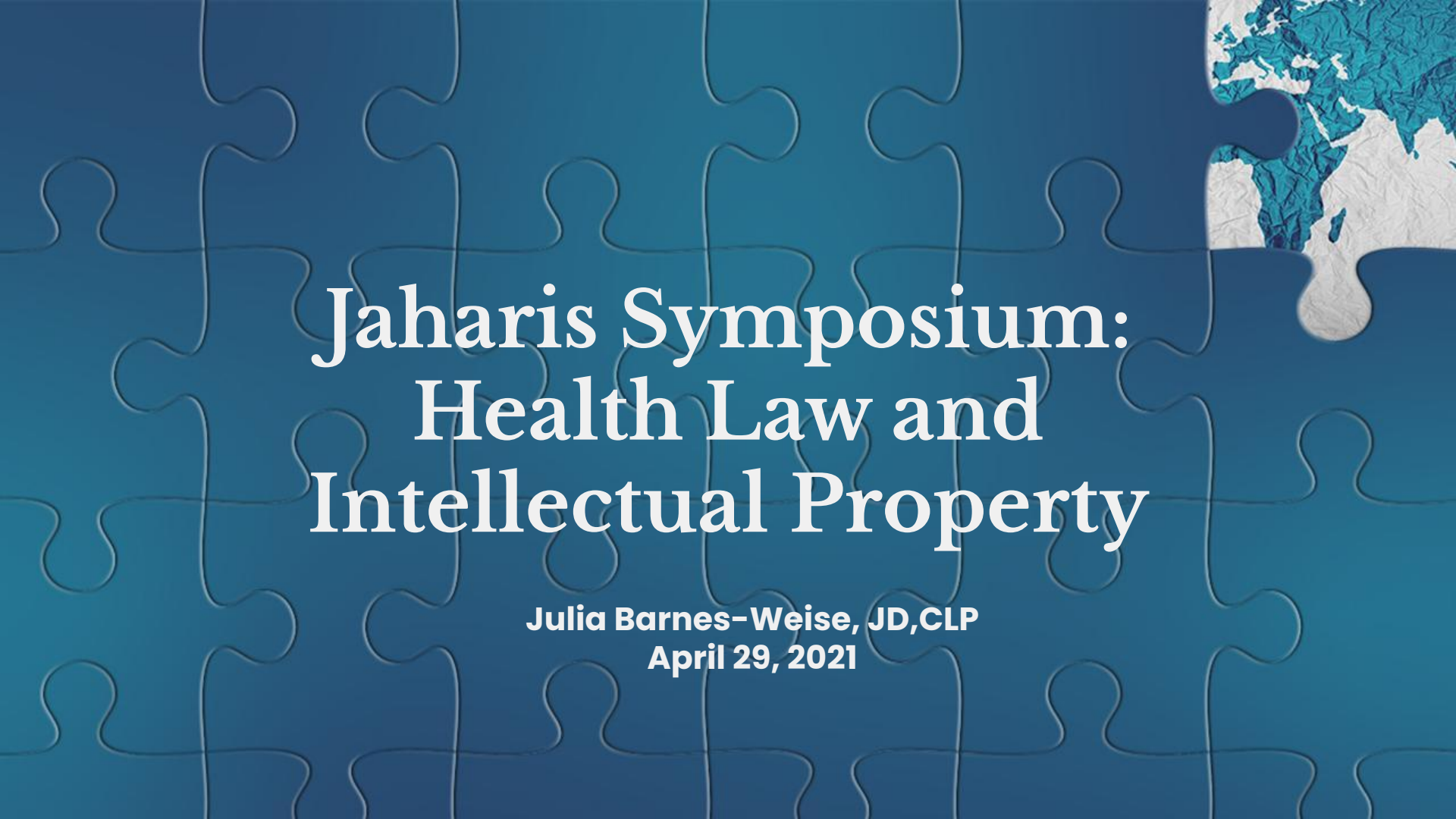

Jaharis Symposium: Health Law and Intellectual Property

Julia Barnes-Weise, JD,CLP

April 29, 2021

GHIAA

Equitable Access To Vaccines: the role of Step-in Rights and Technology Transfer

The Development, Production and Distribution of COVID-19 Vaccines and Medicines

What's Different About Contracts for Public Health Products?

- Intense scrutiny/transparency requests
- Balancing of public/private interests
- Commercial plus public health markets?
- Expectations – how much profit seems fair?
- Pricing terms
- Liability and indemnification coverage
- The main funders/buyers – Foundations, government, procurement agencies
  - Unique funders' requirements (e.g. equitable, affordable and sustainable access)

Key Issues Addressed by Joint Development Funding Agreements

- **Equitable Access – tech transfer, step-in and Trusted Partners**
- **Intellectual property ownership (Background/Foreground)**
- Liability and indemnification
- Sustainability
- Territory and vaccine nationalism
- During and post-pandemic changes
- Termination / enforcement


Equitable Access

The Concept of Equitable Access: Example from a Vaccine Funder

- The **Coalition for Epidemic Preparedness Innovations** (CEPI) is committed to achieving equitable access to the outputs of **all** CEPI-supported programs including vaccines, platforms, data, results, and materials.
- Equitable access to epidemic vaccines in the context of an outbreak means 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.
- It also means that CEPI will ensure **open access** to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development.

The Concept of Equitable Access: Example from a Company

Eli Lilly and Company's monoclonal antibody combination therapy

1. **Allocation**: Treatment will be allocated based on unmet medical needs globally.
2. Patient **Cost**: The goal is for patients to have no out-of-pocket costs for such antibody treatments, wherever possible.
3. **Pricing** to Health Systems: Equitable government pricing will be tiered based on a country's ability to pay.

Key Components of Access

- **Sustainability Mechanisms – tech transfer, step-in and Trusted Partners**
  - **Intellectual property ownership and control**
- Transparency and data sharing
- Cost transparency and price
- Liability and indemnification

All should interact and seek to ensure that the funder's investment results in an affordable, available medical product for populations in need.

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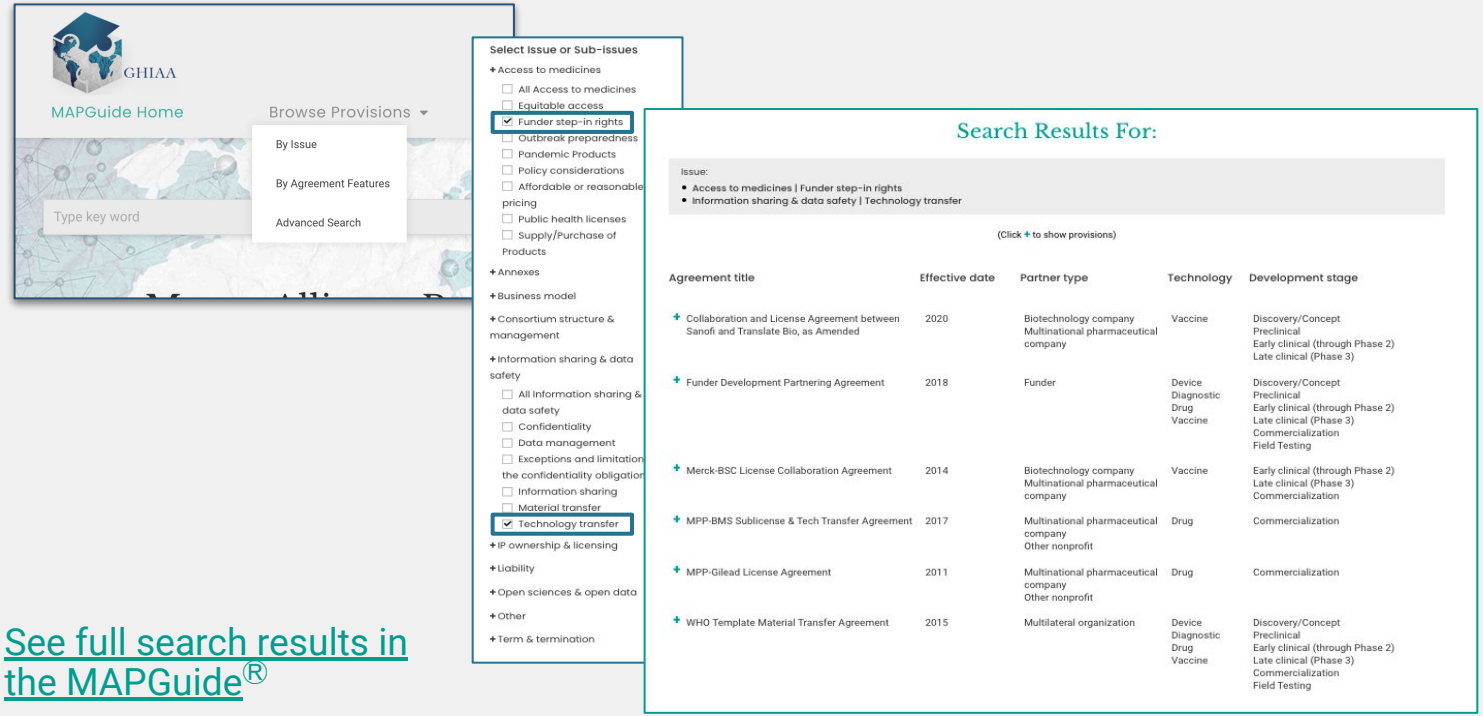
Step-in Rights and Technology Transfer

GHIAA MAPGuide: Step-in Rights and Technology Transfer



[See full search results in the MAPGuide®]

Step-in Rights: Development Agreement Example

U.S. Government/company agreement

"In the event (a) Sanofi elects to terminate the manufacturing or discontinue the sale of the vaccine, and (b) Sanofi has submitted an Emergency Use Authorization or a BLA application, then upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Sanofi Background Patent, Copyright, other Sanofi Intellectual Property, Sanofi Know-How, Sanofi Technical Data rights necessary to manufacture or have manufactured the vaccine;
b. necessary FDA regulatory filings or authorizations owned or controlled by Sanofi related to this product vaccine and any confirmatory instrument pertaining thereto (excluding with respect to [redacted content]); and
c. any outstanding Deliverables contemplated or materials purchased under this Project Agreement."

Also:
The Government has the right to exercise a Most Favored Nation Clause, licensing rights and march-in rights under the Bayh-Dole Act, and reasonable scope of data rights

See the MAPGuide for more detail

Step-in Rights: Purchasing Agreement Example

European Union/company agreement

“In addition, the contractor will transfer, upon the Commission's request to be provided within forty- five (45) days after the receipt of notification about the automatic termination, to the Commission, or a third party named by the Commission, any raw materials and primary components not used and paid for with the up-front payments (the “Refundable Items”). The contractor will also facilitate the discussion of a transfer of reserved capacity with CMOs [Contract Manufacturing Organization] paid for with the up-front payments to a third party selected by the Commission.”

See the MAPGuide for more detail

Technology Transfers - A Limited Remedy

How well do technology transfers actually work and what are the barriers to success?

Success Factors:

- Willing transferor
- Capabilities of recipient
- Complexity of the process
- Underlying IP availability
- Availability of necessary materials and components

Thank you!

Questions?

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Appendix 1: GHIAA Resources

GHIAA Resources

- The GHIAA MAPGuide® - search for global health agreement provisions by partner type, development stage, technology type and/or key issue.
- The Glossary of Global Health Agreement Terms - a new resource containing different interpretations of commonly used terms in global health agreements.
- MAPGuide Resources & Analysis page - we will be adding new blog posts and articles to this page over the coming months. We have just published the first section which provides a summary of funder approaches to the question of equitable access.

Why we developed the MAPGuide?

- **Before** COVID-19…the 2014 Ebola outbreak in West Africa exposed significant gaps in pandemic preparedness.
- Despite rapid scientific progress, the formation of R&D collaborations to develop vaccines/therapeutics was hindered by a lack of legal clarity regarding alliance structures, technology transfer, and data sharing.
- GHIAA began to research the partnerships formed between the public, private, and non-profit sector, and the challenges that they faced. We identified the need for a tool to help stakeholders to consider key issues for global health agreements, and see how they could be addressed.

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Appendix 2: Example provision

Step-in and U.S. COVID-19 Agreements
(different language used in different agreements)

Example provision: Novavax

In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security…

Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government […]