KNOWLEDGE ECOLOGY INTERNATIONAL

KEI request for investigation into anticompetitive aspects of Gilead Voluntary Licenses for patents on Tenofivir and Emtricitabine

12 February 2007

Federal Trade Commission
Washington, DC
Attn: Randy Marks
Via email: mailto:rmarks@ftc.gov

The following is a request for an investigation of anticompetitive aspects of voluntary patent licenses between the patent holder Gilead and certain manufacturers of generic medicines. The licenses involve patents and know-how on products the United States government purchases for the treatment of AIDS using Tenofivir, Emtricitabine and combinations thereof.

At present Gilead bundles rights for know-how and patents, APIs and product sales, for Tenofivir, Emtricitabine, and combinations involving the two products, in a 99 country territory. Patent protection is in fact much more limited. Within the territory, Gilead claimed to have filed patents for Tenofivir in only two countries and Emtricitabine in 45 countries.

While the know-how is arguably a licensable asset in all 99 countries, its utility is not that important to the leading generic producers, given their well-demonstrated ability to manufacture generic APIs and finished products involving Tenofivir, Emtriccitabine and similar ARV drugs.

Gilead is leveraging patent protection in developing countries on the US government funded invention Emtricitabine to segment and control the global market for generic APIs for both Tenofivir and Emtricitabine. This segmentation and control extends even beyond the license Territory. This action imposes higher costs for AIDS drugs in more than 150 developing country markets. The United States government is the largest purchaser of AIDS drugs in the developing world, and is harmed by this anticompetitive practice. The US federal government can seek remedies under US competition laws and through the exercise of US federal government rights in 5 patents on Emtricitabine.

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1621 Connecticut Avenue, Suite 500, Washington, DC 20009, USA +1.202.332.2670
1 Route des Morillons, CP 2100, 1211 Geneva 2, Switzerland +41 22 791 6727
24 Highbury Crescent, London, N5 1RX, UK +44 (0) 207 226 6663 ex 252

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Background

Last year, Gilead Sciences, Inc reportedly signed voluntary non-exclusive licenses with a generic company in South Africa (Aspen) and 11 generic companies in India (Emcure Pharmaceuticals, Hetero Drugs, Strides Arcolab, Alkem Laboratories, Aurobindo Pharma, FDC Ltd., J.B. Chemicals & Pharmaceuticals, Matrix Laboratories, Medchem International, Ranbaxy Laboratories and Shasun Chemicals & Drugs) for the manufacturing and sale of an HIV-AIDS drug Tenofivir disoproxil fumarate (TDF), sold by Gilead under the trade name Viread. At least in some cases, the licenses also include patents on the product Emtricitabine (FTC), sold in the United States under the trade name Emtriva, and combinations of TDF and FTC, such as the fixed dose combination of TDF+FTC marketed under the trade name Truvada, or the once-a-day triple combination product TDF+FTC+Efavirenz (EFV), sold under the trade name Atripla.[1]

In general, many of the terms of the licenses are reasonable. These include but are not limited to a royalty rate of 5 percent, provisions that require production meet WHO or US FDA quality standards, and the granting of a non-exclusive, royalty free, grant-back licenses to Gilead for all improvements on methods, modifications and derivative works developed by or on behalf of the licensee relating to the API or a product. However, there are features of the licenses that are objectionable, and may violate competition laws in the United States and elsewhere. First, the Gilead license requires royalty payments where Gilead does not hold a patent. Second, the license prohibits the supply of active pharmaceutical ingredients (APIs) to firms and markets not approved by Gilead. Third, licensed sellers are required to purchase APIs from Gilead affiliated and licensed suppliers.

According to information we have reviewed, the Gilead license covers 99 countries. In 2004, these countries, which include India, had a combined population of 2.8 billion persons, and a combined GDP of $2.1 trillion. Incomes are low in the licensed countries – the average per capita income was just $755 in 2004. The 53 developing countries (those ranking less than 30 on the 2006 UNDP Human Development Index) that were not covered by the voluntary license had a combined population of 2.5 billion, and GDP of $6.5 billion. The average 2004 per capita income of this group was $2,590.

Gilead claimed to have filed or obtained patents in 48 of the 99 licensed countries, on at least one of the products (or combinations). The lowest level of patent protection was for Tenofivir, where Gilead reported having filed patents in just two countries – India and Indonesia. The low level of patent protection for Tenofivir in developing countries was probably due to the fact that when the product was under development, there was a very small market for AIDS drugs. This changed when the Global Fund and the President's Emergency Plan for AIDS Relief (PEPAR) programs greatly expanded the market for AIDS treatment, largely through funding by taxpayers in the United States, Europe and other high income countries.

The patent protection for Emtricitabine, a product that was approved by the FDA in 2003, after the creation of the Global Fund and PEPFAR, was much more extensive. Gilead reported filing patents on Emtricitabine or combination products involving Emtricitabine in 47 of the 99 licensed countries.[2]

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[1] Various patents for Efavirenz are held by Merck and BMS.

[2] Patent protection for Emtricitabline as a standalone product was filed in 45 of the 47 countries.

The most important patent filing for Tenofivir was in India, the home of leading generic manufacturers of AIDS drugs. There were several pre-grant oppositions to the Tenofivir patent in India. Gilead reportedly required companies seeking voluntary licenses to withdraw patent oppositions.

Impact of the licenses on the global market for generic APIs

Gilead has effectively given two different types of licenses, one for the products, and one for the active pharmaceutical ingredients (APIs). The API license is **a royalty free**, non-exclusive, non-sub-licensable, non-transferable license to use certain technology solely to manufacture APIs for sale in India to parties who have obtained a "Product" license." The "Product" license is for the 99-country territory described above.

One apparent objective of the Gilead license is to cut-off the supply of generic APIs to any generic company who does not have a "Product" license from Gilead, and to require licensed Product sellers to use APIs only from licensed suppliers.

The Product license requires payments of royalties to Gilead for all uses of Tenofivir or Emtricitabine in all 99 countries covered by the license, rather than just the 2 countries where Gilead has filed patents for Tenofivir, or the 47 countries where Gilead has filed patents for uses of Emtricitabine.

While there are 99 developing countries included in the licensed Territory, roughly half the developing world is excluded. **Not included** in the licensed Territory are more than 53 developing countries with a population of 2.5 billion persons, and average 2004 per capita incomes of $2,590.

In reviewing the Gilead license for Tenofivir or Emtricitabine, we note the similarities with the Gilead/Roche licenses to some generic suppliers of oseltamivir phosphate (Tamiflu), which were used to cut off generic supplies of APIs to non-approved manufacturers, and to limit certain generic suppliers to sales in only lower income countries, and only for government (rather than private sector) purchasers.[3] In both cases, the Gilead voluntary licenses are used to argue that compulsory licenses are not necessary in licensed countries where there are patents. In both cases, access to the markets where there are patents are used to enhance control over the entire global API market.

The markets for APIs are generally more sensitive to economies of scale and scarce know-how, and hence more concentrated than are markets for finished products. By segmenting the developing country markets into approved and unapproved manufacturers and licensed and unlicensed territories, Gilead has likely increased the prices for generic APIs in all segments of the market, but particularly for the areas where there are no patents, and certainly for countries excluded from the licensed territory.

US government interest in patents on Emtricitabine (FTC)

[3] As you recall, this was the subject of a 2005 complaint by CPTech to the FTC.

Emtricitabine was discovered by scientists at Emory University and later licensed to Triangle Pharmaceuticals. In 2003, Triangle was acquired by Gilead. The five patents currently listed in the US FDA Orange Book for FTC were originally granted to Dennis C. Liotta, Raymond F. Schinazi and Woo-Baeg Chois, and assigned to Emory University. All five inventions were developed with US government funding (the NIH and the Veterans Administration) and are subject to US Bayh-Dole Rights. The first patent was filed in February 22, 1991. The last Orange Book Patent was filed on June 7, 1995.

Patents listed in US FDA Orange Book for Emtriva

Patent number / Dates filed and granted	**Title/Abstract**	**US government rights in patent**
5,210,085 Filed: February 22, 1991, Granted: May 11, 1993	Method for the synthesis, compositions and use of 2'-deoxy-5-fluoro-3'-thiacytidine and related compounds **Abstract** The present invention relates to a method of preparing the antiviral compounds 2'-deoxy-5-fluoro-3'thiacytidine (FTC) and various prodrug analogues of FTC from inexpensive precursors with the option of introducing functionality as needed; methods of using these compounds, particularly in the prevention and treatment of AIDS; and the compounds themselves. This synthetic route allows the stereoselective preparation of the biologically active isomer of these compounds and related compounds.	The invention described herein was made with Government support under grants no. AI-28731 and no. AI-26055 awarded by the National Institutes of Health. The Government has certain rights in this invention.
5,814,639 Filed: February 16, 1993, Granted: September 29, 1998	Method for the synthesis, compositions and use of 2'-deoxy-5-fluoro-3'-thiacytidine and related compounds **Abstract** The present invention relates to a method of preparing the antiviral compounds 2'-deoxy-5-fluoro-3'thiacytidine (FTC) and various prodrug analogues of FTC from inexpensive precursors with the option of introducing functionality as needed; methods of using these compounds, particularly in the prevention and treatment of AIDS; and the compounds themselves. This synthetic route allows the stereoselective preparation of the biologically active isomer of these compounds and related compounds.	The invention described herein was made with Government support under grants no. AI-28731 and no. AI-26055 awarded by the National Institutes of Health. The Government has certain rights in this invention.
5,914,331 Filed: June 7, 1995 Granted: June 22, 1999	Antiviral activity and resolution of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane **Abstract** A method and composition for the treatment of HIV and HBV infections in humans is disclosed that includes administering an effective amount of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane, a pharmaceutically acceptable derivative thereof, including a 5' or N.sup.4 alkylated or acylated derivative, or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable carrier.	The U.S. Government has rights in this invention arising out of the partial funding of work leading to this invention through the National Institutes of Health Grant Nos. AI-26055, AI-28731, NIH 5-21935, as well as a Veteran's Administration Merit Review Award.

Patents listed in US FDA Orange Book for Emtriva		
Patent number / Dates filed and granted	**Title/Abstract**	**US government rights in patent**
	A process for the resolution of a racemic mixture of nucleoside enantiomers is also disclosed that includes the step of exposing the racemic mixture to an enzyme that preferentially catalyzes a reaction in one of the enantiomers.	
6642245 Filed: June 7, 1995 Granted: November 4, 2003	Antiviral activity and resolution of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane **Abstract** A method and composition for the treatment of HIV and HBV infections in humans is disclosed that includes administering an effective amount of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane, a pharmaceutically acceptable derivative thereof, including a 5' or N.sup.4 alkylated or acylated derivative, or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable carrier. A process for the resolution of a racemic mixture of nucleoside enantiomers is also disclosed that includes the step of exposing the racemic mixture to an enzyme that preferentially catalyzes a reaction in one of the enantiomers.	The U.S. Government has rights in this invention arising out of the partial funding of work leading to this invention through the National Institutes of Health Grant Nos. AI-26055, AI-28731, NIH 5-21935, as well as a Veteran's Administration Merit Review Award.
6,642,245 Filed: June 7, 1995 Granted: November 4, 2003	Antiviral activity and resolution of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane **Abstract** A method and composition for the treatment of HIV and HBV infections in humans is disclosed that includes administering an effective amount of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane, a pharmaceutically acceptable derivative thereof, including a 5' or N.sup.4 alkylated or acylated derivative, or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable carrier. A process for the resolution of a racemic mixture of nucleoside enantiomers is also disclosed that includes the step of exposing the racemic mixture to an enzyme that preferentially catalyzes a reaction in one of the enantiomers.	The U.S. Government has rights in this invention arising out of the partial funding of work leading to this invention through the National Institutes of Health Grant Nos. AI-26055, AI-28731, NIH 5-21935, as well as a Veteran's Administration Merit Review Award.
6703396 Filed: March 13, 1995 Granted: March 9, 2004	Method of resolution and antiviral activity of 1,3-oxathiolane nuclesoside enantiomers **Abstract** A process for the resolution of a racemic mixture of nucleoside enantiomers that includes the step of exposing the racemic mixture to an enzyme that preferentially catalyzes a reaction in one of the enantiomers. The nucleoside enantiomer (-)-2-	U.S. Government has rights in this invention arising out of the partial funding of work leading to this invention through the National Institutes of Health Grant Nos. NIH 5-21935 and NIH AI-26055, as well as a Veteran's Administration Merit Review Award.

Patents listed in US FDA Orange Book for Emtriva		
Patent number / Dates filed and granted	**Title/Abstract**	**US government rights in patent**
	hydroxymethyl-5-(5-flurocytosin-1-yl)-1,3-oxathiolane is an effective antiviral agent against HIV, HBV, and other viruses replicating in a similar manner.	

In 1980, the Bayh-Dole Act liberalized the circumstances under which recipients of federal funds could elect to retain title to inventions conceived in the performance of Federal contracts, subject to specific government rights to use the patent or license its use to others. Congress declared its intention "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."[4]

The US government rights apply to inventions "conceived or first actually reduced to practice in the performance of work under a [Federal] funding agreement."[5] In such cases, the Federal Government has royalty-free rights "to practice or have practiced for or on behalf of the United States any subject invention throughout the world."

> With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreements relating to weapons development and production. [35 U.S.C 202(c)(4)]

In addition to a worldwide royalty-free license in patents, the federal government can grant compulsory licenses to third parties, under the 35 USC 203 "March-in rights" provision of the Bayh-Dole Act:

> (a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, **the Federal agency under whose funding agreement the subject invention was made shall have the right**, in accordance with such procedures as are provided in regulations promulgated hereunder **to require** the contractor, an assignee or exclusive licensee of a subject invention **to grant a** nonexclusive, partially exclusive, or exclusive **license** in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if

[4] 35 U.S.C. § 200.
[5] 35 U.S.C. 201(e).

> the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—
>
> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve **practical application** of the subject invention in such field of use;
>
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or ..

The phrase "practical application" of the invention from 35 USC 203(a)(1) is defined elsewhere in the act to include an obligation that the benefits of inventions be made "available to the public on reasonable terms."[6]

Taken together, the provisions of the Bayh-Dole act provide the US government with considerable leverage when dealing with anticompetitive practices or areas where the US government is directly involved in global public health programs, like PEPFAR or the Global Fund.

The Indian market

The leading manufacturers of APIs for AIDS drugs are located in two countries, China and India. China modified its patent law before India, providing broad protection to pharmaceutical products. Before February 2005, India only provided for patents on processes for manufacturing pharmaceuticals, but not for the product themselves. This has now changed. In February 2005, India enacted a new patent law to bring the country into compliance with new obligations under the WTO TRIPS agreement. The new Indian patent law has a number of different provisions that have yet to be tested and implemented. The future role for India in providing a global source for inexpensive generic APIs and finished products is unknown, and will depend upon the resolution of legal challenges to the new Indian patent law, disputes over patentability of new inventions, and internal policy debates over the standards for patents and procedures for compulsory licensing of patents.

According to Gilead's 2006 offers regarding the voluntary license, patents were filed in India on Tenofivir (TDF), but not for Emtricitabine (FTC), or combinations involving FTC. The Alternative Law Forum has filed opposition to the TDF product patent on behalf of the Delhi Network of Positive People and the Indian Network for People Living with HIV/AIDS. Two India firms were manufacturing TDF -- Ranbaxy and Cipla. Ranbaxy has subsequently signed a voluntary license with Gilead, and must restrict sales to the licensed territories and licensed suppliers.

Impact on foreign consumers

[6] 35 U.S.C. 201(f).

The impact of the Gilead voluntary license on the generic market for TDF (a product that Gilead reports is not widely patented) will be negative, for three reasons. First, Gilead seeks to impose royalties on all product sales for TDF from the licensed suppliers of APIs, including sales where patents do not exist. Second, Gilead seeks to cut off the supply of generic APIs for TDF outside of the licensed territories. Third, the partitioning of the generic TDF API market between approved and non-approved sellers and licensed and non-licensed territories will lead to less competition and less efficient economies of scale in the market for generic TDF APIs.

With regard to the market for Emtricitabine, the Gilead license will have some benefit to foreign consumers living in the licensed territories where Gilead is reasonably expected to have valid patent rights on Emtricitabine. Most (but not all) of these countries have very low incomes. However, consumers in these countries will also be harmed by the reduction in the potential suppliers for APIs and finished products. The license reduces competition for Tenofivir in all of the licensed countries except Indonesia, and to a lesser extent, India, by imposing new royalties and restrictions on key suppliers of APIs.

The 53 licensed countries (including India) where there are no patents on Emtricitabline and the more than 53 developing countries that are excluded from the licensed territory have a combined population of 4.5 billion persons. The persons living in licensed countries with no patents will be harmed by restrictions on the potential sellers of APIs and their less efficient economies of scale. This will lead to higher prices for products involving both Tenofivir and Emtricitabine. The persons living in developing countries excluded from the licensed territories will be harmed by a less competitive and less efficient market for generic APIs.

Role of US taxpayers in paying for AIDS treatment

Often overlooked by policy makers on intellectual property right issues is this fact: The United States government is the leading source of funds for the treatment of AIDS in the developing world.

Announced in his January 28, 2003 State of the Union Address, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) is the largest commitment ever by any nation for an international health initiative dedicated to a single disease – initially $15 billion over five years. Bush's FY 2008 PEPFAR budget request was $5.4 billion, consisting of $4.2 billion for treatment, prevention and care initiatives in 15 focus countries[7], plus an additional $1.2 billion for global HIV/AIDS programs, disease research and contributions to partner organizations. Included in the PEPFAR budget are contributions to the Global Fund To Fight AIDS, Tuberculosis and Malaria. The United States government is by far the largest supporter of the Global Fund, an initiative that has already committed $7 billion to support treatment for a projected 1.8 million persons to receive ARV treatments.

According to PEPFAR press materials, fifty-five percent of the PEPFAR budget is for the treatment of individuals with HIV/AIDS, and in FYs 2006 through 2008, 75 percent of those outlays will be spent on the purchase and distribution of antiretroviral drugs. PEPFAR claims it supports programs in **120 developing countries**.

[7] Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam and Zambia.

As experience with treatment grows, so does resistance to older medicines and the need to acquire access to newer medicines, such as TDF or FTC. Experts say a failure to control the costs for the new medicines will threaten the sustainability of this important initiative.

Programs run by PEPFAR and its partner organization provide treatment in many of the countries that will be required to pay royalties for products off-patent, and which will suffer from a cut-off of key suppliers of APIs for TDF or FTC.

Remedies

We believe the Gilead license is an illegal effort to restrict competition and lower efficiency for generic APIs for both Tenofivir and Emtricitabine. The anti-competitive aspects of the license will impose significant costs on US taxpayers and frustrate US objectives of treating AIDS patients in developing countries.

The federal government can remedy these practices by insisting that Gilead make changes in its voluntary licensing program. The most important changes would be to unbundle the various licensing rights, in order to permit more competition and greater efficiencies for both products.

At present Gilead bundles rights for know-how and patents, APIs and product sales, for Tenofivir, Emtricitabine, and combinations involving the two products, in a 99 country territory.

While the know-how is arguably a licensable asset in all 99 countries, its utility is not that important to the leading generic producers, given their well-demonstrated ability to manufacture generic APIs and finished products involving Tenofivir, Emtriccitabine and similar ARV drugs.

We ask that Gilead be required to make the following changes in its licenses:

1. Offer separate licenses for know-how and patents, in both API and Product markets.

2. For the patent-licenses for the "Products:"

    a. There should be no obligation to pay royalties or restrict sales in countries where Gilead does not hold a patent.

    b. There should no requirement to purchase APIs from licensed suppliers, so long as products meet WHO or FDA quality standards.

3. For the patent-licenses for the API manufacturers, there should be no general restrictions on the markets where or to whom the APIs are sold. Gilead may require that sales be limited to sellers that meet WHO or US FDA quality standards, however, and require payment of royalties for products manufactured in countries where Gilead holds patents.

Separately, the US government may consider whether royalties should be waived in cases where the products are purchased by programs supported by PEPFAR funding, and the US government has world wide royalty free rights "to practice or have practiced for or on behalf of the United States" the relevant inventions.

The United States government is in a very strong position to insist on changes in the Gilead licensing practices. It holds Bayh-Dole rights in each of the 5 FTC patents in the US orange book, and has broad authority to issue compulsory licenses or to exercise world-wide royalty-free rights to use the patents on behalf of US government public health programs, including the right to import generic products to the US market under the royalty free license.

We request a meeting with the Federal Trade Commission to discuss this case further.

Sincerely,

James Love
Knowledge Ecology International

Attachments

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Attachment 1: Patents on FTC

(A) Licensed countries where patents filed for Emtricitabline	(B) Licensed countries no patents filed for Emtricitabline	(C) Middle and lower income developing countries excluded from the licensed territory
GDP per capita - $856	**GDP per capita - $671**	**GDP per capita - $ 2,590**
Barbados, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Democratic Republic of Congo, Egypt, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Indonesia, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malawi, Mali, Mauritania, Moldova, Morocco, Mozambique, Namibia, Nicaragua, Niger, Nigeria, Pakistan, Senegal, Sierra Leone, South Africa, Sudan, Swaziland, Tajikistan, Tanzania, Togo, Tunisia, Uganda, Uzbekistan, Vietnam, Zambia, Zimbabwe	Afghanistan, Algeria, Angola, Antigua & Barbuda, Bahamas, Bangladesh, Belize, Bhutan, Bolivia, Cambodia, Cape Verde, Comoros, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Eritrea, Ethiopia, Grenada, Guatemala, Guyana, Haiti, Honduras, India, Jamaica, Kiribati, Laos, Liberia, Libya, Maldives, Mauritius, Mongolia, Myanmar, Nepal, Papua New Guinea, Rwanda, Samoa, Sao Tome and Principe, Seychelles, Solomon Islands, Somalia, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Syria, Timor-Leste, Trinidad & Tobago, Tuvalu, Vanuatu, Yemen	Albania, Argentina, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, Bulgaria, Burundi, Chile, China, Colombia, Costa Rica, Croatia, Ecuador, El Salvador, Estonia, Fiji, Georgia, Hungary, Iran, Jordan, Kazakhstan, Latvia, Lebanon, Lithuania, Macedonia, TFYR, Malaysia, Malta, Mexico, Occupied Palestinian Territories, Oman, Panama, Paraguay, Peru, Philippines, Poland, Romania, Russian Federation, Slovakia, Sri Lanka, Thailand, Tonga, Turkey, Turkmenistan, Ukraine, Uruguay, Venezuela.

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Attachment 2: Patents on TDF

(A) Licensed countries where patents filed for TDF	(B) Licensed countries no patents file for TDF	(C) Middle and lower income developing countries excluded from the licensed territory
India Indonesia	Afghanistan, Algeria, Angola, Antigua & Barbuda, Bahamas, Bangladesh, Belize, Bhutan, Bolivia, Cambodia, Cape Verde, Comoros, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Eritrea, Ethiopia, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Kiribati, Laos, Liberia, Libya, Maldives, Mauritius, Mongolia, Myanmar, Nepal, Papua New Guinea, Rwanda, Samoa, Sao Tome and Principe, Seychelles, Solomon Islands, Somalia, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Syria, Timor-Leste, Trinidad & Tobago, Tuvalu, Vanuatu, Yemen + Barbados, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Democratic Republic of Congo, Egypt, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malawi, Mali, Mauritania, Moldova, Morocco, Mozambique, Namibia, Nicaragua, Niger, Nigeria, Pakistan, Senegal, Sierra Leone, South Africa, Sudan, Swaziland, Tajikistan, Tanzania, Togo, Tunisia, Uganda, Uzbekistan, Vietnam, Zambia, Zimbabwe	Albania, Argentina, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, Bulgaria, Burundi, Chile, China, Colombia, Costa Rica, Croatia, Ecuador, El Salvador, Estonia, Fiji, Georgia, Hungary, Iran, Jordan, Kazakhstan, Latvia, Lebanon, Lithuania, Macedonia, TFYR, Malaysia, Malta, Mexico, Occupied Palestinian Territories, Oman, Panama, Paraguay, Peru, Philippines, Poland, Romania, Russian Federation, Slovakia, Sri Lanka, Thailand, Tonga, Turkey, Turkmenistan, Ukraine, Uruguay, Venezuela.

Attachment 3: Patents (pending or granted) in 2006 within licensed territory

Country	Viread	Emtriva	Truvada
Algeria			
Afghanistan			
Angola			
Antigua & Barbuda			
Bahamas			
Bangladesh			
Barbados		X	
Belize			
Benin		X	X
Bhutan			
Bolivia			
Botswana		X	X
Burkina Faso		X	X
Burundi		X	
Cambodia			
Cameroon		X	X
Cape Verde			
Central African Republic		X	X
Chad		X	X
Comoros			
Cote d'Ivoire			
Congo			X
Cuba			
Democratic Republic of Congo		X	
Djibouti			
Dominica			
Dominican Republic			
Egypt		X	
Equatorial Guinea		X	X
Eritrea			
Ethiopia			
Gabon		X	X
Gambia		X	X
Ghana		X	X
Grenada			
Guatemala			
Guinea		X	X
Guinea Bissau		X	X
Guyana			
Haiti			
Honduras			
India	X		

Country	Viread	Emtriva	Truvada
Indonesia	X	X	X
Jamaica			
Kenya		X	X
Kiribati			
Kyrgyzstan		X	
Laos			
Lesotho		X	X
Liberia			
Libya			
Madagascar		X	
Malawi		X	X
Maldives			
Mali		X	X
Mauritania		X	X
Mauritius			
Moldova		X	
Mongolia			
Morocco		X	
Mozambique		X	X
Myanmar			
Namibia		X	X
Nepal			
Nicaragua		X	
Niger		X	X
Nigeria		X	
Pakistan		X	
Papua New Guinea			
Rwanda			
St. Kitts and Nevis			
St. Lucia			
St. Vincent and the Grenadines			
Samoa			
Sao Tome and Principe			
Senegal		X	X
Seychelles			
Sierra Leone		X	X
Solomon Islands			
Somalia			
South Africa		X	X
Sudan		X	X
Suriname			
Swaziland		X	X
Syria			
Tajikistan		X	
Tanzania		X	X

Country	Viread	Emtriva	Truvada
Timor-Leste			
Togo		X	X
Trinidad & Tobago			
Tunisia		X	
Tuvalu			
Uganda		X	X
Uzbekistan		X	
Vanuatu			
Vietnam			X
Yemen			
Zambia		X	X
Zimbabwe		X	X

Attachment 4: Anticompetitive harm from partitioning of market for Emtricitabine

Under a strict legal monopoly, prices in markets for patented inventions are determined by the seller's choice of the profit-maximizing price, given the demand for the product. However, to the degree that governments are willing to issue compulsory licenses and purchase from generic suppliers, or to permit parallel trade from markets where generic competition exists, the prices of generic alternatives become a factor, either as an alternative to the version offered by the patent owner, or because the patent owner must lower prices in the foreign market where it faces competition, and those lower priced versions are available through parallel trade, or the lower prices in the foreign market influence domestic price negotiations.

In a competitive market for pharmaceuticals, prices are driven by two factors: the costs of production, and the number of competitors in the market. In areas where fixed costs are substantial, and/or the choice of production technology and methods can be shifted to those that offer lower unit costs at higher levels of output, the average costs of production will fall as output increases, trending toward marginal costs. Experience has shown that the number of actual or potential competitors in a market is also very important. When distribution systems are efficient, as is the case from some of the bulk procurement tenders for ARVs, and the numbers of actual or potential competitors approach five, overt or tacit collusion on prices appears to give way to competition to offer the lowest price.

For most ARV products, the most important element of the value chain is the price of the Active Pharmaceutical Ingredient (API). There are significant barriers of know-how and investment to manufacture APIs, and very significant economies of scale. The relationship between the prices for APIs and finished products varies considerably, but for ARVs, products can generally be produced by manufacturers for less than twice the cost of the APIs. Since 2001, the significant demand for d4T, 3TC and NVP, the most common first line ARV regime in developing countries has drive generic prices down steadily, from more than $1,100 in early 2001, to $350 per year with the January 2001 CIPLA offer, to the $250 per year price for the first 3-in-1 delivery mechanism, to the $140 first Clinton Foundation price, to the current offers of less than $109. Generic suppliers now claim that this combination may be produced for as low as $70 per year, with large purchases and continued improvements in production methods.

Under the Gilead license, API producers will have to choose between sales within the licensed territory, to the licensed sellers, or sales that are legal outside of the voluntary license.

Partition of market for Emtricitabine			
		Sign-voluntary license	Do not sign voluntary license
Licensed territory 45 countries with patents	Licensed/Approved sellers Pay 5 percent royalty	Yes	
	Non-licensed/Approved sellers		If compulsory license is issued
Licensed Territory 54 countries without patents	Licensed/Approved sellers Pay 5 percent royalty	Yes	
	Non-licensed/Approved sellers		Yes
Outside Licensed Territory, more than 50 countries	Licensed/Approved sellers	No	
	Non-licensed/Approved sellers		Yes

The Gilead license clearly decreases the potential size of the market for unlicensed API manufacturers. Sales to **licensed** product sellers goes to zero in the 99 countries inside the licensed territory, including the 54 countries where there is no patent.

For the licensed API manufacturers, the Gilead license also decreases the potential market for APIs in all countries where Gilead does not have a patent (or a compulsory license is issued), since sales are not permitted to unlicensed product sellers in the territory, or to anyone outside the licensed territory.

By dividing the world into licensed and unlicensed API manufacturers, Gilead has reduced the number of competitors for API sales to each product seller. For example, one could imagine a scenario whether there were four API manufacturers, but only two each for the licensed and non-licensed markets.

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Attachment 5: Partitioning of market for Tenofivir and Emtricitabine

Gilead's voluntary license is for patents on Tenofivir and Emtricitabine, and combinations thereof. By combining the two products in the same license, Gilead reduced the incentives for firms to produce Tenofivir outside of the Gilead License, greatly expanding the territory where Gilead will collect royalties for Tenofivir, and by reducing the economies of scale and number of suppliers for unlicensed TDF APIs, raises the costs of APIs to the non-licensed sellers of TDF everywhere.

Partition of market for Tenofivir (TDF) and Emtricitabine (FTC)			
		Sign-voluntary license	Do not sign voluntary license
Emtricitabine or combinations of TDF+FTC **Licensed territory 45 countries with patents**	Licensed/Approved sellers Pay 5 percent royalty	Yes	
	Non-licensed/Approved sellers		If compulsory license is issued
Emtricitabine or combinations of TDF+FTC **Licensed Territory 54 countries without patents**	Licensed/Approved sellers Pay 5 percent royalty	Yes	
	Non-licensed/Approved sellers		Yes
Tenofivir Licensed territory 2 countries with patents	Licensed/Approved sellers Pay 5 percent royalty	Yes	
	Non-licensed/Approved sellers		Yes
Tenofivir Licensed Territory 97 countries without patents	Licensed/Approved sellers Pay 5 percent royalty	Yes	
	Non-licensed/Approved sellers		Yes
Tenofivir and Emtricitabine **Outside Licensed Territory, more than 50 countries**	Licensed/Approved sellers	No	
	Non-licensed/Approved sellers		Yes, where no patent or compulsory license issued