



essentialinventions



March 18, 2015

Mr. Gregg Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences
333 Lakeside Drive
Foster City, CA 94404

Via Email: gregg.alton@gilead.com

Re: Request for license to use patents necessary for hepatitis C medicines

Dear Mr. Alton:

Introduction

Knowledge Ecology International (KEI) is a nonprofit corporation based in Washington, D.C., formed in 2006 to focus on access to knowledge issues including access to medicines. KEI Europe is a nonprofit organization with offices in Geneva, Switzerland. Essential Inventions is a nonprofit corporation with offices in Washington, DC. Collectively, we request the licenses necessary to make, export, import and sell drugs to treat the hepatitis C virus (HCV). The proposed terms of a license are set out below.

Our motivation to obtain licenses

We are seeking to supply governments and private parties with affordable versions of drugs to treat HCV.

Proposal for License

We propose a license along the following terms:

Field of Use: The right for any generic producer to use any and all current, pending, or future patents held by Gilead Sciences (Gilead) for the treatment of hepatitis C, including as standalone drugs, or as part of a combination therapy. The request includes patents that Gilead has rights to regarding its own products, but also patents (if any) that are necessary for the use of drugs developed by third parties.

Term: The license shall be for the term of the patent(s).

Territory: Our preference is for a license covering every country, worldwide. If this is not possible, for the subset of countries Gilead is willing to license. We recognize Gilead has already provided a voluntary license covering a territory of more than 90 countries. This request is designed to expand the number of countries for which generic HCV drugs can be supplied.

Royalty: We propose a system of differential royalties for the use of patents, which depend upon the income of the country, the rate of infection and patient health.

Three Country Categories. Our proposal involves three categories for countries:

Category A Countries are defined as countries with incomes greater than one-half the per capita income of the United States as measured by GNI per capita, using the World Bank Atlas method, for three consecutive years, and a rate of infection for HCV of less than or equal to 2 percent of the population.

Category B Countries is the more complex category. It includes (1) countries with incomes that would otherwise qualify for Category A, but which have an infection rate greater than 2 percent of the population, and also (2) countries with per capita incomes that are above 10 percent of the United State per capita income (but not qualifying as Category A), with HCV infection rates below 2 percent.

Category C: Countries includes all countries not in category A or B.

Table 1: Country Categories for royalties

Category	Income	Infection Rate
A	> 50% US	= or < 2%
B	> 50% US	> 2%
B	50% > US < or = 10%	= or < 2%
C	50% > US < or = 10%	> 2%
C	< 10% US	> 0%

Royalty Rates

For each country category, the royalty rates differ. For categories A and B, the royalty rates differ by the patient health status.

Category A Proposed Royalty: For Category A, the royalties are based upon the patients treated: 10 percent of country GNI per capita for patients with advanced liver disease (stages 3 & 4), and 2 percent of country GNI for patients with less severe liver disease.

Category B Proposed Royalty: For Category B, the royalties are based upon either the patients treated, or the generic price, as follows.

- For patients with advanced liver disease (stages 3 & 4) and with incomes either (1) above 50 percent of US incomes and country infection rates above 2 percent, or (2) incomes above or equal to 10 percent of US incomes, and country infection rates below 2 percent, the royalty shall be 5 percent of country GNI per capita.
- For patients with less advanced liver disease, 7 percent royalty of the generic price.

Category C Proposed Royalty: 7 percent of the generic price.

This proposed royalty system takes into account the income disparity in countries across the world, providing both differential and progressively higher obligations for royalty patients as country incomes (relative to infections) increase, and also recognizes the differential value of treatments to patients depending upon their health status.

Annex 1 provides illustrations of the proposed royalties, based upon country incomes in 2013.

Multiple Patent Holders

Where multiple patent holders hold patents on the same product, royalties shall be allocated among the patent owners according to one of the following methods:

- (i) upon agreement among the patent owners, or, failing agreement among the patent owners, either,
- (ii) Mutually agreed upon arbitration of the dispute, with the costs of arbitration to be paid by the patent owners, or
- (iii) According to the recommendation of an expert appointed by the Court, with the costs of the expert paid by patent owners.
- (iv) When a product consists of a combination of patented and unpatented inventions, the total royalty will be adjusted down to account for the partial patent coverage.

(v) For option (iii), the allocations should be based upon the “utilization ratio,” which considers the relative importance of each patented invention relative to the product.

Countries with no patents

In countries with no patents, the royalty will be zero.

Diversion:

We agree to require purchasers to take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent reexportation of the products that have been imported into their territories, consistent with the need to protect patient privacy and the confidentiality of patient data.

Thank you for considering this request. We would appreciate a response by April 30, 2015.

Sincerely,

A handwritten signature in blue ink, appearing to read "Andrew S. Goldman".

Andrew S. Goldman, Esq.
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Annex:

Table 2 Examples of proposed royalty per patient treated based upon 2013 incomes

<i>Country</i>	<i>HCV infection rate¹</i>	<i>2013 GNI per capita (USD, Atlas Method)</i>	<i>Per capita GNI relative to U.S.</i>	<i>Category</i>	<i>Stage of liver damage</i>	<i>Royalty rate per patient</i>	<i>Royalty amount per patient (USD)</i>
Australia	1.7	65,390	122%	A	3-4	10% GNI per capita	6,539
Australia	1.7	65,390	122%	A	<3	2% GNI per capita	1,308
Denmark	0.7	61,680	115%	A	3-4	10% GNI per capita	6,168
Denmark	0.7	61,680	115%	A	<3	2% GNI per capita	1,234
United States	1.3	53,470	100%	A	3-4	10% GNI per capita	5,347
United States	1.3	53,470	100%	A	<3	2% GNI per capita	1,069
Canada	1.1	52,270	98%	A	3-4	10% GNI per capita	5,270
Canada	1.1	52,270	98%	A	<3	2% GNI per capita	1,044
Germany	.6	47,270	88%	A	3-4	10% GNI per capita	4,727
Germany	.6	47,270	88%	A	<3	2% GNI per capita	945
Japan	1.5	46,330	87%	A	3-4	10% GNI per capita	4,633
Japan	1.5	46,330	87%	A	<3	2% GNI per capita	927
France	.6	43,460	81%	A	3-4	10% GNI per capita	4,346

¹Source (except where otherwise noted): Gower, Erin, et al. "Global epidemiology and genotype distribution of the hepatitis C virus infection." *Journal of hepatology* 61.1 (2014): S45-S57.

France	.6	43,460	81%	A	<3	2% GNI per capita	869
United Kingdom	0.6	41,680	78%	A	3-4	10% GNI per capita	4,168
United Kingdom	0.6	41,680	78%	A	<3	2% GNI per capita	834
Spain	1.7	29,920	56%	B	3-4	5% GNI per capita	1,496
Spain	1.7	29,920	56%	B	<3	7% of generic price	N/A
Greece	1.9	22,690	42%	B	3-4	5% GNI per capita	1,135
Greece	1.9	22,690	42%	B	<3	7% of generic price	N/A
Chile	1.6 ²	15,230	29%	B	3-4	5% GNI per capita	762
Chile	1.6 ³	15,230	29%	B	<3	7% of price of generic	N/A
Poland	0.9	13,240	25%	B	3-4	5% GNI per capita	662
Poland	0.9	13,240	25%	B	<3	7% of generic price	N/A
Brazil	1.6	11,690	22%	B	3-4	5% GNI per capita	585
Brazil	1.6	11,690	22%	B	<3	7% price of generic	N/A
Malaysia	1.5	10,390	19%	B	3-4	5% GNI per capita	522
Malaysia	1.5	10,390	19%	B	<3	7% price of generic	N/A

² Source: Mohd Hanafiah, Khayriyyah, et al. "Global epidemiology of hepatitis C virus infection: New estimates of age - specific antibody to HCV seroprevalence." *Hepatology* 57.4 (2013): 1333-1342.

³ *Id.*

Mexico	1.4	9,940	19%	B	3-4	5% GNI per capita	497
Mexico	1.4	9,940	19%	B	<3	7% price of generic	N/A
China	1.3	6,560	12%	B	3-4	5% GNI per capita	328
China	1.3	6,560	12%	B	<3	7% of price of generic	N/A
Thailand	2.7	5,340	10.0%	C	1-4	7% of price of generic	N/A
Ecuador	2 ⁴	5,760	11%	C	1-4	7% of price of generic	N/A
Uzbekistan	11.3	1,880	4%	C	1-4	7% of price of generic	N/A

⁴ *Id.*