



Dated _____ 2015

(1) THE UNIVERSITY OF LIVERPOOL

(2) MEDICINES PATENT POOL

COLLABORATION AGREEMENT & PATENT AND KNOW-HOW LICENCE

Liverpool IP
University of Liverpool
Business Gateway
Waterhouse Building, Block D
3 Brownlow Street
Liverpool L69 3GL

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THIS AGREEMENT ("Agreement") dated 24 November 2015, is made BETWEEN:

(1) **University Of Liverpool** incorporated by Royal Charter in the United Kingdom and whose administrative offices are at The Foundation Building, 765 Brownlow Hill, Liverpool L69 7ZX ("the University");

and

(2) **Medicines Patent Pool Foundation** a not for profit charitable foundation whose registered office is at Chemin Louis-Dunant 17, 2nd floor, 1202 Geneva Switzerland ("MPP").

Each of the University and MPP is referred to in this Agreement as a Party. The University and MPP are collectively referred to in this Agreement as the Parties.

Background

- I. MPP is a non-profit organisation 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 those medicines.
- II. The University has developed a solid drug nanoparticle technology which may help reduce the oral dosage of certain anti-retroviral HIV treatments and therefore may help reduce the cost of such anti-retroviral based HIV treatment regimens. The University would like to maximise the impact of this technology and to reach as many people living with HIV as possible, in the most affordable manner for low- and middle-income countries. The University acknowledges that outside the Territory (namely high income countries) access to drugs in low income groups can also be a challenge and the University's licensing strategy for HIV drugs and other essential medicines aims to be socially responsible.
- III. The University and MPP wish to collaborate on identifying and engaging with third parties, including funders, product development partnerships, and pharmaceutical manufacturers and distributors, to first create solid drug nanoparticles of antiretroviral drugs and then develop these into formulations as pharmaceutical products at a commercial scale as detailed in this Agreement as outline in Schedule 2.
- IV. The rights afforded under this Agreement will allow MPP to enter into sub-licensing agreements with pharmaceutical manufacturers and distributors for the manufacture and distribution and sale, of anti-retroviral solid drug nanoparticle based pharmaceutical products for public health purposes in certain countries under the rights described in this Agreement.
- V. The intent of this Agreement is to provide access to Licensed Technology, and not to create any non-intellectual property-related barriers.

Agreement

1. Interpretation

1.1 In this Agreement the following expressions have the meaning set opposite:

Additional ARVs: means anti-retroviral active pharmaceutical ingredients used in the treatment of HIV and consisting of (listed alphabetically):

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abacavir, dolutegravir, emtricitabine, lamivudine, tenofovir disoproxil fumarate and tenofovir alafenamide.

Affiliate: means, 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 with 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.

Agreed ARVs: means an anti-retroviral active pharmaceutical ingredients used in the treatment of HIV consisting of (listed alphabetically): atazanavir, cobicistat, darunavir, doravirine, efavirenz, lopinavir (including ritonavir-boosted lopinavir), raltegravir, and ritonavir, and combinations thereof.

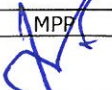
ARV-SDN: means an Agreed ARV and / or Additional ARVs, or combinations thereof, prepared as solid drug nanoparticles using the Licensed Technology and suitable for formulation into a pharmaceutical product.

Combination Product: shall mean a formulated and finished pharmaceutical product containing a Licensed Product in combination with any other active pharmaceutical ingredient, including combinations, including any co-formulation, co-packaged product, or bundled product.

Commercialisation Agreement: means an agreement executed by MPP and a Commercialisation Partner pursuant to this Agreement and under the terms and conditions set forth in Schedule 5 to this Agreement.

Commercialisation Partner: means any firm, corporation, partnership, limited liability company, business trust, joint venture, or other form of business organization to be selected by the MPP to enter into a Commercialisation Agreement under the terms and conditions outlined in Schedule 5 to this Agreement.

Confidential Information: means all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by any Party or any of its Affiliates, or has otherwise become known to a Party or any of its Affiliates, as well as any other information and materials that are deemed confidential or proprietary to or by a Party or any of its Affiliates (including all information and materials of a Party's (or its Affiliates') customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic or electronic form. Confidential Information will include the Licensed Know-How.

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Control: means either ownership of more than 50% of the voting share capital of the relevant entity; or the ability to direct the casting of more than 50% of the votes exercisable in the relevant entity.

Development Plan: means the respective actions and responsibilities associated with the advancement of ARV-SDNs into Licensed Products as described in Schedule 2 and amended from time to time.

Development Agreement: means an agreement executed by MPP and a Development Partner pursuant to this Agreement and under the terms and conditions set forth in Schedule 4 to this Agreement.

Development Partner: means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity or other form of business organization to be selected by the MPP to enter into a Development Agreement under the terms and conditions set forth in Schedule 4 to this Agreement.

Effective Date: means the date of the last signature to this Agreement.

Encumbrance: means any legal obligations to any third party (including but not limited to research funders or collaborators) or rights, interest or objections of an inventor, their department or faculty, that would in the University's sole opinion restrict or adversely affect the University's ability to grant rights over the intellectual property.

Field: means the prevention and treatment of HIV.

Improvement: means any new or improved process, any new or improved manufacturing techniques or any further invention or know-how which relate to the manufacture or formulation of the Licensed Products, or incorporate or are based on the Licensed Technology, developed by or on behalf of an MPP Licensee.



Licensed Know-how: means all technical information or know-how known to or controlled by the University as of the Effective Date (including all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control and testing procedures) that is identified by the University as primarily and directly relating to, and reasonably necessary for, the making of an ARV-SDN or a Licensed Product in the same manner that such ARV-SDN or Licensed Product has been made by the University prior to the Effective Date, as well as any other modification or improvement of such technical information or know-how known to or controlled by the University and unencumbered after the Effective Date.

Licensed Patents: means the solid drug nanoparticle technology as described in the patents and patent applications set out in Schedule 1, as may be amended from time to time, including any continuations, continuations in part, extensions, reissues, divisions, and any supplementary protection certificates and similar rights deriving priority from any of these.

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Licensed Product:	means any pharmaceutical product which entirely or partially uses the Licensed Technology in either its development, manufacture, regulatory approval or whose manufacture, use or sale would constitute an infringement of any patent claim within the Licensed Technology.
Licence Report:	means the report set forth in Clause 8 to be provided annually by MPP to the University.
Licensed Technology:	means the Licensed Patents and the Licensed Know-how;
MPP Licensee:	means Commercialisation Partner and Development Partner
Net Sales:	<p>means the invoiced price of a Licensed Product sold at arm's length or, where the sale is not at arm's length, the price that would have been invoiced if the sale had been at arm's length, after deducting, to the extent not already deducted from the gross amount invoiced or otherwise charged, reasonable and bona fide:</p> <ul style="list-style-type: none"> • normal trade discounts, returns, expiries, rejects, destroyed stock and credits actually given; and • the costs of carriage, insurance, freight and packaging if invoiced separately to the customer; and • VAT, import duties and sales taxes actually paid by Commercialization Partners; and • Free samples for promotional purposes with quantities in accordance with usual practices.
Public Sector:	means (a) the following organizations to the extent that they are not for profit organizations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and agencies based outside of an applicable country to the extent that they are supplying Licensed Products in the Territory, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) above;
Private Sector:	means any entity that is not included in the Public Sector.
Steering Committee:	means as defined under Schedule 2.
Sub-Licence Agreement:	means the Development Agreement and/or the

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Commercialization Agreement.



Territory: means the countries set out in Schedule 3.

2. DEVELOPMENT OBLIGATIONS

- 2.1. MPP will use its best endeavours to identify opportunities for the University to secure funding to create ARV-SDNs from Agreed ARVs and the University shall use its best endeavours to apply to and secure said funding opportunities to create ARV-SDNs.
- 2.2. The Parties acknowledge that Additional ARVs may benefit less from the Licensed Technology and recognise the corresponding difficulty of successfully developing these Additional ARVs into ARV-SDNs. These Additional ARVs are included in this Agreement given the possibility of co-formulating them with ARV-SDNs of the Agreed ARVs and the obligations upon MPP in Clause 2.1 shall extend to Additional ARVs.
- 2.3. MPP will use its best endeavours to identify and enter into agreements with Development Partner(s) that can assist in developing ARV-SDNs into Licensed Products, file them for regulatory approval and transfer technology to MPP's Commercialisation Partner(s).
- 2.4. Under any funding secured in accordance with Clause 2.1, the University will conduct research on and develop SDNs of Agreed ARVs and Additional ARVs, in accordance with Clause 2.3 and subject to commensurate funding, support the Development Partner as envisaged in the Development Plan.
- 2.5. The Parties acknowledge that any future ARV-SDNs created by the University through funding by commercial organisations or funded through grant monies where MPP is not a party to the agreements may have Encumbrances that are inconsistent with the objectives of this Agreement. In such circumstances both parties will work in good faith to ensure the objectives of this Agreement can be realised for those future ARV-SDNs.
- 2.6. Both parties shall adhere to the Schedule 2 "Responsibilities of the Parties" and where necessary mutually agree any amendments to maximise the benefit to both Parties. The Parties agree to form a Steering Committee along with Development Partners, in accordance with Schedule 2, and participate actively in the delivery of any Development Plan agreed by the Parties and the Development Partner.
- 2.7. MPP will use its best endeavours to identify Commercialization Partner(s) capable of commercially exploiting the Licensed Technology and any Licensed Products in accordance with the terms of this Agreement.

3. GRANT OF LICENCE AND RESERVATION OF RIGHTS

- 3.1. Subject to the terms of this Agreement and with effect from the Effective Date, the University grants to MPP:
 - 3.1.1. a non-exclusive, non-transferable worldwide licence under the Licensed Technology to grant sub-licences, in accordance with the terms set forth in Schedule 4, to Development Partner(s) to develop, or have developed, ARV-SDNs into Licensed Products in the Field; and

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- 3.1.2. a non-exclusive, non-transferable, royalty-bearing worldwide licence under the Licensed Technology to grant sub-licences, in accordance with the terms set forth in Schedule 5, to Commercialisation Partner(s) to make, have made, use, offer for sale, sell, have sold, export or import the Licensed Products in the Field exclusively for administration to patients in the Territory.
- 3.2. For the avoidance of doubt no rights are afforded to MPP under this Agreement for MPP or MPP Licensees to:
- 3.2.1. create ARV-SDNs independently of the University; or
- 3.2.2. use the Licensed Technology outside the Field; or
- 3.2.3. offer for sale, sell, have sold or otherwise commercialise Licensed Products for use outside the Territory; or
- 3.2.4. have any right, title or interest to any intellectual property unless otherwise explicitly stated; or
- 3.2.5. in the case of MPP, to directly practice such licences or otherwise exploit the Licensed Technology for any other purpose other than to grant sub-licences under Clause 3.1.1 and 3.1.2 of this Agreement.
- 3.3. Notwithstanding anything contained in this Agreement, it shall not be a breach of this Agreement for MPP, or MPP Licensees, to:
- 3.3.1. supply to a country where a compulsory licence has been issued by the government of such country or;
- 3.3.2. conduct any activities where such activities would not infringe a Licensed Patent granted and in force, or do not rely on Licensed Know-How.
- 3.4. After the first anniversary of this Agreement, the Parties may agree to explore an extension to the Field to include other therapeutic areas such as malaria, tuberculosis, hepatitis B and hepatitis C. In the event that an agreement is reached, any such Field Extension shall be executed as a separate written amendment to this Agreement.

4. RIGHT TO SUB-LICENSE TO MPP LICENSEES

- 4.1. MPP may grant sub-licences and may disclose to MPP Licensees only such of the Confidential Information as is necessary for the exercise of the rights sub-licensed, subject in each case to the following conditions:
- 4.1.1. MPP and the University mutually agree suitable MPP Licensees within 30 days of MPP proposing a potential MPP Licensee, a potential MPP Licensee is deemed to be mutually agreed unless otherwise noted in writing by the University stating the grounds and the mitigation approach; and
- 4.1.2. MPP provides the University with a copy of each Sub-Licence Agreement together with a summary of the same, within 10 days after its grant; and
- 4.1.3. the MPP Licensee accepts obligations and conditions consistent with those in this

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Agreement including Schedule 4 and Schedule 5 (as applicable); and

- 4.1.4. MPP will ensure that the Sub-Licence Agreement(s) will grant to the University a non-exclusive, perpetual, worldwide, royalty-free license to use any Improvement; and
- 4.1.5. MPP will ensure that Sub-licence Agreements contain indemnifying obligations against any direct loss, damages, costs, claims or expenses which are awarded against or suffered by the University, its officers, employees, sub-contractors and agents as a result of any act or omission of the MPP Licensee.
- 4.1.6. University will have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of the Sub-licence Agreement(s).
- 4.2 MPP agrees to monitor compliance of each MPP Licensee. Such monitoring shall include:
 - 4.2.1 reviewing with all reasonable skill and care any reports provided to MPP by the MPP Licensee under the relevant sections of the Sub-Licence Agreement;
 - 4.2.2 fully exercising the audit right set out in the Sub-Licence Agreement(s) as soon as MPP has reasonable cause to believe (or as soon as University and MPP have agreed that they have reasonable cause to believe) an audit is necessary.
- 4.3 If the MPP becomes aware of any act or omission of an MPP Licensee which constitutes a breach of the relevant Sub-Licence Agreement, the MPP shall notify the University immediately and (i) if the breach is capable of correction and does not give rise to an immediate right of termination under the Sub-Licence Agreement, direct the relevant MPP Licensee in writing to cure the breach, with a simultaneous copy of that writing to University; and (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the Sub-Licence Agreement, and in each case if so requested by University, procure the termination of the relevant Sub-Licence Agreement in accordance with its terms.

5. LICENSED KNOW-HOW

- 5.1. For each ARV-SDN, the University will make an initial transfer to MPP for use by an MPP Licensee, of the Licensed Know-how that the University is free to disclose within 30 days of a request from MPP. Further transfer to MPP of Licensed Know-how may occur during the sub-license in accordance with Clause 9 of this Agreement.

6. PUBLICITY AND PUBLICATION

- 6.1. The Parties agree that neither party will issue a press release or public announcement concerning the transactions contemplated hereby without the advance written consent of the other party. If either party intends to issue a press release, it shall submit a draft of such proposed press release to the other party at least five (5) business days prior to the date such party intends to issue the release. After any initial press release or public announcement is made, however, 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.

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6.2. Subject to Clause 12 and any confidentiality obligation to a MPP Licensee, nothing in this Agreement shall prevent or hinder registered students of the University from submitting for degrees of the University theses based on the Licensed Technology; or from following the University's procedures for examinations and for admission to postgraduate degree status.

7. ROYALTIES

7.1. MPP will require that Commercialization Partners will pay royalties over Net Sales of Licensed Products directly to University on a country-by-country basis starting from the date of the first commercial sale of Licensed Products in the Territory. Royalties will be paid as described below:

7.1.1. Royalty-free where the supply of Licensed Products is to any Group 1 country for use solely in that country; and

7.1.2. Royalty-free where the supply of Licensed Products is to Group 2 countries and for use solely in that country and where the Licensed Products are sold to the Public Sector in that country; and

7.1.3. In Group 2 countries where there is a valid issued Licensed Patent in the country of manufacture or sale, a royalty equal to 1% of the Net Sales value of Licensed Products where the Licensed Products are sold in the Private Sector; and

7.1.4. In Group 3 countries where there is a valid issued Licensed Patent in the country of manufacture or sale, a royalty equal to 1.75% of the Net Sales value of Licensed Product.

7.1.5. Notwithstanding the above, no royalties will be owed on specific formulations labelled for the prevention and treatment of paediatric HIV (including the prevention of mother-to-child transmission).

7.2. In the event that there are only pending Licensed Patent(s) not yet granted in the country of manufacture or sale, MPP will require that Commercialisation Partners set aside the royalty amounts in accordance with Clause 7.1 for sales of Licensed Products made under this Agreement during the pendency of the Licensed Patent(s), to be payable to the University only upon the issuance of a valid Licensed Patent in either the country of manufacture or sale. For the avoidance of doubt, no additional royalties will be payable on the basis on Licensed Know-How.

7.3. MPP will require Commercialisation Partners to pay any amounts due to the University in pounds sterling by bank transfer to the account nominated by the University.

8. REPORTING

8.1. MPP will send to University within 30 business days following the end of each calendar year, a written report setting forth each Licensee's (a) Licensed Products development pipeline, (b) status of development of each Licensed Product in development, (c) regulatory filing plan for each Licensed Product, and (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been obtained for any Licensed Product.

9. UNIVERSITY HIV TREATMENT ADVANCES

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- 9.1. The University will communicate in writing to MPP within a reasonable time, but in any case not to exceed 120 days, any technical development that may improve the treatment of HIV, including but not limited to ARV-SDNs, which the University is developing or has developed, is disclosed to the IP Manager of the University after the Effective Date, and is free from any Encumbrances that would prevent such a disclosure. In the event of an Encumbrance, the University will commit its reasonable endeavours to remove any such Encumbrance(s). The University's obligation to communicate technical developments according to Clause 9.1 shall expire on the fifth anniversary of the Effective Date unless renewed or extended in writing.
- 9.2. Upon receiving from the University a disclosure of a technical development that may improve the treatment of HIV, in accordance with Clause 9.1, MPP shall inform the University within 120 days whether the said technical development is of interest.
- 9.3. In the event MPP wishes the technical development to be licensed to MPP and the technical development is free from any Encumbrance and is an advancement of an ARV-SDN, then the University and MPP shall amend Schedule 1 to incorporate any relevant patents and patent applications and/or effect a suitable transfer of know-how in accordance with Clause 5.1.
- 9.4. In the event a technical development in accordance with clause 9.1 has been disclosed to Liverpool IP after the Effective Date, is free from any Encumbrance, is not an advancement of an ARV-SDN and is of interest to MPP in accordance with Clause 9.2, then the University and MPP shall discuss in good faith a new license agreement for said technical development.

10. INTELLECTUAL PROPERTY MAINTENANCE



- 10.1. Neither University nor MPP shall be obliged to maintain or enforce the Licensed Patents.
- 10.2. The MPP shall have no rights in relation to the conduct of any matter relating to the Licensed Patents, including the filing, prosecution and maintenance thereof.

11. INTELLECTUAL PROPERTY INFRINGEMENT

- 11.1. University, or any third party the University elects, will be responsible (at its own expense and discretion) for, and be in control of, the prosecution, maintenance and enforcement of all Licensed Patents.
- 11.2. University will have the transferable right but not any obligation to bring an infringement action and any such action shall be at its own expense and entirely under its own direction and control.
- 11.3. MPP will (at its own expense) reasonably assist the University in any action or proceeding being prosecuted if so requested by University and such reasonable assistance is necessary for University to fully exercise its rights under such proceeding.
- 11.4. MPP will promptly inform the University if it becomes aware of any infringement or potential infringement of any of the Licensed Patents in the Field.

12. CONFIDENTIALITY

- 12.1. Each party agrees that, for so long as this Agreement is in effect, and for a period of 10 years thereafter, a Party receiving Confidential Information of the other Party will:

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- (i) Maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own confidential information;
- (ii) Not disclose such Confidential Information to any third party without the prior written consent of the other Party, except for disclosure expressly permitted under this Agreement; and
- (iii) Not use such Confidential Information for any purpose except those permitted by this Agreement.

12.2. The obligations under clause 12.1 will not apply with respect to any portion of the Confidential Information that the receiving Party can show by written evidence:

- (i) Is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party; or
- (ii) Was known to the receiving Party without any obligations to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or
- (iii) Is subsequently disclosed to the receiving Party by a third party lawfully in the possession thereof and without any obligation to keep it confidential or any restriction on its use; or
- (iv) Is published by a third party or otherwise becomes publicly available, either before or after it is disclosed to the receiving Party; or
- (v) Has been independently developed by employees or contractors of the receiving Party without the aid, application or use of Confidential Information of the disclosing Party.

12.3. The receiving Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

- (i) Regulatory filings;
- (ii) Prosecuting or defending litigation;
- (iii) Complying with applicable governmental laws and regulations;
- (iv) Disclosure in connection with the performance of this Agreement and solely on a "need-to-know basis", to Affiliates, potential collaborators, research collaborators, employees, consultants or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this clause 12; provided however that the receiving Party will remain responsible for any failure by any such person who receives Confidential Information pursuant to this clause 12 to treat such Confidential Information as required under this clause 12.

12.4. The Parties agree that a copy of this Agreement as well as of each Sub-licence Agreement may be publicly disclosed on MPP's website. Such disclosure will not constitute a breach of either Party's obligations under this clause 12.

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13. WARRANTIES AND LIABILITY

- 13.1. The University warrants that as of the Effective Date the University has full ability to enter into this Agreement and the right to license the Licensed Technology and that, so far as it is aware having made enquiries for due diligence, there are no Encumbrances over the Licensed Technology that is inconsistent with this Agreement.
- 13.2. To the fullest extent permissible by law and notwithstanding Clause 13.1, the University does not make any warranties of any kind including, without limitation, warranties with respect to:
 - 13.2.1. The quality of the Licensed Technology;
 - 13.2.2. The suitability of the Licensed Technology for any particular use;
 - 13.2.3. Whether the use of the Licensed Technology or ARV-SDN or any rights granted under this Agreement for the manufacture, sale or use of the Licensed Products will infringe any third-party rights; or
 - 13.2.4. That any of the Licensed Patents is or will be valid or subsisting or (in the case of an application) will proceed to grant.
- 13.3. Neither MPP nor MPP Licensees shall directly or indirectly make a claim against any individual employee, student, agent or appointee of the University, being a claim which seeks to enforce against any of them any liability whatsoever in connection with this Agreement or its subject-matter.
- 13.4. MPP will include appropriate obligations on MPP Licensees that indemnify the University and every employee, student, agent and appointee of the University ("the Indemnified Parties"), and keep them fully and effectively indemnified, against each and every claim made against any of the Indemnified Parties as a result of the use of or licensing of the Licensed Technology, the manufacture, use, sale of, or other dealing in any of the Licensed Products by MPP Licensees provided that the indemnity in this clause will not apply to the extent that the claim arises as a result of the Indemnified Party's negligence.
- 13.5. Subject to clause 13.8, and except under the indemnity in clause 13.4, the liability of either party to the other for any breach of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement will not extend to any indirect damages or losses, or any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity, whether direct or indirect, even if the party bringing the claim has advised the other of the possibility of those losses or if they were within the other party's contemplation.
- 13.6. MPP will require that the obligations set out in Clause 13 will be binding upon MPP Licensees and that MPP Licensees will indemnify the University for any direct loss arising from a breach by a MPP Licensee of the obligation under each Sub-licence Agreement.
- 13.7. Subject to clause 13.8, and except under the indemnity in clause 13.4, the aggregate liability of the University for all and any breaches of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, will not exceed £25,000.
- 13.8. Nothing in this Agreement limits or excludes either party's liability for death or personal injury; any fraud or for any liability that, by law, cannot be limited or excluded.



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14. DURATION AND TERMINATION

- 14.1. This Agreement will take effect on the Effective Date and, unless terminated earlier as provided herein, shall continue in force until the date on which the last to expire Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated.
- 14.2. 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 to cure such breach, or to provide a timeline to cure such breach to the satisfaction of the non-breaching party. If such breach is not cured.
- 14.3. Additional termination rights:
 - 14.3.1. Either Party will have the right to terminate if there has been no active development efforts on any Agreed ARV within the previous one calendar year, or likelihood of development, any time after the second anniversary of this Agreement; or
 - 14.3.2. The other party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other party's assets, or if the other party makes any arrangement with its creditors or takes or suffers any similar or analogous action in any other jurisdiction.
- 14.4. MPP may terminate this Agreement at any time by giving the University not less than 90 days' written notice.

15. CONSEQUENCES OF TERMINATION

- 15.1. In the event that this Agreement is terminated other than under Section 14.1, all Sub-Licence Agreements will be automatically converted into licences between the University and the MPP Licensees, provided that the MPP Licensee is not in breach of the Sub-Licence Agreement, by way of the MPP, the University and the relevant Licensee entering into a novation agreement transferring the rights and obligations of the MPP under the Sub-licence to University.
- 15.2. On termination or expiration of this Agreement, in the event that any MPP Licensees are not converted into licences between the University and the MPP Licensee under Clause 15.1, MPP shall procure that MPP Licensees:
 - 15.2.1. Immediately pay to the University all outstanding royalties and other sums due under this agreement; and
 - 15.2.2. Immediately provide the University with details of the stocks of Licensed Products held at the point of termination; and
- 15.3. Termination of this agreement, whether for breach of this Agreement or otherwise, shall not absolve MPP Licensees of their obligation to accrue and pay royalties under the provisions of

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Clause 7 of this Agreement for the duration of any notice period.

- 15.4. Clauses 12, 13.2, 13.3, 13.5, 13.7, 13.8, 15, and 16 will survive the expiry or termination of this Agreement.

16. GENERAL

- 16.1. Force Majeure: If the performance by either party of any of its obligations under this Agreement (except a payment obligation) is delayed or prevented by circumstances beyond its reasonable control, that party will not be in breach of this Agreement because of that delay in performance. However, if the delay in performance is more than 3 months, the other party may terminate this Agreement with immediate effect by giving written notice.
- 16.2. Notices: Any notice to be given under this Agreement must be in writing, may be delivered to the other party's representative as detailed below, and as updated from time to time:

For the University:

Name: The IP Manager

Address: Business Gateway
University of Liverpool
1st floor, Block D
The Waterhouse Building
3 Brownlow St
Liverpool L69 3GL
Email: lip@liverpool.ac.uk

For MPP:



Name: General Counsel

Address: Chemin Louis-Dunant, 17
1202 Geneva
Switzerland
Email: cpark@medicinespatentpool.org

and by any of the methods set out below, and will be deemed to be received as set out below:

By hand or courier:	the day of delivery and is sent concurrently by email
By pre-paid first class post:	the second working day after posting and is sent concurrently by email



- 16.3. Assignment: MPP may not assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the University. Assignment in respect of MPP Licensees includes the acquisition of Control in the MPP Licensee by a third party. The University may assign its obligations under this Agreement to a for profit company in which the University has equity.
- 16.4. Waiver of rights: If a party fails to enforce, or delays in enforcing, an obligation of the other party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.
- 16.5. No agency: Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the parties, or the relationship between them of principal and agent. Neither party has any authority to make any representation or commitment, or to incur any liability, on behalf of the other.
- 16.6. Entire agreement: This Agreement constitutes the entire agreement between the parties

University	MPP
	

relating to its subject matter. Each party acknowledges that it has not entered into this Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Agreement. For the avoidance of doubt, nothing in this Agreement shall prevent either party from developing any research programs and entering into further collaborations with third parties, provided that they are not in breach of this Agreement and its Schedules.

- 16.7. Conflicts: In the event that there is a conflict between the terms of the main body of this Agreement and its Schedules, the former shall prevail.
- 16.8. Further assurance: Each party will take any action and execute any document reasonably required by the other party to give effect to any of its rights under this Agreement, or to enable their registration in any relevant territory provided the requesting party pays the other party's reasonable expenses.
- 16.9. Amendments: No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each party's representative.
- 16.10. Third parties: No one except a party to this Agreement has any right to prevent the amendment of this Agreement or its termination, and, save in relation to clauses 13.3 and 13.4 no one except a party to this Agreement may enforce any benefit conferred by this Agreement.
- 16.11. Severability: If any of the provisions of this Agreement is or becomes invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions will not in any way be affected or impaired. Where necessary the Parties will negotiate in good faith mutually satisfactory amendments achieving as nearly as possible the same effect to replace the provisions found to be void or unenforceable.
- 16.12. Resolution by senior executives: All disputes, controversies or claims between the Parties in connection with this Agreement, its construction, or the rights, duties or liabilities of either Party under this Agreement (a "Dispute") must be resolved pursuant to the following resolution process in this clause 16.12 and the jurisdiction clause 16.13. The Parties to any dispute may alter or amend these procedures by agreement in writing.
- 16.12.1. To commence the resolution process, any Party may serve notice to the other Party identifying: (i) the nature of the Dispute; and (ii) the amount in Dispute.
- 16.12.2. Once notice is received, the parties must first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves.
- 16.12.3. In the event that such Dispute is not resolved on an informal basis within 30 days after such notice is received, either Party may, by written notice to the other Party, refer the Dispute to the Executive Director in the case of the MPP and to the Pro-Vice Chancellor for Innovation and Enterprise in the case of the University (together the "Designated Officers") for attempted resolution by good faith negotiation.
- 16.12.4. If any Dispute is not resolved by the Designated Officers, then either Party may seek resolution by the English Courts, in accordance to clause 16.13
- 16.13. Governing law: This Agreement is governed by, and is to be construed in accordance with, English law. Except as provided in clause 16.12 if any dispute is not resolved by the Designated Officers, then the English Courts will have exclusive jurisdiction to deal with any Dispute which has arisen or may arise out of, or in connection with, this Agreement.

[signatures appear on following page]

University	MPP
	

SIGNED on behalf of the University:

Professor Janet Beer

Name

Vice-Chancellor

Position

Janet Beer

Signature

19 November 2015

Date

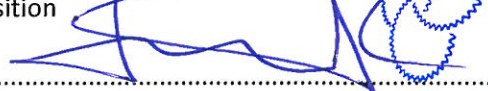
SIGNED on behalf of MPP:

Greg Perry

Name

Executive Director

Position



Signature

24 November 2015

Date

University	MPP
JS	GP

Schedule 1
The Licensed Patent(s):

University Number	Case	Case Title	WO Numbers	Status
#504		Nanoparticles of Efavirin	WO2013/034925	Pending
#515		Nanoparticles of lopinavir	WO2013/034926	Pending
#516		Nanoparticles of lopinavir & ritonavir	WO2013/034927	Pending
#638		Water-Soluble Porous Bodies	WO2005/075547	Granted in India. Pending in USA.
#639		Polymer-Only Compositions	WO2005/073296	Granted in USA, India & China. Pending in European Patent Office.
#640		Emulsion Route	WO2006/079409	Granted in China. Pending in USA, India & European Patent Office.
#648		Spray-Granulation Route	WO2010/020518	Pending in USA, India, China, and European Patent Office.
#635		Original Microporous Beads	WO2004/011537	Granted in USA, Switzerland, Germany, Great Britain & France.
#652		Nanodisperse Antivirals	WO2011/128623	Pending in USA, China, India, Israel, Japan and European Patent Office.
#653		Polymeric Stabilisers	WO2012/045994	Pending in USA, India, Japan, and European Patent Office.

END OF SCHEDULE 1

University	MPP
<i>JS</i>	<i>[Signature]</i>

Schedule 2
The Responsibilities of the Parties

Step	Work required	Responsible party*
0	Identify funding opportunities for the creation of ARV-SDN and their development into Licensed Products.	MPP and University
1	Using the funding identified and secured above, create and optimise ARV-SDN suitable for industrial manufacturing with most suitable preclinical profiles. This includes proving superior pharmacokinetics (PK) in animal models with the potential for improving the dose of such ARV and/or elimination of PK enhancer, and making suitable for formulation into a finished dosage formulation.	University
2	Study the optimised ARV-SDN in pilot PK study(ies), select and assess the dosage of ARV-SDN designed to be bioequivalent with, or improved over the marketed counterpart. Likewise, the minimum criterion from step 1 for moving into further development apply here.	University
3	A. Steering Committee: Formulate the Steering Committee as noted separately in this Schedule. B. Scaling up manufacturing of ARV-SDN at industrial scale C. Formulation of ARV-SDN along with appropriate excipients and other ARVs (as the case may be), into finished dosage formulations as single drug and/or fixed-dose combinations.	Development Partner, depending on circumstances
4	Scaled up manufacturing of optimised ARV-SDN-containing finished dosage formulations	Development Partner and Commercialisation Partner
5	A. Conduct pivotal clinical studies (BE studies and any additional studies required by a Stringent Regulatory Authority (SRA) using the ARV-SDN -containing finished dosage formulations. B. File for regulatory approval needed to ensure access to Licensed Products in the Territory C. Sell/distribute the Licensed Products in accordance with the terms of this Agreement and its Schedules. MPP Licensee can only sell/distribute an SRA-approved Licensed Products in accordance with the terms of this Agreement and its Schedules.	Development Partner (A only) and if appropriate Commercialisation Partner

* Unless otherwise agreed between the Parties in writing following a recommendation of the Steering Committee

Steering Committee (SC)

Purpose: The Steering Committee shall be responsible for the following activities:

- a. Selecting the ARV-SDNs for formulation development by the Development Partner;
- b. Assigning priorities to the ARV-SDN formulations to be developed;
- c. Overseeing and providing guidance during product development to be carried out by

University JB	MPP [Signature]
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- d) the Development Partner; Ensuring that that technology transferred from the University is absorbed in a timely fashion by the Development Partner;
- e) Ensuring that the Development Partner conducts product development, regulatory filing, and technology transfer to Commercialisation Partners in a timely fashion; and
- f) Facilitating the engagement of third parties, including experts, as needed to assist activities identified above.

Composition: The Steering Committee shall consist of one representative from each of the following parties, as appointed annually:

- a) the University and the MPP, prior to the Parties entering into a Sub-Licence Agreement with the Development Partner;
- b) the University, MPP and the Development Partner, after the Parties enter have entered into a Sub-Licence Agreement with the Development Partner.

In the event a Steering Committee representative is unavailable, that representative can nominate someone from their own organisation (including consultants) to represent him/her in meetings.

Observers: In addition to the representatives, the Parties may elect two further observers for each meeting. The observers may be re-appointed or replaced for any subsequent meeting.

Meetings: Steering Committee is only quorate if all three representatives from the Parties are present. The presence of observers is not mandatory. Scientific or technical experts may be invited by the Steering Committee to the development team of the Development Partner on an ad hoc basis. Review meetings shall be held in the most cost effective manner:

- a) Call(s) every month,
- b) In-person or via video-conference at least on a quarterly basis,
- c) In-person meeting at least once every six (6) months.

Cost: Steering Committee members and observers will not be compensated financially for their time spent on the Steering Committee. Travel costs shall be reimbursed from the project budget *if* the project is funded by an external funder. If the project is funded by the Development Partner, all Steering Committee members and observers shall cover their own costs.

Specific activities of the Steering Committee:



1. Review the Development Partner's draft development plan submitted as part of its expression of interest, and suggest improvements and amendments to the plan as needed for the purpose of:
 - i. Helping the Development Partner refine its development steps; and
 - ii. Helping the Development Partner specify its development timelines and milestones.
2. Work with the Development Partner's development team, and help them finalise regulatory strategy/pathway; review and prioritise regulatory filings in the Territory with MPP's assistance.
3. Work with the Development Partner's development team, and help them finalise development and manufacturing strategy for the ARV-SDN (meaning the ARV-SDN powder prior to being formulated into appropriate dosage forms) and appropriate SDN formulations, among other activities, which could be done in-house or out-sourced to third party as deemed acceptable by the Steering Committee.
4. (To be carried out by the Development Partner's designated project manager and MPP's designated business development manager): Schedule review meetings and ensure that the

University	MPP
JS	[Signature]

- meetings take place as planned; run the review meetings, circulate meeting minutes, and follow up on the implementation of suggestions.
5. Through review meetings, monitor product development progress in reference to specified development plan; any change to the specified development plan requires the written approvals of the Steering Committee representatives from all three parties.
 6. Oversee technology transfer from the University to the Development Partner and subsequently from the Development Partner to the Commercialisation Partners; helping the Development Partner and Commercialisation Partners troubleshoot issues whenever possible.
 7. Review, finalise and approve the Development Partner's budget proposal; monitor and ensure adherence to said budget;
 8. Establish milestones for the product development, and
 - i. Approve disbursal requests
 - ii. Approve major capital expense required to be taken out of the project funding
 - iii. Approve major out-sourced vendors that have material bearing on the project time and costs.
 9. Review, provide guidance on and approve staffing plan specific to the product development project.
 10. Decide if audits are required and commission audits on product development activities as needed.
 11. Help set up scientific or advisory panels as required and whenever applicable, recommend experts.
 12. Reporting on product development (to be carried out with help from the project managers designated by the MPP and the Development Partner): review and approve status reports for MPP, University and Development Partner on key parameters of the projects such as: status of technology transfer, progress of product development, milestones met, projected dates of meeting future milestones, deviations from specified development plans with appropriate reasons, challenges and resolution or resolution plan, budget status, regulatory strategy/pathway and updates, regulatory filing status, audit reports, breach of agreements and resolution.
 13. Conferences and meetings: decide on conference participation for presentation on the data relating to the project with the goal of improving visibility of the ARV-SDN formulations and help with uptake; review and approve publications, including conference abstracts, presentations and posters, and publications intended for submission to academic/clinical journals.
 14. Communication: review and approve sections relating to product development in public communications concerning the project.

END OF SCHEUDLE 2

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University	MPP
	

**Schedule 3
The Territories**

Total countries = 137

Group 1 countries (n=65) <Royalty-free> Low-income countries, Least Developed Countries and all countries in sub-Saharan Africa		
Afghanistan	Gambia The	Rwanda
Angola	Ghana	Samoa
Bangladesh	Guinea	Sao Tome and Principe
Benin	Guinea-Bissau	Senegal
Bhutan	Haiti	Seychelles
Botswana	Kenya	Sierra Leone
Burkina Faso	Kiribati	Solomon Islands
Burundi	Korea DPR	Somalia
Cambodia	Lao PDR	South Africa
Cameroon	Lesotho	South Sudan
Cape Verde	Liberia	Sudan
Central African Republic	Madagascar	Swaziland
Chad	Malawi	Tanzania
Comoros	Mali	Timor Leste
Congo	Mauritania	Togo
Congo Dem. Rep.	Mauritius	Tuvalu
Côte d'Ivoire	Mozambique	Uganda
Djibouti	Myanmar	Vanuatu
Equatorial Guinea	Namibia	Yemen
Eritrea	Nepal	Zambia
Ethiopia	Niger	Zimbabwe
Gabon	Nigeria	

Group 2 countries (n=26)		
<Royalty-free if sold in Public Sector; 1% royalty if sold in Private Sector>		
Lower-middle income countries that are not in sub-Saharan Africa and are not Least Developed Countries		
Armenia	Indonesia	Philippines
Bolivia	Kosovo	Sri Lanka
Egypt	Kyrgyzstan	Syria
El Salvador	Micronesia, Fed. Sts.	Tajikistan
Georgia	Moldova	Ukraine
Guatemala	Morocco	Uzbekistan
Guyana	Nicaragua	Vietnam
Honduras	Pakistan	West Bank and Gaza
India	Papua New Guinea	

Group 3 countries (n=46)		
<1.75% royalty>		
Upper-middle income countries that are not in sub-Saharan Africa and are not Least Developed Countries		
Albania	Fiji	Panama
Algeria	Grenada	Peru
American Samoa	Iran	Romania
Azerbaijan	Iraq	Serbia
Belarus	Jamaica	St Lucia
Belize	Jordan	St Vincent and the Grenadines
Bosnia and Herzegovina	Kazakhstan	Suriname
Brazil	Lebanon	Thailand
Bulgaria	Libya	Tonga
China	Macedonia	Tunisia
Colombia	Malaysia	Turkey
Costa Rica	Maldives	Turkmenistan
Cuba	Marshall Islands	Mongolia
Dominica	Mexico	Paraguay
Dominican Republic	Montenegro	
Ecuador	Palau	

Schedule 4
Development Agreement Term Sheet

1. Scope of the grant: MPP will grant a non-exclusive, non-transferable worldwide licence under the Licensed Technology to allow Development Partners to develop, or have developed, ARV-SDNs into Licensed Products in the Field. For the avoidance of doubt no rights are afforded that allow the Development Partner to create new ARV-SDNs or undertake any Licensed Product sales activities.



MPP will require that the Development Partner to perform the following activities:

- (i) Scaling up manufacturing of ARV-SDN at industrial scale
- (ii) Conduct formulation development of ARV-SDNs into Licensed Products in the Field, under oversight of a Steering Committee (as defined below).

For the avoidance of doubt Development Partner will be expressly prohibited from further sub-licensing the Licensed Technology to any other third party.

2. Regulatory/Quality: Development Partner will agree to manufacture all Licensed Product in a manner consistent with (i) World Health Organization ("WHO") pre-qualification standards; and/or (ii) the standards of any Stringent Regulatory Authority, where available. Stringent Regulatory Authority ("SRA") is defined as regulatory authorities which are members, observers or associates of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time. Where such approvals are not yet available, the Development Partner will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.
3. Term: The Sub-licence Agreement will be in force from the date of its signature until the date on which the last to expire Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated.
4. Improvements: If at any time during the term of the Sub-licence Agreement the Development Partner (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it will communicate such Improvement to MPP and University in full together with all available information concerning the mode of working and using the same. MPP and University will treat this information as confidential.
5. Grant-back rights: Development Partner will grant to MPP and University a perpetual, irrevocable, worldwide, royalty-free, non-exclusive, sub-licensable licence over any Improvement (and shall promptly execute such document as University may reasonably request accordingly). Such licence will not affect the Licensee's ownership of the Improvements. MPP will have the right to sub-license such rights to its Commercialisation Partner(s).
6. Waiver of data exclusivity rights: Development Partner 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.

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University	MPP
	


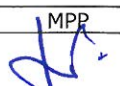
7. Warranty & Indemnity: The Development Partner will acknowledge and agree that the Licensed Technology is licensed to Licensee "as is". University and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Technology is suitable for any purpose for which it may be used by the Development Partner.: The Development Agreement will include indemnification and limitation of liability provisions consistent with Clause 13 of the MPP-University Agreement.

8. Timelines: The Development Agreement will include time lines for the development of ARV-SDN into Licensed Products.

9. Reporting: Within ten (10) business days following the end of each calendar quarter, Development Partner will be required to provide MPP and the University with a quarterly written report setting forth in relation to that quarter the following and those specified under Schedule 2 specific activity 12: (a) summary of project implementation and current schedule of anticipated events or milestones including status of readiness of labs, plants, machinery as required, (b) details of project related specific recruitments and a summary of resources (dollar value) spent in the reporting period if any, (c) scale up of ARV-SDN, (d) Licensed Products in its development pipeline, (e) status of development of each Licensed Product in development, (f) regulatory filing plan for each Licensed Product, and (g) a list of countries within the Territory for which such regulatory approvals or authorizations have been filed or obtained for any Licensed Product, (h) any scientific discoveries or Know-how developed; i)any other information that MPP and University may require to monitor progress and implementation of the projects. MPP and Licensee will agree to meet on a quarterly basis regarding such reports and also review development and filing status of Licensed Products. MPP agrees that information contained in quarterly and other such reports shall be treated as confidential; provided, however, that such information may be shared with the University, MPP's funders, University's funder, and funders, if any, of the project under consideration; and that status update may be publicly disclosed by the MPP or University. Within thirty (30) days of the end of the Development Partner's programme they will deliver to MPP and the University a complete dossier of information allow MPP to effect an efficient technology transfer to the Commercialisation Partner and the University to effect an efficient technology transfer to its licensees outside the Territory.


10. Audit: The Development Partner will permit MPP and University, individually or together, and when required, through a certified public accountant to: (i) inspect and audit the performance of, and compliance with, the Development Agreement and the applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of the Development Agreement. Development Partner will cooperate with and provide all reasonable assistance to MPP or University. MPP or University will provide Development Partner with a commercially reasonable period of notice of the proposed audit. MPP and University, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Development Partner to perform in compliance with the Development Agreement or applicable laws. If any audit reveals a discrepancy of more than 5% to the detriment of the University and/or MPP, Development Partner will reimburse MPP or the University for the cost of that audit.

11. Confidentiality: Confidentiality obligations similar to those established in Clause 12 of the Agreement will be included in the Development Agreement. Subject to such confidentiality obligations, nothing will prevent or hinder registered students of the University from submitting for degrees of the University theses based on the Licensed Technology; or from

University	MPP
	

following the University's procedures for examinations and for admission to postgraduate degree status.

12. Steering Committee: The Development Agreement will contain provisions to create a Steering Committee comprising MPP, University and Development Partner nominated representatives in consistent with the MPP-University Agreement.
13. Trademarks and names: Development Partner will not use the University's or MPP's name or logo nor the name of any of the inventors or other principal researchers in any kind of promotional material other than for the purposes of complying with the Development Agreement, without the prior written agreement of both MPP and University.
14. Third Party Rights: The University will have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of the Development Agreement with the Development Partner.
15. Governing Law/ADR: The governing law for the Development Agreement will be the laws of England in a court of law in England. All disputes will be resolved via an alternative dispute mechanism to be set forth in the agreement.
16. Eligibility: The Development Partner will be eligible to become a Commercialisation Partner by executing a separate Commercialisation Agreement in accordance with Schedule 5.
17. Additional Terms: The Development Agreement will contain other terms necessary or desirable to carry out the intent of the MPP-University Agreement, as well as other mutually agreeable language regarding other additional customary terms.

University	MPP
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Schedule 5
Commercialisation Agreement Term Sheet

1. Scope of the grant: MPP will grant a Commercialization Partner a non-exclusive, non-transferable, royalty-bearing worldwide licence under the Licensed Technology to allow Commercialization Partners to make, use, offer for sale, sell, export and import the Licensed Products for the purposes of commercialising Licensed Products in the Field solely for use within the Territory.



For the avoidance of doubt Commercialisation Partner will be expressly prohibited from further sub-licensing the Licensed Technology to any other third parties and from making sales of Licensed Products for use outside the Territory.

2. Regulatory/Quality: Commercialisation Partner will agree to manufacture all Licensed Product in a manner consistent with (i) World Health Organization ("WHO") pre-qualification standards; and/or (ii) the standards of any Stringent Regulatory Authority, where available. Stringent Regulatory Authority ("SRA") is defined as regulatory authorities which are members, observers or associates of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time. Where such approvals are not yet available, the Commercialization Partner will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.
3. Term: The Commercialisation Agreement will be in force from the date of its signature until the date on which the last to expire Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated.
4. Royalties: Commercialisation Partners will pay royalties over Net Sales within the Territory in accordance with Clause 7 of the MPP-University Agreement and the following terms. Any amounts due to the University shall be paid within 30 days of the end of each calendar year in respect to the amount of royalties generated during that year. All amounts so due will be paid in pounds sterling, by bank transfer to the account nominated by the University, which may be amended from time to time.
- a. For the purpose of calculating royalties, a Licensed Product will be regarded as sold, leased or licensed when invoiced or, if not invoiced, when shipped or delivered by or a Licensee.
 - b. Royalties on Combination Products: If a Licensed Product is not priced separately to a Combination Product, the price of such Licensed Product for the purpose of calculating Net Sales shall be deemed to be the fair market value of the Licensed Product in the country of sale when sold separately. If Licensed Product is sold in combination with other products, the value of the Net Sales of such combination product shall be determined as follows:

$$\text{Net Sales} = A \div (A+B)$$

A is the combined fair market value of all Approved ARVs / Additional ARVs in a Licensed Product,

B is fair market value of the other active pharmaceutical components included in the Licensed Product


University	MPP
	

- c. For the avoidance of doubt sales commissions, costs of collection and disputed amounts are not deductible. If Commercialisation Partner determines the resale price for subsequent transfers of Licensed Product, then Net Sales will be calculated based on the resale invoiced amount. Net Sales accrue at the first of delivery or invoice.
- d. All amounts payable to the University under the Commercialisation Agreement are exclusive of tax or duties which Commercialisation Partner will pay at the rate from time to time prescribed by law.
- e. All payments to the University should be made using the reference "MPP_[Name of Licensee]" to the bank account noted on the invoice.
- f. Royalties shall be calculated using Net Sales and there shall be no royalty stacking provisions applicable to any calculation of the royalties payable to the University.

In the event that there are only pending Licensed Patent(s) not yet granted in the country of manufacture or sale, Commercialization Partner will set aside the royalty amounts for sales of Licensed Products made under the Commercialisation Agreement during the pendency of the Licensed Patent(s), to be payable to the University only upon the issuance of a valid Licensed Patent.

If a Commercialisation Partner receives non-monetary consideration for any Licensed Products, Net Sales are calculated based on the fair market value of that consideration based on the sale of the Licensed Product to an independent third party during the same Royalty Period. Net Sales shall not include any transfers of supplies of the applicable Licensed Product for use in clinical trials, pre-clinical studies or other research or development activities.

- 5. Improvements: If at any time during the term of the Commercialisation Agreement the Commercialisation Partner (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it shall communicate such Improvement to MPP and University in full together with all available information concerning the mode of working and using the same. MPP and University shall treat this information as confidential.
- 6. Grant-back rights: Commercialisation Partner will grant to MPP and University a perpetual, irrevocable, worldwide, royalty-free, non-exclusive, sub-licensable licence over any Improvement (and shall promptly execute such document as University may reasonably request accordingly). Such licence will not affect the Commercialisation Partner's ownership of the Improvements. Commercialisation Partner will agree to engage in good-faith negotiations should MPP desire to further sublicense such Improvements. University shall be entitled to grant sub-licences (without further right to sublicense) to other third parties, provided that it will be prohibited from sublicensing to a Direct Competitor (to be defined in the Commercialisation Agreement) of the Commercialisation Partner in the Territory without its written consent.
- 7. Waiver of data exclusivity rights: Commercialization Partner 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.

University	MPP
JB	

8. Warranty & Indemnity: The Commercialisation Partner will acknowledge and agree that the Licensed Technology is licensed to Commercialisation Partner "as is". University and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Technology is suitable for any purpose for which it may be used by the Licensee. The Commercialisation Agreement will include indemnification and limitation of liability provisions consistent with Clause 13 of the MPP-University Agreement.


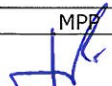
9. Timelines: The Commercialisation Agreement will include time lines for the development, regulatory approvals and placing the Licensed Products in the market.

10. Reporting: Within 10 business days following the end of each calendar quarter, Commercialisation Partner will be required to provide MPP and the University with a quarterly written report setting forth in relation to that quarter (a) Licensed Products in its development pipeline, (b) status of development of each Licensed Product in development, (c) regulatory filing plan for each Licensed Product, (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been filed or obtained for any Licensed Product and (e) the Licensed Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under the Commercialisation Agreement during such agreement quarter, on a country-by-country basis; f) any scientific discoveries or Know-how developed related to the Licensed Technology. MPP and Licensee will agree to meet on a quarterly basis regarding such reports and also review development and filing status of Licensed Products. MPP will agree that information contained in quarterly and other such reports shall be treated as confidential; provided, however, that such information may be shared with the University; and that aggregated data may be publicly disclosed by MPP.

11. Audit: Commercialisation Partner will permit MPP and University, individually or together, through a certified public accountant to: (i) inspect and audit the performance of, and compliance with, the Commercialisation Agreement and the applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of the Commercialisation Agreement. Commercialisation Partner will cooperate with and provide all reasonable assistance to MPP or University. MPP or University will provide Commercialisation Partner with a commercially reasonable period of notice of the proposed audit. MPP and University, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Licensee to perform in compliance with the Commercialisation Agreement or applicable laws. If any audit reveals a discrepancy of more than 5% to the detriment of the University and/or MPP, Commercialisation Partner will reimburse MPP or the University for the cost of that audit.

12. Confidentiality: Confidentiality obligations similar to those established in Clause 12 of the Agreement will be included in the Commercialisation Agreement. Subject to such confidentiality obligations, nothing in the Commercialisation Agreement shall prevent or hinder registered students of the University from submitting for degrees of the University theses based on the Licensed Technology; or from following the University's procedures for examinations and for admission to postgraduate degree status.

13. Trademarks and names: Commercialisation Partner will not use the University's or MPP's name or logo nor the name of any of the inventors or other principal researchers in any kind of packaging and promotional material other than for the purposes of complying with the Commercialisation Agreement, without the prior written permission of both MPP's and the University's authorised representative. Licensed Product manufactured under the

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Commercialization Agreement will be marked (to the extent not prohibited by law): (i) with a notice that such Licensed Product is sold under a license from the University and MPP; and (ii) with all markings and notices as may be required by applicable law, including in relation to patent and other intellectual property.

14. Third Party Rights: The University, will have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of the Commercialisation Agreement with the Commercialisation Partner.
15. Governing Law/ADR: The governing law for the Commercialisation Agreement will be the laws of England in a court of law in England. All disputes will be resolved via an alternative dispute mechanism to be set forth in the Commercialisation Agreement.
16. Compliance with Laws: Commercialisation Partner shall be solely responsible at its own expense for ensuring that its performance, the Licensed Technology and the Licensed Products comply with all applicable laws, rules, regulations, orders, decrees, judgments and other governmental acts of any foreign governmental authorities having jurisdiction over the Commercialisation Partner (including any health and safety rules and regulations and any patent, copyright, trademark or other infringement laws).
17. Insurance: Within 30 days prior to the first commercial launch by Commercialization Partner of a Licensed Product, and each year thereafter for so long as the Commercialisation Agreement is in effect, Commercialisation Partner shall provide to MPP certificates of insurance by insurers acceptable to MPP evidencing comprehensive general liability coverage, including products liability, with a combined limit of no less than 10 million dollars (\$10,000,000.00) for bodily injury, including personal injury, and property damage.
18. Additional Terms: The Commercialisation Agreement will contain other terms necessary or desirable to carry out the intent of the MPP-University Agreement, as well as other mutually agreeable language regarding other additional customary terms.

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