Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Paediatric Collaboration with ViiV Healthcare

Introduction

The Expert Advisory Group of the Medicines Patent Pool (the EAG) submits the following report to the Governance Board of the Medicines Patent Pool on the proposed paediatric collaboration between the Pool and ViiV Healthcare.

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 agreements, and upon receiving an extensive briefing from the Pool on the proposed collaboration between the Pool and ViiV, [1] the EAG answers both questions in the affirmative, and recommends that the Board request the Executive Director of the Pool to finalise and execute the necessary documents with ViiV.

Background, Overview of the Proposed Collaboration

The Pool has been in negotiations with ViiV, a joint venture of GlaxoSmithKline, Pfizer and Shionogi, since 2011. ViiV currently has five antiretroviral drugs (ARVs) commercialised: zidovudine (AZT), lamivudine (3TC), abacavir (ABC), fosamprenavir (FPV) and maraviroc (MVC). ViiV also has some promising ARVs under clinical review, notably dolutegravir (DTG).

Since the beginning of the ViiV negotiations, the Pool has kept the EAG updated. The Pool informed the EAG in a previous consultation that its focus during negotiations with ViiV had shifted to ABC for paediatric use. This shift in focus was due to the fact that ViiV's other current products were either largely off-patent (i.e., AZT, 3TC) or not of medical priority in developing countries at this time (i.e., FPV, MVC). Moreover, ViiV has made clear that it is not in a position to license any of its pipeline products until and unless they receive regulatory approval. In contrast, ABC is recommended for paediatric use by the World Health Organization (WHO) for both first and second line treatment.[2] In addition, the EAG was informed that while the patent on the ABC compound has expired, there remain several patents relating to ABC, including: (i)

[1] The briefing took place in a conference call held on 22 January 2013. All EAG members except Labeeb Abboud participated in the briefing. Mr Abboud was briefed separately on 27 January and endorses these findings and recommendations.

[2] The EAG notes that ABC could potentially play a more significant role in adult regimens in the future, particularly in combination with DTG and 3TC. The EAG understands that discussions with ViiV on the potential licensing of DTG and combinations containing DTG, including DTG/ABC/3TC, are on-going, but that ViiV is not in a position to license any of its pipeline compounds until and unless they receive regulatory approval.

the hemisulfate salt, which is patented in over 65 low- and middle-income countries (L&MICs), (ii) the paediatric formulation, which is also patented in several countries, including India and many countries in Latin America, Asia, Eastern Europe and Central Asia, and (iii) combinations with 3TC and in some cases with AZT/3TC. Since ABC is mostly used in combination with 3TC those patents are also potentially significant where they are in force.[3]

The Pool informed the EAG that the focus of negotiations on paediatric ABC resulted in an opportunity for a broader discussion about potential avenues of collaboration between the Pool and ViiV on the development of needed paediatric HIV formulations. This broader discussion ultimately led to two documents submitted to the EAG for review: a non-binding Memorandum of Understanding (MoU) for collaboration on paediatric HIV product development, as well as a binding Licence Agreement on ABC.

The MoU for Collaboration for Paediatric HIV Product Development

The proposed MoU between the Pool and ViiV lays out a number of areas for present and future collaboration on paediatric HIV product development, of which one key element is the proposed binding licence agreement on paediatric ABC, discussed below. Other areas of potential future collaboration defined in the MoU include: the licensing of products still in clinical development, formulation development and technology transfer, access to ViiV's regulatory data, and jointly seeking out partnerships with third parties for the development of needed fixed-dose combinations (FDCs).

The EAG notes that while many of the commitments identified in the MoU are not legally binding on either party, it lays out some promising areas of future collaboration. In particular, the commitment by ViiV and the Pool to jointly seek out collaboration with third parties holding relevant intellectual property for needed paediatric FDCs could help draw other companies into negotiations with the Pool.

In the context of ViiV's stated commitment in the MoU to license its current pipeline products, the EAG reiterates the importance of obtaining a public health-oriented licence on DTG and DTG-containing combinations for both adults and children if and when DTG receives regulatory approval.

The Licence Agreement for paediatric ABC

The proposed Licence Agreement on paediatric ABC consists of a main Licence Agreement between the Pool and ViiV that grants the Pool the right to sublicense in the form of the Sublicence Agreement attached as an annex to the Licence Agreement. The Licence is non-royalty-bearing, and allows for the manufacture and sale of both active pharmaceutical ingredient (API) and finished product worldwide for use within the Territory, defined as 118

[3] A full list of licensed patents is available in Appendix A of the Licence Agreement.

countries, covering, according to the Pool's estimates, 98.7% of children living with HIV in the developing world.[4]

The proposed Licence Agreement contains a number of important public health-oriented elements. The Preamble to the Agreement makes clear that "the intent of this Agreement is to provide access to Patents, and not to create any non-patent-related barriers where Patents or Non-Territory Patents do not exist." Accordingly, the Licence Agreement expressly provides that supply outside the Territory is permitted where there is no infringement of any granted patents outside the Territory, including where a compulsory licence has been issued. ViiV also agrees to waive any data exclusivity rights it may have within the Territory, and the Sublicensees agree not to seek any such rights within the Territory.

The Pool has the right to enter into the agreed upon Sublicence Agreement with any entity, worldwide, with the willingness and verifiable capacity to manufacture the licensed product in accordance with the specified quality requirements. And the Pool, as a party to both the Licence Agreement and any Sublicence Agreement, retains the power to enforce the terms of the agreements *vis-à-vis* both ViiV and the Sublicensee. A grant-back provision stipulates that any improvements developed by a Sublicensee will flow to both ViiV and the Pool, and the Pool reserves the right to enter into negotiations with the Sublicensee for further sublicensing of the improvements to third parties. Further, the Sublicensees have the right to terminate the Sublicence, without cause, upon 30 days' notice.

During the briefing, the EAG expressed concerns that one of the provisions relating to the termination of the Sublicence Agreement could potentially be interpreted in an unfavourable manner. The EAG is pleased to learn that the Pool took these concerns back to ViiV and agreed on what the EAG views as a satisfactory solution.

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

The Pool'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.

[4] The full list of countries included in the Territory is available in Appendix C of the Licence Agreement.

Relevant Considerations in the Statues 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	• No restrictions on ability of licensees to challenge patents • Agreements to waive data exclusivity rights; prevention of further data exclusivity rights • Preamble makes clear that Agreement is solely to provide access to IP where needed; not to create any contractual barriers to access • Allows for sale outside the Territory where compulsory licence is issued • Allows for sale outside the Territory where there are no patents 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	• Pool retains the right to issue non-exclusive sublicences to any qualified entity in the world

Relevant Considerations in the MoU between the Pool 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 Sublicence standardised across all sublicences via the form Sublicence Agreement
Define the terms and conditions of the licences and sublicences, respecting the differing patentability criteria across jurisdictions	• Royalty free licence, thus avoids problems of royalties on patent applications • Licensee right to terminate without cause, with 30 days notice (e.g. in case considers remaining patents are not blocking) • No breach of the Agreement if sales made outside the Territory where there are no granted patents (i.e., no barriers on the basis of patent applications) • 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, SRA or WHO Expert Review Panel
Ensure that licence agreements specify an alternative dispute resolution mechanism	• Mediation in accordance with WIPO Mediation Rules
Define the terms and conditions under which the sublicensees must make insurance arrangements to cover liability risks linked to products produced under sublicence from the Pool	• 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 ViiV
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	• Commitment to explore opportunities for paediatric formulation development and technology transfer (in the MoU)

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

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

The geographic scope of the proposed Licence Agreement covers 118 countries covering an estimated 98.7% of children living with HIV in the developing world. Nevertheless, certain L&MICs were not included. The Pool informed the EAG that it had made a case for inclusion of every L&MIC, but that ViiV had refused to include certain countries. The EAG notes in this context, however, that the MoU states that the Pool and ViiV will explore mechanisms through which new paediatric formulations developed by Pool licensees would be made available outside the Territory.

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 ViiV'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 Licence 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 domiciled 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 express ability to supply outside the Territory where there is no infringement of a granted patent in that country, including where a compulsory licence has been issued; (iv) the Pool's ability to fully enforce the terms of the agreements *vis-à-vis* both ViiV and its Sublicensees.

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

Recommendation

The EAG concludes that the proposed collaboration with ViiV is consistent with the Pool's mandate as defined in the Pool's 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 Memorandum of Understanding and the Licence Agreement on ABC between ViiV Healthcare and the Medicines Patent Pool. The EAG also recommends the Pool to actively pursue

discussions with ViiV Healthcare in order to incorporate countries currently excluded from the licensed territory.

Signed,

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Chair, Expert Advisory Group