WTO TRIPS waiver for COVID19

Médecins Sans Frontières, Access Campaign

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What happened so far?

- End of July, South Africa public communication to WTO TRIPS Council meeting, pointing out the challenges of ensuring access in developing countries and challenges of using TRIPS flexibilities
- Early July, Africa Union issues a Communique calling urgent actions to address IP barriers
- Since pandemic, pharma companies have continued business-as-usual on IP
- WHO C-TAP initiative openly rejected by IFPMA
- Proposal for a waiver from certain TRIPS provisions on COVID-19 related health technologies
- Ongoing process at the WTO – TRIPS Council and General Council

The waiver proposal

- A waiver to be granted to all WTO members so that they do not have to implement, apply or enforce certain obligations related to patents, undisclosed information, copyrights and industrial design related to COVID-19 health technologies
- The waiver to be in place until the majority of the world population receive effective vaccine and develop immunity

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Myths and realities

(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

- **Therapeutic**s -- 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
- 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

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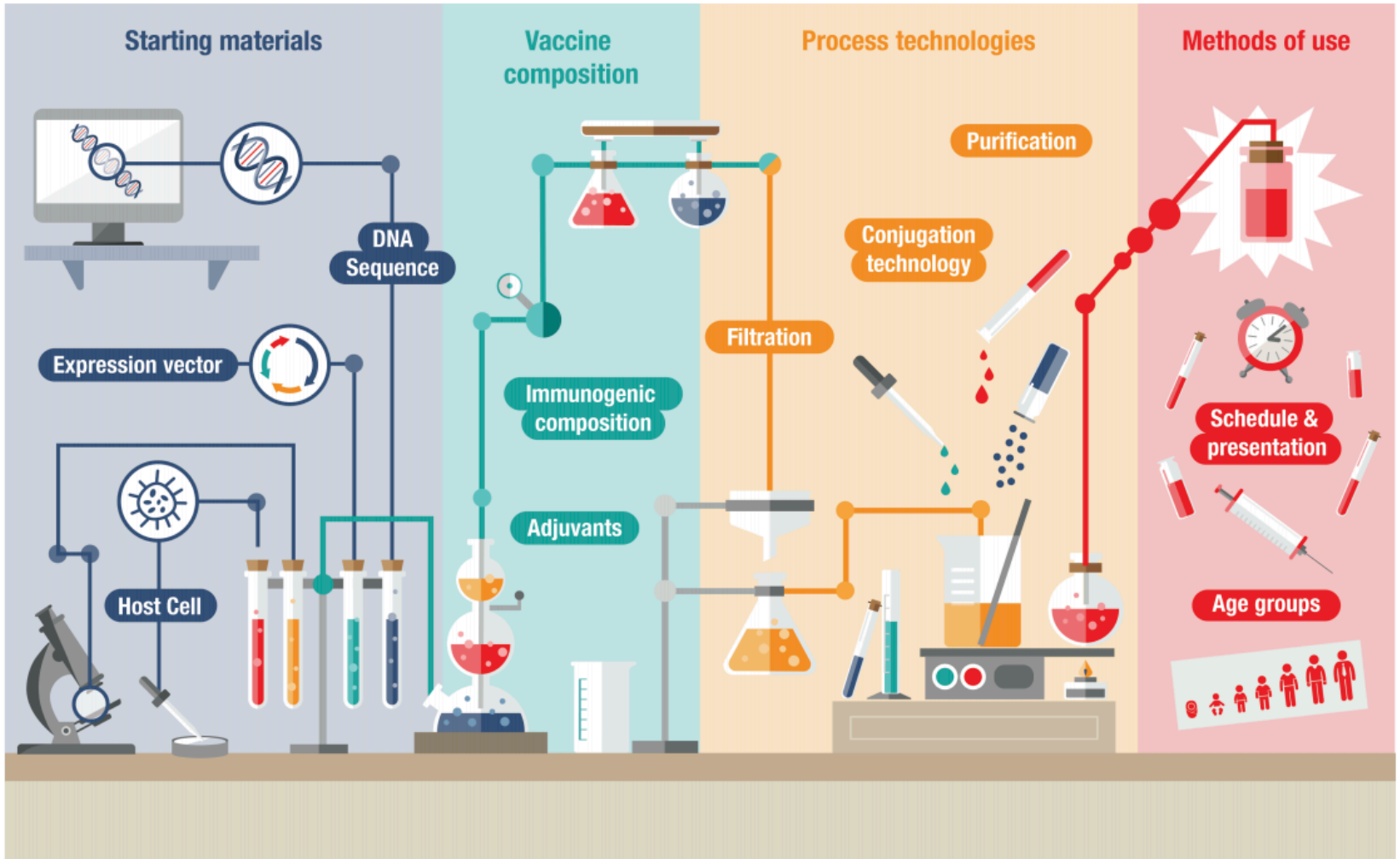
Figure 1: Examples of Patent Barriers Throughout the Vaccine Development Process and Beyond



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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

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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
  - 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
- 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
  - 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**

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Myth: ACT-A and COVAX can deliver equitable access
Reality: Wealthier countries are competing and undermining global initiatives via bilateral deals

- COVAX Facility and ACT-A are important mechanism but remains a donor-led model
- Majority of the countries who opposed the waiver proposal have pre-booked large portion of vaccine doses
- COVAX does not address sustainable access to knowledge, technology and IP issues
  - **EC/EU,** together with some other wealthier nations and regions, have already pre-booked more than 51% of the global supply capacity of the some potential future COVID19 vaccines – leaving limited share for developing countries and least-developed countries to share

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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
- India remains the pharmacy of developing countries
- 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 and China researchers are working on thermostable mRNA vaccines for COVID-19
- Existing capacity in developing countries is critical for ensuring global equitable access to COVID19 tools

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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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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 barriers
- Need to look for a global automatic and expedited solution – a general waiver from certain provisions under the TRIPS provides additional critical public health safeguards

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- 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

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