

**ECUADOREAN INSTITUTE OF INTELLECTUAL PROPERTY (IEPI)  
NATIONAL DIRECTORATE OF INDUSTRIAL PROPERTY (DNPI)**

**Resolution Number: 000001-DNPI-IEPI (Compulsory Licence)**

Dossier N° 000002/2010, for the Granting of a Compulsory Licence for a drug containing the active ingredient **RITONAVIR**.

**ECUADOREAN INSTITUTE OF INTELLECTUAL PROPERTY.**

**National Directorate of Industrial Property.** Quito D.M., 14 April 2010, 8.15 AM.

**BACKGROUND:**

1. On 23 October 2009 and by means of **Executive Decree N° 118**, the President of the Republic of Ecuador, Ec. Rafael Correa Delgado, declared access to drugs used for the treatment of diseases which affect the Ecuadoran population and which constitute a priority for public health, to be in the public interest. To this end, it was determined that Compulsory Licences could be granted on the patents of drugs for human use which are necessary in the treatment of these diseases.

2. On 5 January 2010 **ESKEGROU P S.A.**, a company with headquarters in Guayaquil, Ecuador, through its legal representative, Mr Rajesh RamChand Motwani, submitted to the Ecuadorean Institute of Intellectual Property an application for a Compulsory Licence to be granted for the active ingredient known as **RITONAVIR**, the patent for which is held by **ABBOTT LABORATORIES**.

3. In compliance with Article 349 of the Codification of the Law of Intellectual Property, the President of IEPI is its legal representative and is charged with the institution's technical, financial and administrative management. As such, on 15 January 2010, the President of the Ecuadoran Institute of Intellectual Property, by means of resolution N° 10-04-P-IEPI, resolved to issue an **INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS**. This document provides IEPI users and the general population with a guide regarding the procedures to be followed in applying for Compulsory Licences, as contemplated in Decision 486 of the Andean Community as well as in the Law of Intellectual Property.

4. On 3 February 2010 the applicants were served with a notification in which they were requested to complete their application for a Compulsory Licence, in accordance with the articles contained in RESOLUTION N° 10-04 P-IEPI, entitled INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS. The applicants were therefore required to:

4.1. Complete the appropriate application form, according to the model approved by IEPI, and according to the characteristics of the Compulsory Licence requested; that is, whether for public non-commercial use, or commercial use, and:

4.2. Include the documents indicated in Article 5 or 6 respectively of the INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE

PATENTS OF DRUGS, according to the characteristics of the Compulsory Licence requested.

5. On 19 February 2010 and within the stipulated period, **ESKEGROU P S.A.** proceeded to respond to the decision of 3 February 2010 by submitting the documents required in compliance with the parameters established by the INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS. From this submission it follows that the application is for a Compulsory Licence for the active ingredient RITONAVIR, which will be imported and devoted to **Public Non-Commercial Use**.

The price proposal, as established by the licence applicants in their written application dated 19 February 2010 is: 100mg Tablets (30 Tablet Bottle), at a maximum price of USD29.40.

The price proposal was modified by the applicants in a brief dated 9 April 2010 which stated that: for the Ritonavir product in 100mg Tablets (30 Tablet Bottle), a maximum price of USD 29.40 is fixed, and for the LOPIMUINE product (Lopinavir 200mg + Ritonavir 50mg) a maximum price of USD 68.00 per bottle of 120 tablets is fixed.

Finally, on 12 April 2010 the applicants included the following formulations in their price proposal, contained within their application for a compulsory licence: paediatric formulation in Tablets of Lopinavir 100mg + Ritonavir 25mg, at a maximum non-commercial price of USD 38 per 120 tablet bottle. For the oral solution paediatric formulation of Lopinavir 80mg + Ritonavir 20mg, the maximum non-commercial price shall be USD24 per 120ml bottle.

6. Consultation of IEPI's Database of National Invention Patents Granted and Under Study has determined, to-date, that relevant documentation has been found in which it is established that a patent has been granted for the active ingredient RITONAVIR (Dossier SP-94-1223) under the designation of **COMPOUNDS WHICH INHIBIT RETROVIRAL PROTEASES, THE PROCESS FOR THEIR REPAIR AND PHARMACEUTICAL COMPOUNDS WHICH INCLUDE THEM**, whose holder is ABBOTT LABORATORIES, with USA Priority, 02 Dec 1993, N° 158587, residence 100 Abbott Park Road – Abbott Park, Y1 60064 – 5300, USA, whose legal representative in Ecuador is Dr María Rosa Fabara, residence Fabara & Guerrero Attorneys at Law, IEPI Box N° 12. Date of issue of the patent: 9 MAY 1997; date of expiry of the patent: **30 NOVEMBER 2014**, under Title N° PI-97-1142.

7. By means of a 4 March 2010 decision, notified on 8 March 2010, once the requirements determined by the decision of 3 February 2010 were complied with, the National Directorate of Industrial Property accepted the procedure of application for a Compulsory Licence for a drug submitted by ESKEGROU P S.A., in accordance with Article 7 of RESOLUTION N° 10-04 P-IEPI, entitled INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS. In addition, ABBOTT LABORATORIES was notified of the contents of the application submitted. It was decreed that the Ministry of Public Health be officially notified of that development, in order that it might issue the relevant report specifying whether the active ingredient RITONAVIR is a drug for human use to treat diseases which affect the

Ecuadorian population and which constitute a priority for public health, according to the terms established in Article 8 of the aforementioned instruction.

8. On 10 March 2010 and by means of official notification **N° 012-2010-DNPI-IEPI**, the Ministry of Public Health was required to issue the relevant report.

9. On 11 and 23 March 2010 ABBOTT LABORATORIES, through their legal representative in Ecuador, requested that a term of 60 days be granted for the company, as interested party, to submit its arguments in regard to the requested licence.

10. On 30 March 2010 and by means of official ministerial notification **N° 0004632**, the Minister of Health, Dr Caroline Chang Campos, replied to official notification N° 012-2010-DNPI-IEPI. In responding to the enquiry whether "...RITONAVIR is an active ingredient in the production of drugs used in the treatment of diseases which affect the Ecuadorian population and whether it is considered a priority for public health," the Ministry stated that "this active ingredient is used alone or in combination with others for the production of drugs used in treatment programmes for persons with HIV/AIDS (PLHIV), and **consequently is considered to be a priority for public health**" (emphasis added by this Directorate).

11. On 13 April 2010 ABBOTT LABORATORIES submitted a brief requesting that the National Directorate of Industrial Property's decision of 8 April 2010 be partially revoked, as regards the section which establishes that "this file be subjected to a resolution." ABBOTT LABORATORIES considers that proceedings have not yet reached a point at which resolutions can be made, inasmuch as Abbott's 60 day-request submitted in its competence as patent-holder was not granted and since, in addition, the report of the Ministry of Public Health was not made in accordance with the stipulations contained in executive decree 118-2009, as well as in the INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS.

#### **CONSIDERING:**

**FIRST.** That Article 32 of the Constitution of the Republic of Ecuador establishes that health is a right guaranteed by the State, the realization of which facilitates the exercise of other rights sustaining well-being.

That well-being or *Sumak Káusay*, is based on the democratic and gradual construction of material and spiritual conditions involving the community, guided by the parameters of understanding, cultural identity, social and environmental harmony, solidarity and the respect for health and life. The standard of development stipulated in the Constitution aspires to a state of well-being.

**SECOND.** That Article 3.1 of the Constitution stipulates that it is the State's duty to guarantee, without discrimination of any kind, the effective enjoyment of the rights established in the Constitution and in international agreements; particularly with regard to the rights which are constitutionally acknowledged, such as the right to health.

**THIRD.** That Article 363, item 7 of the Constitution establishes that, for the achievement of well-being, it is the obligation of the state in matters of health to

“guarantee availability of and access to safe and effective drugs of quality, regulate their sale and promote national production and the use of generic drugs which respond to the epidemiological needs of the population. In matters regarding access to medicines, the interests of public health shall prevail over financial and commercial interests”.

**FOURTH.** That Article 25 of the **UNIVERSAL DECLARATION OF HUMAN RIGHTS** stipulates, amongst other matters, that all persons have a right to a decent standard of living which will ensure that they and their families enjoy health and well-being.

**FIFTH.** That Ecuador has been a member of the WTO since 21 January 1996 and Article 31 of the regulations of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) recognizes the right of countries to issue compulsory licences at their discretion, as law permits.

**SIXTH.** In the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, which was adopted on 14 November 2001, the member governments of the WTO stressed that each Member State “has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” In addition, this declaration notes that the TRIPs Agreement should be “interpreted and implemented... ..to promote access to medicines for all.”

**SEVENTH.** That the World Health Assembly’s Global Strategy on Public Health, Innovation and Intellectual Property, WHA 61.21, at paragraph 20 specifies that “Intellectual Property rights do not prevent nor should they prevent Member States from taking measures to protect public health.”

**EIGHTH.** That objective number 3 of the 2007-2010 National Development Plan, enacted under Executive Decree 745 of 7 April, 2008, is: “**To raise the life expectancy and the quality of life of the population**”.

That for the fulfilment of this objective, the aforementioned 2007-2010 National Development Plan establishes policy 3.3, which stipulates that the State must “**ensure universal access to essential medicines, consolidate authority and sovereignty of the State in the management of medicines and phytotherapeutic resources. [Through] ... 2. the import of generic drugs manufactured under compulsory licenses**”.

**NINTH.** That the National Development Plan, designated the National Well-Being Plan for the period 2009-2013, pursuant to Executive Decree 1577 of 26 February 2009, submitted by President Rafael Correa to the National Planning Council and approved during the session of 5 November 2009 by means of resolution number CNP-001-2009, establishes in Objective 3.2.3 that “the mortality rate for deaths caused by AIDS must be reduced by 25% by 2013”.

**TENTH.** That Andean Community Decision 486, which establishes a Common Intellectual Property Regime, provides for compulsory licensing, as does Ecuador’s Law on Intellectual Property.

**ELEVENTH.** That pursuant to Article 65 of Andean Community Decision 486, Article 154 of the Law of Intellectual Property and in compliance with Executive Decree N° 118 of 23 October 2009, the National Directorate of Industrial Property is the competent authority to rule on the granting or denial of applications submitted for Compulsory Licences for drugs.

**TWELFTH.** Article 2 of decree 118-2009 establishes that IEPI shall issue compulsory licences in coordination with the Ministry of Public Health. In addition, the decree indicates that implementation of the compulsory licensing protocol falls within the purview of the Ministry of Public Health and this Institute, each according to its areas of competence. Similarly, Article 8 of the INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS states that when the relevant documents have been reviewed and the patent holder has been duly notified, IEPI shall through the DNPI request the Ministry of Public Health to report on whether the object of the application is a drug for human use, of those used to treat diseases which affect the Ecuadoran population and which constitute a priority for public health.

As recorded on page 48 of the file, the Minister of Health has determined by means of communique N° 0004632 of 30 March 2010, that RITONAVIR is, in fact, an active ingredient used alone or in combination with others for the production of drugs used in treatment programmes for persons with HIV/AIDS, considered to be a public health priority, and as such fulfills the requirements cited above. Contrary to what patent holder ABBOTT LABORATORIES maintains, neither Executive Decree 118-2009 nor the Instruction on the matter referred to above, stipulates that a product's market price must be established prior to publication of the Ministry of Public Health's report. The Minister of Public Health's earlier petitions for information and aforementioned communiqués do not affect the perfection or the legal validity of the required report concerning the granting or denial of the compulsory licence applied for, inasmuch as the basic object of the report involves the treatment of diseases which affect the Ecuadoran population and the product's importance to public health.

From the above it follows that if a price proposal constitutes a requirement for applying for a compulsory license, it is nevertheless not an essential element for issuance of the Ministry of Public Health's report.

The above analysis leads, therefore, to the conclusion that the arguments submitted by ABBOTT LABORATORIES in their brief of 13 April 2010 are contrary to current and relevant law in the matter of compulsory licences. In consequence, the application for partial revocation of the ruling of 8 April 2010 is inadmissible.

**THIRTEENTH.** Regarding ABBOTT LABORATORIES' petitions dated 11 and 23 March 2010, and 13 April 2010 in item 2.1, which request a term of 60 days to put forward arguments, based on Article 62 of Decision 486 of the Common Intellectual Property Regime, that article states:

*“Decisions to grant a compulsory license, as stipulated in the previous article, shall be taken after the patent owners have been notified that they must present such arguments as they see fit within the following sixty days.”*

This article refers to decisions taken under Article 61, which states:

*“At the expiry of a period of three years following the granting of a patent or of four years following the application for a patent, whichever is longer, the competent national office may, at the request of any interested party, grant a compulsory license mainly for the industrial manufacture of the product covered by the patent, or for full use of the patented process, provided that at the time of the request, the patent has not been exploited in the manner specified in articles 59 and 60, in the Member Country in which the license is sought, or that the exploitation of the invention has been suspended for more than one year.”*

The cited articles provide a term of 60 days for patent holders to present arguments only in cases arising from a failure to work the patent, within the periods of time established in Article 61 of Decision 486. In the present case, the application submitted by ESKEGROUPE S.A. does not arise from a working failure of the patent for the active ingredient known as RITONAVIR, held by ABBOTT LABORATORIES, but, rather, is a matter of public interest, pursuant to Article 65 of Andean Community Decision 486, which establishes that: “Following the declaration by a Member Country of the existence of public interest, an emergency, or national security considerations, and only for so long as those considerations exist, the patent may be subject to compulsory licensing at any time...”. It should be noted that the public interest is intertwined with access to medicines used for the treatment of diseases which affect the Ecuadoran population, as declared in Executive Decree N° 118-2009 mentioned above.

Without prejudice to the above, ABBOTT LABORATORIES was notified on 8 March 2010 of the application for a Compulsory Licence submitted by ESKEGROUPE S.A., as recorded in the information provided by the Secretariat and as declared by the holder in the briefs submitted, and was free to submit whatever arguments were considered relevant at any time prior to the issuing of this resolution. However, there is no record on file of any relevant document or argument presented by ABBOTT LABORATORIES on this matter which should be taken into account by the authorities before issuing a resolution.

**FOURTEENTH.** With regard to financial compensation, as established by Article 65 of Decision 486, in agreement with Article 4 of Executive Decree N° 118, the competent authority to set the amount and terms of the financial compensation for the Compulsory Licence is the Ecuadorean Institute of Intellectual Property, through the National Directorate of Industrial Property. It is, therefore, the responsibility of this authority to establish the amount of the financial compensation.

Furthermore, it should be noted that this power derives from the requirement that there be no unnecessary hindrances to the immediate application of the benefits generated by the Compulsory Licence for the general population of Ecuador.

In accordance with Article 31(h) of the TRIPs Agreement, the rights holder should receive “adequate remuneration according to the circumstances in each case, taking into account the economic value of the authorization”. In the case of Compulsory Licences, the TRIPs Agreement, as well as Decision 486 and Executive Decree 118, permit the competent authority to establish the parameters for the payment of financial compensation arising

from the use of the patent. Consequently, this Directorate takes the following factors into account:

“Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies”, published jointly by the United Nations Development Programme and the World Health Organization, is a global guide for royalty rates for pharmaceutical products<sup>1</sup>. It provides examples of experiences involving royalties determined by the authorities in several countries as a reference, and a Tiered Royalty Method, or TRM, is recommended, which takes into account common rates and practices regarding pharmaceutical royalties worldwide. According to the TRM:

Royalties are independent of manufacturing costs, and vary directly with proxies for therapeutic value (the high income price) and capacity to pay. The TRM provides a more rational framework for sharing the costs of R&D, and may be more sustainable for some middle- or high-income countries that are sensitive to global norms concerning the sharing of R&D costs. The TRM provides for much higher royalties in middle- and high-income countries with low burdens of disease, and the lowest royalties for countries that have the lowest incomes and the highest rates of disease burden. The TRM is particularly appropriate for global or regional patent pools that serve countries with very different circumstances in terms of income or disease burdens<sup>2</sup>.

This Directorate has determined to use the TRM as its model and guide in the calculation of royalties, taking into account the need to contribute to and invest in R&D for new pharmaceutical products worldwide.

Bearing in mind that Health is a fundamental right, and pursuant to the WHO’s Decision of 30 August 2003, this Directorate takes into account all of the factors mentioned above, in particular, the human development indices provided by the United Nations Development Programme, in the interest of dealing fairly with both licensor and licensee.

**FIFTEENTH.** The term of duration of a Compulsory Licence is relevant to its purpose of promoting access to medicines. Conditions of public interest or emergency involving catastrophic diseases are rarely short term.

The Doha Declaration of 2001 stipulates that the States are free to determine the grounds on which licences are granted.

For the reasons set forth above, this Directorate exercises the powers conferred upon it by Article 65 of Decision 486 of the Common Intellectual Property Regime and Articles 2 and 4 of Executive Decree 118-2009, and

**RESOLVES:**

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<sup>1</sup> WHO/TCM/2005.1, “Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies”, Health Economics and Drugs, TCM Series N° 18, WHO/UNDP, by James Love.

<sup>2</sup> Ibid, page 85.

1. To grant a Compulsory Licence on patent N° PI-97-1142, designated as “**COMPOUNDS WHICH INHIBIT RETROVIRAL PROTEASES, THE PROCESS FOR THEIR REPAIR AND PHARMACEUTICAL COMPOUNDS WHICH INCLUDE THEM**”, whose holder is ABBOTT LABORATORIES, and which contains the active ingredient **RITONAVIR**, in favour of **ESKEGROUP S.A.** This licence shall be used for the manufacture, offer for sale, sale or use of the product, and its import for such purposes, and dedicated to Non-Commercial Public Use.
2. To grant as term of the compulsory license the remaining life of patent N° PI-97-1142, “**COMPOUNDS WHICH INHIBIT RETROVIRAL PROTEASES, THE PROCESS FOR THEIR REPAIR AND PHARMACEUTICAL COMPOUNDS WHICH INCLUDE THEM**”, whose holder is ABBOTT LABORATORIES; that is, until **14 November 2014**.
3. To instruct **ESKEGROUP S.A.** to pay financial compensation according to the following analysis and calculation based on the TRM:

<b>Factor</b>	<b>Calculation</b>
Norvir USA price per bottle	\$289.99 (drugstore.com)
USA price per capsule	\$9.67
Royalty at 5%	<b>\$0.4835 per capsule</b>
USA GDP per capita (according to International Monetary Fund 2009)	\$46,443.00
Ecuador GDP per capita (according to International Monetary Fund 2009)	\$3,939,00
Ecuador/USA average proportional income	$3,939 / 46,443 = \mathbf{0.084813642}$
Tiered Royalty	$\$0.4835 \times 0.084813642 = \mathbf{\$0.041 \text{ per capsule}}$

The royalties established herein in favour of ABBOTT LABORATORIES are USD 0.04 per capsule for Ritonavir 100mg; USD 0.02 per capsule for LOPIMUINE Lopinavir 200mg + Ritonavir 50mg; USD 0.01 per capsule for Lopinavir 100mg + Ritonavir 25mg, and USD 0.0082 for the paediatric Oral Solution formulation of Lopinavir 80mg + Ritonavir 20mg.

Regarding prices proposed for the drug, the applicant **ESKEGROUP S.A.** did freely and of its own accord **set the prices detailed below as the maximum prices** for the products concerned, pursuant to their 9 April 2010 brief. For Ritonavir 100mg Tablets (30 Tablet Bottle), a maximum price of USD 29.40, and for LOPIMUINE (Lopinavir 200mg + Ritonavir 50mg) a maximum price of USD 68.00 per bottle of 120 tablets. Concomitantly, in their brief dated 12 April 2010, they freely and of their own accord set the following prices: paediatric formulation of Lopinavir Tablets 100mg + Ritonavir 25mg, a maximum non-commercial price of USD 38 per 120 tablet bottle and for the paediatric oral solution formulation of Lopinavir 80mg + Ritonavir 20mg, a maximum non-commercial price of USD24 per 120ml bottle.

Non-fulfilment of these terms; that is, the sale of these products at prices higher than those which were determined freely and of their own accord by **ESKEGROUP S.A.**, will lead to the immediate revocation of the licence, and responsibility of **ESKEGROUP S.A.** for non-fulfilment as stipulated by the relevant laws.

Royalties shall be paid by 31 December of each year, with a possible extension of up to 30 days as from the expiry of the initial period. If the licensee should not fulfil his obligations towards the licensor, the licensor may call upon the National Directorate of Industrial Property to rescind the licence immediately. The licensee must keep accurate and strict records and accounts in order to show all of the data reasonably required for the calculation and verification of the sums payable in settlement of financial compensation.

4. Pursuant to Article 5 of RESOLUTION N° 10-04 P-IEPI, entitled INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS, and in accordance with the initial request contained in the application dated 19 February 2010, the licence is granted exclusively for the manufacture, offer for sale, sale or use of the product, import for such purposes, and dedicated to Non-Commercial Public Use, for national consumption within the territory of Ecuador, on the terms described in the initial request. Violation of these conditions shall lead to a resolution revoking the licence, upon evidence submitted by the licensor or any injured third party.

5. Non-exclusivity. Pursuant to Article 11 of the INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS and in accordance with Article 68 a) of Decision 486, this **Compulsory Licence shall be non-exclusive**. The license shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use. **The granting of Compulsory Licences shall not affect the right of the holder to continue to exploit the patent.**

6. Revocation of Compulsory Licence. Pursuant to Article 14 of the INSTRUCTION FOR THE GRANTING OF COMPULSORY LICENCES FOR THE PATENTS OF DRUGS, the National Directorate of Industrial Property may, *ex officio* or at the request of a third party, revoke the Compulsory Licence when the circumstances giving rise to the licence cease to exist and are unlikely to recur, or when the licensee fails to comply with the provisions established in the resolution granting the Compulsory Licence.

7. Marginal notation of the Compulsory Licence. The Patents and/or Documentation and Filing Managing Unit is hereby ordered to effect a marginal notation of this Compulsory Licence in favour of **ESKEGROUP S.A.** on the patent identified by dossier number SP-94-1223, under the designation of **COMPOUNDS WHICH INHIBIT RETROVIRAL PROTEASES, THE PROCESS FOR THEIR REPAIR AND PHARMACEUTICAL COMPOUNDS WHICH INCLUDE THEM**, whose holder is ABBOTT LABORATORIES, under Title N° PI-97-1142.

Any contestation of the Compulsory Licence shall not meanwhile impede exercise of the rights arising from the licence, nor shall it have any influence on the period the license has been in effect. The lodging of an appeal shall not prevent the patent holder from receiving, meanwhile, the financial compensation established by DNPI on the unclaimed portion.

[UNOFFICIAL TRANSLATION]

This administrative act is susceptible to the effects of appeals as established by Article 357 of the Law of Intellectual Property; a Modification Appeal before this Directorate within a term of fifteen days; an Appeal before the Intellectual Property Commission within a term of fifteen days; an Appeal for Revision before the Intellectual Property Commission within the terms stipulated by the Statute of the Judicial and Administrative Regime for the Executive Function, and once the case is definitively ended, via jurisdictional means before one of the Administrative Law District Courts.

(SIGNATURE)

José Manuel Martínez V. (attorney at law)  
NATIONAL DIRECTOR OF INDUSTRIAL PROPERTY

I served notice of the above resolution by means of a document delivered to ABBOTT LABORATORIES, in Quito on 14 April 2010, through the company's legal representative Fabara & Guerrero Attorneys at Law, IEPI box N° 12 in the city of Quito; to ESKEGROUP S.A. at judicial box N° 4585 in the Provincial Court of Justice of Guayas in the city of Guayaquil, and to the Minister of Public Health in her office, on the corner of Av. República del Salvador and Suecia. I so certify.

(SIGNATURE)

José Andrés Tinajero M. (attorney at law)  
SECRETARY  
Seal of the Secretariat of the ECUADORAN INSTITUTE OF INTELLECTUAL  
PROPERTY and the NATIONAL DIRECTORATE OF INDUSTRIAL PROPERTY