Exempt from access to affordable medicines?

How the US is trying to deny the world's poorest countries full legal protection from having to grant patents on medicines

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The context

The world's poorest countries - those classified as least-developed countries (LDCs) – are currently exempt from having to introduce intellectual property rules, including patents for medicines, until such countries are no longer classified as LDCs. This is according to international trade law agreed by all Member States to the World Trade Organization (WTO). But this exemption is under threat and at stake is whether LDCs will be able to secure access to affordable, generic medicines, enabling countries – and treatment providers such as MSF – to provide life-saving treatment for millions of people.

Since the inception of the WTO TRIPS Agreement in 1995, LDCs have been granted a series of time-limited exemptions that have enabled them to avoid implementing intellectual property rules. These exemptions have been granted – albeit on a continually temporary basis – as it is widely acknowledged that implementing global intellectual property rules would be inappropriate and detrimental to LDCs, given the level of socio-economic development in these countries. While LDCs have repeatedly requested that the exemption remain in place until a LDC 'graduates' from that status, each exemption has only been for a limited period of time, due in large part to pressure by countries, such as the United States.

Although a general exemption for all forms of intellectual property has been approved until 2021, a specific exemption for medicines is set to expire at the end of this year. The request to extend the waiver for pharmaceuticals is a singular opportunity to avoid the introduction of intellectual property rules for pharmaceuticals in these countries for as long as they remain LDCs. This would help safeguard affordable access to medicines for millions of people in some of the world's most vulnerable countries, including Nepal, Bangladesh, Myanmar, Liberia, Haiti and Lesotho.

The issue

As the exemption on medicines is set to expire at the end of this year, Bangladesh, on behalf of all 48 LDCs, has submitted a request to the WTO for this exemption to be extended as long as such countries remain LDCs. LDCs have made this request because 2021 is too short a transition period, and because the existing general exemption (which expires in 2021) does not deal with all the harmful rules that can reduce access to life-saving, low cost medicines and vaccines.

In early September, the European Commission - which has historically opposed granting LDCs the full exemption - changed course and publicly announced that it supported the request for an unconditional and long-term exemption (MSF's response to that, with a link to the EC's announcement, is here).

However, countries such as the United States, Canada, and Australia are refusing to signal their support, and are seeking to once again severely limit the scope and duration of the exemption.

Despite numerous requests, the US has not yet made its position public. However, MSF knows from direct discussions with the US Trade Representative's office, that the US is putting pressure on LDCs to weaken their demands, and that the US is only willing to grant another time-limited exemption with conditions attached.

Under threat is the ability for LDCs to secure access to affordable, generic medicines to promote and protect public health and access to medicines for all. Another time-limited exemption could lead to patents coming into force before these countries emerge from their status as least-developed countries, creating barriers for donor-funded programmes like PEPFAR or the Global Fund, or treatment providers like MSF. It also discourages producers of generic medicines from making the investments to develop, register and sell life-saving medicines in LDCs. Because of their inability to pay high prices, LDCs are unattractive markets for all drug companies – generic or branded – and the threat of intellectual property rules is another reason for generic companies not to invest in selling their medicines to people and medical providers in these countries.

What next?

The negotiation on the exemption request will take place at the WTO in Geneva on 15 and 16 October. In the lead up to the meeting, informal negotiations between LDCs and other WTO countries, including two meetings per week with the US Government at the Ambassadorial level, are on-going.

Information has emerged that US Ambassador to the World Trade Organization, Michael Punke, met 15 Ambassadors from LDCs on Friday 9 October in Geneva, where he noted that the US could not agree to an indefinite exemption due to pressure from some US stakeholders who are upset with the US government's intellectual property concessions on the recently-completed Trans-Pacific Partnership trade agreement.

If WTO Member States cannot achieve consensus at the meeting in October, it heads to the Ministerial-level WTO General meeting, which will take place in Nairobi, Kenya in mid-December.

What needs to happen?

The United States, Canada and Australia, should:

- support the LDCs request that would exempt them from implementing intellectual property for medicines as long as such countries are classified LDCs;
- release their public position on the LDC exemption request ahead of the 15-16 October WTO meeting.

EU Trade Commissioner Cecilia Malmström should:

- Use all possible EU leverage – formal and informal – to convince the US and other less-supportive countries to follow suit and support the request.

Least-developed countries should:

- hold firm against the pressure from the US and pharmaceutical companies to weaken their demands, and insist on the entire TRIPS Council, and especially the US, Canada, and Australia, to approve their request for an exemption until they are no longer categorised as least-developed countries.