EXECUTION COPY

PATENT AND MATERIAL LICENSE AGREEMENT

by and between

AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS M. P.

and

MEDICINES PATENT POOL

In Madrid, on 11/20/2021

REPRESENTATION

On one side, **AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS, M.P.** (hereinafter referred to as CSIC), with Spanish tax code number Q2818002D, having its registered address in calle Serrano 117, 28006 Madrid (Spain) represented by Rosa Menendez López, by virtue of the power conferred to her by article 11.2 of CSIC's Statute (Spanish Royal Decree 1730/2007, BOE 14th of January 2008), and by Spanish Royal Decree 993/2017, 17th of November 2017, which appointed her as President of CSIC.

On the other side, **THE MEDICINES PATENT POOL** (hereinafter referred to as MPP), a Swiss non-governmental organization located at 7 Rue de Varembé, 1202 Geneva, Switzerland.

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

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

WITNESSETH

I. WHEREAS CSIC is the owner in title of patent application EP20382495.8, with title "Assay for the detection of the Cys-like protease (Mpro) of SARSCoV-2", filed on the 8th of June, 2020 at the Spanish Patent and Trade Mark Office (hereinafter referred to as **Patent application**), relating to an invention developed by the research groups led by Dra. María del Mar Vales Gómez, Dr. Jose Miguel Rodriguez Frade, Dr. Jose María Casasnovas Suelves and Dr. Hugh Thomson Reyburn, as well as of Material Biology developed by the research groups led by Dr. Jose María Casanovas Suelves and Dr. Hugh Thomson Reyburn hereinafter referred to as **Material**), all they employees of CSIC in its National Centre for Biotechnology (CNB).

II. WHEREAS the President of the CSIC, by virtue of the competence attributed to her by Order CIN1032/2011 (BOE of 26 April 2011) has declared that the rights transferred in this Agreement are not necessary for the defence or better protection of the public interests, according to the Article 55.1 of Law 2/2011of 4th March, of Sustainable Economy .

III. WHEREAS the transfer of rights in this Agreement is carried out by direct award after appropriate disclose and limiting demand following the articles 55.3 and 55.4 of Law 2/2011 of 4th March, of Sustainable Economy

VI. WHEREAS CSIC is the owner of confidential data and know-how relating to the invention described in the above referred patent application;

V. WHEREAS MPP is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries;

VI. WHEREAS the Covid-19 Technology Access Pool ("C-TAP") was launched by the World Health Organization to facilitate the open sharing of knowledge, intellectual property, and data necessary for the detection, prevention, and treatment of Covid-19, and to ensure equitable, affordable, and timely access to the concerned products.

VII. WHEREAS MPP, as an implementing partner of C-TAP, is interested in obtaining a non-exclusive license of the Patent and the Material with the right to sublicense to Third parties to encourage generic manufacture and the development of COVID-19 diagnostic technologies.

WHEREAS the Parties are interested in executing this agreement on the basis of the clauses detailed hereinafter;

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

CLAUSES

1. DEFINITIONS

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

"Agreement" means this License 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.

"Commercialization", **"Commercializing"**, or **"Commercialize"** 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, 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 MPP's Sublicensees receives any type of revenue derived from the exploitation of the Patent Rights and/or Material.

"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 indicated on the first page of this Agreement.

"Field" means ELISA kits and lateral flow test for the detection of antibodies against COVID-19.

"HICs" means all high-income countries in accordance with the World Bank country classification at the Effective Date.

"Licensed Know-how" means all proprietary know-how and other technical knowledge relating to the Patent Rights and which may be necessary for Sublicensees to exploit the Patent Rights and Material.

"Licensed Technology" means the Patent Rights, Material, and Licensed Know-How.

"LMICs" means all low- and middle-income countries according to the World Bank country classification as at the Effective Date.

"Material" means:

Expression vectors for mammalian cells that contain recombinant DNAs that encode proteins derived from the protein S ("spike") of SARS-CoV-2, mainly: complete protein S, region S1 and a domain ("receptor binding domain ", RBD) involved in binding to the viral receptor ACE2. Likewise, variants of protein S produced in CNB-CSIC.

Expression vectors for E. Coli cells containing recombinant DNAs encoding proteins derived from the nucleocapsid protein (protein N) of SARS-CoV-2. Likewise, variants of the nucleocapsid protein (protein N) produced in the CNB-CSIC.

Expression vectors for E. Coli cells containing recombinant DNAs encoding proteins derived from the SARS-CoV-2 "cysteine-like" protease (MPro) protein. Likewise, variants of the protease protein (MPro) produced in the CNB-CSIC.

"Net Sales" means, with respect to the Product, the gross amount invoiced on sales by Sublicensees to Customers in any country of the World less the following deductions, to the extent included in the sales invoice with respect to such Product:

a) normal and customary trade and quantity discounts actually given (discounts which all together cannot exceed 20% of the sales price); and, in case of returns or rejections of Products, the associated credits and price adjustments; and

b) 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.

When the Product is included as part of any program based on multiple product offers, the discounts referred to in point a) of this Clause shall be coherent with the discounts applied by Sublicensees to the same Customer when the Product is not combined with any other products or services.

Use of the Product in field tests, marketing, or other similar programs or studies where Product is supplied without charge, shall not result in any Net Sales, however if Sublicensees charges for such Product, the amount billed will be included in the calculation of Net Sales.

"Patent application" means the European patent application EP20382495.8, with title "Assay for the detection of the Cys-like protease (Mpro) os SARSCoV-2", filed on the 8th of June, 2020 at the Spanish Patent and Trade Mark Office.

"Patent Rights" means any right recognised by the applicable patent legislation or regulation and generated by claiming the priority of the Patent Application, including the patents and patent applications set out in Schedule 1 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 product which:

a) is covered in whole or partly by any Valid Claim;

b) is manufactured by or made of using the Material; or

c) its use is covered by any Valid Claim.

"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 authorization from any authority required for the Development, manufacture or Commercialization of Product in the Territory.

"Sublicensee" means a Third Party to whom MPP has granted a sublicense under the Patent Rights and/or the Material.

"Third Party" means any entity other than a Party.

"Valid Claim" means a claim:

a) 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

b) in a patent application included within the Patent Rights that is being actively prosecuted in accordance with this Agreement.

2. SCOPE OF THE GRANT

Subject to the terms and conditions of this Agreement, CSIC hereby grants a worldwide, non-exclusive, non-transferable, licence to MPP, under the Licensed Technology, to grant sublicences to sublicensees selected by MPP to:

a) Develop, or have developed, the Licensed Technology into Products in the Field, and

b) Make, have made, use, Commercialize, export or import the Products exclusively for ultimate use in the Field.

3. ROYALTIES

MPP will require Sublicensees to pay royalties on Net Sales of Licensed Products directly to CSIC on a country-by-country basis starting from the date of the first commercial sale of Licensed Products. Royalties will be paid as described below:

A. Royalty-free for sales to any LMICs for use in any LMIC;

B. In HICs where there is a Patent Right granted and in force in the country of manufacture or sale, a non-creditable, non-refundable royalty of fifteen percent (15 %) payable on Net Sales in the previous calendar year and on a country by country basis and commencing on the date of the first sale of Product and continuing until the expiry of the last-to-expire Patent Right in such country.

C. In HICs where there is no Patent Right granted and in force in the country of manufacture or sale but where Licensee has used the Material for the manufacture of the Licensed Products, the royalty as described in 3(B) will be payable for a period of ten (10) years from the Effective Date.

4. TERRITORIAL SCOPE

The license under this Agreement is granted worldwide.

5. KNOWLEDGE TRANSFER

CSIC shall use reasonable efforts to provide MPP and/or its Sublicensees with the Material and Licensed Know-How. The Material will be provided at the manufacturing costs. CSIC shall have no obligation to provide any know-how and technical knowledge which has not been generated by Dra. María del Mar Vales Gómez, Dr. Jose Miguel Rodriguez Frade, Dr. Jose María Casasnovas Suelves and Dr. Hugh Thomson Reyburn or under their supervision during their employment at CSIC.

MPP shall agree with the Sublicensees that they will cover any travel and out-of-pocket costs of CSIC staff required for the better transfer of such know-how, Material, and/or technical knowledge. The effect on normal activities of CSIC produced by any request under this provision shall be minimized by Sublicensee by:

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

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:

a) shall be used in a reserved manner.
b) shall not be copied or disclosed in whole or in part by or to Third Parties without having obtained the express written authorization from the Disclosing Party, except that such written authorization shall not be necessary in the following instances:
    i. Regulatory filings;
    ii. Prosecuting or defending litigation;
    iii. Complying with applicable governmental laws and regulations; and
    iv. 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;
c) 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 for breach of this obligation, whether by its employees, associates, Sublicensees 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 Sub-clause 5.1., no Party shall be liable for use or disclosure of Confidential Information that:

a) is published or becomes generally known to the public through no fault or omission of the Receiving Party; or
b) 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

c) 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

d) The information received comes from a Third Party that does not require secrecy, or

e) 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 as well as all sublicences may be publicly disclosed on MPP'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. Except if it is resolved before according to Clause 12, its duration will continue in force until the date on which the last Patent Right has expired, lapsed or has been invalidated (the "Term"). Following this Term, the licence granted in Section 2 will become a perpetual, irrevocable, fully paid-up, royalty free licence to develop, have developed, make, have made, use, Commercialize, import and export Products for use in the Field. Notwithstanding the above, royalties as provided in Section 3C will continue for the period described therein.

8. ASSIGNMENT AND SUBLICENSES

8.1. 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 CSIC, which shall not be unreasonably withheld. The merger, consolidation, or reorganization 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 CSIC, such consent not to be unreasonably withheld, conditioned or delayed.

8.2. Licenses and sublicenses. MPP and CSIC will discuss and agree upon the identities of interested and suitable Third Parties to whom MPP shall grant sublicences for the purposes of fabricating 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 in LMICs at affordable pricing. Other conditions for these sublicences will be previously agreed between CSIC and MPP.

9. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

9.1. Filing, prosecution and maintenance of Patent Rights. Before any sublicense will be signed by MPP, CSIC (or its licensees) shall be responsible for the preparation, filing, prosecution, and maintenance of Patent Rights in the Territory and shall cover all associated costs. There will be no obligation for the CSIC to maintain the Patent right in any country.

10.DECLARATIONS AND WARRANTIES

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

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

b) has been duly authorized 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

c) 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

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

CSIC does not make any declaration or warranty as regards the patentability of any patent application included in the Patent Rights or the prospect to extent any Patent Right. CSIC does not make any representation or warranty that the use of any of the Patent claims or piece of information or of know-how licensed under this Contract does not infringe any patent or other intellectual or property rights belonging to Third Parties.

11. CONSIDERATIONS AND FOLLOW-UP REPORTS

As consideration for the rights conveyed by CSIC under this Agreement, MPP shall use reasonable efforts to sublicense the rights to develop, use and Commercialize the Patent Rights and Material to companies interested to manufacture and/or Commercialise the Product. MPP will keep CSIC regularly informed of the progress in the search for sublicensees.

12. TERMINATION

12.1. Termination. This Agreement will be terminated either by its fulfillment, i.e. by expiration of the Term as defined in Clause 7, or by its termination by any of the following sub-clauses:

12.2. Termination upon non-compliance. Any Party shall have the right to terminate the Agreement, when there has been a serious breach by the other Party. For the resolution of non-compliance, the following procedure will be followed:

a. If any of the Parties considers that there is a breach of the undertaking of this contract by the other Party, such breach shall be duly notified to the address designated in this contract indicating the grounds and requiring it to be remedy.

b. The other Party can bring such breach to an end within a period of 30 days from the date of notification, or within another timeline agreed upon between the Parties.

c. In this case, the allegedly breaching Party shall notify the other Party who could show agreement or disagreement. In case of agreement, the performance of the contract will continue.

d. In case of disagreement, the final termination of the contract shall be notified by the disagreeing Party.

e. In the event of the allegedly breaching Party not bringing such breach to an end, the contract shall deem to be terminated on the date of the first due notification.

f. When according to the allegedly breaching Party there is not such breach; or the breach is justified as it cannot be overcome or overcoming it makes impossible the performance of the present Contract; or the breach has been already brought to an end, this Party can bring the issue in front of a Court within a period of six (6) months from the last notification, subject to the prior dispute resolution processes described in clause 14.2. In any case, the Contract shall deem to be terminated pending judicial decision.

g. If the Party does not bring the issue in front of a Court or the aforementioned six (6) months term is not followed, termination shall be immediate losing any right to subsequent claim.

During all the procedure listed, the damaged Party shall have the right to seek due compensation for damages that could correspond to any of the Parties.

12.3. Termination for ceasing of the sublicensee search activity by MPP

The Parties may terminate this Agreement by written mutual agreement, before ninety (90) days' written notice in due form is provided by MPP to CSIC of its intention to cease the search of sublicensees because it has not been successful.

12.4. Consequences of Termination.

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

13 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 CSIC
Vicepresidencia Adjunta de Transferencia de Conocimiento (vatc@csic.es)
Consejo Superior de Investigaciones Científicas
Calle Serrano 142, 28006 Madrid (Spain)

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

14 GOVERNING LAW AND JURISDICTION

14.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of Spain.

14.2. 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, the Parties agree, with express resignation to any other jurisdiction that could correspond to them, to solve the differences under the exclusive jurisdiction of the Courts of the city of Madrid, Spain.

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.

15 MISCELLANEOUS

15.1. 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.

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

15.3. No representation. This Agreement does not authorize any 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.

15.4. Severability. If any provision of this Agreement is declared in a final unappealable order by a court 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.

15.5. 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 and sub-clauses.

15.6. Survival. Clauses 12.4, and 15 shall survive the expiry or termination of this Agreement.

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

Agencia Estatal Consejo Superior de Investigaciones Científicas, M.P.

DocuSigned by:
Rosa Menéndez
4BE32B4BE07A496...

Rosa Menéndez López
President of CSIC

Medicines Patent Pool

DocuSigned by:
Charles Gore
4713D0F59C13482...

Mr. Charles Gore
Executive Director

Schedule 1: The Licensed Patents

Patent Type	Patent title	Patent Status	Country	Patent Application Number	Priority Date	Grant Number
PCT	Assay for the detection of the Cys-like protease (Mpro) of SARS-CoV-2	Filed		PCT/EP21/065361	08/06/2020	
Regional	ASSAY FOR THE DETECTION OF THE CYS-LIKE PROTEASE (MPRO) OF SARS-COV-2	Filed	Europe	EP20382495	08/06/2020	