History of Gilead-MPP collaboration

Gilead and MPP signed licence agreement in 2011 for Tenofovir Disoproxil Fumarate (TDF); Cobicistat (Cobi) and Elvitegravir (EVG), with a covenant not to sue for Emtricitabine (FTC)

The Agreement has been modified several times, incorporating Tenofovir Alafenamide (TAF) in 2015 and Bictegravir (BIC) in 2017, to the portfolio of licensed products, together with a territorial expansion across all compounds

Current Territory

- For TAF-TDF-BIC-Cobi 116 countries
- For EVG 109
- Covenant not to sue for FTC in 116 countries
**Scope of the Licence**

- MPP has the right to issue non-exclusive licences to any qualified entity in India, China and South Africa
- Licensee will have the right to make, offer for sale, sale, import and export API and/or Products for use in the applicable Territory
- Licensee may grant sublicenses to its Affiliates located in India/China/South Africa upon prior written notice to Gilead and MPP. Upon Gilead’s or MPP’s request, Licensee shall provide Gilead and/or MPP with the written copies of the applicable sublicense agreement with such Affiliate(s)
- Any Licensee distributor agreement to be consistent with the terms of the Licence

**Territory**

- Gilead drugs licensed to the MPP, to be manufactured in India, China and South Africa for its use in 109 (EVG) and 116 countries (rest of the compounds) representing 87.8% PLHIV in the developing world
- Allows for sale outside the Territory where
  - Compulsory licence is issued
  - There are no patents in force or patent has been held invalid or unenforceable beyond the possibility of any further appeal in the country of manufacture (India/China/South Africa) and the country of sale
**Quality requirements**

- Licensee agrees that it shall manufacture API and Product in a manner consistent with (i) the applicable Indian manufacturing standards; (ii) either World Health Organization (“WHO”) pre qualification standards, standards of the European Medicines Agency (“EMA”), or United States Food and Drug Administration (“FDA”) tentative approval standards (“Minimum Quality Standards”); and (iii) on a country-by-country basis, any applicable national, regional or local standards as may be required by the specific country where Product is sold.

- Timelines for WHO pre-qualification or FDA conditional approval:
  - For the API Drug Master File (DMF), no later than the 2nd anniversary of such API included in the WHO Guidelines
  - For the TAF, BIC, Cobi, EVG Product and Combination Products and TDF Quad, no later than the 3rd anniversary of such Product being included in WHO Guidelines

**Royalties**

- Royalty bearing licence, payable only until expiration of patent “containing a valid claim” in country of manufacture or sale:
  - 5% of Net Sales for BIC, TAF, EVG, Cobi
  - 3% of Net Sales for TDF
Packaging requirements
• Obligation to bear mark and packaging distinctive from Gilead
• Labelling of all Products shall expressly state that the Product is manufactured under a licence from the Medicines Patent Pool and Gilead

Termination by Licensees
• On a product-by-product basis
• Right to terminate the sublicence without cause, with 30 days notice

Data exclusivity waiver
• Agreements to waive data exclusivity rights; prevention of further data exclusivity rights

Other relevant provisions
• Gilead to provide Technology transfer to Indian and South African Licensees
• No restrictions on ability of Licensees to challenge patents
• Licensees to be free to combine the Compound with any other/others APIs
• Product liability insurance obligation on Licensees