



Submission for the Record by Peter Maybarduk, Staff Attorney, Public Citizen.

1. Public Citizen Comments to U.S. Trade Representative for the 2010 Special 301 Report.
2. Critique of the Emergency Committee for American Trade (ECAT) Submission to USTR.
3. Background on Special 301 and Ecuador's TRIPS-Compliant Protocol on Access to Medicines and Compulsory Licensing.



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Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508
USA

February 16, 2010

Re. USTR-2010-003 (2010 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974)

Dear Sir or Madam:

Public Citizen submits the following comments in response to the request by the Office of the United States Trade Representative (USTR) for “written submissions from the public concerning foreign countries’ acts, policies, or practices that are relevant to the decision whether a particular trading partner should be identified under Section 182 of the Trade Act.”

With 150,000 members and supporters, Public Citizen is a national, 501(c)3 nonprofit consumer advocacy organization founded in 1971 to represent consumer interests in Congress, the executive branch and the courts.

Public Citizen believes USTR’s 2010 Special 301 Report should reflect the United States’ commitment, under the 2001 World Trade Organization’s (WTO) Doha Declaration on TRIPS and Public Health (herein “Doha Declaration”), to respect countries’ use of the flexibilities provided in the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to promote access to medicines for all.

In particular, we wish to emphasize that USTR should not cite Ecuador for any matter related to that country’s TRIPS-compliant protocol for the compulsory licensing of pharmaceutical patents in the public interest. USTR should also not sanction Ecuador’s compulsory licensing protocol indirectly, for example, through imprecise references to alleged IPR-protection failings in Ecuador or through otherwise unwarranted elevation in Ecuador’s watch list status.

Antecedents

The WTO's TRIPS agreement reserves to WTO signatory nations certain sovereign rights and flexibilities, including the compulsory licensing of patents¹ to protect public interests.

At the 2001 WTO Doha Ministerial Conference, WTO Members, including the United States, unanimously agreed upon a Declaration on the TRIPS Agreement and Public Health.² The Doha Declaration states:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and 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.³

Further, the Doha Declaration states:

Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.⁴

Despite the adoption of the Doha Declaration, USTR's 2007 Special 301 Report criticized the government of Thailand for its use of compulsory licenses, stating:

In late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern.

Public health groups, in turn, criticized USTR's report. They objected to critical references in the Special 301 report to Thailand's *TRIPS-compliant* actions, and vague and imprecise allegations of a "lack of transparency" for Thai government actions that were both highly transparent and TRIPS compliant.

¹ TRIPS Article 31.

² Adopted November 14, 2001, and *available at*:
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

³ Doha Declaration, Paragraph 4.

⁴ Doha Declaration, Paragraph 5(b).

On October 23, 2009, Ecuador's President Rafael Correa issued Decree 118,⁵ declaring access to priority medicines affecting the health of the Ecuadorean population to be a matter of public interest. Although not required by TRIPS, the Decree satisfies an Andean Community proviso enabling Ecuador's patent office, in cooperation with the Ministry of Public Health, to receive compulsory license requests and issue licenses, case-by-case, on public interest grounds.⁶

As of this submission, Ecuador has yet to issue a compulsory license. Ecuador's patent office, the *Instituto Ecuatoriano de Propiedad Intelectual* (IEPI), has published formal guidance to license applicants (herein, IEPI's "*Instructivo*").⁷ IEPI has also met at least twice with the American Embassy in Quito, as well as the patent-based pharmaceutical companies' trade association in Ecuador, IFI,⁸ which issued a public statement⁹ accepting Decree 118.

Analysis

There is no substantive basis for citing Ecuador's policy on compulsory licensing in the Special 301 Report. The protocol envisioned by Decree 118 is TRIPS-compliant. Indeed, the Decree borrows provisions directly from the TRIPS Agreement, in some cases (non-exclusivity, supplying predominantly the domestic market, adequate compensation to patent holders, license review and termination, etc.) employing the TRIPS language word-for-word. Citing Ecuador's compulsory licensing policy in the Special 301 Report would represent an inappropriate effort by the United States to influence another WTO Member's use of rights preserved by the TRIPS Agreement, with potentially serious consequences for public health.

The Doha Declaration reiterates countries' rights to issue compulsory licenses "on grounds of their choosing." Decree 118 declares a public interest in medicines used to treat "public health priority illnesses."¹⁰ IEPI's *Instructivo* further specifies that this determination is the province of the Ministry of Public Health.¹¹ Interagency agreement

⁵ Available online (in Spanish) at: <http://www.sigob.gov.ec/decretos/>.

⁶ More information on Ecuador's Presidential Declaration on Access to Medicines and Compulsory Licensing is available from Essential Action at: <http://www.essentialaction.org/access/index.php?/categories/8-Country%20Disputes%20and%20Other%20Issues>.

⁷ *Instructivo*, available at: <http://www.iepi.gov.ec/Files/LicenciasObligatorias/InstructivoLicenciasFarmacias.pdf>.

⁸ *Industria Farmacéutica de Investigación*.

⁹ On file with Public Citizen.

¹⁰ Article 1.

¹¹ Chapter IV, Article 8.

is required for the issuance of public interest licenses.¹² Decree 118 and IEPI's *Instructivo* also require that license requests be evaluated according to the "supported" circumstances of each case (in accordance with TRIPS Article 31(a)¹³).

Decree 118 requires payment of royalties to patent holders,¹⁴ which IEPI's *Instructivo* specifies will "take into account the circumstances of the case and the economic value of the authorization."¹⁵ IEPI's *Instructivo* requires license applicants certify in advance their agreement to these and other universally applicable license terms. Decree 118 and IEPI's *Instructivo* each reiterate that all licenses must comply with "applicable legislation."¹⁶

IEPI has published guides and explanatory materials online, held multiple events for the press and public, and has indicated it remains open to meetings with the American Embassy in Quito and pharmaceutical companies' trade association. Under the Ecuadorian policy, if and when a compulsory license is issued, the patent holder would 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. Patent holders would be free to compete with products introduced under compulsory license.

Ecuador's compulsory licensing protocol is in compliance with the TRIPS Agreement and it neither denies adequate and effective protection of intellectual property rights nor does it deny fair and equitable market access to U.S. persons. It therefore does not merit direct mention or any indirect reference in 2010's Special 301 Report.



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¹² See Decree 118 Article 2; *Instructivo* Chapter IV, Article 8.

¹³ TRIPS Article 31(a) requires that "authorization of such use shall be considered on its individual merits."

¹⁴ Article 4.

¹⁵ Article 10, borrowing the exact language of TRIPS Article 31(h).

¹⁶ *Instructivo* Chapter II, Article 4; Decree 118 Articles 2, 4 and 5.



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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.”¹ On its Frequently Asked Questions page, the WTO calls the idea of an emergency requirement “a common misunderstanding.”²
- 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)³. 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,⁴ 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

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

² Available at: http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm.

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

⁴ 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 statement⁵ 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,⁶ 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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⁵ On file with Public Citizen.

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



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Special 301 and Ecuador's TRIPS-Compliant Protocol on Access to Medicines and Compulsory Licensing

– Background –

Washington, D.C., March 3, 2010 – Today, the Office of the United States Trade Representative (USTR) opens public hearings on its annual Special 301 Report to Congress, which lists countries for perceived shortcomings in intellectual property protections. Public health groups have long criticized USTR's 301 process as heavily influenced by the priorities of the big drug companies; pressuring countries to adopt measures not required by global trade rules. These same measures would hamper public access to medicines.

In October, Ecuador's President Rafael Correa declared access to priority medicines affecting the health of the Ecuadorean people to be a matter of public interest. Under Andean Community law, Correa's Decree 118 opens the door to competition of generic medicines with patented brand-name drugs, through use of an internationally recognized legal mechanism called compulsory licensing. The policy could expand access to lifesaving medicines.

Ecuador's compulsory licensing protocol complies fully with the World Trade Organization's TRIPS Agreement on intellectual property. Indeed, Decree 118 borrows provisions directly from the TRIPS Agreement, in some cases employing the TRIPS language word-for-word. Ecuador's patent-office, IEPI, recently issued formal guidance for license applicants in its "Instructivo," further specifying TRIPS-compliant procedures and terms for any licenses considered. Decree 118 and the Instructivo require payments of royalties to pharmaceutical patent holders, procedures for license review and termination, non-exclusivity, and primary supply of the domestic market, among other TRIPS terms. Further analysis is available from Public Citizen.

There would be no defensible rationale for USTR citing Ecuador's TRIPS-compliant compulsory licensing protocol in its 2010 Special 301 Report. Rather, citing the protocol would represent an inappropriate effort by the United States to influence another WTO Member's use of rights preserved by the TRIPS Agreement, with potentially serious consequences for public health.

Globally, competition has consistently proven the most effective method to reduce medicine prices, and ensure prices continue to fall over time. By issuing a compulsory license, a government can authorize generic competition with patented products. Compulsory licenses do not "eliminate" or "override" patents. Instead, they authorize the use of patented technology under enumerated conditions. Countries' right to issue compulsory licenses "on grounds of their choosing" is enshrined in the WTO's unanimous Doha Declaration on the TRIPS and Public Health (2001). Ecuador has yet to issue a compulsory license.

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