medicines patent pool

Gilead-MPP Licence Overview

December 2017

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