Legal/Policy Issues Affecting Access to Vaccines in Pandemic

- **Country Readiness**
  - Strengthening of health systems and primary health care being positioned at the center
  - Maintain sufficient health workers (including competitive salaries)
  - Modernize cold storage infrastructure to help ease logistical and supply chain challenges
  - Spreading manufacturing capacity to both boost overall global capacity.
- **Agreements to Develop New Health Interventions (Vaccines, Drugs, Diagnostics)**:
  - Agreements using public sector funds should require a pathway to achieve "Equitable Access" which that appropriate vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay.
  - The nature of leverage changed during the course of the pandemic as the global market changed
  - Leverage may also be limited due to relative (larger) size of previous investments in technology and companies
- **IP issues:**
  - For individual projects, IP issues are negotiated as part of development agreement – with agreements on market entry, out-licensing, and price/volume commitments
  - June 2022 Ministerial Decision on the TRIPS Agreement enabled waiver of "the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization."
  - Long-term solution to increase speed of response and enable access to vaccines in local market
    - There is a need to increase manufacturing capabilities and capacity in LMICs
    - Need to address technology transfer to LMICs in funding arrangements in an end-to-end fashion: from early discovery, R&D and

Legal/Policy Issues Affecting Access to Vaccines in Pandemic (Continued)

- **Liability & Indemnification**:
  - Companies reluctant to ship new products (especially based on new platforms) without provision to address liability.
  - COVAX established a system of indemnification and no-fault compensation for the "AMC 92" countries to address company liability concerns.
- **Regulatory:**
  - In pandemic, needed rapid decision making by regulatory authorities as to whether a given vaccine can be introduced to local market.
  - Variation in national regulatory systems, requiring multiple submissions, different national approaches to emergency authorization.
  - Efforts to establish regional regulatory systems and taking cognisance of work by other regulatory agencies
- **Tariff and Non-Tariff Barriers**
  - streamlining customs procedures.
  - decreasing and simplifying documentation requirements.
  - temporarily reducing or adjusting tariff rates and other charges on COVID-19 vaccines, therapeutics, diagnostics, and other essential medical goods, including their inputs.
  - regulatory cooperation, as appropriate, and the sharing of regulatory information on a voluntary basis.

IP & Data Access Issues Under Discussion – Future Pandemics

- WTO TRIPS “Waiver” for Vaccines – not Expanded to Drugs and Diagnostics.
- Further integration of IP and licensing matters in public funded early-stage discovery to manufacture and delivery
  - ARPA-H expanded DARPA Heilmeier Questions to include “to ensure equitable access for all people, how will cost, accessibility, and user experience be addressed? https://arpa-h.gov/careers/program-managers/
  - Will this lead to realignment among government, industry, university sector on ownership and licensing of IP rights? Is Bayh-Dole off limits for reform?
- Goal of 100 days from discovery of new pathogen to new vaccine available for use: tighten existing processes, establish library of vaccines against known pathogens?
  - IP-related agreements need to be pre-positioned – pre-pandemic
- Climate change is expanding and accelerating public-health threats
  - UNFCCC requires technology transfer, but what is role of IP?
  - UNFCC (Article 4(5)) requires “developed country Parties . . . [to] take all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, environmentally sound technologies and knowhow to other Parties, particularly developing country Parties, to enable them to implement the provisions of the Convention.”
- Open Science – OSTP launched “year of open science” in January 2023 “to ensure, consistent with law, the public has access to federal government data, research, and information, and to empower citizens to participate in the work of government.” https://www.whitehouse.gov/ostp/news-updates/2023/01/11/fact-sheet-biden-harris-administration-announces-new-actions-to-advance-open-and-equitable-research/
  - What is the role of IP in “open science” – does it call for the absence of IP rights or is it an IP licensing question?
- Data – rapid access to pathogens and digital sequence data is key to ensuring rapid development of needed, new health interventions – questions remain as to benefits to be shared with providers of pathogens and digital sequence data

Deep Dive on Data Access Issues

- Data archetypes in Public Health: (1) patient data, (2) health systems data, (3) routine public health data, and (4) health research data – including from clinical trials.

- Focus here is on sharing health research data – including sharing scientific research data and clinical trial data for transparency and reproducibility.

- Emerging consensus is that while the sharing of data that reveals personal sensitive data should not occur without permission – all other data should be available (under certain circumstances)
  (1) Data may be available with or without conditions on the data recipient
  (2) Clinical Trial Data presents unique challenges due to commercial value of clinical trial results and data exclusivity

- Most vexing issue at present is access to pathogen gene sequence data – necessary for rapid development of public health interventions
  (1) Modern history of issue (CBD, Nagoya Protocol, Pandemic Influenza WHO Pandemic Influenza Preparedness Framework, COVID-19 experience More on this below in section on Pandemic Treaty

Deep Dive on Patent Availability and Licensing Issues

- Efforts have long been underway to exclude certain subject matter from patent protection or limit the scope of patent exclusivity to address access to technology and products to address global issues in health, biodiversity, climate change, traditional knowledge, etc. Focus shifted to TRIPS Agreement after it came into force in 1995.

- June 2022 five-year waiver of certain TRIPS obligations regarding compulsory licenses to COVID-19 vaccine-related patents – but not to limit the availability of such protection. "Waiver" allows compulsory license for domestic use and export, allows for re-export, and allows for some limitations to compensation to be paid to patent owner.

- Effort to establish a similar TRIPS "Waiver" for drugs and diagnostics failed to reach consensus at the WTO and is not being pursued.

- Moderna patent "waiver" of COVID-19-related patents during pandemic – not used.

- mRNA COVID-19 Vaccine Hub: The Medicines Patent Pool, WHO, Afrigen, BIOVAC, South African Medical Research Council.*

  (1) Limited by desire of patent-owning companies to participate and sufficient demand to stand up additional manufacturing capacity.

  (2) Limited by demand to warrant new capacity [Note: Astra-Zeneca announced withdrawal of their COVID-19 vaccine from global market due to lack of demand.**]

* https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub
** https://www.cnn.com/2024/05/08/business/astrazeneca-covid-vaccine-withdrawal/index.html

Deep Dive on Pandemic Treaty Negotiations

In December 2021, the World Health Assembly met in a Special Session (the second-ever since WHO's founding in 1948) and decided to establish the International Negotiating Body to draft and negotiate "a WHO convention, agreement, or other international instrument on pandemic prevention, preparedness and response. The process has involved participation of other United Nations system bodies, non-state actors, other relevant stakeholders, and the public."

29 March 2024 Joint Update by the Department of State and the Department of Health and Human Services on Negotiations Toward a Pandemic Accord - United States Department of State – Generally Supportive

22 April 2024 version of "Proposal for the WHO Pandemic Agreement WHO" - A_inb9_3Rev1-en.pdf (who.int):

(Article 9): "The Parties shall cooperate to build, strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, based on a shared agenda, and shall promote research collaboration and access to research through open science approaches for the rapid sharing of information and results, especially during pandemics."

(Article 10.1): "The Parties commit to achieving more equitable geographical distribution and scaling up of the global production of pandemic-related health products and increasing sustainable, timely, fair and equitable access to such products, as well as reducing the potential gap between supply and demand during pandemics, through the transfer of relevant technology and know-how on mutually agreed terms."

(Article 11.1): "Each Party shall, in order to enable the sufficient, sustainable and geographically diversified production of pandemic-related health products, and taking into account its national circumstances: (a) promote and otherwise facilitate or incentivize the transfer of technology and know-how for pandemic-related health products, in particular for the benefit of developing countries and for technologies that have received public funding for their development, through a variety of measures such as licensing, on mutually agreed terms; (b) publish the terms of its licenses for pandemic-related health technologies in a timely manner and in accordance with applicable law, and shall encourage private rights holders to do the same;"

Deep Dive on Pandemic Treaty Negotiations (Continued)

22 April 2024 version of "Proposal for the WHO Pandemic Agreement WHO" - A_inb9_3Rev1-en.pdf (who.int):

Article 12.1 "Access and benefit-sharing 1. A multilateral access and benefit-sharing system for pathogens with pandemic potential, the WHO Pathogen Access and Benefit-Sharing System (PABS System), is hereby established to ensure the rapid, systematic and timely sharing of PABS material and information for, inter alia, public health risk assessment and, on an equal footing, timely, effective, predictable and equitable access to pandemic-related health products and other benefits, both monetary and non-monetary, arising from such sharing."

- The modalities, terms and conditions, and operational dimensions of the PABS System shall be further defined in a legally binding instrument that will be operational no later than 31 May 2026.
- Provisions that cause concerns as a pass-through obligations from Member States to apply to manufacturers:

(1) "not seeking to obtain intellectual property rights on PABS material and information"

(2) "the fair, equitable and timely sharing of benefits, both monetary and non-monetary, arising from access to PABS material and information, in accordance with modalities, terms and conditions to be determined and agreed"

(3) "in the event of a pandemic, real-time access by WHO to 20% (10% as a donation and 10% at affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related health products"

(4) "a mechanism to ensure the fair and equitable allocation and distribution of the pandemic-related health products . . . shall be developed, taking into account public health risks, needs and demand"

(5) "Each Party that has manufacturing facilities that produce pandemic-related health products in its jurisdiction shall take all necessary steps to facilitate the export of such products, in accordance with timetables to be agreed between WHO and the relevant manufacturers."