

**Professor Brook K. Baker on Behalf of Health Global Access Project_2024
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The Office of the United States Trade Representative has quietly adopted positive policy initiatives in recent Special 301 reports and in its trade agreement negotiations that support expanded policy space in developing countries to adopt, use, and protect TRIPS-compliant flexibilities to access biopharmaceutical and other medical technologies. It has ceased to complain about countries' compulsory licensing practices, it has clarified that there can be public health exceptions to pharmaceutical data protection, and it has ceased to pursue TRIPS-plus intellectual property chapters in its trade agreement negotiation. In addition, on the domestic front, the Biden administration has also shown its willingness to use existing access mechanisms and to promulgate new ones in order to secure medical product supply and fairer prices. It has also signaled strong support for local productions. All of this echoes the Clinton administration's support for access to HIV/AIDS medicines in sub-Saharan Africa. These policy changes and precedent should become more formalized with respect to U.S. trade policy, and the 2024 Special 301 Report is an excellent venue for doing so.

An Announced Ceasefire on Complaints about Compulsory and Government Use Licenses

For the past three years, Special 301 Reports have directly acknowledged, countries' freedom to use compulsory, government use, and production-for-export licenses to respond to the COVID 19 pandemic:

The COVID-19 pandemic certainly qualifies as [a public health emergency]. Consistent with this view, the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement and the Doha Declaration.

Article 31 of the TRIPS Agreement establishes requirements that must be met with respect to compulsory licenses. Importantly, a Member choosing to issue a compulsory license may waive some of these requirements in certain circumstances. For example, in cases of national emergency or extreme urgency or in cases of public non-commercial use, Members may waive the requirement to seek prior authorization from the patent holder before issuing a compulsory license. In addition, under Article 31bis, the requirement that compulsory licenses must be authorized predominantly for the supply of the Member's domestic market may be waived in certain circumstances. Recognizing that Members with insufficient pharmaceutical manufacturing capacities could face difficulties in making effective use of compulsory licensing, Article 31bis and its related Annex set forth a system whereby such Members can import from another Member pharmaceutical products produced subject to a compulsory license. The United States respects the right of its trading partners to exercise the full range of existing flexibilities in the TRIPS Agreement, including Article 30, Article 31, and Article 31bis, and the Doha Declaration. The United

States further recognizes that these flexibilities are available in order to scale up the production and distribution necessary to overcome the challenges of the ongoing COVID-19 pandemic.¹

Notably, this is the only mention of compulsory licenses in these three Reports, a dramatic change from years past, including 2020, when the USTR typically complained about countries adoption and threatened or actual use of compulsory and government use licenses.² In other words, at least de facto, the USTR has announced a “ceasefire” with respect to countries’ use of compulsory licenses to respond to the COVID-19 pandemic and by inference other public health emergencies.

An Announced Tolerance of Public Health Exceptions to Data Exclusivity

Going even further, the USTR has acknowledged in its 2021, 2022, and 2023 Reports that it recognizes countries’ rights, including within existing trade agreements, to make exception to pharmaceutical data protection rules as needed to ensure access to medicines:

The U.S. Government works to ensure that the provisions of its bilateral and regional trade agreements, as well as U.S. engagement in international organizations, including the United Nations and related institutions such as the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), are consistent with U.S. policies concerning IP and health and do not impede its trading partners from taking measures necessary to protect public health. For example, in recent U.S. trade agreements, the U.S. Government has clarified that notwithstanding provisions on the protection of undisclosed test or other data, a Party may take measures to protect public health in accordance with the Doha Declaration, or any waiver or amendment of the TRIPS Agreement to implement the Doha Declaration.³

This acknowledgement signals agreement with the 2007 New Trade Policy which recognized a public health exception to data exclusivity and incorporated the same into several U.S. trade agreements.⁴

Regrettably, the USTR still complains about countries’ pharmaceutical data protection rules, essentially pushing for U.S.-style data exclusivity.⁵ As discussed further below, the USTR should no longer criticize countries for failing to adopt data exclusivity (and patent-registration linkage) rules that go beyond limited data protection rules set forth in the WTO TRIPS Agreement.

A De Facto Decision Not to Pursue TRIPS-plus Intellectual Property and Enforcement Measures

Although it has not been formally announced, the USTR has by all indications signaled that it is no longer pursuing TRIPS-plus intellectual property chapters and enforcement provisions in its

¹ 2023 Special 301 Report, p. 36; 2022 Special 301 Report, p. 36; 2021 Special 301 Report, p. 34.

² 2020 Special 301 Report, p. 14 (pledging to monitor CL concerns in Chile, Colombia, Egypt, El Salvador, India, Indonesia, Malaysia, Russia, Turkey, and Ukraine).

³ 2023 Special 301 Report, p. 37; 2022 Special 301 Report, p. 37; 2021 Special 301 Report, p. 35.

⁴ Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303, 333-337 (2008).

⁵ 2023 Special 301 Report, at 41, 43, 50, 56, 60, 63, 66, 70, 84, 86, 89 (addressing Argentina, Chile, China, India, Indonesia, Russia, Algeria, Brazil, Thailand, Turkey, and Vietnam)

free trade agreement negotiations. This is a positive development showing that it no longer seeks to further strengthen biopharmaceutical exclusivities in agreements with its trading partners.

Recently Used and Newly Announced Domestic Policies Provide Additional Support for New Policy Announcements in the 2024 Special 301 Report

On the domestic front, the Biden Administration repeatedly used its “government use” rights under to 28 U.S.C. sec. 1498 to procure needed supplies of essential COVID-19 countermeasures. The U.S. government used this authority dozens of times to insulate its contracted COVID-19 suppliers from IP infringement claims.⁶ Similarly, the U.S. used its powers under the Production Defense Act to support U.S. producers manufacturing covid-related medical products⁷ and has just announced another Defense Production Act initiative “to enable investment in domestic manufacturing of essential medicines, medical countermeasures, and critical inputs that have been deemed by the President as essential to the national defense.”⁸ In addition, President Biden has recently announced a new effort to use federal “march-in” rights arising from taxpayer-funded inventions to allow alternative producers to manufacture and sell medical products when the needs of U.S. patients are not met because of inadequate supplies or unreasonably high prices.⁹ Under the Bayh-Dole Act, 35 U.S.C. sec. 202(c)(4), the U.S. can also use march-in rights to secure “a nontransferable, irrevocable, royalty-free license to practice or have practiced the invention for or on behalf of the United States throughout the world.” Finally, the U.S. has recently begun to impose very modest fair pricing terms, including “most favored nations clauses” in some of its pharmaceutical R&D funding agreements, for example with Regeneron.¹⁰ Similarly, the Administration for Strategic Preparedness and Response has made fair pricing a standard part of its R&D deals.¹¹ Expanded use of existing rights and pursuit of new policies to assure affordable supplies of important medicines through government use licenses (sec. 1498 and march-in) and fair pricing policies) sets domestic policies and flexibilities that should as a matter of principle be recognized by the USTR and extended to other countries lest the U.S. be accused of hypocrisy or worse.

⁶ Knowledge Ecology International, *Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use of Third-Party Patents*, KEI Briefing Note 2022:1 (July 19, 2022), <https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf>.

⁷ FEMA, *Applying the Defense Production Act* (Jan. 26, 2021), <https://www.fema.gov/press-release/20230510/applying-defense-production-act#:~:text=The%20DPA%20also%20authorizes%20several,to%20use%20government%20Downed%20equipment>.

⁸ White House, *FACT SHEET: President Biden Announces New Actions to Strengthen America’s Supply Chains, Lower Costs for Families, and Secure Key Sectors* (Nov. 27, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/11/27/fact-sheet-president-biden-announces-new-actions-to-strengthen-americas-supply-chains-lower-costs-for-families-and-secure-key-sectors/#:~:text=President%20Biden%20will%20issue%20a,inputs%20that%20have%20been%20deemed>.

⁹ *Request for information Regarding Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, <https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the>.

¹⁰ *HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies* (Sept. 8, 2023), <https://www.hhs.gov/about/news/2023/09/08/hhs-announces-details-partnership-regeneron-develop-life-saving-mono-clonal-antibodies.html>.

¹¹ *New HHS Actions and Research Highlight How President Biden’s Administration is Lowering Prescription Drug Costs* (Dec. 14, 2023), <https://www.hhs.gov/about/news/2023/12/14/new-hhs-actions-and-research-highlight-how-president-bidens-administration-lowering-prescription-drug-costs.html>.

U.S. Global Health Pronouncements in Favor of Expanding Geographically Distributed Pharmaceutical Manufacturing Capacity Supports Recognition of Expanded Use of TRIPS Flexibilities to Support Local and Regional Production

In various global arenas, the U.S. has expressed its support for expanding biopharmaceutical manufacturing capacity in developing countries, particular to create capacity to respond to future pandemics.¹² In particular, from the beginning the U.S. has indicated its support for the main thrust of Article 11 of the International Negotiating Body Pandemic Accord text that addresses supporting geographically dispersed biopharmaceutical manufacturing capacity to deal with future pandemics.¹³ Although the U.S. formally supports the use of voluntary approaches to IP licensing and technology transfer on mutually agreed terms, there may well be circumstances where voluntary measures are unavailing and countries will need to feel free to use TRIPS-compliant compulsory, emergency, and government use licenses and exceptions to data exclusivity in order to secure adequate supplies, affordable prices, and equitable distribution. Accordingly, the USTR should signal support of the use of TRIPS flexibilities to build and sustain regionally distributed biopharmaceutical manufacturing capacity.

U.S Trade Policy on AIDS in Africa Broadly Supports a Cease Fire on Countries Use of TRIPS-Compliant Flexibilities

President Clinton in May of 2000 announced a dramatic change in U.S. trade policy directing the USTR not to interfere with sub-Saharan African countries' use of TRIPS flexibilities to access antiretroviral medicines to treat HIV.

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\(d\)\(15\)](#)).¹⁴

¹² White House, *FACT SHEET: U.S-Africa Partnership in Health Cooperation* (Dec. 13, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/12/13/fact-sheet-u-s-africa-partnership-in-health-cooperation/>; U.S. Dept. of State, *PEPFAR Sets Bold Manufacturing Targets for Africa* (Dec. 13, 2022), <https://www.state.gov/pepfar-sets-bold-manufacturing-targets-for-africa/>; U.S. Dept. of State, *U.S. Joins in Commitment to Strengthen Pandemic Prevention, Preparedness and Response* (Sept. 25, 2023), <https://www.state.gov/united-states-joins-in-commitment-to-strengthen-pandemic-prevention-preparedness-and-response/>;

¹³ Elaine Ruth Fletcher, *US Eager to Move Ahead with Pandemic Accord that Promotes Equity but not 'Transactional' Linkage between Data and Benefit-Sharing*, Health Policy Watch (Feb. 12, 2022), <https://healthpolicy-watch.news/us-eager-to-move-ahead-with-pandemic-accord-that-promotes-equity-but-not-transactional-linkage-between-data-and-benefit-sharing/>.

¹⁴ *Access to HIV/AIDS Pharmaceuticals and Medical Technologies*, Executive order 13155 (May 10, 2000), <https://www.federalregister.gov/documents/2000/05/12/00-12177/access-to-hiv-aids-pharmaceuticals-and-medical>.

This policy catalyzed the success of the U.S. PEPFAR program’s dramatic scale-up of HIV treatment throughout sub-Saharan Africa. Generic antiretroviral prices throughout Africa are now less than .1% the cost of those same medicines in the United States.¹⁵

Recommendations

The USTR should use the 2024 Special 301 Report to formally state, clarify, and expand upon issues discussed above. It should announce that the U.S.:

- Supports countries’ rights to issue compulsory, emergency, and government use licenses and public health exceptions to data exclusivity, if provided for, in response to public health needs and clarify that it will no longer chastise countries that adopt or use compulsory licensing rights in Special 301 Reports or otherwise;
- Supports countries’ rights to adopt and use measures similar to the U.S. with respect to 28 U.S.C. sec. 1498 government-use/indemnifications and contractual provisions, Bayh-Dole march-in rights and non-exclusive world-wide licenses to government funded inventions, and fair pricing conditions in public procurement contracts;
- Supports adoption and use of TRIPS-compliant flexibilities that promote regionally distributed biopharmaceutical capacity;
- Will no longer seek TRIPS-plus intellectual property and enforcement provisions in new trade agreements and will no longer enforce such chapters in existing agreements;
- Will no longer, through negotiation or otherwise, seek non-adoption, revocation, revision, or non-use of any TRIPS-compliant flexibilities and provide reasonable assurance thereof when requested to do so.

¹⁵ See, Global Fund, *Global Fund Agreements Substantially Reduce the Price of First-line HIV Treatment to Below US\$45 a Year* (Aug. 30, 2023), <https://www.theglobalfund.org/en/news/2023/2023-08-30-global-fund-agreements-substantially-reduce-price-first-line-hiv-treatment-below-usd45-a-year/>; *Cost Considerations and Antiretroviral Therapy*, Clinical Info HIV.gov (updated March 23, 2023) (reporting average annual wholesale price of dolutegravir/lamivudine plus tenofovir disoproxil fumarate is \$57,792), <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/antiretroviral-therapy-cost-considerations>.