Report of the Medicines Patent Pool Expert Advisory Group
on the Proposed Licence Agreement with Pfizer, Inc

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 Licence Agreement (the Agreement) between MPP and Pfizer Inc (Pfizer) for sutezolid.

Three members of the Scientific Advisory Panel (SAP) with expertise in tuberculosis (TB) where invited to participate in assessing the proposed collaboration.

The Terms of Reference for the EAG pose two questions that the EAG must address in assessing the results of final negotiations: (i) do the results sufficiently meet the requirements set out in the Statutes, and (ii) do the negotiation results offer sufficient added value over the *status quo*?

Having reviewed the draft Agreement and having received a briefing from the MPP on the proposed collaboration between the MPP and Pfizer, the EAG answers both questions in the affirmative and recommends that the Board request the Executive Director of the MPP to finalise and execute the necessary documents with Pfizer.

Background, Overview of the Proposed Agreement

Sutezolid is an oxazolidinone antibiotic with potential application in TB. It belongs to the same class as linezolid, a WHO-recommended treatment for multidrug-resistant TB (MDR-TB). Sutezolid, if further developed in combination with other drugs, could be used to more effectively treat patients diagnosed with drug-sensitive and multidrug-resistant TB.

The drug was initially developed by Pfizer up to phase II and then exclusively licensed to Sequella in 2013. However, the further development of sutezolid has not progressed significantly since then.

The compound patent on sutezolid has expired and a patent covering the use of sutezolid in combination with other TB drugs was jointly owned by Pfizer and Johns Hopkins University (JHU). The MPP entered into a licence agreement with JHU in January 2017 for these patents and patent applications, but no rights to clinical data were included.

The EAG understands that the terms of the licence agreement between Pfizer and Sequella were renegotiated, making the licence non-exclusive. This allowed Pfizer to offer a licence to MPP, which is significant because this will facilitate access to the preclinical and clinical data that was not available in the licence with JHU.

The proposed Agreement with Pfizer grants a non-exclusive, worldwide, royalty-free licence to MPP to the patents and know-how (pre-clinical and clinical data) to allow MPP sub-licensees to develop, make, have made, use, file for regulatory approval, sell, offer to sell, import and export pharmaceutical combinations and compositions containing sutezolid, for the prevention and treatment of tuberculosis.

Sublicensees will be selected by MPP between entities with demonstrated willingness and capacity to develop and/or, subject to regulatory approval, commercialize the products in a manner consistent with the goal of facilitating affordable access to quality-assured products to those in need.

Assessment of the Proposed Collaboration in Light of MPP's Statutes

MPP's Statutes contain guiding principles against which the results of negotiations are assessed. The EAG and the three experts from SAP find that the proposed collaboration meets the requirements in the Statutes, as summarised in the tables below.

Relevant considerations in the Statutes of the Medicines Patent Pool

Statutes, Art. 4	Terms in Proposed Licence
Negotiating terms and conditions of licence agreements with the aim to maximize public health benefits, taking into account the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the WHO (GSPOA); and consistency with other access to medicines-related multilateral instruments and declarations, such as the WTO Declaration on the TRIPS Agreement and Public Health;	• No restrictions on ability of sublicensees to challenge patents
Entering into licence agreements with patent holding entities, and sublicence agreements with generic manufacturers and other appropriate sublicensees on a non-exclusive and no-discriminatory basis	• MPP retains the right to issue non-exclusive sublicences to any qualified entity in the world
Ensuring that contracts with sublicensees specify that products produced under sub-licence from the Patent Pool must obtain approval from a stringent drug regulatory authority or WHO prequalification, as applicable, with adequate provision for alternative temporary arrangements through a WHO Expert Review Panel in case such approvals are not yet available;	• Quality provisions in line with WHO Prequalification, SRA as defined by WHO or WHO Expert Review Panel
Safeguarding against the diversion and ensuring the traceability of products produced under sub-licence from the Patent Pool in accordance with the guidelines as set out in Art. 2(b)(ii) of the World Trade Organization's Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;	• The geographical scope of the licence is worldwide, and therefore anti-diversion measures are not applicable

As and when necessary, assisting in dispute resolution procedures between licensors and sublicensees. Licence agreements should contain provisions that specify an alternative dispute resolution mechanism, actionable by all signatories to the licence agreements;	• Mediation by senior executives with resolution within 30 days; if no resolution, proceed to mediation in accordance with WIPO Mediation Rules

Assessment of the Proposed Collaboration in Light of the *Status Quo*

The EAG finds that the terms and conditions of the proposed Agreement represent an advance over the *status quo*. The proposed Agreement will provide interested developers with access to data that was previously unavailable and has stalled research or required repeating early clinical studies. The access to the Pfizer data set will hopefully re-ignite interest in and speed the development of this potentially important component of TB treatment.

Recommendation

In light of the foregoing analysis, the EAG recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between Pfizer and MPP. The EAG further recommends that in any future negotiations with potential sublicensees, the MPP stresses the importance of the transparency of clinical trial data and seek to collaborate with entities that share this commitment.

Signed,

Maximiliano Santa Cruz
Chair, Expert Advisory Group

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