September 11, 2015

Ambassador Michael Froman
United States Trade Representative
600 17th Street N.W.
Washington, D.C. 20508

Michelle K. Lee
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (USPTO)
USPTO Madison Building
600 Dulany Street
Alexandria , VA 22314

Re: WTO LDC Members' Request for an extension of their pharmaceutical transition period

Dear Ambassador Froman and Michelle Lee,

Earlier this year, WTO Least Developed Country (LDC) Members requested an extension of the WTO TRIPS transition period that would exempt them from having to implement pharmaceutical patents, data protections, as well as waivers from exclusive marketing rights and mailbox obligations, all of which constrain their ability to make or procure low-cost generic medicines. LDCs are the poorest countries in the world (2014 average per-capita income just $928) where millions currently live without having adequate access to affordable medicines.

The next TRIPS Council meeting on this topic is scheduled for October 15-16, 2015 in Geneva. Informed sources indicate that informal consultations on this issue will be beginning soon. At present, the Office of the USTR has not yet publicly disclosed its position with respect to the extension request. We are writing to request immediate full disclosure of US positions on the requested extension and an opportunity to engage with your office on policy positions that we think would be highly undesirable.

LDCs are seeking an extension for as long as they remain LDCs. They ground their request both on the language of the Doha Declaration on the TRIPS Agreement and Public Health and Article 66.1 of the TRIPS Agreement. These binding, unanimous-consent documents, acceded to by the US, grant LDCs the right to seek further extensions of their TRIPS transition period and require that such extensions "shall" be accorded upon duly motivated request.

Past USTR positions during negotiations on earlier transition periods and their extension, as well as the US position on the August 30th Decision on Paragraph 6 of the Doha Declaration concerning effective use of compulsory licenses for countries with insufficient domestic manufacturing capacity, suggest that the US might pursue policy positions that restrict the rights of LDCs under the TRIPS Agreement and hinder access to affordable medicines for their populations.

First, the US must not seek to shorten the time limit of the proposed extension, as short extensions do not allow LDCs and donors of global health programs like the United States the

legal and policy space to secure durable sources of lower cost generic medicines nor a sufficient time period to develop sustainable local pharmaceutical capacity. LDCs made a request two years ago for a transition period from their basic TRIPS-compliance obligations for as long as they remained LDCs. The US and EU opposed this request and instead insisted on no more than an eight-year extension (2013-2021). The need for a transition period for pharmaceuticals as long as a country remains an LDC couldn't be clearer, as the health needs of LDC populations require preserving policy space to pay the lowest possible prices for generically sourced medicines. It would simply be unacceptable for the US to oppose the duration requested by LDCs and to instead require LDCs to return repeatedly to the TRIPS Council every few years for successive short-term extensions.

Second, the US must not seek to tie the granting of an extension for pharmaceuticals to a declaration, express or implied, that intellectual property protections are necessarily beneficial for development of LDCs. Today the best economic and health evidence is that increased IP protections and continued efforts towards TRIPS compliance do not create favorable conditions for accelerated development in low-income countries and instead such polices increase prices and thereby reduce access to global public goods like medicines. Questions about the negative impacts of easily granted and over-enforced patents are growing even in the US where government programs and private insurers can no longer afford some of the high-priced medicines that have recently hit the market, such as Gilead's sofosbuvir.

Third, the US must not place any other condition or restriction on LDCs including any that may restrict LDCs' pharmaceutical capacity and right to export medicines to other countries. Viable pharmaceutical enterprises in LDCs, especially in the generics context, need to achieve efficient economies-of-scale. LDCs simply cannot build viable pharmaceutical capacity that solely serves small and poor populations. More to the point, new pharmaceutical industries in LDCs need time and maximum policy space to develop, as existing capacities are non-existent or weak. To impose conditions on commercially oriented pharmaceutical production and export would create a perverse carve-out for medicines that is inconsistent with technological development rights affirmed in the 2013-2021 WTO TRIPS-compliance extension.

Fourth, the US must not impose conditions that require LDCs to maintain existing degrees of IP protection. The first general LDC extension for 2006-2013 unfortunately contained a stay-put provision that locked LDCs into their existing levels of IP protection. Fortunately, LDCs succeeded in reversing this stay-put clause in their 2013-2021 extension with the following provision: "Nothing in this decision shall prevent least developed country Members from making full use of the flexibilities provide by the [TRIPS] Agreement to address their needs, including to create a sound and viable technological base and to overcome their capacity constraints supported by, among other steps, implementation of Article 66.2 by developed country Members [relating to technology transfer]." This provision grants LDCs the policy space - free from exclusive rights - to advance their development project and to fulfill their human rights obligations, including the right to health.

We request that the USTR immediately disclose its LDC pharmaceutical extension policy positions. To the extent that its positions include any of the above policies that we have recommended against taking, they should be reversed. Instead, the US should join the emerging global consensus, supported even by the European Commission, that the LDC pharmaceutical extension should be granted on requested terms.

Allowing LDCs unfettered access to more affordable generic medicines will also advance the US policy objectives of halting and reversing the global AIDS pandemic where the US has saved billions of dollars in its PEPFAR program by purchasing over 90% of its antiretroviral supplies from generic sources.

Finally it is important to recall that numerous international declarations have been adopted, to which the US has agreed, that recognize the importance of using to the full TRIPS flexibilities to facilitate access to affordable medicines, and these flexibilities include extensions of transition periods. Relevant undertakings include the 2011 UN declaration on HIV and AIDS, the 2011 UN General Assembly Declaration on the prevention and control of non-communicable diseases and the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 The LDCs' request is geared towards a TRIPS-compliant mandatory extension and the US should support, not hinder, the legitimate request of LDCs.

Very truly yours,

Professor Brook K. Baker, Health GAP, Senior Policy Analyst
James Love, Knowledge Ecology International
Peter Maybarduk, Public Citizen
Judit Ruis, Médecins Sans Frontières, Access Campaign, U.S.
Stephanie Burgos, Oxfam America

cc:
Emily Bleimund, JD, MA
George York, USTR
Shira Perlmutter, USPTO
Nancy Weiss, OSTP