

May 04, 2015

President Ollanta Humala Tasso

SUBJECT: Peru's Right to Issue a Compulsory License for the HIV/AIDS Medicine Atazanavir

Dear President Humala,

We are lawyers, economists, and academics specializing in fields including intellectual property, international trade, and health policy writing to affirm that international rules support Peru's right to issue compulsory licenses on patents covering important medications. A recent article in Peru's *La Republica*¹ newspaper indicated that Peru's Ministry of Health has proposed licensing the patents associated with the HIV/AIDS medication atazanavir (marketed by Bristol-Myers Squibb as Reyataz®). This proposal follows a November 2014 request from Peruvian civil society organizations for such licenses.

High prices for any necessary medicine impose a burden on the public health system responsible for providing it. When a pharmaceutical company holds a patent-facilitated monopoly over a particular medicine, it can charge much higher prices than possible in a competitive environment. In Peru, public programs often shoulder the burden of these higher costs, which necessarily limit the health services that the State can provide to its people.

Fortunately, patent rules also contemplate safeguards for protecting public interests, including health. Among these protections is the right to issue a compulsory license and to engage in government use of patents. Compulsory licensing of patents on medications allows the state to authorize generic manufacturers to produce patented medical products, typically in exchange for royalty payments to the patent holder. Because competition among manufacturers is the most effective means of reducing pharmaceutical prices, compulsory licensing and government use of patents are essential public interest safeguards.

Peru has every right to issue a compulsory license on atazanavir under international law. Article 31 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (WTO's TRIPS) permits all WTO members, including Peru, to issue compulsory licenses at any time on grounds of their choosing.² WTO members are free to issue compulsory licenses irrespective of whether a national emergency exists; in fact, the WTO calls the idea of

¹ Beatriz Jiménez, *Patentes dadas por Indecopi a fármacos afectan a la salud pública*, LA REPUBLICA (Apr. 9, 2015 10:15AM), available at <http://www.larepublica.pe/09-04-2015/patentes-dadas-por-indecopi-a-farmacos-afectan-la-salud-publica-y-causan-sobrecostos> ("Desde hace dos meses, el decreto supremo para declarar de interés público el Atazanavir y permitir el ingreso de competencia está sobre la mesa del consejo de viceministros con la firma del ministro de Salud, Aníbal Velásquez.").

² Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299, http://www.wto.org/english/docs_e/legal_e/27-trips.pdf; see WORLD TRADE ORGANIZATION, *Trips and Health: Frequently Asked Questions: Compulsory licensing of pharmaceuticals and TRIPS*, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Apr. 20, 2015).

an “emergency” requirement a “common misunderstanding.”³ As the WTO itself has explained, “The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing.”⁴ In cases of public non-commercial use, the government can forgo notice to the patent holder prior to the grant of the license.⁵ The only compensation due to patent-holders in instances of compulsory licensing is a reasonable royalty, which governments may determine at their discretion.⁶

The WTO’s Declaration on the TRIPS Agreement and Public Health affirms this interpretation of Article 31 and its importance to public health policy.⁷ The Doha Declaration explicitly recognizes the impact of intellectual property laws on medicine prices and affirms that countries’ patent obligations under WTO rules “should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”⁸ Moreover, the issuance of a compulsory license on atazanavir would not violate any free trade agreement or bilateral investment treaty to which Peru is a party.⁹

Although Bristol-Myers Squibb (BMS) currently licenses atazanavir to 110 countries through the Medicines Patent Pool, BMS has refused to include Peru in the pool.¹⁰ BMS has also rejected Peru’s appeals to purchase atazanavir at the lower prices BMS extends to other Latin American nations that are outside of the pool.¹¹ Accordingly, it is all the more appropriate that Peru issue a license of its own design, on reasonable terms and conditions.

Issuing a compulsory license does not modify or expropriate the property rights of the patent holder. Rather, the right of a government to make use of a patented invention is embedded and reserved in the grant of a patent. Furthermore, a license does not prevent the patent holder from

³ WORLD TRADE ORGANIZATION, *Trips and Health: Frequently Asked Questions: Compulsory licensing of pharmaceuticals and TRIPS*, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Apr. 20, 2015).

⁴ *Id.*

⁵ *Id.* art. 31(b).

⁶ *Id.* art. 31(h).

⁷ World Trade Organization Declaration on the TRIPS Agreement and Public Health, adopted 14 November 2001, *available at*: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

⁸ *Id.*

⁹ The free trade agreement between the United States and Peru permits the Peruvian government to issue compulsory licenses on public interest grounds. The Office of the United States Trade Representative, *Peru-United States Trade Promotion Agreement*, Article 10.7.5, https://ustr.gov/sites/default/files/uploads/agreements/fta/peru/asset_upload_file78_9547.pdf (last visited Apr. 20, 2015). The Peruvian law implementing this free trade agreement, Law No. 29316 (Article 40°), states “the government may, at any moment, subject a patent to a compulsory license through a declaration that reasons of public interest, of emergency or national security exist; that is, national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” Ley que Modifica, Incorpora y Regula Diversas Disposiciones a Fin de Implementar el Acuerdo de Promoción Comercial Suscrito entre el Perú y los Estados Unidos de América N° 29316, Artículo 40, *available at* http://www.wipo.int/wipolex/es/text.jsp?file_id=179604.

¹⁰ Medicines Patent Pool – BMS License, License and Technology Transfer Agreement 37-38, *available at* <http://www.medicinespatentpool.org/wp-content/uploads/MPP-License-and-technology-transfer-agreement-Signed22.pdf>.

¹¹ PUBLIC CITIZEN, LICENCIA OBLIGATORIA PARA ATAZANAVIR: DOCUMENTO TÉCNICO 9 (Nov. 2014), *available at* <http://www.citizen.org/documents/atazanavir-technical-document.pdf>.

continuing to sell its product, prohibit non-licensed uses of the invention, or prohibit non-licensed parties from using the invention.

We hope this letter will help put to rest any concern regarding the international legitimacy of compulsory licensing. The rights of Peru to make government use of patents are ample and clear. Compulsory licensing, in accordance with WTO rules, is a key tool for protecting the financial stability of health systems and ensuring access to medicines and health services for all.

Sincerely,

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