



18 September 2015

Mr. David Smith
Inspector General
Department of Commerce
Office of the Inspector General
1401 Constitution Avenue N.W.
Washington, D.C. 20230
phone: 202.482.4661

Dear Mr. Smith:

This letter is to request that your office initiate an investigation as to whether the United States Patent and Trademark Office (USPTO) has acted and continues to act in violation of Executive Order 13155 of May 10, 2000, Access to HIV/AIDS Pharmaceuticals and Medical Technologies (EO 13155).¹ Specifically, the investigation should address the attempts by the USPTO, alone or together with other United States agencies, to pressure least-developed countries (LDC's) to abandon or narrow requests to have a robust and indefinite waiver of WTO obligations regarding patents on pharmaceuticals, including those on HIV/AIDS pharmaceuticals.

The current waiver is set to expire on January 1, 2016, and this matter may be decided by the WTO TRIPS Council in October 2015.

EO 13155

EO 13155, signed into effect by President Clinton, prevents the United States, in the administration of sections 301-310 of the Trade Act of 1974, from seeking,

through negotiation or otherwise, the revocation of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

¹ EO 13155, available at: <http://www.gpo.gov/fdsys/pkg/FR-2000-05-12/pdf/00-12177.pdf>

- (1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and
- (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

This EO reflected the seriousness of the scope of the HIV/AIDS crisis in sub-Saharan Africa, the moral and medical interest of the United States in stopping the spread of the disease, and the importance, under the TRIPS Agreement, of promoting both “effective and adequate protection of intellectual property rights and the right of countries to adopt measures necessary to protect public health.”²

LDC Request for Indefinite Waiver of WTO Obligations Regarding Patents on Pharmaceuticals

In February of 2015, Bangladesh, on behalf of the LDC’s, submitted a request, pursuant to TRIPS Article 66.1, that they be granted an indefinite exemption from WTO obligations specifically with regard to patents on pharmaceuticals, and on test data, for as long as a country remains a least-developed country.³ Article 66.1 of the TRIPS states:

In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period. [emphasis added]

The reasons for this request included specific reference to the high burden of HIV in LDC’s, citing statistics that in 2011 9.7 million of the of 34 million HIV patients worldwide lived in LDC’s, and that exemption from the WTO obligations with regard to patents on pharmaceuticals is necessary for the access of affordable medicines.⁴

In 2014, 34 of the least-developed countries were located in sub-Saharan Africa.⁵ The LDC’s are the poorest in the world, averaging a mere \$928 per capita income, and representing

² *Id.*, Sec. 2.

³ IP/C/W/605, REQUEST FOR AN EXTENSION OF THE TRANSITIONAL PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT FOR LEAST DEVELOPED COUNTRY MEMBERS WITH RESPECT TO PHARMACEUTICAL PRODUCTS AND FOR WAIVERS FROM THE OBLIGATION OF ARTICLES 70.8 AND 70.9 OF THE TRIPS AGREEMENT, Communication from Bangladesh on Behalf of the LDC Group, 23 February 2015. Available at <http://keionline.org/sites/default/files/W605LDCextension2016.pdf>.

⁴ *Id.*

⁵ http://www.un.org/en/development/desa/policy/cdp/lcd/lcd_list.pdf

thirteen percent of the world's population while only about one percent of the world's income. In 2014, the incomes in LDC countries were just 1.7 percent of incomes in the U.S. Only 34 percent of people living in LDCs even have access to electricity, and the combined public and private sector spending on health was just \$47 in 2014.⁶

Alleged Violation of EO 13155

We are aware that the United States is placing pressure on LDC's to abandon their request in favor of a time-limited extension of a waiver of obligations, with restrictions that render the exception less useful in terms of creating an economic environment to manufacture and provide access to inexpensive generic medicines. The LDC Group has referred to this as an "unconscionable" position.⁷

As the LDC request undoubtedly is of primary concern to countries in those LDC's in sub-Saharan Africa, and as the request (1) specifically mentions the importance of the stated position on those countries' ability to promote access to affordable HIV pharmaceuticals, and (2) is consistent with TRIPS, the LDC request is covered under EO 13155. In this regard we are asking your office to determine if the USPTO, either acting alone or together with other U.S. agencies, has done anything in the administration of sections 301-310 of the Trade Act of 1974 that would violate the prohibition of using negotiation to block or modify a policy of a beneficiary sub-Saharan African country to expand access to medicines.

We request a meeting to discuss this matter further.

Sincerely,

A handwritten signature in blue ink, appearing to read "Andrew S. Goldman".

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⁶ For accumulated data on LDC's, see Elizabeth Rajasingh, "KEI Briefing Note 2015:3, Comparison of Key Indicators Between LDC, Non-LDC, and OECD Countries," 17 September 2015. Available at <http://keionline.org/sites/default/files/KEI-BN-2015-3-LDC-non-LDC-OECD-comparisons.pdf>

⁷ WTO TRIPS Council (June 2015): LDC Group Presentation on the Extension of the Decision for Pharmaceutical Products, 10 June 2015. Available at <http://keionline.org/node/2245>.