PATENT AND MATERIAL LICENCE AGREEMENT

by and between

AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS M. P.

and

MEDICINES PATENT POOL

Signed on 18/07/2023

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 Eloisa del Pino Matute, 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 498/2022, 21st of June 2022, which appointed her as President of CSIC.

On the other side, **THE 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 Organization ("WHO") COVID-19 Technology Access Pool initiative ("**WHO C-TAP**").

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

WHEREAS CSIC is the owner of Modified Vaccinia Virus Ankara (MVA)-based COVID-19 vaccine candidate that has been patented by CSIC, **called MVA-CoV2-S(3P) or MVA-S(3P)**, consisting of an MVA vector expressing a full-length prefusion-stabilized SARS-CoV-2 spike protein.

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

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;

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 worldwide, non-exclusive licence of the CSIC Patents, the Licensed Know-how and the Material associated, with the right to sublicense to third parties to encourage generic manufacture and the development of COVID-19 vaccines.

WHEREAS BIOFABRI S.L.U., a company incorporated under the laws of Spain ("Biofabri") which owns Biofabri Material and Know-how for the industrial manufacturing of the above-mentioned MVA-based COVID-19 vaccine candidate under cGMP principles and according to the requirements given in the European Pharmacopoeia monograph 0153 "Vaccines for human use" and chapter 5.14 "Gene Transfer Medicinal Products for Human Use. Poxvirus vectors for Human Use".

WHEREAS CSIC, Biofabri, MPP and WHO have signed a confidentiality agreement effective from 09 June 2022, so CSIC and Biofabri can disclose to MPP and WHO certain information and data relating to scientific and technological development of a Modified Vaccinia Virus Ankara (MVA)-based COVID-19 vaccine candidate that has been patented by CSIC which information and data CSIC and Biofabri consider to be confidential and proprietary to them.

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 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.

"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.

"COVID-19 Vaccine" shall mean the COVID-19 vaccine developed by the CSIC research group led by Dr. Mariano Esteban and Dr. Juan Francisco García Arriaza, employees of CSIC in its Centro Nacional de Biotecnología; consisting of a Modified Vaccinia Virus Ankara (MVA) vector expressing a full-length prefusion-stabilized SARS-CoV-2 spike protein and called MVA-CoV2-S(3P).

"CSIC new developments"shall mean inventions and improvements conceived by CSIC or on its behalf, by its respective employees and agents after the Effective Date relating to the COVID-19 Vaccine.

"Customers" means any entity of which the 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 COVID 19 vaccine(s).

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

"Licensed Know-how" means all know-how, information, data, including without limitation clinical data, and other technical knowledge owned and/or controlled by CSIC now or in the future, that are useful or otherwise relevant for the development and/or manufacturing of the COVID 19 vaccine, which is set out in Schedule 3 hereto as available on the Effective Date, which shall be updated and complemented from time to time by CSIC.

"Licensed Technology" means the Patent Rights, Material, and Licensed Know-how including CSIC New Developments.

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

"Material" means any materials useful for the development and/or manufacturing of COVID 19 Vaccine as defined above owned and/or controlled by CSIC, including the premaster virus seed for MVA-CoV2-S(3P) and unmodified derivatives.

"Biofabri Material and Know-how" means any materials and know how useful for the manufacturing and quality control of "COVID-19 Vaccines" owned and/or controlled by Biofabri:

- Master virus seeds (MVS) and working virus seeds (WVS) were generated by Biofabri from CSIC Materials and adequately characterized in accordance with the regulatory guidelines.
- DF1 Master Cell Seeds (MCS) and DF1 Working Cell Seeds (WCS) were generated by Biofabri in accordance with the GMP rule. MCS and WCS were characterised by Biofabri following the European Pharmacopoeia (EP) 5.2.3.

"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 section shall be consistent 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(s) and Patent Application(s)" means any patents and/or patent applications owned and/or controlled by CSIC that are useful or otherwise relevant for the development and/or manufacturing of COVID 19 Vaccine.

"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 Schedule 2 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 on the Licensed 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, licence 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 Licensed Technology.

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

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 and WHO C-TAP 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.

For the avoidance of doubt, this Agreement does not grant any rights in relation to Biofabri Material and Know-how.

3. ROYALTIES

MPP will require Sublicensees to pay royalties on Net Sales of Products directly to CSIC on a country-by-country basis starting from the date of the first commercial sale of 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 five percent (5 %) 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 and Licensed Know-how for the manufacture of the Products, a non-creditable, non-refundable royalty of one and a half percent (1,5 %) 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 for a period of ten (10) years from the first sale.

4. TERRITORIAL SCOPE

The license under this Agreement is granted worldwide.

5. KNOWLEDGE TRANSFER

5.1. CSIC shall use reasonable efforts to provide and/or to procure provision to the Sublicensees, upon the Sublicensee's request, with the Material and Licensed Know-how in accordance with the details set out in Schedule 2 hereto. The Material will be provided at the manufacturing costs, which will be disclosed to MPP and the relevant Sublicensee upon request in advance.

5.2. CSIC shall use reasonable efforts to facilitate the transfer of Biofabri Material and Know-how, as CSIC's manufacturing partner, upon the Sublicensee's request.

5.3. MPP shall agree with the Sublicensees that they will cover any travel and out-of-pocket costs of CSIC staff required for the transfer of Licensed Technology. The effect on usual business activities of these entities produced by any request under this provision shall be minimized by the 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;

6.2. 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.

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

6.4. Exceptions in the Treatment of Confidential Information. Notwithstanding Sub-clause 6.1., 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 and WHO C-TAP's websites. 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 Clause 2 will become a perpetual, irrevocable to develop, have developed, make, have made, use, Commercialize, import and export Products for use in the Field. Royalties as provided in Clause 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. Licences and sublicences. 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 developing, 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.

9. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

9.1. CSIC New Developments. CSIC will own the entire right, title and interest in and to any and all inventions and improvements conceived solely by CSIC or on its behalf, by its respective employees and agents after the Effective Date relating to the Licensed Technology ("**CSIC New Developments**"), subject to the licence grant set out in Clause 2 hereof. CSIC shall notify MPP in writing of any CSIC New Developments at the earliest convenience and in any case annually or at MPP's reasonable request.

9.2. Filing, prosecution and maintenance of Patent Rights. 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 Licensed Know-how 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 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 30 days after receiving a written notice specifying the nature of the breach.

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 sublicence 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.

14.3. 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.

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:
Eloisa Delpino
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Eloisa del Pino Matute
President of CSIC

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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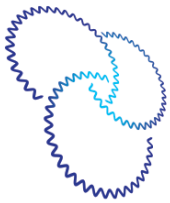
[1] Letter to Dr Tedros Adhanom Ghebreyesus. 23 March 2020. https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf
[2] World Health Organization. COVID-19 response. WHA73.1. 19 May 2020. https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf
[3] World 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.

[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=ee8f882b_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.

[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: The Licensed Patents

Patent Type	Patent title	Patent Status	Country	Patent Application Number	Priority Date	Grant Number
European priority patent	MVA-BASED VACCINE AGAINST COVID-19 EXPRESSING A PREFUSION-STABILIZED SARS-CoV-2 S PROTEIN	Pending	Europe	EP21382557	23/06/2021	
PCT Application	MVA-BASED VACCINE AGAINST COVID-19 EXPRESSING A PREFUSION-STABILIZED SARS-CoV-2 S PROTEIN	N/A	N/A	PCT/EP2022/067271	23/06/2022	

Schedule 3: Licensed Know-how and Materials

a) **Materials:** Premaster virus seed for MVA-CoV2-S(3P) and derived materials, and any other Materials useful for the manufacturing and/or development of the Product owned and/or controlled by CSIC.

b) **Licensed Know-how:** as of the Effective Date is mostly related to scientific background and preclinical development of MVA-based COVID-19 vaccine candidate, MVA-CoV2-S(3P). Transfer of the Licensed Know-how will consist of the following items:

- **Technical support**:

  Plant visits and training: training of Sublicensee technical engineers, at, as the case may be, the Sublicensee's facilities or CSIC facilities that are developing or using the licensed process and/or making and selling the Product.

  Direct assistance: qualified and experienced professional from or on behalf of CSIC to advise the Sublicensee on the use of Licensed Know-how for manufacture of the Products.

  Consultation: Sublicensee shall have the right to contact CSIC by mail or telephone through representatives appointed by each party in relation to the use of Licensed Know-how, including without limitation for any quality and regulatory questions.

- **Timeline**: each transfer shall be performed directly to the Sublicensee in the shortest time possible and in any case within 60 days from MPP's request.