JOINT SUBMISSION ON THE DRAFT NATIONAL INTELLECTUAL PROPERTY POLICY, 2013

INTRODUCTION

1. Having worked for many years to limit the negative impact of intellectual property ("IP") on public health, most recently through the "Fix the Patent Laws" campaign,[1] Médecins Sans Frontières ("MSF"), the Treatment Action Campaign ("TAC") and SECTION27 welcome the publication of the draft National Policy on Intellectual Property, 2013 ("the draft policy")[2] for public comment.[3]

2. In particular, we welcome the invitation to participate in a policy-making process that creates the much-needed space for a reconsideration of South Africa's approach to IP in light of the constitutional obligations arising from the Bill of Rights and the opportunities provided by the international trade framework,[4] which recognises that protecting public health must be a priority for all member states.

3. Since late-2001, when the World Trade Organization ("WTO") adopted the *Declaration on the TRIPS agreement and public health* ("the Doha

[1] See http://www.fixthepatentlaws.org
[2] General Notice 918 of 2013, *Government Gazette* No. 36816 (4 September 2013).
[3] MSF is also known by its English name: Doctors Without Borders. Prior to its launch in 2010, SECTION27 was known as the AIDS Law Project ("ALP").
[4] The Agreement on Trade-related Aspects of Intellectual Property Rights ("TRIPS").

Declaration"),[5] we have called for the amendment of existing laws – including the Patents Act 57 of 1978 ("the Patents Act") – to make better use of public health safeguards and flexibilities such as compulsory licensing, parallel importation and substantive patent examinations.

4. We are therefore pleased to note that the draft policy makes particular reference to and takes guidance from the Doha Declaration. In addition, we welcome –

4.1. the tenor of the draft policy, which places the right to have access to health care services – entrenched in section 27 of the Constitution of the Republic of South Africa, 1996 ("the Constitution") – at the centre of IP policy;

4.2. the recognition of the direct link between the patent regime, as implemented in South Africa, and the high cost of medicines and medical products;

4.3. the recognition that South Africa's IP policy must take into consideration the country's health and developmental needs;[6] and

4.4. indications that South Africa is seeking to develop an IP policy that learns from the way in which India and Brazil – two of its BRICS partners – have dealt with the IP and public health relationship.

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[5] WT/MIN(01)/DEC/2 (20 November 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[6] Objectives 13 and 14.

SUMMARY OF KEY RECOMMENDATIONS

5. Given the stage of the policy-making process in question, we do not make any particular proposals in respect of the draft text provided. Instead, in focusing on a range of substantive issues considered in the draft policy, we provide a set of recommendations in respect of each.

6. Amongst others, this submission makes the following key recommendations:

6.1. On patentability criteria:

6.1.1. The Patents Act should be amended to include stricter patentability criteria; and

6.1.2. In the context of medicines and other health-related products, new uses and methods of treatment should expressly be precluded from being granted patent protection; new forms of known substances should not be patentable to the extent that they fail to demonstrate the required degree of inventive step, strictly construed;

6.2. On patent searches:

6.2.1. CIPC online patent search database should be improved to facilitate access to accurate information on patents for ordinary users of the system. This would in turn help stakeholders, such as civil society take action to limit the

granting of abusive medicines patents.

6.3. On substantive patent examination and opposition proceedings:

6.3.1. Recognising that the Patents Act already requires substantive patent examination, we call for the making of regulations dealing with the establishment and phased implementation of a substantive patent examination system; and

6.3.2. The Patents Act should provide for meaningful pre- and post-grant opposition mechanisms that recognise broad standing requirements inclusive of civil society and adequate access to information to facilitate such interventions;

6.4. On the relationship between medicines registration and patent protection:

6.4.1. Other than what is already contained in section 69A of the Patents Act, no linkage between medicine registration and patent protection should be recognised; and

6.4.2. Remedies for addressing delays in medicine registration processes should exclude patent extensions;

6.5. On compulsory licensing and parallel importation:

6.5.1. The current process in terms of section 56 of the Patents Act should be replaced by a simple, expeditious administrative

procedure that is subject only to review proceedings in the High Court or the Court of the Commissioner of Patents. Government use licenses should not require any review proceedings in the High Court;

6.5.2. Pending any review of the grant of a compulsory licence, interim relief should only be available – upon application – in exceptional circumstances and should not be available for the exercise of government use licenses;

6.5.3. Default positions regarding licence conditions (including but not limited to royalty rates) and negotiation timelines should expressly be included in sections 4 and 56 of the Patents Act;

6.5.4. Licensing practices should expressly be regulated, as contemplated by Article 40 of TRIPS; and

6.5.5. Regulation 7 of the General Regulations made under the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act") should be amended to give full effect to section 15C(b) dealing with parallel importation;

6.6. On research and development ("R&D"), public funding, innovation and access:

6.6.1. The Department of Trade and Industry ("the dti") should collaborate with relevant departments and statutory councils to ensure that publicly-financed R&D in South Africa is aimed at delivering affordable inventions; and

6.6.2. In particular, the dti should engage with the Department of

Science and Technology ("DST") regarding the need to consider possible amendments to the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008 ("the IPRs from Publicly Financed R&D Act");

6.7. On exceptions to patent infringement:

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

6.7.2. The Patents Act should also include an educational use exception;

6.8. On data protection and exclusivity:

6.8.1. Calls for data exclusivity should be rejected on the basis that they are not required by Article 39.3 of TRIPS and they unreasonably and unjustifiably limit access to medicines; and

6.8.2. The status quo in this regard should be retained, with the Patents Act only making provision for data protection.

7. We draw the dti's attention to the recently-published United Nations Development Program ("UNDP") report entitled "The Role of the Law in Consolidating Treatment Gains in South Africa: an analysis of patents, competition and medicines law". The UNDP report, a copy of which is attached as an annexure to this submission, provides a detailed analysis of South Africa's legislative landscape insofar as access to medicines is

concerned and makes clear recommendations for legislative reform.[7]

STRUCTURE OF THIS SUBMISSION

8. In this submission, we address the issues identified in paragraphs 6.1 to 6.8 above in greater detail. But before doing so, we consider the following:

   8.1. MSF's, TAC's and SECTION27's interests in making this submission;

   8.2. The legal framework that provides the context within which IP policy is to be considered, developed and implemented;

   8.3. Aligning IP legislation with local developmental goals; and

   8.4. The relationship between competition law and IP, with a particular focus on patent protection and access to medicines.

MSF's, TAC's AND SECTION27's INTERESTS

9. MSF is an independent medical humanitarian organisation. Founded in 1971, it now operates in over 60 countries (including South Africa and other countries in the region), with a particular focus on providing medical care to populations in distress, regardless of race, religion, creed or political convictions. In 1999, MSF was awarded the Nobel Peace Prize.

10. In response to unequal access to treatment for HIV infection and other neglected diseases, MSF launched its Campaign for Access to Essential

[7] Chan Park et al, *The Role of the Law in Consolidating Treatment Gains in South Africa: an analysis of patents, competition and medicines law* (UNDP, New York: 2013). Accessible at <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-law-to-accelerate-treatment-access-in-south-africa.html>

Medicines in 1999. Known today as the MSF Access Campaign, its sole purpose is to advocate for access to – and to ensure the development of – life-saving and life-prolonging medicines, diagnostics and vaccines for patients in MSF programmes and beyond, with particular emphasis on IP-related barriers.

11. TAC, a membership-based organisation that has been campaigning for access to quality health care services since 1998, represents and acts on behalf of people living with and affected by HIV and TB in South Africa. In particular, it has a proud history of using the law and legal processes to increase access to ARV medicines and other HIV-related drugs. Much of this has been achieved by working closely with partner organisations such as MSF and SECTION27.

12. SECTION27 is a public interest law centre that uses and develops the law to advance human rights. It conducts research, advocacy and litigation to achieve its goals, which include a focus on the right to have access to health care services in general and medicines of proven quality, safety and efficacy in particular. SECTION27's primary interest in IP policy and law reform flows from its understanding of the manner and extent to which patent protection has been used to undermine access to medicines.

THE RELEVANT LEGAL FRAMEWORK

13. The Constitution and various international human rights instruments – such

as the Universal Declaration of Human Rights ("UDHR") [8] and the International Covenant on Economic, Social and Cultural Rights ("ICESCR")[9] – recognise health as a fundamental human right. 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.[10]

14. TRIPS, read together with the Doha Declaration, makes it plain that WTO members have at their disposal a range of public health safeguards and flexibilities to ensure that IP policies and laws do not undermine public health.[11] But while TRIPS is merely permissive, not requiring countries to make use of these safeguards and flexibilities, the Constitution – read in light of the UDHR and the ICESCR – requires positive action.

15. In line with these constitutional obligations, South Africa – as a member of the African Union ("AU"), the Southern African Development Community ("SADC") and the BRICS grouping – has already committed itself to act in a manner that deals appropriately with IP policy and law:

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[8] Article 25(1) of the UDHR provides as follows:
"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."

[9] Article 12(1) of the ICESCR provides as follows:
"The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

[10] Amongst other things, this includes a right to have access to medicines.

[11] For a comprehensive discussion on these safeguards and flexibilities, see UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press, New York: 2005).

15.1. Pursuant to an AU decision taken in January 2005,[12] the AU Conference of Ministers of Health undertook – in October 2005 – "to making full use of the flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration on TRIPS and Public Health";[13]

15.2. On 27 June 2007, SADC members agreed to a plan aimed at addressing the public health needs of member states,[14] which includes the following goals:

15.2.1. "Coordinate the implementation of TRIPS flexibilities to improve access to essential medicines within the SADC region"; and

15.2.2. "Collaborate with development partners to enable countries to protect, include and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude agreements that are not detrimental to public health";[15] and

15.3. At the Second BRICS Health Ministers' Meeting, held in New Delhi on 11 January 2013, members reiterated their commitment to ensure that bilateral and regional trade agreements do not undermine TRIPS

[12] AU Assembly decision 55 mandated the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa. See http://www.au.int/en/content/abuja-30-31-january-2005-assembly-african-union-fourth-ordinary.
[13] Gaborone Declaration Doc. CAMH/Decl.1(II) 3 (10 – 14 October 2005).
[14] SADC Pharmaceutical Business Plan (2007-2013), available at http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf
[15] At paragraph 4.1.8.

flexibilities so as to ensure the availability of affordable generic ARV drugs to developing countries.[16]

16. It is with this legal framework in mind that we have considered the draft policy and the extent to and the manner in which it addresses our concerns and interests. We have done so also mindful of the ways in which our law already addresses these issues, albeit inadequately in many cases. For example –

16.1. section 56 of the Patents Act recognises a limited number of grounds on the basis of which a compulsory licence may be sought;

16.2. section 4 of the Patents Act makes provision for government-use licences, a specific category of compulsory licences, and what process must follow if there is no agreement between the parties on the terms and conditions under which the invention is to be used;

16.3. section 61 of the Patents Act sets out the grounds upon which a patent may be revoked;

16.4. section 15C(a) of the Medicines Act empowers the Minister of Health to "prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public", with

[16] See Delhi Communiqué, available at http://pib.nic.in/newsite/erelease.aspx?relid=91533, at paragraph 8. In this regard, we welcome the statement at page 12 of the draft policy recognising that free trade agreements ("FTAs") have the potential to undermine the public health safeguards and flexibilities available under TRIPS. We support the negotiating position that South Africa should not enter into bilateral agreements that undermine these safeguards and flexibilities. Similarly, we also welcome the statement at page 26 of the draft policy which recognises that Bilateral Investment Treaties ("BITs") "may frustrate the flexibilities and discretions under TRIPS".

section 15C(b) permitting him or her to make regulations dealing with parallel importation; and

16.5. chapter 2 of the Competition Act 89 of 1998 ("the Competition Act") contains a range of prohibitions that apply – amongst others – to the exercise of exclusive rights in IP.

ALIGNING IP LEGISLATION WITH LOCAL DEVELOPMENTAL GOALS

17. During the TRIPS negotiations, developing countries were assured by their industrialised counterparts that strengthening IP protection would result in greater foreign direct investment ("FDI"). The experience in South Africa, however, has been largely the opposite, with the expansion of IP protection being accompanied by disinvestment:

17.1. In 1994, upon becoming a member of the WTO, South Africa signed onto TRIPS (which came into force on 1 January 1995).

17.2. In 1997, South Africa amended its laws, purportedly to make them TRIPS-complaint.

17.3. Since 1994, 37 pharmaceutical manufacturing plants have shut down, the vast majority of them belonging to foreign-based R&D pharmaceutical companies.[17]

[17] Maloney C & Segal N. (2007). The Growth Potential of the Pharmaceuticals Sector in South Africa. Genesis Analytics 29 May 2007; DTI. (2011). The South African Pharmaceutical Sector

18. South Africa is not alone. In this regard, the draft policy notes that "[a]s for now, there is no empirical evidence that developing countries with low promotion of indigenous technologies or innovation are gaining benefits from the IP system".[18] Rather than expanding investment in developing countries with strong IP protection, R&D companies have largely consolidated operations in regions with skilled labour, low costs of labour and production, and other economic incentives.[19]

19. Another common misconception is that high standards of IP protection will stimulate growth of the domestic pharmaceutical industry.[20] Over the past decade, investment by local generics manufacturers has far outpaced that of R&D companies. Yet our laws, which offer patent protection significantly in excess of what is required by TRIPS, have effectively limited the growth of this industry.[21] Put differently, our laws work to the advantage of that part of the industry that employs few people, offers little opportunity for real growth and has been shrinking (in terms of manufacturing capacity) for some time.

20. In contrast, the Indian experience shows how weak levels of patent protection allowed for the development of a strong domestic generics industry. From 1970 to 2005, India did not recognise pharmaceutical product patents. From

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Profile for the Consideration of Designation of Pharmaceutical Products in Terms of the PPFFA. Final Version, 9 November 2011.

[18] At page 39.

[19] Naude C & Luiz J. (2013). An Industry Analysis of Pharmaceutical Production in South Africa' in South African Journal of Business Management 2013, 44 (1).

[20] Yet research conducted by Oxfam in 2007 showed that despite offering less IP protection than Jordan, Egypt benefitted from high levels of FDI in the pharmaceutical sector. See Oxfam, "All costs, no benefits: How TRIPS-plus IP rules in the US-Jordan FTA affect access to medicines", available at http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf.

[21] DTI. (2011). The South African Pharmaceutical Sector Profile for the Consideration of Designation of Pharmaceutical Products in Terms of the PPFFA. Final Version, 9 November 2011.

humble beginnings, the country's generics industry flourished. As a net importer of medicines until 1988, India managed to reverse this deficit by the mid-1990s, generating a large trade surplus and becoming what is now referred to as the "pharmacy of the developing world".[22]

21. Many of today's developed countries were once able to borrow and copy technology from wealthier countries to develop their own industries. They have now been accused of "kicking away the ladder" that would allow developing countries to catch-up by pressuring them to adopt strong standards of IP protection.[23] Academics have argued that, instead of mirroring the levels of IP protection currently found in the industrialised world, developing countries should adopt standards that are more in line with their developmental needs.[24]

22. What does this mean for South Africa? In the context of the pharmaceutical industry, we submit that there are two interrelated developmental goals that the IP policy should take into consideration: the strengthening of South Africa's generics manufacturing industry; and ensuring that locally-produced medicines are affordably priced. Yet we note that the dti's Industrial Policy Action Plan 2013/14 – 2015/16 speaks about strengthening the domestic

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[22] In 2005, when its TRIPS obligations came into force, India amended its national legislation. Yet unlike South Africa, India took (almost) full advantage of the safeguards and flexibilities to protect public health as well as its local industry. Today, India retains its dominance as a global supplier of affordable generic medicines. See Pharma Focus Asia. Generic to Innovative: Transition of Indian Pharmaceutical Companies. Available at http://www.pharmafocusasia.com/strategy/indian_pharma_transition.htm

[23] Ha-Joon Chang, (2003). Kicking Away the Ladder: Development Strategy in Historical Perspective. Anthem Press, London.

[24] 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. (2002). Kicking away the ladder: Development Strategy in Historical Perspective. Anthem Press - Business & Economics <http://www.google.co.uk/search?tbo=p&tbm=bks&q=subject:%22Business+%26+Economics%22&source=gbs_ge_summary_r&cad=0>

pharmaceutical manufacturing sector, without making any mention of the role of IP. We trust that this oversight will be corrected.

THE RELATIONSHIP BETWEEN COMPETITION LAW AND IP

23. Under the heading "IP, Competition, Public Policy-making, compulsory licensing and technology transfer", Chapter 5 of the draft policy appears to be based on the recognition that competition law may be used to curtail – or at least ameliorate – the abuse of exclusive rights in IP. In particular, it seems to acknowledge – correctly in our view – that competition law may be used to counter the potentially negative effects of patent protection on public health.

24. In substance, however, Chapter 5's focus is somewhat limited. For example, it appears to suggest that the reach of competition law is limited to the regulation of restrictive licensing practices (under Article 40 of TRIPS) and the use of compulsory licensing (presumably under Article 31 of TRIPS). In addition, the chapter's primary concern is the potential impact of BITs and FTAs on the state's ability to develop and implement competition policy.[25]

25. In this part of our submission, we begin by considering the relationship between exclusive rights in IP on the one hand and competition law on the other, with a particular focus on patents and access to medicines. We do so because we take the view that without a clear understanding of this relationship, it is difficult to understand how best to interpret and use

[25] While we agree that the draft policy should reject any IP provisions in FTAs or BITs that might undermine access to medicines and go beyond what is required by TRIPS, we submit that the appropriate place to develop this objective is in a policy paper dealing with foreign policy and/or international trade.

competition law in accordance with the constitutional right to have access to health care services. Thereafter we deal with key aspects of Chapter 5 we support, those aspects that require amendment, and what is missing.

Relationship between IP and competition law

26. IP is often considered to epitomise the very antithesis of the goals that competition law and policy seek to advance, with the statutory grant of exclusive rights preventing price competition for a defined period. Thus product patent protection in the pharmaceutical sector, for example, prevents the market entry of generic equivalents until after patent expiry.

27. The difficulty that often arises is how to make sense of apparently conflicting statutes. In the context of patents, this means reconciling the Patents Act and the Competition Act. While some may argue that the latter cannot be used to weaken the protection granted to exclusive rights holders by the former, its section 10(4) – which deals with exemptions from Chapter 2 – makes it plain that this is not the case.[26] Absent the application for and the grant of an exemption in terms of section 10(4), Chapter 2 of the Competition Act ordinarily applies to the exercise of exclusive rights in IP.

28. But this cannot mean that the ordinary exercise of the rights under a patent,

[26] Section 10(4) provides as follows:

> "A *firm* may apply to the Competition Commission to exempt from the application of this Chapter an *agreement* or practice, or category of *agreements* or practices, that relates to the exercise of IP rights, including a right acquired or protected in terms of the Performers' Protection Act, 1967 (Act 11 of 1967), the Plant Breeders' Rights Act, 1976 (Act 15 of 1976), the Patents Act, 1978 (Act 57 of 1978), the Copyright Act, 1978 (Act 98 of 1978), the Trade Marks Act, 1993 (Act 194 of 1993), and the Designs Act, 1993 (Act 195 of 1993)."

Section 10(4) refers is Chapter 2: Prohibited Practices, which deals with the prohibition of restrictive horizontal and vertical practices in Part A and abuse of dominance in Part B.

for example, may be considered as anti-competitive. As Berger argues in "Advancing Public Health by Other Means: Using Competition Policy":[27]

> "The simple exercise of exclusive rights in IP cannot in and of itself provide a basis for using competition policy to advance public health. In such circumstances, which IP law ordinarily does not regard as abusive, states are nevertheless permitted by the TRIPS Agreement to take a range of regulatory measures to increase access to essential medicines and other patented technologies."

29. Many of these other regulatory measures are addressed elsewhere in this submission. What we consider in this part are the circumstances within which the exercise of exclusive rights crosses the line as set by the Competition Act – where it cannot be a defence merely to assert that the Patents Act, for example, permits the conduct in question.

30. Given the requirement in section 233 of the Constitution that requires every court "[w]hen interpreting any legislation … [to] prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law", the starting point must be the manner in which TRIPs deals with the relationship between patents and competition law.

31. There are two provisions of TRIPS that deal expressly with anti-competitive practices: Articles 31 and 40:

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[27] In P Roffe, G Tansey and D Vivas-Eugui (eds.), *Negotiating Health*, (Earthscan, London: 2005) at 188 (footnote omitted).

31.1. Insofar as it is relevant, Article 31 – entitled "Other Use Without Authorization of the Right Holder"[28] – provides as follows:[29]

> "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
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> (a) …;
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> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. …;
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> (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
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> (d) …;
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> (e) …;
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> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
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> (g) …;
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> (h) …;
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> (i) …;
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> (j) …;
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> (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is

[28] In footnote 7, TRIPS defines "other use" as "use other than that allowed under Article 30."
[29] Footnote omitted and emphasis added.

permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) …."

31.2. Insofar as it is relevant, Article 40 – the sole provision falling under the heading "Control of Anti-competitive Practices in Contractual Licences" – provides as follows:[30]

"1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member. …"

[30] Emphasis added.

32. Given that TRIPS does not define what is meant by an anti-competitive practice, South Africa has significant flexibility to determine for itself what conduct in relation to exclusive rights in IP is to be considered as anti-competitive for the purposes of the Competition Act. That said, Article 31 makes it plain that "anti-competitive practices involving patents are particularly egregious".[31]

33. There are two other provisions of TRIPS that are of assistance: Article 1.1, which grants WTO members the freedom to determine an "appropriate method of implementing the provisions of … [TRIPS] within their own legal system and practice"; and Article 8.2, which recognises that WTO members may need to take steps "to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology":[32]

33.1. Article 1.1 "permits significant flexibility about the exact manner in which the obligations under TRIPS are implemented".[33] In the context of patents, this means that South Africa is free to deal with anti-competitive practices in the Patents Act, the Competition Act or both. Both statutes currently address the issue: the former in a limited way in section 56 dealing with compulsory licences;[34] and the latter in Chapter 2 dealing with prohibited practices.

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[31] Berger, above note 25 at 185.
[32] Article 8.1 permits WTO members, "in formulating or amending their laws and regulations, [to] adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with [TRIPs]."
[33] Berger, above note 25 at 183.
[34] Section 56(2) sets out the grounds that are deemed to constitute an abuse of rights justifying the grant of a compulsory licence.

33.2. Article 8.2 contemplates the use of measures designed to curtail IP-related conduct that undermines international trade and technology transfer. In the context of our generics-dominated pharmaceutical industry, Article 8.2 permits the use of measures – including competition law and policy – to strengthen the local industry to ensure a sustainable supply of affordable medicines locally as well as the ability of locally-based companies to compete internationally.

34. Properly understood, TRIPS makes it plain that in relation to statutorily-granted rights in IP, WTO members (such as South Africa) are entitled to –

34.1. regulate those practices they consider to be anti-competitive, including – but not limited to – anti-competitive licensing practices;

34.2. determine for themselves the particular form in which they wish to regulate such practices; and

34.3. make use of a range of remedies to address anti-competitive practices, including – but not limited to – compulsory licensing as contemplated by Article 31 of TRIPS.

Key aspects of Chapter 5

35. While we share the concerns relating to the potential negative impact of BITs and FTAs, we submit that the focus in this chapter should be on what South

Africa is both permitted to do under TRIPS and required to do by the Constitution. We take the view that South Africa's approach to international trade, including the form and content of BITs and FTAs, should be informed by domestic needs – in this case, as encapsulated in a finalised IP policy.

36. With this in mind, we welcome the express recognition in the draft policy –

36.1. of Article 40 of TRIPS and the flexibility it affords WTO member states in dealing with anti-competitive licensing practices;[35]

36.2. that compulsory licensing constitutes an integral aspect of competition law and policy insofar as exclusive rights in IP – and their regulation – are concerned;[36] and

36.3. that the grant of compulsory licences is not limited to emergency situations.[37]

37. However, we are concerned about the following three statements:[38] first, that exclusive rights in IP are equated with rights of ownership; second, that a compulsory licence is an exception to an exclusive right; and third, that "IP and health legislations must be amended to allow competition laws to apply."[39] We are concerned because –

[35] At page 26.
[36] At page 27.
[37] Ibid.
[38] In our view, these statements should not appear in any final IP policy.
[39] At page 31.

37.1. the statutory rights granted by IP are rights to exclude – they do not confer any rights of ownership;

37.2. compulsory licensing is not exceptional – it is an integral part of the principle of balance that lies at the heart of patent protection and its theoretical underpinnings;[40] and

37.3. as indicated above, the Competition Act already applies to IP and IP-related conduct – there is no need to amend it for this to happen.

What is missing from Chapter 5

38. In addition, we submit that the draft policy might be enriched significantly by a consideration of the way in which the Competition Act has already been the focus of two abuse of dominance complaints relating to patented products: *Hazel Tau and Others v GlaxoSmithKline South Africa (Pty) Ltd and Others*;[41] and *Treatment Action Campaign v MSD (Pty) Ltd and Another*.[42]

39. As a result of these complaints, locally-based generics pharmaceutical companies were licensed to manufacture and/or import certain patented ARV

[40] See Edwin Cameron and Jonathan Berger, "Patents and Public Health: Principle, Politics and Paradox", (2005) 131 *Proceedings of the British Academy* 331.
[41] See Treatment Action Campaign, "Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines" (10 December 2003), available at http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm. The case is also discussed in Jonathan Berger, "Litigating for Social Justice in Post-Apartheid South Africa: a Focus on Health and Education", in Varun Gauri and Daniel M. Brinks (eds.), *Courting Social Justice: Judicial Enforcement of Social and Economic Rights in the Developing World* (Cambridge University Press, New York: 2008).
[42] See Treatment Action Campaign, "TAC complaint increases access to efavirenz: MSD finally agrees to grant licenses on reasonable terms" (1 June 2008), available at http://www.tac.org.za/community/node/2329

medicines used in the prevention and treatment of HIV infection. Neither complaint, however, gave rise to jurisprudence, as both were resolved prior to any determination by the Competition Tribunal on whether abuse of dominance had indeed been established.

40. In addition, in the context of merger control, the relationship between exclusive rights in IP and competition law has been considered in at least two matters: *Glaxo Wellcome Plc and Another v Competition Commission of South Africa*;[43] and the merger in 2009 between GlaxoSmithKline South Africa (Pty) Ltd ("GSK") and Aspen Pharmacare Holdings Limited ("Aspen").[44] The merger between GSK and Aspen was approved subject to a key ARV medicine being licensed.

PATENTABILITY CRITERIA

41. Before considering the issue of patentability criteria, it is important to address a related concern: the recommendation in chapter 8 of the draft policy that supports the inclusion of "utility patent systems". In line with our submissions regarding patentability criteria, we do not support the adoption of utility model patents largely because they lower the standard for innovation – usually forgoing or greatly easing the "inventive step" requirement.[45]

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[43] [2000] ZACT 33 (28 July 2000), available at http://www.saflii.org/za/cases/ZACT/2000/33.html

[44] See Treatment Action Campaign, "Competition Commission places condition on GSK and Aspen merger – GSK must license abacavir to generic manufacturers" (11 September 2009), available at http://www.tac.org.za/community/node/2744. See also Competition Commission, "Competition Commission approves pharma merger on condition that Abacavir is out-licensed to generic manufacturers" (2 September 2009), available at http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/02-Sept-09-Competition-Commission-approves-pharma-merger-on-condition-that-Abacavir-is.pdf

[45] Utility patents typically have much shorter periods of validity. There is no requirement for utility model patents in TRIPS. It is also very unlikely that the potential risks associated with utility model

42. South Africa grants a high number of patents. In part, this is because South Africa does not conduct substantive examinations of patent applications. But it is also as a result of the low standards of patentability criteria recognised in our law and as applied by the courts.[46] In our view, both of these issues have to be addressed to ensure a patent system that serves the public interest and advances South Africa's developmental needs. We consider the issue of patentability criteria now and deal with substantive examinations below.

43. Article 27.1 of TRIPS governs the patentability of inventions but also affords WTO members significant flexibility when setting criteria for patentability. All that Article 27.1 requires is that patents be granted for inventions that are new, involve an inventive step and are capable of industrial application. TRIPS does not set out what is meant by these three requirements. Instead, the footnote to Article 27.1 provides as follows:[47]

> "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."

44. 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 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

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patents outweigh any potential benefits. For more information on utility models, see WIPO, "Utility Models", available at http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm.

[46] See for example section 25(9) of the Patents Act.

[47] Emphasis added.

more specific than "useful".[48]

45. WTO member countries have adopted widely varying patentability criteria.[49] In India, the bar for patentability is set particularly high, in order to restrict the practice of patent "evergreening".[50] For example, section 3(d) of the Patents Act, 1970 states that the following are not inventions for purposes of that Act:[51]

> "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

46. Thus new use patents are not available in India, with new forms of any known substance being patentable only if they "result in the enhancement of the known efficacy of that substance". The lawfulness of section 3(d) was upheld by India's Supreme Court earlier this year in *Novartis AG v Union of India*.[52] The Indian Supreme Court decision in Novartis AG v Union of India & Others is an important example of the implementation of national patent laws in a

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[48] It is also worth recalling that the UK Commission on Intellectual Property Rights report recommended that developing countries exclude medical methods from patentability, avoid patenting new uses of known products, and "apply strict standards of novelty, inventive step and industrial applicability or utility (consider higher standards than currently applied in developed countries)". See: "Integrating Intellectual Property Rights and Development Policy," CIPR, 2001, page 122.

[49] 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.

[50] Evergreening" is the practice of obtaining, in the case of pharmaceuticals, multiple patents on the same medicine for minor incremental changes, in order to extend monopoly protections and thus higher prices.

[51] Emphasis added.

[52] Civil Appeal Nos. 2706-2716 of 2013, available at http://www.indiankanoon.org/doc/165776436/

manner that takes account of public health considerations. The court expressed its concern that 'patent protection to pharmaceutical and agricultural chemical products might have the effect of putting life-saving medicines beyond the reach of a very large section of people'.[53]

47. India is not alone in adopting such high standards – there are similarly strict standards in the Philippines[54] and Argentina, which has excluded from patentability polymorphs and salt forms of drugs, as the various chemical attributes and benefits of these and other forms are common knowledge within the pharmaceutical industry.[55] Argentina has in some ways created even stricter criteria than India by not including in its law an enhanced efficacy provision that is open to interpretation. Other countries, such as Brazil,[56] are contemplating a move in this direction.

48. So what should South Africa do? Guided by its positive constitutional obligations, we submit that there are at least three considerations that must be taken into account in determining which approach to patentability criteria 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. We deal with these considerations in turn.

48.1. Higher patentability criteria can serve to reject methods of treatment,

[53] Civil Appellate Jurisdiction of the The Supreme Court of India, *Novartis AG v Union of India & Others,* Page 38 <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>.
[54] See Philippines IP Code § 26.2.
[55] Argentina has adopted the Guidelines for Patentability Examination of Patent Applications for Chemical and Pharmaceutical Inventions. See Joint Resolution 118/2012, 546/2012 and 107/2012 (Ministry of Industry, Ministry of Health and National Industrial Property Institute), available at http://www.moellerip.com/index.php?PN=news_detail&FX=1&DX=139&EX=1.
[56] 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.

new uses and/or new formulation/dosage patents, as well as known processes for making medicines and medical products, and new forms of known medicines that do not meet the required degree of inventive step, when strictly defined. Coupled with substantive search and examination procedures, this can thereby reduce the number of secondary patents granted on pharmaceutical products. This will result in earlier competition from generics manufacturers, which in turn will result in price reductions that will increase access.[57] This is particularly important for South Africa, with its high communicable and non-communicable disease burden.

48.2. Setting higher patentability criteria should create incentives for pharmaceutical companies – whether originator or generic - to invest in new molecular entities and new classes of medicines. By contrast, low patentability criteria may simply encourage evergreening by means of successive secondary patents by all pharmaceutical companies. From a developmental perspective, an approach that seeks to reward significant innovation is clearly preferable.

48.3. Weak patentability criteria have a deleterious economic impact. By granting secondary patents which are concurrently considered to be of poor quality in other jurisdictions, pharmaceutical companies are able to secure extended periods of monopoly protection. This

[57] 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%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en

enables companies to charge artificially high prices for lengthy periods of time, even after the base compound patent has expired, and even though the public health returns generated by such medicines are comparatively low. Thus in South Africa, the importation of patented foreign medicines has contributed to pharmaceuticals being the fifth largest contributor to the country's trade deficit.[58]

49. In the result, we make the following recommendations:

49.1. The Patents Act should be amended to include stricter patentability criteria. In the context of medicines and other health-related products, patentability criteria should ensure that patent offices, when examining compound and secondary patents, can distinguish the patentability of new chemical entities, new uses and new forms of known compounds.

49.2. Specifically, new uses of known substances, including methods of treatment, or new properties of known substances can be excluded from patentability. In this respect, Sections 25(9), 25(11) & 25(12) of the Patents Act will require amendment.

49.3. New forms[59] of known substances should not be patentable to the

[58] DTI. (2011). The South African Pharmaceutical Sector Profile for the Consideration of Designation of Pharmaceutical Products in Terms of PPFFA. Final Vers9 November 2011.
[59] This submission takes supports the definition of a 'new form' of a known substance that has been previously enumerated in Argentina and India. The Argentinean Guidelines for Patentability Examination of Patent Applications for Chemical and Pharmaceutical Inventions do not consider the

extent that they fail to demonstrate the required degree of inventive step, strictly construed. Setting the bar high for inventive step, as has been done in Argentina and India, is compatible with TRIPS.

49.4. South Africa should reject the introduction of utility model patents, either at all or at least in the medicines context.

PATENT SEARCHES

50. A number of third parties seek information from the CIPC for information on medicines patents.[60] However, the current state of the CIPC online search database makes it extremely difficult to find complete or accurate information.. At present, the only functional search fields are the title of the invention, the name of the inventor, and the South African patent number, with a number of other search fields returning no results. In the case of medicines patents, where the title of invention may be a complicated chemical formula, and the name of the inventor is rarely the company marketing the drug, this information is not often known by a member of the public searching for a patent.

51. In order to learn whether a particular patent has been filed in South Africa, one must search the WIPO database, However, finding the South African patent number of interest through the WIPO database, and subsequently entering this

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following 'new forms' to meet the inventive step requirement: polymorphs, pseudopolymorphs (hydrates and solvates), enantiomers, salts, esters and other derivatives of known substances, active metabolites, prodrugs, formulations and compositions, combinations and dosage.
The Indian Patent Act, section 3(d), states – "For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance…"

[60] These include the Ministry of Health, generic companies, R&D institutions, and academics, as well as civil society groups such as MSF, TAC and SECTION27.

information into the CIPC database does not return a large amount of information. None of the patent claims or specifications can be viewed, and the patent status is not always available or up-to-date.

52. Lack of information on patent status and specifications may lead to sub-optimal decisions by a variety of players ranging from the Ministry of Health to generic companies.[61] An improved CIPC online search database, on the other hand, would help South Africa take full advantage of TRIPS flexibilities,[62] help implement recommended systems outlined in this submission, such as patent opposition, and allow the public to ensure patent examination is conducted in line with patentability criteria.

53. We recommend the CIPC online patent search database be improved to facilitate access to accurate information on patents for ordinary users of the system. This would in turn help stakeholders, such as civil society take action to limit the granting of abusive medicines patents. A number of search fields should be added to the database, or become fully functional:

    53.1. More searchable fields should be functional, including the PCT application or publication number, or any other Priority Number.

    53.2. The international non-proprietary name (INN) of drugs should be

[61] In 2003 MSF published 'Patents Under the Spotlight' with a view to increasing knowledge about the patent barriers for HIV medicines and included information on relevant patents covering formulations, combinations and new medical uses. This allowed a number of governments and PLHIV networks to search for local patents, leading to informed decisions about addressing the barriers to procuring affordable generic medicines from India. See: MSF Access Campaign.MSF Drug Patents under the Spotlight: Sharing practical knowledge about pharmaceutical patents, May 2003 Available from: http://apps.who.int/medicinedocs/pdf/s4913e/s4913e.pdf

[62] The *WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* acknowledged the need for accurate, thorough, and up-to-date patent information, in order to effectively use TRIPS flexibilities such as research exceptions, pre-grant opposition, and compulsory licensing. For more, see: Correa, Carlos (2006). "Guidelines for the examination of pharmaceutical patents: developing a public health perspective. Working Paper, WHO, ICTSD and UNCTAD: Geneva. Available from www.ictsd.org .

included in patent application titles and abstracts, either when known at the time of the filing of a patent application, or when available following the grant of a patent. This would allow medicine patents to be easily found by using the INN as a keyword in the "title" or "abstract" search field.

53.3. Complete documents and specifications of a patent application or granted patent should be available, including the abstract and full disclosure of claims,[63] as well as any transactions, including the terms and status of any licensing agreements.[64]

53.4. The legal status of patents and patent applications—i.e. pending, granted, rejected, opposed, withdrawn, abandoned, expired or not renewed— should be current and available.

SUBSTANTIVE PATENT EXAMINATION AND OPPOSITION PROCEEDINGS

54. The draft policy recommends the establishment of a substantive patent examination system in South Africa. This is in line with section 34 of the Patents Act, which requires that patent applications be examined for compliance with the patentability requirements:[65]

> "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."

[63] Singapore offers complete specifications on all patents in a convenient, user-friendly "results formatter". See: http://www.epatents.gov.sg/PE/

[64] See s. 33(3) of the UK Patents Act 1977 which lists the following as able to be registered: assignment of a patent or application, mortgage or grant of a security of a patent or application, grant or assignment of a license, any direction of the court.

[65] Emphasis added.

55. Section 2 of the Patents Act defines the registrar as "the Commissioner, appointed in terms of section 189 of the Companies Act, 2008" – one of a number of provisions dealing with the Companies and Intellectual Property Commission ("CIPC").[66] Amongst other things, CIPC's objectives include "the efficient and effective registration of intellectual property rights",[67] as well as promoting compliance with and the enforcement of the Patents Act.[68]

56. The regime envisaged by the Patents Act is 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 ordinary flow. Yet, at present, CIPC does not examine patent applications prior to granting a patent to ensure the required criteria are met. Instead, it 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.

57. Insofar as it is relevant to substantive examinations, section 91 of the Patents Act empowers the Minister of Trade and Industry to make regulations –

    57.1. "prescribing the procedure in any proceedings before the registrar";[69]

    57.2. "prescribing the contents of any application, notice or form provided for in this Act";[70] and

[66] Part A of Chapter 8.
[67] Section 186(1)(a)(iii) of the Companies Act.
[68] Sections 185(1)(c) and (d) of the Companies Act.
[69] Subsection (c).
[70] Subsection (f).

57.3. "as to any other matter required or permitted by this Act to be prescribed by regulation".[71]

58. To date, the Minister of Trade and Industry has published two sets of regulations:[72] the Patent Regulations of 1978,[73] which deal with a range of procedural matters; and the Patents Examination Regulations,[74] which deal with the qualifications of patent agents and patent attorneys. The first set of regulations deals with patent examinations but does not set out the procedure as envisaged in section 34 of the Patents Act. Rather than ensure examination determines compliance with the requirements of the Patents Act, the regulations are limited to administrative matters:[75]

58.1. 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."

58.2. 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."

[71] Subsection (g).
[72] These sets of regulations have been amended repeatedly since 1978.
[73] Government Notice No. R 2470, *Government Gazette* No. 6247 (15 December 1978).
[74] General Notice 25, *Government Gazette* No. 24290 (17 January 2003).
[75] Emphasis added.

59. We are keenly aware that CIPC currently lacks capacity to carry out substantive examinations, as recognised by the draft policy. But that does not absolve it of its obligation to do so. At least insofar as health-related patents are concerned, we submit that section 27(2) of the Constitution places an obligation on the Minister of Trade and Industry, the dti and CIPC in collaboration with other organs of state to take the following reasonable measures to ensure that we move swiftly towards a substantive patent examination system:[76]

59.1. Develop guidelines for substantive patent examinations;

59.2. Recruit patent examiners with the necessary skills;

59.3. Train existing staff to undertake examinations and ancillary tasks;

59.4. Recruit and/or train management staff to take responsibility for various aspects of the examination process;

59.5. Develop appropriate IT systems to ensure transparency and access to information, in line with the above recommendations on patent searches;

59.6. Improve the classification of patents system currently in use at

[76] There is no need to conduct a cost-benefit analysis to determine whether an examination system should be adopted – it is already legally required. However, a cost-benefit analysis may be appropriate to determine the most efficient and effective way to introduce an examination system. Such an analysis may be able to answer questions as to whether the system should be introduced in phases, and whether health-related patents should be prioritised in any phased implementation.

CIPC;[77] and

59.7. Most importantly, make provision for a reasonable budget to achieve these objectives.[78]

60. It is also useful to understand how other countries have established patent examination systems in the recent past, and consider how these countries could provide South Africa with technical assistance on such matters going forward. In India, the Patents Office has a fee structure that has made it a self-sustaining, revenue-generating office.[79] In Brazil, the national drug regulatory authority, ANVISA, has a right to review pharmaceutical patent applications for medicines relevant to public health prior to examination by the patent office. This system plays a critical role in curbing evergreening by multinational companies, and has resulted in previously-granted patents on key drugs being overturned on review,[80]

61. We agree with the recommendation that the examination system should be established in conjunction with pre- and post-grant opposition proceedings.[81] These provide additional checks to ensure that only those inventions that

[77] The current system combines pharmaceutical products with cosmetic products, is not easily searchable and is not readily available to the public.
[78] Other countries have committed the resources to establish patent examination systems. In light of South Africa's constitutional obligations in respect of health, it should do so without undue delay.
[79] Briefing by TAC, MSF and RIC, 'Why South Africa Should Examine Pharmaceutical Patents' (January 2013) <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Brief_SApharmapatents_ENG_2013_final.pdf> accessed September 15, 2013.
[80] One recent example from Brazil is the breast and ovarian cancer drug, docetaxel; in 2006 the drug had its patent revoked after a review by ANVISA, and local production of an affordable generic alternative was allowed. Please see: Rede Brasileira pela Integração dos Povos (*REBRIP*) and Grupo De Trabalho Sobre Propriedade Intelectual (GTPI), 'INDIVIDUAL COMPLAINT AGAINST BRAZILIAN STATE URGENT APPEAL' <http://www.deolhonaspatentes.org.br/media/file/Urgent%20appeal%20against%20Brazil%20-%20by%20GTPI%20%28with%20annexes%29.pdf>, page 4, accessed September 15, 2013
[81] At page 12 of the draft policy.

meet the statutory requirements for patentability are granted patent protection.

62. There are a number of important considerations for the dti to address in regards to patent opposition:

62.1. First, it must be decided at which stage opposition procedures should be introduced – whether before, at the time or after substantive examination begins.[82] [83]

62.2. Second, procedures must be in place to ensure adequate time for filing an opposition[84], and take into consideration the state of access to timely information on patent applications.

62.3. Third, the cost of filing an opposition should not be prohibitive, [85] nor initially subject to proceedings at the High Court of the Commissioner of Patents.

63. Finally, standing to file a pre-post grant opposition should be a broad as possible, and include not only generic competitors, but also civil society,

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[82] The dti should also give consideration to transitional arrangements. In addition, given that phased implementation is likely, the dti should commit itself to reasonable timelines in this regard.
[83] In India, a third party can file an opposition once the patent application has been published. Accessed September 15, 2013 at: <http://www.patentoppositions.org/how_to_build_an_opposition>
[84] 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. Accessed September 15, 2013 at: <http://www.patentoppositions.org/how_to_build_an_opposition>
[85] In Argentina, for example, documents must be officially translated in order to file an opposition; this in itself can cost $10,000, making it prohibitively expensive for patient groups. Accessed September 15, 2013 at: <http://www.patentoppositions.org/how_to_build_an_opposition>

academics, and patients. While pharmaceutical companies have challenged the right of patient groups in other countries to file pre- and post-grant oppositions, a court case in Thailand clearly determined the right of such groups to file oppositions, as "interested parties to the granting of a patent".[86]

64. In the result, we make the following recommendations:

64.1. Recognising that the Patents Act already requires substantive patent examination, we call for the making of regulations dealing with the establishment and phased implementation of a substantive patent examination system.

64.2. The Patents Act should provide for effective pre- and post-grant opposition mechanisms that recognise broad standing requirements inclusive of civil society and adequate access to information to facilitate such interventions.

64.3. The dti and CIPC should –

64.3.1. Develop and implement a reasonable plan for the phasing in of a substantive patent examination system, accompanied by pre- and post-grant opposition proceedings; and

64.3.2. Determine the resources needed and budget appropriately

[86] In October 2002, civil society won its first major battle in opposing a patent when Thailand struck down Bristol-Myers Squibb's monopoly on the HIV drug didanosine, after a challenge led by the Thai AIDS Foundation. See: http://patentoppositions.org/case_studies/500e9b8c7718ea0002000018

for the development and implementation of this system.

MEDICINES REGISTRATION AND PATENT PROTECTION

65. Under the heading "Connectivity of Databases of MCC and Companies and IP Commission (CIPC)",[87] the draft policy discusses some form of relationship between the statutory bodies responsible for granting patents and registering medicines. We submit that our law should not recognise any link between these entities,[88] which ordinarily takes the form of patent linkage – when a medicine's registration is subject to considerations regarding its patent status, or when a patent's validity is extended as a result of a delay in registration.

66. Patent linkage is problematic in two respects:

66.1. First, it conflates the mandate of two separate institutions with distinct functions – one to grant patent protection for inventions and the other to register medicines on the basis of quality, safety and efficacy; and

66.2. Second, it may have the effect of shifting the enforcement of exclusive rights in patents from the private rights-holder to a public institution that is mandated to focus on public health, effectively marshalling public resources for private purposes.

[87] At page 14.
[88] Section 69A of the Patents Act could be viewed as creating such a link. But as we explain below, it simply clarifies that it is not an act of infringement to undertake steps "on a non-commercial scale and solely for purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product". In other words, the conduct associated with seeking regulatory approval in respect of a generic version of a patented medicine cannot be viewed as patent infringing.

67. In South Africa, a medicine's patent and registration status are derived from two separate processes under separate statutes. This is in line with TRIPS, which imposes no obligations in respect of patent linkage. Importantly, many jurisdictions – including the European Union – do not consider patent status when registering medicines.[89]

68. We are aware of significant delays in medicines registration and understand the concerns of parties in this regard. But this does not provide a basis for patent extensions. Extending the life of a patent as a result of regulatory failure punishes the public without addressing the root cause of the problem, and enables patent holders to use patent linkage to engage in evergreening. Instead, we submit that the focus should be on what legislative and/or other measures are necessary to ensure that the Medicines Control Council ("MCC") discharges its statutory mandate efficiently and effectively.

COMPULSORY LICENSING AND PARALLEL IMPORTATION

69. Compulsory licensing and parallel importation are important flexibilities recognised by Articles 31 and 6 of TRIPS respectively. But while they are already part of our law, they have yet to be used directly to increase access to medicines. In this regard, the draft policy recognises the need to amend existing legislation to address the shortcomings in the utilisation of

[89] See Article 81, Regulation (EC) No 726/2004 of the European Parliament and of the Council (31 March 2004); and Article 126, Directive 2001/83/EC of the European Parliament and of the Council (6 November 2001). For a discussion on how various jurisdictions deal with the issue of patent linkage, see Ravikant Bhardwaj et al, "The Impact of Patent Linkage on Marketing of Generic Drugs", (2013) 18 *Journal of Intellectual Property Rights* 316, available at http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf

compulsory licensing and parallel importation measures. But what it does not do is address the manner in and the extent to which our law is deficient and what this means for legislative and regulatory reform.

Compulsory licensing

70. Article 31 of TRIPS, entitled "Other Use Without Authorization of the Right Holder",[90] 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.[91] 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).

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

[90] The footnote to Article 31 defines "other use" as "use other than that allowed under Article 30."
[91] 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.

> determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee";

71.2. Section 55, which deals with "[c]ompulsory 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 –

> "[a]ny 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.

Section 4 licences

73. In terms of section 4, any Minister may grant a compulsory licence to an organ of state (such as the Department of Health ("DoH")) or a third party (such as a domestic generics 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.[92]

74. The problem with section 4 is that the relevant Minister must agree with the

[92] This would constitute public non-commercial use.

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. This problem could most easily be addressed by not mandating any prior consultation with the patentee in order to issue a license under section 4, since government use licences require no prior consultation with the patent holder. In addition, the problem could be addressed by the express inclusion in section 4 of default positions regarding licence conditions, including but not limited to royalty rates. Absent agreement on conditions, the default positions would automatically come into force, allowing for the immediate use of the licence. To address concerns regarding the adequacy of the royalty rate, section 4 could also make provision for the Commissioner to be approached to raise or lower the rate, on application and upon good cause shown. Should the rate be adjusted, 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[93] to ensure access to medicines.

76.2. In terms of process, section 56 is unwieldy. Consider the following, amongst other, concerns:

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 noting of an appeal against the grant of a licence automatically suspends the operation of that licence;[94] and

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 and in pursuance of the realisation of the right to have access to health care services. The process could be simplified: as already indicated, Article 1.1 of TRIPS provides that WTO "[m]embers shall be free to

[93] Grounds should include when; medicine prices prohibit access, supply is inadequate to need, there is a need for multiple suppliers to avoid shortages or stock-outs, the patent holder has refused to grant a voluntary license 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.

[94] This could be addressed, resources and time permitting, by a Rule 49(11) application for interim execution pending an appeal.

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, a number of countries have issued compulsory licences to improve access to medicines, including India, Thailand, Brazil, Malaysia, Zambia and Ecuador.[95]

77.2. Indonesia recently issued a decree authorising government use of patents for seven HIV and hepatitis medicines, which is likely to introduce generic competition and result in large cost savings.[96]

77.3. 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.[97] [98]

78. We do not suggest that access to medicines should be reliant on the

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[95] Beall. R, Kuhn. R (2012). Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis. PLoS Med 9(1): e1001154. doi:10.1371/journal.pmed.1001154 Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154

[96] Public Citizen. (2012). "*Indonesia Licenses Patents for Seven HIV & Hepatitis B Medicines".* Available at: http://www.citizen.org/PC-statement-on-compulsory-licensing-in-Indonesia

[97] KEI. (2013). "The US Department of Justice and USPTO call for compulsory licenses on thousands of "standards-essential" patents". Available at: http://keionline.org/node/1663; KEI. (2012). "Posner's dismissals of the patent infringement suits in Apple versus Motorola cites eBay and compulsory licensing". Available at: http://keionline.org/node/1449; KEI. (2012). "Posner's dismissals of the patent infringement suits in Apple versus Motorola cites eBay and compulsory licensing". Available at: http://keionline.org/node/1449.

repeated grant of compulsory licences (although other country experiences demonstrate that they can reduce the cost of key medicines in the public and private health sectors). To the contrary, we make our submissions mindful that the mere existence of easy-to-use compulsory licence provisions could, in many cases, result in the conclusion of negotiated voluntary licence agreements that can achieve drastic price reductions. But without statutory backup, those seeking licences on reasonable conditions have little to no negotiating power.

79. Part of this backup includes the appropriate regulation of licensing conditions, as permitted by Article 40 of TRIPS. While some of the following problematic licencing practices[99] may already be prohibited under the Competition Act, others may need to be addressed in the Patents Act:

79.1. Undermining oppositions on pending patents and restricting patent challenges by licensees;

79.2. Retaining control of the active pharmaceutical market by permitting licensees to source only from approved suppliers;

79.3. Securing exclusive grant-back rights over developments or improvements made by licensees; and

[99] Pharmaceutical companies often impose other restrictions that are recognised as being anti-competitive and sub-optimal from a public health perspective. Specific restrictions that undermine access to affordable medicines include (this is not exhaustive): offering exclusive licenses that do not enhance competition, deterring governments from using compulsory licenses or Government Use provisions, or prohibition of generic manufacturers against becoming a compulsory licensee and delaying generic entry through unsuitable technology transfer.

79.4. Tying in licensees beyond the term of the patent.

Parallel Importation

80. Article 6 of TRIPS 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.

81. 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". This principle should apply to international, branded or generic products as well as those manufactured under a compulsory license.[100]

[100] Existing Kenyan legislation (Article 58.2 of the Kenyan Industrial Property Bill) has not been challenged to date by the WTO and allows for the parallel importation of international products, either branded or generic, including those manufactured under a compulsory license: "The rights under the patent shall not be enforceable against any person who imports or in any way deals in the patented product, or a product obtained by the patented process, once the said product has been lawfully placed on the market in any country with the consent of the owner, a licensee or any other authorised person". For more information on parallel importation in Kenya please see: Munyi. P, Lewis-Lettington. R. (September 2004). "Willingness and Ability to Use TRIPs Flexibilities: Kenya case study" DFID Health Systems Research Centre, Issue Paper – Access to Medicines accessible at http://www.hlsp.org/LinkClick.aspx?fileticket=rB0enzg20-I%3d&tabid=1643

82. Section 15C(b) of the Medicines Act 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 –

82.1. 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;

82.2. 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;

82.3. 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

82.4. 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.

83. Because state tenders are 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.

84. We make the following recommendations in respect of compulsory licensing and parallel importation:

84.1. The current process in terms of section 56 of the Patents Act should be replaced by a simple, expeditious administrative procedure that is subject only to review proceedings in the High Court or the Court of the Commissioner of Patents;

84.2. Pending any review of the grant of a compulsory licence, interim relief should only be available – upon application – in exceptional circumstances;

84.3. Default positions regarding licence conditions (including but not limited to royalty rates) and negotiation timelines should expressly be included in sections 4 and 56 of the Patents Act. In addition, a government entity should have the right to issue a compulsory licence under section 4 without any prior consultation with the patent holder;

84.4. Licensing practices should expressly be regulated, as contemplated by Article 40 of TRIPS; and

84.5. Regulation 7 of the General Regulations made under the Medicines Act should be amended to give full effect to section 15C(b) dealing with parallel importation.

R&D, PUBLIC FUNDING, INNOVATION AND ACCESS

85. The draft policy includes among its objectives the development of a technology transfer strategy for the purposes of building local skills and capacity, as well as the promotion of research, development and innovation.[101] This is to be welcomed, as is the inclusion of a section on alternatives to IP in the context of encouraging innovation.[102] In particular, we welcome the suggestion that the state should finance prize funds or provide subsidies in order to create incentives for R&D – particularly in the health field – that might otherwise not be conducted by the private sector.[103]

86. The World Health Organization ("WHO") has recognised the challenges the existing R&D system poses to addressing global health needs. A report issued by its Consultative Expert Working Group ("CEWG") in 2012 recognises the importance of member states identifying research gaps in the health field that the private market has failed to address and funding such priorities in a strategic manner. The report also identifies the importance of utilising innovative financing mechanisms to "de-link" the cost of R&D from

[101] Objectives 15 and 17, at page 7.
[102] Page 22.
[103] The granting of exclusive rights in a patent, even if based on high standards of innovation, does not guarantee that the private sector will develop the medicines most needed by South Africa and other developing countries. Instead, it ordinarily results in R&D focused on medicines for wealthy markets. In addition, legal mechanisms are often not in place to ensure that R&D financed by public resources results in affordable products. Creating adequate financial incentives to stimulate research in neglected fields and ensure ultimate affordability of resulting products thus rests with governments.

the price of resulting products.[104]

87. The CEWG report proposes a number of innovative mechanisms aimed at ensuring that R&D addresses the health needs of all:

87.1. Open-source approaches to expedite follow-on innovation;

87.2. Pooled funds to raise adequate and reliable capital for research;

87.3. Direct grants to companies for priority product development;

87.4. Milestone and end-stage prizes as an addition to grants for the development of medical tools; and

87.5. Patent pools that openly license medicines or medical technologies to allow for collaborative development, follow-on innovation of combination therapies, or for more affordable production by generic companies.

88. We submit that the public interest requires publicly-financed R&D to be aimed at securing accessible innovations. Put simply, public funds should only be available if the final products of R&D are to be affordable, adapted to the

[104] "Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination: Report of the Consultative Expert Working Group on Research and Development Financing and Coordination" (April 2012), available at www.who.int/phi/CEWG_Report_5_April_2012.pdf. This is also in line with the recommendation to establish "knowledge and innovation centres" which finance the innovation gap between basic research and commercialisation in a recent report initiated by the dti (Anastassios Pouris, *Technology Trends: A Review of Technologies and Policies* (University of Pretoria, 2012) available at www.thedti.gov.za/industrial_development/docs/Final_Technology_Trends.pdf.

context where they are needed and available. This could be achieved in a number of ways, such as through conditions that require funded entities to grant non-exclusive licences on reasonable terms.[105]

89. South Africa's IPRs from Publicly Financed R&D Act already places an obligation on research institutions in South Africa to identify, protect and commercialise IP arising from publicly-funded R&D for the benefit of the country's people. It also requires researchers receiving public funds to disclose any new IP in a timely manner to their relevant Technology Transfer Offices. But what it does not do is 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.

90. We therefore make the following recommendations:

90.1. The dti should collaborate with relevant departments and statutory councils to ensure that publicly-financed R&D in South Africa is aimed at delivering affordable inventions.

90.2. In particular, the dti should engage with the DST regarding the need to consider possible amendments to the IPRs from Publicly Financed R&D Act.

[105] Such terms should be defined in the relevant funding contract.

90.3. The IP policy should engage more fully with the alternative funding mechanisms for promoting R&D that South Africa supports, with a particular focus on how these may be given effect domestically – both in terms of legislation and budgetary allocations.

EXCEPTIONS TO PATENT INFRINGEMENT

91. 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 promote the public interest in sectors of vital importance to a country's socio-economic and technological development. It is generally understood that under Article 30, any entity, whether commercial, public non-commercial or not-for –profit, can conduct work related to or on a patented invention, and, under certain circumstances, with a patented research tool through the use of a licence.[106] WTO members may provide exceptions for regulatory purposes (such as medicines registration), as well as for broader research and education purposes.[107]

92. South African law only makes provision for an exception for regulatory

[106] Such research may be carried out for the following activities: experimentation; scientific research; technological research, which may be done with the intent of advancing commercial or for-profit objectives; non-commercial purposes; registration purposes; activities with a commercial intent that, for example, may be aimed at improving on patented technology insofar as the activity can be classified as experimentation or technological research—this could for example require a compulsory license on a dependent patent to conduct research for follow-on innovations, or be based on independent innovation where a third party develops a new technology which does not infringe upon the patents on which the research was based.

[107] Phoebe H Li 'Rights and responsibilities in patents: a precautionary patent framework in WTO law' European Intellectual Property Review 2013. See especially page 4-5; Carlos Correa 'the international dimension of the research exception (January 2005) available from http://sippi.aaas.org/Pubs/Correa_International%20Exception.pdf.

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 Supreme Court of Appeal in *Cipla Medpro (Pty) Ltd v Aventis Pharma SA and related appeal*, [108] in which the court held that the concept of contributory infringement is part of our law.

93. 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.

94. 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.[109] A number of them also make express statutory provision for broad research exceptions.[110]

95. Brazil's patent law, for instance, provides for "acts carried out by unauthorised third parties for experimental purposes, in connection with

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[108] 2013 (4) SA 579 (SCA).

[109] 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

[110] Switzerland's Federal Act on Patents for Inventions, Art. 9.b makes exception for "any scientific research": http://www.admin.ch/ch/e/rs/232_14/index.html

scientific or technological studies or researches":[111]

95.1. The wording of this provision appears designed to leave open to broad interpretation the definitions of "experimental purposes" and "scientific research".

95.2. 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.[112]

96. In addition to adopting a broad research exception, South Africa should also adopt a broad educational use exception to patent rights.[113] Academics and researchers must be able to train the next generation of inventors and scientists on research and product development methods. Tertiary institutions, and even secondary institutions, should be permitted to use patented products or processes for the purpose of instruction.[114] Again, Article 30 of TRIPS allows such an exception and there is precedent in Brazil, India, and Argentina.[115]

97. One final issue on exceptions needs to be addressed: the draft policy's suggestion that the stockpiling of generic medicines prior to patent expiry be

[111] Article 43, Paragraph II, Law n. 9.279 of 14 May 1996, available at http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/brazil/industrial_property_law.pdf
[112] See: Slide 10 http://unctad.org/sections/dite_totip/docs/tot_ip_0024_en.pdf
[113] South Africa should also be open to exploring limited exceptions for broader education with respect to copyright, so as to secure greater access to affordable educational and informational resources.
[114] For suggested wording of educational use exceptions, see Section 1.b of: www.twnside.org.sg/title2/chapter6.doc
[115] 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

prohibited. While a WTO panel found a Canadian stockpiling exception to be in violation of TRIPS in 2000,[116] 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. What we recommend is 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.

98. On exceptions to patent infringement, we therefore make the following recommendations:

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

98.2. The Patents Act should be amended also to include an educational use exception; and

98.3. The Patents Act should specifically allow generic companies to manufacture, import and/or store generic product to allow for immediate marketing upon patent expiry.

DATA PROTECTION AND EXCLUSIVITY

99. Insofar as it is relevant, Article 39.1 of TRIPS notes that "[i]n the course of ensuring effective protection against unfair competition …, Members shall

[116] *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.

protect … data submitted to governments or governmental agencies in accordance with paragraph 3." In other words, the protection of test data is required to ensure "effective protection against unfair competition" – and not to create a new substantive right of exclusivity.

100. Article 39.3 provides as follows:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

101. Data exclusivity is something else. In the United States and Europe, data exclusivity ordinarily prohibits drug regulatory authorities – for a specified period of time – from relying on or referring to test data submitted by the exclusive rights holder when considering applications for the registration of generic equivalents of the already-registered patented invention. By doing so, they may delay the registration and market entry of generic equivalents.

102. In most developing countries, generics manufacturers only have to show that their products are "bio-equivalent" to the already-approved medicine – rather than duplicating test data.[117] This is also the case in South Africa. There is

[117] For explanation of generic bio-equivalence and more on data exclusivity, see WHO Briefing Note on Access to Medicines, available at http://www.wpro.who.int/hiv/documents/docs/BriefingNote2DataexclusivityMarch2006_47A0.pdf.

no good reason why, in this regard, our law should be changed. Importantly, there is nothing in TRIPS which requires data exclusivity.[118]

103. While the draft policy recognises that one of the principal consequences of a period of data exclusivity would be the high cost to generics manufacturers of repeating clinical trials, we submit that it is important to recognise that duplicating clinical trials in respect of a medicine whose safety and efficacy has already been proven would violate medical ethics. This is because prescribing placebos for certain patients (as is done in the ordinary course of phase III clinical trials), despite proven knowledge that an effective treatment is available, would be unethical.

104. Data exclusivity provisions apply regardless of the patent status of a medicine. As noted in the report of the WHO's Commission on Intellectual Property, Innovation and Public Health ("CIPIH"):[119]

> "If the patent period has expired, or there is no patent on the product, this sui generis data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent, where required. The only

[118] TRIPS does not require data exclusivity or any of the following provisions: patent term extensions, new forms of IP enforcement measures such as detaining shipments suspected of non-criminal trademark infringement, the inclusion of investment provisions whereby foreign investors are able to challenge any action that led to the 'expropriation' of their investment in private arbitration proceedings. These provisions are widely acknowledged as TRIPS-plus provisions and would severely restrict access to medicines in the country. As such, South Africa should reject the inclusion of such measures as outlined in the policy and this submission. At a recent Workshop on IP and Public Health held by the dti in Pretoria on 7/8 August 2013, representatives of the WTO and WIPO affirmed that Article 39.3 does not refer to data exclusivity.

[119] WHO, *Public health, innovation and intellectual property rights, Report of the commission on Intellectual property rights, innovation and public health* (WHO: Geneva, 2006) at 126, available at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf

alternative for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues since it would involve replicating tests in humans to demonstrate what is already known to be effective. These sui generis regimes, which provide for data exclusivity need to be clearly differentiated from the TRIPS agreement's requirement for data protection."

105. The example of Jordan is telling, where data exclusivity was introduced following the country's conclusion of an FTA with the US. A 2006 study by Oxfam showed that of the 103 medicines registered and launched since 2001 that had no patent protection, at least 79 per cent had no competition from a generic equivalent as a direct consequence of data exclusivity.[120] A more recent analysis by the Medicines Transparency Alliance estimates that delayed market entry of generics resulting from the TRIPS-plus requirements in the US-Jordan FTA cost consumers $18 million annually.[121]

106. Where a legitimate patent does exist, data exclusivity provisions could be used to render public health flexibilities meaningless. In 2006, for example, the European Patents Office revoked outstanding patents on esomeprazole ("Nexium").[122] Because the data exclusivity provisions were to remain in force until 2010, generic versions of the acid reflux medicine were prevented from being marketed. Thus where the data exclusivity period extends beyond patent protection, generic entry may still be delayed.

107. We therefore make the following recommendations:

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[120] Oxfam, above note 20 at 7.
[121] RB Abbott et al, "The price of medicines in Jordan: the cost of trade-based intellectual property" (2012) 9 *Journal of Generic Medicines* 75, available at http://jgm.sagepub.com/content/9/2.toc
[122] Ratiopharm GmbH v AstraZeneca AB EPO Board of Appeal, 19 December 2006.

107.1. Calls for data exclusivity should be rejected on the basis that they are not required by Article 39.3 of TRIPS and they unreasonably and unjustifiably limit access to medicines; and

107.2. The status quo in this regard should be retained, with the Patents Act only making provision for data protection.

MSF, TAC AND SECTION27

Johannesburg and Cape Town

17 October 2013