Unweaving our tangled patent web: Negotiating a framework for the sharing of influenza viruses with human pandemic potential

Prof. Frederick M. Abbott

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A problem with three elements

- Defining ownership of the basic materials used in the research and development of vaccines and drugs to address influenza viruses with pandemic potential
- Defining rights to patents and other forms of intellectual property based on or derived from shared virus samples
- Defining the nature of benefits to be shared from authorized access to virus samples

Sovereign ownership of natural resources

- Surprised initial WHO and media reaction to the Indonesia's decision to withhold virus samples
  - Assumption that because materials necessary to protect public health such materials constituted international public goods
  - WHO Collaborating Centers served as conduit to originator industry and did not constrain use of samples (e.g., restricting patenting of derivative products)
- Materials necessary to protect public health today commonly subject to legal restriction
  - Line-drawing is problematic
  - What distinguishes a cure for cancer, a treatment for HIV-AIDS and a virus sample?

Public international law

- Sovereign rights over natural resources found within the national territory (and exclusive economic zone, etc.) widely recognized
  - United Nations General Assembly resolution 1803 (XVII) of 14 December 1962, "Permanent sovereignty over natural resources"
  - United Nation's Convention on the Law of the Sea in 1982 (UNCLOS)
  - Decisions of International Court of Justice and WTO Appellate Body
    - E.g., North Sea Continental Shelf Cases (Federal Republic Of Germany/Denmark; Federal Republic Of Germany/Netherlands), International Court of Justice, Judgment of 20 Feb. 1969
  - Petroleum, natural gas, coal, copper and iron, fisheries

Biological materials are natural resources

- Biological materials containing virus samples, absent some special exception, should fall within natural resources located within the territory of the state as a matter of public international Law
- This does not imply that host state is not constrained by international legal obligations, such as obligation to protect human rights to life and health, obligation to protect against harm to neighboring states (e.g., precautionary principle), etc.

Convention on Biological Diversity (CBD)

- Broad language of CBD may cover virus samples
- If so, then set of rights and obligations is established
- Preamble of the CBD *"Reaffirm[s]* that States have sovereign rights over their own biological resources."
- Article 15.1 of the CBD: "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."
- "Biological resources" and "genetic resources" are defined differently, with potentially different consequences for virus-sharing

Biological resources and genetic resources

- Biological resources
  - Article 2 of the CBD provides: "*Biological resources*" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
- "Genetic resources" is defined in Article 2 of the CBD by these related references:
  - " '*Genetic material'* means any material of plant, animal, microbial or other origin containing functional units of heredity.
  - *'Genetic resources'* means genetic material of actual or potential value."

Are virus materials “biological resources” and/or “genetic resources?

- Do viruses contain “functional units of heredity” within the meaning of genetic resources?
- Do viruses have actual or potential use or value for humanity within the meaning of biological resources?
- Are virus samples taken from humans “human genetic resources”? Are “human genetic resources” excluded from CBD?
- Compare definition of “living organism” in the Cartagena Protocol on Biosafety to the CBD: “3(h) ‘Living organism’ means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids”

CBD establishes rights and obligations

- With respect to “genetic resources”, access and benefit sharing regime (ABS) (i.e. prior informed consent (PIC) and equitable benefit sharing (EBS)
- With respect to biological diversity and biological resources, obligations to preserve and protect
- Genetic resources and biological resources and regimes encourage transfer of technology
- CBD does not provide detailed treatment of obligations, leaving development to Conference of the Parties (COP)
  - Bonn Guidelines adopted; Working Group on Access and Benefit-Sharing operational

The heart of the problem

- Developing countries providing virus samples do not receive
  - adequate access to vaccines
  - technology and manufacturing capacity
- Materials used by OECD-based originator pharmaceutical companies to develop and patent vaccines sold at prices unaffordable to developing countries
- Vaccines present special problems because state-of-the-art manufacturing facilities expensive and require significant lead times; manufacturing concentrated in OECD
- Problem heightened in pandemic situation because "hoarding" predicted by OECD modeling

The patent question

- Should enterprises that have failed to secure informed consent from host country for obtaining and using virus samples be permitted to patent inventions based on or derived from the virus samples?
- Should developing countries be entitled to refuse and/or invalidate patents based on lack of compliance with international norms?
- Is there an alternative regime that would (a) establish standard conditions of access and/or (b) define benefit sharing obligations?

Some basic principles

- Some proposed key elements to a multilateral system for virus-sharing:
- It should promote the expeditious development of new vaccines and drugs
- It should promote adequate production and equitable distribution of vaccines and drugs, recognizing the importance of assuring that the system operates fairly in a situation of global emergency. Transfer of technology and production capacity among geographic regions is important to accomplishing this objective
- It should respect the right of states to control access to natural resources within their territories, including the right to benefit from providing access to those resources, and;
- The system and its implementation should be transparent. It should provide current information regarding virus materials obtained and/or transferred.

CBD and ITPGR/FAO models

- CBD presently provides basis for country-by country, case-by case, access and benefit sharing negotiations
  - Recognition and/or adoption of CBD framework would require PIC and EBS, but not establish generally accepted terms and conditions
- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) may provide more useful model relying upon contributions of biological material to "multilateral system" facilitating access by all interested researchers through standard virus material transfer agreement (SVMTA)
- Rights and obligations regarding patenting and consequent benefit-sharing may be defined in SVMTA and elsewhere

ITPGR components

- Range of plant genetic resources contributed into multilateral system is limited
- ITPGR provides for use of funds generated by patenting and commercialization of inventions derived from accessed materials to benefit developing countries
- Implemented standard material transfer agreement (SMTA) system includes transparency requirements
- Establishes obligations with respect to transfers of technology

Limitations of ITPGR model

- Financial returns from patenting of vaccines cannot realistically be relied upon to provide funding for acquisition of vaccines and/or construction of manufacturing facilities
- Substantial commitment of funding by multilateral organizations (e.g., World Bank), governments, etc. required
- Private market for purchase of pandemic influenza vaccines in lesser developed countries presumed virtually nonexistent

Advantages of ITPGR model

- Provides agreed terms of access to resources
- Defines rights and obligations of patent holders
- Establishes transparency, including central clearinghouse mechanism
- Provides framework for negotiation of technology transfer rights and obligations
- Variations on these components already under negotiation at WHO

Potential broadening to sharing of biological materials with human pathogenic potential

- Pathogens, or infectious agents that cause human disease, take a variety of forms. These include bacteria, fungi, helminthes (worms), protozoa, and viruses and prions
- Access to pathogen materials constituting or harboring disease-causing agents, whether found within or outside the human body, is important to scientific analysis and the development of new drugs and vaccines