

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

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 on the proposed licence agreement (the Agreement) between MPP, as the implementing partner of the Covid-19 Technology Access Pool (C-TAP), and Consejo Superior de Investigaciones Científicas (CSIC) for a COVID-19 vaccine.

This report reflects the outcome of a consultation with the EAG by correspondence between 23 and 30 of June 2023, chaired by Peter Beyer, and joined by EAG members, Luis Gil Abinader, Zeba Aziz, Jennifer Cohn, Carlos Maria Correa, Manuel Gonçalves, Mariatou Tala Jallow, Deepa Joshi, Martha Gyansa-Lutterodt, Jordan Jarvis, Gugu Mahlangu, Deus Mubangizi, Valérie Paris and Fatima Suleman, as well as Nathan Ford and Francois Venter of the Scientific Advisory Panel (SAP) and Maka Gogia and Javier Bellocq from the Communities Advisory Panel (CAP).

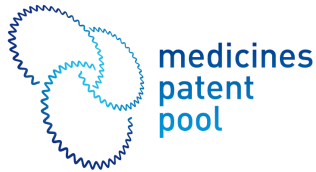
Background, Overview of the Proposed Agreement

In May 2020, the World Health Organization (WHO) launched the Covid-19 Technology Access Pool (C-TAP) to facilitate timely, equitable, and affordable access to 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. The EAG understands that WHO has conducted a technical assessment of the patents, patent applications and the scope of the technology transfer, and has concluded that those outlined here would be suitable for inclusion into C-TAP. Furthermore, the EAG notes that the C-TAP advisory group has reviewed the terms of the licence and provided a positive opinion thereafter. The results of that review were shared by WHO with MPP in a report. The EAG has reviewed the report which recommends that MPP proceed with the proposed Agreement and agrees with its recommendation and the comments made on possible improvements.

CSIC has developed a prototype COVID vaccine based on the MVA vector platform, a highly attenuated Modified Vaccinia virus Ankara (MVA) vector that has been engineered to express a prefusion-stabilized human codon-optimized full-length SARS-CoV-2 spike (S) protein. The vaccine has been evaluated in several animal models, with clinical trials yet to begin. CSIC is currently preparing the first phase 1 clinical study, using the vaccine made under Good Manufacturing Practices by Biofabri, a Spanish manufacturer.

Key aspects of the proposed licence are as follows:

- **Aim of the Licence:** To facilitate the manufacture and commercialization of Covid-19 vaccine around the world.



- **Products:** Any product that is covered by the Patents or uses the know-how or material.
- **Know-how:** CSIC to provide all necessary know-how and materials (including the premaster virus seed for MVA-CoV2-S(3P) and unmodified derivatives) to the licensees. The licence does not include any Know-How held by Biofabri.
- **Field of use:** COVID-19 vaccine
- **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 low and middle-income countries.
 - 5% for high-income countries, where there is a Patent granted and in force.
 - 1.5% for high-income countries, where no Patent but if the licensee has used the know-how or material.

The EAG has doubts about the justification of the 1,5% royalty for 10 years since:

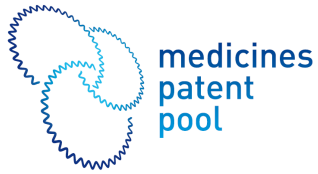
-it would apply whether the 'know-how' remains confidential or is in the public domain, thereby creating a disadvantage to the sublicensees vis-à-vis other potential manufacturers;

-Schedule 3 does not clarify what are the 'other Materials useful for the manufacturing and/or development of the Product owned and/or controlled by CSIC' (as done in Schedule 2 of the agreement with University of Chile). These materials should be specified to provide legal certainty and to assess the extent to which they would be critical for the manufacture of the product so as to justify the required payment.

-Schedule 3 further indicates that 'Licensed Know-how' 'is mostly related to scientific background and preclinical development of MVA-based COVID-19 vaccine candidate, MVA-CoV2-S(3P)'. It does not seem a good precedent to suggest that 'scientific background' can be 'owned' rather than be openly available (as advocated by UNESCO, see: <https://unesdoc.unesco.org/ark:/48223/pf0000378841>) and access thereto subject to a royalty payment. It is understandable that the licensor would wish to charge for training and assistance but this could be done on a cost basis rather than a 10 years royalty payment.

-It does not seem justified either to pay a royalty for preclinical data which can hardly be defined as 'know-how'.

- **Term:** Continuing until the date the last Patent has lapsed, expired, or been invalidated. Payment of know-how royalties continue for 10 years from the first sale on a country-by-country basis.



There is no form of the sublicense agreement included in the Agreement. CSIC and MPP will agree on terms for a sublicense. As pointed out by the C-TAG Advisory Group it could be problematic that the licensor and the licensee will have to discuss and agree upon the identities of interested and suitable sublicensees.

Assessment of the Proposed Agreement

The EAG finds the proposed Agreement is aligned with MPP's statutory requirements.

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, as the implementing partner of C-TAP.

A handwritten signature in black ink, appearing to read "P. Beyer".

Peter Beyer
Chair, Expert Advisory Group
Date: 07 July 2023