



Access to COVID-19 Medical Tools

Challenges and Barriers concerning Intellectual Property

Médecins Sans Frontières, Access Campaign

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Introduction

- 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
 - Example of short of access to Oxygen supplied had led to rationing of support to our patients in Yemen
 - Access needs to be guaranteed for both existing and future medicines, vaccines and diagnostics

“Don’t trade our lives away”

“Health is not a commodity”



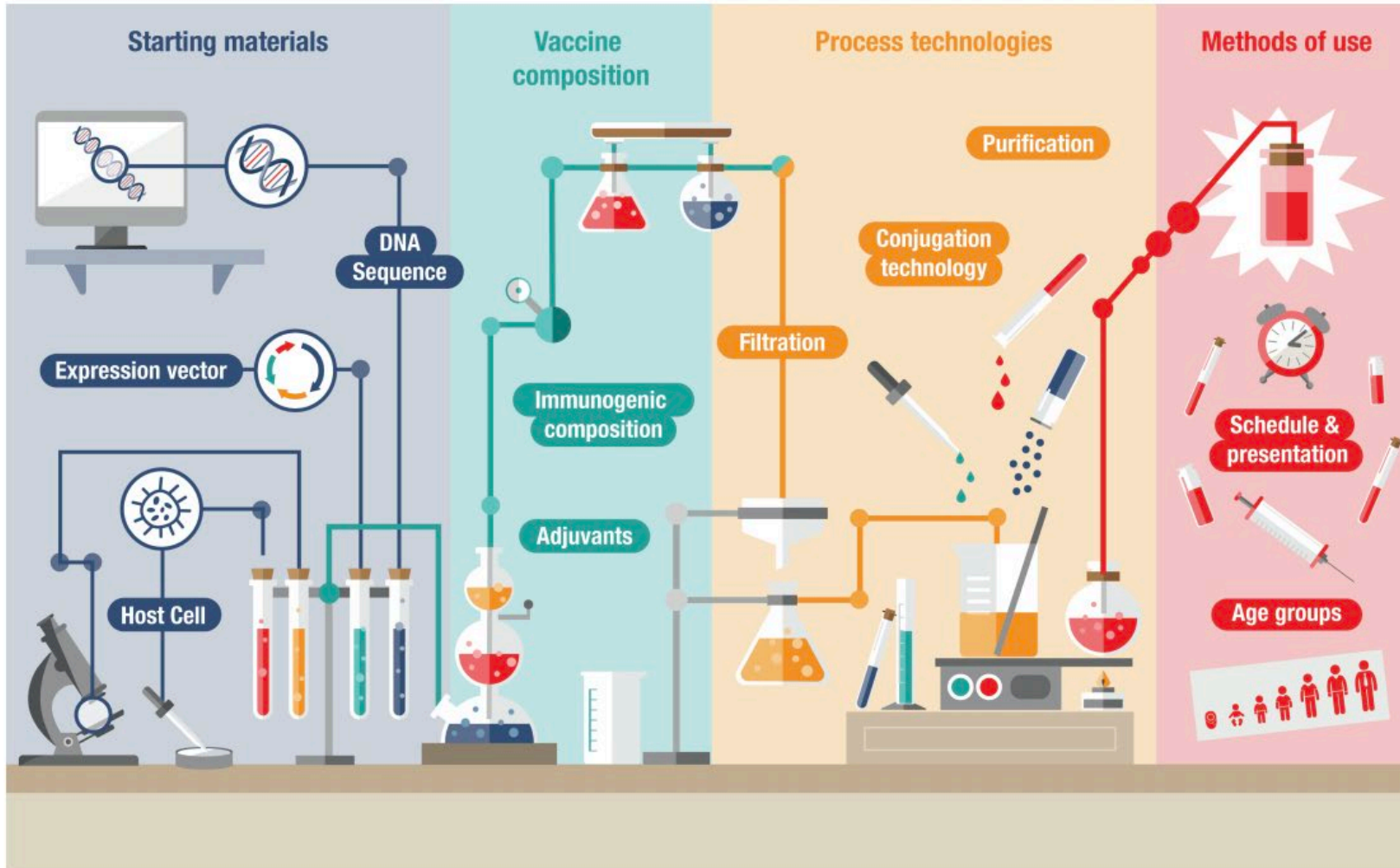
IP issues with COVID19 therapeutics

- 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:
 - 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
- Biologics pipelines --- new candidates and high level of patenting (TWN)
- MSF briefing: https://msfaccess.org/sites/default/files/2020-09/MSF-AC_COVID_Rx_briefing-doc_Ed02-20200824_0.pdf

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>

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



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.
- While conclusively saying one or two access-blocking patents are the key hinderance is not possible, 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>
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- In COVID19 diagnostics – effects of the current development for the future diagnostics development remains unknown

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

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 secrets, 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**

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>
- Voluntary license and access to medicines: <https://msfaccess.org/voluntary-licenses-access-medicines>