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

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 Collaboration Agreement and Patent and Know-How Licence (the Agreement) between MPP and the University of Liverpool (UoL).

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 requirements set out in the Statutes and the Memorandum of Understanding between the Patent Pool 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 MPP on the proposed collaboration between MPP and UoL, the EAG answers both questions in the affirmative, and recommends that the Board request the Executive Director of MPP to finalise and execute the necessary documents with UoL.

Background, Overview of the Proposed Agreement

Despite significant progress in scaling up access to antiretroviral therapy in the developing world, many millions of people living with HIV (PLHIV) are still in need of treatment, particularly in light of the World Health Organization's recent recommendations to start ART immediately upon diagnosis, regardless of CD4 count. With this increased need, it has become imperative to find new ways in which the cost of treatment can be reduced, so that more people can be treated with the same amount of money. The MPP has already taken promising steps towards this end, with its licences on tenofovir alafenamide, dolutegravir and atazanavir, all of which have the potential to offer significant cost savings in first- and second-line treatments. The MPP, through its proposed Agreement with UoL, aims to explore another promising avenue towards reducing the cost of treatment: dose reduction through nanotechnology.

Nanotechnology can potentially offer cost savings by reducing the total amount of active pharmaceutical ingredient (API) needed per dose. By dramatically reducing the particle size of an API, faster dissolution and better bioavailability can potentially be achieved, thereby requiring smaller amounts of the API to be manufactured per dose. Less API per dose could thus result in cheaper manufacturing costs, as well as lesser toxicity in humans.

UoL has developed a nanotechnology called Solid Drug Nanoparticles (SDNs) that is potentially applicable to a number of antiretrovirals (ARVs). UoL has already developed SDNs of two ARVs, efavirenz and lopinavir, and MPP and UoL have identified a number of other ARVs to which the SDN technology could further be applied. However, in order to further advance its existing ARV-SDNs into final products, as well as develop further ARV-SDNs, the UoL and MPP will need to secure funding for such further development work, as well as identify third parties with the necessary expertise to develop and ultimately commercialise the final products.

The Agreement aims to achieve this through a collaboration agreement between UoL and MPP to work on a specified list of ARVs, as well as a non-exclusive patent and know-how license from UoL to MPP that will allow MPP to sublicense such technology to Development and Commercialisation partners. The primary list of ARVs that the parties have agreed to work on are known as the "Agreed ARVs," comprising: atazanavir, cobicistat, darunavir, doravirine, efavirenz, lopinavir (including ritonavir-boosted lopinavir), raltegravir, and ritonavir, and combinations thereof. A secondary list of ARVs, called "Additional ARVs," are comprised of ARVs that are not likely to benefit directly from the SDN technology but could potentially be co-formulated with the Agreed ARVs in fixed-dose combinations.

Under the proposed Agreement, the MPP will assist UoL in identifying funding opportunities to further develop the Agreed ARVs into ARV-SDNs. As such new ARV-SDNs are developed, the MPP and UoL will work with a Development Partner that the MPP identifies to further develop each ARV-SDN into approved pharmaceutical formulations that can be manufactured at industrial scale. Once such development work has been completed, the MPP will then identify Commercialisation Partners to manufacture and sell the Licensed Products throughout the licensed Territory: 137 countries, comprising all low- and middle-income countries as currently defined by the World Bank.

The proposed Agreement grants to the MPP a non-exclusive licence to issue sub-licences to both Development Partners and Commercialisation Partners in the Field (treatment and prevention of HIV) for ultimate sale in the Territory (all low- and middle-income countries). For the purposes of calculating royalties payable by Commercialisation Partners directly to UoL, the countries in the Territory are divided into three groups: Group 1, comprising all low-income countries, least-developed countries (LDCs) and Sub-Saharan African countries (SSA), in which no royalties are payable; Group 2, comprising all lower-middle income countries (that are not LDCs or SSA) in which a royalty of 1% of net sales are payable for private sector sales only (and royalty-free in public sector); and Group 3, comprising all upper-middle income countries (that are not LDCs or SSA) in which a royalty of 1.75% of net sales are payable.

As in all previous MPP licences, royalties are waived for paediatric-specific formulations, regardless of country grouping. The Agreement further makes clear that no royalties become payable to UoL unless a patent is ultimately granted in the country of manufacture or sale, and as in other MPP licences, contains a broad provision stating that nothing prevents an MPP licensee from engaging in activities that do not infringe a patent granted and in force or rely on undisclosed know-how.

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 Agreement meets the requirements in both the Statutes and MoU with UNITAID, as summarised in the tables below.

Relevant Considerations in the Statutes of the Medicines Patent Pool

Statutes	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.	• Preamble makes clear that Agreement is solely to provide access to IP where needed; not to create any contractual barriers to access. • No restrictions on ability of licensees to challenge patents. • All low- and middle-income countries included within the scope of the Territory.
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 anywhere in the world. Licensee is deemed to be mutually agreed unless otherwise noted in writing by the University within 30 days from notification, stating the grounds and the mitigation approach.

Relevant Considerations in the MoU between the Pool and UNITAID

MoU	Terms in Proposed Licence
Use all reasonable efforts to define standard terms and conditions of licence agreements.	• Main terms and conditions of Sub-licence included in the form of a term sheet in the schedules of the Agreement. • Key public health provisions increasingly standardised across MPP licences.
Define the terms and conditions of the licences and sublicences, respecting the differing patentability criteria across jurisdictions.	• No breach of the Agreement if sales made outside the Territory where there are no granted patents and in force or Licensees do not rely on Licensed Know-How. • No restrictions on challenging patents.
Ensure contracts with sublicensees specify that products must obtain approval from a stringent drug regulatory authority or WHO prequalification or temporary arrangements under WHO Expert Review Panel.	• Quality provisions require approval by WHO Prequalification or any SRA approval. Where such approvals aare not yet available, temporary approval through WHO Expert Review Panel.
Ensure that licence agreements specify an alternative dispute resolution mechanism.	• Mediation by Senior Executives, if the dispute is not resolved, then jurisdiction of the English Courts.
Define the terms and conditions under which the sublicensees must make insurance arrangements to cover liability risks linked to products produced under sublicence from MPP.	• Product liability insurance obligation will be specified for Commercialization Partners. • Agreement to contain additional customary terms of our licences.
Safeguard against the diversion and ensuring the traceability of products…by specifying terms and conditions in accordance with WTO [30 Aug Decision] guidelines.	• Product to be labeled as manufactured under a licence from the MPP and University.
Facilitate activities promoting transfer of technology, capacity building and local manufacturing of medicines in developing countries, consistent with the Purpose of the Foundation, and in consultation with other international partners	• Technology transfer of Licensed Know-How. • Licensees can be based anywhere in the world.

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

The EAG finds that the proposed Agreement with UoL represents a significant improvement over the *status quo*; in terms of promoting transparent, public-health oriented licensing terms and in terms of expanding the coverage of geographical scope of former MPP-negotiated licences.

The geographic scope of the proposed Agreement covers 137 countries amounting to all low- and middle-income countries. The EAG believes this represents a significant advance over any existing voluntary licensing policy. The EAG encourages the MPP's movement towards the licensing of promising technologies for further development, and stresses the importance of having broad and equitable access provisions "baked-in" from the start, as in this proposed Agreement.

The EAG concludes that this Agreement further strengthens the key public-health oriented terms and conditions of MPP-negotiated licences that are increasingly becoming the norm in the field of voluntary licensing in HIV products.

The EAG also notes that the proposed licence will be made public on MPP's website, contributing to the goal of injecting greater transparency in the field of HIV licensing, a core mission of MPP.

Recommendation

The EAG concludes that the proposed Collaboration Agreement and Patent and Know-How Licence with UoL 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 a wider coverage of treatment in all developing countries and the public-health oriented nature of the licensing terms and conditions. Therefore, the EAG recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between MPP and UoL.

Signed,

Maximiliano Santa Cruz
Chair, Expert Advisory Group