

# What Will Work in My Country?

Thinking Through Health Rights and Patents in Differing  
Political and Legal Contexts

**Peter Maybarduk & Luz Marina Umbasia**

**Public Citizen**

**[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org); [lumbasia@citizen.org](mailto:lumbasia@citizen.org)**

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# REGULATORY FRAMEWORK COLOMBIA- ECUADOR & PERU

## International treaties

- TRIPS (art 31)
- Doha Declaration on TRIPS and Public Health
- París Convention for the I.P protection (1883)
- Budapest Treaty. Treaty on the international recognition of the deposit of microorganisms for the purpose of patent procedure/WIPO
- PCT



# COLOMBIA- ECUADOR Y PERU

## Supranational rules

Andean Decision 486- Common regime on Industrial Property

Andean Decision 632 Clarification of the second paragraph of article 266 of Decision 486 Released on 2006

Andean Decision 689 adequacy of certain articles of Decision 486

Andean Decision 291

Andean Court Jurisprudence

# COLOMBIA

## NATIONAL REGULATORY FRAMEWORK

Political Constitution of 1991

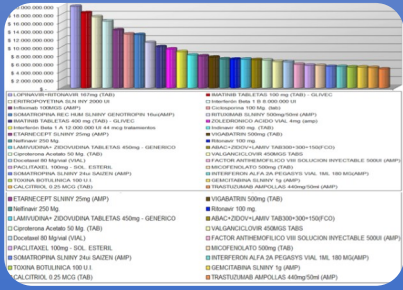
Decree 4302 of 2008

Decree 4966 of 2009

Code of administrative  
procedure and administrative  
litigation

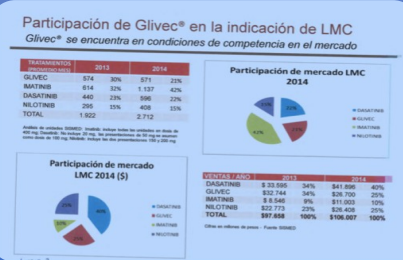
# Colombia: Case Studies

## Compulsory Licenses



- Application for C.L for Kaletra L/r
- Legal monopoly

## Competition related provisions



- Application for C.L. for imatinib
- Market with several competitors

## Use by the government



- Public Interest Declaration PID Application for Direct Acting Antiviral DAA
- More than 15 patented medicines

# Request Mechanisms

- Requested by civil society organizations
- Administrative route. Public interest declaration, compulsory license
- Judicial route. Popular Action, guardianship

# There was no application of flexibilities

- Colombia must optimize capacity to respond to the imposition of measures that constitute barriers to the A2M
- It is important foreign policy that allows to face asymmetric environments, support competence, civil society participation, legal security and structures of political opportunity
- Colombia must assume regional leadership that promotes a balance between trade and human rights.

Strict criteria are needed to guarantee novelty and inventive height and industrial application.

Active participation of the MOH

- Inconsistency between inventors' rights, legislation, trade rights and human rights.

# Impact of Applications for Compulsory License/Government Use

Kaletra  
L/r

Judicial decision declares the public interest

- Price Reduction 90%

Imatinib

Public interest in access is declared

- Price control is carried out, 44% reduction of the brand-name drug

DAAAs

Centralized purchasing that favored the price of tenofovir

- Attention of the State to the issue of prices



# ACCIONES JURÍDICAS DE NOVARTIS EN CONTRA DE LA DECLARACIÓN DE INTERÉS PÚBLICO

Resultados Encontrados: 88

Ya Consultados	Número Proceso	Fecha Radicación	Clase	Ponente	Demandante(s)	Demandado(s)
<input type="checkbox"/>	11001032400020160036700	24/06/2016	LEY 1437 NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	MARIA CLAUDIA ROJAS LASSO	- ESSATECH A NOVARTIS COMPANY LLC	- SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
<input type="checkbox"/>	11001032400020170001800	12/01/2017	LEY 1437 NULIDAD Y RE-STABLECIMIENTO SUSP. PROV.	MARIA ELIZABETH GARCIA GONZALEZ	- NOVARTIS A.G.	- MINISTERIO DE SALUD Y PROTECCION SOCIAL
<input type="checkbox"/>	11001032400020170007300	03/03/2017	LEY 1437 NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	CARLOS ENRIQUE MORENO RUBIO (E)	- NOVARTIS A.G.	- COMISION NACIONAL DE PRECIOS DE MEDICAMENTOS Y DISPOSITIVOS MEDICOS
<input type="checkbox"/>	11001032400020170012700	04/04/2017	LEY 1437 NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	MARIA ELIZABETH GARCIA GONZALEZ	- NOVARTIS A.G.	- SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
<input type="checkbox"/>	25000232700020020098801	06/12/2004	ACCION DE NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	LIGIA LOPEZ DIAZ	- NOVARTIS DE COLOMBIA S.A.	- U.A.E DIAN
<input type="checkbox"/>	25000232700020030050001	07/07/2005	ACCION DE NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	JUAN ANGEL PALACIO HINGAPIÉ	- NOVARTIS DE COLOMBIA S.A.	- U.A.E. DIAN
<input type="checkbox"/>	25000232700020040163901	10/11/2005	ACCION DE NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	RAFAEL E. OSTAU DE LAFONT PLANETA	- NOVARTIS DE COLOMBIA S., A.	- DIAN
<input type="checkbox"/>	76001233100020030226501	07/04/2005	ACCION DE NULIDAD Y RE-STABLECIMIENTO DEL DERECHO	MARTHA SOFIA SANZ TOBON	- NOVARTIS DE COLOMBIA S. A.	- DIAN

1 2 3 4 5



# Ecuador

  
INSTITUTO ECUATORIANO DE LA PROPIEDAD INTELECTUAL IEPI  
DIRECCIÓN NACIONAL DE PROPIEDAD INDUSTRIAL

TRAMITE No.: 000006 (Licencia Obligatoria para Fármaco)  
SOLICITANTE: ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A.

PATENTE No.: PI-08-1913  
DENOMINACION: "UNA NUEVA SAL"  
TITULAR: GLAXO GROUP LIMITED  
RESOLUCION No.: 041-2012-DNPI-IEPI

INSTITUTO ECUATORIANO DE LA PROPIEDAD INTELECTUAL IEPI.- Dirección Nacional de Propiedad Industrial.-

Quito, a 12 de noviembre del 2012; las 09h35.

**ANTECEDENTES:**

El 15 de junio del 2012, ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. solicitó la emisión de una licencia obligatoria para uso público no comercial del principio activo LAMIVUDINA + ABACAVIR, protegido bajo la patente No. SP-98-2505, solicitada el 14 de mayo de 1998, concedida el 05 de enero del 2007, mediante título No. PI-08-1913, vigente hasta el 14 de mayo del 2018.

Mediante escrito de 15 de junio de 2012, María José Zurita en su calidad de procuradora judicial y apoderada general de la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. manifiesta que: "... la combinación LAMIVUDINA + ABACAVIR se encuentra actualmente patentado, bajo el No. De Patente SP 98-2505, concedida el 5 de enero del 2007, cuyo título es PI 08-1913, vigente hasta el 14 de mayo de 2018, perteneciente a la compañía GLAXO GROUP LIMITED, representada por su apoderado el Dr. Enrique Chiriboga." Señala también que: "Esta combinación antirretroviral, destinada a los medicamentos que son inhibidores de la Frascriptase inversa análoga de los nucleosidos, cuya acción farmacológica es el tratamiento de la enfermedad VIH/SIDA, es necesario para la fabricación de medicamentos requeridos para el tratamiento de pacientes con la enfermedad anteriormente indicada... El Ecuador en su afán de combatir esta enfermedad, incluso expidió la Ley 2000-11 de Prevención y Asistencia Integral del VIH/SIDA, promulgada en el Registro Oficial 58 del 14 de abril del 2000, así mismo en el art. 56 de la decisión 486 de la Comunidad Andina de Naciones, a la cual pertenece el Ecuador, establece 'previa declaratoria de un país miembro de la existencia de razones de



No. 118  
RAFAEL CORREA DELGADO

CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

... 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

***"Our vision of intellectual property ... a mechanism for the development of the people."***

***--Rafael Correa Delgado, Former President of the Republic of Ecuador***

# ECUADOR NATIONAL REGULATORY FRAMEWORK

Political Constitution of Ecuador

Organic Code of the Social Economy of Knowledge, Creativity and Innovation – COESCCI

COESCCI transitional regime

Knowledge Management Regulations (2020)

Executive Decree 118 - Declaration of Public Interest (2009)

- Instructions for the granting of LO on drug patents (2010)

# C.L. Requests

41 drug patent applications

1 agrochemical patent application

31 applications withdrawn, abandoned and rejected mainly for reasons of form

11 compulsory licences granted

(10 are no longer in force and 1 contested)

**Compulsory licenses transform Ecuadorian health**



# Compulsory licenses

Active substance	Market price	Proposed price	Variation (%) savings
Ritonavir	\$289.99 per 30 100 mg tablets (\$9.66 each)	\$ 29,40 (\$ 0,98 each)	89,86%
Ritonavir	\$2.10 per 200 mg + 50 mg tablet	\$ 0,67	68,09%
Abacavir	\$9.17 per 600 mg + 300 mg tablet	\$ 6,11	33,37%
Etoricoxib	\$0.84 per 120 mg tablet	\$ 0,0084	99%
Abacavir	\$275.28 per 30 tablets of 600 mg + 30 mg (\$9.18 each)	\$ 199 (\$ 6.63 each)	27,77%
Micofenolato sódico	\$200.01 per 120 180 mg tablets (\$1.66 each) \$389.96 per 120 360 mg tablets (\$3.25 each)	\$ 168 (\$ 1.4 each)	15,66%
		\$ 299 (\$ 2.49 each)	23,38%
Abacavir	\$9.17 per 600 mg + 300 mg tablet	\$ 3,45	62,37%
Abacavir	\$136.36 per 60 300 mg tablets (\$2.27 each)	\$ 120 (\$ 2 each)	11,89%
Abacavir	\$192.94 per 30 tablets of 600 mg + 300 mg (\$6.43 each)	\$ 140 (\$ 4.66 each)	27,53%

# Peru: Compulsory License for Atazanavir



Until 2019 patent monopoly for Reyataz  
Marketed by BMS.

Patented Material: Atazanavir bisulfate salt

Patent granted Peru, Chile, Argentina

- Patent rejected Uruguay, Brazil, Colombia and Venezuela

# PERU. National Legislation

Legislative Decree 1033. Law on the Organization and Functions of the National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI). Published in the official newspaper El Peruano on June 25, 2008.

Supreme Decree No. 09-2009-PCM. INDECOPI

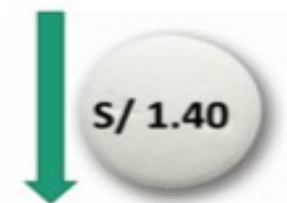
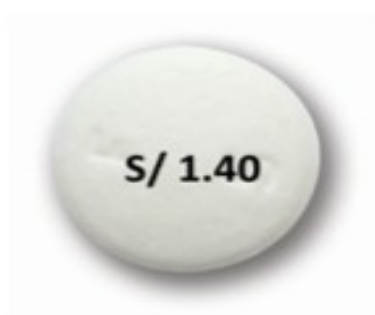
Resolution No. 104-2019-INDECOPI. Administrative procedures

Decrees No. 1075, No. 1397 and No. 059-2017-PCM Complementary to Decision 486

- Decree No. 004-2019-JUS Administrative Procedure

## Porque una licencia obligatoria para atazanavir

- Porque introduce competencia al mercado reduciendo el precio y mejorando el acceso a los medicamentos que salvan vidas.



2013 un solo genérico

2014 más de 4 genéricos en el  
mercado internacional



## Comparación de precios en cinco países de América Latina - mercado monopólico

REYATAZ® (ATAZANAVIR) 300 mg			
PAIS	PRECIO PPA	PATENTE VIGENTE	PROTECCIÓN DE DATOS
ARGENTINA	8.91	SI	NO
BRASIL	2.90	SI	NO
COLOMBIA	9.54	NO	NO
MÉXICO	10.55	SI	NO
PERÚ	18.60	SI	NO



Fuente: Resultados de preliminares del estudio "Situación de medicamentos con protección de Propiedad Intelectual en Cinco Países de América Latina". Los resultados se expresan en dólares pariaados (PPA) a fin de hacerlos comparables. Los datos corresponden a las compras publicas 2012

Health  
Commission  
of the  
Congress of  
the Republic  
Law 275/2016

- Lima, May 25, 2017.- The Health Commission of the Congress of the Republic approved by majority the bill of Law 275/2016-CR, which proposes to declare of public interest the drug Atazanavir, which is used in antiretroviral therapy for people living with HIV and has had an overexpenditure of 75 million soles, in the last four years, due to the monopoly that the pharmaceutical company Bristol Myers Squibb has for its drug Reyataz.

# COMPULSORY LICENSE NOT GRANTED

The Ministry of Health understood that it is feasible to issue a license, however it recognizes external pressures.

- During the process they found a viable way out of donation from government to government of the same atazanavir (Reyataz), which by exhaustion of the right does not violate the IPRs.
- The state reduced spending by buying atazanavir, and did not give in to pressure from the drugmaker.

	<b>Colombia</b>	<b>Ecuador</b>	<b>Perú</b>
<b>Grounds for legal action</b>	Right to health Public Interest	Right to health Public Interest	Right to health Public Interest
<b>C.L Requests</b>	3	42	1
<b>C.L. granted</b>	0	11	0
<b>Impact of the Application</b>	Reduced drug prices Policy change Govt engagement in medicine pricing	Reduced drug prices Policy change Govt engagement in medicine pricing	Cost reduction for health system Govt engagement in medicine pricing
<b>Reaction of the pharmaceutical industry</b>	Political reaction, threats, demands, without major effects	Political pressure, demands on competitors	Political pressure, threats, demands, without major effects

# Bibliography

Colombia MOH <https://www.minsalud.gov.co/salud/MT/Paginas/medicamentos-propiedad-intelectual.aspx>

USTR: <https://ustr.gov/about-us/policy-offices/press-office/reports-and-publications/2018/2018-trade-policy-agenda-and-2017>

<https://www.citizen.org/our-work/access-medicines>

Umbasía, L. (2015). Requesting a Compulsory License for Kaletra, an HIV/AIDS antiretroviral drug in Colombia. In K. A. G., & J.M. Pogge (Ed.), *Protecting the Health of the Poor. Social Movements in the South* (pp. 17-39). London, UK: Zed Books.

Umbasía L. 2019 Right to health and application of flexibilities of the Trade-Related Aspects of Intellectual Property (TRIPS) agreement in Colombia. Period 2008-2018. Military University. <http://hdl.handle.net/10654/32398>

Maybarduk P. & Weissman R. (2008). *Issuance of Compulsory Licenses in Colombia. Essential Action*. Washington D.C: Essential Action.

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[https://www.propiedadintelectual.gob.ec/covid\\_19/index.html](https://www.propiedadintelectual.gob.ec/covid_19/index.html)

<https://aisperu.org.pe/peru-continua-el-debate-sobre-la-licencia-obligatoria-para-atazanavir/>

- <http://www.redge.org.pe/node/1924>

Thank you

**Peter Maybarduk & Luz Marina Umbasia**  
**Public Citizen**

[pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org); [lumbasia@citizen.org](mailto:lumbasia@citizen.org)