee exporters and government bodies. The key, they agreed, was to achieve wider recognition of the distinctive qualities of these coffees as brands and so position them strategically in the expanding specialty coffee market; while at the same time to protect Ethiopia's ownership of the names so as to prevent their misappropriation.

... The stakeholders opted for a trademark-based solution. The EIPO began filing applications to register the names Harrar/Harar, Sidamo and Yirgacheffe as trademarks in key market countries. In a novel move, this was to be combined with the offer of royalty-free licenses to foreign coffee companies to create a network of licensed distributors, who, in return would actively promote Harrar, Sidamo and Yirgacheffe to consumers in the specialty coffee market. "The theory is: make the pie bigger. Let the market pay,"

But in summer 2006 the strategy had threatened to unravel. The U.S. Patent and Trademark Office (USPTO) had approved the application to register Yirgacheffe. But the National Coffee Association (NCA), representing U.S. coffee roasters, objected to the EIPO's applications to trademark first Harrar, then Sidamo. The grounds for opposition in both cases were that the name had become too generic a description of coffee, and as such was not eligible for registration under U.S. trademark law. The USPTO turned down the application for Harrar in October 2005 and for Sidamo in August 2006.

Starbucks, which was widely held in media reporting to have been a driving force behind the objection, publicly offered to assist the EIPO in setting up a national system of certification marks to enable the farmers to protect and market their coffee as "robust" geographical indications. "These systems are far more effective than registering trademarks for geographically descriptive terms, which is actually contrary to general trademark law and customs," said the company in a statement. But the EIPO and its advisors disagreed. The designations, they argued, referred not to geographical locations but to distinctive coffee types. Moreover, appropriate intellectual property tools had to be chosen to meet specific needs and situations. "You have to understand the situation in Ethiopia," Mr. Mengistie explained. "Our coffee is grown on four million very small plots of land. Setting up a certification system would have been impracticable and too expensive. Trademarking was more appropriate to our needs. It was a more direct route offering more control."

....

So what was the solution? In essence, Starbucks agreed to sign voluntary licensing agreements which immediately acknowledge Ethiopia's ownership of the Harrar, Sidamo and Yirgacheffe names, regardless of whether or not a trademark has been granted. Legal commentators have homed in on the use of the term "designation" in the agreement as a means of circumventing the obstacle caused by the status of the Harrar and Sidamo applications. "Yes," acknowledges Mr. Mengistie, "designation is used here as a broader term than trademark, to encompass some of the trademarks that are still pending registration. It is not related to certification."

...

The media coverage has had the effect of greatly increasing public knowledge of, and interest in, Ethiopia's coffees. "Partly because of this recognition, we have begun to see increases in their price," says Mr. Mengistie. "I learned from the coffee farmers' cooperatives and exporters just three months ago that the price of Yirgacheffe had already increased by \$0.60 cents to \$2 a pound."²⁴⁶

Colombia

Colombia's coffee growers have a long history of developing strategies to protect and promote their coffee. Luis Fernando Samper, Intellectual Property Director of the National Federation of Coffee Growers of Colombia (FNC) which represents the interests of 560,000 small coffee growers, offers this instructive account of the road they have traveled.

During the late 1950s, the price of Colombian coffee plummeted from US\$0.85 to 0.45 per pound due to an excessive supply of coffee on the world market. The market was dominated by the coffee roasters, who would blend coffee beans from various unspecified origins in their

²⁴⁶ Elizabeth March "Making the Origin count: Two Coffees (Geographical Indications to Colombian and Ethiopian Coffees)," September 2007, *WIPO Magazine*.

products in order to give themselves the flexibility that would maximize their profit margins. As a result, public awareness of the origin of coffees was low. Only 4 percent of consumers in the U.S., the largest coffee market at the time, were aware that Colombia produced coffee. This, the federation of growers felt, had to change. "The FNC thought: Our coffee is good," said Mr. Samper. "We have to tell consumers where it comes from." So Colombia became the first coffee producing country to embark on an active strategy of differentiating and marketing its product.

They began by putting a face on Colombian coffee – literally. With the help of a New York advertising agency, the FNC created the character of Juan Valdez®, to represent the archetypal Colombian coffee grower. Television commercials shown in North America in the 1960s featured Juan Valdez in the coffee fields with his faithful mule, painstakingly selecting and hand-picking the ripest beans. Consumers began to respond to the message that Colombian beans are grown and harvested with great care, with little help from machines, in ideal climatic conditions with plenty of rain, sun and fertile volcanic soil. Demand grew. Many coffee roasters began marketing their products as Colombian coffee. And a number launched high end products consisting exclusively of Colombian coffee.

To obtain a license to use the Juan Valdez trademark, a product must consist of 100% Colombian coffee and meet quality standards stipulated by the coffee growers' federation. (Photo © FNC)

A number of coffee roasters and marketers proved unwilling to fulfill the conditions of the trademark license agreement that would allow them to use the Juan Valdez ingredient brand alongside their own product brand. So a complementary strategy was devised to capture this segment. Working with the FNC, the Republic of Colombia registered the word "Colombian," in relation to coffee, as a certification mark in the U.S. and Canada. The formal standards attached to these certification marks now provided a guarantee that the actors in the market place would meet minimum quality standards when selling Colombian coffee, thereby protecting its hard-earned reputation.

...

Yet the certification mark route was not proving an easy ride. The FNC found enforcing their certification marks in North America difficult and expensive, and their lawyers had to make regular presentations to the USPTO so as to prevent registrations of trademarks containing the word Colombian which would give brand owners the right to sell products containing little or no Colombian coffee.

Stepping forward – Geographical indications

The way forward, the FNC concluded, lay in the use of geographical indications (GIs).

Colombia already had in place the same legislation as Peru for the protection of GIs, and in December 2004 the FNC presented the Colombian government with an application to recognize Café de Colombia as a GI. Within three months it was ratified. In 2005, the FNC broke new ground by applying to protect Café de Colombia as a Protected Geographical Indication under the European Union (EU) system - the first time this had ever been done for a product from a country outside the EU following the opening of the EU system for non-European GI products. After some ups and downs along the way, the EU procedure concluded successfully in June this year, when the two-year period of opposition expired and the formal

recognition of Café de Colombia as a Protected Geographical Indication under the EU system became official in September.

Summing up, Mr. Samper highlighted the attraction of GIs for the Colombian coffee industry, where origin is a key tool for differentiating and adding value to the product, but where coffee marketers prefer to downplay origin in order to gain flexibility. Unlike trademarks and certification marks, GIs are intrinsically linked to attributes and quality standards related to origin. GI systems, which guarantee origin and methods of production, he concluded, are set to flourish in today's climate of increasing demand from consumers for more and better information about the products they consume.²⁴⁷

3.8.5. Beijing Treaty

3.8.5.1. Policy proposal

No policy proposal was included in the Draft National IP Policy.

3.8.5.2. Status quo

The Performers Protection Act of 1967 protects performers. A "performer" means an actor, singer, musician, dancer or other person who acts, sings, delivers, declaims, plays in or otherwise performs literary or artistic works. Performers shall be granted the protection provided for in section 5 of this Act in respect of their performances- (a) taking place, (b) broadcast without a fixation, or (c) first fixed, in the Republic.

Section 5(1) provides that a performer must consent to:

(a) broadcast or communicate to the public a performance of such performer, unless the performance used in the broadcast or the public communication is itself already a broadcast performance or is made from a fixation of the performance or from a reproduction of such a fixation; or

(b) make a fixation of the unfixed performance²⁴⁷ of such performer; or

(c) make a reproduction of a fixation of a performance of such performer-

(i) if the original fixation, other than a fixation excluded by section 8 from the necessity for obtaining the consent of the performer, was itself made without his consent; or

(ii) if the reproduction is made for purposes other than those in respect of which such performer gave his consent to the making of the original fixation or of a reproduction thereof; or

(iii) if the original fixation was made in accordance with the provisions of section 8, and the reproduction is made for purposes not covered by those provisions.

Section 8(1) of the Performers Protection Act then severely curtails the remuneration rights of actors in films. It provides that if a performer consents to the incorporation of his performance in a visual or audio-visual fixation, section 5 (1) shall cease to apply in respect of the performance so fixed.

²⁴⁷ Elizabeth March "Making the Origin count: Two Coffees (Geographical Indications to Colombian and Ethiopian Coffees)," September 2007, *WIPO Magazine*.

3.8.5.3. Problem statement and evidence

The profound impact of the development and convergence of information and communication technologies on the production and use of audiovisual performances mandated the adoption of new international rules. The treaty was drafted in light of the need to maintain a balance between the rights of performers in their audiovisual performances and the larger public interest, particularly education, research and access to information. The underlying objective of this treaty is to develop and maintain the protection of the rights of performers in their audiovisual performances in a manner as effective and uniform as possible.

Nothing in The Beijing Treaty derogates from existing obligations that Contracting Parties have to each other under the WPPT or the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations done in Rome on October 26, 1961 and it does not affect protection of copyright in literary and artistic works.

The definition of “performers” include “*actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore*” and an “*audiovisual fixation*” means “*the embodiment of moving images, whether or not accompanied by sounds or by the representations thereof, from which they can be perceived, reproduced or communicated through a device*”.

The Beijing Treaty also provides performers with protection in the digital environment, giving them some measure of control over how and when their works – their films and videos – are used on the Internet. The definition of “broadcasting” means the “*transmission by wireless means for public reception of sounds or of images or of images and sounds or of the representations thereof; such transmission by satellite is also “broadcasting”; transmission of encrypted signals is “broadcasting” where the means for decrypting are provided to the public by the broadcasting organization or with its consent*”. A “communication to the public” of a performance means “*the transmission to the public by any medium, otherwise than by broadcasting, of an unfixed performance, or of a performance fixed in an audiovisual fixation*” and for the purposes of Article 11, “communication to the public” includes making a performance fixed in an audiovisual fixation audible or visible or audible and visible to the public.

The treaty has adopted the principle of national treatment²⁴⁸. In addition to enhanced economic rights, the Beijing Treaty grants performers moral rights to prevent lack of attribution for or distortion of their performances.²⁴⁹ Actors and other audiovisual performers will also enjoy a minimum term of 50 years of protection computed from the end of the year in which the performance was fixed²⁵⁰, compared to the 20-year term previously available under the 1961 Rome Convention (the Rome Convention) for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations. The duration of moral rights is at least until the expiry of the economic rights although contracting parties may provide that the moral rights will after a performers death, cease to exist.²⁵¹

In terms of article 6 of the Beijing Treaty performers shall enjoy the exclusive right of authorizing, as regards their performances:

²⁴⁸ See article 4 of the Beijing Treaty .

²⁴⁹ See article 5(1) of the Beijing Treaty.

²⁵⁰ See art 14 of the Beijing Treaty.

²⁵¹ See art 5(2) of the Beijing Treaty.

- (i) the broadcasting and communication to the public of their unfixed performances except where the performance is already a broadcast performance; and
- (ii) the fixation of their unfixed performances.

Performers shall enjoy the exclusive right of authorizing the direct or indirect reproduction of their performances fixed in audiovisual fixations, in any manner or form.²⁵² Performers shall enjoy the exclusive right of authorizing the making available to the public of the original and copies of their performances fixed in audiovisual fixations through sale or other transfer of ownership, although parties are free to adopt national or international exhaustion. Performers shall enjoy the exclusive right of authorizing the commercial rental to the public of the original and copies of their performances fixed in audiovisual fixations²⁵³ unless the commercial rental has led to widespread copying of such fixations materially impairing the exclusive right of reproduction of performers.²⁵⁴ Article 10 provides that performers shall enjoy the exclusive right of authorizing the making available to the public of their performances fixed in audiovisual fixations, by wire or wireless means, in such a way that members of the public may access them from a place and at a time individually chosen by them. Article 11(1) grants performers the exclusive right of authorizing the broadcasting and communication to the public of their performances fixed in audiovisual fixations. A right to equitable remuneration for the direct or indirect use of performances fixed in audiovisual fixations for broadcasting or for communication to the public may be granted in lieu of the right of authorization provided for in article 11(1).²⁵⁵

A Contracting Party may provide in its national law that once a performer has consented to fixation of his or her performance in an audiovisual fixation, the exclusive rights of authorization provided for in Articles 7 to 11 of this Treaty shall be owned or exercised by or transferred to the producer of such audiovisual fixation but a performer will nevertheless retain a right to remuneration for the making available and communication or broadcasting of the audiovisual performance.²⁵⁶

Article 13 provides that contracting Parties may provide for the same kinds of limitations or exceptions with regard to the protection of performers as they provide for in connection with the protection of copyright in literary and artistic works. However, such limitations or exceptions to rights provided for in the Beijing Treaty shall be confined to certain special cases which do not conflict with a normal exploitation of the performance and do not unreasonably prejudice the legitimate interests of the performer.²⁵⁷ Articles 15 to 16 of the Beijing Treaty also provide for the protection of technological protections measures and rights management information. However, a Contracting Party may adopt effective and necessary measures to ensure that TPMs and rights management information do not impinge on limitations and exceptions referred to in article 13.

²⁵² See art 6 of the Beijing Treaty. The Agreed statement concerning Article 7: The reproduction right, as set out in Article 7, and the exceptions permitted thereunder through Article 13, fully apply in the digital environment, in particular to the use of performances in digital form. It is understood that the storage of a protected performance in digital form in an electronic medium constitutes a reproduction within the meaning of this Article.

²⁵³ See art 9(1) of the Beijing Treaty.

²⁵⁴ See art 9(2) of the Beijing Treaty.

²⁵⁵ See art 11(2) of the Beijing Treaty .

²⁵⁶ See art 12(3) of the Beijing Treaty.

²⁵⁷ See art 13(2) of the Beijing Treaty. The Agreed statement concerning Article 13: The Agreed statement concerning Article 10 (on Limitations and Exceptions) of the WIPO Copyright Treaty (WCT) is applicable *mutatis mutandis* also to Article 13 (on Limitations and Exceptions) of the Treaty.

The enjoyment of the rights vesting in audiovisual performances is not subject to any formalities and contracting parties must ensure that enforcement procedures are available under their law so as to permit effective action against any act of infringement of rights covered by this Treaty, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.

It is clear that the Beijing Treaty will strengthen the economic and moral rights of performers in their audiovisual performances. The Beijing Treaty on Audiovisual Performances – so named in honour of the city hosting the final negotiations – will enter into force upon ratification by 30 eligible parties, including countries and certain intergovernmental organizations. WIPO Magazine considers what this new treaty, over 15 years in the making, means to performers around the world. To date, the treaty has been signed by 72 members of WIPO including China, signifying their preliminary endorsement. As noted, the treaty will not enter into force until it is ratified or acceded by at least 30 eligible countries or intergovernmental organizations. And China is, after Syria and Botswana, the third country to ratify the treaty.

Evidence:

The development of a new industry around silent films and, soon after, talking pictures meant that, for the first time, performers - such as actors and singers - were being recorded, and their performances reproduced and widely distributed to audiences at home and abroad. The reach of these productions extended well beyond that of a live audience. This was one important reason for concluding the Rome Convention in 1961. While the Rome Convention provides protection for audio performers, it only offers audiovisual performers limited rights.

The conclusion of the WIPO Performances and Phonograms Treaty (WPPT) in 1996, and its subsequent entry into force in 2002, modernized international standards of protection for musicians in their sound performances. Audiovisual performers and their performances, however, remained largely unprotected by international law. The Beijing Treaty concluded in 2012, brings actors and other performers into the international fold, providing them with rights equivalent to those available to musicians and recording artists.

The Treaty effectively brings the rights of actors and performers into line with those available to musicians and recording artists under the WIPO Performances and Phonograms Treaty (WPPT) concluded in 1996. "The conclusion of the Beijing Treaty is an important milestone toward closing the gap in the international rights system for audiovisual performers," Mr. Gurry said. "The international copyright framework will no longer discriminate against one set of performers."

"Digital technology and the Internet offer the promise of a global audience and the unprecedented availability of creative works. At the same time, they make creative works increasingly vulnerable to unfair exploitation," explained WIPO Director General Francis Gurry. "The Beijing Treaty will enable performers to interact with greater confidence with the digital environment," he said. "This is a pivotal time in the performers' battle for IP protection, because of the increased variety and use of digital technology that makes producing, manipulating and disseminating an artist's work so easy," Ms. Streep observed.

The career and livelihood of actors "depend on the control of our performances and our image and likeness. Sadly, many actors do not have control of their performances and do not have the right to fair and equitable compensation for the use of their faces, bodies and voices," said Segun Arinze, President of the Actors Guild of Nigeria. In many countries the Treaty will mean

that the performances of actors in audiovisual works such as movies, television programs and pop music videos will be protected for the very first time.

Further evidence:

The Beijing Treaty on Audiovisual Performances will strengthen the precarious position of many struggling film actors and other performers by providing a clearer international legal framework for their protection. It will give performers stronger economic rights and valuable extra income. Exactly how much will depend on how the treaty is put into national legislation and implemented. The Treaty provides a legal framework setting an expectation that countries that become party to it will pay for the use of foreign audiovisual performances, and encourage some or all of that revenue to go to the performers involved, the vast majority of whom earn very little.

For example, this could mean that when a film is reproduced, sold, rented or broadcast in a foreign country, some money would go to the country of origin and can then be shared with performers. *“In the same way that writers and composers depend upon royalty income for their survival in the long term, performers around the world must benefit as well from the income from the exploitation of their works,”* explained Academy Award-winning actress Meryl Streep in the lead-up to the Diplomatic Conference.

For many actors around the world who have been driving the process, the conclusion of the Beijing Treaty is a historic landmark and an important turning point. *“Finally... audiovisual performers are not second-class citizens. Along with audio performers, producers and authors, we are now recognized as having economic and moral rights over the content that we perform in,”* said Australian actor Simon Burke. *“It’s crazy that it hasn’t happened before, but it’s just so, so important that it has happened now,”* he added. *“It is something that is so right, so just and it’s finally coming true.”*

“Actors all over the world will be actually able to keep on working and be protected when they work,” said Agnete Haaland, Norwegian actress and President of the International Federation of Actors (FIA). *“We have been working for this for more than 20 years... to make it possible for actors to keep on acting and for the audience to actually have the privilege of seeing all kinds of films... all kinds of audiovisual content,”* noted Benoît Machuel, cellist and representative of the International Federation of Musicians.

“This is a very exciting moment, I think, for actors around the world,” said Jean Rogers, Vice President of the British actors’ union, Equity. *“This treaty will actually put on record how important our role is,”* she said. *“We interpret what people write. Writers have had these intellectual property rights, but audiovisual performers have not. But now, the future is starting to open up for us,”* she said *“and the value of performers is now being recognized.”*

Chilean actress and representative of LatinArtis, Esperanza Silva, urged governments to implement the treaty as soon as possible, because *“this treaty is going to benefit not only performers but the world’s culture in general.”*

3.8.5.4. Policy objective

To strengthen the economic and moral rights of performers in their audiovisual performances.

3.8.5.5. Affected stakeholders

The following stakeholder are identified:

- Actors
- Content Providers
- Collecting Societies
- Government

3.8.5.5.1. Actors: mostly positive

New exclusive rights: Actors/performers will enjoy the right to benefit from the exploitation of works on Internet. This would translate into an increase in revenue base for performers.

3.8.5.5.2. Content providers: negative

Content providers will be faced with the responsibility of respecting authors' rights in the online environment. This would entail:

- Amendment to business models: Content providers will have to conclude new license agreements with collecting societies and performers – a negative effect.
- Escalation of costs: Content providers have to pay for the exploitation of exclusive rights and royalties will be payable to collecting societies – a negative effect.
- Decrease in revenue: As content providers have to pay for the exploitation of exclusive rights profit margins will decline. In addition, royalties will be payable for what has been a free use up to now – a negative effect.

3.8.5.5.3. Collecting Societies: mostly positive

Effective collective management of rights: Collection societies will be able to conclude license agreements for the digital exploitation of works. If the Beijing Treaty is adopted it will expand the legal base for the collective management of copyright.

One negative aspect in the difficulties collecting societies will experience in providing adequate training and information to their members and users alike.

In the long term the increase in income and the ease of keeping digital records of the use of works will enable collecting societies to manage their members' interests more efficiently. This will in turn result in an enhancement of business environment for the collective management of copyright.

3.8.5.5.4. Government: mostly negative

Legislative amendment: Government will be burdened by the associated costs involved in the amendment of the Performers Protection Act in order to implement the Beijing Treaty. These costs inter alia entail the obtaining expert advice, consulting with stakeholders and costs related to the drafting process, Government will also need to train and up skilling staff to be able to devise policy and public awareness campaigns.

Government should ensure capacity because if the Beijing Treaty is implemented successfully it will have a positive impact on the cultural industries especially the development of local performers. Similarly, the implementation of the Beijing Treaty will also have a positive impact on digital economy.

3.8.5.6. Assessing benefits / pros

There are so many different categories of performance industry, including radio, television and stage. Beijing Treaty will attract more people coming into the cultural industry, especially show industry, promote the development of related industries, enhance the level of national economy development, and give people more chance to enjoy the rich spiritual and cultural products.

Performers would enjoy the right to benefit from exploitation of works on Internet. Collection societies will be able to conclude license agreements for the digital exploitation of work and online exploitation. This will result in an increase in revenue base for rights holders.

The positive outcome would be the stimulation of South African cultural and creative industries. The Beijing Treaty incorporates performers of "literary folk art expression" in its scope of protection. This is a great opportunity for South Africa to expand the protection of traditional expressions.

3.8.5.7. Assessing costs / cons

TPMs could bar access to works unless owners are obliged to provide the key to decrypt. Practical implementation of exceptions and limitations where works are protected by TPMs would be difficult especially in the online environment where reciprocal obligations are not imposed on copyright owners in other countries.

The protection of digital works could result in the diminishing of the public domain. The capacity to enforce the legal provisions is problematic as jurisdictional borders become fused in cyberspace.

3.8.5.8. Application of the framework

Theoretically, can the policy objective be met through the proposal?

Yes.

What is the probability of critical success factor being secured?

| Critical success factor | Low | Medium | High |
|---|-----|--------|------|
| Amendment of the Performers Protection Act to implement the Beijing Treaty and the drafting of regulations. | | | x |
| Resources with technical expertise to manage the process. | | | x |

What is the probability of severe risks occurring?

| High severity risk | Low | Medium | High |
|--|-----|--------|------|
| Imbalance of public/private rights – TPMs to bar access | | | x |
| Although legislative provisions will attempt to address this it may not translate into ease of access for all users. | | | x |

Can these risks be mitigated?

Yes through proper implementation and awareness campaigns.

3.8.5.9. Recommendations

Accede to the Beijing Treaty.

4. OTHER CONSIDERATIONS

4.1. INTER-RELATIONSHIP BETWEEN PROPOSED POLICIES

The recommendations in Section 3 above have largely been developed with the assumption that all else remains unchanged except for the proposal under review. Implementation of multiple policies simultaneously may result in unintended synergies and externalities. For the purposes of all-inclusive policymaking this section seeks to highlight issues for consideration when adopting more than a single proposal. In some cases different proposals aim to achieve different objectives. Where these objectives are similar, it is possible that implementation of more than one policy proposal may be redundant or unnecessarily cumbersome, and costly. Where these objectives are opposing, the overall outcome may be that neither objective is effectively achieved. This too will likely have negative costs implications.

The sometimes competing objectives of the government which have been considered in the analysis are:

1. Increased strength of the patent system and the quality of protection afforded by patents;
2. Increased innovation;
3. Increased access to healthcare;
4. Increased access to education;
5. Reduction in excessive IP barriers to entry for producers / manufacturers; and
6. Better alignment of local IP systems to international practice and other developing countries.

Adoption of SSE with stricter patentability criteria

One of the objectives of implementing an SSE system is to curb the practice of evergreening by increasing the rigour of the patent registration system such that patent applications are subjected to a thorough inquisitorial process. It is expected that the process of patent registration in an SSE system results in fewer 'weaker' patents being granted which if granted frustrate the public's access to healthcare.

Similarly, the proposal to strengthen the patentability criteria against which patent applications are assessed is expected to result in stronger patents being granted – meaning the probability that a patent that is granted is enforceable is higher. By introducing a criterion that prevents the patenting of known substances, it is expected that pharmaceutical companies will be precluded from the practice of evergreening patented drugs.

The proposal to implement an SSE system and the proposal to strengthen the patentability criteria are both geared towards curbing evergreening practice. The question then arises: *is it necessary to adopt both policy proposals?* This question is best answered by considering the converse: *can evergreening be effectively curbed by adopting one of the policy proposals only?*

First, *is it possible to curb evergreening by implementing the SSE without changing the patentability criteria?*

An effective SSE system will reduce the likelihood of granting invalid patents. This results in a stronger patent system. The more intense inquisitorial registration process will deter but not prevent the practice of evergreening; superficial changes to pharmaceuticals under patent will not be granted new patents unless these changes meet the existing patent criteria. This means there will remain potential to extend pharmaceutical patents on the basis of evergreening, but, this potential is reduced.

An important consideration when implementing proposals that target the prevention of evergreening practices is the extent to which the policy proposed has the adverse effect of impeding incremental innovation. Evergreening refers to the process through which changes are made to a pharmaceutical drug such that it is possible to extend the patent of or re-patent the drug. Similarly, incremental innovations may result in a valid patent claim for an invention. The measures in place to prevent evergreening may also form obstacles to incremental innovation.

Second, is it possible to curb evergreening by changing the patentability criteria without implementing an SSE system? Implementing stricter criteria to curb evergreening may be redundant in the absence of an SSE system. This is potentially because patent applications which aim to facilitate evergreening will not be rejected under the current depository system given the lack of examination. However, once the patent is granted any subsequent revocation proceedings will find the patent invalid in light of its failure to adhere to the (stricter) patentability criteria. This would be more cost efficient than the setting up of the SSE, a stated objective of which being to curb evergreening (i.e. objectives 3 and 5). It should be noted that many of the costs and benefits discussed in Sections 3.1 and 3.3 would still hold. This decision requires policymakers to weigh up objectives 1, 2, 3 and 5 above. While objectives 1 and 2 are aligned with the interests of IP generators, objectives 3 and 5 are in opposition to this and align better with those opposed to monopoly powers of IP generators.

Adoption of SSE with Pre- and Post-grant opposition

The objective of the proposal to adopt an SSE in South Africa is to strengthen the patent system by reducing the likelihood of granting a patent that cannot be legally enforced. Similarly, the proposal to make provision for pre- and post-grant opposition aims to strengthen the patent system by creating affordable opportunities early in the process of patent registration to challenge the validity of a patent claim – this provision is expected to reduce the likelihood of granting invalid patents.

Since these proposals serve a common purpose, it is necessary to consider whether the implementation of SSE together with making provision for pre- and post-opposition amounts to redundancy and the ineffective outlay of resources.

It is argued that if the SSE system functions effectively, the substantive examination of claims will ensure that only valid patent claims are registered. In practice, SSE examiners may not always have the information or technical skill required to evaluate every patent claim to the same degree of inquisition. The pre-grant opposition provision therefore complements the SSE system by allowing third parties to bring forward information to challenge patent claims that would otherwise be deemed valid.

It is not always the case that all information required to challenge a patent claim is available at the early onset of patent registration. The provision for post-grant opposition therefore allows third parties to challenge patents granted when information becomes available. The existing revocation process makes it possible for third parties to challenge the validity of patents in a

similar fashion, however, the revocation process is necessarily a judicial process which is associated with high costs of litigation.

Therefore, while opposition proceedings complement the SSE system to enhance the efficacy of efforts to strengthen the patent system, there is an emphasis placed on the need for opposition proceedings to be kept simple, swift and affordable.

Adoption of SSE and stricter patentability criteria with compulsory licensing and parallel importation

The adoption of SSE and stricter patentability criteria both speak to objective 1 which looks to strengthen the patent system. Objective 3 is aligned with TRIPS flexibilities such as compulsory licensing and parallel importation. These contrary objectives will likely erode each other if implementation occurs simultaneously.

4.2. POLICY ISSUES REQUIRING ATTENTION

This report deals with the main focus areas as mentioned in the Methodology. This section provides a list of proposals that were excluded from analysis due to insufficient detail, as well as a (non-exhaustive) list of proposals that were not included in the Draft Policy but need to be considered.

Topics mentioned in the Draft Policy but not articulated in sufficient detail:

- **SSE & depository system**

The Draft Policy proposes that an SSE be implemented for patent registration. The Draft Policy is not clear on the form of its implementation, but suggests that the SSE be adopted to co-exist with the current depository system, stipulating that: “*South Africa should adopt a multi-faceted approach in as far as registration of patents is concerned; that is, use the depository (registration), substantive search and examination and the utility patent systems.*”

This report examines the merits and demerits of an SSE system, based on theoretical analysis and drawing on case studies. The effects of implementing an SSE system are analysed in relation to the major affected stakeholders. The report does not specifically investigate the impact of a co-existing depository system and SSE system as it is understood that the intention of the policy proposal is to shift entirely to the SSE system over time.

- **BITs and regional integration**

The Draft Policy recommends that ‘South Africa encourages the region not to conclude economic and partnership agreements (EPAs) that are TRIPS-plus as these may compromise enforcement of IP.’ This report does not provide an analysis on the implications of enhanced or reduced regional IP integration. As a critical stakeholder in this regard, DIRCO was consulted during the stakeholder consultation. However, inputs from DIRCO were not received in time for inclusion in the report.

The dti should investigate:

1. How bilateralism can actually be utilised the benefit SA more than the current TRIPS position; and

2. How the investment policy and IP policy can dovetail to correctly carve out policy space not only on the bilateral level in BITs but also at the multilateral level.

There needs to be a concerted effort to harmonise policy across various policy areas, it is proposed that the relevant line functions coordinate in order reinforce an integrated policy perspective.²⁵⁸

Other areas in the Draft Policy that are vague, poorly articulated or poorly evidenced which require further attention include:

- **The Bolar provision**

Firstly, the Draft Policy mentions the Bolar provision only by stating that ‘...*generics can use the Bolar provision before patent expiry*’ and ‘*Generic companies should optimally use the Bolar provision without resorting to stockpiling...*’. Secondly, the Bolar provision is currently included in section 69(a) of the Patents Act and, from stakeholder consultations, it would seem that players are making use of this provision. From this it is evident that the Bolar provision has neither an explicit policy recommendation in the Draft Policy, nor an implicit one which points to an obstacle in current policy that prevents ‘optimal use’ of the provision. For this reason, an analysis on the Bolar provision would not apply to the policy of the provision but rather a separate implementation investigation of the Bolar provision.

- **Data exclusivity**

The Draft Policy does not specifically mention data exclusivity. Regarding a similar concept, data protection, the law states that ‘*Protection of “confidential information” from clinical trials on indigenous medicines should be protected through the law of data protection in terms of Article 39.3 of the TRIPS Agreement*’. Indigenous knowledge and medicines did not form part of the focus themes identified for the analysis. The Draft Policy also states that ‘*There should be no general or blanket data protection of information that is at the disposal of medicines regulatory authority, but unfair trade practices and protection of confidential information relevant for competitiveness should be in place*’. In this regard, laws specific to the Medicines Control Council (MCC) have not formed part of the project scope. Finally, the Draft Policy also refers to data protection when stating that ‘*Entry of generic medicines in the South African market should not be frustrated per se due to the law of Data Protection*’. Data protection regarding generic medicines is captured in section 34 of the Medicines and Related Substances Control Act and is regulated by the MCC. This is also a separate issue, unrelated to IP legislation.

- **Collective management of rights**

The Draft Policy recommends that ‘*The Farlam Commission on Copyright Review recommends that one collecting society must be administered by one powerful collecting society*’. The Copyright Review Commission’s recommendation regarding a single collecting society referred to one for each type of IP right, as opposed to an overarching collecting society. As such, this recommendation appears to be based on a misinterpretation and should be better detailed for a more accurate future analysis.

- **Impact of IP on plant breeders**

²⁵⁸ Unisa Comment.page 9-10.

It would appear that the effects of the proposals contained in the Draft Policy are far-reaching. The analysis in this report pays particular attention to the pharmaceutical industry, mirroring the focus of the Draft Policy. However, the implications of this policy for the agriculture sector and its participants may warrant a separate focused impact study.

- **Domain name regulation and domain name dispute resolution in the .za domain name space**

South Africa's Alternative Dispute Resolution (ADR) Regulations²⁵⁹ were promulgated in November 2006, in terms of section 69 read with section 94 of the ECT Act. The Regulations are intended to resolve disputes over .za domain names registered under the .co.za sub-domain.

- **FOSS principles**

The statement on the principles of FOSS. Open access is supported (especially for educational purposes), but it should rather be discussed in the context of the Creative Commons and the Open Educational Resources (OERs).

- **Trade Practices Act of 1999**

The reference to the Trade Practices Act 1999 is not clear. (Australia has such an Act with this date.) Both the TPA 76 of 1976 and the Unfair Business Practices Act 71 of 1988 were repealed by the Consumer Protection Act 68 of 2008.

Topics not mentioned in the Draft Policy but which need to be considered:

- **Classification treaties and agreements²⁶⁰**

Should the SSE be adopted then South Africa should become a member of the IPC – the Strasbourg Agreement Concerning the International Patent Classification of March 24, 1971, as amended on September 28, 1979.

The International Classification of Goods and Services under the Nice Agreement (9th edition) currently applies to South African trade mark applications, although South Africa has not acceded to the Nice Agreement.

Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks (1973) establishes a classification (the Vienna Classification) for marks that consist of, or contain, figurative elements. The competent offices of Contracting States must indicate in official documents and publications relating to registrations and renewals of marks the numbers of the categories, divisions and sections of the Classification to which the figurative elements of those marks belong. The Classification consists of 29 categories, 144 divisions and some 1,667 sections in which the figurative elements of marks are classified.

Although only 29 States are party to the Vienna Agreement, the Classification is used by the industrial property offices of at least 30 States, as well as by the International Bureau of WIPO, the African Intellectual Property Organization (OAPI), the Benelux Organisation for Intellectual Property (BOIP) and the European Union Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM).

²⁵⁹ See <http://www.domaindisputes.co.za/downloads/AlternativeDisputeResolutionRegulations.pdf>

²⁶⁰ Locarno, Nice, Strasbourg and Vienna Agreements.

The International Classification of Industrial Designs (Locarno Agreement) adopted by the Locarno Union (as subsequently amended) is applicable to South African design registrations, although South Africa is not a member of the Union. South Africa only uses the classification up to the second level as it makes use of a depository system.

- **Non-traditional marks**

Singapore Treaty on the Law of Trademarks ("Singapore Treaty") was adopted in 2006. The aim of the Singapore Treaty, following closely on the Trademark Law Treaty, is the adoption of a modernized framework for the harmonization of administrative trademark registration procedures, including registration of non-traditional marks.

The registration of non-traditional marks is deemed to be of importance to South Africa in light of the regulation of traditional marks in the Intellectual Property Laws Amendment Act of 2013. Trademark Law Treaty (TLT) and the Singapore Treaty harmonize and streamline trademark office rules of practice for the application and renewal of registrations.

- **Trade Mark Law Treaty**

South Africa signed but has not implemented the Trademark Law Treaty. This should be addressed in the IP Policy. Trademark Law Treaty (TLT) and the Singapore Treaty harmonize and streamline trademark office rules of practice for the application and renewal of registrations.

- **Nagoya Protocol**

There should also be a reference to the Nagoya Protocol (2010), which South Africa ratified.

- **Orphan works**

Orphan works should be regulated.

- **International Commercial Arbitration Bill**

This Bill that has been long overdue and in the making since 1998. Nothing is mentioned in the Policy of the proposed new act and to what extent, if any, the new act would provide for the resolution of intellectual property disputes by way of arbitration.

- **The primary statute of interest is the Counterfeit Goods Act 37 of 1997**

Various judgments by the SCA have emphasised drafting deficiencies in this Act, and it is regretted that their correction has not been mentioned in the policy.

Finally, an explanation of the interface of the proposed Intellectual Property policy framework with existing intellectual property-related legislation and recommendations is needed, specifically with reference to:

- **The Intellectual Property Laws Amendment Act of 2013 (Traditional Knowledge Bill);**
- **The Intellectual Property Rights from Publicly-funded Research & Development Act of 2008; and**
- **The recommendations of the Copyright Review Commission.**

APPENDIX A: REFERENCES

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APPENDIX B: LIST OF STAKEHOLDERS

| Organisation / department consulted | Interest group |
|---|------------------------------|
| Adams & Adams | IP Lawyers |
| Council for the Blind | Blind citizens |
| Council for Scientific and Industrial Research (CSIR) | Research institution |
| Denise Nicholson (Wits Librarian) | University (copyright) |
| Department of Communication | Government |
| Department of Higher Education | Government |
| Department of Health | Government |
| Department of International Relations and Cooperation (DIRCO) | Government |
| Department of Science & Technology | Government |
| Doctors without Borders | Access to health |
| Dr. Tim Burrell | IP Academic and consultant |
| Eli Lilly | Originator manufacturers |
| Innovation Hub | Government |
| Innovative Pharmaceutical Association of SA (IPASA) | Originator manufacturers |
| MCC Registrar | Government |
| National Association of Pharmaceutical Manufacturers (NAPM) | Generic manufacturers |
| National Intellectual Property Management Office (NIPMO) | Management of IP |
| Pharma Dynamics | Generic manufacturers |
| Prof. Paul Ruff | IP Academic and consultant |
| Prof. Owen Dean | IP Academic |
| Publishers Association of South Africa (PASA) | Publishers |
| Section 27 | Access to health |
| South African Chamber of Commerce & Industry (SACCI) | General business association |
| South African Institute of Intellectual Property Law (SAIIPL) | IP Lawyers |
| Treatment Action Campaign (TAC) | Access to health |
| Organisation / department contacted* | Interest group |
| Cipla | Pharmaceutical manufacturers |
| Department of Basic Education | Government |
| Prof. Anastassios Pouris | IP Academic and consultant |
| South African Music Performance Rights Association (SAMPRA) | Music producers |
| South African Music Rights Organisation (SAMRO) | Copyright management |

* These organisations / departments were contacted for an interview but did not engage any further.

APPENDIX C: ANALYTICAL FRAMEWORK

This framework is used to reach a policy conclusion by

- Confirming the policy as a being able to achieve the policy objective.
- Weighing up the probability of the critical success factors and severe risks.

Theoretically, can the policy objective be met through the proposal?

- Are there additional elements that need to be considered so that the policy objective is met?
- Are these essential?

What is the probability of critical success factor being secured?

If current circumstances were to prevail, what guarantee would there be that the critical success factors would be in place?

| Critical success factor | Low | Medium | High |
|-----------------------------|-----|--------|------|
| e.g. administrative systems | | X | |

What is the probability of severe risks occurring?

- If current circumstances were to prevail, with what probability would the most severe of risks occur?
- Risks have been defined as any severe broader, negative impacts

| High severity risk | Low | Medium | High |
|-----------------------|-----|--------|------|
| e.g. extensive delays | | X | |

Can these risks be mitigated?

- Where risks are considered medium or high, ask whether these may be mitigated
- Consider the possibility of alternatives or amendments

What is the conclusion on the implementation of the policy?

Based on the above considerations, conclusion is made on whether policy implementation should be:

- Adopted without changes
- Adopted with revision
- Rejected
- Delayed
- Considered in light of alternative measures