

Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Licence Agreement with Consejo Superior de Investigaciones Científicas (CSIC) on a Covid-19 Diagnostic Test

Introduction

The Expert Advisory Group (EAG) of the Medicines Patent Pool (MPP) submits the following report to the Governance Board of the Medicines Patent Pool (Board) on the proposed License Agreement (the Agreement) between MPP and Consejo Superior de Investigaciones Científicas (CSIC) for a COVID-19 diagnostic test.

This report reflects the outcome of a consultation with the EAG on 21 October 2021, chaired by Peter Beyer and joined by EAG members Alexandra Calmy, Akthem Fourati, Jan Gheuens, Manuel Gonçalves, Martha Gyansa-Lutterodt, Jordan Jarvis, Giten Khwairakpam, Gugu Mahlangu, Deus Mubangizi, Valérie Paris, Fatima Suleman and Ellen 't Hoen, as well as Nathan Ford of the Scientific Advisory Panel (SAP).

Having reviewed the proposed Agreement between MPP and CSIC and having received a briefing from MPP on the Agreement, the EAG recommends that the Board requests the Executive Director of MPP to finalise and execute the necessary documents with CSIC.

Background, Overview of the Proposed Agreement

In May 2020, the World Health Organization (WHO) launched the Covid-19 Technology Access Pool (C-TAP) to facilitate the timely, equitable, and affordable access of Covid-19 health products via sharing of intellectual property, data, and know-how for the subsequent scale-up of production. MPP is an implementing partner of C-TAP, responsible for handling negotiations of licences and subsequent licence management while C-TAP retains responsibility for fielding and screening submissions of interest.

This proposed agreement would be the first C-TAP licence. In a ceremony marking the first anniversary of C-TAP, CSIC and the Spanish Ministry of Foreign Affairs announced their intention to make its Covid-19 diagnostic test available to C-TAP. Following the screening of the technology and signal to proceed from C-TAP, MPP subsequently entered negotiations with CSIC in July 2021.

The CSIC technology is a serological test capable of identifying and quantifying three different types of antibodies and differentiating between antibodies produced by vaccination from those produced naturally from Covid-19 infection. The test uses ELISA (enzyme-linked immunoabsorbent assay) kit format, but can be developed in lateral flow format, and is currently under nonexclusive from CSIC to a Spanish company called Immunostep.

Key aspects of the proposed licence are as follows:

- **Aim of the Licence:** To facilitate the rapid manufacture and commercialization of CSIC's Covid-19 diagnostic test around the world.
- **Technology:** Patent for an "Assay for the detection of the Cys-like protease (Mpro) of SARSCoV-2", and expression vectors necessary for manufacture of the diagnostic test.

- **Products:** Any product that is covered by the Patents or uses the Material.
- **Know-how:** CSIC to provide all necessary know-how to MPP and/or licensees.
- **Field of use:** ELISA kits and lateral flow test for the detection of antibodies against COVID-19.
- **Territory:** Worldwide.
- **Scope of the grant:** Non-exclusive right to grant sublicences to develop the licensed patents/know-how/material into licensed products, and to commercialize licensed products.
- **Royalties:** Royalty-free for LMICs; 15% for HICs where there is a Patent granted and in force, or where no Patent if Licensee has used the Material.
- **Term:** Continuing until the date the last Patent has lapsed, expired, or been invalidated.

There is no form sublicense included in the proposed agreement. CSIC and MPP will agree on terms for a sublicense, and additionally will discuss and agree upon the identities of interested and suitable sublicensees.

Assessment of the Proposed Agreement

The EAG finds the proposed agreement aligned with MPP's statutory requirements and recognizes that the successful negotiation of the first C-TAP licence is a symbolic achievement of potentially great significance that will send an important message to governments and research institutions around the world: the path out of the pandemic will necessarily be forged by the sharing of intellectual property and know-how. The EAG congratulates CSIC and the country of Spain on demonstrating leadership and hopes that many others will follow their example without delay.

Recommendation

The EAG therefore recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between CSIC and MPP.



Peter Beyer
Chair, Expert Advisory Group
Date: 2 November 2021