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# ASSESSING THE IMPACT OF TRIPs-PLUS PATENT RULES IN THE PROPOSED US-SACU FREE TRADE AGREEMENT

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## Introduction

On 4 November 2002, former United States Trade Representative (“USTR”) Robert Zoellick formally notified US Congressional leaders of President Bush’s intention to initiate negotiations for a free trade agreement (“FTA”) with the Southern African Customs Union (“SACU”). In his letters to the Speaker of the House of Representatives and the President of the Senate, Mr Zoellick set out reasons for entering into such negotiations, as well as the USTR’s “specific objectives for negotiations with the SACU countries”.<sup>2</sup> In particular, Mr Zoellick raised the following US objectives:

“We plan to use our negotiations with the SACU countries to ... address barriers in these countries to U.S. exports – including high tariffs on certain goods, overly restrictive licensing measures, inadequate protection of intellectual property rights, and restrictions the SACU governments impose that make it difficult for our services firms to do business in these markets. We also see the negotiations as an opportunity to advance U.S. objectives for the multilateral negotiations currently underway in the World Trade Organization (WTO).”<sup>3</sup>

This briefing paper looks at the potential impact of the proposed US-SACU FTA (“the SACU FTA”) on access to essential medicines in SACU countries, with a focus on minimum standards of patent protection – in excess of those required by the World Trade Organization (“WTO”) Agreement on Trade-related Aspects of Intellectual Property (“TRIPs”) – that are likely to be sought by the USTR.<sup>4</sup> In particular, this paper considers the potential impact of the SACU FTA on South Africa’s *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* (“the Operational Plan”), adopted by its Cabinet on 19 November 2003.

A comprehensive strategy for HIV/AIDS care, management and treatment, the Operational Plan aims to accomplish two interrelated goals: to provide comprehensive care and treatment for people living with HIV and AIDS; and to facilitate the strengthening of the national health system in South Africa. Antiretroviral (ARV) treatment is one of the key interventions of the Operational Plan available to persons who comply with relevant clinical assessment.

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<sup>2</sup> The congressional notification letters are available online at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Southern\\_Africa\\_FTA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Southern_Africa_FTA/Section_Index.html).

<sup>3</sup> Emphasis added

<sup>4</sup> Such measures are referred to as TRIPs-plus measures.

The paper begins by considering a few key economic and health care indicators in SACU countries, with a focus on HIV/AIDS. It then looks at the potential impact of the TRIPs-plus measures that the USTR is likely to seek, based on USTR documents and FTAs that have already been concluded with a range of countries. Before considering the potential impact of such provisions on the Operational Plan, this paper briefly sets out a few important considerations regarding state procurement of medicines in South Africa, with a focus on the procurement of ARV medicines. In conclusion, this paper makes certain recommendations regarding the steps that SACU members can and should be taking to protect the health of their populations.

## **SACU and South Africa**

SACU, which was established as far back as 1910, comprises South Africa, Namibia, Botswana, Lesotho and Swaziland. The broad purpose for SACU was to facilitate the free interchange of goods and services between member states, and harmonise imports through a Common External Tariff ("CET"), with the resulting revenue shared among members. In 1994, following the democratisation of South Africa, SACU members held a series of meetings to revise the original mandate to reflect changed priorities, culminating in a new SACU agreement being signed on 21 October 2002 in the Botswanan capital Gaborone.

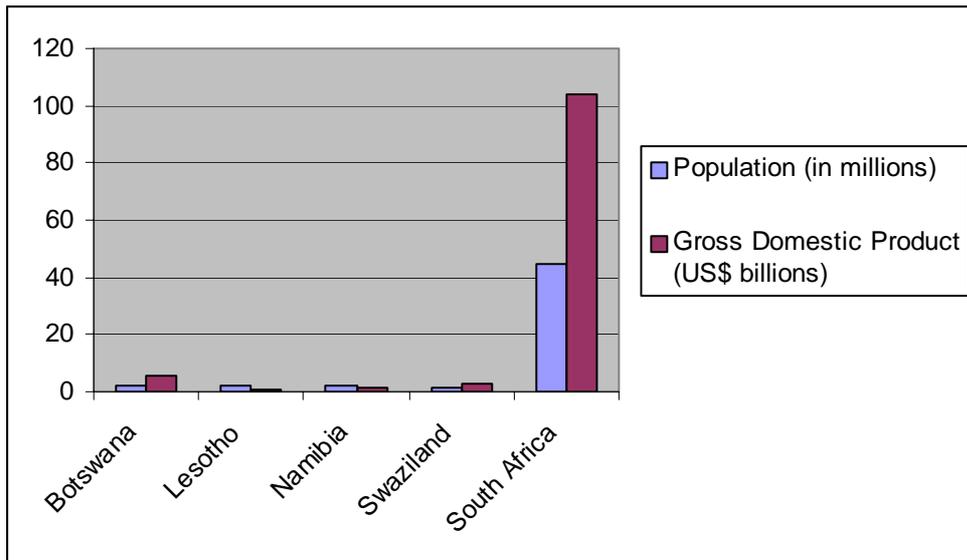
Of the five country members of SACU, only one (Lesotho) is classified by the WTO as a Least Developed Country (LDC), meaning it has no obligations with respect to patents for pharmaceutical products until 1 January 2016. As such, any imposition of minimum standards of patent protection imposed on Lesotho – including those that apply to the other SACU members as a result of TRIPs – would in effect be considered as being TRIPs-plus.

But even if Lesotho were to be exempted from any requirements in the SACU FTA regarding patents, its ability to access medicines in large part remains dependant on the ability of its neighbours – especially South Africa – to access the same medicines. As suppliers of affordable generic medicines such as India give effect to their TRIPs obligations,<sup>5</sup> countries such as South Africa may be called upon to play a greater role.

This briefing paper largely focuses on South Africa, in part because of the economic dominance of the country in the region and the lead role that it is playing in the negotiating process. South Africa accounts for 91% of the SACU regional economy (product) and houses 87% of the regional population. Of further significance is South Africa's regional leadership in manufacturing, and consequently, regional export. South Africa manufactures 95% of SACU's net output and is responsible for 88% of the manufacturing export in the region.

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<sup>5</sup> India's obligations under TRIPs only became effective on 1 January 2005. On that date, the Patents (Amendment) Ordinance, 2004, promulgated by the President of India on 27 December 2004 (when Parliament was not in session), came into effect. Amongst other things, the ordinance amended the Indian Patents Act, 1970 to introduce product patent protection for drugs, food and chemicals.



### SACU economic snapshot:<sup>6</sup>

	<b>Botswana</b>	<b>Lesotho</b>	<b>Namibia</b>	<b>Swaziland</b>	<b>South Africa</b>
Gross Domestic Product/capita (US\$)	3080	402	1463	1091	2299
Public health expenditure as % of GDP	4.4	4.3	4.7	2.3	3.6
Public health expenditure: as % of total government spending <sup>7</sup>	10.4%	7.4%	--	7.4%	15.4%
Public health expenditure/capita (US\$)	381	101	342	167	652

A further cause for this focus is related to the prevalence and treatment of HIV/AIDS. 82% of all people living with HIV/AIDS from the SACU region live in South Africa, as do 81% of people in need of treatment. In 2004, South Africa accounted for 80% of the deaths due to HIV/AIDS in the region. Simply put, South Africa's ability to deal effectively with the treatment of HIV infection is essential if SACU, as a region, is to be able to deal effectively with the same issue.

<sup>6</sup> From UNDP Human Development Report (HDR) 2004

<sup>7</sup> From the Human Sciences Research Council, South Africa – *Comparative Analysis: Health Expenditure*, available online at [www.hsrcpublishers.ac.za](http://www.hsrcpublishers.ac.za)

HIV/AIDS in SACU countries<sup>8</sup>:

	<b>Botswana</b>	<b>Lesotho</b>	<b>Namibia</b>	<b>Swaziland</b>	<b>South Africa</b>
People estimated to be living with HIV/AIDS	350,000	320,000	210,000	220,000	5,300,000
Estimated deaths due to AIDS	33,000	29,000	16,000	17,000	370,000
Adults with HIV/AIDS on treatment	18,000	1000	400	3200	20,000
People with HIV/AIDS who need treatment	60,000	54,000	29,000	32,000	750,000

**What are the TRIPs-plus provisions that the US will likely seek?**

With respect to intellectual property (IP), the US' specific objectives – as identified in the USTR's formal notification letters to Congress, are as follows:

- “-- Seek to establish standards that reflect a standard of protection similar to that found in U.S. law and that build on the foundations established in the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPs Agreement) and other international intellectual property agreements, such as the World Intellectual Property Organization Copyright Treaty and Performances and Phonograms Treaty, and the Patent Cooperation Treaty.
- Establish commitments for SACU countries to strengthen significantly their domestic enforcement procedures, such as by ensuring that government agencies may initiate criminal proceedings on their own initiative and seize suspected pirated and counterfeit goods, equipment used to make or transmit these goods, and documentary evidence. Seek to strengthen measures in SACU countries that provide for compensation of right holders for infringements of intellectual property rights and to provide for criminal penalties under the laws of SACU countries that are sufficient to have a deterrent effect on piracy and counterfeiting.<sup>9</sup>

The letters to Congress identify two IP-related goals sought by the USTR. First, the USTR seeks to ensure that SACU countries increase IP protection to bring it more in line with US law. This necessarily means standards in excess of those required by TRIPs being seen as a floor and not as a ceiling.<sup>10</sup> Second, the USTR seeks to strengthen domestic IP enforcement procedures, such as by the use of the criminal law. This is to be done in two ways: first, giving powers to “government agencies” to “initiate criminal proceedings”; and second, providing for criminal sanctions “sufficient to have a deterrent effect on piracy and counterfeiting”.

<sup>8</sup> From UNAIDS/ WHO Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections, 2004 Update

<sup>9</sup> Emphasis added

<sup>10</sup> The letters speak of “build[ing] on the foundations established in the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPs Agreement) and other international intellectual property agreements”.

The approach to IP protection in the FTA negotiations with SACU is supported by the USTR's 2004 "Special 301" Report ("the 301 Report"), "which examined in detail the adequacy and effectiveness of intellectual property protection in approximately 85 countries."<sup>11</sup> In particular, the report provides as follows:

"The United States is committed to a policy of promoting increased intellectual property protection. In this regard, we are making progress in advancing the protection of these rights through a variety of mechanisms, including through the negotiation of free trade agreements (FTAs). We are pleased that the recently concluded FTAs with Central America including the Dominican Republic, Morocco and Australia will strengthen the protection of IPR in those countries. Specifically, the intellectual property chapters of these agreements provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement. We are also seeking higher levels of protection and enforcement in the FTAs that are currently under negotiation with Bahrain, Panama, the Southern African Customs Union, in the upcoming FTA negotiations with Andean countries and Thailand, and in the ongoing negotiation of a Free Trade Area of the Americas."<sup>12</sup>

On enforcement, the 301 Report provides as follows:

"The most significant piracy and counterfeiting problems require measures that may go beyond the minimum standards of TRIPS to ensure effective enforcement at the national and local levels ... The global scourge of piracy and counterfeiting requires stronger and more effective border enforcement to stop the import, export, and transit of pirated and counterfeit goods."<sup>13</sup>

Despite the clear intentions of the letters to Congress and the 301 Report are somewhat vague on a number of important issues. What do TRIPs-plus provisions mean? In what way will SACU be asked to increase its standards of IP protection? What is meant by "piracy and counterfeiting"? Does this apply to pharmaceutical products? These issues are dealt with in turn, beginning with the issue of piracy and counterfeiting, to be followed by standards of IP protection.

## Piracy and counterfeiting

The FTA concluded between the US and Morocco on 15 June 2004 ("the Morocco FTA")<sup>14</sup> provides the following definitions:<sup>15</sup>

"**counterfeit trademark goods** means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the country of importation".

"**pirated copyright goods** means any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation."

<sup>11</sup> The report is available online at

[www.ustr.gov/Document\\_Library/Reports\\_Publications/2004/2004\\_Special\\_301/Section\\_Index.html](http://www.ustr.gov/Document_Library/Reports_Publications/2004/2004_Special_301/Section_Index.html).

<sup>12</sup> Page 2 (emphasis added)

<sup>13</sup> Page 2-3 (emphasis added)

<sup>14</sup> The text of the Morocco FTA is available online at

[http://www.ustr.gov/Trade\\_Agreements/Bilateral/Morocco\\_FTA/Final\\_Text/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/Section_Index.html).

<sup>15</sup> The definitions are contained in footnote 19 (to Article 15.11.20) of the text of the Morocco FTA.

Even assuming that the reference to “piracy and counterfeiting” in the letters to Congress applies to medicines, it does not necessarily follow that TRIPs-plus protections in this regard would limit access to a sustainable supply of affordable medicines of recognised quality, safety and efficacy. Strong protections against counterfeiting are necessary for guaranteeing that the products in question are indeed the same products that have been recognised by the relevant drug regulatory authority as satisfying the relevant quality, safety and efficacy criteria applied in the drug registration process.

But issues of “piracy” are different. A “pirated” copy of a patented medicine, for example, may or may not be of acceptable quality, safety and efficacy, as is also the case with the patented medicine itself. Protection against “patent piracy” does not necessarily take into account drug regulatory authority concerns or even whether it is lawful to manufacture the particular “pirated” copies in the country of production. If the USTR’s approach to “piracy” were to extend to pharmaceutical products, it would mean that the importation of safe and efficacious generic medicines of acceptable quality – in a way that infringes the patent – would be subject to the criminal law.

Criminal sanctions initiated by the state would constitute a major departure from the current civil nature of enforcement proceedings, threatening to undermine medicines access. Under existing law in South Africa, a defendant may request a compulsory licence as a defence to an action of patent infringement.<sup>16</sup> This allows for generic companies to be proactive, knowing that they have a strong defence in the event of the patentee taking legal action in response. Threats of criminal prosecution, on the other hand, would have a chilling effect, even if a similar defence were instituted.

In explaining why the USTR seeks the use of the criminal law through its FTAs and bilateral consultations, it makes the allegation that “counterfeit and pirated products are usually made with substandard materials, and undergo little or no quality control or even basic health and safety testing.”<sup>17</sup> Without taking issue with the accuracy of this statement, what it does suggest is that both “counterfeiting” and “piracy” are applicable to pharmaceutical products.

It is therefore possible that the USTR letters to Congress in November 2002 may indeed be interpreted to mean that the USTR will seek an FTA that mandates the use of the criminal law to prevent the importation of safe and effective generic medicines of acceptable quality. In practice, however, not one of the FTAs already concluded seeks criminal sanctions for “patent piracy”. The focus of “anti-piracy” criminal sanctions is ordinarily limited to copyright and related rights. It seems unlikely that such an agenda will be pursued actively in the SACU FTA negotiations.

### **Unpacking TRIPs-plus standards**

The SACU position on IP seems to be largely defensive in nature. Instead of placing its position on record, SACU is simply waiting to see how the US moves on the issue before it responds. In addition, SACU negotiators have to date not been forthcoming with the details of the US proposals. Instead, it has simply been suggested that those seeking to get an idea of the specific standards of IP protection proposed by

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<sup>16</sup> *Circuit Breaker Industries v Barker and Nelson* 1993 BP 431

<sup>17</sup> Special 301 at 3

the US should refer to FTAs already concluded with other countries or regions, working on the assumption that the US position adopted in those negotiations will not differ markedly from that being adopted in the SACU negotiations.<sup>18</sup>

Because of the lack of transparency of the negotiating process, this briefing paper therefore has no option but to consider a range of FTAs negotiated by the USTR so as to get an idea of what TRIPs-plus provisions are likely to be placed on the negotiating table. This is unfortunate. A foundational principle of the South African Constitution is that “government and those exercising public power should be held accountable to the broader community for the exercise of their powers.”<sup>19</sup> Conducting talks in the manner that has characterised the SACU FTA negotiations thus far is fundamentally at odds with South Africa’s new constitutional order.

### *The Morocco FTA*

Chapter 15 of the Morocco FTA, which deals with IP including patents, represents a significant “victory” for the USTR and a major setback for access to essential medicines in Morocco. This is despite the attempt at damage control implicit in the two side letters on public health between the USTR and the Moroccan Minister Delegate for Foreign Affairs and Cooperation, which “constitute an agreement” between the two countries and came into force “on the date of entry into force” of the Morocco FTA.<sup>20</sup> Those letters state that the obligations set out in the IP chapter “do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.”

While the side letters clearly employ the language of the *Declaration on the TRIPS Agreement and Public Health* (“the Doha Declaration”),<sup>21</sup> they do not incorporate the express provisions of that declaration. In contrast, the letters expressly refer to the provisions of the WTO General Council decision on the *Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health* (“the August 30<sup>th</sup> agreement”),<sup>22</sup> which deals with the use of compulsory licensing by countries without sufficient domestic manufacturing capacity to import generic medicines. Given that the side letters only incorporate the provisions of the August 30<sup>th</sup> agreement, the IP provisions of the Morocco FTA – at best – can be interpreted in a manner to promote access for all.<sup>23</sup> This cannot be used to overcome express access barriers in the text of the agreement.

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<sup>18</sup> This suggestion was made at a 1 December 2003 meeting between representatives of South Africa’s Treatment Action Campaign and AIDS Law Project, and Xavier Carim, the Chief Negotiator of Trade negotiations in the South African Department of Trade and Industry.

<sup>19</sup> *Rail Commuters Action Group and Others v Transnet Ltd t/a Metrorail and Others*, unreported decision of the Constitutional Court in case no: CCT 56/03 (26 November 2004) at paragraph 73 (footnote omitted)

<sup>20</sup> The side letters are available online at

[http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Morocco\\_FTA/Final\\_Text/asset\\_upload\\_file258\\_3852.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/asset_upload_file258_3852.pdf).

<sup>21</sup> WT/MIN(01)/DEC/2, 4th Sess., adopted at the WTO Ministerial Conference at Doha, Qatar, on 20 November 2001.

<sup>22</sup> WT/L/540, 1 September 2003, available online at

[www.wto.org/english/tratop\\_e/TRIPs\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/TRIPs_e/implem_para6_e.htm)

<sup>23</sup> The Doha Declaration states (at paragraph 5(b)) that “[e]ach [WTO] Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are

The problematic (from an access to medicines perspective) TRIPS-plus patent provisions of the Morocco FTA can best be categorised by the following questions that are dealt with in greater detail below:

- Do the new minimum standards of patent protection have retrospective effect?
- What “inventions” can be patented?
- What can be done regarding compulsory licensing, parallel importation and patent revocation?
- What is the effect of regulatory delays in the grant of patents and/or the registration of patented medicines?
- What does the FTA say about data exclusivity?
- What role is assigned to the relevant medicines regulatory authority?

#### Do the new minimum standards of patent protection have retrospective effect?

Article 15.1.8 of the Morocco FTA extends the new rules to products and processes that were already under patent protection at the time the FTA came into effect, as well as to all newly patented products and processes. This does not appear to have any direct retrospective effect. Instead, it effectively upgrades existing exclusive rights in patents to a level that was not necessarily expected or anticipated at the time such rights were initially granted.

#### What “inventions” can be patented?

Article 15.9.1 does not allow for the full range of exceptions permitted in terms of Article 27 of TRIPs, permitting only those listed in Article 27.2. This effectively excludes exceptions such as those in Article 27.3(a), which deals with “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”.<sup>24</sup> Of greater concern in the area of access to medicines, however, is the requirement that patents “be available for any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals.”

This appears to require second-use patents on products that are no longer under patent for their original first use (such as zidovudine (AZT) for the treatment of HIV-infection, originally developed as an anti-cancer treatment), new dosages of existing drugs (such as the 600mg dosage of efavirenz that has replaced the standard dose of three 200mg tablets) and new combinations of existing drugs (such as fixed-dose combination (FDC) products like Combivir<sup>®</sup> (AZT/lamivudine)).<sup>25</sup>

While FDCs – which lower the pill burden – are an essential tool in ensuring patient adherence to treatment regimens, their existence is by no means dependant on the availability of product patent protection.<sup>26</sup> The same could be said of new dosages. By granting patent protection to such “new” products, access to a sustainable supply

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granted”. In addition it expressly authorises parallel trade (at paragraph 5(d)). In contrast, Article 15.9.4 of the Morocco FTA seems to limit compulsory licensing and outlaw parallel trade.

<sup>24</sup> Further, Article 15.9.2 expressly requires patents for plant and animal “inventions”, despite Article 27.3(b) of TRIPs, which allows for exceptions in this regard.

<sup>25</sup> TRIPs does not require patent protection for “new uses or methods of using a known product”.

<sup>26</sup> Many FDCs have been developed and produced in India in the total absence of product patents.

of medicines is effectively limited, without any corresponding innovation benefit that would not have been achieved in the absence of patent protection.

#### What about compulsory licensing, parallel importation and patent revocation?

Article 15.9.4 of the Morocco FTA precludes parallel trade in patented products. This is clearly TRIPS-plus. It is also likely that the provision may be interpreted to limit the use of compulsory licensing to local production. In other words, with the exception products imported in terms of the cumbersome – and possibly unworkable – provisions of the August 30<sup>th</sup> agreement, compulsory licensing may not be used to import medicines produced in circumstances not contemplated by that agreement.

In terms of Article 15.9.5, patents may only be revoked “on grounds that would have justified a refusal to grant the patent.” This effectively precludes the use of provisions that give effect to Article 5A(3) of the Paris Convention for the Protection of Industrial Property (1967) (“the Paris Convention”), which provides as follows:

“Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses 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 license.”

Article 5A(3) of the Paris Convention, which has been directly incorporated into TRIPs,<sup>27</sup> recognises that the grant of a compulsory licence may be insufficient in certain circumstances to deal with the abuse that may arise from the exercise of the exclusive rights conferred by a patent. If used, it allows for the removal of patent protection, which in turn automatically opens up the market to all without prohibiting the erstwhile patentee from continuing to produce and market its product.

#### What is the effect of regulatory delays?

Articles 15.9.7 and 15.10.3 of the Morocco FTA allow for the extension of the term of a patent to deal with the shortening of market exclusivity that flows from the grant of a patent. In terms of Article 15.9.7, the term of a patent should be extended “to compensate for unreasonable delays that occur in granting the patent”. In terms of Article 15.10.3, certain delays in marketing approval should be compensated by patent extension. While both provisions have the potential to limit access to essential medicines, the latter may be dealt with effectively by ensuring that drug regulatory processes operate efficiently.<sup>28</sup>

Simply introducing greater efficiencies, however, may not mitigate the effect of the former. It may preclude the use of pre-grant opposition mechanisms such as has been historically provided in India. Read in the light of the limited scope for exclusions from patentability in Article 15.9.1, this may not be a significant problem, as the scope for the use of pre-grant opposition mechanisms has already been undermined. But in cases where this is not the case, such a provision may limit access to essential medicines even further.

<sup>27</sup> It has been directly incorporated by Article 2.1: “In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).”

<sup>28</sup> Both forms of “compensation” harm the consumer.

What does the FTA say about disclosure and data exclusivity?

Article 15.9.10, which precludes strict disclosure requirements by the prospective patentee regarding the claimed invention, may result in delays in generic market entry. While full information may be available offshore in jurisdictions with better disclosure requirements for the corresponding patents, this requirement nevertheless raises the costs of search for material that should be in the public domain – full disclosure, it must be remembered, lies at the heart of the patent bargain. The limits on disclosure have implications for medicines access.

Article 15.10, which deals with “Measures Related to Certain Regulated Products” and focuses on pharmaceutical products, introduces a range of provisions dealing with the protection of data used to satisfy the drug regulatory process. In relation to products involving new chemical entities, the term of data protection is to last five years. For all other products, the term is limited to three years. By precluding generic companies from using test and/or registration data, delays in the introduction of generic competition are likely to result. On a close reading of Article 15.10, it appears as if the only data that is not protected is “information related to bioequivalency”. It is unclear to what extent this may assist generic manufacturers, if at all. Of particular concern is the ban on using “evidence of prior approval” of a patented medicine outside of the country concerned.

What role is assigned to the relevant medicines regulatory authority?

We have already mentioned Article 15.10.3 in relation to compensation for regulatory delay. It is the first provision in the FTA dealing with patents that links drug regulatory authority processes to patent protection. Another such provision is Article 15.10.4, which applies to circumstances where a Bolar provision has already been enacted in the law.<sup>29</sup> Where such a provision exists in law, the state must “implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent”. It is also obliged to notify the patent holder of such applications and inform the patentee of the identity of the person seeking marketing approval in terms of the relevant Bolar provision. This effectively turns the drug regulatory authority into a patent enforcer, significantly strengthening the position of the patentee.

*The Chile FTA*

The Chile FTA incorporates fewer of the problematic provisions that litter the Morocco FTA.<sup>30</sup> But it also makes provision for some new obstacles to medicines access. One provision, Article 17.1.14, reflects an agreement between the parties that they “will cooperate, on mutually agreed terms and subject to the availability of

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<sup>29</sup> Such as provision permits generic manufacturers to take all necessary steps to secure marketing approval from the relevant drug regulatory authority before the patent expires. It gets its name – in part – from the US Court of Appeals for the Federal Circuit case of *Roche Products, Inc. v Bolar Pharmaceutical Co.*, 733 F.2d 858. This case held that testing for the purpose of drug regulatory authority approval could not take place before the patent had expired. As a result of the case, lawmakers in the United States amended patent legislation in 1984 so that it would permit generic companies to complete all drug registration requirements for their products without infringing existing patents.

<sup>30</sup> The text of the Chile FTA is available online at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Chile\\_FTA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Section_Index.html).

appropriated funds” to take a range of steps to strengthen “the development and protection of intellectual property”. It also deals with public education on IP as “a research and innovation tool, as well as on the enforcement of intellectual property”, makes provision for co-operation between IP offices and for the use of electronic systems to manage IP. Collectively, these provisions not only make it easier to grant and protect exclusive rights in IP, but also ensure that a pro-IP approach to the issue is adopted. This does not bode well for medicines access.

### *The Australia FTA*

The Australia FTA is the first agreement “to include specific provisions dealing with non-tariff market access issues related to pharmaceuticals.”<sup>31</sup> A central concern to the USTR was the Australian Pharmaceutical Benefits Scheme (PBS), which “has a process for determining which drugs it will cover under its national health care program and the amount it will reimburse for these drugs.” In effect, certain provisions of the FTA make it more difficult for the PBS to extract price reductions from patent holders, such as by complicating procedures and strengthening the role of drug manufacturers in decisions regarding the choice of medicines to be covered by the PBS.<sup>32</sup>

### *The Dominican Republic – Central America – US FTA*

The Dominican Republic – Central America – US FTA (“the CAFTA-DR FTA”), signed as recently as 5 August 2004, is interesting in two respects. First, it expressly retains Article 5A(3) of the Paris Convention in Article 15.9.4, which also allows for the revocation, cancellation or the holding of a patent unenforceable in cases of “inequitable conduct” of the patentee. Second, it firmly entrenches strict data exclusivity provisions in Article 15.10.1, building on the Morocco FTA.

In terms of Article 15.10.1, generic manufacturers cannot even rely on the prior approval of a medicine containing a new chemical entity – in a third country – for up to five years. This can be limited if a party includes in its law (as it is entitled to do in terms of Article 15.10.1(b)) that the party seeking data protection make an application for registration of that medicine domestically within a five-year period. In practice, however, this will mean that reference to the prior approval must wait until the party seeking data protection decides to seek domestic regulatory approval. By the time such a decision may be made, the five-year period of data exclusivity may be over.

### **What is the US likely to push for in the SACU FTA?**

It is most likely that the US will focus on a few key issues, such as limiting the scope of compulsory licensing. Article 17.1.13 of the Chile FTA and Article 15.1.5 of the CAFTA-DR FTA, for example, state that the relevant chapters on IP do not prevent a party “from adopting measures necessary to prevent anticompetitive practices that

<sup>31</sup> See “U.S.-Australia Free Trade Agreement -- Questions and Answers About Pharmaceuticals”, available online at [http://www.ustr.gov/Document\\_Library/Fact\\_Sheets/2004/U.S.-Australia\\_Free\\_Trade\\_Agreement\\_-\\_Questions\\_Answers\\_About\\_Pharmaceuticals.html](http://www.ustr.gov/Document_Library/Fact_Sheets/2004/U.S.-Australia_Free_Trade_Agreement_-_Questions_Answers_About_Pharmaceuticals.html). The text of the Australia FTA is available online at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Australia\\_FTA/Final\\_Text/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/Section_Index.html).

<sup>32</sup> See the side letters on the PBS available online at [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Australia\\_FTA/Final\\_Text/asset\\_upload\\_file840\\_3886.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file840_3886.pdf).

may result from the abuse of the intellectual property rights set forth in ... [the] Chapter.” This would be in line with US law, where abuse of rights is dealt with in antitrust law and not patent law.

This focus on anticompetitive practices suggests a retreat from the full range of regulatory tools considered in the Doha Declaration, as is evident in the Morocco FTA, with the use of compulsory licensing perhaps being limited to local production and imports in terms of the August 30<sup>th</sup> agreement, with a focus on dealing with major epidemics and national emergencies. In addition, and largely on the basis of the FTAs discussed above, we conclude that the following other TRIPS-plus issues are likely to form part of the US approach to the IP chapter in the SACU FTA:

- New use and method patents;
- Limited grounds for patent revocation;
- Data exclusivity;
- No parallel trade;
- Patent extension to “compensate” for delays in patent registration and/or drug registration; and
- A patent enforcing role for the medicines regulatory authority.

### **What effect will this have on existing South African law?**

In some respects, South African law is already in line with some of the TRIPS-plus provisions that we have reason to believe the US will seek to entrench in the SACU FTA. In particular, the Patents Act, 57 of 1978 (“the Patents Act”), does not make use of the full range of regulatory tools considered in the Doha Declaration (insofar as compulsory licensing is concerned). In particular, the Patents Act ordinarily limits third party applications for compulsory licences to circumstances involving the abuse of rights in a patent. It also fails to deal appropriately with health emergencies and other situations of extreme urgency.<sup>33</sup> In addition, the law already allows for new use and method patents, and further limits the grounds of patent revocation.

But in many respects, the TRIPS-plus provisions that the US is likely to seek would, if applied, result in a substantial change to the law as it currently stands, notwithstanding it already granting patent protection in excess of what TRIPS requires. This is because:

- Data exclusivity is not protected in the way ordinarily expected by the USTR;
- Parallel trade (albeit limited) is permitted by section 15C(b) of the Medicines and Related Substances Act, 101 of 1965 (“the Medicines Act”), read together with regulation 7 of the General Regulations issued in terms of the Medicines Act (*Government Gazette* No. 24727, Government Notice No. R.510, 10 April 2003);
- Patent extensions are not granted as “compensation” for delays in drug registration;
- Patent extensions are not granted as “compensation” for delays in the grant of a patent; and

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<sup>33</sup> For more discussion on this point, see Edwin Cameron and Jonathan Berger, “Patents and Public Health: Principle, Politics and Paradox”, Inaugural British Academy Law Lecture, available online at <http://www.britac.ac.uk/pubs/src/law04/index.html>.