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The legal and political imperatives for proposed amendments of the South African Patents Act to implement TRIPS flexibilities and enhance the framework for access to medicines

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I hereby declare that I have read and understood the regulations governing the submission of Master of Laws dissertations/research papers, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation/research paper conforms to those regulations.

Signed by candidate

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API	Active pharmaceutical ingredient
ART/AVT	Antiretroviral therapy
CIPC	Companies and Intellectual Property Commission
CL	Compulsory Licence
DoH	Department of Health
DTI	Department of Trade and Industry
FDI	Foreign direct investment
IBSA	India-Brazil-South Africa Dialogue Forum
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICTSD	International Centre for Trade and Sustainable Development
IP	Intellectual Property
IPR Commission	UK Government Commission on Intellectual Property Rights
GATT	General Agreement on Tariffs and Trade
MDG	Millennium Development Goal
MSF	Médecins Sans Frontières (Doctors Without Borders)
NCE/NME	New chemical entity/new molecular entity
PhRMA	Pharmaceutical Research and Manufacturers of America
PTA	Preferential Trade Agreement (interchangeable with definitions of 'Regional Trade Agreement' and 'Free Trade Agreement')
TAC	Treatment Action Campaign
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
USTR	United States Trade Representative (Office of)

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Abstract

A multitude of factors affect the ability of South Africans to access the essential medicines, intellectual property (IP) is one of them. This dissertation considers some of opportunities open to South Africa through international IP flexibilities, which are aimed at safeguarding public health rights against the sometimes access-restricting effects of patent right monopolies. Potential pitfalls are also highlighted, noting strategies for South Africa to avoid the worst of them. The paper begins by giving an overview of the way in which patents affect access to medicines, and contending that the time for making the proposed amendments is now. Specific proposals for the patent framework in South Africa should be considered to i) tighten the standards of patentability to ensure that only those medical inventions which are truly inventive and demonstrate therapeutic improvements are rewarded with patent protection, ii) introducing opportunities for pre- and post-grant opposition, iii) streamlining the compulsory licensing framework to encourage use on public health grounds, and iv) resist introducing measures which go beyond what is required under South Africa's international commitments, such as data exclusivity and patent linkage. Read together, the chapters of this dissertation encourage a shift in public policy making by the Government of South Africa, towards a proactive prioritisation of the public health needs of the country.

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Introduction

17 years have passed since the Members of the General Agreement on Tariffs and Trade (GATT) brought into force the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, as part of a package of 17 agreements setting up the World Trade Organisation (WTO). Amongst other things, TRIPS requires countries to adopt minimum standards of intellectual property (IP) protection. For many countries, this meant extending patent protection for pharmaceutical products for the first time; for others it meant extending the life of patents which were already granted. Some developing and least developed countries were granted transition periods for implementing the full range of standards. In South Africa, where pharmaceutical patent protection did exist for both products and processes prior to 1995, the life of a patent was extended from 16 to 20 years.

Prior to TRIPS coming into force in 1995, as well as in the years that followed, many governments and public health organisations became increasingly concerned that the Agreement, which has strengthened protections on potentially life-saving medicines in many countries, was restricting abilities to respond to public health emergencies by accessing the essential, life-saving medicines, because of the high prices patent monopolies afford.

This crisis came to a head in the late 1990s and early 2000s, and culminated in WTO Members agreeing to the Declaration on the TRIPS Agreement and Public Health (the 'Doha Declaration') in 2001, which affirmed agreement by Members that

> *"the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".*[1]

In a broad sense, the Doha Declaration does not provide new flexibilities for countries *per se*, but is rather a clarification on the rights that have been contained in TRIPS since its inception. When considering the specific ways South African laws should be amended to

[1] Paragraph 4, *Doha Declaration*, adopted 14 November 2001.

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support access to medicines, therefore, we look to the TRIPS Agreement itself, which spells out a number of ways to use the existing IP framework in a way which supports public health. We refer to these as 'flexibilities' because they provide, in some circumstances, exceptions to the exclusive right of patent holders to monopolise the use of their inventions, and because they provide a degree of openness for countries to determine, according to local needs, exactly how to implement certain provisions.

Over the years, a number of international organisations have called for developing countries to implement the TRIPS flexibilities. The *WHO Global Strategy and Plan of Action*, for example, urges Member States to 'take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by [TRIPS], without prejudice to the sovereign rights of Member States.'[2] To that end, much has been written around strategies to assist developing countries to make the most of available TRIPS flexibilities to achieve goals around securing stronger access to medicines[3] – this dissertation tailors some of the most important of this strategies f or the uniquely South African situation.

While these sentiments have, by and large, been supported by local public health organisations over time, it is in late 2011 that the HIV advocacy organisation in South Africa, the Treatment Action Campaign (TAC), in conjunction with the constitutional health and education rights organisation, Section 27, began to seriously agitate for the South African Government to recognise that the time has come to implement these TRIPS flexibilities. [4] The 'Fix the Patents Law' campaign went live on 26 January 2012,[5] and calls

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[2] Paragraph 36, (5.2)(b), WHO, World Health Assembly, 'Global Strategy and plan of action on public health, innovation and intellectual property' 2008.

[3] See ,for example, Avafia, T, Berger J and Hartzenberg T, 'The ability of select sub-Saharan countries to utilise TRIPS flexibilities and competition law to ensure a sustainable supply of essential medicines: a study of producing and importing countries' *Trade Law Centre for Southern Africa (TRALAC)* 2006; IPR Commission, 'Patent reform' *Integrating Intellectual Property Rights and Development Policy,* UK Government; Correa C, 'Guidelines for the examination of pharmaceutical patents: developing a public health perspective' *WHO-ICTSD-UNCTAD Working Paper* (2007); El Said, M, 'A policy guide for negotiators and implementers in the WHO Eastern Mediterranean region' ICTSD/WHO, 2010; Kettler, E and Collins C, IPR Commission 'Study paper 2b: Using innovative action to meet global health needs through existing intellectual property regimes' UK Government; Musungu, S and Oh, C, 'The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?' Study 4C, Commission on Intellectual Property Rights, Innovation and Public Health, WHO (2005); Thorpe, P 'Study paper 7: study on the implementation of the TRIPS Agreement by developing countries' IPR Commission.

[4] See TAC media release, 'The Treatment Action Campaign calls on government to amend South Africa's Patents Act and protect our right to health'16 November 2011.

on the South African Government to finally make use of the flexibilities under international law by enshrining them into national law. The proposed changes centre on reviewing the patent examination process to tighten the criteria for patentability and introduce pre and post grant opposition procedures, and clarifying the methods for granting compulsory licences on public health grounds.

This dissertation aims to expand on those Campaign proposals. It identifies the South African legislation which needs to be changed, and examines the legal basis under TRIPS; the Constitution; human rights law: and other international legal instruments to make such changes. The dissertation also draws on a much wider literature to examine the social and economic arguments for and against such changes, and to develop a critical legal and policy analysis of the changes at a more nuanced level. The experiences of other countries in implementing specific TRIPS flexibilities provide particularly useful case studies to guide South Africa while it considers exactly how it will implement the measures, according to the local legal framework, and to suit local needs.

The first chapter answers the broad questions behind the proposals: *why* South Africa should make these changes; *what* are the changes; *how* these changes are supported by international law; *how* to implement locally; *how* the changes would benefit public health; and *why* the time to make the changes is now. It also touches on the benefits of incorporating human rights into the advocacy for these changes.

The second chapter describes the deleterious practice of evergreening in the field of pharmaceutical patents. It goes on to explain how amending the *Patents Act,* by introducing stricter grounds for granting a patent in South Africa, can lead the way in fighting against evergreening, and associated longer patent monopolies.

The third chapter argues for the introduction of pre- and post-grant opposition against patent applications. Introducing opportunities for pre-grant opposition will improve the quality of patents granted in South Africa, as more evidence is brought to the attention of examiners by third parties during the decision-making process. Post grant opposition opportunities would act as a safeguard if earlier Chapter 2 suggested measures do not result

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[5] See ‘Fix The Patent Laws’ website http://www.fixthepatentlaws.org/ [Accessed 27 January 2012].

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in a correct determination as to patentability. The measures in this chapter are also aimed at stemming evergreening.

The fourth chapter examines how the compulsory licensing framework should be amended in South Africa to facilitate acquisition of licenses to manufacture or import patented medicines on expanded public health grounds. The amendments should incorporate a simplified, administrative framework to ensure that non-government parties are more easily able to apply for and pursue compulsory licenses in South Africa.

The fifth chapter explores the so-called 'TRIPS Plus' practices of data exclusivity (providing protection on test data submitted to regulatory agencies for the purposes of gaining marketing approval) and patent linkage (requiring regulatory agencies to consider the patent status of drugs before granting market approval), arguing that South Africa should avoid incorporating these into national law. While these are not TRIPS flexibilities, like the other mechanisms discussed in the dissertation, they have been included as a chapter because they are IP standards which are becoming increasingly common in international trade agreements. It is therefore important to highlight the detrimental impacts of these mechanisms now, as it is likely that the South African Government will be pressured, in international trade agreements and elsewhere, to incorporate them, if it has not been already.

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Chapter 1: Making the case for implementing the TRIPS flexibilities to protect and promote access to medicines

The TRIPS flexibilities provide safeguard for the ability of all WTO Members to address public good objectives, by providing exceptions to the monopoly rights of patent holders. While particular emphasis, in this dissertation and elsewhere, is made on flexibilities of special application and availability for developing countries, it is important to note that by and large,[6] they are open to countries at all stages of development.

How does patent law affect access to medicines?

To bring it to its simplest, there are two important ways in which patent law has the potential to restrict access. The first is by creating protections on existing drugs, which give patent holders exclusive control to licence, manufacture and distribute their product. The lack of competition on many patented drugs inevitably leads to high prices, meaning that a large proportion of the world's poor cannot afford, and therefore, access essential medicines.[7]

The second important way patent law affects access is by influencing the kind of innovation which is undertaken in the first place. The IP model engrained under TRIPS requires countries to reward innovation with the exclusive right to exploit an invention under a patent. But when countries extend this reward to incremental innovations (which represent little to no therapeutic improvement over existing therapies), the incentive to make major medical advances for developing countries without large demand-driven markets declines. Because TRIPS sets the minimum standards for IP protection, while at the same time provides flexibilities in its implementation, this dissertation focuses on how South Africa should strike the balance to enhance access to medicines, while at the same time living up to its international commitments.

Focusing on the patent framework as a way of enhancing access to medicines is not without its detractors. Critics of a forward looking and flexible patent framework for

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[6] There are a few exceptions – for example transition periods and Doha Paragraph 6 solutions only extend to developing and least developed countries (discussed in Chapter 4).

[7] 'Essential medicines' in this dissertation should be understand to align with the WHO 'Model List of Essential Medicines', which comprises of a core list, representing minimum medicine needs for a basic healthcare system, and a complimentary list, comprising essential medicines for priority diseases. http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf [Accessed 3 February 2012].

developing countries often argue that intellectual property protections are not the main barrier to better access to medicines in poor regions of the world. They argue that the lack of access to medicines in developing countries is the result of a wide range of factors, mostly to do with misplaced government priorities, policy failures, and/or corruption.[8] One critic complains bluntly of the access to medicines movement, '[l]aying blame for the problem on the WTO and the TRIPS Agreement is overly simplistic and wrong, and does nothing to alleviate the crisis.'[9]

This dissertation does not seek to argue that changing the Patents Act in such a way as proposed is the only, or indeed the most important way of enhancing access to medicines. This author acknowledges, and would not seek to underplay, the importance of other factors affecting access, including, *inter alia*, the slow registration of medicines in developing countries; inefficiencies in procurement and budgeting; the presence or absence of a viable generics industry; human resources constraints; and wider health system distribution and capacity. But a patent regime which is sensitive to public health needs should certainly be part of the drive for better access.

It has also been pointed out by other critics that because medications are not widely patented in Africa[10]; patents, therefore, do not represent a barrier to access.[11] Why not simply exploit all the unpatented medical inventions in Africa? While such a strategy is worthy of further attention, as it could potentially result in near-term affordable access to a number of medications for a number of important illnesses, it is not the focus of this dissertation. Briefly however, it is worth addressing these arguments. Those studies finding low rates of patenting in Africa do not take into account the particular distributions of patent protections against the most medically relevant and marketable drugs in countries.

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[8] See, for example, Kogan, L, 'Brazil's IP Opportunism Threatens U.S. Private Property Rights, *The University of Miami Inter-American Law Review*, Vol. 38, No. 1 (Fall, 2006), p 56.

[9] The International Intellectual Property Institute, 'Patent protection and access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa' *A report prepared for the World Intellectual Property Organization* http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf [Accessed 4 January 2012].

[10] One 2004 patent survey found that in 65 lower and middle income countries, patenting of the 319 medicines on the WHO's Model List of Essential Medicines list is rare, sitting at **1.4 per cent** (source: Attaran A, 'How do patents and economic policies affect access to essential medicines in developing countries?*' Health Affairs* 23, no.3 (2004):155-166). Another survey found that in a theoretically possible 795 cases of patentable ARVs in 53 African countries, only **21.6 per cent** actually exist (source: Attaran A and Gillespie-White, L, 'Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?' *Journal of the American Medical Association* Vol. 286 No.15 (2001).

[11] The International Intellectual Property Institute, *op cit.*

For example, every three drug ARV cocktail is blocked by patents in South Africa, with the majority of remaining ARVs also patent protected.[12]

Such a strategy, furthermore, is unlikely to yield the same long-term positive effects of a revised, flexible patent framework. It is arguable whether drug companies, with their strong history of asserting their interests,[13] would not simply respond to such a trend by recognising that there is some kind of a market, and then stepping up their patenting and prosecuting behaviour in Africa as a response. This is not to say that unpatented medicines should not be exploited to enhance access to medicines in South Africa – indeed this option should be exploited where it is available – but this dissertation is directed rather, at achieving a longer-term patent framework which is supportive of only true innovation, and which provides the flexibility for exceptions on private monopoly rights to be made on public interest grounds.

Political imperatives

The reasons for taking these proposals forward at this point in time lie on a mix of legal and social grounds, as well as political: taking the Government to task for commitments it has made, and in order to fulfil its constitutional as well as public commitments.

Making changes to the Patents Act in South Africa should represent, for the Government, one straightforward way of achieving better access to medicines with minimal political and economic costs. It requires minimal political buy-in because such proposed flexibilities are specifically provided for under international law. From history, we see that many developed countries have, and will most likely continue, to take steps to discourage, challenge, and even punish developing countries for making use of TRIPS flexibilities.[14] However, if implementation is carefully managed to reflect the intentions of the TRIPS Agreement, such measures are easily defendable under international law. This

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[12] Faunce, T 'Global intellectual property protection of "innovative" pharmaceuticals' in *Globalization and health: challenges for health law and bioethics*, (Bennett B and Tomossy G, eds) p 101.
[13] For a discussion on the development of increased patenting and enforcement activities by patent right holders, see Hall, B, 'Exploring the patent explosion' *Essays in Honor of Edwin Mansfiel*d Part 4, 195-208, Springer (2005).
[14] For an overview of pressure by developing countries see Skyes, A 'TRIPS, pharmaceuticals, developing countries, and the Doha "solution"', *Chicago Journal of International Law,* Volume 3 No. 1 (2002) pp 58-60.

thesis attempts to set out suggestions for implementation which can help South Africa realise its public health objectives, while at the same time remain compliant with international commitments on health, intellectual property and trade.

Aside from social and economic arguments in favour of making these amendments at any point in time, there are other indications that the time to act is *now*. World Health Organisation adviser, Dr Zafar Mirza has well articulated that there are several reasons for renewed concern about intellectual property among the UN organizations, chief among these the fact that 'diseases are becoming more difficult to treat and the available health tools, be it medicines or diagnostics, are becoming "increasingly blunt", thus requiring new medicines that are governed by strong and lengthy patent regimes'.[15]

In considering proposed amendments to the Patents Act in 2002, which sought to introduce an administrative procedure to access the provisions of compulsory licensing, rather than the judicial provisions as then provided for, the DTI put forward a number of reasons why the proposals were unnecessary, at that point in time. Chief amongst these was that efforts to implement changes in line with the Doha Declaration would be premature, because 'the exact nature of these efforts... still needs to be negotiated and may result in changes to the TRIPS Agreement that can be implemented once negotiations have been concluded.'[16] While the DTI might have argued in 2002 that exactly what was envisaged by the meaning of the original TRIPS flexibilities, as elaborated upon with the Doha Declaration, this argument stands up less well today. A body of practice (in the form of examples by other countries) has since emerged to indicate the kinds of compulsory licensing practices which are acceptable and effective, and adequately satisfy requirements of due process under TRIPS.

Although the Government has not publicly announced a timeframe for the commencement of a process to review and implement TRIPS flexibilities into the Patents

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[15] Third World Network, 'Use TRIPS flexibilities to reduce HIV drug prices, urges UN bodies' 18 March 2011 http://www.twnside.org.sg/title2/health.info/2011/health20110305.htm [Accessed 4 January 2012].
[16] DTI submission on the Proposed amendments to the Patents Act, presented to the Standing Committee on Private Members' Legislative Proposals and Special Petitions, 19 June 2002 http://www.pmg.org.za/docs/2003/appendices/030618dti.htm [Accessed 2 December 2011].

Act,[17] it has indicated in a number of forums its intention that a review may be up-coming. The DTI reportedly wrote in 2011 to TAC and Section 27 as follows:

> *'The Government is developing an Intellectual Property Policy (IP Policy) which will also address access to medicines and public health issues… The IP Policy will also establish a framework for legislative reform across all areas of IP policy to ensure a consistent approach that contributes positively to the economic and social interest of South Africa.*
>
> *The Policy will provide clarity as to which sections of the Patents Act 57 of 1978 and the Medicines Control and Related Substances Act 101 of 1965 require amendment to ensure that the flexibilities relating to access to medicine and health are incorporated into national legislation.'*[18]

The above, while encouraging and seemingly quite specific, will require careful scrutiny by public health organisations and commentators to ensure that it is implemented in a way which does indeed prioritise public health interests and access to medicines, rather than commercial interests. To that end, it is important that the Government consult widely and take a holistic view of the 'economic' implications of a patent framework review – to take into account the wider economic benefits of a healthy population, and not submit to narrow commercial pressures.

The Government is also under an obligation stemming from recent announcements to implement TRIPS flexibilities under the auspices of the India-Brazil-South Africa (IBSA) Dialogue Forum. Meeting in October 2011, leaders of this group declared as follows:

> *'The Leaders expressed their conviction that universal access to healthcare and affordable medicines is an indispensible step to achieve the ambitious goals adopted by the international community in the fight against communicable and non communicable diseases, as set forth by the Political Declaration on HIV and AIDS*

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[17] As far as this author can determine.

[18] Letter from Minster for Trade and Industry, Rob Davies, reproduced in TAC's 'Fix the Patent Laws: Campaigning for pro-public health reform of South Africa's Patents Act' briefing document, 26 January 2012 http://www.fixthepatentlaws.org/?p=79 [Accessed 27 January 2012].

of 2011 and by the Political Declaration on the Prevention and Control of Non-communicable diseases of 2011.

Furthermore, the Leaders recognised that the effective impact of intellectual property on health, access to drugs and prices can best be tackled by enabling developing nations to scale up production of through the full use generic medicines of the flexibilities provided by the [TRIPS] agreement, in accordance with the Doha Declaration on TRIPS and Public Health, and, with the support of the World Health Organisation, by the Global Strategy on Public Health, Innovation and Intellectual Property, (WHO).'[19]

The IBSA Dialogue is a particularly relevant forum to be pursuing policy and legislative options for implementing TRIPS flexibilities, since India and Brazil, as will be discussed in this dissertation, have both implemented TRIPS flexibilities in various ways which can provide guidance for South Africa. It is hoped that this relationship, through advice and close cooperation, will be capitalised upon by South Africa, as it considers these important access to medicines IP policy review issues.

One final sign of the Government's commitment to pursue patent amendments in the near future can be found in the DTI's Medium-Term Strategic Framework (2010-2013), in which it commits itself to 'ensuring consumer protection' by, *inter alia*, '[c]omprehensively reviewing various intellectual property laws and policies on an ongoing basis'. [20]

It is important to spend a large section of this dissertation canvassing public Government commitments to implement the TRIPS Agreement, because clear and detailed intentions have not yet been revealed. While the above is encouraging, there is growing concern among some sectors that, despite South Africa's history of activism in driving the early access to medicines movement, and despite the massive public health challenges the country continues to face, there is a growing trend for conservative (read: prioritisation of business over public interests) IP policy among government officials. This has created a

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[19] Paras 57-58, IBSA Dialogue Forum Fifth Summit of Heads of State and Government, *Tshwane Declaration*, 18 October 2011.
[20] DTI Medium-Term Strategic Framework, 2010, p 49.

sense of unease as to whether such amendments and future policies will be made which prioritises public health.

For example, there will be a conference in Cape Town in April 2012 entitled, 'Africa Intellectual Property Forum: Intellectual Property, Regional Integration and Economic Growth in Africa'. This ministerial level meeting will bring together the governments of the France, Japan, South Africa, and the United States, WIPO, and in collaboration with the African Intellectual Property Organization (OAPI), the African Regional Intellectual Property Organization (ARIPO), and the international private sector.[21] It is reported to address the 'dynamic role of intellectual property protection and enforcement in promoting knowledge-based economies through innovation, trade and investment.'[22] It is sponsored by an anti-piracy business coalition, Microsoft and two brand name pharmaceutical companies.

This is the first conference of its kind, so it will remain to be seen how this meeting might impact, if at all, on policy making in South Africa. However the sessions are set to cover issues like regional integration on IP, fostering innovation through IP, protection and enforcement, and administration and management of IP. Notably absent from the agenda is any discussion of the relationship between public health and IP (except in the counterfeiting arena), or the WIPO development agenda or any other developing country issues. The skewed agenda has not escaped the attention of public health commentators, who have lamented the focus on IP strengthening and enforcement, without any concurrent attention to stimulating innovation in developing countries.[23]

Also of concern is the significant pharmaceutical company sponsorship, and notable lack of the presence of any public health or other non-government, not for profit entities. Lack of input from civil society similarly was evident in the recently agreed Anti-Counterfeiting Trade Agreement (ACTA), a trade agreement signed by ten mostly

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[21] US Department of Commerce website, 'Africa Intellectual Property Forum: Intellectual Property, Regional Integration and Economic Growth in Africa' website http://www.cldp.doc.gov/programs/Africa-intellectual-property-forum [Accessed 2 February 2012].
[22] *Ibid.*
[23] See Davidson, B, 'Africa should be wary of US propaganda on intellectual property', *Open Society Foundations* blog, 3 February 2012, and Balasubramaniam, T, 'US, France, Japan, South Africa, WIPO, ICC-BASCAP, Lilly, Microsoft and Pfizer co-sponsor Africa IP Forum in Cape Town', *KEI* blog, 1 February 2012.

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developed countries, plus the EU, and is aimed at 'effectively combating global proliferation of commercial-scale counterfeiting and piracy.'[24] Throughout negotiations for ACTA, the negotiating countries came under significant, but largely unheeded, criticism for consulting closely with industry while providing bare-minimum access for public interest organisations.[25]

One final structural concern is that this forum brings together (exclusively) the governments of South Africa plus three countries which are home to significant originator pharmaceutical industries, and which have been active in pushing for stronger IP protection and enforcement on the international stage. This is just one conference, and it would be unfair to assume the government may be so impressionable to lead it to direct substantive future policy. But this skewed influence in policy forums is illustrative of a wider, concerning focus away from how IP can be used to help public health, towards a more insistently business-centric IP protection framework.

In developing legislation and policy around implementation of TRIPS flexibilities, it is important that the South African Government depart from such a non-transparent and non-inclusive tendency which, unfortunately, is becoming more common in intellectual property policy-making processes.

Collectively, the commitments by Government mentioned in this section to use to IP flexibilities which will work for public health need to be recalled – for the positive obligation they place on the Government to live up to what it has promised. That is, to implement TRIPS flexibilities by amending the Patents Act in a way this is not only inclusive of, but prioritises public health objectives. The Government is not only bound to live up to its political promises, but it is also constitutionally obliged to fulfil an imperative to progressively realise the human right to health.

Human rights law imperative to amend the Patents Act

In putting forward the positive legal, social and economic implications to be achieved through full implementation of TRIPS flexibilities, it is helpful to take a human

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[24] ACTA, signed on 1 October 2011, see http://www.ustr.gov/acta for more detail.
[25] See, for example, letter from KEI (Knowledge Ecology International) and others, 'Petition to President Obama regarding transparency of the Anticounterfeiting Trade Agreement' http://keionline.org/acta-petition [Accessed 2 February 2012].

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rights approach. Inserting human rights into the case highlights that not only are the changes a good idea for the health and wellbeing of the people of the Republic, but reminds us that the Governments is in fact under an *obligation* to make such changes, by virtue of the human rights instruments to which it is subscribed. The human right to health, along with the associated obligations on Government to take steps to progressively realise it, is codified in international agreements, to which South Africa is party, as well as in national legislation.

The Universal Declaration of Human Rights states that 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including…medical care'.[26] The International Covenant on Economic, Cultural and Social Rights (ICESCR) elaborates on this right, recognising 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' and placing an obligation on states to take steps to 'achieve the full realisation of this right'.[27] As a signatory to the ICESCR, South Africa has committed to 'take steps, individually and through international assistance and co-operation…to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant.'[28]

Identifying that an assessment of 'progressive realisation' of ICSECR rights may attract very different points of view, and determining the exact extent of states obligations difficult, the Committee on Economic, Cultural and Social Rights has provided the following guidance:

> *'the fact that realization over time, or in other words progressively, is foreseen under the Covenant should not be misinterpreted as depriving the obligation of all meaningful content. It is on the one hand a necessary flexibility device, reflecting the realities of the real world and the difficulties involved for any country in ensuring full realization of economic, social and cultural rights. On the other hand, the phrase must be read in the light of the overall objective, indeed the raison d'être, of the Covenant which is to establish clear obligations for States parties in*

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[26] Article 27(1) United Nations, *Universal Declaration of Human Rights* (1948).
[27] Article 12 *ICESCR* (1976).
[28] Article 2, *ICESCR* (1976).

> *respect of the full realization of the rights in question. It thus imposes an obligation to move as expeditiously and effectively as possible towards that goal.'*[29]

Specific to the right to health, that Committee has also clarified that provision of essential medicines, as defined by the WHO Action Programme on Essential Drugs, forms part of this obligation,[30] and that the duties of States includes the duty to, inter alia, 'to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; [and] to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services.'[31] Given that in practice, availability depends on affordability, which in turn depends on whether the price is within the reach of users,[32] this author would argue that South Africa is under a clear obligation to adopt measures to make medicines more affordable, and thus accessible. Part of such a strategy must include making the Patents Act changes to make full use of the TRIPS flexibilities.

The South African Constitution also codifies the right of everyone to have access to healthcare.[33] Like the relevant international law, the South African Constitution places a positive obligation on the Government to take legislative and other measures, within its available resources, to achieve the progressive realisation of that right to healthcare.[34] The right to health, and the extent of obligation on the Government to take steps to realise it, was a central tenet of the battles to secure affordable access to some generic ARTs in South Africa in the late 1990s and 2000s. The successful use of human rights by TAC in those battles, Mark Heywood has argued, lay in imparting among the poor and affected, 'not just an understanding of how to mouth human rights, but also how to apply them as demands in relation to specific social issues.'[35]

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[29] Paragraph 9, UN Committee on Economic, Cultural and Social Rights, 'Substantive issues arising in the implementation of the ICESCR: The nature of States parties obligations (Art. 2, par.1)', General Comment No. 3 (1990).
[30] Article 43(d) UN Committee on ECSR, 'Substantive issues arising in the implementation of the ICESCR: the highest attainable standard of health (article 12)', General Comment No. 14 (2000)
[31] Paragraph 35, *ibid.*
[32] Klopper H et al, 'Law of Intellectual Property in South Africa' *LexisNexis Group*, 2010, p 442-443.
[33] Section 27(1)(b) *Constitution of the Republic of South Africa*, No 108 of 1996.
[34] Section 27(3) *Constitution of the Republic of South Africa*, No 108 of 1996.
[35] Heywood, M, 'South Africa´s Treatment Action Campaign (TAC): An example of a successful human rights campaign for health', *TAC website,* 26 March, 2008.

The human right to health should remain paramount for the South African government as it now is urged to consider the next wave of action to achieve the right to health, by enhancing access to medicines through the Patents Act proposed amendments. But to keep human rights front and centre of debates and consultations around the amendments would not be a uniquely South African fixation – the human right to health is also extensively codified in national instruments in a number of countries, with health rights now appearing in over two thirds of constitutions worldwide.[36] For the South African Government to take these proposed amendments forward on the grounds that they support progressive realisation of the right to health, therefore, would not be to stand on a distant limb by itself.

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[36] Forman, L "Health 'rights" and wrongs: what utility for the right to health in reforming trade rules on medicines? *Health and Human Rights*, Vol. 10, No. 2 (2008), p 39.

Chapter 2: Introduce stricter criteria for granting patentability

This chapter argues that the grounds for patentability are too broad in South Africa, and that amendments to the Patents Act should be made to ensure that only those medicines which are truly innovative receive patent protection. Not only must the legal criteria be tightened around patentability, but these criteria should be more closely scrutinised against each application so that frivolous applications – those which do not meet these stricter standards of patentability – are not successful.

South Africa should take advantage of the degree of flexibility contained in TRIPS for Members to determine appropriate standards for granting a patent. This chapter firstly describes the process of pharmaceutical patent evergreening, arguing the public health imperatives to avoid it, and demonstrating, through a number of examples, how it is damaging both to both to the level of access to existing drugs, as well as to the incentive to make real innovations for healthcare. The chapter then outlines the current criteria for patentability in South Africa, and makes suggestions as to how patentability of medical inventions under the Patents Act (and national policy) should be tightened.

The specific proposals for establishing stricter grounds for patentability in South Africa focus on excluding or limiting from patentability 'new use' and limiting 'new form' patents. The term 'new use' applies to patents which are filed at a later date than the original patent, when new uses for an existing invention are subsequently discovered. In the pharmaceutical sector, new use patents may apply to applications on new formulations or delivery methods of a drug, new and improved manufacturing processes, reduced dosage regimens, new versions of the active compound or other variations that meet the patentability requirements.[37] 'New form' patents can be found when new patents are granted on known substances – in the pharmaceuticals arena, this might mean slightly tweaking the form of a known active ingredient, for example, by encasing in alternative preservatives, or changing the mode of delivery.

Rewarding incremental innovation with new use and new form patents is not an unusual international practice – many countries have chosen to allow it. But it is not

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[37] WIPO, 'Intellectual Property Rights for SMEs in the Pharmaceutical Industry' http://www.wipo.int/sme/en/documents/ip_pharma.html [Accessed 4 January 2012].

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required under TRIPS and should not be considered best practice, for the reasons outlined below. Many countries also provide alternative frameworks for innovations which do not meet patentability criteria, but which are considered worthy of protection nonetheless. These protections for minor innovations are often granted protection for a shorter period, and called 'innovation patents' in Australia, 'petty patents' in Thailand and Indonesia, 'new utility models' in Taiwan, and 'utility solutions' in Vietnam,[38] – they all provide alternative models where full patent protection is considered inappropriate because of an insufficient level of innovation. Similar alternative models in South Africa may also be worth further study.

What is 'evergreening'? How can amending the criteria for patentability work to prevent it?

A patent is granted for twenty years from the date of application in most countries, including South Africa[39], but drug manufacturers will often try to extend the effective life of their monopoly by gaining additional patents on very similar products. This activity, described as evergreening, and sometimes called 'me too' patenting, has been defined as a 'strategy consisting of acquiring patents on minor, often trivial, modifications of existing pharmaceutical products or processes in order to indirectly extend the period of patent protection over previously patented compounds".[40] Evergreening is detrimental to public health because it means that patented products remain unaffordable for longer periods of time, and is particularly detrimental for access to medicines which are not eligible, or for which there is little political impetus for, a compulsory licence.

Within the drug development, approval and registration process, the technical terms for those new drugs which have gone down the most rigorous and lengthy approval process, are new chemical entities (NCEs) and new molecular entities (NMEs). It is important to differentiate between NCEs/NMEs and those which are 'new' in the sense that they have become newly available, but which are merely combinations of existing drugs, or new uses of known compounds. Despite the fact that NCEs/NMEs are often treated the same by drug companies promoting their product, and subsequently by the popular press,

[38] Suthersanen U, et al, 'Innovation without patents', Edward Elgar Publishing Ltd, UK (2007), p iv.
[39] Section 46(1) *Patents Act*, No 57 of 1978 (as last amended by Act no 49 of 1996).
[40] Correa C, *op cit,* p 29.

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these drugs have undergone very different development processes and reflect a different level of innovation, and as such, should receive different levels of protection.[41]

An example of evergreening can be found in the evolution of use of the popular heartburn drug emeprazole (marketed as Prilosec) and the follow-on drug, esomeprazole (marketed as Nexium). There is significant evidence that Prilosec and Nexium have very similar characteristics in chemistry and mechanism, apart from a minor difference in the salt encasing of the two drugs.[42] In the lead up to the patent expiry of Prilosec in 2001 however, the patent holder, AstraZeneca began a concerted public affairs, marketing and patenting campaign to shift users to the follow-on, Nexium, despite the near-identical characteristics of the two drugs.

In order to support this campaign, AstraZeneca undertook a multifaceted strategy. On the marketing and regulatory side, the company relied on a study which found that Nexium worked slightly better for a single, uncommon condition called esophagitis, in order to garner support for Nexium as a new and improved version; the next generation 'Purple Pill'.[43] The company also relied on a patenting, where they strategically employed minor, but potentially significant changes to already patented compounds, by seeking patents on inactive compounds (which block use and market access by others), and by listing patents on the register specifically to deter or initiate litigation.[44] One study identified 82 patents granted over 20 years associated with the two compounds, giving a 50 year cumulative term of patent protection.[45]

The excesses of this example play out with the highest impact in the United States, where direct-to-consumer advertising is permitted. However, negative effects because of the patenting strategies and litigation have also been felt in other countries.[46] If higher

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[41] Ho, C 'Access to medicines in the global economy: International agreements on patents and related rights', Oxford University Press, 2011, p 7.
[42] See, for example Bouchard, R et al, 'The Pas de Deux of pharmaceutical regulation and innovation: Who's leading whom?' *Berkeley Technology Law Journal* Vol 24.3 (2009), p 1504, and Ho, C, *ibid,* p 7.
[43] Washington, H, 'Deadly Monopolies', Doubleday publishing, United States, 2011, p 1503.
[44] Bouchard, R et al, *op cit* p 1504.
[45] *ibid.*
[46] E.g., Canada also experienced significant litigation over the two drugs (Source: Bouchard, R et al, in *op cit*, as did Indian company, Ranbaxy, when it attempted to launch generic versions (Source: Astra Zeneca 'AstraZeneca Settles US Nexium Patent Litigation with Ranbaxy' Media release, 15 April 2008, http://www.astrazeneca.com/Media/Press-releases/Article/20080415--AstraZeneca-Settles-US-Nexium-Patent-Litigation-with- [Accessed 6 January 2012].

standards of novelty, inventiveness and industrial application were required by law in South Africa (and assessment at time of application for patent is made against these criteria), it is possible that this sort of situation, where patents can be litigated on highly similar drugs to extend the effective life of that particular drug, or drugs like it, can be avoided (or at least limited – as we will see the Indian legislation, which does reject new use patents, has still attracted litigious behaviour from pharmaceutical companies).

A more recent, and even more extreme, example of attempted evergreening can be found, again in the United States, in the recent litigation by Warner Chilcott to prevent attempts by Mylan Pharmaceuticals to launch a generic version of the acne antibiotic product, DORYX 150mg, which Warner Chilcott produces on exclusive license from the patent holder.[47] The Warner Chilcott-produced Doryx tablet previously had one score across the tablet, and generic firms were planning to introduce a generic of this version in late 2011. According to reports, however, around that same time Warner Chilcott added a second score to its tablet, and two days later filed a citizen's petition asking the Food and Drug Administration to reject any generics that lacked the new design.[48]

While the final outcome of this dispute is yet to be determined (at the time of printing, proceedings are ongoing and have reportedly been remanded to the New Jersey District Court to fulfil requirements of evidentiary hearing[49]), this example highlights an alarming trend of frivolous patenting becoming increasingly apparent in the United States, where the threshold for novelty and inventiveness are not high.

Of course there are many factors which have contributed to the success of evergreening practices such as those described above, to extend the effective life of patent monopolies, and which consequently contribute to unaffordable drug prices. In the medical technology field, these include regulations around direct-to-consumer advertising, quality of peer-review, as well as industry-doctor financial relations, all of which also have

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[47] See Rockoff, J, 'Drug maker's ploy to delay generics: Add a line to pill', *Wall Street Journal*, 7 October 2011 http://online.wsj.com/article/SB10001424052970204294504576615273524482778.html?mod=rss_Health#articleTabs%3Darticle [Accessed 4 January 2012].
[48] Silverman, E 'How to delay generics? Draw a line on a pill' *Pharmalot,* 7 October 2011 http://www.pharmalot.com/2011/10/how-to-delay-generics-draw-a-line-on-a-pill/
[49] Anonymous, Wall Street Journal 'Warner Chilcott Announces Decision on Appeal of DORYX Preliminary Injunction' 12 December 2011 [Accessed 4 January 2012].

important effects on the ongoing prices of particular medicines, but which are beyond the scope of this dissertation. The interesting point for current purposes however, is to explore the extent to which South Africa may, under international law, and should, according to public interest, limit those circumstances, so that only those medicines which are truly innovative receive a patent in the first place. The main ways to limit those circumstances are to exclude new use and new form patents. These proposed measures are discussed below.

Standards of patentability under the TRIPS Agreement

The TRIPS Agreement specifies that patents must be available in Member countries 'for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.'[50] For the purposes of that requirement, the TRIPS Agreement clarifies that 'inventive step' may be deemed by a Member as synonymous with the terms 'non-obvious'. And 'capable of industrial application' may be deemed synonymous with 'useful'.[51]

While the above establishes a *prima facie* obligation to make available patent protection across all fields of technology, the Agreement does not, however, go on to define further the concepts of novelty, inventiveness, and industrial applicability, thus granting a degree of flexibility for countries to determine how these criterion should be interpreted and applied.[52] One seminal commentary on this requirement observes that all countries thus have ample scope to determine how strictly the common standards of TRIPS would be applied, as well as where the burden of demonstrating novelty out to lie.[53] Countries therefore, are only subject to the rules of interpretation under the Vienna Treaty, and in line with this flexibility, have thus adopted a wide variety of national approaches to address how these characteristics are defined and applied.[54]

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[50] Article 27(1) *TRIPS.*
[51] Footnote to Article 27(1) *TRIPS.*
[52] Musungu, S and Oh, C, 'The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?'Study 4C, Commission on Intellectual Property Rights, Innovation and Public Health, WHO (2005); p 34.
[53] Commission on Intellectual Property Rights (UK Government) 'Patent reform' *Integrating Intellectual Property Rights and Development Policy* http://www.iprcommission.org/papers/pdfs/final_report/ch6final.pdf [Accessed 4 January 2012].
[54] Correa C, *op cit,* p 3.

How to tighten standards of patentability – strengthening the definitions of 'novelty, inventiveness and industrial application' in South African law

The South African Companies and Intellectual Property Commission (CIPC) [55], (which, since May 2011, incorporates the previous functions of the former Companies and Intellectual Property Registration Office, CIPRO), has a non-examining role when it considers patent applications. That is to say that the CIPC does not examine the merits of each application to determine whether it represents a sufficient degree of novelty, inventiveness and industrial application before granting the patent. Some commentators thus, refer to the South African patents office as merely a 'registration office', where applications are examined only for formalities, and not for substance.[56]

While the Patents Act does not specifically provide for new use patents, it does not specifically forbid it either. The Act specifies that a patent may be granted for 'any new invention which involves an inventive step and which is capable of being used in trade or in agriculture.'[57] The Act goes on to specify just two circumstances where a patent will not be granted: where the publication or expected to encourage offensive or immoral behaviour, or for any variety of animal or plant or any other essentially biological process for the production of animals or plants, not being micro-biological process. [58]

These relatively broad set of circumstances under which a patent may be granted has led to a situation where a new use application, or an application for a tweaked invention, will generally be successful unless someone opposes it. Pre- and post-grant opposition to patents is provided for under current South African law (albeit under effectively limited circumstances, and suggestions for amending this opposition requirements are provided in the next chapter). This chapter deals rather with how to improve the application process, requiring a critical examination of the claims, so that spurious or exaggerated patents are not granted or considered in the first place.

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[55] See CIPC website http://www.cipro.co.za/ [Accessed 4 January 2011].
[56] Klopper H et al, *op cit,* p 297.
[57] Section 25(1) *Patents Act.*
[58] Section 25(3)(a)-(b) *Patents Act.*

Excluding 'new form' and 'new use'?

Under TRIPS it is possible to argue that the South African Government is free to exclude from patentability altogether new uses on known, patented pharmaceutical substances. As explained above, TRIPS leaves a certain level of flexibility for countries to determine for themselves the appropriate definitions of novelty, inventiveness, and industrial applicability. But in addition to that flexibility, TRIPS also explicitly allows countries to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals',[59] and it has been argued that new uses on known substances can also be excluded under this permissible exception, because new uses are essentially equivalent to therapeutic methods.[60]

The Andean community is one example of complete exclusion from patentability '[p]roducts or processes already patented and included in the state of the art... may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.'[61]While it is theoretically possible for a new use patent under this provision, i.e., if accompanied by innovations other than new use, such a provision simply establishes that new use alone will not be enough to establish patentability. Egypt also excludes from patentability second medical use patents.[62] Even if frivolous patents are then also theoretically possible under such provisions (new formulations do not appear to be excluded under the regime), one might expect that it might at least discourages such applications.

Moreover, there may be reason why the South African Government might not chose to exclude altogether new use or new form patents in such a way as the Andean Community countries have, as above. It has been pointed out by some that the benefits of excluding new use patents altogether may be greatest for developing countries with little to no research and development capacity.[63] This might be because incremental innovation sometimes has an important role to play – for example, the development of a heat stable

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[59] Article 27 (3)(a) *TRIPS.*
[60] IPR Commission, 'Patent reform', *Integrating Intellectual Property Rights and Development Policy,* UK Government, p 49.
[61] Article 27, *Common Intellectual Property Regime,* Andean Community
[62] Thorpe, P 'Study paper 7: study on the implementation of the TRIPS Agreement by developing countries' Commission on Intellectual Property Rights (UK), p 19.
[63] IPR Commission, *op cit,* p 50.

version of an existing drug years after the original drug was patented would likely yield benefit for patients in many parts of South Africa.

Objections might be raised for fear of negative implications for investment and research incentives if any kind of new use or new form patent were excluded altogether, since South Africa does, in fact, have a certain level of research capacity. The Government may be wary of avoiding negative pressures to FDI, although should not overestimate the effect it would have on incentives in this developing country market.[64] Working within the existing 'virtuous cycle' model of encouraging innovation, by rewarding investment in innovation with patent protection, it may be that the South Africa Government should chose to rather to more closely control the level of novelty, inventiveness and industrial applicability for new use and new form patents.

Limiting 'new use' and 'new form'

Providing exceptions to the blanket acceptability of new use and new formulation patents, rather than outright excluding, would still represent an improvement upon current arrangements, but likely represent a more politically palatable amendment. India's experience in determining for itself the appropriate criteria for patentability presents an excellent starting point for South Africa in developing its own model to tighten patentability, where patents for new uses or formulations are only granted if an applicant can demonstrate increased therapeutic effectiveness over existing uses or formulations. This model has not, however, operated without controversy, and the provisions have been subject to sustained litigation over time. The final outcome is yet to be determined, but the story is worth expanding on below.

India's example

India has been dubbed the 'pharmacy of the developing world,' for its role in manufacturing and exporting generic medicines, which have often been on patent elsewhere. Indian-produced generic ARVs accounted for over 80 per cent of the donor-

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[64] This author recognises that levels of private, non-philanthropic investment in R&D to develop technologies for those illnesses which do not have a large potential markets will likely not, in any case, be affected by whether patent protection is available or not for follow-on products. How to de-link the costs of research and development from patent protection is an important question, but beyond the scope of this dissertation. The dissertation focuses rather on achieving a number of proposals within the exiting IP and R&D framework.

funded purchases of ARVs between 2006-2008.[65] However this situation is under threat – India has had to comply with more stringent intellectual property measures since 2005, when it joined the WTO and was obliged to become fully compliant with the TRIPS Agreement.[66]

Among other things, TRIPS implementation has meant that India has had to begin granting patents for pharmaceutical products (not just processes) for the first time.[67] The concerns and implications of this development in Indian patent law on access to newer medicines in developing countries are great, but beyond the scope of this dissertation. What is relevant for this section, is the public health safeguard that India has implemented alongside its enhanced intellectual property protections. In implementing TRIPS compliant provisions, India has developed additional provisions which narrow (by many international standards) the circumstances under which patents in general may be granted. As mentioned above, because TRIPS does not specify the terms for patentability, this move is completely legitimate with international law.

India has introduced tighter standards for granting new use and new form pharmaceutical patents, and its experience can lend lessons to what might be envisaged under such changes to South African law. The 1970 Indian Patents Act sets out a number of inventions which are not patentable, including, *inter alia*, any invention which is frivolous or which claims anything obvious contrary to well established natural laws; inventions whose primary use would be contrary to law or morality or injurious to public health; mere discovery of scientific principle or the formulation of an abstract theory; and certain medicinal or surgical processes and treatments.[68]

In developing implementing legislation to comply with TRIPS provisions, an amendment was made this text on of non-patentable inventions, replacing wording of one invention which would not fall within the meaning of the Act, as follows:

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[65] Waning, B, Diedrichsen, E and Moon, S,' A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries', *Journal of the International AIDS Society* (2010) 13:35, p 3.
[66] WTO, 'Pharmaceutical patents and the TRIPS Agreement' http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm [Accessed 30 December 2011].
[67] *Ibid.*
[68] Section 3(a)-(i), *Patents Act,* No 39 of 1970.

'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.'[69]

An explanatory note to this provision was further inserted, providing that

'for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.'[70]

This section effectively rules out patentability of many of the kinds of 'me-too' patents which are claimed on flow on inventions from other medicines, which are experienced in other parts of the world. While Section 3(d) has attracted much interest and controversy for its compliance with TRIPS, the provision doesn't necessarily place stricter requirements than are used elsewhere; but it simply shifts the burden on to the applicant to prove that their produce represents a new chemical compound, rather than a me-too version of an existing drug.[71]

The most controversial test of Section 3(d) has played out in ongoing litigation in Chennai, regarding the patentability of Novartis's drug for Chronic Myeloid Leukemia, Gleevec/Glevic. Novartis filed its first patent on Glevic in the United States in 1992, before India granted patent protections on pharmaceutical products. In 1997, Novartis started to apply for patents for a second version of that drug, the beta-crystalline version of imatinib mesylate. At that time, the application for the chrystalline version (the 'follow-on') drug was received in India under 'mailbox' provisions, whereby India had agreed to receive patent applications to be reviewed in 2005, when it was to become TRIPS compliant.[72] But in January 2006, Novartis's application for a patent on Glivec was rejected, on the grounds

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[69] Amendment of Section 3(d) *Patents (Amendment) Act*, No 15 of 2005.
[70] *Ibid.*
[71] Mueller, J, 'Taking TRIPS to India – Novartis, Patent Law, and Access to Medicines', *New England Journal of Medicine*, (2007) 356:541-543.
[72] Eks, S 'Global pharmaceutical markets and corporate citizenship: The case of Novartis' anti-cancer drug Glivec' *BioSocieties*, Cambridge, UK,Vol 3 (2008): 171.

that a patent had already been granted for the active molecule, imnatib, and the follow-on was merely a new form of an old drug, and therefore not patentable under Indian law.[73]

In June 2006, Novartis issued a series of writ petitions (later converted to statutory appeals) against the Government of India's decision not to grant the follow-on patent, as well as against the validity of Section 3(d), arguing that it was it was incompatible with TRIPS, and the meaning of 'efficacy' in terms of the Act's requirement that that an applicant demonstrate 'increased efficacy' in order to receive a patent for any follow-on products.[74] Also, that the provision was vague and ambiguous, and therefore violated the Article 14 'right to equality before the law' provision of the Indian Constitution.[75]

The High Court refused to consider the question of TRIPS compatibility, on the grounds that such a challenge to the manner of implementation of its TRIPS obligations should go to the WTO Dispute Settlement Body only.[76] While the US Government has alluded to potential conflicts of the Section 3(d) provisions with the TRIPS agreement,[77] no formal proceedings have ever been brought before WTO dispute settlement bodies.

More interestingly, responding to Novartis's challenge of the Section 3(d) requirement that an applicant demonstrate 'increased efficacy' in order to receive a patent for any follow-on products, the Court held that the provision did not, as claimed by Novartis, suffer from the vice of vagueness, ambiguity and arbitrariness.[78] This was a erroneous claim, the Justices said, because efficacy meant therapeutic efficacy in the pharmaceutical field; where such efficacy is assessed by patent controllers who are experts in the pharmaceutical field, and whether the efficacy of a substance could be deemed 'enhanced' could also be clinically found by those in the field.[79]

This ruling is important for any South African plans to introduce similar legislation, as the reasoning that 'therapeutic efficacy' was not, in fact, vague, depends on the presence

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[73] Srinivasan, S, *op cit,* pp. 3686-3690.
[74] Lawyers Collective, Novartis case: background and update- Supreme Court of India to recommence hearing' 5 September 2011 http://www.lawyerscollective.org/news/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html [Accessed 4 January 2012].
[75] *Ibid.*
[76] *Novartis v Union of India and Others,* High Court of Judicature at Madras (6 August 2007) W.P. Nos.24759 and 24760 of 2006: at 4.
[77] Lawyers Collective, *op cit* at 2.
[78] *ibid* at 18.
[79] *ibid* at 4.

of pharmaceutical experts assessing pharmaceutical patent applications. It is also relevant to note that in South Africa, where Gleevec is only available in the private sector, this particular drug costs ten times that of its generic Indian equivalent.[80]

The introduction of tighter standards of patentability then, by inserting requirements for follow on would-be patentees to demonstrate improved 'therapeutic efficacy' (or something similar) in South Africa, should be coupled with some form of assessment by pharmaceutical experts. In the eventuality of such legislation in South Africa, and any subsequent challenges by the pharmaceutical industry or others, it is would be likely that this Indian ruling would be referred to. Specifically, it is possible that claims might be made that, without expert assessment of pharmaceutical patent applications, any assessment against substantial improvement of therapeutic efficacy would be invalid.

The above ruling was appealed and heard by a bench of the Intellectual Property Appellate Board during September 2012, who held that while Novartis did satisfy the requirements of novelty and inventive step, they did not provide data to show that the beta-crystalline form the drug exhibited significantly enhanced therapeutic efficacy over the known substance (imatinib mesylate), and therefore did not satisfy the section 3(d) test.[81]

Novartis is now asking the Supreme Court to define of "efficacy" in a way that would include increases in bioavailabiliy (absorbability of a given drug by the body), rather than the more stringent definition of 'therapeutic effect in healing a disease', which was applied by the Madras High Court.[82]

For a South African model, it may not be advisable to expand further on the definition of therapeutic efficacy, lest it be claimed that such a list of circumstances which might meet the definition be considered conclusive. Rather, a way to avoid attracting such litigation on the definition may be for the South African legislation to include reference to an administrative process to determine advancements in therapeutic efficiency, in the event of a dispute or appeal from the patents application process. This proposal would of course need to be supported by budgetary increases, in order to attract appropriate expert advice,

[80] See TAC, 'Highlighting medicines affected by strict IP laws' (Source: Mediscor Medicines Review 2010), 3 February 2012 http://www.fixthepatentlaws.org/?p=98#_ftn1 [Accessed 4 February 2012].
[81] Lawyers Collective, *op cit,* at 18.
[82] Palmedo, M, 'India Supreme Court to Hear Arguments In Case Over Section 3(D)' *Info Justice* blog, 28 November 2011.

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but need not amount to extensive, permanent and costly structures. It could, for example, comprise simply of a list of experts which might intermittently be called upon, only in cases where the determination of the patent examiners is not straightforward.

Regardless of the final outcome of this litigation in India, the case should result in some important judicial analysis on the meaning of Article 3(d), as well as other untested patent rules.[83] The South African Government should therefore pay close notice to the how this case proceeds and the final outcome, to attempt to draft around apparent pitfalls, as they have emerged throughout the case, and particularly as they become evident in the final ruling.

Brazil's example – involving health ministry

Brazil has also come up with an innovative way to raise the bar of patentability under its patent law, especially for follow-on pharmaceutical products, by introducing measures which require the involvement of health ministries in patent applications. South Africa ought to introduce similar provisions which either require or allow assessors to consult other qualified third parties, to make public health assessments on the desirability of granting a patent on a follow-on product.

Brazil has had TRIPS compliant legislation since 1997, and introduced an amendment to its Lei de Proprieadade Industrial (LPI), coming into effect in 2001, which meant that any patent not be issued until the Ministry of Health's 'Health Surveillance Unit' issued its approval that the drug is patentable. This requirement, known as 'prior consent' provisions, provides that '[t]he granting of patents on pharmaceutical products or processes shall depend on the prior consent of the National Sanitary Supervision Agency (ANVISA)',[84] where ANVISA is a wing of the Ministry of Health.

ANVISA has had a track record of generally rejecting applications for drug patents that lack 'genuine' novelty and where it evaluates that providing exclusive rights would be

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[83] Mueller, J, *op cit* p 41.
[84] Section 229(C), *Brazilian Amending Law on Industrial Property*, Law No. 10.196 of 14 February 2001.

harmful to public health.[85] ANVISA consequently tends to prevent patents that, by its judgment, would extend the terms of existing patents.[86]

At the date of August 2008, of the applications sent to it for approval since 2001, 68.9 percent of applications sent to ANVISA were approved (4.9 per cent rejected and 26.3 percent were pending or other). Interestingly, of the 68.9 per cent approved, 42 per cent of these cases were first sent to the applicant to reduce the scope of the patent.[87]

The 'prior consent' requirement has, however, been plagued with controversy and opposition since its inception. ANVISA has come under sustained attacks for overstepping its ambit, with general claims that officials of the health portfolio are not suitably qualified or equipped to deal with the private and commercial issues of intellectual property. An important and specific criticism around the intent of the legislation, made by the national intellectual property organisation, was that the amendment was never meant to apply so broadly – that it was only ever intneded for it to apply to pipeline patents (those which preceded the enactment of the amendments).[88] Under these complaints, ANVISA's functions have been subject to injunctions under legal challenges.

The powers of ANVISA to grant its prior consent was again watered down in 2009, when the Attorney-General ruled that ANVISA may continue to make assessments of pharmaceuticals, but may only hold back its consent in cases where the granting of a patent would actually pose health risks (and thus no longer investigate novelty and inventiveness claims).[89] Given that medicines which do not meet the human safety standards would not (one would hope and assume), meet the criteria of industrial applicability under current IP standards in Brazil,[90] this ruling effectively rendered the provision ineffectual.

Despite an outcry from public health groups, and formal petitioning to reverse the Attorney-General's position, the Solicitor-General of the new Brazilian Government

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[85] Shadlen, K, 'The Politics of patents and drugs in Brazil and Mexioco: The industrial bases of health policies' *Comparative Politics* (Tufts), October 2009, p 48.
[86] *Ibid.*
[87] *Ibid.*
[88] See Shadlen, K, *ibid,* for a full overview of the political controversies which plagued the measures.
[89] Shadlen, K, *ibid,* pg 11.
[90] Like many other IP laws, Article 8 of the Brazilian *Law on Industrial Property* 1996 holds an invention patentable if it satisfies the requirements of novelty, inventive step, and industrial application.

upheld this position,[91] confirming the effective withdrawal of the health department's power to intervene in the patent granting process on public health grounds.

While the insertion of prior consent provisions in Brazilian law have been hailed by some for reinserting the public interest into patents at the time of their granting, time has shown that the idea behind the amendments clearly worked better than their implementation. South Africa is in the fortunate position of having the example of Brazil to learn from, if it is to consider similar requirements from its health department. Firstly, the legislation needs more detail than that provided by the short one-lined provision found in the Brazilian Industrial Property amendment. This would leave less room for (mis)interpretation on what grounds the health ministry may make its determinations, like that which made the Brazilian legislation so vulnerable.

Furthermore, because this piece of legislation was made by executive decree, and not by the full legislative process, which would have included discussion and debate, it has been difficult for the judiciary to determine with conviction what the intent was[92] – perhaps partly leading them to err on the side of caution with conservative estimates as to what was intended. When considering introducing similar legislation, South Africa should ensure that wide consultation is undertaken and full documentation of that process is recorded, in the aim of avoiding such controversy.

Closer legislative attention to the processes for granting or withholding consent would also be advisable. As can be seen from the statistics above in Brazil, almost 70 percent of applications had been approved by 2008, with less than 5 per cent outright rejected. This is not a terribly high rate of rejection. Almost half of the finally approved were sent of 'back and forth' between ANVIZA and the applicants. The requirements to revise and resubmit have probably led to better quality patents. But this more flexible, 'willingness to discuss' approach is not made clear in the legislation – the legislation appears to have provide for outright approval or rejection. For similar consent requirements in South Africa, clear guidelines on processes and expected timeframes, as part of any transparent and accountable administrative scheme, should be envisaged.

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[91] Shadlen, K, *op cit,* pg 10.
[92] *Ibid.*

Resource considerations

South Africa is a developing country, and with that, some may argue, comes resource constraints against closely examining the merits of every application coming before it. An argument might therefore be made for the carve-out of essential medical technologies then; applying the above stricter hurdles to proving inventiveness only for a class of technologies, deemed of most public health interest. This would achieve the public policy goals of achieving closer scrutiny for medical technologies, while at the same time not creating undue administrative burdens on the CIPC.

However it should be recognised that singling out pharmaceuticals, as has done the Indian Section 3(d), may give rise to controversy about whether this discriminates against 'a field of technology', which would be contrary to the non-discrimination provisions of TRIPS.[93] If such a provision is envisaged under South African legislation then, particular reference must be made to the legal basis giving rise to the authority to single out. Correa argues that the Doha Declaration might provide such legal basis, as it provides clear grounds that public health patents, in particular pharmaceutical patents, require special attention, if it is intended to protect public health.[94]

Stricter patentability summarised

The benefits of setting up a stricter framework for establishing patentability are twofold: firstly, South Africa escapes, at least to some extent, the effects of patent evergreening and is able to introduce generics much sooner, and secondly, innovators will be incentivised to pursue truly novel innovation, in the knowledge that second use and me-too patent activity will not be supported and protected by the state.

Not only would introducing these stricter grounds for patentability lead to better outcomes for South Africa, but it would contribute to a normative shift in the way we think about patentability internationally. With an ever-increasing pressure from other countries, particularly from those host to significant originator drug industries to lower the standards of patentability and introduce TRIPS pus measures (discussed in more detail in chapter 5), the value of any move by South Africa to tighten standards of patentability cannot be

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[93] Article 27(1) *TRIPS.*
[94] Correa C, *op cit,* p 25.

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overstated. To do so would expand the acceptability of such provisions and boost confidence for other countries to also reject frivolous patenting activities. As one patent activist in India has exclaimed, 'If only South Africa would stand up and introduce stricter grounds for patentability, like India has done, I think the [Indian] Government would feel more confident in what it's doing around section 3d and patentability'.[95]

The benefits of requiring stricter patentability of any patentable product are realised as the perverse effects on incentives for making real innovation, are avoided. The case for requiring stricter standards of patentability in the pharmaceutical sector is all the stronger because of the immediate and opportunity costs associated with pharmaceutical patent evergreening. While care in drafting must be taken to avoid conflict with non-discrimination requirements of TRIPS, the case can and should be made. Special carve outs have been made in other, arguably less life-threatening sectors. The US banking sector, for instance, has been able to carve out legislative provisions on 'business methods and procedures' to protect themselves against frivolous patenting. These arguments are made on the basis that patents would impede their ability to do business (examples are automated methods of producing digital copies of cheques, or specialised financial and trading software).[96] Making a similar case against frivolous patenting in the area of essential, potentially life-saving medicines, should be obvious.

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[95] Menghaney L, Access Campaign Project Manager, MSF India, personal communication, Baltimore, USA, 30 October 2011.

[96] See Ross Sorken, A, 'In a bill, Wall Street shows its clout' *New York Times*, 4 July 2011, http://dealbook.nytimes.com/2011/07/04/in-a-bill-wall-street-shows-clout/ [Accessed 2 January 2012].

Chapter 3: Introduce pre- and post- patent grant opposition

Like Chapter 2, this chapter proposes measures aimed at preventing evergreening. Chapter 3 proposes that South African legislation be amended to introduce an administratively user-friendly way to oppose patents which do not meet the (proposed) higher standards of patentability. In South Africa currently, the Government may oppose patent applications and grants relatively easily, but it is much more difficult and expensive for third (non-government) parties to do so. At present, the only way for third parties to challenge a patent is through the courts, which is expensive and time-consuming for a great many organisations or individuals who may hold an interest in the success or not of a particular patent.

Because of such obstacles, wrongly granted patents remain in place for the full duration of the patent, thus unduly creating a barrier to competition, with consumers ultimately prejudiced.[97]This section proposes the introduction of a transparent, administrative system for third parties to access easily and cheaply information about applications, and where third parties are provided with opportunity to make oppositions, within the context of a more rigorous patent examination system (as described in Chapter 2).

Introducing third party pre- and post-grant opposition to patent applications might be seen as a kind of safeguard where the patent assessment process falls short of spotting frivolous patenting, or patenting that falls short of satisfying novelty and inventive step. The process of calling for and accepting pre- and post-grant opposition essentially assists examiners, because competitors or other interested parties may be in a good position to recognise lack of inventive step or prior art.[98] While opening up the examination process to competitors might at first glance appear to invite more litigation (as opposition is open to public health organisations as well as industry), it is important that these risks of improper use of an opposition system be considered in light of the opportunity costs incurred when protection is granted on undeserved inventions. It must be recalled also that competitors,

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[97] Correa C, *op cit,* p 25.
[98] UNDP/WHO Report of the Workshop on the Examination of Pharmaceutical Patents: Developing a Public Health Perspective, 30-31 October 2008.

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even if motivated for different reasons, are in a good position to bring new evidence to an examiner's attention, for example, precedents or evidence of prior art.[99]

What TRIPS says about pre- and post-grant opposition

In introducing pre- and post-grant opposition procedures, South Africa has a great deal of flexibility because TRIPS does not include any specific provisions on whether or how opposition to patents should be implemented, and no indications of an obligation not to allow it as a standard for every patent application. The only TRIPS restriction is that patent examinations are conducted 'within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection'.[100]

Proposed South African treatment of pre- and post-grant opposition

In South Africa currently, a complete patent application becomes available for public inspection only when acceptance of the complete application is advertised.[101] Until that time, particulars about the application (the scope of the patent, details of the patentee etc) remain confidential.[102] Another party, thus, can only apply for revocation of the patent, without opening himself up to threat of an infringement claim, within a 9 month period after the date of the patent's grant.[103] In this way then, the South African framework gives a 9 month period for third parties to apply for revocation, but not adjustment.

However it could be foreseen in many cases that grounds for opposition would fall on just one aspect of a patent claim, not the entire claim, with opponents therefore requesting adjustment on the scope or details, rather than complete annulation or revocation. If we envisage an opposition scheme in South Africa with both objectives in mind (revocation and adjustment), this could help lead to better quality patents and less cause for disputes and litigation down the line. Despite claims by some industry and countries that pre-grant opposition creates undue delays and uncertainties for patent applicants, others disagree. Public interest advocacy organisation, Public Citizen, for example, points out that pre- and post-grant opposition actually *enhances* certainty for both

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[99] Correa C, *op cit,* p 25.
[100] Article 62(2) *TRIPS.*
[101] Section 43(1) *Patents Act.*
[102] Klopper H et al, *op cit*, p 321.
[103] *Ibid.*

generic and brand-name pharmaceutical companies, because contested patent claims are actually settled much earlier, and (by virtue of the administrative nature of opposition), more cheaply than post grant judicial proceedings could.[104]

Encompassing either complete or partial objections then, the purpose for hearing objections is to allow third parties to put forward evidence to the patents office which may help it avoid making frivolous or poor quality patents.[105] As a minimum, South African legislation might require the CIPC to either receive objections, or ideally, require the office to take them into consideration when making final determinations.

Correa also points out that the success of an opposition scheme will depend on the capacity for pharmaceutical companies, health ministry officials, and public health organisations to monitor, identify and lodge oppositions.[106] In South Africa, where a widespread culture of opposition does not currently exist then, training in interpretation of applications and a certain level of fluency around the patents process, will be required. In aspiring to build such a capacity, South Africa should call on developed countries in the WTO to fulfil their obligations to 'provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members.'[107]

India's pre and post grant opposition framework

Again, we look to India's pioneering example, where generous amounts of time and opportunities to voice a challenge have been incorporated into legislation around patent applications. Indian law allows 'any person' to oppose a patent after publication but before granting on a wide range of grounds, but all based on the broad foundation that the invention is not patentable. [108] Further clauses provide for opposition for a period of up to one year after grant. After the expiry of one year, standard private law opposition will be the only option to oppose a patent. This time limitation might prove restrictive in some

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[104] Public Citizen and others, 'Analysis of the leaked U.S. paper on eliminating pre-grant opposition', *Briefing memo,* 7 July 2011.
[105] UNCTAD, 'Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide', p 45.
[106] Correa C, *op cit*, p 25
[107] Article 67 *TRIPS.*
[108] Article 25(1) India, *Patents (Amendment) Act*, 2005 covers pre grant opposition, while Article 25 (2) covers grounds for the opposition for a period of one year after grant.

circumstances, where information legitimately does not come to light until a later date. However a limit on the available period is probably necessary for sustainability of the framework, and to afford some level of confidence to legitimate inventors. South Africa might consider, in implementing its own framework, similar time constrictions for opposition, but include a clause that 'exceptional circumstances', such as fraud on the part of the applicant, for example, may justify opposition being launched outside of this timeframe.

The grounds provided for opposition in India include a range of technical circumstances, including, amongst others, where the invention was published prior to application, and for administrative incompleteness. But more interestingly for current purposes, one ground for opposition lies where the invention 'is obvious and clearly does not involve any inventive step'.[109]The majority of cited grounds for launching an opposition in India fall where an application is allegedly incompliant with Section 3(d) – these oppositions have resulted in an 80 per cent success rate.[110]

The fact that opposition is open to an 'interested person' (in the case of post-grant), rather than 'any person' (in the case of pre-grant opposition) might be an indication of intention for the provisions to apply to a narrower class of opponents in the case of post-grant opposition. However it might be argued that such a distinction is insignificant, given that any applicant taking the time to oppose an application does, naturally, hold an interest in the outcome of the application. This author suggests that South African legislation not replicate this distinction, which is unnecessary but also could potentially attract litigation around the intentions underpinning the differences in drafting.

In either event, these broad classes of potential opponents grant non-government actors, including public health organisations, the important opportunity to intervene where they believe that the granting of a patent might be detrimental to public health. Indeed, MSF has used pre-grant opposition provisions and the opportunity open to it as 'any person' in a legal sense, to oppose HIV and follow-on cancer drug patents in India[111]

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[109] Article 25 (1) India, *Patents (Amendment) Act*, 2005
[110] Kapczynski (2009) in Ho, C *op cit,* p 101.
[111] Ho, C, *ibid.*

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(MSF's ongoing opposition to patents on the follow-on chrystalline version of the cancer drug, Glivec, has been discussed in Chapter 2).

India also has a 'presumption of no validity' attached to granted patents, even after the one year opposition period after the grant has passed.[112] This is a sensible approach, Oh has argued, given that most patents are granted without any opposition, and that even with patent examination (for substantial patentability, rather than just procedural correctness), the examination process cannot be considered exhaustive.[113]

This chapter on pre- and post-grant opposition is not large, but has been included as a chapter in its own right because it is imperative that it is included as a key component of any TRIPS implementation package in South Africa. Without the transparency and accountability afforded by inexpensive and timely opportunities for interested parties to oppose patent applications, the safeguards for a framework which is geared towards wider societal public health interests, goes unchecked.

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[112] *Ibid.*
[113] *Ibid.*

Chapter 4: Simplify and expand compulsory licensing

The granting of compulsory licences on pharmaceutical patents is the TRIPS flexibility which has perhaps attracted the most attention in access to medicines debates. Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner.[114] At a first glance, this practise would seem like an ideal solution for a country like South Africa, which cannot afford a great chunk of the medicines it needs. Yet many governments, including South Africa, have been slow to take up the practice on any wide scale. Part of the reason for this is pressure from developed nations not to grant compulsory licenses. Other reasons are attributable to concerns about what effect such an acquisition of property by government might have on the country's ability to attract foreign direct investment (FDI). While the risks to FDI are overblown in many instances, South Africa, as a middle income country, can mitigate these risks by working collaboratively with other developing countries (particularly its neighbours).

Locally, amendments should be made to the South African Patents Act to expand on current grounds to explicitly allow compulsory licences to be granted for public health imperatives in cases where prices are unaffordably expensive, and where there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple rights holders.[115] Amendments should also include clear guidance as to process, details on evidentiary requirements, and guidance on what is a fair compensation to a patent holder. Clearer grounds for granting a compulsory license will deliver more certainty for all players – the Government, public health organisations, and industry (both brand name companies and generic manufacturers considering entering the market).

Meanwhile internationally, South Africa should maintain pressure in the WTO to create user-friendly systems to import quality generics from other countries, as well as APIs to enable the development of a viable generics industry in South Africa.

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[114] WTO website, 'Compulsory licensing of pharmaceuticals and TRIPS'

[115] TAC, 'Fix the Patent Laws: Campaigning for pro-public health reform of South Africa's Patents Act', briefing document, 26 January 2012.

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Compulsory licensing under TRIPS

This flexibility against absolute control of an inventor's intellectual property is established under Article 31 of the TRIPS Agreement, which provides that a government, or third party authorised by the government, may use the subject matter of a patent without the authorisation of the right holder, where:

> *'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. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.'*[116]

The right of countries to issue compulsory licences by, or under the supervision of government, has thus existed since the beginning of TRIPS in 1994. However, amongst disagreement and confusion by many countries around the level of how a government would be entitled to invoke this flexibility, the Doha Declaration, in 2001 clarified that:

> *'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'*[117]

At the same time as confirming the right of countries to determine for themselves appropriate grounds, the Declaration goes on to elaborate on the circumstances which might justify a compulsory license:

> *'Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'*[118]

The fact that the Doha Declaration specifically names some health issues under which a compulsory license might be granted, has mixed implications. On the one hand, it provides unequivocal grounds for South Africa to take compulsory licensing measures on the very

[116] Article 31(b) *TRIPS.*
[117] Paragraph 5(b) Doha Declaration.
[118] Paragraph 5(c) Doha Declaration.

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diseases which disproportionately affect it. On the other hand, it may have contributed to the reluctance to attempt compulsory licenses for health issues other than the big three: HIV, tuberculosis and malaria, even though 'other epidemics' are technically provided for without negotiation. This needs to be written into national law.

Compulsory licensing under South African law

Compulsory licences are technically provided for under South African law, but none have ever been issued. In some instances, compulsory licences have been threatened, but the licences have rather been settled out of court, or in a result of pressure flowing from competition rulings, in the eventual form of a voluntary licence, under which the terms of the licence have been negotiated.

Government use compulsory licences are relatively straightforward under South African legislation. The right of the government to intervene on patent rights for public purposes is established in Section 4 of the Patents Act 'on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by, or on behalf of such minister and after hearing the patentee.'[119]

The South African Government's power to issue compulsory licenses is also supported by Medicines and Related Substances Control Act. Following ongoing crisis in public health around the price of HIV medicines, in 1997 the South African Government initiated amendments to the Medicines and Related Substances Control Act, to empower the Minister for Health to 'prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public'.[120] The consequence of these Section 15C provisions is to empower the Minister to authorise the parallel importation and use of patented medicines, even in circumstances where such actions may conflict with the Patents Act.[121]

The introduction of these amendments, in 1997, lead thirty nine pharmaceutical companies (under the PhRMA banner), along with the South African Pharmaceutical

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[119] Section 4 *Patents Act,* No 57 of 1978 (as last amended by Act no 49 of 1996).
[120] Section 15C, *Medicines and Related Substances Control Amendment Act*, No 18505 of 1997.
[121] Section 15C(a)-(c), *Medicines and Related Substances Control Amendment Act*, No 18505 of 1997.

Association, seeking injunctions in the High Court on several constitutional grounds (including for not setting out legislative and policy considerations in line with Section 43 and 44; depriving or expropriating right holders of their IP rights under section 25 general property rights; and on the grounds that the provisions discriminated against pharmaceutical patents in contradiction with a number of constitutional provisions).[122] Following strong international pressure, however, the case did not proceed to trial, and South Africa began importing affordable ARVs from India.

Although formerly untested through the courts, it might be assumed that the presence of these provisions, or the threat to invoke them, has lead to a sufficient level of pressure to force a number of successful voluntary license negotiations. But a particular consequence of a restricted framework for third parties accessing compulsory licences arises when the Government is either unwilling, unable, or under-resourced to be pursuing compulsory licences in the public interest. Since more extensive occurrence of government use compulsory licensing (threatened or actual) has not transpired, many commentators argue for a simplified, financially accessible system for third parties to apply for compulsory licenses.

The TAC, for example, would like to see the a more user-friendly system for granting CLs in South Africa, through the introduction of a simple, expeditious administrative (rather than judicial) procedure for hearing applications for compulsory licenses, and amendments to clarify royalty rates (section 4) and set time periods for negotiations (section 56).[123]

The circumstances under which a non-government actor might apply to compulsorily acquire the right to a licence are rather less straightforward than the circumstances described above for the Government. A third party ('any interested person'[124]) is eligible to apply for a compulsory licence, where it can be shown that the right holder is abusing the patent. The conditions under which a patent will be deemed to be 'abused' are set out in 56(2)(a)-(e) and are worth reproducing here:

[122] Klopper H et al, *op cit*, p 449.
[123] TAC, 'Fix the Patent Laws: Campaigning for pro-public health reform of South Africa's Patents Act', briefing document, 26 January 2012 http://www.fixthepatentlaws.org/?p=79 [Accessed 27 January 2012].
[124] Section 56(1) *Patents Act*, No 57 of 1978 (as last amended by Act no 49 of 1996).

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(a) *the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent…;*

(b) *the working of the invention in the Republic on a commercial scale or to an adequate extent is being prevented or hindered by the importation of the patented article;*

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

(d) *by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic… is being prejudiced; and*

(e) *the demand in the Republic for the patented article is being met by importation and the price charged by the patentee…for the patented article is excessive in relation to the price charged therefore in countries where the patented article is manufactured by or under licence from the patentee..."*

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Abuse under one of the above provisions would prove challenging to establish in a judicial setting. On a pervasive level, it may be difficult to establish behaviour by a right holder which is consistent with a strong, emotive term as 'abuse'. At a more detailed level, the Patents Act should be expanded from the above list to explicitly include broader public-health oriented circumstances which would justify a compulsory license.

TRIPS does require efforts to be made 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'[125] before a compulsory license may be granted. However, this requirement 'may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[126] Because the Doha Declaration confirms the right of Members to decide for themselves what constitutes a such circumstances, the TAC argues that South African legislation should broaden the above list to include issuing licenses if a medicine 'remains inaccessible due to its cost, where patent holders refuse to grant voluntary licenses on

[125] Article 31(b) *TRIPS*.
[126] Article 31(b) *TRIPS*.

reasonable terms, and where there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple rights holders.'[127]

The current framework is overly complicated. A more simplified administrative framework is necessary because bringing claims to a court is expensive and time consuming, obstacles which are only intensified when the opposing side will (often) be a well-resourced brand-name pharmaceutical company. One commentator points out the irony that these arrangements are so burdensome and administratively complex, given that the WTO website maintains that its main function is to ensure that 'trade flows as smoothly, predictably and freely as possible.'[128] Creating administrative, rather than judicial, mechanisms for interested persons to apply for a compulsory license not only reduces pressure on an already stretched judicial system, but enhances the likelihood that this TRIPS flexibility is invoked to address public health challenges.

The political context for compulsory licensing

The administrative and technical difficulties in using compulsory licenses only partly explain the broad underuse of the measures. The political pressures not to use compulsory licenses, by industry and other governments, also go some way in explaining their under use. Despite the clear legal foundations for granting compulsory licenses, as outlined in above sections, many developing countries remain reluctant, by and large, to pursue compulsory licenses. Fear of trade retaliation remains a not-imagined threat. Reactions by drug companies may include, and has included in the past, threats to withdraw investments, declining to bring forecast products into the country, and even withdrawal altogether from certain countries.[129]

In respect of government responses, the experience of Thailand in invoking compulsory licenses (described in more detail below), for example, does not provide confidence to developing countries. Following the issue of a number of compulsory licenses in 2007, the US placed Thailand on its Section 301 'Priority Watch List' in 2007, and threatened to withdraw its trade preferences in other areas afforded under the

[127] TAC, 'Fix the Patent Laws: Campaigning for pro-public health reform of South Africa's Patents Act', briefing document, *op cit.*
[128] Love, R 'Corporate wealth or public health? WTO/TRIPS flexibilities and access to HIV/AIDS antiretroviral drugs by developing countries' *Development in Practice*, Vol. 17, No. 2 (April 2007), p 211.
[129] Reichman, J, *op cit,* p 17.

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Generalised System of Preferences.[130] Yet other scholars argue that while such trade retaliation (especially unilateral) represents a very real threat to export markets for developing counties, developing countries should be aware that such action is often unfounded, in a legal sense. Reichman contends that if such a conflict was examined by WTO dispute settlement bodies, it would rather likely be retaliating state which would be found to violate WTO rules for trade concession withdrawal, rather than the state issuing the compulsory license.[131]

Furthermore, the point that compulsory licensing is a mechanism open to all countries needs to be reinforced. All WTO members, as parties to TRIPS, are able to make use of compulsory licenses under the terms outlined above. Indeed, developed countries have been among the most prolific users of the flexibilities. Canada, for example, used threat of compulsory licensing to negotiate a licence for a H1N1 vaccine, (Tamiflu),[132] and the United States has successfully threatened to invoke a compulsory licence to negotiate lower prices for ciprofloxacin (Cipro), which it intended to stockpile as a defense against anthrax.[133]

Some developed, along with developing, countries have enacted comprehensive legislation to better facilitate the use of compulsory licensing where required. Belgium, Switzerland and France, for instance, have all entrenched public health as grounds for compulsory licensing in their patents legislation. [134] The Swiss Patents Act provides the explicit justification for compulsory licensing for persons who have attempted to gain a license from a patent holder, but were not provided adequate justification for refusal, based on 'public interest' grounds.[135] And Belgian compulsory licensing is open to any person who can demonstrate that he or she has *bona fide* resources or intention to obtain necessary

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[130] *Ibid.*
[131] *Ibid.*
[132] Deslongchamps, A, 'Canada to Let Biolyse Make Generic Version of Roche's Tamiflu' Bloomberg news 27 September 2006.
[133] Reichman, J, *op cit,* p 249.
[134] Van Zimmeran, E and Van Overwalle, G, 'A paper tiger? Compulsory license regimes for public health in Equrope', *International Review of Intellectual Property and Competition Law,* January 2011, p 18.
[135] Article 40, *Swiss Patents* Act, in Van Zimmeran, E and Van Overwalle, G, 'A paper tiger? Compulsory license regimes for public health in Europe', *International Review of Intellectual Property and Competition Law,* January 2011, p 18.

resources for the continued manufacture in Belgium, on public health grounds.[136] These examples can be drawn on to model and justify expanding the grounds for compulsory licensing in South Africa.

In putting forward proposals for an enhanced compulsory licensing framework, there will likely be objections raised that the compulsory licenses are bad for investment, innovation incentives, research, and development.[137] Against such claims however, is the claim that any such impact is minimal, because costs of research and development for drugs is exaggerated, where medicines are developed and tested with the developed world in mind.[138] Another author proposes that negative impacts on investor confidence might be mitigated by countries working collaboratively on licenses on patents of mutual interest.[139] Through collective action, it might be possible for countries with relative level of FDI immunity (middle income countries like South Africa, for instance) to share that immunity with other countries more susceptible to FDI economic retribution.[140]

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South Africa as an exporter of medicines manufactured under compulsory licence?

Aside from the direct benefits potentially flowing to South Africa in being able to more simply acquire compulsory licences for importing or manufacturing medicines, South Africa also has a potential role to play in supporting access to medicines priorities of other developing countries.

Until 2003, WTO compulsory licensing arrangements only applied to countries to compulsorily acquire licences to manufacture medicines in their own territories.[141] Because many developing countries lack the skills, resources and infrastructure necessary to manufacture drugs, compulsory licensing arrangements under TRIPS represented a redundant opportunity for those countries. Recognising this important flaw, the Doha Declaration acknowledged that WTO Members with insufficient no manufacturing

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[136] Article 31(2) *Belgian Patents Act*, in Van Zimmeran, E and Van Overwalle, G, *op cit*, p 26.
[137] See for example Mansfield, E, 'Unauthorized use of intellectual property: effects on investment, technology transfer and innovation' Chapter 5 of *Global dimensions of intellectual property rights in science and technology* (Wallerstein M et al), (1993), pp 107-146.
[138] Washington, H, *op cit*, p 323.
[139] Bird R and Cahoy, D, 'the impact of compulsory licensing on foreign direct investment: a collective bargaining approach' *American Business Law Journal*, Vol 45, Issue 2 (2008), pp 283-330.
[140] *Ibid.*
[141] Section 31(f) *TRIPS* requires that 'any such use [without authorization of the right holder] shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement or, and instructing the Council for TRIPS to find an expeditious solution to that problem.[142] The resolution of this problem by the WTO took the form of a decision by the General Council entitled 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, or the 'Paragraph 6 decision'.

The crux of the Paragraph 6 decision is a set of conditions under which least developed countries, with insufficient or no manufacturing capacities in the pharmaceutical sector may nonetheless gain a compulsory license to import from another generic manufacturing Member.[143] These arrangements in theory address an important problem in TRIPS, but in practice they have not been productive.[144] Technically furthermore, the Paragraph 6 decision has not been accepted by the requisite two thirds WTO members to bring it into effect.[145]

Reasons for the reluctance of countries to make use of this mechanism might include the fact that Members must meet strict burdens of proof that they are an eligible least developed country [Paragraph 2(a)(ii)], the rigorous labelling requirements of medicines produced in such a way [Paragraph 2(b)(ii)], and the final burdensome requirements that importing countries then ensure that the products are not subsequently re-exported [Paragraph 4].

Implementing legislation to give effect to this flexibility (again, at an administrative, rather than judicial level), would likely help encourage generic manufacturers and health organisations to make use of the mechanism. There is nothing in the Patents Act which should prevent South Africa from manufacturing and exporting essential medicines to countries which do not have sufficient manufacturing capacity; but

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[142] Paragraph 6, *Doha Declaration*.
[143] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, the 'Paragraph 6 decision', adopted 30 August 2003.
[144] Just one such arrangement has been notified to the WTO, by Rwanda and Canada for the manufacture and export of triple combination AIDS therapy drug, TriAvir (see 'Canada is first to notify compulsory licence to export generic drug' News item, 4 October 2007).
[145] WTO, 'TRIPS and public health: dedicated webpage for notifications' http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm [Accessed 2 December 2011].

nonetheless a specific provision which allows it should be inserted.[146] South Africa should at the same time maintain pressure in the WTO to simplify these procedures or at least provide model guidelines for implementation.

Such an ability to export drugs to South Africa's LDC neighbours (those with no or insufficient manufacturing capacity) presents not only an immediate public health benefit for those LDC countries, but it also would help achieve economies of scale for a burgeoning South African generics industry. Economies of scale in this respect, suggests UNCTAD, is achieved by approaching groupings of countries to pool procurement activities and compulsory licensing activities for the same list of medicines.[147]Collaborating in this way is facilitated in LDC-dominated regional trade agreements under draft Article 31 of the TRIPS Agreement.'[148]

Brazil

Brazil has a compulsory licensing framework which is often cited as an encouraging model for other developing countries. Brazil has become notorious for the successful use of compulsory licenses to manufacture a number of drugs to address its most pressing public health challenges.

The success of Brazil's AIDS treatment programs, for example (between 1996 and 2002 AIDS-related mortality was reduced by 50 per cent), has been attributed to its ability to manufacture medicines locally, and cheaply, under compulsory license, or threat of compulsory license which has resulted in negotiated licenses.[149] Brazil first used the threat of compulsory licensing to achieve significant price reductions on HIV medicine, efaviranz and nelfinavir in 2001, moving on to similar price reductions on lopinavir in 2003; the lopinavir/ritonavir combination in 2005; and tenofovir in 2006.[150] Brazil finally used a compulsory license (rather than the threat of one) in 2007 to allow the import and

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[146] Avafia, T, Berger J and Hartzenberg T, *op cit,* p 19.
[147] UNCTAD, 'Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide', *op cit,* p 122
[148] *Ibid.*
[149] t'Hoen, E 'The global politics of pharmaceutical monopoly power' AMB Publishers, The Netherlands (2009), pp 44-45.
[150] UNAIDS/UNDP/WHO joint policy brief, 'Using TRIPS flexibilities to improve access to HIV treatments' 15 March 2011, p 6.

production of generic versions of efavirenz, leading to a drop from 580 USD per patient/per year from the brand name to 165 USD for the generic version.[151]

Notwithstanding resistance from some parts of the pharmaceutical sector, and certainly from international pharma groups, Brazil has enjoyed a level of support from a relatively sizeable proportion of the local pharmaceutical sector in pursuing its compulsory licensing strategy. One commentator has attributed this to the significant support the government has provided the sector, including through investing heavily in research; maintaining public sector labs in partnership with suppliers; supporting private firms to develop necessary intermediates; and assisting firms to acquire capacities for reverse-engineering of APIs.[152] South Africa should consider these wider measures to support a more active compulsory licensing system.

It must be noted that part of Brazil's success can be placed on its relative size, and status as an innovative developing country, with a significant capacity to manufacture pharmaceutical products – not all developing countries could follow through on such threats. But South Africa; the only country in southern Africa with a well-established pharmaceutical manufacturing industry, and with an (albeit limited) capacity to manufacture APIs,[153] is also well-positioned to make similar stands, and replicate Brazil's example.

Thailand

Thailand's compulsory licensing framework also has some appealing features. Thailand's standing as a compulsory licenser began in late 2006 and early 2007, when it issued compulsory licenses for two HIV drugs (Efavirenz and Kaletra) and one heart disease drug (Plavix). These compulsory licenses were made on the grounds that they were not affordable. While the Thai government came under criticism for not following the Article 31TRIPS requirement (that before a compulsory license is entered into, negotiations must take place),[154] the Government retorted that such negotiation was not required

[151] t'Hoen, E *op cit,* p 45.
[152] Shadlen, K, 'The Politics of patents and drugs in Brazil and Mexico: The industrial bases of health policies' *Comparative Politics* (Tufts), October 2009, p 50.
[153] Avafia, T, Berger J and Hartzenberg T, *op cit,* p 3.
[154] Article 31(b) *TRIPS* requires that the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions…'

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because it its generic manufacturing was destined for non-commercial purposes.[155] The USTR, however, reacted strongly, but in response to significant public and even congressional pressures to respect Thailand's moves, eventually conceded that 'We have not suggested that Thailand has failed to comply with particular national or international law'.[156]

In response to the controversy facing his country over the issuing of compulsory licenses, the Thai Minister for Public Health nicely summed up the non-sequitur concerns from commercial sectors as follows:

> *'When a government such as ours declares a "compulsory license" to allow for public non-commercial use of patented products by the government for the greater public good, we are doing so to increase access to these essential, often life-saving, medications for the poor and marginalized members of our communities who were not consumers of these expensive, patented drugs. The more well-off members of our society continue to consult their own private physicians and continue to pay – out of their own pockets – the price of patented medications. Thus, both the patent and compulsory license for the same product can exist harmoniously side by side in a country such as Thailand, with maximum benefits for all.'*[157]

This same reasoning applies in South Africa, where the production of essential medicine generics represent little, if any, loss of market for brand name companies. Of further interest for South Africa is the determination Thailand has shown to issue compulsory licenses for a range of illnesses. Unlike the general trend with compulsory licenses, where licenses have by and large been granted on drugs to address HIV/AIDS,[158] Thailand has quickly become the most prolific user of compulsory licenses for non-communicable diseases (NCDs).[159] As host to the world's largest population of HIV infected

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[155] UNCTAD, 'Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide' p 137.
[156] Schwab, S 2007, in t'Hoen, E *op cit,* p 45.
[157] Dr Mongkol na Songkla, Minister of Public Heatlh, Thailand (2006-1008),UNAIDS/UNDP/WHO joint policy brief, *op cit*, p 7.
[158] Two thirds of compulsory licensing episodes observed in a survey since 1995 involved HIV/AIDS (Beall, R and Kuhn, R, *op cit,* Table 2).
[159] Beall, R and Kuhn, R, *op cit,* p 4.

individuals,[160] effective compulsory licensing on HIV drugs will obviously be a priority for South Africa. But it is also important, as the greatest burden of disease in Africa is set to shift in coming years to NCDs,[161] that South Africa adopt a longer-term vision. This should not involve the development of an exhaustive list of diseases against which compulsory licenses might be invoked, but rather a flexible framework which provides South Africa with the freedom to grant CLs on any health grounds which the country is facing.

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[160] UNAIDS 'South Africa country situation' report 2008, p 1 http://data.unaids.org/pub/FactSheet/2008/sa08_soa_en.pdf [Accessed 1 December 2011]

[161] In African nations, NCDs are rising rapidly and are projected to exceed communicable, maternal, perinatal, and nutritionaldiseases as the most common causes of death by 2030 (Source: WHO, 'Global status report on non-communicable diseases 2010')

Chapter 5: Resisting TRIPS plus provisions: Data exclusivity / patent linkage

Unlike the measures described in other chapters, the measures of data exclusivity and patent linkage do not appear in TRIPS, and it is not proposed that these measures be incorporated into South African law. The purpose of including this chapter in the dissertation rather, is precautionary. These two measures are emerging as increasingly common provisions in trade agreements to expand patent protection, and thus restrict further access to medicines. Because they are seen as granting protection which goes beyond what the minimum standards require under TRIPS, they are often referred to as 'TRIPS Plus' measures. In the pharmaceutical field, TRIPS Plus measures cover an array of IP measures, such as patent term extensions for certain classes of medicines, regulatory protections, undertakings *not* to use compulsory licences, except under very limited circumstances; and more limited circumstances for the revocation of patents.

While all these measures should be resisted, this chapter covers detail of just two examples: data exclusivity clauses and patent linkage, for their particularly perverse potential to restrict access to medicines, and because of their increasing popularity in PTAs. As South Africa negotiates trade agreements with a number of countries, it is important that the Government remain vigilant against these negative implications, and refuse their inclusion.

Data exclusivity

Data exclusivity, in the pharmaceutical context, refers to the process by which data, which is submitted by originator drug manufacturer as part of its application to gain marketing approval, may not be used by generic manufacturers, also for the purpose of gaining marketing approval, for a specified period of time. Because it is economically and, some argue, ethically, unfeasible for generic manufacturers to produce original data to prove efficacy and safety, generic manufacturers generally rely on the same test data as is submitted to relevant authorities for the originator drug.

Protection of such undisclosed data, when required for marketing approval processes, must be protected against 'unfair commercial use' by TRIPS,[162] but

[162] Article 39(3) *TRIPS.*

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specification on timeframes or what constitutes unfair commercial are not made. The language of this provision would seem not to apply to government sponsored (non commercial) use generic manufacturing. Furthermore, some argue that this TRIPS provision ought only to apply to prevent third parties from using the data except where some unfair (dishonest) practices are involved.[163] Protection of test data against the legitimate attempts of generic manufacturers to register generic versions after the expiry of the patent for the originator therefore, under that line of argument, would not be included.

Yet PTAs often lock in protection for specified periods after it is submitted. Depending on the length of data protection required, and when the original data was first submitted, data protection provisions are harmful for access because the effective life of the monopoly on a drug can be extended through such protection. For example, where data protection by authorities is required for a period of five years, yet data for its marketing approval is only submitted to relevant authorities for a particular drug 17 years after the grant of the patent, generic manufacturers are effectively blocked out of the market for an additional two years after the expiry of the patent, because generic manufacturers cannot use the data for part of the approval process.

Because protection of test data is not required under TRIPS, except in circumstances of unfair commercial use, South Africa should avoid limiting future policy space in this area by including it in any PTAs it negotiates because it has the potential to restrict the entry of generics.

Patent linkage

Broadly, the term 'patent linkage' refers to the connecting in any way of the patent status of a drug to the regulatory, or marketing, approval of that same drug. At its strongest, patent linkage can preclude the regulatory approval of a drug if there is a possibility that it may infringe a patent. In most countries, the patents office, which concerns itself with the patentability of medicines, is separate from the marketing approval bodies, which concerns itself with the safety and efficacy of a drug, and often has links to the health ministry.

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[163] El Said, M, 'A policy guide for negotiators and implementers in the WHO Eastern Mediterranean region' ICTSD/WHO, 2010, p 136.

This separation is the case in the South African context, where patent linkage is not currently provided for in South African law. It will be important to maintain the separation of these two different processes into the future. Pharmaceutical patent linkage is becoming increasingly widespread, not only in incidence, but also in scope.[164] Since the expansion of linkage has the potential to impact not only domestic IP, but also the movement of drugs for humanitarian reasons,[165] it is worth considering its potentially deleterious effects. It is not a distant possibility that South Africa will be asked at some stage to incorporate them in bilateral or regional trade agreements, if it has not already.

Patent linkage provision vary, but generally work in two ways to prevent the entry of generics: by precluding the regulatory approval of a drug if would infringe a patent, and often by requiring that regulatory authorities notify the original patent holder if a generic manufacturer is seeking approval. This is problematic for access to medicines because it has the potential to delay registration of essential medicines under spurious or frivolous IP claims.

The Australia-US Free Trade Agreement, for example, required that regulatory authorities, where they require, as part of marketing approval processes the provision of test data, to provide measures to prevent marketing, where that product is claimed in a patent.[166] Where an application is made for marketing approval for a drug which is affected by a patent, the applicant is required to submit certification to the effect it is acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent.[167] These burdensome requirements have been criticised for unnecessarily confusing the role of regulatory and patents agencies and discouraging generic entry. The negative effects of this particular provision were partially mitigated during implementation by the insertion of a reciprocal requirement on patent holders who instigate litigation against generic entry; requiring certification that any such litigation is commenced in good

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[164] Bouchard, R et al, *op cit*, p 27.
[165] *Ibid.*
[166] Article 17.10.4 *Australia-United States Free Trade Agreement*.
[167] Section 26(B) *Therapeutic Goods Administration Act*, 1989 (as amended).

faith, has reasonable prospects of success, and will be conducted without unreasonable delay.[168]

Nonetheless, in a developing country context in South Africa, where the expansion of a viable generics industry should be a national priority (as discussed in Chapter 1), linking the marketing approval process to patent linkages in such a complex manner would insert an unnecessary level of administrative burden and potential barriers to generic market entry, which is *not* required under TRIPS, and which potential provides additional avenues for encouraging litigation against generic entry.

Resisting TRIPS Plus measures in trade agreements

Countries are theoretically free to implement TRIPS plus measures, although provisions requiring them are more likely to appear in national legislation as a result of external pressure (generally by way of implementation requirements associated with PTAs).[169] In PTA negotiations, developing countries are often are often asked to implement stronger IP protection rules in exchange for market access in other areas in developed countries, and, as it has been pointed out, any country which wants to improve its export market will be vulnerable to pressure to modify its patent protection framework.[170]

An additional point of concern is the fact that the standard of protection seems to be increasing over time with each new PTA that is concluded. For example, while the Jordan-US FTA calls for the protection of 'undisclosed test or other data', more recent FTAs with the US refer broadly to 'information' which would seem to imply that protection should be extended to test data even where that information has become public.[171]

In summary, while South Africa does not have these TRIPS plus provisions integrated into its patent framework, it is necessary to be vigilant against their introduction by way of PTA or other pressure. The measures of data protection and patent linkage have the potential to restrict and delay the entry of generic medicines. As argued in this dissertation, better and more generic competition in generic manufacturing should be a

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[168] Section 26(C) *Therapeutic Goods Administration Act*, 1989 (as amended). Similar certification is required under Section 26(D) in respect of interlocutory injunctions applied for against generic market entry.

[169] Ho, C*, op cit*, p 226.

[170] *Ibid.*

[171] El Said, M, *op cit,* p 137.

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national priority, and any measures which constrain policy space in this area ought to be avoided.

Conclusion – the way forward

South Africa needs to enhance its ability to take measures to ensure access to reliable, safe and affordable medicines. The challenges faced by South Africa against HIV and related illness are well documented – and the improvements in access to HIV medicines eventually achieved through the exercise of TRIPS flexibilities are inspiring. But South Africa is entitled, under international law, and compelled, under the constitution, to take more steps to protect and promote measures aimed not just at the big well known threats, but *any* public health challenges. Through harnessing intellectual property to achieve better medicines access then, this dissertation argues that South Africa must

- introduce and enforce stricter standards of patentability, so that only those new medicines which are truly innovative , representing an enhanced therapeutic effectiveness over existing treatments, are granted a patent;
- introduce pre- and post-grant opposition to patents; and administrative procedures for third parties to challenge a patent outside the court system;
- introduce a more flexible and user-friendly compulsory licensing framework, specifically legislating for a wider range of circumstances under which a compulsory licence may be granted; and
- resist pressure to implement data exclusivity, patent linkage and other TRIPS plus provisions.

These measures should by no means be considered to represent an exhaustive list of the intellectual property measures which are needed. But they are a very good starting point and will be pursued by TAC and other public interest groups as they push the South African Government in 2012 and beyond to amend the Patents Act. These organisations will argue that now is the time to take measures to protect public health enshrined in Constitution and under international law. They will argue that it is time to hold the government to account of its constitutional obligation to ensure access to life saving medicines in South Africa.[172]

[172] See the 'Fix the Patent Law' campaign website http://www.fixthepatentlaws.org/?p=79 [Accessed 9 February 2012].

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Some commentators have lamented the lack of commitment to public health promotion in intellectual property policy making in South Africa. One study, which considers the extent to which IP can be harnessed for development, concludes that unfortunately, national and international and decision-making on IP policy in Africa are all too often based on 'false perceptions, unrealistic expectations, insufficient knowledge, and a lack of awareness and public responsibility.'[173] South Africa, as it revises the patent framework, must inform itself of the true costs of IP protection and opportunities for development of a flexible framework.

Other countries, particularly and in several ways, India, have lead by example. However, as one commentator has pointed out, 'India provides not only an example of how to fashion patent laws to promote access to medicine, but how to provoke the ire, controversy, and expense of litigation with wealthy companies. It remains to be seen whether India has the political will to maintain the patent laws it designed'.[174]

Making such moves then, will require sustained commitment and determination on the part of the South African Government; many international actors, such as the US, EU and multinational brand name pharmaceutical companies have not shown a tendency to shy away from instances where countries have exercised their TRIPS flexibilities, even in the face of massive outcries from civil society and humanitarian sectors. But it is important to recall that none of the amendments suggested in this dissertation are radical proposals – all are provided for under international law and can be defended as such.

Costs in implementing these proposed measures will need to be considered. Closer patent application examination, experts to consider pre- and post-grant oppositions, administrative costs in a compulsory licensing scheme which is more open to applicants – these will all require additional budgetary allocations. Some options for minimising costs have been presented in this dissertation, for example, by using a list of experts to consider patentability disputes where needed, rather than maintaining a permanent structure. South Africa might also recoup some of its costs by petitioning more intently that developed countries, in the WTO, to fulfil their obligations to assist developing and least developed

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[173] Maister, B and van Woensel, C et al 'Harnessing intellectual property rights for development objectives: the double role of IPRs in the context of facilitating MDGs Nos. 1 and 6', (2011), p 413.
[174] Ho, C *op cit*, p 123.

member states with TRIPS implementation in the areas of capacity building and legislative assistance. Other costs, however, should be considered against the potentially significant savings (in a direct economic sense, as well as the flow-on economic benefits of a healthier society) achieved through a patents system more geared towards protecting and promoting public health.

Finally, a recognition must be stated that intellectual property is just one part of a broader suite of changes that needs to be made to enhance access to medicines. An oversimplification of the access to medicines crisis as all down to patent access would be unhelpful, and unfair. But, to borrow again from Dr Mirza, "We recognize that they *[the TRIPS flexibilities]* are not the simplest mechanisms to use...but it's a tool that we can use and should use to improve access to treatment as much as we can."[175]

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[175] Third World Network, *op cit.*.

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