

## **LICENSE AGREEMENT**

This LICENSE AGREEMENT is made as of \_\_\_\_\_, 200\_ (the “**Effective Date**”) by and between **Gilead Sciences, Inc.** (“**Gilead**”), and \_\_\_\_\_ (“**Licensee**”).

### **RECITALS**

WHEREAS, Gilead wishes to facilitate access to its antiviral agents to patients in the developing world to help satisfy unmet medical needs;

WHEREAS, to accomplish this goal, Gilead wishes to grant widespread, non-exclusive licensing rights to qualified manufacturers to manufacture Gilead’s proprietary antiviral agent tenofovir in India;

WHEREAS, Gilead wishes to allow such manufacturers to sell manufactured product comprising such agent to end users in India and elsewhere in the developing world; and

WHEREAS, Licensee wishes to manufacture such agent in India and/or sell such products to help achieve the goal set forth above.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and other good and valuable considerations, the receipt of which is hereby acknowledged, the parties hereto mutually agree as follows:

#### **1. Definitions**

“**Active Pharmaceutical Ingredient**” or “**API**” shall mean the active pharmaceutical ingredient Tenofovir Disoproxil Fumarate, also known as “**TDF**”.

“**Alternate Dosage**” shall have the meaning set forth in Section 6.2(d).

“**Combination Product**” shall mean a formulated and finished pharmaceutical product comprising API in combination with any other active pharmaceutical ingredient, including any co-formulation, co-packaged product, bundled product, or other type of combination product. All references in this Agreement to Product shall be deemed to include Combination Product.

“**Confidential Information**” shall have the meaning set forth in Section 11.1.

“**Distributor**” shall mean a third party wholesaler or distributor that is operating under an agreement with Licensee for the distribution and sale of Product in the Licensed Territory.

“**Emtricitabine Patents**” shall have the meaning set forth in Section 7.6.

“**Field**” shall mean the treatment and prophylaxis of HIV infection.

“**Gilead Mark**” shall have the meaning set forth in Section 2.5(b).

“**Gilead Supplier**” shall mean PharmaChem Technologies (Grand Bahama), Ltd.

“**Improvements**” shall have the meaning set forth in Section 2.3.

“**Licensed API**” shall mean API that is either (a) made by Licensee pursuant to the license grant in Section 2.1; or (b) acquired by Licensee from the Gilead Supplier or from a Licensed API Supplier on the terms and conditions set forth in Section 3.

“**Licensed API Supplier**” shall mean an entity (other than Licensee) that is licensed by Gilead to manufacture and sell API to third parties in the Field in India.

“**Licensed Know-How**” shall have the meaning set forth in Section 5.5.

“**Licensed Product Supplier**” shall mean an entity (other than Licensee) located in India that is licensed by Gilead to make, use, sell, have sold, offer for sale and export Product in the Field in the Licensed Territory.

“**Licensed Technology**” shall mean the Patents and the Licensed Know-How.

“**Licensed Territory**” shall mean those countries listed on Appendix 1.

“**Minimum Quality Standards**” shall have the meaning set forth in Section 6.2(a).

“**Net Sales**” shall mean, with respect to a given period of time, the total amount invoiced by Licensee for sales of Product in the Licensed Territory, less landed cost (including freight, insurance, packing, shipping and custom duty) of imported components, all applicable taxes including VAT/Indian excise tax, sales tax, packing for shipment and shipping costs actually incurred, to the extent consistent with Generally Accepted Accounting Principles as consistently applied across all products of Licensee. In no event shall the total deductions allowed exceed ten percent (10%) of the total amount invoiced by Licensee without Licensee providing Gilead with supporting documentation justifying such excess.

“**Patents**” shall mean the patents described in Appendix 2 hereto and any other patents and patent applications (and resulting patents therefrom) owned by Gilead as of and after the Effective Date solely to the extent necessary for Licensee to practice the

licenses granted in Section 2 hereof, and solely to the extent the claims in such patents and patent applications cover the manufacture, use or sale of API.

“**Product**” shall mean a formulated and finished pharmaceutical product comprising API, and shall include Combination Products where appropriate.

“**Quarterly Report**” shall have the meaning set forth in Section 4.3.

“**Third-Party Resellers**” shall mean Licensed Product Suppliers and Distributors.

## 2. License Grants

2.1 API License. Subject to the terms and conditions of this Agreement, Gilead hereby grants to Licensee a royalty-free, non-exclusive, non-sublicensable, non-transferable license under the Licensed Technology to make, use, offer to sell and sell API in the Field and in India, in each case solely for the purpose of offering to sell and selling API to Licensed Product Suppliers, or for Licensee’s own internal use.

2.2 Product License. Subject to the terms and conditions of this Agreement, Gilead hereby grants to Licensee a royalty-bearing, non-exclusive, non-sublicensable (except as set forth in Section 2.4(b)), non-transferable, license under the Licensed Technology solely to make, use, sell, have sold, offer for sale and export Product in the Field in the Licensed Territory; provided that such Product shall be made only from Licensed API.

2.3 License Grant to Gilead. Licensee hereby grants to Gilead a nonexclusive, royalty-free license to all improvements, methods, modifications and derivative works developed by or on behalf of Licensee and relating to API or a Product (“**Improvements**”), subject to the restrictions on further transfer of Licensee’s technology by Gilead as set forth in Section 5.3.

### 2.4 Licensee Right to Sell Through Third Party Resellers.

(a) Licensed Product Suppliers. Licensee agrees that it will not sell or offer to sell API to any entity other than to Licensed Product Suppliers in India that have been approved by Gilead in accordance with Section 2.4(d).

(b) Distributors. Licensee agrees that it will not sell, offer for sale, or assist third parties in selling Product *except for* the sale and offer for sale of Product for end use in the Field and in countries in the Licensed Territory. Licensee agrees that it will prohibit its Distributors from selling Product (i) to any other wholesaler or distributor, (ii) outside the Licensed Territory, or (iii) for any purpose outside the Field.

(c) Terms of Agreements with Third Party Resellers. Licensee shall require any such Third Party Reseller to agree, in a written agreement with Licensee, (i) to comply with the applicable terms of this Agreement; and (ii) to report to Licensee

such information as will allow Licensee to provide Gilead with the information described in Section 4.3. Gilead has the right to audit, on no less than thirty (30) days' advance notice to Licensee, such records of Licensee solely to the extent necessary to verify such compliance. Gilead will bear the full cost of any such audit.

(d) Gilead Approval of Third Party Reseller Agreements. Licensee shall not enter into any agreements with Third Party Resellers without obtaining Gilead's prior written approval. If Licensee wishes to enter into an agreement with any Third Party Reseller, then Licensee shall notify Gilead in writing, and shall certify that its arrangement with such Third Party Reseller is consistent with the terms and conditions of this Agreement. Licensee shall provide Gilead with written copies of all agreements between Licensee and Third Party Resellers prior to their execution. Gilead shall have the right to review all such agreements prior to their execution to verify consistency with the terms and conditions of this Agreement. Gilead agrees to review such agreements and respond to such requests within ten (10) business days following Gilead's receipt of each such agreement, and shall not unreasonably withhold its consent. Gilead acknowledges that Licensee may not have written contracts in place with all of its Third Party Resellers in India, and that Licensee has written contracts in place with some, but not all, of its Third Party Resellers outside of India. To the extent that no written contract exists with a Third Party Reseller, Licensee shall provide Gilead with a written notification of its arrangement with such Third Party Reseller. Any such notification will include a brief description of the business relationship between Licensee and such Third Party Reseller, including the name of the entity, the identity and quantity of the product(s) being sold to such entity, to whom such Third Party Reseller may sell such product(s), and in what territory(ies).

(e) Termination of Third Party Agreements by Licensee. Licensee shall immediately terminate its agreement(s) with a Third-Party Reseller in the event that such Third Party Reseller engages in material activities that Licensee is prohibited from performing under this Agreement, or that are inconsistent with Licensee's covenants under this Agreement, including without limitation the unauthorized use, sale or diversion by such Third Party Reseller of API or Product outside the Field or the Licensed Territory, or upon Licensee first reasonably believing that such Third-Party Reseller has engaged in such activities.

(f) Termination of Third Party Agreements by Gilead. Gilead may terminate the right of Licensee to sell Product to any Third-Party Reseller pursuant to this Section 2.4, if in Gilead's reasonable belief the Third-Party Reseller is not acting in a way that is consistent with Licensee's covenants under this Agreement, or if Licensee does not terminate the agreement with such Third-Party Reseller under the circumstances described in Section 2.4(e).

## 2.5 License Limitations.

(a) Gilead Retained Rights. Licensee hereby acknowledges that Gilead retains all rights in API and Products except as otherwise provided in this

Agreement, and that Gilead may license or otherwise convey to third parties its rights in API and Products as it wishes without obligation or other accounting to Licensee.

(b) Gilead Marks. The licenses granted hereunder do not include any license or other right to use any Gilead trademark, trade name, logo or service mark (each, a “**Gilead Mark**”) or any word, logo or any expression that is similar to or alludes to any Gilead Mark, except as provided in Section 6.5.

(c) No Other Licenses

(i) Licensee agrees that it shall not use any contract manufacturers without obtaining Gilead’s prior written consent, or grant any sublicenses except as expressly provided under Sections 2.4(a), 2.4(b), 3.1 and 3.2.

(ii) Except as expressly set forth in this Agreement, Gilead does not grant any license under any of its intellectual property rights (including, without limitation, Patents) to Licensee.

### **3. Sourcing of API**

3.1 Sourcing of API from API Suppliers. Licensee agrees that it shall not make, use or sell any Product that contains API other than API that is Licensed API. If Licensee wishes to manufacture Product using API made by either a Gilead Supplier or a Licensed API Supplier, then Licensee shall notify Gilead in writing, and shall certify that its arrangement with such Gilead Supplier or Licensed API Supplier, as applicable, is consistent with the terms and conditions of this Agreement. Licensee shall provide Gilead with written copies of all agreements in respect of Licensed API between Licensee and such Gilead Supplier or Licensed API Supplier prior to their execution. Gilead shall have the right to review all such agreements prior to their execution to verify consistency with the terms and conditions of this Agreement. Gilead agrees to review such agreements and provide such approval within ten (10) business days following Gilead’s receipt of each such agreement. If Gilead does not review and comment on such agreements within ten (10) business days following Gilead’s receipt of each such agreement, the Licensee shall be free to execute such agreement with the Gilead Supplier or Licensed API Supplier as the case may be. The Licensee shall not be obliged to disclose to Gilead the financial terms of the agreement with such Gilead Supplier or Licensed API Supplier, but shall disclose to Gilead the identity of the API supplier, the nature of the API being supplied by such supplier, and the amounts being supplied to Licensee by such supplier.

3.2 Gilead Assistance with Gilead Suppliers. Upon receipt of a notice described in Section 3.1 of Licensee’s intention to obtain Licensed API from a Gilead Supplier, Gilead shall use commercially reasonable efforts to assist Licensee in procuring any sublicense from such Gilead Supplier. Gilead shall not be obligated to assist Licensee in procuring any supply of API from a Licensed API Supplier.

3.3 Conditions of Supply from Gilead Suppliers. Gilead shall be a party to any agreement between Licensee and a Gilead Supplier that provides for the supply of API to Licensee from such Gilead Supplier. Any such agreement between Gilead, Licensee and a Gilead Supplier shall include and be subject to the following conditions:

(a) Gilead Supply Needs. Licensee shall not obtain API from the Gilead Supplier until Gilead has received confirmation in writing from the Gilead Supplier of its ability to continue to supply Gilead with Gilead's forecasted requirements of API, as reflected in Gilead's then-current twelve (12) month forecast for API provided to the Gilead Supplier.

(b) Consistency with Agreement. The Gilead Supplier shall be permitted to supply API to Licensee only to the extent that any such supply does not (A) adversely affect its ability to meet Gilead's forecasted requirements or (B) adversely affect the Gilead Supplier's ability to supply Gilead's requirements, whether or not such requirements are consistent with Gilead's twelve (12) month forecast. Gilead shall have the right to terminate any such agreement if such supply adversely affects Gilead as set forth in this Section 3.3(b).

3.4 No Other Arrangements. Licensee agrees that it shall not enter into any agreements, nor amend any existing agreements, for the supply of API without Gilead's prior written approval as provided for in this Section 3.

3.5 Supply of other components. The obligations set forth in Sections 3.1, 3.2 and 3.3 with respect to Licensee's supply of API shall not apply to active pharmaceutical ingredients other than API that Licensee may incorporate into Combination Products.

#### **4. Consideration/Payment Terms/Audit**

4.1 Royalty. As consideration for the license granted in Section 2, Licensee shall pay Gilead a royalty of five percent (5%) on Net Sales of Product in the Licensed Territory for the period specified in Section 4.9. Gilead agrees that the rate of royalty payable by the Licensee under this Agreement shall be at no time higher than the royalty collected by Gilead from other authorized licensees of Gilead for the sale of Product in the countries in the Licensed Territory.

4.2 Adjustment for Combination Products. The parties shall discuss in good faith and shall determine an appropriate adjustment to the royalty rate provided in Section 4.1 if the Product sold is a Combination Product. Any royalty paid by Licensee to Gilead with respect to the sale of a Combination Product will apply only to the TDF component of such Combination Product.

4.3 Reports. Within sixty (60) days after the end of each calendar quarter, Licensee shall (a) provide Gilead with a detailed report of amounts of API and Product produced, API and Product on stock, total invoiced sales, Net Sales, the deductions used to determine Net Sales, total royalties owed for the calendar quarter, the countries to

which the Product has been sent and in what quantities, the Third Party Resellers, if any, to which Licensee has provided Product and in what quantities, and Net Sales by each Third-Party Reseller, and, in the case of the sale of any API to third-party manufacturers of Product, the identity of such third parties and quantities of API sold to each such third party (the “**Quarterly Report**”); (b) provide Gilead with a written certification of the accuracy of the contents of the Quarterly Report, signed by an appropriate Licensee senior officer; and (c) pay royalties due to Gilead for the calendar quarter on a Product-by-Product and country-by-country basis. Licensee shall provide Quarterly Reports to Gilead at the address listed below. Licensee shall pay royalties to Gilead by wire transfer to the bank account indicated by Gilead from time to time.

4.4 Payment Terms. Licensee shall make all payments to Gilead in US Dollars. With regard to sales in currencies other than US Dollars, conversion from local currency into US Dollars shall be at the rate of exchange of the local currency to the US Dollar on the day of payment as reported by the Reserve Bank of India.

4.5 Records. Licensee shall keep complete and accurate records of API and Product produced and sold in sufficient detail to enable Licensee to determine the amount of royalties due, the parties to whom Product was sold, and the countries in which sales occurred.

4.6 Audit. Gilead has the right to engage an independent public accountant to perform, on no less than thirty (30) days’ advance notice to Licensee, an audit, conducted in accordance with generally accepted auditing standards, of such books and records of Licensee that are deemed necessary by such public accountant solely for the purpose and to the extent required to report amounts of API and Product produced, gross sales, Net Sales for the periods requested and accrued royalties. Gilead will bear the full cost of any such audit unless such audit discloses a difference of more than five percent (5%) from the amount of royalties due. In such case, Licensee shall promptly pay Gilead any underpayment and shall bear the full cost of such audit.

4.7 Interest. Any amount payable hereunder by Licensee, which is not paid on a timely basis, shall bear a pro rata monthly interest rate of one percent (1%), subject to any necessary approvals that may be required.

4.8 Taxes

(a) Withholding Taxes. Licensee shall promptly pay the withholding tax for and on behalf of Gilead to the proper governmental authority and shall promptly furnish Gilead with the tax withholding certificate furnished by the Licensee. Licensee shall be entitled to deduct the withholding tax actually paid from such payment due Gilead. Each party agrees to assist the other party in claiming exemption from such withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

(b) Other Taxes. Except as provided in this Section 4.8, all taxes or duties in connection with payments made by Licensee shall be borne by Licensee.

4.9 Royalty Term. Royalty payments shall be paid to Gilead by Licensee on a Product-by-Product and country-by-country basis starting on the date of the first commercial sale of a Product in a country and continuing until the last to occur of the following:

(a) the expiration or abandonment of the last-to-expire Patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of API or the Product in such country; or

(b) the date of expiration or abandonment of the last-to-expire Patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of API or the Product in India.

## **5. Intellectual Property**

5.1 Maintenance of Patents. Gilead shall seek to maintain and enforce the Patents in India.

5.2 Reporting of Improvements. Licensee shall provide Gilead with an annual report, in writing and in reasonable detail that sets forth any Improvements. Licensee shall transfer to Gilead, upon request by Gilead and at Gilead's expense, any know-how owned or controlled by Licensee relating to such Improvements. Any failure to report any such Improvements to Gilead in accordance with the terms of this Agreement shall constitute a breach of this Agreement and shall provide Gilead with the right to terminate this Agreement pursuant to Section 10.3(b). Gilead shall not transfer any Improvements obtained from Licensee to any third party, provided, however, that Gilead may transfer Improvements to Gilead's own suppliers and provided such suppliers utilize such Improvements solely for the benefit of Gilead.

### **5.3 Trademarks**

(a) Any Product offered for sale or sold shall have a different trade dress, including a distinct color, shape and trade name, than the comparable product sold by Gilead.

(b) Licensee shall provide to Gilead, prior to any regulatory submissions for any Product, or selling or offering for sale any Product, samples of the Product and any packaging, labeling information, or marketing materials to be used with the Product to permit Gilead to review and approve the Product and packaging as consistent with the requirements of this Section 5.3(b). If Gilead reasonably objects to the trade dress or other aspects of the Product or product packaging based on the requirements of this Section 5.4, the parties shall discuss in good faith the changes to be made to the Product or packaging to address Gilead's concerns.

5.4 Technology Transfer. Promptly following the Effective Date, Gilead shall make a one-time technology transfer of know-how owned or controlled by Gilead as of the Effective Date relating to the manufacture of API and Product to the extent and in the manner specified in Appendix 3 hereto (“**Licensed Know-How**”). Such Licensed Know-How shall be sufficient to enable Licensee to manufacture API and Product at commercial-scale quantities. Gilead shall have no further obligation to transfer any other know-how to Licensee.

## **6. Manufacturing and Commercialization of Product**

6.1 Promotion of Sales in the Licensed Territory. The parties agree that an important purpose of this Agreement is to increase patient access to the Product licensed under this Agreement in the Licensed Territory. Except as otherwise provided in this Agreement, Licensee shall have the sole discretion to manage its own commercial strategy to promote and sell the Product in the Licensed Territory, *provided, however*, that Licensee shall not engage in activities that are inconsistent with the purpose of this Agreement. By means of example and without limitation, Licensee agrees that Licensee shall not accept patient orders that Licensee does not have the capacity to fill, and shall not obtain API or Product without having the means, either directly or through the use of permitted third parties, to manufacture such API into Product and/or distribute such Product to patients within the Licensed Territory.

### 6.2 Manufacturing Requirements

(a) Minimum Standards. 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 Agency for the Evaluation of Medicinal Products (“**EMEA**”), 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. Licensee shall apply for WHO pre-qualification or FDA conditional approval no later than the first anniversary of the Effective Date.

(b) Audit Right. Licensee hereby agrees to allow Gilead reasonable access to Licensee’s books and records, facilities and employees solely for the purpose and to the extent required for Gilead to audit Licensee’s compliance with the requirements of this Section 6.2. Gilead agrees to provide at least thirty (30) days prior notice of the proposed audit, and agrees that such audits shall not be conducted more than once a year unless circumstances outside the ordinary course of business warrant such an audit (such as an investigation or other government action).

(c) Remedy for Failure. If Licensee fails at any time to meet the Minimum Quality Standards or has not received either WHO pre-qualification or FDA

conditional approval, as applicable, by the second anniversary of the Effective Date, Gilead may elect, in its sole discretion and notwithstanding Section 10.2 or 10.3 hereof, to suspend the effectiveness of the licenses granted hereunder until such time Gilead has determined that Licensee has corrected any such failure to Gilead's reasonable satisfaction. During any such suspension, Gilead and Licensee shall coordinate with each other to provide for the supply of API or Product, as appropriate, to ensure that end-user patient requirements are not disrupted as a result of such suspension.

(d) Dose Requirements. All Product manufactured, used or sold by Licensee shall consist of a single dose concentration of 300 milligrams of TDF per dose. Licensee agrees that it shall not manufacture or sell Products formulated at a single dose concentration other than 300 milligrams of TDF per dose (each an "**Alternate Dosage**"), provided, however, that Licensee may manufacture or sell Products consisting of an Alternate Dosage if such Alternate Dosage has been approved for use in the Field by the appropriate regulatory authority having jurisdiction over such Product. By means of example, dosage concentrations of TDF lower than 300 milligrams will be allowed for pediatric administrations only if such lower dosage has been approved by the FDA or the appropriate foreign regulatory authority for such administration.

6.3 Regulatory Filings and Inspections. Except as provided otherwise herein, Licensee shall be responsible for obtaining and maintaining all applicable regulatory or other approvals or authorizations to carry out its activities under this Agreement. Gilead may, in its discretion, elect to file for regulatory or other approval or authorization to make and sell API and Product anywhere in the Territory. Upon either party's request, the other party shall provide non-proprietary data that the other party perceives that is reasonably necessary to obtain any such approvals, authorizations, permits or licenses. Licensee shall obtain, have and maintain all required registrations for its manufacturing facilities. Licensee shall allow appropriate regulatory authorities to inspect such facilities to the extent required by applicable law, rule or regulation.

6.4 Marketing Materials. The marketing materials used by Licensee and its Third-Party Resellers shall not contain any misstatements of fact, shall be fully compliant with the applicable laws, rules and regulations, and shall be distinct from, and not cause any confusion with, any marketing materials or Products used or sold by Gilead. Any statements made in such marketing materials regarding Gilead, including without limitation Licensee's collaboration with Gilead, require Gilead's prior written approval.

6.5 Product Labeling. The labeling of all Products sold or offered for sale under this Agreement shall expressly state, "Tenofovir disoproxil fumarate is manufactured under a license from Gilead."

## **7. Representations, Warranties and Covenants**

7.1 Ability to Perform. Licensee and Gilead each represent and warrant that

(a) they are duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and have full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) this Agreement has been duly executed and delivered, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof; and

(c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party

7.2 Diversion of Product and Technology. Licensee covenants and agrees that it shall not: (i) divert or allow the diversion of API, or any intermediates or other chemical entities generated during the process of manufacturing API, outside of India, (ii) divert or allow the diversion of Product outside the Licensed Territory, (iii) divert or allow the diversion of Licensed Technology to any third party, including, without limitation, any entity in China, or (iv) assist or support, directly or indirectly, any third party in the conduct of the activities described in clauses (i) - (iii).

7.3 Access Promotion. Licensee covenants and agrees that it shall not engage in activities that are contrary to the goal of promoting patient access to Product to satisfy unmet medical needs within the Licensed Territory.

7.4 Law Compliance

(a) General. Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all applicable laws and regulations, including, without limitation, with respect to recalls, safety and reporting requirements and shall obtain, have and maintain all necessary regulatory approvals (including in India), marketing authorizations, permits and licenses, at Licensee's expense for the manufacture and sale of the API and/or Product and any other Licensee activities contemplated hereby.

(b) FCPA. Licensee covenants and agrees that it shall provide to Gilead on the Effective Date and within thirty (30) days after the beginning of each calendar year thereafter, certification in writing by Licensee of Licensee's compliance with the United States Foreign Corrupt Practices Act of 1977.

7.5 Patent Infringement. Licensee covenants and agrees that it shall not infringe the Patents outside the scope of the licenses granted to it pursuant to Section 2, and shall not infringe the Emtricitabine Patents outside the scope of the covenant not to sue set forth in Section 7.6.

7.6 Covenant Concerning Certain Gilead Patents. Gilead covenants and agrees that it shall not bring any claim or proceeding of any kind or nature against Licensee in relation to any of the pending and issued patents identified in Appendix 4 hereto (the “**Emtricitabine Patents**”) to the extent that Licensee decides to make, use, sell, have sold and export any Product in the Licensed Territory during the term of this Agreement that may infringe any claims covering the manufacture, use and sale of emtricitabine contained in such Emtricitabine Patents.

7.7 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, GILEAD DOES NOT GIVE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT IN THE LICENSED TERRITORY. Gilead also does not give any warranty, express or implied, with regard to the safety or efficacy of API or the Product and it shall be the sole responsibility of the Licensee to ensure such safety or efficacy.

## **8. Liability and Indemnity**

(a) Licensee Indemnity. Licensee shall jointly and severally indemnify, hold harmless and defend Gilead, and its licensors, directors, officers, employees and agents, from and against any and all losses, damages, expenses, cost of defense (including, without limitation, attorneys’ fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Gilead becomes legally obligated to pay because of any claim against it (i) arising out of any breach by Licensee of the terms and conditions of this Agreement, or (ii) for any product liability, liability for death, illness, personal injury and improper business practice, or any other statutory liability or any other liability under any law or regulation, to the extent that such claim or claims are due to reasons caused by or on behalf of Licensee related to Licensed API or Product (including, without limitation, their manufacture, use or sale). The indemnification obligations of Licensee stated in this Section 8(a) shall apply only in the event that Gilead provides Licensee prompt written notice of such claims, grants Licensee the right to control the defense or negotiation of settlement, and makes available all reasonable assistance in defending the claims. Licensee shall not agree to any final settlement or compromise with respect to any such claim that adversely affects Gilead without obtaining Gilead’s consent.

(b) Product Liability. Licensee shall be solely responsible in respect of any product liability or any other statutory liability under any regulation, in respect of API or the Product.

(c) Gilead Liability. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, IN NO EVENT SHALL GILEAD BE LIABLE TO LICENSEE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOSS OF BUSINESS OR PROFITS) RELATED TO THIS

AGREEMENT, AND SHALL NOT HAVE ANY RESPONSIBILITIES OR LIABILITIES WHATSOEVER WITH RESPECT TO API OR PRODUCT, EVEN IF, IN ANY SUCH CASE, ADVISED OF THE POSSIBILITY OF SUCH CLAIMS OR DEMANDS, REGARDLESS OF THE FORM OF ACTION OR LEGAL THEORY WHETHER UNDER CONTRACT LAW, TORT LAW (INCLUDING WITHOUT LIMITATION NEGLIGENCE), STRICT LIABILITY, STATUTE, WARRANTY OR OTHERWISE.

## **9. Insurance**

Within thirty (30) days prior to the first commercial launch by Licensee of a Product, and each year thereafter for so long as this Agreement is in effect, Licensee shall upon Gilead's request provide to Gilead certificates of insurance by insurers acceptable to Gilead evidencing public liability coverage in India, including products liability, with a combined limit of no less than one million dollars (\$1,000,000.00) for bodily injury, including personal injury, and property damage. Coverage with respect to public liability will be in India and will be global under product liability policy, and shall name Gilead as additional insured. Licensee shall not cancel any such policy without at least sixty (60) days prior written notice to Gilead, and agrees that such policy shall be maintained (or have an extended reporting period) of at least seven (7) years after the termination of this Agreement.

## **10. Term and Termination**

10.1 Term. This Agreement shall enter into force upon the Effective Date and, unless earlier terminated as provided herein, shall continue until the expiration of the obligation to pay royalties as provided in Section 4.9.

10.2 Termination for Breach. A party ("non-breaching party") shall have the right to terminate this Agreement in the event the other party ("breaching party") is in material breach of any of its material obligations under this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party shall have a period of ninety (90) days after such written notice is provided to cure such breach. If such breach is not cured within the thirty day period, this Agreement shall effectively terminate.

### 10.3 Gilead Right to Terminate

(a) Gilead shall have the right to terminate this Agreement and/or one or both of the licenses granted pursuant to Section 2.1 or Section 2.2 (whether or not such event constitutes a right of termination pursuant to Section 10.2), immediately if in the reasonable opinion of Gilead, control (through ownership or otherwise) of Licensee changes.

(b) Gilead shall have the right to terminate this Agreement and/or one or both of the licenses granted pursuant to Section 2.1 or Section 2.2 or the covenant contained in Section 7.6 (whether or not such event constitutes a right of termination pursuant to Section 10.2), if:

(i) Gilead reasonably determines that a material quantity of API or Product made and/or sold by Licensee has been diverted to countries outside the Licensed Territory, whether or not by any fault or action or inaction of Licensee;

(ii) Gilead reasonably determines that, due to material deficiencies in Licensee's compliance, or repeated failure to comply, with the Minimum Quality Standards, Licensee is unable to reliably and consistently manufacture API or Product in accordance with the Minimum Quality Standards; or

(iii) Gilead reasonably determines that Licensee has obtained material quantities of API from sources outside the Territory, or in ways that are inconsistent with the terms and conditions of Section 3.

Gilead shall give Licensee written notice of either such event and provide Licensee with a period of sixty (60) days after such notice to demonstrate that the conditions giving rise to Gilead's determination no longer exist to Gilead's reasonable satisfaction. If Licensee is unable to do so, then Gilead shall have the right to terminate this Agreement and such termination shall be effective upon the sixtieth (60<sup>th</sup>) day following such notice. Upon such an uncured breach, Gilead reserves the right, in its sole discretion, to determine whether the Agreement shall be terminated in its entirety, or only terminated in part, as applicable to the nature uncured breach.

10.4 Insolvency. In the event that Licensee becomes insolvent, makes an assignment to the benefit of creditors, or has a petition in bankruptcy filed for or against it, Gilead shall have the right to treat such event as a material breach.

10.5 Waiver. The waiver by either party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

10.6 Survival. Sections 2.3, 3.4, 5.2, 5.3(a), 8, 10.6, 11 and 12 shall survive termination or expiry of this Agreement.

## **11. Confidentiality and Publications**

11.1 Confidential Information. All technology and know-how disclosed by one party (the "**Disclosing Party**") to the other party (the "**Receiving Party**") hereunder ("**Confidential Information**") shall be used solely and exclusively by Receiving Party in a manner consistent with the licenses granted hereunder and the purposes of this Agreement as stated in the preamble and recitals hereto; maintained in confidence by the

Receiving Party; and shall not be disclosed to any non-party or used for any purpose except to exercise its rights and perform its obligations under this Agreement without the prior written consent of the Disclosing Party, except to the extent that the Receiving Party can demonstrate by competent written evidence that such information: (a) is known by the Receiving Party at the time of its receipt and, not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party's business records; (b) is in the public domain other than as a result of any breach of this Agreement by the Receiving Party; (c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a third party who may lawfully do so; or (d) is independently discovered or developed by the Receiving Party without the use of Confidential Information provided by the Disclosing Party, as documented by the Receiving Party's business records. Within thirty (30) days after any expiration or termination of this Agreement, Receiving Party shall destroy (and certify to the Disclosing Party such destruction) or return all Confidential Information provided by the Disclosing Party except as otherwise set forth in this Agreement. One (1) copy of the Confidential Information may be retained in the Receiving Party's files solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement.

11.2 Press Release. Either party may at any time disclose, by press release or otherwise, the general terms, conditions, and subject matter of this Agreement, and make other statements about this Agreement, to third persons and entities without the prior written consent of the other party, provided, however, that neither party shall disclose, by press release or otherwise, any details of this Agreement that may be specific to the relationship between Gilead and Licensee, or use the other party's name in connection with any such release, without the prior written consent of the other party.

11.3 Use of Name. Neither party shall use the other party's name, logo or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.

## **12. Miscellaneous**

12.1 Agency. Neither party is, nor will be deemed to be, an employee, agent or representative of the other party for any purpose. Each party is an independent contractor, not an employee or partner of the other party. Neither party shall have the authority to speak for, represent or obligate the other party in any way without prior written authority from the other party.

12.2 Entire Understanding. This Agreement embodies the entire understanding of the parties with respect to the subject matter hereof and supersedes all previous communications, representations or understandings, and agreements, whether oral or written, between the parties relating to the subject matter hereof.

12.3 Severability. The parties hereby expressly state that it is not their intention to violate any applicable rule, law or regulation. If any of the provisions of this Agreement are held to be void or unenforceable with regard to any particular country by

a court of competent jurisdiction, then, to the extent possible, such void or unenforceable provision shall be replaced by a valid and enforceable provision which will achieve as far as possible the economic business intentions of the Parties. The provisions held to be void or unenforceable shall remain, however, in full force and effect with regard to all other countries. All other provisions of this Agreement shall remain in full force and effect.

#### 12.4 Notices

(a) Any notice or other communication to be given under this Agreement, unless otherwise specified, shall be in writing and shall be deemed to have been provided when delivered to the addressee at the address listed below (i) on the date of delivery if delivered in person or (ii) three days after mailing by registered or certified mail, postage paid:

In the case of Gilead:

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404  
Attention: General Counsel  
Facsimile: (650) 522-5537

In the case of Licensee:

[Insert contact information]

(b) Either party may change its address for communications by a notice in writing to the other party in accordance with this Section 12.4.

12.5 Governing Law. This Agreement is made in accordance with and shall be governed and construed under the laws of the United Kingdom, without regard to its choice of law principles.

#### 12.6 Arbitration

(a) All disputes arising out of or in connection with the present Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators.

(b) Each party shall nominate one arbitrator. Should the claimant fail to appoint an arbitrator in the Request for Arbitration within thirty (30) days of being requested to do so, or if the respondent should fail to appoint an arbitrator in its Answer to the Request for Arbitration within thirty (30) days of being requested to do so, the other party shall request the ICC Court to make such appointment.

(c) The arbitrators nominated by the parties shall, within thirty (30) days from the appointment of the arbitrator nominated in the Answer to the Request for Arbitration, and after consultation with the parties, agree and appoint a third arbitrator, who will act as a chairman of the Arbitral Tribunal. Should such procedure not result in an appointment within the thirty (30) day time limit, either party shall be free to request the ICC Court to appoint the third arbitrator.

(d) London, England shall be the seat of the arbitration.

(e) The language of the arbitration shall be English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with an English translation.

(f) This arbitration agreement does not preclude either party seeking conservatory or interim measures from any court of competent jurisdiction including, without limitation, the courts having jurisdiction by reason of either party's domicile. Conservatory or interim measures sought by either party in any one or more jurisdictions shall not preclude the Arbitral Tribunal granting conservatory or interim measures. Conservatory or interim measures sought by either party before the Arbitral Tribunal shall not preclude any court of competent jurisdiction granting conservatory or interim measures.

(g) In the event that any issue shall arise which is not clearly provided for in this arbitration agreement the matter shall be resolved in accordance with the ICC Arbitration Rules.

12.7 Assignment. Gilead is entitled to transfer and assign this Agreement and the rights and obligations under this Agreement on prior notice to Licensee. Licensee is not entitled to transfer or assign this Agreement or the rights and obligations under this Agreement.

12.8 Amendment. No amendment or modification hereof shall be valid or binding upon the parties unless made in writing and signed by both parties.

END OF PAGE

*[signatures appear on following page]*

IN WITNESS WHEREOF, the parties hereto have executed this License Agreement as of the Effective Date.

*GILEAD:*

**Gilead Sciences, Inc.**

By \_\_\_\_\_  
Name:  
Title:

*LICENSEE:*

**[Licensee]**

By \_\_\_\_\_  
Name:  
Title:

## **Appendix 1**

### **Countries in the Licensed Territory**

- |                                 |                                |                                       |
|---------------------------------|--------------------------------|---------------------------------------|
| 1. Afghanistan                  | 34. Guatemala                  | 68. Saint Lucia                       |
| 2. Angola                       | 35. Guinea                     | 69. Saint Vincent &<br>the Grenadines |
| 3. Antigua and Barbuda          | 36. Guinea-Bissau              | 70. Samoa                             |
| 4. Bahamas                      | 37. Guyana                     | 71. Sao Tome and<br>Principe          |
| 5. Bangladesh                   | 38. Haiti                      | 72. Senegal                           |
| 6. Barbados                     | 39. Honduras                   | 73. Seychelles                        |
| 7. Belize                       | 40. India                      | 74. Sierra Leone                      |
| 8. Benin                        | 41. Indonesia                  | 75. Solomon Islands                   |
| 9. Bhutan                       | 42. Jamaica                    | 76. Somalia                           |
| 10. Bolivia                     | 43. Kenya                      | 77. South Africa                      |
| 11. Botswana                    | 44. Kiribati                   | 78. Sudan                             |
| 12. Burkina Faso                | 45. Kyrgyzstan                 | 79. Surinam                           |
| 13. Burundi                     | 46. Lao, People's Dem.<br>Rep. | 80. Swaziland                         |
| 14. Cambodia                    | 47. Lesotho                    | 81. Syria                             |
| 15. Cameroon                    | 48. Liberia                    | 82. Tajikistan                        |
| 16. Cape Verde                  | 49. Madagascar                 | 83. Tanzania, U. Rep.<br>of           |
| 17. Central African<br>Republic | 50. Malawi                     | 84. Thailand                          |
| 18. Chad                        | 51. Maldives                   | 85. Timor-Leste                       |
| 19. Comoros                     | 52. Mali                       | 86. Togo                              |
| 20. Congo                       | 53. Mauritania                 | 87. Trinidad and<br>Tobago            |
| 21. Congo, Dem. Rep. of<br>the  | 54. Mauritius                  | 88. Tuvalu                            |
| 22. Cote d'Ivoire               | 55. Moldova, Rep. of           | 89. Uganda                            |
| 23. Cuba                        | 56. Mongolia                   | 90. Uzbekistan                        |
| 24. Djibouti                    | 57. Mozambique                 | 91. Vanuatu                           |
| 25. Dominica                    | 58. Myanmar                    | 92. Vietnam                           |
| 26. Dominican Republic          | 59. Namibia                    | 93. Yemen                             |
| 27. Equatorial Guinea           | 60. Nepal                      | 94. Zambia                            |
| 28. Eritrea                     | 61. Nicaragua                  | 95. Zimbabwe                          |
| 29. Ethiopia                    | 62. Niger                      |                                       |
| 30. Gabon                       | 63. Nigeria                    |                                       |
| 31. Gambia                      | 64. Pakistan                   |                                       |
| 32. Ghana                       | 65. Papua NewGuinea            |                                       |
| 33. Grenada                     | 66. Rwanda                     |                                       |
|                                 | 67. Saint Kitts and Nevis      |                                       |

## **Appendix 2**

### **Patents**

<b>Country</b>	<b>Filing Date</b>	<b>Serial No.</b>	<b>Grant Date</b>	<b>Patent No.</b>
India	July 25, 1997	2076/DEL/1997		
India	July 24, 1998	2174/DEL/1998	March 15, 2004	190780
India	Sept 4, 2002	896/DEL/2002		
India	Sept 24, 2002	963/DEL/2002		
India	July 23, 2004	1362/DEL/2004		
Indonesia	July 23, 1998	W-991548	April 11, 2002	000 7658

### **Appendix 3**

#### **Terms for Technology Transfer**

Gilead shall provide Licensee with the following information to fully enable Licensee to manufacture API and Product at commercial-scale quantities and in compliance with Gilead's required quality specifications:

1. Manufacturing process descriptions, specifications and methods;
2. Stability data;
3. Analytical method validation; and
4. Discussion of impurities.

**Appendix 4**

**Emtricitabine Patents**

**[To be attached prior to execution]**