

No. 118
RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

WHEREAS:

Article 32 of the Constitution of the Republic establishes that health is a right ensured by the State, the fulfillment of which is linked to the exercise of other rights sustaining well being;

Article 3.1 of the Constitution of the Republic provides that it is an essential duty of the State to ensure without any discrimination whatsoever the effective enjoyment of the rights provided in the Constitution and in international instruments, particularly, constitutionally recognized rights, such as health;

Article 363 No. 7 of the Constitution of the Republic provides that, for the fulfillment of a regimen of well being, it is the obligation of the State, in matters of health, to “ensure availability and access to quality, safe and effective medicine, regulate the commercialization thereof and promote domestic production and use of generic drugs that meet the epidemiological needs of the population. In access to medicines, public health interests shall take precedence over economic and commercial interests.”

Article 31 of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) recognizes the right of countries to issue compulsory licenses for drug patents to combat and mitigate diseases of public interest;

The Doha declaration on the TRIPS Agreement and Public Health, adopted unanimously by the Member States of the World Trade Organization, specifies that each Member State “*has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*” Additionally, the declaration specifically states that the TRIPS Agreement should be interpreted and applied to “*promote access to medicines for all;*”

The global strategy and plan of action on “public health, innovation and intellectual property” of the World Health Assembly, WHA 61.21, paragraph 20, states, “Intellectual Property rights do not prevent nor should they prevent Member States from taking measures to protect public health.”

Objective No. 3 of the 2007-2010 National Development Plan, enacted under Executive Decree 745 of April 7, 2008, is: “*To raise the life expectancy and the quality of life of the population;*”

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The Andean Norm set forth in Decision 486, establishing a Common Industrial Property Regime, contemplates compulsory licensing, as does the Ecuadorean Law of Intellectual Property;

For fulfillment of this objective, the aforementioned National Development Plan establishes policy 3.3 *"To ensure universal access to essential medicines, consolidate authority and sovereignty of the State in management of medicines and phyto-therapeutic resources,"* with one of the strategies being the use of compulsory licenses as an instrument for lowering the cost of medicines;

It is an interest of the State in the field of public health to safeguard the equitable access to health care and, consequently, to medicine, especially of the most vulnerable socio-economic classes.

In exercising the powers vested under sections 1 and 3 of Article 147 of the Constitution of the Republic and as provided under Article 65 of Decision 486 of the Andean Community of Nations:

DECREES:

Article 1.- Hereby declares of public interest access to medicines used for the treatment of diseases that affect the Ecuadorean population and are priorities for public health, for which compulsory licenses may be granted for patents on any human use medicine that may be necessary for treatment. Cosmetic, esthetic, personal hygienic medicines and, in general, those that are not used for the treatment of disease, shall not be considered public health priorities.

Article 2.- The Ecuadorean Institute of Intellectual Property (IEPI), through the National Directorate of Industrial Property, is the Competent National Office to grant compulsory licenses to those who apply for them, provided that such persons fulfill the requirements set forth in applicable legislation and this decree. Authorization of Compulsory Licenses shall be considered in light of their particular circumstances and shall be supported by a factual basis in each case. IEPI shall grant compulsory licenses in coordination with the Ministry of Public Health.

Article 3.- The "Leopoldo Izquieta Perez" National Institute of Hygiene and Tropical Medicine shall take the steps necessary to register medicines that may be produced or imported under the rules of compulsory licensing, within a maximum period of thirty days counted...

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... from the date of filing of the application, provided the legal requirements are satisfied and the necessary procedures followed to verify the quality, safety and efficacy of the medicines.

Article 4.- The Ecuadorian Institute of Intellectual Property, through the National Directorate of Industrial Property, shall establish the scope, purpose and time period for which licenses shall be granted; as well as the amount and conditions of royalty payments, and other requirements set forth in applicable law.

Article 5.- The Ecuadorean Institute of Intellectual Property, through the National Directorate of Industrial Property, in accordance with applicable legislation, shall notify patent holders who are subject to the rules of compulsory licensing.

Article 6.- The time period of the compulsory license shall be set by the competent body of the Ecuadorean Institute of Intellectual Property. This period may be declared terminated by said authority, without prejudice to adequate protection of the legitimate interests of persons who have received authorization for them, should the circumstances giving rise to the license cease to exist and are unlikely to recur.

General provision. – The Ministry of Public Health and the Ecuadorean Institute of Intellectual Property are charged to execute this decree, according to their fields of competence.

Final provision.- This Decree shall enter into force as of the time of signing, without prejudice to the publication thereof in the Official Record.

Signed in San Francisco de Quito, on October 23 of 2009.

[Signature]
RAFAEL CORREA DELGADO
CONSTITUTIONAL PRESIDENT OF THE REPUBLIC