Access to COVID-19 Medical Tools

Overcoming Intellectual property and technology barriers towards a just and sustainable future

Panel of “Making int’l IP & trade regimes work to address the health response to COVID 19”

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MSF projects

Médecins Sans Frontières (MSF) is an independent and international non-governmental medical humanitarian organization. MSF provided humanitarian assistance in 72 countries in 2019.

"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

Access Campaign created in 1999

to push for access to live-saving/prolonging medicines, diagnostics & vaccines for patients around the world

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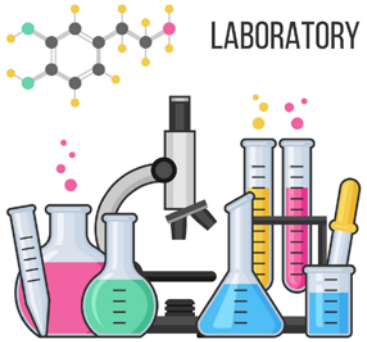
“Don’t trade our lives away”

“Health is not a commodity”

Architecture of excessive patenting



Patent Application | Patent Examination | Patent Term | Patent Expiry

Evergreening

Broad patentability

Linkage

Extensions

Data exclusivity

Investor-State

Border measures

Endless monopolies | Legal uncertainty for generics | Bankruptcy of health systems | Cyclic access crisis

IP and Access challenges in COVID-19

- COVID-19 pandemic context
  - Mobilization of R&D communities
  - Large number of pipeline medicines and vaccines, and unclear outcomes
  - Unprecedented public funding, and no strings attached
  - Pandemic affecting all types of countries and population
  - Double burdens for population suffer from existing hardship of healthcare
- Challenges to ensure universal equitable access
  - IP enables privatisation of public funded research and outcome
  - IP hinders full leverage of global capacity of development, manufacturing and supply
  - IP poses immediate and future hinderance to ensure universal access

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IP issues with COVID19 therapeutics

- Large group of therapeutics under testing
- Issues of concerns:
  - Repurposed therapeutics --- possible second medical use/indication patents
  - Patents on formulations for different patients groups
  - Methods of use patent applications
- Example of Remdesvir:
  - Negative example of IP management; limited to no medical efficacy Granted patents or applications in more than 70 developing countries
  - Voluntary license signed bilaterally
  - Excluding high burden middle income countries such as Brazil, and most of South American countries; excluding countries with manufacturing capacity and all HICs
- Biologics pipelines --- new candidates and high level of patenting: https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&page=1
- MSF briefing: https://msfaccess.org/sites/default/files/2020-09/MSF-AC_COVID_Rx_briefing-doc_Ed02-20200824_0.pdf

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IP issues with COVID19 vaccines

- Large number of candidates under testing
- Constant deny of industry that IP is an issue
- Broader range of IP issues of concerns for COVID-19 vaccines
  - Background technologies --- patents on main platforms
  - Foreground technologies --- patents on COVID19 vaccine products
  - Manufacturing knowhow and clinical data --- could be a hinderance when claimed as trade secrets or under exclusivity protection
  - Bilateral technology transfer and licensing remains non-transparent
- Past experience:
  - PCV13 patents hindered follow-on development and manufacturers in South Korea and India
  - Broader scope of patenting
    - Patents applied for across the entire process vaccine R&D, manufacturing and use
- MSF report on patents and vaccines: https://msfaccess.org/fair-shot-vaccine-affordability

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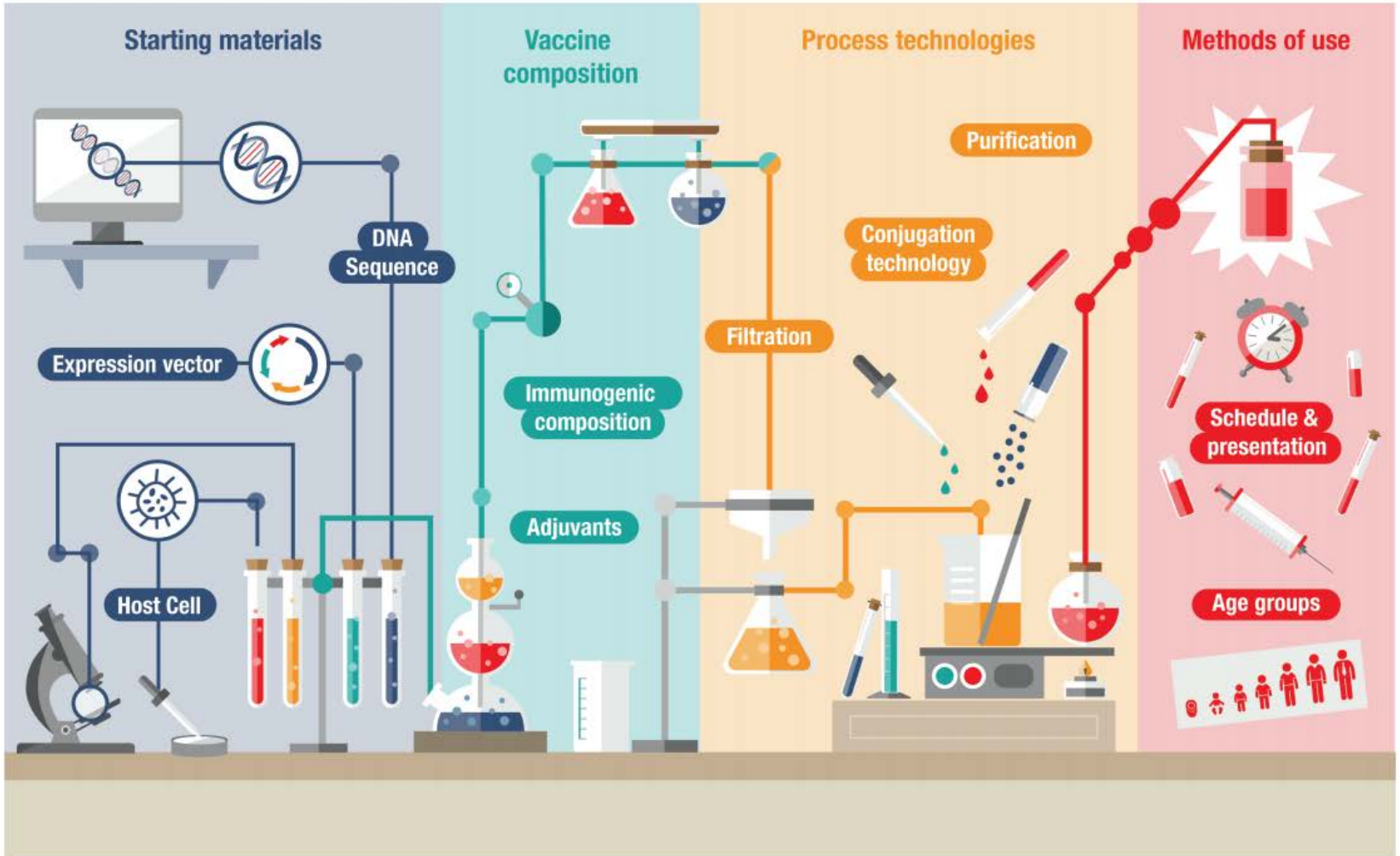
Figure 1: Examples of Patent Barriers Throughout the Vaccine Development Process and Beyond



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IP concerns on diagnostics

- MSF 2017 study on Xpert MTB/RIF (Cepheid), AlereQ HIV-1/2 Detect (Abbott) and OraQuick HCV Rapid Antibody Test (OraSure)
- The overall business model for diagnostics results in multiple dominant closed diagnostics systems, making competition extremely difficult.
- The high cost and burden of switching between systems results in a “locked-in” effects for end users.
- Major diagnostics companies in fact hold considerable numbers of patents, often bundled into thickets for various instrumentation, assays, methods and software, related to different aspects of the technologies, methodologies and devices.
- This proliferation of patenting may contribute to discouraging the development of open platforms for interoperable diagnostics.
- https://msfaccess.org/sites/default/files/2020-05/Diagnostics%20monopoly%20and%20IP%20-preliminary%20notes%20-%20MSF.pdf

- In COVID19 diagnostics – effects of the current development for the future diagnostics development remains unknown

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Overcoming IP and technology barriers

- 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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Cont.

- Limitations of voluntary licensing
  - Lack of legal obligation for transparency --- uncertainty on supply options
  - Terms and conditions limiting competition and hindering research and development
    - restrictive geographic scope;
    - restrictions on raw material supplies;
    - unethical terms of restricting domestic supply (eg. India as manufacturing only countries for AbbVie medicine glecaprevir/pibrentasvir for hep C)
    - Exclusive grant-back from licensee to licensor IP holding company
  - MSF report on voluntary license: https://msfaccess.org/voluntary-licenses-access-medicines
- Voluntary initiatives results in limited outcome in COVID-19
  - IFPMA openly rejected WHO C-TAP initiative
  - AbbVie non-assert announcement came after Israel compulsory license
  - Moderna non-assert announcement came after losing patent disputes and did not disclose manufacturing data and know-how

Cons.

- Limitations of resorting to “case by case”, “product by product” and “country by country” approach in the context of COVID-19
  - Compulsory license mechanism limiting to territorial
  - Art31bis remains within the territorial logic – one country (region) to another country (region) focused on dedicated products
    - Does not provide automatic and expedited solution
  - Public health safeguards unclear for trade scretes, manufacturing knowhow and data, subject to national and regional laws
  - Challenges of COVID-19:
    - Global needs of all effective products at once
    - Unequal manufacturing capacities in different countries – some can produce raw materials, other can do finished products or some other parts of the process
    - **Requires a truly global expedited and automatic solution in overcoming IP challenges**

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TRIPS waiver proposal – an opportunity

- South Africa, India, Kenya, Eswatini proposal to the WTO TRIPS Council in October
  - A waiver from certain provisions of TRIPS agreement during the pandemic
  - Scope: patents, industrial design, undisclosed information (test data, trade secrets), copyrights
  - Applicable to all WTO members who can choose to use the waiver when granted
  - Duration: until the majority of the world population received vaccine and develop immunity
  - Allow WTO members not to apply, implement and/or enforce IP
- First negotiation on October 15
  - Wide support by developing countries
  - EU + 8 countries opposed
- Following up negotiations in later November and December 2020

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Significance of the waiver proposal

- Addressing the limitation of the international IP law directly
- Provide critical legal option for countries to choose
- Taking governments back to the driving seats to ensure access
- Applicable to all countries

- MSF calls for all countries to join South Africa, India, Kenya and Eswatini to sponsor the waiver proposal
- The waiver proposal provides an unique opportunity to ensure truly global collaboration and delivery of universal access to COVID19 medial tools

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Remarks

- COVID-19 poses unprecedented challenges to ensure global uninterrupted access to technologies, materials and intellectual property to ensure sufficient production, supply and affordable access
- The measures supporting production and supply should support longer term sustainability of supply by supporting independent manufacturing and supply
- Clear limitations of relying on voluntary measures and traditional measures of overcoming IP
- Need to look for a global automatic and expedited solution – suspension of IP obligations through a general waiver under the TRIPS

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- Briefing: https://msfaccess.org/sites/default/files/2020-10/COVID_Brief_ProposalWTOWaiver_ENG_2020.pdf

- 5 reasons of supporting the waiver: https://msfaccess.org/5-reasons-new-proposal-india-and-south-africa-could-be-gamechanger-covid-19-response

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