

INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK

FIX THE PATENT LAWS COALITION SUBMISSION

30 September 2016

The Fix the Patent Laws is a joint coalition 31 patient groups, including:

Advocates for Breast Cancer
AmaBele Belles' Project Flamingo
Breast Course 4 Nurses
Breast Health Foundation
Can-Sir
Cancer Association of South Africa (CANSA)
Cape Mental Health (CMH)
Childhood Cancer Foundation of South Africa (CHOC)
DiabetesSA
Doctors without Borders (MSF)
EpilepsySA
Hospice Palliative Care Association (HPCA)
Igazi Foundation
Look Good Feel Better
Marie Stopes South Africa
National Council Against Smoking
Oncology Nursing Association of SA
Pancreatic Cancer Network of SA
People Living With Cancer (PLWC)
Pink Trees
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)
Stop Stock Outs Project (SSP)
The Sunflower Fund
Treatment Action Campaign
Vrede Foundation
Wings of Hope.

INTRODUCTION

- 1 On 6 July 2016, the International Trade and Economic Development division of the Department of Trade and Industry (“the dti”) published the Intellectual Property Consultative Framework (“the Framework”) for public comment. The Framework notes that its purpose is *“not to prescribe South Africa’s IP policy position, but to put forward the perspective of the dti in a consultative instrument to facilitate what will be continuous engagement with governmental partners and society at large.”*¹
- 2 The publication of the Framework comes almost three years after the dti published a draft National Policy on Intellectual Property, 2013 (“the draft IP policy”),² also for public comment. Thus instead of finalising the policy-making process that it began in 2013, the dti has effectively embarked on a fresh process. Of concern is that no explanation is provided in the Framework for this significant change in direction.
- 3 As members of the Fix the Patent Laws Campaign (“the Campaign”), we have engaged with the substantive policy questions at issue for many years. Some of our activities are reflected in the attached timeline of events related to patent law reform in South Africa over the period 1994 to 2016 and is attached as annexure A.³ Importantly, the timeline reflects the very slow “progress” towards patent law reform. Few areas of public policy reform in South Africa have advanced at such a glacial pace.
- 4 Nevertheless, the Campaign welcomes the opportunity to make these submissions, which are to be read together with the joint submission of Médecins Sans Frontières (“MSF”), the Treatment Action Campaign (“TAC”) and SECTION27 dated 17 October 2013 (“the 2013 submission”). That submission, a copy of which is attached as annexure B, was made in response to the publication of – and calls for public comment on – the draft IP policy. As the Campaign, we endorse and align ourselves with the 2013 submission.
- 5 We begin these submissions by addressing the urgent need to speed up the policy-making process, which – amongst other things – includes a call for the dti to commit to reasonable

¹ At para 1.iii

² General Notice 918 of 2013, *Government Gazette* No. 36816 (4 September 2013)

³ See annexure A

timeframes for the finalisation of the process, and the tabling of a Patents Amendment Bill in Parliament. Thereafter, we address the context within which we make our submissions on the substantive IP-related issues. We conclude by addressing the substantive issues.

ADVANCING THE POLICY-MAKING PROCESS

- 6 In recognising the need for urgent action in respect of key aspects of IP policy, which is to be balanced with *“further in depth study in others”*, the Framework recommends that *“the issues be categorized as immediate, medium term and monitoring and evaluation.”*⁴ In particular, it states that in respect of the immediate issues, *“in depth, tangible reforms [will be] suggested in consultation with intergovernmental partners and external stakeholders.”* Significantly, *“[f]inite timelines would be attached to these.”*⁵
- 7 While we welcome the dti’s recognition that urgent steps need to be taken in respect of the issues identified at paragraph 4 of the Framework, we note the absence of any commitment to particular timeframes, as well as the failure to specify the introduction of a Patents Amendment Bill as the relevant endpoint. This is of particular concern given the fact that almost 15 years have elapsed since member states of the World Trade Organization (“WTO”) adopted the Doha Declaration on the TRIPS Agreement and Public Health.
- 8 In terms of process, the Framework must therefore be seen as a step back. Not only does it take the form of a precursor to an IP policy, but it fails to specify an appropriate endpoint, and makes no attempt to express any views on the identified issues. Indeed, the very purpose of highlighting such issues for immediate review is to *“garner the view of governmental partners on how best to achieve an appropriate balance [between private and public interests]”*:⁶

“The aim is to ensure that South Africa protects IPRs and at the same time achieves its objectives of promoting national development imperatives which include among others boosting local manufacturing, innovation and ensuring equitable access to medicines. This will require development of an appropriate framework for granting patents. A number of interventions as outlined below will be explored.”

⁴ At para 2.ii

⁵ At para 2.iii. See also, para 2.i

⁶ Para 4.1.iv

- 9 It is important to reflect that this exploration has taken place since June 2009, when the dti first announced plans to release a policy document dealing with the reform of South Africa's IP legislation.⁷ It took a further four years for the dti to publish the draft policy, and thereafter another three to publish the Framework.
- 10 In such circumstances, we request that the dti state clearly what the immediate domestic review will entail, commit to the introduction of amendment legislation as the relevant endpoint, and provide appropriate timeframes for the completion of each step. In our view, a period of no longer than 18 months should be more than sufficient to embark on and complete the immediate domestic review.

THE RELEVANT CONTEXT

- 11 Before considering the substantive issues that are the focus of the Framework, it is important to address the context within which we make our submissions. In what follows below, which is to be read together with the 2013 submission, we deal with the following three aspects of the relevant context:

- 11.1 First, the relevant legal framework;
- 11.2 Second, the nature of the relationship between IP on the one hand, and industrial development, economic growth, and innovation on the other; and
- 11.3 Third, recent international developments regarding IP and access to medicines.

Legal framework

- 12 As with all laws and policies, the Framework must comply with the Constitution of the Republic of South Africa, 1996 ("the Constitution"). This is clear from section 2 of the Constitution, entitled "*Supremacy of Constitution*", which provides as follows:

"This Constitution is the supreme law of the Republic; law or conduct inconsistent with it is

⁷The Department of Trade and Industry (the dti) Budget Vote Address delivered by Dr Rob Davies, Minister of Trade and Industry, June 30 2009, available online at: <http://www.politicsweb.co.za/documents/rob-davies-plans-for-industrial-policy>

invalid, and the obligations imposed by it must be fulfilled.”

- 13 While the Framework recognises that the Constitution is to play a key role in the development of the IP policy, its centrality does not appear to be appreciated:⁸

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

- 14 Further, in dealing with the Constitution, the Framework places an undue focus on section 25 entitled “Property”:⁹

“The South African Constitution guarantees the right to property and that no law may permit arbitrary deprivation of property. In terms of the Constitution, property is not limited to land and would by implication include IP. This interpretation is consistent with Constitutional Court jurisprudence. In addition, the Constitution provides a balanced approach to property rights by also taking into account public interest. In this regard, public interest includes the nation’s commitment to bring about reforms that promote equitable access. A balanced approach will be taken in the development of the IP policy in line with the Constitution.”

- 15 We have at least three principled objections to the manner in which the Framework deals with the Constitution:

- 15.1 First, the relevance of the Constitution is not limited to section 25. In line with a range of international and regional human rights instruments and declarations, the Constitution expressly recognises health as a fundamental human right. In particular, section 27 imposes an obligation on all organs of state to take reasonable legislative and other measures, within available resources, to achieve the progressive realisation of the right to have access to health care services.¹⁰

⁸ Para 1.v

⁹ At para 1.vii (footnotes omitted)

¹⁰ Section 27(2)

- 15.2 Second, section 25 of the Constitution does not expressly guarantee a right to property.¹¹ Instead, subsection (1) – which is framed in the negative – states that “[n]o one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property”.
- 15.3 Third, while IP is most likely to be considered as property for the purposes of section 25 of the Constitution, there is a distinction to be drawn between existing rights on the one hand, and rights that have yet to vest. Any variation in the statutory framework prior to the vesting of such rights cannot constitute a deprivation of property, given that the source of such rights is the relevant statute.
- 16 In any event, the way the Framework addresses the issue simply assumes that IP is to be treated the same as any other form of property. But this does not accord with our law. As a retired judge of the Supreme Court of Appeal (“the SCA”) recently stated in a paper prepared for the World Intellectual Property Organization (“WIPO”) Advisory Committee on Enforcement:¹²
- 17 This position is in line with the Constitutional Court’s approach to IP in its first judgment on the certification of the Constitution:¹³

“South Africa does not regard IPRs as something superior to other forms of legal rights. There is no constitutional right to an IPR. IPRs are on the same level as other rights and their enforcement is dealt with in a similar manner.”

“A further objection lodged was that the [new text] fails to recognise a right to intellectual property. Once again the objection was based on the proposition that the right advocated is a ‘universally accepted fundamental right, freedom and civil liberty’. Although it is true that many international conventions recognise a right to intellectual property, it is much more rarely recognised in regional conventions protecting human rights and in the constitutions of acknowledged democracies. It is also true that some of the more recent constitutions, particularly in Eastern Europe, do contain express provisions protecting intellectual property, but this is probably due to the particular history of those countries and cannot be

¹¹ This is in contrast to section 28(1) of the Constitution of the Republic of South Africa Act 200 of 1993 (“the interim Constitution”), which expressly recognises that “[e]very person shall have the right to acquire and hold rights in property and, to the extent that the nature of the rights permits, to dispose of such rights.”

¹² Justice Louis Harms, “A South African Experience” (at para 5, p 15), available online at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_11/wipo_ace_11_7.pdf

¹³ *Ex parte Chairperson of the Constitutional Assembly: In re Certification of the Constitution of the Republic of South Africa*, 1996 1996 (4) SA 744 (CC) at para 75 (footnotes omitted)

characterised as a trend which is universally accepted. In the circumstances, the objection cannot be sustained.”

- 18 In going forward, we urge the dti to take our three principled concerns into consideration. In particular, instead of maintaining a focus on property rights, the dti would be well-advised to recognise the utilitarian purposes underpinning the statutory grant of exclusive rights in property. To the extent that the granting of such rights undermines the constitutionally-entrenched right of access to health care services, it cannot be justified.

IP and industrial development, economic growth, and innovation

- 19 The introduction to the Framework expressly recognises IP as *“an important policy instrument in promoting innovation, technology transfer, research and development (R&D), industrial development and more broadly – economic growth.”*¹⁴ But what is presented as uncontroversial fact is in reality highly contested. This much was recognised by the Minister of Trade and Industry in his 7 April 2016 keynote address to WIPO’s International Conference on Intellectual Property and Development.¹⁵ In the following two parts of this section, we refer to specific passages from Minister Davies’ address that make this clear.

IP, industrial development and economic growth

- 20 The Framework identifies the pharmaceutical sector as a *“priority sector”* for industrial development with the potential for *“tremendous growth”*, noting that the IP Policy still to be developed should complement government’s industrial development aims, including growth of the pharmaceutical sector. Yet the available evidence demonstrates the contrary: that IP protections may actually inhibit the growth of the pharmaceutical sector, particularly in countries with strong capacities for generic production.¹⁶
- 21 South Africa’s pharmaceutical sector experienced a decline after the country increased IP protection in 1997, purportedly in an attempt to implement its obligations under the WTO’s

¹⁴ Para 1(i)

¹⁵ The Minister’s address is available at <https://www.thedti.gov.za/delegationspeechdetail.jsp?id=3704>

¹⁶ C Tomlinson and L Rutter, “The Economic and Social Case for Patent Law Reform in South Africa”, February 2014, found online at: <http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf> at 4

Agreement on Trade-related Aspects of Intellectual Property Rights (“TRIPS”).¹⁷ Over the same period, the local pharmaceutical sector in India experienced massive growth. Unlike South Africa, India made full use of the transition period granted under WTO rules until 2005 for the implementation of its TRIPS obligations.¹⁸

- 22 India’s experience is not unique. Many of today’s developed countries were able to borrow and copy technology from wealthier countries to develop their own industries during the twentieth century (and prior to the introduction of the TRIPS Agreement).¹⁹ As Minister Davies explained in his address to WIPO, in which he considered the relationship between IP, industrial development and economic growth:

“Considerable work has been undertaken in the relationship between IPR and economic development, including excellent work under the aegis of WIPO. In our reading of this literature, it seems clear that the international community is far from reaching a convergence on the question. Indeed, this field of work remains a site of contestation.

While few policymakers, commentators or academics deny the importance of IP protection and enforcement, the questions revolve around nature of the standards that should be implemented and enforced, and whether this changes over time as countries industrialize and develop.

...

During the 19th Century, today’s advanced economies used the IP system and the flexibility it accorded in a judicious manner as they pursued their industrialization. This allowed those countries to strengthen their IP regimes at their own pace, and in support of overall progress in their economic development.

...

More recently, we see that India pursued an alternate path in so far as it has taken advantage of the transitional provisions in TRIPS to develop a globally competitive pharmaceutical industry. By so doing, India has been able to increase global output and competition, thereby enhancing economic welfare. In the process, the industry in that country has become increasingly innovative and has sought to make greater use of the patent system.

¹⁷ C Maloney C and N Segal, “The Growth Potential of the Pharmaceuticals Sector in South Africa”, South Africa, Johannesburg: Genesis Analytics (Pty) Ltd; 2007, available online at: [http://ipasa.co.za/Downloads/IPASA%20and%20Pharmaceutical%20Industry%20Profile/GENESIS%20Pharmaceuticals%20Report%20070529%20\(2\).pdf](http://ipasa.co.za/Downloads/IPASA%20and%20Pharmaceutical%20Industry%20Profile/GENESIS%20Pharmaceuticals%20Report%20070529%20(2).pdf) at 7

¹⁸ Tomlinson and Rutter, at 3

¹⁹ H Odagiri, A Goto, A Sunami and R Nelson, *Intellectual Property Rights, Development and Catch-up: An International Comparative Study* (Oxford University Press: Oxford, 2011) at 451. See generally, Ha-Joon Chang, *Kicking away the ladder: Development Strategy in Historical Perspective* (Anthem Press: London, 2002)

The essential point of drawing on these examples is simply to reiterate that countries have taken different paths in pursuing economic development and they have used IP protection in different ways and at different times to support their development effort.”

- 23 With this in mind, we welcome the Framework’s proposal that South Africa pursue a “*development-oriented IP policy which is cognizant of the international, regional and domestic context*”,²⁰ stating that it will look to the experiences of other BRICS countries in using TRIPS flexibilities to respond to countries’ developmental needs.²¹ But as we explain below, South Africa should also consider the experiences of other developing countries, including – for example – Argentina and the Philippines.

IP and innovation

- 24 While the introduction to the Framework identifies IP as “*an important policy instrument in promoting innovation*”,²² other parts of the document recognise the inherent limitations of IP, providing a more nuanced perspective – for example – on the relationship between patent protection and innovation in the health sector:²³

“[The World Health Organization (“WHO”)] has been engaged in efforts to address identified weaknesses in the global R&D system which is reliant on market based incentives such as patents. The current R&D regime has stimulated significant innovations and will continue to do so but it has not been able to address issues such as lack of affordability, limited research where market returns are small or uncertain (including the ‘neglected diseases’ that predominantly affect the world’s poorest), inefficient overlap of research efforts, and overuse of medicines such as antibiotics.”

- 25 At the international level, there is increasing recognition that the patent system is failing to address global health needs.²⁴ Historical evidence from the US National Bureau of Economic Research “*suggests that patents were not a necessary condition for innovation, and the large majority of innovations occurred outside of the patent system.*”²⁵ On the contrary, “[p]olicies that limit the scope of patents (such as compulsory licensing) have encouraged innovation, while policies that strengthen the monopoly power conveyed by patents (such as unregulated

²⁰ See para 1.ix

²¹ Para 4.2

²² Para 1.i

²³ Para 4.3.vii

²⁴ See, for example, A Kesselheim, B Wang, and J Avorn, “Defining ‘Innovativeness’ in Drug Development: A Systematic Review” (2013) 94(3) *Clin Pharmacol Ther.* 336

²⁵ P Moser, “Patents and Innovation in Economic History”, (28 January 2016), available online at Social Science Research Network: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2712428

patent pools) have unambiguously discouraged innovation".²⁶

- 26 The failure of the IP system to deliver affordable health technologies that address global health needs has led to calls from civil society, governments, UN agencies, and even members of the pharmaceutical industry for the adoption of new innovation models that prioritise such needs.²⁷ In this regard, the recently-adopted Johannesburg Declaration – a civil society declaration on the UN Secretary-General’s High-Level Panel on Access to Medicines – explains:²⁸

“A system of financing biomedical research and development that relies upon the grant of monopolies – and the search for profits through high prices – produces innovation gaps, inefficiencies, and distortions in the development of new health technologies, as well as avoidable death and suffering due to high prices and lack of access to health technologies.

...

All governments have a duty to invest public resources in basic science and in medical research and development and to ensure efficient and effective systems of private research and development as well. Public funding whether through grants, contracts, innovation inducement prizes, or other incentive mechanisms and research subsidies must be adequate, sustained, and responsive to health needs, and policies should maximize the benefits to the public. To the extent possible, and where appropriate, coordination mechanisms should be established for national, regional, and global R&D efforts.”

- 27 In his address to WIPO on 7 April 2016, Minister Davies recognised that the “[t]he role of patent protection in promoting innovation has also been controversial.” He explained:

“There are arguments that patents are unlikely to foster innovation in developing countries at early stages of industrialization. The evidence on the extent to which patent protection contributes to encouraging innovation is, at best, inconclusive. This point is of particular relevance to industrial policies since some studies contend that other factors, notably ‘first mover’ advantages, are more decisive in promoting innovation.

Proponents of stronger IPR regimes, by contrast, suggest that IPR protection fosters innovation in reforming countries. They also argue that stronger IPR facilitates transfers of technology to reforming countries, increases foreign direct investment (FDI), and spurs

²⁶ Ibid

²⁷ See recommendation of the UN High Level Panel on Access to Medicines at para 4.3.4 Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to (i) the costs of R&D, production, marketing and distribution of health technology for procurement or marketing approvals and (ii) any public funding received in the development of health technology, including tax credits, subsidies and grants.

²⁸ The Johannesburg Declaration was adopted on 17 March 2016. The text is available at

<http://tac.org.za/sites/default/files/Johannesburg%20Declaration%20.pdf>

industrial development. They point to the growing literature that shows a correlation between IPR reform and industrial development and argue that the concerns that a shift to stronger IPR would undermine industrial development are overstated.”

- 28 Implicit in Minister Davies’ address is the recognition that correlation is not the same as causation. Significantly, he noted that high levels of IP protection may only be appropriate once a particular level of innovation has already been achieved:

“In countries at an early stage of industrialization where technologically mature technologies may be embedded in equipment, strong IPR regimes may be unnecessary. As the manufacturing production of a country becomes more diversified and higher value added is sought (e.g. fine chemicals, electronic equipment and consumer goods) IPRs may growingly narrow down the freedom to operate in the absence of a license authorizing the use of the protected technologies and designs. Where countries begin to develop their own innovation through greater investment in R&D, the demand for stronger IPR protection is likely to grow in tandem.”

- 29 In our view, IP policy in South Africa should not only expressly recognise the severe limitations of the IP system in delivering innovation to address global health needs, but should also be mindful of the importance of pursuing new (non-patent based) innovation models. Thus while South Africa is required by its international obligations to recognise certain levels of IP protection, it must do so in a manner that does not hinder the country’s ability to foster innovation in other ways.

Recent international developments on IP and access to medicines

- 30 On 14 September 2016, the UN Secretary General’s High-Level Panel on Access to Medicines released its much-anticipated report.²⁹ Chaired by two former presidents,³⁰ the panel’s objective was *“to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”* Its members included South Africa’s current Director-General of Health, Ms Malebona Matsoso.

- 31 Amongst other things, the report recommends that WTO members *“must make full use of the*

²⁹ For information on the panel’s composition and work, see <http://www.unsgaccessmeds.org/new-page/>

³⁰ Mr Festus Mogae, the President of Botswana from 1998 to 2008; and Ms Ruth Dreifuss of Switzerland, who was also the chairperson of the WHO’s Commission on Intellectual Property Rights, Innovation, and Public Health (which concluded its work in 2006).

... [TRIPS] flexibilities as confirmed by the Doha Declaration to promote access to health technologies when necessary.” It adds that countries should also use the policy space available to them 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”, which “includes amending laws to curtail the evergreening of patents and awarding patents only when genuine innovation has occurred.”³¹

- 32 Insofar as the use of TRIPS flexibilities is concerned, the executive summary of the report also includes the following recommendations:³²

“Governments should adopt and implement legislation that facilitates the issuance of compulsory licences. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licences for legitimate public health needs, and particularly with regards 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 licences left to the discretion of governments.”

“Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be reported to ... the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure which includes taking punitive measures against offending WTO Members.”

- 33 We attach a copy of the executive summary of the report as annexure C. The full report is available online.³³ In our view, the report should assist the dti in taking the immediate domestic review agenda forward as a matter of urgency.

COMMENTS ON SUBSTANTIVE PROVISIONS OF THE IP FRAMEWORK

- 34 In the last section of this submission we address eight of the substantive issues identified under the heading “Immediate domestic review”.³⁴ We do not consider two issues: local manufacture and export in line with industrial policy; and voluntary licensing. While IP policy must be aligned – wherever possible – with industrial policy, we submit that this cannot be done at the expense of the right of access to health care services. And insofar as voluntary

³¹ At page 9

³² Ibid

³³ See <http://www.unsgaccessmeds.org/final-report/>

³⁴ We addressed these issues in our 2013 submission on the draft IP policy.

licensing is concerned, we submit that this is integrally linked to the existence and application of user-friendly compulsory licensing provisions.

Substantive search and examination³⁵

35 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.”

36 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”)³⁶ – 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 formal requirements.

37 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”,³⁷ “prescribing the contents of any application, notice or form provided for in this Act”,³⁸ and “as to any other matter required or permitted by this Act to be prescribed by regulation”.³⁹ To date, the Minister has published two sets of regulations: the Patent Regulations of 1978;⁴⁰ and the Patents Examination Regulations.⁴¹

38 Contrary to what is contained in section 34 of the Patents Act, neither set of regulations deals

³⁵ Substantive search and examination is addressed in the 2013 submission at paragraphs 54 to 60 and 64.

³⁶ Section 2 of the Patents Act, read together with section 189 of the Companies Act, 2008

³⁷ Section 91(c)

³⁸ Section 91(f)

³⁹ Section 91(g)

⁴⁰ Government Notice No. R 2470, *Government Gazette* No. 6247 (15 December 1978)

⁴¹ General Notice 25, *Government Gazette* No. 24290 (17 January 2003)

with substantive patent examination.

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

38.2 The Patent Regulations are limited to administrative matters:

38.2.1 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.”

38.2.2 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.”

39 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 innovations. 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:⁴²

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

39.2 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;

⁴² 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.

- 39.3 prioritise the recruitment of and training of more patent examiners;
 - 39.4 train existing staff to undertake examinations and ancillary tasks;
 - 39.5 recruit and/or train management staff to take responsibility for various aspects of the examination process;
 - 39.6 develop appropriate IT systems to ensure transparency and access to information, in line with our recommendations on patent searches and patent opposition procedures;
 - 39.7 improve the classification of patents system currently in use at CIPC;⁴³ and
 - 39.8 make provision for a reasonable budget to achieve these objectives.
- 40 With these recommendations in mind, we welcome the following aspects of the Framework dealing with substantive search and examination:
- 40.1 an interpretation of Article 27.1 of TRIPS that recognises that health-related or other classes of patents may be prioritised for examination;
 - 40.2 the recognition that the current depository system has major drawbacks;
 - 40.3 the indication that the recruitment of patent examiners has already begun; and
 - 40.4 the recognition that the examination system should be established in conjunction with pre- and post-grant opposition proceedings.

Patent oppositions⁴⁴

⁴³ The current system combines pharmaceutical products with cosmetic products, is not easily searchable, and is not readily available to the public.

⁴⁴ The 2013 submission deals with this topic at paragraphs 61 to 64.

41 We welcome the Framework’s recognition that revocation proceedings, which are currently the only way to challenge a patent, “*entail the prohibitive costs and risks of litigation*”, and that “*South Africa should consider the most efficient ways of utilizing opposition procedures in line with international best practice and pursuant to stakeholder input.*”⁴⁵ In so doing, the dti is urged to consider the following four issues carefully:⁴⁶

41.1 First, the stage at which opposition procedures should be introduced – whether before, at the time of, or after a substantive examination begins, or a combination;⁴⁷

41.2 Second, the need for procedures that provide adequate time for the filing of a patent opposition,⁴⁸ and take into consideration the state of access to timely information on patent applications;

41.3 Third, the need to contain the costs associated with the filing of a patent opposition; and

41.4 Fourth, the need to recognise that standing to file a patent opposition should be as broad as possible, including in particular standing to oppose the grant of a patent in the public interest.

42 We thus make the following recommendations in relation to patent opposition procedures:

42.1 The Patents Act should be amended to –

42.1.1 provide for easy-to-use pre- and post-grant opposition mechanisms that recognise broad standing requirements;

42.1.2 facilitate timely access to all information necessary to oppose effectively; and

⁴⁵ At para 4.1.3.ii

⁴⁶ See generally, MSF’s Patent Opposition Database, available at <http://www.patentoppositions.org>.

⁴⁷ In India, a third party can file an opposition once the patent application has been published.

⁴⁸ In Thailand, there is only a three-month window to file a pre-grant opposition, meaning that, even before patient groups have found the relevant patent application relating to a drug, the deadline for filing the opposition has usually expired. In Argentina, for example, documents must be translated officially in order to file an opposition; this in itself can cost \$10,000, making it prohibitively expensive for patient groups.

42.1.3 ensure that the costs of opposition are not prohibitive, meaning that they should be dealt with administratively (and not by the Commissioner of Patents); and

42.2 The dti and CIPC should –

42.2.1 develop and implement a reasonable plan for the phasing in of pre- and post-grant opposition proceedings (as part of setting up a substantive patent examination system); and

42.2.2 determine the resources needed, and budget appropriately for the development and implementation of such proceedings.

Patentability criteria⁴⁹

43 South Africa grants an exceptionally high number of patents. In part, this is because the country does not conduct substantive patent examinations. But it is also as a result of the weak patentability criteria recognised in our law,⁵⁰ and as applied by the courts. In our view, both of these issues must be addressed in order to ensure a patent system that serves the public interest, and advances South Africa’s developmental needs.

44 Article 27.1 of TRIPS, which deals with the patentability of inventions, affords WTO members significant flexibility when setting criteria. All that the provision requires is that patents be granted for inventions that are new, involve an inventive step, and are capable of industrial application. Significantly, TRIPS does not set out what is meant by these three requirements. Instead, the footnote to Article 27.1 provides as follows:

“For the purposes of this Article, the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious and ‘useful’ respectively.”

45 In other words, WTO members may – but are not required to – treat the term “*inventive step*” as the same as the term “*non-obvious*”, and to treat the term “*capable of industrial*

⁴⁹ The 2013 submission deals with this topic at paragraphs 41 to 49.

⁵⁰ See for example section 25(9) of the Patents Act.

application” as the same as the term *“useful”*. Implicit in this deeming provision is that inventive step may indeed mean something more than non-obvious, and that capable of industrial application may be more specific than useful.

- 46 The Framework thus correctly recognises that TRIPS gives South Africa the flexibility to improve and strengthen patentability criteria. In line with section 27(2) of the Constitution, the Framework correctly states that public health concerns should be taken into account when considering patentability criteria. Both of these recognitions are to be welcomed.
- 47 WTO member countries have adopted widely varying patentability criteria.⁵¹ For example, there are strict standards in Argentina⁵², for example, that ensure that only applications that are novel, involve inventive step and capable of industrial application are granted.⁵³
- 48 In dealing with patentability criteria, the Framework correctly states that *“[i]nternational best practice from a broad range of sources should be considered in order to develop an appropriate approach for South Africa.”*⁵⁴ In so doing, however, we submit that the dti should pay particular attention to the relevance of international comparators, keeping in mind what is appropriate for South Africa’s socio-economic context and constitutional dispensation. Put differently, we should prioritise the approaches of other developing countries (such as Argentina, Brazil and the Philippines in particular).
- 49 In determining an appropriate course of action, we submit that there are at least three considerations that must be taken into account in determining which approach to adopt: the impact of patentability criteria on access to medicines; the impact of patentability criteria on innovation; and the economic impact of patentability criteria. All must be guided by the state’s constitutional obligations. We deal with these considerations in turn.

⁵¹ See Lionel Bently et al, “Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights”, WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I (2010), available at http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf

⁵² Argentina introduces tougher standards for patentability. South Africa should follow suit., Fix the Patent Laws, May 28 2012, available online at: http://www.fixthepatentlaws.org/?p=288#_ftn1

⁵³ Other countries, such as Brazil, have contemplated a move in this direction. In Brazil’s case, this has included the drafting and consideration of legislation to expand the use of TRIPS flexibilities. See “Open Letter from Global Academics in Support of Proposal to Amend Brazil’s Patent Law to Take Advantage of TRIPS-Compliant Flexibilities”, available at <http://infojustice.org/support-brazil>.

⁵⁴ At para 4.1.4.ii

- 49.1 Stricter patentability criteria could serve to reject methods of treatment, new use and/or formulation/dosage patents, known processes for making medicines, and new forms of known medicines. Coupled with substantive examination procedures, this could reduce the number of secondary patents granted on pharmaceutical products. In turn, this would result in the earlier introduction of generic competition, which in turn would result in significant price reductions.⁵⁵ This is particularly important for South Africa, with its extremely high burden of both communicable and non-communicable diseases.
- 49.2 Setting higher patentability criteria should create incentives for pharmaceutical companies to invest in the development of truly innovative medicines, such as new molecular entities and new classes of medicines. In contrast, low patentability criteria simply encourage evergreening. From a developmental perspective, an approach that seeks to reward significant innovation is clearly preferable.
- 49.3 Weak patentability criteria often have a deleterious economic impact. By granting secondary patents, pharmaceutical companies are enabled to charge high prices for extended periods of time, in return for relatively low public health returns. There is no evidence to suggest that many of these “improved” products would not make it to market in the absence of patent protection.
- 50 In the result, we make the following recommendations:
- 50.1 The Patents Act should be amended to include stricter patentability criteria. In the context of medicines and other health-related products, patentability criteria should be sufficiently detailed and specific to ensure that patent examiners are able to distinguish between what is and is not patentable.
- 50.2 In particular, new uses of known substances should be expressly excluded from patentability as should compounds or admixtures of known substances. This will

⁵⁵ See Carlos Correa, “Pharmaceutical Innovation, Pharmaceutical Patenting and Compulsory Licensing”, South Centre Research Paper 41 (2011), available at http://www.southcentre.org/index.php?option=com_content&view=article&id=1601%3Apharmaceutical-innovation-incremental-patenting-and-compulsory-licensing&catid=41%3Ainnovationtechnology-and-patent-policy&Itemid=67&lang=en

require amendments to sections 25(9), 25(11) and 25(12) of the Patents Act.

- 50.3 New forms of known substances should not be patentable, either at all, or to the extent that they fail to demonstrate the required degree of inventive step. Setting the bar for inventive step high, as has been done in Argentina, is TRIPS-compliant.

Disclosure requirements

51 TRIPS Article 29.1 requires disclosure in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, it implicitly allows requirements that applicants disclose all methods of implementing the invention known to the inventor at the time of filing and explicitly allows identification of the best known method of implementation. China has taken this flexibility in Article 26.4 of the Patent Law amended as of 2008.

52 TRIPS Article 29.2 specifically permits Member States to require disclosure of the status of foreign patent applications for the same invention. Such disclosure can be very useful to countries such as South Africa, where patent examination capacity will be limited initially. With an initial disclosure requirement and an explicit duty to supplement such information regularly, patent examiners in South Africa can be informed of grants, denials, suspensions, and even invalidations. India has taken partial advantage of this flexibility in section 8 of the Indian Amended (2005) Patents Act.

53 It is often extremely difficult to identify the subject matter of a patent application on medicines given their technical nature and often obscure or meaningless titles. Likewise, there can also be multiple patents filed with respect to a particular final pharmaceutical product and it may be extremely difficult to discover all these related patents. As a result, South Africa should require applicants filing patent applications pertaining to pharmaceuticals to disclose the international non-proprietary name (INN) of the medicines to which the patent application applies. Where an INN has not yet been assigned, the patent holder should be required to submit the relevant INN within 30 days of it being assigned.

Parallel importation⁵⁶

⁵⁶ The 2013 submission addresses parallel importation at paragraphs 80 to 84.

- 54 Article 6 of TRIPS facilitates parallel importation which allows for the 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. Given that patented products are sold at different prices in different markets, this measure allows for the importation of a patented product from countries in which it is sold at a lower price into those countries where the same patented product is being sold at a higher price.
- 55 Parallel importation gives effect to the principle of exhaustion of rights, which provides that once patentees or other authorised parties have sold a patented product, they cannot prohibit the subsequent resale of that product (since their rights in respect of that market have already been exhausted). Once a product has been sold, the exclusive rights holder has no further right over the sold product – the patentee’s rights are therefore “exhausted”.
- 56 Section 15C(b) of the Medicines Act 101 of 1965 makes provision for parallel importation. Yet to date, no medicines have been imported into South Africa using regulation 7 of the General Regulations, 2003, which purports to give effect to section 15C(b). We submit that various provisions in regulation 7, which are not required by TRIPS, undermine the parallel importation regime contemplated by section 15C(b). Amongst others, these include –
- 56.1 regulation 7(2), which requires the submission of extensive documentation to the Minister of Health, despite there being no administrative infrastructure to handle such submissions;
- 56.2 regulation 7(2)(e)(iv), which requires the applicant to provide documentary evidence of the price at which the imported medicine will be sold, even though this may not be known at the time the application is made;
- 56.3 regulation 7(3), which limits the parallel importation permit to two years, in so doing placing competition in jeopardy at the end of the two-year period; and
- 56.4 regulation 7(5), which requires the applicant to seek full registration of the imported medicine, despite the product being the subject of a two year importation permit.

- 57 Because state tenders are typically only issued every two years, the chances of any parallel trader being able to secure a permit and registration in time to make a competitive bid are slim to non-existent. Without adequate economic incentives and easier-to-use procedures, parallel importation will not occur – to the detriment of both patients and the public purse.
- 58 The Framework is therefore correct to note that there are problems with South Africa’s current parallel importation regime. Noting that “[a] narrow interpretation of section 45(2) of the Patents Act in its current form could potentially give rise to challenges should parallel importation be pursued”,⁵⁷ the Framework recommends “explicitly incorporating total international exhaustion into the Patents Act”, which it says “would clarify matters”.⁵⁸ We welcome the retention of an international exhaustion of rights regime.
- 59 What remains unclear, however, is what would happen to section 15C(b) of the Medicines Act and regulation 7 of the General Regulations, 2003. In our view, any amendments to the Patents Act should be accompanied by appropriate amendments to regulation 7 of the General Regulations, whilst keeping section 15C(b) of the Medicines Act in place. In the absence of this empowering section, parallel importation would not be able to take place without full domestic registration. If this were to be required, a regulatory barrier would effectively have replaced an IP barrier.

Exceptions⁵⁹

- 60 Article 30 of TRIPS allows WTO members to legislate “limited exceptions” to the exclusive rights conferred by a patent. This provision is to 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 technological development.
- 61 Under Article 30, WTO members may provide exceptions for regulatory purposes (such as medicines registration), as well as for broader research and education purposes.⁶⁰ As the

⁵⁷ Footnote 19

⁵⁸ Para 4.1.6.ii

⁵⁹ Exceptions to patent infringement are dealt with at paragraph 91 to 98 of the 2013 submission.

⁶⁰ Phoebe H Li, “Rights and responsibilities in patents: a precautionary patent framework in WTO law” (2013) 35:9 *European Intellectual Property Review* 516.

Framework notes, the WHO “has recommended that member States should consider, where appropriate, use of a ‘research exception’ to address public health needs in developing countries.”⁶¹ The exact scope of Article 30 remains somewhat contested. For current purposes, however, we need not concern ourselves with this debate.

- 62 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*,⁶² in which the court held that the concept of contributory infringement is part of our law.
- 63 Put simply, the MCC 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.
- 64 In our view, section 69A 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.⁶³ A number of them also make express statutory provision for broad research exceptions.⁶⁴
- 65 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”:⁶⁵

⁶¹ At para 4.1.7.iii

⁶² 2013 (4) SA 579 (SCA).

⁶³ See Richard Gold and Yann Joly, “The Patent System and Research Freedom: A Comparative Study”, WIPO SCFP/15/3 (2010), available at www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex6.doc; Evans Misati and Kyoshi Adachi, “The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda”, ICTSD Policy Brief Number 7 (2010), available at <http://ictsd.org/i/publications/74497/?view=document>

⁶⁴ 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

⁶⁵ Article 43, Paragraph II, Law n. 9.279 of 14 May 1996, available at http://www.jpo.go.jp/shiryuu_e/s_sonota_e/fips_e/pdf/brazil/industrial_property_law.pdf

- 65.1 The wording of this provision appears designed to leave open to broad interpretation the definitions of “*experimental purposes*” and “*scientific research*”.
- 65.2 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.
- 66 In addition to adopting a broad research exception, we submit that 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.⁶⁶
- 67 One final issue on exceptions needs to be addressed: the draft IP policy’s suggestion that the stockpiling of generic medicines prior to patent expiry be prohibited. While a WTO panel in 2000 found a Canadian stockpiling exception to be in violation of TRIPS,⁶⁷ we submit that the nature and scope of that exception – which allowed for the manufacturing and stockpiling of generic products up to six months before patent expiry – was indeed problematic. We recommend instead 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.
- 68 On exceptions, we therefore make the following recommendations:
- 68.1 The Patents Act should exempt those aspects of scientific research and experimentation that are not covered by section 69A;
- 68.2 The Patents Act should be amended also to include an educational-use exception; and

⁶⁶ See Christopher Garrison, *Exceptions to Patent Rights in Developing Countries*, ICTSD Issue Paper No. 17, p. 66 (2006), available at http://unctad.org/en/Docs/iteipc200612_en.pdf

⁶⁷ *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.

- 68.3 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.

Compulsory licenses⁶⁸

69 Article 31 of TRIPS, entitled “*Other Use Without Authorization of the Right Holder*”,⁶⁹ grants to WTO members the right to legislate “*other use of the subject matter of a patent without the authorization of the right holder*”. This use of a patent, without the patentee’s consent, may be “*by the government or third parties authorized by the government*”. In other words, the state may issue compulsory licences – either to third parties or to itself.⁷⁰ If it does make provision for compulsory licensing in its laws, a WTO member is obliged to respect the provisions set out in Articles 31(a) to 31(l).

70 While compulsory licensing is already part of our law, it has yet to be used directly to increase access to medicines. In this regard, both the draft IP policy and the Framework recognise the need to amend existing legislation to address the shortcomings in the utilisation of compulsory licensing measures. Amongst other things, the Framework recognises that TRIPS “*does not require the grant of compulsory licenses to be made subject to a judicial process.*” With this in mind, it suggests that “[*a*] *more streamlined and accessible administrative process should be considered.*”⁷¹

71 Three provisions of the Patents Act already deal with the grant of compulsory licences – sections 4, 55 and 56:

71.1 Section 4, in terms of which “*a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee*”;

⁶⁸ Compulsory licensing is addressed in detail in the 2013 submission at paras 69 to 84

⁶⁹ The footnote to Article 31 defines “*other use*” as “*use other than that allowed under Article 30.*”

⁷⁰ A compulsory licence issued by the state to itself, for public non-commercial use, is often referred to as a government-use license. In contrast to compulsory licenses, government-use licenses (as well as emergency and urgent need licenses) do not require prior notice or negotiation with the patent holder, though notification and payment of adequate compensation is required after-the-fact.

⁷¹ Para 4.1.9.1.ii

- 71.2 Section 55, which deals with *“compulsory licences in respect of dependent patents”*; and
- 71.3 Section 56, under the heading *“Compulsory licence in case of abuse of patent rights”*, which entitles *“any interested person who can show that the rights in a patent are being abused ... [to] apply to the commissioner in the prescribed manner for a compulsory licence under the patent.”*
- 72 Our concerns are in respect of sections 4 and 56, both of which we see as problematic from the perspective of access to health care services. In what follows below, we set out the basis upon – and the manner in – which these provisions ought to be amended.

Section 4 licences

- 73 In terms of section 4, any national minister may grant a compulsory licence to an organ of state (such as the Department of Health) or a third party (such as a domestic generic manufacturer). The only qualification is that the grant must be for a public purpose. While the outer limit of what constitutes a public purpose is not clear, at the very least – in a health context – it includes the provision of health care services in public facilities.⁷²
- 74 The problem with section 4 is that the relevant Minister must agree with the patentee on the conditions of such use, failing which they will be set by the Commissioner of Patents *“on application by or on behalf of such Minister and after hearing the patentee”*. In other words, it effectively takes a High Court application to resolve the issue of conditions of use. Even that may not be enough – the decision of the Commissioner may be taken on appeal.
- 75 While we welcome the recognition in the Framework that section 4 *“goes beyond what is provided for in TRIPS by requiring Ministers of State to enter into ... negotiations before an application to the Commissioner of Patents can be made”*,⁷³ we recommend that the provision be reviewed and amended in the following additional ways:⁷⁴

⁷² This would constitute public non-commercial use.

⁷³ Para 4.1.9.3.i

⁷⁴ In addition to removing the requirement for prior negotiations with patent holders.

- 75.1 By the express inclusion in section 4 of default positions regarding licence conditions, including but not limited to royalty rates. Absent agreement on conditions (once the decision to issue the licence has already been taken), the default positions would automatically come into force, allowing for the immediate use of the licence.
- 75.2 To address concerns regarding the adequacy of the royalty rate, section 4 could also make provision for the Commissioner to be approached – in exceptional circumstances – to amend the rate upon good cause shown. Importantly, such an application would not suspend the operation of the licence. Should the rate be adjusted in this way, prior overpayment or underpayment could be addressed.

Section 56 licences

- 76 Section 56 raises substantially more concerns – both in respect of the limited grounds upon which a licence may be issued, and the sub-optimal procedures in terms of which a request for a licence is to be considered:
- 76.1 Section 56 only recognises the concept of abuse of rights in a patent, despite paragraph 5 of the Doha Declaration noting that WTO members are free to determine the grounds upon which compulsory licences may be issued. Accordingly, South Africa could – and we submit, should – amend section 56 to include a wide range of public health grounds to ensure access to medicines.⁷⁵
- 76.2 In terms of process, section 56 is unwieldy. The following aspects are instructive:
- 76.2.1 it relies on judicial proceedings for the grant of a compulsory licence, which requires the use of specialist lawyers;
- 76.2.2 the lodging of an application for leave to appeal against the grant of a licence automatically suspends the operation of that licence; and

⁷⁵ Grounds could include the following: when medicine prices prohibit access; when supply is inadequate to satisfy need; when there is a need for multiple suppliers to guard against shortages or stock-outs; when the patent holder has refused to grant a voluntary license on reasonable terms; and when there is a need for a novel fixed-dose combination medicine comprising active ingredients patented by multiple right holders.

76.2.3 there is no guidance in the law on the time periods within which prior negotiations must occur, nor on the royalty rates that should be paid to patentees.

76.3 Both cost and time factors make this process unsuitable for many applications that could be made in the public interest, in pursuance of the realisation of the right to have access to health care services. The process could – and indeed should – be simplified. This would be in line with Article 1.1 of TRIPS, which provides that WTO *“members shall be free to determine the appropriate method of implementing the provisions of ... [TRIPS] within their own legal system and practice.”*

77 Many countries have used compulsory licences to promote the public interest and/or remedy anti-competitive practices in a range of technology sectors:

77.1 In recent years, some have issued compulsory licences to increase access to medicines. These include India, Thailand, Brazil, Malaysia, Zambia and Ecuador.⁷⁶

77.2 The United States is perhaps the world’s most frequent user of compulsory licensing, including the government use of defence technologies, and court-issued licences to remedy anti-competitive practices in information technology and biotechnology.⁷⁷

78 We do not suggest that access to medicines should be reliant on the need for the repeated grant of compulsory licences. Instead, the existence of easy-to-use compulsory licensing provisions, coupled with the credible threat of their use, and the use when it is merited on the basis of strong public health grounds, would go a long way towards also ensuring that –

78.1 governments have the power to negotiate effectively to ensure the lowest sustainable prices for medicines and other much-needed technologies; and

78.2 where necessary, the terms of voluntary licences can easily be negotiated so as to ensure the timely availability of generic medicines, particularly in circumstances

⁷⁶ R Beall and R Kuhn, “Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis” (2012) 9(1) PLoS Med: e1001154, available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154>

⁷⁷ Tomlinson and Rutter at 5

where sustainability of supply concerns require the existence of multiple suppliers.

IP and competition

79 In a footnote,⁷⁸ the Framework makes reference to “[a] 2013 UNDP Study” which is said to suggest “*expressly stating that the section 56 grounds constitute anti-competitive practices.*” In dealing with “[c]ompulsory licences granted to remedy anti-competitive practices”, the document in question notes as follows:⁷⁹

“[T]he Patents Act could expressly recognize certain actions by a patentee deemed by the Competition Tribunal to be anti-competitive (such as abuse of dominance) as an additional ground for compulsory licensing. Indeed, the existing grounds in the Patents Act for granting a compulsory licence appear to be aimed largely at remedying what could be considered anti-competitive practices. However, the Patents Act does not specifically state that they are remedies for anti-competitive practices, and does not expressly avail of the flexibilities available in the TRIPS agreement in such situations.”

80 While we associate ourselves with these comments, we do not suggest that the grounds recognised by section 56 of the Patents Act be moved to the Competition Act. That said, we recognise the need – in the medium term – for a consideration of whether the Competition Act needs to be amended to deal expressly with the interface between competition and IP law.⁸⁰ Should the Competition Act be reviewed in this manner, we recommend that consideration also be given to the appropriate regulation of IP licensing conditions, as permitted by Article 40 of TRIPS.

CONCLUSION

81 We once again thank the dti for this opportunity to make these submissions. That said, we remain extremely concerned about the slow pace of IP policy reform. Nevertheless, we trust that – at least insofar as the immediate issues are concerned – the dti will move swiftly to finalise the process, and publish an amendment bill for public comment.

⁷⁸ Footnote 36

⁷⁹ Chan Park et al, *Using law to accelerate treatment access in South Africa: an analysis of patents, competition and medicines law* (UNDP, New York: 2013), available at http://www.undp.org/content/dam/undp/library/hiv/aids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf

⁸⁰ In this regard, we stand by the representations made in the 2013 submission.