WHO BioHub System technical consultation sessions

Session Three: Intellectual property and the WHO BioHub System

Background note and discussion questions
I. Introduction

In the context of the continued development of the World Health Organization (WHO) BioHub System, the WHO Secretariat is conducting a series of virtual technical consultation sessions. The aim is to gather views and ideas on specific topics that will support WHO’s work on the BioHub System, to ensure that the system meets its global public health objectives.

This consultation session, scheduled for 9 December 2021, focuses on the topic of intellectual property (IP) and the WHO BioHub System, an issue that has important implications for the design and implementation of the system.

The technical consultation is expected to stimulate robust discussions and expression of different views and ideas on the topic, to support WHO’s development of options for handling IP in the context of the WHO BioHub System.

The purpose of this background note is to facilitate such discussion; thus, this document does not present a conclusive view or reflect the position of WHO on any specific subject or topic.

Discussions about the WHO BioHub System are anchored in the System’s guiding principles, which are the basis for the development and operation of this initiative. Particularly relevant for this consultation session are the principles of timeliness, equity and fairness; consistency with applicable law; and consistency with applicable ethical regulations, norms, and standards requirements.

This background note provides:

- suggestions on where IP might be applicable within the WHO BioHub System; and
- questions for discussion, intended to steer the consultation towards identifying options and associated implications for handling IP in the context of the WHO BioHub System.

The WHO Secretariat anticipates that those participating in this technical consultation session already have an understanding of the core concepts related to IP and related matters. Hence, this background note does not provide a detailed description of these matters, either generally or in the specific context of health.

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1 See https://www.who.int/initiatives/who-biohub.
2 The World Intellectual Property Organization (WIPO) (see https://www.wipo.int/about-ip/en/) defines IP as creations of the mind (e.g. inventions, literary and artistic works, designs, and symbols, names and images used in commerce) and notes that IP is protected in law (e.g. by patents, copyright, trademarks, industrial designs and trade secrets). The 2020 joint publication by WHO, WIPO, and the World Trade Organization Promoting access to medical technologies and innovation (intersections between public health, intellectual property, and trade) provides useful background information (see https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf).
II. IP entry-points within the WHO BioHub System

When speaking of IP in the context of the WHO BioHub System, novel inventions could include, for example, innovative biotechnologies or bioproducts, new trade secrets developed during research and development (R&D), or copyrighted information technology (IT) arrangements.

When considering IP within the particular context of the WHO BioHub System, different types of IP could apply in the following three cases (perhaps among others).

Three (primary) cases for IP and the BioHub System

1. **IP and the physical biological materials with epidemic or pandemic potential (BMEPP) provided to a BioHub Facility**: IP considerations could arise with respect to the BMEPP samples themselves (i.e. the biological and genetic materials) and, possibly, to derivatives (e.g. genetic sequence data), depending on national laws in the provider country and any relevant contractual arrangements.

2. **IP developed by a BioHub Facility**: This would include any discoveries made by the Facility in performing its work in that capacity, pursuant to the Terms of References (e.g. it could include a newly discovered use or process).

3. **IP developed by a Recipient (Qualified Entity) using BMEPP**: This would include any development or IP discovered by the recipient using the BMEPP including, importantly, creation of medical countermeasures (MCM).

Each of these categories of IP is related to the BMEPP continuum within the WHO BioHub System, and might be handled and managed in different ways. The technical consultation will seek to foster an in-depth and comprehensive understanding of what these options and their corresponding implications for the WHO BioHub System’s objectives might be, bearing in mind the objectives of the WHO BioHub System (especially the facilitating of rapid, safe and efficient sharing of BMEPP).

Standard terms may be beneficial in the WHO BioHub System documentation, including standard material transfer agreements (SMTAs), which ensure predictability and certainty for those using or providing BMEPP.

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3 Including, without limitation, vaccines, therapeutics, diagnostics.
4 For example, private, commercially confidential databases managed in such a way that legal measures can be applied in cases where trade secrets are divulged.
5 For example, databases containing advanced characterization data on BMEPP.
III. Questions for discussion at the consultation session

The following questions are posed for discussion during the consultation, bearing in mind the guiding principles and core objectives of the WHO BioHub System (i.e. promoting rapid and timely sharing of BMEPP, facilitating rapid characterization of such pathogens and rapid risk assessments, facilitating the development of safe, protective countermeasures and other public health products and ensuring fair and equitable access to such products by all countries based on public health needs):

1. What do you consider to be the most important factors and considerations relating to IP in relation to the WHO BioHub System?
   • Are there relevant laws, frameworks, principles, policies, norms or “success cases” from other arrangements or projects, that you feel should be considered when considering this topic of IP and the BioHub System?

2. Regarding the three “entry points” listed in Section II:
   • Do the entry points accurately and clearly address the IP considerations relating to the WHO BioHub System?
   • Are there any other categories or considerations that should be added?

3. How should the WHO BioHub System address each of the three entry points listed in Section II:
   • Should there be a standardized approach across the WHO BioHub System or should there be some flexibility or optionality?
   • Should the approach depend on the nature of the IP (e.g. copyright, patent or other)?
   • Should the approach depend on the subject area (e.g. type of MCM)?