



KEI Europe  
CP 2100  
1 Route des Morillons  
1211 Genève 2  
Suisse

July 29, 2014

Gregg H. Alton  
Executive Vice President, Corporate and Medical Affairs  
Gilead Sciences  
333 Lakeside Drive  
Foster City, CA 94404  
Phone: (650) 574-3000  
Fax: (650) 578-9264

Via email: [gregg.alton@gilead.com](mailto:gregg.alton@gilead.com)

Re: Request for license to Ledispavir, Sofosbuvir, GS-5816, Ledispavir/Sofosbuvir and Sofosbuvir/GS-5816 patents, for territory of Romania

Dear Mr. Alton:

KEI Europe is a not-for-profit Swiss association formed in 2013, in part to improve access to medicines.

Further to our request dated July 8, 2014, we are writing today with a revised request to license patents relating to the treatment of the Hepatitis C Virus in Romania. Specifically, the revised request now includes any and all patents held by Gilead that are necessary for the making, importing and/or selling for treatments for hepatitis C, including but not limited to inventions relating to sofosbuvir, ledispavir, and GS-5816, including rights in any combinations of those products. Our request is limited to the territory of Romania.

We are seeking to either manufacture the drugs in Romania, or to import the drugs into the Romanian market.

Although estimates vary, it is believed that anywhere from 3.2 to 6 percent of the Romanian population is infected with the Hepatitis C virus. For a nation with a 2013 per capita GDP of \$9,500 (USD) -- roughly 11 percent of the Gilead price for Sovaldi, and an extraordinarily high rate of infection, it is highly unlikely that persons living with the Hepatitis C virus will receive sofosbuvir from Gilead.

KEI Europe was recently incorporated as an entity with a separate legal status from Knowledge Ecology International (KEI), in order to expand work on access to knowledge goods in Europe. The names and biographies of the KEI Europe Board of Directors and staff are described in an attachment to this letter.

We propose a license along the following terms:

**Field of Use:** We request a field of use, the right to use ledispavir, sofosbuvir and GS-518 patents for the treatment of Hepatitis C, including as standalone drugs, or as part of a combination therapy, including with other

drugs, including drugs developed by Gilead, but also possibly drugs invented developed by companies or other third other than Gilead.

**Geographic Area:** We are requesting sufficient licenses to import finished product or portions of the finished products, such as the active ingredients, into Romania, to treat patients in the territory of Romania.

**Royalty:** We are prepared to pay royalties for the use of the invention in a product.

When the Gilead inventions are used in a product that does not include patented inventions held by third parties, the options for a royalty would include:

- (i) an amount equal to 7 percent of the generic price,
- (ii) an amount consistent with the 2005 World Health Organization (WHO) Tiered Royalty Method,
- (iii) an amount equal to 5 percent of the per capita income of Romania, for each patient who is cured of Hepatitis C after being treated..
- (iv) a fixed amount of money, per year, to supply a generic product (such as sofosbuvir, ledispavir or GS-518) to the territory of Romania, or
- (v) another mutually agreed upon royalty.

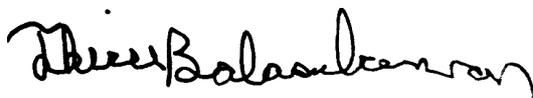
When the Gilead inventions are used in a product that combines the Gilead inventions with patented inventions held by third parties other than Gilead, the options for a royalty would the same, except for an adjustment to share the royalty payments with relevant third parties. For example, if sofosbuvir would be used in combination with daclatasvir, the royalty would be equally divided between the patent holders for sofosbuvir and daclatasvir.

**Registration:** Any product made available to patients in Romania would first be registered by the Romania National Agency for Medicines and Medical Devices, or the European Medicines Agency.

KEI Europe also advises Gilead that we are requesting additional HCV patent licenses from Bristol-Myers Squibb, Merck, AbbVie, Roche and other holders of HCV patents.

Thank you for considering this request. We look forward to your response.

Sincerely,



Thiru Balasubramaniam  
Managing Director  
KEI Europe  
CP 2100  
1 Route des Morillons  
1211 Geneva 2, Switzerland  
thiru@keieurope.org  
+41 76 508 0997

Attachment: KEI Europe Board of Directors and Staff