

The background is split into two vertical panels. The left panel is light gray with several realistic water droplets of various sizes scattered across it. The right panel shows a close-up of a laboratory setting with a petri dish, a beaker containing yellow liquid, and several blue and purple microcentrifuge tubes. The overall aesthetic is clean and scientific.

# REFLECTIONS ON FOUR SETS OF CHALLENGES

## NAVIGATING THE PATH FORWARD IN IMPROVING ACCESS WITH COLLECTIVE ACTION AFTER THE WLPF

World Health Organization Local  
Production and Assistance (LPA) Unit  
Panel

12<sup>th</sup> Annual Investment Meeting (AIM  
Global 2023)

Abu Dhabi, UAE, May 8, 2023

**Prof. Frederick Abbott**  
Member LPTT-Technical  
Advisory Group  
FSU College of Law

# WHO NEGOTIATIONS

- PANDEMIC ACCORD
- INTERNATIONAL HEALTH REGULATIONS (2005) AMENDMENTS
- DRAFT PROVISIONS DIRECTED TOWARD ENHANCING THE CAPACITY OF LMIC IS TO PRODUCE HEALTH PRODUCTS, INCLUDING VACCINES, THERAPEUTICS AND DIAGNOSTICS, AS WELL AS MEDICAL EQUIPMENT
- RECOMMENDATIONS REGARDING INTELLECTUAL PROPERTY RIGHTS AND TECHNOLOGY TRANSFER

# WHO NEGOTIATIONS

- CONTENTIOUS SUBJECT MATTER
- TRYING TO NEGOTIATE INSTRUMENTS ON SIMILAR SUBJECT MATTER IN PARALLEL,
- SUBJECT MATTER SCOPE FOR IHR IS LIMITED BY PROVISIONS OF THE WHO CONSTITUTION
- ISSUES REGARDING THE PROCESSES BY WHICH AGREEMENTS WOULD ULTIMATELY BE BROUGHT INTO FORCE
- MOVING FORWARD ON LOCAL PRODUCTION SHOULD NOT AWAIT OUTCOME

# FOCUS ON AFRICA

- THE AFRICAN UNION HAS REPEATEDLY ENDORSED REGIONAL IMPROVEMENT OF LOCAL PRODUCTION CAPACITY
- AFRICAN FREE TRADE AGREEMENT PROVIDES MECHANISM FOR IMPROVING THE INTEGRATION OF THE AFRICAN ECONOMIES THROUGH REDUCTION OF TARIFF AND OTHER TRADE BARRIERS
- AFRICAN MEDICINES AGENCY HAS BEEN CREATED AND ITS CENTRAL AUTHORITY SITUATED IN KIGALI, RWANDA.
  - THE INITIAL AIM OF THE AGENCY IS TO MOVE TOWARD HARMONIZATION OF REGULATORY REQUIREMENTS ON THE CONTINENT

# FOCUS ON AFRICA

- IMPLEMENTING CONTINENTAL INTEGRATION INVOLVES A MYRIAD OF CHALLENGES
- “DEFAULT” MECHANISM FOR ENHANCING LOCAL PRODUCTION IN AFRICA IS PRIVATE SECTOR INITIATIVE AND COUNTRY BY COUNTRY ADOPTION OF LEGISLATIVE AND OTHER POLICIES DESIGNED TO PROMOTE LOCAL PRODUCTION
- ASSUMING REGIONAL HUBS AND THAT CERTAIN GEOGRAPHIC LOCATIONS WOULD NEED TO BE IDENTIFIED FOR REGIONAL PRODUCTION HUBS, HOW WILL THOSE BE SELECTED?
- HOW WOULD DECISIONS ABOUT ALLOCATING PRODUCTION AND BUDGETARY ISSUES QUESTIONS BE ADDRESSED? WOULD PRODUCERS AND REGIONAL CENTERS PAY TAXES AND, IF SO, TO WHAT AUTHORITY?
- ALTERNATIVES OF DISTRIBUTING VALUE CHAIN AND REGIONAL CHAMPIONS

# FINANCING AND MARKETS

- MARKET FOR PANDEMIC VACCINES IS ALMOST BY DEFINITION “EPISODIC”
- WILL THE PRIVATE FINANCING MARKET BE INTERESTED IN CREATING STANDBY CAPACITY FOR VACCINE MANUFACTURING?
- GERMAN GOVERNMENT RECENTLY ESTABLISHED A PANDEMIC PREPAREDNESS ARRANGEMENT WITH GSK AND CUREVAC
- PRINCIPAL FUNDING FOR THE RAPID SCALE UP OF COVID-19 VACCINES CAME FROM THE US GOVERNMENT OPERATION WARP SPEED WITH ADVANCE PURCHASE COMMITMENTS AND DEVELOPMENT FINANCING, AS WELL AS LARGE-SCALE EUROPEAN UNION ADVANCE PURCHASING COMMITMENTS
- THE GATES FOUNDATION PLAYED A SUBSTANTIAL ROLE IN FINANCING THE ASTRAZENECA/OXFORD VACCINE THAT WAS ULTIMATELY PRODUCED IN LARGE QUANTITY BY THE SERUM INSTITUTE INDIA

# FINANCING AND MARKETS

- VACCINES, AND PARTICULARLY PANDEMIC VACCINES, ARE BUT A SMALL COMPONENT OF MEDICINES THAT ARE MANUFACTURED AND ULTIMATELY TO BE SUPPLIED BY LOCAL PRODUCTION
- WIDE SPECTRUM AMONG COMPANIES OPERATING IN LOW INCOME ENVIRONMENTS FACING CHALLENGES IN TERMS OF FINANCING THEIR OPERATIONS, EITHER THROUGH PRIVATE INVESTORS OR BANK FINANCING, AND IN MANUFACTURING AND SELLING PRODUCTS PROFITABLY IN LOCAL MARKETS
  - COMPETE WITH FOREIGN SUPPLIERS, INCLUDING LOW-COST CHINESE AND INDIAN SUPPLIERS
- AFRICAN DEVELOPMENT BANK TAKING INTEREST IN PHARMACEUTICAL PRODUCTION IN AFRICA, INCLUDING VACCINE PRODUCTION, AND THIS IS ONE PROMISING DEVELOPMENT. DE-RISKING INVESTMENTS FOR OUTSIDE INVESTORS, SUCH AS FOREIGN SOVEREIGN WEALTH FUNDS, INCLUDING BY PROVIDING INSURANCE BACKSTOP IS APPROACH THAT MAY PROVE IMPORTANT

# INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

- FOR MANY PRODUCTS THAT MAY BE PRODUCED LOCALLY IN LMICS, IP BARRIERS SHOULD NOT BE A MAJOR ISSUE.
- SO-CALLED GENERIC DRUGS ARE LONG-ESTABLISHED, WITH FORMULAS PUBLISHED IN PUBLICLY AVAILABLE FORMULARIES, AND WITH PRODUCTION EQUIPMENT AVAILABLE AT INTERNATIONAL TRADE SHOWS
- LOCAL PRODUCTION AND ASSISTANCE UNIT OF WHO PROVIDES GUIDANCE TO LMIC MANUFACTURERS WITH RESPECT TO GMP COMPLIANCE AND REGULATORY APPROVALS
- ORIGINATOR PHARMACEUTICAL COMPANIES RELUCTANT TO OUT-LICENSE HIGH-VALUE PRODUCTS, SUCH AS NEWER ANTI-CANCER AND ANTI-INFLAMMATORY BIOLOGIC MEDICINES, PREFERRING TO KEEP TECHNOLOGY CONTROLLED “IN-HOUSE”



# INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

- LMIC THAT WANTS TO MANUFACTURE NEWER HIGH-VALUE ADDED PRODUCTS WILL EITHER NEED TO DEVELOP THE TECHNOLOGY ITSELF, OR OBTAIN IT FROM AN ORIGINATOR. OTHERWISE, BLOCKED BY PATENTS AND OFTEN TRADE SECRETS THAT ARE NEEDED TO IMPLEMENT MANUFACTURING PROCESSES, TESTING AND SO FORTH
- POTENTIAL FOR JOINT VENTURE ARRANGEMENT WITH THE ORIGINATOR PATENT OWNER
  - LOCAL PURCHASING PREFERENCES MAY HELP INDUCE
- GOVERNMENTS HAVE AUTHORITY TO GRANT LOCAL ENTERPRISES SO-CALLED COMPULSORY LICENSES THEM TO USE FOREIGN-OWNED PATENTS, ON PAYMENT OF ADEQUATE REMUNERATION TO THE PATENT OWNER.
  - GOVERNMENTS MAY ALSO USE A FORM OF COMPULSORY LICENSING, KNOWN AS GOVERNMENT USE LICENSING, TO USE PATENTS FOR GOVERNMENTAL PURPOSES, SUCH AS PRODUCTION TO SUPPLY LOCAL PUBLIC HEALTH NEEDS

# INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

- DURING COVID-19 PANDEMIC INDIA AND SOUTH AFRICA INITIATED DEMAND FOR A WAIVER OF THE TRIPS AGREEMENT AT THE WTO TO FACILITATE ACCESS TO TECHNOLOGY FOR LOCAL PRODUCTION. ENSUING NEGOTIATIONS HIGHLY CONTENTIOUS, LIMITED RESULT
- FROM GLOBAL STANDPOINT IS THERE BETTER WAY TO DEAL WITH THE DEVELOPMENT AND USE OF THE TECHNOLOGY THAT GOES INTO HEALTH PRODUCTS, INCLUDING VACCINES AND PHARMACEUTICALS? IS THERE A WAY TO FINANCE THE CREATION OF NEW TECHNOLOGIES IN A WAY THAT MAKES THEM WIDELY AVAILABLE TO PRODUCERS AROUND THE WORLD, AND ULTIMATELY MORE ACCESSIBLE TO PATIENTS?
- QUESTION GOING BACK TO 1960S AND DISCUSSIONS THAT BEGAN AT UNCTAD. A LONG-STANDING CHALLENGE, WITH ANY NUMBER OF IDEAS FOR SOLVING IT HAVING BEEN PUT FORWARD OVER THE YEARS
- NO EASY END IN SIGHT ....