Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Licence Agreement with SD Biosensor Inc. on a Rapid Diagnostic Testing (RDT) technology

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 SD Biosensor Inc. (SDB) on Rapid Diagnostic Testing (RDT) technology.

This report reflects the outcome of a consultation by correspondence between the 1st and 8th of December 2023 of 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, , Valérie Paris, Fatima Suleman, and Katherine Gill and François Venter of the Scientific Advisory Panel (SAP) and Maureen Luba and Wim Vandevelde 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 secretariat 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 that report which recommends that MPP proceed with the proposed Agreement and agrees with its recommendation.

SDB is a manufacturer of rapid diagnostic tests (RDTs), including but not limited to standard Q COVID-19 Ag Test. SDB's RDTs are rapid chromatographic immunoassays for the qualitative detection of proteins specific to a particular pathogen, e.g. a RDT for COVID -19 detects nucleocapsid protein antigen from SARS-CoV-2 present in human nasal or nasopharyngeal specimens.

The scope of the initial discussions were focused on a potential licence on RDTs specifically for COVID –19, it became clear that SDB was prepared to broaden the field of use for RDTs for other pathogens, including, for example, HIV, syphilis and malaria, which to the WHO Secretariat represented a significant development as the potential value of the licence would be amplified.

The successful conclusion of a license with SDB is considered important by the WHO Secretariat given the suitability of the technology for use in LMIC settings; the support SDB intends to provide selected manufacturers to ensure their viability and the quality of products produced; and the fact that the licence would move beyond COVID-19, thereby increasing the value of the technology to recipients and LMICs.

Key aspects of the proposed licence are as follows:

- **Aim of the Licence**: To facilitate local manufacture and the development of RDTs for COVID-19 and other diseases.

- **Products**: Any RDT product based on the Licensed Technology, including without limitation the Standard Q COVID-19 Ag Test.

- **Licensed Technology**: SDB to provide rights to SDB Patents, Material and Know-How that are useful or otherwise relevant for manufacturing of RDT including without limitation for COVID-19 and other RDTs in the Field.

- **Field:** Detection of any antigen, including without limitation for SARS-Cov-2.

- **Territory**: Worldwide, except the countries where SDB production plants are located: Brazil, India, Indonesia, Korea, and Panama.

- **Scope of the grant**: Non-exclusive right under the Licensed Technology for MPP to grant sublicences to develop, make and sell the Products, commercialise, and sell the Product for use in the Territory and in the Field.

- **Royalties**: Royalty rates apply on the net sales of the Products where there is a patent right granted and in force in the country of manufacture or sale as follows:
  - royalty free for LMICs;
  - a royalty of 15% for HICs.

- **Term**: Continuing until, (i) for the countries where exist a Patent Right, the date the last patent right has lapsed, expired, or been invalidated or (ii) for the countries without Patent Rights, which is valid and in force, for a term of ten (10) years.

SDB and MPP with the involvement of WHO will 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 and notes that the report from the WHO Secretariat on the proposed licence concluded as follows:

> On the strength of the recommendation from the WHO technical assessment and the fact that most of the actionable recommendations from TAG members to the WHO C-TAP Secretariat were discussed with the MPP legal team and incorporated into the draft Agreement, the C-TAP Secretariat recommends the MPP Board approve the execution of the proposed Agreement on behalf of the WHO C-TAP.

As such, the EAG therefore recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between SDB and MPP, as the implementing partner of C-TAP.

Peter Beyer, Chair, Expert Advisory Group Date: 14 December 2023