The Honorable Robert Lighthizer
United States Trade Representative
Executive Office of the President
600 – 17th Street, NW
Washington DC 20508

November 6, 2017

Dear Ambassador Lighthizer,

We, the undersigned, write to you in our capacity as US-based organizations working on health, intellectual property, and human rights issues to urge the US government and industry not to interfere with South Africa's efforts to promote access to lifesaving medicines.

In August, the South African government released a draft intellectual property policy that contains new protections for public health. We are gravely concerned that the US government and industry representatives will try to undermine the South African government's plan to reform patent laws over the next few months. South Africa currently grants virtually all patents as it does not engage in substantive patent examination nor does it apply stringent patentability criteria. A patent policy that strikes the right balance between public health and intellectual property would help increase access to medicines, and save many lives. The US government should not interfere with South Africa's democratic process.

South Africa faces a number of pressing health challenges. Drug-resistant tuberculosis is growing, cancer rates are rising dramatically, and as the population ages, several other non-communicable diseases are becoming a significant burden on the health system.[1] Many of the drugs needed to treat these conditions remain out of reach for patients. For example, one recent report found that only seven out of 24 cancer drugs were available in the public health system, which serves more than 80 percent of the population.[2] 21 were available in the private sector. These disparities are a direct result of the high prices that patent monopolies induce.

The South African draft intellectual property policy is an important first step towards increasing medicine access. It contemplates 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 UN High-Level Panel on Access to Medicines. These measures are fully compliant with international law. They include setting strict patentability criteria, initially prioritizing patents related to health technologies for substantive search and examination, and developing a simple and expeditious process for compulsory licensing of patents. These policies

[1] Pooja Yerramilli, South Africa's Quadruple Burden of Disease (March 2015), available at http://blogs.plos.org/globalhealth/2015/03/southafrica_quadrupleburden/.
[2] Fix the Patent Laws, Exploring Patent Barriers to Cancer Treatment Access in South Africa: 24 Medicine Case Studies, available at https://www.canceralliance.co.za/wp-content/uploads/2017/10/Exploring-Patent-Barriers-to-Cancer-Treatment-Access-in-SA-24-Medicine-Case-Studies-October-2017.pdf.

are not only consistent with South Africa's international obligations. They are also morally necessary.

The US has adopted similar policies. For example:

- The US Supreme Court recently developed a more stringent standard for patent subject matter-eligibility.[3]
- The US maintains one of the most flexible and expansive compulsory licensing regimes in the world.[4] Indeed, the US government historically used such provisions to purchase generic versions of patented medicines and assure fair prices.[5]

The United States has a complicated — and shameful — history in South Africa with respect to access to medicines. After then-President Mandela tried to import cheaper medicines to halt the AIDS crisis, the United States tried to stop the reforms through Congressional threats and trade sanctions. The pharmaceutical industry launched a lawsuit. These attempts to stifle access were not successful and today, South Africa has the largest HIV/AIDS treatment program in the world. But too many medicines for other health conditions still remain inaccessible to all but the wealthiest.

The United States faces a similar problem. In recent years, a hepatitis C drug launched at a price of $84,000 for a course of treatment; multiple cancer drugs are priced at more than $120,000 for one year of treatment; and a genetic neuromuscular disease drug costs $750,000 for the first year of treatment.[6] More than one in four Americans currently taking prescription medications report difficulty affording them.[7] To address these unaffordable prices, the federal government, along with a number of states, have considered a range of policies, including promoting greater competition and using compulsory licenses.[8]

Every country, including the US and South Africa, has the right to take steps to increase access to medicines and implement a patent system in line with its public health needs. At a time when the high price of medicines is a global concern, we urge the US government and industry to not interfere in the South African government's plan to reform its patent laws and expand access to lifesaving medicines.

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[3] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

[4] U.S.C. § 1498 permits the government to "use" patents at any time without prior negotiation, as long as reasonable compensation is provided. Under § 1498, patent holders may seek damages for, but not enjoin, patent infringement. The government routinely relies on § 1498 to use or acquire patented inventions from non-patent holders. Notably, the government has invoked § 1498 even in situations where the patent holder is willing and able to negotiate. Leesona Corp. v. U.S., 599 F.2d 958, 963-64 (Ct. Cl. 1979). In any case, courts typically award a "reasonable royalty" to the patent holder. *See* Hannah Brennan et al., A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*,* 18 YALE JOURNAL OF LAW & TECHNOLOGY (2017).

[5] Charles Pfizer & Co., Inc., B-141459, 119 U.S.P.Q. 187 (Comp. Gen.), at *1 (1960) (upholding purchase by Defense Department of cheap generic antibiotics even when patent holder was willing to offer lower prices).

[6] Kantarjian et al., Cancer Drugs in the United States: Justum Pretium—The Just Price, *Journal of Clinical Oncology* 31, no. 28 (2013): 3600–3604. doi:10.1200/JCO.2013.49.1845; Pollack, Andrew, High Cost of Sovaldi Hepatitis C Drug Prompts a Call to Void Its Patents, *New York Times* (May 19, 2015), https://tinyurl.com/y8c9lddr; Picchi, Aimee, The Cost of Biogen's New Drug: $750,000 per Patient, *CBS Moneywatch* (December 29, 2016), https://tinyurl.com/yah66s4x.

[7] Kirzinger et al., Kaiser Health Tracking Poll: September 2016, The Henry J. Kaiser Family Foundation (September 29, 2016), http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/

[8] See e.g., Sarah Jane, Louisiana proposes tapping a century-old patent law to cut hepatitis C drug prices, *The Washington Post*, https://tinyurl.com/y7jmc2ds (May 2, 2017) and Federal Trade Commission, FTC to Conduct Workshop on November 8, Examining Competition Issues Related to Prescription Drug Markets, http://tinyurl.com/ybr6vxhj(October 3, 2017).

Respectfully,

Doctors Without Borders/Médecins Sans Frontières USA

Health GAP (Global Access Project)

Housing Works

Knowledge Ecology International

Oxfam America

People of Faith for Access to Medicines

Public Citizen

Treatment Action Group

Yale Global Health Justice Partnership

CC:
Eric Hargan, Acting Secretary, U.S. Department of Health & Human Services
Julia Friedman, Director for Innovation and Intellectual Property, Office of USTR
Thomas Donahue, President and CEO, US Chamber of Commerce
Orrin Hatch, Senate Finance Committee Chairman (R-UT)
Ron Wyden, Senate Finance Committee Ranking Member (D-OR)
Kevin Brady, House Ways and Means Committee Chairman (R-TX)
Richard Neal, House Ways and Means Committee Ranking Member (D-MA)