medicines patent pool

10 March 2023

Mr. Vikas Vij
Head API & Cipla Global Access
Cipla Limited
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg,
Lower Parel, Mumbai-400013

Dear Mr. Vij

RE: Side Letter re obligations of Cipla Limited

We refer to the Licence Agreement between ViiV Healthcare Company ("**ViiV**") and The Medicines Patent Pool Foundation ("**MPPF**") executed on 23 July 2022 ("the **Head Licence**") and the Sub-Licence Agreement between MPPF and Cipla Limited ("**Cipla**") in the form set out in Schedule 2 of the Head Licence that is to be executed ("the **Sub-Licence**"), subject to Cipla agreeing to the terms contained in this Side Letter, to enable broad access in resource-limited countries to the Licensed Product (as defined in the Sub-Licence) to reduce the risk of HIV-1 infection in persons (weighing at least 35kg) at risk of acquiring HIV-1.

Background

Pursuant to Clause 3 of the Sub-Licence, Cipla will be granted the right to, either by itself or through an 'Approved Affiliate', manufacture the Licensed Product solely for use in the Field in the Permitted Market, as defined in the Sub-Licence, among other things.

Cipla wishes to manufacture the Licensed Product through its partner, Abryl Laboratories Private Limited ("**Abryl**"), however Abryl cannot be an Approved Affiliate as it is not directly or indirectly controlled by Cipla and is a separate corporate entity that is outside of Cipla's corporate group.

In this regard, MPPF and ViiV agree to allow Abryl to manufacture the Licensed Product solely for supply to Cipla notwithstanding that the Sub-Licence only permits Cipla or its Approved Affiliate to manufacture the Licensed Product.

Separately, in June 2022, Cipla received an overall ECOVADIS score below the expected minimum of 45 in relation to its environmental, labour and human rights, ethics and sustainable procurement policies and practices ("**ECOVADIS Score**").

In light of the above, MPPF and ViiV agree that the granting of the Sub-Licence is conditional on Cipla agreeing to the terms set out in this Side Letter.

Terms

Under this Side Letter, MPPF, ViiV and Cipla agree to the terms below. Hereafter, all capitalised terms below shall have the same meaning as in the Sub-Licence unless otherwise defined.

1. Abryl manufacturing

1.1. Notwithstanding the licence granted under Clause 3 of the Sub-Licence being non-sublicensable other than to an Approved Affiliate with respect to the manufacturing of the Licensed Product, MPPF approves for Cipla to have the right to grant a sublicence of the Patent Rights to Abryl, to the extent necessary, for Abryl to manufacture the Licensed Product solely for supply to Cipla. For the avoidance of doubt, such Patent Rights only include the 3mL/600mg strength dosage of cabotegravir for pre-exposure prophylaxis (extended-release suspension injection).

1.2. Cipla shall:

(a) ensure that Abryl complies with all the terms of the Sub-Licence as if it was Cipla under that Sub-Licence;

(b) not permit Abryl to sub-contract or assign any part of the manufacturing of the Licensed Product without the prior written approval of MPPF and ViiV; and

(c) be liable for the acts and omissions of Abryl as if such acts and/or omissions were the acts and/or omissions of Cipla.

1.3. In the event Abryl fails to comply with any terms of the Sub-Licence, MPPF shall have the right to withdraw its approval under Clause 1.1 above with immediate effect by providing written notice to Cipla.

1.4. In the event that Abryl is acquired by a third party, Cipla acknowledges and accepts that the acquisition of Abryl by a third party would be considered a change in control pursuant to Clause 21.4.4 of the Sub Licence and gives MPPF the right to terminate the Sub-Licence.

2. ECOVADIS conditions

2.1. Cipla undertakes to:

(a) use its best efforts to engage in any reasonable activities to improve its overall ECOVADIS Score, specifically covering the facilities involved in the manufacture of the Licensed Product (which includes API, as well as OSD and LAI forms), to an ECOVADIS Score of a minimum of 45 or above ("**ECOVADIS Activities**");

(b) without limitation to (a) above, no later than three months from the Effective Date, share with MPPF a detailed action plan setting out the ECOVADIS Activities that it will perform, including the timeline for the completion of such activities ("**ECOVADIS Action Plan**");

(c) with respect to the ECOVADIS Action Plan:

(i) at each Quarterly Meeting, review and discuss with MPPF progress on the ECOVADIS Action Plan and agree with MPPF to any necessary amendments to the ECOVADIS Action Plan; and

(ii) upon the request of MPPF, permit and allow MPPF's representatives to visit and inspect Cipla's facilities involved in the manufacture of the Licensed Product (which includes API, as well as OSD and LAI forms) for the purpose of evaluating Cipla's performance of the ECOVADIS Action Plan. Cipla will assist MPPF in scheduling such visits, and MPPF shall comply with all local rules and policies during each visit.

2.2. Within three years from the Effective Date:

(a) to the extent Cipla has not achieved an ECOVADIS Score a minimum of 45 or above, Cipla acknowledges that MPPF has the right to audit Cipla for compliance with the Sub-Licence pursuant to Clause 19.2 of Sub-Licence, including but not limited to compliance with Clause 20 of the Sub-Licence; and

(b) without limiting MPPF's rights under the Sub-Licence, if the audit reveals a breach of Clause 20 of the Sub-Licence, Cipla shall promptly take corrective actions in relation to the identified non-compliance and agree with MPPF to any necessary amendments to the ECOVADIS Action Plan, failing which MPPF reserves all its rights under the Sub-Licence.

This Side Letter will be governed by the terms of Clause 34 (Governing Law and Dispute Resolution) of the Sub-Licence, and ViiV shall have such Third Party Rights under this Side Letter as agreed pursuant to Clause 24 (Third Party Rights) of the Sub-Licence. The parties intend this Side Letter to be legally binding.

Please acknowledge receipt and acceptance of this Side Letter by signing and returning a copy of this Side Letter.

Yours sincerely

Medicines Patent Pool

DocuSigned by:
Charles Gore
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Name: Charles Gore
Position: Executive Director

ViiV Healthcare Company

lynn baxter

Name: Lynn Margaret Baxter
Position: President

We hereby acknowledge receipt and accept the contents of this Side Letter

Cipla Limited

DocuSigned by:
Vikas Vij

Name: Vikas Vij
Position: SVP and Head - API & CGA Business
Date: 24Mar23