

Access & Benefit Sharing Mechanism

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Why a Mechanism for ABS is Important?

Pathogens, their Sequences have Commercial value: Vaccines, Diagnostics & Therapeutic

Developed Countries stress on timely sharing of pathogens & sequence

Pathogen & sequences

Vaccines, Therapeutics and Diagnostics

No Access and Benefit Sharing Mechanism

INEQUITY

- Supply to developed countries prioritized as no legal commitments on manufacturers to supply vaccines/diagnostics/therapeutics to developing countries
- No legal commitment to transfer technology & know-how
- IP system used to appropriate biological material/sequence shared (see next slides)
- Enormous private profits and inequity in access

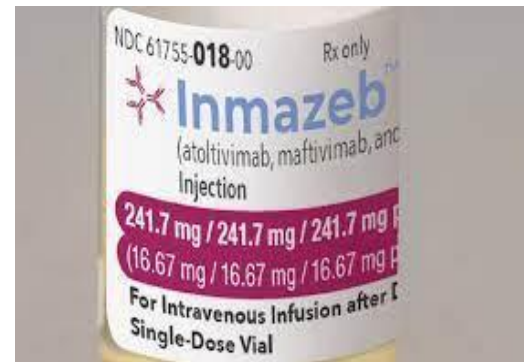


Following posting of sequence, within 2 days Moderna designed vaccine



Inovio claims it only needed 3 hours to do the same.

CLINICAL TRIAL UPDATE



A monoclonal antibody drug developed from sequence from ebolavirus called C15 or Makona strain isolated from a woman from Guinea without consent, before sample exported to Europe and sequenced – uploaded to INSDC. Regeneron downloaded sequence, synthesized the virus and developed Inmazeb. It received more than US\$ 800 million funding from US and orders from US.

Not limited to COVID. With influenza, the US government has contracted production of H7N9 influenza vaccine without obtaining a sample from China.

TWN Info Service on Health Issues (Jun23/02)

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Third World Network

Ebola Inequity Reinforces Need for Comprehensive Access & Benefit Sharing Mechanism

Sangeeta Shashikant (London) – Access by affected countries to Ebola treatments is at a “standstill”, more than two years since their approval and five outbreaks of Ebola virus disease (EVD) later.

This was exposed by MSF Access Campaign in its recently launched report titled “Ensuring Access to New Treatments for Ebola Virus Disease”.

Decisions concerning availability and affordability are left to the goodwill of corporations and rich countries, despite research and development (R&D) of the treatments only made possible with public funding and collaborative effort, the report states.

It further reveals that the U.S. government has set up its own emergency stockpile of Ebola virus disease (EVD) treatments which contains nearly all currently available treatments, deploring that “these treatments have not been adequately rolled out as lifesaving public health tools for people in countries where outbreaks occur and are instead retained primarily as biosecurity tools”. The European Union (EU) and other actors, also appear interested in setting up stockpiles as part of their pandemic preparedness efforts, the report adds.

The inequity narrated by the MSF report is now a recurring occurrence during a health emergency resulting in unnecessary suffering and deaths in developing countries. In 2005, developing countries, especially South-East Asian countries hardest hit by the H5N1 outbreaks, failed to get access to vaccines developed using the flu strains circulating in affected countries.

Pathogens, their sequences have commercial value: Vaccines, Diagnostics & Therapeutic

Pathogens (hard—copy)

Pathogens are a key aspect of development of nearly all vaccines, treatments, and diagnostics for infectious disease.

- For vaccines, (modified) pathogens or their genes frequently are the vaccine.
- For antibody drugs, the specific genetic structure of a pathogen sequence gives rise to the structure of the therapeutic.
- For small molecules, activities including testing and regulatory approval require use of pathogen strains.
- Diagnostics typically rely upon a piece of pathogen genome or a molecular product

Genetic Sequence Data/Information (soft copy)

Increasingly for many commercial purposes, access to physical material of pathogens is less required if sequence information is available.

- Uploading sequences to databases such as GenBank and GISAID, countries lose sovereignty and benefit sharing rights. These databases are **not accountable to WHO Members**.
- GSD/I or also known as “digital sequence information” is a priority issue for CBD. Developing countries are united in demanding benefit sharing for GSD/I.
 - While CBD discussions are ongoing, it is clear that **GSD/GSI are arising from utilization of genetic resources and hence subject to benefit sharing**.
 - **Scope of GSD/GSI to be determined** but should generally include all DNA and RNA sequences, and amino acid sequences as well as other information such as epigenetic, gene function and assembly information, etc.

Pathogens = sequence (they are one and the same)

29 May 2003, ETH

Patent Applications for SARS Virus and Genes

Background

The media have recently reported that teams of scientists in Canada, Hong Kong, and the U.S have filed patent applications on all or part of the SARS virus genome and on the virus itself. The detailed claims in these applications have not yet been made public but are reported to be sufficiently broad to allow their holders to claim rights in most diagnostic tests, drugs, or vaccines that have been or would be developed to cope with the outbreak. In addition to the claims filed by these laboratories, several other institutes and companies involved in decoding the SARS genome have announced that they will not file patent applications; still others have not disclosed whether or not they have filed or will do so but are believed to have done so.

Some of the university and public health laboratories that have filed patents assert that they have acted "defensively." That is, by filing patent applications, they intend to preempt commercial applicants from obtaining intellectual property rights that might hinder further research and development on SARS. It has been reported, however, that some of the university or governmental patent applicants have themselves begun negotiations with commercial partners to develop diagnostic tests and other products.

Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases--particularly as genomic sequencing becomes more routine and less "inventive"--remain matters of dispute.

WHO and SARS-Patents

For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome.

At the moment, it is too soon to know all the effects that the patenting of SARS-related discoveries will have, but the filing of the patent applications does not in itself erect any barriers to continued scientific collaboration on SARS.

The "defensive" use of patents can be a legitimate part of researchers' efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.

WHO intends to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use and on the manner in which prices are set for these technologies.

In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.

Examples of how IP system appropriates materials shared through WHO flu system.

WHO GISN Prototype Vaccine Strains and Patent Claims

(Searches performed of the WIPO PatentScope Database, through August 2008)

Date of WHO Notice	WHO Vaccine Strain includes gene(s) from:	Company/Institution Patent Application No. (indicative – more claims exist for some strains)	Patent Claim
February 2005	A/Vietnam/1194/04	Remedal WO2007065967	The HA gene used in any H5N2 vaccine
	A/Vietnam/1203/04	MedImmune (AstraZeneca) WO2006098901	Entire HA and NA gene sequences
		St. Jude's (WHO CC) WO2007019094	Modified HA sequence
		Univ. of Pittsburgh WO2006063101	HA gene used in adenovirus-based vaccine
	A/Hong Kong/213/03	MedImmune (AstraZeneca) WO2006098901	Entire HA and NA sequences
March 2006	A/Indonesia/5/2005	Hawaii Biotech Inc. WO2007022425	Partial HA sequence in cell culture vaccine
		Novavax WO2007047831	HA + NA genes in VLP vaccines in cell culture
May 2006	A/Bar-headed goose/Qinghai/1A/2005	Novavax WO2007047831	HA + NA genes in VLP vaccines in cell culture
	A/Whooping swan/Mongolia/244/05	Paul Ehrlich Institut WO2008061939	HA gene in modified vaccinia virus (Ankara MVA) vaccine
June 2006	A/turkey/Turkey/1/2005	Paul Ehrlich Institut WO2008061939	HA gene in MVA vaccine
December 2006	A/Anhui/1/2005	Novavax WO2007047831	HA + NA genes in VLP vaccines in cell culture

PCT Application WO2007100584 (7 September 2007)

Title: **Antiviral agents and vaccines against influenza**

Owner: US National Institutes of Health and Centers for Disease Control

What is it? This patent application relates to a new kind of influenza vaccine called a DNA vaccine. The DNA vaccines are composed of loops of DNA, called plasmids, that cause an immune response when injected into humans. Many of these plasmids contain genetic material from H5N1 strains including full genes and shorter sequences. The patent application claims the genetic sequences contained in the plasmids by themselves (in Claim 1) and as used in the DNA vaccine.

In addition to A/Indonesia/5/05, the patent application also claims parts of flu strains from Thailand (A/Thailand/1(KAN-1)/04) and A/Ck/Thailand/1/04), Hong Kong (A/Hong Kong/156/97) and South Korea (A/Ck/Korea/ES/03).

PCT Application WO2007019094

Title: **Modified influenza virus for monitoring and improving vaccine efficiency**

Owner: St. Jude's Children's Hospital (US) (a WHO Collaborating Centre)

What is it? This patent application, published on 8 February 2007, claims small changes to influenza HA genes. These changes are intended to strengthen the immune system reaction (boost immunogenicity) to the genetically engineered virus. This might improve possible pandemic influenza vaccines because people vaccinated may exhibit a stronger immune reaction against H5N1.

Pertinent claims: This patent application claims any influenza HA gene modified in a certain way. It specifically claims the modified HA gene from an influenza virus isolated in Vietnam in 2004 (A/Vietnam/1203/04). This is the same strain whose entire HA and NA sequences have been claimed by MedImmune.

Government interest: The US government has rights in this patent application (see discussion of this issue under MedImmune's patent applications).

Legal Basis for ABS

Convention on Biological Diversity

- Near universal membership, signed at the Rio Summit in 1992
- Established sovereign rights of States over biological resources. So no obligation to share.
- Objectives: (1) conservation of biological diversity, (2) sustainable use and (3) **the fair and equitable sharing of benefits arising from the utilization of GR.**
 - Article 15 of CBD: authority to determine access to genetic resources rests with national government & subject to national legislation
 - access subject to **prior informed consent (PIC)** and **measures for fair and equitable benefit sharing arising from the utilization of genetic resources** with the Contracting Party providing such resources on **Mutually Agreed Terms (MAT)**



Nagoya Protocol on ABS

- Protocol is result of a decade of developing country effort. Adopted in 2010. Entered into force in 2014.
- 138 Parties
- Inclusion of pathogens affirmed in negotiations, & by public health references in Preamble. Art. 8 also refers to expeditious access to GR and to expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments
- Elaborates that access subject to PIC & MAT including fair and equitable benefit sharing
- ABS is usually bilaterally agreed but, under Article 4(4), there is a possibility for the establishment of a specialized international instrument on ABS. (e.g. the PIP Framework)

Discussions underway in CBD regarding benefit sharing from the use of DSI. COP 15 in Dec.

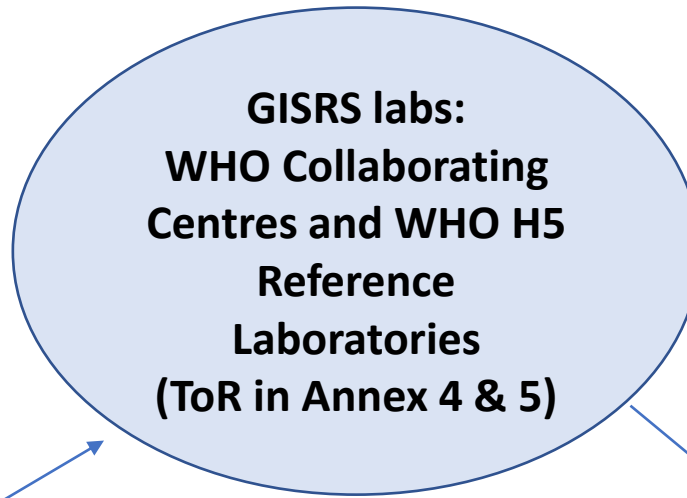
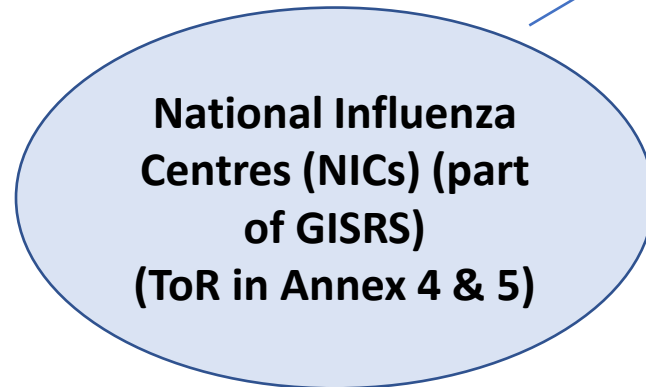
PIP Framework (scope limited to influenza virus of pandemic potential): A Precedent

- **PIP Framework is the result of Inequity** in the then Global Influenza Surveillance Network (GISN), sharing of flu viruses/sequences not reciprocated with access to vaccines during H5N1 outbreak.
- WHA 2007, adopted Resolution 60.28 titled “Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits”.
- **1st time:** recognized CBD’s principle of sovereign right of States over their biological resources
- **1st time:** sharing of viruses linked to fair and equitable sharing of benefits, (e.g. access to, and distribution of, affordable diagnostics and treatments) to those in need, especially in developing countries, in a timely manner.
- Led to discussions/negotiations which eventually led to PIP Framework that recognizes in its Preamble:
 - “recognize that Member States have a commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health”;
 - “recognize the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks”;

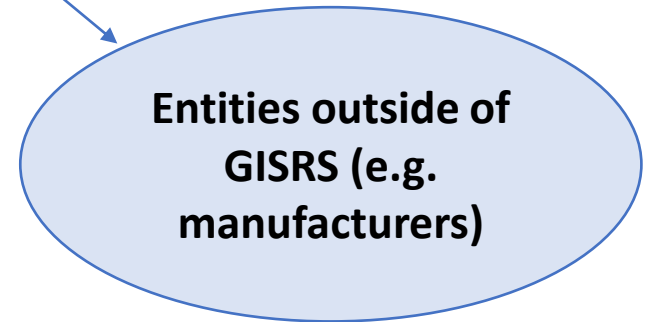
Section 5, PIP Framework

Sharing subject to **SMTA 1 (Annex 1 of PIP Framework)** which contains **rules governing access by recipients**. Transfers are recorded in the **influenza virus tracking mechanism (IVTM)**.

<https://extranet.who.int/ivtm2>



On Genetic Sequence Data: Included within the scope of the Framework. Some benefit sharing is accruing with respect to GSD use. **But there are some important issues on the governance of GSD and benefit sharing from its use that remains unresolved.**



Transfers subject to **SMTA 2 (Annex 2)** which details benefits a company must provide during flu pandemic + USING GISRS requires **monetary contributions**. To date more than **14 SMTAs** signed between WHO and manufacturers.

GISRS=Global Influenza Surveillance and Response System

Benefit Sharing (from Entities outside GISRS)

- **SMTA 2 (STANDARD MATERIAL TRANSFER AGREEMENT 2 – Annex 2 of PIP Framework):**
 - Details benefits that manufacturers of vaccines and anti-virals and non-manufacturers should provide during a flu pandemic. (see next slide)

IN ADDITION

- **PC (PARTNERSHIP CONTRIBUTION):** Annual **cash contribution** to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers that **use GISRS** to strengthen pandemic preparedness capacities where they are weak & build response fund
 - Section 6.14.3 of PIP Framework: **annual contributions equivalent to 50% of the running costs of GISRS** (in 2010 estimated as approx. US\$ 56.5 million, may change over time) i.e. **\$28 million annually**
 - **Collection to date is US\$296.55 million (as at 18 Oct. 2023)**
 - **70% of this amount is used for capacity building and 30% kept in a response fund to be used during a flu pandemic.**

Summary of Benefit Sharing Options

(see Annex 2 for specific language and terms)



	CATEGORY A (Select 2/6)	CATEGORY B (Select 1/6)	CATEGORY C (Consider)
1	Donate % of real-time vaccine production to WHO	Donate diagnostic kits to WHO	Consider contributing to the measures listed below, as appropriate: <ul style="list-style-type: none"> • Donations of vaccines; • Donations of pre-pandemic vaccines; • Donations of antivirals; • Donations of medical devices; • Donations of diagnostic kits; • Affordable pricing of pandemic products; • Transfer of technology and processes; • Granting of sublicenses to WHO; • Laboratory and surveillance capacity building.
2	Reserve % of real-time vaccine production at affordable pricing to WHO	Reserve diagnostic kits at affordable pricing to WHO	
3	Donate antivirals to WHO	Support laboratory and surveillance capacity strengthening	
4	Reserve antivirals at affordable pricing to WHO	Support transfer of technology, know-how and/or processes	
5	License on technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants to developing country manufacturers, on mutually-agreed fair terms	License on technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants to developing country manufacturers, on mutually-agreed fair terms	
6	Royalty-free license to developing country manufacturers or WHO for production of influenza vaccines, antivirals or adjuvants	Royalty free license to developing country manufacturers or WHO for production of influenza vaccines, antivirals or adjuvants	

Top Achievements

The PIP Framework, a successful partnership with industry and other stakeholders, is proving itself as a model for global cooperation in strengthening preparedness and pandemic response.

Core pandemic influenza preparedness and response capacities in all 6 regions and in over 100 countries have been strengthened through

US\$235m

collected to date under the PIP PC.

Standard Material Transfer Agreements are significantly improving the predictability of equitable access to future pandemic influenza vaccines and other products:

The Framework has supported the improvement of national regulatory systems, and helped countries to accelerate the authorisation of pandemic vaccines and other products.

In the event of a pandemic, 10 of every 100 doses of vaccine manufactured (over

400 million doses based on current technologies) will be set aside for WHO – and 8 will come to WHO on a donation basis.

Over 10 million treatment courses of antivirals, 250,000 diagnostic test kits, and 25 million syringes will also be available when the next influenza pandemic strikes.



2016: Expert Review of PIP Framework

- Concluded: “**bold and innovative tool** for pandemic influenza preparedness, is being well implemented, and that the principle of the PIP Framework of placing virus sharing and benefit sharing on an equal footing remains relevant today”.

Expert Review Report:

http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1

Pandemic Access & Benefit Sharing System (PABS)

“The proposal for the negotiating text of the WHO pandemic agreement A/INB/7/3 (proposal for negotiating text) released by the Bureau in preparation for the 7th meeting of the Intergovernmental Negotiating Body (INB) reveals significant shortcomings in the access and benefit-sharing provisions, potentially resulting in a fragmented and ineffective system”.

See “Pandemic Access & Benefit Sharing System in Proposed Text flawed”

https://www.twn.my/title2/intellectual_property/info.service/2023/ip231102.htm

Civil society organisations demand for a fair negotiating process for a pandemic instrument

https://www.twn.my/title2/intellectual_property/info.service/2023/ip231103.htm

INB Bureau proposes unbalanced draft negotiating text; no concrete deliverables on equity

<https://www.twn.my/title2/health.info/2023/hi231006.htm>

- One of the key mechanism proposed to operationalize equity
- In latest INB negotiation round, **72 developing countries have proposed text** on Article 12 (which is on PABS).
- Proposal built on lessons learnt from the PIP Framework and COVID-19
- **Essentially the proposal** is that the sharing of pathogen biological material and genetic sequence data relevant to PHEIC/pandemic, is **subject to terms and conditions on recipients (including manufacturers) of materials incl. sequence data**, on use and concrete legal obligations for fair and equitable benefit sharing.

The PABS mechanism should have transparency and accountability in the sharing of materials incl. sequence data and fair and equitable benefit sharing

Some Key Elements of PABS system proposed by developing countries:

- **Standard Terms and Condition on Access to and Use of Pathogens and GSD (key to operationalize fair and equitable benefit sharing and prevent misuse through IP system)**
 - Sharing of pathogen biological material and sequences **among WHO designated laboratories** (WHO Coordinated Laboratory Network) should be **subject to terms and conditions** (SMTA 1).
 - Sharing of pathogens biological material and sequences **with entities (e.g. manufacturers) outside the WHO designated laboratories** should be **subject to terms and conditions** (SMTA 2).
 - **Access to and use of genetic sequence data (GSD)** should be through **WHO PABS Sequence Database** and subject to **standard click-wrap data access agreement**. *Standard Agreements outlines terms and conditions of use including on fair and equitable benefit sharing. Use of such agreement for GSD is not unique.*
- **WHO PABS Sequence Database**
- **Fair and Equitable Benefit sharing (reflected in standard terms and conditions):**
 - **Monetary Benefit Sharing** arising from use of biological materials and data &
 - **Non-monetary benefit sharing:**
 - Legal obligation to provide 20% donation of real-time production to WHO during PHEIC and pandemic and prior to PHEIC;
 - Legal obligation to comply with WHO's allocation mechanism, if available;
 - Legal obligation to license to developing country manufacturers with respect to technology and know-how to address supply and access challenges during PHEIC and pandemic.
- **Transparent & accountable governance** under WHO.
- **Annexes (SMTA 1, SMTA 2, Data Access Agreement)**
- PABS system should apply to pathogens - pandemic potential and PHEIC related pathogens). Should also apply to all WHO Members.
- **Important:** Key elements of the PABS system must not be postponed to a later date. Details of the terms and conditions should be decided and negotiated by WHO Members as part of negotiations and annexed and not be postponed to be sorted out later. Otherwise we will not have an effective PABS system.

**ABS: An important mechanism for operationalizing equity for
developing countries**

AND

**we need to ensure that it has the right elements to be able to deliver
equity for developing countries during PHEIC and pandemic.**

Thank You

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