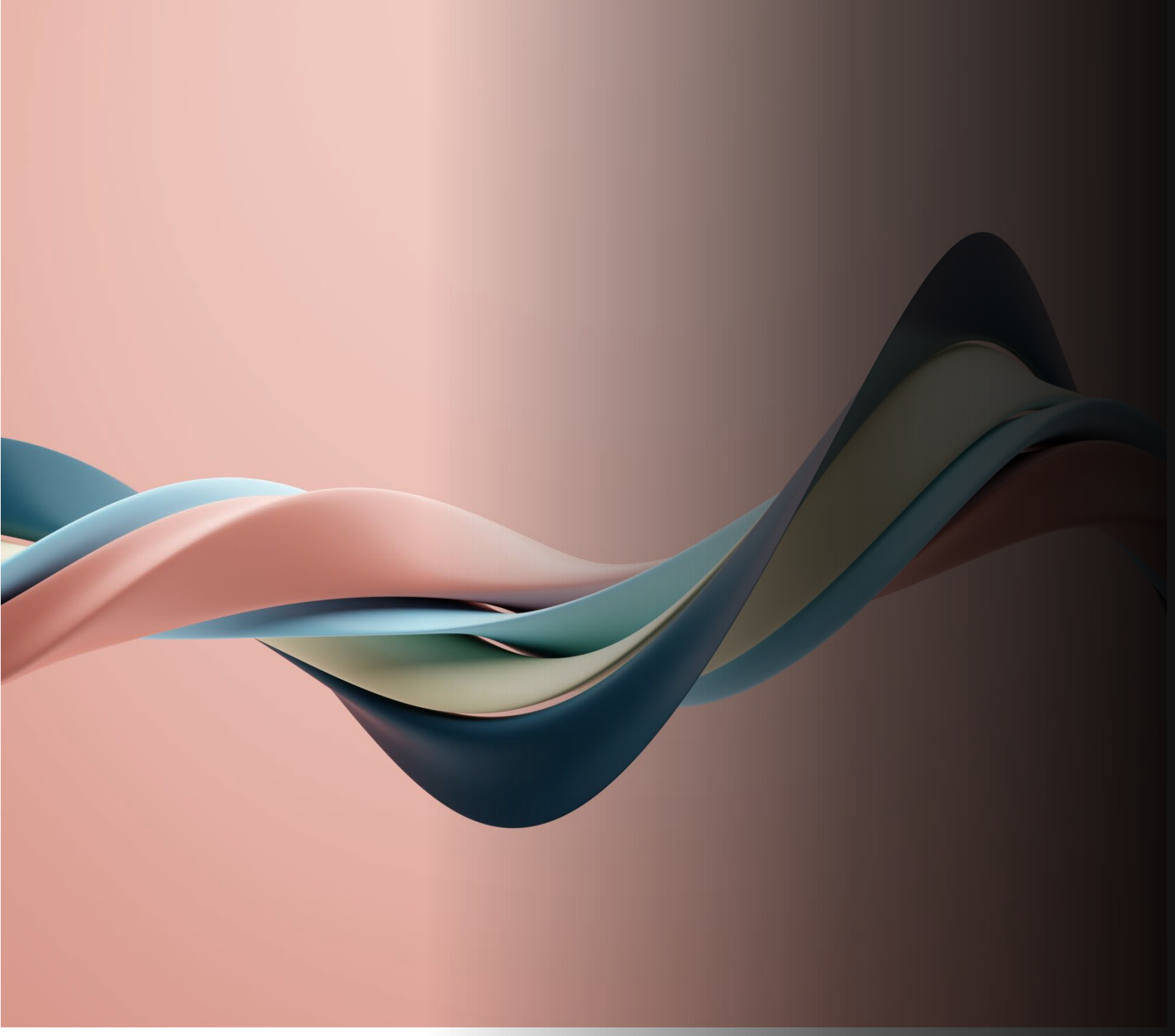

Intellectual Property and Technology Transfer for COVID-19 Vaccines

Assessment of the Record

AVPA-AVMI Private Sector Workshop on Technology Transfer

November 17, 2023

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Background

- In March 2023 presented fundamentals of technology transfer licensing at AVPA workshop
- Today will discuss findings of Study prepared for World Intellectual Property Organization (WIPO):
  - Frederick Abbott, Intellectual Property and Technology Transfer for COVID-19 Vaccines : Assessment of the Record, World Intellectual Property Organization, Geneva (2023); also, Executive Summary
  - https://tind.wipo.int/record/48613
  - https://tind.wipo.int/record/48614

Premise and Query

- COVID-19 vaccine response inequitable in terms of sequence and quantity: high- and upper-middle income countries (HICs and UMICs) preferred over low- and middle-income countries (LMICs)
- Query: What role did intellectual property (IP) and technology transfer play?
  - Were IP rights the cause of the inequity?
- Answer: IP and technology transfer played their customary role in securing and moving technology through the vaccine development, production and distribution value chain

Multiple Factors Affected Response

- At “Day 0” world was unprepared for pandemic
- Development of candidates and regulatory approval delayed rollout about 1 year despite accelerated procedures (e.g., emergency use authorizations) and development subsidies
- Relatively smooth path of Pfizer/BioNTech, Moderna, and with qualification, AstraZeneca/Oxford - not matched by other private sector actors
  - Johnson & Johnson prime manufacturer (Emergent) failed, Curevac vaccine failed, Novavax heavily delayed
  - AstraZeneca early manufacturing/clinical trial problems, India export ban

Multiple Factors Affected Response

- Sinovac/Sinopharm served domestic China market and exported, including technology (e.g., Sinovac-Vacsera (Egypt))
  - Gamaleya/Sputnik V production delays
- Supply sequencing largely determined by advanced purchase agreements (APAs) used to fund and “derisk” by US, EU and other HICs
  - Result was front-of-line position for supplies
  - APAs characterized by “atypical” terms
- Foundations such as CEPI/Gates provided funding including “access” conditions (e.g., pricing for LMICs), leading to USD 3/dose for AZD1222 from Serum Institute of India (SII)

Technology transfer

- Technology licensing a central feature of COVID-19 response
- In-licensing of foundational mRNA technologies (e.g., uracil substitute, lipid nanoparticle) from Univ. of Penn., Acuitas and others – these licenses “non-exclusive”
- Out-licensing to contract manufacturing organizations (CMOs
- AstraZeneca to SII (India) and Fiocruz (Brazil)
- No major party “opened” its technology (i.e., remained under control)

Patents and trade secrets

- On one hand, producer/patent/trade secret owners retained control over their technology; on the other hand, they did not threaten third parties with infringement actions or seek to enjoin
- Moderna refused to provide technical assistance to Afrigen, instead committing to build plant in Africa
  - Query whether feasible to retrofit or build facilities, achieve cGMP, obtain regulatory authorization, and produce at scale within emergency phase of pandemic
- Evidence lacking of patents blocking additional entrants into “vaccine race”. Would have faced same challenges as others
  - Alternatives in adenovirus vector technology that may have avoided potential patent barriers
  - A range of technological approaches pursued by vaccine developers

Conclusion

- Lessons from the HIV-AIDS epidemic are not easily transposed to COVID-19 from a technology standpoint
  - HIV-AIDS access demands addressed previously developed small molecule technology covered by discrete number of patents with alternative suppliers (e.g., Cipla) ready to produce
  - COVID-19 involved multiple vaccine technologies, mRNA previously unused, and complex supply chains
  - Developing vaccine candidates and new production processes not “solved” by access to patents – know-how a key factor

Conclusions

- Vaccine inequity was result of multiple factors including vaccine science, regulatory requirements, supply chain issues
  - IP may have played a role, but not the principal cause
- Improvements needed in various areas, including rapidly adaptable vaccine candidate platforms, reduced regulatory timelines and “standby” production capacity (e.g. Germany-GSK/Curevac), financing facility
- Mechanism for developing and sharing technical solutions beyond reference to flexibilities. Technology acquisition financing facility may help overcome tensions
  - mRNA Hub concept may be broadened
  - In-licensing of component technologies when needed
  - Governments have options for overcoming patent barriers when required – national laws should be in place – should not wait for emergency to prepare legal framework
- “Pandemic vaccines” are not a “normal market” and should not be treated as such

Thank you

Collaboration and innovative solutions needed to prepare for future emergencies.

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