Parallel
Session 8

Intellectual property challenges to promote innovation and timely global equitable access and affordability

Viviana Muñoz-Tellez, South Centre

https://ipaccessmeds.southcentre.int

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A public health approach to Intellectual property rights

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WHO Pandemic Treaty & IHR Case law database e-learning
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Public Health Related Flexibilities in the TRIPS Agreement

- Flexibility to determine how to define “invention” and to apply rigurous standards of patentability
- Disclosure requirement, particularly for biologics
- Compulsory licensing
- Government use authorisation
- Exclusions and Exceptions: Bolar, research, experimental
- Flexibility in and implementation of TRIPS Agreement Article 31bis amendment to address access to medicines of countries lacking manufacturing capacity
- Flexibility in test data protection
- Parallel importation
- Avoidance of TRIPS-plus provisions and policies, including extension of patent term, data exclusivity, second use patents, border measures
- Special TRIPS flexibilities (including exemptions) for LDCs
- Pre and post patent grant opposition
- Use of competition principle and law to address misuse of patent
- Flexibility in provisional and permanent injunctions
- Flexibilities in enforcement of IP

Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf (southcentre.int)

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Boyan Konstantinov, UNDP

"Competition policies are important levers that governments can employ to ensure that health technology markets operate competitively and that the public benefits from low prices and innovation. Should governments pay closer attention to competition law, it could serve as an important tool for increasing access to health technologies."

Report of the UN Secretary General's High-Level Panel on Access to Medicines (2016).

Mustaqeem de Gama, Afrigen

Paul Torkehagen,
Medigen Vaccine Biologics Corp

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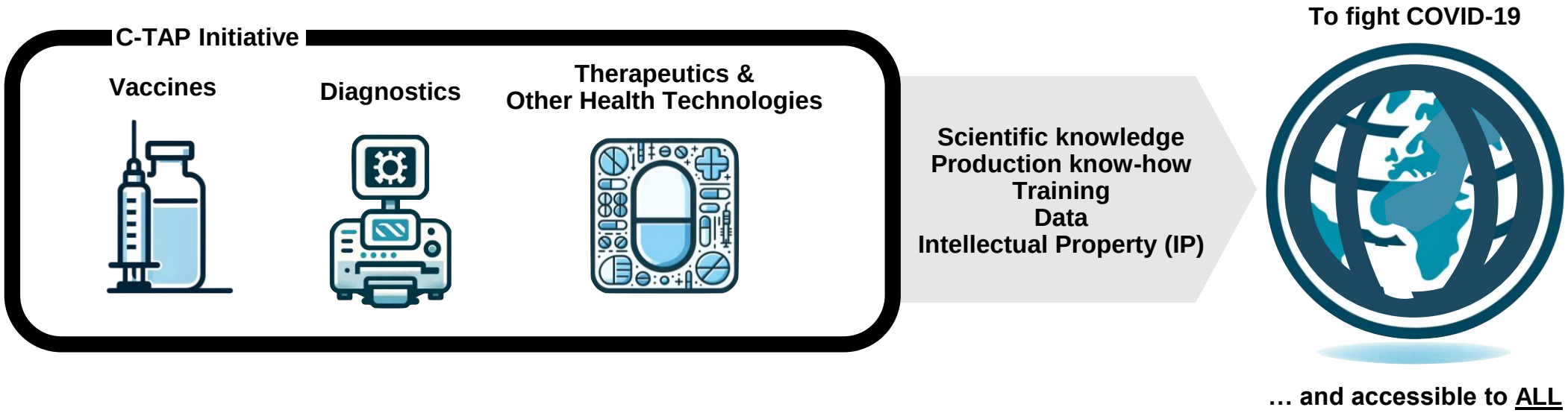
What is The COVID-19 Technology Access Pool (C-TAP)?

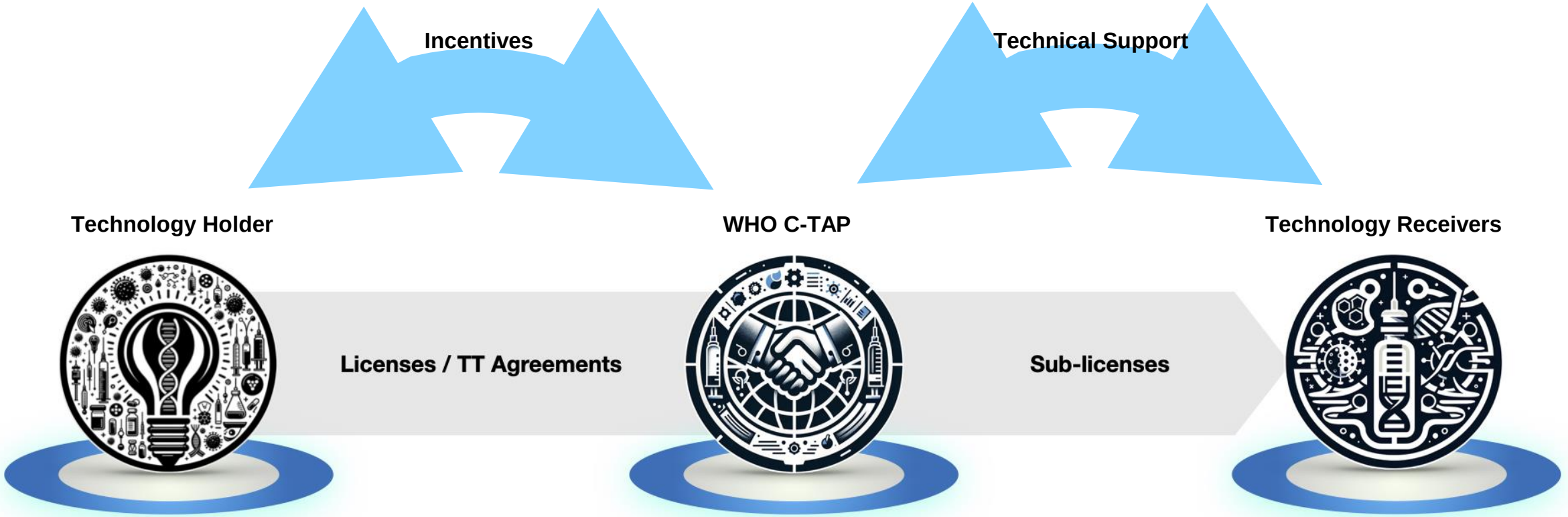
Voluntary and Equitable Access Program



To Promote Open Innovation
& Fast Track Availability of Science and Products to fight COVID-19

Icon Illustrations created using ChatGPT 4, images are meant for illustration purposes only. Source: WHO C-TAP with modifications

How Does C-TAP Work to Facilitate Technology Sharing and Increase Scale Up?



- MPP

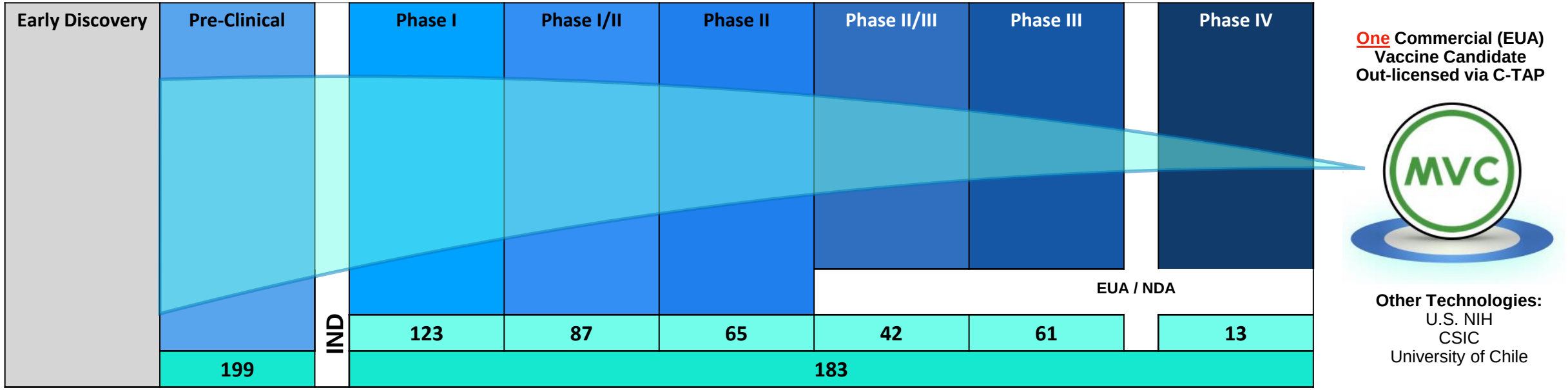
- Open COVID Pledge
- WHO Global R&D Observatory
- UNDP, Unitaid, UNAIDS,

WHO member States

Icon Illustrations created using ChatGPT 4, images are meant for illustration purposes only. Source: WHO C-TAP with modifications

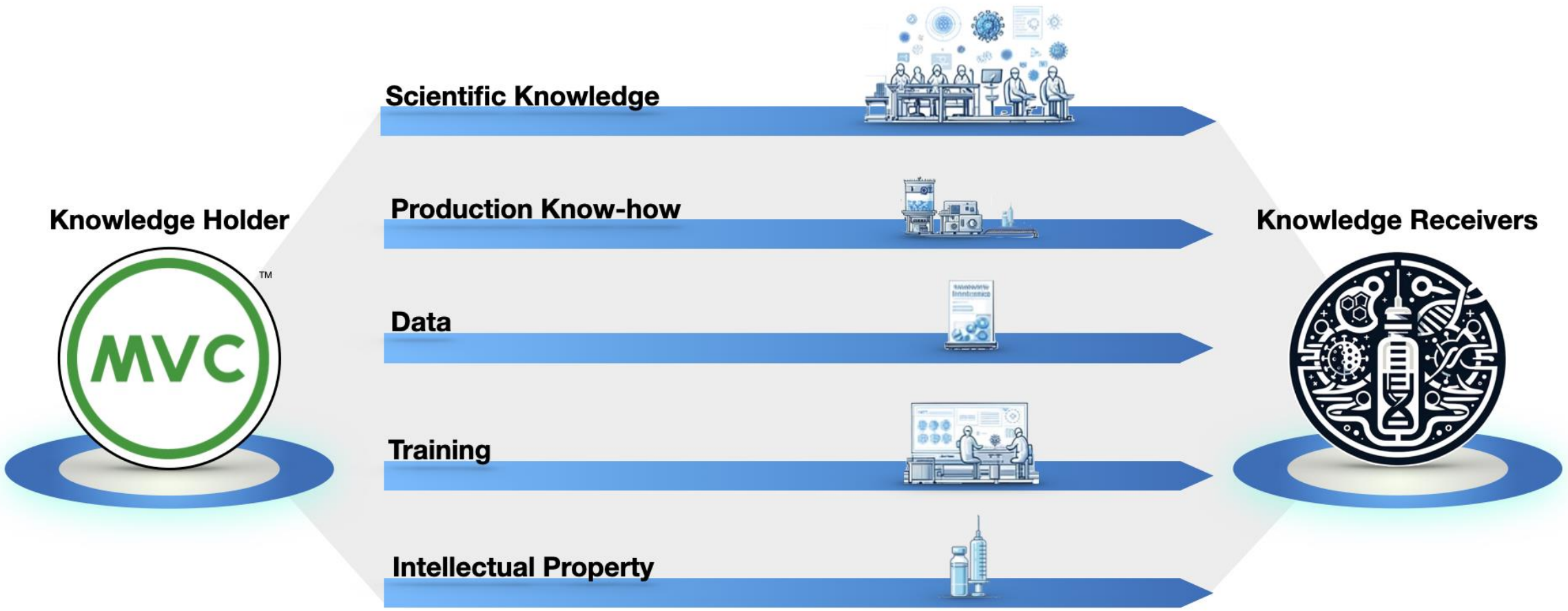
Why Am I here?

Global COVID-19 Vaccine Landscape*



Data Source: *WHO COVID-19 vaccine tracker and landscape, 30 March 2023. Data may overlap due to a candidate vaccine having conducted multiple phases of clinical studies. Human error on total counts, may have occurred.

What Did MVC Make Available via WHO C-TAP Initiative?



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Why Did MVC Out-License via C-TAP?

1.

To Help End The Pandemic

2.

To Assist Others
(Promises made)

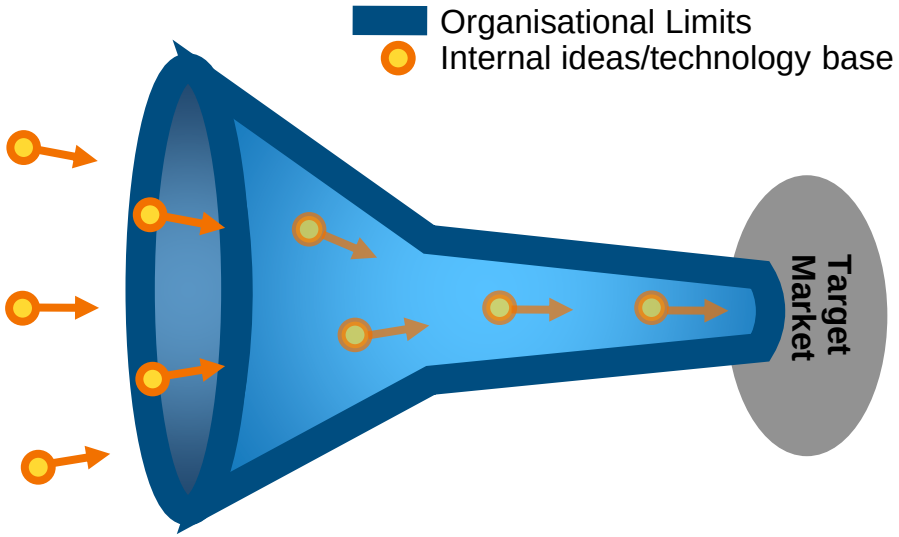
3.

Commercial Opportunities

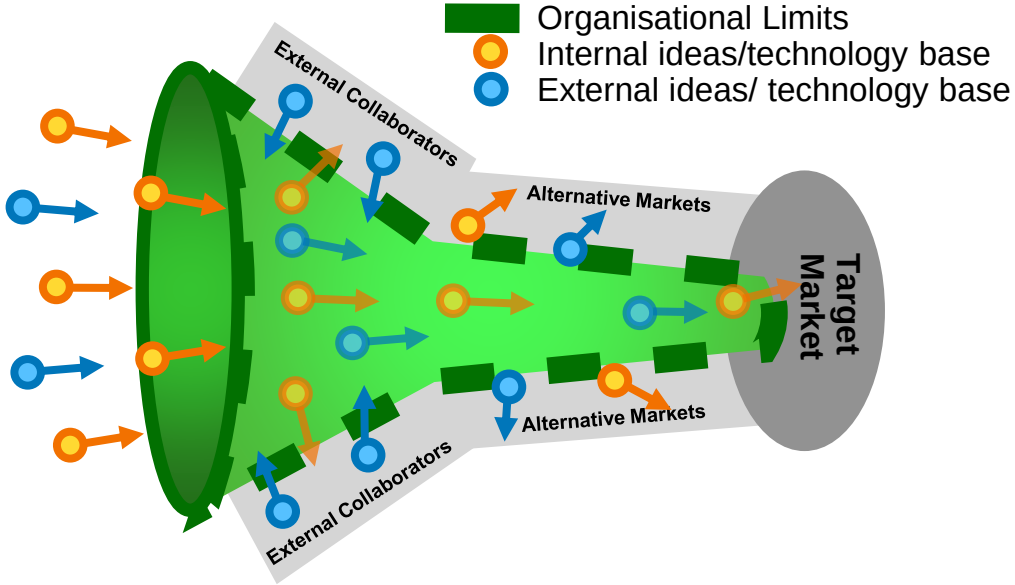
4.

Pandemic Preparedness

Closed Innovation



Open Innovation



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The Potential Pitfalls to Watch Out For - Building Barriers to IP Access

BARRIERS:

(Some Examples)

Speed Breaks
Bureaucracy - Hoops
Protocols
Legal (Lawyers!)

Death by Committee
One-size-fits All
Lack of Awareness/Engagement
Gatekeeper/Wrong Mentality

Politics
Mandates
Selection
Perfection

Selective Financing
…

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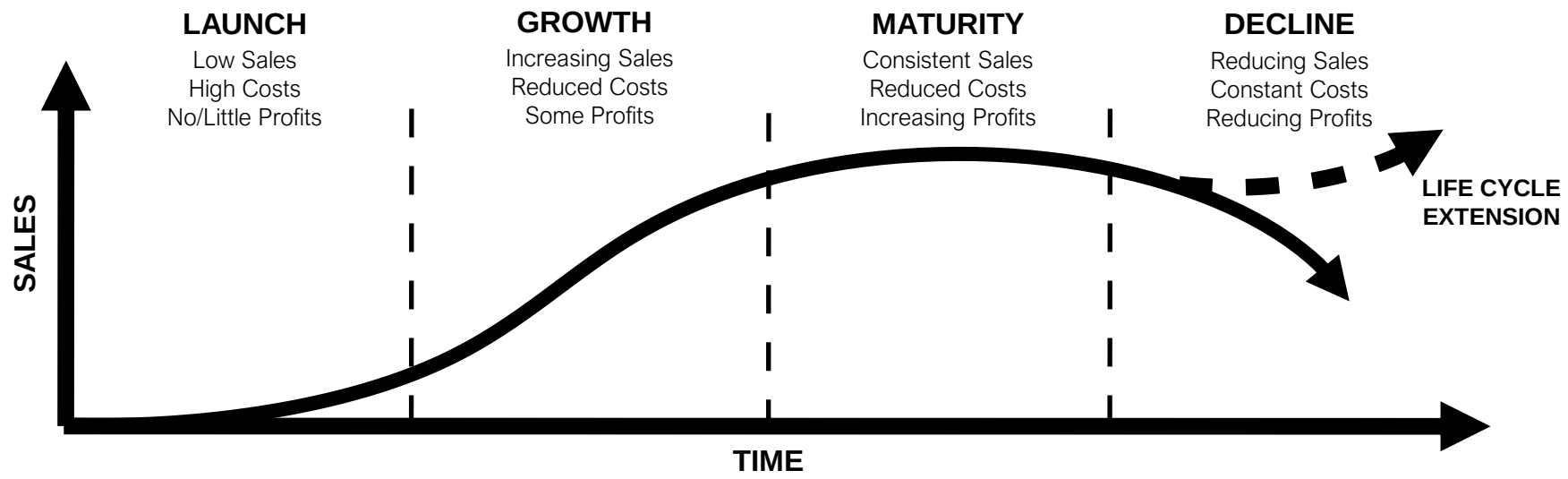
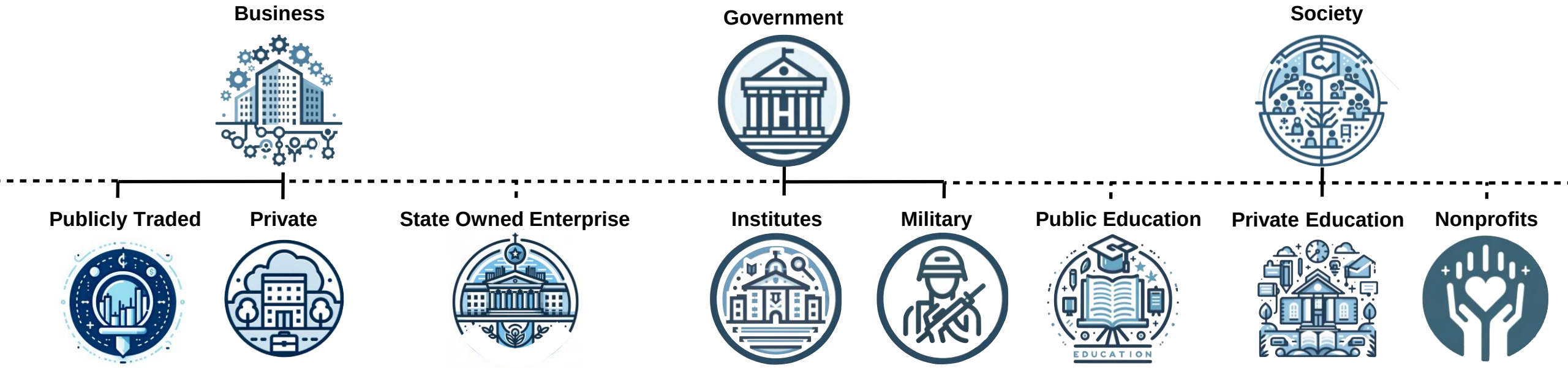
Understand and Involve Your Stakeholders - Build An Open Technology Platform





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Thank You

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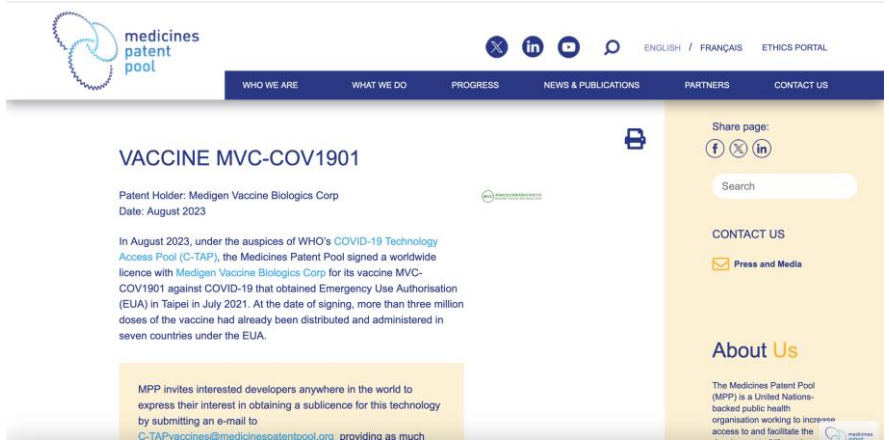
Title: Vice President, International Business Development
Contact: paul@medigenvac.com

Please Visit the Following Websites

WHO C-TAP

https://www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap

Medicines Patent Pool



https://medicinespatentpool.org/licence-post/vaccine-mvc-cov1901

Screenshot of WHO C-TAP and MPP, images for reference purposes only, All Rights Reserved of Respective Organisation

Sergiy Kondratyuk, ITPC Global

Community-led patent oppositions

Sergiy Kondratyuk

Fair Pricing Forum 2024

ITPC
INTERNATIONAL TREATMENT PREPAREDNESS COALITION

make medicines affordable
END UNFAIR MONOPOLIES

Evergreening practice

Report on evergreening patents in Ukraine 2020

132

patents were analyzed

54,55%

not «evergreening» patents

45,45%

«evergreening» patents

ITPC 100%LIFE

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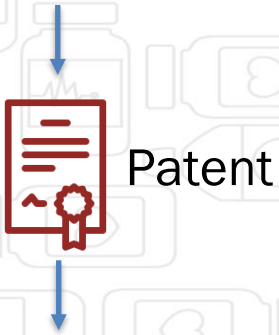
Source: https://network.org.ua/wp-content/uploads/2020/12/Report-eng-curves-1-1.pdf

Patent oppositions

Patent opposition - an administrative process available under the patent law of many jurisdictions which allows third parties to formally challenge the validity of a pending patent application or of a granted patent.

Types of patent oppositions:

- Pre-grant opposition – challenge to patent application (before the grant of a patent)



- Post-grant opposition – challenge to granted patent (after the grant of a patent)

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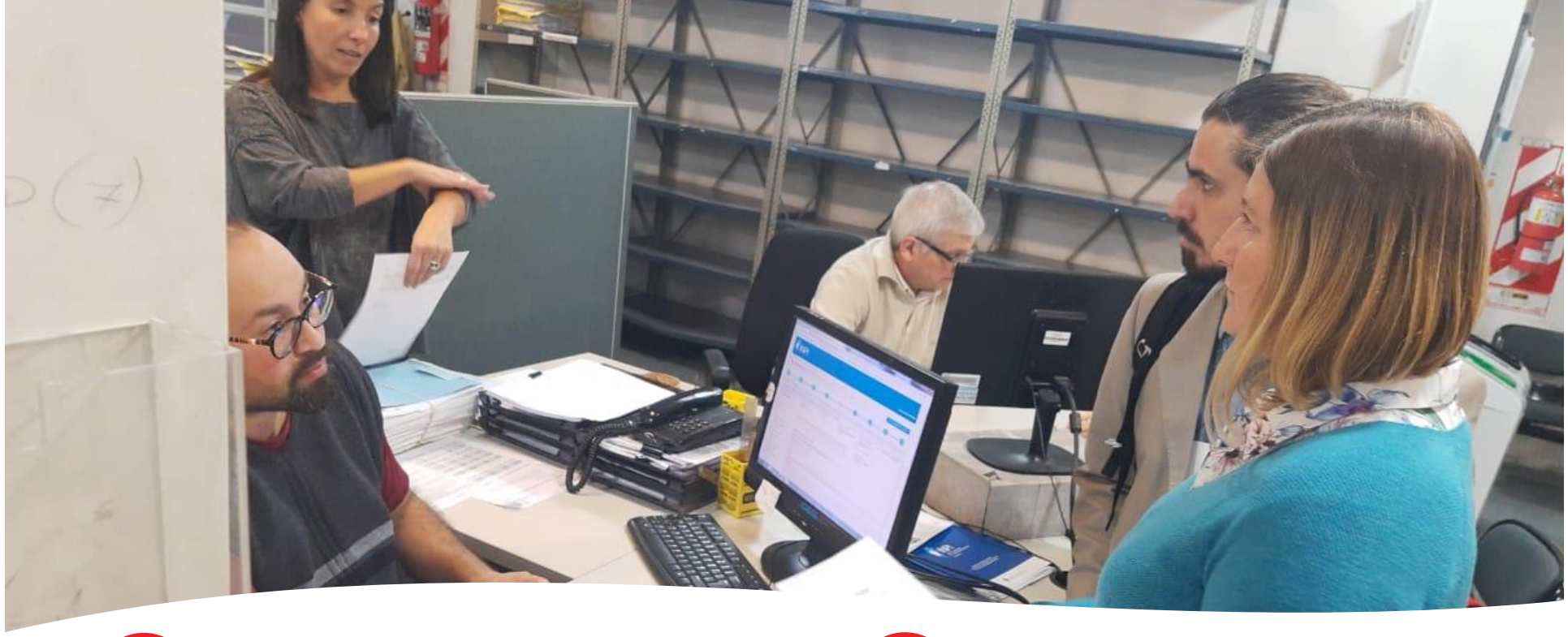

104 oppositions filed with 36 having positive outcome

By 17 community-led organizations in 17 middle-income countries

$901 million of total estimated cost savings (2015-2022)

A nearly 50x return on donor investment in community-led IP work

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Patent oppositions in Argentina

GEP

TDF/FTC

2,6x price reduction

TDF/FTC/EFV

23x price reduction

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Patent oppositions in Thailand

- AAF & TNP filed patent opposition on Favipiravir and patent application was rejected
- GPO was allowed to import and then to produce and supply generic favipiravir to hospitals in Sep 2021

AIDS ACCESS FOUNDATION

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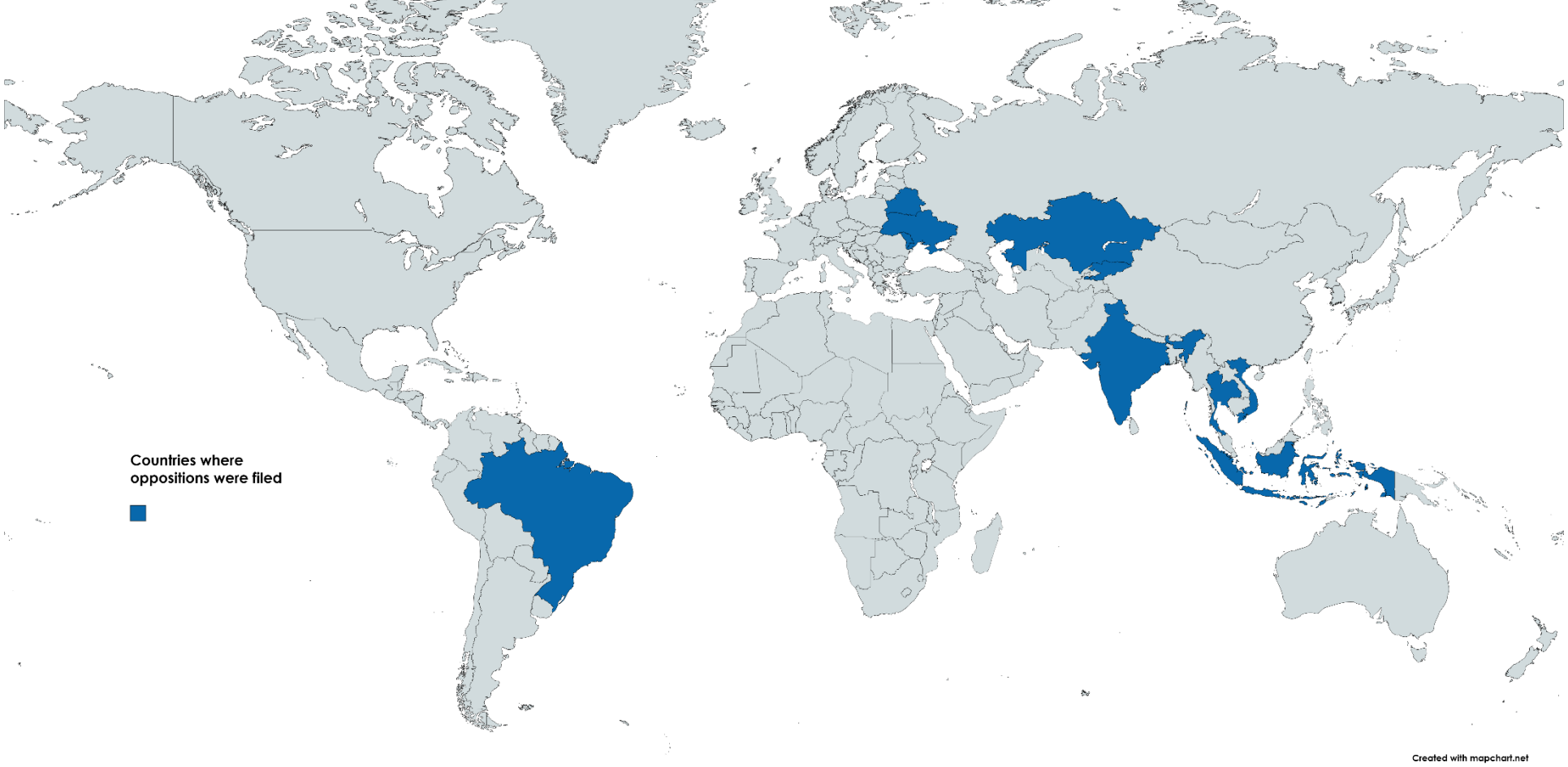

- 18 CSO-led Patent Oppositions on Bedaquiline filed in 2020-2023
- After India rejected secondary patent - J&J announced non-enforcement of patents in almost all (134) LMICs in September 2023

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Challenges

- When there is no formal pre-grant opposition procedure
- Lack of sovereignty - regional patent offices, EPO validation agreements
- Very quick examination processes in some patent offices
- Need of law reform (e.g. to delete methods of treatment from patentable subject matter, etc.)

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Thank you for attention

skondratyuk@itpcglobal.org

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Heba Wanis, Third World Network

TWN

Third World Network

Egypt's Experience Utilising Intellectual Property Policy Space to Promote Local Production and Improve Access to Medicines

Heba Wanis

Third World Network

WHO 4th Fair Pricing Forum, 6-8 February 2024

Context: Pharmaceutical Industry

- Egypt has an established pharmaceutical manufacturing base, covering 80% of local needs
- Large pharmaceutical market: USD 4.87 billion (EGP 78.7 billion) in 2020
- 82% of medicines on the market are locally produced
- Local industry is dependent on imported raw materials, comprising 90-95% of locally produced finished products

Rostom, O. (2020, November 17). *Industry development in Egypt: The road to sustainable development 2030 in light of COVID-19.* [Paper presentation, Chamber of Pharmaceutical Industry]. Seminar at the Institute of National Planning, Cairo, Egypt.

Context: Medicine Pricing

- High out-of-pocket expenditure on health: approx. 62.75%, of which nearly 50% is on medicines
- Medicine pricing mechanisms involve price negotiations with industry
- Pricing system currently in place is based on external referencing; replaced the cost plus mark-up system in 2009, raising concerns of future rise in prices

WHO. 2022. Global Health Expenditure Database. Egypt: Out-of-Pocket Expenditure on Health 2000-2019. Available at: https://apps.who.int/nha/database/country_profile/Index/en

Context: Intellectual Property Legislation

- Development-oriented Intellectual Property Protection Law (82/2002), issued in 2002
- Incorporated the minimum standards set by the TRIPS Agreement (Articles 1 and 8) on the interpretation of the Agreement within the legal system and practice, and adopting measures necessary to protect public health
- The Law incorporates a wide range of flexibilities, including patent opposition and compulsory licensing

Context: Patent Examination Practices

- The Egyptian Patent Office applies high patentability standards to the examination of pharmaceutical patent applications.
- Rejection of Gilead Sciences' sofosbuvir patent application in 2014 for lack of novelty and inventiveness
- Gilead's deal with the Egyptian government: Sovaldi for USD 300 per box
- Rejection of SOF patent application was the opportunity for generic versions of direct acting antivirals (DAAs) to enter the Egyptian market.

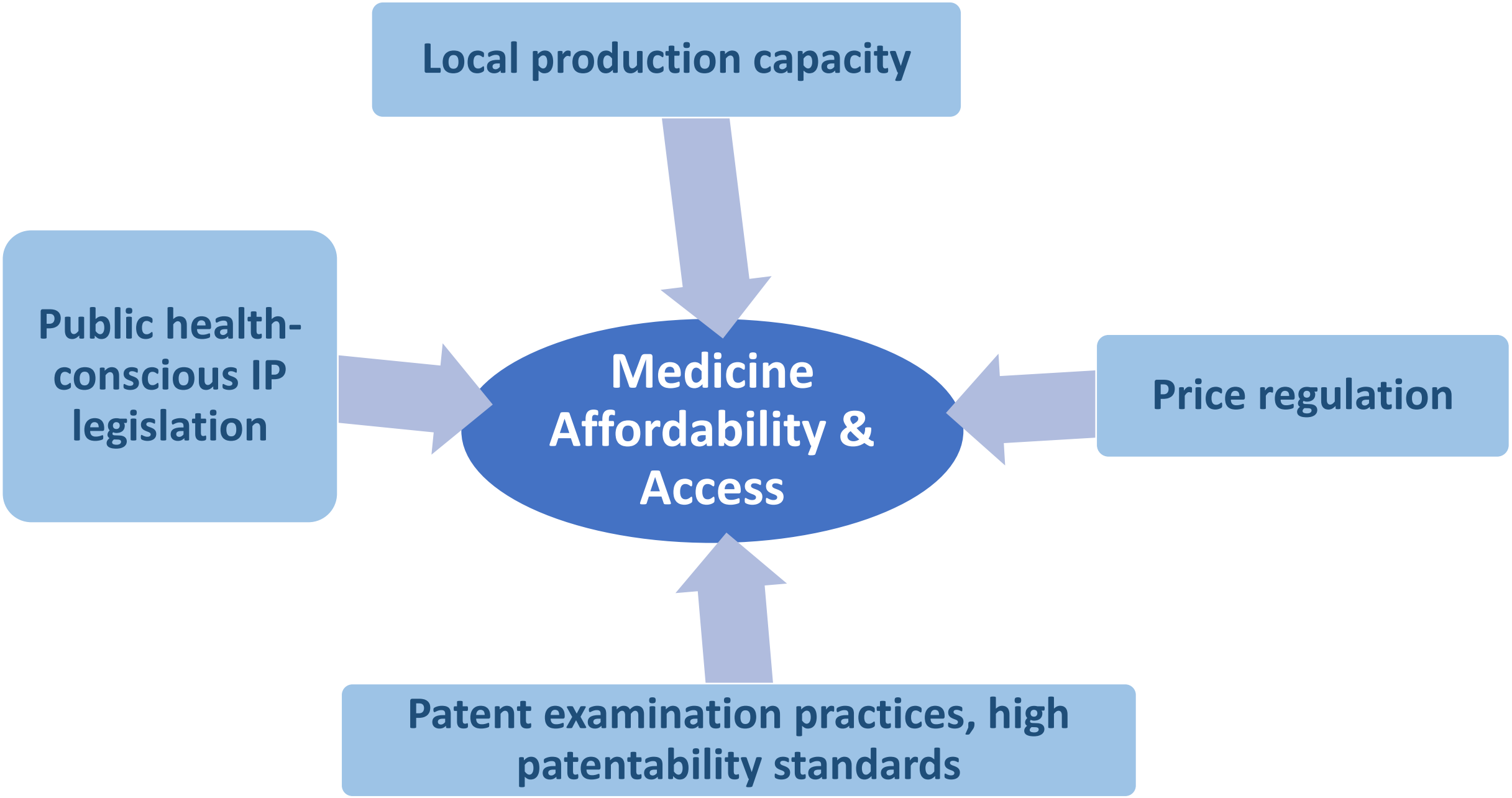
Generic Production = Improved Access

- Absence of patent protection led to domestic production of low-cost generic DAAs
- Price reduction: 5.2% of initial price in 3 years
- Cost of 12-week treatment course of SOF/DAC: from USD 1,650 in early 2015 to only USD 85 in 2018
- >2 million patients were treated by 2018 (40% of the total HCV-infected population), with cure rates >90%

Waked, I., Esmat, G., Elsharkawy, A., El-Serafy, M., Abdel-Razek, W., Ghalab, R., Elshishiney, G., Salah, A., Abdel Megid, S., Kabil, K. and El-Sayed, M.H., 2020. Screening and treatment program to eliminate hepatitis C in Egypt. New England Journal of Medicine, 382(12), pp.1166-1174. DOI: 10.1056/NEJMsr1912628
WHO. 2018. Progress Report on Access to Hepatitis C Treatment: Focus on Overcoming Barriers in Low and Middle-Income Countries. March 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/260445/WHO-CDS-HIV-18.4-eng.pdf;jsessionid=CDAB0EA39F0F28A0877C8289CF63D4A7?sequence=1

IP Public Domain: Opportunities for Generic Production

- High patentability standards → Large public domain of unpatented medicines
- Need for better utilisation by local industry to produce low-cost generics.
- Key medicines in the public domain:
  - Bedaquiline and delamanid (multidrug resistant TB treatment)
  - Dolutegravir (antiretroviral for HIV treatment)
  - Imatinib (tyrosine kinase inhibitor cancer treatment, no patent application)


Local production capacity
Public health-conscious IP legislation
Medicine Affordability & Access
Price regulation
Patent examination practices, high patentability standards

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Thank you..

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Intellectual property challenges to promote innovation and timely global equitable access and affordability