Report of the Medicines Patent Pool Expert Advisory Group
on the Proposed Licence Agreements with ViiV Healthcare for Dolutegravir

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 Licence Agreements (the Agreements) between MPP and ViiV Healthcare (ViiV) for dolutegravir (DTG).

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 having received a briefing from MPP on the proposed collaboration between MPP and ViiV, 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 ViiV.

Background, Overview of the Proposed Agreement

In February 2013, the MPP and ViiV agreed on broader paediatric collaboration by means of a Memorandum of Understanding (MoU), including a licence for paediatric abacavir (ABC) covering 118 countries. The MoU contained a commitment by ViiV to license pipeline compounds, such as DTG, upon regulatory approval for the same territorial scope for paediatric use. The EAG understands from MPP that negotiations with ViiV on DTG for both paediatric and adult use started soon after the paediatric ABC licence agreement was concluded.

DTG is an integrase inhibitor that was approved by the United States Food and Drug Administration on 12 August 2013. The MPP informed the EAG that DTG is of particular interest due to its clinical profile and is expected to be comparatively inexpensive to manufacture due to its low amount of active pharmaceutical ingredient. Notably, the World Health Organization (WHO) included DTG in the list of medicines for WHO PQ despite it not yet being recommended by the latest edition of the WHO HIV treatment guidelines. DTG was identified as a high priority in the MPP's latest edition of *ARV Priority List for the Medicines Patent Pool*.[1]

The MPP informed the EAG that there are two main patents on DTG: the compound patent and a patent on DTG use in combination with ABC and/or lamivudine (3TC). The compound patent expires around 2026, and the combination patent expires around 2031. The DTG compound

[1] http://www.medicinespatentpool.org/wp-content/uploads/Priority-Antiretrovirals-for-the-Medicines-Patent-Pool-Unabridged-Third-Edition-Final-Web.pdf

patent is granted or pending in key countries, including India and South Africa. The DTG combination patent is granted in South Africa and pending in several other countries.

The proposed collaboration with ViiV is comprised of two agreements covering DTG for paediatric and adult use, respectively. The DTG paediatric licence builds upon the previous paediatric ABC licence, but with the introduction of three additional countries into the Territory: Peru, Ukraine and Venezuela. The adult licence territory covers 73 countries: 67 royalty-free countries comprising Sub-Saharan African countries, Least Developed Countries and Low Income Countries, and 6 additional Middle-Income Countries in which royalties will be paid: India, Vietnam, Philippines, Indonesia, Egypt and Turkmenistan.

The MPP also informed the EAG that the adult licence is segmented between the public and private markets in the six additional royalty countries, with the licensees having access to the public market.[2] However, this segmentation only applies in countries where there is a patent granted and in force in the country.

The paediatric licence is royalty-free, and in the adult licence, royalties are payable for sales into six middle-income countries, differentiated into three royalty levels at 5%, 7.5% and 10% of generic sales price. The MPP informed the EAG that the royalty levels were determined using per capita GDP of each country. As with the segmentation obligations, royalties are payable only in countries where there is a patent on DTG granted and in force within that country. The proposed agreements also contain broad language contemplating the sale of DTG outside the Territory in the event that there is no infringement of a granted patent in the country outside the Territory. The broad language would potentially allow the sale of DTG outside the Territory where: (1) there are no patents on DTG in such country; (2) there are only pending patents in such country; (3) there are granted patents, but not infringed (e.g., DTG as a single agent where only the combination patent exists); (4) there is a patent but a compulsory licence has been issued; or (5) under national laws certain acts are not defined as patent infringement. According to the data provided by MPP, this would mean that DTG could be made available in countries with 99.3% of children living with HIV for the paediatric licence and 93.4% of people living with HIV in the adult licence.

[2] The Public Market is defined as: "(a) the following organisations to the extent that they are not for profit organisations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and agencies based outside of an applicable country to the extent that they are supporting implementation locally in an applicable country, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) of this Clause."

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.

Relevant Considerations in the Statues of the Medicines Patent Pool

Statutes	Terms in Proposed Licences
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, or where there is otherwise no infringement • Allows for sale inside the Territory into the private sector and/or for adult markets if there is no infringement of a granted patent, including where a compulsory licence is issued. • Lists Non-Territory Patents in low and middle-income countries
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

Relevant Considerations in the MoU between the MPP and UNITAID

MPP-UNITAID MoU	Terms in Proposed Licences
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; provisions on royalty allocation for combination products harmonised with Gilead formula
Define the terms and conditions of the licences and sublicences, respecting the differing patentability criteria across jurisdictions	• Royalties payable only on granted patents in force • 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 is no infringement of Non Territory Patents • 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 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 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	• Sublicensees can be based anywhere in the world

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

The EAG finds that the proposed agreements with ViiV represent 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 EAG finds that the effective coverage of the proposed agreements, covering 99.3% of children living with HIV and 93.4% of people living with HIV for the paediatric and adult licences, respectively, represent a significant advance over the *status quo*.

The EAG concludes that the public health-oriented licensing terms and conditions, including: (i) broad provisions allowing for sales outside the Territory where there is no patent infringement; (ii) broad provisions excluding obligations within the Territory where there is no patent infringement; and (iii) the innovative use of segmentation and tiered royalties in an effort to expand geographical scope represent an advance over the *status quo.*

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 the MPP.

Recommendation

The EAG concludes that the proposed Agreements with ViiV 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 Agreements between ViiV and MPP.

Signed,
Maximiliano Santa Cruz
Chair, Expert Advisory Group