

No. 118

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

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WHEREAS:

under Article 32 of the Constitution of the Republic, health is a right guaranteed by the State and its realization is linked to the exercise of other rights that provide support for collective wellbeing;

under Article 3.1 of the Constitution of the Republic, the State has a fundamental duty to guarantee, without any discrimination whatsoever, the effective enjoyment of the rights established in the Constitution and in international instruments, in particular, rights recognized by the Constitution, such as health;

under article 363(7) of the Constitution of the Republic, in order to establish the collective wellbeing regime, in the field of health the State is duty-bound to “guarantee the availability of and access to safe and effective quality medicines, regulate their marketing, and promote the national production and use of generic drugs that meet the epidemiological needs of the population. With respect to access to medicines, public health interests shall prevail over economic and commercial interests.”;

Article 31 of the standards concerning the availability, scope and use of Intellectual Property Rights contained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) recognizes the right of countries to issue compulsory licenses for medicine patents which may serve to combat and mitigate the effects of diseases of public interest;

the Doha Declaration on the TRIPS Agreement and Public Health, unanimously adopted by the Members of the World Trade Organization, specifies that each Member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”. Furthermore,

the above-mentioned Declaration states that the TRIPS Agreement should be interpreted and implemented to “promote access to medicines for all”;

Paragraph 20 of the Global strategy and plan of action on public health, innovation and intellectual property, WHA 61.21, of the World Health Assembly states that “Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.”;

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

the Andean Standard provided for in Decision 486, which establishes the Common Intellectual Property Regime, makes provision for a Compulsory Licensing Regime, as does Ecuador’s Law on Intellectual Property;

in order to meet this objective, the above-mentioned National Development Plan establishes policy 3.3 *“To ensure universal access to essential medicines, strengthening State authority and sovereignty in the management of medicines and herbal remedies”*, one of the strategies being the use of compulsory licenses as an instrument for reducing the cost of medicines;

it is in the State’s interest, in the field of public health, to safeguard equitable access to healthcare and consequently to medicines, in particular for the most vulnerable social and economic groups.

exercising the powers conferred by indents 1 and 3 of Article 147 of the Constitution of the Republic and the provisions of Article 65 of Decision 486 of the Andean Community of Nations:

DECREES:

Article 1.- Declaring of public interest access to medicines used in the treatment of diseases which affect the Ecuadorian population and which constitute a priority in terms of public health, and consequently authorizing the issuing of compulsory licenses for patents for medicines for use on human beings which are necessary for their treatment. Cosmetic and aesthetic medicines and bathroom products and, in general, those medicines that are not used to treat diseases, shall not be deemed to be a public health priority.

Article 2.- The Ecuadorian Institute of Intellectual Property (IEPI), through the National Directorate of Industrial Property, is the competent national office for granting compulsory licenses to applicants, on the condition that they meet the requirements laid out in the relevant legislation and in this Decree.

Authorization of compulsory licenses shall be considered depending on the specific circumstances and grounds must be provided in each case. IEPI shall grant compulsory licenses in coordination with the Ministry of Public Health.

Article 3.- The “Leopoldo Izquieta Pérez” National Institute of Hygiene and Tropical Medicine shall take the necessary steps in order to grant registration for medicines produced or imported under the compulsory licensing regime, within a maximum of 30 days as of the filing of the application, on the condition that they meet the legal requirements and necessary procedures for the verification of their quality, safety and effectiveness.

Article 4.- the Ecuadorian Institute of Intellectual Property (IEPI), through the National Directorate of Industrial Property, shall establish the scope, object and time period for which the license is granted, as well as the amount and conditions of payment of the royalties of said license and other conditions specified in the relevant standard.

Article 5.- the Ecuadorian Institute of Intellectual Property (IEPI), through the National Directorate of Industrial Property, in accordance with the provisions of the relevant legislation, shall notify patent holders who are subject to the compulsory licensing regime.

Article 6.- the period of duration of the compulsory license shall be set by the competent body of the Ecuadorian Institute of Intellectual Property (IEPI). This period of duration may be declared at an end by the same authority on the condition that the legitimate interests of the persons who have received authorization for such licenses are adequately protected and if the circumstances that gave rise to the licenses no longer exist and it is improbable that those circumstances will arise again.

General provision.- the Ministry of Public Health and the Ecuadorian Institute of Intellectual Property shall be responsible for the implementation of the present Decree, depending on the scope of their competency.

Final provision.- The present Decree shall enter into force as of its signing, without prejudice to its publication in the Official Register.

Done at San Francisco de Quito, on October 23, 2009.

Signature

RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC