KEI Policy Brief 2014:2: Freedom/Restrictions as regards exports to countries outside of the licensed territory for Gilead's 2014 HCV voluntary license

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Notes by KEI[1]

This memo presents a matrix that describes the freedom or restrictions that exist for making and supplying generic drugs or APIs for SOF and LDV, under the Gilead voluntary license (VL), to and from countries outside the 91 countries in the licensed territory. The matrix only addresses patent related issues, and does not extend to other barriers, such the requirements to register products with drug regulators.

For an importing country outside of the licensed territory, we consider cases where the country has granted patents (column 2), where patents have been not been granted and are not expected to be granted (column 3), and where the patents have been filed, but have an uncertain status (column 4).

For countries seeking to supply the countries outside of the territory, we consider each of the same scenarios. For a country with a patent (rows B and E), with no patent and/or no reasonable possibility of a patent in a reasonable period of time (rows C and F), and when patents have been filed, but the patent status is uncertain (rows D and G).

This memo includes references to various provisions in the license, which are included in the annex, with some key definitions and other terms of the Gilead license. Note that the license defines product patents quite broadly. We do not address the anti-diversion language in the license, which may also become relevant.

The license treats the issue of exports and imports on a product by product and country by country basis, for the countries outside of the territory.

In general, when a patent has been either granted, or not granted with no **reasonable possibility** of being granted in a **reasonable time**, it is possible for the company signing the voluntary license to supply APIs and products outside of the licensed territory.

When patents have been filed, but not yet granted, and there is a **reasonable possibility** of being granted in a **reasonable time,** outcomes are less clear, and may depend upon the ability to obtain a compulsory license for patents that have been filed, and not granted, something that will be true in some but not all countries.

For countries where patent status is uncertain, freedom to supply under the license will depend upon how a "**reasonable possibility"** of being granted in a "**reasonable time"** is interpreted. Licensing terms are governed and construed **under the laws of England,** without regard to its choice of law principles.

Exports outside the territory from countries with no patents, and/or no reasonable possibility of obtaining patents in a reasonable amount of time, are allowed. (Rows E and G).

Exports from countries outside the territory, with patents, and/or a reasonable possibility of obtaining patents in a reasonable amount of time, are not authorized by the license. (Row F).

[1] Gilead has reviewed and provided comments. Pascale Boulet, Ellen 't Hoen, and several others providing helpful feedback on earlier drafts.

Gilead says that actions that are legal, in the absence of the license, are not necessarily constrained by the license, even if they are not explicitly authorized. For example, if a country outside the licensed territory grants a compulsory license to make and export products to other countries, it is not necessarily a breach of the license, for a company like CIPLA to operate under this compulsory license, even though the voluntary license does not specifically authorize or prohibit this. In such a case, CIPLA would be operating outside of the voluntary license, without its benefits, but not necessarily in breach of the voluntary license for doing so. This possibility is broadly relevant, but particularly to the cases described in row F.

Table 1: Freedoms and Restrictions on supplying APIs and drugs outside of the licensed territory

	(1)	(2)	(3)	(4)
(A)		Importing country has no patent. (Includes cases where the patent was never filed, or was filed and rejected or found to be invalid, and there are no appeals).	Importing country has patent and issues compulsory license.	Importing country has patent filed, not granted, and status uncertain. (Includes cases where the patent was filed, and then rejected, or granted but then ruled invalid, but there is an appeal.)
(B)	India has granted a **patent**	Exports from India to importing country allowed, under 10.3(c)(ii) of the license.	Exports from India to importing country allowed. See 10.3(d) of the license This may involve the use 92A of the Indian Patents Act (See text below), or the Indian manufacturer to seek a compulsory license under a different ground.	Relevant license terms: 10.3(d). Comment: Even if the status in the importing country is uncertain, under the terms of the licence (and under 92A of the Indian Patents Act), the importing country could submit a request to India for a CL for export, and upon issuance of that CL for export, the licence would allow export. However, the importing country would either have to grant a compulsory license on patents filed but not granted, or the exporting company would have to claim Gilead had no "reasonable possibility" to obtain a patent, and what constitutes "reasonable period of time."
(C)	India has **no patent** (and no reasonable possibility of patents in a	Exports from India to importing country allowed. See 10.3(c)(i).	Exports from India to importing country allowed See: 10.3(d)	Relevant license terms: 10.3(c)(i) It depends on a legal grey area: can CLs be issued on pending or rejected patent in the

	reasonable amount of time.) (Maybe a null set for now. Could be important later).	(As discussed below, exports from a country outside of the territory to the importing country are also possible under 10.3(c)(ii) of the license).		importing country? It also depends on an assessment of whether Gilead has a 'reasonable possibility' to obtain a patent, and what constitutes "reasonable period of time."
(D)	India has **patent filed, not granted**, and status uncertain.	Perhaps, if India can issue a CL on a patent filed but not granted, or if Gilead does not have a "reasonable possibility" of getting a patent, in a "reasonable period of time."	Exports from India to importing country allowed. Note that section 10.3(d) of the agreement contains an **"and/or"** regarding the requirement for a CL in India or the importing country.	Relevant license terms: 10.3(c)(i) and 10.3(d) It depends on a legal grey area: can CLs be issued on pending or rejected but appealed patents in the importing country and/or India? If yes, then 10.3(d) allows licensee to supply. It also depends on an assessment of whether Gilead has a 'reasonable possibility' to obtain a patent, and what constitutes "reasonable period of time."
(E)	Production from a country outside of the territory, with **no patent.** (and no reasonable possibility of patents in a reasonable amount of time.)	Exports allowed from the country outside the territory, to a country outside the territory. Relevant license terms: 10.3(c) (ii).	Exports allowed from the country outside the territory, to a country outside the territory. See 10.3(c)(ii) and 10.3(d)	Relevant license terms: 10.3(c)(ii) and 10.3(d) It depends on a legal grey area: can CLs be issued on pending or rejected patent in the importing country? It also depends on an assessment of whether Gilead has a 'reasonable possibility' to obtain a patent, and what constitutes "reasonable period of time."
(F)	Production from a country outside of the territory, with **patent**, and compulsory license that allows exports.	Perhaps. Perhaps not. See 10.3(d), which allows supply of API and products into a country, " provided that Licensee's supply of Product or API into such country is **solely within the scope and geographic range of such Compulsory License."** If the compulsory	Perhaps. Perhaps not. See 10.3(d), which allows supply of API and products into a country, " provided that Licensee's supply of Product or API into such country is **solely within the scope and geographic range of such Compulsory License."** If the compulsory	Perhaps. Perhaps not. See 10.3(d), which allows supply of API and products into a country, " provided that Licensee's supply of Product or API into such country is **solely within the scope and geographic range of such Compulsory**

		license allows exports to third countries, this may be a yes. There is also the possibility of operating without explicit authorization from the license, without being in breach, according to GIlead.	license allows exports to third countries, this may be a yes. There is also the possibility of operating without explicit authorization from the license, without being in breach, according to Gilead.	**License."** If the compulsory license allows exports to third countries, this may be a yes. There is also the possibility of operating without explicit authorization from the license, without being in breach, according to Gilead. It depends on a legal grey area: can CLs be issued on pending or rejected patent in the importing country? It also depends on an assessment of whether Gilead has a 'reasonable possibility' to obtain a patent, and what constitutes "reasonable period of time."

(G)	Production from a country outside of the territory, with a **patent filed, but not granted,** and status uncertain.	Relevant license terms: 10.3(c) (ii). 10.3(d). It depends on a legal grey area: can CLs be issued on pending or rejected patent in the exporting and the importing country? It also depends on an assessment of whether Gilead has a 'reasonable possibility' to obtain a patent, and what constitutes "reasonable period of time." There is also the possibility of operating without explicit authorization from the license, without being in breach, according to GIlead.

Terms from the license

1. Definitions

1.22 **"Patents" means** (a) the patents and patent applications set forth in Appendix 2 hereto **and (b) any other patents or patent applications (and resulting patents therefrom)** that are (i) owned and controlled by Gilead and its Affiliates during the term of this Agreement and (ii) necessary for Licensee to practice the licenses granted in Section 2 hereof, including patents and patent applications claiming improvements or modifications to the manufacture of API , in each of (a) and (b) solely to the extent the claims in such patents and patent applications cover the manufacture, use or sale of API.

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4. Consideration/Payment Terms/Audit

Page 8, in subpara (h)

As used in this Agreement, **"Product Patent" shall mean** any patent or patent application claiming any Product or any API contained in such Product, including any patent or patent application claiming the composition of matter for such Product or API, or their formulation, or any patent or patent application claiming the method of use or method of manufacture with respect to such Product or such API.

10. Term and Termination

10.3 (c) (i)
For clarity, and notwithstanding anything to the contrary in this Agreement, with respect to a particular Product, and on a Product-by-Product and country-by-country basis, if there is **no Product Patent** owned or controlled by Gilead (or its Affiliates) in India and a particular country outside of the Territory, and if there is **no reasonable possibility** of obtaining such a Product Patent **within a reasonable period of time** (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals)) in India and such country outside of the Territory, it shall not be deemed to be a breach of this Agreement for Licensee to supply such Product in such country and Licensee shall not be obligated to pay Gilead any royalty therefor; provided that Licensee obtained applicable regulatory approval in such country.

10.3(c) (ii)
Similarly, on an API-by-API and Product-by-Product basis, it shall not be deemed to be a breach of the Agreement for Licensee: (x) to manufacture API in any country where there is **no Product Patent** owned or controlled by Gilead (or its Affiliates) covering such API in such country, and there is **no reasonable possibility** of obtaining such a Product Patent **within a reasonable period of time** (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country; (y) to sell such API referred to in clause (x) of this Section 10.3(c)(ii) in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such API in such country, and there is **no reasonable possibility** of obtaining such a Product Patent **within a reasonable period of time** (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country; or (z) to manufacture and/or sell Product incorporating such API referred to in clause (x) of this Section 10.3(c)(ii) in in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such Product (or the API contained therein) in such country, and there is **no reasonable possibility** of obtaining such a Product Patent **within a reasonable period of time** (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country.

10.3(d)
For further clarity, and notwithstanding anything to the contrary in this Agreement, it shall not be deemed to be a breach of the Agreement for Licensee to supply an API or Product outside the Territory into a country where: (i) **the government of such country has issued a Compulsory License** relating to such API or Product allowing for the importation of such API or Product into such country, provided that Licensee's supply of Product or API into such country is **solely within the scope and geographic range of such Compulsory License** and only for the duration that such Compulsory License is in effect; **and/or** (ii) the **Government of India has issued a Compulsory License allowing for the export** of an API or Product from India and into such country, provided that: (Y)(1) there are **no Product Patents** owned or controlled by Gilead (or its Affiliates) issued in such country **or** (2) a **Compulsory License has also been issued** by the relevant authorities of such country; and (Z) Licensee's supply of Product or API into such country is solely within the scope and geographic range of the Compulsory License issued by the Government of India, and only for the duration that such Compulsory License is in effect.

12.5 Governing Law.

This Agreement is made in accordance with and shall be governed and construed **under the laws of England,** 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 notice to Licensee. Licensee is not entitled to transfer or assign this Agreement or the rights and obligations under this Agreement.

Section 92 A of the India Patent Act

THE PATENTS ACT, 1970, Section 92A

Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances

(1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

Explanation.—For the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

THE PATENTS ACT, 1970, Section 100(1)

Power of Central Government to use inventions for purposes of Government

(1) Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may use the invention for the purposes of Government in accordance with the provisions of this Chapter.