Intellectual Property and Access to Medicines: Perspectives of Médecins Sans Frontières

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"We will not ignore this. Our patients are dying, not because their diseases are incurable, but because as consumers, they do not provide a viable market"

WTO Conference, 1999

Dr. Bernard Pécoul, Médecins Sans Frontières,

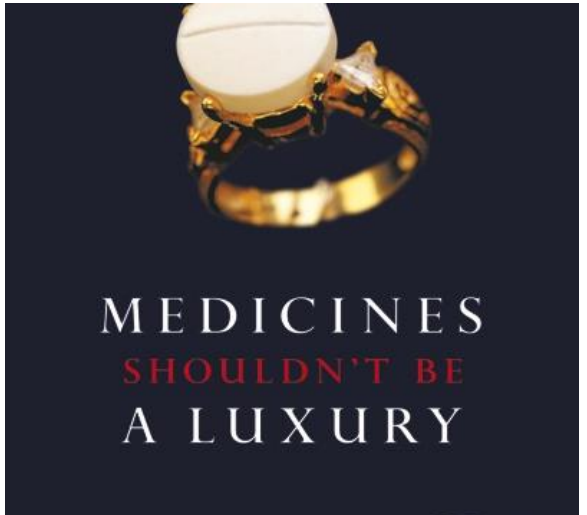
ED of the Access Campaign

"Today, a growing injustice confront us (...) what we as a civil society movement demand is change, not charity"

Nobel Peace Prize Lecture, 1999

Dr. James Orbinski

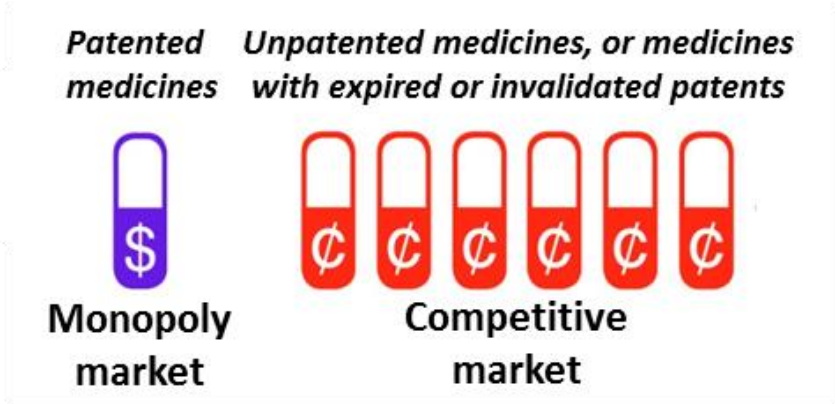
Médecins Sans Frontières International President

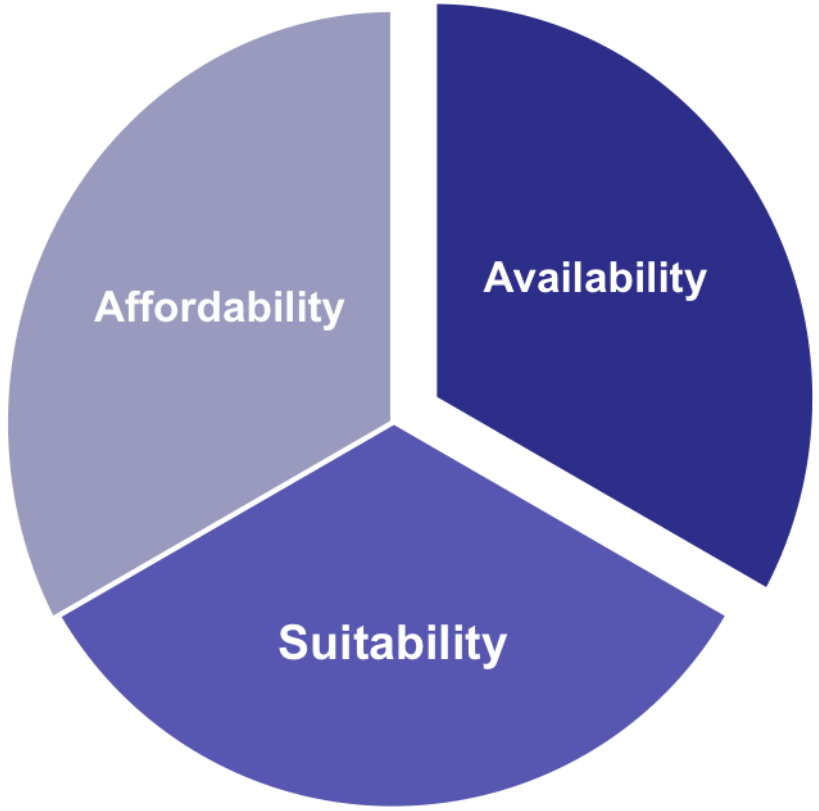


MSF Access Campaign created in 1999 to push for access to live-saving/prolonging medicines, diagnostics & vaccines for patients around the world

Dimensions of Access and Innovation

- Access to existing medicines/treatment
- Develop and access to new medicines/treatment



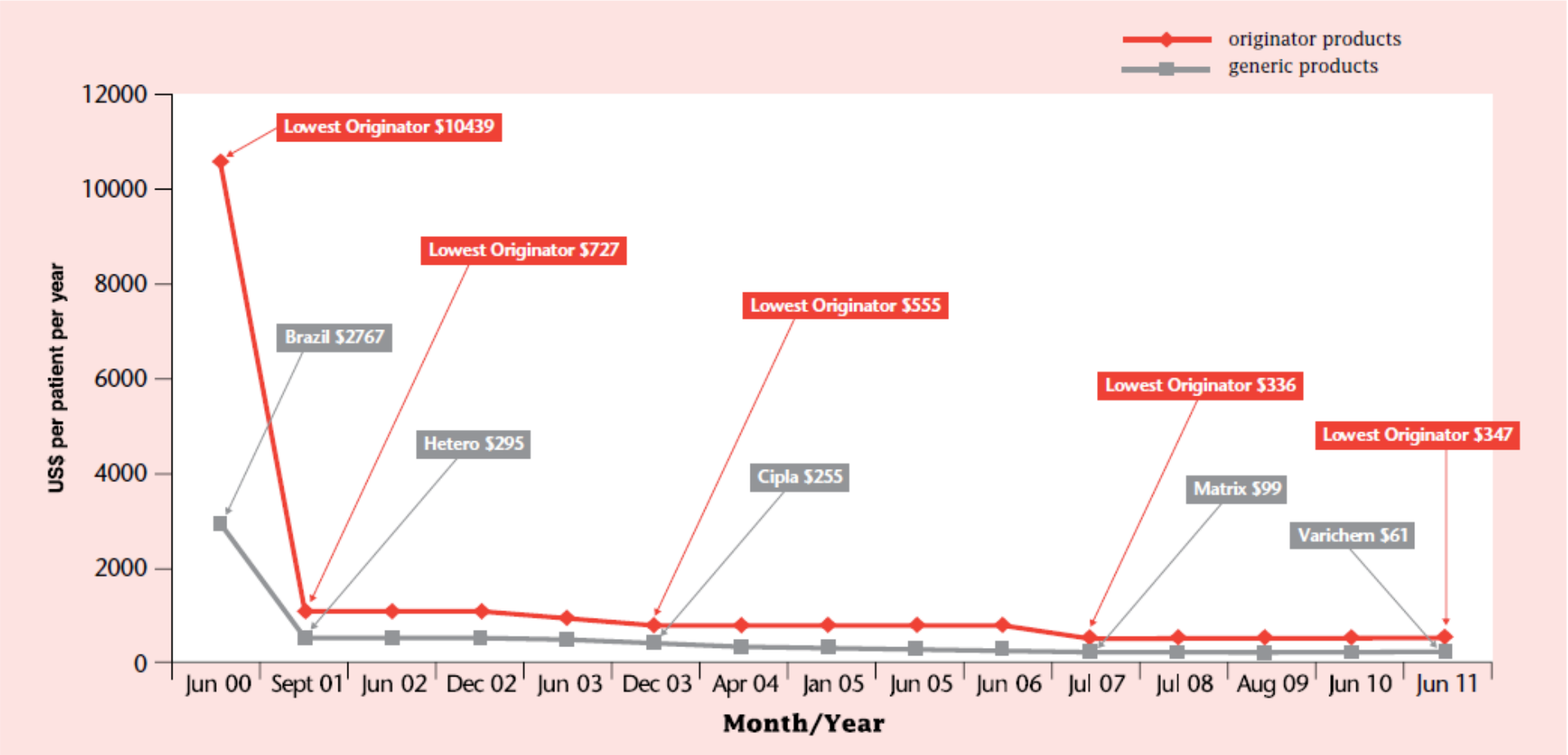


- While many factors affect the status of access to medicines, monopoly power that is often supported by intellectual property, particularly patents and other exclusivities, have a more direct impact on pricing, production and supply options.

Generic Competition as a Catalyst for Price Reduction

GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.

The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.



Source: MSF Untangling the Web of Antiretroviral Price Reductions, 15th Edition, July 2012

Expansion of IP rules and monopolies

1995 Agreement on Trade Related Intellectual Property Rights (TRIPS), WTO

Pre-TRIPS

- Non binding
- Diversified

- Patent on pharmaceutical products
- Minimum 20 years protection
- General criteria for patenting
- Compulsory license incl. gov. use
- Exceptions and limitations
- Data protection
- Parallel Import/ Voluntary License

Post-TRIPS

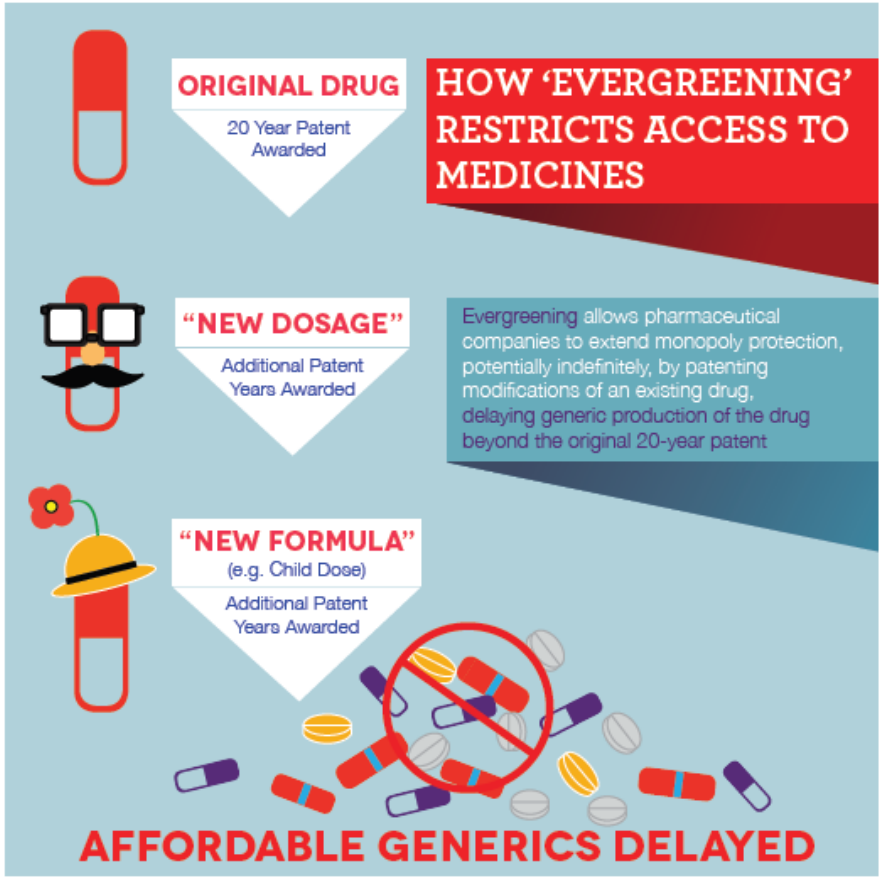
- Binding
- Unified/flexible

TRIPS-plus provisions in Free Trade Agreements (FTA) and Bilateral Investment Treaties (BIT)

- **Data exclusivity**
- **Broad patentability**
- **Patent term extension**
- Narrow exceptions and limitations
- Limitations of compulsory license
- Investor protection/ ISDS
- **Patent linkage**
- Border enforcement- goods in transit
- Judicial enforcement- expanding scope of liabilities

Patent “Ever-greening” issues

Video on “ever-greening”
https://www.msfaccess.org/content/evergreening-drugs-attack-access-medicines-0

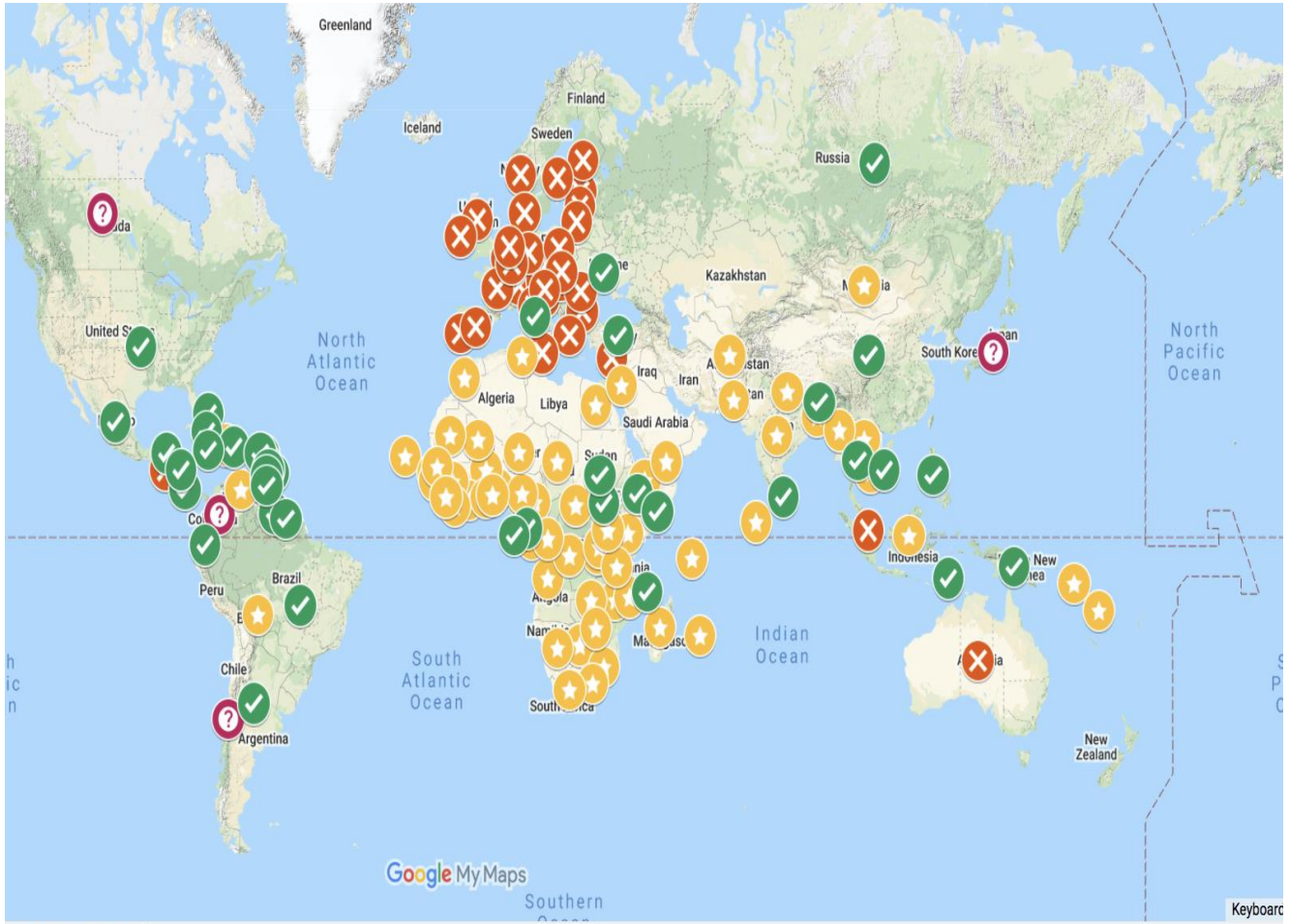


- It’s not ‘ever-green’ a particular patent, BUT the monopoly through multiple patents and exclusivities on one medicine

- The actual monopoly will be longer than 20 years if those “ever-greening” patents are granted

MSF AC works on intellectual property issues

- International level
  - International laws and policy-making processes, e.g. WTO Doha declaration, WTO TRIPS waiver negotiation, WHO Pandemic Accord negotiation
- National level
  - National law and policy reform processes concerning IP on medical products
  - MSF operational context whereby specific products may not be available due to IP barriers
- Priority products
  - Analysing and documenting IP barriers on priority medicines identified by MSF
  - Strategies and actions to overcome IP barriers



ational, TWN & WTO] Note: The discussions at the WTO are taking place behind closed doors. As such, we strive to update the map as soon as we have confirmation of each country's ev

Access challenges in COVID19

- MSF's work regarding COVID-19
  - Responding in more than 60 countries
  - Care and treatment for COVID19 patients; ensure essential health care not interrupted
- Challenges of ensuring access
  - Access to essential medical tools compromised since the start of the pandemic
  - Frontline healthcare workers in Southern African countries where MSF works, including MSF team, continue facing access challenges, including in South Africa, Eswatini, Malawi and Mozambique
  - Access needs to be guaranteed for both existing and future medicines, vaccines and diagnostics

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Inequality and inequity in global access

- Structural barriers:
  - IP enables private enclosure of R&D outcomes funded and supported by public resources
  - IP enables the controlling of technology ownership and market which leads to sharp inequality in industrial development in global south
- Normative barriers:
  - Inherent limitation of relying on companies' voluntary actions in solving access challenges
  - Limitations in international IP and trade regimes
  - Overall lack of transparency and accountability mechanism on companies' IP strategies
- Political barriers:
  - Trading and political pressures on using public health safeguards – TRIPS flexibilities -- by developing countries
- Practical barriers:
  - Need to address IP in an inclusive manner --- not only patents, but also trade secrets, manufacturing knowhow, data, industrial design, blueprint and others

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Law and policy considerations to address monopolies in the pandemic

- Governments being the main duty bearers to ensure universal access to COVID19 medicines, vaccines, diagnostics and other medical tools needed
- Need immediate strategies to address:
  - Thickets -- present and future – of IP/patents on key technologies
  - Limitation of relying on companies' voluntary actions
  - Address exclusivities on regulatory data and other confidential information
- Options to consider:
  - Suspend the implementation of certain intellectual property – tackle patents thickets and evergreening– i.e. many patents on the same old technology
  - Pursue additional legal tool – WTO TRIP waiver to facilitate increased production and supply
  - Make the full use of public health safeguarding such as compulsory licensing on IP for governments use to
- MSF briefing on overcoming IP monopolies in COVID-19: https://msfaccess.org/overcoming-intellectual-property-monopolies-covid-19-pandemic

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Proposal for WTO IP waiver for COVID19

- October 2020, initiated by South Africa and India, at Word Trade Organization
- To date, officially sponsored by 63 developing countries, including all countries in Africa Group and Least-developed countries group
- A waiver to be granted to all WTO members so that they do not have to implement, apply or enforce certain obligations related to certain intellectual property on COVID19 medical tools
  - MSF briefing on the waiver: https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies
  - Scope of technologies: include, but are not limited to, diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture.
  - Scope of IP: patents, undisclosed information, industrial design and copyrights

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Myths and realities in the debates on IP and access in COVID-19

(https://msfaccess.org/sites/default/files/2020-12/MSF-AC_COVID_IP_TRIPSWaiverMythsRealities_Dec2020.pdf)

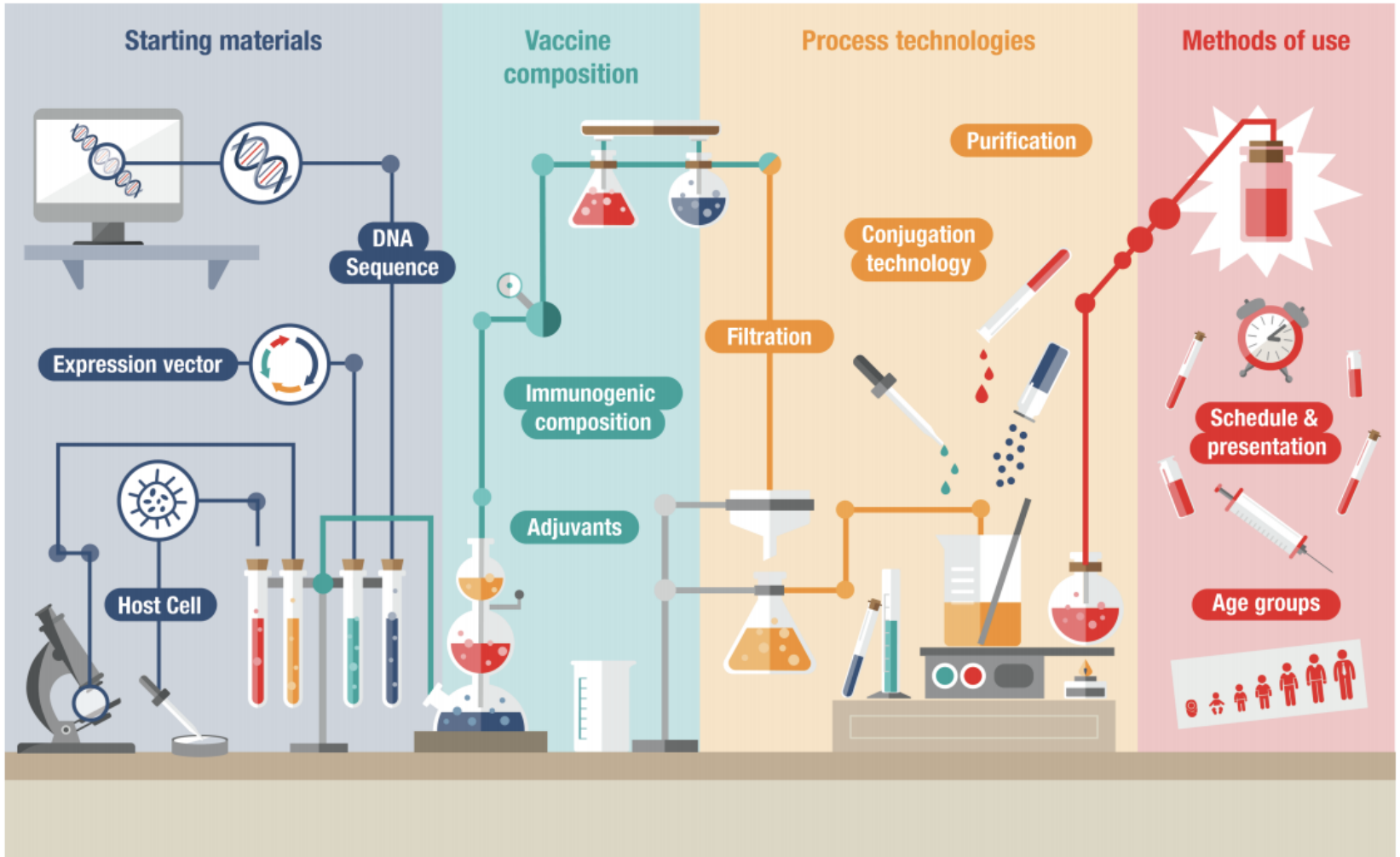
Myths

1. IP is not an barrier
2. IP enabled R&D in COVID19
3. Voluntary license is sufficient
4. Existing TRIPS flexibilities are sufficient
5. Global initiatives- COVAX, ACT-A – can deliver equitable access
6. Even if IP is removed, developing countries cannot produce COVID19 technologies
7. IP holders are the best to produce safe and quality products

Realities

1. Past and present evidences
2. Public funding and global collective efforts enabled R&D in COVID19
3. Voluntary licenses are limited
4. TRIPS flexibilities are important but can be limited
5. Wealthier countries bilateral actions undermine global initiatives
6. Presumption has been proven to be wrong
7. Developing countries can produce products with robust quality and safety

Figure 1: Examples of Patent Barriers Throughout the Vaccine Development Process and Beyond



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Final outcome a disappointment

- No waiver as originally proposed was agreed
- Final decision does not allow waiving IP obligations; but with a procedural adjustment for using compulsory license during pandemic for COVID vaccines
- https://msfaccess.org/inability-agree-real-pandemic-intellectual-property-waiver-wto-devastating-global-failure-people

- Negotiations on whether the MC12 decision to be extended to COVID therapeutics and diagnostics continue

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Remarks

- COVID19 access challenges and debates reveal the historical and structural inequality in health
- CSO engagement difficult in WTO processes due to lacking transparency and participation
- Lifesaving science and technology advancements remain controlled by private interests and lacking effective mechanism to ensure sharing and benefiting to all
- Multiple challenges require legal strategies at the present and for the future reforms
  - TRIPS waiver → WTO normative framework responding to global pandemic
  - National law response
  - Challenges and issues with transparency
    - Transparency of contracts in general and IP licensing
    - Overcoming trade secrets and other confidentiality claims by the industry
  - Other legal issues related to liability indemnity requested by the industry
  - Accountability derived from of public funding
  - Human rights obligations – national and transnational

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IP issues in WHO Pandemic Treaty and IHR amendment negotiations

- Shortcomings of relying on existing international IP rules for pandemic
  - WTO and WIPO treaties do not aim to protect public health as the primary objectives
  - Doha declaration and UN policy instrument endorsement not enough to establish rules to address the tension between IP and access to medicines
- Challenges:
  - Unilateral trade and political pressures
  - Insufficient national laws to use public health flexibilities
  - Failure to using TRIPS Art 31bis on compulsory license for exportation
  - Failure to deliver meaning waiver for pandemic under WTO process
  - Insufficient voluntary licensing

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MSF recommendations

- https://msfaccess.org/trips-ppr-addressing-intellectual-property-barriers-lifesaving-medical-products
- During pandemics:
  - At the global level, time-bound waivers should be instituted in order to provide expeditious legal options for governments to restrict the use of relevant forms of IP on all medical products needed to tackle the pandemic;
  - At the national level, all legal and policy options, public health safeguards and flexibilities should be used by governments to address all barriers to access created by IP protections and facilitate rapid prod
- Outside of pandemic situations,
  - Governments should review and revise national laws, policies and regulations to ensure full incorporation of all relevant IP flexibilities protecting access to medical products; and
  - Governments should refrain from introducing IP provisions beyond existing TRIPS requirements in unilateral actions and bilateral/regional trade and investment negotiations and agreements or any other provisions that could undermine states' ability to use TRIPS flexibilities

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Justifications

- Inadequacy to rely on WTO and WIPO competences to address global public health challenges
- Establishing positive responsibilities for member states for the protection of right to health is in consistent with WHO Constitution and the mandate of PPR negotiation
- In consistent with international law practices
  - Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled mandates parties to establish and use copyrights exceptions to facilitate access

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Challenges to follow WHO PPR negotiations

- Multiple parallel processes addressing PPR and access issues, and only two concern norm settings
- CSO participation limited
- Political dynamic among member states to reach consensus; broken trust during COVID
- Timeline of negotiation very tight and key issues remain lacking consensus

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- MSF position paper on equity issues in PPR negotiations: https://msfaccess.org/msf-position-paper-ensuring-timely-and-equitable-access-medical-products-global-public-health
- From TRIP to PPR, IP clauses in WHO PPR negotiations: https://msfaccess.org/trips-ppr-addressing-intellectual-property-barriers-lifesaving-medical-products
- Compulsory licensing and TRIPS waiver: https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies
- Canada: compulsory licensing and TRIPS waiver: https://msfaccess.org/msf-canada-briefing-note-wto-covid-19-trips-waiver
- EU: compulsory licensing and TRIPs waiver: https://msfaccess.org/analysis-eu-position-compulsory-licensing-and-trips-waiver-covid-19-pandemic
- Blog post: rebutting IFPMA rejection: https://msf-access.medium.com/will-history-repeat-itself-87b622
- 5 reasons of supporting the waiver: https://msfaccess.org/5-reasons-new-proposal-india-and-south-africa-could-be-gamechanger-covid-19-response
- Myths and realities regarding the COVID19 TRIPS waiver proposal: https://msfaccess.org/sites/default/files/2020-12/MSF-AC_COVID_IP_TRIPSWaiverMythsRealities_Dec2020.pdf
- Access challenges on COVID19 therapeutics: https://msfaccess.org/sites/default/files/2020-12/MSF-AC_COVID_IP_TRIPSWaiverMythsRealities_Dec2020.pdf
- Voluntary license and access to medicines: https://msfaccess.org/voluntary-licenses-access-medicines
- Overcoming IP barriers in COVID19: https://msfaccess.org/sites/default/files/2020-07/MSF-AC_COVID-19_IP-monopolies_briefing-doc_July2020.pdf

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