Removing Obstacles in Production, Supply and Access Challenges in COVID19

Médecins Sans Frontières, Access Campaign

April 07, 2021

"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

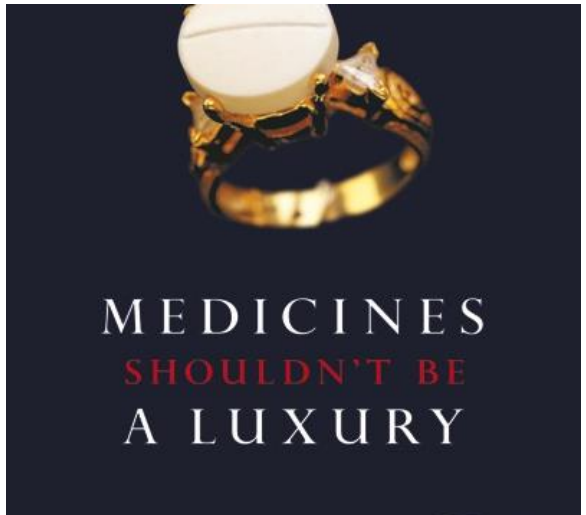
"Today, a growing injustice confront us (...) what we as a civil society movement demand is change, not charity"

Nobel Peace Prize Lecture, 1999

Dr. James Orbinski

Médecins Sans Frontières International President

Connecting to the history

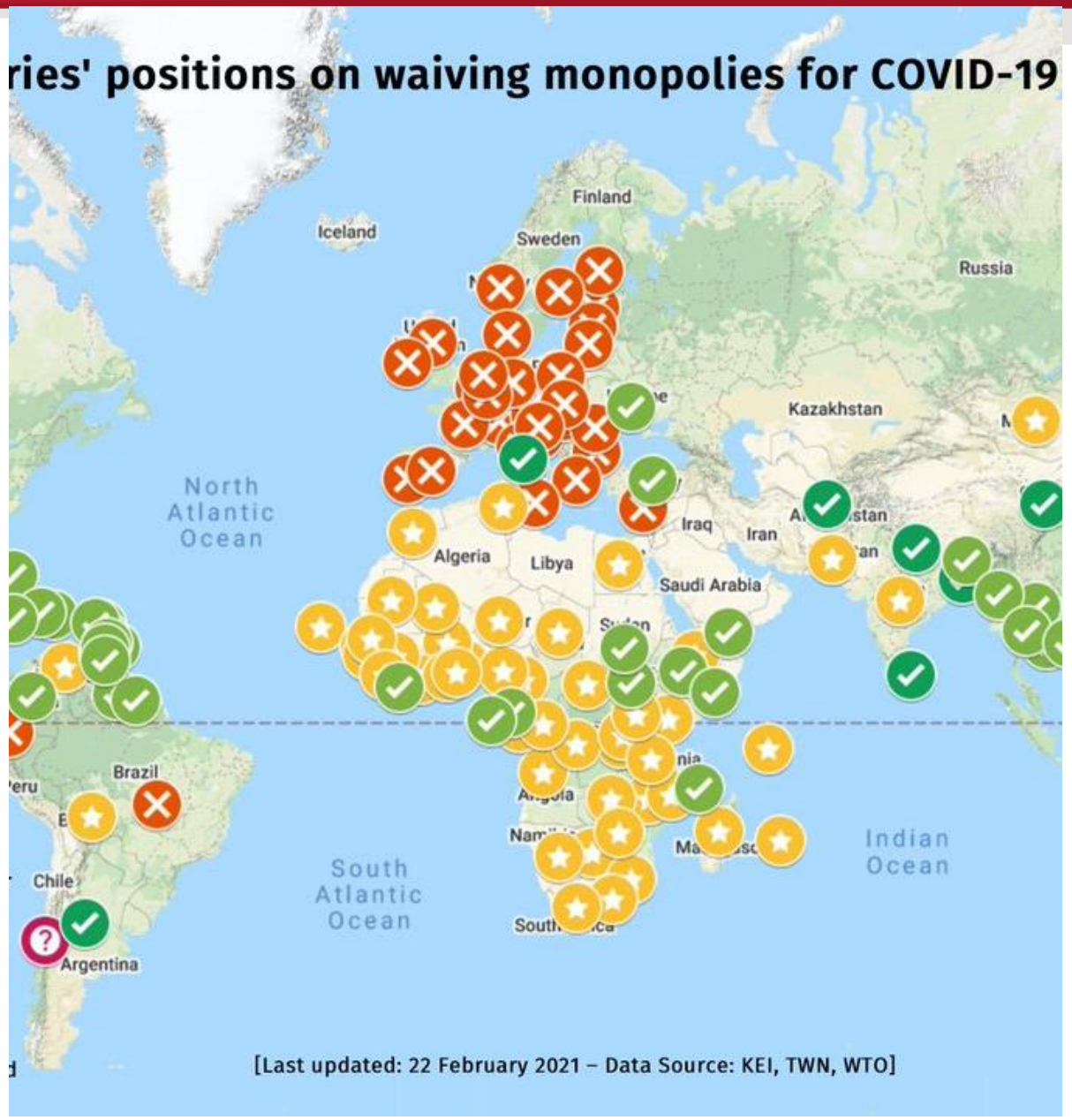


Access Campaign created in 1999 to push for access to live-saving/prolonging medicines, diagnostics & vaccines for patients around the world


Don't ruin it for everyone else.
Simple and clear,
DON'T BLOCK
THE PATENT WAIVER
NO PATENTS MONOPOLIES IN A PANDEMIC


BLACK LIVES MATTER
VACCINES FOR ALL!


Governments are taking a stand at WTO and you can get behind it
NO PATENTS PROFITEERING IN A PANDEMIC
URGENT
COVID-19
JAPAN AMBASSADOR
DELHI NETWORK OF POSITIVE PEOPLE
EUROPEAN UNION AMBASSADORS


ries' positions on waiving monopolies for COVID-19
Finland
Iceland
Sweden
Russia
Kazakhstan
North Atlantic Ocean
Iraq
Iran
Algeria
Libya
Saudi Arabia
Brazil
Chile
Argentina
South Atlantic Ocean
Indian Ocean
[Last updated: 22 February 2021 – Data Source: KEI, TWN, WTO]

Monopolies and 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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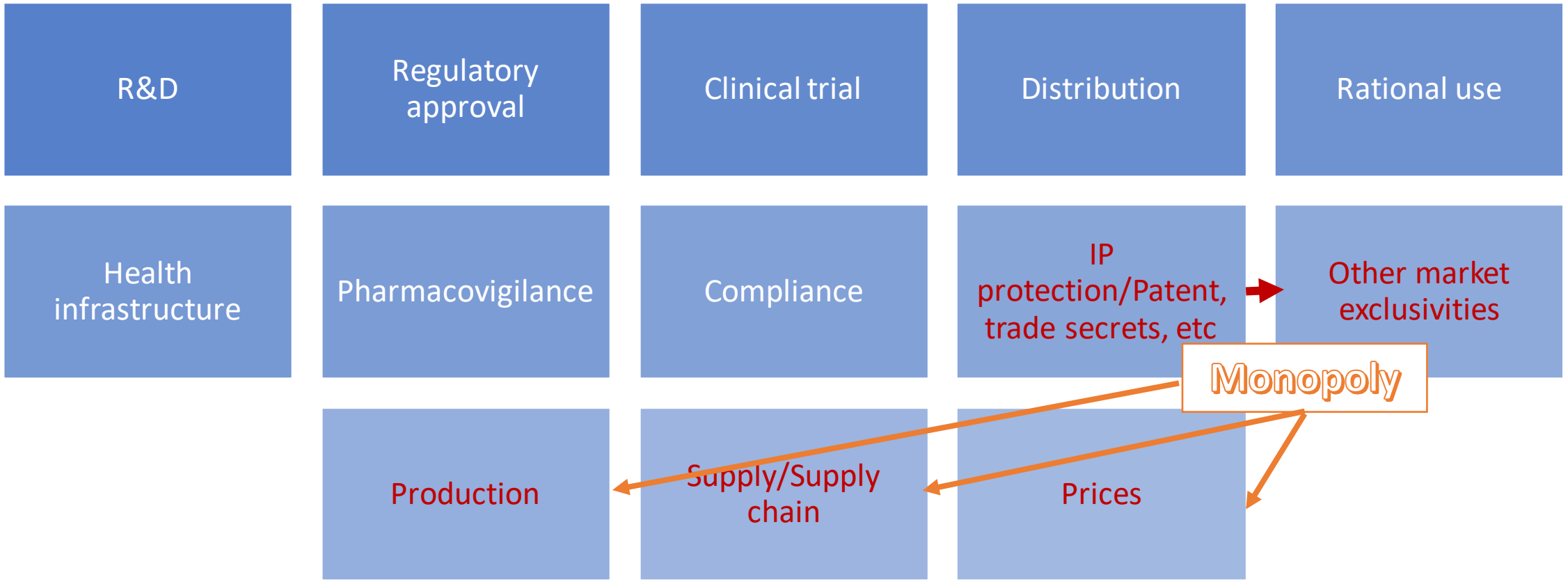

Many factors can have an impact on access to medicines

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 59 developing countries, including all countries in Africa Group and Least-developed countries group
- Opposed by a small group of countries, particularly high income countries including UK, EU, US, Australia, Switzerland, Japan, Norway, Canada, Brazil
- Negotiation ongoing but challenging due to different ideas; next meetings
  - April 22, informal WTO TRIPS Council meeting
  - April 30, formal WTO TRIPS Council meeting
  - May 5-6, WTO General Council meeting
- 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
- The waiver to be valid until vaccine is widely available and the majority of the world population developed immunity. Specific deadline unknow

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Myths and realities on the TRIPS waiver proposal

(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

Myth: IP issues are not barriers
Realities: past experience and emerging evidences of IP barriers

- **Therapeutics** -- Issues of concerns:
  - Repurposed therapeutics --- possible second medical use/indication patents
  - Patents on formulations for different patients groups
  - Methods of use patent applications
  - Other exclusivities such as Data Exclusivity and manufacturing data
- Example of Remdesvir:
  - Granted patents or applications in more than 70 developing countries
  - Voluntary license signed bilaterally
  - Excluding high burden middle income countries and most of South American countries
  - Efficacy in question, but IP practice sets negative example
  - Russia, Hungary issued compulsory license – but cannot export
- Other anti-viral and Biologics pipelines --- new candidates and high level of patenting need to be addressed
  - At-527, baricitinb --- patents filed and/or granted in more than 50 developing countries
  - Sarilumab --- patents granted and filed in more than 55 developing countries

MSF briefing: ***https://msfaccess.org/sites/default/files/2020-12/MSF-AC_COVID_IP_TRIPSWaiverMythsRealities_Dec2020.pdf***

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Cont.

- Vaccines: 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; large portfolio and legal risk
  - 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 or limited
- Past experience:
  - PCV13 patents hindered independent 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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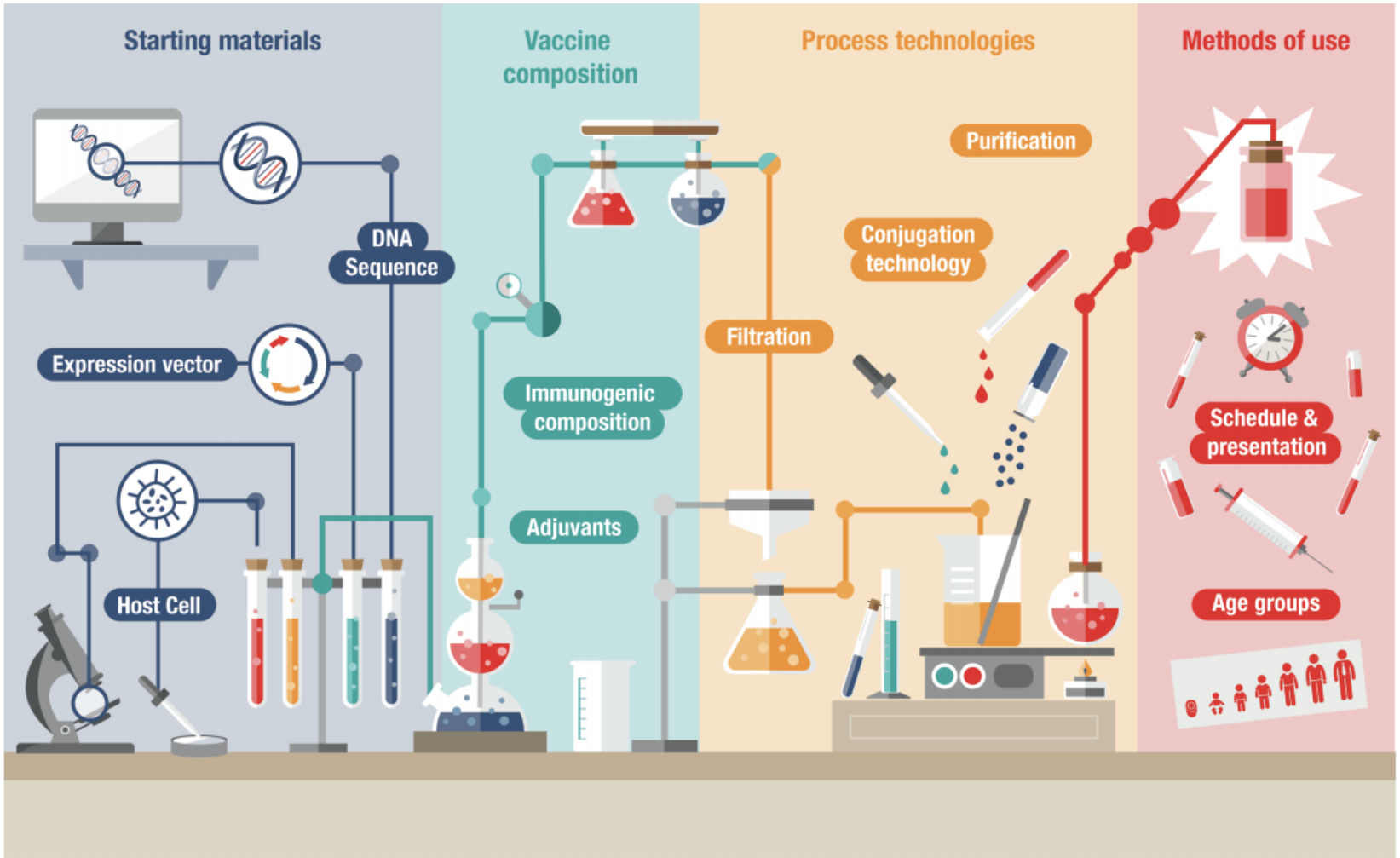
Figure 1: Examples of Patent Barriers Throughout the Vaccine Development Process and Beyond



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Myth: IP enabled R&D in COVID-19
Reality: R&D in COVID19 as a collective effort and driven by public funding

- Governments have been funding the development of COVID drugs and vaccines, and no company is able to meet the global demand.
- Billions of taxpayer dollars invested in R&D, and announcements that COVID-19 vaccines should be considered a public good, no government has openly stated committed to this undertaking.
- Monopoly-based and market-driven R&D model has proven as not fitting the purpose based on MSF experience
- COVID19 R&D involves global collective efforts by many different actors, it's not IP that have incentivised these efforts --- the profound impact of the pandemic and the common sense of trying to get out of the pandemic is the key incentive

- Additional claim by pharma: government is less risk-tolerate than private sector and government facilities should not produce medicines
  - In reality --- companies are pushing governments to take risk and take over products liabilities
  - Public facilities are mobilized to produce medicines and vaccines in the pandemic

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Myth: Voluntary measures are taking place and are sufficient
Reality: Limitations of voluntary measures

- 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;
    - Excessive anti-diversion requirement
    - 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
- IFPMA representing MNCs have rejected open voluntary licensing initiative led by WHO
- Bilateral voluntary licensing signed between companies remain mostly non-transparent, barring public scrutiny and accountability
- More contracted manufacturing -- with controlled supply, than independent producers who can decide on supply; some companies remain being denied to get production license despite negotiation
- MSF report on voluntary license: https://msfaccess.org/voluntary-licenses-access-medicines

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Myth: TRIPS flexibilities are sufficient
Reality: political, technical and practical challenges

- Trading and political pressures on using public health safeguards – TRIPS flexibilities -- by developing countries; i.e. USTR Special 301; EU IP enforcement report
- Industry condemn all countries who have considered or used public health safeguarding in the Pandemic –PhRMA submission to USTR Special 301 report criticises
  - Russian and Hungary overcome patents barrier to allow local production of remdesivir
  - EU for discussion of improving public health safeguarding in intellectual property laws
- Flexibilities focus on patents, less flexibilities on other IP, e.g. data exclusivity, undisclosed information, etc.
- 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
  - Public health safeguards unclear for trade secrets, manufacturing knowhow and data, subject to national and regional laws

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Myth: Even IP removed, developing countries cannot produce
Reality: Experience and evidences have proven that is wrong

- Developing countries have been producing medicines and vaccines
- Developing countries researchers and companies independently developed recombinant and conjugate vaccines, monoclonal antibodies, RCT testing platform
- Independent developers in India, South Korea and China have developed PCV which technologies were once claimed too complex
- India, China, Thai, Turkish researchers and companies are working independently on mRNA vaccines for COVID-19, esp. thermostable versions
- Existing capacity in developing countries is critical for ensuring global equitable access to COVID19 tools

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Remarks

- COVID19 access challenges and debates reveal the historical and structural inequality in health
- Lifesaving science and technology advancements remain controlled by private interests and lacking effective mechanism to ensure sharing and benefiting to all
- Longer term strategies and actions are urgently needed to interrogate the flaws of the current system of development, production and supply of health technologies that leaves disproportional disadvantages in LMICs
- Strategies and actions need to start from now in preparing for the future pandemic, particularly ensuring access to technologies by LMICs, and that the R&D would be truly based on and accounted for public health

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- Blog post: rebutting IFPMA rejection: https://msf-access.medium.com/will-history-repeat-itself-87b622
- Briefing: https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf
- 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
- 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
- Briefing on Canada position on compulsory license: https://msfaccess.org/msf-canada-briefing-note-wto-covid-19-trips-waiver.

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