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## **Analysis of key clauses from Gilead Sciences, Inc's example licence Agreement**

**17 September 2006**

### **Recitals**

The second recital expresses Gilead's desire to grant non-exclusive licensing rights to qualified manufacturers to manufacture Gilead's proprietary agent Tenofovir in India.

Although a rather pedantic point and possibly difficult for Gilead to express in any other way without being seen to be conceding its rights, Gilead chooses to use the term "proprietary" when referring to the manufacture of Tenofovir in India. As we are sure you are aware, Gilead does not currently have a proprietary right in Tenofovir in India or the several other licensed territories proposed in the licence (with the exception of South Africa we believe). While the granting or rejection of Gilead's patents will ultimately decide this matter, it does serve as some form of admission on part of a Licensee that Gilead is the proprietor of Tenofovir in India.

The Licensee might request a different use of wording here so as not admit any proprietary rights on the part of Gilead until a patent is issued.

### **Definitions**

The Licence refers to Gilead's "patents", including its patent applications, as set out in Appendix 2. Note that Gilead does not distinguish between patents and patent applications – "the words any other patents and patent applications (and resulting patents therefrom)".

### **Licence Grants**

The Licence in effect grants three different types of licences:

1. Clause 2.1 is the API Licence and offers a royalty free, non-exclusive, non-sub-licensable, non-transferable licence under licensed technology to make, use, offer to sell and sell API in India only and only for the purpose of offering to sell such API to a Licensed Product Supplier (see Clause 2.2 below) or for the Licensee's own internal use. The API licence is based on the process patent granted in India under No. 190780.



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Therefore, the API Licence is limited only for use or sale in India for the Licensee's own internal use or for "Licensed Product Suppliers" and prevents supply to countries such as Brazil and Argentina which may be dependent on Indian API. More significantly, should a scenario arise where Brazil or any other country were to issue a compulsory licence to produce Tenofovir, this clause would prevent the Indian API Licensee from exporting any API for such purpose.

This is obviously a deliberate clause to control the API market both inside and outside of India.

2. Clause 2.2 provides for a royalty bearing non-exclusive product licence. However, such product may only be made from Licensed API; the Licensed API may be made by the Licensee itself, Gilead's supplier (PharmaChem Technologies (Grand Bahama Ltd)) or another Licensed API Supplier.

The significance of Clause 2.2 is that it prohibits Licensed Product Suppliers from purchasing API from other legal and low-cost producing non-licensed API suppliers. The Licensed Product Supplier is compelled to only purchase API from a Licensed API Supplier (see Clause 2.1) or Gilead's supplier.

It is strongly recommended that Licensees negotiate the right to purchase API from other non-licensed suppliers, or at least be able to purchase from non-licensed suppliers in countries where Gilead does not have or is not pursuing patent protection. Of course, such non-licensed supply should meet WHO and/or FDA quality standards.

Another scenario arises if the Gilead patent situation in India for Tenofovir remains undecided for another year and Company X (India) was interested in selling the formulated version, but did not wish to take a product licence until the patent matter was decided and also was not capable of producing its own API. In such a situation Company X would not be able to purchase the API from an API Licensee, as the API Licensee can only sell to a Licensed Product Supplier. While Company X could technically seek API from elsewhere, it may prove more costly or difficult.

3. Clause 2.3 provides for non-exclusive royalty free grant-back licence 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.

This royalty free grant-back licence, for a product at least, is rather one-sided considering the Licensee pays a royalty of 5% on the original version of the Product.



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The effect of the above clause is made even more one sided when read with Clause 5.3. Clause 5.3 requires the Licensee to provide Gilead with an annual report that sets out all improvements, modifications, or derivative works described in Clause 2.3. Furthermore, Clause 5.3 requires the Licensee to transfer to Gilead, upon Gilead's request at its expense, any know how owned by the Licensee relating to such improvements etc. Any failure to do so by the Licensee could constitute a breach of the Agreement and furthermore give Gilead the right to terminate the Agreement. What could make this particular clause problematic in light of Gilead's right to terminate the Agreement is how the terms "improvements, modifications, or derivative works" would be defined.

We believe it would be reasonable and advisable for the Licensee to request a narrow and clear definition of "improvements, modifications, or derivative works." In addition, Licensees might request a mutual exchange; in other words, that Gilead be required to supplement its initial transfer of Licensed Technology by keeping the Licensee apprised of any further technology improvements that Gilead itself develops over the term of the license.

In the alternative, Licensees may request a royalty from Gilead in return for any improvements, modifications or derivative works developed by the Licensee.

4. Clause 2.4(a) reiterates again Gilead's restriction on the sale of API, in that the Licensee of an API Licence (under Clause 2.1) will only be permitted to sell API to Licensed Product Suppliers in India as approved by Gilead.

### **Consideration/Audit/Payment Terms**

1. Clause 4.2 provides that an appropriate adjustment to the royalty rate of 5% (in Clause 4.1) shall be discussed in good faith if the Product is sold in a Combination Product. Therefore, should any of the Licensees wish to use Tenofovir in a Combination Product, such as Truvada®, then the royalty rate will have to be renegotiated.

Licensees might be advised to attempt to negotiate, and include in the license, a clear formula for the calculation of royalty rates in instances where the Product is later sold in a Combination Product so as to avoid delays and unreasonable increases in the royalty rate at a future date.



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2. Clause 4.9 bases the duration of the royalty payment on the expiration of the last patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of API or the Product in a country or India.

It is imperative to note here that while the royalty term of the licence is based on the expiration of the last patent containing a valid patent in India, the license itself does not in any way appear to be contingent on Gilead's key Tenofovir product patents being granted in India.

Clause 4.9 states in particular that the royalty payments shall be made until "the expiration of the last to expire patent containing a valid claim covering the **manufacture of API** or the product." The key issue with this wording is that Gilead could well argue that as they have a granted process patent in India (IN190780) which has a valid claim with respect to the manufacturing of API, then Licensees are tied into paying royalties for the manufacture of API at least for the term of the process patent, which expires 2017. This is irrespective of whether the technology transfer is useful or not or whether a product patent is granted. Therefore, this wording serves potentially to 'lock' the licensee in to paying royalties for the duration of the process patent Gilead has, even if Gilead's product patents are not granted. Moreover, should no product patent be granted and the Licensee then wishes to revert back to its own process of making the API i.e not using Gilead's process, the Licensee may still have to continue paying a royalty unless it settles to get out of the licence with Gilead.

While it is a positive that the duration of the Product Licence is not short, the wording in Clause 4.9 does leave open the possibility of the royalty period being continuously extended if Gilead obtains patents which are seen as minor or incremental improvements of the original patent and, therefore, include a valid claim over the Product. As you are aware, companies are adept at prolonging the protection over a compound and the various formulations.

To that end, the Licensees that take the licence might insist on Clause 4.9 being attached to the life of the first patent granted for the process and also the product which covers a valid composition-of-matter claim over Tenofovir Disoproxil or Tenofovir Disoproxil Fumarate in India. For example, the first patent filed for Tenofovir which would include a valid claim over the API and Product was 26 July 1996 (or if taking the filing date for the Indian application, 25 July 1997). Should a patent be granted in India, then the royalty payments should only last until 2017.



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## **Intellectual Property**

1. Clause 5.2 offers an interesting requirement of the Licensee, namely that it shall assist Gilead with regard to the issuing of its patents.

As you may be aware, some of the Indian manufacturers have opposed the granting of Gilead's patent applications for Tenofovir. By including such a request it could be read as Gilead using the influence of domestic companies who accept the licence to encourage the granting of its patents.

Clause 10.3(a)(i) further adds that Gilead has the right to terminate the Agreement should the Licensee directly or indirectly challenge any of the patents (including the Emtricitabine patents) or lend support to a third party for making such a challenge.

While it is accepted that the relationship in a licence needs to be conducted in a bona fide manner, the terms "indirectly challenge" or "lend support to a third party" are an obvious attempt to ensure that any Licensees do not collude with civil society groups or other interested parties which are opposing its patents. Moreover, it appears to be a direct attempt to remove any opposition by potential licensees to its patent applications in India given the uncertainty of whether they will be granted.

## **Manufacturing and Commercialisation of Product**

Clause 6.2 of the License requires that the Licensee will manufacture API and product in accordance with Indian manufacturing standards, WHO-Pre-qualification standards, EMEA standards, FDA tentative approval standards and any other country/local standards required.

It is noticeable that the License remains silent as to whether meeting Global Fund standards would be sufficient for the Licensee to begin selling API or Product during the period before WHO and/or FDA approval is first obtained. The Licensee should clarify this position.

## **Representations, Warranties and Covenants**

Under Clause 7.2 the Licensee shall not divert or allow the diversion of Licensed Technology or assist and support any third party in the process of manufacturing API or intermediates. It is notable that China has been specifically addressed as a country to which the Licensee must covenant not to divert any Licensed Technology.

The significance of this provision is that API Licensees will be prohibited from transferring to third-party manufacturers (in India or abroad) Licensed Technology or



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providing any assistance/support to third parties in order to manufacture API and key intermediates. This effectively removes the possibility of Licensees using third-party manufacturers who may be able to reduce production costs significantly, but which depend upon some technology transfer in order to do so.

### **Termination**

It is a notable omission that should no product patent be granted in India, there is no clause for the Licensee to terminate the API/Product Licence on that basis.

Should Gilead not agree to the condition that the licence should only come into effect upon issuance of the first patent containing a valid claim over Tenofovir Disoproxil or Tenofovir Disoproxil Fumarate in India (see Clause 4.9), we recommend that the Licensee at least negotiate a clause that allows it to terminate the API/Product Licence in the event that the product patent applications are denied or that a patent does not issue within a reasonable timeframe (perhaps within one year). This is to avoid any complications that may arise in such a case.

### **Appendix 1**

Gilead has chosen to leave a number of middle income countries out of this licence agreement, notably Brazil, China and Argentina. Therefore, Licensees will not be able to supply API or the end product to such countries.

### **Appendix 3**

It is recommended for the terms of technology transfer, Licensee's thoroughly review the terms of the transfer and specify in detail the parameters of the desired technology.