Report of the Medicines Patent Pool Expert Advisory Group
on the Proposed Licence Agreement with Johns Hopkins University

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 the Johns Hopkins University (JHU) for sutezolid.

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 the Memorandum of Understanding (MoU) between the MPP and UNITAID, 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 JHU, 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 JHU.

Background, Overview of the Proposed Agreement

Sutezolid is an oxazolidinone antibiotic with potential application in TB as part of a multi-drug regimen. The drug was originally developed by Pfizer up to Phase IIa clinical trials, but was exclusively licensed to Sequella in 2013. Since then, the EAG understands that no significant development work has taken place, and that many in the TB community have expressed a desire to see the further development of sutezolid. In particular, the Global Alliance for TB Drug Development (the TB Alliance) has expressed an intention to further develop sutezolid for use in TB.

The original compound patent on sutezolid expired in 2014, but there is a patent on the combination of sutezolid with other TB compounds that is jointly owned by Pfizer and JHU, set to expire on or around 2029. As JHU was evaluating its out-licensing options, the campaign launched by a coalition of civil society organisations to encourage JHU to engage in public health-oriented licensing was critical to JHU considering MPP as a licensing partner.

The MPP entered into formal negotiations with JHU in May 2016 for a licence agreement over the patents and patent applications on sutezolid.

The proposed Agreement with JHU grants an exclusive licence to MPP, that is sub-licensable, royalty free, and fully paid, for the purposes of develop, make, have made, use, file for regulatory approval, sell, offer to sell, import and export Licensed Products in the Field in the Territory (defined as any country in the world in which there are patents or patent applications).

In addition, the Agreement stipulates that nothing will prevent Sublicensees from engaging in any activity inside or outside the Territory if there is no infringement of a valid claim of a patent granted and in force.

Sublicensees will be selected by MPP between entities with demonstrated willingness and capacity to develop and/or commercialize the Licensed Products in a manner consistent with the goals of accessibility worldwide. The MPP also commits to a "most favoured licensee" provision, whereby the terms granted to one sublicensee are no more favourable than those granted to other sublicensees.

The proposed Licence Agreement contains, in addition, a number of other important public health-oriented terms and conditions, such as:

> (i) Sublicensees are required to commercialize the Products in accordance with MPP's Quality Policy, that currently requires WHO PQ, SRA Approval or ERP approval (if applicable and available).
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> (i) There is an express recognition of the importance of facilitating proper development, stewardship and use of new TB drugs and regimens in line with the national TB programmes and with national regulatory requirements. In this respect, MPP and Licensee will confer, prior to the commercialization of any Licensed Products, in order to reach good faith agreement on terms governing the manufacture, use and sale of Licensed Products in a manner consistent with what is then recognized to be best practices for the proper stewardship of new drugs for TB, taking into account, for example, findings from the MPP's work on TB drug stewardship**.**
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> (iii) MPP will require that Sublicensees share study plans or synopses and agree to development milestones and commercialization and registration timelines, and MPP will monitor compliance by Sublicensees of such timelines.

Finally, the Agreement will be in force from its signature until the date of expiration or abandonment of Patents, on a country-by-country basis, with the possibility of conversion into a JHU-Licensee direct licence, in case main licence (MPP-JHU) terminates.

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

MPP's Statutes and MoU with UNITAID contain guiding principles against which the results of negotiations are assessed. The EAG finds that the proposed collaboration meets the requirements in both the Statutes and MoU with UNITAID, as summarised in the tables below.

(i) 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 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); Doha Declaration	• No restrictions on ability of licensees to challenge patents • Allows for any activity outside the Territory where such activities would not infringe a patent granted and in force

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 sub-licensees 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 MPP's Quality Policy, as amended from time to time, which requires approval by WHO Prequalification, SRA or WHO Expert Review
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;	• Obligation to include in packaging that the product has been manufactured under a licence by the MPP to be included in any subsequent sublicence

(ii) Relevant Considerations in the MoU between the MPP and UNITAID

MoU	Terms in Proposed Licence
Ensure that license agreements specify an alternative dispute resolution mechanism;	• Mediation by senior executives, before appealing to Court proceedings
Define the terms and conditions under which the sub-licensees must make insurance arrangements to cover liability risks linked to products produced under the sub-licence form the MPP;	• Product liability insurance obligation specified
Safeguard against diversion and ensuring traceability of products produced under sub-licence from the MPP by specifying sub-licence terms and conditions in accordance with the guidelines set out in Art. 2(b)(ii) of the Word Trade Organization's Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;	• Obligation to include in packaging that the product has been manufactured under a licence by the MPP, in the text of the Sublicence
Broad geographical scope	• Worldwide licence
Access to medicines through TRIPS and other mechanisms The MPP negotiates provisions that enable licensees to sell outside the licensed territory under certain circumstances, such as, for example: (a) In the event of a compulsory licence being issued, (b) In the event that sales do not infringe on any granted patents or patent challenges are successful (e.g. licence on dolutegravir), (c) By allowing generic manufacturers to terminate licences for which they no longer need a licence, thereby allowing them to sell in additional countries (e.g. licence on tenofovir disoproxil fumarate) MPP agreements also provide licensees the freedom to challenge the validity of the licensed patents	• Allows for any activity outside the Territory where such activities would not infringe a patent granted and in force Effectively, a worldwide licence • No restrictions on challenging patents • Termination of licence on country-by-country basis, until the expiration of the last to expire patent

Prompt availability of quality, low cost generic medicines (a) Ensure the speedy registration of licensed products through a waiver of the licensor's data exclusivity rights (where applicable) (b) Generic company products must meet internationally-recognised quality standards (c) MPP's generic partners must adhere to strict timelines for development and regulatory approval of products or face licence termination	• Quality provisions according to MPP's Quality Policy, which requires approval by WHO Prequalification, SRA or WHO Expert Review Panel • Development and registration timelines to be included in any sublicence
Transparency of patent and licensing information (a) All MPP licences contain provisions to ensure that the MPP may publish the licences in full on the MPP website (b) Patent holders provide patent disclosure of relevant patents within (and sometimes outside) the licensed territory	• The Agreement will be published in MPP's web page, as well as any future sublicence agreements signed by the MPP with generic manufacturers • Disclosure of patents and patent applications worldwide

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

The EAG finds that the terms and conditions of the proposed Agreement represent a significant advance over the *status quo*, both in terms of geographic scope and in terms of promoting transparent, public health-oriented licensing terms and conditions. From both a quantitative and qualitative perspective, the EAG finds that the worldwide scope of the licence, and key terms that aim to ensure the prompt development and ultimate accessibility of quality-assured, appropriately developed TB regiments represent a significant advance over the *status quo*. In addition, the MPP's promotion of socially responsible, transparent and public health-oriented licensing with a major research-based university represents a promising advance over the *status quo* that could encourage other universities to follow suit.

Recommendation

The EAG concludes that the proposed Agreement with JHU is consistent with MPP's mandate as defined in its Statutes and MoU with UNITAID, and represents a significant improvement over the *status quo* in terms of the public health-oriented nature of the licensing terms and conditions.

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

Signed,

Maximiliano Santa Cruz
Chair, Expert Advisory Group