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# **USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA**

## **An Analysis of Patent, Competition and Medicines Law**

United Nations Development Programme





# Using Law to Accelerate Treatment Access in South Africa:

## **AN ANALYSIS OF PATENT, COMPETITION AND MEDICINES LAW**

Chan Park, Achal Prabhala and Jonathan Berger

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One United Nations Plaza  
New York, NY 10017  
U.S.A.

Website: <http://www.undp.org/>

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## ABOUT THE STUDY

This study was conceived and commissioned by UNDP's Regional Service Centre for Eastern and Southern Africa in 2007 as one of a number of country studies initiated to examine the extent to which the domestic legal and regulatory environment enabled countries in Africa to increase access to essential medicines. A first version of the paper served a background document for a consultation organised by UNDP in November 2007, for government officials from Ghana, South Africa and Zambia which took place in Pretoria. The paper was updated in 2013 by the authors and edited by Kajal Bhardwaj. The authors thank representatives from government, industry and civil society for sharing their time and insights, and are particularly grateful to SECTION27 (formerly known as the AIDS Law Project) for research and logistical support. The authors are grateful to Kajal Bhardwaj for her helpful suggestions and editorial review and to Tenu Avafia and Katie Kirk from UNDP's HIV, Health and Development Practice in New York who oversaw the publication process.





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## FOREWORD

South Africa is reported to have the highest number of people living with HIV of any country in the world. Providing life-saving antiretroviral treatment to over 5 million people living with HIV—especially as new, more effective medicines and treatment regimens emerge—is a health and development priority that could significantly increase the burden on already over-stretched public budgets. Against this backdrop of high HIV prevalence, coupled with significant rates of tuberculosis (TB) co-infection and a growing burden of non-communicable diseases, the Government of South Africa has released a draft intellectual property (IP) policy that cites increased access to IP-based essential goods pertaining to health, food and education as a key objective.

South Africa is not alone in its ambition to secure a sustainable supply of pharmaceutical products to improve public health. These issues are also at the heart of a number of continental initiatives, including the African Union’s Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria, as well as the Pharmaceutical Manufacturing Plan for Africa, the implementation of which UNDP is supporting. The implementation of South Africa’s IP policy will require legislative reform, which could contribute to South-South cooperation efforts among the BRICS countries whose ministers of health have already committed to cooperating on matters of intellectual property and public health.

It is well established that a multitude of factors affect the availability, affordability and accessibility of essential medicines. The South African Government has already demonstrated great leadership in addressing some of these factors. Since 2010, the National Department of Health has managed to reduce expenditure on antiretroviral medications (ARVs) by 53 percent, amounting to an estimated cost saving of US\$ 685 million over a two-year period from 2011 to 2012. The Government achieved this cost reduction by promoting the registration of multiple ARVs at the Medicines Control Council, publishing a reference price and requiring suppliers to provide a breakdown of unit costs.

While these measures have yielded great dividends, South Africa could secure even greater gains through the adoption of an enabling legal and regulatory environment across patent, competition and medicines laws. This study focuses on policy options available to South Africa through the reform of these three interrelated areas of law. The reforms suggested here are aimed at safeguarding public health. Potential drawbacks and challenges are also highlighted, as are strategies for adoption that draw on the experiences of other low- and middle-income countries.

## FOREWORD

As with recent country studies of the legal and regulatory environment in India and in China, undertaken in 2010 and 2013 respectively, this study of national legislation in South Africa offers concrete suggestions on how intellectual property, competition and medicines legislation can be tailored to improve public health outcomes while complying with international obligations, with a particular focus on the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

TRIPS requires WTO members, with the exception of least developed countries, to adopt minimum standards of intellectual property protection, including at least 20 years of patent protection in all fields of technology. However, it also establishes specific measures that may be used to limit exclusive patent rights. These public health related TRIPS flexibilities allow countries to balance the minimum standards of intellectual property with public health needs.

If the benefits of TRIPS flexibilities are to be more fully realized in South Africa, the flexibilities must be incorporated in national law—including patent, competition and medicines regulation laws. For example, the study found that a stricter patentability standard, where the overwhelming majority of patent applications are from foreigners, would result in a decline in the number of patents, which in turn could increase competition and result in price reductions of essential medicines. Yet implementation in law of a stricter patentability standard is only the first step, and complimentary practices, such as substantive examination and patent opposition processes, are also needed.

This study comes at an opportune time. It offers a number of policy options that from a public health perspective could contribute to strengthening South Africa's legal and regulatory environment in ways that make a tangible difference to the health of millions and to sustainable development in South Africa.



**Dr Mandeep Dhaliwal**  
**Director**  
**HIV, Health and Development Practice**  
**United Nations Development Programme New York**



## EXECUTIVE SUMMARY

Accelerating access to affordable, quality-assured treatment is an essential component of South Africa’s National Strategic Plan (NSP) on HIV, STIs and TB 2012–2016. Of note, the NSP recognizes that the cost of anti-retroviral medicines remains the single greatest expenditure in the NSP’s annual budget. The NSP also calls attention to “ensuring an enabling and accessible legal framework that protects and promotes human rights in order to support implementation of the NSP”. This study aims to contribute to the implementation of the NSP, by making specific recommendations on law and policy reforms to achieve such an enabling and accessible legal framework in three key areas: **patent, competition, and medicines law**.

The study begins with an overview of the current landscape for treatment access in South Africa, as well as an introduction to one of the major challenges to achieving lower prices of essential medicines—an international legal framework, under the World Trade Organization’s (WTO) Agreement on Trade Related Aspects of Intellectual Property Protection (TRIPS)—which requires countries, including South Africa, to apply minimum intellectual property protections on the essential medicines used in the country, regardless of whether they are imported or domestically manufactured. However, the study goes on to elaborate a number of public health-related TRIPS flexibilities, which provide countries with options to increase treatment access.

Chapter 2 focuses on the flexibilities provided for under the current South African Patents Act. The chapter also provides an analysis of existing policy space; compares the experiences of other countries in implementing and using each flexibility; and provides recommendations on reform options to maximize outcomes on accelerating access. On the issue of patentability criteria, Chapter 2 suggests that in the interests of public health, promoting pharmaceutical innovation and growth of the domestic pharmaceutical industry, South Africa could move towards an examination system, by initially implementing an opposition-based and/or partial examination system. This would reduce the number of patents currently being granted through its current registration system, which does not involve a substantive examination of patent applications. The transition to a substantive patent examination system could be facilitated by establishing easy-to-apply rules on patentability requiring significant disclosures by the patent applicant, and allowing interested parties including civil society to participate in and oppose, where appropriate, patent applications and grants.

Chapter 2 goes on to note that the South African Patents Act, as it currently stands, does not take full advantage of the flexibilities available in respect of limitations to patent rights. It recommends that the Patents Act make use of the full range of express exclusions from



patentability available under TRIPS, and proposes that the process for issuing compulsory licenses be significantly streamlined, with clear legislative guidelines for determining the grounds upon which compulsory licenses can be granted, as well as their terms and conditions to prevent unnecessary delays. The study notes that the disclosures contained in patent specifications can provide much-needed technological know-how to ensure long-term security in the supply of essential medicines. Therefore, stricter requirements for full disclosure of information in patent applications are recommended. Chapter 2 concludes by scrutinizing the risks to treatment access inherent in a system that imposes harsh penalties in patent infringement proceedings – in particular, broad forms of interdictory relief – which could also pose a significant disincentive for domestic pharmaceutical companies to enter the market, and thereby limit competition. It includes recommendations for minimizing such risks, while at the same time meeting minimal obligations to rights holders.

Chapter 3 examines how to strengthen the competition enforcement framework in South Africa to address anticompetitive practices. South Africa's Competition Act is relatively young and largely untested in the realm of intellectual property. In theory, the main flexibilities found in TRIPS (compulsory licensing to remedy anticompetitive practices and the power to regulate specific types of abuse of rights that would constitute anti-competitive behaviour) are potentially available to complainants, though the legislation does not expressly recognize such flexibilities. Anticompetitive practices which have the potential to restrict access to treatment include, *inter alia*, restrictive licensing agreements, patent 'evergreening' and litigation aimed to prevent competition, patent settlements and 'pay-for-delay' agreements between originator and generic companies, excessive pricing, refusal to license, and undue market concentration as a result of acquisitions and mergers. Chapter 3 also addresses how the law might be reformed to boost South Africa's ability to identify and respond to such practices. Amendments to the Competition Act that explicitly clarify such flexibilities (Articles 8, 31 and 40 of TRIPS are the main provisions) are one option.

Another recommended option is to encourage more cases involving intellectual property to be brought to the Competition Commission, by issuing non-binding guidelines that make the task of a complainant clearer. A related intervention would be to make licensing information about intellectual property more transparent, to aid in putting together a complaint, through the increased use of the existing mandatory public register of patent-related licenses under the Patents Act.

Chapter 4 examines the issues of the regulatory framework in South Africa. South Africa is generally viewed as complying with Article 39.3 of TRIPS, while taking advantage of the flexibility inherent in TRIPS by providing for a system of 'test data protection' as opposed to 'data exclusivity'. However, while South Africa currently takes advantage of this TRIPS flexibility to a certain degree, the medicines regulatory system in South Africa could still do much more to safeguard against barriers raised by the drug registration process. It is possible



to improve the process for granting marketing approval for drugs – without compromising safety – by addressing the manner in which data is requested and examined, and by leveraging opportunities provided by international certification. By providing additional flexibilities and options in the medicines regulatory system – including explicit fast-tracking that is bound by short timelines – acknowledged delays in the drug registration process could be shortened, while also easing human resource capacity constraints and significantly reducing the backlog of pending applications for approval. Such an approach could ultimately benefit patients and the domestic pharmaceutical industry as a whole. Resources to improve the regulatory environment in South Africa are also presented in the chapter, including opportunities for collaboration with other countries, and making use of alternative regulatory mechanisms, such as WHO’s prequalification of medicines programme.

The study concludes by emphasizing that the recommendations in the report are aimed at achieving mutually reinforcing goals. First and foremost, it focuses on promoting access to essential medicines. But the recommendations are also made with a second objective in mind: to develop and support policies conducive to the growth and development of the domestic generic pharmaceutical industry. There is opportunity to better align and harmonize the three laws in question, both with each other and – particularly in the case of the Patents Act – with the South African Constitution. The process of reforming these laws could benefit from a policymaking approach that is consultative, coherent and developed with the input of all relevant actors, governmental and non-governmental alike.

With the specific commitments found in the NSP, the Government of South Africa has recognized the role of human rights in achieving its objectives around HIV, TB and STIs. The pursuit of the law reform recommendations found in this paper can contribute to the Government’s achievement of its policy objectives and Constitutional commitments to respect, protect, promote and fulfil the right to medicines not only for these diseases, but also for other HIV co-infections and non-communicable diseases.





# 1. INTRODUCTION

This study focuses on the flexibilities inherent in the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as they relate to patent, competition and medicines law in South Africa. The application of public health related TRIPS flexibilities aims to achieve two mutually reinforcing goals.<sup>1</sup> The first – and primary – goal is to increase access to essential medicines. The second, related goal is the growth of South Africa’s domestic pharmaceutical industry.

## 1.1 Why TRIPS flexibilities?

Intellectual property (IP) protection has become a flashpoint within the WTO and increasingly, a source of dispute among its Members. The WTO was established in an era of increased attention to access to medicines; a focus on HIV and AIDS in the developing world led to a focus on access to health care in general. Stakeholders have repeatedly cited IP rules at the WTO, encapsulated in TRIPS, as an underlying and fundamental barrier to increasing access to HIV and other essential medicines. Over the nearly two decades since the introduction of TRIPS, a process of clarifying its contents has occurred at the WTO, under pressure from (mainly) developing countries. This has led to a better understanding of the boundaries of TRIPS flexibilities, as illustrated perhaps most clearly in Indian patent law.

In the last decade, several developing countries took decisive action with respect to IP within their jurisdictions, usually intended to benefit patients and local industry. This, in turn, often led to long, drawn-out contestations in courts, in trade relations, and in international trading forums.

However, over the last decade, explicitly implementing TRIPS flexibilities into domestic law and policy has started to become a more widely accepted practice; using TRIPS flexibilities is now considered a more realistic possibility. Indeed, given many countries’ obligations under international human rights treaties such as the International Covenant on Economic, Social and Cultural Rights, which recognizes the right to the “highest attainable standard of physical and mental health”,<sup>2</sup> as well as domestic constitutional obligations of similar

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1. Based on the presumption that a functioning domestic generic pharmaceutical industry not only provides broad economic benefits, but to an extent also secures the supply of pharmaceuticals within the country and the continent.

2. UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, Article 14.



effect,<sup>3</sup> taking steps to use such flexibilities to improve access to medicines can be seen as an affirmative obligation.

While TRIPS provides both guidance and binding policy directives, there are several areas in which countries have a degree of freedom to decide for themselves how to interpret certain provisions, and indeed, interpretations can be wide-ranging. In recent years, several important interpretations have been tested in bilateral negotiations, in national courts and at the WTO. While ‘TRIPS flexibilities’ cover a diverse range of policy directions, this paper examines the implementation of those specific TRIPS flexibilities that would increase access to medicines and also provide growth opportunities to the domestic pharmaceutical sector in South Africa.

It should also be emphasized that a country’s use of TRIPS flexibilities to promote access to medicines or the growth of its domestic pharmaceutical industry does *not* indicate a reluctance to promote innovation. Indeed, several of the flexibilities discussed in this study create a higher bar for innovation, thus promoting genuine innovation while simultaneously de-incentivising trivial innovation.

Further, local incentives to innovate are largely irrelevant with respect to products primarily destined for foreign markets. This may explain, at least in part, why a country such as Switzerland – home to companies such as Novartis, Hoffman-La Roche and Janssen-Cilag – only adopted full patent protection for pharmaceutical products as late as 1977.<sup>4</sup>

The key concept in the management of IP rights is, perhaps, balance<sup>5</sup> (see figure 1). The appropriate level of IP protection will vary across countries in light of each country’s level of development, innovative capacity and other countervailing circumstances, including the need to promote access to medicines.

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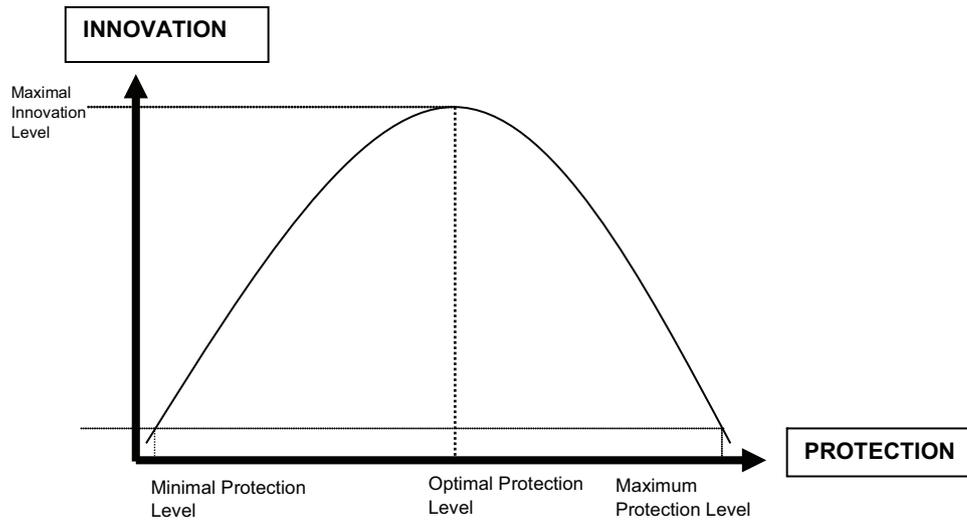
3. See, e.g., Constitution of South Africa, section 27.

4. See Ordinance on Patents for Inventions, 1977 (Switzerland) available at <http://www.wipo.int/wipolex/en/details.jsp?id=11917>

5. See, e.g., Edwin Cameron and Jonathan Berger, “Patents and Public Health: Principle, Politics and Paradox”, (2005) 131 *Proceedings of the British Academy* 331 at 345.

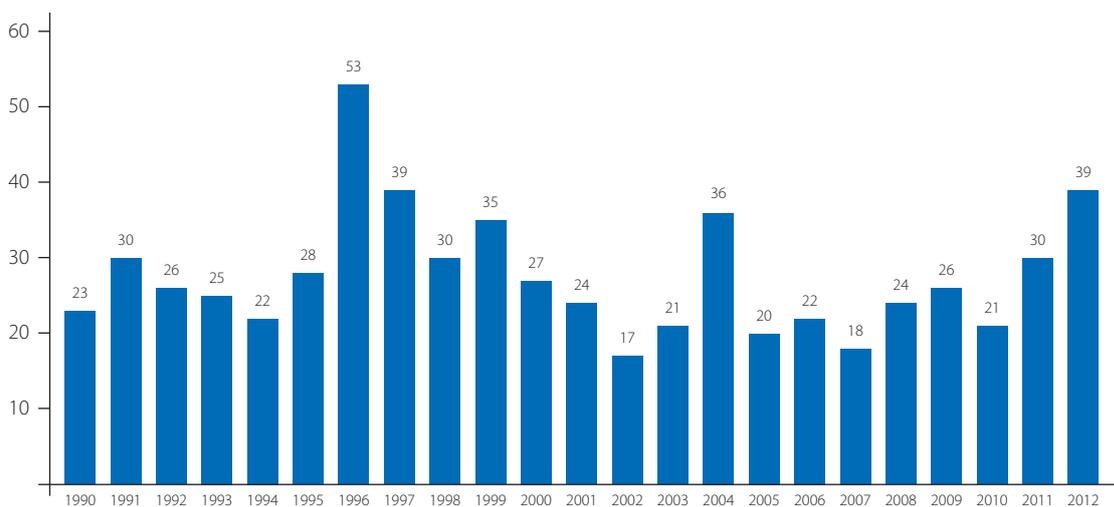


**Figure 1. Innovation and intellectual property<sup>6</sup>**



In the context of medicines, the evidence of a definitive link between high prevailing norms of IP protection (as seen in many high income countries) and innovation is both scant and disputable. TRIPS moved IP protection into the global arena; however, since then, and despite attempts to harmonize IP around the world, there has not been a corresponding increase in the output of new medicines (see figure 2).

**Figure 2. New drug approvals by the US Food and Drug Administration from 1990–2012<sup>7</sup>**



6. From the Swiss Federal Institute of Intellectual Property, October 2006.

7. Data extrapolated from the US Food and Drug Administration archives, available at: <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SummaryofNDAApprovalsReceipts1938tothepresent/default.htm>



In addition to a lack of a definitive correlation between prevailing norms of IP protection and innovation, there have been instances in which significant innovation has occurred in the absence of patent protection. Indeed, the existence of patent protection has, on occasion, posed an obstacle to innovation. For instance, Indian generic companies, unhindered by product patent protection in India during that time, were able to develop a single fixed-dose combination of stavudine, lamivudine and nevirapine that dramatically simplified the HIV treatment regimen and allowed for the scale-up of treatment in many resource-limited settings.<sup>8</sup> Because three different companies owned the patents on these drugs, there was little incentive for the patent-holding companies in the developed countries to enter into complicated cross-licensing arrangements in order to produce a single product that drastically reduced pill burden and improved patient compliance.<sup>9</sup>

The lack of innovation around neglected diseases also calls into question the relationship between IP protection and innovation. In 2008, the World Health Assembly adopted the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (Global Strategy), recognizing that intellectual property as an incentive “alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain”.<sup>10</sup> Multinational pharmaceutical companies have invested limited resources in research and development on diseases predominantly affecting developing countries – such as tuberculosis (TB), malaria, leishmaniasis and kala azar. This has resulted in a push for alternative mechanisms such as prize funds and partnerships like the Drugs for Neglected Diseases Initiative, and government-led initiatives such as the Indian government’s Open Source TB Drug Discovery project.

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8. This combination is no longer a preferred regimen. Nonetheless, it is still widely used in many resource-limited settings.

9. See B. Baker, “U.S.’s Misguided and Bad-Faith Attack on the WHO’s 3-by-5 Plan”, Health GAP (2003), available at [http://www.healthgap.org/press\\_releases/03/121803\\_HGAP\\_BP\\_USG\\_3x5.html](http://www.healthgap.org/press_releases/03/121803_HGAP_BP_USG_3x5.html)

10. World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21, 24 May 2008 available at [http://apps.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf)



## 1.2 South Africa and treatment for HIV infection

While South Africa is estimated to have the highest absolute number of people living with HIV of any country in the world,<sup>11</sup> it is also home to the world's largest public sector antiretroviral (ARV) treatment programme.<sup>12</sup>

In 2003, a South African government publication recognized that:

Two years ago, this programme for comprehensive care and treatment would have been impossible, amongst other things due to the cost of the medicines and laboratory tests required.<sup>13</sup>

More recently, South Africa's *National Strategic Plan on HIV, STIs and TB 2012–2016* (NSP) counts among past successes, “the reduction in prices for key commodities, including antiretroviral (ARV) drugs and TB drugs, which enabled the further expansion of access to treatment”.<sup>14</sup> A key intervention for the NSP is “ensuring access to affordable, high-quality drugs to treat HIV, sexually transmitted infections (STI) and TB” (see box 1). The cost of ARVs remains the single greatest expenditure in the NSP's budget (see figure 3).

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11. According to UNAIDS figures from 2012 there are 5.6 million people living with HIV in South Africa; see UNAIDS, World AIDS Day Report, 2012 at [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434\\_WorldAIDSday\\_results\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf)

12. According to UNAIDS, South Africa has scaled up its treatment services to 1.7 million people – an increase of 75 percent over the past two years. See UNAIDS, World AIDS Day Report, 2012 at [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434\\_WorldAIDSday\\_results\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf)

13. See “Question and Answer: Cabinet's decision on the Operational plan for comprehensive care and treatment of people living with HIV and AIDS, 19 November 2003”, available at <http://www.info.gov.za/issues/hiv/aidsqa19nov03.pdf>

14. National Strategic Plan on HIV, STIs and TB 2012–2016, South African National AIDS Council, Republic of South Africa, available at <http://www.doh.gov.za/docs/stratdocs/2012/NSPfull.pdf>



## BOX 1.

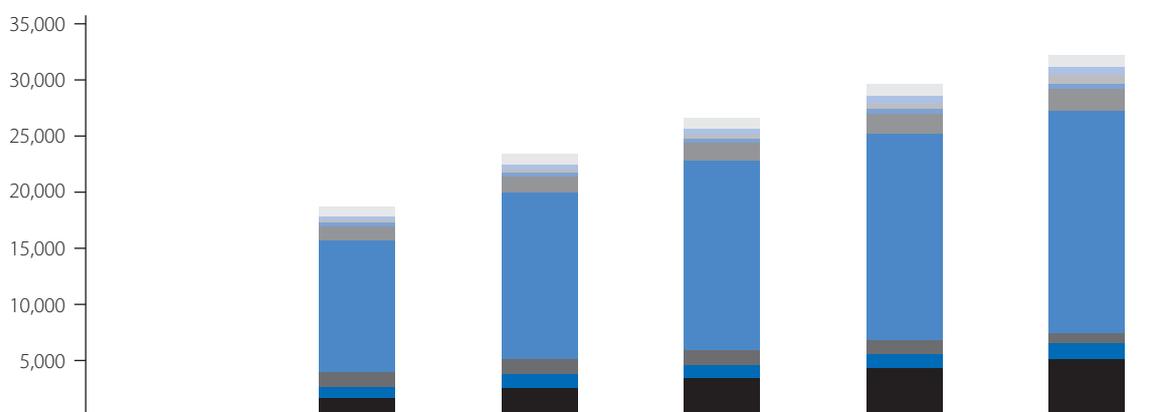
### Intervention 3.1.4: Ensuring access to affordable, high-quality drugs to treat HIV, sexually transmitted infections and TB

Ensure adequate supply of affordable ARV and STI and TB drugs through pooled procurement, negotiated price reductions, improved regulatory approval and better supply chain management. In addition, access to age-appropriate paediatric formulations for HIV and TB must be assured. Common drug combinations should be available as fixed-dose combinations to reduce the pill burden, improve adherence, reduce dosage mis-prescribing, and reduce the dispensing load of pharmacies. New drugs for drug resistant TB need to be made available to patients with complicated drug-resistant TB. Expanded access to opportunistic infection medication should be made available at PHC level”.

– National Strategic Plan on HIV, STIs and TB 2012–2016

**Figure 3. Annual costs of the National Strategic Plan on HIV, STIs and TB in South Africa<sup>15</sup>**

	2012/13	2013/14	2014/15	2015/16	2016/17
Remainder	870	960	967	1,061	1,070
Youth HIV prevention	323	451	529	689	756
MMC	244	293	293	488	781
Condoms	329	355	399	442	469
OVC support	1,227	1,400	1,575	1,750	1,930
Antiretroviral treatment	11,681	14,783	16,827	18,352	19,737
TB treatment	1,329	1,337	1,356	1,253	869
TB screening	985	1,243	1,175	1,291	1,418
HIV screening	1,739	2,609	3,478	4,348	5,217



Notes: MMC: mother to child transmission. OVC: orphans and vulnerable children.



It is important to note that largely due to sustained pressure and action by developing country governments and civil society organizations, the cost of ARV medicines has fallen dramatically over the last decade. Simultaneously, it has been shown that there can be vast differences between current generic and originator prices for the same drug.

Médecins Sans Frontières, for instance, notes<sup>16</sup> that the price for the first-line ARV regimen (tenofovir + emtricitabine + efavirenz) preferred and recommended by the World Health Organization (WHO) now stand at US\$119 per person per year.

In South Africa, however, such successes have largely been limited to older medicines used for HIV and HIV-related conditions. While certain legislative, regulatory and administrative steps have secured a modest price reduction for all patented medicines, the degree of reduction seen in the HIV arena has yet to be replicated for newer, more effective first-, second- and third-generation HIV medicines, and for medicines for other diseases adversely affecting health outcomes in South Africa.

Undoubtedly, the challenge ahead is to ensure that the South African government is equipped with a public health-sensitive legal framework that can achieve the price reductions needed to sustain a public HIV treatment programme and ensure all people's access to medicines. It is equally important that the domestic generic pharmaceutical industry be provided a level playing field to participate in the production and supply of these medicines once TRIPS flexibilities are invoked.<sup>17</sup> As the Indian experience post-1970 has shown, the nature and extent of patent protection may have a direct impact on the development of the domestic generic pharmaceutical industry. This study reflects this twin focus.

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15. Figure 4: Categorized Annual Costs (ZAR Millions in 2011 Prices), National Strategic Plan on HIV, STIs and TB 2012-2016, South African National AIDS Council, Republic of South Africa, available at <http://www.doh.gov.za/docs/stratdocs/2012/NSPfull.pdf>, p. 77.

16. Médecins Sans Frontières, *Untangling the Web of Price Reductions*, 15th Edition, July 2012, p. 4, available at: <http://utw.msfaccess.org/>

17. For instance, a study by Genesis, *The Growth Potential of the Pharmaceutical Sector in South Africa* (Genesis, 16 May 2007) states that “Despite the presence of 94 registered pharmaceutical operations in South Africa, the majority of firms are operating only as sales and marketing offices, with R&D and production being undertaken overseas... Today, only ten companies have production factories in South Africa, with another six using local companies for contract manufacturing and packaging”. (p. 7). The report observes that “South African pharmaceutical manufacturers... have no option but to import close to 90% of the inputs for their drugs, mainly from India and China”, and goes on to state that “the ratio of imported to exported pharmaceuticals ready for retail sale rose from around 8:1 in 1998 to 17:1 in 2006”. (pp. 7, 10).



## 1.3 TRIPS flexibilities and the South African legal system

Global consensus that WTO members are free to use and implement TRIPS flexibilities emerged from events in South Africa in the late 1990s. Within a few years of becoming a founding member of the WTO and signing the TRIPS Agreement in 1995, South Africa amended its patent law in 1997 to increase protection for patentees. At the same time, however, the HIV epidemic was unfolding across South Africa and the high costs of patented ARVs made treatment unaffordable for the millions of people living with HIV. In response to this situation, the Government moved to amend the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) in an attempt to increase access to medicines more generally.

Several multinational pharmaceutical companies and their local subsidiaries – 39 corporate entities in total – challenged the Medicines and Related Substances Control Amendment Act 90 of 1997, seeking to prevent the amendment from coming into force. When the case finally went to court some two years later, the litigation drew strong reactions from people living with HIV, who marched in thousands through the streets of South Africa demanding the withdrawal of the case. The Government’s steadfast commitment to the new law, along with increasing international outrage and a strategic legal intervention by South Africa’s Treatment Action Campaign (TAC),<sup>18</sup> eventually led the companies to drop the lawsuit in April 2001.

But the lawsuit’s reverberations reached the WTO and in November 2001, WTO members met in Doha and adopted the Declaration on TRIPS and Public Health<sup>19</sup> (the Doha Declaration). The Doha Declaration, signed by developed and developing WTO member countries alike, stated:

We agree 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.

In light of the Doha Declaration, this paper explores ways in which South Africa can refine its implementation of the TRIPS agreement to make it more responsive to public health concerns.

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18. See Mark Heywood, “Debunking ‘Conglomo-talk’: A case study of the amicus curiae as an instrument for advocacy, investigation and mobilisation” (2001) 5:2 *Law, Democracy & Development* 133. The TAC was represented by the AIDS Law Project.

19. World Trade Organization, Declaration on the TRIPS Agreement and Public Health (Doha Declaration), Ministerial Conference, Fourth Session, Doha, 9–14 November 2001.



## 2. ANALYSIS OF THE SOUTH AFRICAN PATENT SYSTEM

### SUMMARY

*TRIPS affords numerous flexibilities for countries to formulate their patent laws, including:*

- (1) Setting patentability criteria;*
  - (2) Defining limited exceptions to patent rights;*
  - (3) Providing for the exclusion of certain subject matter;*
  - (4) Requiring disclosure of information in patent applications;*
  - (5) Providing for patent examination and oppositions;*
  - (6) Authorizing parallel importation of patented medicines;*
  - (7) Permitting limited exceptions to patent rights, including for compulsory licensing;*
- and*
- (8) Establishing enforcement mechanisms, including remedies for infringement.*

*Each flexibility is discussed here, and policy options relating to these flexibilities are presented. South Africa does not currently undertake substantive examinations of patent applications against standards of patentability. However, this paper suggests that in the interest of public health, genuine innovation and growth of the domestic pharmaceutical industry, South Africa could move towards an examination system and initially implement an opposition-based and/or partial examination system. Such a move could enable South Africa to prevent questionable patents from being granted. This transition could be facilitated by establishing easy-to-apply per se rules on patentability, requiring significant disclosures by the patent applicant, and allowing civil society to participate in the processes of the patent office.*

*Moreover, the South African Patents Act, as it currently stands, fails to take advantage of the flexibilities available in the issuance of compulsory licences. It is suggested that the process for issuing compulsory licences be streamlined dramatically, with clear legislative guidelines for determining the grounds upon which compulsory licences can be granted as well as their terms and conditions.*



South Africa's patent office is housed in the Companies and Intellectual Property Commission (CIPC), a government agency established under the Companies Act 71 of 2008 and falling under the aegis of the Department of Trade and Industry. Under the Patents Act 57 of 1978 (the Patents Act), the registrar of patents is responsible for accepting, publishing and registering patent applications.<sup>20</sup> The CIPC is the designated registrar. Significantly, the Patents Act does not currently require the registrar to undertake a substantive examination of patent applications prior to grant to ensure that they satisfy the substantive criteria for patentability.<sup>21</sup> Consequently, all patent applications, insofar as the appropriate forms are filled and the fees paid, proceed to grant.

Patent disputes are filed in the Court of the Commissioner of Patents. Only judges of the North Gauteng High Court, Pretoria may sit as a Commissioner. Proceedings before the Commissioner are governed by the rules and procedures of the High Court.<sup>22</sup> The Commissioner is vested with authority under the Patents Act to make essentially all substantive determinations under the Patents Act, including infringement and revocation proceedings and applications for compulsory licences.<sup>23</sup> The Patents Act also creates a Patent Examination Board, comprising the registrar of patents and appointees from the law societies, university law schools and the South African Institute of Intellectual Property Law.<sup>24</sup>

South Africa acceded to the Patent Cooperation Treaty in 1999, and it is understood that the majority of patent applications are now being filed via the Patent Cooperation Treaty.<sup>25</sup> According to data from the World Intellectual Property Organization, which administers the Patent Cooperation Treaty, the vast majority of patent applications in South Africa are filed by foreign entities. In 2011, for example, 656 patent applications were filed by residents as opposed to the 6,589 patent applications filed by non-residents.<sup>26</sup> These numbers are consistent with the experience of most developing countries.

Under the Patents Act, granted patents are required to be published in the Patent Journal, and the patent register is made available for public inspection upon payment of the prescribed fees.<sup>27</sup> However, more recently the patent office has moved from the publication of a paper

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20. Patents Act, section 15.

21. Patent Regulations, 1978, regulations 41, 44.

22. Patents Act, sections 8, 19.

23. Patents Act, Sections 17, 61 and 56; also see Patent Regulations, sections 89, 96, 98.

24. The Patent Examination Board is conferred with the authority to determine the syllabus for patent agent examinations, qualification and registration of patent attorneys and patent agents. The Patent Examination Board in the Patents Act is not charged with the substantive examination of patents.

25. Interview with A. Dyer, Spoor & Fisher (retired), 12 October 2007. Notes of interview on file with authors.

26. World Intellectual Property Organization, Statistical Country Profiles – South Africa, available at [http://www.wipo.int/ipstats/en/statistics/country\\_profile/countries/za.html](http://www.wipo.int/ipstats/en/statistics/country_profile/countries/za.html)

27. Patents Act, sections 12, 14.



journal to an electronic journal that is available for viewing and downloading online at no cost.<sup>28</sup> The CIPC also provides a free and fully searchable online database of granted patents.<sup>29</sup> Initial feedback suggests that the online database requires improvements to become truly user-friendly. CIPC also offers patent search services for a fee.<sup>30</sup>

## 2.1 Patent criteria

Section 25(1) of the Patents Act lays out the basic requirements for patentability:

A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.

This accords with South Africa's obligations under Article 27.1 of TRIPS, which provides that "patents shall be made available for any inventions, whether products or processes, provided that they are new, involve an inventive step and are capable of industrial application".<sup>31</sup>

However, the terms 'new', 'inventive step' and 'industrial application' are not defined in TRIPS, with the implicit recognition that these standards will vary from country to country. Indeed, Article 4bis of the Paris Convention for the Protection of Industrial Property (Paris Convention), which was incorporated by reference into Article 2.1 of TRIPS, explicitly states that the grant or denial of a patent in one country shall be independent of the grant or denial of a patent in another country.<sup>32</sup>

What this means is that countries have significant flexibility to set their basic criteria for patentability – novelty, inventive step and industrial applicability – according to their policy priorities. It is notable that the South African constitution imposes an obligation upon "every court, tribunal or forum" in South Africa to interpret legislation to "promote the spirit, pur-

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28. Patent Journal (Including Trademarks, Designs and Copyright in Cinematograph Films), CIPC, available at <http://www.zaip.org/e-journal>

29. 'Search the Online Patent Register,' CIPC, available at <http://patentsearch.cipc.co.za/patents/patentsearch.aspx>

30. 'Patent Searches,' CIPC IP Online Services, available at <http://iponline.trevenna.net/home/default.aspx>

31. TRIPS provides that for the purposes of Article 27.1, the term 'industrial application' may be deemed to be synonymous with 'useful'. Thus, the use of the phrase 'capable of being used' in section 25(1) may, for all intents and purposes, be deemed to be synonymous with the TRIPS requirement of industrial applicability.

32. Article 4bis of the Paris Convention states, in relevant part, "(1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not. (2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration".



port and objects of the Bill of Rights”, which includes the right to access to medicines – an integral part of the right to access to health care services.<sup>33</sup>

Public health concerns aside, many high-, middle- and low-income countries set strict levels of patent criteria in order to incentivise only genuine innovation. An additional motivation for some countries to set strict patentability criteria arises where the vast majority of patent applicants are from abroad.

Even in an advanced economy such as the United States, traditionally viewed as having some of the most liberal patentability standards in the world, there is a growing recognition that overbroad patent protection can actually harm innovation. In a 2007 landmark decision, the US Supreme Court established a significantly more stringent test for ‘inventive step’. The court observed, “Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress, and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility”.<sup>34</sup>

Setting high standards for the basic criteria for patentability, then, is an important (and often overlooked) flexibility that is inherent in TRIPS. Simply put, setting the bar higher for obtaining a patent will result in fewer and better quality patents. Fewer patents will result in greater generic competition, which will then in turn lower drug prices as well as ensure a sustainable supply of these drugs from multiple manufacturers. Higher patentability criteria will also result in real incentives for research and development. Each of the three criteria for patentability will be discussed in turn.

## 2.1.1 Novelty

The novelty requirement is designed to ensure that knowledge that already exists in the public domain is not subjected to a statutory monopoly, which would be unjustified and would undermine the very basis for the grant of patent protection. Novelty can be interpreted narrowly or broadly, and a distinction is drawn between ‘relative’ novelty and ‘absolute’ novelty. Relative novelty is determined by whether an alleged invention exists only within the country in which the patent is sought. In contrast, absolute novelty is determined by whether an alleged invention exists anywhere in the world. Therefore, from the perspective of setting stricter patentability criteria, an absolute novelty standard is preferable.

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33. Constitution, sections 27(1)(a); 39(2).

34. *KSR Int’l v. Teleflex, Inc.*, 550 U.S. 398 (2007) at p. 15 (slip opinion).



The Patents Act contains several provisions that define whether an invention can be considered ‘new’. Section 25(5) states the basic rule that:

An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention.

Section 25(6) then defines the meaning of ‘state of the art’:

The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.

In addition to all matter that has been made available to the public, certain information contained in other patent applications filed prior to the patent application but only published thereafter is deemed to form the state of the art under Section 25(7):

The state of the art shall also comprise matter contained in an application, open to public inspection, for a patent, notwithstanding that that application was lodged at the patent office and became open to public inspection on or after the priority date of the relevant invention, if – (a) that matter was contained in that application both as lodged and as open to public inspection; and (b) the priority date of that matter is earlier than that of the invention.

Moreover, section 25(8) provides that even secret use can be used for determining novelty:

An invention used secretly and on a commercial scale within the Republic shall also be deemed to form part of the state of the art for the purposes of subsection (5).

These last three provisions – sections 25(6)–(8) – comprise a fairly comprehensive definition of the ‘state of the art’ for purposes of determining novelty. As section 25(6) provides, the ‘state of the art’ is broadly defined to constitute all matter that has existed anywhere in the world. This constitutes an absolute novelty standard. Further, sections 25(7) and (8) allow for certain limited situations where matter that was not ‘made available to the public’ can nevertheless be deemed to destroy novelty.

Despite this legislative framework, South African courts have interpreted the novelty requirement narrowly, such that even a small difference between what has been known before and what is being claimed in a patent is sufficient to satisfy this standard. The Supreme Court of Appeal has held that “if the description in the prior document differs, *even in a small*



*respect, provided it is a real difference, such as the non-recital of a single essential integer, the anticipation fails”.*<sup>35</sup>

Such a narrow definition of novelty would make it relatively easy for a patent applicant to ‘draft around’ the prior art in such a manner so as to make the claimed invention appear sufficiently different from what was known before. Thus, for instance, even if a medical substance has been known in the field for years, a patent applicant may be able to circumvent the novelty requirement by drafting the patent claims not for the substance *per se*, but for the ‘method of treating’ a particular disease with the known substance.

Indeed, section 25(9) specifically allows for the patenting of new uses of known substances:

In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.

In effect, section 25(9) creates an exception to the novelty rule, and states that even if a substance falls under the definition of the ‘state of the art’ as defined in sections 25(6)-(8), the novelty requirement can still be satisfied if the claim is drafted in a particular manner so as to cover the use of the known substance rather than the substance itself. However, there is nothing within the TRIPS agreement that confers an obligation to interpret the novelty standard in this manner. From the perspective of improving access to affordable medicines and fostering the growth of an indigenous generic industry, South Africa may wish to expressly give the novelty standard a more stringent interpretation. There are at least two legislative policy options that South Africa could consider in this regard.

### 2.1.1.1 *New uses of known substances*

As noted above, section 25(9) of the Patents Act expressly creates an exception to the novelty requirement. Essentially, it states that even if a substance was already known, the novelty requirement can still be satisfied if the particular medical or therapeutic use for that substance had not been known. Recognizing such an exception to the novelty requirement

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35. *Schlumberger Logelco Inc. v. Coflexip SA*, 2003 (1) SA 16 (SCA), quoting *Netlon Ltd and Another v. Pacnet (Pty) Ltd*, 1977 (3) SA 840 (A) (emphasis added). Interestingly, the 2003 decision relies on the authority of a pre-constitutional decision.



greatly expands the scope of patentability for pharmaceutical products, as many of the ‘new’ medicines used today are in fact new uses of already known substances.

For instance, the active substance in the ARV drug zidovudine (AZT) had been in existence since the 1960s, and was initially investigated as a cancer drug.<sup>36</sup> Then, in 1985, researchers supported with public sector funding from the US National Institutes of Health (and informed by earlier research on the use of AZT against retroviruses generally), discovered that AZT could also be used in the treatment of HIV infection. Although the novelty requirement prevented the patenting of the active substance *per se*, the exception to the novelty rule, as embodied in section 25(9), allowed the researchers to obtain a patent by drafting their claims to cover ‘the method of treating’ HIV and AIDS by administering AZT.<sup>37</sup> Thus, Burroughs Wellcome – now incorporated into GlaxoSmithKline (GSK) – was able to obtain a 20-year patent on a critical component of ARV treatment, the patent for which only expired in 2005. Had a more stringent standard for novelty been in place, the ‘new use’ of AZT would not have been patentable at all.

TRIPS does not require South Africa to recognize such an exception to the novelty requirement. South Africa therefore may amend section 25(9) to expressly preclude the patenting of new uses of already-known substances, irrespective of the manner in which the patent claim is drafted.

### 2.1.1.2 Selection patents

Another consequence of a narrow interpretation of the novelty requirement is the possibility of granting multiple, staggered patents on essentially the same technology. It is common within the pharmaceutical industry for a company to file for and obtain a patent covering a broad range of possible compounds. Then, as the company narrows the range of compounds that are most effective for a specific purpose, it generally applies for a subsequent patent that ‘selects’ a smaller subset of compounds from the first patent. These subsequent patents are generally called ‘selection patents’, and are recognized as valid in South Africa.<sup>38</sup>

From a public health perspective, a particularly harmful feature of this practice is that they can extend a monopoly even beyond the 20 years conferred by the original patent. Thus if a company filed for a patent covering a broad range of compounds in 2005 (with the resulting patent set to expire in 2025), and then filed for a selection patent covering a narrower range

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36. J.R. Horwitz, et al., *J. Org. Chem.* 29, July 1964, pp. 2076–2078.

37. See U.S. Patent No. 4724232 to J. Rideout, et al.

38. See *B-M Group Ltd. v. Beecham Group Ltd.*, 1980 BP 343 (selection patents valid insofar as “the selected members” have some substantial, special, peculiar advantage over the other, unselected members).



of compounds in 2010, generic companies would effectively be barred from entering the market until five years after the original patent had expired. However, a more robust reading of the novelty standard could curb or even eliminate the grant of selection patents.

In May 2012, Argentina's Ministry of Industry, Ministry of Health, and National Institute for Intellectual Property issued a joint resolution approving new guidelines for the examination of patent applications related to chemical-pharmaceutical substances.<sup>39</sup> The new guidelines were issued with the right to health in the Argentine constitution in mind, among other things. Incorporating public health concerns, the Argentine patent examination guidelines specifically reject selection patents, stating:

(v) Selection Patent Applications

Selection patent applications are those where a single element or small group of elements is selected from a larger group, and they are claimed independently, based on a characteristic or characteristics not previously attributed to the larger group. Selections can be made from products (chemical compounds, their salts, isomers, esters, compositions, etc.) and/or processes (obtention of compounds or pharmaceutical compositions and others).

1. The disclosure of a group of chemical compounds (Markush formula) or groups of pharmaceutical compositions, even generically, discloses all the components of that group, which in this way become part of the state of the art.
2. There is no novelty in the selection of one or more elements already disclosed by the prior art, even though they may have different or improved properties, not previously demonstrated.
3. The discovery of a different or improved characteristic or property for a particular element or group of elements already known in the prior art does not mean that the product or process is novel.
4. Pharmaceutical compositions, their methods of preparation and medicaments containing them are not patentable if they are specifically related to an element or elements selected from a larger group of elements, since the product or process are not considered new.

As the Argentine experience shows, there is nothing inherent in the TRIPS novelty requirement that precludes South Africa from adopting a more stringent definition of novelty. With

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39. Joint Resolution No. 118/20012, 546/2012 and 107/2012 of May 2, 2012, of the Ministry of Industry, Ministry of Health and the National Industrial Property Institute, approving the Guidelines for the Examination of Patent Applications of Pharmaceutical and Chemical Inventions, Date of Entry into Force: 16 May 2012, available at <http://www.wipo.int/wipolex/en/details.jsp?id=13007>; Unofficial English translation from "New guidelines for the examination of pharmaceutical patents adopted in Argentina" Posting by Carlos Correa on 29 May 2012, IP-Health List Serve, available at [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2012-May/002145.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2012-May/002145.html)



respect to selection patents in particular, South Africa could amend section 25 of the Patents Act to state that the selection of a ‘species’ of compounds from a previously disclosed ‘genus’ shall be deemed not to satisfy the novelty requirement.

## 2.1.2 Inventive step

The inventive step requirement is one of the most difficult, most subjective, and most important concepts in patent law. The rationale behind the inventive step requirement is that a patent applicant should not be granted exclusive rights to an idea that was so obvious that the ‘innovation’ would have happened anyway. Although there are varying tests for determining whether an invention is sufficiently ‘inventive’ as compared to the state of the art, the final determination always requires an essentially subjective judgment of whether the invention was sufficiently inventive, or ‘non-obvious’.

Precisely due to its subjectivity, the inventive step requirement affords countries a wide degree of flexibility in determining how high to set the bar for inventiveness. Professor Carlos Correa has observed that “[t]he best policy from the perspective of public health would seem to be the application of a strict standard of inventiveness so as to promote genuine innovations and prevent unwarranted limitations to competition and access to existing drugs”.<sup>40</sup> Setting the bar high for inventive step could prevent the grant of a large number of patents on minor (and oftentimes trivial) improvements to existing drugs, which can be used unfairly to prevent the entry of more affordable generic medicines (see Chapter 3).

Section 25(10) of the Patents Act provides, in relevant part:

[A]n invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art.

South African courts have interpreted this provision as requiring, as a preliminary matter, a determination of “what the art or science to which the patent relates is, who the person skilled in the art is and what the state of the art at the relevant date was”.<sup>41</sup> Once these facts have been determined, the courts ask the following four questions:

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40. C. Correa, Guidelines for the examination of pharmaceutical patents: developing a public health perspective, A Working Paper, ICTSD, WHO, UNCTAD, UNDP (2007) at p. 4.
  41. *Ensign-Bickford, Ltd. v. AECI Explosives & Chemicals Ltd*, 1999 (1) SA 70 (SCA) at 80, citing *Roman Roller CC and Another v. Speedmark Holdings (Pty) Ltd.*, 1996 (1) SA 405 (A) at 413. *Ensign-Bickford* was recently cited with approval in *Cipla Medpro (Pty) Ltd. v. Aventis Pharma SA, Aventis Pharma SA and Others v. Cipla Life Sciences (Pty) Ltd. and Others* [2012] ZASCA 108.



- (1) What is the inventive step said to be involved in the patent in suit?
- (2) What was, at the priority date, the state of the art (as statutorily defined) relevant to that step?
- (3) In what respect does the step go beyond, or differ from, the state of the art?
- (4) Having regard to such development or difference, would the taking of the step be obvious to the skilled man?<sup>42</sup>

Central to this analysis, of course, is determining who the hypothetical person ‘skilled in the art’ is. Obviously, the more ‘skilled’ this imaginary person is, the greater the number of alleged inventions that would be obvious to him or her, resulting in fewer granted patents. However, U.K. courts (from which South African courts have adopted the above test for obviousness) have set the bar fairly low. The courts have defined the person ‘skilled in the art’ as someone who is familiar with the background literature, but is “incapable of a scintilla of invention”.<sup>43</sup> In practice, this means that unless the prior literature contains what often must amount to an explicit instruction or suggestion to make the invention, the claimed invention will be deemed sufficiently non-obvious to meet the inventive step requirement. This is particularly the case in situations where two or more pieces of prior art must be combined, or ‘mosaicked’, in order to derive the claimed invention.

Take, for instance, Roche’s patent for PEG-interferon, a treatment for hepatitis-C.<sup>44</sup> The patent essentially concerns the linking together of interferon, a naturally occurring protein with antiviral activity, with polyethylene glycol (PEG).<sup>45</sup> However, interferon (and its antiviral activities) was well known in the field for years. Likewise, the benefits of linking PEG to biologically active proteins, known as ‘PEG-ylating’ a protein, were also well known. Among other things, these benefits include enabling the protein to stay in the bloodstream for longer periods.

However, because the document that disclosed the technology of linking PEG with biologically active proteins did not specifically mention *interferon* as one of the biologically active proteins to which it could be linked, the patent application was deemed sufficiently non-obvious and granted by the Indian Patent Office. This patent was then successfully challenged in the public interest by Indian civil society groups working with injecting drug users.<sup>46</sup>

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42. Ibid., citing *Mölnlycke AB and Another v. Procter & Gamble Ltd and Others* (No. 5) [1994] RPC 49 (CA) at 115.

43. *Technograph Printed Circuits Limited v. Mills and Rockley (Electronics) Limited* (1972) RPC 346.

44. The drug is marketed by Roche as Pegasys®.

45. See Indian Patent No. 198952 to F. Hoffman-LaRoche AG, granted 21 February 2006.

46. The patent on PEG-interferon was the first pharmaceutical product patent granted under the new TRIPS-mandated patent regime in India. The prohibitive cost of this vital treatment for hepatitis-C (Roche offers it for approximately US\$ 5,500 for a six-month course) has precluded the Indian Government from procuring it for its ART programme, despite the rates of HIV and hepatitis-C co-infection being as high as 92 percent in some parts of the country. See Saha MK, et al. “Prevalence of HCV and HBV infection among HIV seropositive intravenous drug users and their non-injecting wives in Manipur, India”. *Ind. J. Med. Res.* (2000), 111:37–9.



Overturing the patent granted for ‘PEG-ylated’ interferon, India’s Intellectual Property Appellate Board held, with regard to the person of ordinary skill, that:<sup>47</sup>

We must remember that this ordinary man has skill in this art. He is not ignorant of its basics, nor is he ignorant of the activities in the particular field. He is also not ignorant of the demand on this art. ‘He is just an average man..... Well... just an ordinary man’. But he is no dullard. He has read the prior art and knows how to proceed in the normal course of research with what he knows of the state of the art. He does not need to be guided along step by step. He can work his way through. He reads the prior arts as a whole and allows himself to be taught by what is contained therein.

Roche has appealed this ruling in the higher courts in India and a final decision is pending.

South Africa is not obligated to prevent the hypothetical person ‘skilled in the art’ from exercising his or her common sense in determining what is obvious. Indeed, in the 2007 US Supreme Court case discussed previously, the Court warned that “[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it”.<sup>48</sup> The Intellectual Property Appellate Board in India quoted the US Supreme Court decision at length in support of its findings on the standard for the ordinary person skilled in the art. South Africa is not obligated to make the hypothetical skilled person simply a person of *ordinary* skill. Professor Correa has suggested an alternative description of the person skilled in the art as having:

some specialized knowledge and not simply somebody with very general or ordinary knowledge in the relevant technical field. A person skilled in the art is not just an expert in his technical field but a person who should have some degree of imagination and intuition.<sup>49</sup>

By simply defining what is *meant* by ‘skilled in the art’, or defining the person as *highly* skilled in the relevant art, who possesses some degree of common sense and imagination, and who is able to exercise these faculties in combining different pieces of prior art to achieve the claimed invention, the inventive step requirement could be made much more rigorous than the current standard.

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47. *Sankalp Rehabilitation Trust v. F.Hoffmann-La Roche AG and the Asst. Controller of Patents & Designs*, Intellectual Property Appellate Board, Order No. 250/2012, 2 November 2012 (India).

48. *KSR v. Teleflex*, supra note 34 at 17.

49. Correa, supra note 40 at p. 4.



Supplementing the test outlined above, South African courts often resort to what are called ‘secondary considerations’ to aid in the inventive step analysis, such as asking whether the alleged invention addressed a ‘long-felt need’ or whether the alleged invention enjoyed ‘commercial success’.<sup>50</sup> However, reliance upon such secondary considerations need not, and from the perspective of public health, should not, be part of the inventive step analysis, as they often favour the patent holder without truly addressing the central question of whether there was an inventive step.

Generally, only patents of significant economic value will proceed to litigation. Given the underlying economic value of the subject matter, it will be much more likely that these patents will be found by the courts to have enjoyed ‘commercial success’ or addressed a ‘long-felt need’. However, these factors are just as likely to be found simply due to the importance of the underlying subject matter rather than the inherent inventiveness of the claimed invention.

Importantly, they do not help in any way to answer a central question that lies at the heart of the innovation and access debate: but for patent protection, would the product have come to market? There are a number of innovative products in the HIV treatment field, such as the fixed-dose combination of stavudine, lamivudine and nevirapine that came to market without patent protection. A product such as this satisfied a ‘long-felt need’ and was indeed a ‘commercial success’. But it did not deserve patent protection.

### 2.1.3 Industrial application/utility

In most countries, the standard of industrial applicability (or utility, in some jurisdictions) is a relatively easy standard to satisfy. As long as the claimed invention can be put to some commercial use, this requirement is generally met. There are, however, some applications of this requirement that are particularly important for ensuring that the basic components necessary for experimental research do not come under monopoly by one party. For developing countries interested in fostering domestic capacity for research and development, strict application of this standard should be a priority.

In Europe, the industrial applicability standard has been interpreted as requiring that the claimed invention can be put to some ‘profitable use’.<sup>51</sup> Thus, experimental chemical sub-

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50. See, e.g., *Schlumberger Logelco Inc. v. Coflexip*, 2003 (1) SA 16 (SCA) (holding that claims in question were sufficiently inventive given commercial success and long-felt need for invention).

51. European Patent Office Board of Appeals, Decision T 870/04 (2005) (holding that merely because a substance could be produced in some ways, the industrial applicability requirement was not satisfied absent some description of some “profitable use” for which the substance could be employed).



stances with ultimate uses or benefits that are unknown, are deemed not to be industrially applicable. Likewise, the United States, which operates under the utility standard, has rejected patent applications that covered substances that “are the subject of serious scientific investigation but of unverified and speculative utility”.<sup>52</sup> In doing so, the United States observed that granting such speculative patents “may confer power to block off whole areas of scientific development, without compensating benefit to the public”.<sup>53</sup> In recent cases, Canadian courts have required patent applicants to demonstrate a “sound prediction” of utility in their applications.<sup>54</sup>

Allowing patent protection to cover experimental substances whose benefits are not yet fully understood allows the patent holder to preclude others from conducting research and development on these substances. In this situation, patent protection could serve as a deterrent to innovation, by allowing the patent holder to exclude others from conducting potentially useful scientific investigations. A strict application of the industrial applicability standard could prevent such patents from being allowed.

The Patents Act includes another potentially important exclusion in section 25(11):

An invention of a method of treatment of the human or animal body by surgery or therapy or diagnosis practiced on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.

This provision follows the practice of the European Patent Office, which has deemed methods of treating the human body incapable of industrial application,<sup>55</sup> “so that no one could be hampered in the practice of medicine by patent legislation”.<sup>56</sup> Such an exclusion is expressly allowed in TRIPS under Article 27.3, which states that countries may exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”.

As noted, the standard manner in which patent applicants ‘draft around’ the novelty requirement for new uses of known substances is to draft the claims in the form of ‘the method of treating X by administering Y’. Thus, for example, GSK was able to obtain a patent on the known substance, AZT, by formulating its claims as ‘a method of treating a human’ with HIV by administering AZT. However, by the plain terms of section 25(11), such a claim would be a ‘method of treatment’ claim and could be deemed not to satisfy the industrial applicability requirement.

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52. Ex parte Aggarwal, 23 U.S.P.Q. 1334 (Bd. Of Appeals) at \*18.

53. Ibid., quoting *Brenner v. Manson*, 383 U.S. 519 (1966).

54. See, e.g., *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97.

55. European Patent Convention, Article 52(4).

56. European Patent Office Board of Appeals, Decision T 992/03 (2007).



However, the Patents Act includes an important exception to this rule. Section 25(12) expressly creates an exception to the bar on method of treatment claims:

Subsection (11) shall not prevent a product consisting of a substance or composition being deemed capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method.

Thus, section 25(12) creates an exception to the general rule that method of treatment claims are not capable of industrial application, and states that a method of treatment claim may be valid if a substance or composition is used for such treatment. However, there is nothing in the language of TRIPS Article 27.3 that requires such an exception. Indeed, for the very same reasons that apply to broadening the novelty standard to preclude the patenting of new uses of already known substances, it may be preferable to limit the scope of industrial applicability to preclude all method of treatment claims.

## 2.1.4 Summary of policy options relating to patentability criteria

In summary, TRIPS affords countries considerable flexibility in defining the basic criteria for patentability. Setting the bar high for patentability would likely prevent excessive patenting around essential medicines. The benefits of fewer trivial patents being granted is compounded in countries where the vast majority of patent applications are from abroad, such as South Africa. (Indeed, this principle works just as well for domestic patents; a higher bar will filter the strong patents from the weak and encourage genuine domestic innovation, for instance, in the mining industry.) From this perspective, a number of policy options are available to South Africa for defining the basic criteria for patentability in a manner consistent with these policy priorities:

- Delete section 25(9) of the Patents Act, which expressly allows for the patenting of new uses of known substances, and expressly state that any new use for a known substance shall not satisfy the novelty requirement.
- Amend the Patents Act to state clearly that novelty is not satisfied where a compound is selected from a previously disclosed group of compounds.
- Define the person ‘skilled in the art’ as someone who is capable of exercising some degree of imagination, intuition and common sense, and who is able to use such abilities in combining multiple sources of prior art to arrive at the claimed invention.



- Amend the Patents Act to state that absent exceptional circumstances, secondary factors such as ‘long-felt need’ and ‘commercial success’ shall not be considered in determining whether an invention possesses inventive step.
- Define the requirement of ‘industrial applicability’ expressly to state that compounds of experimental or speculative use shall not be capable of industrial application.
- Delete section 25(12) of the Patents Act, which allows for the patenting of the use of a substance or compound for the treatment of human beings, and amend section 25(11) expressly to state that all method of treatment claims shall not satisfy the industrial applicability requirement.

## 2.2 Defining limited exceptions to patent rights, including for compulsory licensing

In addition to setting the bar higher for the basic criteria for patentability, countries have the flexibility to preclude certain things from patentability altogether. This is an extremely important flexibility that has been used with some success, notably in India.

### 2.2.1 Exclusions expressly allowed under TRIPS

Articles 27.2 and 27.3 of TRIPS enumerate the specific exclusions from patentability that countries may adopt:

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
  - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
  - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof...



The Patents Act partially incorporates these exclusions in section 25(4):

A patent shall not be granted—

- (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or
- (b) for any variety of animal or plant or any essentially biological processes for the production of animals and plants, not being a micro-biological process or the product of such process.

Further, as previously noted, the exclusion specified in Article 27.3(a) relating to methods of treatment is partially incorporated in section 25(11) of the Patents Act.

## 2.2.2 Other exclusions from patentability

In addition to the exclusions specifically enumerated under Articles 27.2 and 27.3 of TRIPS, many countries – including South Africa – routinely exclude from patentability many other broad categories not specifically enumerated under TRIPS. For instance, many countries' patent laws specify that business methods are excluded from patentability.<sup>57</sup> Similarly, computer programs are excluded from patentability in many jurisdictions.<sup>58</sup> Indeed, the South African Patents Act contains numerous exclusions from patentability in section 25(2):

Anything which consists of—

- (a) a discovery;
- (b) a scientific theory;
- (c) a mathematical method;
- (d) a literary, dramatic, musical or artistic work or any other aesthetic creation;
- (e) a scheme, rule, or method for performing a mental act, playing a game or doing business;

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57. See, e.g., European Patent Convention, Article 52(c); Brazil, Industrial Property Law, Article 10; Chile, Industrial Property Law, section 37; India, Patents Act, section 3(k); Malaysia, Patents Act, section 13; Philippines, Intellectual Property Code, section 22; Sri Lanka, Code of Intellectual Property Act, section 59.3; United Kingdom, Patents Act, section 2(c).

58. See, e.g., European Patent Convention, Article 52(c); Argentina, Patent Law, Article 6; Brazil, Industrial Property Law, Article 10; India, section 3(k); Philippines, Intellectual Property Code, Section 22; Thailand, Patent Act, section 9; United Kingdom, Patents Act, section 2(c).



- (f) a program for a computer; or
  - (g) the presentation of information,
- shall not be an invention for the purposes of this Act.

None of these exclusions from patentability is expressly considered by TRIPS, but a review of patent laws from around the world reveals that it is generally accepted practice to exclude broad categories from patentability even where they are not expressly mentioned as valid exceptions under Article 27 of TRIPS. This could be justified under TRIPS in at least two ways.

First, although Article 27.1 of TRIPS requires that patents be made available for “any inventions” that are new, inventive and capable of industrial application, it fails to define precisely what an ‘invention’ is. Put simply, the absence in TRIPS of a specific definition of what constitutes an invention, together with the right of countries to enforce its provisions within their own legal systems, provides the requisite policy space to narrow the definition.

Countries thus have a degree of flexibility in defining what will and will not be considered an ‘invention’. For instance, while many countries distinguish between ‘discoveries’ and ‘inventions’, (providing protection only for the latter), the United States defines ‘invention’ as “an invention *or discovery*”<sup>59</sup> and provides that “whoever invents *or discovers* any new and useful process, machine...” is entitled to a patent.<sup>60</sup> Other countries maintain the distinction between invention and discovery, but carve out an exception to make only some discoveries patentable.<sup>61</sup>

Alternatively, many of these exclusions can simply be read as *per se* rules that relate back to the basic criteria for patentability. Thus, rather than burden the patent office with having to make a case-by-case determination that, say, a patent application claiming a business method is not capable of industrial application, countries may simply create a bright-line rule to preclude the patenting of all such applications, on the reasonable assumption that all patent applications claiming a business method will be incapable of industrial application.<sup>62</sup>

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59. US Patent Laws, 35 U.S.C. 100(a) (emphasis added).

60. US Patent Laws, 35 U.S.C. 101 (emphasis added).

61. See, e.g., Rule 23(e)(2) of the European Patent Convention, which provides that “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”.

62. The use of *per se* rules is not uncommon in the law. For example, South Africa’s Competition Act establishes certain activities as *per se* anti-competitive, irrespective of the actual anti-competitive effects of such activities, based upon the reasonable assumption that all such activities will have anti-competitive effects. See *Competition Act No. 89 of 1998*, section 4(1)(b)(i)–(iii) (prohibiting price fixing, division of markets, and collusive tendering as *per se* anti-competitive).



As noted, countries have considerable flexibility in raising the bar for patentability criteria. It follows, then, that they have equal flexibility in laying down *per se* rules that relate back to these criteria. Such easily applied *per se* rules could be of particular value in countries where there is limited capacity for patent examination.

Whatever the justification, countries have the flexibility to adopt many more exclusions from patentability that could improve access to medicines and foster growth in the domestic generic pharmaceutical industry. Although Article 27.1 of TRIPS requires that patents be made available without discrimination as to the field of technology, the WTO Dispute Panel has observed that there is a distinction between discrimination and differentiation, and that “Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas”.<sup>63</sup> Given the potential impact of pharmaceutical patents on public health, there are strong grounds for the differential treatment of pharmaceutical patents.<sup>64</sup> That said, there may be no need to differentiate on the basis of field of technology; public health concerns can provide a basis for the differential treatment of all health-related inventions, whether or not they specifically relate to pharmaceutical patents.

Of particular note in this regard is the complement of exclusions from patentability that India has enacted into its Patents Act of 1971 (Indian Patents Act), which apply primarily – or only – to pharmaceuticals. These include the exclusion from patentability of (1) naturally occurring substances; (2) new forms of already known substances; (3) new uses of known substances; (4) mere admixtures; and (5) methods of treatment. Excluding the patenting of new uses of known substances and of methods of treatment have already been discussed in the context of novelty and industrial applicability. The remaining bases for exclusion will be explored further below.

### 2.2.2.1 Naturally occurring substances

The Indian Patents Act, section 3(c), provides that the “mere discovery of a scientific principle or the formulation of *or discovery of any living thing or non-living substance occurring in nature*” is not an invention (emphasis added). Under a plain reading, this provision would presumably preclude the patenting of any naturally occurring thing or substance, including gene sequences, as well as the identification and isolation of pharmaceutically active substances occurring in plants and animals.

63. WTO, Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R, para 7.92.

64. See Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPs Agreement, UNCTAD-ICTSD, (2005), pp. 368–374 for a full discussion on the justifications for differential treatment of pharmaceutical patents.



For instance, exenatide (a treatment for type-2 diabetes marketed as Byetta<sup>®</sup> by Amylin), was granted approval by the US Food and Drug Administration (US FDA) in April 2005. The original patent for exenatide, US 5,424,286, discloses that exenatide was discovered in the venomous saliva of the gila monster, a poisonous lizard found in the deserts of North America. As such, the subject matter of this patent would relate to the discovery of a substance occurring in nature and would not be patentable in India under section 3(c).<sup>65</sup>

It is important to note that excluding the patenting of naturally occurring substances would likely result in many discoveries derived from indigenous biological resources being excluded from patentability.<sup>66</sup> However, this would not affect the benefit-sharing obligations under the National Environmental Management: Biodiversity Act 10 of 2004 (the Biodiversity Act), which requires any person engaged in bio-prospecting to enter into an acceptable benefit-sharing agreement with the local community or communities from which the indigenous biological resources are taken.<sup>67</sup> Moreover, excluding such discoveries from patenting in South Africa would not preclude the commercial exploitation of the indigenous biological resource. Thus, any successful commercial use of an indigenous biological resource would result, under the Biodiversity Act, in benefits flowing into the local communities, whether it be from many different sources (if not patented) or from one source (if patented). Patents may be granted, for example, on the process for isolating the active substance; method of synthesizing the substance; or developing a new, different compound that uses the same mechanism of action, subject to fulfilling other patentability criteria.

#### 2.2.2.2 *New forms of known substances*

Section 3(d) of the Indian Patents Act states that “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” is not an invention. To the extent that it addresses new forms of known substances, this provision was designed to curb a practice commonly known as ‘evergreening’, in which patent holders artificially extend the life of their existing patents by obtaining patents on what are often trivial changes or improvements

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65. Likewise, the ‘method of treating’ diabetes by administering exenatide would be unpatentable in India as it would relate to a method of treatment and thus fail under section 3(i) of the Indian Patents Act.

66. Though it should be noted here that new chemical entities that mimic the action of the naturally occurring substance are not excluded from patentability.

67. Biodiversity Act, sections 81–83.



on existing drugs. The recent ruling by the Indian Supreme Court, upholding the applicability and applying a strict interpretation of section 3(d) in relation to the previous rejections of Novartis' patent application on the beta-crystalline form of imatinib mesylate,<sup>68</sup> is a powerful illustration of the principle described here.<sup>69</sup>

Section 3(d) is accompanied by an explanation that specifies that “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”. This means that all new forms of existing substances, such as salts, esters, polymorphs and the like, will be deemed to be the same substance as the already existing substance (and thus not patentable) unless the patent applicant can demonstrate that the new form made the drug more effective. In this regard, the Indian Supreme Court held that, “in the case of a medicine that claims to cure a disease, the test of efficacy can only be ‘therapeutic efficacy’. The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy?”<sup>70</sup>

However, many – if not most – patents that are granted for ‘new forms’ of already existing drugs do not result in any improvement in the actual therapeutic effect of the active substance. Rather, many of these derivative patents are granted because the new form of a drug exhibits improved solid-state properties that may make the drug cheaper to manufacture or easier to store.

The Indian Supreme Court has referred to the explanation of Section 3(d) and the substances listed there. The Supreme Court found, “that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of ‘invention’. Hence, the mere change of form with properties inherent to that form would not qualify as ‘enhancement of efficacy’ of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy”.<sup>71</sup> Accordingly, the Indian Supreme Court held that, “that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be

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68. The drug is marketed by Novartis under the brand name Glivec/Gleevec.

69. *Novartis AG v. Union of India and Ors*, CIVIL APPEAL Nos. 2706–2716 OF 2013, Supreme Court of India, Date of Judgment: 1 April 2013, available at <http://supremecourtfindia.nic.in/outtoday/patent.pdf>

70. *Ibid.* at para 180.

71. *Ibid.* at para 181.



taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy”.<sup>72</sup> The Court also held in relation to bioavailability, “just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data”.<sup>73</sup>

Take for example, US patent 7,157,466 – a patent that covers the breast cancer drug lapatinib (marketed as Tykerb<sup>®</sup> by GSK), which the US FDA approved for marketing in March 2007. This patent claims the ditosylate salt form of lapatinib. However, the only stated benefits, according to the patent specification, is that this particular form absorbs lower amounts of water and can be prepared in a physically stable crystal form. As such, this patent would cover a ‘new form of a known substance’ without an ‘enhancement of the known efficacy’, and would not be patentable in India under section 3(d).

The Argentinean guidelines incorporate an even higher standard than that of the Indian law, stating that such new forms would not be patentable regardless of any increase in efficacy.<sup>74</sup> Of course, just showing an increase in efficacy would not – on its own – be sufficient to

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72. Ibid. at para 187.

73. Ibid. at para 189.

74. The guidelines state:

3) Consideration of chemically related elements

(vi) Salts, esters and other derivatives of known substances.

New salts of known active ingredients, esters of known alcohols, and other derivatives of known substances (such as amides and complexes) are deemed to be the same known substance and are not patentable.

(vii) Active metabolites.

In some cases, pharmaceutical compounds generate, when administered to a patient, an active metabolite, which is the product of the metabolism of the compound in the organism. Metabolites are products derived from the active ingredients used. They cannot be considered to have been “created” or “invented”. Metabolites are not patentable independently from the active ingredient from which they derived, even though they may have safety and efficacy profiles differing from those of the parent molecule.

(viii) Prodrugs.

There are inactive compounds referred to as prodrugs, which when hydrolyzed or metabolized in an organism, can give rise to a therapeutically active ingredient. In some cases, patent claims protect a drug and the prodrug(s) thereof. A prodrug may produce benefits if it can be administered more easily than an active compound. Patents on prodrugs, if granted, should exclude from the claim the active ingredient as such, if the latter has already been disclosed or if it is not patentable. As any subject matter claimed in a patent, a prodrug must be sufficiently supported by the information provided in the specification. It must comply with the requirements of novelty, inventive step and industrial application and include a description of the best method of obtaining it with an adequate characterization of the product obtained. In addition, the application should contain evidence that the prodrug is inactive or less active than the claimed compound, that the generation of the active compound (in the organism) ensures an effective level thereof, while minimizing the direct metabolism of the prodrug. *Supra* n.39.



secure patent protection in India. Satisfying this requirement does not necessarily mean that the inventive step requirement has also been met; that is a separate inquiry.

### 2.2.2.3 *Mere admixtures*

It is common practice in the pharmaceutical industry for companies to file for and obtain patents on the final dosage form of a drug, usually long after the patent for the active substance has been issued. In most of these cases, the active pharmaceutical ingredient will be combined with any number of inactive ‘excipients’ and ‘carriers’, which are commonplace substances used throughout the industry. Under section 3(e) of the Indian Patents Act, all such ‘formulation’ or ‘composition’ patent applications would not be patentable unless the patent applicant was able to demonstrate some sort of synergistic effects between the ingredients.

In particular, section 3(e) states that a “substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance”, is not an invention.<sup>75</sup>

Take, for instance, one of GSK’s several patents relating to Combivir<sup>®</sup>, a fixed-dose combination of two important first-line ARVs: lamivudine (3TC) and AZT. US Patent 6,113,920, entitled “Pharmaceutical Compositions”, covers the fixed dose combination of 3TC and AZT, plus what the patent specifies as a “pharmaceutically acceptable glidant”. The patent application was first filed for in 1996, even though AZT was first identified in 1964 and discovered as an anti-HIV drug in 1985, and 3TC was identified as an ARV agent in 1988.<sup>76</sup> Additionally, the synergistic effects created by the *combination* of 3TC and AZT were already known and the subject of a separate patent owned by GSK.<sup>77</sup> Thus, the only truly *novel* aspect of this patent was that it combined an already-known fixed-dose combination of ARVs with a glidant. However, glidants are nothing more than pharmaceutically inactive and often commonplace substances routinely used in the pharmaceutical industry to compress drugs into tablet form, such as silicon dioxide, talc and corn starch.

Although the patent was granted in the United States, the same application was opposed by Indian civil society groups, claiming, as one of the grounds of opposition, that the patent application concerned nothing more than a ‘mere admixture’ and was unpatentable under

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75. The Australian Patents Act, section 50, likewise states that a patent may be refused where “a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients”.

76. See U.S. Patent 5,047,407.

77. See European Patent 0513917.



section 3(e). Shortly after the opposition was filed, GSK announced that it would withdraw the patent application from India.

## 2.2.3 How effective are these exclusions from patentability?

The exclusions discussed above (along with the exclusions for new use and method of treatment) are likely to be extremely effective in drastically reducing the number of derivative patents granted on medicines, thereby removing significant barriers to entry for generic competition.

A forthcoming study attempts to determine the effect of the exclusions from patentability in the Indian Patents Act on the patents that protect new medicines. The study examines the new drug approvals granted by the US FDA since India introduced its product patent regime for pharmaceuticals in 2005, as well as the corresponding patent information listed for these drug approvals in the FDA's Orange Book. Of the 110 patents corresponding to 34 new drug approvals from 1 January 2005 to 31 March 2007, the study concludes that as many as 77 of the 110 patents would be invalidated under one or more of the five exclusions from patentability. This suggests that these exclusions, if rigorously applied, could mean that up to 70 percent of the applications in respect of new medicines entering the market would not be granted a patent.<sup>78</sup>

## 2.2.4 Summary of policy options relating to exclusions from patentability

The adoption of a suite of broad exclusions from patentability would have clear public health benefits. Broad exclusions would allow domestic generic companies to begin manufacturing a greater selection of medicines without the delay and expense of having to negotiate voluntary licence agreements with the patent holders, or applying to a court for compulsory licences. In addition, the task of determining patent validity would become considerably easier with the application of these relatively easy-to-apply *per se* exclusions. This is a particularly important feature in a country with limited capacity and resources to implement a system of full examination of patent applications. Finally, such exclusions would drastically reduce the opportunity for patent owners to use follow-on patents to artificially extend the term of the original patent.

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78. Park C., Jayadev A. & Prabhala A. "The Protection of Pharmaceutical Test Data: Implications for the Indian Economy", forthcoming in 2013, draft of study on file with authors.



From this perspective, there are a number of policy options that South Africa could pursue:

- Expand section 25(4) to give effect to the *ordre public* / morality exception in Article 27.2 of TRIPS.
- Exclude from patentability the mere discovery of any substance occurring in nature.
- Limits the patentability of new forms of already known substances, including but not limited to salts, polymorphs and esters, following the Indian and Argentinian models. The South African Government may follow either the Indian approach of allowing patents on new forms only if the new form is significantly more therapeutically effective, or follow the Argentinean model of an absolute exclusion.
- Exclude from patentability admixtures of substances that do not result in a demonstrable synergistic effect.

## 2.3 Disclosure of information in patent applications

One of the primary justifications for having a patent system is the notion that it is essentially a *quid pro quo* between society and the inventor. In exchange for the *quid* of disclosing to the public useful information and technology, the state awards the inventor the *pro* of a limited monopoly, after the expiration of which the invention can be freely used by all. An essential component to this hypothetical contract, however, is ensuring that such knowledge actually is made available to the general public.

Several key stakeholders in South Africa suggest that for a number of reasons, the ‘contractual’ requirement that useful information and technology be disclosed to the public is not being met. Although information relating to patents and patent applications are now available in a fully searchable electronic database, CIPC may still consider including an annual review of pharmaceutical patents granted and applications pending, and provide such information to the public in report form. Such a document could also aid civil society and the Department of Health in monitoring the grant of patents on critical medicines in order to prepare for the use of measures to ensure access to such medicines, if the need arises. (The Indian patent office has recently adopted this mechanism by providing a compilation of pharmaceutical patents and patent applications on its website.<sup>79</sup>)

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79. Pending Applications and Granted Patents related to Food and Pharmaceutical along with Traditional Knowledge, Controller General of Patents, Designs and Trademarks, Department of Industrial Promotion and Policy, Ministry of Commerce and Industry, India, available at <http://164.100.176.38/tk/>



In addition to making information regarding patents and patent applications easily accessible to the general public, there are several legislative options that are available to South Africa to ensure it gets a fairer share of the theoretical contract. The key element underpinning all of these options is placing the onus on the patent applicant to disclose essential information regarding its patent application. These policy options are discussed below.

## 2.3.1 Flexibilities in TRIPS with respect to disclosure of information in patent applications.

Article 29 of TRIPS allows countries to require that the patent applicant disclose certain information in its patent application. It provides:

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants".

Section 32(3) of the Patents Act only complies with the mandatory portion of Article 29, without availing of the optional flexibilities:

- (3) A complete specification shall—
  - (a) have an abstract as prescribed;
  - (b) sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be performed by a person skilled in the art of such invention; and
  - (c) ...
  - (d) end with a claim or claims defining the invention for which protection is claimed.

Thus, although the patent applicant is required to sufficiently describe the invention such that a person skilled in the art is able to practice it, the applicant is not required to disclose the



‘best mode’ of practicing the invention. Nor is the applicant required to provide information concerning the status of corresponding foreign applications.

### 2.3.1.1 *Disclosure of best mode*

US patent law requires that the patent specification “set forth the best mode contemplated by the inventor of carrying out his invention”.<sup>80</sup> The rationale behind this requirement is to ensure that society receives sufficient consideration for the grant of a limited monopoly: “The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention”.<sup>81</sup>

Without strict or enforceable standards for disclosure, there is often a strong incentive for patent applicants to only partially disclose the details of their invention, while keeping the knowledge of the ‘best mode’ undisclosed, so that they retain a competitive advantage even after the patent expires.

Until 2002, South African patent law required the disclosure of the best mode.<sup>82</sup> The requirement that the inventor disclose the best mode is particularly important for countries seeking to strengthen their domestic technological capacity. The disclosures contained in a patent specification should therefore be sufficient to allow someone skilled in the art to be able to reproduce the invention. Thus, patents could be a key source of technological knowledge transfer, provided that the best mode requirement is implemented and strictly enforced. Specifically with respect to the domestic pharmaceutical industry, the disclosures contained in patent specifications can provide much-needed technological know-how to ensure long-term security in the supply of essential medicines.

### 2.3.1.2 *Disclosure of the status of foreign applications*

For countries with limited capacity to examine patent applications, it is often helpful for the examiner to know the examination status of the same application in other countries. As we have seen, Article 29 of TRIPS allows countries to require that patent applicants proactively

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80. U.S. Patent Laws, 35 U.S.C. 112.

81. *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

82. See Section 1, Patents Amendment Act No. 58 of 2002, available at <http://www.info.gov.za/view/DownloadFileAction?id=68095>



disclose this information to the patent offices. India has taken advantage of this flexibility in section 8 of the Indian Patents Act, which provides:

- (1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or within the prescribed period as the Controller may allow –
  - (a) a statement setting out the detailed particulars of such application; and
  - (b) an undertaking that, up to the date of grant of the patent, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.
- (2) At any time after an application for patent is filed in India and till the grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

Thus, patent applicants in India are obligated not only to provide information regarding the corresponding foreign applications at the outset, but to keep the patent office informed of any developments in foreign jurisdictions until the final grant of a patent. Additionally, the Indian Patents Act expressly recognizes the failure to comply with this section as a ground for opposition, both prior to and after the grant of the patent.<sup>83</sup>

Although, as mentioned, the grant or denial of a patent application in one country is independent of the grant or denial of the same application in other countries,<sup>84</sup> it will often be helpful for patent offices in developing countries with limited examination capacity to know how other patent offices have dealt with the same patent application. Rather than leave it to the patent

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83. See India, Patents Act, sections 25(1)(h) (pre-grant) and 25(2)(h) (post-grant). Patent oppositions will be discussed in further detail below.

84. See Paris Convention, Article 4bis, *supra*, note 32.



examiner to retrieve this information, the burden can easily be shifted to the patent applicant – who will generally have such information readily available – to provide this information.

### 2.3.1.3 Other disclosure requirements

The disclosure requirements in Article 29 of TRIPS are not exhaustive of all the disclosure requirements that countries can require of patent applicants. In fact, South Africa amended its Patents Act in 2005 to impose an additional duty: the duty to disclose whether an invention has been derived from an “indigenous biological resource, genetic resource, or traditional knowledge or use”.<sup>85</sup> Failure to comply with this disclosure obligation is an express ground for revocation of the patent.<sup>86</sup> This model of imposing a disclosure requirement – and making the failure to disclose grounds for revocation or denial of patent – can be expanded to include the above disclosure requirements, as well as other disclosure requirements. These additional disclosure requirements could help in the examination process should South Africa choose to move to a full or partial examination system. Some of these disclosure requirements are described below.

### 2.3.1.4 Duty to disclose all relevant material prior art

During the patent examination process, the patent examiner might be tasked with conducting a thorough literature search on the technical matter embodied in the patent application, in order to determine whether the claimed invention is both novel and sufficiently inventive. Often, however, the patent applicant is far more knowledgeable about the relevant literature than the patent examiner, as the patent applicant is actively engaged in the relevant field. There can be, however, a perverse incentive for the patent applicant to conceal the existence of some relevant material, especially in those cases in which the prior art may be particularly damaging to the application’s patentability.

In an effort to ensure that all relevant materials are available to patent examiner, the US Patents and Trademark Office imposes upon the patent applicant a “duty of candour and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability”. The intentional failure to disclose material prior art that the applicant was aware of can be deemed to be a “fraud upon the [Patents and Trademark Office]”, and can result in an invalidation of the patent, and subject the patent holder to treble damages under US antitrust laws.<sup>87</sup>

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85. Patents Act, section 3A.

86. Patents Act, section 61(g).

87. See, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1377 (Fed. Cir. 2007) (Case No. 05-1330).



In any country, but especially in countries with limited capacity for patent examination, placing the duty to disclose all relevant literature regarding the technology embodied in the patent on the patent applicant may be an especially effective means of facilitating the examination process and improving patent quality. Such a requirement must be coupled with severe sanctions for non-compliance, such as the invalidation of the patent. Additionally, any benefit obtained pursuant to a patent that is subsequently invalidated on this basis could pave the way for possible sanctions under the Competition Act.

### *2.3.1.5 Duty to disclose international non-proprietary names for pharmaceutical applications*

Patent applications, by their very nature, are technical documents that are often difficult to decipher because to the complexity of the underlying technology. Often, however, difficulty also arises as a result of deliberate obfuscation by the drafter of the patent application. It is not always in the interest of the patent applicant to openly disclose the specific technology to which a patent application relates, as it may attract unwanted attention or even opposition.

As a result, the titles given to many patent applications are often vague or meaningless. Recall, for instance, that GSK's patent for Combivir<sup>®</sup> discussed above was entitled "Pharmaceutical Compositions". A search of the US Patents and Trademark Office patent database for all patents owned by GSK with the words 'pharmaceutical composition' in the title resulted in 44 separate patents. Because of these practices, government entities, generic manufacturers and civil society groups face difficulties in identifying a particular patent or patent application that may relate to a drug of public health importance.

The Indian Pharmaceutical Alliance, an association of many of the major Indian generic producers, has placed a proposal before the Indian Government to require applicants filing for pharmaceutical patents to disclose the international non-proprietary name (INN)<sup>88</sup> of the drug to which a particular patent application relates. For patent applications that have yet to be assigned an INN, the proposal would require the patent holder to submit the INN within 30 days of the drug being assigned one.<sup>89</sup> More recently, in 2012, the Centre for Health, Human Rights and Development in Uganda made a similar recommendation to the Ugandan Government in the context of a proposed industrial property bill. The Centre for Health,

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88. INNs are the generic names of drugs that are assigned to pharmaceutical substances, assigned by the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

89. See B. Shrivastava, "Leave Formula in Lab Is Activists' Prescription for Drug Companies", Mint, 22 October 2007, available at <http://www.livemint.com/2007/10/22224934/Leave-formula-in-lab-is-activi.html>.



Human Rights and Development has further recommended that the Registrar of Patents be obliged to include the INN, when made available by the patent applicant, in the public database of patents and patent applications.<sup>90</sup>

Requiring the identification of the INN in the title of a patent application would greatly assist a government in the administration of its patent database, as well as facilitate the active participation of the generic industry and civil society in the patent examination process. Rather than sorting through thousands of applications with ambiguous titles and complicated formulas, a person who is interested in patents relating to a particular drug – for example, AZT – would need only to search for this word in the title of the patent application. Again, compliance with this requirement could be ensured in the same manner as the existing mechanism in the Patents Act to ensure the disclosure of the patenting of traditional knowledge.

### *2.3.1.6 Duty to disclose whether an application relates to a disease of public health priority*

Given the existing limitations in South Africa in staffing a sufficiently qualified cadre of patent examiners to examine every individual patent application, it is critical, should South Africa move towards an examination system, that limited resources – in government, generics industry and civil society – be devoted to those patent applications with the greatest impact on public health. Again, the burden of identifying those patent applications that relate to diseases of public health priority could be shifted to those who are in the best position to provide this information – the patent applicants themselves. Patent applicants would be under a duty to disclose whether a particular patent application relates to a substance that is, or can be, used to treat a disease or condition of public health priority.

### *2.3.1.7 Summary of policy options with respect to disclosure of information in patent applications*

Public disclosure of information relating to patents and patent applications is a critical component of the theoretical exchange between society and the inventor. As such, there is an obligation on the State to make this information freely available, and the State in turn should impose an obligation on the patent applicant to disclose all of the knowledge at its disposal

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90. The Centre for Health, Human Rights and Development, Model provisions to promote access to affordable medicines in the Industrial Property Bill 2009, September 2012, available at <http://www.cehurd.org/wp-content/uploads/downloads/2012/09/IP-Bill-model-provisions.pdf>



and to make the information easily accessible. Several policy options could be considered to achieve these goals:

- Require the CIPC to provide online and on an annual basis in report form the number and details of the pharmaceutical patents granted and patent applications pending.
- Reintroduce the requirement that the patent applicant disclose the best mode of practicing an invention.
- Require the patent applicant to keep the patent office informed of the status of corresponding applications in other countries.
- Require the patent applicant to disclose all relevant prior art in the patent specification.
- Require the patent applicant to disclose the INN of a patent application relating to a pharmaceutical substance, with the continuing obligation to provide the INN for those substances not yet assigned one.
- Require the patent applicant to disclose whether the patent application relates to a disease or condition of public health priority.
- For all disclosure requirements, specify that failure to comply with the disclosure requirements can be a ground for opposition and/or revocation of the patent and result in the imposition of a penalty on the patent applicant.

## 2.4 Patent examination and oppositions

Despite a statutory requirement that patents be examined, South Africa is, in practice, a non-examining country.<sup>91</sup> Thus, all patent applications, insofar as the appropriate forms are correctly filled and fees paid, proceed to grant. Although there are some provisions designed to ensure that the lack of a substantive examination does not result in the proliferation of frivolous claims,<sup>92</sup> how effective these provisions are in curbing questionable patenting

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91. Section 34 of the Patents Act prescribes that the patent registrar “shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it”. In contrast, regulation 41 of the Patent Regulations, 1978 provides that the patent registrar “shall examine the application accompanied by a complete specification in order to ensure that it *complies with the prescribed formalities*”. (Emphasis added).

92. For example, section 68 of the Patents Act provides that in patent infringement proceedings, if the patent commissioner determines that an infringed patent is only partially valid, “the patent commissioner may postpone the operation of any order issued thereon for such time as may be required to enable the patentee to effect any amendment of the specification”. This section further confers upon the patent commissioner the discretion to determine the date from which damages may be calculated, taking into consideration “the conduct of the patentee in inserting in the specification those claims which had been found, before amendment, to be invalid or permitting such claims to remain there”. Thus, there is at least a theoretical incentive for the patent holder to ensure that all of the claims in the patent application meet the substantive requirements of patentability.



practices is not known.<sup>93</sup> What is known is that once a questionable patent is issued, it is extremely expensive and time consuming under the current system to invalidate it.

While legal costs may vary, it has been estimated that on average it would take up to three years to litigate the validity of a single patent in court proceedings.<sup>94</sup> This presents a considerable obstacle in the challenge of questionable patents – one that government health officials, generic companies and, in particular, civil society groups, may choose to forego altogether even though the Patents Act allows ‘any person’ to challenge a granted patent. In practice, the validity of a patent is ordinarily only challenged in the context of an infringement claim.

The advantages of having an examination system, particularly along with a system of pre- and post-grant oppositions to patent applications and granted patents respectively, is borne out in the experience of a number of developing countries. For instance, the Indian Patents Act allows for oppositions by civil society groups. Taking advantage of provisions like section 3(d), networks of people living with HIV have filed oppositions on several key medicines. Indian generic companies have also filed oppositions. Patent applications for a syrup form of nevirapine,<sup>95</sup> lopinavir/ritonavir and tenofovir have been rejected, allowing generic production of these ARVs to continue.<sup>96</sup>

While the specifics of such a proposal lie beyond the scope of this paper, some general features of an examination system could include:

- Amending the Patents Act to allow for publication of pending patent applications prior to grant;<sup>97</sup>
- Making the publication of pending patent applications in the identified priority areas available online in fully searchable database format;
- Amending the Patents Act to allow for any natural or juristic person, even if acting solely in the public interest,<sup>98</sup> to file a pre-grant opposition at any time after publication

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93. However, we do know that even in a country with a comprehensive examination system such as the United States, in the vast majority of patent infringement lawsuits filed by patent-holding pharmaceutical companies against their generic competitors, the final outcome is ultimately decided in favour of the generic company. See US Federal Trade Commission, “Generic Drug Entry Prior to Patent Expiration: An FTC Study” July 2002, Chapter 2 at page 19. That said, the majority of granted patents are not challenged.

94. Interview with A. Dyer, supra note 25.

95. Nevirapine hemihydrate.

96. In the case of Combivir®, as discussed above, the opposition resulted in a withdrawal of the patent application.

97. Currently, the Patents Act provides for the publication of patent applications only after they have been accepted, and the date of publication of the patent application is deemed to be the date of grant of the patent. See Patents Act, section 42.

98. Currently, the Patents Act confers standing to only interested persons, which could be interpreted to exclude entities that are not engaged – or planning to be engaged – in the manufacture and/or production of the patented product. Such a conservative interpretation would have the result of excluding civil society groups.



but prior to grant, with ample time between the publication and grant to give parties an opportunity to oppose;<sup>99</sup>

- Setting up a patent examination body to examine the patent applications on an expedited and simplified administrative procedure, and, where applicable, to hear patent oppositions; and
- Establishing broad grounds for opposition, including failure to comply with any of the disclosure obligations discussed above.

Moving towards an examination system, whether or not including mechanisms for opposition, is worthy of consideration. Collectively, the following policy options – if adopted as a comprehensive package of reforms – could ease South Africa’s short- and medium-term challenges if it chooses to move towards full examination in the long term:<sup>100</sup>

- Including a number of broadly applicable and easily applied exclusions from patentability that would make the task of examination considerably easier;
- Requiring numerous mandatory disclosures by the patent applicant; and
- Imposing a duty on the patent applicant to identify, based on its own information, the disease, condition, or illness that its invention may be used in respect of.

## 2.5 Limited exceptions to patent rights

Article 30 of TRIPS provides for “limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”. This provision allows for some important flexibilities that countries can adopt to improve access to medicines.

### 2.5.1 Early working and parallel imports

South Africa has adopted two of these limited exception flexibilities. Section 69A(1) of the Patents Act, introduced through an amendment in 2002, provides that it “shall not be an act of infringement” to use an invention solely for the purposes of acquiring information to sub-

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99. For example, the Indian Patents Act, section 25(1), states, “Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of the patent...”

100. It should be noted that in developed countries with patent examination systems, the administrative costs of such systems are passed on to patent applicants through the imposition of fees.



mit for regulatory approval. This ‘early working’, or ‘Bolar’, provision is an important tool for generic manufacturers to be able to enter the market shortly after a patent on a medicine expires or is revoked, or when the manufacturer has been licensed by the patentee or through the grant of a compulsory licence before patent expiry.

In addition, South Africa has, in section 15C of its Medicines and Related Substances Act 101 of 1965 (Medicines Act), provided for the parallel importation of medicines from other countries. The Regulation 7.1 of the General Regulations to the Medicines Act provides that medicines obtained by parallel import may be sold if:

- (a) the medicine is being sold outside the Republic with the consent of the holder of the patent of such medicine;
- (b) the medicine is imported from a person licenced by a regulatory authority recognised by the council;
- (c) the person desiring to import such medicine is in possession of a permit issued by the Minister; and
- (d) the medicine is registered in terms of the Act.

This provision is discussed in greater detail in Chapter 3.

## 2.5.2 Other exceptions

There are several other limited exceptions that countries can employ to exempt from infringement: (1) the use of a patented invention for research purposes; (2) the use of a patented invention for teaching purposes; and (3) the use of an invention for personal medical use.<sup>101</sup> Of course, this is not an exhaustive list of the valid ‘limited exceptions’ allowed under Article 30 of TRIPS. South Africa could consider adding these and other potential exclusions permitted under Article 30.

## 2.5.3 Summary of policy options related to limited exceptions to patent rights

Article 30 of TRIPS allows for many limited exceptions to patent rights that have not been fully utilized in the Patents Act. Among the exceptions that South Africa could consider enacting are:

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101. Third World Network, *Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws*, (2003), Chapter 6.



- An express provision in the Patents Act that states that the importation of patented products from anywhere in the world shall not be considered an act of infringement;
- Use of a patented invention for research purposes;
- Use of a patented invention for teaching purposes; and
- Use of an invention for personal medical use.

## 2.6 Compulsory licensing and government use

As discussed previously, the implementation of robust patentability criteria, broad exclusions from patentability and an opposition-based examination system can potentially result in a dramatic reduction in the number of patents granted on medicines. Even with such a system, however, there will be numerous instances in which patents nonetheless remain a barrier to access – particularly insofar as truly innovative medicines are concerned. Moreover, under current law, many of the drugs of public health importance are already under patent.<sup>102</sup>

Because of these factors, it is important for the law to accommodate a wide range of flexibilities in allowing others to practice a patented invention, even without the express permission of the patent holder. Such uses are commonly referred to as ‘compulsory licences’, but for the sake of highlighting some important distinctions, this paper will refer to two distinct policy tools: ‘compulsory licences’, as issued by courts, and “government use” as issued by the state.

As currently drafted, the Patents Act does not take advantage of the full complement of flexibilities relating to compulsory licensing available under TRIPS. In particular, the enumerated grounds for the grant of compulsory licences are limited; the process for obtaining a compulsory licence is risky, cumbersome and expensive; the provisions for government use are inadequate; and the guidelines for determining adequate remuneration with respect to both compulsory licenses and government use are vague.

The analysis here assumes that the efficient and predictable negotiation of voluntary licenses on reasonable terms is ordinarily preferable to court or State intervention when negotiations break down or fail to yield acceptable results.<sup>103</sup> For several reasons, it is preferable to create

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102. Even if South Africa were to adopt broad exclusions from patentability as has been suggested here, it is unlikely to have any retrospective effect on patents that have already been granted.

103. This does not apply to situations of national emergency, where there is – by definition – a need for swift and decisive action. Under TRIPS, there is no need for prior negotiations in respect of compulsory licences issued in the case of a national emergency and/or other circumstances of extreme urgency. This also applies to licences issued for public non-commercial use. It is beyond the scope of this paper to determine whether there is any need under South African administrative law to afford a patentee the opportunity to negotiate in such circumstances.



a legal framework in which voluntary licences can be negotiated and agreed to between the patent holder and the licensee on reasonable terms. For one, creating such a legal framework reduces the strain on limited public resources in litigating issues related to compulsory licences.

In short, the availability of easy-to-use compulsory licencing provisions contributes to the creation of conditions where patent holders might be well-advised to seek out voluntary licence arrangements. Even so, this is often not enough. Increasingly, developing countries are resorting to the use of compulsory licences:

- In 2007 and 2008, Thailand issued compulsory licences for key medicines related to HIV, heart disease and cancer.<sup>104</sup>
- In 2010, Ecuador declared several medicines to be of public interest, announcing that it would examine each of these if they were fit cases for compulsory licences. Ecuador subsequently issued a compulsory licence for ritonavir, a booster used with second-line HIV medicines (in 2010)<sup>105</sup> and for the paediatric form of abacavir/lamivudine, a combination HIV medicine (in 2012).<sup>106</sup>
- In 2012, India issued a compulsory licence for a cancer medicine.<sup>107</sup>
- In 2012, Indonesia issued compulsory licences for seven HIV medicines.<sup>108</sup>
- In 2012, Ecuador issued a compulsory licence for HIV medicine abacavir/lamivudine.<sup>109</sup>

A legal framework, in which licences— whether voluntary or compulsory— are obtained without undue delay, burdensome red tape or excessive expense, would include several key fea-

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104. Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, Ministry of Public Health and The National Health Security Office, Thailand, February 2007, available at <http://apps.who.int/medicinedocs/documents/s18718en/s18718en.pdf> and The 10 burning questions on the Government Use of Patents on the four anti-cancer drugs in Thailand, The Ministry of Public Health And The National Health Security Office, Thailand, February 2008, available at [http://www.moph.go.th/hot/Second\\_white\\_paper\\_on\\_the\\_Thai\\_CL\\_%5BEN%5D.pdf](http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf)

105. Compulsory License for Ritonavir, granted to Eskegroup, Unofficial English Translation (Public Citizen), 14 April 2010 available at <http://www.citizen.org/documents/EcuadorCompulsoryLicenseTranslationUNOFFICIAL.pdf>

106. Ecuador's Compulsory License for Abacavir+Lamivudine – Brief Summary, Unofficial English Translation (Public Citizen), 12 November 2012, available at <http://www.citizen.org/English-summary-ecuador-CL-2012>

107. Bayer Corporation v. Union of India and Ors, Intellectual Property Appellate Board, M.P.Nos.74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM, 14 September 2012, available at <http://www.ipab.tn.nic.in/223-2012.htm>

108. *President Decree of the Republic of Indonesia No. 76 of 2012 About Implementation of the Government of Patent Medicines*, 2012, Unofficial English Translation (Public Citizen), available at <http://www.citizen.org/documents/PresidentialDecree20121.pdf>

109. Knowledge Ecology International, 'Ecuador issues a compulsory license on abacavir/lamivudine on 12 November 2012' <http://keionline.org/node/1589>



tures. It would include specific guidelines on what constitutes reasonable terms for a licence and what constitutes adequate remuneration, strict timelines during which negotiations for voluntary licences must be completed (when they are required), and a clear default policy in favour of the issuance of compulsory licences.

### 2.6.1 TRIPS requirements for compulsory licences and government use

Article 31 of TRIPS allows for the use of an invention covered by a patent without the patent holder's authorization subject to the following conditions:

- Each case is considered on its individual merits;
- The proposed user has made a prior unsuccessful attempt to obtain a voluntary licence;
- The scope and duration is limited for the purpose in which the use was authorized;
- The use is non-exclusive and non-assignable;<sup>110</sup>
- The use is 'predominantly for the supply of the domestic market';
- The patent holder is paid adequate remuneration for such use; and
- The legal validity of any decision relating to the authorization of the use, as well as the amount of remuneration, is subject to judicial or other independent review by a 'distinct higher authority'.<sup>111</sup>

Article 31 further clarifies that the requirement of prior negotiation is not required in circumstances of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use", as well as in those cases in which a compulsory licence is granted to correct anti-competitive practices.<sup>112</sup> Moreover, the requirement that the compulsory licence be issued 'predominantly for the supply of the domestic market' is waived in certain circumstances, in particular where the compulsory licence is issued to rectify

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110. The Patents Act has already incorporated this condition in section 56(5).

111. Moreover, Article 5A(4) of the Paris Convention, which was incorporated by reference into TRIPS, requires that in cases where the compulsory licence is being sought on the grounds of failure to work the invention, a compulsory licence shall not be granted before the expiration of four years after filing of the patent application or three years after the grant of the patent, whichever is later. The Patents Act has already incorporated this requirement in section 56(1)(2)(a). However, it should be made clear that the waiting period only applies to the specific situation of non-working, and is not applicable to other grounds for compulsory licences. For a detailed analysis of each of the conditions in Article 31, see Resource Book on TRIPS, supra note 64, pp. 460–480.

112. TRIPS, Article 31(b), (k).



anti-competitive practices<sup>113</sup> and where a compulsory licence is issued for export using the August 30<sup>th</sup> mechanism.<sup>114</sup>

The Doha Declaration clarified that “[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”, and that “[e]ach 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”.<sup>115</sup>

As these provisions make clear, countries have complete freedom in determining the grounds on which compulsory licences can be granted. Contrary to common misconception, compulsory licences are not limited to situations of national emergency; they can be granted as a matter of course for any number of reasons.<sup>116</sup> Moreover, countries have complete freedom in determining what constitutes a national emergency or a situation of extreme urgency, and can declare that such a situation exists in any number of public health crises, including, but not limited to, HIV/AIDS, tuberculosis, malaria and other epidemics.<sup>117</sup>

As is evident from reading Article 31 of TRIPS in light of the Doha Declaration, there can also be several different types of authorizations – whether by the State or courts – for the use of patented inventions, each treated differently under TRIPS, including but not limited to the following (with each category elaborated on below):

- ‘Public non-commercial use’, where there is no obligation on the government to hold prior negotiations with the patent holder, and where there are no restrictions on what constitutes acceptable government use;
- A compulsory licence issued to address public health crises or other circumstances of national emergency or extreme urgency, where again, there is no obligation to hold prior negotiations with the patent holder, and where the country is free to determine what constitutes such emergency or urgency;

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113. Ibid., Article 31(k).

114. The August 30<sup>th</sup> Mechanism refers to the mechanism adopted by the WTO to address the concern raised in paragraph 6 of the Doha Declaration. This system is addressed in section 2.6.2.6, below.

115. World Trade Organization, Declaration on the TRIPS Agreement and Public Health (Doha Declaration), Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, paragraph 5(b), (c).

116. Indeed, countries such as the United States issue compulsory licences as a matter of course for any number of reasons, including for government use and to remedy anti-competitive practices. For a list of examples of compulsory licences granted in the United States, see <http://www.cptech.org/ip/health/cl/us-cl.html>.

117. It is a misconception that this requires the declaration of a state of emergency or that any formal parliamentary process is needed.



- A compulsory licence issued to remedy anti-competitive practices, where there is no obligation of prior negotiation *and* no restrictions on predominantly domestic use; and
- Recognizing that countries are free to determine the grounds upon which licences are granted, a compulsory licence is issued on any other ground, where prior negotiation is required.<sup>118</sup>

## 2.6.2 Compulsory licensing under South African law

### 2.6.2.1 Proceedings before the Commissioner of Patents

The Patents Act subjects all applications for compulsory licensing to a lengthy and costly judicial process prior to grant. However, there is no obligation under TRIPS to implement such a procedure in authorizing the grant of a compulsory licence. From the perspective of creating a legal framework in which voluntary agreement is encouraged and protracted litigation discouraged, it makes sense to streamline this process. Such streamlining would not necessarily remove the jurisdiction of the Court of the Commissioner of Patents, because any proceedings conducted before administrative tribunals are themselves subject to review in the High Court.

Under section 56(1) of the Patents Act, an applicant for a compulsory licence must apply to the Commissioner of Patents in the prescribed manner. The Patents Act specifies, however, that the Commissioner of Patents shall be a judge selected from the North Gauteng High Court, Pretoria, and all proceedings before the Commissioner shall be conducted “in accordance with the law governing procedure in civil cases”.<sup>119</sup> Moreover, in any proceedings before the Commissioner where the Commissioner is vested with discretionary authority (such as in applications for compulsory licences), the Commissioner is prohibited from exercising his or her authority without providing the interested party an opportunity to be heard.<sup>120</sup>

In short, *any* application for a compulsory licence<sup>121</sup> must be heard by the Commissioner in what amounts to a full judicial proceeding. As noted, it may take up to three or more

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118. A fifth type of compulsory licence – for export to countries with insufficient manufacturing capacity – will be discussed below. Yet another type of compulsory licence contemplated under Article 31(l) of TRIPS – where it is necessary to permit the use of a patent that cannot be exercised without violating another patent – is already incorporated into the Patents Act in section 55.

119. Patents Act, sections 8, 19(1).

120. *Ibid.*, section 16(1).

121. Proceedings before the patent commissioner in circumstances of government use are limited to situations in which the state and the patent holder are unable to reach agreement on the terms of a voluntary licence. See Patents Act, Section 4. However, where there is disagreement between the state and the patent holder as to the terms of a government use licence, the state must make an application to the commissioner to determine what the terms will be in what amounts to a full judicial proceeding.



years fully to litigate a matter that begins before the Commissioner,<sup>122</sup> including subsequent appeals. During the pendency of the appeal, operation of the compulsory licence could be stayed.<sup>123</sup> Such a delay is unacceptable in circumstances of national emergencies, and would discourage private parties – such as generic companies, and in particular, civil society groups – from applying for compulsory licences in the public interest. Of course, such litigation is likely to be very costly.

There is, however, no TRIPS obligation to provide for such cumbersome procedures in granting a compulsory licence. Article 1 of TRIPS states that members are “free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”. Given this flexibility and the flexibilities inherent in Article 31, there are numerous ways to expedite the issuance and implementation of compulsory licences. The process before the Commissioner could be streamlined by inserting express provisions dealing with stays during the appeal process. In short, only in exceptional circumstances would the grant of a licence not be implemented pending the resolution of any appeal.

## 2.6.2.2 Determining adequate remuneration

One of the most important factors in facilitating the efficient negotiation of voluntary licences on reasonable terms is having clear, predictable guidelines for calculating adequate remuneration in the compulsory licensing context. If an applicant for a compulsory licence can show that the patent holder has refused voluntarily to license its invention more or less in accordance with such guidelines, then the applicant could make a *prima facie* case that the patent holder has unreasonably refused to license its invention and is thus entitled to a compulsory licence.

However, the Patents Act does not provide such clarity, and instead allows the Commissioner considerable discretion in determining the compensation to be paid to the patent holder in the event of a compulsory licence. Section 56(7) states:

In determining the conditions on which any licence is granted the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.

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122. Interview with A. Dyer, *supra* note 25.

123. The Patents Act, section 76 allows for any order or decision of the commissioner to be appealed to a higher court. It is possible that such a decision could ultimately be appealed all the way up to the Constitutional Court.



The lack of specificity guiding the Commissioner in determining what constitutes adequate remuneration could result in lengthy litigation during which the issuance of the licence could be delayed, and produce excessively high royalty rates that would substantially diminish the efficacy of the compulsory licence. Moreover, the lack of specificity impairs the ability of generic companies to negotiate voluntary licences on reasonable terms.

Several models for determining adequate remuneration that have been proposed that would result in greater transparency and predictability.<sup>124</sup> For example, legislation in Canada that provides for compulsorily licensed products for export caps the royalty rate at 4 percent of the price of the generic product, and adjusts the royalty rate downwards according to the importing country's rank on the UNDP Human Development Index.<sup>125</sup>

The advantages of adopting clear, predictable guidelines for determining adequate remuneration include the assurance, for the party applying for the compulsory licence, that a successful application will come with a reasonably affordable royalty rate. Moreover, as mentioned above, the existence of a predictable benchmark of what constitutes a reasonable royalty can be instrumental in determining whether there was a refusal to licence on reasonable terms. Finally, an adjustable royalty rate might be preferable to a single, fixed royalty rate because it would allow the final royalty rate to be adjusted for factors such as anti-competitive practices. In short, this could be achieved by:

- Implementing, either in the Act or Regulations, clear and predictable guidelines for determining adequate remuneration in the compulsory licensing context.
- Expressly establishing a link between these guidelines and the establishment of a *prima facie* case of refusal to licence on reasonable terms.

### 2.6.2.3 Government use

Section 4 of the Patents Act states that “a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee”. Thus, the State is obligated to enter into prior negotiations with the patent holder regarding the terms of a voluntary licence, and failing agreement, must make an application to the Commissioner, thus triggering potentially lengthy and expensive court proceedings.

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124. See J. Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, UNDP and WHO (2005) at pp. 67–76 for a comprehensive review of the various remuneration guidelines that have been proposed.

125. *Ibid.*



Although Article 31(b) of TRIPS expressly waives the requirement of prior negotiation with the patent holder in cases of public non-commercial use, section 4 of the Patents Act does not utilize this flexibility, and imposes the requirement of prior negotiation in all cases of government use.

This stands in stark contrast to the broad powers of government use that are reserved by the US Government, for example, which allows the government or its contractors to use any patented invention without any procedural formalities, subject only to the payment of adequate remuneration after the fact.<sup>126</sup> Similarly, in the United Kingdom, “any government department and any person authorised in writing by a government department may, for the services of the Crown ... make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it”.<sup>127</sup>

Maximum flexibility in allowing the State to use patented inventions is especially important in a country such as South Africa, where the vast majority of the population depends on public health care services, and where considerable cost savings can be achieved by procuring lower cost generics for use in such services.

From this perspective, South Africa may wish to consider amending section 4 of the Patents Act to allow for the use of patented inventions after a fixed period of unsuccessful voluntary negotiations (as and when appropriate), subject to the determination of adequate royalties after the fact and limitations on the ability of patentees to obtain interim relief pending appeal proceedings.<sup>128</sup> Such a framework, in conjunction with clear and predictable remuneration guidelines, as and when appropriate, would make it all the more likely that the patent holder would agree to a voluntary licence within the specified time period.

In short, with respect to government use licences, the process could be streamlined by:

- setting a statutory time limit during which the parties must conclude their negotiations which – in the case of national emergencies and other circumstances of extreme urgency – could be extremely abbreviated;
- specifying remuneration guidelines that allow the determination of the royalty rate, especially in the absence of agreement between the State and the patent holder within the prescribed time period; and

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126. See 28 U.S.C. 1498.

127. United Kingdom, Patents Act, section 55(1).

128. For instance, upon an unlikely showing of irreparable harm. However, as will be discussed in further detail below, evincing a clear legislative policy that the payment of royalties is a sufficient legal remedy for infringement will make the finding of irreparable harm extremely unlikely. See section 2.6, *supra*.



- including a statutory provision that expressly provides that any appeal against or review of a decision taken in terms of section 4 shall, absent exceptional circumstances, not suspend the operation of the licence pending the appeal proceedings.<sup>129</sup>

#### 2.6.2.4 Situations of national emergency or extreme urgency

As we have seen, the Doha Declaration expressly leaves it to individual countries to determine what constitutes a national emergency or a situation of extreme urgency.<sup>130</sup> The Patents Act, however, does not contain any mention of national emergencies or extreme urgency, and no expedited procedure for issuing a compulsory licence in such circumstances is provided.

In India, when the Government determines that a situation of national emergency or a circumstance of extreme urgency exists in relation to a particular patent, the procedural formalities of conducting a hearing and giving the patent holder an opportunity to be heard can be waived. Under these circumstances, the patent controller “shall, on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms and conditions as he thinks fit”.<sup>131</sup> As the ‘shall’ indicates, the issuance of a compulsory licence is mandatory once the national emergency or circumstance of extreme urgency is announced, and no discretion is left to the patent controller to deny an application for a compulsory licence.

In order to quickly and effectively deal with emergency situations and situations of urgency in which compulsory licences are issued, it is important that administrative hurdles are kept to a minimum. Commentators have noted that Article 31(b) of TRIPS does not require a formal declaration of a national emergency.<sup>132</sup> Such a decision could be taken by the Minister of Health or its Director-General. Once a determination of national emergency or urgency is made, the licence should be issued as a matter of course, on standard terms and conditions as set out in the law. All processes to challenge the grant or terms and conditions of the licence should be permitted, as is constitutionally required, but should ordinarily not be permitted to prevent the licence from being used.

In summary, the procedures for granting compulsory licences in situations of national emergency or extreme urgency could be expedited by:

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129. See *National Treasury and Others v. Opposition to Urban Tolling Alliance and Others* 2012 (6) SA 223 (CC).

130. *Supra*, note 116.

131. India, Patents Act, section 92 (emphasis added).

132. See Resource Book on TRIPS, *supra* note 64, at p. 471.



- Conferring the authority to senior officials, such as the Director-General within the Department of Health, to determine that a situation of national emergency or extreme urgency exists, and to issue compulsory licences for this purpose; and
- Ensuring that any challenge to the grant or terms and conditions of the licence should ordinarily not suspend the operation of that licence.

## 2.6.2.5 *Compulsory licences granted to remedy anti-competitive practices*

Compulsory licences granted to remedy anti-competitive practices are particularly significant, as the restriction that a compulsory licence be issued predominantly for the supply of the domestic market does not apply in such circumstances.<sup>133</sup> The lack of such a restriction could result in a significant drop in prices, as the licensees could achieve economies of scale by manufacturing for both the South African and foreign markets. However, there are no provisions in the Patents Act that either specify that compulsory licences are to be issued predominantly for the domestic market, or that certain compulsory licences issued as a result of anti-competitive practices do not come with this restriction.

As will be discussed in Chapter 3, there are numerous forms of anti-competitive practices that patent holders may engage in. Article 8 of TRIPS recognizes the inherent tension between intellectual property protection and the promotion of free competition, and provides for “appropriate measures” to be taken to prevent practices that “unreasonably restrain trade or adversely affect the international transfer of technology”. South Africa is free to determine which practices have such an anti-competitive effect; one of the appropriate remedies for such abuses could be to deprive the patent holder of its exclusive rights to the patent, and issue compulsory licences to its competitors.<sup>134</sup>

Although the Competition Act contains some broad prohibitions on anti-competitive practices that are also applicable to intellectual property, there is no express provision that links the abuse of exclusive rights in patents to anti-competitive conduct, nor is compulsory licensing expressly made a remedy for such conduct. However, there is no reason why the Patents Act could not, independently of the Competition Act and under an expedited administrative procedure, expressly recognize certain practices as anti-competitive and provide a basis for issuing compulsory licences.

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133. TRIPS, Article 31(k).

134. The United States, for example, has countless examples where a compulsory licence was held to be the appropriate remedy for anti-competitive practices. See Remuneration Guidelines, *supra* note 126 at pp. 29–30 for some illustrative examples.



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

Section 56 of the Patents Act, which is entitled “Compulsory licence in case of abuse of patent rights”, lists four grounds upon which an applicant for a compulsory licence can establish an abuse of patent rights:

- failure to work the invention in South Africa within the prescribed time;<sup>135</sup>
- insufficient supply to meet demand on reasonable terms;<sup>136</sup>
- refusal of the patent holder to grant a licence on reasonable terms;<sup>137</sup> and
- excessive pricing in comparison to the price charged for the same item in other countries by the patent holder.<sup>138</sup>

Any of these grounds could be deemed to have an anti-competitive effect in South Africa, thereby removing the TRIPS requirements of prior negotiation and export restriction for the issue of compulsory licences. To remove any uncertainty however, it may be advisable to expressly state in the statute that compulsory licences granted on these grounds shall be deemed to be remedies for anti-competitive practices, and that licensees are not constrained to the domestic market.

Having clear examples of what may constitute ‘reasonable terms’ in section 56(2)(b) and (d) would expedite the negotiation of voluntary licences. With such clear examples, a patent holder would be put on notice that a refusal to agree to a voluntary licence on the terms as set out in the Act or Regulations would be grounds for the issuance of a compulsory licence. This would create a strong incentive for the patent holder to agree to a voluntary licence and avoid unnecessary litigation. (See also Chapter 3.)

In summary, the policy options relating to compulsory licences as a remedy for anti-competitive practices are:

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135. Patents Act, section 56(2)(a).

136. *Ibid.*, section 56(2)(b).

137. *Ibid.*, section 56(2)(d).

138. *Ibid.*, section 56(2)(e).



- Specify that the existing grounds for issuing compulsory licenses under section 56 of the Patents Act are to remedy anti-competitive practises, and that the limitation on exports and the need for prior negotiations do not apply to such situations.
- Expressly state that any action by a patent holder found by the Competition Tribunal to constitute an abuse of dominant position would be deemed an additional ground for issuing a compulsory license.
- Provide clear examples of what may constitute ‘reasonable terms’ with respect to section 56(2)(b) of the Patents Act, to specify, for instance, that a price charged by the patent holder that bears no reasonable relation to the marginal or average variable cost of manufacturing the item shall be deemed unreasonable.
- Provide clear examples of what may constitute ‘reasonable terms’ with respect to section 56(2)(d) of the Patents Act, to specify that the refusal of a patent holder to grant a licence in accordance with the remuneration guidelines within a specified time period shall constitute an unreasonable refusal to license.

## 2.6.2.6 *Compulsory licences solely or largely for export*

South Africa is one of the few countries in sub-Saharan Africa with substantial domestic generic manufacturing capacity.<sup>139</sup> This represents a potential opportunity for South African generic manufacturers to play a larger role in supplying affordable medicines throughout the continent. Currently, however, South African companies lag far behind Indian companies in this regard.<sup>140</sup> While this is likely due to a number of reasons, most of which are beyond the scope of this paper,<sup>141</sup> one key factor is India’s adoption of industrial policies in the 1970s that allowed the domestic industry to flourish. However, in terms of creating a legal framework in which patented medicines produced under a compulsory licence can be exported to other African countries, there are legislative options at South Africa’s disposal that have not yet been incorporated into the Patents Act.

The Doha Declaration recognized that the right of member countries to issue compulsory licences was not particularly helpful to those countries with insufficient domestic manu-

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139. Avafia et al., “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”, *tralac* (2006) at pp. 3–4.

140. *Ibid.* at p. 4. According to the authors, Indian generics account for 85 percent of total volume of the market share for ARVs in Africa, while South Africa accounts for only 15 percent.

141. Such reasons would likely include the ability of the larger, more established and more vertically integrated Indian generic companies to manufacture medicines at larger volumes and lower costs, the larger number of Indian medicines that have been WHO prequalified, and the lack of patent protection in India for most (if not all) of the medicines that are being procured.



facturing capacity.<sup>142</sup> This was because Article 31(f) of TRIPS provides that compulsory licences be issued predominantly for the supply of the domestic market of the country in which they are issued.<sup>143</sup> Thus, countries with surplus manufacturing capacity were largely handcuffed from exporting medicines produced under a compulsory licence to these countries. Recognizing this fact, the Doha Declaration directed the Council for TRIPS to find an “expeditious solution” to this problem.<sup>144</sup>

On 30 August 2003, the WTO General Council issued a decision (the 30 August Decision) designed to remedy this situation.<sup>145</sup> The 30 August Decision provides exporting countries a waiver of the Article 31(f) restriction, upon satisfaction of a number of conditions.<sup>146</sup> Thus far, only a handful of potential exporting members have incorporated the 30 August Decision into their national laws,<sup>147</sup> and there has only been one instance in which the 30 August Decision was used to export drugs under a compulsory licence to a country with insufficient manufacturing capacity.<sup>148</sup>

The burdens that the 30 August Decision imposes upon both importing and exporting countries, and the practical difficulties in meeting its requirements, have led some to criticize the Decision as “neither expeditious, nor a solution”.<sup>149</sup> For example, the obligation under TRIPS Article 31(b) to enter into prior negotiations with the patent holder is not waived, and is required for both the importing and exporting countries.<sup>150</sup> Moreover, a generic company

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142. Doha Declaration, *supra* note 116, paragraph 6.

143. Unless, of course, the compulsory licence was issued to remedy anti-competitive practices.

144. *Ibid.*

145. Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The “temporary waiver” of the Decision was made into a permanent amendment to TRIPS in December 2005, under a new Article 31bis. The amendment will become part of TRIPS on ratification by at least two-thirds of the WTO members. As of November 2012, less than a third of all WTO members had ratified the amendment.

146. These conditions include notifying the WTO of the names and expected quantities of drugs needed, limiting the scope of the compulsory licence for manufacture of only the amount necessary to meet the stated needs of the importing country; and clearly identifying the licence products as having been produced for this purpose. See 30 August Decision, section 2.

147. This list includes Canada, China, India, the Netherlands, the European Commission, Korea, and Switzerland. See, Members’ laws implementing the ‘Paragraph 6’ system, World Trade Organization, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm)

148. In September 2007, Canada issued a compulsory licence under its legislation implementing the 30 August Decision for export of a triple fixed-dose ARV combination to Rwanda. See “Canada Confirms to WTO it will be First to Export Cheap, Generic AIDS Drugs”, *International Herald Tribune*, 5 October 2007.

149. *Medecins Sans Frontieres Canada*, “Neither Expeditious, Nor a Solution: the WTO August 30 Decision is Unworkable”, (2006) at p. 2.

150. See C. Correa, “Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, WHO (2004) at p. 21.



interested in exporting to more than one country would be forced to apply for separate compulsory licences for each separate order.<sup>151</sup> In 2010, the TRIPS Council discussed the use of the 30 August Decision, and developing countries highlighted some of these difficulties at that meeting.<sup>152</sup>

Importantly, the 30 August Decision also provided a broader waiver of Article 31(f) for countries that are parties to a regional trade agreement in which at least half of the membership consists of least developed countries. In such situations, the Decision states that the export restriction “shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question”. In other words, the regional market is to be considered the domestic market.

This broad waiver would apply to South Africa and the other member countries of the Southern African Development Community (SADC), in which eight of the 15 current members are on the United Nations list of least developed countries.<sup>153</sup> Under the terms of this waiver, any product produced under a compulsory licence in South Africa could be exported to other SADC members without first having to satisfy the numerous requirements under the 30 August Decision, provided that the other SADC countries share the same health problem. If South Africa wishes to make use of the framework allowing export of medicines produced under compulsory licence in South Africa to other SADC members, the Patents Act should be amended to expressly provide for that option.

As far as exports to countries outside SADC are concerned, to the extent that South Africa chooses to operate within the constraints of the 30 August Decision, it is imperative that the procedure not be made more cumbersome than necessary.<sup>154</sup> Thus, for instance, South Africa could set a fixed time after which voluntary negotiations are deemed to have been unsuccessful (e.g., 30 days), and waive the requirement of prior negotiations altogether where the importing country has issued its compulsory licence under a situation of emergency,

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151. See R. Elliott, “Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export”, Canadian HIV/AIDS Legal Network, (2007) at p. 5.

152. For a summary of the discussion, see WTO, Little-used ‘Par.6’ system will have its day, WHO tells intellectual property and health review, News Item, 26 and 27 October 2010, available at [http://www.wto.org/english/news\\_e/news10\\_e/trip\\_26oct10\\_e.htm](http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm). For a more detailed report on the discussions see, Members discuss implementation of TRIPS “Para 6” Solution, TWN Info Service on WTO and Trade Issues, 22 February 2010, available at <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100212.htm>

153. The least developed countries in SADC are: Angola, the Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Tanzania and Zambia.

154. For instance, the Canadian legislation implementing the 30 August Decision has been heavily criticized for imposing requirements that go above and beyond what the Decision requires. See Elliot, *supra* note 153 for full discussion.



extreme urgency or for government use.<sup>155</sup> Finally, whatever measures are adopted under the Decision, it should be made clear that such measures are in addition to – not instead of – the right to export medicines produced under a compulsory licence granted to remedy an anti-competitive practice.

To facilitate the export of products produced under a compulsory licence in South Africa to countries with insufficient manufacturing capacity, the following policy options are available:

- Expressly allow for the export of products produced under compulsory licence under *any* of the available grounds to other members of SADC, provided that the other members share the same health problem as South Africa.
- Expressly allow for the export of products produced under compulsory licence under *any* of the available grounds to countries that are not members of SADC provided that the compulsory licence was issued primarily for use in South Africa or SADC.
- Implement the 30 August Decision to allow for the issuance of compulsory licences solely or largely for export to non-SADC countries.
- Expressly waive the requirement of prior negotiation where the compulsory licence in the importing country was issued as a result of a national emergency or situation of extreme urgency, or where the licence was issued for public non-commercial use.
- Ensure procedural and administrative hurdles in issuing compulsory licences for export are minimized, including ensuring that the lodging of an appeal against the issue of the compulsory licence does not ordinarily suspend its operation pending appeal proceedings.

### 2.6.2.7 Other grounds for issuing compulsory licences

In addition to government use licences, compulsory licences in situations of national emergency or extreme urgency, compulsory licences to remedy anti-competitive practices and compulsory licences granted for solely or largely export, there may be other situations in which the grant of compulsory licences is necessary and appropriate. One such additional ground could be broadly based on public health grounds, allowing for any third party to apply for a compulsory licence in the public interest. Such a ground would effectively serve as a ‘catch-all’ to allow compulsory licences to be granted in situations that may not necessarily fit neatly into one of the above-mentioned grounds.

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155. See Correa, *supra* note 40 at p. 7.



Again, the determination of whether sufficient grounds exist for the issuance of a compulsory licence on general public health grounds could be determined under an expedited administrative procedure, with a fixed timetable for prior negotiation, and – absent exceptional circumstances – no possibility of obtaining a stay on the operation of the licence pending any review or appeal. Thus, an additional policy option could include a broad third-party compulsory licensing provision based on public health grounds, with a fixed timetable for voluntary licence negotiations and clear royalty guidelines.

### 2.6.3 Patent revocation and acquisition by the State

There may be cases in which the issuance of a compulsory licence is not a sufficient remedy for certain anti-competitive practices. Indeed, Article 5A(3) of the Paris Convention, incorporated by reference into TRIPS, contemplates that there may be situations in which compulsory licences may be an insufficient remedy. It provides that “[f]orfeiture of the patent shall not be provided for except in cases where the grant of compulsory licences would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory licence”.

However, section 61 of the Patents Act does not make this an express ground for revoking a patent. To address particularly egregious forms of patent abuse that are not cured by the issuance of a compulsory licence, the Patents Act could expressly allow the revocation of a patent any time after the expiration of a two-year period following the grant of the first compulsory licence, if the compulsory licence(s) have not been sufficient to prevent abuse.

Further, there may be extreme situations in which the State determines that it is in the public interest to acquire a patent altogether rather than issue compulsory licences. However, the right of acquisition by the State conferred under the Patents Act is considerably narrower, providing that any Minister may acquire “any invention or patent” on behalf of the State “on such terms and conditions as may be agreed upon”.<sup>156</sup>

As the language of this provision makes clear, a patent may only be acquired if the patent holder and the State can come to an agreement on terms and conditions. In those rare and extreme cases in which outright expropriation may be appropriate, the State should have the explicit flexibility to acquire a patent in the public interest, subject only to compliance with section 25 of the Constitution insofar as it deals with expropriation.

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156. Patents Act, section 78.



Thus, the policy options with respect to these circumstances would be to:

- Amend section 61 of the Patents Act to provide for the revocation of a patent to remedy abuse of patent rights in situations in which compulsory licensing has been insufficient to curb such practices.
- Amend section 78 of the Patents Act to allow for the State to acquire a patent in exchange for just compensation even where there is no agreement between the State and the patent holder.

## 2.7 Enforcement mechanisms, including remedies for infringement

Recently, concerns about the enforcement of IP rights have become even more important. The enforcement of IP rights covers proceedings that a rights holder may institute in court and the remedies that may be sought following the infringement of these rights. Attempts in various forums, internationally and within countries (particularly in Africa), to broaden the scope of enforcement measures available to rights-holders – and particularly the involvement of customs authorities and other government agencies – are of grave concern.

### 2.7.1 Remedies available for infringement

The vast majority of patents in South Africa are likely to be owned by foreign entities, particularly in the pharmaceutical industry, where the domestic pharmaceutical industry is largely generics-based. Thus, especially with respect to pharmaceuticals, patent infringement proceedings in South Africa will often involve a foreign-based company (or its local wholly-owned subsidiary) alleging patent infringement against a locally based entity. From the perspective of removing unnecessary barriers to entry for domestic pharmaceutical companies, it would make sense for South Africa to impose reasonable limits on the remedies available to patent holders in patent infringement proceedings.

The risk of incurring harsh penalties in infringement proceedings – in particular, broad forms of interdictory relief – could pose a significant disincentive for domestic companies to enter the market with affordably priced generics. The mere threat of being enjoined from selling its product, after investing considerably in bringing a product to market, could deter a generic company from making such investments at all. However, there are options at South Africa's disposal to effectively curb – although not entirely eliminate – the grant of interdictory relief in cases of patent infringement.



## 2.7.2 Limiting the grant of interim interdicts

One of the most powerful tools by which patent holders can prevent the entry of generic competitors is the use of interim interdicts – that is, an interdict preventing the respondent from selling or marketing the allegedly infringing product pending full resolution of the underlying dispute. Because interim interdicts cannot ordinarily be appealed,<sup>157</sup> the entry of a generic product could potentially be delayed for years until final resolution of the infringement proceedings. Limiting the availability of interim interdicts is particularly important in the pharmaceutical context, where patentees have been known to file frivolous patent infringement proceedings solely for the purpose of delaying the entry of generic competitors (see Chapter 3).

Under the Patents Act, a plaintiff in an infringement proceeding is entitled to the following forms of relief:

- (a) an interdict;
- (b) delivery up of any infringing product or article or product of which the infringing product forms an inseparable part; and
- (c) damages.<sup>158</sup>

The Patents Act makes no explicit mention of whether a plaintiff is entitled to an interim interdict, although they are generally available under common law. Moreover, Article 50.1 of TRIPS provides:

The judicial authorities *shall* have the authority to order prompt and effective provisional measures:

to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;  
... (emphasis added)

The mandatory language of this section would appear to preclude South Africa from eliminating the grant of interim interdicts altogether. However, some clarifications could be included within the Patents Act to limit the grant of interim interdicts. It may be noted that

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157. But see *National Treasury and Others v. Opposition to Urban Tolling Alliance and Others* 2012 (6) SA 223 (CC), in which the Constitutional Court overturned an interim interdict granted against the State by the High Court.

158. Patents Act, section 65(3).



the TRIPS requirement is limited *only* to empowering judicial authorities with the authority to issue such interdicts.

The grant of an interim interdict is recognized as available under common law, and may be provided if the plaintiff can establish: (a) a prima facie right; (b) a well-grounded apprehension of irreparable harm if the interim relief is not granted; (c) that the balance of convenience favours the granting of an interim verdict; and (d) that the applicant has no other satisfactory remedy.<sup>159</sup> As these requirements make clear, an interim interdict may only be granted if there is no other satisfactory remedy, and if irreparable harm will be caused to the patent holder.

However, if South Africa, as has been suggested here, were to adopt a clear legislative policy in favour of the grant of compulsory licences in exchange for adequate remuneration, it is difficult to imagine a situation in which a simple act of infringement alone could not be deemed to be adequately remedied by the payment of royalties after the issues of patent validity and infringement have been fully litigated and decided in the patent holder's favour.

Thus, the Patents Act could specify that in any application for an interim interdict in infringement proceedings, the payment of royalties shall be deemed to be a satisfactory remedy, unless the plaintiff can prove the existence of exceptional circumstances in which royalties would not be sufficient to make the plaintiff whole. At present, the Patents Act provides for this remedy at the option of the patentee in lieu of damages to be paid for an infringement that has actually been established.<sup>160</sup>

The importance of statutory amendments to limit the grant of interim interdicts is highlighted by the case law on the subject. The issues around the grant of interim interdicts and payment of royalties in their stead have arisen in infringement proceedings. In 2005, the Commissioner of Patents, in dismissing a plea from a generic company against the issue of an interim interdict, held:<sup>161</sup>

The prejudice to the [patent holders] if an interdict were not to be granted, is obvious. The applicants have had the benefit of patent protection for 17 years. They have an established product with sales of R64 million for the last year and which is the market leader in its field. If no interdict is granted all the forces and incentives that favour generic products will operate against Norvasc. If one looks at the broad picture: The respondents have hardly entered the market. The applicants have only two years of their patent left. In two years

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159. See *Setlogelo v. Setlogelo* 1914 AD 221, read together with *Webster v. Mitchell* 1948 (1) SA 1186 (W).

160. Patents Act, section 65(6).

161. *Pfizer Limited and Another v. Cipla Medpro (Pty) Limited and Others* [2005] ZACCP 1 (24 March 2005).



the respondents will be at liberty to sell Nortwin in any event. The applicant is a manufacturer that relies on patent protection to recoup the cost of research and development. The respondent is a manufacturer of generic products that are manufactured without the expense of original research. For that reason it is wrong to argue, as the respondents have done endlessly, that the applicants can retain their market share by reducing their prices. The regime of an open market is only something to which they have to submit on the expiry of the patent.

The Commissioner also dismissed the plea for royalties to be paid instead of an interim interdict, stating that there was no guidance on what a reasonable royalty would be.

In a significant departure from the approach of the Commissioner, the Supreme Court of Appeal – as a result of an amicus curiae intervention by TAC – considered the potential impact of the grant of an interim interdict on the public interest.<sup>162</sup> In doing so, the Court accepted that the public interest was a valid consideration in determining whether the interim interdict should be granted. In particular, the Court considered the public interest as part of its consideration of the balance of convenience. Prior to this decision, applications for interim interdicts in respect of patent infringement proceedings had only considered the parties' interests in dealing with the balance of convenience.

However, on the facts of the case, the Supreme Court of Appeal concluded that the interim interdict should be granted. The Court reasoned that patients would not be prejudiced by the removal of one generic medicine from the market as the patent holder already had its own generic version in the market priced only 10 percent higher than the generic price. The option of awarding a royalty instead of an interim interdict was rejected by the Court.

### 2.7.3 Limiting the grant of final interdicts

Final interdicts, as distinguished from interim interdicts, may be granted once an infringement of a valid patent has been proven. As previously noted, the Patents Act provides for interdicts as one of the remedies available to a plaintiff in infringement proceedings. Of special relevance in this regard is Article 44 of TRIPS, which provides:

1. The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs

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162. *Cipla Medpro v. Aventis Pharma; Aventis Pharma SA v. Cipla Life Sciences* [2012] ZASCA 108 (26 July 2012).



clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

As Article 44.1 makes clear, judicial authorities must have the authority to issue interdicts as and when they are deemed necessary. However, the last sentence of Article 44.2 states that “where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available”. This sentence has been interpreted to mean that in infringement proceedings, a court is not compelled to issue a final interdict prohibiting the infringer from practicing the invention, and may order the payment of ‘adequate compensation’ instead.<sup>163</sup>

In a 2006 decision, the US Supreme Court held that a finding of patent infringement need not always result in a final interdict (or ‘permanent injunction’), but rather, the following factors must be satisfied:

A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.<sup>164</sup>

Thus, rather than allowing a final interdict to issue as a matter of course upon a finding of patent infringement, countries have the flexibility, under Article 44.2 of TRIPS, to provide the patent holder with ‘adequate compensation’ instead. Justice Louis Harms – who served

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163. See J. Love, “Abbott Recently Sought Compulsory License in U.S. Patent Dispute”, Knowledge Ecology International, 1 May 2007, available at [http://www.keionline.org/index.php?option=com\\_content&task=view&id=43](http://www.keionline.org/index.php?option=com_content&task=view&id=43)

164. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).



as a Supreme Court of Appeal judge until his retirement – has indicated that South Africa could move in this direction, particularly with pharmaceutical patents:

[F]inal interdicts are granted as a matter of course in South Africa. Otherwise it would amount to granting the defendant a compulsory licence. It is nevertheless foreseeable that in, say, pharmaceutical patent cases, where public health concerns or the constitutional rights to health care arises, a court may have to consider whether or not to leave the rights holder to a damages claim instead of a final interdict.<sup>165</sup>

TRIPS does not require the automatic issuance of a final interdict upon a finding of patent infringement. Indeed, in light of South Africa’s constitutional obligation to “promote the spirit, purport and objects of the Bill of Rights”, which includes the right to have access to medicines,<sup>166</sup> it may be a positive obligation of the State to *refuse* the grant of final interdicts in cases where public health concerns are intertwined. The Patents Act can recognize this obligation expressly by providing that final interdicts shall not be granted where the payment of damages is sufficiently adequate to compensate the patent holder or where it would not be in the public interest to do so.

Finally, in order to further ensure that final interdicts are not unnecessarily granted, the defendant in a patent infringement proceeding should be allowed under the Patents Act to counterclaim for a compulsory licence on any of the grounds discussed above. Thus, rather than leave it to the court’s discretion to issue a final interdict upon a finding of infringement, the alleged infringer should be given an affirmative opportunity to demonstrate that he or she is entitled to a compulsory licence on any of the enumerated grounds that have been discussed.

## 2.7.4 Summary of policy options related to remedies available for infringement

As we have seen, limiting the scope of interdictory relief can significantly reduce the risks for generic companies seeking to enter the market. The availability of both interim and final interdicts can be narrowed by the Patents Act, evincing a clear legislative policy that adequate compensation is, in the vast majority of cases, a sufficient legal remedy for infringement. To that effect, the policy options at South Africa’s disposal can be summarized as:

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165. L. Harms, “The Role of the Judiciary in Enforcement of Intellectual Property Rights; Intellectual Property Litigation under the Common Law System with Special Emphasis on the Experience in South Africa”, WIPO, Advisory Committee on Enforcement, Second Session (2004) at p. 20 (emphasis added; internal references omitted).

166. Constitution, sections 27(1)(a); 39(2).



- Specify within the Patents Act that in any application for an interim interdict in infringement proceedings, the payment of royalties shall be deemed to be a satisfactory remedy, unless the plaintiff can prove exceptional circumstances in which royalties would not be sufficient to make the plaintiff whole.
- Expressly provide that absent exceptional circumstances, final interdicts shall not be granted where the payment of damages is sufficiently adequate to compensate the patent holder or where it would not be in the public interest to do so, in light of the Constitutional duty to promote the right to have access to medicines.
- Amend section 65(4) expressly to state that in infringement proceedings, the defendant may counterclaim for a compulsory licence on any of the grounds recognized in the law.<sup>167</sup>

## 2.7.5 Counterfeit goods

The CIPC has noted that although IP rights are private rights to be defended by the right holder, there may be instances that involve government agencies, such as when the infringement is of a criminal nature. Criminal remedies and provisions that involve government agencies in the enforcement of IP rights are contained in South Africa's Counterfeit Goods Act of 1997 (the Counterfeit Goods Act).

The Counterfeit Goods Act covers trademarks, copyrights and designs as defined in their respective laws. Counterfeit goods are defined as those where without the permission of the owner of any of these IP rights, production or manufacturing takes place in such a manner so that the goods look substantially similar to or are calculated to be confused for the right holder's goods. The Act specifies criminal remedies for various actions related to counterfeit goods and actions to be taken by customs officials at borders in relation to such goods.

Although the Counterfeit Goods Act does not cover patents, there may be some measure of concern in the inclusion of trademarks in this law. It should be noted that in relation to trademarks, TRIPS requires criminal remedies and border measures only in the case of "wilful" "trademark counterfeiting" on a "commercial scale". The WTO Dispute Settlement Body has distinguished between trademark infringement and trademark counterfeiting, noting that counterfeit trademark goods are defined in TRIPS as those that bear an identical mark or one that cannot be distinguished in its essential aspects from a trademark.<sup>168</sup> This is a far narrower definition than that contained in the Counterfeit Goods Act.

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167. This is already permitted by the common law.

168. Panel Report, China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WT/DS362/R (Jan. 26, 2009).



The concern over the imposition of border measures or even criminal remedies in relation to trademark infringements involving medicines arises from multiple seizures by European customs officials of generic medicines that were on their way from India to Africa and Latin America. One shipment was detained in Frankfurt airport because the customs officials suspected the infringement of GSK's trademark 'amoxil' when they saw the name 'amoxicillin' on an Indian generic medicines shipment. 'Amoxicillin' is in fact the INN for this particular medicine.<sup>169</sup>

Civil trademark disputes are common in the area of pharmaceuticals for precisely this reason. More often than not, companies will use the INN of a medicine to derive their brand names, inevitably ending up with similar names. Roche's Valcyte<sup>®</sup> and Cipla's Valcept<sup>®</sup> both derive their name from valganciclovir, the INN of this medicine used to treat cytomegalovirus, a common HIV co-infection. The WHO has recommended that governments prevent the use of INNs in trademarks and brand names for medicines to ensure that the non-proprietary names do not become proprietary.<sup>170</sup> Although the Medicines Control Council (MCC) follows WHO guidance on the use of INNs in registering brands of medicines,<sup>171</sup> this is likely to remain a common occurrence in the industry. Policymakers may, therefore, wish to consider an amendment to limit the criminal remedies and customs actions to those situations specified in TRIPS, i.e., "wilful trademark counterfeiting on a commercial scale".

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169. *Drug Seizures in Frankfurt Spark Fears of EU-wide Pattern*, IP-Watch, 5 June 2009 available at <http://www.ip-watch.org/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern/>

170. *Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*, World Health Organisation, WHO/ PHARM S/NOM 1570, 1997, available at [http://whqlibdoc.who.int/hq/1997/WHO\\_PHARM\\_S\\_NOM\\_1570.pdf](http://whqlibdoc.who.int/hq/1997/WHO_PHARM_S_NOM_1570.pdf)

171. Section 3.2.7 of the MCC guidance on the 'Proprietary Names for Medicines' states: "As a general principle, proprietary names should not be derived from an INN by deletion or alteration of any component part of the INN or through use of a homophone or near-homophone of an INN". See 'Proprietary Names for Medicines, Medicines Control Council, Department of Health, December 2011, available at [http://www.sacraza.com/files/2%2015\\_Proprietary\\_Names\\_for\\_Medicines\\_Oct11\\_v4.pdf](http://www.sacraza.com/files/2%2015_Proprietary_Names_for_Medicines_Oct11_v4.pdf)



### 3. ANALYSIS OF SOUTH AFRICAN COMPETITION POLICY

#### SUMMARY

*Articles 8, 31 and 40 of TRIPS are the main provisions that apply to the regulation of anti-competitive practices with respect to IP protection. South Africa's Competition Act is relatively young and largely untested in the realm of intellectual property. In theory, the main flexibilities attached to TRIPS (compulsory licensing to remedy anti-competitive practices, the allowance to regulate specific types of abuse of rights that would constitute anti-competitive behaviour) are potentially available to complainants, though the legislation does not expressly recognize such flexibilities.*

*Amendments to the Competition Act that explicitly clarify such flexibilities are one option. Another is to encourage more cases involving intellectual property to be brought to the Competition Commission, by issuing non-binding guidelines that make the task of a complainant clearer. A related intervention would be to make licensing information about intellectual property more transparent, to aid in putting together a complaint, through the increased use of the existing mandatory public register of patent-related licenses under the Patents Act.*

#### 3.1 Overview

The South African Competition Act 89 of 1998 (the Competition Act) came into effect on 1 September 1999. It set up three specialist institutions: the Competition Commission (the Commission), which investigates and ‘prosecutes’;<sup>172</sup> the Competition Tribunal (the Tribunal), which adjudicates; and the Competition Appeal Court.

The stated purpose of the Competition Act is to promote and maintain competition in South Africa in order to achieve the following objectives:<sup>173</sup>

- To promote the efficiency, adaptability and development of the economy;
- To provide consumers with competitive prices and product choices;

172. The Commission also has particular responsibilities in respect of merger control.

173. Competition Act, section 2.



- To promote employment and advance the social and economic welfare of South Africans;
- To expand opportunities for South African participation in world markets and recognize the role of foreign competition in the Republic;
- To ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy; and
- To promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons.

Chapter 2 of the Competition Act deals with ‘prohibited practices’ and chapter 3 addresses ‘merger control’. Chapter 4 outlines the establishment, functions and procedures of the specialist bodies that implement and enforce the Act – the Commission, the Tribunal and the Competition Appeal Court. Chapters 5 and 6 are concerned with investigation and adjudication procedures and enforcement, respectively. Chapter 8 deals with general provisions.

A violation of the Competition Act is established by a violation of one of the several *per se* rules, as outlined further on, or upon evidence of a clear anticompetitive effect. Prohibitions regarding horizontal and vertical restraints are also set out. While merger control is intended to prevent monopolies from forming, the Competition Act regulates the behaviour of existing/sanctioned monopolies (single-firms) through abuse of dominance, rather than simply on the basis of monopoly. Procedures for merger control are generally considered to be detailed.

In 2009, the President of South Africa signed an amendment to the Competition Act into law.<sup>174</sup> Most of the amendment has yet to be brought into force.<sup>175</sup> Once it comes into effect, the amendment will clarify the concurrent jurisdiction of the Commission and other regulatory bodies. It will also address ‘complex monopoly conduct’. Although not specified *per se* as a prohibited practice, complex monopoly conduct has been included to facilitate inquiries by the Commission in situations where, even in the absence of formal agreements between firms, their coordinated conduct results in anti-competitive behaviour. Criminal liability will also be introduced for managers of firms convicted of cartel conduct. This is the most controversial provisions in the 2009 amendment.

The only part of the amendment in force at the time of this paper’s publication – with effect from 1 April 2013 – is a new chapter 4A, which deals with the Commission’s powers to conduct market inquiries.<sup>176</sup> Although the Commission has always been able to conduct inquiries,

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174. Competition Amendment Act, 2009, No. 1 of 2009, Government Gazette, Republic of South Africa, No. 32533, Vol. 530, 28 August 2009.

175. Certain amendments are considered controversial. This is apparently why most of the amendments have yet to be brought into force.

176. Sections 43A–43C of the Competition Act.



without specific provisions it was unable to use its normal powers of investigation in such inquiries. The Commission recently published draft terms of reference for its first market inquiry, into the private health care market. Stakeholders have been afforded the opportunity to comment on the draft terms of reference.<sup>177</sup>

### 3.2 Relevant standards for anticompetitive behaviour

Chapter 2 of the Competition Act, which deals with prohibited practices (restrictive horizontal and vertical practices and abuse of a dominant position is, in the main, constitutive of the relevant standards for anti-competitive behaviour.

Certain horizontal practices – that is, agreements, concerted practices, or decisions by an association of competitors – are ordinarily prohibited if they have the effect of substantially lessening or preventing competition in a market.<sup>178</sup> To justify such practices, implicated firms must show that the negative effects of the conduct are outweighed by any technological, efficiency or other pro-competitive gain. Horizontal agreements such as price fixing, market division and collusive tendering are prohibited *per se*, without requiring a showing of actual harmful effect or permitting a showing of net efficiency.

The competitive effects of vertical agreements are usually complex. Under South Africa's statute, a vertical agreement is prohibited if it has the effect of substantially preventing or lessening competition in a market, unless a party can prove that any technological, efficiency or other pro-competitive gain resulting from that agreement outweighs the anti-competitive effect. Thus finding a violation usually depends on showing an actual anti-competitive effect.<sup>179</sup> The only vertical practice that is prohibited *per se* is minimum resale price maintenance.<sup>180</sup>

Abuse of dominance is dealt with through a list of prohibited practices.<sup>181</sup> The first of these is charging an 'excessive price' that harms consumers. This term is separately defined: an 'excessive price' must have no reasonable relationship to the economic value of the particular good or service in question, and must be in excess of that value. The second prohib-

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177. See Market Inquiry into Private Healthcare: Call for Public Comment, Competition Commission, South Africa, 2013, available at <http://www.compcom.co.za/assets/Healthcare-Inquiry/Alert-New-Date.pdf>

178. Competition Act, section 4.

179. Competition Act, section 5.

180. A supplier may recommend resale prices as long as they are clearly not binding.

181. Competition Act, section 8.



ited practice is refusing a competitor access to an essential facility when it is economically feasible to grant access. The term ‘essential facility’ is also defined – as an infrastructure or resource that cannot reasonably be duplicated and without access to which competitors cannot reasonably provide their customers.

In addition, the Competition Act prohibits ‘exclusionary acts’ by dominant firms. The term is defined as “an act that impedes or prevents a firm entering into, or expanding within, a market”. Two categories of exclusionary acts are prohibited:

- First, the Act prohibits a list of exclusionary acts: requiring or inducing exclusive dealing, refusing to supply scarce goods to a competitor, tying or forcing unrelated contract conditions, selling below marginal or average variable cost, and cornering the supply of intermediate goods needed by a competitor.
- Second, section 8(c) prohibits a general category of exclusionary act “if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain”. In this regard, a dominant firm could avoid liability for exclusive dealing, refusal to supply, tying, predation, cornering or even other unspecified exclusionary acts by showing that the net effect of the conduct on competition in the relevant market is positive.

The Competition Act also prohibits price discrimination: in relation to prices broadly, discounts, rebates, allowances, credits, services, or payment terms, for products or services.<sup>182</sup> Again, market power is a prerequisite – only a dominant firm acting as a seller can be liable. Liability is subject in all cases to a competitive effects test: is the discrimination likely to have the effect of substantially preventing or lessening competition?

Finally, section 10 outlines exemptions in respect of all the identified prohibited practices. Exemptions may be granted upon application if the act(s) or agreement(s) concerned are aimed at fulfilling certain, specific national priorities. In particular, section 10(4) permits firms to apply for exemptions in respect of any agreement or practice regarding the exercise of IP rights. The grant or refusal of such an exemption, which is at the discretion of the Commission, constitutes a reviewable administrative action.

The Competition Tribunal has the power to order a wide range of remedies. These can include enjoining prohibited practices, requiring a respondent to supply another party on terms reasonably required to end a prohibited practice, ordering divestiture, declaring conduct to constitute a prohibited practice in order to establish the basis for a civil action, declar-

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182. Competition Act, section 9.



ing an agreement to be void, or ordering access to an essential facility on reasonable terms. An administrative (financial) penalty may also be imposed in certain circumstances.

In the context of IP-related cases, it is important to note that compulsory licensing is not explicitly listed as an ‘appropriate order’ that the Tribunal might issue in relation to a prohibited practice, though the wording of section 58(1)(a)<sup>183</sup> strongly suggests that the list of orders specified is not exhaustive. In any event, if the prohibited conduct is a refusal to licence, then an order compelling a firm to stop such conduct would, in effect, be an order granting a compulsory licence. Additionally, it appears that the Commission views compulsory licensing as an appropriate remedy.<sup>184</sup>

### 3.3 TRIPS and anti-competitive practices

TRIPS provides some direction as to how WTO member countries may regulate anti-competitive practices related to patented goods. While there is little in the Competition Act that expressly references IP, the guidelines and flexibilities provided by relevant sections of TRIPS are still applicable, whether presently – by interpretive scope – or in the future – by means of express statutory or regulatory inclusion through any amendment. While the latter might be preferable to prevent decisions leading to interpretations that limit access to medicines and the growth of the domestic generic pharmaceutical industry, the fact that few IP-related cases have been considered to date means that the widest flexibilities offered within TRIPS are, at least theoretically, currently available.

#### 3.3.1 Intellectual property and anti-competitive practices

Article 8(1) of TRIPS lays out the broad principle that WTO member countries may exercise sovereign interests related to health, among other concerns, while complying with the text of TRIPS. Article 8(1) can be best understood in the context of the Doha Declaration, which is to say that any interpretation of compliance must favour access to medicines and the betterment of public health. In effect, Article 8(2) links IP to anti-competitive practices, noting that member countries are free to act (as consistent with other sections of TRIPS) to ease impediments to trade and the transfer of technology:

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183. Section 58(1)(a) specifies that the Competition Tribunal may “make an appropriate order in relation to a prohibited practice, including...”

184. Interview with S. Ramburuth and S. Roberts, Competition Commission, 12 October 2007. Interview notes on file with the authors.



Article 8(1). Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 8(2). Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

### 3.3.2 Compulsory licences and anti-competitive practices

Article 31 of TRIPS lays out the procedures and conditions by which patents may be used without the authorization of the rights holder, referring mainly to government use and compulsory licensing. Article 31(k) explicitly provides compulsory licensing or government use as a remedy for anti-competitive practices and places no obligation to negotiate commercial terms with the original rights holder, or restrict supply to the domestic market of the member authorizing such use:<sup>185</sup>

Members are not obliged to apply the conditions set forth in subparagraphs (b)<sup>186</sup> and (f)<sup>187</sup> where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

### 3.3.3 Anti-competitive behaviour and licensing practices with intellectual property goods

Article 40 of TRIPS allows WTO member countries to recognize that licensing practices, as well as other conditions attached to IP, may be anti-competitive. As Article 40(1) provides:

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185. TRIPS conditions on a compulsory license granted as a remedy to anticompetitive practice are much less restrictive than for the same granted under other circumstances (see Chapter 2.6.1).

186. Referring to negotiation on commercial terms.

187. Referring to production for domestic use.



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

Article 40 allows wide sovereign scope in dealing with, and remedying, such behaviour. In particular, Article 40(2) lists a non-exhaustive set of typical licensing practices that would constitute anti-competitive behaviour:

- a) Exclusive grant-back conditions – that is, when the licensor of an innovation requires its licensee to return any improvements made on the innovation licensed back to the licensor, exclusively.
- b) Prevention of challenges to validity – that is, when licensing conditions prohibit any subsequent legal challenge by the licensee to the validity of the intellectual property protection afforded to the innovation in question or a related innovation.
- c) Coercive package licensing, meaning the forced licensing of a pool of patents when, in fact, not all patents might be relevant or necessary to legally bring the invention in question to market.

### 3.3.4 Case studies of competition law and intellectual property

There are only a few cases in South Africa dealing with anti-competitive practice by an IP rights holder, examined below. From beyond South Africa, there are several noteworthy categories of tested anti-competitive behaviour, the most significant and well-documented of which are also recounted here.

As explained earlier, there are a variety of anti-competitive practices tied to IP. For instance, anti-competitive licensing behaviour would include exclusive grant-backs, prevention of challenges to validity, and coercive package licensing. Wilful deception regarding the non-disclosure of prior art when filing a patent application is another possible instance. The cases relayed here, from South Africa and beyond, relate a wide range of anticompetitive practises.

It is worth noting that in countries with weak standards of patentability, the potential to file trivial patents with respect to medicines is usually acted upon. While this in itself may not constitute an anti-competitive practice, weak patent criteria nevertheless encourage anti-competitive conduct.



### 3.3.4.1 Restrictive licensing agreements

A common anti-competitive practice, as related to patented goods, is imposing unreasonable conditions in licensing agreements. Simply put, restrictive licences are those that impose conditions above and beyond what could be considered fair practice in relation to the licensing of the patent. Typically, such restrictive conditions include the licensee signing away the right to challenge the patents related to the licence under question or patents of the licensor in general, and various forms of horizontal or vertical restriction in terms of sales, supply and limits to manufacture.

### 3.3.4.2 Evergreening and frivolous litigation

‘Evergreening’ is a practice commonly observed in the pharmaceutical industry. It is a strategy of extending patent protection on a pharmaceutical compound by filing patent applications for multiple (and often trivial or obvious) attributes of a single drug. According to the European Generic Medicines Association, “[t]hese patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolised by the patient”.<sup>188</sup>

In 2003, the US Federal Trade Commission (US FTC) announced a consent order and decision based on its investigation of three key drugs marketed by Bristol-Myers Squibb (BMS): the anti-cancer drugs Taxol® and Platinol®, and the anti-anxiety agent BuSpar®. Joe Simons, Director of the FTC’s Bureau of Competition, explained:

Through Bristol’s decade-long pattern of alleged anticompetitive acts, Bristol avoided competition by abusing federal regulations in order to block generic entry; deceived the U.S. Patent and Trademark Office to obtain unwarranted patent protection; paid a would-be generic rival over \$70 million not to bring any competing products to market; and filed baseless patent infringement lawsuits to deter entry by generics.<sup>189</sup>

The US FTC order placed several restrictions on BMS relating to licensing and royalties on these three medicines, including a requirement that BMS submit certain future agreements and arrangements for US FTC review. In 2009, the US FTC fined BMS US\$ 2.1 million for

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188. For a detailed explanation of evergreening, see the European Generic Medicines Association definition at <http://www.egagenerics.com/gen-evergm.htm>

189. FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition, US FTC, 7 March 2003; available at <http://www.ftc.gov/opa/2003/03/bms.shtm>



failing to reveal that as part of an agreement with generic manufacturer Apotex, the latter had agreed not to launch the generic version of another drug, Plavix™.

In 2009, the European Competition Directorate General (ECDG) issued the final report of its *Pharmaceutical Sector Inquiry*,<sup>190</sup> which included several findings similar to those of the US FTC. Among the key strategies identified by the report that originator companies use to delay the entry of generic competition are patent filing strategies and litigation.

The report found that the filing of numerous patent applications for the same medicine, (creating ‘patent clusters’ or ‘patent thickets’) was a common practice. Documents gathered in the course of the inquiry confirmed that a key objective of this approach is to delay or block the market entry of generic medicines. The ECDG found that:

In this respect the inquiry finds that individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States . . . When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market. Statements in internal documents collected in the context of the sector enquiry point at the awareness by patent holders that some of their patents might not be strong.

Similar to the US FTC, the ECDG noted that while the enforcement of patent rights is a legitimate right, “litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants”. An analysis of the disputes and litigation related to pharmaceutical patents revealed 1,300 patent-related out-of-court settlements and disputes relating to a sample of 219 molecules between 2000 and 2007. In the European Union, generic companies won 62 percent of the 149 cases in which courts rendered final judgments. The inquiry also found that originator companies mainly invoked secondary patents during litigation.

In South Africa, it is likely that the conduct of BMS and the actions identified by the ECDG would – if challenged – be found to constitute prohibited exclusionary acts, as contemplated by section 8(c) of the Competition Act.

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190. See, *Pharmaceutical Sector Inquiry – Final Report*, Competition DG, European Commission, 2009; available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)



### 3.3.4.3 Patent settlements and 'pay-for-delay' arrangements

Patent holders and generic companies sometimes enter into agreements or settlements that include 'pay-for-delay' provisions. These arrangements are characterized by an agreement by the patent holder to compensate a generic competitor in return for the latter's agreement to refrain from entering the market for a period of time.

In 2013, the US FTC published a review of all patent settlements between originator and generic companies effected from 1 October 2011 to 30 September 2012. The review found a significant increase in the number of settlements that featured pay-for-delay arrangements.<sup>191</sup> The settlements involved 31 branded pharmaceutical products with a combined annual sale in the United States of US\$ 8.3 billion. Reacting to this finding, the US FTC stated in a press release:

Sadly, this year's report makes it clear that the problem of pay-for-delay is getting worse, not better. More and more brand and generic drug companies are engaging in these sweetheart deals, and consumers continue to pay the price. Until this issue is resolved, we will all suffer the consequences of delayed generic entry – higher prices for consumers, businesses, and the U.S. taxpayer.<sup>192</sup>

The US FTC has filed multiple cases requesting US courts to strike down these arrangements. These challenges have met with mixed results. In a move that gave definition to a landscape of conflicting judicial approaches, the US Supreme Court finally decided 5-3 to authorize the federal government to investigate pay-for-delay deals and 'reverse payment settlements'.<sup>193</sup>

The ECDG's report similarly focused on patent settlements as a key area for monitoring. The ECDG found multiple instances of patent settlements in the context of litigation, out-of-court settlements and patent opposition proceedings. The inquiry found:

In approximately half of the settlements in question the generic company's ability to market its medicine was restricted. A significant proportion of these settlements contained – in addition to the restriction – a value transfer from the originator company to the generic company, either in the form of a direct

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191. Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2012, A Report by the Bureau of Competition, 2013, available at <http://ftc.gov/os/2013/01/130117mmareport.pdf>

192. Federal Trade Commission, FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market, Press Release, 17 January 2013, available at <http://ftc.gov/opa/2013/01/mmarrpt.shtm>



payment or in the form of a licence, distribution agreement or a “side-deal”. Direct payments occurred in more than 20 settlement agreements and the total amount of these direct payments from originator companies to generic companies exceeded € 200 million.

The report identified the monitoring of these settlements as a key component of the ECDG’s work going forward. In 2011, the European Commission initiated formal antitrust proceedings against Johnson & Johnson and Novartis on the issue of whether the contractual arrangements entered into by their subsidiaries may have had the intent to, or had the effect of, hindering entry of generic fentanyl (a strong pain killer) into the market in the Netherlands.<sup>194</sup> In 2013, the European Commission sent its statement of objections to both companies regarding the ‘co-promotion’ agreement entered into by their subsidiaries.<sup>195</sup>

### 3.3.5 Anti-competitive acts tied to patents in South Africa: case studies

#### 3.3.5.1 Excessive pricing

In September 2002, a group of concerned individuals and organizations – led by the TAC – lodged a complaint with the Competition Commission against certain pricing practices of the pharmaceutical companies GSK and Boehringer Ingelheim (BI). The AIDS Law Project, now known as Section 27, represented the complainants. The basis of the complaint was excessive pricing in respect of certain patented ARV medicines produced and marketed by these firms.<sup>196</sup> It was framed within the context of South Africa’s particular HIV epidemic, drawing attention to the constitutional right to have access to medicines and its impact on the interpretation and implementation of the Competition Act.

The complaint was launched at a time when the South African Government had not yet committed itself to implementing a public sector ARV treatment programme. This meant that the

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193. See, Supreme Court Lets Regulators Sue Over Generic Drug Deals, The New York Times, 17 June 2013, available at [http://www.nytimes.com/2013/06/18/business/supreme-court-says-drug-makers-can-be-sued-over-pay-for-delay-deals.html?\\_r=0](http://www.nytimes.com/2013/06/18/business/supreme-court-says-drug-makers-can-be-sued-over-pay-for-delay-deals.html?_r=0)

194. European Commission, *Anti-Trust: Commission Opens Proceedings Against Johnson and Johnson and Novartis*, Press Release, IP/11/1228, 21 October 2011 available at [http://europa.eu/rapid/press-release\\_IP-11-1228\\_en.htm](http://europa.eu/rapid/press-release_IP-11-1228_en.htm)

195. European Commission, *Antitrust: Commission sends Statement of Objections to J&J and Novartis on delayed entry of generic pain-killer*, Press Release, IP/13/81, Brussels, 31 January 2013 available at [http://europa.eu/rapid/press-release\\_IP-13-81\\_en.htm](http://europa.eu/rapid/press-release_IP-13-81_en.htm)

196. The medicines in question were GSK’s AZT and lamivudine (and combinations) and BI’s nevirapine.



use of ARVs to treat HIV infection was largely limited to the private sector – either bought directly (out of pocket), provided by an employer or covered through a medical scheme (insurance). While the complaint focused on private sector prices, the complainants were intent on reducing the public and private sector prices of ARVs sold in South Africa.

The complaint took a strategic approach to establishing excessive pricing by claiming that even after allowances for reasonable profits, licensing costs and research and development expenditure, evidence of prohibited excessive pricing existed.<sup>197</sup> The strategy also hinged on establishing a case that would require GSK and BI, were the matter to be heard by the Tribunal, to publicly justify their pricing practices. Given the considerable uncertainty as to how such a complaint would be handled by the Tribunal, which at that time had yet to consider any excessive pricing complaint at that stage,<sup>198</sup> and given the urgent treatment needs, it was understood that the complaint would be pursued in a manner that was likely to force GSK and BI to the negotiating table.

In October 2003, the Commission decided to refer the case to the Tribunal for adjudication, stating:<sup>199</sup>

The Competition Commission has found that pharmaceutical firms GlaxoSmith-Kline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) have contravened the Competition Act of 1998. The firms have been found to have abused their dominant positions in their respective anti-retroviral (ARV) markets.

In particular the Commission has found the firms have engaged in the following restrictive practices:

1. Denied a competitor access to an essential facility
2. Excessive pricing
3. Engaged in an exclusionary act

The Commission has decided to refer the matter to the Competition Tribunal for determination.

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197. See Avafia et al supra note 141 at pp. 29–31.

198. The Tribunal has since had an opportunity to consider the prohibition on excessive pricing in section 8(a) of the Competition Act. That decision was overturned by the Competition Appeal Court in *Mittal Steel South Africa Limited and Others v. Harmony Gold Mining Company Limited and Another* [2009] ZACAC 1 (29 May 2009). While the Competition Appeal Court decision helps us to understand the meaning of section 8(a), it does not address excessive pricing in the context of patented products.

199. See Competition Commission, Competition Commission finds pharmaceutical firms in contravention of the Competition Act, Media Release, 16 October 2003, available at [http://www.tac.org.za/newsletter/2003/ns16\\_10\\_2003.htm](http://www.tac.org.za/newsletter/2003/ns16_10_2003.htm)



Meanwhile, settlement negotiations had begun prior to the Commission announcement. By December 2003, not two months after the case had been referred to the Tribunal, both GSK and BI had entered into settlement agreements with the complainants. The agreements effectively allowed for multiple, non-exclusive and low-royalty licences for the production and/or importation of the ARVs by generic companies in South Africa, and granted permission to sell domestically (in both public and private sectors) and export (in respect of locally produced products) to all other countries in sub-Saharan Africa.<sup>200</sup>

### 3.3.5.2 Refusal to license

In November 2007, the AIDS Law Project, again acting on behalf of the TAC, filed a complaint at the Commission against MSD, the South African subsidiary of the international pharmaceutical giant Merck (and related entities), for “refusing to license other firms to import and/or manufacture generic versions of [efavirenz] on reasonable and non-discriminatory terms”.<sup>201</sup>

The legal basis for the complaint was outlined thus:

In refusing to license on reasonable and non-discriminatory terms, the respondents have – without good cause – threatened access to comprehensive treatment for HIV/AIDS in both public and private sectors, and in doing so have engaged in exclusionary acts where the anti-competitive effects of those acts outweigh their technological, efficiency or other pro-competitive gains, as prohibited by section 8(c) of the Competition Act 89 of 1998.<sup>202</sup>

The complaint was limited to efavirenz (EFV), an ARV medicine that was (and still is) procured by the State for use in the public sector to treat people living with HIV. EFV is also widely used for the same purpose in the private sector.

The argument in the legal submission followed this approach:

- Establishing dominance;
- Establishing abuse of dominance;

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200. The settlement agreements are available in full at: [http://www.tac.org.za/newsletter/2003/ns10\\_12\\_2003.htm](http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm)

201. Legal Submission, In the complaint submitted by Treatment Action Campaign, Concerning the conduct of MSD (Pty) Ltd, MERCK & CO., INC. and related companies, In the Competition Commission of South Africa, p.1. The complete complaint, including the Legal Submissions is available at <http://www.tac.org.za/community/node/2127>

202. Ibid.



- The manner in which the Commission should conduct the investigation; and
- The relief the Commission should pursue in the event that the case is referred to the Tribunal.

The abuse of dominance argument covered vast ground to consider how a refusal to license in this case might be a prohibited exclusionary act as contemplated by section 8(c) of the Competition Act:

Given that the aim of section 8 is to advance consumer welfare, which in this instance is ensuring access to a sustainable supply of a wide range of affordable EFV products, the question to ask in interpreting and applying the section is whether sufficient reason has been advanced, in the circumstances, for depriving the respondents of their exclusive rights in the IP concerned. In other words, can the respondents justifiably be ordered to license other firms – on reasonable and non-discriminatory terms – to import and/or manufacture generic versions of these medicines in circumstances where –

- a refusal to license on such terms results – or has the strong potential to result – in the negative impact on consumer welfare as set out in the statement of complaint;
- the respondents are on record stating that they are in any event selling their ARV medicines at cost; and
- the respondents appear unlikely to suffer any real harm if they were to be compelled to license?

In June 2008, TAC announced that the Commission had decided not to refer the complaint to the Tribunal after MSD had taken corrective measures to ensure that its conduct was no longer anti-competitive.<sup>203</sup> TAC revealed that according to the records of their legal representative and correspondence with the Commission, MSD had:

- Licensed four generic drug companies – two local producers and two local importers – to bring stand-alone EFV products to market;
- Agreed that all four licensees are entitled to bring co-packaged products containing EFV to market;
- Agreed that all four licensees will not unreasonably be refused consent to bring co-formulated products containing EFV to market;

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203. TAC complaint increases access to efavirenz: MSD finally agrees to grant licenses on reasonable terms, 1 June 2008 available at <http://www.tac.org.za/community/node/2329>



- Agreed that all licensed products can be sold to both public and private sectors in South Africa and 10 other southern African countries (Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Mauritius, Namibia, Seychelles, Swaziland and Zimbabwe); and
- Waived any right to a royalty.

TAC agreed with the Commission that based on these developments there was no reason to refer the complaint to the Tribunal. According to TAC:

In practical terms, this means that there are now a sufficient number of competitors to ensure that EFV prices are kept as low as is reasonably possible. It also means that the public sector, which until relatively recently was paying 64 cents in every rand spent on first-line ARV treatments for EFV alone, can now choose to procure from up to five suppliers. This fact also means that we no longer have concerns regarding the sustainability of ex-manufacturer supply.

Without these MSD licences, generic companies would not have been able to register EFV-containing fixed-dose combination products that form the backbone of HIV treatment. At the time, patent protection of EFV was the only IP barrier to such generic fixed-dose combinations coming to market. The price reductions, particularly in the case of the combinations, were expected to be – and in fact have been – substantial. At the time, MSD’s version of TDF/FTC/EFV, marketed as Atripla®, was available at the patentee’s global best price of US\$613 per patient per year.<sup>204</sup> Most recently, South Africa’s Department of Health has procured generic TDF/FTC/EFV for as low as US\$120 per patient per year.<sup>205</sup>

### 3.3.5.3 Market concentration as a result of acquisitions and mergers

On at least two occasions, the Commission has had to consider the impact of mergers in the pharmaceutical sector on access to HIV-related medicines.

In 2000, the international merger of Glaxo Wellcome PLC (Glaxo) and Smithkline Beecham PLC (SKB), as it affected the South African market, came before the Commission.<sup>206</sup> The

204. This is still the best price at which Merck sells Atripla in “98 access countries”. See <http://www.merckresponsibility.com/focus-areas/access-to-health/hiv/hiv-pricing-policies/home.html>

205. Contract Number HP13-2013ARV PROVISION OF ANTI-RETROVIRAL MEDICINES TO THE DEPARTMENT OF HEALTH. PERIOD: 1 January 2013 TO 31 December 2014. Available at <http://www.doh.gov.za/docs/contracts/2013/HP132013ARVReplace.pdf>

206. Competition Tribunal Republic Of South Africa, In The Matter Between Glaxo Wellcome Plc and SmithKline Beecham Plc And the Competition Commission, Case Number: 58/Am/May00, 28 July 2000, available At <Http://Www.Comtrib.Co.Za/Assets/Uploads/Case-Documents/58amay00.Pdf>



Commission initially prohibited the merger, on the basis that the merged entity would have a high market share in two therapeutic categories. When the companies agreed to license the implicated medicines, the Commission agreed to a consent order reflecting this arrangement and placed it before the Tribunal for approval. The Tribunal identified a third category of therapeutic products where the merger could harm competition.

The Tribunal relied heavily on the approach and findings of the European Commission, which had previously considered the same merger. After determining that both companies were involved in research, development and manufacture in the pharmaceutical sector, the Tribunal determined that, “the merger will result in overlaps in a number of therapeutic categories for human pharmaceuticals”.

The Tribunal adopted the Anatomical Therapeutic Chemical Classification (ATC) level 3 to define the relevant market – an approach that will likely affect future mergers. As noted by the Tribunal:

“[T]his is the classification commonly used by competition authorities around the world, especially the European Commission, in defining markets for pharmaceutical products. The ATC classification is a hierarchical classification with 16 categories. Each category has four levels, the first level is the most general and the fourth level is the most specific. In the third level (ATC 3) products are classified into therapeutic categories in terms of their intended use. Each therapeutic category constitutes a market.

It is important to note that the ATC3 level “is generally used as the starting point for investigating and defining relevant product markets [in the pharmaceutical sector] in competition cases”. As the European Commission noted in the Teva/Barr merger:<sup>207</sup>

[I]t is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition.

With the ATC3 level in mind, the therapeutic categories where the merged entity – to be known as GlaxoSmithKline (GSK) – would have a significant market share were identified as “anti-virals (excluding anti-HIV) (J5B), topical anti-biotics (D6A) and anti-emetics (A4A)”.<sup>208</sup>

207. Case No COMP/M.5295 at paragraphs 10–11.

208. As part of the agreement, SmithKline Beecham undertook to out-license *granisteron* in the anti-emetics category and *famciclovir* in the anti-virals category. Glaxo Wellcome undertook to out-license *polysporin*, *cicatin* and *neosporin* in the topical antibiotics category.



As the Tribunal heard the matter, TAC filed submissions on the impact of the merger on the availability of HIV-related medicines, which were not included within the anti-virals segment. TAC requested the Tribunal to approve the merger only on the condition that generic competition was allowed for all HIV medicines produced by the two companies.

However, the Tribunal determined that the companies did not compete in the HIV therapeutic sector. It further concluded that in the one area in relation to opportunistic infections where they did compete (anti-emetics), licencing had already been agreed. The Tribunal agreed with the Commission and did not impose any additional conditions with respect to HIV-related medicines.

In 2009, conditions were also imposed on GSK South Africa's acquisition of 16 percent stock in Aspen Pharmacare Holdings Ltd.<sup>209</sup> The acquisition, which made GSK the single largest shareholder in Aspen and fell within the Competition Act's definition of a merger, was scrutinized by the Commission, which "considered the likely effects of this merger under current market conditions as well as on potential competition in the future".

TAC, the Centre for the AIDS Programme of Research and the Southern African HIV Clinicians Society, assisted by the AIDS Law Project, made submissions to the Commission urging it to pay close attention to the impact of the merger on generic competition for the ARV medicine abacavir. TAC pointed out that Aspen was a "natural competitor" to GSK and would have normally entered the generic market for abacavir. Now it would be the preferred licensee for GSK to the detriment of other generic producers. TAC recommended that generic competition for abacavir be a condition of the merger.

Agreeing with TAC's submission, the Commission required GSK, "to grant licences, on a non-exclusive basis, to Adcock Ingram, Cipla Medpro, Ranbaxy, Biotech Laboratories and Feza Pharmaceuticals and any other interested generic manufacturer for the manufacture and/or import of Abacavir, on terms and conditions no less favourable than those granted to Aspen".<sup>210</sup> The Competition Commission's actions mirrors actions by the US and EU competition authorities which, in several cases of mergers and acquisitions, have also required the licencing of IP to prevent market concentration.

In terms of the impact of the merger on future competition, the Commission determined that several of GSK's medicines would go off-patent in the coming years and there would be sufficient generic competition. The Commission's press release noted that "the Commission

209. Competition Commission, Competition Commission approves pharma merger on condition that Abacavir is out-licensed to generic manufacturers, Press Release, 2 September 2009.

210. Emphasis added. The five identified companies were the beneficiaries of the licences granted by GSK pursuant to the settlements in the 2002 excessive pricing complaint.



was particularly concerned with this aspect in the light of the effective competition that the generic drug manufacturers are increasingly providing to patent manufacturers”.

The experience of TAC in these merger cases is particularly illuminating. For instance, TAC’s submissions on GSK’s acquisition of the stake in Aspen highlighted the fact that TAC did not have access to the competition analysis or to the licensing arrangement between GSK and Aspen relating to abacavir. In the absence of this information, TAC was at a disadvantage in offering “an informed submission”.

## 3.4 Policy options related to ensuring competition

### 3.4.1 Amendments to the Competition Act

One option is to amend the Competition Act to take cognizance of experience from recent cases and make full use of TRIPS flexibilities, especially as expressed in Articles 31 and 40 of TRIPS. It must be noted that the Commission is not currently considering amendments to the Competition Act, and instead, is interested in building the number and range of cases that it handles.<sup>211</sup>

Drawing on the experience of the GSK and BI complaints, it has been suggested that “the complainants had to deal with complex issues (such as market definition and the establishment of dominance) in the absence of limited statutory (and no regulatory) guidance and without being able to rely on the financial and institutional resources that were within the grasp of their corporate counterparts. With each hurdle, the odds of a successful challenge for the exposure of unjustifiable pricing practices were lowered”.<sup>212</sup>

Accordingly, a summary of potential amendments to the Competition Act include:

- Clarifying the interface between competition law and intellectual property through policy guidelines;
- Explicitly incorporating compulsory licensing and other licensing options as a statutory remedy to anti-competitive practice, in accordance with Article 31 of TRIPS; and
- Explicitly incorporating anti-competitive licensing and contractual practices as prohibited by statute, in accordance with Article 40 of TRIPS.

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211. Interview with S. Ramburuth and S. Roberts, Competition Commission, 12 October 2007. Notes of the interview on file with the authors.

212. See Avafia et al supra note 141 at pp. 36–38.



### 3.4.2 Amendments to the Patents Act

Related to potential amendments to the Competition Act – but also distinct – would be the option to amend the Patents Act to take full cognizance of flexibilities afforded by Articles 31 and 40 of TRIPS, in the spirit of the Doha Declaration, and as already detailed in policy suggestions to the South African patent system (see Chapter 2).

### 3.4.3 Growing the number cases involving IP and health

Another option to clarify the Competition Act would be to create the circumstances in which more complaints related to IP and health are brought to the Commission for investigation.

### 3.4.4 Making patent-related licences transparent

A significant barrier to bringing a complaint against restrictive licensing practices is the typical secrecy by which licences are negotiated and undertaken. In the absence of information as to what the details of medicine-related licences are, and even as to whether licences exist in some cases, it is virtually impossible to exercise the flexibilities inherent in Article 40 of TRIPS.

One innovative mechanism to create transparency in licensing is to create a mandatory public register of patent-related licences. Section 21(1)(a) of the Competition Act lays out a rationale by which such a mechanism may be instituted: “The Competition Commission is responsible to ... implement measures to increase market transparency”. That, however, may not be necessary given what is already contained in the Patents Act and the Patent Regulations, 1978.

The Patents Act requires the registration of patent-related licences. Section 10 requires the maintenance of a register with such details, including copies of all deeds and licences as may be prescribed by regulations. Form P2 – to which Regulation 4 refers and is contained in Schedule 2 to the Patent Regulations – specifies the information to be provided for the registration of a patent, and includes details of licences. Regulation 5 requires the Patent Office to maintain, in alphabetical order, assignees of patents or patent applications, registered licensees and hypothec holders on the patent register.

Regulation 62 requires a licence against a patent to be recorded within six months of the signing of the licence or of the grant of the patent if the licence agreement was signed earlier.



Section 12 of the Patents Act requires the Patent Register as well as any document kept at the Patent Office to be open for public inspection on the payment of prescribed fees. Section 13 of the Patents Act further requires the Registrar to provide information to any person on request and on payment of the prescribed fees. However it is unclear whether the requirement for the registration of licences is strictly followed and whether the patent register is publicly available in reality. The online patent search provided by CIPC does not include information on licensees or copies of the licences.

A working example of a similar mechanism with greater safeguards to serve the public interest is found in Thailand, where all patent-related licences are required to be filed in a public register and examined prior to acceptance for anti-competitive measures, if any, in which case the licence will be rejected. A failure to file licences can result in revocation of the patent.<sup>213</sup> Alternatively, even the current South African system – were it to be properly implemented – would aid in the process by which potentially anti-competitive, restrictive licensing practices could be curbed in South Africa.

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213. For more information, see the Thailand Patent Regulations, available at [http://www.jpo.go.jp/shiryoku\\_e/sonota\\_e/fips\\_e/pdf/thailand/patents\\_regulations.pdf](http://www.jpo.go.jp/shiryoku_e/sonota_e/fips_e/pdf/thailand/patents_regulations.pdf); for an explanation, see [http://www.tillekeandgibbins.com/Publications/Articles/ip\\_registration/patent\\_th.htm](http://www.tillekeandgibbins.com/Publications/Articles/ip_registration/patent_th.htm)



## 4. ANALYSIS OF MEDICINES REGULATION

### SUMMARY

*Article 39.3 of TRIPS – which relates to the protection of pharmaceutical test data against unfair commercial use – is the primary trade rule that affects medicines regulation. South Africa is generally thought to both comply with Article 39.3 and take advantage of the flexibility inherent in that trade rule by following a system of ‘data protection’ rather than ‘data exclusivity’. However, while taking advantage of this TRIPS flexibility in a minimum way, the medicines regulatory system in South Africa could potentially do much more to safeguard against barriers raised by the drug registration process.*

*By addressing the manner in which data is requested and examined, and leveraging international certification and drug approval, it is possible to expand the routes and means towards marketing approval for drugs, without compromising safety. By providing additional flexibilities and options in the medicines regulatory system – including explicit fast-tracking that is bound by short timelines – acknowledged delays in the drug registration process could be shortened, while also easing human-resource capacity constraints and significantly reducing the backlog of pending applications for approval, thus ultimately benefiting patients and the domestic pharmaceutical industry as a whole.*

### 4.1 Overview of Medicines Regulation

The Medicines Control Council (MCC) is the focal point for medicines regulation in South Africa. The MCC is a statutory body that was established under the Medicines Act. Consistent with its statutory mandate, the MCC defines its purpose as ensuring that medicines sold and used in South Africa are “safe, therapeutically effective and consistently meet acceptable standards of quality”.<sup>214</sup>

The MCC consists of a council of 24 experts who meet on average every two months, supported by a number of expert committees. Council members also sit on, and usually chair, expert committees. Data sets, or dossiers of clinical data submitted at the time of drug registration, are evaluated by experts from the medical and pharmacy academies, who form the bulk of the membership of the MCC’s committees.

214. See <http://www.mccza.com/>



The Registrar of Medicines, as the executive secretary of the MCC, is assisted by a team who together constitute the cluster: Pharmaceutical & Related Product Regulation and Management. The cluster, in turn, consists of four directorates: Operations and Administration, Inspectorate and Law Enforcement, Clinical Evaluations and Trials, and Medicine Evaluation and Research. In the course of its functions, the cluster performs a certain amount of technical evaluation of generic medicine applications in-house.<sup>215</sup>

## 4.2 What aspects of TRIPS are relevant to medicines regulation?

Medicines regulation is affected, in the main, by Article 39.3 of TRIPS, which prescribes the protection of clinical test data submitted to a national drug regulatory authority.<sup>216</sup>

With respect to pharmaceuticals, Article 39.3 states:

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

Compliance with Article 39.3 requires a careful evaluation of the wording of this trade rule, as there is some debate whether to ‘protect ... against unfair commercial use’ implies an exclusive right similar to IP (resulting in ‘data exclusivity’) or merely requires non-disclosure and confidentiality (resulting in ‘data protection’). Prevailing legal opinion on Article 39.3 of TRIPS suggests the latter,<sup>217</sup> meaning that:

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215. Ibid.

216. It is important to note here that Article 39.3 also applies to test data submitted for the approval of agrochemicals. However, this paper considers only the pharmaceuticals aspect of Article 39.3.

217. Carlos Correa, Protecting test data for pharmaceutical and agrochemical products under Free Trade Agreements, UNCTAD-ICTSD Dialogue, Bellagio, December 2004. Correa asserts that “Test data must be protected under the discipline of unfair competition, as established in the Paris Convention for the Protection of Industrial Property (article 10bis) and the TRIPS Agreement (article 39.1). Under such discipline no exclusive rights are granted, but only the right to take legal action against whom has obtained a commercial advantage by means of a dishonest practice”. (p. 4)



- (A) Clinical test data need be protected only if –
- a) submission of such data is required by the national pharmaceutical regulator;
  - b) the data pertains to a new chemical entity (NCE);
  - c) the data requires considerable effort to create; and
  - d) the data is undisclosed, i.e., previously unpublished and not available publicly.
- (B) Provided the conditions in (A), clinical test data must be protected against –
- a) unfair commercial use; and
  - b) disclosure; excepting in situations where to protect the public, but only so long as unfair commercial use is still protected.
- (C) Notwithstanding obligations in (B), ‘unfair commercial use’ does not apply to a national regulator carrying out its statutory duty, such as seeking limited or abbreviated information from drug manufacturers, or granting marketing approval to generic drugs based on an earlier approved product, as this would not be considered a dishonest commercial practice or an unfair ‘use’.

For the purposes of this paper, the flexibility inherent in Article 39.3 of TRIPS would be to implement a system that protects data rather than a system that creates exclusive rights in data. The former has been shown to create a fair and practicable environment for pharmaceutical industry competition by not placing any further barrier to the entry of generic medicines (over and above the barriers that patents and anti-competitive practices already place). The latter, as extensively documented,<sup>218</sup> can further delay the entry of generics, and is therefore not in the interests of consumers or domestic pharmaceutical producers in the developing world.

South Africa is generally considered to be compliant with Article 39.3 of TRIPS. Other than an early US Trade Representative complaint charging South Africa with violating Article 39.3 of TRIPS by the MCC’s approval of generic Paciltaxel (which began with industry complaints in 1997 and contributed to South Africa’s appearance on the watch list of the US Trade Representative’s Special 301 Review in 1999<sup>219</sup>), South African law and practice have rarely been questioned in multilateral forums. Indeed, South Africa had been dropped from the watch list (and merited no mention in) the US Trade Representative’s Special 301 Review in 2000.<sup>220</sup>

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218. For a relatively comprehensive list of reports and studies, see: <http://www.cptech.org/ip/health/dataexcl/>

219. For a timeline of the Paciltaxel data dispute in South Africa, see: <http://www.cptech.org/ip/health/taxol/taxol-timeline2001.html>

220. Archived from the USTR at <http://www.keionline.org/ustr/2000special301>



Section 34 of the Medicines Act provides:

No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer.

However, while ensuring compliance with Article 39.3 of TRIPS, section 34 of the Medicines Act vastly exceeds its mandate by seemingly requiring all of the functions of the Department of Health and the MCC to be carried out in confidentiality and secrecy – a requirement that conflicts with the necessarily public nature of much of the information that they handle, especially when it comes to patient concerns regarding the registration status of urgently needed pharmaceuticals.

The *General Information Guidelines* issued by the MCC clarify that to use such confidential information in the course of performing statutory functions, within the MCC, is not considered a breach of non-disclosure as outlined in section 34 of the Medicines Act.<sup>221</sup> This implies that such data as may be submitted regarding a particular drug to the MCC may be relied upon to approve subsequent generic versions of the same drug.<sup>222</sup>

## 4.3 The process of drug registration in South Africa

The MCC's broad function is to decide whether medicines are suitable for their intended purpose, by examining the relative risks and benefits, and deciding whether the risk is outweighed by the benefits. Section 1 of the Medicines Act defines a medicine as:

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221. General Information, Medicine Control Council, Department of Health, Republic of South Africa, available at <http://www.kznhealth.gov.za/research/mccinfo.pdf>

222. “The confidentiality of information submitted to the MCC is governed by Section 34 of the Act. The MCC, committee members or staff of the [cluster], may NOT disclose to any person, any information acquired in the exercise of powers or performance of functions under the Act and relating to the business affairs of any person, except

- for the purpose of exercising his/her powers, or for the performance of his/her functions under the Act, or
- when required to do so by any competent court or under any law, or
- with the written authority of the Director-General, or
- use such information for self-gain or for the benefit of his employer”. Section 2.3, Ibid.



As any substance or mixtures of substances used or purporting to be suitable for use of manufacture or sold for use in:

- a) diagnosis, treatment, mitigation, modification, or prevention of a disease, or abnormal physical or mental state, or the symptoms thereof in man, or
- b) restoring, correcting, or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

In the standard procedure, which is subject to three exceptions discussed below, any new drug application to the MCC must be accompanied by a full dossier of test data, including pre-clinical and clinical studies, and information related to prior approvals in other legislations and clinical reports.<sup>223</sup> Typically, clinical trials and ensuing studies are only carried out by originator pharmaceutical companies, and thus the standard procedure applies mainly to this category of firm. According to the Department of Health, standard review can take from anywhere between two and three years.<sup>224</sup>

It is important to note that not all medicines require registration. Section 14 of the Medicines Act outlines the MCC's role in determining which medicines require registration. In particular, section 14(2)(a) provides:

The council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.

The inclusion of Section 14 can largely be attributed to the fact that the Medicines Act came into force in 1965 and had to contend with a vast number of previously used, but unregistered, drugs.

The first level of exception to the standard procedure is known as the 'Abbreviated Medicine Review Process'.<sup>225</sup> No fixed timeline is attached to Abbreviated Medicine Review, but indications are that in practice it takes between one and two years. The Abbreviated Medicine Review Process is applicable only if:

- The drug under consideration is a new chemical entity;

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223 See General Information, Clinical, Pharmaceutical and Analytical Guidelines attached to the MCC, available at <http://www.kznhealth.gov.za/research/mccinfo.pdf>

224. Interview with Dr Anban Pillay, Department of Health, 10 October 2007. Interview notes on file with the authors.

225. Supra note 222.



- The new chemical entity has been previously approved in a country whose drug regulatory authority is recognized and the MCC “aligns itself” with;<sup>226</sup>
- The application is identical to the application made in the country of prior approval, and authorization to sell in that other country was granted less than three years ago; and
- Correspondence between the MCC and the drug regulatory in the aligned country is permitted and authorized by the applicant.

The second level of exception to the standard procedure is an expedited review as contemplated by section 15 of the Medicines Act (read together with regulation 5 of the General Regulations to the Medicines Act). Reference to this process is made in item 6 of the General Information Guidelines issued by the MCC.

Section 15(2)(b) of the Medicines Act outlines the conditions under which a drug application may be considered for expedited review:

The Registrar shall ... ensure that such an application in respect of medicine which appears on the latest Essential Drug List or medicine which does not appear thereon but which, in the opinion of the Minister, is essential for national health is subject to such procedures as may be prescribed in order to expedite the registration.

Regulation 5 of the General Regulations clarifies the timeline for expedited review:

The Council shall, within nine months from the date of receipt of the application by the registrar, make a decision with regard to the application and inform the applicant of such decision.

The third level of exception is a waiver of any or all of the statutory requirements for the use of a medicine in South Africa, as well as authorizations to use unregistered medicines. In general, there are no timelines associated with these procedures, as submission requirements are partially or wholly waived, sometimes pending registration, at any stage. Theoretically, therefore, such waivers can be effective immediately as desired. The waivers, in general, are possible through four means:

*(i) Personal consumption*

Persons entering into and departing from South Africa may use unregistered medicines in small quantities as long as they are prescribed for treatment and documented proof of that

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226. “The Council aligns itself with the following regulatory authorities: USA (FDA), UK (MHRA), Sweden (MPA), Australia (TGA), Canada (Health Canada), European Union (EMA) and Japan (MWH). Members of the PIC/S (Pharmaceutical Inspection Co-operation Scheme) for quality matters relating to GMP”, Section 3.1.4, supra n. 222.



prescription is available on hand. Personal use does not require permission, as suggested by section 35(xxii) of the Medicines Act and regulation 16, which provides that “any person entering or departing from the Republic may be in possession, for personal medicinal use, of a quantity of a Schedule, 3, 4, 5 or 6 substance, which shall not exceed a quantity required for use for a period of one month”.

*(ii) Authorized sale of unregistered medicines*

According to section 21 of the Medicines Act, “Council may authorize sale of unregistered medicine for certain purposes:”

1. The council may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine which is not registered.
2. Any medicine sold in pursuance of any authority granted under sub-section (1) may be used for such purposes and in such manner and during such period as the council may in writing determine.
3. The council may at any time by notice in writing withdraw any authority granted in terms of sub-section (1) if effect is not given to any determination made in terms of sub-section (2).

Although not intended for this process, section 21 could theoretically be used to bypass registration backlogs. In practice, however, it is used to secure access to new chemical entities that have been registered elsewhere and are not yet available in South Africa; it is ordinarily not used to provide access to more affordable generic products. Permission is only granted on a named patient or institution basis. The process is usually quick, but has to be repeated every six months in respect of each patient or institution.<sup>227</sup>

*(iii) Exemption from the Medicines Act*

Section 36 of the Medicines Act authorizes the Minister of Health to suspend all or any aspects of the Medicines Act in relation to a particular medicine, provided the MCC unanimously recommends that he or she does so. This provision is likely to be used in sudden health emergencies, but could also be applied to situations where, for any reason, an unregistered drug (whose safety has been validated in a country whose drug regulatory authority is recognized by and aligned with the MCC) is urgently required in the private or public sectors in South Africa. Section 36 provides:

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227. See Nathan Geffen et al., Accessing life-saving medical technologies for HIV, Treatment Action Campaign, June 2007; available at <http://www.tac.org.za/documents/AccessingEssentialMedicalTechnologiesFINAL-20070625.pdf>



The Minister may, on the unanimous recommendation of the members present at any meeting of the council, by notice in the Gazette exclude, subject to such conditions as he may determine, any medicine from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

*(iv) Parallel importation of patented drugs*

Among other things, section 15C of the Medicines Act empowers the Minister to authorize the parallel importation of any medicine:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

Further detail is provided in regulation 7 of the General Regulations to the Medicines Act. Although the statute is silent on the issue of which medicines may be imported, regulation 7 makes it clear that parallel importation only applies to medicines that are under patent in South Africa. Counter intuitively, this would prevent the importation of cheaper medicines if the medicines were not under patent in South Africa. The rationale for such differential treatment is unclear, in particular given that section 15C(b) makes no mention of patent status. Accordingly, the regulation may be unlawful. It appears to assume – without any basis – that once a patent has expired, there will be sufficient generic competition to keep medicine prices in check.



Lastly, an important and additional level of review exists for applications pertaining to a generic drug. Regulation 2 of the Medicines Regulations outlines the requirements for therapeutic equivalence that need be in place for the MCC to approve a generic version of a compound it has previously approved.

The application requirements for manufacturers of such generics are abbreviated to:

- Bio-equivalence establishment;
- Bio-availability studies; and
- Pharmaceutical equivalence proof.

Additionally, the timeline for generic drug approval at the MCC is estimated by the Department of Health to be in the region of 18 months.<sup>228</sup> The vast majority of applications considered by the MCC relates to generics.

#### 4.4 Limitations to the current drug registration process in South Africa

Several aspects of medicines regulation and control in South Africa have attracted criticism from stakeholders. Medicine registration timelines, poor communication and the delays in clinical trial approvals have all been identified as problem areas.<sup>229</sup>

Delays in drug registration in South Africa have in particular drawn concern from civil society<sup>230</sup> and industry.<sup>231</sup> In 2010, the South Africans Clinicians Society wrote to the MCC asking for the urgent registration of key second- and third-line ARVs.<sup>232</sup> In 2011, delays in the registration of fixed-dose combinations of ARVs by the MCC meant that the South African Government was unable to procure such combinations for the national programme. These products have since been registered and in 2012–13.

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228. Interviews with the Department of Health. Notes on file with the authors.

229. See, e.g. South Africa: Medicines Control Council Delays HIV Drug Trials, AllAfrica, 14 September 2011.

230. See, e.g., Treatment Action Campaign, Campaign for Tenofovir to be registered, TAC Electronic Newsletter, 6 February 2007, available at <http://www.tac.org.za/nl20070206.html>

231. In its 2005 annual report, for example, the Pharmaceutical Industry Association of South Africa (an industry association primarily composed of multinational, originator pharmaceutical companies) wrote: “Continuing problems of lengthy delays in medicines registration and clinical trial approvals remained a key issue for industry during 2005”. See [http://www.sapma.co.za/assets/attachments/0287\\_Annual\\_Report\\_JAN05\\_DEC\\_05.pdf](http://www.sapma.co.za/assets/attachments/0287_Annual_Report_JAN05_DEC_05.pdf)

232. Delays in Registration of ARVs: Letter by the HIV Clinicians Society, 3 March 2010, available at <http://www.tac.org.za/community/node/2825>



In part, the time that MCC takes to process applications for the registration of medicines results from its structure. As already noted, it relies on external experts who report to various committees, which in turn make recommendations to a Council that only meets every two months. While expert committees engage with applicants on an ongoing basis, addressing concerns directly without Council input, the scheduling of committee and Council meetings often means that decisions are not timely.

In addition, the confidentiality requirements in section 34 make it difficult for concerned parties to determine who is actually responsible for the delay – the party filing a registration application, or the MCC itself.

It is understood that limited resources – including but not limited to financial resources – remain a challenge in addressing these concerns.

## 4.5 Potential opportunities in drug registration

A 2006 report of the Joint United Nations Programme on HIV/AIDS (UNAIDS) entitled ‘Towards universal access: assessment by the Joint United Nations Programme on HIV/AIDS on scaling up HIV prevention, treatment, care and support’ states:<sup>233</sup>

Countries should reform their legislation and regulations, as necessary, to allow medicines pre-qualified by WHO, or medicines approved by other widely recognized stringent drug regulatory bodies, to obtain provisional marketing approval to allow access to life-saving HIV medicines and diagnostics prior to full registration by national drug regulatory authorities. (Immediate and ongoing)

The opportunities contemplated by this UNAIDS recommendation fall into two, non-exclusive categories that are not mutually exclusive. The first is explicit reliance on prior certification and approval. The MCC could rely on several certification schemes and drug regulatory authority evaluations, including the WHO’s prequalification programme – a register of medicines certified periodically by the WHO after extensive clinical analysis and manufacturing inspection.<sup>234</sup> The MCC could also rely on the list of countries whose drug regulatory authorities it recognizes. These include Australia, Canada, the European Union, Japan, Sweden, the United Kingdom and the United States. In virtually no instance is a drug registration application filed in South Africa prior to being filed in one of these countries.<sup>235</sup>

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233. Available online at [www.unaids.org](http://www.unaids.org)

234. See <http://www.who.int/mediacentre/factsheets/fs278/en/index.html>

235. Interview with Dr Anban Pillay, Department of Health. Interview notes on file with the authors.

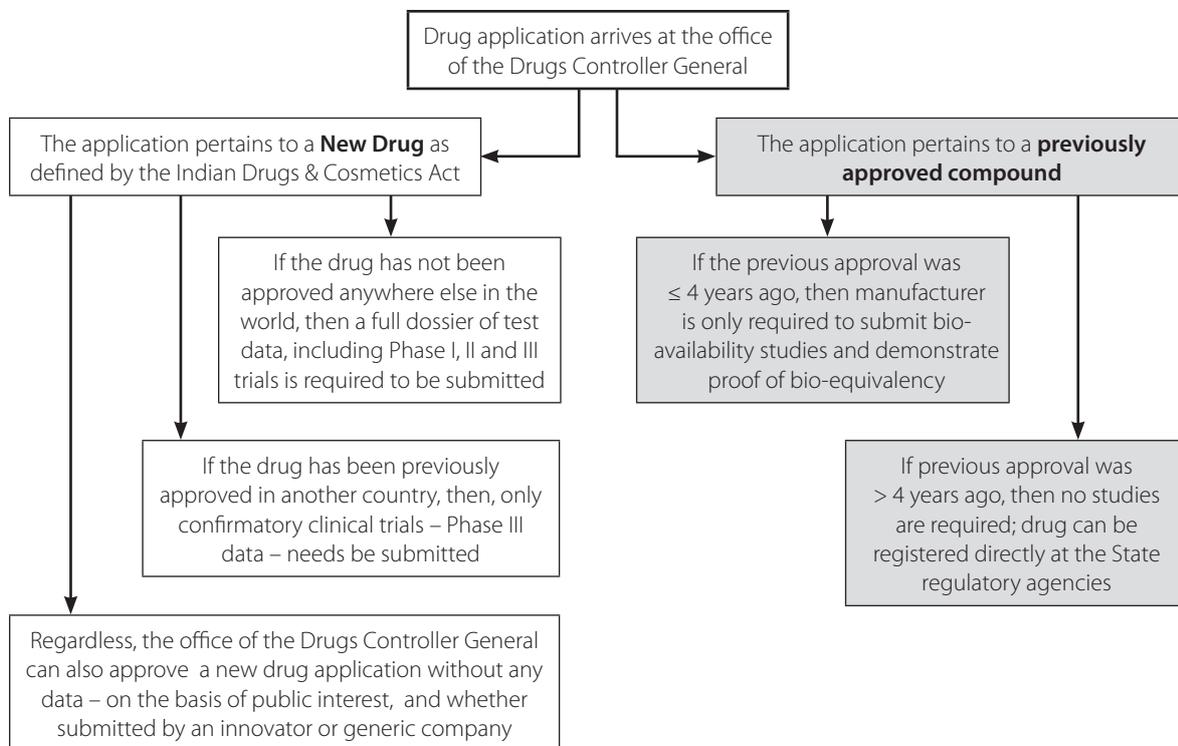


The second category of opportunities contemplated by the UNAIDS recommendation is procedural ease to implement exceptions to the standard process of drug approval by the MCC. As outlined previously, the Abbreviated Medicine Review Process does not come with either fixed or particularly expeditious timelines, and is therefore only a minor improvement over standard procedure. Expedited review is only procedurally easy if the drug in question is listed in the essential drugs list in South Africa, which is neither comprehensive nor frequently updated. For any other new chemical entities that seek expedited review, the permission of the Minister of Health is required. Finally, all waivers, exemptions and authorizations of use are expressly at the discretion of the Minister of Health.

Therefore, for existing fast track mechanisms (as well as those discussed above) to work, procedures must be easily implemented under clear, transparent guidelines that require high-level, discretionary consideration only in exceptional circumstances. This would only be possible in South Africa with both legislative and institutional reform.

In contrast, equivalent rules for drug approval in India largely provide such flexibilities (see figure 4).<sup>236</sup> Without procedural ease and official, legal sanction to find safe and reliable ways to address the specific context within which Indian medicines are registered, a large percentage of drugs available in the world market might have never been available in India.

**Figure 4. The process of drug approval in India**



236. In terms of the Drugs and Cosmetics Act.



## 4.6 Policy options in relation to medicines regulation

- Amend section 34 of the Medicines Act so that it applies only to the confidentiality/non-disclosure of clinical test data submitted at the time of registration, so that the provision does not conflict with the public's right to know about the status of drug registration in South Africa.<sup>237</sup>
- Establish clear timelines for abbreviated review (AMRP) in the manner of the expedited review of medicines.
- Broaden the registration exemption afforded to parallel imports by amending regulation 7 of the General Regulations to the Medicines Act; that is, extend the registration exemption afforded to patented medicines to non-patented medicines as well.
- Implement explicit and more efficiently laid-out procedures to take advantage of international certification schemes like the WHO prequalification programme, as well as drug approvals in countries whose authorities are aligned with the MCC; make such procedures legally binding rather than subject to discretionary approval.
- Allow for procedurally clearer, wider and less discretionary (and more rule-based) approval powers regarding expedition, abbreviated reviews, waivers and exemptions in the drug registration process in order to make existing and potential fast-track mechanisms work.
- Pending legislative reform, make use of Section 34A of the Medicines Act,<sup>238</sup> which expressly allows the Minister of Health and the Director-General to delegate authority on most matters covered by the Act, to *any* member of the Department of Health. This procedure would need to be implemented in a transparent manner subject to published guidelines.

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237. This is not strictly required because section 34 must be read subject to the Promotion of Access to Information Act 2 of 2000 (PAIA). In particular, section 5 of PAIA states that it “applies to the exclusion of any provision of other legislation that ... prohibits or restricts the disclosure of a record of a public body or private body; and is materially inconsistent with an object, or a specific provision, of [PAIA]”.

238. Section 34A(1): “The Minister may in writing authorise the Director-General or any officer of the Department of Health to exercise any of the powers conferred upon the Minister by this Act other than the powers referred to in sections 3, 24 (1) and 35, or to exercise or perform any of the duties or functions conferred or imposed on the Minister in terms of this Act”. Section 34A(2): “The Director-General may in writing authorize any officer of the Department of Health to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function, excluding any power, duty or function referred to in subsection (1), conferred or imposed on the Director-General by or in terms of this Act”.



## CONCLUSION AND WAY FORWARD

This study focuses on two mutually reinforcing goals. First and foremost, it focuses on promoting access to essential medicines. Second, it focuses on supporting the growth and development of the domestic generic pharmaceutical industry. With attention to the flexibilities inherent in TRIPS, this study has considered and presented a range of policy options related to patent, competition and medicines law in South Africa.

The right to have access to health care services is entrenched in section 27 of the South African Constitution. This fundamental right includes access to medicines, as the Constitutional Court held in *Minister of Health v Treatment Action Campaign (No 2)*.<sup>239</sup> Not only does this right protect against negative infringements, such as when existing access is unlawfully denied, but it also imposes a range of positive obligations on the State regarding its progressive realization within available resources.

These positive obligations, which are contained in sections 7(2) and 27(2) of the Constitution, require the State to take reasonable legislative and other measures to ensure that the right is respected, protected, promoted and fulfilled. While the Constitution also applies to the private sector, the nature and extent of that application is unclear in the jurisprudence. Arguably, the State's positive obligations include appropriate regulation of the private sector. As Hassim et al. explain in *Health & Democracy*.<sup>240</sup>

The Constitution thus places an obligation on the government to take all reasonable steps to put in place and make use of a legal framework that facilitates increased access to essential medicines. This does not mean that government must just act as a provider of goods and services. It must also put in place a legal framework so that individuals are able to realise their rights through their own action. This duty refers directly to the government's role as a regulator, rather than as a provider.

Thus, even if the Government provides certain essential medicines free of charge in the public sector, it is still under a constitutional duty to take steps towards reducing the prices of these drugs in the private sector and ensuring a sustainable supply. The Constitutional Court recognized this obligation in 2005 in *Minister of Health v New Clicks South Africa (Pty) Ltd* when it:

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239. 2002 (5) SA 721 (CC).

240. Adila Hassim, Mark Heywood and Jonathan Berger (eds.), *Health & Democracy: A guide to human rights, health law and policy in post-apartheid South Africa* (SiberInk, Cape Town: 2007) at 445.



In this case the Court:

- Unanimously agreed that the Medicines Act permits the Government to control prices and to make medicines “more accessible and affordable by means of a transparent pricing system.”
- Confirmed that the Government has a constitutional obligation to take these types of measures.
- Stressed that when the State regulates, it must do so in a reasonable fashion, ensuring that measures intended to make medicines affordable do not—by design or accident—make them unavailable.

The case law makes it clear that the obligation to respect, protect, promote and fulfil the right to have access to medicines rests on the State as a whole, not just a single department. In South Africa, responsibility for medicines law and policy falls under the Department of Health, responsibility for IP law and policy falls under the Department of Trade and Industry, and responsibility for competition law and policy falls under the Economic Development Department.<sup>241</sup>

There is opportunity to further align and harmonize the three laws in question, both with each other and—particularly in the case of the Patents Act—with the Constitution. The process of reforming these laws could benefit from a policymaking approach that is consultative, coherent and developed with the input of all relevant actors, governmental and non-governmental alike.

For the public health and local manufacturing priorities described here to feature more prominently in the IP policymaking process, a wide range of stakeholders and sectors must be represented. Relevant stakeholders include elected and public officials, civil society, industry, academia, patient and professional groups. Relevant sectors include the public health, science, education, economic, industrial, and innovation policy and practice sectors. Improving the channels for communication and participation among these diverse groups will result in laws and policies that are more inclusive and public health-orientated. Stronger coordination and inclusion across domestic governance structures will be central to achieving this.

Hence, if policy coherence is to be achieved, an important first step within government might be to promote the development and implementation of a law reform process that promotes increased coordination among the relevant national departments. While this kind of coordination is not currently the norm with the laws discussed here, there is precedent in other areas of law.

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241. These are all national departments.



With the requisite political leadership, a law reform process that rests on close collaboration, as envisioned in this paper, is possible. It is certainly permissible under the Constitution, and indeed, desirable from a policy coherence perspective. While the outcome may not be a statutory framework in which one minister has to agree with another, at a minimum what is required—and arguably mandated by the Constitution—is a set of laws designed to work in tandem to achieve mutually reinforcing goals.







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**United Nations Development Programme**

Bureau for Development Policy

One United Nations Plaza

New York, NY, 10017 USA

Tel: +1 212 906 5081

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