

Compulsory Licensing For Pharmaceutical Patents In Ecuador: A Primer

By Sasha Mandakovic Falconi

Introduction

Following a public announcement on TV a few weeks ago by Ecuadorian President Rafael Correa,¹ an executive decree was issued on October 23, 2009.² The decree establishes access to medicines that are used for the treatment of priority diseases that affect the Ecuadorian population as a matter of public interest. More specifically, it enables access by compulsory licenses that will be issued when pharmaceuticals needed for treatment are protected by a patent.

While the decree does not indicate which diseases are priorities, it does indicate that cosmetic, aesthetic, hygienic and other medicines not used for the treatment of diseases are not public health priorities.

Background of the Executive Decree

Establishing the grant of compulsory licenses of pharmaceutical patents has the clear public policy purpose of driving down the prices of medicines. The government's initiative was coordinated with the Ecuadorian Intellectual Property Institute—IEPI- (the IEPI is the Ecuadorian Patent, Trademark and Copyright Office) and relies on international agreements to which Ecuador is a signatory.

Particular emphasis was given to the World Trade Organization's (WTO) "Declaration on the TRIPS agreement and public health,"³ which recognizes the gravity of public health problems that affect developing countries (such as Ecuador). According to the declaration, the TRIPS Agreement should be interpreted and implemented in a manner to promote access to medicines for all (paragraph 4).

The above includes the right of Member States to grant compulsory licenses and the freedom to determine the grounds upon which those licenses are

granted (paragraph 5b), including determining what constitutes a national emergency or other circumstances of extreme urgency, which affords granting compulsory licenses (paragraph 5c).

The Ecuadorian Pharmaceutical Market

The Ecuadorian pharmaceutical market has sales of approximately U.S. \$720 million a year.⁴ The 66 local laboratories that manufacture generics and local brands (most active ingredients are imported and not produced locally due to technology constraints) constitute about 18 percent of sales, while the lion's share of 82 percent of the market is generated by international laboratories.

The potential growth in sales for local laboratories through compulsory licenses is huge. Therefore, without a doubt, local laboratories will seek to obtain as many compulsory licenses as possible for profitable medicines.

Initially, it is most likely that compulsory licenses will be sought on the medicines which are covered by one of the about 500 pharmaceutical patents that are in force in Ecuador. A second step might involve obtaining compulsory licenses on patents which do issue on approximately 2,500 pending applications.

Legal Framework for Compulsory Licensing

To grant compulsory license applications, the IEPI will apply Article 31 of the TRIPS Agreement,⁵ as well as the procedure established in Andean Community Decision 486 Articles 61 to 69.⁶

The process will start with an application to the IEPI filed by an interested local laboratory, requesting a

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1. The announcement was made on October 17, 2009 and it is available in Spanish at http://www.ecuadorenvivo.com/2009101739292/sociedad/gobierno_impondra_licencias_obligatorias_a_farmaceuticas.html.

2. The executive decree No. 118 is available in Spanish at <http://www.sigob.gov.ec/decretos/>.

3. This part of the DOHA Ministerial Declaration is available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

4. According to a non-official study made by "Intercontinental Marketing Services."

5. Available at http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5.

6. Available at <http://www.comunidadandina.org/ingles/normativa/D486e.htm>.

compulsory license for a particular granted patent.⁷ The IEPI will notify the patent owner, so that it may file any arguments it deems appropriate, and will request the Ministry of Public Health to indicate if the disease is a public priority.

While the media has reported that the Ministry of Public Health intends to issue a list of priority diseases, this seems unlikely. It is more probable that the IEPI will consult with the Ministry on a case by case basis when it receives an application. HIV/AIDS, tuberculosis, malaria and other epidemics are expected to be priorities because they are expressly recognized in the “Declaration on the TRIPS Agreement and Public Health.” Cancer will surely be considered a priority as well.

If the Ministry of Public Health does not consider a particular disease as a public priority, the compulsory license application will be rejected. However, if the disease is a priority, the IEPI will process the application and decide the terms on which the compulsory license is granted. Terms of a compulsory license should establish the time frame, conditions for economic compensation, production / importation limits, if any, among others.

The criteria that will be used for a compulsory license has not been reported yet, but sources inside the IEPI suggest that the time frame for licenses will be concurrent with the expiration of the patent and royalties will vary anywhere from 0.5 percent to 5 percent of the price at which the patented drug is sold to the consumer.

Characteristics of a Granted Compulsory License

The principal characteristics of compulsory licenses will be:

- Non-exclusive.
- No sublicensing permitted.
- Licenses cannot be assigned without the

underlying business.

- Revocable.
- Must establish royalties for the patent owner.
- Must be used in the Ecuadorian market.

Revoking a Granted Compulsory License

When a compulsory license is issued, an appeal may be filed both at the PTO and in the courts to have it revoked. The appeal process however does not stay a granted license.

A cause for revocation may be a change in the circumstances that originated the license (e.g., the price of the drug is not prohibitive; the disease is not part of public policy; royalties are not being paid; etc.)

Final Comments and Recommendations

The Ecuadorian government’s public policy decision to authorize compulsory licenses in order to deal with public health problems will make it difficult for patent owners to prevent their patents from being forcibly licensed unless they substantially reduce prices.

If a patent owner is notified about a compulsory license application, we recommend that efforts be primarily directed to obtaining a fair compensatory royalty. We also suggest attention to the potential impact of compulsory licenses on advertising and trademark use. For example: Will compulsory license holders advertise their products using the name of the active ingredient? Will they indicate that their products are equivalents or bioequivalents to X brand product?

There are still many issues “hanging in the air” regarding compulsory licensing in Ecuador. What is clear is that active monitoring of both the situation and of pharmaceutical/health related patent portfolios is essential. ■

Disclaimer: *Opinions in this primer are solely the author’s and are not meant to provide advice on a particular case to existing or potential clients.*

7. It is not clear yet if compulsory licenses will be applicable to pending applications. Decision 486 permits granting voluntary licenses even for pending patent applications.