

## *LICENSE AGREEMENT*

This LICENSE AGREEMENT (the “**Agreement**”) is made as of 18 April 2016 (the “**Effective Date**”) by and among the **Medicines Patent Pool**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Chemin Louis-Dunant 17, Geneva 1202, Switzerland (“**Licensor**”), and Lupin Limited, a company registered under the laws of India, and having as principal place of business at 159, CST Road, Kalina, Santacruz (East), Mumbai 400098 India (“**Licensee**”). Each of Licensor and Licensee is referred to in this Agreement as a **Party**. Licensor and Licensee are collectively referred to in this Agreement as the **Parties**.

### **RECITALS**

WHEREAS, the Licensor has been granted by Merck Sharp & Dohme Corp. and MSD Italia s.r.l. (collectively “Merck”) the right to sublicense certain patents and patent applications, which relate to the antiretroviral compounds known as raltegravir for paediatric use;

WHEREAS, the Licensor is a non-profit organization with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property on these medicines;

WHEREAS, the Licensee desires to obtain a licence from the Licensor to use the aforesaid patents and the Licensor is willing to grant to the Licensee such a licence in accordance with the terms and subject to the conditions of this Agreement;

WHEREAS, the purpose of this Agreement is to provide a license to patents, and not to create any non-patent-related barriers where Licensed Patent Rights (as defined below) do not exist;

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**

1.1 **Affiliate** shall mean in relation to a Party, any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control of such party. For the purposes of this definition “control” shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of a Party hereto are conducted in accordance with the wishes of such corporation, firm, partnership or other entity.

1.2 **Agreement Quarter** shall mean any period of three months ending on the last day of March or June or September or December.

1.3 **Business Day** shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.

1.4 **Child Patients** shall mean children under 12 years of age.

1.5 **Field of Use** shall mean the treatment of HIV/AIDS for use in children under 12 years of age.

1.6 **Patented Improvements** shall mean any new or improved process, any new or improved manufacturing technique, or any further invention that relates to the manufacture or formulation of the Licensed Products and/or Licensed Compound or incorporate or are based on the Licensed Patent Rights, developed by Licensee after the Effective Date and claimed in a patent or patent application filed by Licensee.

1.7 **Licensed Compound** shall mean raltegravir (RAL).

1.8 **Licensed Patent Rights** shall mean Territory Patents and Non-Territory Patents.

1.9 **Licensed Products** shall mean pharmaceutical combinations and compositions designed specifically for paediatric use (e.g. granules for suspension, dispersible and chewable tablets) containing the Licensed Compound as the sole active ingredient or in combination with other active ingredients, subject to Section 2, Scope of the Grant.

1.10 **Merck-MPP Agreement** shall mean the Licence Agreement entered into between Merck Sharp & Dohme Corp., and Licensor on February 20, 2015.

1.11 **Non-Territory Patents** shall mean those patents and patent applications outside the Territory covering the Licensed Compound and/or the Licensed Product corresponding to those listed in Appendix 2 and any other patent and published patent applications (and resulting patents therefrom) owned by Merck as of the Effective Date claiming a method of manufacturing of the Licensed Compound and/or Licensed Products ("Manufacturing Patents"); provided that the licence under the Manufacturing Patents shall be limited to manufacturing the Licensed Compound and/or Licensed Products. In the event that Merck publishes any applications with respect to Manufacturing Patents after the Effective Date, Merck and MPP shall discuss in good faith the potential inclusion of such patent applications (and resulting patents therefrom) in the scope of the Licensed Patent Rights, having due regard to the objectives of this Agreement.

1.12 **Stringent Regulatory Authority (SRA)** shall mean a regulatory authority which is a member, observer or associate of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for

Human Use, as may be updated from time to time.

1.13 **Territory** shall mean those countries set forth in Appendix 1.

1.14 **Territory Patents** shall mean those patents and patent applications covering the Licensed Compound and/or the Licensed Product in the Territory as listed in Appendix 2.

1.15 **“Third Party(ies)”** shall mean any party other than a party to this Agreement.

## 2. **Scope of the Grant**

2.1 Subject to the terms and conditions of this Agreement, and to the extent to which Licensor has a right to grant a licence in respect of Licensed Patent Rights, Licensor hereby grants to Licensee a royalty-free, non-exclusive, non-sublicensable, non-transferable licence under the Licensed Patent Rights to:

(a) make and have made the Licensed Compound anywhere in the world solely for the purpose of making the Licensed Product for sale within the scope of Section 2.1(d), provided that the Licensed Compound is made in a facility that has been approved by a Stringent Regulatory Authority (SRA) or prequalified by the World Health Organization;

(b) to use, sell, or have sold, export and import the Licensed Compound anywhere in the world solely for the purpose of making the Licensed Product for sale within the scope of Section 2.1(d); provided that any sale or other transfer of the Licensed Compound must be to a Sublicensee under the Merck-MPP Agreement;

(c) to make and have made the Licensed Product anywhere in the world for sale within the scope of Section 2.1(d), provided that Licensed Product is made in a facility that has been approved by a SRA or prequalified by the World Health Organization; and

(d) to use, sell, have sold, export and import the Licensed Product solely for use in the Field in the Territory, provided that the Licensed Product may only be sold if the specific formulation and dosage of such Licensed Product has been recommended for pediatric use by the World Health Organization and the United States Department of Health and Human Services, or if Merck, MPP and the Licensee reasonably agree that adequate clinical data exists to support the safety and efficacy of the specific formulation and dosage of such Licensed Product for pediatric use.

2.2 The licenses granted hereunder do not include any licence or other right to use any trademark, trade name, logo or service mark registered or used by Merck or any Merck Affiliate (each, an “Merck Mark”) or any word, logo or any expression that is similar to or alludes to any Merck Mark, and Licensee shall not register, appropriate or

otherwise use any Merck Mark in connection with the sale, distribution, promotion or marketing of the Products in the Territory. A complete description and sample of any trademark, label or artwork which Licensee proposes to use in connection with the sale of the Licensed Products in the Territory shall be submitted to Merck for written approval prior to use. Such approval shall be deemed to have been granted in the absence of a response by Merck within thirty (30) business days from Merck's receipt of the Licensee's proposal, and may be withheld if the subject trademark, label or artwork is determined by Merck at its sole discretion to be confusingly similar to any Merck Mark. In addition to the foregoing, Licensee shall not use trade dress, packaging (both internal and external) or labeling which is similar to that of Merck (as Merck shall reasonably determine in its sole discretion) or any Affiliate of Merck in connection with the sale of any Products. Furthermore, Licensee shall not give the impression to the public, to physicians or to the trade that the Products are manufactured by or in any way connected with Merck or any of its Affiliates.

2.3 Except as expressly set forth in this Agreement, Licensor does not grant any licence to Licensee under any of Merck intellectual property rights (including, without limitation, Licensed Patent Rights or rights to any Merck proprietary compounds or drug substances other than Licensed Compounds). Licensee shall not take any action which would constitute an infringement of any of the Licensed Patent Rights granted and in force.

### **3. Development and Registration**

3.1 As of the Effective Date and subject always to Merck's retained rights to the Licensed Patent Rights, the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation of the Products to be sold or supplied by the Licensee in the Territory under this Agreement.

3.2 Licensee agrees that it will manufacture the Licensed Compound and the Licensed Product in a manner consistent with (i) WHO Pre-qualification standards; or (ii) the standards of any SRA. Licensee will not sell any Licensed Product without WHO Prequalification or SRA approval, and will comply with applicable regulatory requirements in the country of manufacturing and the country of sale.

3.3 Licensee shall submit a complete file for FDA tentative approval or WHO Pre-qualification or any SRA approval within 36 months from the Effective Date for any existing formulation of the Licensed Products, or within a period to be agreed among Merck, Licensor and Licensee for any new formulation of the Licensed Product. Licensee will diligently pursue such applications following submission. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Licensed Products.

3.4 Within 10 Business Days following the end of each Agreement Quarter,

Licensee shall provide Licensor with a quarterly written report setting forth in relation to that Agreement Quarter (a) Licensed Products and/or Licensed Compound in its development pipeline, (b) status of development of each Licensed Product and/or Licensed Compound in development, (c) regulatory filing plan for the Licensed Compound and/or each Licensed Product, and (d) a list of regulatory authorities, including as applicable the FDA, WHO and authorities in the countries within the Territory with which such regulatory approvals or authorizations have been filed and/or obtained for the Licensed Compound and/or any Licensed Product. The Parties agree to meet on a quarterly basis or as reasonably requested by the Licensor, to review development and filing status and also regarding such reports concerning Licensed Products and/or Licensed Compound. Licensor agrees that information contained in quarterly and other such reports shall be treated as Confidential Information; provided, however, that such information may be shared with Merck (with Merck treating such reports as Confidential Information); and that aggregated data may be publicly disclosed by Licensor.

3.5 The Licensee will manufacture and sell the Licensed Compounds and Licensed Products in accordance with all laws and regulations relevant to the manufacture and sale of the Licensed Compounds and Licensed Products and in accordance with good industry practice in addition to provisions contained in 3.2.

#### **4. Non-Diversion**

4.1 Diversion. Licensee shall not, directly or indirectly, divert Licensed Compound and/or Licensed Product outside the Territory or outside the Field of Use. Without limitation of the foregoing, except to the extent provided under this Agreement, the Licensee shall not, directly or indirectly, sell or supply:

- (a) Licensed Products or Licensed Compound outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
- (b) Licensed Compound to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Licensed Compound outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
- (c) Licensed Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Licensed Products outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent, and/or
- d) Licensed Products to any Third Party that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products to be administered to any patient other than Child Patients in the Territory, unless such sale or

supply is performed in compliance with separate written agreement(s) that the Licensee may have with Licensor and/or Merck.

Notwithstanding the foregoing, nothing in this Agreement shall be construed to prevent Licensee from engaging in any activity in relation to the Licensed Compound and/or Licensed Product where such activities would not infringe any Merck patent granted and in force.

4.2 Product Labeling. The labeling of all Licensed Products sold or offered for sale under this Agreement shall expressly state that

- a) the Licensed Product is manufactured under a license from the Medicines Patent Pool;
- b) the Products are not for administration to anyone other than Child Patients, provided however that this obligation shall only apply in relation to Products which are in jurisdictions with packaging specific to that jurisdiction; and
- c) any other use is not authorized.

4.3 Notice to Third Parties. The Licensee shall give written notice, prior to the first sale of Products, to any third Party to which it sells Products of the restrictions contained in this Clause 4 and the licensee shall use its best endeavors, without prejudice to any other provision of this Agreement, to ensure that such Third Parties will undertake to abide by the restrictions contained in this Clause 4 and will assist the Licensor and Merck in securing compliance with this Clause 4 and the restrictions which it contemplates.

## **5. Intellectual Property**

5.1 Licensees will grant to Merck and MPP a royalty-free, non-exclusive, sublicensable license to any Patented Improvement. For avoidance of doubt, such license will not affect the Licensee's ownership of such Patented Improvements. MPP may not sublicense such rights to any Third Party provided, that if MPP wishes to sublicense any such rights, MPP and the Licensee will enter into good faith negotiations regarding any such sublicensing. Merck shall be entitled to grant sublicenses under such rights only to its Affiliates and other third parties such as contract manufacturers solely for use in connection with the commercialization of Merck products.

5.2 The Licensee shall have no rights in relation to the conduct of any matter relating to the Licensed Patent Rights, including the filing, prosecution and maintenance thereof.

5.3 Improved Formulations. In the event that Licensee develops a new formulation of the Licensed Product, Licensee will grant to Merck an option and right of first refusal to negotiate further mechanisms to make the new formulation available in

countries outside the Territory, including but not limited to licensing or purchase of such new formulations by Merck.

## 6. Representations, Warranties and Covenants

6.1 Ability to Perform. Each of the parties hereby represents and warrants that:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of their incorporation and has 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.

### 6.2 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 export controls and sanctions, and shall obtain, have and maintain all necessary regulatory approvals, marketing authorizations, export licenses and other permits and licenses, at Licensee's expense for the manufacture and sale of the Licensed Compound and/or Licensed Product and any other Licensee activities contemplated hereby.

(b) Conflicts. None of the parties shall be required to take any action or perform any obligation under this Agreement to the extent that such action or obligation is in direct conflict with any applicable law, rule or regulation.

6.3 OFAC. The Licensee represents that neither the Licensee nor, to the knowledge of the Licensee, any director, officer, employee of the Licensee, is an individual or entity ("Person") that is, or is owned or controlled by Persons that are the target of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control ("Sanctions") or located, organized or resident in a country or territory that is the target of country-wide or territory-wide Sanctions (collectively "Sanctions Target"). The Licensee shall, prior to making the Licensed Compound or any Licensed Product available, directly or indirectly to any Person that is a Sanctions Target, obtain prior written approval from Merck. Notwithstanding the foregoing, it is hereby confirmed that the activities described in

Section 2.1 of this Agreement are permitted with respect to all of the countries in the Territory, except that neither the Licensed Compound nor the Licensed Products may be manufactured by a Person or in a country or territory that is the target of country-wide or territory-wide Sanctions without prior written approval from Merck.

6.4 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, THE LICENSOR DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE LICENSED TECHNOLOGY, PRODUCTS, OR ANY OTHER MATTER UNDER THIS AGREEMENT INCLUDING, WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE LICENSED PATENT RIGHTS, OR WITH RESPECT TO THE LICENSED PRODUCTS OR THE LICENSED COMPOUND. FURTHERMORE, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY THAT ANY LICENSED PATENT RIGHT IS VALID OR ENFORCEABLE OR THAT LICENSEE'S USE OF THE LICENSED PATENT RIGHTS AS CONTEMPLATED HEREUNDER WILL NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. Licensor also does not give any warranty, express or implied, with regard to the safety or efficacy of the Licensed Compound or the Licensed Products and it shall be the sole responsibility of the Licensee to ensure such safety or efficacy.

## 7. Liability and Indemnity

7.1 Licensee Indemnity. Licensee shall jointly and severally indemnify, hold harmless and defend Licensor and Merck (together, the "Indemnitees"), 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 an Indemnitee 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, (ii) Licensee's infringement of any Third Party's Intellectual Property rights, or (iii) for any product liability, liability for death, illness, personal injury or 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 Compound or Licensed Product (including, without limitation, their manufacture, use or sale). The indemnification obligations of Licensee stated in this Section 7 shall apply only in the event that Licensor or Merck, as applicable, provides Licensee with 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.

7.2 Product Liability. Licensee shall be solely responsible in respect of any product liability or any other statutory liability under any regulation, in respect of Licensed Compound or the Licensed Product.

7.3 Licensor Liability. NOTWITHSTANDING ANYTHING TO THE



CONTRARY CONTAINED IN THIS AGREEMENT, IN NO EVENT SHALL LICENSOR 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 LICENSED COMPOUND OR LICENSED 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.

**8. Insurance**

Within 30 days prior to the first commercial launch by Licensee of a Licensed Product, and each year thereafter for so long as this Agreement is in effect, Licensee shall provide to Licensor certificates of insurance evidencing comprehensive general liability coverage, including products liability, with a combined limit of no less than 1 million dollars (\$1,000,000).

**9. Statements, reporting and right to audit**

9.1 At all times the Licensee shall keep, and shall require its Affiliates and any Third Party manufacturers and Third Parties making sales on its behalf to keep complete and accurate records for the previous two years (or for the period from the Effective Date to the then current date if such period is less than two years) of all quantities of Licensed Compounds and Licensed Products manufactured and/or sold under the licences granted by this Agreement, together with that information contemplated by this Agreement. The Licensor shall have the right (and the Licensee shall procure such right), at its expense, through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the term of this Agreement and for six months after its termination or expiry; provided, however, that such examination shall not take place more often than twice in any calendar year and shall not cover such records for more than the preceding two calendar years and provided further that such accountant or like person shall report to Licensor only as to:

(a) the accuracy of the manufacturing and sales statements of the Licensee (and/or its Affiliates and/or its Third Party manufacturers contemplated by this Agreement) in relation to such manufacture and sales;

(b) the appropriateness of quantities of Licensed Compounds and Licensed Products imported or manufactured pursuant to this Agreement by reference to what quantities of Licensed Compounds and Licensed Products would reasonably be required to meet demand for actual sales made by the Licensee;

(c) verification that all sales and other supplies of Licensed

Compounds and Licensed Products made by the Licensee have been made in the Territory, except to the extent expressly provided for in this Agreement;

(d) verification that all sales and other supplies of the Licensed Compounds and Licensed Products made by Third Party manufacturers contemplated by this Agreement have been made to the Licensee in accordance with this Agreement.

9.2 Within 10 Business Days following the end of each Agreement Quarter, the Licensee shall deliver to Licensor a statement accounting for all Licensed Products and/or Licensed Compound (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter in the Reporting Template as set forth in Appendix 3. Licensor agrees that information contained in quarterly and other such reports shall be treated as Confidential Information, provided, however, that such information may be shared with Merck (with Merck treating such reports as Confidential Information); and that aggregated data may be publicly disclosed by Licensor.

## 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 remain in force until October 31, 2022.

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 30 days after such written notice is provided to cure such breach. If such breach is not cured within the 30 period, this Agreement shall effectively terminate.

10.3 Licensor Right to Terminate. Licensor shall have the right to terminate this Agreement, either in whole or in relation to a particular Licensed Patent Right, with immediate effect by notice in writing to Licensee if:

(a) Licensee breaches any of the anti-diversion provisions of Section 4;

(b) Licensor becomes aware of any action (including any official notifications or communications) taken by any regulatory authority involving a determination of Licensee's failure to comply with good manufacturing practices as prescribed in the applicable legal or regulatory standards in connection with for the manufacture and handling of the Products, or otherwise reasonably determines that, due to material deficiencies in Licensee's compliance, or repeated failure to comply, with the quality requirements of Section 3.2, Licensee is unable to reliably and consistently manufacture Licensed Compound or Licensed Product in accordance with such quality

requirements;

(c) Licensee fails to comply with the obligations contained in Section 3.3 of this Agreement;

(d) Licensee repeatedly fails to comply with or to timely provide Licensor with the reports contemplated under Sections 3.4 and 9.2 of this Agreement; or

(e) The legal or beneficial ownership of Licensee or any of its Affiliates changes in such a manner as Licensor after consulting with Licensee reasonably determines to be significant and adversely impacts the ability of the parties to achieve the objectives of this Agreement.

10.4 Failure to Promote Access. If, in the reasonable opinion of the Licensor, the Licensee fails to promote access or appears in Licensor's reasonable opinion, will fail to promote access to the Licensed Products in the Territory in accordance with this Agreement, the Licensor shall give notice to the Licensee requiring it to cure such failure. If, in the reasonable opinion of the Licensor, the Licensee fails to present an acceptable plan within 60 days and report reasonable progress within 180 days after receiving written notice with respect to the default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee. In making such determination of reasonable progress, the Licensor shall take into account the period within which the relevant authorities provide the necessary approvals and normal development lead time for the Licensed Products, and progress reported by Licensee in its quarterly reports and meetings provided under Section 3.4 of this Agreement.

10.5 Conversion to Direct Licence with Merck. Unless notice to the contrary is given, this Agreement shall terminate immediately in the event that the Merck-MPP Agreement is terminated or expires. This Agreement shall be converted into a direct licence between Merck and Licensee, provided that Licensee is not in breach of this Agreement.

10.6 Insolvency. Either Party may terminate this Agreement in the event that the other Party becomes insolvent, makes an assignment to the benefit of creditors, or has a petition in bankruptcy filed for or against it.

10.7 Waiver. The waiver by any 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.

10.8 Survival. Sections 10.5, 11 and 12 shall survive termination or expiry of this Agreement.

## **11. Confidentiality and Publications**

11.1 Confidential Information. All technology, know-how, business information, quarterly reports or any other confidential information disclosed by one

party (the “**Disclosing Party**”) to another 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 without obligations of confidentiality 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 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 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. The confidentiality obligations under this Agreement shall survive this Agreement for a period of five years.

11.2 Press Release. Each party may disclose to third parties or make public statements, by press release or otherwise, regarding the existence of this Agreement, the identity of the parties, the terms, conditions and subject matter of this Agreement, or otherwise in reference to this Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.

## 12. **Miscellaneous**

12.1 Third Party Beneficiary. The Parties hereto acknowledge that Merck is intended to be and constitutes a third party beneficiary of the representation, warranties, covenants and agreements of Licensee, and Merck is entitled to enforce the terms and provisions of this Agreement on its own behalf, to the same extent as Licensor.

12.2 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.

12.3 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.

12.4 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.

12.5 Notices

(a) Any legal 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 by facsimile (receipt confirmed) or email (receipt confirmed) or (ii) three days after mailing by registered or certified mail, postage paid:

In the case of Licensor:

Medicines Patent Pool  
Chemin Louis-Dunant 17  
Geneva 1202  
Switzerland  
Attention: General Counsel  
E-mail: [office@medicinespatentpool.org](mailto:office@medicinespatentpool.org)

In the case of Licensee:

Lupin Limited, Laxmi Towers, B Wing 4th Floor  
Bandra Kurla Complex, Mumbai 400051  
Attention: Shrikant Kulkarni  
E-mail: [shrikantkulkarni@lupin.com](mailto:shrikantkulkarni@lupin.com)

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

12.6 Language; Governing Law. This Agreement is entered into and will be governed by and construed in accordance with the English language. This Agreement is made in accordance with and shall be governed and construed under the laws of England

and Wales, without regard to its choice of law principles.

12.7 Dispute Resolution.

(a) The parties agree that in the event of a dispute they shall first attempt in good faith to resolve such dispute. In the event that such dispute is not resolved on an informal basis, either Party may refer the dispute to the Executive Director of the MPP, and to Mr. Naresh K Gupta, President API Plus (together, the Designated Officers). If such dispute is not resolved by the Designated Officers within 30 days, the Parties shall submit such dispute to mediation in accordance with the WIPO Mediation Rules. In the event that the dispute remains outstanding after 60 days from the date when it was first discussed (in any manner) between the parties, either party may commence court proceedings. The foregoing however shall not prevent any person from seeking and obtaining injunctive relief at any time.

(b) Subject to paragraph (a) of this Section, the English courts have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to any non-contractual obligations arising out of or in connection with this Agreement) and the parties submit to the exclusive jurisdiction of the English courts.

(c) Without prejudice to the foregoing, nothing in this Agreement shall prevent or restrict Merck or its Affiliates from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country outside England, to which election Licensor and Licensee hereby agree.

12.8 Assignment. Neither Party is entitled to transfer or assign this Agreement or the rights and obligations under this Agreement without the other Party's prior written consent.

12.9 Amendment. No amendment or modification hereof shall be valid or binding upon the Parties unless made in writing and signed by all of the Parties.

*[signatures appear on following page]*



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

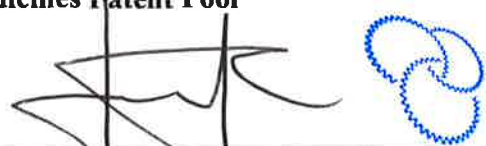
*MEDICINES PATENT POOL:*

**Medicines Patent Pool**

By \_\_\_\_\_

Name: Greg Perry

Title: Executive Director



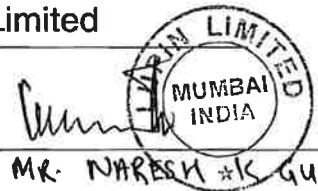
*LICENSEE:*

**Lupin Limited**

By \_\_\_\_\_

Name: MR. NARESH \*K GUPTA

Title: PRESIDENT API PLUS



## Appendix 1

### Countries in the Territory

- |                                 |                   |                           |
|---------------------------------|-------------------|---------------------------|
| 1. Afghanistan                  | 31. Guatemala     | 62. Papua New Guinea      |
| 2. Angola                       | 32. Guinea        | 63. Paraguay              |
| 3. Armenia                      | 33. Guinea Bissau | 64. Philippines           |
| 4. Bangladesh                   | 34. Guyana        | 65. Rep Kyrgyz            |
| 5. Benin                        | 35. Haiti         | 66. DPR of Korea          |
| 6. Bhutan                       | 36. Honduras      | 67. Rwanda                |
| 7. Bolivia                      | 37. India         | 68. Samoa                 |
| 8. Botswana                     | 38. Indonesia     | 69. São Tomé and Príncipe |
| 9. Burkina Faso                 | 39. Kenya         | 70. Senegal               |
| 10. Burundi                     | 40. Kiribati      | 71. Seychelles            |
| 11. Cambodia                    | 41. Lao, PDR      | 72. Sierra Leone          |
| 12. Cameroon                    | 42. Lesotho       | 73. Solomon Islands       |
| 13. Cape Verde                  | 43. Liberia       | 74. Somalia               |
| 14. Central African<br>Republic | 44. Madagascar    | 75. South Africa          |
| 15. Chad                        | 45. Malawi        | 76. South Sudan           |
| 16. Comoros                     | 46. Maldives      | 77. Sri Lanka             |
| 17. Congo Dem Rep               | 47. Mali          | 78. Swaziland             |
| 18. Congo Rep                   | 48. Mauritania    | 79. Syrian Arab Rep       |
| 19. Côte d'Ivoire               | 49. Mauritius     | 80. Tajikistan            |
| 20. Djibouti                    | 50. Micronesia    | 81. Tanzania              |
| 21. Timor Leste                 | 51. Moldova       | 82. Togo                  |
| 22. Egypt                       | 52. Mongolia      | 83. Tuvalu                |
| 23. El Salvador                 | 53. Morocco       | 84. Uganda                |
| 24. Equatorial Guinea           | 54. Mozambique    | 85. Ukraine               |
| 25. Eritrea                     | 55. Myanmar       | 86. Uzbekistan            |
| 26. Ethiopia                    | 56. Namibia       | 87. Vanuatu               |
| 27. Gabon                       | 57. Nepal         | 88. Vietnam               |
| 28. Gambia                      | 58. Nicaragua     | 89. West Bank and Gaza    |
| 29. Georgia                     | 59. Niger         | 90. Yemen                 |
| 30. Ghana                       | 60. Nigeria       | 91. Zambia                |
|                                 | 61. Pakistan      | 92. Zimbabwe              |





## Appendix 2

### Territory Patents

**Applications corresponding to PCT/GB02/04753 which published as WO2003/035077**

COUNTRY	APPLICATION NO.	APPLICATION DATE	PATENT NUMBER	GRANT DATE
Gambia	1441735	07/04/2006	3/2006	07/04/2006
Georgia	AP2002005592	10/21/2002	P3848	06/12/2006
India	868/CHENP/2004	10/21/2002	212400	12/03/2007
Indonesia	W-00200401042	10/21/2002		
Kiribati	144735	10/21/2002	4/2006	11/09/2006
Philippines	1-2004-500540	10/21/2002	1-2004-500540	10/03/2008
Seychelles Island	1441735	06/29/2006	1441735	06/29/2006
*Sierra Leone			021606	
Solomon Islands	J37/213	06/30/2006	J37/213	07/17/2006
South Africa	2004/2796	10/21/2002	2004/2796	03/30/2005
Tuvalu	TVP1441735	07/05/2006	TVP1441735	07/05/2006
Ukraine	20040503960	10/21/2002	77454	12/15/2006
Uzbekistan	IAP20040189	10/21/2002	IAP03323	03/12/2007
Vanuatu	22043	06/16/2006	22043	06/16/2006
Vietnam	1-2004-00347	10/21/2002	5949	10/24/2006

*\*Applied for registration of UK Patent*

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**Applications corresponding to PCT/US05/043728 which published as WO2006/060712**

COUNTRY	APPLICATION NO.	APPLICATION DATE	PATENT NUMBER	GRANT DATE
Egypt	534/2007	12/02/2005		
Georgia	AP2005010157	12/02/2005	P5086	10/11/2010
Indonesia	W-00200701697	12/02/2005	IDP0031730	09/14/2012
Mongolia	3980	12/02/2005	2999	05/31/2007
Morocco	PV30041	12/02/2005	29120	12/03/2007
Nicaragua	2007-000138	12/02/2005	1959RPI	01/07/2010
Pakistan	1139/2005	12/01/2005	140098	06/09/2009
Philippines	1-2007-501118	12/02/2005	1-2007-501118	10/15/2012
South Africa	2007/04130	12/02/2005	2007/04130	08/27/2008
Ukraine	200707372	12/02/2005	87884	08/25/2009
Vietnam	1-2007-01323	12/02/2005	10582	08/22/2012

**Applications Corresponding to PCT/US05/043781, Published as WO2006/060730**

COUNTRY	APPLICATION NO.	APPLICATION DATE	PATENT NUMBER	GRANT DATE
India	4187/DELNP/2007	12/02/2005		

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**Applications corresponding PCT/US2005/043727 which published as WO2006/060711**

COUNTRY	APPLICATION NO.	APPLICATION DATE	PATENT NUMBER	GRANT DATE
India	4028/DELNP/2007	12/02/2005		
South Africa	2007/03866	12/02/2005	2007/03866	03/26/2008

**Applications based on PCT/US2010/053507 which published as WO2011/053504**

COUNTRY	APPLICATION NO.	APPLICATION DATE	PATENT NUMBER	GRANT DATE
India	3377/DELNP/2012	10/21/2010		
South Africa	2012/03012	10/21/2010	2012/03012	12/27/2012

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**Appendix 3**

**Quarterly Reporting Template**

**Reporting Template for Licensed Products**

<b>Country</b>	<b>Product</b>	<b>Strength</b>	<b>Formulation (Tablet/g ranules/li quid/pow der for suspension)</b>	<b>Pack Size</b>	<b>Quantity (number of packs)</b>	<b>Total Value in USD (FOB)*</b>	<b>Country of Origin</b>

\* Please mention FOB (Free on Board) price basis country of origin

Note: this format is to be filled and sent to Licensor on a quarterly basis, 10 Business days from end of each calendar quarter.

**Reporting Template for Licensed Compounds**

<b>Month</b>	<b>Country</b>	<b>Purchaser</b>	<b>Product</b>	<b>Quantity (kg)</b>	<b>Total Value (USD)</b>

g