

PATENT AND KNOW-HOW LICENCE AGREEMENT
by and between

MEDICINES PATENT POOL
and
[SUBLICENSEE]

MEDICINES PATENT POOL (hereinafter referred to as **MPP**), a Swiss foundation located at 7 Rue de Varembe, 1202 Geneva, Switzerland, acting as implementing partner of the World Health Organisation (“WHO”) COVID-19 Technology Access Pool initiative (“WHO C-TAP”)

AND

[SUBLICENSEE] [complete] (hereinafter referred to as **Sublicensee**)

Each of MPP and the Sublicensee shall be referred to as a “Party”, and collectively, as the “Parties”.

The Parties, mutually recognising each other’s legal capacity to execute this Agreement (as defined below), for this purpose

PREAMBLE

WHEREAS MPP is a non-profit organisation with a mission to improve the health of people by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property to allow for the rapid development and manufacturing of these medicines;

WHEREAS WHO C-TAP was established to implement the Solidarity Call to Action launched by WHO Costa Rica and 44 WHO Member States to provide a platform for the developers of COVID-19 vaccines, medical devices including diagnostics, and therapeutics to share their data, know-how and intellectual property rights, with quality assured manufacturers. Technology holders are called to voluntarily license such rights on a transparent, non-exclusive, and worldwide basis through implementing partners like the MPP to facilitate further development and widescale production, distribution, sale and use of such health technologies throughout the world promoting equitable, affordable and timely access to their products for all countries, as further described in WHO C-TAP concept paper, attached to the MEDIGEN-MPP Agreement.

WHEREAS MPP, as an implementing partner of WHO C-TAP, obtained a non-exclusive licence of the Licensed Technology with the right to sublicense to Third Parties to encourage generic manufacture and the development of COVID-19 vaccine (“**MEDIGEN-MPP Agreement**”).

NOW THEREFORE, for and in consideration of the above recitals and the mutual covenants contained herein, MPP and the Sublicensee, intending to be legally bound, hereby AGREE AS FOLLOWS:

1. DEFINITIONS

In this Agreement the following terms, whether used in the singular or plural, shall have the following meanings:

“Agreement” means this sublicense agreement including any and all annexes, appendices and other addenda to it as may be added and/or amended in accordance with the provisions of this document.

“Agreement Quarter” means any period of three months ending on the last day of March, July, October or December.

“Commercialisation”, “Commercialising”, or “Commercialise” means any and all activities relating to the labelling, advertising, promotion, marketing, pricing, distribution, storage, handling, offering for sale and selling or having sold, and customer service and support.

“Confidential Information” means any and all information, including but not limited to technical, scientific and business information, knowledge, Licensed Know-how, data and Materials of a confidential or proprietary nature owned or controlled by a Party (“Disclosing Party”) and disclosed to the other Party (“Receiving Party”) under this Agreement.

“Customers” means any entity of which the Sublicensees receives any type of revenue derived from the exploitation of the Licensed Technology.

“Development”, “Developing” or “Develop” means activities associated with the development of Product, including but not limited to, validation, product studies and analysis, stability testing, process development, quality assurance, quality control, pre- and post- Regulatory Approval studies, and regulatory affairs.

“Disclosing Party” means, in reference to a piece of Confidential Information, the Party that first discloses such piece of Confidential Information to the other Party under this Agreement.

“Effective Date” means the date of last signature of this Agreement.

“Field” means all Covid-19 vaccines for human use, which includes without limitation: (i) MEDIGEN’s intramuscular subunit COVID-19 vaccine, (ii) MVC-COV1901, its updated constructs to address mutations of the SARS-CoV-2 virus and/or other coronaviruses and any variants thereof, (iii) the vaccine consisting of the stabilised prefusion spike protein of the coronavirus – antigen - in combination with adjuvants for use in humans.

“HIEs” means all high-income economies in accordance with the World Bank country classification as of January 1 of each year.

“Improvement” means any new or improved process, any new or improved know-how, or manufacturing techniques or any further invention which relate to the manufacture or formulation of the Products or incorporate or are based on the Patent Rights.

“Licensed Know-how” means know-how, information, data and other technical knowledge owned and/or controlled by MEDIGEN that are useful or otherwise relevant for the development and/or manufacture of COVID 19 vaccine as described in ANNEX 2 hereto.

“Licensed Technology” means the Patent Rights, Material, and Licensed Know-How, including without limitation MEDIGEN New Developments actually licenced to the Sublicensee as contemplated hereby.

“LIEs” means all low-income economies according to the World Bank country classification as of January 1 of each year.

“LMIEs” means all lower-middle income economies according to the World Bank country classification as of January 1 of each year.

“Material” means materials useful for the development and/or manufacturing of COVID 19 vaccines owned and/or controlled by MEDIGEN as described in Schedule 2 of the Medigen-MPP Agreement.

“MEDIGEN New Developments”, “Inscope MEDIGEN New Developments”, “Additional MEDIGEN New Developments”, and “Significant Inscope MEDIGEN New Developments” have the meanings attributed thereto in Clause 9.1 of this Agreement.

“Net Sales” means, with respect to the Product, the gross amount invoiced on sales by Sublicensees, their affiliates or distributors to arm’s length Customers (or, where the sale is not at arm’s length, the price that would have been so invoiced if such sale had been at arm’s length) in any country of the world less the following deductions, to the extent included in the sales invoice with respect to such Product:

- i. normal and customary trade and quantity discounts actually given (discounts which all together cannot exceed 20% of the sales price provided, that, where the Product is included as part of any program based on multiple product offers, such discounts shall be consistent with the discounts applied to the same Customer when the Product is not combined with any other products or services; and, in case of returns or rejections of Products, the associated credits and price adjustments; and
- ii. sales, value-added, and excise taxes, tariffs, and other taxes and government charges directly related to the sale of the Product and actually borne by Sublicensees without reimbursement from any Third Party, excluding any taxes assessed against the income derived from such sale.

provided, that, Net Sales shall not include the use of the Product in field tests, marketing, or other similar programs or studies where Product is supplied without charge, (but shall include any amount invoiced for such use).

“Patent Rights” means any right recognised by the applicable patent legislation or regulation and generated by claiming the priority of the patent application, the patents and patent applications set out in ANNEX 1 hereto as may be amended from time to time, such as the rights generated by:

- i. any patent application, any continuation-in-part, division, extension for any such application, and any patent issuing on such application;
- ii. inventor certificates, utility models and petty patents.

“Product” means any COVID-19 vaccine which is based, in whole or in part on the Licenced Technology.

“Receiving Party” means, in reference to a piece of Confidential Information, the Party that receives such piece of Confidential Information from the Disclosing Party under this Agreement.

“Regulatory Approval” means any approval, registration, license or authorisation from any authority worldwide required for the Development, manufacture or Commercialisation of Product.

“Stringent Regulatory Authority” means a regulatory authority which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

“Third Party” means any entity other than a Party.

“UMIEs” means all upper middle-income economies according to the World Bank country classification as of January 1 of each year.

“Valid Claim” means a claim:

- i. of an issued and unexpired patent included within the Patent Rights, which has not been permanently considered as non-applicable under a decision of a court or other competent governmental agency, or
- ii. in a patent application included within the Patent Rights that is being actively prosecuted in accordance with this Agreement.

2. SCOPE OF THE GRANT

2.1. Subject to the terms and conditions of this Agreement, MPP hereby grants a worldwide, non-exclusive, non-transferable, licence to the Sublicensee to use the Licensed Technology, to:

- i. Develop, or have developed Products in the Field, and
- ii. Make and have made, use, Commercialise, export or import the Products exclusively for ultimate use in the Field.

2.2. No rights are hereby granted for the Additional Technologies, as defined in the Medigen-MPP Agreement, and the Sublicensee will require the prior written approval of each owner.

2.3. The Sublicensee shall ensure that the Products are made available worldwide at affordable pricing.

3. FEES and ROYALTIES

3.1. **Technology fees.** The Sublicensee shall pay directly to MEDIGEN by bank transfer to the account indicated on the invoice the following technology fees:

- i. a one-time fee of 10,000 US Dollars for Sublicensees from LIE and LMIEs or a one-time fee of 100,000 US Dollars for the Sublicensees from UMIEs and HIEs, due at the Effective Date (the "**Licence Fee**"). The Licence Fee is not refundable and is in addition to and not creditable against any other sums payable by Sublicensee under this Agreement; and
- ii. a one-time fee of 150,000 US Dollars for Sublicensees from LIE and LMIEs, or a one-time fee of 300,000 US Dollars for the Sublicensees from UMIEs and HIEs due at the receipt of by the Sublicensee of the Licensed Technology documentation listed in Annex 2 hereto, and
- iii. a one-time fee of 100,000 US Dollars for Sublicensees from LIE and LMIEs, or a one-time fee of 200,000 US Dollars for the Sublicensees from UMIEs and HIEs due and payable on the date falling six (6) months after the Effective Date as compensation for Basic Support and Training as described in ANNEX 2 hereto, and
- iv. a one-time fee of 100,000 US Dollars for Sublicensees from LIE and LMIEs, or a one-time payment of 200,000 US Dollars for the Sublicensees from UMIEs and HIEs due upon notice from MEDIGEN that the Materials are ready for pick up as compensation for Materials preparation work.
- v. a one-time payment upon the first launch of the Product amounting to:
 - a) 25,000 US Dollars in the first country of LIEs; and
 - b) 75,000 US Dollars in the first country of LMIEs; and
 - c) 150,000 US Dollars in the first country of UMIEs; and
 - d) 300,000 US Dollars in the first country of HIEs,
- vi. a running technology fee of:
 - a) 3% of Net Sales in LIEs; and
 - b) 5% of Net Sales in LMIEs; and
 - c) 8% of Net Sales in UMIEs; and
 - d) 10% of Net Sales in HIEs,

payable on a country-by-country basis starting from the date of the first commercial sale of the Product in each country and continuing until the date falling (15) years after

the date of each such first commercial sale ("Base Period"); provided, that, if, at any time during the Base Period, there occurs one or more transfers of technology arising out of Inscope MEDIGEN New Development, the above period shall continue to the later of (i) last day of the Base Period or (ii) the date falling **five (5) years** after the date of the last such transfer related to a Significant Inscope MEDIGEN New Developments (such later date to be referred to herein as the "**Expiry Date**").

3.2. **Patent royalties.** The Sublicensee shall pay directly to MEDIGEN by bank transfer to the account indicated on the invoice the royalties on Net Sales of the Products on a country-by-country basis starting from the date of the first commercial sale of the Products will be paid as described below:

- a) a royalty of 0,5% of Net Sales in LIEs; and
- b) a royalty of 1% of Net Sales in LMIEs; and
- c) a royalty of 3% of Net Sales in UMIEs; and
- d) a royalty of 5% of Net Sales in HIEs,

provided, that the royalties are due where there is a Patent Right granted and in force in the country of manufacture or sale, until the expiry of the last-to-expire Patent Right in such country.

3.3. **Additional payment obligations for Additional MEDIGEN New Developments.** If at any time during the Base Period, there shall occur one or more transfers of technology arising out of an Additional MEDIGEN New Development, the technology fees and term ("**Additional MEDIGEN New Development Term**") therefor shall be agreed between the Parties and MEDIGEN in consultation with WHO C-TAP, at the time of such transfer.

3.4. **Payment modalities.** All payments to be made to MEDIGEN hereunder shall be made in freely transferable U.S. Dollars to the account specified by MEDIGEN in a jurisdiction other than the jurisdiction of the Sublicensee, free and clear of foreign exchange controls, taxes and duties (other than income taxes payable by MEDIGEN in the location where MEDIGEN operates from at the time of payment) ("**Taxes**"), all of which Taxes shall be borne by the Sublicensee. If any Taxes are imposed on any such payment whether by withholding or otherwise, the Sublicensee shall gross up the amount paid such that after giving effect to such Taxes, MEDIGEN receives the amount it would have otherwise received had no such Taxes been imposed.

4. DEVELOPMENT AND REGISTRATION

4.1. The Sublicensee agrees that it will manufacture the Product in a manner consistent with (i) WHO pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority, defined as a regulatory authority which was a member or observer of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**"), or associated with an ICH member through a legally-binding, mutual recognition agreement, in each case as before 23 October 2015. Where such standards are not yet available, the Sublicensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.

4.2. The Sublicensee shall:

- i. obtain from the relevant authorities in each country and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorisations relating to the importation, manufacture and sale of the Products which are necessary to enable the Products to be sold or supplied in each country in accordance with this Agreement.

- ii. file for WHO Pre-qualification or any Stringent Regulatory Authority approval as soon as possible and in any event not later than within 24 months from the Effective Date in each case using the fastest approval route possible and will diligently pursue such applications following submission.
- iii. manufacture and sell the Products in accordance with all laws and regulations relevant to the manufacture and sale of the Products and in accordance with good industry practice.

4.3. If the Sublicensee manufactures, sells, supplies or otherwise disposes of any Product but has not obtained the necessary compliance with laws or approvals as per this Agreement, MPP shall be entitled to immediately terminate this Agreement by providing written notice to the Sublicensee.

5. KNOWLEDGE AND MATERIAL TRANSFER

5.1. MEDIGEN shall, subject to any applicable technology export control regulations or policies in any applicable jurisdiction, make the transfer of Licensed Know-How and Material to the Sublicensee, in accordance with the scope, quantities and timelines set out in Annex 2 hereto or as otherwise agreed between MEDIGEN and the Sublicensee. The technology transfer hereunder shall be considered successful when the Sublicensee has accomplished vaccine production, meeting the requirements of this Agreement and the associated transfer plan to be agreed among MPP, MEDIGEN and the Sublicensee. MEDIGEN will provide the Sublicensee with applicable regulatory exclusivity waivers, to the extent required by the Relevant Regulatory Authorities for national registration of the Products).

5.2. The Material will be provided at cost (including manufacturing and direct overhead), which costs will be disclosed to MPP and Sublicensee upon request in advance. Risks of loss shall pass to the Sublicensee, Ex-Factory, factory location as defined by MEDIGEN at time of shipment. All transportation from MEDIGEN designated factory and all matters related to import into country of destination shall be for the account, and at the cost, of the Sublicensee.

5.3. Sublicensee agrees to:

- i. accept remote (telephone, e-mail, on-line, etc.) assistance where applicable; and
- ii. allocate a sufficient and technically capable workload to knowledge transfer activities and ensuring that its contract manufacturer does the same.

5.4. Save as expressly provided in Clause 3 above, or ANNEX 2 hereto, each of MPP, Sublicensee and MEDIGEN will carry its own costs related to knowledge and material transfer under this clause 4.

5.5. MPP shall promptly notify the Sublicensee in writing of any MEDIGEN New Developments which is notified by MEDIGEN to MPP specifying whether such is an Inscope MEDIGEN New Development or Additional MEDIGEN New Development and the Sublicensee may elect, upon written notice given to MPP and MEDIGEN to include such MEDIGEN New Development in the licence grant hereunder whereupon the relevant know how and Materials (if any) shall be transferred to the Sublicensee as contemplated in ANNEX 2 hereto on the terms as provided in Clause 3 above, or, if applicable, as separately agreed.

6. CONFIDENTIALITY

6.1. Treatment of Confidential Information. Each of the Parties shall ensure that, during the Term of this Agreement and during ten (10) years thereafter, Confidential Information:

- i. shall not be copied or disclosed in whole or in part by or to Third Parties without having obtained the express written authorisation from the Disclosing Party, except that such written authorisation shall not be necessary in the following instances:
 1. Regulatory filings;
 2. Prosecuting or defending litigation;
 3. Complying with applicable governmental laws and regulations; and
 4. Disclosure in connection with this Agreement to its staff, consultants, actual or potential donors, advisors, officers and non-voting Board Members, subcontractors, or licensees on a “need-to-know” basis and using the same diligence as that used by the Receiving Party in protecting its own proprietary information;
- ii. shall not be used in whole or in part for any purpose other than the execution of this Agreement;

The Parties shall be liable to each other and MEDIGEN for breach of this obligation, whether by its employees, associates or any other person to whom the Confidential Information was disclosed.

In the event that there is current legislation on the protection of personal data, the Parties declare their recognition and respect for it.

6.2. Exceptions in the Treatment of Confidential Information. Notwithstanding Clause 6.1., neither Party shall be liable for use or disclosure of Confidential Information that:

- i. is published or becomes generally known to the public through no fault or omission of the Receiving Party; or
- ii. is independently developed by or for the Receiving Party without reference to or reliance upon the Confidential Information and such development can be evidenced by written documentation upon request by the Disclosing Party; or
- iii. is rightfully known by the Receiving Party prior to the date of disclosure to the Receiving Party and such knowledge can be evidenced by written documentation upon request by the Disclosing Party; or
- iv. The information received comes from a Third Party that does not require secrecy, or
- v. is required to be disclosed by law or by judicial or administrative request. In this case, the Receiving Party will immediately notify the Issuing Party of such request so that it can file the appropriate precautionary measures, and will not disclose more Confidential Information than that which is strictly required by the judicial or administrative order.

6.3. Publication of this Agreement. The Parties agree that a copy of this Agreement may be publicly disclosed MPP’s, WHO C-TAP’s and MEDIGEN’s and the Sublicensee’s website. Such disclosure will not constitute a breach of either Party’s obligations under this Clause 6.

7. TERM

This Agreement shall enter into force on the Effective Date and, unless earlier terminated in accordance with Clause 12, its duration will continue in force until the later to occur of (i) date the on which the last Patent Right has expired, lapsed or has been invalidated, or (ii) the Expiry Date (the “Term”); provided, that, with respect to each transfer of technology arising from an Additional MEDIGEN New Development, “Term” shall be read to mean the relevant MEDIGEN New Development Term.

8. ASSIGNMENT

The Sublicensee is not entitled to assign, transfer, partially or totally by any means, its position in the subject Agreement in favour of a Third Party. This Agreement, the rights, duties and obligations hereupon granted to or due by the Sublicensee are all personal to the Sublicensee. The Sublicensee agrees not to sell, assign, transfer, mortgage, pledge, or hypothecate any such rights in whole or in part, or delegate any of its duties or obligations under this Agreement without the prior written consent of MPP and MEDIGEN, which shall not be unreasonably withheld. The merger, consolidation, or reorganisation of the Sublicensee with one or more Third Parties shall not entitle the Sublicensee to transfer substantially any of the rights granted by this Agreement without the written consent of MPP and MEDIGEN, such consent not to be unreasonably withheld, conditioned or delayed.

9. INTELLECTUAL PROPERTY RIGHTS

9.1. MEDIGEN will own the entire right, title and interest in and to any and all inventions conceived solely by MEDIGEN (or its Affiliates) or on its behalf, by its respective employees and agents after the Effective Date relating to the Product in the Field, including any adaptation of any manufacturing process or proprietary drug delivery or formulation technology of MEDIGEN or its Affiliates for the production of the Product in the Field, and any patents covering such invention ("**MEDIGEN New Developments**"), subject to the license grant to the Sublicensee set out in Clause 2 hereof. MPP shall notify Sublicensee in writing of any MEDIGEN New Developments as soon as it receives relevant information from MEDIGEN pursuant to the MEDIGEN-MPP Agreement.

9.2. (i) If the MEDIGEN New Developments do not involve an adjustment in antigen or adjuvant amount, change in vaccine composition to bivalent or multivalent vaccine containing multiple antigens, a delivery method other than intramuscular delivery or a combination vaccine, such shall be considered "**Inscope MEDIGEN New Developments**".

(ii) If such Inscope MEDIGEN New Developments require comprehensive additional phase 3 clinical efficacy study(ies) such developments shall be considered **Significant Inscope MEDIGEN New Developments** and may be made available to the Sublicensee at the Sublicensee's election as provided in Clause 3.1(vi) above and ANNEX 2 hereto. If such Inscope MEDIGEN New Developments are not Significant Inscope MEDIGEN New Developments, they will be made available without additional charge or extension of the Expiry Date.

(iii) If such MEDIGEN New Developments are other than Inscope MEDIGEN New Developments such shall be considered an **Additional MEDIGEN New Developments** and may be made available to the Sublicensee at the Sublicensee's election as provided in Clause 3.3 above and ANNEX 2 hereto.

9.3. If at any time during the term of this Agreement, the Sublicensee (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 MEDIGEN in full together with all available information concerning the mode of working and using the same. MPP and MEDIGEN shall treat this information as Confidential Information.

9.4. The Sublicensee hereby grants to MPP and MEDIGEN a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use any Improvement, Improvement Patent and related Know-How (and shall promptly execute such document as MEDIGEN may reasonably request accordingly) in the Field. MEDIGEN shall be entitled to grant sublicences (without further right to sublicense) under such licence only to its Affiliates; and/or contract manufacturers, distributors and service providers solely for use in connection with their engagement of Commercialising MEDIGEN products. The Sublicensee

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

9.5. If any suit or claim by a Third Party is instituted against MPP or the Sublicensee for patent infringement involving the Products, the Party sued shall promptly notify MPP and MEDIGEN in writing. MEDIGEN shall have the right, but not the obligation, to defend or to conduct the defense of such suit or claim at its own expense. The Sublicensee shall assist MEDIGEN and co-operate in any such litigation at MEDIGEN's request and expense.

9.6. MEDIGEN (and in no circumstances the Sublicensee) shall be entitled to bring infringement action in relation to the Patent Rights and Licensed Know-How at its own expense. To the extent MEDIGEN decides not to bring any such infringement action, MEDIGEN shall not be liable to the Sublicensee in any respect for such decision. The Sublicensee shall assist MEDIGEN and co-operate in any such litigation at MEDIGEN's request without expense to the Sublicensee.

9.7. The Sublicensee shall have the right to apply any trademark or brand name on vaccines based on Licensed Technology which vaccines are Commercialised by MEDIGEN in the Field and worldwide so long as none thereof infringe the trademarks or brands of MEDIGEN.

10. WARRANTIES and INDEMNITY

10.1. Parties Representations and Warranties

- i. Each Party declares and warrants to the other Party as of the Effective Date that it: (a) has the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; and (b) has been duly authorised to execute this Agreement and that this Agreement constitutes a legal, valid and binding obligation enforceable against such Party in accordance with its terms except to the extent that enforceability may be limited by bankruptcy, insolvency or other similar situation affecting creditors' rights.
- ii. The Sublicensee:
 1. represents and warrants that it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity) and aims to achieve greater equity along those lines in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates.
 2. shall be respectful of its employees' right to freedom of association and shall encourage compliance with the standards referred to in Clause 10 by any supplier of goods or services that it uses in performing its obligations under this Agreement.
 3. shall comply fully at all times with all applicable laws and regulations, including but not limited to drugs' safety, pharmacovigilance, anti-corruption and anti-bribery laws.

10.2. Disclaimer of Warranties. No Party makes any declaration or warranty other than those expressly provided hereunder.

10.3. Indemnity. The Sublicensee hereby agrees to indemnify MPP and MEDIGEN and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "Indemnified Person") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgments, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("Losses"), that arise in connection with (i) the Sublicensee's breach of this Agreement; or (ii) the Sublicensee's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Products manufactured by or on behalf of the Sublicensee pursuant to this Agreement), provided that the indemnification obligation established in this Clause shall not apply to the extent such Losses arise out of negligence or willful misconduct by MPP or MEDIGEN and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns.

10.4. Insurance. Immediately upon the first administration of a Product to a human in accordance with this Agreement, and for a period of ten (10) years after the expiration or earlier termination of this Agreement, the Sublicensee shall obtain and/or maintain, at its sole cost and expense, product liability insurance in amounts which are reasonable and customary in the pharmaceutical industry of the countries in which the Products are manufactured, distributed and sold (as relevant). Such product liability insurance shall insure against all liability, including product liability, personal liability, physical injury or property damage naming MPP and MEDIGEN as additionally insured. The Sublicensee shall provide written proof of the existence of such insurance to MPP and MEDIGEN within 30 days after entering into or renewing each such policy or otherwise upon request.

11. REPORTS

11.1. The Sublicensee shall keep MPP and MEDIGEN regularly informed of the progress made by the Sublicensee under this Agreement. Within 30 days following the end of each Agreement Quarter, the Sublicensee shall, including for its distributors, provide MEDIGEN and MPP with a written quarterly report, in a format to be agreed, on:

- i. all Products in its development pipeline and the status of each Product in development;
- ii. all Products sold or supplied by the Sublicensee under this Agreement during such Agreement Quarter including, without limitation the vaccine name, number of doses/number of vaccine container units of the vaccines, net sales value, royalty percentage and sum of royalty;
- iii. all regulatory activities regarding the Products worldwide in relation to that Agreement Quarter i.e. (a) the regulatory filing status and plan for every Product worldwide, and (b) a list of the countries in which applications for Regulatory Approval have been filed and/or Regulatory Approvals have been obtained for any Product; and

11.2. The Parties agree to confer on a bi-annual basis regarding such reports. MPP agrees that information contained in quarterly and other such reports shall be treated as Confidential Information.

11.3. At all times the Sublicensee 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 a period of five (5) years of all quantities of Materials and Products manufactured, sold and/or supplied under the licences granted by this Agreement and such information of the type and in sufficient detail at MPP's discretion. MPP and MEDIGEN shall each have the right (and the Sublicensee shall procure such right), through a certified public accountant or like person appointed by it, to examine such records in order to verify the compliance with this Agreement during regular

business hours during the term of this Agreement and for six months after its termination or expiry; provided, however, that such examination:

- i. shall be at the expense of the person exercising such right (save where such examination reveals a breach of this Agreement by the Sublicensee, in which case the Sublicensee shall pay for all costs incurred by MPP in carrying out the examination),
- ii. 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.

12. PHARMACOVIGILANCE

The Sublicensee shall comply with the following Pharmacovigilance obligations.

12.1. The Sublicensee shall, upon the request of any health authority, pharmacovigilance regulator, MPP, WHO C-TAP or MEDIGEN, provide information required with respect to any adverse event as follows (or within any such shorter period as may be required by law):

- (i) Within 48 hours of notification or first awareness by employee or contracted worker (“Known Time”) in case of death or life-threatening event;
- (ii) Within 7 calendar days of Known Time by employee or contract worker in case of:
 - Persistent or significant Disability/incapacity
 - Congenital Anomaly / Birth defect
 - Hospitalization or prolongation of existing Hospitalization
 - Other medically important condition

12.2. If Sublicensee discovers any potential Emerging Safety Issue which may lead to an Urgent Safety Measure (USM) or Urgent Safety Restrictions (USR), Sublicensee shall report to MPP and MEDIGEN what measures will/have been taken and the reasons why via pmpv@medigenvac.com within 48 hours of Known Time.

12.3. Sublicensee shall provide MPP and MEDIGEN a Periodic Benefit Risk Evaluation Report (formerly known as Periodic Safety Update Report). Every 6 months for the first 2 years from date of [emergency use authorisation] in each country and then annually for the following 3 years.

12.4. Should Emergency Use Authorization be discontinued by regulatory authorities in any country in which the Product is sold, or WHO no longer declares COVID-19 a Public Health Emergency (PHE), the Sublicensee shall mutually agree with MEDIGEN or on reporting schedule per the strictest schedule imposed upon MEDIGEN by any regulatory authority for which MEDIGEN must report Adverse Events.

13. TERMINATION

13.1. Termination. This Agreement will be terminated either by its fulfilment, i.e., by expiration of the Term as defined in Clause 7, or by its termination by the following Clause.

13.2. Termination for breach. Any Party shall have the right to terminate the Agreement when there has been a material breach by the other Party, which is not cured within 60 days after receiving a written notice specifying the nature of the breach.

13.3. Consequences of Termination.

13.3.1. In the event that this Agreement is terminated prior to the expiry of the Term and due to breach by the MPP this Agreement, will, upon written approval by MEDIGEN, such consent not to be unreasonably withheld, be converted into a licence between MEDIGEN and the Sublicensee, provided that the Sublicensee shall not be in breach of this Agreement, by way of MPP, MEDIGEN and the Sublicensee entering into a novation agreement transferring the rights and obligations of the MPP under this Agreement to MEDIGEN.

13.3.2. In the event that this Agreement is terminated prior to the expiry of the Term, each Party shall promptly return to the Other Party or the MEDIGEN, as applicable, or (at the other Party's or, if applicable, MEDIGEN'S election) destroy and irretrievably erase all embodiments of the other Party's, MEDIGEN's Confidential Information and remaining Materials which are in its power, possession, custody or control; provided that and each Party may retain one copy of such Confidential Information or a Materials' sample for the sole purpose of performing any continuing obligations hereunder or for archival purposes or as (and to the extent) required by applicable laws and shall continue to comply with the terms of Clause 6 in respect of the same.

14. NOTICES

Any notice given in connection with this Agreement shall be in writing and shall be deemed given upon actual receipt by the addressee. Notices may be given by email followed by prompt confirmation by registered or certified air mail, postage prepaid and shall always be sent by registered or certified air mail, postage prepaid, addressed to the Party to be notified at the following address, or at such other address as the Party may designate:

At MPP:

Attn: General Counsel
Rue de Varembé 7, 1202 Geneva Switzerland
Tel: +41 (0)22 533 50 50
legal@medicinespatentpool.org

At Sublicensee:

Attn.:
Address:
Email:

15. GOVERNING LAW AND JURISDICTION

15.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of Switzerland. Parties hereby waive of any of the privileges and immunities enjoyed under national or international law.

15.2. Jurisdiction and Dispute Resolution. The Parties shall use all reasonable efforts to solve any dispute, controversy or claim that may arise under this Agreement through good faith negotiations. In the event that the Parties are unable to resolve a dispute within sixty (60) calendar days from the date such dispute is first brought to the other Party's attention, any dispute, controversy, or claim arising out of, or in relation to, this contract, including regarding the validity, invalidity, breach, or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Arbitration Centre in force on the date on which the Notice of Arbitration is submitted in accordance with those Rules. The number of arbitrators shall be three. The seat of the arbitration shall be Geneva, Switzerland. The arbitral proceedings shall be conducted in English.

15.3. If there are any disputes in connection with this Agreement, including its termination under Clause 12, all rights and obligations of the Parties shall continue until such time as any dispute has been resolved in accordance with the provisions of this Clause.

16 MISCELLANEOUS

16.1. Entire Agreement. This Agreement and its annexes contain the entire agreement between the Parties and shall supersede all previous agreements and understandings between the Parties and predecessors with regards to the contents of this Agreement. The Parties waive the right to rely on any alleged express provision not contained in this Agreement, as regards the specific aspects related to its provisions.

16.2. Modification. Any modification to the Agreement shall only be valid if made in writing and duly signed by the authorised representatives of the Parties and approved in writing by MEDIGEN.

16.3. No representation. This Agreement does not authorise any Party to act as representative or agent of the other Party, nor shall it represent that it in fact has such authority. No Party shall have any authority to make statements, representations or commitments of any kind or take any other action binding on the other, except as specifically provided in this Agreement.

16.4. Third Party Beneficiary. MEDIGEN and/or any of its Affiliates shall be considered a third-party beneficiary to this Agreement and shall have the right to enforce and rely on the terms of this Agreement. The Sublicensee expressly agrees that MEDIGEN and/or any of their Affiliates shall be entitled to enforce any of the provisions of this Agreement as if they were named as a Party to this Agreement in place of the MPP. The rights of MPP under this Agreement shall be applicable to MEDIGEN to the same extent as for MPP.

16.5. Severability. If any provision of this Agreement is declared in a final unappealable order by a court/tribunal of competent jurisdiction to be invalid, illegal, unenforceable, or void, then both Parties shall be relieved of all obligations arising under such provision, but only to the extent that such provision is invalid, illegal, unenforceable, or void in the jurisdiction. If the remainder of this Agreement is capable of substantial performance, then each provision not so affected shall remain binding upon the Parties hereto to the extent permitted by law.

16.6. Headings. The headings in this Agreement are for reference only and shall not in any way control the meaning or interpretation of the corresponding clauses.

16.7. Survival. Clauses 14 and 15 shall survive the expiry or termination of this Agreement.

IN WITNESS WHEREOF, MPP and the Sublicensee have caused this Agreement to be duly executed by their authorised representatives, in two counterparts on the Effective Date.

MEDICINES PATENT POOL

[SUBLICENSEE]

Mr. Charles Gore
Executive Director
Date:

Name:
Title:
Date:

ANNEX 1: The Patents [to MEDIGEN – to update before the signature]

Patent Portfolio for MVC-COV1901

Client Name: Medigen Vaccine Biologics Corp.
(M0018)

Updated on: [complete]

Series	Docket No.	Title [Inventors]	Applicant	Country	Filing Date Filing No.	Status/ Note
VC-COV1901 (filed by MVC)	This series of patent application relates to an immunogenic composition against SARS-CoV-2, and the composition comprises prefusion spike protein of SARS-CoV-2 (Wuhan strain) and adjuvant selected from an aluminum-containing adjuvant and/or an unmethylate cytosine-phosphate-guanosine (CpG) motif.					
	P21-0140	Immunogenic Composition Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) [Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU, John D. CAMPBELL 、 Robert S. JANSSEN 、 David NOVACK]	MVC, Dynavax	TW	2021/06/18 110122289	Not published yet.
	P21-0141	Immunogenic Composition Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) [Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU, John D. CAMPBELL 、 Robert S. JANSSEN 、 David NOVACK]	MVC, Dynavax	PCT	2021/06/18 PCT/CN2021/100826	Claiming priority of US 63/040,696 (2020/06/18) and PCT/US21/20277 (2021/03/01) WO Pub. No.: WO2021254473; Pub. date: 2021/12/23 National Phase entry due: 2022/12/18

	P21-0142	Immunogenic Composition Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) [Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU, John D. CAMPBELL, Robert S. JANSSEN, David NOVACK]	MVC, Dynavax	US	2021/06/18 17/351,363	Claiming priority of US 63/040,696 (2020/06/18) and PCT/US21/20277 (2021/03/01) US Pub. No.: 2021-0308257; Pub. date: 2021/10/07
MVC-COV1901 (filed by Dynavax)	This series of patent application relates to an immunogenic composition for stimulating an immune response against SARS-CoV-2, and the composition comprises prefusion spike protein of SARS-CoV-2 (Wuhan strain) and a toll-like receptor 9 (TLR9) agonist, which is an unmethylate cytosine-phosphate-guanosine (CpG) motif.					
	37788-20078.41TW	CORONAVIRUS VACCINES COMPRISING A TLR9 AGONIST [John D. CAMPBELL, Robert S. JANSSEN, David Novack, Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU]	MVC, Dynavax	TW	2021/03/02 110107350	Claiming priority of US 62/983,737 (2020/03/01) TW Pub. No.: 202146045; Pub. date: 2021/12/16
	37788-20078.40PCT	CORONAVIRUS VACCINES COMPRISING A TLR9 AGONIST [John D. CAMPBELL, Robert S. JANSSEN, David Novack, Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU]	MVC, Dynavax	PCT	2021/03/01 PCT/US2021/20277	Claiming priority of US 62/983,737 (2020/03/01) and US 63/040,696 (2020/06/18) WO Pub. No.: WO2021178306; Pub. date: 2021/09/10 National Phase entry: US and EP
	NA	CORONAVIRUS VACCINES COMPRISING A TLR9 AGONIST [John D. CAMPBELL, Robert S. JANSSEN, David Novack, Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU]	MVC, Dynavax	US	NA	

	NA	CORONAVIRUS VACCINES COMPRISING A TLR9 AGONIST [John D. CAMPBELL, Robert S. JANSSEN, David Novack, Tsun-Yung KUO, Charles CHEN, Chung-Chin WU, Yi-Jiun LIN, Meei-Yun LIN, Yu-Chi WU]	MVC, Dynavax	EP	NA	
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