



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

Introduction

The Hepatitis C (HCV) sub-group of 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 Licence Agreement (the Agreement) between MPP and AbbVie Inc. and AbbVie Deutschland GmbH & Co KG (collectively “AbbVie”) for glecaprevir and pibrentasvir (G/P).

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 AbbVie, the HCV sub-group of 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 AbbVie. The HCV sub-group of the EAG wishes nonetheless to voice its disappointment with regards to the geographical scope of the licence, particularly with respect to the exclusion of India, a lower middle-income country with a high HCV burden that has been included in the other licences.

Despite this, the HCV sub-group of the EAG believes that it is better to sign the licence now, so as to allow generic manufacturers to begin development as soon as possible, and encourages the MPP to continue working with AbbVie to make the case for expanding the Territory while the product is still under development.

Background, Overview of the Proposed Agreement

G/P was developed by AbbVie as an pangenotypic direct-acting antiviral regimen for treating chronic hepatitis C.

G/P is safe to use in patients with kidney impairment, without dose adjustment. Both G and P have higher resistance barriers than prior generation inhibitors from their respective class. The treatment has received European Medicines Agency (EMA) and Food and Drug Administration (FDA) approval in 2017 for adults. Phase 3 clinical trials are ongoing in children and adolescents.

The proposed collaboration between MPP and AbbVie comprises a Licence Agreement, that includes as annex a form sublicense agreement to be executed by the MPP and future Sublicensees.

The MPP acquires a non-exclusive licence over the patents with the ability to grant non-exclusive royalty free sublicences to eligible Sublicensees.



Manufacturers of pharmaceutical products will be selected by the MPP as Sublicensees, as long as they have the capability to engage in the manufacture of Licensed Compound and/or Licensed Products in a manner consistent with stringent quality standards.

Sublicensees could be based anywhere in the Territory of the Licence and in India, which is described as a manufacturing-only country.

In addition to the licence over the patents, AbbVie will provide MPP with a copy of clinical data and other non-commercial and non-manufacturing documents necessary for the registration of the Licensed Compounds and Licensed Products in the Territory.

The Territory of the licence comprises 95 countries, accounting for 47.5% of the HCV burden worldwide, including high HCV prevalence countries such as Nigeria, Uganda, Tanzania, Ethiopia, Morocco, Cameroon, Zimbabwe, Sierra Leone, Egypt, Myanmar, Cambodia, Nepal, South Africa, Pakistan, Indonesia, Vietnam, Philippines and Georgia.

The proposed Licence Agreement contains several other important public health-oriented terms and conditions. AbbVie agrees to waive any data exclusivity rights it may have within the Territory and obliges Sublicensees not to seek any further regulatory exclusivity, foresees a potentially broader geographical scope and distribution outside the Territory if no infringement of AbbVie Patents granted and in force, and Sublicensees will be able to sell outside the Territory in any country that has issued a compulsory licence.

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 HCV sub-group of the EAG finds that the proposed collaboration meets the requirements in both the Statutes and MoU with UNITAID, as summarised in the tables below.

(i) 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	<ul style="list-style-type: none"> • No restrictions on ability of Sublicensees to challenge patents • Agreements to waive data exclusivity rights; prevention of further data exclusivity rights • Allows for sale outside the Territory where there are no patents in force • Allows for sale outside the Territory where such country has issued a compulsory licence
Entering into licence agreements with patent holding entities, and sublicense agreements with generic manufacturers and other appropriate Sublicensees on a non-exclusive and non-discriminatory basis	<ul style="list-style-type: none"> • MPP retains the right to issue non-exclusive sublicences to any qualified entity in the Territory and India

(ii) **Relevant Considerations in the MoU between the MPP and UNITAID**

MoU	Terms in Proposed Licence
Ensure that license agreements specify an alternative dispute resolution mechanism;	<ul style="list-style-type: none"> Mediation by senior executives with resolution within 30 days; if no resolution, proceed to Alternative Dispute Resolution as provided in Exhibit E
Define the terms and conditions under which the sub-licensees must make insurance arrangements to cover liability risks linked to products produced under the sub-licence form the MPP;	<ul style="list-style-type: none"> Product liability insurance obligation specified
Safeguard against diversion and ensuring traceability of products produced under sub-licence from the MPP by specifying sub-licence terms and conditions in accordance with the guidelines set out in Art. 2(b)(ii) of the World Trade Organization’s Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;	<ul style="list-style-type: none"> MPP to include usual terms and conditions in the sublicense agreements, such as differential trade mark, trade dress and packaging, and obligation to include in packaging that the product has been manufactured under a licence by the MPP
Broad geographical scope	<ul style="list-style-type: none"> 95 countries and four territories
<p>Access to medicines through TRIPS and other mechanisms</p> <p>The MPP negotiates provisions that enable Sublicensees to sell outside the licensed territory under certain circumstances, such as, for example:</p> <ol style="list-style-type: none"> In the event of a compulsory licence being issued, In the event that sales do not infringe on any granted patents or patent challenges are successful (e.g. licence on dolutegravir), By allowing generic manufacturers to terminate licences for which they no longer need a licence, thereby allowing them to sell in additional countries (e.g. licence on tenofovir disoproxil fumarate) <p>MPP agreements also provide Sublicensees the freedom to challenge the validity of the licensed patents</p>	<p>In the Whereas: “The intent of this Agreement is to provide access to patents and not to create any non-patent-related barriers where Patents do not exist”</p> <ul style="list-style-type: none"> No breach of the Agreement if sales made outside the Territory where there are no patents in force No breach of the Agreement in case of sales to a country outside the Territory that has issued a compulsory licence No restrictions on challenging patents Termination of licence on country-by-country basis, until the expiration of the last to expire patent

<p>Prompt availability of quality, low cost generic medicines</p> <ul style="list-style-type: none"> (a) Ensure the speedy registration of licensed products through a waiver of the licensor’s data exclusivity rights (where applicable) (b) Generic company products must meet internationally-recognised quality standards (c) MPP’s generic partners must adhere to strict timelines for development and regulatory approval of products or face licence termination 	<ul style="list-style-type: none"> • Waiver of data exclusivity; prevention of further data exclusivity rights by Sublicensees • Quality provisions according to MPP’s Quality Policy, which requires approval by WHO Prequalification, SRA as defined by WHO, or WHO Expert Review Panel (where the above are not available) • Obligations on Sublicensees to obtain and maintain all health registrations, permissions, consents and regulatory authorisations; Licensor/Licensee to confer as soon as practicable to establish milestones for registrations; MPP has right to immediately terminate for failure to meet milestones
<p>Transparency of patent and licensing information</p> <ul style="list-style-type: none"> (a) All MPP licences contain provisions to ensure that the MPP may publish the licences in full on the MPP website (b) Patent holders provide patent disclosure of relevant patents within (and sometimes outside) the licensed territory 	<ul style="list-style-type: none"> • The Agreement will be published in MPP’s web page, as well as the sublicense agreements signed by the MPP with generic manufacturers • Disclosure of Patents in the Territory and India in the Exhibits of the Agreement
<p>Promote robust generic competition</p> <ul style="list-style-type: none"> (a) Licences are non-exclusive, pro-competitive and encourage the participation of a broad range of generic manufacturers — in most cases from anywhere in the world — in order to ensure sustained and effective competition (b) Potential generic manufacturers must demonstrate their ability to develop and manufacture quality-assured, affordable products promptly 	<ul style="list-style-type: none"> • Licenses are non-exclusive • MPP will identify Sublicensees with a view to entering into sublicense and will provide AbbVie with information on the manufacturer including the manufacturer’s ability to manufacture consistent with MPP’s Quality Policy, and complete development plans including timelines of key steps and country filing plans • Sublicensees to be located anywhere in the Territory, plus India • Upon MPP request, AbbVie will provide Sublicensees with non-commercial and non-manufacturing documents including clinical data necessary registration of the Licensed Compound or Licensed Product



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

The HCV sub-group of the EAG finds that the terms and conditions of the proposed Agreement represent a significant advance over the *status quo*, in terms of promoting transparent, public health-oriented licensing terms and conditions.

The HCV sub-group of the EAG notes that the proposed Territory covers significantly fewer people living with HCV (47.5%) than other HCV licences, namely for sofosbuvir (62.3%) and daclatasivir (54.3%). In this regard, the EAG voices its disappointment, particularly with respect to the exclusion of India, a lower middle-income country with a high HCV burden that has been included in the other licences. The recommendation to proceed with this proposed agreement is based on the anticipated health benefits of getting generic manufacturers begin development as soon as possible, but should not be interpreted as the EAG's acceptance of a lower standard for geographical scope in future licences.

Despite this, the HCV sub-group of the EAG believes that it is better to sign the licence now, so as to allow generic manufacturers to begin development as soon as possible. As the development and registration of a generic equivalent will take around three years, this gives the MPP time to continue working with AbbVie to make the case for expanding the Territory while the product is still under development. The EAG notes that the MPP has successfully negotiated the expansion of territory in the MPP-BMS licence for atazanavir (ATV), the MPP-Gilead licence tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), cobicistat (COBI), elvitegravir (EVG) and bicitgravir (BIC), and the MPP-ViiV licence for dolutegravir (DTG), and strongly recommends the MPP to seek an expansion of the Territory with AbbVie after execution.

The HCV sub-group of the EAG also notes that the proposed Agreement will be made public on MPP's website, contributing to the goal of injecting greater transparency in the field of voluntary licensing, a core mission of the MPP.



Recommendation

The HCV sub-group of the EAG concludes that the proposed Agreement with AbbVie 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 the public health-oriented nature of the licensing terms and conditions.

The HCV sub-group of the EAG recommends that the Medicines Patent Pool Governance Board request the Executive Director to sign the proposed Agreement between AbbVie and MPP, while continuing to work with AbbVie in expanding the Territory after execution.

Signed,

A handwritten signature in blue ink, appearing to read "Maximiliano Santa Cruz".

Maximiliano Santa Cruz
Chair, Expert Advisory Group