

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

### 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 Agreement (the Agreement) between MPP and Merck Sharp & Dohme Corp. and MSD Italia s.r.l. (collectively “Merck”) for raltegravir (RAL) for paediatric use.

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 Merck, 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 Merck.

### Background, Overview of the Proposed Agreement

MPP formally entered into negotiations with Merck in the second quarter of 2014 for paediatric formulations of RAL. RAL has been recently approved for use in infants under 4 weeks and is the only integrase inhibitor approved for children living with HIV (CLHIV) under 12 years old. Presently it is recommended by WHO in 3<sup>rd</sup> line regimens. However during the 2014 Paediatric Antiretroviral Drug Optimization conference, experts agreed on the potential use of RAL in 1<sup>st</sup> line (as an alternative to LPV/r) and in 2<sup>nd</sup> line (on failing LPV/r) for CLHIV under three 3 years old.

RAL is well tolerated and is currently available in chewable tablets and oral suspension. According to the information in the MPP Patent Status Database, RAL is widely patented in developing countries, with the main patent due to expire in or around 2022. Importantly, RAL is patented in key manufacturing countries, such as Brazil, China, India and South Africa. Due to its potential public health importance and widespread patenting, RAL has been designated as a priority ARV in its Priority Antiretrovirals for the Medicines Patent Pool (3<sup>rd</sup> ed).

Since the MPP and Merck formally entered into negotiations for the licensing of paediatric formulations of RAL in the second quarter of 2014 negotiations have progressed rapidly. The MPP has placed the final results of its negotiations with Merck before the EAG.



The collaboration consists of a main Agreement between MPP and Merck 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 a bilateral and royalty free agreement to be signed between MPP and the potential sublicensee, and allows for the manufacture and sale of both active pharmaceutical ingredient and finished products worldwide for use within the Territory, defined as 92 countries (plus Sudan once Merck obtains the necessary clearances from the United States Office of Foreign Assets Control), covering, according to MPP's estimates, 98% of CLHIV in developing countries.

Under the proposed Agreement, MPP has the right to enter into Sublicense Agreements with any entity, worldwide, to be identified by MPP with demonstrated commitment, ability and readiness to develop Licensed Compound or Product. Merck consent of potential sublicensees to be given within 30 days, otherwise understood as provided. The Agreement allows for the freedom for sublicensees to develop and sell new paediatric formulations of RAL, and contemplates a mechanism by which new formulations developed by MPP sublicensees are made available to children outside the Territory by Merck.

The proposed Licence Agreement contains a number important public-health oriented terms and conditions that have been part of previous MPP-negotiated licence agreements. The Agreement states that its aim is to provide access to patents and not to create any non-patent-related barriers where patents do not exist. Towards this end, the Agreement specifies that nothing in the Agreement would prohibit MPP licensees from engaging in any activities that would not infringe a Licensed Patent Right granted and in force, inside and outside the Territory. The EAG views this provision as sufficient to allow, for example, sales outside the Territory where a compulsory licence has been issued, as such sales would not, by definition, constitute patent infringement.

Additionally, as in all previous MPP licences, Merck has agreed to waive any data exclusivity rights it may have within the Territory, and prohibits MPP Sublicensees from seeking such exclusivity to the extent that it may be available. Lastly, in case of termination of MPP-Merck licence, existing sublicences will be automatically converted into direct sublicences with Merck, provided that such licensee is not in breach of the Agreement.

### **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
<p>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.</p>	<ul style="list-style-type: none"> <li>• Preamble makes clear that Agreement is solely to provide access to IP where needed; not to create any contractual barriers to access.</li> <li>• No restrictions on ability of Sublicensees to challenge patents.</li> <li>• Agreements to waive data exclusivity rights; prevention of further data exclusivity rights.</li> <li>• Allows for sale outside the Territory where there are no patents granted and in force in the country of manufacturing and the country of sale.</li> </ul>
<p>Entering into licence agreements with patent holding entities, and sublicense agreements with generic manufacturers and other appropriate sublicensees on a non-exclusive and no-discriminatory basis.</p>	<ul style="list-style-type: none"> <li>• MPP retains the right to issue non-exclusive sublicences to any qualified entity anywhere in the world. Merck to provide express consent in 30 days from notification. The lack of express notification will imply acceptance.</li> </ul>

## 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.	<ul style="list-style-type: none"> <li>• Terms and conditions of Sublicence standardized across all sublicences via the form Sublicence Agreements.</li> <li>• Increasingly, with each new licence the MPP negotiates, certain key terms are beginning to be standardized into all MPP licences, such as ability to supply outside the Territory where such activities would not infringe a granted patent; waiver of data exclusivity; stringent quality requirements, etc.</li> </ul>
Define the terms and conditions of the licences and sublicences, respecting the differing patentability criteria across jurisdictions.	<ul style="list-style-type: none"> <li>• No breach of the Agreement if sales made inside or outside the Territory where there are no granted patents and in force (so, no barriers on the basis of patent applications or rejected applications).</li> <li>• No restrictions on challenging licensed patents.</li> </ul>
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.	<ul style="list-style-type: none"> <li>• Quality provisions require approval by WHO Prequalification or any SRA approval.</li> </ul>
Ensure that licence agreements specify an alternative dispute resolution mechanism.	<ul style="list-style-type: none"> <li>• Mediation by Senior Executives, if the dispute is not resolved, then mediation in accordance with WIPO rules.</li> </ul>
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.	<ul style="list-style-type: none"> <li>• Product liability insurance obligation specified.</li> </ul>
Safeguard against the diversion and ensuring the traceability of products...by specifying terms and conditions in accordance with WTO	<ul style="list-style-type: none"> <li>• Obligation to bear mark and packaging distinctive from Merck.</li> <li>• Product labeling will state that it has</li> </ul>

[30 Aug Decision] guidelines.	been manufactured under a licence from the MPP.
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	<ul style="list-style-type: none"> <li>• Sublicensees can be based anywhere in the world.</li> <li>• Provisions to allow for grant back to MPP/Merck to ensure access to new products developed under licence in countries inside and outside the Territory.</li> </ul>

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

The EAG finds that the proposed Agreement with Merck 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 CLHIV and geographical scope of former voluntary licences signed by Merck.

The geographic scope of the proposed Agreement covers 92 countries (plus Sudan once OFAC licence is cleared by Merck), with a coverage of 98% CLHIV. The EAG believes this represents a significant advance over Merck’s existing voluntary licensing policy, which the EAG understands includes only 58 countries.

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 Agreement with Merck 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 CLHIV in 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 Merck. The EAG also recommends that the



MPP seek to expand the relationship with Merck to include the licensing of adult formulations of RAL and other Merck products.

Signed,

A handwritten signature in blue ink, appearing to read "Maximiliano Santa Cruz". The signature is fluid and cursive, with a long horizontal stroke at the end.

Maximiliano Santa Cruz  
Chair, Expert Advisory Group