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

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 License and Technology Transfer Agreement (the Agreement) collaboration between MPP and Bristol-Myers Squibb (BMS).

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 BMS, 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 BMS.

Background, Overview of the Proposed Agreement

MPP has been in negotiations with BMS since 2011. The immediate product of interest in BMS's HIV portfolio is atazanavir (ATV), a key antiretroviral that is one of the two protease inhibitors recommended as part of the preferred second-line regimens in the 2013 WHO treatment guidelines. BMS has a pre-existing access programme for ATV providing royalty-free access to a limited geography: just Sub-Saharan Africa (49 countries), and in two instances, Sub-Saharan Africa plus India (50 countries). The EAG understands from MPP that ATV is of particular interest as it offers significant benefits over the other preferred protease inhibitor, lopinavir[1] (LPV), in that ATV can be dosed once daily and the lower daily dosage (300 mg for ATV vs. 800 mg for LPV) means that ATV-based second-line regimens can potentially be made substantially more affordable and co-formulated.

The proposed Agreement on ATV consists of a main Agreement between MPP and BMS that grants MPP the right to sublicense in the form of the Sublicense Agreement attached as a schedule to the Agreement. The Sublicense Agreement is royalty-bearing in certain circumstances and allows for the manufacture and sale of both active pharmaceutical ingredient (API) and finished product worldwide for use within the Territory, defined as 110 countries, covering, according to MPP's estimates, 88.4% of people living with HIV in the developing world.[2] Under the proposed Agreement, there is a 3% royalty charged in certain

[1] WHO recommends that both ATV and LPV be boosted with ritonavir.

[2] The full list of countries included in the Territory is available in Schedule D of the Agreement.

countries where there are Licensed Patent Rights *in force*, which MPP informed the EAG was meant to denote those countries in which there are *granted* patents in force. Further, regardless of patent status, royalties are not payable in those countries that were previously included in BMS's royalty-free access programme; namely, Sub-Saharan Africa and India.[3] The proposed Agreement further stipulates that BMS will not collect any of the royalties collected; rather the money will be collected by MPP and channelled back to a community-based HIV organisation based in the country from which the royalties are collected. Royalties are also waived for any paediatric formulations of ATV that are developed and sold under the Agreement.

Under the proposed Agreement, MPP has the right to enter into the agreed upon Sublicense Agreement with any entity, worldwide, with the demonstrated capability to manufacture the licensed product, subject to a due diligence mutually conducted by BMS and MPP regarding the potential sublicensee's compliance with quality and anti-corruption laws. A technology transfer package is provided to all Sublicensees, but the Sublicensees have the option, upon review of the package, to decline to use BMS's technology package. A grant-back provision stipulates that any improvements developed by a Sublicensee will flow to both BMS and MPP, and MPP reserves the right to enter into negotiations with the Sublicensee for further sublicensing of the improvements to third parties.

The proposed License Agreement contains a number important public health-oriented terms and conditions. BMS agrees to waive any data exclusivity rights it may have within the Territory. Any royalties, where payable, are limited to those countries where Licensed Patent Rights are *in force*, meaning that royalties are not payable on pending patent applications that may ultimately not be granted by the local patent offices. And the Agreement stipulates that it does not constitute a breach of the Agreement for the Sublicensees to supply outside the Territory; provided that such activities (i) do not infringe Licensed Patent Rights or Non-Territory Patents; and (ii) Sublicensees do not rely on BMS's technology transfer package for such activities. This provision clarifies that "to infringe" means to conduct an activity infringing a granted patent, or other activities that may be enjoined under local laws relating to non-granted patents. With respect to this provision, MPP also clarified that regarding any potential disputes as to whether a Sublicensee "relied" upon BMS's technology transfer, the proposed Agreement expressly provides that the normal defences against trade secret misappropriation (e.g., information available in the public domain, independent derivation by Sublicensees) were made available to the Sublicensees (sec. 4.2(b)). MPP explained to the EAG that under this provision, Sublicensees would potentially not be contractually prohibited from supplying outside the Territory where (i) there are no patents; (ii) where there are only patents pending; (iii) where a compulsory licence has been issued; and (iv) where there may be patents in force but not infringed by the Sublicensee (e.g., via a non-infringing process).

[3] Those countries where royalties are not payable are denoted with an asterisk (*) in Schedule D. The EAG notes that in addition to Sub-Saharan Africa and India, there are also no royalties payable in Armenia, the Dominican Republic and Nicaragua.

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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.

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Relevant Considerations in the Statutes of the Medicines Patent Pool

Statutes	Terms in Proposed MoU/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	• Agreement to waive data exclusivity rights • Allows for sale outside the Territory where such activities do not (i) infringe Licensed Patent Rights and Non-Territory Patents; and (ii) rely on the Licensed Manufacturing Know-How. For the purposes of this provision, "to infringe" will mean the infringement of a patent in force, or any other activities that are prohibited under applicable laws in relation to Licensed Patent Rights. • No restrictions on ability of licensees to challenge the validity of licensed 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 has the right to issue non-exclusive sublicences to any qualified entity in the world. BMS to perform due-diligence together with MPP to ensure Sublicensees' compliance with GMP, anti-corruption laws

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Relevant Considerations in the MoU between the MPP and UNITAID

MoU	Terms in Proposed MoU/Licence
Use all reasonable efforts to define standard terms and conditions of licence agreements	• Terms and conditions of Sublicense standardised across all sublicenses via the form Sublicense Agreement
Define the terms and conditions of the licences and sublicences, respecting the differing patentability criteria across jurisdictions	• Royalty only if patents are in force (granted) in country of sale • No royalties for countries included in pre-existing royalty free BMS licences • No breach of the Agreement if sales made outside the Territory where there are no infringement of Licensed Patent Rights and Non-Territory Patents • No restrictions on challenging licensed 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, SRA or WHO Expert Review Panel
Ensure that licence agreements specify an alternative dispute resolution mechanism	• Arbitration in accordance with ICC rules stipulated
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 specified
Safeguard against the diversion and ensuring the traceability of products...by specifying terms and conditions in accordance with WTO [30 Aug Decision] guidelines	• Obligation to bear mark and packaging distinctive from BMS
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	• Technical transfer package provided to all sublicensees • Sublicensees can be based anywhere in the world

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

The EAG finds that the proposed Agreement with BMS represents a significant improvement over the *status quo*; both in terms of geographic scope and in terms of promoting transparent, public health-oriented licensing terms and conditions.

The geographic scope of the proposed Agreement covers 110 countries covering an estimated 88.4% of people living with HIV in the developing world. This represents a significant expansion beyond the *status quo* of BMS's current licensing practices, which covers, at most, 50 countries. The EAG notes further that a number of other countries outside the Territory could also benefit via the diversion provision discussed above.

Having reviewed the publicly available information on existing licences, the EAG concludes that this licence represents an improvement on the *status quo*, both with respect to BMS's current licensing policy and the practice within the industry as a whole.

The EAG is pleased to note that many concerns previously expressed by some civil society organisations had been taken into account in the proposed License Agreement. The EAG views this as a significant improvement over the *status quo* in terms of promoting public health-oriented terms and conditions in voluntary licences. These include: (i) the ability for Sublicensees to be located anywhere in the world for purposes of supplying within the Territory; (ii) freedom to manufacture and sell API and finished product anywhere in the world for purposes of supplying within the Territory; (iii) the stipulation that royalties, where payable, are only payable where there are patents in force; (iv) MPP's ability to fully enforce the terms of the agreements *vis-à-vis* both BMS and its Sublicensees.

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 Agreement with BMS is consistent with MPP's mandate as defined in its Statutes and MoU with UNITAID, and represents a significant improvement over the *status quo*, both in terms of geographical scope 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 BMS and MPP. The EAG also recommends that MPP actively continue discussions with BMS seeking to incorporate countries currently excluded from the Territory.

Signed,

Maximiliano Santa Cruz
Chair, Expert Advisory Group