Joint submission by the Treatment Action Campaign (TAC), SECTION27, Doctors Without Borders/Médecins Sans Frontières (MSF), and the Stop Stock Outs Project (SSP) on the out-of-cycle review on South Africa's eligibility for benefits under the African Growth and Opportunity Act (AGOA)

August 12, 2015

INTRODUCTION

1. The Treatment Action Campaign (TAC) is a civil society organization based in South Africa that advocates for the rights and interests of people living with and affected by HIV and TB. SECTION27 is a public interest law center based in South Africa. Doctors Without Borders/Médecins Sans Frontières (MSF) is an international medical humanitarian organization that has programs based in South Africa and sub-Saharan Africa that primarily provide HIV and tuberculosis (TB) treatment to vulnerable populations. The Stop Stock Outs Project (SSP) is a civil society coalition that seeks to ensure that all people have access to the medicines they require and to which they have a right by monitoring and communicating about shortages and stock outs of medication, and ensuring that transparency and accountability exists along the supply chain in public health facilities across South Africa.

2. TAC and MSF jointly formed the Fix the Patent Laws campaign in 2011 to support South Africa in adopting critical flexibilities to protect health – allowed under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement") and other international laws – into its national legislation. Fix the Patent Laws has since expanded to include 13 other health organizations, including SECTION27 and SSP, which support the needs of people in South Africa with regard to cancer, diabetes, epilepsy, mental health conditions, other non-communicable diseases, and sexual and reproductive health.

3. We welcome the opportunity to provide comments to the AGOA Implementation Subcommittee ("the Subcommittee") of the Trade Policy Staff Committee, chaired by the Office of the United States Trade Representative (USTR), on the out-of-cycle review of South Africa's eligibility for ongoing inclusion in the African Growth and Opportunity Act (AGOA), as required by the Trade Preferences Extension Act of 2015 (TPEA).

4. This submission aims to highlight the negative public health effect for people in South Africa if the AGOA out-of-cycle review of eligibility is used to pressure South Africa not to pursue pro-

public health reforms of its national intellectual property (IP) legislation or to impose extraordinary IP standards beyond South Africa's obligations under international laws.

5. Both the United States and South Africa's governments agreed to the Doha Declaration on the TRIPS Agreement and Public Health ("the Doha Declaration")[1] as Members of the WTO, which affirms countries rights and obligations to adopt public health safeguards in implementation of TRIPS IP obligations. Commitments to supporting the protection of public health in the implementation of IP international obligations were also reiterated by both the United States and South African governments in the 2008 World Health Organization Resolution WHA 61.21 that adopted a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.[2] Furthermore, the United States unilaterally committed to protect access to medicines and public health in its trade relations with sub-Saharan African countries when it adopted the United States Executive Order 13155 in May 2000.[3]

An excerpt of the WTO Declaration on the TRIPS Agreement and Public Health ("the Doha Declaration"), November 20, 2001:

> *"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 this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

An excerpt of the United States Executive Order 13155, May 12, 2000:

> *"(a) In administering sections 301–310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:*
>
> > *(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and*
> >
> > *(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).*
>
> *(b) The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of,*

[1] See World Trade Organization. Declaration on the TRIPS agreement and public health. Available from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[2] See World Health Organization. WHA 61.21: Global strategy and plan of action on public health, innovation and intellectual property. Available from: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

[3] See Executive Order 13155 of May 10, 2000: Access to HIV/AIDS Pharmaceuticals and Medical Technologies. Available from: http://www.gpo.gov/fdsys/pkg/FR-2000-05-12/pdf/00-12177.pdf

vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa."

6. This submission also responds to a submission made by the American Chamber of Commerce in South Africa (AmCham) on behalf of American companies operating in South Africa, which argues that South Africa's eligibility to participate in AGOA must be contingent on South Africa abandoning certain IP law reforms. We note with deep concern that AmCham's submission requests that the U.S. Government use this out-of-cycle AGOA eligibility review process as leverage to discourage South Africa from pursuing TRIPS-compliant policy reforms that are in line with the country's national public health objectives and constitutional obligations.

7. Any attempt by the U.S. Government to impede South Africa's progress towards adopting flexibilities to protect public health allowed under the TRIPS Agreement would threaten access to medicines and promotion of public health and undermine United States public health commitments to South Africa.

THE SOUTH AFRICAN PUBLIC HEALTH CONTEXT

8. South Africa is facing dual epidemics of HIV and TB, as well as increasing burdens of non-communicable diseases. South Africa has the largest number of people living with HIV globally. An estimated 6.8 million people are living with HIV in South Africa,[4] of which around 3.1 million are currently receiving antiretroviral treatment (ART).[5] The vast majority of patients on ART are receiving it through government-run, public sector clinics.

9. South Africa has the highest global incidence and prevalence of TB,[6] which is the leading cause of death among adults in South Africa.[7] South Africa has the second highest incidence of drug-resistant TB globally.[8] Currently, approximately half of patients with drug-resistant TB in South Africa are receiving the treatment that they need. While the Department of Health is at the global forefront of making new TB treatments available, the price of new medicines is high, and prior to public sector availability, patients with extensive resistance have been unable to access new, more effective medicines partly due to their high costs.

10. Scaling-up ART and TB treatment is essential to reducing HIV and TB-related mortality, as well as to curbing new infections, as treatment offers strong preventative benefits that significantly reduce the risks of onward transmission for both diseases. Preventive therapies, treatments for other opportunistic infections associated with HIV and TB, and medical devices for diagnosing and monitoring the diseases must also be affordable to adequately address the dual epidemics in a comprehensive manner.

[4] See UNAIDS. South Africa. Available from: http://www.unaids.org/en/regionscountries/countries/southafrica/
[5] UNAIDS. (2015). How AIDS Changed Everything. Available from: http://www.unaids.org/sites/default/files/media_asset/MDG6Report_en.pdf
[6] WHO. (2013). Global Tuberculosis Report 2013. Geneva. Retrieved October 8, 2014, from http://apps.who.int/iris/bitstream/10665/91355/1/9789241564656_eng.pdf
[7] STATSSA. (2014). Mortality and causes of death in South Africa, 2011: Findings from death notifications. Retrieved January 10, 2014, from http://beta2.statssa.gov.za/publications/P03093/P030932011.pdf.
[8] WHO. (2013). Global Tuberculosis Report 2013. Geneva. Retrieved October 8, 2014, from http://apps.who.int/iris/bitstream/10665/91355/1/9789241564656_eng.pdf

11. In addition, and related to the dual HIV and TB epidemics, South Africa is facing large burdens of non-communicable diseases (NCDs) related morbidity and mortality. According to the World Health Organization, NCDs accounted for 29% of all deaths in South Africa in 2008, 18% of which was attributable to cardiovascular diseases and cancer.[9] It is also estimated that nearly one-third of all South Africans will experience a mental health disorder during their lifetime.

12. Given South Africa's high communicable and non-communicable disease burdens, there is an urgent need to ensure better and continued access to safe and effective medicines, vaccines, and medical devices. In its Draft National Policy on Intellectual Property ("the Draft IP Policy"), the South African Government has set a course to meet the country's health needs while remaining fully compliant with the WTO's rules. It is unconscionable that AmCham is attempting to derail this process because of the financial interests of their members.

THE HISTORICAL CONTEXT

13. During the past two decades South Africa has faced significant pressure from multinational pharmaceutical corporations and USTR to provide IP protections in excess of what is required by the TRIPS Agreement, and not to make use of the legal flexibilities allowed under TRIPS and other international laws to protect health.

14. South Africa amended its Patents Act in 1997 to provide for a 20-year patent period as required by the TRIPS Agreement,[10] despite its eligibility for an extension period until 2005 in providing such TRIPS-compliant patent protection. South Africa therefore became TRIPS-compliant well ahead of schedule. In 1997, South Africa also passed amendments to its Medicines and Related Substances Act ("the Medicines Act") to promote generic substitution of off-patent medicines and parallel importation. In an attempt to block the South African Government from adopting the 1997 amendments to the Medicines Act, 39 multinational pharmaceutical companies – represented by the Pharmaceutical Manufacturers Association (PMA) – brought a legal case against Nelson Mandela's administration in 1997. USTR supported the position of the PMA and placed South Africa on the Special 301 Watch List. The PMA case against the South African Government was eventually dropped in 2001, following a massive international outcry against the pharmaceutical companies involved.

THE DRAFT NATIONAL IP POLICY

15. In September 2013, South Africa's Department of Trade and Industry (DTI) published the Draft IP Policy for South Africa. The Draft IP Policy recommended the adoption of flexibilities to protect health, permitted under TRIPS, into South Africa's national legislation. This included the adoption of a substantive search and examination system for patent applications. AmCham made a submission on the Draft IP Policy to the DTI, calling for the expansion of IP protection in South Africa and arguing against the adoption of TRIPS flexibilities to protect health. The DTI

[9] http://www.hsrc.ac.za/uploads/pageContent/3893/NCDs%20STRAT%20PLAN%20%20CONTENT%208%20april%20proof.pdf

[10] Prior to 1997, South Africa provided 16 years of patent protection.

received well over 100 submissions from various stakeholders. TAC, SECTION27 and MSF also provided a joint submission[11] and were supportive of the DTI's plans for IP reform.

16. In January 2014, leaked documents revealed a plot by 25 multinational pharmaceutical companies to block South Africa's efforts to adopt flexibilities to protect health allowed under the TRIPS Agreement into national legislation, in what became known as the "Pharmagate scandal." In response to a request by the Pharmaceutical Research and Manufactures of America (PhRMA) and the Innovative Pharmaceutical Association of South Africa (IPASA), the U.S. lobby group Public Affairs Engagement (PAE) drew up a plan to thwart South Africa's IP policy reform. The plan outlined attempts to interfere with South Africa's democratic processes, including financing in the amount of $600,000 for "independent" research studies, and supporting a front organization that would push back against the Fix the Patent Laws campaign. South Africa's Minister of Health, Dr. Aaron Motsoaledi referred to the plot as tantamount to "genocide"[12] by the companies involved. Many of the pharmaceutical companies who are members of AmCham were implicated in this scandal. Several of the organizations intended to act as a front for the pharmaceutical company lobby have actively campaigned against IP reform,[13] despite promises from IPASA that the PAE plan would not proceed.[14] Subsequently, IPASA disbanded their executive committee and have since re-constituted their executive committee.

17. During USTR's Special 301 Review in 2014, the U.S. Chamber of Commerce suggested in its submission that it is important to work with the South African Government to ensure incremental innovation still stands. On the same note, the IP Owners Association mentioned South Africa as one of the countries that intends to lower IP standards and stated that it was troubled by the Draft IP Policy's assertions that in order for South Africa to thrive, IP standards must be lowered. We submit that these submissions are a mischaracterization of the policy process.

18. In their August 5, 2015 submission on South Africa's eligibility for ongoing inclusion in AGOA ("AmCham AGOA submission"), AmCham raises a number of concerns with the Draft IP Policy. This is clearly an effort to request support from the U.S. Government to use AGOA as leverage to prevent the Government of South Africa from adopting a finalized version of the Draft IP Policy and requesting South African Parliament to amend legislation.

19. Our submission addresses the following issues raised in the AmCham submission on AGOA eligibility (some of which is echoed in the AmCham submission to the DTI on the Draft IP Policy), including:
    a. The consultative process
    b. Substantive search and examination
    c. Patentability criteria
    d. Patent term extensions
    e. Data exclusivity
    f. Compulsory licensing
    g. Foreign direct investment and economic development
    h. Local innovation and the protection of IP of local innovators

[11] TAC, SECTION27 and MSF joint submission to South Africa's Department of Trade and Industry regarding the Draft IP Policy is available here: http://www.fixthepatentlaws.org/?p=764
[12] http://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide
[13] http://www.freemarketfoundation.com/issues/intellectual-property-rights-where-to-south-africa
[14] http://ipasa.co.za/wp-content/uploads/2013/07/IPASA-Press-statement.pdf

ON THE CONSULTATIVE PROCESS

20. In their submission on AGOA eligibility, AmCham raised its concern with the consultative process that has been undertaken on the Draft IP Policy by the South African Government. We contend that foreign companies have been given adequate opportunity to consult on the Draft IP Policy and at times have, worryingly, been given preferential opportunity to provide input. Prior to the public release of the Draft IP Policy, a leaked version of the policy revealed that IPASA – which represents foreign originator pharmaceutical companies operating in South Africa – was given the opportunity to provide input to the DTI on the draft document. Following the release of the Draft IP Policy for public comment, foreign pharmaceutical companies and industry bodies were once again given the opportunity to give input on the document. At this time, submissions on the Draft IP Policy were made by AmCham and IPASA. Further, the DTI has organized consultation meetings with stakeholders, which were attended by IPASA.[15]

21. The DTI hired Genesis Analytics, an economic consultancy firm, to conduct a Regulatory Impact Assessment (RIA) in early 2014. Consultation with pharmaceutical companies was a part of this. The RIA was concluded in August 2014 and according to the DTI at an IP Summit hosted by TAC and MSF in October 2014, that the adoption of TRIPS flexibilities among other aspects have been recommended in the final report of the assessment.

ON SUBSTANTIVE SEARCH AND EXAMINATION

22. In their AGOA submission, AmCham expresses concern that the Draft IP Policy seeks to "weaken" IP protections in South Africa through the adoption of a number of policy reforms, including the adoption of a substantive search and examination system for granting patents. It is odd that AmCham views the adoption of a substantive search and examination system as a mechanism that would weaken South Africa's IP protections, given that this type of system is used by many TRIPS-compliant countries, including the United States to strengthen the patent system and ensure weak or undeserved patents are not granted. The World Intellectual Property Organization (WIPO) specifically names search and examination as a mechanism "to ensure that patent protection is only granted to inventions which fully comply with national legal requirements for patentability, and that grants are made in a timely and cost-efficient manner."[16]

23. Currently South Africa utilizes a depository system for granting patents. Under the depository system, no substantive examination is undertaken to ensure that patentability criteria are met prior to the granting of patents. As a result many low-quality patents are granted that do not meet South Africa's patentability criteria and are rejected in other parts of the world with substantive examination, including the United States. A comparative review of pharmaceutical patents granted on identical applications filed in South Africa and the United States between 2000 and 2002, demonstrated that South Africa granted 66% more patents than the United States on

[15] http://www.politicsweb.co.za/party/we-rejected-paes-lobbying-proposal--ipasa
[16] http://www.wipo.int/patents/en/topics/quality_patents.html

identical applications. Many of these patents would not have been granted in the first place if a substantive examination system was put in place in South Africa.[17]

24. The granting of low-quality patents that fail to meet South Africa's patentability criteria as a result of the depository system used for granting patents, allows pharmaceutical companies to extend their patent monopolies through gaining multiple secondary patents on individual medicines. As a result, generic versions of many medicines are unavailable in South Africa despite their widespread availability in other countries, including the United States. Generic versions of aripiprazole (originator product sold as Abilify®) – used to treat depression and bipolar disorder – are now available in the US, yet secondary patents may prevent generic versions of this medicine from being marketed in South Africa until 2033. Additionally, generic versions of the birth control pill containing drospirenone and ethinyl estradiol (originator product sold as Yasmin®) may be blocked in South Africa until 2024 due to secondary patent protection. Yet a generic version of this contraceptive has been available in the U.S. and other countries since 2010.[18]

25. The adoption of a substantive search and examination system is mandated by section 34 of the Patents Act and will improve the quality of IP rights upheld in South Africa by ensuring that patents are only granted on applications that meet patentability criteria. There is already a willingness on the part of the South African Government and its agencies to implement substantive search and examination. The Companies and Intellectual Property Commission (CIPC) in South Africa has formally advertised 20 posts for Patent Searchers.[19] CIPC therefore undertakes to train Patent Searchers extensively on the law related to patents and ensure all patent applications comply with patentability criteria. This means that there are already resources and formal commencement of substantive search and examination.

26. It is unconscionable that, under the current depository system, South Africa is granting patent protection on applications that are widely rejected by other TRIPS-compliant countries, including the United States.

ON PATENTABILITY CRITERIA

27. In their AGOA submission, AmCham notes with concern that the Draft IP Policy proposes restrictions on patentable subject manner. Under the TRIPS Agreement, South Africa is required to grant patents on applications that are "new," "innovative" and "capable of industrial application." The TRIPS Agreement explicitly states that countries are free to determine what is meant by "new" and "innovative." This is important as it allows countries to limit or prevent the granting of secondary patents on new uses, new dosages, new forms and new formulations of existing medicines that do not merit the novelty and inventiveness thresholds. A narrow definition of patentable subject matter can help to combat evergreening of pharmaceutical patents. A number of international bodies have recognized this flexibility as essential for countries to streamline their patent law and safeguard public health.[20] As described in paragraph 24 of this submission, evergreening takes place in South Africa and blocks access to more

[17] Kapczynski A, Park C, Sampat B. South African Pharmaceutical Patenting: An Empirical Analysis. 2012. http://www.tac.org.za/sites/default/files/resources/Create%20Resources/files/Sampat%20presentation.pdf
[18] http://www.fixthepatentlaws.org/?p=911
[19] See http://www.cipc.co.za/files/3414/3895/2521/Patent_Searcher_External.pdf
[20] http://www.ictsd.org/themes/innovation-and-ip/research/guidelines-for-the-examination-of-pharmaceutical-patents

affordable generic versions of many medicines in the country. Stricter patentability criteria – seeking to limit evergreening – have been adopted by India, Argentina and the Philippines. Stricter criteria, within the TRIPS framework, are also under consideration in South Africa and Brazil.

ON PATENT TERM EXTENSIONS

28. AmCham's AGOA submission notes concerns regarding the impact of regulatory delays on length of market access under monopoly protection. In its submission to the DTI on the Draft IP Policy, AmCham recommends patent term extensions to compensate companies for regulatory delays. Delays in the registration process of medicines in South Africa do not, however, provide a basis for patent term extensions. Patent term extensions delay access to affordable medicines, do not improve regulatory processes and are not required by international law.

29. Extending the life of a patent as a result of regulatory delay punishes the public via high medicine prices, without addressing the root causes of the problem within the regulatory agency. Instead, we submit that the focus should be on necessary measures to ensure that the regulatory body of South Africa (the Medicines Control Council [MCC], which is transitioning to the South African Health Products Regulatory Agency [SAHPRA]) discharges its statutory mandate efficiently and effectively. What is necessary to address the delays are adequate human resources and measures that prioritize decision-making based on public health needs – not commercial subsidies that increase medicine prices and limit the ability of the government to make the right investments to strengthen SAHPRA and protect public health.

ON DATA EXCLUSIVITY

30. AmCham's AGOA submission notes its concerns regarding the Draft IP Policy's absence of data protection measures related to the registration of medicines and medical devices. Further in its submission to the DTI on the Draft IP Policy, AmCham recommends South Africa adopt data exclusivity on medicines and medical devices, misleadingly arguing that this is a requirement of the TRIPS Agreement.

31. The requirements for protecting data are covered in Article 39.3 of the TRIPS Agreement, which 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."*

32. The mandate of drug regulatory authorities is to ensure the efficacy and safety of medicines. The use of test data to carry out these functions does not entail unfair commercial use. We would like

to recall that the negotiation history of the TRIPS Agreement does not support the argument of including "data exclusivity" under the "data protection" of Article 39.3.[21]

33. Moreover, requiring generic companies to develop their own test data by repeating trials would violate medical ethics. Prescribing placebos or sub-standard alternatives for patients (as is done in the ordinary course of phase III clinical trials), despite proven knowledge that an effective treatment is available would be unethical and in potential violation of the Helsinki Declaration on Ethical Principles for medical research on human subjects.

34. Finally, the creation of "data exclusivity regimes" could severely and negatively impact access to affordable, generic medicines. This is because data exclusivity can block the introduction on the market and the use of generic versions of medicines even if there is no patent protection upon the medicines concerned, as the following example illustrates:

> *The Jordan Example:*
> *A 2006 study by Oxfam showed that of the 103 medicines registered and launched since 2001 that had no patent protection, at least 79 per cent had no competition from a generic equivalent as a direct consequence of data exclusivity. A more recent analysis by the Medicines Transparency Alliance estimates that delayed market entry of generics resulting from the TRIPS-plus requirements in the US-Jordan FTA cost consumers $18 million annually.*[22]

35. The concern with "data exclusivity" has also been highlighted by the WHO, for example in the 2006 report by the Commission on Intellectual Property, Innovation and Public Health. The commission stated that:

> *"If the patent period has expired, or there is no patent on the product, this sui generis data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent, where required. The only alternative for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues since it would involve replicating tests in humans to demonstrate what is already known to be effective. These sui generis regimes, which provide for data exclusivity need to be clearly differentiated from the TRIPS agreement's requirement for data protection"*

ON COMPULSORY LICENSING

36. The AmCham AGOA submission further notes concerns regarding South Africa's potential intentions to utilize compulsory license provisions, and to amend its national legislation to adopt

[21] See. "Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement", Carlos Maria Correa (South Centre, 2002) 53-55, available at: http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf

[22] All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Briefing Paper, Oxfam International, 2007. Full report available at: https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf

more workable procedures for granting compulsory licenses.[23] AmCham does not recognize that compulsory licenses are expressly allowed under the TRIPS Agreement.[24] Two types of compulsory licenses are considered in South Africa with recommendations for reform in our submission to the DTI in terms of the current legislative framework in South Africa – sections 4 and 56 of the Patents Act. These provisions relate to government use licenses and compulsory licenses where rights in patents are deemed to be abused respectively. Section 28 of the US Code 1498 authorizes the United States Government to use a patent or authorize third-party use for practically any public use without previous negotiation.[25] This comparative example exhibits, in contrast with AmCham's submission, that government use licenses with simplified procedures are not an anomaly in national patent laws.

37. We also find the AmCham comments deeply questionable given that the United States is a frequent user of compulsory licensing, including the government use of defense technologies and court-issued licenses to remedy anti-competitive practices in information technology and biotechnology.[26,27,28] There is a clear imbalance in the issuing of compulsory licenses versus public health need between the two countries. The adoption of more useable procedures for granting compulsory licenses in South Africa would assist in remedying some of this imbalance.

ON FOREIGN DIRECT INVESTMENT AND ECONOMIC DEVELOPMENT

38. In their submission on South Africa's eligibility for ongoing inclusion in AGOA, AmCham states:

> *"There is substantial evidence to show that countries that entrench and enforce strong IP pillars benefit economically, and those which have failed to do so suffer relative economic underperformance until they address this policy pillar."*

The submission further states:

> "*in South Africa, not enough has been done to address several gaps, for instance in the area of IP; the Bio-Economy Strategy does not address incentives for investment through enhanced IP protection."*

In its submission to the DTI, AmCham states:

[23] See TAC's, MSF's and SECTION27's submission on the Draft IP Policy.
[24] Article 31 of TRIPS.
[25] See: http://www.gpo.gov/fdsys/granule/USCODE-2011-title28/USCODE-2011-title28-partIV-chap91-sec1498/content-detail.html.
[26] KEI. (2013). "The US Department of Justice and USPTO call for compulsory licenses on thousands of "standards-essential" patents". Available at: http://keionline.org/node/1663
[27] KEI. (2012). "Posner's dismissals of the patent infringement suits in Apple versus Motorola cites eBay and compulsory licensing". Available at: http://keionline.org/node/1449; KEI. (2012). "Posner's dismissals of the patent infringement suits in Apple versus Motorola cites eBay and compulsory licensing". Available at: http://keionline.org/node/1449.
[28] KEI. (2013). "The US Department of Justice and USPTO call for compulsory licenses on thousands of "standards-essential" patents". Available at: http://keionline.org/node/1663

"Based on our members' experience, we believe that an enabling policy environment that includes the effective protection of IP rights could help South Africa attract foreign investment."

39. During the TRIPS negotiations, developing countries were assured by their more industrialized counterparts that strengthening IP protection would result in greater foreign direct investment (FDI). The experience in South Africa, however, has been largely the opposite, with the expansion of IP protection being accompanied by disinvestment. In 1994, upon becoming a member of the WTO, South Africa signed onto TRIPS (which came into force on January, 1 1995). In 1997, South Africa amended its laws, to make them TRIPS-compliant. Since 1994, 37 pharmaceutical manufacturing plants have shut down, the vast majority of them belonging to foreign-based originator pharmaceutical companies.[29]

40. Another common misconception is that high standards of IP protection will stimulate growth of the domestic pharmaceutical industry.[30] Over the past decade, investment by local generics manufacturers has far outpaced that of patent-holding companies. Yet South Africa's laws, which offer patent protection significantly in excess of what is required by TRIPS, have effectively limited the growth of this industry.[31] Put differently, expanding IP protections would work to the advantage of the foreign pharmaceutical industry that employs few people, offers little opportunity for real growth and has been shrinking (in terms of manufacturing capacity) for some time, while reducing opportunities for growth by local producers of generic medicines.

ON LOCAL INNOVATION AND THE PROTECTION OF IP OF LOCAL INNOVATORS

41. In their AGOA submission, AmCham states that:

"It is widely recognized that where countries have strong and effective IP protection in place, there is significant connection between increased incentives for local innovation".

42. What the AmCham submission does not consider is the ability of South African innovators to protect their IP in the United States market. A 2011 study demonstrated that only 20% of patents held by local academics in South Africa were also upheld abroad. The reason was largely due to the high costs of filing patent applications abroad, which are unaffordable for many local inventors.[32]

43. Conversely, South Africa offers very low application and renewal costs for IP protection to foreign inventors. Patent application fees in South Africa are on average 20 to 30 times cheaper

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

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

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

[32] Pouris A, Pouris A. Patents and economic development in South Africa: Managing intellectual property rights. S Afr J Sci 2011; 107(11/12), Art. #355, 10 pages. [http:// dx.doi.org/10.4102/sajs. v107i11/12.355]

than fees in other countries' patents offices.[33] The low costs of filing fees often results in frivolous applications that fail to meet South Africa's patentability criteria (discussed below).

44. While South African inventors struggle to protect their IP abroad, United States companies hold the majority of pharmaceutical patents in South Africa. During 2008, South Africa granted 2,442 pharmaceutical patents. More than 50% of these patents were granted to U.S. companies.[34] Pharmaceutical patents held by international companies in South Africa are mainly granted as a result of Patent Co-Operation Treaty (PCT) applications.

CONCLUSION

45. In conclusion, TAC, SECTION27, MSF and SSP support South African authorities' use of existing legal public health flexibilities to increase access to affordable medicines. We further support law reforms aimed at making these flexibilities part of national law. Given that these law reforms are consistent with international agreements to which the United States is a party and public health commitments made by the U.S., it would be inappropriate to use trade pressure to prevent these reforms.

46. The submission of AmCham on South Africa's ongoing eligibility for AGOA, includes numerous causes for concern as it relates to U.S. law and international trade agreements. South Africa should continue down the path of IP reform – indeed, it has the mandate and obligation to do so within its constitution, WTO rules, and international agreements.

47. We trust that the U.S. Government will not use South Africa's eligibility for AGOA as a bargaining chip to undermine South African IP reform to better protect the health of millions.

We once again thank you for the opportunity to submit comments. Please direct future correspondence and response on this submission to:

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[33] Ibid.
[34] YA Vawda. Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa. 2011