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Global Patents: Poorest Countries Seek Permanent Waiver; PhRMA Wants Time Limit

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Executive Summary

World Trade Organization to hear request by least developed countries for exemption from pharmaceutical patent protections until they lose LDC status; current waiver under TRIPS expires Jan. 1.

There is a fierce campaign by a group of least developed countries – backed by the European Commission, members of Congress and nongovernmental organizations – to obtain permanent exemption from issuing pharmaceutical patents as long as they hold least developed status.

The group submitted the request to the World Trade Organization, which is to take it up during the WTO’s TRIPS Council meeting in Geneva Oct. 15-16.

Least developed countries (LDCs) are currently exempt from the pharmaceutical patent obligations of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement under a transition period that is set to expire on Jan. 1. In force since 1995, the TRIPS agreement requires WTO member countries to follow minimum standards for protecting and enforcing IP rights.

There are currently 48 countries designated as LDCs, 34 of which are members of WTO.

The Pharmaceutical Research and Manufacturers of America is not opposed to extending the waiver but believes there should be a time limit. LDCs are exempt

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from TRIPS requirements broadly until 2021.

“We believe strongly that robust IP enforcement and protection is essential to driving innovation and economic growth in developing and developed countries,” PhRMA spokesperson Mark Grayson said. He added that the association believes full implementation of TRIPS by all parties “should be time based.”

US Opposition Follows Concessions On Trade Deal, MSF Says

Médecins Sans Frontières and the nongovernmental group Knowledge Ecology International have reported that the United States is opposed to the permanent exemption. MSF linked US opposition to the concessions it made in negotiating the Trans-Pacific Partnership (TPP) agreement. The trade pact aims to provide eight years of biologics data protection rather than the 12 years industry sought ([“Trade Deal Looking Worse For Pharma As More Details Emerge” — “The Pink Sheet” DAILY, Oct. 9, 2015](#)).

“Information has emerged that US Ambassador to the World Trade Organization, Michael Punke, met with representatives of 15 LDCs last Friday 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,” MSF said in an Oct. 12 release.

The White House did not immediately respond to a request for the administration’s views on the waiver request. Grayson said PhRMA does not know anything about the meeting cited by MSF.

James Love, director of Knowledge Ecology International, said a temporary waiver will not be useful because countries will not amend their patent laws to eliminate infringement liability unless the waiver is permanent.

“It is a consequential negotiation,” Love stated. “About a billion people would be in the patent free zone with regard to pharmaceuticals.”

Bangladesh Has Launched Generic Sovaldi

The exemption request was put forward by Bangladesh on behalf of the LDC group and formally presented to the WTO’s TRIPS Council in June.

At that time the World Health Organization urged the council to favorably consider the request. It said that being exempted from granting patents allows least developed countries to either locally produce or to import generic products even when they are still under patent in other countries.

The European Commission issued a statement on Sept. 10 saying it agreed to support the least developed countries’ call for easier access to cheaper medicines by means of an indefinite exemption from WTO intellectual property rules for pharmaceuticals.

“This exemption allows generic medicines to be imported, and produced locally, regardless of patents, for example when licenses are not available. It means producers of generics and international programmes can supply drugs like HIV treatment in affected countries without fear of patent infringement suits,” the EC stated.

The United Nations Development Programme and the Joint United Nations

Programme on HIV/AIDS also back exemption of countries from patent and clinical trial data protections until they are no longer deemed least developed.

The UN groups noted in a May 21 statement that access to medicines like [Gilead Sciences Inc.](#)'s hepatitis C treatment *Sovaldi* (sofosbuvir) "remains a grave challenge in LDCs because of high prices."

They said the drug could cost as much as \$84,000 for a 12-week course in developed countries and that while lower prices via generic licenses are being offered by the patent holder in some developing countries, the cost still places a burden on health budgets. They noted that Bangladesh had taken advantage of its LDC status to launch its own version of the drug for \$900 for a 12-week course.

Sen. Sanders, House Reps Support Waiver

On Oct. 2, seven Democratic members of the US House of Representatives sent a letter to US Trade Representative Michael Froman calling for a waiver of WTO obligations to grant and enforce pharmaceutical patents until a country is no longer classified as an LDC.

The 48 LDCs represent nearly 13% of the world's population but only about 1% of the world's income, with an average \$928 per capita income in 2014, the letter notes. Signatories include Reps. Jan Schakowsky, D-Ill., Rosa DeLauro, D-Conn., Barbara Lee, D-Calif., and Jim McDermott, D-Wash.

Senator and Democratic presidential candidate Bernie Sanders, I-Vt., also sent Froman a letter voicing support for the LDC group's request.

The International Federation of Pharmaceutical Manufacturers & Associations issued a statement saying it supported the existing waiver for LDC implementation of the entire TRIPS agreement until 2021 and that "additional waivers or extension do not appear to be necessary at this stage."

According to KEI, Australia, Canada, and Switzerland also oppose indefinite exemption.

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