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## ***Unsupported claims in ECAT's submission to USTR on Ecuador, intellectual property and ATPA***

On May 12, the Emergency Committee for American Trade (ECAT) submitted comments to USTR regarding eligibility of Andean states for benefits under the Andean Trade Preference Act (ATPA). ECAT states Ecuador “began issuing compulsory licenses ... and appears to be doing so in a manner contrary to the WTO [TRIPS Agreement].” ECAT provides no specific or accurate facts to support this claim.

- ECAT states TRIPS and the Doha Declaration “provide countries the right to use compulsory licensing when there is a national health emergency.” ECAT fails to note that under WTO rules, countries have “the freedom to determine the grounds upon which such licenses are granted.”<sup>1</sup> On its Frequently Asked Questions page, the WTO calls the idea of an emergency requirement “a common misunderstanding.”<sup>2</sup>
- ECAT states Ecuador “appears to be basing its compulsory licensing findings on the presidential degree [sic], rather than making individualized decisions.” But Ecuador's Decree 118 and the patent office's formal instruction to license applicants each require that license requests be evaluated according to the supported circumstances of each case, in accordance with TRIPS Article 31(a)<sup>3</sup>. License requests must be reviewed case-by-case by the patent office (IEPI) and Ministry of Public Health, each according to its area of competence. Ecuador has thus far issued only one compulsory license, for the HIV/AIDS drug Kaletra.
- ECAT accuses Ecuador of “failing to promptly notify rightholders,” and asserts “patentholders are denied the ability to participate in a meaningful way in the proceedings.” But IEPI notified Abbott Laboratories of Eske Group's license request within days of admitting Eske's completed application for consideration,<sup>4</sup> five weeks before IEPI granted the compulsory license on April 14. IEPI received written submissions from Abbott on March 11 and 23 and answered in accordance with established administrative procedures. In recent months IEPI has met at least twice each

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<sup>1</sup> Declaration on the TRIPS Agreement and Public Health, Paragraph 5(b).

<sup>2</sup> Available at: [http://www.wto.org/English/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm).

<sup>3</sup> TRIPS Article 31(a) requires that “authorization of such use shall be considered on its individual merits.”

<sup>4</sup> Resolution 1 DNPI IEPI, Granting of a Compulsory License for a drug containing the active ingredient ritonavir.



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with Abbott, the American Embassy in Quito, and the patent-based pharmaceutical companies' trade association in Ecuador, IFI, which issued a public statement<sup>5</sup> accepting Decree 118. Under Ecuadorean law and the license protocol, Abbott and other patent holders have recourse to seek review of license terms and/or the grant of the license itself within IEPI, as well as through independent judicial process.

- ECAT states, “Ecuador’s flat five-percent royalty formula fails to provide the adequate remuneration required under TRIPS.” But Ecuador does not use a flat royalty. Ecuador’s first compulsory license uses the Tiered Royalty Method,<sup>6</sup> which calculates case-specific royalties based on an approximation of the therapeutic value of the product.

ECAT cites Ecuador’s protocol on the compulsory licensing of pharmaceutical patents for public health priority illnesses as an effort “to nullify the protection of intellectual property.” But the TRIPS Agreement reserves to WTO signatory nations sovereign rights and flexibilities, including the compulsory licensing of patents to protect public interests. Ecuador has complied with all WTO rules. Abbott retains its patent. Rather than nullifying IP protection, Ecuador’s protocol, which evaluates license requests case-by-case under established rules and provides for case-specific royalty payments, is part and parcel of its working intellectual property system.

***For more information, contact:***

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<sup>5</sup> On file with Public Citizen.

<sup>6</sup> Resolution 1 DNPI IEPI, Granting of a Compulsory License for a drug containing the active ingredient ritonavir.