PATENT AND KNOW HOW LICENCE AGREEMENT

Dated: 18/07/2023

between

MEDIGEN VACCINE BIOLOGICS CORPORATION ("**MEDIGEN**"), a corporation located at 7/F, No. 16, Lane 120, Section 1, Neihu Road, Neihu District, Taipei; and

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

Each of MEDIGEN and MPP shall be referred to as a "Party", and collectively, as the "**Parties**".

PREAMBLE

WHEREAS MEDIGEN is a for profit publicly traded corporation with a mission to develop safe, effective, and qualified medical products, such as vaccines and biosimilars which has developed a vaccine MVC-COV1901 against COVID-19 and aims to meet the Solidarity Call to Action launched by WHO by out-licensing know how and patents via WHO C-TAP and MPP;

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 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 in Schedule 1 hereto;

WHEREAS MPP, as an implementing partner of WHO C-TAP, is interested in obtaining a non-exclusive licence of the MEDIGEN patents, the know-how and the material together with the right to sublicence to Third Parties to encourage generic manufacture and the development of COVID-19 vaccines;

WHEREAS MEDIGEN is willing to grant such a licence provided that such sublicences are in the form of Schedule 3.

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

1. DEFINITIONS

Capitalised terms not defined in this Agreement have the meaning given to such terms in the form of Schedule 3 to this Agreement. For the purposes of this Agreement, including the preamble and annexes, the following terms, whether used in the singular or plural, shall have the following meanings:

"**Additional Technologies**" means

- the stabilised prefusion spike protein (S-2P) of the SARS-CoV-2 spike protein owned or controlled by United States National Institutes of Health,
- the CpG 1018 adjuvant owned or controlled by Dynavax Technologies; and
- the Expi-CHO cell owned or controlled by Thermo Fisher Scientific,

which are all necessary for the development of the Products.

"**Agreement**" means this Licence Agreement including any and all schedules, appendices and other addenda to it as may be added and/or amended in accordance with the provisions of this document.

"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, the 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 from which the Sublicensees receive 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 an item which constitutes Confidential Information, the Party that first discloses such item to the other Party under this Agreement.

"Effective Date" means the date indicated on the first page 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, any updated constructs thereof 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.

"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 manufacturing of COVID 19 vaccines as described in **Schedule 2**.

"Licensed Technology" means the Patent Rights, Material, and Licensed Know-how from MEDIGEN including without limitation MEDIGEN New Developments actually licenced to a Sublicensee as contemplated hereby.

"LIEs" means all low-income economies in accordance with 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.

"Patent Rights" means any right recognised by the applicable patent legislation or regulation and generated by claiming the priority of the patents and patent applications, including the patents and patent applications set out in ANNEX 1 of Schedule 3 hereto as may be amended from time to time, such as the rights generated by:

a) any patent application, any continuation-in-part, division, extension for any such application, and any patent issuing on such application;

b) inventor certificates, utility models and petty patents.

"Product" means any COVID 19 vaccine which is based in whole or in part on the Licensed Technology.

"Receiving Party" means, in reference an item which constitutes Confidential Information, the Party that receives such item from the Disclosing Party under this Agreement.

"Regulatory Approval" means any approval, registration, licence or authorisation from any authority required for the Development, manufacture or Commercialisation of Product.

"**Sublicence**" means the licence agreement between MPP and the Sublicensee in the form set out in Schedule 3 hereto.

"Sublicensee" means a Third Party to whom MPP has granted a Sublicence under the Licensed Technology.

"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.

2. SCOPE OF THE GRANT

Subject to the terms and conditions of this Agreement, MEDIGEN hereby grants a worldwide, non-exclusive, non-transferable, license to MPP to grant sublicences to sublicensees mutually selected by MPP and WHO C-TAP to use the Licenced 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.

No rights are hereby granted for the Additional Technologies and the Sublicensees will require the prior written approval of each owner thereof.

The entering into of each Sublicense hereunder shall require the prior written approval of MEDIGEN, which shall not be unreasonably withheld or delayed. MPP shall not agree to any amendment or modification of any Sublicence or waive any obligation of the Sublicensee thereunder without the prior written consent of MEDIGEN, which shall not be unreasonably withheld or delayed.

3. FEES AND ROYALTIES

3.1. MPP will require Sublicensees to pay directly to MEDIGEN the royalties and fees as per Clause 3 of each Sublicence.

3.2. MEDIGEN shall invoice the Sublicensee in US Dollars for the royalties payable pursuant to this Agreement for the immediately preceding Agreement Quarter as soon as reasonably practical following receipt by MEDIGEN of the report from the Sublicensee. All royalty amounts payable to MEDIGEN under this Agreement are exclusive of tax or duties which the Sublicensee will bear at the rate from time to time prescribed by law.

4. KNOWLEDGE AND MATERIALS TRANSFER

4.1. 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 each of the Sublicensees, in accordance with the scope, quantities and timelines set out in Schedule 2 hereto. The technology transfer hereunder shall be considered successful with respect to each Sublicensee when such Sublicensee has accomplished vaccine production, meeting the requirements of this Agreement and the associated transfer plan to be agreed by MPP and MEDIGEN with each Sublicensee. MEDIGEN will also provide the Sublicensee with applicable regulatory exclusivity waivers, to the extent required by the Relevant Regulatory Authorities for national registration of the Products).

4.2. The Material will be provided at cost (including manufacturing and direct overhead) which costs will be disclosed to MPP and Sublicensees upon request in advance. Risk 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 risk, of each Sublicensee.

4.3. MPP shall cause each Sublicensee to agree 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.

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

4.5. Without prejudice to the foregoing, prior to entering into the first Sublicence contemplated hereby, the Parties shall, in collaboration with WHO C-TAP agree on the need of a “train the trainer” program, according to the number of interested manufacturers, under which WHO C-TAP and MEDIGEN will prepare an implementation plan to better assist and facilitate the transfer of Licensed Technology to multiple Sublicensees.

4.6. MEDIGEN shall notify WHO C-TAP and MPP in writing of each MEDIGEN New Developments, specifying whether such is an Inscope MEDIGEN New Development or Additional MEDIGEN New Development (all as defined in Schedule 3) at MEDIGEN’s earliest convenience and, in any case, annually or at MPP’s reasonable request and each Sublicensee may elect, by written notice given to MPP and MEDIGEN to include such MEDIGEN New Development in the licence grant under the relevant Sublicense whereupon the relevant know how and materials (if any) shall be transferred to the Sublicensee as contemplated in Schedule 2 hereto on the terms provided for in the relevant Sublicence or, if applicable, as separately agreed.

5. CONFIDENTIALITY AND IP RIGHTS

5.1. Treatment of Confidential Information. Each of the Parties shall ensure that, during the Term of this Agreement and thereafter until the date falling ten (10) years after the date of the expiry of the last Sublicence to expire, the 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 implementation of this Agreement;

Each Party shall be liable to the other Party for breach of this obligation, whether by its employees, associates, Sublicensees or any other person to whom the Confidential Information was disclosed.

Parties shall enter into a confidentiality agreement with WHO C-TAP to comply with this Clause 5 with respect to any MEDIGEN Confidential Information received by WHO C-TAP in the course of the implementation of this Agreement.

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

5.2. 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.

5.3. Publication of this Agreement. The Parties agree that a copy of this Agreement as well as all Sublicences may be publicly disclosed on Parties and WHO C-TAP's websites. Such disclosure will not constitute a breach of either Party's obligations under this Clause 6.

5.4. IP RIGHTS.

i. MEDIGEN will own the entire right, title and interest in and to the Licenced Technology as well as any and all MEDIGEN New Developments, subject only to Clause 9 of Schedule 3 hereto;

ii. If, at any time during the term of this Agreement any Sublicensee (or any of their respective employees, agents, or other persons acting under their authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement, MPP shall request such Sublicensee or any of their employee, agent or other person (each, an "Improvement Creator") to communicate such Improvement to MEDIGEN in full together with all available information concerning the mode of working and using the same. MEDIGEN shall treat this information as Confidential Information;

iii. MPP shall, and shall cause any such Improvement Creator to grant to MEDIGEN a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use any Improvement,

Improvement Patent and related Know-How (and shall promptly execute and cause to be executed such documents as MEDIGEN may reasonably request accordingly) in the Field. MEDIGEN shall be entitled to grant sublicences (without further right to sublicence) 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. No Improvement Creator shall have any rights in relation to the conduct of any matter relating to the Patent Rights, including the filing, prosecution and maintenance thereof;

iv. If any suit or claim by a Third Party is instituted against MPP, WHO C-TAP or any Sublicensee for patent infringement involving the Products, MPP shall promptly notify 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. MPP shall and shall request WHO C-TAP (if relevant) and the relevant Licensee assist MEDIGEN and co-operate in any such litigation at MEDIGEN's request and expense;

v. MEDIGEN (and in no circumstances MPP, WHO C-TAP nor any Sublicensee) shall be entitled to bring infringement actions 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 MPP, WHO C-TAP, or any Sublicensee in any respect for such decision. MPP shall, and shall request WHO C-TAP and each Sublicensee to, assist MEDIGEN and co-operate in any such litigation at MEDIGEN's request without expense to the cooperating party.

6. 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 last to occur of (i) the date on which the last Patent Right has expired, lapsed or has been invalidated, (ii) the Expiry Date of the last to expire of the Sublicences entered into pursuant hereto (the "**Term**"); provided, that, with respect to any transfer of technology arising out of an Additional MEDIGEN New Development, "Term" shall be read to mean the relevant Additional MEDIGEN New Development Term.

7. ASSIGNMENT AND SUBLICENCES

7.1. Assignment. MPP 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 MPP are all personal to MPP. MPP 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 MEDIGEN, which shall not be unreasonably withheld. The merger, consolidation, or reorganisation of MPP with one or more Third Parties shall not entitle MPP to transfer substantially any of the rights granted by this Agreement without the written consent of MEDIGEN, such consent not to be unreasonably withheld, conditioned or delayed.

7.2. Sublicences. MPP/ WHO C-TAP and MEDIGEN will discuss and agree, acting reasonably, upon the interested and suitable Third Parties to whom MPP shall grant sublicences for the purposes of developing, manufacturing and/or Commercialising the Product. MPP will require in the Sublicences that Sublicensee(s) use commercially reasonable efforts to ensure that the Product(s) be made available worldwide at affordable pricing.

7.3. MPP shall take all actions necessary to facilitate MEDIGEN's exercise of any rights granted to MEDIGEN under each Sublicence including without limitation the inspection and audit rights under clause 11.3 thereof.

8. DECLARATIONS AND WARRANTIES

8.1. Parties Representations and Warranties. Each Party declares and warrants to the other Party as of the Effective Date that:

i. it has the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; and

ii. 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; and

iii. Neither Party has granted or will grant to any Third Party any of its right, licence or interest in, to or under the Licensed Technology that would conflict with, limit, or adversely affect the Parties' ability to comply with the terms of this Agreement.

8.2. MEDIGEN's Warranty. MEDIGEN hereby warrants (i) that the commercial use of the rights licensed hereunder which includes the Licensed Technology does not infringe any known intellectual property right, including patents or pre-existing licenses; and (ii) its ownership, control and right to license the rights licensed hereunder. For the avoidance of doubt, MEDIGEN makes no representations or warranties as regards the Additional Technologies.

8.3. Disclaimer of Warranties. Neither Party makes any declaration or warranty other than those expressly provided hereunder.

9. CONSIDERATIONS AND FOLLOW-UP REPORTS

As consideration for the rights conveyed by MEDIGEN under this Agreement, MPP shall use reasonable efforts to sublicence the rights to develop, use and Commercialise the Licensed Technology to companies interested to manufacture and/or Commercialise the Product. MPP will keep MEDIGEN regularly informed of the progress in the search for Sublicensees.

10. TERMINATION

10.1. Termination. This Agreement will be terminated either by its fulfilment, i.e., by expiration of the Term as defined in Clause 6, or by its termination by any of the following Clauses:

10.2. 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.

10.3. Consequences of Termination

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

10.3.2 In the event that this Agreement is terminated prior to the expiry of the Term, each Party shall promptly return or (at the other Party's election) destroy and irretrievably erase all embodiments of

the other Party's, Sublicensee'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.

11 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 MEDIGEN
Attn: Paul Torkehagen
7Fl, No. 16, Lane 120, Neihu Road, Section 1, Taipei
+ 886 (02) 7745 0830
paul@medigenvac.com

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

12 GOVERNING LAW AND JURISDICTION

12.1. 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.

12.2. 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.

12.3. If there are any disputes in connection with this Agreement, including its termination under Clause 10, 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.

13 MISCELLANEOUS

13.1. Entire Agreement. This Agreement and its Schedules 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.

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

13.3. No representation. This Agreement does not authorise either Party to act as representative or agent of the other Party, nor shall it represent that it in fact has such authority. Neither 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.

13.4. 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.

13.5. 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.

13.6. Survival. Clauses 10.3, and 13 shall survive the expiry or termination of this Agreement.

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

MEDIGEN VACCINE BIOLOGICS CORPORATION

DocuSigned by:
Charles Chen
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Dr. Charles Chen
Chief Executive Officer

Medicines Patent Pool

DocuSigned by:
Charles Gore
4713D0F59C13482...

Mr. Charles Gore
Executive Director

Schedule 1: A CONCEPT PAPER ON OPERATIONALISING THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

(encl. 8 pages) COVID-19 technology access pool (who.int)

Concept Note
WHO-covid-19-tech·

OPERATIONALISING THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

A CONCEPT PAPER

INTRODUCTION

On 23 March 2020 the President of Costa Rica, Carlos Alvarado Quesada, asked the Director-General of the World Health Organization (WHO), Dr Tedros Adhanom Ghebreyesus, to "undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."[1] The letter envisaged a voluntary arrangement whereby owners of intellectual property (IP) and other forms of knowledge, clinical data and know-how relevant to the development and manufacture of diagnostic tests, devices, medicines, or vaccines would contribute these to a pool. The details of the arrangements would need to be determined through consultation with the holders of the relevant knowledge and technologies.

The resolution on the COVID-19 response passed at the World Health Assembly in May 2020 called on international organizations and other stakeholders to work together to develop, test, and scale-up production of diagnostics, medicines and vaccines for the COVID-19 response, including existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access.[2]

On 29 May 2020, the Pool was formally launched by President Carlos Alvarado Quesada and Dr Tedros Adhanom Ghebreyesus with the Solidarity Call to Action.[3] The initiative has to date been endorsed by 40 countries along with Office of the United Nations High Commissioner for Human Rights (OHCHR), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Programme (UNDP), the United Nations Educational, Scientific and Cultural Organization (UNESCO), Unitaid, the UN Technology Bank and several non-governmental organizations and individuals.[4]

Dr Tedros Adhanom Ghebreyesus noted that based on strong science and open collaboration, this information-sharing platform would help provide equitable access to life-saving technologies around the world. The aim was to accelerate the development of all kinds of technologies needed for the prevention, detection, and treatment of COVID-19 through open-science research and to fast-track product development and availability by mobilizing additional manufacturing capacity.[5]

The COVID-19 Technology Access Pool (C-TAP) is intended to provide a means to accelerate the development of products needed to fight COVID-19 as well as to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally. Sharing information, knowledge, data and other resources is a powerful way to accelerate product development and avoid unnecessary duplication of efforts arising from the absence of such sharing.

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[1] Letter to Dr Tedros Adhanom Ghebreyesus. 23 March 2020. https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf
[2] World Health Organization. COVID-19 response. WHA73.1. 19 May 2020. https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf
[3] World Health Organization. Making the response to COVID-19 a public common good: Solidarity Call to Action. 1 June 2020. https://www.who.int/docs/default-source/coronaviruse/solidarity-call-to-action/solidarity-call-to-action-01-june-2020.pdf?sfvrsn=a6c4b03d_4
[4] World Health Organization. Endorsements of the Solidarity Call to Action https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action
[5] World Health Organization. International community rallies to support open research and science to fight COVID-19. 29 May 2020. https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19

Key Points in the Solidarity Call to Action

RESEARCH FUNDERS SHOULD:

- Take action to promote innovation, remove barriers, and facilitate open sharing of knowledge, IP and data necessary for COVID-19 detection, prevention, treatment and response through measures to ensure availability, affordability and assured-quality of the concerned products.
- Make appropriate provisions in funding agreements regarding accessibility and affordability of resulting health products globally including through non-exclusive voluntary licensing and other means to expand access by sharing know-how and other data.
- Ensure that all research outcomes are published under open licenses that allow access free of charge with appropriate provisions for their use, adaptation and redistribution by others, including through initiatives such as the FAIR Guiding Principles for scientific data management and stewardship.[6]
- Encourage open and collaborative approaches in pre-competitive drug discovery and work together with international organizations towards equitable distribution and access to products needed for COVID-19.
- Ensure that research results are registered and published in line with WHO's Joint statement on public disclosure of results from clinical trials[7]

RESEARCH ORGANIZATIONS SHOULD:

- Voluntarily license technologies developed to the Medicines Patent Pool (MPP) or through other public health research and development mechanisms that facilitate global access, for example voluntary non-enforcement of IP rights, in order to facilitate equitable, affordable and timely access for all countries.
- Share relevant knowledge, IP and data to enable widescale and worldwide production, distribution and use of such technologies and necessary raw materials through mechanisms such as the Technology Access Partnership (TAP) hosted by the UN Technology Bank or the Open COVID Pledge Initiative hosted by Creative Commons.
- Share viral genome sequences and associated metadata in a timely manner through transparent mechanisms, such as the one provided by the Global Initiative on Sharing All Influenza Data (GISAID) initiative, to contribute essential knowledge to the response efforts, recognizing the need for fair and equitable access to health products that are developed using genetic sequence information.
- Place in the WHO Global Observatory on Health Research and Development, relevant information and analyses on COVID-19 research and development activities.

This paper seeks to clarify how C-TAP might work in practice, how its constituent parts fit together and its governance. It covers the following:

- Why C-TAP?
- The respective roles and objectives of the COVID-19 Tools Accelerator (ACT-A) and C-TAP
- How C-TAP will be structured
- How C-TAP will operate
- C-TAP Governance
- C-TAP Consultative Arrangements

[6] MD Wilkinson et al. The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data*. 2016; 3: 160018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4792175/

[7] World Health Organization. Joint statement on public disclosure of results from clinical trials. May 2017. https://www.who.int/ictrp/results/jointstatement/en/

WHY C-TAP?

In order to achieve its objectives C-TAP needs to be able to make a coherent case to the holders of knowledge and technologies for the benefits to be achieved by pooling their data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how' as well as making IP available for public health-driven non-exclusive licensing through the Medicines Patent Pool, the UN-backed Technology Access Partnership, the Open COVID Pledge and other initiatives.

The International Monetary Fund (IMF) estimated in June 2020 that COVID-19 could cost the world economy $12 trillion up to the end of 2021, equivalent to a daily cost of over $15 billion with further large losses projected even if the pandemic is controlled in 2021.[8] This number conceals the sheer scale of the devastation it is wreaking on livelihoods and indeed health outcomes throughout the world which could persist for years to come. But it also indicates the urgency of bringing the pandemic to an end as soon as possible in order to stem the damage to health and the global economy by whatever means possible. C-TAP, along with other initiatives, offers one way to do this.

Commitments by partners to promote development, access and affordability by any means, including non-exclusive licensing of new technologies, will be particularly important in achieving this objective. Limiting the scale of this devastation as much as possible depends on developing vaccines, therapeutics, medical devices and diagnostics and making them widely available globally as soon as possible. Every day counts and every part of the world needs to be covered if the pandemic is finally to be ended.

Sharing data and information which is normally kept secret or protected by IP could materially advance the speed at which technologies are developed and avoid, for example, the repetition and duplication of research carried out by others and reducing transaction costs in negotiations. Making the know-how associated with new technologies available and widely licensing it around the world would shorten the time needed to make them available as soon as possible to all who need them.

Success for C-TAP objectives will depend on the active participation of key partners including funders and innovators in the private, public, philanthropic and academic sectors. Private sector companies need to consider where their best interests lie. No company in the world will benefit by the prolongation of the pandemic. Their collective interest must be in restoring the world economy to health as quickly as possible, which will be facilitated by much greater openness in sharing their data, knowhow and IP. Several companies have already demonstrated their readiness to do that by making relevant IP available for licensing during the pandemic. Similarly, other research organizations in the public, academic and philanthropic sectors possess valuable knowledge products whose value could be increased by wider sharing in order to promote development and accelerate global access.

Governments, in their role as policymakers, regulators and funders have an important role to play in stimulating collective action to facilitate sharing. Some decisions have already being taken in respect of product development, licensing and allocation that may be at odds with the collective approach.[9] It is a challenge in the face of intense pressures on governments to look after their own populations to convey the message that collaboration and knowledge sharing are preferable to competitive nationalism. There are powerful arguments for collective action. For example, in respect of vaccines, some governments are contracting bilaterally to secure potential vaccines which in the end may prove ineffective or unsafe. In that case they will need access to ones they have not backed.

Funders, whether in the public, private or philanthropic sectors, also have a very important role to play in encouraging or obliging funding recipients to practise open sharing of knowledge and data and the licensing of products to maximize global access.

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[8] International Monetary Fund. Reopening from the Great Lockdown: Uneven and Uncertain Recovery. 24 June 2020. https://blogs.imf.org/2020/06/24/reopening-from-the-great-lockdown-uneven-and-uncertain-recovery/

[9] Tedros Adhanom Ghebreyesus. Tedros Adhanom on why vaccine nationalism harms efforts to halt the pandemic. *Economist*. 8 September 2020. https://www.economist.com/by-invitation/2020/09/08/tedros-adhanom-on-why-vaccine-nationalism-harms-efforts-to-halt-the-pandemic

ACT-A AND C-TAP ROLES AND OBJECTIVES

ACT-A is a partnership between WHO and a number of global health actors including the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, the Global Fund, Unitaid and Wellcome Trust as well as participants from industry, civil society and other organizations. Its mission is the accelerated development, equitable allocation and scaled-up delivery of vaccines, therapeutics and diagnostics. Underpinning these three pillars are two cross-cutting programmes, the Health Systems Connector, to strengthen local capacities to deliver new tools, and an Access and Allocation Programme, which is developing the principles, frameworks and mechanisms needed to ensure the fair and equitable allocation of these tools. The current estimate of funding requirements is $38 billion with the objective of providing two billion vaccine doses by the end of 2021, 245 million therapeutic courses by mid-2021 and 500 million tests for low- and middle-income countries (LMICs).[10]

Thus ACT-A is principally about funding the development of the new tools necessary to fight COVID-19 with associated activities seeking to promote equitable access to these new tools.

C-TAP has the overall objective of promoting open science in order to accelerate product development and to facilitate access to the resulting health technologies by pooling IP, data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how'. Sharing knowledge of all kinds which is normally only available to funders, originators or technology holders, or confidentially held by regulators will facilitate accelerated innovation and the scale-up of manufacturing globally. It will facilitate more affordable access to new tools, through non-exclusive and public-health driven licensing accompanied by enhanced arrangements for technology transfer. In particular, it will support technology transfer to boost local production of relevant products in LMICs through the Medicines Patent Pool and the Technology Access Partnership.

Thus ACT-A and C-TAP are complementary initiatives. ACT-A is principally about mobilizing funds to develop new tools for COVID-19, prioritizing technologies needed, coordinating international action, and ensuring that new products that are safe and effective become available at country level through scaling up production.

C-TAP provides additional and complementary advantages including concrete interventions to increase access to data, IP and knowledge that are key for accelerating product development and manufacturing by promoting through voluntary means open innovation models, knowledge sharing and technology transfer as well as promoting equitable global access through non-exclusive and access-oriented licensing or other voluntary strategies that facilitate technology transfer and access. These include, for example, free licenses and pledges offered by the Open COVID Pledge and other initiatives and the waiving of patent rights by some companies on products that may prove effective against COVID-19.

As complementary initiatives, the linkages and mutual benefits between the two should be made more explicit and further promoted, for example, the data, know-how and IP associated with technologies prioritized for development and subsequent manufacture under ACT-A could be made available for sharing within C-TAP mechanisms.

HOW C-TAP WILL BE STRUCTURED

It is envisaged that the operational parts of C-TAP will be built around existing institutions which will constitute the engine room of C-TAP. These are:

- **The Technology Access Partnership (Tech Access Partnership)[11] launched by the UN Technology Bank in partnership with UNDP, WHO and United Nations Conference on Trade and Development (UNCTAD), focuses particularly on promoting technology transfer to, and local production of, personal protective equipment (PPE), medical devices such as ventilators and other oxygen-related technologies and diagnostics and testing materials/components in LMICs.** The Tech Access Partnership draws on the respective expertise and mandates of partner agencies to comprehensively vet and make recommendations for effective technology transfer transactions between technology seekers in LMICs and technology holders from anywhere in the world. The partners make these assessments, and provide procedural guidance, in close consultation with organizations and institutions expert in particular aspects of the focal technologies, including the regulatory, political, legal

[10] World Health Organization. Status Report & Plan September 2020 – December 2021. 25 September 2020. https://www.who.int/docs/default-source/coronaviruse/act-accelerator/status-report-plan-final-v2.pdf?sfvrsn=ee8ff82b_4&download=true

[11] Technology Access Partnership. https://techaccesspartnership.net/

and financial contexts in which the transactions will be completed. The Tech Access Partnership currently focuses on supporting technology transfer and local production for the production of COVID-19 technologies, to mitigate the immediate impact of the crisis and resultant supply chain shortages, disproportionately impacting LMICs. In its first five months to date, the Tech Access Partnership has received requests for assistance from 10 countries, the majority in Africa.

- The Medicines Patent Pool (MPP)[12] expanded its mandate in March this year to include any health technology that could contribute to the global response to COVID-19. **MPP's experience in facilitating access to medicines through its voluntary licensing mechanism means that it could play a central role in applying its IP and licensing expertise to patented products and technologies identified in the fight against COVID-19 to facilitate availability to those who need them most.** The MPP is also, through its MedsPaL database of patents and licenses in LMICS, including medicines candidates that may have relevance for treating COVID-19 infections. The database provides transparency on the patent status and licensing of these products.
- **The Open COVID Pledge (OCP)[13] currently operates as a repository for mainly soft and hard technologies relevant to COVID-19 but is open to offers from vaccine or therapeutic manufacturers. The OCP is a mechanism whereby companies make available a non-exclusive, royalty-free, world-wide license for a time-limited period - until one year after WHO declares the COVID-19 pandemic over, or 1 January 2023**, whichever is earlier, unless further extended by the pledgor. So far about 30 companies have made pledges – these include large technology companies such as Microsoft and IBM. In Japan, a similar initiative has been launched – the Open COVID-19 Declaration – supported by 90 companies and covering nearly a million patents.[14]
- **Global Initiative on Sharing All Influenza Data (GISAID) enables the unprecedented sharing of genomic and associated data from cases of COVID-19, thereby enabling genomic epidemiology and real-time progress in the understanding of the new disease and in the R&D of candidate medical countermeasures.** Since 2008, GISAID provides Member States with a choice on how to make their genomic sequences and associated virus data publicly accessible, providing transparency on its use and an effective mechanism to safeguard contributors' interests in their data.[15] GISAID's data access and usage license agreement (DAA) was developed with Member States' participation. While all data are publicly accessible, those sharing data through GISAID do not forfeit their inherent rights to the data.[16] Data in GISAID is open to everyone, provided they identify themselves, to foster collaboration and to permit an effective oversight to uphold the sharing principles enshrined. A guiding principle for those using data in particular in publications is the requirement to acknowledge the contribution of data providers. By contrast, traditional public-domain archives (e.g. Genbank) offer only anonymous access and use of data without consideration of data providers' interests.
- **The WHO Global Observatory on Health R&D[17] is a comprehensive and authoritative 'one-stop-shop' for up to date information and analysis on health R&D, including resources, processes, outputs and capacity. It supports evidence-informed decisions related to health R&D gaps and funding based on public health needs.** It does so by consolidating, monitoring and analyzing relevant information on health R&D, building on existing data collection mechanisms, and supporting coordinated actions on health R&D. The 'Observatory' covers all health-related fields and all types of research. It includes data and analyses on health products in the pipeline, clinical trials, R&D investments and research capacity, among others. In response to the COVID-19 pandemic, the Observatory is pulling together and continuously updating a comprehensive list of data tracking and synthesis systems on R&D for COVID-19 and will be developing relevant analyses and interactive data visualizations of these resources, which will include C-TAP repositories.
- **The WHO C-TAP database will be at the core of C-TAP operations, being the repository for data and know-how on key Covid-19 health technologies to be part of C-TAP and for the submission of Member States pledges to support C-TAP.** The WHO C-TAP database will act as a coordination platform and be connected to other data-sharing platforms and databases where Covid-19 related health technology information is already available.

[12] Medicines Patent Pool. https://medicinespatentpool.org/
[13] Open COVID Pledge. https://opencovidpledge.org/
[14] Open COVID-19 Declaration. https://www.gckyoto.com/s/COVID.docx
[15] Shu, Y. et al (2017) GISAID: Global initiative on sharing all influenza data
[16] Elbe, S. et al (2017) GISAID's innovative contribution to global health
[17] Global Observatory on Health R&D. https://www.who.int/research-observatory/en/

HOW C-TAP WILL OPERATE

C-TAP would operate on the basis that there is mutual advantage in a crisis in sharing data and know-how in ways that accelerate product development, widespread manufacturing and reduce barriers to access. The need is to identify an operating model that is attractive to the funders and holders of IP, knowledge, data and technology recognizing the exceptional circumstances the world currently faces.

Some of the incentives for participation by funders and owners of knowledge may be commercial. The holders of knowledge and technology will also wish to make their own contribution to the defeat of COVID-19 for non-commercial reasons.

In respect of accelerating product development of healthcare products, there are a number of relevant examples which have often drawn on the experience of open source software development such as the Linux model.[18] Examples include the Medicines for Malaria's Open Source Drug Discovery programme which already has a COVID Box[19] which has made available 80 compounds with potential for treating COVID-19 in return for which researchers are expected to share data resulting from research on the molecules from the box in the public domain within two years of its generation. Other initiatives include the Open Source Pharma Foundation,[20] Open Source Malaria,[21] and the Structural Genomics Consortium.[22]

In respect of promoting access and affordability, the experience and expertise of the Medicines Patent Pool is very relevant particularly in relation to non-exclusive public-health oriented licensing of medicines in LMICs. MPP estimates that its generic licensees have been responsible in 2012-19 for 31.4 million patient years of treatment saving $1.44 billion in treatment costs.[23]

In devising the operating model, there are a number of issues that need to be addressed, including through consultation with different groups of potential C-TAP partners. An important aspect will be for WHO to establish a prioritization process (with clear criteria and a rationale) to identify which products/technologies and "pooled assets" C-TAP should initially focus on for near term impact, while recognizing C-TAP's more ambitious longer term objective of covering a broad range of products and types of "assets" necessary to tackle COVID-19.

C-TAP has immense potential to deliver as an emergency operation in the short term by supporting faster development of, and equitable global access to, vaccines, therapeutics and diagnostics and necessary medical equipment for this phase of the COVID-19 pandemic. The experience to date is that the great majority of countries in the world, both LMICs and high-income countries (HICs), were drastically underprepared to address the pandemic. Notably, most countries were woefully short of PPE, testing capacity and tools needed in intensive care. Thus, there is a medium- to long-term role for C-TAP in being one element in helping build country capacities to produce and/or secure the range of products which will be needed to address future epidemics. Indeed, success of C-TAP could lay a foundation to address the looming pressure on healthcare systems everywhere from increasing longevity, expansion of non-communicable disease, and resistance of established infectious diseases to conventional antivirals and antibiotics.

C-TAP GOVERNANCE

WHO has an important leadership role in mobilizing and interacting with key actors, such as Member States, funders and strategic partners such as industry, research institutes and academia and civil society, to participate actively in making commitments or pledging support and in sharing their information, know-how and IP. This will require the strategic engagement of senior WHO officials such as Assistant Director-Generals (ADGs), Regional Directors and up to the Director-General. It should also seek to involve other UN agencies with relevant expertise.

There is an important role for WHO in the governance of C-TAP at a strategic level in setting standards and providing guidance for information, know-how and IP to be shared/"pooled" (through the Technical Advisory Group) prioritizing products to be considered by C-TAP and its implementing partners, carrying out coordination of implementing partners, monitoring C-TAP outcomes and communicating about it in an open and transparent manner with C-TAP Steering Committee and C-TAP partners and stakeholders.

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[18] **About the Linux Foundation.** https://www.linuxfoundation.org/about/
[19] **COVID Box.** https://www.mmv.org/mmv-open/covid-box
[20] **Open Source Pharma Foundation.** https://www.ospfound.org/
[21] **Open Source Malaria.** http://opensourcemalaria.org/
[22] **Pioneering Science to Inspire Pioneering Medicines.** https://www.thesgc.org/about/what_is_the_sgc
[23] **MPP in Numbers.** https://medicinespatentpool.org/progress-achievements/impact/

Steering Committee

The C-TAP Steering Committee is a group of international partners involved in C-TAP implementation and advising on the overall direction of C-TAP. It is chaired by the WHO Assistant Director-General for Access to Medicines and Health Products and composed of C-TAP key partner organizations such as Unitaid, the UN Technology Bank, MPP, GISAID and the Open COVID Pledge, UNDP, and UNAIDS. The Chairs of the Member States Working Group and the Technical Advisory Group have observer status in the Steering Committee. The Committee will:

- Provide strategic guidance to the WHO Secretariat on the operationalization of C-TAP
- Serve as a platform to update partner organizations members of the Steering Committee on C-TAP implementation and to exchange information on ongoing and planned activities of C-TAP partners
- Support development of the physical structure and governance of C-TAP, for example, by advising in the process of defining interoperability standards and/or standard operating procedures
- Monitor and assess implementation and outcomes thereof, including taking stock of key challenges and level of achievement of results
- Promote policy dialogue and advocacy on C-TAP objectives
- Advise on and facilitate collaboration and coordination with other relevant initiatives, such as ACT-A

Technical Advisory Group

A Technical Advisory Group (TAG) will be composed of experts in fields relevant to C-TAP operations. They may include experts from key stakeholder groups including funders, civil society, academics, researchers and the private sector, providing that these experts act in their personal capacity, as independent experts, and be clear of conflicts of interest. The role of the TAG would be to provide guidance on tools and methods for sharing of information, know-how and IP needed for C-TAP, advise on priority products to be considered by C-TAP and inform the Steering Committee and the WHO C-TAP Secretariat accordingly. It should be established paying due regard to diversity and equitable geographic representation. Its chair should also be an observer on the Steering Committee.

The exact terms of reference of the TAG need to be determined but could include:

- Providing independent advice on the scientific, technical and strategic matters related to the COVID-19 Technology Access Pool (C-TAP)
- Advising on relevant information and know-how packages on C-TAP candidate health products to be made available in the C-TAP database and disseminated
- Making recommendations to the WHO C-TAP Secretariat regarding license negotiations and other technology transfer agreements taking account of C-TAP partners' existing mechanisms for negotiations.
- Advising on best practices to facilitate technology transfer and local production for needed COVID-19 technologies and how to work with the implementing partners and other stakeholders to implement them.

C-TAP Secretariat

The WHO C-TAP Secretariat will be located in the WHO Access to Medicines and Health Products Division, will work in collaboration with the Science Division in charge of the Global R&D Observatory and coordinate with other relevant WHO departments. C-TAP Secretariat will compile, in one place, the C-TAP Database, pledges of commitment made under the Solidarity Call to Action as well as the voluntarily shared COVID-19 health technology-related knowledge, IP and data. The secretariat will draw on relevant data from existing mechanisms like the MPP or the Technology Access Partnership (TAP) and will need to manage and maintain the website and database platform for C-TAP. The WHO C-TAP Secretariat will:

- Plan and monitor C-TAP related work carried out by WHO and other C-TAP partners
- Carry out day to day coordination of C-TAP related work including from implementing partners, on strategic and technical issues
- Support organization of meetings of the C-TAP Steering Committee and of the Technical Advisory Group
- Prepare C-TAP related activity progress reports
- Develop C-TAP advocacy and communication materials
- Share information on C-TAP progress and implementation plans with the Co-sponsors Working Group, Member States and other partners' groups involving key stakeholders.

C-TAP Member States Working Group

In addition to the core governance bodies, the Steering Committee, the Technical Advisory Group and the C-TAP Secretariat, it will be important to have strong mechanisms for consultation with Member States and the key stakeholders involved in C-TAP.

The **Member States Working Group** will be the interface between the Steering Committee and the global Member States community. Its Chair should participate in the meetings of the Steering Committee as an observer, and act as a liaison and ensure information sharing on C-TAP related issues between the Steering Committee, co-sponsors and Member States. Its role will be to carry out advocacy on behalf of C-TAP and to encourage more Member States and other stakeholders to join the Solidarity Call to Action. C-TAP Secretariat should meet regularly with the Working Group to share information and seek feed-back on progress of C-TAP implementation.

Schedule 2: Transfer of Materials and Licensed Know-how

I. <u>Initial Know-how transfer:</u>

Medigen shall provide all documents in accordance with Appendix 1 of the up-to-date WHO guidelines on technology transfer in pharmaceutical manufacturing, set out following this link ("The Guidelines"): https://cdn.who.int/media/docs/default-source/essential-medicines/norms-and-standards/qas20-869-transfer-of-technology.pdf?sfvrsn=2a4723bc_5 ; provided that if any change to the Appendix 1 after February 1, 2023 increases Medigen's cost for providing such documents, such increase cost should be borne by the Sublicensee. In such event, Medigen shall undertake all reasonable efforts to minimize the cost of providing any additional documents.

Above documents shall be delivered within approximately 3 months after Effective Date of each Sublicense.

II. **<u>Initial Material Transfer</u>**

Transfer of Licensed Know-how will consist of the following items (**Quantities to be as separately agreed between MEDIGEN and each Sublicensee)**:

i. Cell line or working cell bank;

ii. stable clone expressing the stabilised prefusion spike protein of COVID-19, its variants thereof and adjuvanted to produce COVID-19 vaccine MVC-COV1901 and its derivatives for intramuscular injection delivery, including related production technology, clinical data, technical dossiers, Standard Operating Procedures (SOPs) and documentation;

iii. Reference product in reasonable quantities to support analytical characterisation and non-clinical/clinical studies within [x] months from the Stringent Regulatory Authority approval of MEDIGEN's Product;

iv. Critical impurities, standards etc.;

v. Each transfer shall be made directly from MEDIGEN to each Sublicensee within a time period to be agreed between MEDIGEN and such Sublicensee;

vi. All Material shall be provided at cost (including manufacturing and direct overhead). Delivery and risk of loss shall be 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 risk, of each Sublicensee.

III. <u>Initial Technical Support and Training</u>:

- Basic Support and Training: MEDIGEN will provide up to 200 hours of remote assistance (150 of such hours to be available during the six-month period commencing on the Effective Date of the relevant Sublicence) and up to 50 hours of training at MEDIGEN's facilities (available within the one-year period commencing on such Effective Date) as follows:
    i. Hours for remote assistance will be documented by MEDIGEN and shall include answering emails, document preparation and audio and video calls;
    ii. Training at MEDIGEN's facilities shall be arranged and made available at MEDIGEN's discretion and coordinated by Sublicensee with MEDIGEN. Travel, lodging, meals and like expenses shall be borne by Sublicensee.

- Additional Training and Support: Remote training and support beyond Basic Training and Support will be charged at US$250 per hour. Onsite training and support at a Sublicensee's facilities will be charged at US$500 per hour with travel, lodging, meals and similar costs to be covered by the Sublicensee.

IV. **Activities and transfers related to additional components required by WHO guidelines** on technology transfer in pharmaceutical manufacturing, set in The Guidelines

Any costs beyond those set out under Section I, II and III of this Schedule 2 shall not be borne by Medigen and shall be discussed with the Sublicensee in advance.

V. <u>Transfers Related to MEDIGEN New Development</u>:

The contents, process and timing of any transfer of know-how and Materials (if any) related to a MEDIGEN New Development which a Sublicensee elects to Sublicence shall be as agreed among the parties at the time of such transfer.

VI. Sublicensee Obligations

Each Sublicensee shall, at its own cost, carry out all activities contemplated to be carried out by the Receiving Unit ("RU") under The Guidelines.

SCHEDULE 3: FORM OF SUBLICENCE

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 Varembé, 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 sublicence 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 sublicence 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.

"**LIE**s" 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 1st 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 sublicence) 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	