





## WHO, WIPO, WTO Workshop on Innovation in, and Access to, COVID-19 Technologies Intellectual property licensing, technology transfer, and sharing of know-how and clinical trial information

#### Summary of the key issues

On September 27, 2021, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) jointly organized a Workshop on Innovation in, and Access to, COVID-19 Technologies. The workshop focused on intellectual property licensing, technology transfer, and sharing of know-how and clinical trial information. It aimed at strengthening the capacity of policymakers and experts in the members of WHO, WIPO and WTO to address the COVID-19 pandemic. This capacity-building activity was conceived to help members update their knowledge and understanding of how intellectual property (IP), know-how and technology transfer work in actuality.

The activity was agreed in a June 15, 2021 meeting among the Directors General of WHO, WIPO and WTO, in which they underscored their commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies.

# Realizing global equitable access for vaccines, diagnostics, therapeutics and other COVID-19 health technologies

The first panel highlighted access and delivery challenges for COVID-19 therapeutic asset types, including older repurposed therapies, more recent repurposed therapies, and novel therapies. Low- and middle-income countries, in particular, face market challenges that constrain access to COVID-19 therapeutics, for example, by having a limited existing market for biologics. The panel noted that intellectual property constraints are more likely for recent repurposed therapies and novel therapies. Expected to be expensive, these therapies might not be available in sufficient quantities. The panel continued with a consideration of access measures along the value chain to ensure improved access to safe, quality treatments, vaccines, medical devices, including in vitro diagnostics and personal protective equipment, and technology transfer. The Access to COVID-19 Tools Accelerator (ACT-A), a collaboration to accelerate the development, production and global equitable access to new COVID-19 essential health technologies, aims to address health technology disparities.

The panel further outlined that transparent, non-exclusive, public health-oriented licensing of COVID-19 health products, using non-traditional mechanisms for sharing knowledge and licensing intellectual property, for example, through technology pools such as the WHO COVID-19 Technology Access Pool (C-TAP), can accelerate the scale-up of manufacturing and facilitate global equitable access. Through collaboration with implementing partners, such as the Medicines Patent Pool (MPP), C-TAP engages with technology holders and progresses discussions for the licensing of technologies such as CRISPR (gene-editing technology) diagnostics to detect COVID-19. MPP presented its collaboration within ACT-A and its support to WHO and South African partners in establishing the first mRNA vaccine technology transfer hub, which will facilitate manufacturers in low- and middle-income countries to produce vaccines locally. In addition, MPP recently launched VaxPaL, which tracks patents on COVID-19 vaccines. The panel emphasized that all mechanisms to promote access and boost manufacturing of COVID-19 health products must be explored.

The panel concluded with a consideration of critical pathways for building technological competence as well as the risks of setting up local production in low-income countries, calling for a move away from "business as usual" discussions on technology transfer in favor of local production for sustainable, global equitable access to COVID-19 health technologies. Overall, the panel emphasized the need for a vast range of health technologies and medical devices to be timely, affordable, available and appropriate to respond to the pandemic.

# Mechanisms and processes to support technology transfer and intellectual property licensing

The second panel discussed practical support to technology transfer and IP licensing. With the emergence of life-saving vaccines, multi-stakeholder international cooperation is imperative to addressing global access challenges. Upgrading local capacity in developing countries to create, transfer and use innovation is a long-term solution for pandemic preparedness. Creating enabling

innovation ecosystems is a sustainable solution and a challenge. Focused international collaboration, in particular with international organizations and development banks, can influence innovation capacity building for the benefit of all.

WIPO is committed to effective pandemic response and to IP as a tool for sustainable development that helps build lasting innovation ecosystems, including legal frameworks, human capital, business sophistication and markets – to enable the creation and acquisition of technology and know-how. Technology transfer is a collaborative process among equal partners that involves multiple stakeholders and, often times, international organizations.

Human capital is an important component of innovation and technology transfer. WIPO offers standard and customized programs to upgrade IP licensing and technology transfer skills in developing countries. Where research capacity might be limited, collaborative arrangements can support technology development and local ownership.

Different types of technology transfer contracts and their contractual relations lead to different outcomes. For example, sales of medical goods and services are not IP licenses. Sales do not directly serve poverty alleviation, economic development, education, or innovation, but in the appropriate context may serve public health. Licensing and collaborative development agreements may engage indigenous research and development (R&D) and create opportunities for manufacturing and distribution channels in developing countries. The panel looked at types of technology licensing agreements and their characteristics. True technology transfer enables the use and further development of technology. Consistent investments that foster capacity building in developing countries, including research institutions, innovation infrastructure and manufacturing capacity, is an added challenge

Finally, the panel reviewed mechanisms and initiatives to strengthen domestic innovation ecosystems, such as specific infrastructure initiatives to generate impact at the local level using local capability. All panelists agreed that there is a great need to ensure that health technologies reach people who need them. Any arrangement for technology transfer ought to be fair, reasonable, and non-discriminatory. Solutions need to be intentional to avoid approaches that are anti-competitive and anti-innovative.

## Enabling factors and policies for technology transfer

The third panel explored factors and policies that enable successful and sustainable technology transfer. Technology transfer is a practical craft, which requires experience in specific sectors in accordance with domestic needs and circumstances, as well as different approaches due to its complexity and dynamism. Available data demonstrate that R&D activities are taking place across the world. There is a need for policy discussions to be based on data and published research that map patent activity, global licensing, and contract trends to generate practical responses.

The panel also explored how IP license terms can be designed to facilitate technology transfer, enable knowledge sharing with the wider research community and ensure access. Examples included perpetual royalty-free, non-exclusive and sub-licensable licenses; worldwide research

and manufacturing rights; and commitments to make the final product available at cost plus a minimal margin. Maintaining licensing rights at the end of collaboration agreements is a means to permit continued technology transfer. During a pandemic and amidst disrupted value chains, interinstitutional coordination, willingness to take risks and technical readiness and competence on the side of the recipient are prerequisites for the transfer of technology and know-how. Experience and investment in development and production of health technologies provides fertile ground for successful technology transfer. Particularly as part of the COVID-19 pandemic response, some governments have had to procure or invest in products that were/are yet approved. This requires new tools, such as mechanisms to finance procurement and the use of existing legal instruments in a new context, i.e., the application of procurement laws and regulations to pre-commercial contracts during a pandemic.

The vaccine manufacturing process is complex. The main challenges to technology transfer revolve around the availability of adequate facilities and equipment, skilled workers and materials. Preparing a site to receive new technology and know-how requires many activities in parallel, such as the creation of team structures, preparation of instructions and test methods, and ensuring the facility is adapted to meet the necessary regulatory standards. Investing in training and building a reserve force of technical specialists, may help prepare for future pandemics. Longer expiry periods for certain materials are also important, as well as stockpiling and improved logistics to meet demand and secure availability of inputs, including basic supplies, such as disposable gloves and pipettes. There is now an opportunity to bring stakeholders together to brainstorm and develop solutions for future challenges.

#### **Presentations**

Presentations shown during the workshop are posted on the <u>meeting webpage</u> as far as they are available.

### Background

WHO, WIPO and WTO have, since 2009, stepped up their cooperation and practical coordination on issues relating to public health, IP and trade. This <u>trilateral cooperation</u> intends to enhance the empirical and factual information basis for policy makers and to support them in addressing public health in relation to IP and trade. It has entailed a series of practical technical assistance activities, at the national, regional and multilateral levels, a series of <u>high-level Policy Symposia</u> intended to track emerging issues and inform future policy, and the <u>trilateral study</u>, which provides a comprehensive overview of the full array of policy issues with bearing on innovation and access to medical technologies.