Report of the Medicines Patent Pool Expert Advisory Group
on two proposed licence agreements with
National Institutes of Health (NIH) on Covid-19 related technologies

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 two proposed licence agreements (the Agreements) between MPP as the implementing partner of the Covid-19 Technology Access Pool (C-TAP) and NIH on a number of patent applications and materials related to COVID-19 .

This report reflects the outcome of an on-line consultation with the EAG and SAP that took place between 30 April and 4 May 2022.

Having reviewed the proposed Agreements between MPP and NIH and the EAG recommends that the Board requests the Executive Director of MPP to finalise and execute the necessary documents with NIH.

Background, Overview of the Proposed Agreements

In May 2020, the World Health Organization (WHO) launched C-TAP to facilitate the timely, equitable, and affordable access to Covid-19 related health products via sharing of intellectual property, data, and know-how necessary for the 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 receiving and screening submissions of interest.

The in-licensed patent applications and materials cover a variety of technologies developed at NIH that are potentially relevant in the response to Covid-19, including patent applications on the spike protein that have been licensed to several Covid-19 vaccine developers. The EAG understands that WHO has conducted a technical assessment of the licensed patent applications and materials and concluded that they would be suitable for inclusion into C-TAP.

Key aspects of the proposed licences are as follows:

- **Aim of the Licences**: To facilitate the manufacture and commercialization of Covid-19 related health products and vaccines around the world.
- **Technology**: One licence covers different patents and materials on technologies potentially relevant in the fight against Covid-19. The second licence specifically covers patents on the spike protein.
- **Products:** Any product or vaccine that is covered by the Patents or Patent Applications or uses the Licensed Material.
- **Field of use:** While one licence on the different technologies is granted for SARS-CoV-2 products for the WHO C-TAP program, the second licence, in relation to spike protein, refers to SARS-CoV-2 vaccines for the WHO C-TAP program.
- **Territory:** Worldwide.
- **Term:** Continuing until the date the last Patent has lapsed, expired, or been invalidated.
- **Scope of the grant:** Non-exclusive right to grant sublicences to develop the licensed patents/material into licensed products or vaccines, and to commercialize the licensed products or vaccines.

- **Sublicence**: There is no form sublicence included in the proposed agreements. NIH and MPP will agree on terms for a sublicence, and additionally will discuss and agree upon the identities of interested and suitable sublicensees.

- **Royalties:**
  Both licences follow the same general structure (see the table below). The various technologies licence stipulates low royalty rates and is royalty-free for Least Developed Countries (49 countries, defined by the United Nations). As NIH already licensed the spike protein patents to other entities, it had to align the royalty schemes with the existing licences.

	Type of Royalty	Various technologies licence	Spike protein licence
1	One-time royalty at the sub-licence signature	USD 10,000	USD 50,000
2	Annual royalty	USD 5.000 before the first commercial sale and 10.000 after	USD 10.000 before the first commercial sale and 15.000 after
3	Royalty based on Net Sales	5% if Licensed Patent Rights exist in a country of manufacture or sale 2.5% if the Licensed Patent Rights do not exist in a country of sale, but Licensed Materials are used	0.5% (LDC) 2% - 2.5% (depending on the financial threshold) if Patents and Valid Claims exist in a country of manufacture or sale 0.25% (LDC) and 1%-1.5% (depending on the financial threshold) if Licensed Patent Rights exist but Valid Claims do not exist in a country of manufacture or sale
4	Benchmark royalty	vary form USD 50.000 to 10M USD depending on the R&D benchmark	

Assessment of the Proposed Agreements

The EAG finds the proposed agreements aligned with MPP's statutory requirements. The EAG further recognizes that the signing of these additional C-TAP licences is a major achievement that will send an important message to governments and research institutions around the world to enter into further license agreements with C-TAP. The EAG congratulates NIH, which was also the first licensor to MPP, on demonstrating this kind of leadership.

Recommendation

The EAG therefore recommends that the Medicines Patent Pool Governance Board requests the Executive Director to sign the proposed Agreements between NIH and MPP as the implementing partner of C-TAP.

Peter Beyer
Chair, Expert Advisory Group
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