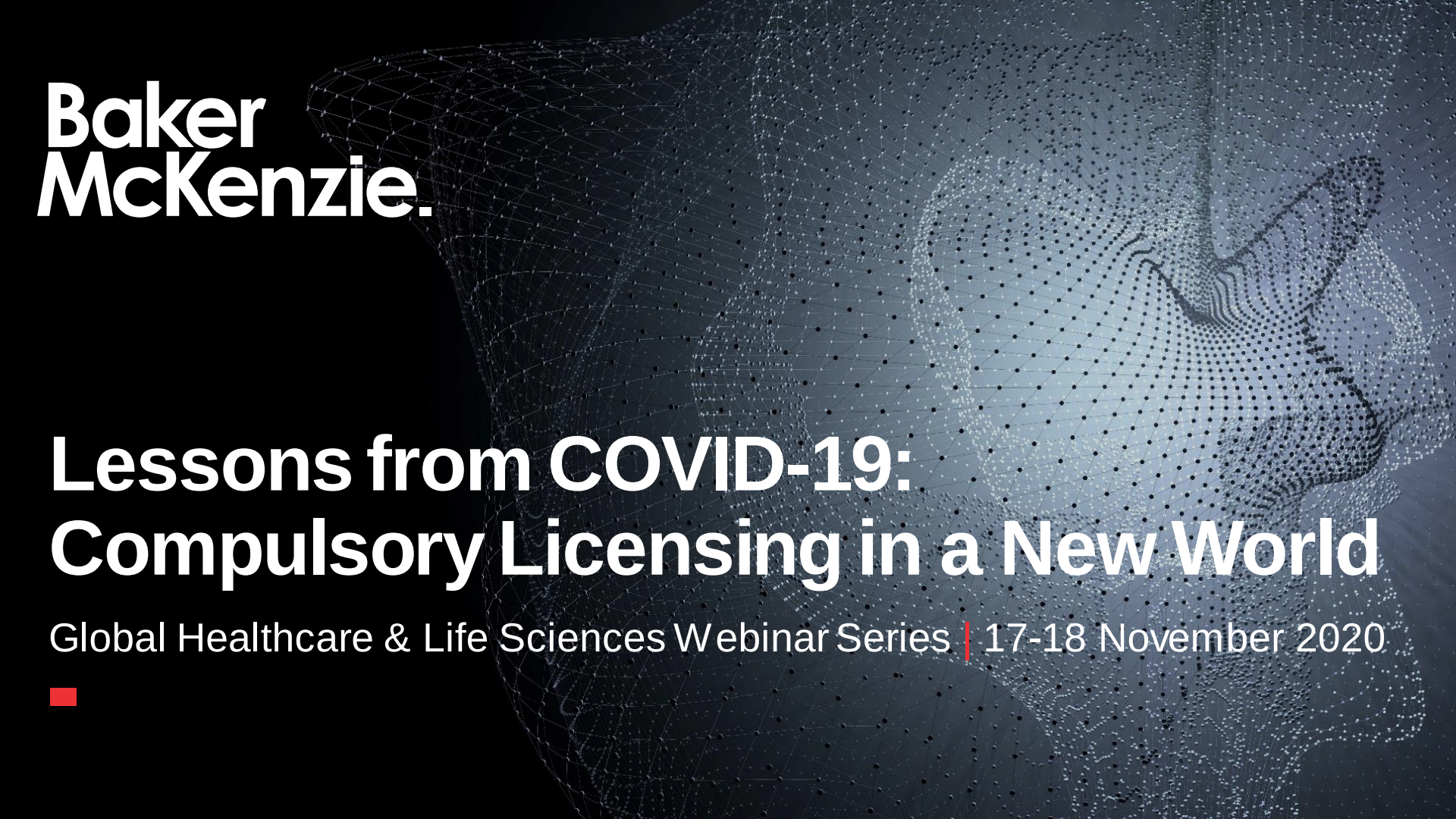

Lessons from COVID-19: Compulsory Licensing in a New World

Global Healthcare & Life Sciences Webinar Series | 17-18 November 2020

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To ask a question, please use the Q&A button at the bottom of your screen. We will address questions at the end of the presentations.

If we are not able to respond to all of your questions due to time constraints, we will reply by email after the webinar.

We will have four sets of poll questions throughout the session in compliance with CLE and CPD requirements.

Please respond to the poll within 20 seconds.

The instructions to obtain your CLE credit will be emailed to you after the webinar.

The New York CLE code will be read and flashed halfway through the session.


Introduction

Definition

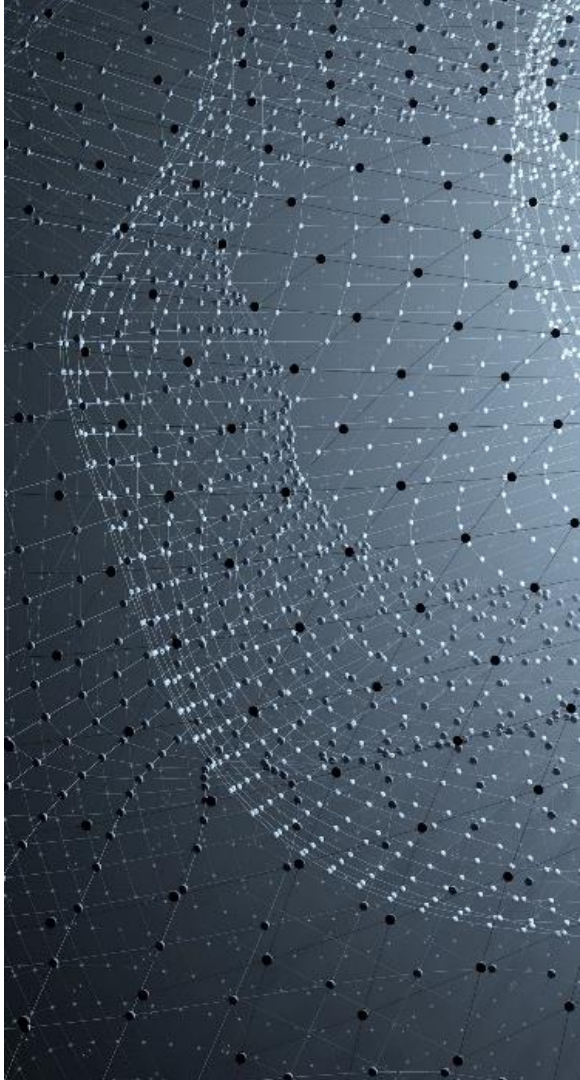
> Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.

World Trade Organization

TRIPS Exceptions (Article 31)

Non-discriminatory provisions in IP rights exceptions

- Individual merit to be considered in the authorization process
- Previously unsuccessful attempts to acquire voluntary license based on reasonable terms and duration
- Scope and duration limited to the purpose for which it was granted
- Provisions to be used primarily to ensure domestic supply or support another country who may be lacking production capacity
- Economic value to be considered in determining appropriate remuneration in the circumstance of each case



Agenda

1. INTRODUCTION
2. ASIA PACIFIC
3. LATIN AMERICA
4. EUROPE, MIDDLE EAST & AFRICA
5. NORTH AMERICA
6. Q&A
7. CONCLUSION


Asia Pacific

Compulsory Licensing in Asia Pacific

- Countries in the Asia Pacific region have established compulsory licensing regimes which are relatively harmonious (TRIPS compliant), but largely untested
- **Hong Kong, Singapore:** particular focus upon importation
- Data protection and regulatory regimes unaffected by compulsory license framework
- Focus so far on government-negotiated access (and funding) for COVID-19 vaccine candidates

Asia Pacific

History of compulsory licences and next steps

Thailand

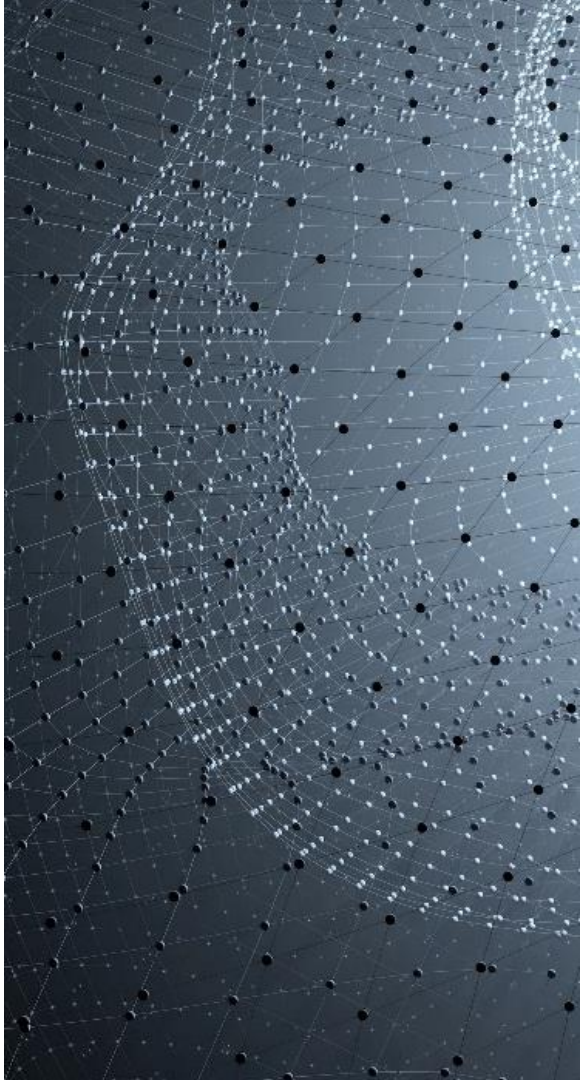
- 2017 CL for LOPINAVIR / RITONAVIR (HIV) also studied for COVID-19
- Amendments currently under consideration: Cabinet approval and exports

Indonesia

- HIV and Hepatitis B drugs compulsory licenses in 2012

Taiwan

- 2005 compulsory licenses for Tamiflu (subject to exhaustion of patentee stocks)
- COVID-19: Government has taken active steps to prepare for manufacture of REMDESIVIR by two national institutes



Key points – Asia Pacific

Latin America

Compulsory Licensing in Latin America

Overview

- Most countries are members of TRIPs, but local laws provide specific rules on legal requirements, procedure and remuneration
- Already threatened a few times (Brazil and Colombia) and granted once (Brazil)
- Increased risk in the COVID-19 context. Most countries have enacted new regulations, laws and/or bills of laws
- What happens in one LA country often impacts others in the region

Compulsory Licensing in Latin America

Legal requirements and compensation

Most countries allow a compulsory license based on:

- lack of exploitation
- anticompetitive actions
- public interest/national emergency (Government use only)

All require reasonable compensation be paid to patent owner

May not be granted if patentee:

- satisfies the demand (with no abuse/anticompetitive behavior) – price considerations highly important
- justifies non-use for legitimate reasons (force majeure or legal obstacle, for instance)
- Proves that serious and effective preparations for exploitation have been carried out

Compulsory Licensing in Latin America

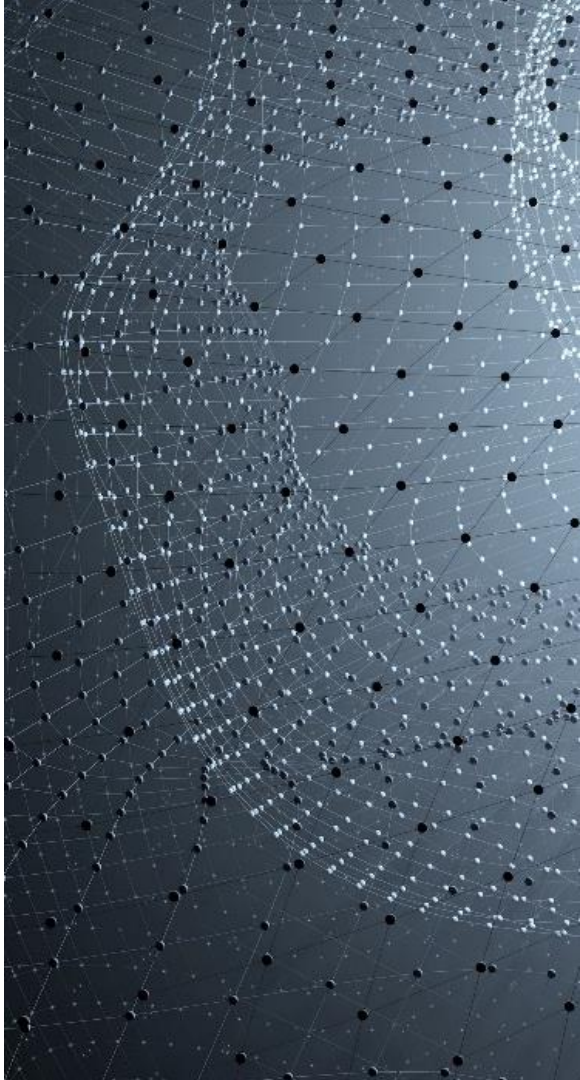
License to unpatented technology and access to confidential information

Laws specifically refer to patent compulsory licenses but…

- Patentee may need to give access to all necessary information for Government to manufacturer (or have manufactured by third party) (Master cell bank included?)

What about new COVID-19 patent applications?

- Some countries have new regulations allowing for expedited examination (Brazil) and Congress pressing for the compulsory license of pending patent applications (Brazil)



Compulsory Licensing in Latin America

Actual cases

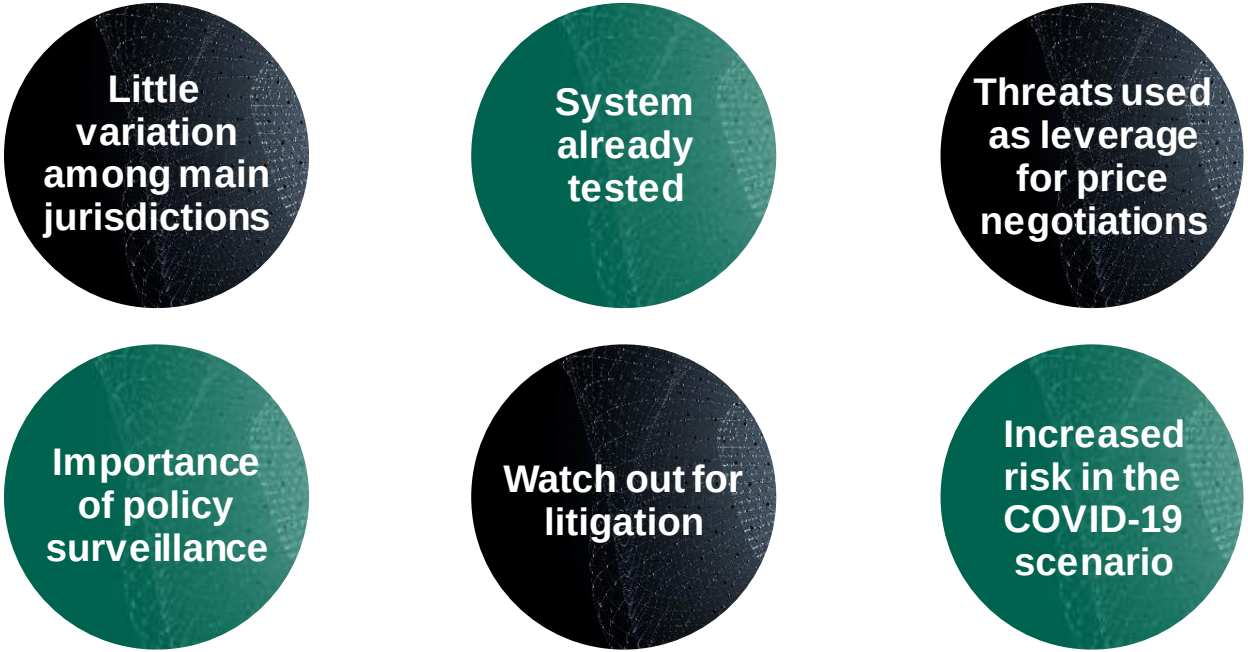
Brazil: one compulsory license granted and a few pending related lawsuits

- Efavirenz by MSD : CL granted based on public interest, MoH had to pay a royalty of 1.5%
- Kaletra by Abbott: Lawsuit pending to force Government to grant CL and technology transfer to allow local manufacturing "if specification is insufficient to be replicated".
- Trastuzumab by Roche: Lawsuit pending to order the BPTO to grant the CL based on abuse/high prices.

Colombia: compulsory license threatened

- Glivec by Novartis: price considerations as grounds for the request

Key points – Latin America



Europe, Middle East and Africa

EMEA overview

Patent position

- All EEA members of WTO but exceptions in MEA
- Patent laws not harmonised under EU or EPC, leading to variations in approach to CL
- Compulsory licenses rarely decided on; procedural hurdles cause delay
- State use / emergency / public health provisions most likely to be relevant for COVID-19
- Some jurisdictions have passed specific legislation
- 23 March: Israel issued first product specific license on lopinavir/ ritonavir (AbbVie's Kaletra)
- All require reasonable compensation to be paid to patent owner

EMEA Overview

EU Regulatory data position

- EU Regulatory data protection (8+2+1) is largely "bullet proof", meaning that (within the EU), compulsory patent licenses may be redundant
  - Even if a follow-on COVID treatment could be made, it could not rely on originator regulatory data for its MA
- But EMA is encouraging transparency for COVID trials
- Exception for manufacturing for export to LDCs [Reg 816/2006]*.
  - Result: EU manufacturers of Gx COVID treatments for supplying LDCs (but not EU).

The Commission recognizes that a balanced approach is needed in the search for effective treatments and vaccines for patients suffering from COVID-19, ensuring not only innovation, but also a sufficient, rapid and affordable supply.

The Global Intellectual Property (IP) framework includes flexibilities, such as compulsory licensing, that may be used in public emergency situations, e.g. in the event of insufficient supply of IP-protected medicines.

Except for the specific situation covered by Regulation 816/2006, the rules on compulsory licensing are not harmonised or unified at EU level, and do not waive the data and market protection periods set in EU pharmaceutical law.

The Commission is investing substantial efforts to accelerate the development, manufacturing and deployment of vaccines as highlighted in the EU Strategy for COVID-19 vaccines. In this context, the Commission supports voluntary pooling and licensing of intellectual property related to COVID-19 therapeutics and vaccines, in line with the recent resolution of the World Health Assembly, to promote equitable global access as well as a fair return on investments.

*Written answer dated 29 September 2020 to EU Parliamentary question E-003626/2020

EMEA Overview

EU Access to data / materials

- Access to regulatory data by third parties permitted under FOI principles (Regulation (EC) No 1049/200)
- Subject to proving CCI (*Case C-175/18 P 22 January 2020 PTC Therapeutics International Ltd*)
- No mechanism for access to materials

UK

- Compulsory license regime inadequate for COVID – 3-year grace period after grant
- Crown use – generally (s55) or in emergency (s59) is interpreted broadly (*IPCOM v Vodafone*)
  - Offers flexibility in approach by the government
- Early signs during the pandemic suggested a collaborative approach and hinted at possible government indemnity for IP infringement (for ventilators)

France

Compulsory license (Art. L. 613-16 et seq. IP Code)

- Insufficient quantity, abnormally high prices, exploited contrary to public health or anticompetitive
- Exercised by ministerial discretion (so potentially very quick)

Law of 23 March 2020

- Art. L. 3131-15 allows requisitioning of all goods and services; temporarily control prices; to take any measures necessary to make relevant medicines available to patients
  - Exercised for requisition of face masks, tax-free import of remdesivir, hydroxychloroquine, export ban of promising medicines

Italy

Compulsory license hampered by grace period (4 years from app, 3 years from grant)

General expropriation (*Articles 141-143 IP Code*) available for "public health" predominantly satisfying the need of the country, requested by the Ministry in consultation with IPO, authorized by a Presidential Decree.

Decree no. 18 of 17 March 2020 enacted into Law 24 April 2020, n. 27 – Article 6) Procedure

- Allows requisition of IP rights but does not involve IPO
- Extends until expiry of civil emergency
- Executed by the Head of Civil Defence or the COVID-19 Commissioner
- Fair remuneration based on market value

Germany

Compulsory license under section 24 of the German Patent Act requires unsuccessful attempt to license and public interest - Merck v Shionogi 2017 (HIV raltegravir)

- But delays and procedure prevail - Sanofi v Amgen 2018 (hypercholesterolaemia alirocumab)

COVID law (*Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite*) 27 March 2020

- Amends section 5 of the German Infection Protection Act and permits limitations of patents under section 13 of the German Patent Act

Key points – EMEA

North America

Compulsory Licensing in North America

Overview – US

Approaches and compensation:

- *Bayh-Doyle Act* (35 USC 203) –
  - Covers government-funded inventions ("march-in rights")
  - Silent on compensation and provides that the US Government may "march-in" "upon terms that are reasonable under the circumstances" (s. 203(a))
- 28 USC 1498
  - Covers non-government funded inventions
  - Provides for "reasonable and entire compensation" to patent owner (s. 1498)
- Use of patent by infringer
  - Lack of injunction can permit the infringer to continue to use an invention provided it pays an ongoing royalty through to the expiry of the patent

Compulsory Licensing in North America

Overview – US

Access to confidential information as part of a compulsory license

- Bayh-Doyle Act protects confidentiality of any document filed as part of any patent application (USPTO or foreign patent office)
- 28 USC 1498 is silent on confidentiality
- For pharmaceutical/device products, FDA regulatory confidentiality protections apply, including data exclusivity rights that are specific to pharmaceutical products

Compulsory Licensing in North America

Overview – US

What is unusual and especially interesting?

- Neither regime has been used in the health product context although various requests have been made
- 28 USC 1498 more likely to be used to ensure access to treatments, diagnostics, vaccines, etc. for COVID-19 because of its broader reach
- Products must obtain regulatory approvals. Expedited pathways have been adopted by both US and Canada Regulatory Authorities due to COVID-19.

Compulsory Licensing in North America

Overview – Canada

Approaches and compensation:

- National emergency or urgency
  - Domestic emergency – recently amended in response to COVID-19
  - Foreign emergency
  - Patent Commissioner will fix "adequate" remuneration taking into account the economic value of the license
  - If medicine is exported for foreign humanitarian use, royalties will be paid in accordance with complex formula
- Abuse of patent rights
  - Requirements include being in public interest as domestic (Canadian) market would be prejudiced if license not granted

Compulsory Licensing in North America

Overview – Canada

Does the system allow access to confidential information as part of a compulsory license?

- Confidentiality is not specifically provided under either regime.
- For pharmaceutical/device products, regulatory confidentiality protections apply, including data exclusivity rights that are specific to pharmaceutical products

Compulsory Licensing in North America

Overview – Canada

What is unusual and especially interesting?

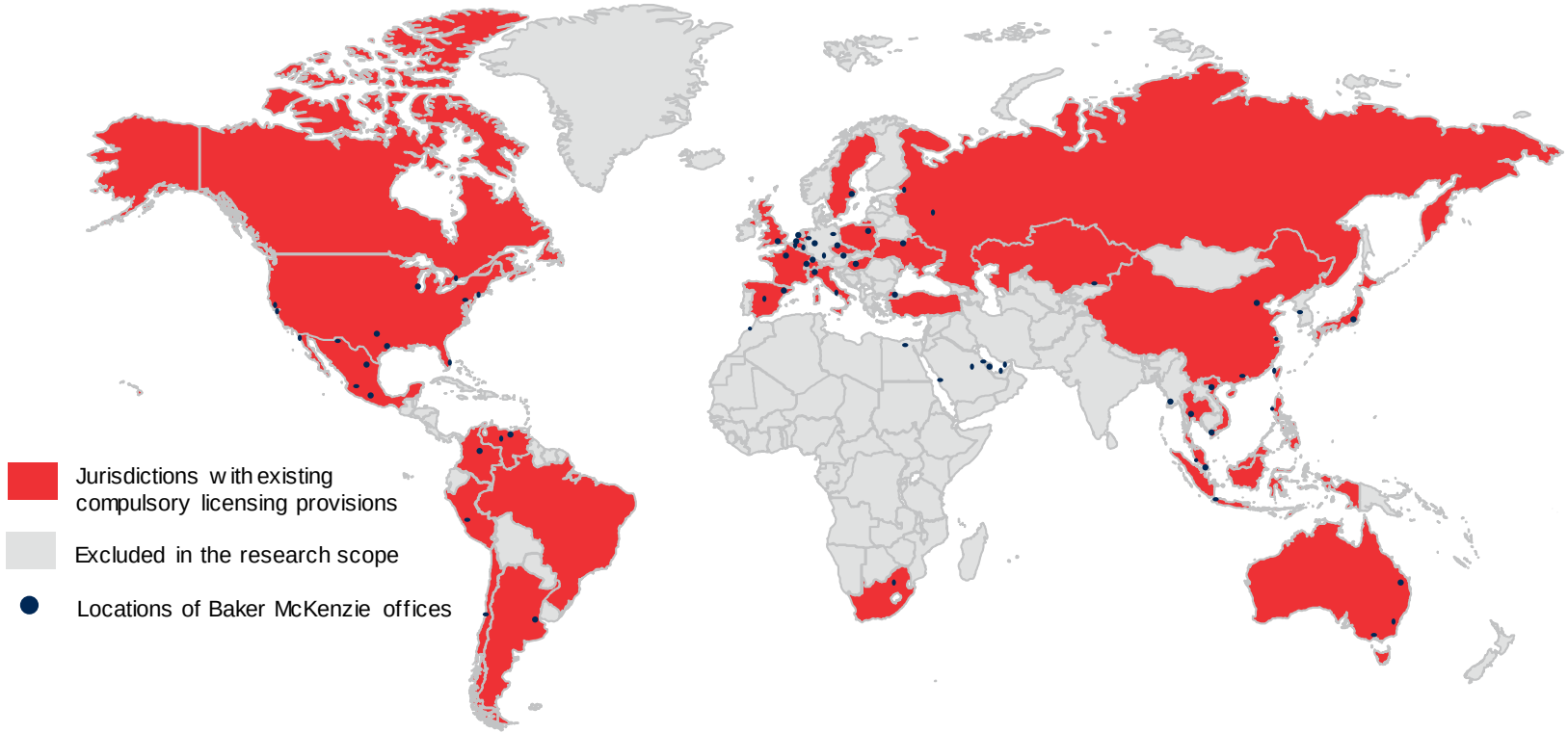
- While Canada's regime directed to drug exportation for humanitarian need was widely heralded as the first of its kind adopted by any country, its use has been described as cumbersome and inefficient and has only been utilized once to export two shipments of HIV anti-retroviral to Rwanda in 2007
- The COVID-19 amendment (Patent Act, s. 19.4) provides, where a national public health emergency has been declared by the Minister of Health, the Patent Commissioner must grant the compulsory license to make, construct, use or sell a patented invention, upon the application of any person
  - Expired on September 30 with no uptake

Key points – North America

Questions

Conclusion

Mapping jurisdictions with existing compulsory licensing provisions



Political development at the WTO

Proposal to waive TRIPS obligations for COVID-related products/services

India and South Africa tabled a motion at the 14/15 October 2020 TRIPS council meeting:

- "The obligations of Members to implement or apply Sections 1, 4, 5 [patents] and 7 [undisclosed data] of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council."
- Opposed by the EU, US, Switzerland, Norway, Canada, Japan, Australia, Brazil and the UK
- Still pending

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