

**FIX THE PATENT LAWS SUBMISSION ON THE DRAFT INTELLECTUAL PROPERTY  
POLICY OF THE REPUBLIC OF SOUTH AFRICA, PHASE I, 2017**

**24 October 2017**

*The Fix the Patent Laws is a joint coalition of 36 patient groups, including: AmaBele Belles' Project Flamingo, Breast Course 4 Nurses, Breast Health Foundation, Cancer Alliance, Cancer Association of South Africa (CANSA), Can-Sir, CanSurvive Cancer Support, Cape Mental Health (CMH), Care for Cancer Foundation, Childhood Cancer Foundation of South Africa (CHOC), Community Technology Enablement and Collateral Harnessing (Community TECH), DiabetesSA, Doctors without Borders (MSF), EpilepsySA, Hospice Palliative Care Association (HPCA), Igazi Foundation, Look Good Feel Better, Marie Stopes South Africa, Movember, National Council Against Smoking, Oncology Nursing Association of SA, Pancreatic Cancer Network of SA, People Living With Cancer (PLWC), Pink Trees, Pocket Cancer Support, Reach for Recovery, Schizophrenia and Bipolar Disorders Alliance (SABDA), SECTION27, South African Depression and Anxiety Group (SADAG), South African Federation of Mental Health (SAFMH), South African Non-Communicable Diseases Alliance (SANCD Alliance), South African Oncology Social Workers Forum (SAOSWF), Stop Stock Outs Project (SSP), The Sunflower Fund, Treatment Action Campaign (TAC), Vrede Foundation, and Wings of Hope.*

“Emerging economies should take the lead in creating a balanced IP system that recognizes the importance of knowledge for development, growth, and wellbeing. What matters is not only the production of knowledge, but also that it is used in ways that put people’s health and welfare ahead of corporate profits. South Africa’s potential decision to enable access to medicine may be an important milestone on the road toward that goal.”

**Joseph E Stiglitz, Nobel Prize winning economist**

## INTRODUCTION

1. On 8 August 2017, the Department of Trade and Industry (“the dti”) published the Draft Intellectual Property Policy of the Republic of South Africa: Phase 1, 2017 (“draft IP Policy”) on its website. The draft IP policy was thereafter published in the Government Gazette on 25 August 2017.<sup>1</sup>
2. The Fix the Patent Laws Campaign (“FTPL”) supports the draft IP policy. In a press statement dated 14 August 2017, the FTPL welcomed the release of the draft IP policy for public comment, stating in part:

*“The draft policy states that the final policy must “first and foremost engender the ethos of the South African Constitution” and that a developmental and rights centred approach to IP is “urgently necessary”. We welcome the government’s commitments to cooperate to achieve the advancement of Constitutional rights and developmental goals and to do so urgently.”*

*“The draft policy identifies public health as a priority on the basis of important public interest considerations. It indicates that the DTI, together with key government departments, intends to address substantively in the immediate term, access to medicines, vaccines and diagnostics and South Africa’s approach to international IP cooperation. This policy and law reform process could thus be an important constitutional measure “to achieve the progressive realisation” of the right to health.”*

3. Members of the FTPL have been advocating for the advancement of the right to access health care services, in particular, access to medicines, for decades and continue to support the policy process that has been underway for the last 10 years. In 2013, Médecins Sans Frontières (“MSF”), the Treatment Action Campaign (“TAC”) and SECTION27 made written submissions on the draft National Policy on Intellectual Property, 2013.<sup>2</sup> Thereafter, in 2016, MSF, TAC and SECTION27 together with 28 health advocacy organisations provided the dti with a written submission in response to the dti’s publication of the Intellectual Property Consultative Framework, 2016.<sup>3</sup> Given the extensive involvement of members of the FTPL on the policy issues at the centre of the draft IP policy, we attach a timeline of events related to patent law reform and access to medicines over the period

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<sup>1</sup> General Notice 636 in Government Gazette 41064 of 25 August 2017.

<sup>2</sup> 2013 Submission available from [http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission\\_on\\_IP\\_Policy.pdf](http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission_on_IP_Policy.pdf).

<sup>3</sup> 2016 Submission available from <http://www.fixthepatentlaws.org/wp-content/uploads/2016/09/Submission-on-IP-Consultative-Framework-FINAL-2016-09-26.docx>.

1994 to 2017 as appendix A. As the FTPL, we endorse and align ourselves with the 2013 and 2016 submissions.

4. In all our previous submissions and in our advocacy work, we have made plain that our primary motivation is to address the inequality in access to treatment for a range of diseases, including HIV, TB and cancer and to address the structural barriers that continue to undermine access to medicines. We do so to advance the rights in the Bill of Rights and to hold the state accountable to its international human rights obligations. In particular, section 27 of the Constitution imposes a positive obligation on the state to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right to have access to health care services. We argue that the Constitution requires the kind of positive steps to promote public health as envisaged in the draft IP policy.
5. In this submission, the FTPL makes its comprehensive comments to assist the dti and its government partners to finalise the policy and to implement the necessary reforms urgently and in line with their constitutional obligations.
6. We deal with Phase 1, in particular, IP and public health, including the following topics:
  - 6.1. Local manufacture and export in line with industrial policy;
  - 6.2. Substantive search and examination;
  - 6.3. Patent opposition;
  - 6.4. Patentability criteria;
  - 6.5. Transparency and disclosure requirements;
  - 6.6. Parallel importation;
  - 6.7. Exceptions;
  - 6.8. Voluntary licences;
  - 6.9. Compulsory licences; and
  - 6.10. International cooperation.
7. In light of our previous submissions, we do not address the relevant legal framework and we do not repeat our submissions on IP and competition law in this submission.

## SUMMARY OF KEY RECOMMENDATIONS

8. Among others, this submission makes the following recommendations:

8.1. On local production:

8.1.1. South Africa should ensure application of strict patentability criteria to restrict undeserved, frivolous and secondary patenting that undermines the growth of its local pharmaceutical industry.

8.1.2. South Africa should establish a policy environment that promotes local manufacturing and ensures that it is responsive to its socio-economic development objectives. This should include a simple to use compulsory licensing system that encourages local production.

8.2. On substantive search and examination:

8.2.1. Recognising that the Patents Act already requires substantive patent examination, the Patent Regulations should require substantive patent examination in respect of applications dealing with health-related innovations.

8.2.2. Under its constitutional obligations, South Africa must take a range of reasonable measures to introduce a substantive patent examination system that takes into account the public interest and public health, including developing guidelines, prioritising recruitment of staff, training existing staff, developing appropriate systems and providing a reasonable budget.

8.3. On patent opposition:

8.3.1. To limit the granting of poor quality patents, South Africa should adopt broad grounds and standing for patent oppositions, and adopt both pre- and post-grant opposition procedures.

8.3.2. Given the costs associated with litigation, to ensure the workability and accessibility of opposition procedures, South Africa must adopt administrative procedures.

8.3.3. A range of measures should be adopted to ensure broad data transparency, and to help facilitate third party patent opposition procedures. These are outlined in the Transparency and Disclosure section, below.

8.4. On patentability criteria:

8.4.1. To grant patents for only genuine innovation, South Africa should adopt rigorous definitions of invention and patentability, such as those adopted by Argentina.

8.4.2. New uses of known substances, including methods of treatment, or new properties of known substances should be expressly excluded from patentability.

8.4.3. New forms and formulations of known substances should not be patentable

8.5. On transparency and disclosure requirements:

8.5.1. To facilitate substantive examination of patents, and opposition by third parties, the Companies and Intellectual Property Commission (“CIPC”) should upload full patent applications, data on prior art, and patent status of applications in other jurisdictions, to a public, searchable, online database.

8.5.2. CIPC should require that patents are filed under their international non-proprietary names, and publish updates of patents applied for and granted.

8.6. On parallel importation:

8.6.1. Recognising that South Africa has never used parallel importation, the government should pursue regulatory reforms to facilitate parallel importing and prevent undue delay, including addressing medicine registration challenges.

8.6.2. The government should adopt a more expansive definition of parallel importation that permits importation of products put on the market in another country by a third party.

8.7. On exceptions:

8.7.1. The Patents Act should exempt those aspects of scientific research and experimentation that are not covered by section 69A.

8.7.2. The Patents Act should include an educational-use exception.

8.7.3. The Patents Act should specifically allow generic companies to manufacture, import and/or store generic medicines sufficient to allow for immediate marketing and sale upon patent expiry.

8.8. On voluntary licences:

8.8.1. To address the current limitations of voluntary licensing in South Africa – including geographic restrictions, the lack of inclusion of South African producers, restrictions on sourcing requirements and price floors -- South Africa should develop a mandatory public register of patent-related licences to create transparency in licensing; once restrictions included in the VLs are known, appropriate legal remedies through competition or other laws should be initiated. Given that the Patents Act requires the registration of patent-related licences, open for public inspection, transparency in respect of voluntary licensing agreements can be operationalised through the existing provisions of the Act to

ensure voluntary licences are available for public scrutiny and legal action, where necessary.

8.9. On compulsory licences.

8.9.1. The current process should be replaced by simplified, expeditious compulsory licensing processes and procedures.

8.9.2. South Africa should introduce specific grounds for compulsory licensing related to availability, affordability and accessibility of pharmaceutical products and processes.

8.9.3. South Africa should encourage competitors/generic producers to file for compulsory licences, and introduce standing for civil society in compulsory licences and government use licence proceedings.

8.9.4. South Africa's patent law reform should put in place a compulsory licensing mechanism that regularly reviews the situation of access to patented medicines and a framework for the issue of compulsory licences when patents prohibit access.

8.10. On international cooperation:

8.10.1. South Africa should continue to play a leading role in advocating for policies that place the right to health and reasonable incentives for real and needs-based innovation ahead of the private interests of private companies. This should include, but not be limited to:

8.10.1.1. advocating for the full adoption of public health-related TRIPS flexibilities and against the use of TRIPS-plus measures in all countries;

8.10.1.2. implementing TRIPS flexibilities in concert with other countries facing common health challenges;

8.10.1.3. investing public funds in innovative and needs-based R&D projects that fully delink the cost of R&D from the price of products;

8.10.1.4. leading international efforts to amend and simplify WTO requirements for compulsory licences for export; and

8.10.1.5. standing in solidarity with, and speaking out for, other countries often excluded from voluntary licensing and pricing deals to ensure that no developing countries are left out.

9. We once again urge the dti to proceed swiftly to finalise the National IP Policy and to proceed thereafter to publish draft bills to implement Phase 1. We call on the dti to commit

to reasonable timeframes for the finalisation of the policy process and the tabling of amendment bills in Parliament.

## LOCAL PRODUCTION

10. In addition to improving medicine access, the full use of TRIPS flexibilities can provide important benefits to the local economy through facilitating expanded local production and growth. Currently, the vast majority of patents granted in South Africa on pharmaceutical products are held by multinational companies.<sup>4</sup> Restricting underserved, frivolous and secondary patenting would therefore allow for earlier entry of domestic products onto the local market. In addition, a simple to use and effective compulsory licensing system would allow local generic producers to supply affordable medicines even where patents are granted while providing remuneration to patent holders. This would reduce the country's reliance on expensive imported medicines and reduce the contribution of pharmaceutical product imports to the country's trade deficit.<sup>5</sup>

11. It is a common misconception that greater intellectual property protection will stimulate industrial development and economic growth. Rather, as a number of academics have demonstrated, greater IP protections can hinder economic growth in developing countries by hindering access to patented technologies and knowledge. Historical data has demonstrated that many of today's wealthy nations underwent periods of rapid economic development and industrial growth during periods of less intellectual property protection.<sup>6</sup> Similarly, India's experienced large growth of its domestic pharmaceutical sector between 1970 and 2005, when the country did not provide patents on pharmaceutical products.<sup>7</sup>

12. Highlighting the potential of strict patentability criteria as a vehicle for growth of local industry, the World Health Organisation recently noted that *"(t)he refusal of a patent as a*

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<sup>4</sup> Vawda YA. (2011). Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa.

<sup>5</sup> Draft Intellectual Property Policy of the Republic of South Africa, Phase 1, 2017.

<sup>6</sup> See Odagiri H, Goto A, Sunami A & Nelson R. (2011). Intellectual Property Rights, Development and Catch-up. An International Comparative Study, Oxford University Press, pp. 451; Ha-Joon Chang, (2003). Kicking Away the Ladder: Development Strategy in Historical Perspective. Anthem Press, London; Baker D, Jayadev A & Stiglitz J. (2017). Innovation, Intellectual Property and Development: A better set of approaches for the 21<sup>st</sup> Century. Available at: <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>

<sup>7</sup> Tomlinson & Rutter. (2014). The Economic and Social Case for Patent Law Reform in South Africa. Available at: <http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf>.

result of not meeting a country's legal requirement of patentability can pave the way for local production. Strict patent standards alongside opposition procedures can therefore facilitate local production".<sup>8</sup> As a generic medicine and burgeoning biosimilar producer, South Africa should restrict underserved, frivolous and secondary patenting that undermines the growth of its local pharmaceutical industry.

13. In his most recent paper, Joseph E Stiglitz, a Nobel prize winning economist, states:

*"The more recent experience of Japan, Korea, and even more recently China, also provides strong evidence against the view that stringent IPRs are necessary for the inflow of foreign investment, domestic technological development and the transfer of technology. Indeed, as Maskus (2004) and others have argued, Korea and Japan made explicit use of weak enforcement of IPRs and an extensive use of 'creative imitation' to promote a whole range of frontier technology industries. Similarly, weak IPRs have allowed China to develop a range of frontier technology firms and industries, ranging from cell phones (Xiaomi) or Solar Cell Technology."<sup>9</sup>*

14. South Africa should establish a policy environment that promotes local manufacturing and ensures that it is responsive to its socio-economic development objectives.

## **SUBSTANTIVE SEARCH AND EXAMINATION<sup>10</sup>**

15. We welcome the following aspects of the new draft IP policy dealing with substantive search and examination:

- 15.1. the recognition of the serious drawbacks of the so-called depository system currently used by South Africa, and the acknowledgement of the strong benefits of implementing a substantive search and examination procedure, including "greater legal certainty for patent owners and ensur[ing] that the public interest is served by ensuring that the patent system truly promotes innovation";

<sup>8</sup> World Health Organisation. (2016). The Role of Intellectual Property in Local Production in Developing Countries.

<sup>9</sup> Baker D, Jayadev A & Stiglitz J. (2017). Innovation, Intellectual Property and Development: A better set of approaches for the 21<sup>st</sup> Century, 30. Available at: <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>

<sup>10</sup> Substantive search and examination is addressed in the 2013 submission at paragraphs 54 to 60 and 64 and in the 2016 submission at paragraphs 35 to 40.



- 15.2. the view that properly interpreted, Article 27.1 of TRIPS recognises that health-related fields of technology or other classes of patents may be prioritised for examination; and
- 15.3. the acknowledgement of human and financial resources constraints and the accompanying suggestion of an incremental approach of initially limiting examination to specific strategic fields of technology, which we submit can be achieved by starting with the pharmaceutical sector and by exploring options to partner with other patents offices in countries with similar patentability criteria and developmental status to undertake examination of patent applications and make recommendations regarding their granting.
16. The establishment of a substantive patent examination system in South Africa is already contemplated by section 34 of the Patents Act, which requires that patent applications be examined for compliance with the patentability requirements. Section 34 provides:
- “The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it.”*
17. The regime envisaged by the Patents Act is thus one in which compliance with the requirements of patentability is a prerequisite for the granting of a patent and all the rights of exclusivity that ordinarily follow. Yet, at present, the registrar – defined as the Commissioner of the Companies and Intellectual Property Commission (“CIPC”)<sup>11</sup> – does not examine patent applications prior to granting a patent to ensure the required criteria are met. Instead, CIPC makes use of a depository system in which applicants merely have to complete the relevant forms, pay the prescribed fee, and meet other minimal formal requirements.
18. Section 91 of the Patents Act empowers the Minister of Trade and Industry to make regulations *“prescribing the procedure in any proceedings before the registrar”*,<sup>12</sup> *“prescribing the contents of any application, notice or form provided for in this Act”*,<sup>13</sup> and *“as to any other matter required or permitted by this Act to be prescribed by regulation”*.<sup>14</sup>

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<sup>11</sup> Section 2 of the Patents Act, read together with section 189 of the Companies Act, 2008

<sup>12</sup> Section 91(c)

<sup>13</sup> Section 91(f)

<sup>14</sup> Section 91(g)

To date, the Minister has published two sets of regulations: the Patent Regulations of 1978;<sup>15</sup> and the Patents Examination Regulations.<sup>16</sup>

19. Contrary to what is contained in section 34 of the Patents Act, neither set of regulations deals with substantive patent examination.

19.1. Despite their name, the Patents Examination Regulations only deal with the qualifications of patent agents and patent attorneys.

19.2. The Patent Regulations are limited to administrative matters:

19.2.1. Regulation 40 sets out the extent to which applications will be “examined” by the CIPC:

*“Any application accompanied by a provisional specification shall be examined to ensure that the documents lodged are legible and capable of reproduction.”*

19.2.2. Regulation 41 clarifies the nature of the “examination”:

*“The registrar shall examine the application accompanied by a complete specification in order to ensure that it complies with the prescribed formalities.”*

20. At least insofar as health-related patents are concerned, we submit that section 27(2) of the Constitution places an obligation on the Minister to amend the Patent Regulations so as to require substantive patent examination in respect of applications dealing with health-related products and processes. In addition, it places an obligation on the Minister, the dti, CIPC and/or other relevant organs of state to take the following reasonable measures to ensure that we move swiftly towards a substantive patent examination system:<sup>17</sup>

20.1. undertake a comprehensive review of the regulations to ensure consistency with search and examination;

20.2. develop guidelines and training documentation for substantive patent examinations with assistance not only from WIPO but from development partners such as UNDP, UNCTAD, the South Centre and other experts;

20.3. prioritise the recruitment of and training of more patent examiners;

20.4. train existing staff to undertake examinations and ancillary tasks;

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<sup>15</sup> Government Notice No. R 2470, *Government Gazette* No. 6247 (15 December 1978)

<sup>16</sup> General Notice 25, *Government Gazette* No. 24290 (17 January 2003)

<sup>17</sup> There is no need to conduct a further cost-benefit analysis to determine whether an examination system should be adopted – it is already legally required - but rather the question is how to implement it.

- 20.5. recruit and/or train management staff to take responsibility for various aspects of the examination process;
- 20.6. develop appropriate IT systems to ensure transparency and access to information, in line with our recommendations on patent searches and patent opposition procedures;
- 20.7. improve the classification of patents system currently in use at CIPC;<sup>18</sup> and
- 20.8. make provision for a reasonable budget to achieve these objectives.

21. We are aware that in line with these recommendations, the CIPC has begun training of the first batch of patent examiners, who are expected to be ready to begin examining patents by early 2019. We are encouraged to see this action taken but make the following recommendations with regard to the examiners and their training:

- 21.1. that examiners receive a balanced training which allows them to prioritise human rights, public health and public interest;
- 21.2. that training should be modelled on countries in a similar socio-economic position to South Africa and with similar health burdens, such as Brazil or India, and not on the systems of highly industrialised countries like Japan or the EU, where diseases burdens are lower, the economies are very different, and the approach to patents is not focused on development and protection of human rights, including the right to access health care services;
- 21.3. that patent examination guidelines must be timeously produced in order to inform the training of examiners and to enable examiners to begin examining patents when their training is complete. These should be produced through a transparent and open system and should be subject to public participation in the same way that the draft IP policy has been; and
- 21.4. ensure that enough examiners are trained as quickly as possible in order to avoid a backlog which would slow the system.

## **PATENT OPPOSITION<sup>19</sup>**

22. The draft IP policy makes provision for three mechanisms for third parties to comment on and/or oppose the validity of patents applied for and/or granted in South Africa. The described mechanisms include:

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<sup>18</sup> The current system combines pharmaceutical products with cosmetic products, is not easily searchable, and is not readily available to the public.

<sup>19</sup> Patent oppositions are addressed in the 2013 submission at paragraphs 61 to 64 and in the 2016 submission at paragraphs 41 to 42.

- 22.1. an observation mechanism;
  - 22.2. pre-grant opposition procedures; and
  - 22.3. post-grant opposition procedures.
  - 22.4. The draft IP policy notes that implementing opposition procedures will require greater capacity strengthening in the patents office than adoption of an observation mechanism, as well as regulatory and legislative reforms.
23. On its own, implementation of an observation mechanism will expand patent examiners' access to relevant data, but will not necessarily trigger procedures to ensure the validity of patents applied for or granted. Implementation of patent opposition procedures (potentially coupled with an observation mechanism) therefore remain critical to protecting medicine access and ensuring a healthy and effective patent system that incentivises and rewards legitimate innovation.
24. As demonstrated in the medicines patent landscape in appendix B, weak secondary patents are commonly granted in South Africa - including patents that are rejected, withdrawn or overturned in other jurisdictions following patent opposition. As a result, people living in South Africa are often unable to access generic products long after they become available in the global market. For example, the patent landscape analysis revealed a total of 92 secondary patents on 24 cancer medicines. Of these patents, 39 were rejected or withdrawn in another region. Only 7 case study medicines were available in the public sector in South Africa. The other medicines were not available in the public sector likely due to the unaffordable prices for the still-patented versions.
25. Implementation of patent opposition procedures (potentially supplemented by an observation mechanism) would provide important benefits to the Patents Office, inventors, competitors and the general public, including:
- 25.1. enhancing both perceived and actual legitimacy of granted patents;
  - 25.2. promoting and upholding local patentability criteria;
  - 25.3. guarding against the granting of weak, illegitimate patents that have negative consequence for health, health expenditure, economic development and innovation;
  - 25.4. incentivising and rewarding legitimate innovation to address unmet health needs, rather than R&D expenditure towards the extension of patent lives on profitable products; and
  - 25.5. enhancing the capacity of patent examiners to make valid decisions on patentability through:

- 25.5.1. providing relevant supplementary data (beyond data supplied by applicants) to patent examiners;
- 25.5.2. evaluating the validity of decisions made with regards to patentability (through post-grant oppositions); and
- 25.5.3. reducing the need for expensive and lengthy judicial procedures to challenge illegitimate patents that significantly delay medicine access.

26. In establishing patent opposition procedures, South Africa must consider the following:

- 26.1. grounds for opposition;
- 26.2. timing;
- 26.3. standing and accessibility;
- 26.4. procedures; and
- 26.5. transparency.

### **Grounds for opposition**

27. TRIPS does not limit the grounds on which patents can be opposed, leaving countries with policy room to establish grounds for opposition that are relevant to each country's policy priorities and legal obligations. To ensure a healthy patent system that rewards legitimate applications and promotes medicine access, South Africa should adopt broad grounds for patent oppositions, including when:

- 27.1. the pursued or granted patent fails to fulfil local criteria for patentability (including standards of novelty, inventiveness, industrial application) or other procedural or substantive requirements of the patent law;
- 27.2. the application for patent protection fails to adequately disclose the nature of the invention to provide a "full and fair" understanding and allow for societal benefit through sharing the invention in a manner that allows others to make and utilize the invention;
- 27.3. the protection applied for exceeds the scope of disclosure (i.e. Markush patents); and
- 27.4. the application fails to fully disclose information related to foreign filings and/or failure of the applicant to apply within 12 months of the first patent application filed in another Convention country (Paris Convention).

### **Timing**

28. TRIPS provides for both pre- and post- grant patent opposition. Pre-grant patent opposition allows for opposition of patent applications prior to the granting of patents. Post-grant patent opposition allows for opposition of patents after their granting during a designated timeframe.<sup>20</sup> The draft IP policy makes provisions for both pre- and post- grant oppositions. The adoption of pre-grant opposition procedures can prevent the granting of undeserved patents that delay access to more affordable generic medicines. The adoption of post-grant opposition procedures provides a mechanism to evaluate, validate and/or amend the decisions of patent examiners without undergoing lengthy judicial proceedings. Given that each approach provides different benefits, both pre- and post-grant opposition procedures should be adopted in South Africa.

29. The draft IP policy states that “legislative provision should be made to allow for the introduction of pre-grant opposition proceedings once the Minister of Trade and Industry is satisfied that there is sufficient capacity within the substantive examination system to make appropriate use of such proceedings.” However, the capacity burden of pre-grant oppositions should be minimal: in India, for example, 49,904 patent applications were filed in 2015-2016, with only 290 patent oppositions.<sup>21</sup> In addition, pre-grant oppositions will in fact provide capacity to the patents office by providing research and help in countering defenses or arguments put up by patent applicants. For this reason, the policy should provide that the patent office introduce pre-grant oppositions simultaneously or soon after implementing a substantive examination system.

30. Additionally, given that analysing patent applications and developing observations and oppositions is a timeous process, third parties should be allowed to oppose patents granted for at least a year after their granting as allowed in India<sup>22</sup> where patent opposition have successfully secured access to generic HIV and cancer treatments.<sup>23</sup> Pre-grant oppositions should be allowed any time up to the grant of a patent.

### **Standing and equitable accessibility**

31. In establishing opposition procedures, South Africa must identify who is eligible to file an opposition. Table 1 provides an overview of eligibility in a number of countries and the

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<sup>20</sup> WIPO Standing Committee on the Law of Patents. Opposition Systems. Fourteenth Session Geneva, January 25 to 29, 2010

<sup>21</sup> [http://www.ipindia.nic.in/writereaddata/Portal/IPOAnnualReport/1\\_71\\_1\\_Annual\\_Report\\_2015-16\\_English\\_2\\_.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOAnnualReport/1_71_1_Annual_Report_2015-16_English_2_.pdf)

<sup>22</sup> Section 25, The Indian Patents Act 1970 (India Patent Law).

<sup>23</sup> <https://www.patentoppositions.org/>.

European Union. To ensure full realisation of this flexibility, South Africa must not limit eligibility for filing patent oppositions and observations.

Table 1

	Argentina	Brazil	India	US	EU
Grounds	'Any person may raise objections...' <sup>24</sup>	'interested parties may submit documents and data to assist the examination' <sup>25</sup>	'any person may, in writing, represent by way of opposition to the Controller' <sup>26</sup>	'a person who is not the owner of a patent may file with the Office...' <sup>27</sup>	'any member of the public except for the proprietor himself' <sup>28</sup>

### Procedures

32. The draft IP Policy acknowledges that currently the only way to oppose a patent in South Africa is through litigation, which is lengthy and expensive and only available after a patent has already been granted.<sup>29</sup> To ensure the workability and accessibility of opposition procedures, South Africa must adopt administrative procedures, as utilised in Argentina, Brazil, India, the US, other countries and the EU.

### Fees

33. To further ensure the equitability and accessibility of opposition procedures, South Africa must ensure that fees for filing oppositions are not prohibitive to local individuals, civil society, academics and industry, as these groups will often incur substantial costs in developing observations and oppositions for submission to the patents office. South Africa

<sup>24</sup> Section 28. Patent and Utility Models Law (Argentina Patent Law).

<sup>25</sup> Article 31, Industrial Property Law No 9279/96 (Brazil Patent Law).

<sup>26</sup> Section 25, The Indian Patents Act 1970 (India Patent Law).

<sup>27</sup> 35 U.S.C. § 311, Leahy-Smith America Invents Act (US Patent Law).

<sup>28</sup> [https://www.epo.org/law-practice/legal-texts/html/guidelines/e/d\\_iii\\_5.htm](https://www.epo.org/law-practice/legal-texts/html/guidelines/e/d_iii_5.htm) (EU Guidelines).

<sup>29</sup> UNDP. (2013). Using Law to Facilitate Treatment Access in South Africa. Available at:

[http://www.undp.org/content/dam/undp/library/hiv/aids/English/using\\_law\\_to\\_accelerate\\_treatment\\_access\\_in\\_south\\_africa](http://www.undp.org/content/dam/undp/library/hiv/aids/English/using_law_to_accelerate_treatment_access_in_south_africa).

can adopt a varying fee structure for filing patent oppositions as used in the US<sup>30</sup> and India.<sup>31</sup>

### **Transparency**

34. Broad data transparency is necessary for effective implementation and use of patent opposition procedures to ensure the validity of patents granted and upheld. Commendably, South Africa has already developed an online searchable patent database. However, the functioning of this database is inadequate for enabling patent monitoring and oppositions by third parties. In implementing patent opposition, South Africa should take steps to improve transparency of patent data, as outlined below in the Transparency and Disclosure section.

### **PATENTABILITY CRITERIA**

35. Paragraph 7.1.4. of the draft IP policy recognises that “article 27.1 of the TRIPS Agreement affords WTO members much flexibility when setting patentability criteria.” We welcome the recognition that this includes “the flexibility to interpret and implement the patentability requirements” in a manner consistent with “constitutional obligations, developmental goals, and public policy priorities.”

36. Paragraph 7.1.4. of the draft IP policy provides:

*“In line with emerging international best practice, patentability criteria will be developed in order to promote genuine innovation through the patent system in South Africa. Such criteria will be implemented in the process of examination of patent applications and will aim to strike the optimal level of IP protection, promote innovation, and balance the rights of IP holders and users alike.”*

37. We agree that only “genuine innovation” should be promoted through our domestic patent system. We are however concerned that the policy remains vague on what “genuine innovation” means in practice.

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<sup>30</sup> See “Request for ex parte reexamination” fees at <https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule>.

<sup>31</sup> See [http://www.ipindia.nic.in/writereaddata/Portal/IPOFormUpload/1\\_11\\_1/Fees.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOFormUpload/1_11_1/Fees.pdf)



38. We draw attention to the relevant recommendation made in the report of the United Nations Secretary General's High-Level Panel on Access to Medicines ("UNHLP Report") published in September 2016:

*"WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that are in the best interests of the public health of the country and its inhabitants. This includes amending laws to curtail the evergreening of patents and awarding patents only when genuine innovation has occurred."<sup>32</sup>*

39. In our view South Africa's IP policy should adopt this recommendation in full – including an explicit reference to "curtail the evergreening of patents".

40. As per the legal flexibilities available in the TRIPS agreement (as clarified in the WTO Doha Declaration on Public Health), WTO member countries have adopted widely varying patentability criteria. For example:

- 40.1. In Argentina, patent examination regulations adopted in 2012 detailed how new use and, with some limited exceptions, new forms and new formulation patents did not meet patentability criteria of novelty, inventive step, and/or industrial application.<sup>33</sup>
- 40.2. The patent regimes of the Andean Community countries (Bolivia, Colombia, Ecuador and Peru) all rule out new use patents.<sup>34</sup>
- 40.3. In India, new forms of existing medicines are only patentable if the new form results in the "enhancement of known efficacy" (interpreted to mean therapeutic efficacy) while new uses of known substances are excluded entirely from patentability. Section 3(d) of India's Patents Act, 1970 withstood a challenge in the Indian Supreme Court in respect of whether Novartis could patent the cancer medicine Gleevec.<sup>35</sup>

<sup>32</sup> United Nations Secretary General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 9. (2016).

<sup>33</sup> Adoption of Guidelines for Patentability Examination of Patent Applications Directed to Chemical and Pharmaceutical Inventions, Joint Resolution 118/2012, 546/2012 and 107/2012, available at [http://www.moellerip.com/index.php?PN=news\\_detail&FX=1&DX=139&EX=1](http://www.moellerip.com/index.php?PN=news_detail&FX=1&DX=139&EX=1).

<sup>34</sup> MSF. Drug Patents Under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents, 3.3. (2003), available at <http://apps.who.int/medicinedocs/en/d/Js4913e/3.3.html>.

<sup>35</sup> Novartis v Union of India & Others Civil Appeal No. 2706-2716 of 2013.

- 40.4. In Israel, patent examiners were instructed in 2015 to exclude polymorphs from patentability and to restrict patents on salts and crystals of known substances.<sup>36</sup>
41. There are thus clear and legally sound precedents, in developmentally similar countries to South Africa, of definitions of “genuine innovation” that exclude new uses or new forms or new formulations of existing medicines, with some exceptions. South Africa also has the option to exclude new uses, new forms or new formulations of existing medicines from patentability.
42. Granting patents on new uses, new forms or new formulations of existing medicines leads to patent evergreening and adversely impacts the right to access health care services, medical innovation and the South African economy:
- 42.1. The granting of new use, new form and new formulation patents extends market exclusivity and higher prices and thus restricts access to new medicines and impedes the realisation of the right to access health care services. For current examples of this relating to cancer medicines in South Africa, see the patent landscape in appendix B.
- 42.2. Allowing for the patenting of new uses, new forms and new formulations of existing medicines creates an incentive to invest in the development and marketing of new uses, new forms and new formulations to extend patent monopolies on existing products. There is growing evidence that this comes at the expense of investment in the development of actual new medicines and thus dilutes the incentive to invest in “genuine innovation” to meet unmet medical need. For example, a 2017 WHO report on antimicrobial resistance found that of 51 new antibiotic agents in the pipeline, only eight were classed by the WHO as innovative treatments that will add value to the current antibiotic treatment Arsenal. The rest are modifications of drugs that already exist and may already be compromised.<sup>37</sup> Similarly pursuit of evergreening patents and the development of me-too drugs have stifled innovation for cancer with the majority of new treatments only offering marginal benefits to patients.<sup>38</sup>

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<sup>36</sup> <https://bricwallblog.com/2015/08/12/new-guidelines-for-the-examination-of-polymorph-and-salt-patents-issued-by-the-israeli-patent-and-trademark-office/>

<sup>37</sup> <http://www.who.int/mediacentre/news/releases/2017/running-out-antibiotics/en/>.

<sup>38</sup> Fojo T et al. (2014). Unintended Consequences of Expensive Cancer Therapeutics—the Pursuit of Marginal Indications and a Me-too Mentality That Stifles Innovation and Creativity, 12 JAMA Otolaryngol Head Neck Surg, available at <https://www.ncbi.nlm.nih.gov/pubmed/25068501>.

- 42.3. Partly because South Africa has a depository patent system and partly because of South Africa's lax patentability standards (currently allowing for new use, new form and new formulation patents), South Africa grants many pharmaceutical patents that have been rejected in other jurisdictions. Most of these patents are granted to multinational companies. These poor-quality patents effectively function as a rent on the South African economy and thus contributes to South Africa's trade deficit.<sup>39</sup>
43. The state's constitutional obligations require a framework that achieves the progressive realisation of the right to have access to health care services. In these circumstances, only "genuine innovation" should be considered patentable.
- 43.1.1. To grant patents for only genuine innovation, South Africa should adopt rigorous definitions of invention and patentability, such as those adopted in Argentina, for example.
- 43.1.2. New uses of known substances, including methods of treatment, or new properties of known substances should be expressly excluded from patentability.
- 43.1.3. New forms and formulations of known substances should not be patentable
44. FTPL supports the recommendation in the draft IP policy that states as follows: "It is recommended that patentability criteria form a part of the Patents Act, as well as any subsequent regulations and guidelines for the examination of applications." We urge the dti to implement this urgently as it is core to the reforms envisaged in the policy document.

## TRANSPARENCY & DISCLOSURE REQUIREMENTS

45. The UNHLP report recommends that:

*"Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include: (1) standard international common names for biological products; (2) international non-*

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<sup>39</sup> See Tomlinson & Rutter. (2014). The Economic and Social Case for Patent Law Reform in South Africa. Available at: <http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf>; Baker D, Jayadev A & Stiglitz J. (2017). Innovation, Intellectual Property and Development: A better set of approaches for the 21<sup>st</sup> Century, 30. Available at: <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>.

*proprietary names for products, either as known at the time of application or after the granting of a patent; and (3) dates of grant and expiry.”<sup>40</sup>*

46. We urge that the dti ensure the full adoption of this recommendation in the final IP policy and in the law.

47. In addition, as pointed out in the draft IP policy,

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

48. We also fully support this recommendation. Taken together, we recommend that:

- 48.1. The CIPC should upload full patent applications to a public, searchable, online database. Currently only a ‘cover page’ of patents applied for can be accessed on CIPC’s online patent database that provides details of the patent application’s status and the payment of renewal fees. Full applications should be uploaded to allow third party monitoring and inform the development of observations and oppositions on undeserving applications. To facilitate this, future patent applicants should be required to provide electronic versions of their patent applications.
- 48.2. The CIPC should include data on prior art, best mode of practicing an invention, and patent status of matching applications in other jurisdictions on a public, searchable, online database. To facilitate substantive examination of patent applications, as well as oppositions by third parties, patent applicants should be required to provide an overview of prior art related to patent applications, as well as an overview of “matching” patents applied for in other jurisdictions and the status of these applications to the patents office.
- 48.3. The CIPC should require that patents are filed with disclosure of the relevant international non-proprietary name (INN) or biological qualifiers of chemical and biological medicines. Transparency regarding patent status and length is critical to informing decision making related to medicine procurement by the Department of Health, and use of TRIPS flexibilities to improve medicine

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<sup>40</sup> United Nations Secretary General’s High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 11. (2016).

access by government and other actors. It is currently extremely difficult to identify all relevant patents applied for and granted on specific medicines, as patent applicants are not required to file patent applications under the relevant INN or biological qualifiers of medicines on which patent protection is sought. When available, patent applicants seeking patents on pharmaceutical products should be required to file their applications under relevant medicines' INN or biological qualifiers to enhance transparency of medicines' patent landscapes. In the event that INNs or biological qualifiers are not designated prior to the filing of patent applications, companies should be obliged to supply INNs or biological qualifiers retroactively within a given timeframe. The mandatory disclosure of INNs or biological qualifiers in the abstract or title of patent applications has been identified as an important issue to be addressed by the WIPO Africa Group and Developmental Agenda Group, which resolved "that the patent system should be consistent with fundamental public policy priorities, and in particular the promotion and protection of public health."<sup>41</sup> Disclosure requirements should also include disclosure of best mode of practicing an invention, and, disclosure of all prior art in the patent specification.<sup>42</sup>

- 48.4. The CIPC must publish updates of patents applied for and granted. Updates regarding patents applied for and granted must be publicly available and easily accessible as a pre-requisite for third party observations and oppositions.

## **PARALLEL IMPORTATION**

49. Article 6 of TRIPS allows for the parallel importation and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. Given that patented products are sold at different prices in different markets, this measure enables the import of patented products from countries in which they are sold at lower prices into those countries where the same patented product is being sold at a higher price.

50. We welcome the draft IP policy's acknowledgement that,

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<sup>41</sup> [http://www.wipo.int/edocs/mdocs/scp/en/scp\\_16/scp\\_16\\_7.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_16/scp_16_7.pdf)

<sup>42</sup> UNDP. 2013. Using Law to Accelerate Treatment Access in South Africa, 53. Available at <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-law-to-accelerate-treatment-access-in-south-africa.html>

*“South Africa’s unique developmental needs, particularly in public health, require the exploration of every legal opportunity to support the viability and expansion of the public health system, including, in the case of patented products such as medicines, the ability to purchase said medicines from any external territory that is necessary.”*

51. We remain concerned, however, with the unwieldy and impractical design of the General Regulation governing parallel importation. Despite the adoption of a regulatory scheme in 2003 pursuant to Section 15C of the Medicines Act, and despite subsequent revisions, South Africa has never used parallel importation to procure more affordable generics. The regulatory regime poses a number of challenges.

51.1. Regulation 5(2) requires the submission of extensive documentation to the Minister of Health even though there is no existing administrative infrastructure to handle such submissions, so applicants might anticipate considerable delays.

51.2. Regulation 5(3) arbitrarily limits the parallel importation permit to two years.

51.3. Most importantly, regulation 5(5) requires the applicant to seek registration of the parallel traded medicine with the South African Health Products Regulatory Authority (SAHPRA) before a certificate of registration can be granted. Such registration is dependent on inspections of manufacturing facilities, which can be much delayed in the case of non-PIC/S countries.

51.4. Another key inflexibility is the requirement in regulation 5(2)(e)(iv) that the applicant must reveal the price at which the parallel traded medicine will be sold. Based on this disclosure, the patent holder or its authorised licensee or distributor would be able to lower the price to match or under-cut the parallel trader, thus negating any price advantage and thereby retain market share. Because state tenders are only issued every two years, the chances of a parallel trader being able to navigate the parallel-importation permit and registration steps in time to make a sealed (and hence undisclosed) bid for the tender business, while under-cutting the patent holder, are slim. Without adequate economic incentives and easier to use procedures, parallel importation will not occur to the detriment both of patients and the public purse.

52. While the law provides for the parallel importation of both branded and generic medicines,

regulations in respect of generic medicines have not yet been published. Both Kenya<sup>43</sup> and the Philippines<sup>44</sup> have amended their patent law to allow international exhaustion and to not limit the possible source of importation to products put on the market in a third country by the original patent holder. Instead, they permit importation of equivalent products placed on the market by anybody who was authorised to do so. Thus, in addition to products placed on the market by the patent holder or any of his authorised licensees, the laws in these countries permit the import of a medicine placed on the market by a generic company if no domestic patent protection existed. The provision also applies to products that were produced, for example, under a compulsory licence, as the recipient of the compulsory licence would have been authorised to use the invention. Since Kenya's change of legislation, the provision has been used to import a range of generics that were still under patent protection in the third country. To date, Kenya has not been challenged for its interpretation of international exhaustion, or its use, at the WTO.

53. Given the salient price differences of pharmaceutical products on the South African market compared to many other developing countries, parallel importation is an important tool to enable access to more affordable medicines in the country.

54. On parallel importation, we therefore make the following recommendations:

54.1. The government should adopt a more expansive definition of parallel importation that permits importation of products put on the market in another country by a third party.

54.2. The government should pursue regulatory reforms to facilitate the easy use of parallel importation and prevent undue delay, including addressing medicine registration challenges.

## **EXCEPTIONS<sup>45</sup>**

55. Article 30 of TRIPS allows WTO members to legislate "limited exceptions" to the exclusive rights conferred by a patent. This provision should be read together with Article 8.1, which permits the adoption of measures necessary to protect public health, and to promote the public interest in sectors of vital importance to a country's socio-economic and

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<sup>43</sup> Clause 37 of Kenya's Intellectual Property Regulations (2002) provides for the importation of "...articles that are imported from a country where the articles were legitimately put on the market."

<sup>44</sup> The Philippines' wording of the provision allows for the importation into the country if they have been placed on the market anywhere in the world by "the patent owner, or by any party authorized to use the invention."

<sup>45</sup> Exceptions to patent infringement are dealt with at paragraph 91 to 98 of the 2013 submission and at paragraphs 60 to 68 of the 2016 submission.

technological development.

56. Under Article 30, WTO members may provide exceptions for regulatory purposes (such as medicines registration), as well as for broader research and education purposes.<sup>46</sup>

57. As such, we welcome the following aspects of the draft IP policy with regard to research exceptions:

- 57.1. the acknowledgement that “it is essential to facilitate research, development and testing of IP products in the commercial and industrial sectors prior to the expiry of the patent term” and that “exceptions placed on patent rights are an important means of achieving the appropriate set of policies that best foster R&D and technology diffusion”;
- 57.2. the acknowledgement that the benefits of research exceptions extend beyond the health sphere and have been used already in many jurisdictions to advance knowledge and innovation;
- 57.3. the acknowledgement of the importance of the “Bolar” provision in accelerating the entry of generic competition into the market; and
- 57.4. that the IP policy will develop “a broad and carefully crafted set of exceptions for research and experimental activities.”

58. Current South African law only makes provision for an exception for regulatory purposes – the so-called “Bolar provision” in section 69A of the Patents Act. But that provision must be read together with the decision of the SCA in *Cipla Medpro (Pty) Ltd v Aventis Pharma SA and related appeal*,<sup>47</sup> in which the court held that the concept of contributory infringement is part of our law.

59. Put simply, the SAHPRA could be held liable for contributory infringement in circumstances where it authorises health research using generic versions of products in circumstances where the research in question is not necessary for regulatory approval. This would apply, for example, to operational research aimed at determining the most appropriate way – in a public sector context – for implementing a particular intervention using a patented product.

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<sup>46</sup> Phoebe H Li. (2013). Rights and responsibilities in patents: a precautionary patent framework in WTO law, 35:9 European Intellectual Property Review 516.

<sup>47</sup> 2013 (4) SA 579 (SCA).



60. As mentioned in our previous submission, in our view, section 69A of the Patents Act does not go far enough: it does not accommodate much of the health research that is commonly carried out in South Africa. In contrast, many other countries allow broad research and experimentation exceptions by both non-commercial and commercial entities.<sup>48</sup> A number of countries also make express statutory provision for broad research exceptions.<sup>49,50</sup> South Africa should adopt a broad research exception in order to properly take account of health research done in the country that could contribute to innovation of new or improved medicines in the market.

61. In addition to adopting a broad research exception, South Africa should also adopt a broad educational-use exception. Academics and researchers must be able to train the next generation of inventors and scientists on research and product development methods. At minimum, tertiary institutions should be permitted to use patented products and/or processes for the purpose of instruction. Again, Article 30 of TRIPS allows such an exception, and there is precedent for its use in Brazil, India, and Argentina.<sup>51</sup> This kind of exception is not addressed in the new draft IP policy.

62. The new draft IP policy also does not address the issue of whether stockpiling of generic medicines prior to patent expiry should be prohibited. While a WTO panel in 2000 found a Canadian stockpiling exception to be in violation of TRIPS,<sup>52</sup> the Canadian exception permitted stockpiling 6 months prior to patent expiry and was thus exceptionally broad. We recommend a narrow stockpiling provision that is designed to ensure that a sufficient amount of generic product is available for local distribution immediately upon patent expiry.

63. On exceptions, we therefore make the following recommendations:

- 63.1. The Patents Act should exempt those aspects of scientific research and experimentation that are not covered by section 69A.

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<sup>48</sup> See Richard Gold and Yann Joly. (2010). The Patent System and Research Freedom: A Comparative Study, WIPO SCFP/15/3, available at [www.wipo.int/edocs/mdocs/scp/en/scp\\_15/scp\\_15\\_3-annex6.doc](http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex6.doc); Evans Misati and Kyoshi Adachi. (2010). The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda, ICTSD Policy Brief Number 7, available at <http://ictsd.org/i/publications/74497/?view=document>.

<sup>49</sup> Article 9.b of Switzerland's Federal Act on Patents for Inventions makes exception for "any scientific research". In this regard, see [http://www.admin.ch/ch/e/rs/232\\_14/index.html](http://www.admin.ch/ch/e/rs/232_14/index.html).

<sup>50</sup> Brazil's patent law, for example, provides for "acts carried out by unauthorised third parties for experimental purposes, in connection with scientific or technological studies or researches." The wording of this provision appears designed to leave open to broad interpretation the definitions of "experimental purposes" and "scientific research." The provision does not identify the "third parties", suggesting that commercial, public non-commercial, and not-for-profit bodies are all entitled to conduct scientific research under the exception.

<sup>51</sup> See Christopher Garrison. (2006). Exceptions to Patent Rights in Developing Countries, ICTSD Issue Paper No. 17, p. 66, available at [http://unctad.org/en/Docs/iteipc200612\\_en.pdf](http://unctad.org/en/Docs/iteipc200612_en.pdf).

<sup>52</sup> *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000, available online at [www.wto.org/english/tratop\\_e/dispu\\_e/distab\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm).

- 63.2. The Patents Act should be amended also to include an educational-use exception.
- 63.3. The Patents Act should specifically allow generic companies to manufacture, import and/or store generic medicines sufficient to allow for immediate marketing upon patent expiry.
- 63.4. The process of developing broad research exceptions as mentioned in the draft IP policy, which will be done in consultation with stakeholders, must be transparent and open and should take place urgently.

## **VOLUNTARY LICENSING**

- 64. We welcome the inclusion of voluntary licensing provisions in the draft IP policy. Voluntary licences are an important tool, when used properly, to help increase access to medicines and we submit that this is integrally linked to the existence and application of user-friendly compulsory licensing provisions, which we deal with below. The policy must recognise that compulsory licences are not the last resort or that voluntary licences are not the first resort for achieving price reductions.
- 65. In South Africa, the issuance of voluntary licences that have led to dramatic price reductions of ARVs has only occurred after complaints were made at the Competition Commission using competition law. For example, in 2002, TAC lodged complaints against GlaxoSmithKline (GSK) and Boehringer Ingelheim for the excessive prices of zidovudine (AZT) and nevirapine (NVP). The Competition Commission found that the prices of these drugs were excessive and referred the case to the Competition Tribunal. At this point, the patent holding companies backed down and agreed to licence generic manufacturers to produce generic versions of AZT and NVP. Since this case, there has been a hundred-fold drop in the cost of these medicines. However, this process has not yet worked outside of medicines for HIV and Hepatitis C.
- 66. Across the world, government action has led to licences and price reductions from patent holding companies. This must be recognised at the policy level and government processes to investigate compulsory licences should not wait on voluntary licence or price negotiations that are needlessly protracted at the cost of health and lives; indeed, government determination, simple to use legal processes and automatic investigations into access and affordability of patented medicines are more likely spur voluntary licence negotiations to faster and better conclusions.

67. We agree with the dti assessment that the terms and conditions of voluntary licences vary so widely, and that “this is why increased transparency with respect to the terms and conditions in voluntary licences, such as terms exemplified by Medicines Patent Pool (MPP) licences, should be encouraged, thereby enabling voluntary licences that promote access and innovation, come with effective transfer of technology, and do so in full in line with existing TRIPS allowances.” MPP licences are “published in full form on the MPP website”,<sup>53</sup> which has “introduced significant transparency in access-orientated licensing of pharmaceuticals and contributed to setting new standards.”<sup>54</sup> Essentially, the transparency of voluntary licences has allowed for the evaluation of terms and conditions to move towards better practise.<sup>55</sup> To better address the current limitations of voluntary licensing in South Africa – including geographic restrictions, sourcing requirements and price floors -- South Africa should develop a mandatory public register of patent-related licences to create transparency in licensing, and once restrictions are known, appropriate legal remedies through competition law should be initiated - as in Thailand, where all patent-related licences are required to be filed in a public register and examined prior to acceptance for anti-competitive measures, if any, in which case the licence will be rejected.
68. The UNHLP Report recognised that “voluntary approaches are problematic because they are inadequate and not sustainable, and are limited to geographic scope, among other concerns, that is defined by industry”.<sup>56</sup> The restrictions imposed by pharmaceutical companies in voluntary licence agreements, which can include geographical restrictions on where the product can be sold, the price at which it may be sold, or where the active pharmaceutical ingredient for the product may be sourced<sup>57</sup>, can have adverse implications for access to medicines. Also, a licensor who controls where licensee’s source API may prevent them from “seeking out cheaper API in order to drive prices down further.”<sup>58</sup>

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<sup>53</sup> Perry G. (2016). Patent Pooling in Public Health, submission to the UNHLP, available at <http://www.unsgaccessmeds.org/inbox/2016/2/28/greg-perry>.

<sup>54</sup> Ibid, page 3.

<sup>55</sup> Park et al. (2012). el., “Voluntary Licensing: An Analysis of Current Practises and Key Provisions in Antiretroviral Voluntary Licenses” (2012) XIX AIDS Conference, Washington, available at <http://www.medicinespatentpool.org/wp-content/uploads/Voluntary-Licensing.-An-analysis-of-current-practices.pdf>.

<sup>56</sup> The United Nations Secretary General’s High Level Panel on Access to Medicines Report. (2017). Annex 1: Commentaries by J Bermudez, W Byanyima and S Phurailatpam, at page 54, available at <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

<sup>57</sup> Amin T. (2007). Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?, available at <http://apps.who.int/medicinedocs/en/d/Js19793en/>.

<sup>58</sup> Ibid, page 14.

69. The transfer of technology is a significant factor which can determine whether and when a generic company will bring a generic version to market and further access to medicines through competition, insofar that such receipt of technology transfer does not introduce restrictions on the use of the product in South Africa or other countries. Although technology transfer is not always needed to effectively produce low cost generic medicines, a voluntary licence “without the suitable technology transfer may only delay entry to market”.<sup>59</sup> Worse still, generic manufacturers which rely on the technology of originator companies to develop their own product, but do not consider the technology transfer package as the best way to obtain the highest yield, may find the cost of bringing the product to market at a competitive price too costly, where such technology transfer provides such material assistance.<sup>60</sup> The result of only a few generic producers actually going to market often does not affect the price of medicines in a meaningful way to improve access.<sup>61</sup> In some cases, then, the effective transfer of technology is essential to enhance generic competition and consequently drive prices down, insofar that such technology transfer is necessary and to the extent such technology transfer does not create unnecessary restrictions on the sale and use of the product in South Africa and other countries.

70. In respect of voluntary licences, we therefore recommend that transparency in respect of voluntary licensing agreements be operationalised to ensure voluntary licences are available for public scrutiny. The Patents Act already requires the registration of patent-related licences, open for public inspection.<sup>62</sup> Section 10 requires the maintenance of a register with such details, including copies of all deeds and licences as may be prescribed. Such transparency may go a long way to address the current limitations of voluntary licensing in South Africa. We note that this is also in keeping with the constitutional principles of an open society. There is an important public interest in terms and conditions of licences, particularly those concerning royalties to be paid, price restrictions, and geographic restrictions.

### **Publicly funded research**

71. The Intellectual Property Rights from Publicly Financed Research and Development Act (“IPR Act”) has prioritised the transfer of technology by establishing offices of technology

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<sup>59</sup> Ibid, page 13.

<sup>60</sup> Ibid, page 15.

<sup>61</sup> <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>

<sup>62</sup> Section 10 (1) of the Patents Act, read together with Section 12 (1).

transfer in certain institutions.<sup>63</sup> These institutions are tasked with, amongst other things, developing and implementing “benefit-sharing” arrangements in respect of publicly financed research and development (“R&D”).

72. Section 11 of the IPR Act directs recipients of public finance for R&D to give preferences to non-exclusive licensing in intellectual property agreements<sup>64</sup> and to parties that seek to use the intellectual property in ways that provide optimal benefits to “the quality of life of the people of the Republic”<sup>65</sup>. Furthermore, the IPR Act provides that the recipient of State funding must take into account that:

*“each intellectual property transaction must provide the State with an irrevocable and royalty-free license authorising the State to use or have the intellectual property used throughout the world for the health, security and emergency needs of the Republic.”*<sup>66</sup>

73. We consider the IPR Act as instructive in directing non-exclusive licensing, and we support the inclusion of these pro-public health aspects of the IPR Act into the draft IP policy.

74. While the IPR Act requires researchers receiving public funds to disclose any new IP in a timely manner to their relevant Technology Transfer Offices, it does not ensure that use of the relevant institution’s IP does not serve as a barrier to access. While there is nothing stopping these institutions from developing and implementing access-friendly policies that govern the terms and conditions of funding agreements, we are of the view that this should be a statutory requirement. In this regard, the dti should engage with the DST regarding the need to consider possible amendments to the IPRs from Publicly Financed R&D Act.

## **COMPULSORY LICENCES**

75. Compulsory licensing is an important TRIPS flexibility recognised in Article 31. While South African law provides for compulsory licences, the provisions have yet to be used

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<sup>63</sup> Intellectual Property Rights from Publicly Financed Research and Development Act 51, of 2008. The institutions referred to are established at section 6 of the IPR Act, as is defined as “(a) any higher education institution contemplated in the definition of “higher education institution” contained in section 1 of the Higher Education Act, 1997 (Act No. 101 of 1997); (b) any statutory institution listed in Schedule 1; and (c) any institution identified as such by the Minister under section 3(2).”

<sup>64</sup> Ibid, section 11(1)(a).

<sup>65</sup> Ibid, section 11(1)(c).

<sup>66</sup> Ibid, section 11(1)(e).

directly to increase access to medicines. The FTPL welcomes the dti's commitment to ensuring simple and expeditious procedures in respect of compulsory licensing.

76. The 2001 Doha Declaration affirmed that the provisions of the TRIPS agreement do not prevent governments from taking the necessary policy and legal measures to achieve the right to health. The Doha Declaration explicitly states that the TRIPS agreement should be interpreted in a way that promotes access to medicines for all, and that countries are within their rights to take certain measures to limit intellectual property rights (TRIPS flexibilities) when public health interests demand it to enable access to affordable medicines.

77. More recently the UNHLP affirmed and promoted countries' rights to fully utilise TRIPS flexibilities stating:

*“World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies.”<sup>67</sup>*

78. And specifically, on compulsory licensing:

*“(b) Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regard to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.”*

79. Compulsory licensing and public non-commercial use (government use) are important TRIPS flexibilities authorised by Article 31. While the policy recognises both, it is vague in defining the inadequacies present in the current system that have meant neither provision

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<sup>67</sup> United Nations Secretary General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 27. (2016).

has been successfully utilised on a pharmaceutical product to date, and providing recommendations to address these specific challenges within the existing framework.

80. The draft IP policy acknowledges the right of each WTO Member to grant compulsory licences and the freedom of members to determine the grounds upon which licences are granted. Further it recognises that the scope of compulsory licensing must be strengthened and clarified in a manner fair and compliant with TRIPS. In addition, there is recognition that the current judicial process for granting licences is time consuming and costly.
81. In terms of public non-commercial use (government use), the policy recognises that in terms of TRIPS, the South African law unnecessarily requires the government to undergo prior negotiation with companies before making an application to the Commissioner of Patents – and where companies disagree with the conditions attached to a licence, litigation proceedings are required. The draft IP policy suggests that government use be in line with “procedural fairness requirements in South African law”. The draft IP policy should also make clear that the law will be amended to be in line with the minimum requirements of the TRIPS agreement.
82. The draft policy must distinguish government use licenses from national emergency or urgent need licenses, which can be granted expeditiously without prior notice or negotiation with the patent holder (e.g., in the case of a health emergencies.) Like national emergency licenses, government use licenses do not require prior notification or negotiation with the patent holder, though notification and payment of adequate compensation is required after the use. Government use licences, however, do not require a national emergency.
83. South Africa should introduce specific grounds for compulsory licensing related to availability, affordability and accessibility of pharmaceutical products and processes. The Patents Act already allows South Africa to issue compulsory licences, however these provisions have not been used on a pharmaceutical product – in part due to sub-optimal terms and procedures. The grounds for issuing compulsory licences are underspecified and the process of issuing a compulsory licence in South Africa is unclear, both of which act as a substantial barrier to utilising this important flexibility. As clarified in Paragraph 5 of the Doha Declaration, South Africa is free to specify grounds for compulsory licences. Accordingly, South Africa should amend its Patent Act to allow for compulsory licences in cases where: medicine prices prohibit access, supply is inadequate to need, there is a

need for multiple suppliers to avoid stockouts and shortages, the patent holder has refused to grant a voluntary licence on reasonable terms, the medicine is an “essential facility,” there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple right holders, and the medicine is not being adequately worked in South Africa. In addition to these specific grounds, there should be specific allowance of compulsory licences to remedy anti-competitive behaviour (authorised by Article 31(k)) and a more general, “public interest” ground for compulsory licences.

84. South Africa should also simplify compulsory licensing processes and procedures. In terms of process, the South African Patent Act is also unwieldy. It relies on adjudicatory procedures and reviews and allows injunctions that prohibit the early working of the compulsory licence. There are also no guidelines on the time period within which prior negotiations must occur nor on the remuneration that should be paid to patent holders, again complicating the process. Currently an application for a compulsory licence typically has to be brought before the Commissioner of Patents, who is a Judge of the High Court. It is a complex process requiring the use of specialist lawyers, and subject to the vagaries of the system, namely, filling of papers, hearing of arguments, adjournments and often undue delays in the finalisation of the application. The costs to the applicants are prohibitive and they will invariably encounter opposition from patent holders who are usually multinational corporations with deep pockets. Additionally, right holders have the right to appeal adverse decisions and seek injunctions against the operation of the compulsory licence during the period of review. According to a report from United Nations Development Programme (UNDP), in South Africa it may cost up to R1,000,000 and take over three years to undergo court procedures to issue a compulsory licence.<sup>68</sup>

84.1. Both the cost and time factors make this process unsuitable for applications made in the public interest and even more so in situations of health emergencies. TRIPS Article 1 allows Members the freedom to determine the appropriate method of implementing the provisions and hence to adopt a simpler procedure that does not act as a barrier to issuing compulsory licences. The Patents Act should set up a simple, expeditious, administrative (rather than judicial) procedure for hearing applications for compulsory licences, with opportunity for the patent holder to be heard. The Patents Act should also clarify presumptive royalty rates (Section 4) and set time periods for negotiations (Section 56). In addition, as seen below in the example of Ecuador, the process and time periods for the registration of generic

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<sup>68</sup> UNDP. (2007). TRIPs flexibilities, access to medicines and the domestic pharmaceutical industry in South Africa: An analysis of patents, competition and medicines law.



medicines introduced as a result of the compulsory licence should also be simplified and streamlined. Utilising the Bolar provision, the SAHPRA should consider incentives for early registration of generic medicines and biosimilars to ensure that even if a patent exists, these products can be registered. Having products available will support the grounds for issuing government use licences, or for generic companies to apply for compulsory licences. Finally, patent holders should not be entitled to stay the operation of a compulsory licence should the right holder seek review of the issuance of a compulsory licence.

84.2. As clarified in Paragraph 5 of the Doha Declaration, South Africa is free to specify grounds for compulsory licence. Accordingly, South Africa should amend its Patent Act to allow for compulsory licences in cases where: medicine prices prohibit access, supply is inadequate to need, there is a need for multiple suppliers to avoid stockouts and shortages, the patent holder has refused to grant a voluntary licence on reasonable terms, the medicine is an “essential facility,” there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple right holders, and the medicine is not being adequately worked in South Africa.

85. In addition, South Africa should encourage competitors/generic producers to file for compulsory licences. With optimal terms and procedures, competitors and generic companies could be encouraged to file for compulsory licences. Compulsory licence applications by generic companies or competitors provide an important fillip to the government's efforts particularly where a medicine is not provided in the public sector or patient numbers are relatively small, for instance in the case of sorafenib. Sorafenib is indicated for the treatment of advanced renal cell carcinoma and advanced inoperable hepatocellular carcinoma. In South Africa, only originator company Bayer's version of sorafenib is available, sold under the brand name Nexavar. Nexavar is not available in the public sector and can only be accessed in the private sector.

85.1. Sorafenib is generally provided at 800mg daily for as long as clinical benefit is provided. At this dose, a year of sorafenib treatment in South Africa costs approximately ZAR 334,720. Comparably, in India where a generic version is available under compulsory licence, a year of sorafenib treatment costs around ZAR 21,900. Four patents have been granted to Bayer on sorafenib in South Africa that may prevent the use of generic products in the country until 2027 – 26 years after the earliest identified patent was granted. Compulsory licensing could be used as an expedited mechanism to access more affordable generic sorafenib in South Africa – as seen in India.

85.2. In 2011, generic pharmaceutical company Natco Pharma Ltd. filed an application for a compulsory licence on sorafenib tosylate before India's patent controller. The compulsory licence was granted in 2012 for the eight years the medicine would remain patented in India (until 2020), and against the payment of a royalty rate fixed at 6% (at the high end of the UNDP royalty guidelines; in appeal, this rate was increased to 7%). The compulsory licence was issued on the grounds that a) no adequate steps were taken by originator company Bayer to start the working of the invention in India on commercial scale; b) the reasonable requirements of the public were not satisfied; and c) the patented invention was not available to the public at a reasonably affordable price. This is because while Bayer received a licence to import and market the medicine in India in 2007, the company only imported small quantities in 2009 and 2010 which were sold at USD 51,432 per person per year. Natco agreed to supply its generic version for less than USD 1,700 per person per year. On appeal, the decision of the Patent Controller to issue the compulsory licence was upheld. There has since been a 97% price reduction in sorafenib tosylate in the country.<sup>69</sup>

85.3. In 2009, Ecuador introduced Presidential Decree 118 "declaring of public interest, access to medicines used in the treatment of diseases which affect the Ecuadorian population and which constitute a priority in terms of public health, and consequently authorizing the issuing of compulsory licences for patents for medicines for use on human beings which are necessary for their treatment."<sup>70</sup> The Decree requires the Ecuadorian Institute of Intellectual Property (IEPI) to grant compulsory licences together with the national Ministry of Public Health<sup>71</sup>.

85.4. Since the Decree was issued, 32 compulsory licence applications have been made and 9 have been successfully granted. This includes HIV medicines ritonavir in 2010 and abacavir/lamivudine in 2012, cancer medicine Sutinib in 2014, and Rheumatoid Arthritis medicine Certolizumab in 2014. The lower prices achieved from the licences have resulted in cost savings of between 30% and 70% for the Ministry of Public Health<sup>72</sup>. In the case of abacavir/lamivudine, Ecuador used the 2005 WHO/UNDP Tiered Royalty Method (TRM) to set the royalty at 11.7 cents per capsule with the aim of achieving a 75% price reduction from the high price of USD 9,036.<sup>73</sup>

<sup>69</sup> HIV and the Law Commission, 153. (2014). <https://hivlawcommission.org/wp-content/uploads/2017/06/UNDP-Using-Competition-Law-to-Promote-Access-to-Medicine-05-14-2014-1.pdf>.

<sup>70</sup> Ecuador Presidential Decree No. 118, [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=281152](http://www.wipo.int/wipolex/en/text.jsp?file_id=281152)

<sup>71</sup> Ecuador Resolution No. 10-04 P-IEPI. Instructions for Compulsory Licensing of Drug Patents, <http://www.wipo.int/wipolex/en/details.jsp?id=8062>

<sup>72</sup> Resolution of two new compulsory licenses for the country. Press Conference Invitation. Ecuadorian Institute of Intellectual Property. 25 July 2014. Available at <https://www.propiedadintelectual.gob.ec/invitacion-rueda-de-prensa-resolucion-de-dos-nuevas-licencias-obligatorias-para-el-pais/> (in Spanish).

<sup>73</sup> Carlos M. Correa. (2013). The Use of Compulsory Licenses in Latin America. South Views No. 60.

86. While the draft IP policy rightly identifies the need for reforming the patent law in relation to compulsory licensing, the approach to law reform and implementation of compulsory licences should also take into account the role of other laws and institutions in granting them. For instance, in the United States which is perhaps the world's most frequent user of compulsory licensing, there are several examples of licences issued to remedy anti-competitive practices. Thus, the US Federal Trade Commission has required the grant of licences on key pharmaceutical products and technologies in the contexts of several mergers (merger of Ciba-Geigy and Sandoz in 1997, merger of Amgen Inc. and Immunex Corporation in 2002, Guidant's acquisition by Boston Scientific in 2006).<sup>74</sup> In Italy the Competition Authority examined the refusal to licence from a perspective of local production and the ability to use and manufacture API and has for instance required.<sup>75</sup>

87. South Africa should implement laws to encourage the use of royalties, instead of interdicts, as remedies in patent infringement cases. As noted above, the current patent law approach to compulsory licences requires a judicial process which is cumbersome, expensive and prohibitive and must be reformed and replaced with a simpler process to use. However, the judiciary can still play a role in granting compulsory licences during infringement proceedings. Article 44.2 of TRIPS provides for limitations on remedies available for enforcement and recognises the sovereignty of national laws in providing for situations where the only remedies available would be declaratory judgments and adequate compensation. For instance, US courts have declined to issue injunctions and instead have granted royalties as a remedy in infringement cases – in essence issuing a judicially-authorized compulsory licence as authorised by TRIPS Article 44.2.<sup>76</sup> In 2010, the court refused a permanent injunction on a contact lens product even though it infringed patents as it considered the public interest: the court noted, “millions of innocent lens wearers will suffer real adverse consequences if sale is stopped” and the case was not just about “issues of comfort or cosmetics” but about “concerns of proper vision and eye care.”<sup>77</sup>

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<sup>74</sup> See US Federal Trade Commission. (2013). Overview of antitrust actions in health care services and products, available at <https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf>

<sup>75</sup> Autorità Garante della Concorrenza e del Mercato (AGCM). (2007). Press Release: Pharmaceuticals: Antitrust Authority Rules Merck Must Grant Free Licences for the Active Ingredient Finasteride, available at <http://www.agcm.it/en/newsroom/press-releases/1096-a364-merck-active-ingredients-conclusion-of-investigation.html>

<sup>76</sup> See [https://www.keionline.org/sites/default/files/KEI\\_USITC\\_IVN\\_332-543\\_14Feb2014.pdf](https://www.keionline.org/sites/default/files/KEI_USITC_IVN_332-543_14Feb2014.pdf)

<sup>77</sup> Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., Nos. 3:05CV135J32TEM, 3:06CVJ32TEM (US District Court, M.D. Fla., March 26, 2009).

88. South Africa should also introduce standing for civil society in compulsory licences and government use licence proceedings. According to a civil society report released in 2015:

*“Civil society’s role expands far beyond advocacy. Its technical expertise has been integral to removing barriers to medicines access, driving and shaping research agendas, and creating momentum for policy and programmatic changes at the national and global levels. Many CSOs laid the foundation for demand creation, treatment literacy, service delivery and drug affordability for HIV/AIDS, creating a strong base from which other institutions were able to scale up treatment programs.”<sup>78</sup>*

88.1. We recommend that such groups be able to initiate compulsory licensing proceedings through petitions to the government.<sup>79</sup> These would have to be investigated in a time bound manner and result in a written decision. For this to work, access to patent information and the Patent Office for these groups must improve and such groups should be recognised as stakeholders and interested parties. The Patent Office should publish an annual list of patented pharmaceutical products and processes and require patent holders to provide information on which medicine or product the patent relates to. As information provided by patent holders regarding the scope of their patents can be misleading and to ensure that they do not use the provision of such information to deter generic producers, the Patent Office should also publish regularly updated patent landscapes for pharmaceutical products which would assist the government, generic producers and CSOs in identifying where there are truly blocking IP barriers that need to be overcome.

88.2. This recommendation is in line with recommendation 4.3.6 (a) of the UNHLP Report, which provides that “governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines.”<sup>80</sup> The report acknowledges that transparent patent information is an important determinant of health outcomes, in as far as allowing interested parties to more easily review and oppose questionable patent applications and grants and

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<sup>78</sup> Civil Society Coalition. (2015). The Critical Role of Civil Society in Shaping the Market for Antiretroviral Therapy and Direct-acting Antiretrovirals, available at [http://hepcoalition.org/IMG/pdf/report\\_on\\_civil\\_society\\_april\\_1\\_2015\\_1-2.pdf](http://hepcoalition.org/IMG/pdf/report_on_civil_society_april_1_2015_1-2.pdf).

<sup>79</sup> In September 2017, the Malaysian government issued a government use licence on sofosbuvir, which was initiated through a petition submitted by the Positive Malaysian Treatment Access and Advocacy Group (MTAAG+) to the Health Minister in 2015 calling for, amongst other things, a compulsory license to make sofosbuvir based treatment regimens available in Malaysia at an affordable price.

<sup>80</sup> United Nations Secretary General’s High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 37. (2016).

monitor whether officials are applying patentability criteria as required by national laws.<sup>81</sup>

89. South Africa's patent law reform should put in place a compulsory licensing mechanism that regularly reviews the situation of access to patented medicines and a framework for the issue of compulsory licences on multiple medicines at the same time. One potential mechanism in order to ensure access to patented medicines could be the development of an annual review held by the Patent Office, Department of Health and community based groups in order to review of availability, affordability, accessibility of patented medicines. This review process should recommend patented products that could be candidates for compulsory licences and lead to a compulsory licence investigation. Government should proactively seek information from generic manufacturers, patients and doctors on availability, need, and pricing in order to assess the case for a compulsory licence.

## **INTERNATIONAL COOPERATION**

90. We recognise the positive and progressive role that South Africa- both unilaterally and together with the African group - has in recent years played in discussions at the World Health Organization and the World Intellectual Property Organization. South Africa has often been a voice of reason and a moral compass in these forums. We also recognise the South African government's support of the UNHLP and its support of the 3P Project (currently being rebranded as the Life Prize), two important public health initiatives globally.

91. We welcome the recognition in paragraph 7.2. of the draft IP policy that South Africa must continue to play a leading role in these forums as well as the statement that "South Africa will continue to participate in R&D initiatives and multilateral IP forums in a coordinated fashion ensuring that the positions adopted are consistent."

92. In line with the values enshrined in our Constitution, and in the best interests of all people who need medicines across the world, South Africa should continue to play a leading role in advocating for policies that place the right to health and reasonable incentives for real and needs-based innovation ahead of the private interests of private companies. This should include, but not be limited to:

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<sup>81</sup>United Nations Secretary General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 36. (2016).

- 92.1. advocating for the full adoption of public health-related TRIPS flexibilities and against the use of TRIPS plus measures in all countries;
  - 92.2. implementing TRIPS flexibilities in concert with other countries facing common health challenges; and
  - 92.3. investing public funds in innovative and needs-based R&D projects that fully delink the cost of R&D from the price of products.
93. South Africa should also lead international efforts to amend and simplify WTO requirements for compulsory licences for export. The draft IP Policy acknowledges the shortcomings of the Paragraph 6 decision and seeks to simplify this mechanism at the WTO level. The fact that the TRIPS Agreement requires medicines produced under compulsory licensing to be predominantly for domestic use poses significant challenges for countries with limited pharmaceutical manufacturing ability. However, the Paragraph 6 decision fails to adequately address these limitations. The single time the mechanism was used proved to be complex and unwieldy. South Africa should lead the way in ensuring an amendment to the TRIPS Agreement that will ensure easier export of medicines to countries that have issued compulsory licences. This is also in keeping with Recommendation 2.6.1(c) of the UNHLP Report.
94. Furthermore, South Africa should stand in solidarity with other countries often excluded from voluntary licensing deals. South Africa's inclusion is often used as a cover for excluding other countries, like those in North Africa. For instance, the recent pricing agreement on dolutegravir excluded several countries like Thailand and Malaysia who could have benefitted. South Africa should speak out in solidarity with other governments to ensure that no developing countries are left out of licensing arrangements or pricing deals.
95. We fully agree with the draft IP policy's assertion that "It is crucial that we do not erode the gains made multilaterally by assuming TRIPS "plus" IP obligations in bilateral and regional engagements.
96. In addition to not adopting TRIPS-plus IP obligations domestically, South Africa should actively advocate against TRIPS-plus IP obligations in multinational forums such as the African Union.
97. The UNHLP report recommends that:

*“Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfill the right to health.”<sup>82</sup>*

98. It goes on to recommend that governments should not enter into trade agreements without first conducting public health impact assessments:

*“As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.”<sup>83</sup>*

99. We recommend that, in line with this recommendation, South Africa should make public the socio-economic impact assessments conducted in respect of proposed law and policy as well as assessments conducted prior to entering into any trade agreements. All such assessments should involve the relevant stakeholders.

## **CONCLUSION**

100. The FTPL thanks the dti for the opportunity to make these submissions. We note the many instances in which our previous submissions have been taken into account and implemented in this draft IP policy by the dti. FTPL welcomes the focus in this draft policy on IP and public health and encourage the dti’s efforts to respect, protect, promote and fulfil the rights in the Bill of Rights. We once again urge the dti to proceed swiftly to finalise the National IP Policy and to proceed thereafter to publish draft bills to implement Phase 1. We call on the dti to commit to reasonable timeframes for the finalisation of the policy process and the tabling of amendment bills in Parliament.

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<sup>82</sup> United Nations Secretary General’s High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 9. (2016).

<sup>83</sup> United Nations Secretary General’s High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies, 9. (2016).

SEE APPENDIX A - FIX THE PATENT LAW TIMELINE OF INTELLECTUAL PROPERTY REFORM [HERE](#).

SEE APPENDIX B - EXPLORING PATENT BARRIERS TO CANCER TREATMENT ACCESS IN SOUTH AFRICA: 24 MEDICINE CASE STUDIES [HERE](#).