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**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC**

07/17/2019

Pre-hearing briefs and statements on the Public Hearing Regarding U.S. Trade and Investment with Sub-Saharan Africa: Recent Trends and New Developments

Investigation No. 332-571

Public Citizen submits the following comments in response to the request by the United States International Trade Commission for comments analyzing United States trade and investment in Sub-Saharan Africa, including the intellectual property environment. Public Citizen is a nonprofit consumer advocacy organization with 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines affordable and available for all through tools in policy and law.

The submission draws on our experience providing technical assistance to public agencies, particularly in developing countries, on patent and other intellectual property rules to protect access to medicines.

Principles

The United States had a complicated and, in some cases, shameful role in promoting intellectual property expansion in sub-Saharan Africa at the expense of public health. Any new attempt to promote intellectual property must contend with the tragic history of the HIV/AIDS crisis.¹

In the early 2000s, HIV/AIDS had devastated the African continent. South Africa, in particular, faced a growing epidemic.² In 1990, 160,000 people living in South Africa had HIV. By 2000,

¹ This story has been documented in detail online. SECTION27, Standing up for Our Lives: A History of the Access to Medicines Movement in South Africa, <https://standingupforourlives.section27.org.za/> (interviewing treatment activists and government officials who helped bring HIV treatment to South Africa).

² HIV/AIDS/STD strategic plan for South Africa, 2000-2005 (Feb. 2000), available at http://www.gov.za/sites/www.gov.za/files/aidsplan2000_0.pdf.



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4.2 million people did. That year, more people were dying in their 30s and 40s than in their 60s and 70s. Treatment, however, was unaffordable to all but the wealthiest, priced at \$10,000 per year.

President Mandela tried to import cheaper medicines from abroad to control the AIDS crisis.³ But the United States government intervened, at the behest of the pharmaceutical industry, to try to block the legislative reforms.⁴ The pharmaceutical industry argued that the measures, such as the parallel importation of patented goods, violated their patent rights.⁵ Industry filed a lawsuit in Pretoria, the United States Ambassador to South Africa wrote a stinging letter urging the government to change course, and the United States Trade Representative withheld trade benefits.⁶ Many people died.

Activists mobilized around the world and, confronted with public pressure, the United States government eventually stepped back.⁷ President Clinton issued an executive order noting that the United States government would 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. . .”⁸ A few years later, on the heels of activist work, HIV/AIDS medicine prices dropped significantly. Today, South Africa has the largest HIV/AIDS treatment program in the world.⁹ Millions of people in sub-Saharan Africa are alive because generic medicines are available. But too many medicines for other health conditions still remain inaccessible. As we

³ SECTION27, Standing up for Our Lives: A History of the Access to Medicines Movement in South Africa, Chapter 2, <https://standingupforourlives.section27.org.za/chapter-2/>.

⁴ William Fisher & Cyrill Rigamonti, The South Africa AIDS Controversy: A Case Study in Patent Law and Policy, The Law and Business of Patents (2005), available at <https://cyber.harvard.edu/people/ffisher/South%20Africa.pdf>.

⁵ Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98 (PMA case), available at <http://www.cptech.org/ip/health/sa/pharmasuit.html>

⁶ Simon Barber, U.S. Withholds Benefits Over Zuma’s Bill, Africa News (July 15, 1998), available at <http://allafrica.com/stories/199807150119.html>.

⁷ NY Times, Clinton Issues Order to Ease Availability of AIDS Drugs in Africa (May 11, 2000), available at <https://www.nytimes.com/2000/05/11/world/clinton-issues-order-to-ease-availability-of-aids-drugs-in-africa.html>.

⁸ See Executive Order 13155, <https://www.federalregister.gov/documents/2000/05/12/00-12177/access-to-hiv-aids-pharmaceuticals-and-medical>

⁹ UNAIDS, The Right to Health, (Nov 2017), p.48, available at http://www.unaids.org/en/resources/documents/2017/20171120_right_to_health.



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explain below, intellectual property barriers still play a significant role in curbing medicine access.

We urge the United States government to refrain from repeating this tragic history. The United States government should not promote maximalist intellectual property policies or condemn countries for pursuing intellectual property policies that safeguard public health. The United States government should also not wield its trade benefits, including those under the African Growth and Opportunity Act, to coerce countries to promote intellectual property. Many lives depend on it.

The international trade system and regional intellectual property institutions have been harmful, but patent reform is promising in South Africa

In terms of intellectual property and access to medicines, the international trading system has failed sub-Saharan African countries. Sub-Saharan Africa is composed of 46 countries,¹⁰ of which 33 (about three quarters) are considered ‘least developed countries’¹¹ (LDCs). 7 of these countries are not members of the World Trade Organization (WTO).¹² In terms of intellectual property rights, as LDCs these 33 countries are not required to provide patent protection on pharmaceutical products until 1 January 2033.¹³ The extension based on Article 66 of the WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) not only provides LDCs more time to comply with the provisions of TRIPS but also aims to assist LDCs with the implementation of TRIPS.

Developed country members are required to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfers to LDC

¹⁰ Namely; Angola, Benin, Botswana, Burkina Faso, Burundi, Cape Verde, Cameroon, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Republic of Congo, Cote d’Ivoire, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Eswatini, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, South Africa, South Sudan, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

¹¹ Namely; Angola, Benin, Botswana, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Eritrea, Ethiopia, The Gambia, Guinea, Guinea-Bissau, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, South Sudan, Sudan, Tanzania, Togo, Uganda, Zambia.

¹² Equatorial Guinea, Comoros, Sudan, South Sudan, Sao Tome and Principe, Somalia, Ethiopia.

¹³ TRIPS Council decision, 6 November 2015, IP/C/73.



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members and enable them to create a sound and viable technological base in their respective economies. However, there is no clarity around how such a transfer can be carried out and if specific WTO measures need to be undertaken to encourage such flows of technology. The lack of implementation of this provision continues to be an outstanding issue for Sub-Saharan Africa.

There are two regional patent offices in Africa, which provide a harmonized system of intellectual property protection for 36 member countries. The African Regional Intellectual Property Organization (ARIPO) established in 1976 in Lusaka, Zambia, under the framework of the Lusaka Agreement through the joint efforts of the United Nations Economic Commission for Africa (UNECA) and the World Intellectual Property Organisation (WIPO); and the Organisation Africaine de la Propriété Intellectuelle (OAPI) established in 1977 by the Bangui Agreement.

ARIPO was established by English-speaking sub-Saharan African countries to pool their resources together in industrial property matters¹⁴ and has 18 Member States.¹⁵ Based on the Protocols establishing ARIPO, a single patent application can be filed to cover one or more Member States designated in the application, and the effect of a patent granted by ARIPO is that of a national registration in each designated country. ARIPO grants undeserved pharmaceutical patents at the regional level which become valid in LDC Member States. By failing to recognize and implement the exemption from providing patent protection on pharmaceuticals in LDCs, ARIPO not only undermines regional development strategies, but also “kicks away the ladder” for these countries.¹⁶

OAPI was created by French speaking sub-Saharan African countries¹⁷ to implement common administrative procedures deriving from a uniform system for the protection of intellectual

¹⁴ <https://www.aripo.org/about-us/our-history/>.

¹⁵ Namely; Botswana, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Somalia, Sudan, Eswatini, Tanzania, Uganda, Zambia, and Zimbabwe.

¹⁶ Civil Society Organizations in South Africa have called for reforms at ARIPO <https://healthgap.org/press/over-60-health-organisations-demand-aripo-reform-to-increase-access-to-more-affordable-medicines-in-eastern-southern-africa/>.

¹⁷ Namely; Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Union of the Comoros and Togo.



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property.¹⁸ All patents granted by OAPI are automatically valid in all OAPI Member States, including LDCs. This creates similar public health challenges in LDCs and leads to high drug prices.

These regional intellectual property organizations have never sought to differentiate standards for granting intellectual property based on countries' development ranking, and patent protection is granted on pharmaceuticals at the regional level. These patents become automatically valid in the individual member countries, including least developed countries, despite the waiver by the WTO. These requirements have resulted in an ironic situation where in spite not being required to do so by the WTO, LDCs grant pharmaceutical patents. This practice causes serious unnecessary public health problems as access to medicines and other health technologies are stalled.

Neither ARIPO nor AOPI has ever encouraged their Members States to utilize flexibilities like parallel importation, compulsory licensing, government use and competition law which are recognized by the TRIPS Agreement and reiterated in the Doha Declaration on TRIPS and Public Health. Even in developing countries like Ghana, Nigeria, South Africa, and Cote d'Ivoire, these flexibilities are necessary for public health reasons as access to medicines remains a challenge.

South Africa provides a salient example. South Africa currently grants virtually all patents as it does not engage in substantive patent examination nor does it apply stringent patentability criteria. In 2009, South Africa began considering patent law reform. The pharmaceutical industry has tried to undermine the process at every step. In 2014, a leaked document showed industry plans to delay the policy and fund "experts" that would downplay public health concerns.¹⁹ In 2015, the American Chamber of Commerce in South Africa sought to tie South Africa's eligibility for trade benefits to abandoning its proposed patent reforms.²⁰ United States

¹⁸ Martin Musaluke, A critical analysis of Intellectual Property Rights Protocols administered by the African Intellectual Property Rights Agreement (ARIPO) with particular attention to Zambia, 11-12 2016.

¹⁹ Motsoaledi: Big pharma's 'satanic' plot is genocide, Mail & Guardian, 2014, available at <https://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide>

²⁰ TAC, SECTION27, MSF, Joint submission on the out-of-cycle review on South Africa's eligibility for benefits under AGOA, available at <https://agoa.info/images/documents/5795/submissionoftacs27msfssoregardingsouthafricaagoacr-3.pdf>



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pressure then reportedly stalled the process. A new patent law has still not been implemented, although a promising public-health friendly intellectual property policy was recently adopted.

The South African intellectual property policy is an important first step towards increasing medicine access. It includes a number of measures to maximize the use of flexibilities available to protect public health in international law, as permitted by the Doha Declaration (2003) and recommended by the United Nations High-Level Panel on Access to Medicines. These measures, such as setting rigorous patentability criteria, are fully compliant with international law.

Intellectual Property Protection Leads to Public Health Challenges

While access to HIV/AIDS treatment has significantly increased in sub-Saharan Africa, viral Hepatitis B and C, which affect 325 million people globally (making it 10 times larger than the global HIV epidemic)²¹ affects over 70 million people (60 million with Hepatitis B and 10 million with Hepatitis C) in Africa.²² Yet the cost of 12-weeks of generic Direct Acting Antivirals (DAAs) is \$750 per patient in sub-Saharan Africa, and \$1200 per patient if bought from the originator, Gilead.²³ The total cost of generic DAA to achieve universal coverage of all those presently living with Hepatitis C ranges from 2% of current total health expenditure in South Africa to 92% in Cameroon.²⁴ To achieve the same outcome with originator DAAs would increase these projections from 3% of total health expenditure in South Africa to 148% of total health expenditure in Cameroon.²⁵

In addition to Hepatitis B and C, cancer prevalence is also growing rapidly in Africa. But treatment access lags behind, in part due to high prices. One report by the Fix the Patent Laws Coalition and Cancer Alliance in South Africa found that only 7 of 24 cancer drugs were

²¹ WHO Regional office for Africa, Hepatitis, <https://www.afro.who.int/health-topics/hepatitis>.

²² WHO Regional office for Africa, Hepatitis, <https://www.afro.who.int/health-topics/hepatitis>.

²³ Assefa et al., Access to medicines and hepatitis C in Africa: Can tiered pricing and voluntary licencing assure universal access, health and fairness?, *Globalization and Health* 4-6 (2017) 13:73 DOI 10.1186/s12992-017-0297-6

²⁴ *Ibid.*

²⁵ *Ibid.*



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available in the public health system, which serves 80 percent of the population.²⁶ 10 medicines unavailable in the public sector – likely due to their cost – were available in India for less than half the price offered to the South African private sector. These different prices reflect differences in patent law. South Africa granted 92 patents on the 24 cancer medicines, 39 of which were rejected or withdrawn in at least one other jurisdiction. These patents extend monopolies and delay affordable generic access.

Recent United States negotiated trade agreements have put pharmaceutical companies' interests before patients' interests. The United States-Mexico-Canada Agreement (USMCA), for example, contains several provisions similar to those frequently pushed for by the United States in the Transpacific Partnership (TPP) and threatens to increase intellectual property exclusivity periods in myriad ways, which has the potential to cause drug prices to rise significantly. In particular, sections 20.36 (mandating secondary patents), 20.44 (extending patent terms to compensate for delays at the patent office), 20.46 (extending patent terms to compensate for delays during the regulatory review period), 20.48 (market exclusivity for small molecules), 20.49 (market exclusivity for biologics) and 20.51 (mandating patent linkage) would contribute harmfully to high drug prices. This would be damaging for public health in sub-Saharan Africa.

²⁶ Fix the Patent Laws and Cancer Alliance, *Exploring Patent Barriers to Cancer Treatment Access in South Africa: 24 Medicine Case Studies* (2017), available at <https://www.canceralliance.co.za/wp-content/uploads/2018/02/Exploring-Patent-Barriers-to-Cancer-Treatment-Access-in-SA-24-Medicine-Case-Studies-October-2017-update-January-2018.pdf>