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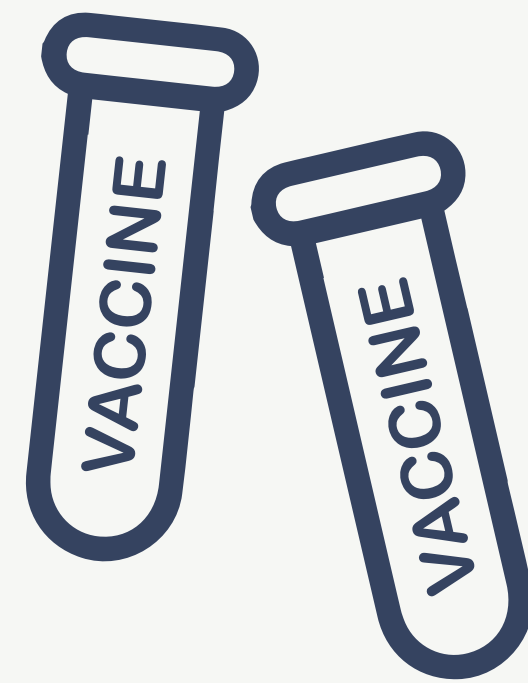
**FROM COOPERATION TO UNILATERALISM:
COMPULSORY LICENSING AND COMPETITION LAW AMIDST
COVID-19 PANDEMIC**

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From Cooperation to Unilateralism: Compulsory Licensing and Competition Law Amidst COVID-19 Pandemic

Alexey Ivanov, BRICS Competition Law and Policy Center

Fighting the Flu Together: the Open Science of GISRS



- Starting from 1968 influenza pandemics were successfully contained thanks to the WHO-established Global Influenza Surveillance and Response System (GISRS)
- Data sharing and data pooling among the research institutions from 122 countries became “vital to global pandemic preparedness”
- Flu vaccine development is centralized and standardized thanks to the GISRS network
- **GISRS network relies on open science principles and has almost no recourse to IPR**

COVID-19 and the Move to Unilateralism



\$24 billion



Additional

115 million

of expected profits for
Pfizer and BioNTech in
2021

people in poverty in
2020

Source: CBC, The World Bank (2020)

Flaws of the Current System



Vaccines developed and stockpiled by the richest countries. Data sharing and data pooling proposals failed. Opacity of data makes approval processes slow

1

Vaccine Race and Lack of Int'l Cooperation

Developed countries refused to support South Africa and India in their proposal to suspend IPRs for COVID-19 vaccines and treatment at the WTO

2

IPRs became a significant obstacle for development

Competition has failed on the global level as there is no system for surveillance of compliance with the fair competition rules on the global pharma market

3

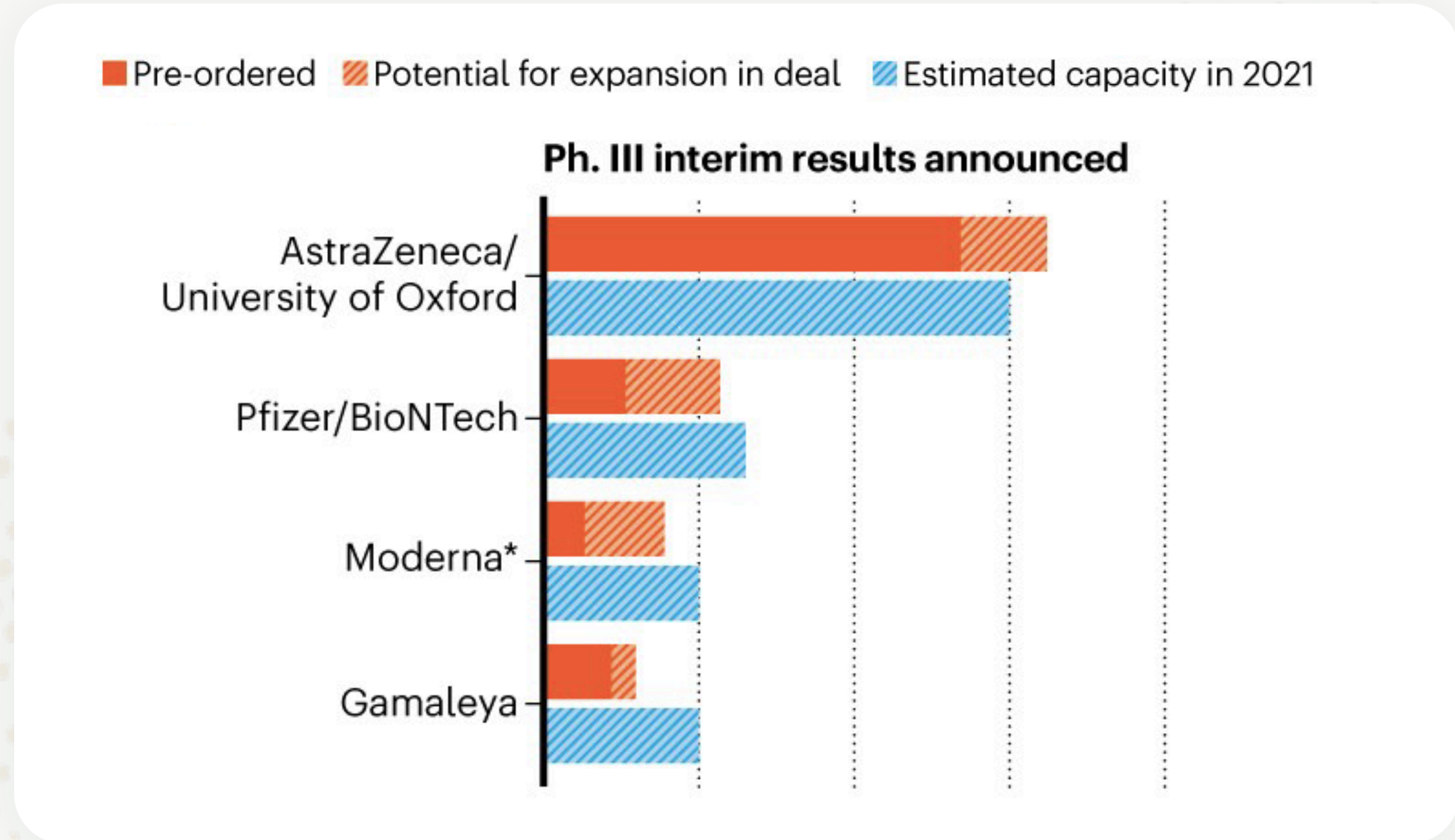
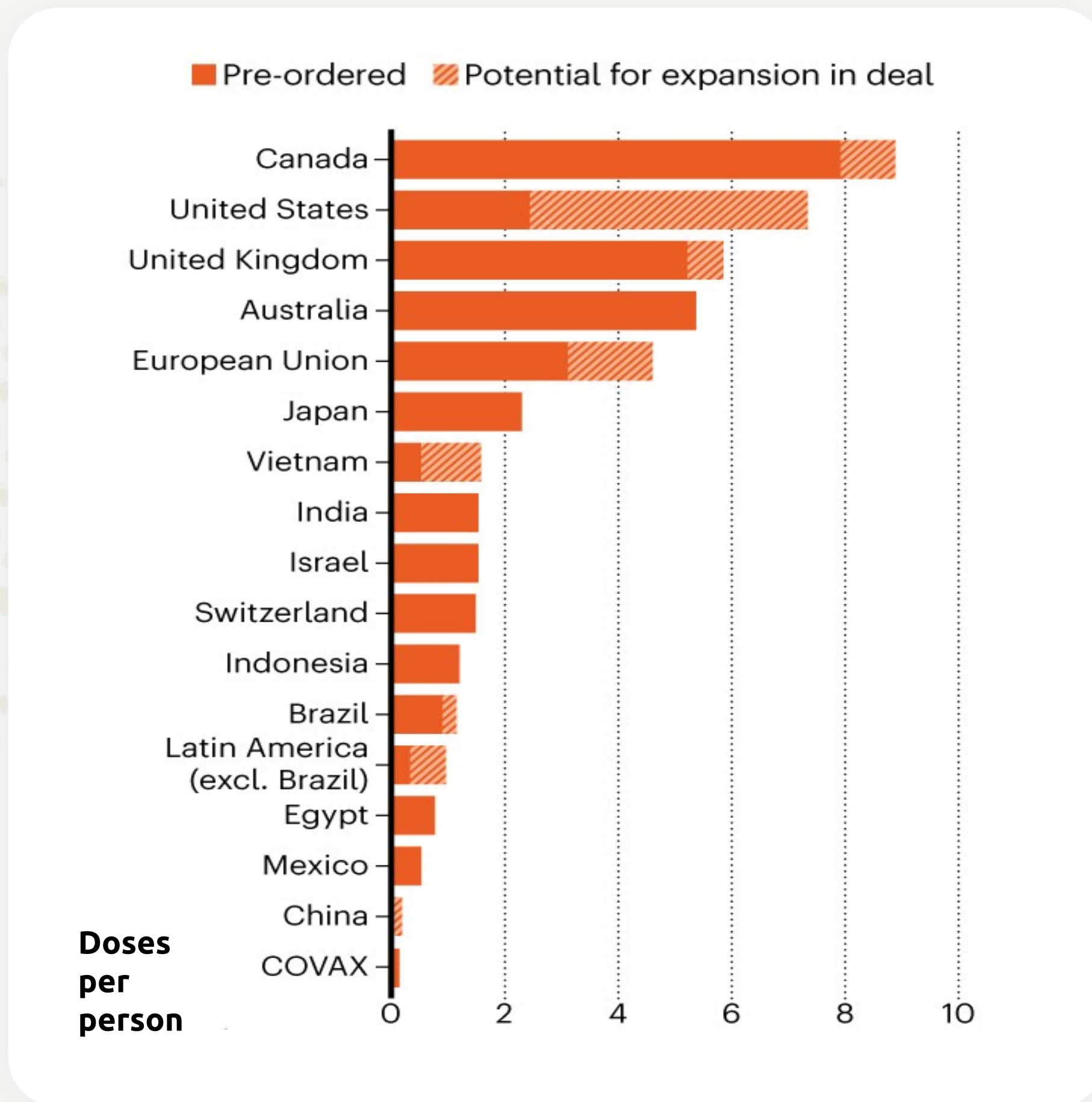
Competition rules only respected nationally

COVID-19 and the Move to Unilateralism



Best and worst supplied

Canada has pre-ordered almost 9 doses of COVID-19 vaccines per person



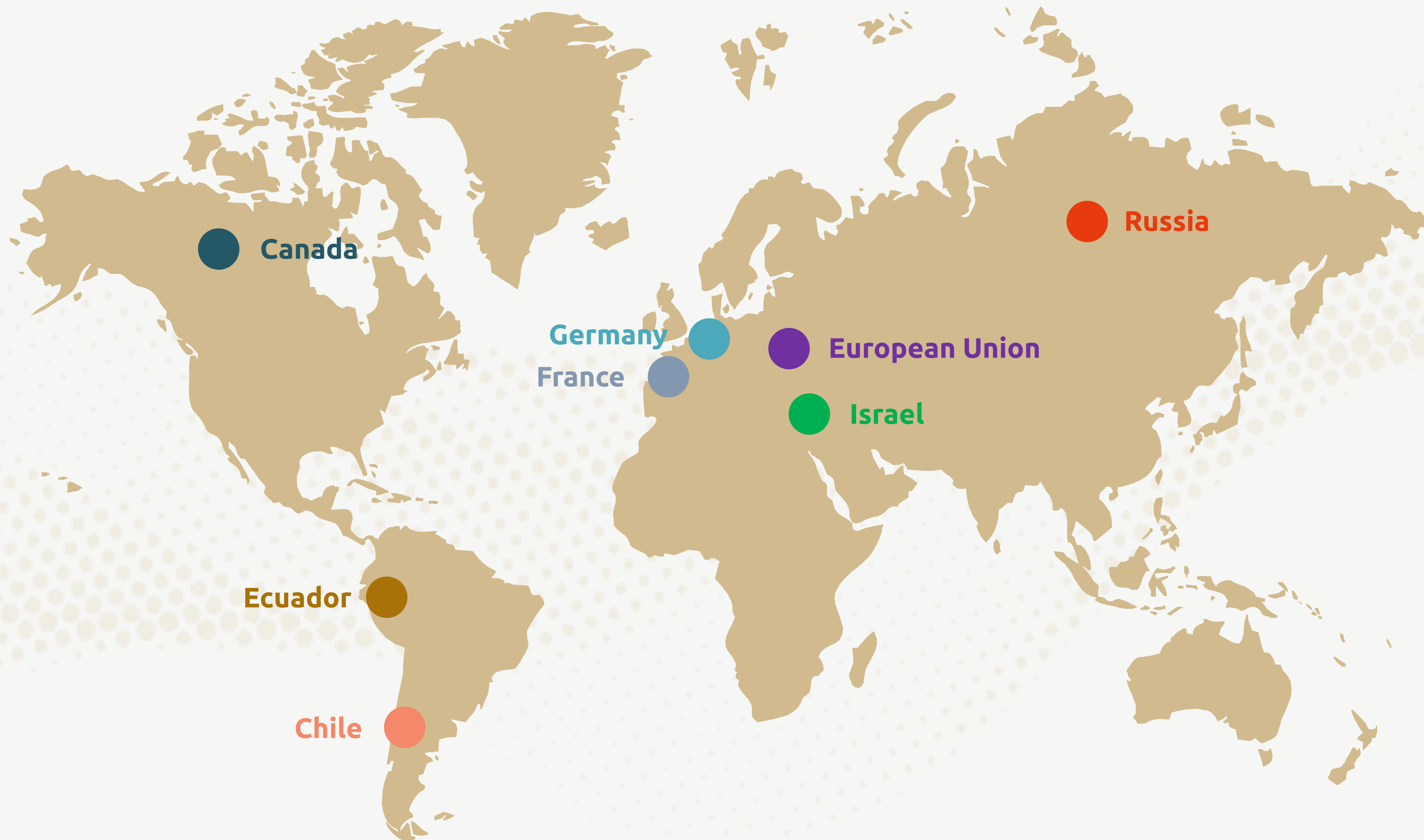
Through ***bilateral*** advance-purchase agreements, developed countries have ordered enormous amounts of vaccine leaving many other countries underserved.

Source: Nature



As a response to COVID-19 emergency,
**countries turned to compulsory
licensing** as an ordinary TRIPS-compliant
tool to address healthcare shortages

COVID-19 Refresh for Compulsory Licensing



COVID-19 Refresh for Compulsory Licensing



COVID-19 Emergency Response Act

Enacted 25 March 2020

Expired 30 September 2020

Compulsory licensing clause for patents that enables the Government «to make, construct, use and sell a patented invention to the extent necessary **to respond to a public health emergency** that is a matter of national concern»

«The Government of Canada... shall pay the patentee **any amount that the Commissioner [of Patents] considers to be adequate remuneration** in the circumstances, taking into account the economic value of the authorization and the extent to which they make, construct, use and sell the patented invention»

COVID-19 Refresh for Compulsory Licensing



Prevention and Control of Infectious Diseases in Humans Act

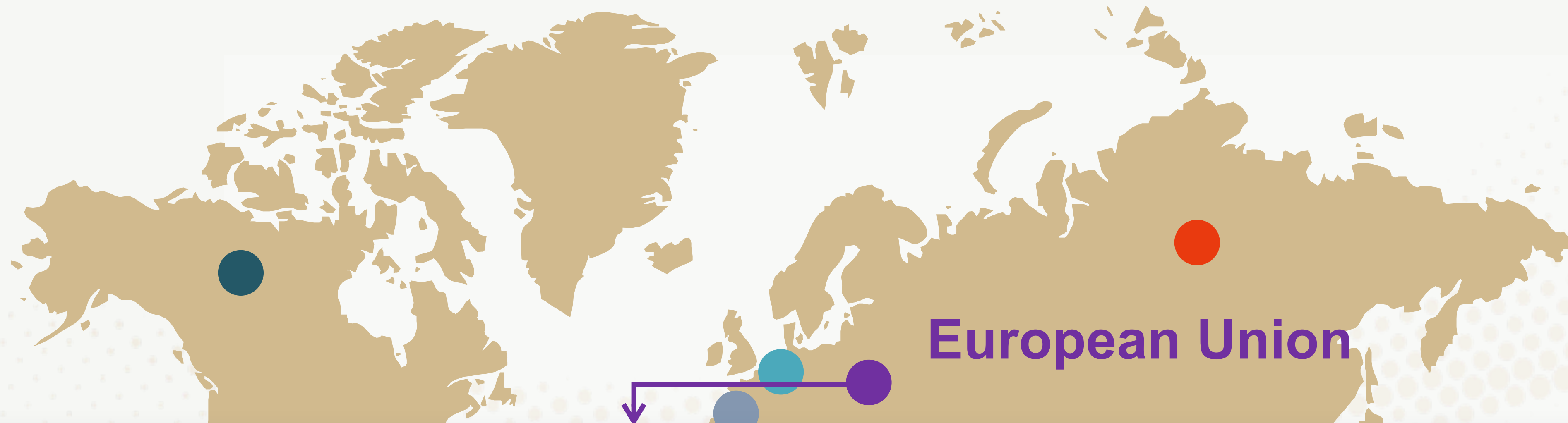
Enacted 28 March 2020

Expires March 2021

Provides **the Federal Ministry of Health** with a range of extra powers should the Bundestag declare a national epidemic. These include the ability **to issue a compulsory license** under the existing Section 13(1) of the Patent Act, which has never been used before.

Section 13(1) allows the circumvention of patent rights by the government or selected third parties **“in the interest of public welfare or in the interest of public security”** of the country as whole. Licenses granted under this provision can be challenged administratively but will not be suspended pending the outcome of the challenge.

COVID-19 Refresh for Compulsory Licensing



Making the Most of the EU's Innovative Potential. An Intellectual Property Action Plan to Support the EU's Recovery and Resilience.

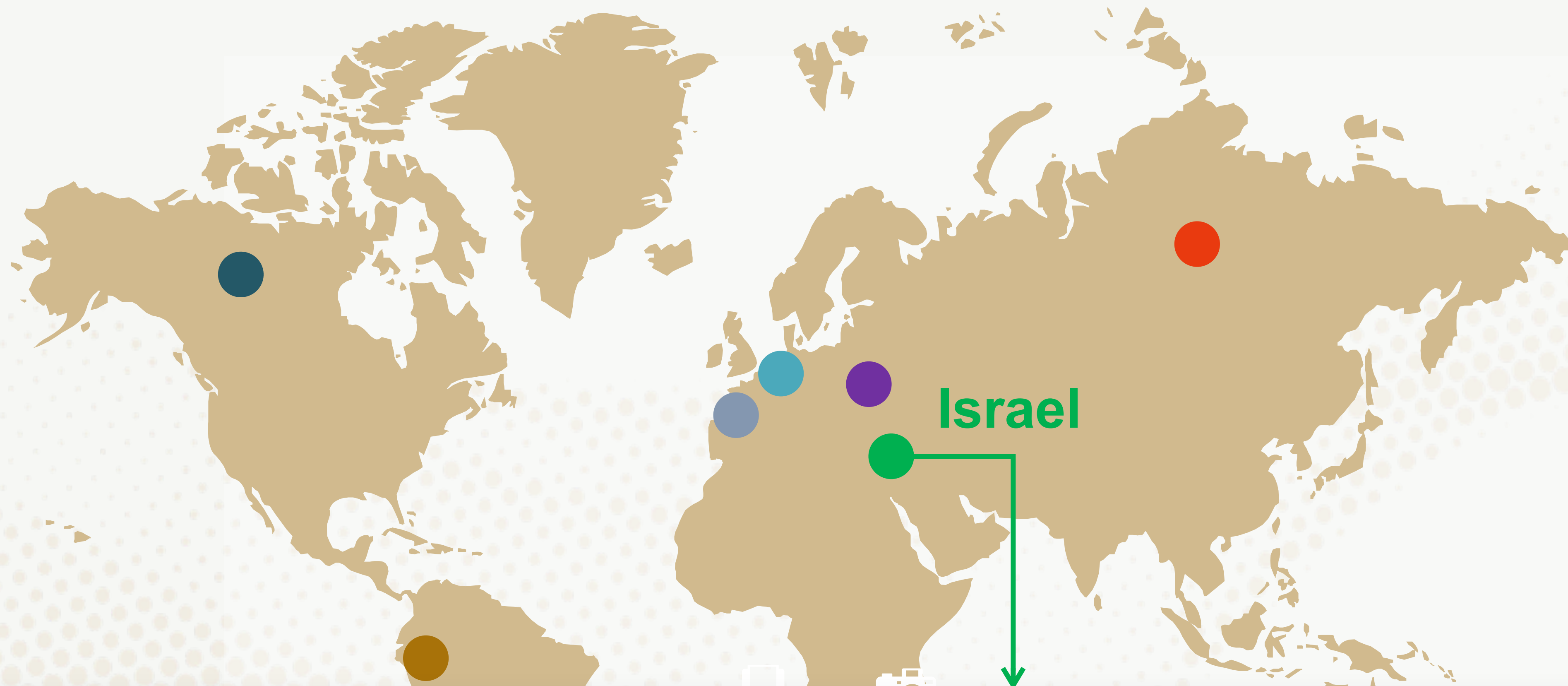
Enacted 25 November 2020

Commission sees the need to ensure that effective systems for issuing compulsory licenses are in place, to be used as a means of last resort and a safety net, when all other efforts to make IP available have failed. The Commission **calls on Member States to ensure** that the tools they have are as effective as possible, for instance, by putting in place **fast-track procedures for issuing compulsory licenses** in emergency situations.

EU goal 2021-2022:

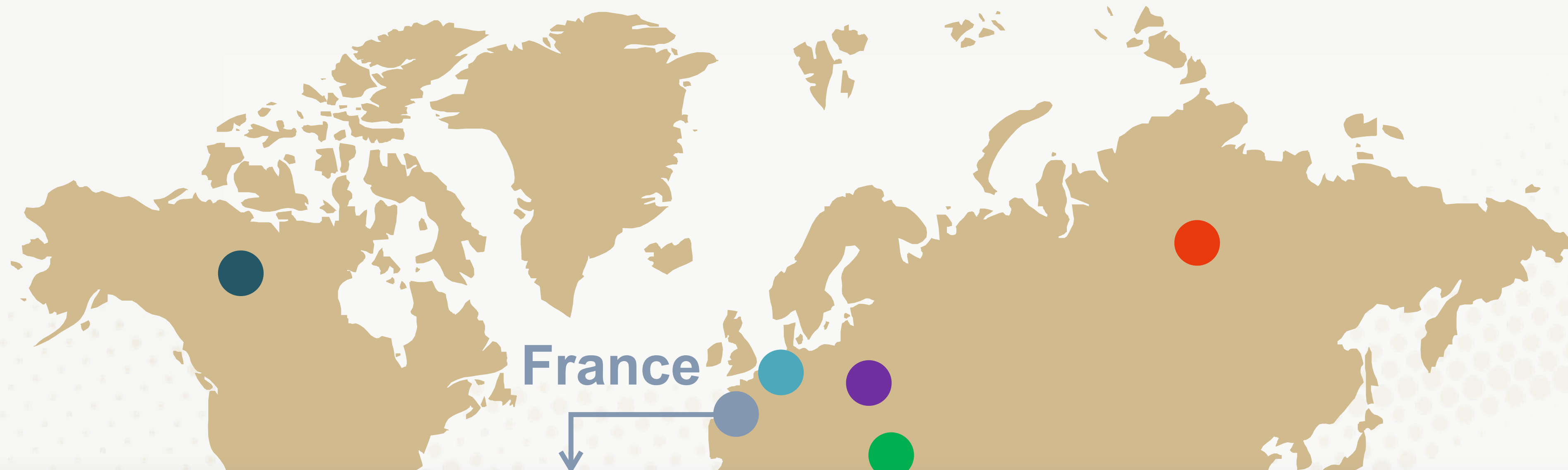
“to facilitate licensing and sharing of IP, the Commission will ensure the availability of critical IP in times of crisis, **including via new licensing tools and a system to co-ordinate compulsory licensing**”

COVID-19 Refresh for Compulsory Licensing



On **18th March 2020**, the minister of health and attorney general **issued a compulsory license** allowing the state to import a generic version of AbbVie's Kaletra from India for the treatment of coronavirus patients.

COVID-19 Refresh for Compulsory Licensing



Emergency Law N 2020-290 to Deal with the COVID-19 Epidemic

Enacted 23 March 2020

SEIZURE!

New article L.3131-15 introduced to the France Public Health Code, allowing the Prime Minister to order the seizure of all goods and services necessary to:

- fight against sanitary disaster;
- to temporarily control the prices of products;
- to take any measures necessary to make relevant medicines available to patients.

COVID-19 Refresh for Compulsory Licensing



In Russia, compulsory licensing for public health is non-existent.
The first bill of this kind has just passed the first reading in the State Duma on December 15, 2020

Chile
And it is highly criticized in the press as a form of “pirating” of Big Pharma innovation

Russian Bill on compulsory licensing for public health



22 November 2019: submitted to the State Duma

15 December 2020: passed the first reading in the State Duma

Grounds for CL:

The bill introduces into Russian Civil Code **"protecting the life and health of citizens"** as a ground for compulsory licensing

1

Conditions:

- Prior notification of patentholder
- Only in cases of urgent need
- Compensation provided

2

Compensation:

Compensation for the compulsory license will depend on the revenues of the patent holders

3

Why Did We Fail?

- Competition jumped from fairness to a war-like race aimed at value extraction, not sustainable cooperation
- As noted by Stiglitz, market alone is no longer enough to address the rising inequality. Transit to a fair, green economy calls for a global effort beyond just economy and just business
- As of now, there is no global legal order for fair competition, data sharing and pooling that could have enabled us to fight the crisis better
- The system came to be a vicious circle supported by power relations and private interests



“The pandemic is a clear test of international cooperation — a test we have essentially failed”

Antonio Guterres at the UNSC Meeting 24.09.20.

In absence of global competition law and cooperative framework, compulsory licensing is becoming a popular remedy for failure

- 1 As the international system of IP protection is rigid to change even now, compulsory licensing is legit to cover deficit in vaccines and healthcare
- 2 The pandemic showed only scarce evidence of grassroots cooperation (e.g.COVAX) and a strong trend for unilateral action
- 3 States appealed to compulsory licensing and similar protective measures to ensure their national interest



In view of state practices during the COVID-19 pandemic and the TRIPS flexibilities, Russia's uncertainty on compulsory licensing is **illogical**



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