

# COVID – 19

An update about compulsory licenses for  
pharma products in the Americas

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**All information shared in this event  
express opinions of the respective  
speakers and should not be taken as legal  
advice. If needed, legal advice should be  
sought on a case-by-case basis.**



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## Cristian Daniel Bittel

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## Compulsory licenses

### Paris Convention:

- Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent.

### TRIPS:

- Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government(...) (Art. 31).

### Argentine Patent Law (Law 24,481):

- Art. 45 of the Patent Law: “The NATIONAL EXECUTIVE POWER may, due to **sanitary emergency** or national security reasons, dispose upon the use of certain patents by granting the user right conferred by a patent; its **scope and duration shall be limited to the purposes of such grant(...)**”.

**No Compulsory Licenses granted.**

## Compulsory licenses

### Process:

There are no specific details.

- i. The NATIONAL EXECUTIVE POWER shall grant the compulsory licenses through the intervention of the MINISTRY OF ECONOMY, the NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY, and the MINISTRY OF HEALTH;
- ii. The patentee will receive a reasonable compensation taking into account the economic value of the authorization being granted;
- iii. Scope and duration shall be limited to the purposes of such grant.

**Prophetically**, the Argentine government considered compulsory licenses in a Law passed in December 2019:

- The Ministry of health is entitled to monitor the pricing of pharmaceuticals and consider direct imports or compulsory licenses upon availability or unjustified or unreasonable price increases affecting access to medicaments.

The **Sanitary Emergency was extended** for the term of one year as a result of the COVID 19 outbreak.

### Current status

#### Compulsory Licenses:

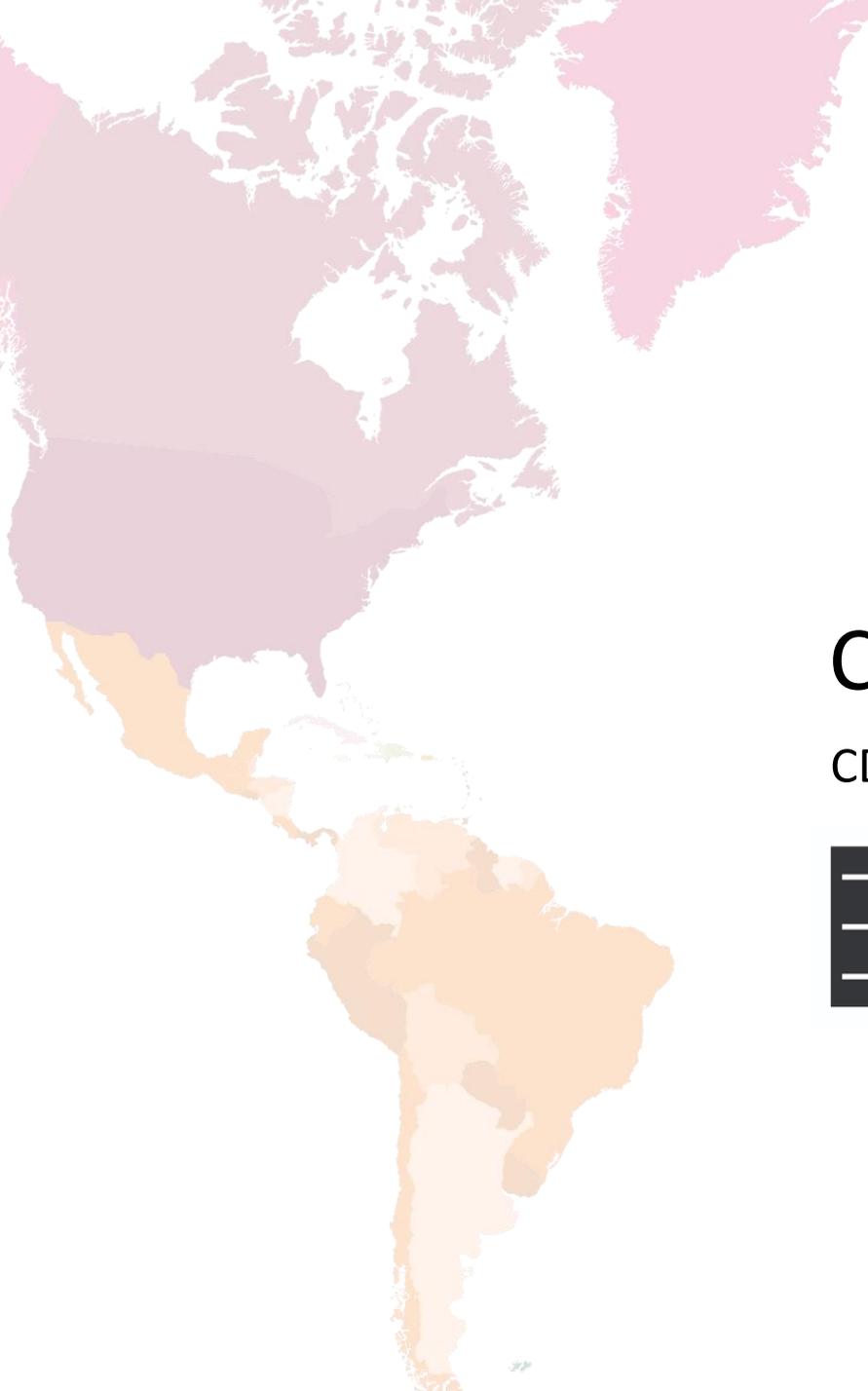
- Even though Sanitary Emergency is declared already, no requests have been filed. Candidate patents will be directed to devices such as ventilators or masks, or compounds (use patents are not granted by the PTO).

#### Patent Office:

- The Patent Office is closed but working remotely. It is possible to file on-line: applications, responses to Office Actions, etc. All the terms have been suspended (March 13, 2020 – 24 May, 2020).

#### Judiciary:

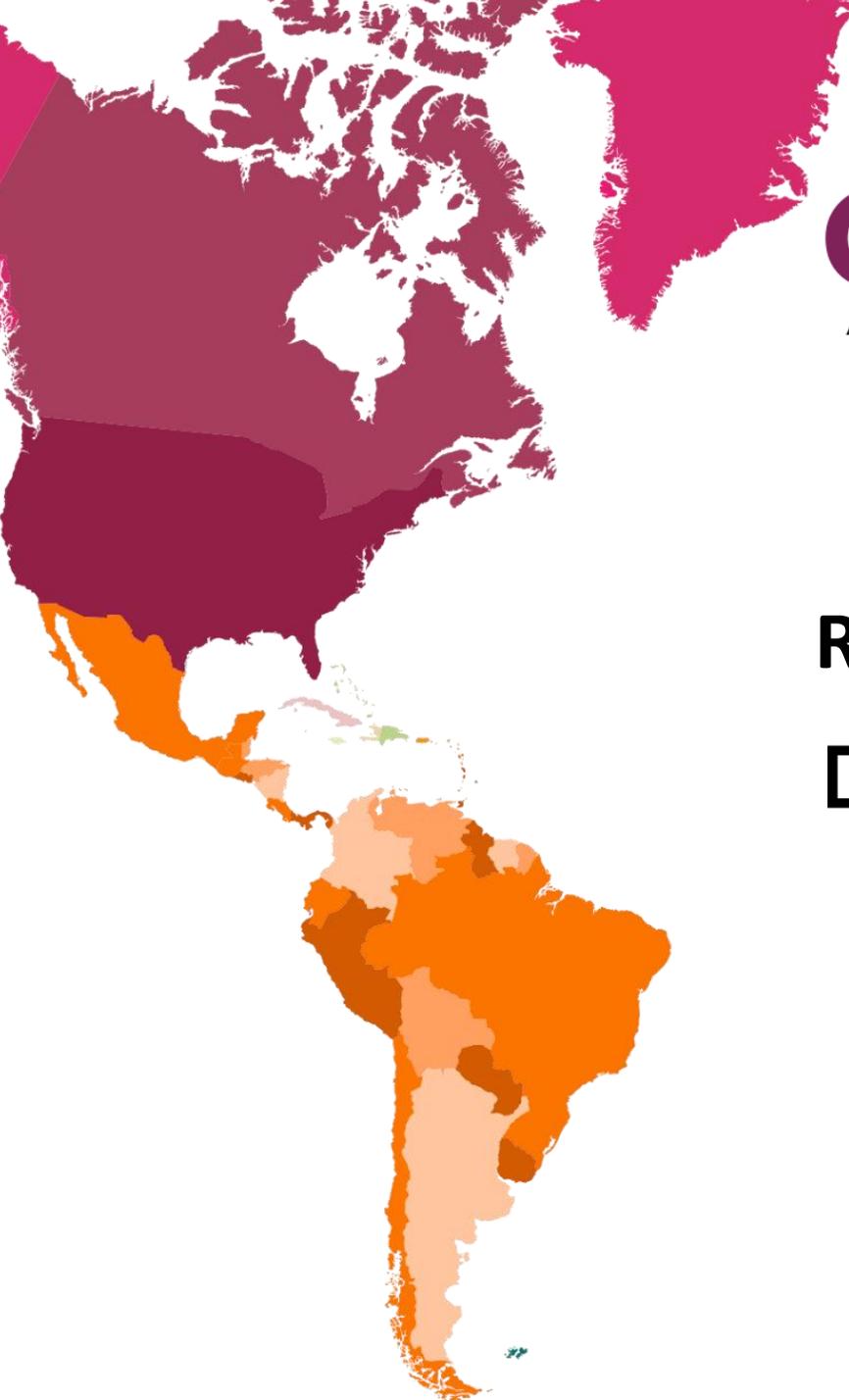
- Argentine Federal Courts, which hear most of the local patent cases, have been in extraordinary recess since March 20, 2020. All judicial terms have been suspended since then. However, it is possible to request the Courts to continue prosecuting ongoing cases during this recess as an exception on the basis of urgency.

A stylized map of the Americas, with North America in shades of purple and pink, and South America in shades of orange and yellow.

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### The PTO agenda:

- The program to reduce patent backlog is ongoing normally;
- All deadlines for existing processes were postponed to 31 May 2020;
- INPI servants continue working remotely;
- New applications can be normally filed, however, all virtually.

### The Judiciary:

- Lawsuits prosecuting in paper are suspended until 15 May;
- Electronically filed suits: terms resumed on 04 May (except Supreme Court (STF) and Electoral Court);
- Oral hearings and judgement sessions working normally, however, virtually.

### Infringement:

- Lawsuits incl. seeking injunctive measures inter partes or ex parte are being processed normally;
- Personal hearings are not allowed.

## **Patenting second medical use in Brazil**

**IP law 9.279/96 does not explicitly foresee it nor forbids it.**

**Legal treatment as any other invention.**

### **Non-binding jurisprudence:**

- Ely Lilly vs. The Brazilian PTO (“INPI”);
- More robust evidences;
- “Invention starting from something already known”.

**Swiss-type claims are allowable.**

**Coverage does not encompass treatment or the substance per se.**

## Compulsory licenses (CL)

### Law 9279/96 – art 71:

- “(...) insofar as the patentee or his licensee does not meet such necessity, a temporary ex officio non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee.” (emphasis added)

### Decree 3201/99:

- reiterates “insofar as the patentee or his licensee does not meet such necessity” and “non-commercial use”.

### Decree 4830/03:

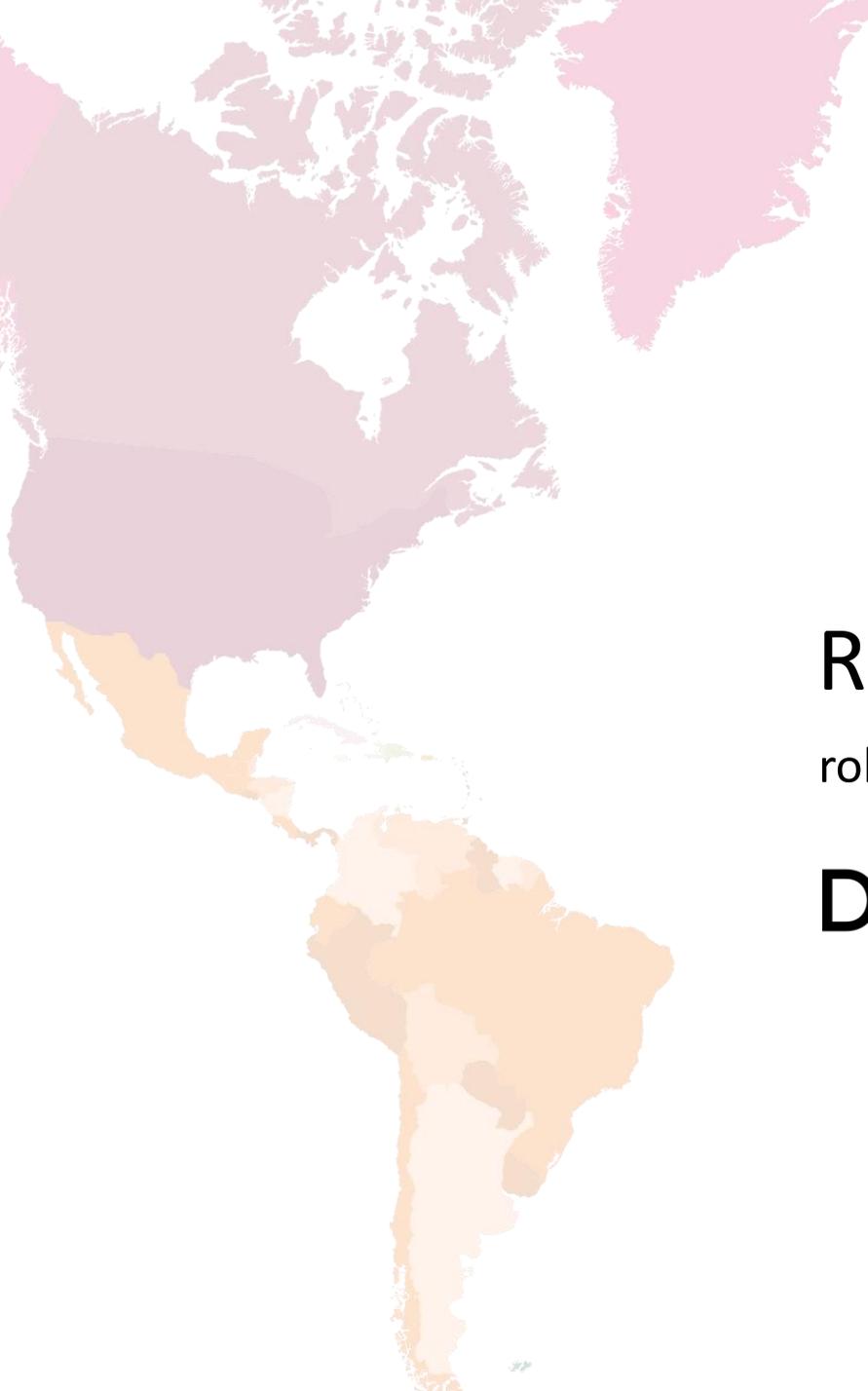
- among other things, allows importation to meet needs.

### Bills of law (PL):

- 1320/2020
- 1462/2020
- 1184/2020

Main aspect:

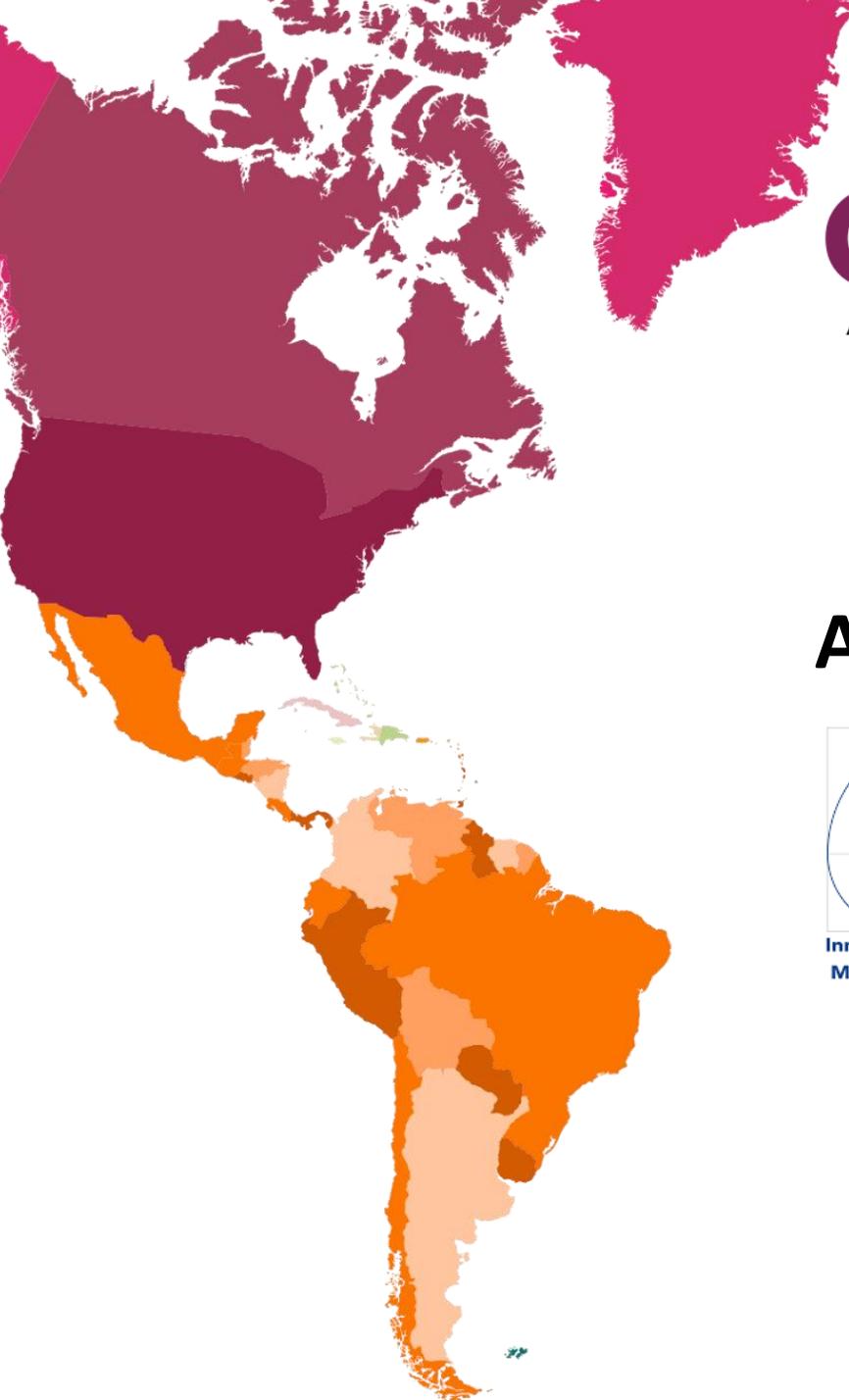
CL regardless of patentee or licensee meeting the necessity.



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## Deadlines and Extensions (CIPO)

### Canadian Intellectual Property Office:

- Open and operational, but can expect some delays;
- Deadlines from March 16 to May 18, 2020 extended to **May 19, 2020**;
- Applies to Patent, Trademark, and Industrial Design deadlines;
- Further extension?

### Recommendations:

- Avoid taking advantage of extended deadline unless necessary;
- Beware: extension does NOT cover all timelines;
  - e.g. grace period, confidentiality period, appeal to Federal Court, divisional filing.
- Expedite examination procedures for critical matters.



## Deadlines and Extensions (Courts)

### Federal Court:

- Suspension Period currently extended to May 29, 2020;
- Does not apply to deadline for commencing an action where federal court does not have jurisdiction (e.g. limitation period for patent infringement action);
- Hearings scheduled before June 29, 2020 adjourned, and general sittings cancelled;
- Exceptions (amongst others): **Urgent or exceptional matters**;
- Increasing cases to be heard via teleconference.

### Federal Court of Appeal:

- Parties invited to file appeals and applications by prescribed deadlines;
- Suspension period extended to May 15, 2020.

### Recommendation:

- Don't delay and seek case-specific recommendations on timelines.



## Patented Medicines And Medical Devices

### Complex Regulatory Framework:

- Patented Medicine Notice of Compliance (PMNOC) and Data Protection Regulations apply to defer introduction of generic bioequivalents in Canada for 8 years.

### New and Inventive Use Patents Available:

- Example: Use of X in the manufacture of a medicament for the treatment of Y;
- Beware of referencing method of medical treatment or invoking professional skill or judgement in claim language;
- Not limited to compounds, extends to new and inventive use of any known technology.



## Compulsory Licence – Pre-Covid19

### Abuse of Rights Under Patents:

- Request for relief can be made three years after date of grant;
- ... if demand in Canada is not being met to an adequate extent and on reasonable terms;
- ... to grant a licence on such terms as the Commissioner may think expedient.

### Use of Patents for International Humanitarian Purposes:

- A compulsory licence under Canada's Access to Medicines Regime authorizes the manufacture and export of an eligible drug or medical device to an eligible country;
- Only invoked once in 2008 (procedurally demanding);
- Attempt to negotiate voluntary licence required before issuance of CL.



## Compulsory Licence – Pre-Covid19

### Use of Patents by Government:

- Commissioner may, on application by the Government (Federal/Provincial), authorize the use of a patented invention by that government;
- ... predominantly to supply the domestic market;
- ... if it has made unsuccessful efforts to obtain a licence from patentee (exception: in the case of a national emergency).

## Compulsory Licence - As of March 25, 2020

### Use of Patents by Gov't – Application by Minister of Health (S19.4):

- The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application;
- TIME-LIMITED:
  - No authorization to be made after September 30, 2020;
  - Cessation earlier of one year after authorization and when deemed no longer necessary by Minister.
- Government and any authorized person shall pay the patentee adequate remuneration given circumstances;
- Patentee can apply to Federal Court to order cessation of authorization.



## General Recommendations

### Applicant for Covid-19 innovation:

- Expedite prosecution in Canada – low cost, 1st action in < 3 months (preferably to seek Grant before September 30, 2020).

### Patentee for Covid-19 innovation:

- Proactively promote capability to meet local demand to avoid, or apply to Federal Court to cease, CL under new S19.4;
- Monitor local activity for possible infringement to immediately invoke S19.4CL:
  - Directly via Minister of Health;
  - Indirectly via possible infringer / infringement action.

### Product manufacturers, Importers, Exporters, etc.:

- Beware unspecified S19.4CL terms (cost?, duration?);
- Consider Canadian manufacture of generic drug for export to eligible country.

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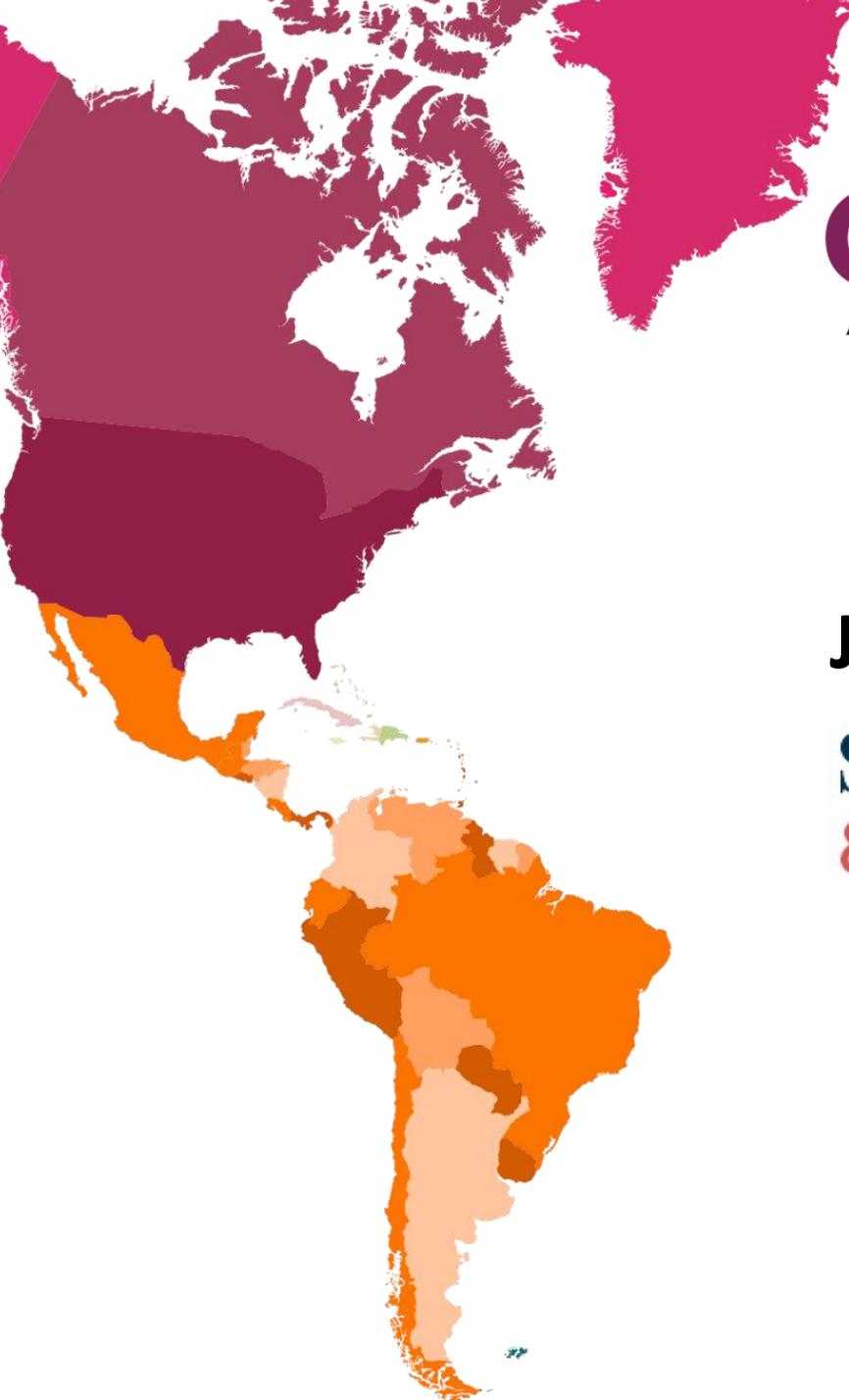
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## Traditional Strong Patent Pharmaceutical Protection

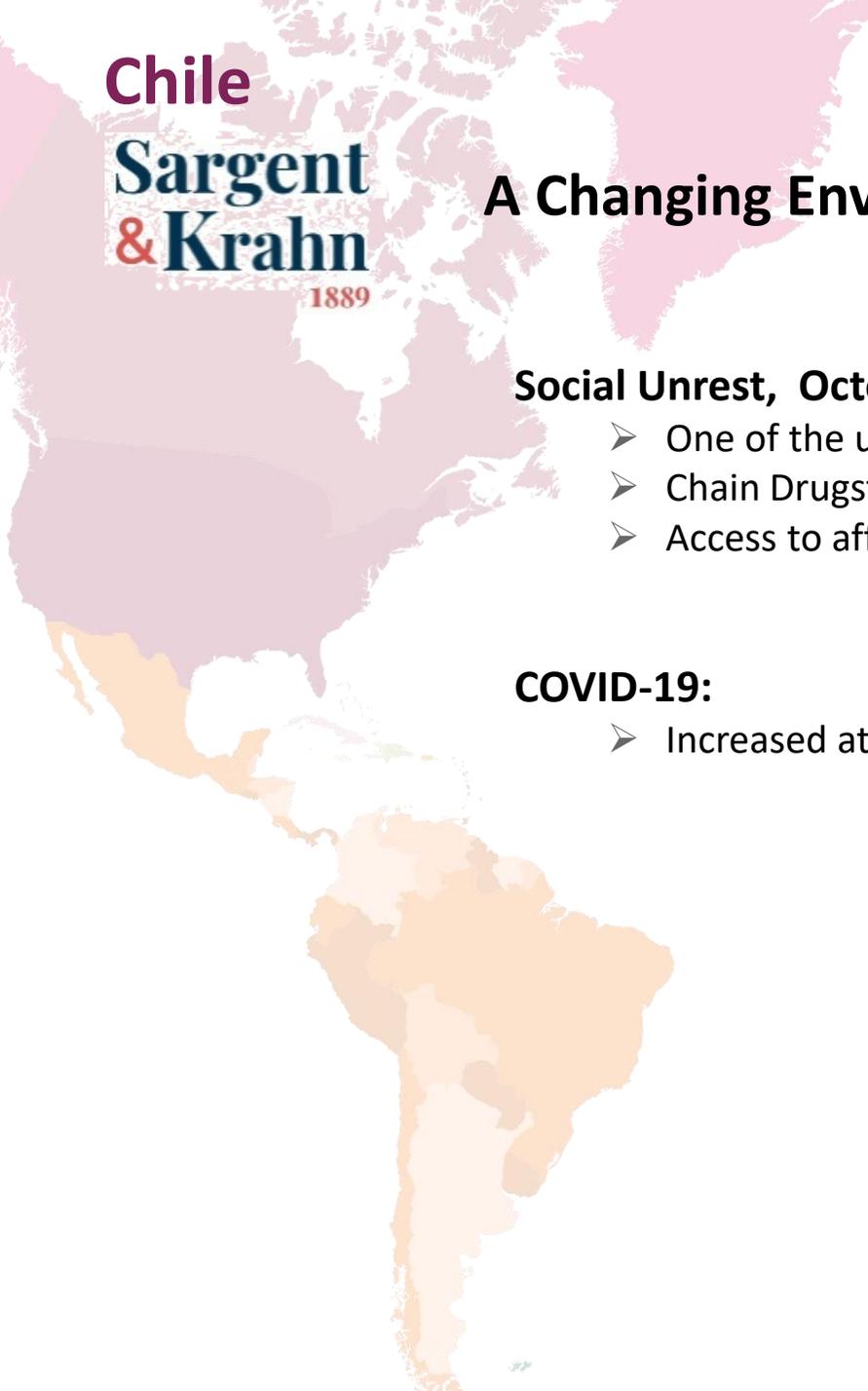
All kind of pharmaceutical inventions are patentable, with the exception of surgical and therapeutic methods of treatment to the human or animal body (**but patentable as second medical use inventions**).

**Civil and Criminal infringement actions available.**

**Exceptions to patent rights in line with international order:**

- So Yes:
  - Exhaustion;
  - Bolar;
  - Compulsory Licenses;
  - but, no local creativity.

**Compulsory License has never been granted.**



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## A Changing Environment

### **Social Unrest, October 2019:**

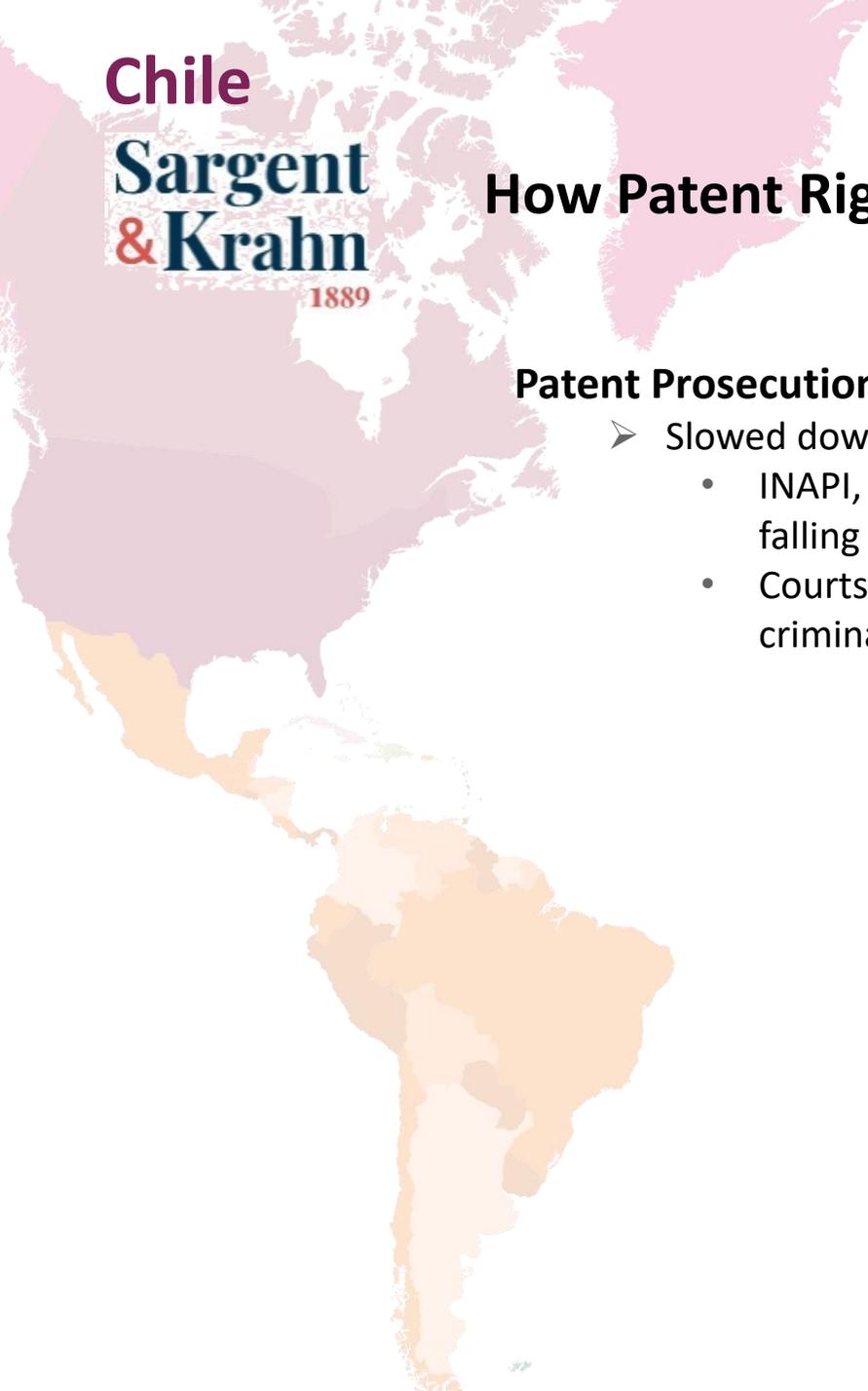
- One of the undisputed causes, corporations' abuses;
- Chain Drugstores colluding 2008 - 2012;
- Access to affordable medicines in the political agenda ever since.

### **COVID-19:**

- Increased attention on Pharma Industry.

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## How Patent Rights Can Be Affected?

### Patent Prosecution and Enforcement:

- Slowed down only:
  - INAPI, automatic half term extensions for deadlines falling May 1-15;
  - Courts, generally audiences not permitted but only for criminal and family cases.

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## How Patent Rights Can Be Affected?

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### Pharmacies II Law Project:

- If medicines in public health plans are judged inaccessible for economic reasons, this will automatically imply a “public health situation”, which will permit requesting a compulsory license. **No need a public health situation declared by the Health Authority to request a Compulsory License;**
- If the party requesting a compulsory license in a public health situation duly declared by the Authority, is a public entity it will be entitled to provisionally import, manufacture or distribute the patented product as of the date of the public health declaration. **No need to request , less so having obtained a compulsory license to begin exploitation of the patent.**

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## How Patent Rights Can Be Affected?

### Law Project to amend Patent Law:

- Senator's motions to include working requirement for patents;
- And other motions on Compulsory Licensing roughly in the same terms of Pharmacies II Law Project.

### Resolution Project 896 of the Chamber of Deputies:

- Approved March 17<sup>th</sup> ;
- COVID 19 and Compulsory Licensing .

**Nothing We Cannot Live With.**

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A stylized map of the Americas, showing North and South America. The map is color-coded: North America is in shades of purple and blue, Central America is in green, and South America is in shades of orange and red. The map is positioned on the left side of the slide.

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## COVID-19 Impact

### **Administrative proceedings:**

- PTO (Superintendence of Industry & Commerce):
  - Open via e-filings (some waivers on fees, e.g. annuity payments until further notice).

### **Judicial Branch:**

- PTO - Judicial Division:
  - open, infringement lawsuits via e-filings (cases filed before 17 March are suspended until 30 May. Priority on new cases filed after 17 March).
- PTO - Judicial Civil Circuit Judges (where you can also pursue infringement):
  - closed until 30 May.
- Council of State (all validity issues):
  - closed until 30 May (except for actions on constitutional control).

## Compulsory Licenses (CL)

### CLs governed by Andean Law: Decision 486

#### 4 grounds for CLs:

- non-working the patent;
- PUBLIC INTEREST; emergency; national security;
- abuse of dominant position;
- cross-license.

#### Procedure is regulated in Colombia:

- PUBLIC INTEREST (Art. 65) requires a Declaration:
  - DPI - Ministry of Health –MoH.
- Once a DPI is made:
  - bidding process starts at the PTO;
  - reasonable compensation is always required.

## Compulsory Licenses (CL)

### **Presidential Decree 476 (25 March 2020):**

- Provides extraordinary powers to the Ministry of Health;
- Issue DPis for Drugs and Medical Devices related to COVID-19;
- In theory, would facilitate CLs;
- Bidding process before the PTO not addressed.

### **However... under traditional regulation:**

- CLs require identifying specific patents; and
- a specialized committee within the Ministry of Health.

**Bottom line, it would be difficult to conclude that said decree alone would be enough for obtaining a CL.**

## Compulsory Licenses (CL)

	KALETRA	GLIVEC	Hep-C
Product under price control?	YES (price formula)	YES (international price referencing)	Many products
CL granted?	NO	NO	NO
DPI issued?	NO	YES, but NOT for CL purposes. Instead, to implement special price control, finding the cheapest Gx in the region and forcing Novartis to sell at that price.	Investigation started. Unidentified patents covering Hep-C products
Petitioners	Patient NGOs (alleged Indian Gx manufacturer support)	Same NGOs and actors.	Same NGOs and actors.
Type of Patent	Compound	Polymorph (alternative non-infringing options available on the market)	Many products
Evidence of lack of patient access to product?	NONE	NONE	NONE
Government attempted to negotiate new price using CL process as leverage?	YES	YES	N/A

## Colombia is part of the Andean Community

Same IP Law (Decision 486);

NO regional patent;

Differences in practice, interpretation  
and speed;

NO second use patents (Art. 22).



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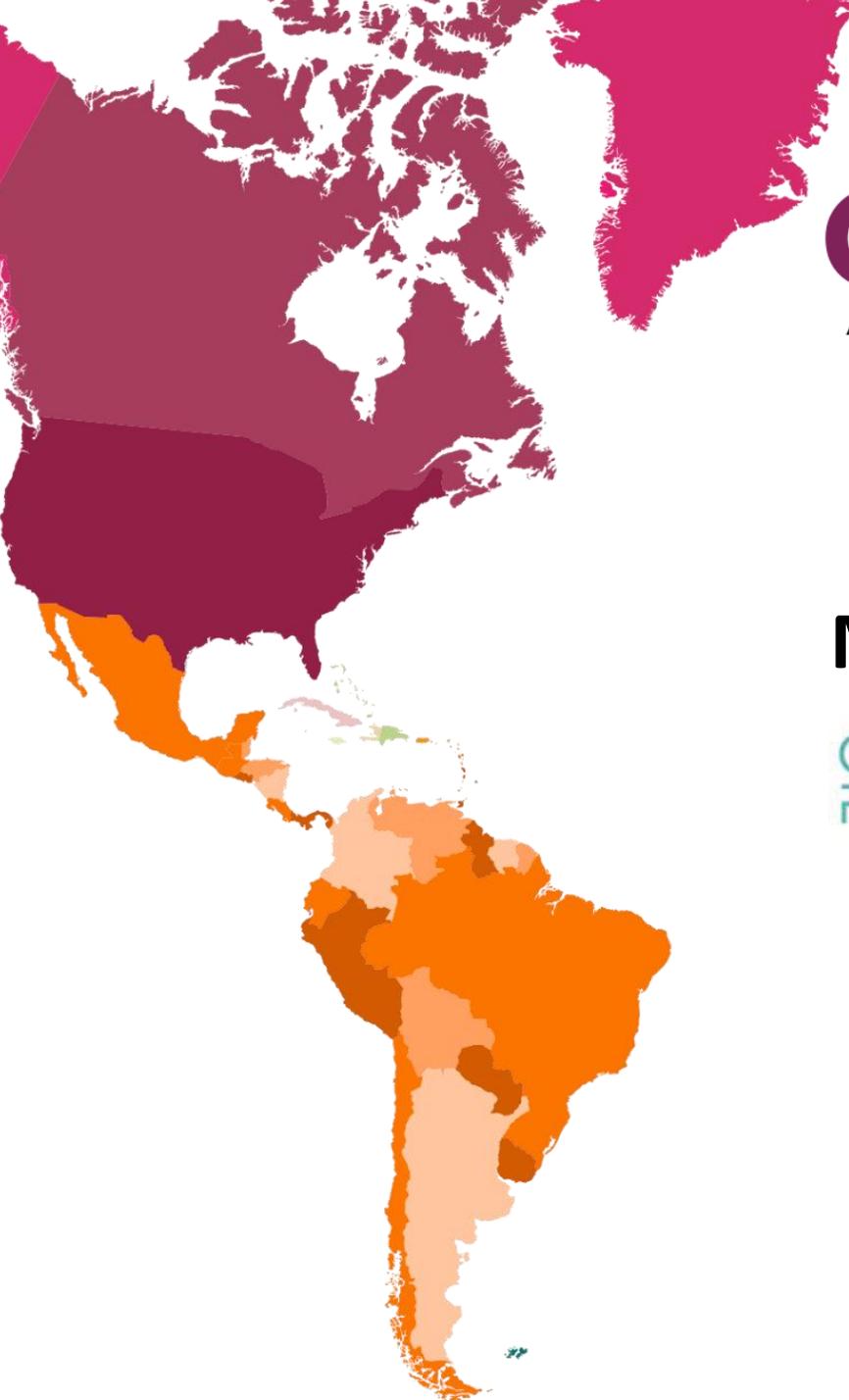
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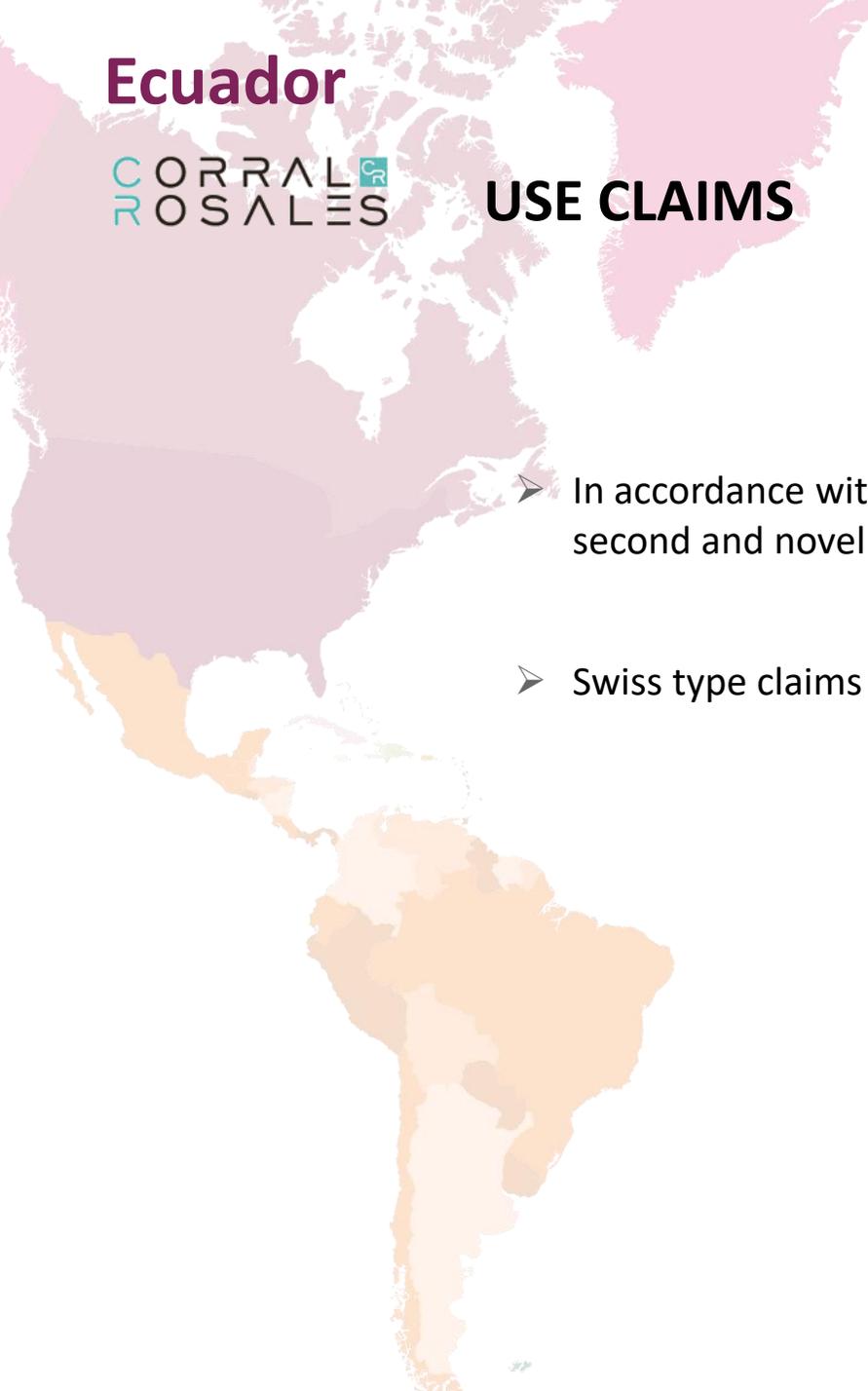
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### Infringements During Covid Mandatory Quarantine

- All terms suspended since March 16, 2020, when mandatory quarantine was declared;
- IP Office is working remotely accepting online applications but is not processing any case that, as a consequence, has deadlines or requires inspections. It is possible to submit claims which will not be processed;
- Second Instance and Supreme Court started to work remotely as of May 11th. Civil actions would not be possible at this time as first instance courts are not hearing these cases;
- There are no criminal actions for patent infringements. It is necessary to explore Regulatory/tax related Information to opt for a criminal action;
- Police conduct raids during the quarantine, mostly for COVID related infringements;
- Border measures are in practice not possible, and in any case they do not apply for patents.



Ecuador

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## USE CLAIMS

- In accordance with judgment 89-AI-2000 of the Andean Court of Justice, second and novel uses are not patentable;
- Swiss type claims are not allowed.

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## Compulsory Licenses – Patents - Supranational Law

### **Ecuador as member of the Andean Community applies the Communitarian Law - Decision 486- as a Supranational Law:**

- Art. 61 to 64 establish the conditions to grant compulsory licenses in observance to the Paris Agreement (Art 5) and the TRIPS (art 31);
- Art. 65.- CL at any time in case of public interest, emergency, national security and only for so long as those considerations exist;
- Art. 66.- CL as response to free competence;
- Art. 67.- CI for second or complementary patents;
- Art. 68.-General rules: non-exclusive and may not be sublicensed; non-assignable, could be revoked, limited scope and duration, adequate remuneration for the right holder, predominantly for the supply of the domestic market;
- Art 69.- CL not complying with conditions have no legal effects.

## Compulsory Licenses - Local Law

**The local law includes additional rules for CL which will be contrary to the Communitarian Law:**

- Art. 310, CL for lack of use is understood if there is no use in the Ecuadorian market;
- Art. 313, 3 years for the licensee to work the patent;
- Art. 315, Cl in case of anti trust practices including abuse in the dominant position;
- Art. 317. Cl of a patent in favor of a plant variety right holder and vice versa;
- Art. 318. Cl for lack of an agreement between patent right holders of inventions carried out in Universities and investigation centers.
- Art. 319. For internal markets and for export. Interesting to learn how export satisfies the conditions of D. 486.

## Compulsory Licenses - Background

**Ecuador declared of public interest all pharmaceuticals to treat sicknesses without any time limit**

- Decreto Ejecutivo 118 del 23 de octubre de 2009, Art. 1.

### DECRETA:

**Artículo 1.-** Declarar de interés público el acceso a las medicinas utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana y que sean prioritarias para la salud pública, para lo cual se podrá conceder licencias obligatorias sobre las patentes de los medicamentos de uso humano que sean necesarios para sus tratamientos. No se considerarán de prioridad para la salud pública las medicinas cosméticas, estéticas, de aseo y, en general, las que no sean para el tratamiento de enfermedades.

## Compulsory Licenses - Background

### Ecuador Issued Rulings For Granting Cl:

- Resolution No. 10-04 P-IEPI dated January 15, 2010;
- CL for non-commercial use (use through the public health system);
- CL for commercial use (in case no agreements are achieved in 45 days);
- The Public Health Minister must inform if the pharmaceutical is included in the basic chart of pharmaceuticals which contrasts with TRIPS Art 31 requests analysis on a case by case basis.

## Compulsory Licenses - Cases

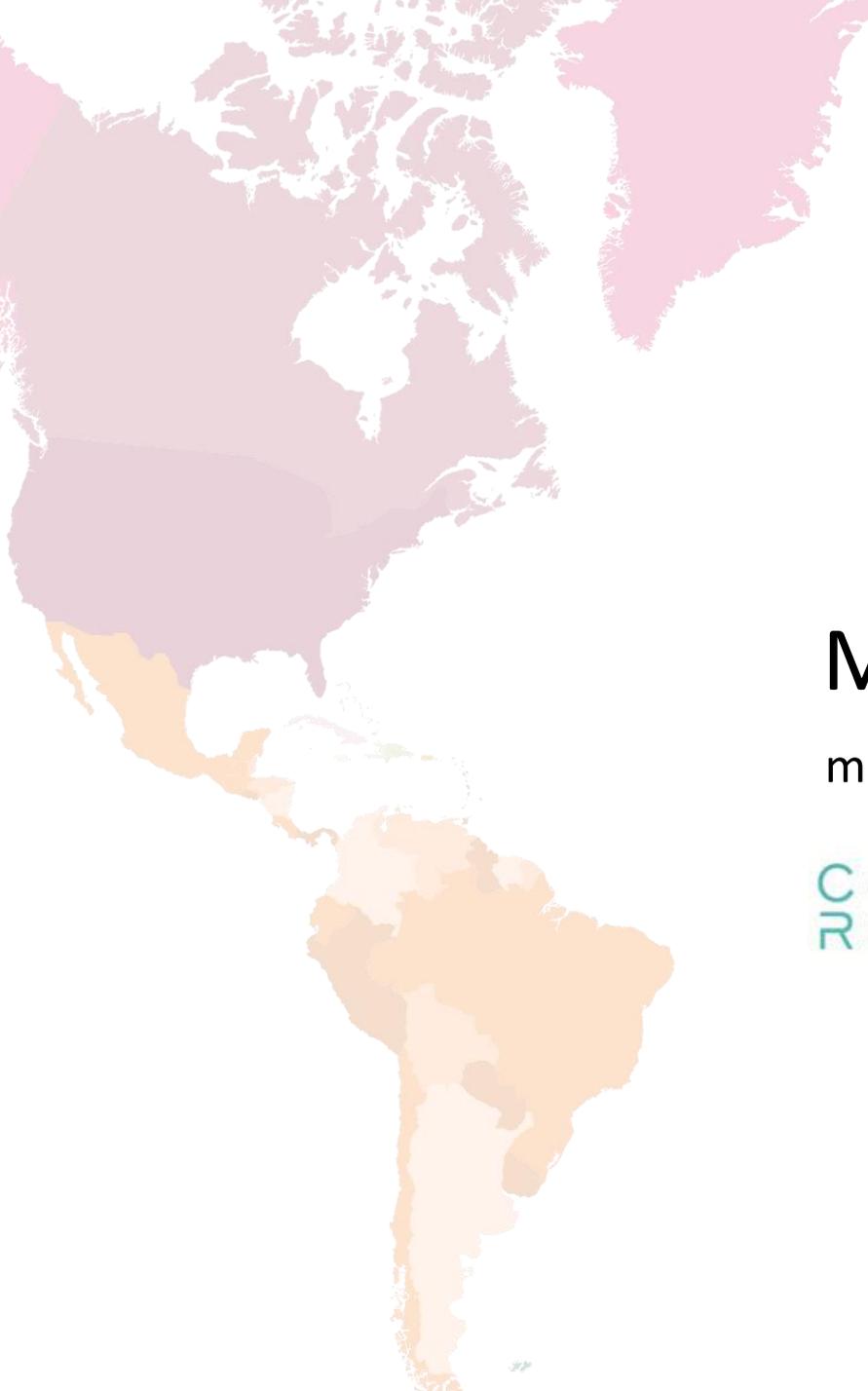
- Applied CL: 41;
- CL granted: 10, from which all lapsed. None were commercially successful in the local market;
- Rejected, withdrawn or abandoned: 31;
- Currently there are no pending CL.

## Compulsory Licenses - COVID-19

- Through Resolution dated March 20, 2019, Congress, requested that the Executive Branch includes compulsory patent licenses in the emergency declaration: access to testing data and access to other technologies for the availability of vaccines, drugs, diagnoses, devices, supplies, and other useful means for surveillance, prevention, detection, diagnosis and treatment of people infected by Coronavirus (COVID-19);
- This request was issued without analysis or information from the IP Office.

## Compulsory Licenses- COVID-19

- The IP Office responded on April 4;
- Congress should have requested technical information;
- Criteria for granting CL;
- Detail of the patents used internationally regarding COVID 19, which none are granted in Ecuador;
- General Information regarding compulsory data.



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**Alejandro Luna**



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## Mexican Patent and Trademark Office (IMPI) and Mexican Courts

**The Mexican Patent and Trademark Office (IMPI) suspended activities and no terms run from March 24 to May 31:**

- On line filing for new patent and trademark applications;
- “Electronic reception window” for other motions, under test.

**New decree May 11, 2020:**

- “Emergency physical window” has been requested;
- Terms will start running as from June 1st.

**New uses:**

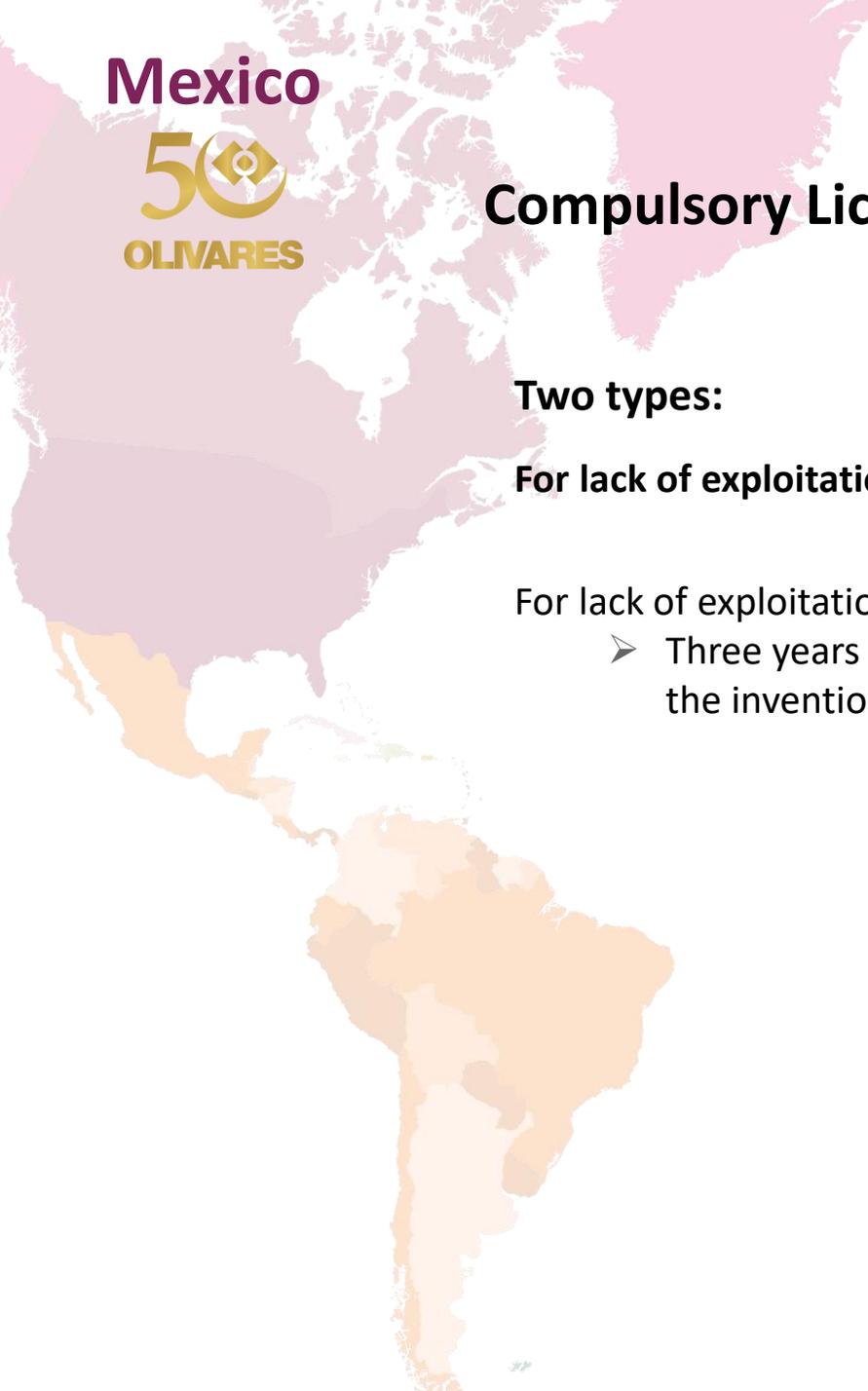
- Patents for new uses are granted by IMPI under the current practice;
- For purposes of patent linkage, we suggest the purpose-limited product patent claim.

## Enforcement of IP rights, appeal proceedings, criminal and administrative legal actions

- IMPI is always the first stage and the only venue to enforce and review validity of patents, designs and trademark registrations;
- During this period of suspension of activities, no contentious proceedings are available before IMPI, exception provided to release imposed preliminary injunctions and any proceedings related to face the pandemic;
- Criminal actions to pursue and sanction piracy and counterfeiting remain available before Federal and State Criminal Prosecutors.

## Enforcement of IP rights, appeal proceedings, criminal and administrative legal actions

- Federal and many Local Courts, including the one at Mexico City, and the Specialized IP Court, suspended activities and terms until June 1<sup>st</sup>;
- The Federal Courts maintain numerous guards along the country for causes of emergency, urgency and relevant cases, especially for the pandemic;
- The Mexican regulatory agency, COFEPRIS, is not open to the public but is active in all matters in connection to proceedings, inspections and authorizations related to COVID-19, there is a catalogue of applications, authorizations and proceedings which can be submitted during the sanitary contingency.



Mexico



## Compulsory Licenses

**Two types:**

**For lack of exploitation** and causes of emergency.

For lack of exploitation:

- Three years after granting of the patent or four years after applications if the invention is not used. One single precedent in 1962.

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## Compulsory Licenses

### Two types:

For lack of exploitation and **causes of emergency**.

For causes of emergency:

#### Proceeding:

- A declaration of a cause of emergency or national security, including the declaratory of a disease of priority attention by the General Health Counsel;
- The declaratory of a disease of priority attention can be requested by specialized national institutions qualified before the General Health Counsel;
- IMPI will determine the patents that would be exploited through compulsory licenses;
- All these acts of authority should be published in the “National Gazette”;
- After publication of a disease of priority attention, all parties can request a compulsory license of the published patents;
- IMPI has up to 90 days to decide whether or not grant the compulsory license.

## Causes and conditions

**The compulsory license will be granted if by not doing that, there would be shortage, overprice or undue control over the production of essential products or medicines:**

- Right to be heard;
- Quality, production and duration of the licenses by the Ministry of Health;
- Reasonable payment of royalties;
- Personal and non-exclusive.

### **Precedent 2009:**

- Influenza H1N1. Step 1 and 2 were fulfilled but the causes and conditions were never met.

### **Current situation COVID-19:**

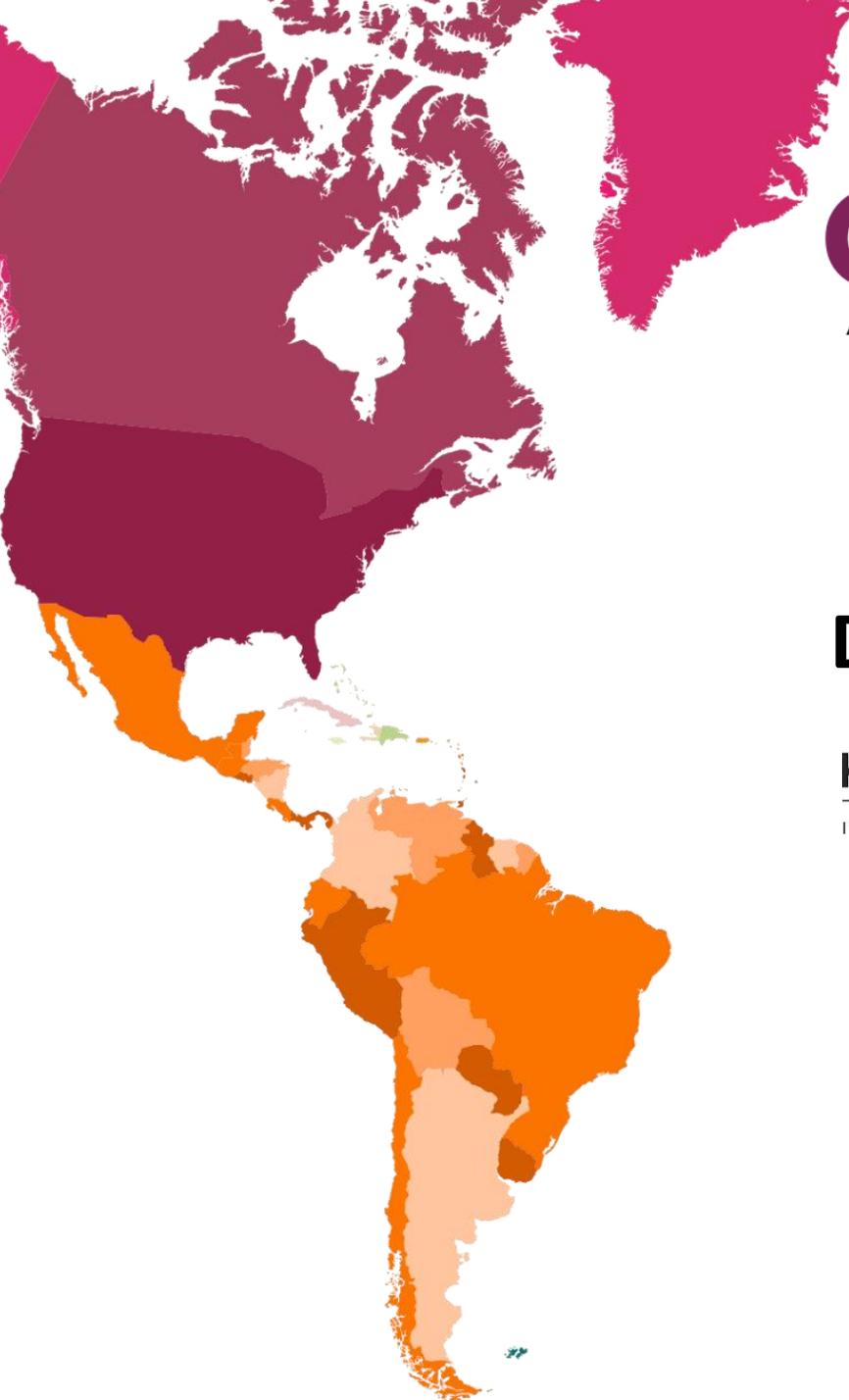
- Step 1 was exhausted with the declaratory of emergency;
- One Mexican Senator requested the Senate to encourage IMPI to detect the patents which could be subject of compulsory licenses.

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## State of USPTO and Courts

### **USPTO is open and functioning essentially normally:**

- Majority of Examiners normally work from home;
- Facilities still open to USPTO staff.

### **Federal Courts:**

- Lawsuits still being filed;
- Many hearings postponed—Other hearings conducted via videoconference;
- Each District has own rules in accordance with state and local requirements.

### **State Courts:**

- Each of the 50 states has its own rules.

## Infringement

**All strategies for making and responding to allegations of infringement remain:**

- Infringement suits can still be brought;
- Temporary Restraining Orders (TROs) and Preliminary Injunctions still possible.

**Delays should be expected:**

- Generally aids accused infringer;
- May require more aggressive action by rights-holder.

## Compulsory Licenses

### No compulsory patent license provisions

#### 28 U.S.C § 498(a):

- Grants U.S. government right to infringe any patent;
- Extends to contractors and subcontractors;
- Compensation to patent owner.

### March-In Rights:

- Government-funded inventions owned by recipient of funds;
- Government can “march in” to require license to third party:
  - Government’s own initiative or by request of third party;
  - Since 1980, fourteen requests made by third parties, none have been accepted.

## Second Medical Uses

### Medical method claims are patent-eligible:

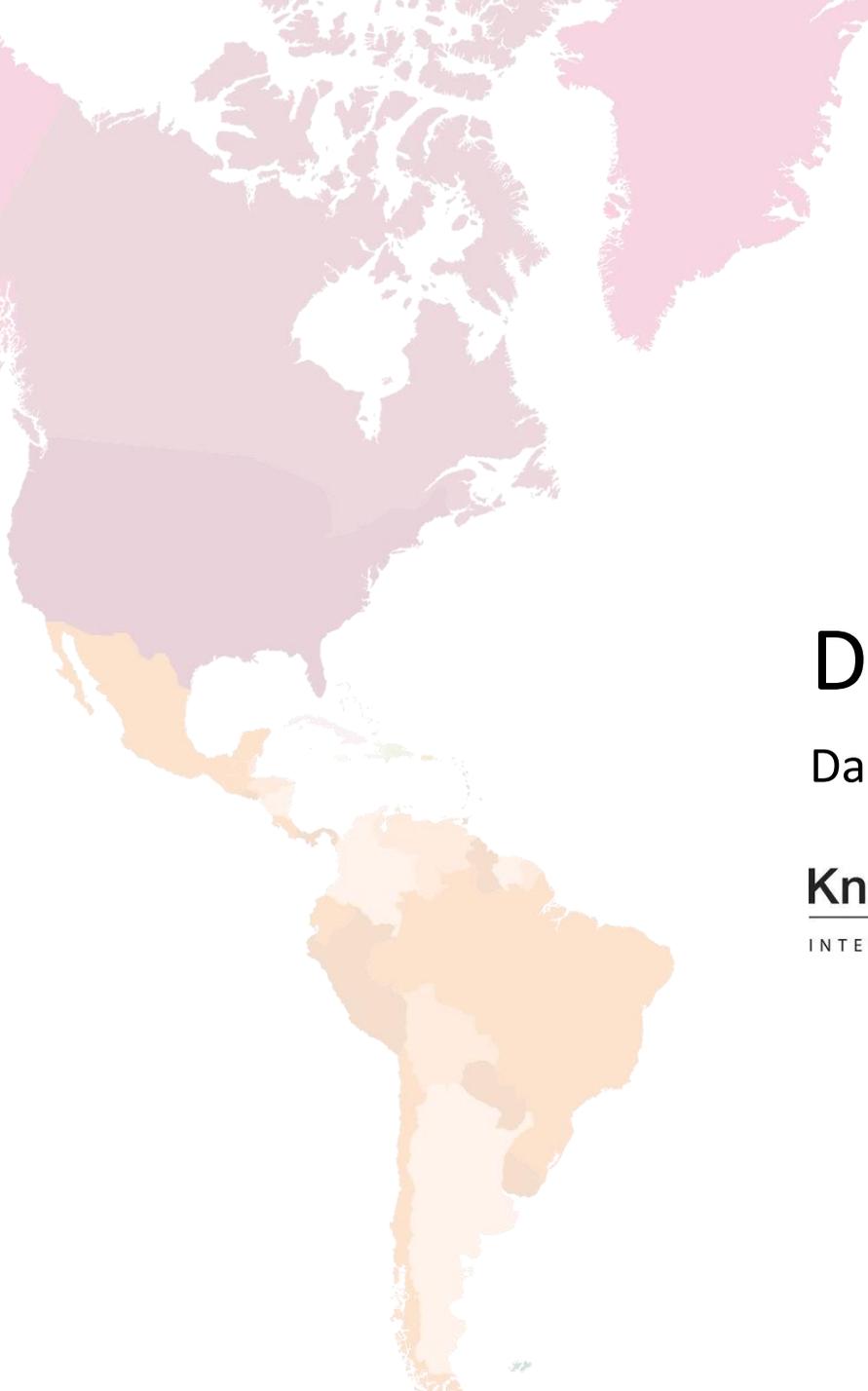
- Permits broad coverage of second medical uses;
- Not just new use of old substances, but also old devices.

### 35 USC § 287(c):

- Healthcare entities, including medical practitioners, cannot be sued for infringement of method claims for medical procedures;
- However, whoever “induced” the infringement can still be sued:
  - Pharmaceutical companies;
  - Device manufacturers.

# COVID – 19

An update about compulsory licenses for  
pharma products in the Americas



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INTELLECTUAL PROPERTY LAW



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**Agustina Fernández Giambruno**



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## Patent Office And Judicial System

### UYPTO:

- Normal operations.

### Judicial System:

- May 11th and June 1<sup>st</sup>;
- Sanitary Court Recess. Law 19.879;
- SCJ Resolution 66/2020 and TCA Resolutions 8/2020 and 8/2020;
- Status of criminal and civil actions.

## Compulsory Licenses

### Section 55 and 56 of the Patent Law 17.164:

#### ➤ Requisites:

- Health emergency or special situations that could affect general interest, economic or social development;
- Insufficient supply to meet needs of internal market;
- Scope and duration must be adapted to the end;
- 30-day notice;
- The process must guarantee the participation in equal conditions to all the interested parties in the exploitation, foreseeing conciliation and arbitration.

## Compulsory Licenses

### Section 55 and 56 of the Patent Law 17.164:

➤ Problems:

- Wording of Section 55;
- New wording of Section 99. Damages the use of patents pending registration;
- Consensual licenses foresee the license of patent applications.

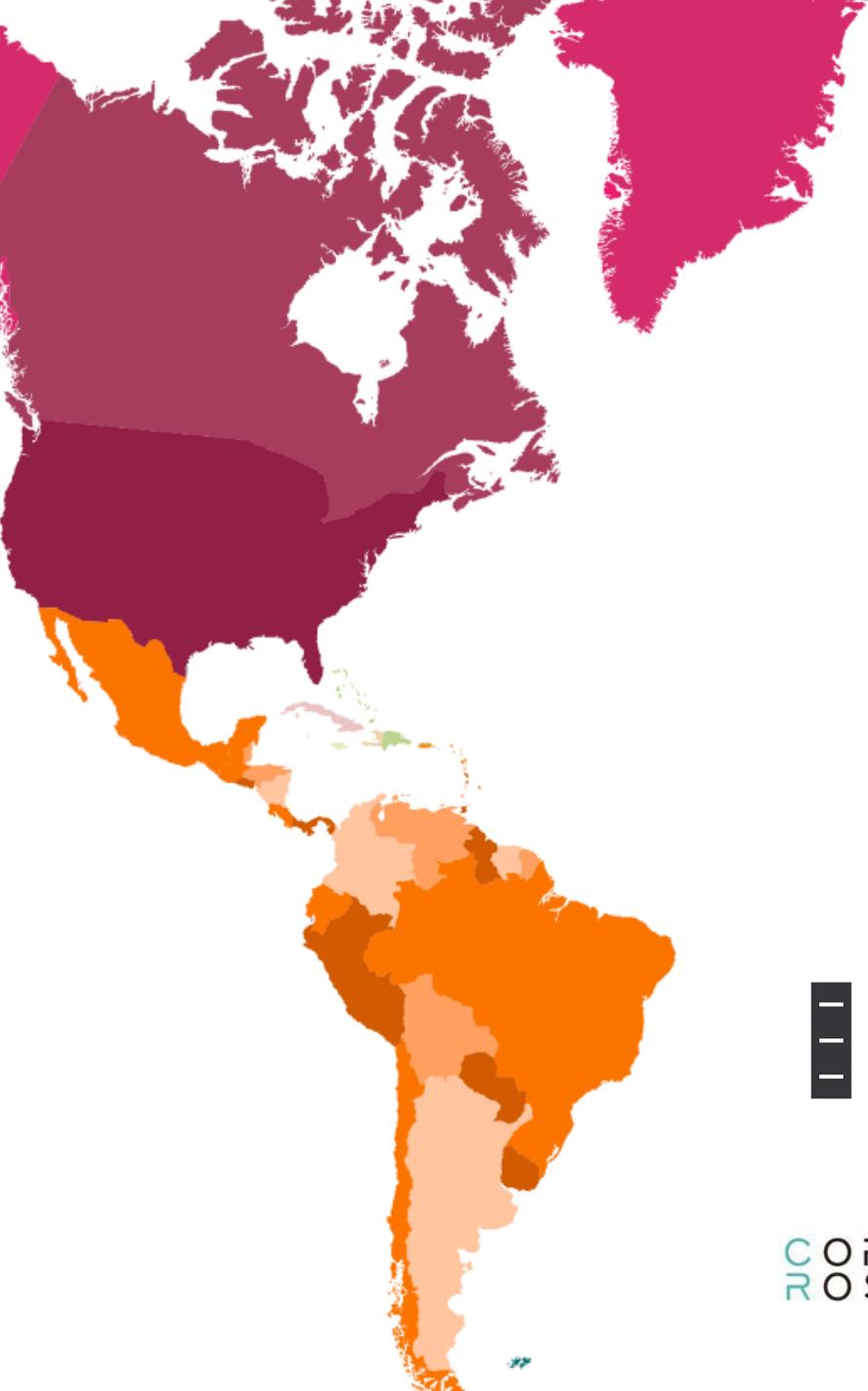
## Second Medical Uses

- Are typically not admitted to registration by the UYPO;
- Section 55 refers to compulsory licenses for “other uses”.

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