

## **Clarifications concerning Ecuador's Declaration on Compulsory Licensing**

In October 2009, Ecuador's President Rafael Correa announced a bold new national access to medicines policy through decree no. 118<sup>i</sup>, declaring access to medicines for priority public health needs a matter of public interest, and establishing procedures<sup>ii</sup> for issuing compulsory licenses. Such licenses would authorize price-lowering competition with expensive patented drugs.

Many news articles, in Spanish, English and French, reported on the decree, as well as on subsequent comments and analyses by the patent office, national and international pharmaceutical companies, and observers. Unfortunately, several inaccuracies circled the globe through some of these reports.

### ***1. Compulsory licenses do not eliminate or break patents.***

Compulsory licenses authorize use of a patented technology. Under compulsory licenses, patent holders retain their patents and a variety of related rights, including the right to be adequately compensated through royalty payments and any rights reserved through restrictions set out in the license. For example, sometimes compulsory licenses are limited to public, non-commercial use (also called "government use"). In these cases the patent holder retains exclusive rights in the private market (i.e., the right to be the exclusive seller to private pharmacies and insurers). Ecuador will issue compulsory licenses, which is qualitatively different from annulling patents.

### ***2. Ecuador has not predetermined the number of licenses it intends to issue, nor will it license all medicines en masse.***

According to the Declaration, Ecuador's patent office (IEPI) will consider compulsory license requests on a case-by-case basis. IEPI will consult with the Ministry of Public Health and take into account the public interest that licensing a particular medicine would serve. Some news articles reported Ecuador would "license 2,214 medicines" or "eliminate over 2,000 medical patents." 2,214 is actually the total number of granted and/or requested patents for pharmaceuticals in Ecuador. Often, multiple patents apply to a single medicine. Because there are not 2,214 patented drugs, it is not technically possible for Ecuador to issue compulsory licenses for 2,214 medicines. IEPI will proceed more methodically and deliberately than reported, considering license requests for priority medicines case-by-case.

### ***3. Ecuador's patent office has not predetermined the royalty rates it will require licensees to pay patent holders.***

IEPI will instead determine royalties according to the unique circumstances of each case. IEPI is currently studying international best practices in setting royalty rates, including models and equations used in other countries. Royalty rates established by IEPI are therefore likely to correspond to international precedent.

#### ***4. Ecuador has not announced whether licenses would be issued for public use, but if so, Ecuador would not be required to negotiate first.***

Some reports have suggested the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) requires Ecuador to negotiate with pharmaceutical companies before issuing compulsory licenses, because Ecuador has not declared a public health emergency.

To remedy confusion about these points, the member countries of the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health. It specifically states:

“Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” (Paragraph 5(b))

There is no requirement for a country to declare an emergency before issuing a compulsory license. Under WTO rules, countries are free to issue licenses to serve the public interest, as announced in Ecuador's declaration. TRIPS says only that certain otherwise-required procedures can be bypassed in emergencies and other situations.<sup>iii</sup> For example, licenses issued for public, non-commercial use are exempt from the general requirement that negotiations must take place prior to their issuance (TRIPS Article 31(b).) The United States, among other nations, makes use of this flexibility and does not require prior negotiations in cases of licenses issued for government use.<sup>iv</sup>

Ecuador has not announced whether compulsory licenses would be issued for public use, but if so, Ecuador would not be required to negotiate first. In cases where negotiation is required, the government need only offer reasonable terms and conditions. If the patent holder fails to reply, or refuses reasonable conditions, the government can then proceed to issue a compulsory license. In other words, pharmaceutical companies cannot hold up the government for whatever royalty rates they want. In that case the license would no longer be compulsory at all, but voluntary, and the WTO rules would cease to make sense.

#### ***For more information, please contact:***

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<sup>i</sup> The declaration is available online, in Spanish, at <http://www.sigob.gov.ec/decretos/>. An unofficial English translation is available at <http://www.essentialaction.org/access/index.php?/archives/227-Ecuador-issues-Presidential-Declaration-on-Access-to-Priority-Medicines.html>

<sup>ii</sup> Ecuador's patent office, Intellectual Property Institute of Ecuador (IEPI), has posted information about Ecuador's compulsory licensing policy online at <http://www.iepi.gov.ec/>.

<sup>iii</sup> For more information on these and other common misunderstandings about compulsory licensing, TRIPS and the Doha Declaration, please see the World Trade Organization document “TRIPS and Health: Frequently asked questions compulsory licensing of pharmaceuticals and TRIPS,” 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>iv</sup> For more information about compulsory licensing practices in the United States and other countries, see James Packard Love, KEI Research Note 2007:2 “Recent examples of the use of compulsory licenses on patents,” Knowledge Ecology International, revised 6 May 2007 at <http://keionline.org/content/view/41/1>.