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Honorable Ambassador Katherine Tai
United States Trade Representative
Office of the United States Trade Representative
600 17th Street N.W.
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The Special 301 Report Should Not Target Countries Using or Planning to Use Compulsory Licensing for Access to Medicines

Dear Ambassador Tai,

Congratulations on your confirmation as the United States Trade Representative. As an international medical humanitarian organization, Médecins Sans Frontières/Doctors Without Borders (MSF) has been following the trade policy of the United States and its impact on access to medicines in countries where we work for more than a decade. We are encouraged by your April 15th statement about the COVID-19 crisis at the World Trade Organization (WTO) articulating the need to live up to the spirit of the Doha Declaration on the TRIPS Agreement and Public Health. In this time of crisis, you recognized that the market has once again failed to meet the health needs of developing countries.

In this regard, we respectfully request your assistance to ensure that the Special 301 Report, starting from the 2021 edition and onward, does not penalize countries for using public health safeguards in their national laws or flexibilities contained in the TRIPS Agreement. Countries should be able to facilitate production, supply and access to protective equipment, treatments, vaccines or other medical technologies without undue pressure.

The practice of previous US Trade Representatives and Special 301 Reports have been to represent the interests of pharmaceutical corporations, to the detriment of access to medicines. In the past decade, we have witnessed how the US government has systematically pressured developing countries over intellectual property rules and practices that could support access to medicines. Even in the midst of the COVID-19 pandemic, we regretfully observed how the 2020 Special 301 Report completely ignored the ongoing global crisis and continued the attacks on countries for overcoming intellectual property barriers to address access to medicines challenges. The COVID-19 pandemic presents unprecedented challenges. With the loss of millions of lives, and the ongoing inequality and inequity of access to health care and to COVID-19 medical tools that is disproportionately affecting low- and middle-income countries, the consequences of the

pandemic will be felt for years to come. Yet even through the worst global health crisis in our lifetimes, large pharmaceutical corporations have continued to pressure governments for undertaking measures such as compulsory licensing of medicines to boost access to COVID-19 treatments. This is clear in industry submissions to the 2021 Special 301 review process, demonstrating complete ignorance of the global crisis we are experiencing.

For example:

- The U.S. Chamber of Commerce 2021 Special 301 submission notes: "*Already, legislative bodies in **Chile, Canada, Germany, and Thailand** have tabled compulsory license proposals. This is even though other options—such as working alongside industry to ensure broad access—exist. Meanwhile, other countries have also introduced emergency regulations that call for the indiscriminate use of compulsory licenses for COVID-19 products or those implemented under vague national security grounds. For instance, the **Hungarian government** used its compulsory licensing mechanism for remdesivir, a treatment for COVID-19, following a request by a local company….*"
- The Biotechnology Innovation Organization (BIO), which includes Pfizer, Moderna, Johnson & Johnson, and Merck, notes in its submission: "*BIO has also been concerned about the ongoing CL [compulsory license] threats during the COVID-19 pandemic… We are, therefore, concerned that **the European Commission**, for instance, in their proposed IP Action Plan seeks to 'ensure the availability of critical IP in times of crisis, including via new licensing tools and a system to co-ordinate compulsory licensing.' The misguided claim by the European Commission to ensure that effective systems for issuing CLs are in place and, thereby, suggesting that IP in and of itself poses a barrier to manufacturing and delivery of treatments and vaccines during the COVID-19 pandemic constitutes an unreasonable and regretful mischaracterization by a key U.S. ally.*" The submission goes on to attack various countries for issuing compulsory licenses for remdesivir after the IP-holding firm's voluntary license deals excluded most of the worst affected countries and half the world's population.
- The Pharmaceutical Research and Manufacturers of America (PhRMA) submission notes: "*Some countries like **Hungary, Colombia and Indonesia**, have adopted emergency regulations that allow the grant or blanket use of CLs for COVID-19 products without due process or basic engagement with the patent holder … PhRMA and its members are concerned about the Indonesian Government's implementation of government-use licensing for COVID-19 medicines such as remdesivir ….*" The submission also directly attacks World Health Organization, United Nations Development Programme and United National Conference of Trade and Development for supporting the use of public health safeguards and TRIPS flexibilities.

Developing country governments and civil society organizations have explained repeatedly how the pressure and threats of trade sanctions are key reasons why the existing flexibilities in the TRIPS Agreement have not been widely used by developing countries to date.

Governments are struggling to adopt policies necessary to save lives and livelihoods. This includes efforts to facilitate domestic manufacturing of life-saving health products and to promote a temporary, emergency waiver of certain WTO intellectual property rules to boost worldwide production of COVID-19 vaccines, treatments and diagnostics.

Recently, we heard that your staff in Geneva have made favorable comments about compulsory licensing. A US Special 301 Report that does not target countries seeking compulsory licenses would be a powerful new approach of the US trade policy that does not undermine the protection of the right to health and access to medicines in other countries.

However, this is not enough to address the access challenges in this pandemic. While recognizing that existing TRIPS flexibilities are crucial to facilitate access for COVID-19 medical tools, we also request that your office not block the temporary COVID-19 TRIPS waiver.

In reality, the long-term discouragement of using compulsory licenses has created barriers for access to more affordable treatments for different diseases. In addition, the complexity presented by the pandemic also requires new legal tools to empower governments to be more responsive and take quicker actions.

The ongoing discussion at the WTO on the temporary TRIPS waiver for COVID-19 provides a unique opportunity for governments to recognize the limitations of existing tools and adopt an emergency waiver in this pandemic. In this regard, the US position to support, or at least not to block, the formal negotiation of the waiver could positively influence the process.

To conclude, we respectfully urge you to reject pharmaceutical corporations' efforts to use the US government to undermine the existing TRIPS flexibilities and to block new tools that could help countries respond to this pandemic. We sincerely hope your leadership will open a new chapter of the US trade policy that truly values the rights to health and access to medicines as a common goal worldwide.

Respectfully yours,

Avril Benoît

Executive Director
Doctors Without Borders / Médecins Sans Frontières USA