2007 Journal for Juridical Science 32(2): 116-131

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Free Trade Agreements with the US — Are they good for your health?

Abstract

Through its participation in the South African Customs Union (SACU), South Africa has been involved in negotiations with the United States government on the finalization of a free trade agreement (FTA). Although the US-SACU negotiations eventually ground to a halt, they are more than likely to be reinstated some time soon, and the far-reaching implications they portend will have to be confronted afresh. The concern of this contribution is the effect of the US insistence on stronger intellectual property protection for pharmaceutical patents in these bilateral agreements, the resultant impact on the prices of medicines for life-threatening conditions such as HIV/AIDS and related opportunistic diseases. This paper explores some critical issues related to FTAs, examines some of the pressure impacting on the negotiations, reviews the trends around the protection of pharmaceutical patents in some recently concluded agreements, and considers their implications for SACU countries.

Vrye handelsooreenkoms met die VS — Is hulle goed vir u gesondheid?

As gevolg van die deelname van die Suid-Afrikaanse Doeane Unie (SADU), het Suid-Afrika betrokke geraak in onderhandelinge met die regering van die Verenigde State oor die finalisering van 'n vrye handelsooreenkoms. Alhoewel die VS-SADU onderhandelinge uiteindelik tot stilstand gekom het, is dit meer as waarskynlik dat dit binnekort weer hervat sal word en dat die verreikende implikasies wat dit inhou weer aangespreek sal moet word. Die bekommernis vervat in hierdie bydrae is die effek van die VS se aandrang op sterker beskerming van intellektuele eiendom vir farmaseutiese patente in hierdie belaterale ooreenkomste soos HIV/VIGS en verwante toestande. Hierdie artikel ondersoek sommige kritiese vraagstukke verwant aan vrye handelsooreenkomste, ondersoek die druk wat 'n effek op die onderhandelinge het, bespreek die tendense met betrekking tot die beskerming van farmaseutiese patente in sommige onlangs gefinaliseerde ooreenkomste en oorweeg die implikasies daarvan vir SADU-lande.

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1. Introduction

Hailed as the "African century", the turn of the millenium has thus far delivered one devastatingly stark fact: that Africa bears the brunt of the HIV epidemic, with southern Africa having the highest burden of the disease on the continent. At a conservative estimate, around 5.5 million people were living with HIV in South Africa alone, by the end of 2003.[1]

And now, inequitable trade rules threaten to add to Africa's burden.

South Africa, through its participation in the Southern African Customs Union (SACU), has been involved in negotiations with the United States government on the finalization of a free trade agreement (FTA). These talks have been on and off the table for the past 3 years, breaking down as a result of disagreements on a number of key issues. Recently, there have been attempts to revive the negotiations. The talks have been mired by disputes over matters such as telecommunications, health care and the protection of intellectual property rights, among others.

These negotiations resumed in 2006 against the backdrop of several agreements concluded between the United States and, in particular, developing countries, in terms of which the US has secured higher protection for intellectual property rights in exchange for greater trade access for products from those countries.

Although the US-SACU negotiations eventually ground to a halt again, they are more than likely to be reinstated some time soon, and the far-reaching implications they portend will have to be confronted afresh.

The concern of this contribution is the effect of the US insistence on stronger intellectual property protection for pharmaceutical patents in these bilateral agreements, the resultant impact on the prices of medicines for life-threatening conditions such as HIV/AIDS and related opportunistic diseases, and the ability of southern African countries to respond adequately to the HIV/AIDS pandemic and other public health crises.

This is particularly significant in the light of existing multilateral agreements (such as the TRIPS Agreement) which already address harmonization and uniform standards for intellectual property. Because of the United States' superior economic muscle, questions have also been raised about whether the playing fields are level and, in particular, the extent to which developing countries are able to negotiate as equal partners.

How "free" are these trade agreements, and are they good for your health?

This paper explores some critical issues relating to the FTAs, examines some of the pressures impacting on the negotiations, reviews the trends around the protection of pharmaceutical patents in some recently concluded agreements, and considers their implications for SACU countries.

1 Abdool Karim & Abdool Karim 2005:37. See also UNAIDS 2006.

2. Intellectual property protection in the wake of the TRIPS Agreement

One of the major impacts of the adoption of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement,[2] which aimed to harmonise intellectual property rights globally, was the requirement that all member countries provide patent protection for pharmaceutical products.[3] In over a decade of implementation of TRIPS, the prices of medicines have soared, with a resultant decline in access to essential medication.[4] This result was achieved through the manner in which the exclusive rights of owners were defined,[5] exceptions to these rights limited,[6] conditions imposed for the grant of compulsory licences,[7] the term of protection provided,[8] and the protection of undisclosed data against unfair competition.[9]

As the negative impact on public health became evident, developing country governments and activist groups lobbied for a change in the rules, resulting in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health.[10] This Declaration sought to restore the balance in the implementation of TRIPS, through the use of permitted flexibilities, between intellectual property protection and public health imperatives.

Having lost some ground on the multilateral front, the US in particular, sought to impose its (and the pharmaceutical industry's) agenda through bilateral trade negotiations concluded under "free trade agreements" (FTAs).

3. Free trade agreements

Interestingly, since 2001 (about the time of Doha negotiations and the Declaration), the US has initiated 11 bilateral and regional free trade agreements with 23 countries[11] and more recently with several others.[12] Most of these agreements contain TRIPS-plus standards, namely, they require signatories to guarantee stronger intellectual property protections than is mandated by TRIPS. While there are significant differences from one agreement to the next, "all these FTAs increase the scope and protection for pharmaceuticals, on the general argument that the current levels of protection (even if TRIPS-compliant), do not permit adequate recovery of R&D costs."[13]

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2 World Trade Organisation 1994.
3 Article 27(1).
4 The consequences of increased patent protection in pharmaceuticals have been extensively documented and treated in the literature. See, for example, DFID UK 2004.
5 Article 28 of TRIPS.
6 Article 30.
7 Article 31.
8 Article 33.
9 Article 39.
10 World Trade Organisation 2001.
11 Correa 2006:399.
12 US Trade Policy Review 2005.
13 Correa 2006:400. "R&D" is a reference to the costs of research and development of new medicines.

4. Recently-concluded FTAs

In the past 5 years, the US has signed FTAs with several countries, among them Jordan, Singapore, Chile, Central America and the Dominican Republic, Australia, Morocco, Bahrain, Peru, Colombia, Oman and Singapore. Negotiations are pending with countries such as Panama, South Korea, Thailand, Malaysia, Ecuador, the United Arab Emirates, as well as the SACU.

A survey of a number of recently-concluded free trade agreements by Morin[14] demonstrated that while most of these agreements with the US included intellectual property provisions which are TRIPS-equivalent, many others are TRIPS-plus.

A brief exposition of the main TRIPS-plus standards follows:

4.1 Patent term extension

Not content with the protection of patents for 20 years from the date of application, the pharmaceutical industry has argued that the need to obtain marketing approval for medicines reduces the effective term of patent protection, and thus the prospects of recouping research and development costs. Recent FTAs[15] have obliged signatories to extend the patent term to compensate for delays in the examination of the patent application, and in the process of obtaining marketing approval.

This is a seriously flawed argument, In the case of commercially successful medicines, R&D costs may be recovered by several months of sales at the prices charged in isolation from competition, under exclusive patent rights. Secondly, the time required to comply with marketing approval procedures has, in many cases, shortened. Finally, only a few patents protect new active ingredients.[16] The possibility of extension creates uncertainty for generic producers, and constitutes a real barrier to access.[17]

4.2 Data exclusivity

The TRIPS Agreement requires drug regulatory authorities to protect undisclosed test or other data "against unfair commercial use."[18] There is no obligation on members to grant exclusive rights over data, as is the case in

14 Morin 2006:1.

15 Such provisions are included in the FTAs entered into between the US, on the one hand, and the following countries/blocs: Singapore; Chile; Central American countries; Australia; Morocco; and Bahrain.

16 Correa 2006:401.

17 For example, a leading generic producer in South Africa, Aspen, which manufactures generic medicines under compulsory licences may be precluded from actually competing with originator companies for many years on the newest antiretroviral drugs. See Baker 2004.

18 Article 39.3.

the US, the EU and other countries.[19] However, many FTAs[20] require the parties to grant data exclusivity rights for a minimum of 5 years irrespective of whether it is patented or not, or whether it is undisclosed or not.[21]

Furthermore, in countries that have only recently introduced patent protection for pharmaceuticals, one implication of data exclusivity is that medicines that are off-patent will then become subject to exclusive rights. This is a further barrier, as even if the product is off-patent, no marketing approval can be granted unless trials are conducted to obtain a full set of data, which trials are questionable on several counts.[22]

4.3 Linkage between registration and patent

FTA provisions are seeking increasingly to link drug registration with the patent system. The TRIPS Agreement makes no provision for such linkage. The result is that where a patent exists on a drug, the regulatory authority will be obliged to refuse marketing approval in respect of a generic equivalent of the medicine. The authority is also required to inform the patent owner about all applications for the approval of generic versions.

Linkage ignores the fact that patents are private rights, and shifts the responsibility of preventing possible infringements to WTO members.[23] It burdens drug regulatory authorities with assessing and enforcing patent claims, for which task they are not ordinarily equipped. Under a linkage system, such patents may erect a formidable barrier to legitimate generic competition.

4.4 Other standards

These include restraints on the freedom of WTO members to determine the grounds for issuing compulsory licences (often limited to cases of anticompetitive practices, public non-commercial use, national emergency or other circumstances of extreme urgency); narrowing the available exceptions to the rights conferred; restraints on the use of parallel importation through a proscription of the international exhaustion doctrine; and recognition of the patentability of second therapeutic uses of pharmaceutical products.

Exclusivity and linkage issues can nullify granting of compulsory licences, since prospective licensees are unlikely to replicate test data. Assurances that FTA provisions are compatible with the Doha Declaration, contained in

19 Correa 2006.

20 Such as the agreements between the US and: Singapore, Chile, Morocco, Australia and Bahrain.

21 US-Singapore Free Trade Agreement 2003. See, for example, Article 16.8.1-16.8.3, which mandates 5 years of data exclusivity for the originator of clinical data, thereby taking away any flexibility available as a consequence of the Doha Declaration.http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html. (Accessed 21 August 2007).

22 Felmeth 2004; Skillington & Solovy 2003; Correa 2006:401.

23 Correa 2006:402.

"side letters" or memoranda of "understanding", are insufficient (having merely interpretive value), unless embodied in the text of the agreements.

4.5 The case of Peru

It is perhaps instructive to review the intellectual property provisions in the recently-concluded FTA between the US and Peru,[24] in order to understand the impact on public health.

For some 18 months in the run-up to the agreement, representatives from the health ministries of Peru and other Andean countries worked hard to oppose the imposition of the new TRIPS-plus rules demanded by the US. In the end, the intransigence of US negotiators forced the Peruvian Health Ministry to withdraw from the negotiations.[25]

The agreement entrenches new and extensive protections for patent holders, while largely overlooking any measures to ensure access to generic medicines in the following ways:

- The Peruvian government is required to extend the patent term beyond 20 years, to compensate for delays in the processing of patent applications and marketing approval, a provision which even exceeds that which is required by US law.
- The agreement succeeds in blocking the registration and marketing of generics, by entrenching data exclusivity rights, barring the drug regulatory authority from using the clinical trial data already on file, in their consideration of the application by the generic manufacturer.
- The FTA prohibits the regulatory authority from registering generic versions of a drug until after a patent has expired. This forces the regulatory authority to assume the role of "patent police", required to do the bidding of the multinational proprietary pharmaceutical industry.[26]

Research by the Peruvian Health Ministry revealed that the protection and exclusive use of test data would limit competition from generic producers. "It is estimated that, compared to Peru's current expenditure on medicines, prices could rise by an average of 9.6 per cent in the first year, by almost 100 per cent in 10 years, and by 162 per cent in 18 years. In the first year alone this would mean that Peruvians would have to spend an additional $34.4 million to enjoy the same level of access to medicines and health care as they do today …" rising to an additional $199.3 million in 10 years. It estimates that between 700 000 and 900 000 people per year would be denied access to medicines, unless there was increased public spending and individual households were able to afford greater costs.[27]

24 US-Peru Free Trade Agreement 2005.
25 Oxfam International 2006:13-14.
26 Oxfam International 2006:14.
27 Oxfam International 2006:15-16.

5. Background to US-SACU Negotiations

That United States-Southern African Customs Union trade negotiations have foundered yet again, should come as no surprise.[28] Ever since past US Trade Representative Robert Zoellick spelled out his government's intentions, the talks were doomed to fail. Zoellick set the tone for the negotiations back in 2002 when he outlined the objective of the talks as the need to address barriers in SACU countries to US exports, such as "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."[29] The talks collapsed in 2004 because of vast differences between the negotiating sides, particularly on so-called "new generation" issues ordinarily outside the purview of trade talks, such as government procurement, intellectual property and competition policy.

6. Talks resume

Fresh efforts were made from mid-2005 to revive the talks, and a series of meetings was scheduled for April 2006. On the eve of these meetings, South African Deputy Minister of Trade and Industry Rob Davies warned that the US needed to demonstrate more flexibility if the talks were to succeed. He cited the US's inflexible proposals on tariff reductions which did not take account of different levels of development of partner countries.[30] By 18 April 2006, it became evident that consensus on a trade deal was elusive, both sides having acknowledged as much. Deputy US Trade Representative Karan Bhatia while holding that "new generation" issues were non-negotiable and "mandatory for any free trade agreement" insisted that the US position was not inflexible.[31] SACU countries clearly considered the US insistence on its standard template for negotiations too demanding, and beyond the commitments required at WTO level. From the US perspective, a contributory factor was the lack of common policy positions within the SACU community.[32]

Notwithstanding the lack of a trade deal, the parties agreed to set up a framework for future negotiations, in essence an agreement in principle to establish a joint working programme to address trade and investment issues. This signalled an end to the pursuit by the US, in the short-term, of a free trade agreement with southern African countries.[33] No new deadlines for concluding a trade deal are envisaged, and one is unlikely to be signed before the expiry of the Trade Promotion Act in 2007, which makes provision for "fast tracking" of such agreements.

28 South African Broadcasting Corporation 2006.
29 Zoellick 2002.
30 Addressing Parliament on 29 March 2006, as reported in the *Cape Argus* 2006.
31 *Business Day* 2006 (Benjamin).
32 *Business* Day 2006 (Benjamin).
33 Inside US Trade 2006.

How do the respective parties view the impasse, and the prospects for future agreement?

South Africa's Director-General for Trade and Industry Tshediso Matona sees the framework agreement as an opportunity to "negotiate in a fair manner" outside the constraints of the "normal free trade agreement congress meeting".[35] Bhatia held out hope that the parties "may potentially" conclude trade and investment-enhancing agreements, such as bilateral investment treaties, and trade and investment framework agreements.[36] According to private sector sources, "the new work programme with SACU means that US government has given up on an FTA with these countries".[37] By settling for much less than the envisaged free trade agreement based on standard US template, Bhatia appears to have signalled failure.

On the other end of the spectrum of opinion, this development has been hailed by activists as a major setback for the Bush Administration's trade agenda. SACU has refused to bow to "a one-size-fits-all" FTA with the US,[38] and in so doing, posted a small, but significant victory against the relentless march of the US Trade Representative to promote its aggressive trade policy.

While the exact terms of the negotiations are not public, it is clear that the intellectual property provisions are contentious because southern African countries depend heavily on generic medicines to address the AIDS epidemic.[39] These countries enjoy special protection because of the burden of the HIV/AIDS pandemic. In particular, where sub-Saharan African countries are concerned, US trade negotiators are required not to seek revocation or revision of any intellectual property law or policy regulating HIV/AIDS pharmaceuticals and medical technologies which promote access to these products by their populations.[40]

In the wake of the retreat by pharmaceutical companies from their lawsuit challenging amendments to the *Medicines Act*, then President Clinton issued Executive Order 13155 on 10 May 2000, preventing the US from pursuing intellectual property policies in sub-Saharan Africa which impact on access to medicines for people living with HIV/AIDS,[41] a position subsequently confirmed by the Bush Administration.[42]

34 *Business Day* 2006 (Lourens).
35 BuaNews 2006.
36 Inside US Trade 2006.
37 Inside US Trade 2006.
38 Church World Service 2006.
39 Church World Service 2006.
40 Executive Order 13155 — Access to HIV/AIDS pharmaceuticals and medical technologies, May 10 2000. http://www.presidency.ucsb.edu/ws/print.php?pid=61648.
41 Church World Service 2006. See also Treatment Action Campaign & AIDS Law Project 2004.
42 US Trade Representative 2002.

However, the US position on this issue is nothing, if not contradictory. While the USTR has been reported as stating that the United States intends to respect the executive order[43] Bhatia informed the media after talks with SACU representatives that the US would not compromise on issues like intellectual property.[44] Thus the issue appears to be far from settled.

7. Free Trade Agreement jurisprudence

As most free trade agreements have been concluded relatively recently, there is not much decided case law, at national or international level, on their provisions. One likely area of contention is that many agreements concluded by the US allow for a choice-of-forum option in their dispute settlement provisions.[45] Whereas the TRIPS Agreement[46] envisages comprehensive dispute settlement mechanisms under the auspices of the WTO, the free trade agreement provisions enable a complaining state, in the event of a breach, to select the forum in which the dispute may be settled.[47]

However, having multiple fora for dispute settlement can lead to problematic consequences such as prolonging dispute resolution, or re-contestation of an issue in a new forum after a prior forum has already made a ruling. An example of such a problem is the dispute between the US and Canada over Softwood Lumber, which has resulted in protracted litigation involving both NAFTA and WTO dispute resolution panels.[48] In contrast, with regard to pharmaceuticals, the WTO Dispute Settlement process has proved to be relatively efficient, as evidenced by several recent decisions.[49]

8. How can a Free Trade Agreement help us?

Elements of the business sector maintain that negotiating a free trade agreement with a high-wage country such as the US rather than with a low-wage country makes more sense because of huge expected benefits to the South African economy.[50] It has been suggested that such an agreement

43 *New York Times* 2006.
44 *Namibia Economist* 2006.
45 Bridges Monthly 2006.
46 Article 64.
47 Such provisions are contained in Art 22.3 of the US-Chile FTA, Art 20.4.3 of the US-Singapore FTA, and Art 21.4 of the US-Australia FTA, among others.
48 The dispute concerns the importation of softwood lumber from Canada to the US, a trade worth some $7 billion in 1999. Several rounds of negotiations had resulted in the Softwood Lumber Trade Agreement, 1996 which established a tariff-regulated quota system on Canadian softwood lumber imports.
49 A survey of WTO DSB decisions reveals that the expeditious resolution of disputes is the norm, many such disputes having been resolved in just over one year. See, for example, disputes involving US/Argentina (DS196); Brazil/US (DS 199); US/Canada (DS 170), among others. http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm.
50 See, for example, comments by Krawitz CEO of Cape Union Mart quoted in the *M & G Business* 2006.

would extend the benefits of the Africa Growth and Opportunity Act (AGOA)[51] and by attracting stronger US investment, would assist the government achieve its 6% growth target. Further, it is anticipated to make it easier for South African companies to tender for US government contracts. However, this would also require South Africa to make its government contracts accessible to US companies. Organised labour, on the other hand, is not so positive about such a deal because, among other things, South Africa already enjoys substantial benefits under AGOA, with some 94% of South African goods entering the US market free of customs duty.[52]

Further, it is doubtful whether the promise of access to US markets is at all realistic. Since 1994, annual imports into the US increased by more than $1.3 trillion, on the back of a massive trade and current account deficit.[53] However, analysts doubt this can be sustained, presaging the type of adjustments which will dramatically reduce the volume of US imports. Projections by the Center for Economic and Policy Research suggest that the annual value of US imports is expected to contract by $208 billion (or 9.5 per cent) over the next decade. Developing countries will be forced to compete with other exporters, such as Mexico and China, for a share of a "shrinking market".[54]

This factor has a direct bearing on bilateral trade negotiations between the US and developing countries. If the latter are considering trade-offs involving concessions in respect of intellectual property and investment provisions in exchange for access to US markets, they may find this *quid quo pro* to be highly illusory.

9. How can a Free Trade Agreement hurt us?

In addition to opening government contracts to US companies, the standard-type agreement would be extended to trade in services, modification of investment rules to suit US companies, and compliance with stiff intellectual property protection. Draper, of the South African Institute of International Affairs commented: "(t)he real question is why did we enter into free trade negotiations with the US in the first place when we knew we would be asked to open up our markets to the US and to make uncomfortable concessions?"[55] And as has been made abundantly clear by the USTR, as recently as the latest round of talks with SACU, the FTAs may only be concluded according to the US's standard template or "congress will not pass it otherwise".[56]

51 In July 2004 President Bush signed the AGOA Acceleration Act of 2004, which extends the preferences available under AGOA until 2015. See US Trade Policy Review 2005:33.
52 *M & G Business* 2006.
53 Weisbrot & Rosnick 2006:1.
54 Weisbrot & Rosnick 2006:1.
55 *M & G Business* 2006.
56 Bhatia, quoted in *Business Day* 2006 (Benjamin).

Specifically, as regards the intellectual property provisions, the following problems loom.

1. Any provisions in a proposed FTA to extend the terms of a pharmaceutical patent will sound the death knell of generic manufacturing, and as a result, greater access to life-saving medication.
2. Data exclusivity provisions will effectively close the door on generic production, as replication of the tests will be costly, time-consuming, and possibly unethical.
3. The linkage provision has the potential to completely immobilise regulatory capacity, as most developing country systems do not have the knowledge or experience to adequately deal with the dual requirements of patent registration and drug regulatory approval.
4. Specifically, as regards dispute resolution, the choice-of-forum option is not cost-effective for developing countries, given their disadvantages of resources and expertise. Furthermore, the more "flexible" procedural rules of the WTO[57] process which allow for third party participation, provide greater scope for co-operation and collective action by smaller countries seeking to initiate or defend such disputes, an advantage that the free trade agreement provisions appear to nullify.

9. Free trade or fair trade?

In explaining the skewed nature of intellectual property rules such as TRIPS, Maskus[58] advances the view that international patent negotiations were conducted in a context of asymmetrical power and interests between developed and developing countries. In similar vein, bilateral trade negotiations are blighted by the unequal power relations between developed and developing countries. The US, in particular, has effectively bypassed multilateral forums (where the voices and concerns of developing countries are heard by sheer force of numbers, if not by the merits of their arguments) to extract greater concessions through bilateralism.[59] Morin[60] argues that through the mechanism of "forum shifting" developed countries have succeeded in relocating intellectual property lawmaking outside of the multilateral sphere. Under these circumstances, the negotiations involving the US can hardly be said to be fair. Fair trade, "when conducted within the framework of a reasonable and fair set of rules that adheres to the triple-bottom line of environmental, social and commercial sustainability has the potential to act as a tool for attaining developmental priorities".[61]

57 See note 44.
58 Maskus 2000. For a detailed discussion of the power politics behind the TRIPS Agreement, see Drahos and Braithwaite 2004.
59 See, for example, Drahos 2001.
60 Morin 2006.
61 Treatment Action Campaign & AIDS Law Project 2004.

10. Implications for SACU countries

It is perhaps fortuitous that the latest round of negotiations failed to yield a free trade agreement. Despite being possibly the oldest customs union in the world[62] SACU is beset by several problems, most notably, the uneven development of the economies of its constituent countries. A comprehensive agreement catering to differing standards of performance and compliance would always be problematic.

However, the dangers lurking within the free trade agreement relate not to southern Africa's internal deficiencies, but the real threats of excessive conditions demanded by the US. Will a free trade agreement help unlock southern Africa's growth potential, as is sometimes contended? To what extent can it contribute to the realisation of pressing social needs such as employment creation, extension of the social welfare net, and the delivery of essential services. There is little evidence to suggest that such benefits are likely to accrue. On the contrary, the effects of increased patent protection on medicines will impede access to affordable medicines, and have a significantly adverse effect on health. The provisions are a major reversal of a developmental agenda, far exceed the requirements of agreements at multilateral level, and constitute a violation of both the letter and spirit of the Doha Declaration.[63] Trade and Industry's Matona has stated that "(t)he US standards and conditions on these [new generation trade agreements] are such that they reduce space for our governments to get involved in and apply own developmental strategies".[64]

When evaluating the potential benefits against the pitfalls of a SACU free trade agreement, it would be well to remember that southern African countries already enjoy some of the benefits under AGOA,[65] and that there is possibly little new market access to be gained, in exchange for substantial concessions on other fronts. On the other hand, spokespersons for US business, such as Luanne Grant, director of the American Chamber of Commerce in South Africa, maintain that the unilateral AGOA will not last forever.[66]

Southern African countries have other entrenched advantages which should not be compromised, for example, the protection afforded by Clinton's Executive Order (reaffirmed by Bush), prohibiting the US from demanding intellectual property protection which negatively impacts sub-Saharan Africa's AIDS pandemic. Given the "emergency" proportions of the pandemic in this region, heightened protection for pharmaceutical patents is simply not tenable.

As is evident form the Peruvian example cited here, the impact on the national budget can be devastating, effectively denying access most particularly to poor and vulnerable members of society. South Africa is lagging woefully behind in its rollout of antiretroviral therapy for the treatment of HIV/AIDS. It is estimated that the rollout programme reaches about 200 000 persons, constituting a

62 See Department of Foreign Affairs, Republic of South Africa 2005.
63 See, for example, the comments of Abbott 2004 and Correa 2006:402.
64 BuaNews 2006.
65 See note 39.
66 *Business Day* 2006 (Lourens 2).

approximately 20% of all those in need of treatment.[67] Furthermore, on the back of this rampant pandemic comes news of a rare, extreme drug-resistant tuberculosis strain (known as XDR TB), which has been isolated in some parts of the country.[68]

Clearly, the provisions of the standard template of free trade agreements do not augur well for access to medicines, unless SACU is able to negotiate new, substantially different terms. Brendan Vickers, of the Trade Strategy Group, blames the failure of the talks on the inability of the US to recognise the differing degrees of economic policy development within SACU, and hails the refusal of the union to sign the "one-size-fits-all" free trade template as something of a victory.[69] Does the most recent development to enter into "framework agreements", such as BITs and FITAs, signal a new approach by the US, or is it merely another false dawn? Is it merely a new strategy to keep negotiations going, until a more favourable climate makes it possible to revisit some of the most controversial issues? Only time will tell. In the meantime, Southern African governments must resist all attempts by the US to push them into a free trade "straitjacket", which will have devastating consequences for public health.

11. Conclusion

Recent reports suggest that the US may be revising its intellectual property and health policy provisions in such agreements, evidently to facilitate access to medicines. For example, changes to the US-Peru Free Trade Agreement reflect a new bipartisan agreement which includes explicitly in the text, an exception from marketing exclusivity with regard to the grant of compulsory licences. This represents a departure from the standard agreement where such exception was recorded in a "side letter", the legal force of which has long been in doubt.[70]

In the final analysis, however, the US has failed to honour its undertaking in terms of the Doha Declaration to support developing countries' access to medicines, by adopting provisions in free trade agreements which run counter to this commitment. There have been increasing calls, both within and outside the US, for Congress to ensure that respect for public health imperatives is maintained in negotiations for, and ratification of future free trade agreements.[71] Future SACU-US trade negotiations must not fail to heed such imperatives.

67 Natrass 2006:3-9.
68 Singh 2007:1
69 *Business Day* 2006 (Lourens 2).
70 Intellectual Property Watch 2007.
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