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6th February, 2020

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

Re: Concerning Intellectual Property and Access to Medicines

Dear Ambassador Lighthizer,

As an international humanitarian medical organization, Médecins Sans Frontières (MSF)/ Doctors Without Borders regularly purchases and dispenses medical products to patients in the programmes it runs all over the world. We believe it is a shared responsibility to ensure scientific and technological progress benefits all people – especially the most vulnerable.

Every day, MSF staff confronts significant gaps in the availability of medicines and vaccines to address the health needs of the people we aim to care for, in crisis-affected communities in more than 60 countries. These gaps – which have persisted for as long as MSF has been in operation – contribute to preventable deaths and exacerbate ongoing humanitarian and medical crises. [1]

In this context we have been witness to the negative impact of intellectual property - particularly pharmaceutical patents and data exclusivity- on access to lifesaving pharmaceutical products.[2]

A recent MSF report documents the negative impact of such monopoly driven incentives on the biomedical R&D ecosystem, highlighting that it fails to deliver for diseases that aren't

[1] Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 JAMA 361–367 (1999), https://jamanetwork.com/journals/jama/fullarticle/188412 (last visited Feb 6, 2020) also available at https://msfaccess.org/access-essential-drugs-poor-countries-lost-battle; Campaign for Access to Essential Medicines and Drugs for Neglected Diseases, Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases (2001) available at https://msfaccess.org/sites/default/files/MSF_assets/NegDis/Docs/NEGDIS_report_FatalImbalance_CrisisInR%26D_ENG_2001.pdf (last visited Feb 6, 2020).

[2] For more than 15 years, the MSF Access Campaign has been monitoring the patent barriers, prices and availability of antiretroviral medicines through its Untangling the Web report series Untangling the Web of Antiretroviral Price Reductions, (1-18 editions), MÉDECINS SANS FRONTIÈRES, https://msfaccess.org/utw (last visited Feb 6, 2020); Leena Menghaney, *Pfizer patent for pneumonia drug could have a deadly impact on public health*, HINDUSTAN TIMES, August 30, 2017, https://www.hindustantimes.com/analysis/pfizer-patent-for-pneumonia-drug-could-have-a-deadly-impact-on-public-health/story-GjK0yXU1j1asOd9xT5CDvJ.html (last visited Feb 6, 2020).

sufficiently lucrative; ignores public health criteria in the choice of R&D priorities; interferes with competition necessary to deliver affordable products; and hampers efficient use of scientific and financial resources. [3]

USTR's role in undermining access to medicines globally

For the past 20 years, MSF has consistently raised these concerns with the USTR and highlighted that its efforts to dramatically expand stringent intellectual property standards on pharmaceuticals- including the push for the Agreement on Trade-related Intellectual Property Rights (TRIPS) in the World Trade Organization (WTO) and continuing with ever-increasing standards across the globe, is without due consideration of the negative impact on access to medicines, right to health and biomedical innovation.

Post TRIPS, USTR continued to undermine the implementation of the 2001 Doha Declaration on TRIPS and Public Health. For example, when governments were struggling to address the HIV/AIDS epidemic, it used the Special 301 Watch List to apply pressure against governments when they attempted to take steps to increase access to life saving antiretroviral drugs (1998 South Africa, 2007 Thailand).[4]

In 2005, forced to comply with the TRIPS agreement, India, a key global supplier of affordable generic medicines, introduced an amendment to its 1970 Patents Act to include medicines in its product patent regime. Today many lifesaving medicines for drug-resistant tuberculosis (DR-TB), cancer and rare diseases are patented and alternative suppliers are blocked from supplying generics, not just domestically but across the developing world.

Over the past few decades USTR, by using the Special 301 and bilateral and multilateral trade deals, has consistently pressured countries to introduce measures including but not limited to extended patent terms, patent linkage, and data exclusivity; pushed for restrictions on public participation in pre- and post-grant oppositions; and undermined sovereign rights of countries to issue compulsory licenses and establish strict criteria for the examination of pharmaceutical patents.[5]

These provisions block or delay the onset of generic competition, keeping medicine prices high. Higher treatment costs are devastating to poor people, and they undermine the sustainability of public health programs—particularly in developing countries, where public finance for health care is limited.

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[3] Lives on the Edge: Time to align medical research and development with people's health needs, (28 April 2016), MÉDECINS SANS FRONTIÈRES, https://msfaccess.org/lives-edge-time-align-medical-research-and-development-peoples-health-needs (last visited Feb 6, 2020).

[4] Anand Grover, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (31 March 2009), 11th Session of Human Rights Council, A/HRC/11/12 available at https://documents-dds-ny.un.org/doc/UNDOC/GEN/G09/127/11/PDF/G0912711.pdf?OpenElement (last visited Feb 6, 2020).

[5] For example, the 2019 USTR Special 301 report targets Argentina, Brazil, China, Chile, Colombia, Ecuador, India, Indonesia, Malaysia, Turkey, and Ukraine regarding policies, laws, decisions that allow stricter patent examination for pharmaceuticals, issuance of compulsory licenses, encouragement of domestic production and pushes for the countries to introduce patent term extension, patent linkage, data exclusivity and over broad IP enforcement measures favoring US pharmaceutical corporations.

In particular we would like to draw your attention to the USTR's unwarranted pressures on Brazil, India, Malaysia, and more recently China for their use of flexibilities under the TRIPS agreement to ensure access to medicines.

Brazil

Brazil has been vocal globally on issues of access to medicines and had incorporated several health safeguards in line with the TRIPS agreement. However, the United States have been critical of such efforts by Brazil to ensure universal access to medicines. Currently, USTR is using continuous pressure including the annual Special 301 reports to undermine the role of Brazil's National Sanitary Regulatory Agency (ANVISA) on issues relating to the patentability of new biopharmaceutical products[6], a key safeguard against granting of poor quality patents on key essential medicines.

The US government is also instrumental in pushing measures that are undermining the autonomy of the patent examination performed by the Brazilian Patent Office (INPI). The recent expansion of the Patent Prosecution Highway (PPH) agreement between the INPI and the USPTO, applies to pharmaceuticals[7] and Brazil is more likely to grant frivolous patents on medicines, what can be extremely harmful for the country's public health system that is already under severe budgetary constraints.

India

India's patent and drug regulatory laws and policies have helped to protect price-lowering generic competition, so much so that the country is known as the "pharmacy of the developing world". However, India has continuously encountered pressure from the USTR for the country's strict patentability criteria, any application of compulsory licensing provisions[8], and the rejection of data exclusivity.

The USTR's continued criticism of section 3(d) of Indian patent law[9] that keeps out evergreening patents[10] is fully complied with TRIPS and in 2013, the Supreme Court of India had upheld the validity of section 3(d) during the Novartis case. However, the government of India's failure to consider requests from civil society to consider compulsory licensing for patented DR-TB drugs raises concerns that the pressure is having a chilling effect on the use of the various compulsory licensing provisions. Thus, the USTR's criticism directly interferes with the country's sovereign powers to protect right to health under national and international law.[11]

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[6] Special 301 Report, Office of the United States Trade Representative (2019), available at https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf, page 78 (last visited Feb 6, 2020).
[7] Special 301 Report, Office of the United States Trade Representative (2019), available at https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf, page 78 (last visited Feb 6, 2020).
[8] Special 301 Report, Office of the United States Trade Representative (2019), available at https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf, page 51 (last visited Feb 6, 2020).
[9] Special 301 Report, Office of the United States Trade Representative (2019), available at https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf, page 51 (last visited Feb 6, 2020).
[10] Evergreening allows pharmaceutical corporations to extend monopoly protection, potentially indefinitely, by patenting modifications of an existing drug, delaying generic production of the drug beyond the original 20 year protection.
[11] U.S. Puts Unwarranted Pressure on India for Taking Legal Steps to Increase Access to Affordable Medicines, (24 September 2013), MÉDECINS SANS FRONTIÈRES available at https://msfaccess.org/us-puts-unwarranted-pressure-india-taking-legal-steps-increase-access-affordable-medicines (last visited Feb 6, 2020).

Malaysia

In 2017, Malaysia issued a government use license on sofosbuvir to accelerate the Malaysian Ministry of Health's efforts to scale-up hepatitis C virus (HCV) treatment, enabling procurement of generic sofosbuvir for availability in public hospitals throughout the country. Since then the Malaysian government has been pressured continuously by Gilead Sciences. This pressure was also backed by the USTR when it announced an out of cycle review of Malaysia's IP policies and extended it in 2019.[12] Such pressure is aimed at discouraging other countries from using compulsory licensing to address high drug costs stemming from patent monopoly.

China

China's role as the major producer of active pharmaceutical ingredient at the global level also faces increasing challenges due to continuous USTR pressures, thus causing unpredictability of pharmaceutical trade and production in the international market. Despite of China's efforts of improving public health safeguards in its intellectual property and regulatory system over the past decade, the US together with its pharmaceutical corporations, have explicitly undermined those efforts by pressing China to adopt and implement provisions that go beyond TRIPS obligations (TRIPS-plus provisions), such as data exclusivity, patent term extensions and patent linkage. The demand for more stringent standards of intellectual property standards and TRIPS-plus provisions are now explicitly reflected in the recently signed Economic and Trade Agreement between US and China.[13] China, a key producer of medicines, will face delayed introduction of competition in its domestic market and manufacturers will not be able to register and supply generic formulations of many essential medicines till the extended patent terms expire.

Based on the above, MSF raises concerns regarding the actions of USTR that undermine WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Business-as-usual approaches adopted by USTR towards continuously increasing intellectual property standards will not address the global problem of excessive pricing of pharmaceutical products in developed and developing countries. We therefore call on USTR to:

1. Recognize that the pharmaceutical patenting standards needs urgent reform to prevent abusive evergreening and pricing practices;
2. Refrain from listing countries on the Special 301 Priority Watch list and Watch list on the grounds of their national laws, policies and practices that are aimed to fulfill their obligation to protect public health and, in particular, to promote access to medicines for all by making use of flexibilities available under the TRIPS agreement;
3. Eliminate TRIPS-plus intellectual property provisions in trade deals that increase the cost of medicines.

[12] Special 301 Report, Office of the United States Trade Representative (2019), available at https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf, page 10-11 (last visited Feb 6, 2020).
[13] Economic And Trade Agreement Between The Government Of The United States Of America And The Government Of The People's Republic Of China Text | United States Trade Representative, (2020), https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf (last visited Feb 6, 2020).

The USTR's policies hampers the ability of countries to ensure the protection of public health and the promotion of access to medicines. As a medical humanitarian organization, we must speak out when we witness policies that protect the pharmaceutical industry instead of the needs of patients who need access to medicines.

Finally, we submit a comment on the USTR's upcoming visit to India, and request that the USTR not pursue damaging policies that are aimed at changing the country's pro-access intellectual property and regulatory laws. India's production and supply of affordable medicines is a vital lifeline for MSF's medical humanitarian operations and millions of people in need in all countries.

Sincerely,

Leena Menghaney and Yuanqiong Hu
Medecins Sans Frontieres Access Campaign