

Why Transparency of Contracts is Important

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KEI

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Contracts are important for pandemic preparedness and response

- Governments, for profit and nonprofit entities, intergovernmental organizations, all use contracts to undertake the funding of research and development and the procurement of products. Contracts are used to license assets.
- There is great diversity regarding the specific terms in contracts, and the policies by governments and nongovernmental entities regarding the transparency of contracts.

Finding contracts

- HHS FOIA reading room.
<https://www.hhs.gov/foia/electronic-reading-room/index.html>
- KEI web page on COVID contracts: <https://www.keionline.org/covid-contracts>
- KEI Briefing Note 2022:1, Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents
<https://www.keionline.org/bn-2022-1>
- <http://drugdatabase.info/databases/patent-licenses/>
- [Licences - MPP](#)

Let's look at a few contract provisions

Pfizer contract W58P0522C0001 for Paxlovid, page 33

H.7 Most Favored Nation Clause

(a) If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase (i) the same or a lesser volume of Product than the U.S. Government commits to purchase (ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.

(b) Upon any such election by the U.S. Government, this contract shall be deemed to have been amended and modified such that, from the date on which the lower priced courses are first supplied or delivered to the applicable Covered Nation (the "Amended Pricing Effective Date"), the U.S. Government will receive that lower price for Product for which Contractor has not invoiced the U.S. Government following that Amended Pricing Effective Date.

(c) Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the U.S. Government of any Contractor product.

(d) For purposes of this section, "Covered Nation" shall mean a nation that is a member of the Group of Seven (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States) plus Switzerland and "Product" shall mean the 5-day treatment courses of Contractor's COVID-19 oral antiviral treatment (i.e., PF-07321332) that is the subject of this contract.

Lilly Contract: W911QY21C0016, page 19

H.7 Sales to Covered Nations

(i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 June 2021 sell any COVID-19 therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland (“Covered Nation”) at a lower price than the prices set forth in this contract.

(ii) If, at any time prior to 30 June 2021, Lilly enters into any agreement with a Covered Nation to sell the COVID19 therapeutic supplied to the Government under this Agreement at a price lower than the price currently paid by the U.S. Government for the same COVID-19 therapeutic doses under this contract, Lilly shall provide notice within 30 days to the U.S. Government and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and receive such COVID-19 therapeutic doses at that lower price.

(iii) Upon any such election by the U.S. Government, this contract shall be deemed to have been amended and modified such that, from the date on which the more favorable pricing was first provided to any Covered Nation (the “Amended Pricing Effective Date”), the U.S. Government will receive that lower price for all orders of COVID-19 therapeutic doses following that Amended Pricing Effective Date.

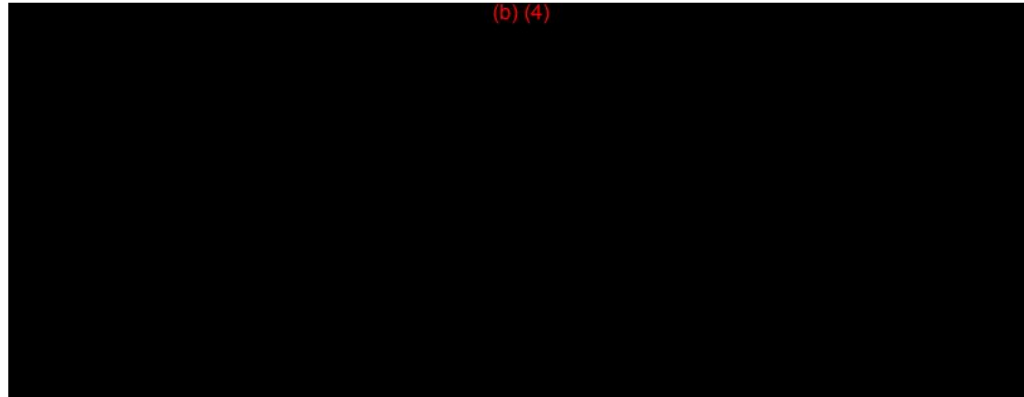
(iv) Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the U.S. Government of any Lilly product.

Merck contract W911QY21C0031 for COVID antiviral

H.7 is redacted

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Merck prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.



H.8 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's need to provide sufficient quantities of a COVID-19 therapeutic in the amounts contemplated under this Agreement, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet its needs. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

(a) Merck gives written notice, required to be submitted to the Government no later than 15 business days, of:

Pfizer contract: OTA W15QKN-16-9-1002

As background, to help ensure delivery of the doses, Pfizer is undertaking the following CMC activities:

(Technology transfer for local manufacturing in US)

1. Continue with BioNTech to manufacture initial clinical trial material for EU and US Phase 1/2/3 studies, through mRNA production in Germany and EU (Puurs, Belgium for fill-finish) and drug product/labelling operations at EU CMOs and establish EU based supply chain for lipid nanoparticle (LNP) formulation, fill, finish and distribution for commercial supply.

2. Complete knowledge transfer of the technology and manufacturing process from BioNTech (and its CMO partners) to Pfizer in order to establish the process at Pfizer in the US, (b) (4)

3. Obtain all raw material supplies for manufacturing. This may include support of existing third-party suppliers of raw materials, qualifying new third-party suppliers and/or in-house production of certain raw materials, (b) (4)

4. Establish (b) (4) mRNA (drug substance), lipid nanoparticle (LNP) formulation/fill finish (drug product) capacity for GMP Covid-19 pandemic supply of the RNA-based COVID-19 vaccine on US soil.

FOIA exemption (b)(4)

5 U.S.C. § 552(b)(4)

(b) This section does not apply to matters that are—

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

Lilly contract W911QY21C0016

H.12 Buy Back

It is the intention of the parties that Lilly does not want to sell, nor does the Government want to purchase, therapeutics that are not FDA-authorized or approved or for which an EUA has been revoked. In the event that the EUA for the monoclonal antibody therapeutic is revoked, Lilly agrees to buy back from the Government all treatments (as defined in the CLIN) accepted by the Government. Lilly shall notify the contracting officer immediately upon notification of revocation. Lilly shall repurchase the treatments within (30) days of the EUA revocation at the same price as purchased by the Government unless otherwise agreed.

Federal Acquisition Regulations

FAR 52.227-1 Authorization and Consent, in
US contracts

FAR 52.227-1 Authorization and Consent.

(a) The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent-

(1) Embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract;
or

(2) Used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or a subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance. the entire liability to the Government for infringement of a United States patent shall be determined solely by the provisions of the indemnity clause, if any, included in this contract or any subcontract hereunder (including any lower-tier subcontract), and the Government assumes liability for all other infringement to the extent of the authorization and consent hereinabove granted.

(b) The Contractor shall include the substance of this clause, including this paragraph (b), in all subcontracts that are expected to exceed the simplified acquisition threshold, as defined in Federal Acquisition Regulation (FAR) 2.101 on the date of subcontract award. However, omission of this clause from any subcontract, including those at or below the simplified acquisition threshold, as defined in FAR 2.101 on the date of subcontract award, does not affect this authorization and consent.

Lilly Contract: W911QY21C0016

- 52.227-1 Authorization and Consent, JUN 2020
- 52.227-2 Notice And Assistance Regarding Patent And Copyright Infringement, JUN 2020
- 52.227-3 Patent Indemnity, APR 1984

Moderna

FAR 52.227-1 Authorization and Consent, December 2007

FAR 52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement, December 2007

FAR 52.227-11, Patent Rights-Ownership by the Contractor, May 2014

KEI Briefing Note 2022:1, Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents

<https://www.keionline.org/wp-content/uploads/KEI-bn-2022-1.pdf>

See also: <http://drugdatabase.info/databases/patent-licenses/> tab on 52.227-1

Other Transaction Agreements

KEI Briefing Note 2020:3 Other Transaction Agreements: Government Contracts that May Eliminate Protections for the Public on Pricing, Access and Competition, Including in Connection with COVID-19. KEI Briefing Note 2020: June 29, 2020

<https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf>

Known as OTA contracts, when authorized, permits agencies to ignore standard patent and clauses in U.S. government contracts. Often used to eliminate or narrow government rights in patented inventions.

OTA recommendations

Page 49-50 of [KEI Briefing Note 2020:3](#)

Aggressive redactions are common

OTHER TRANSACTION AGREEMENT (OTA)
OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6717

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
200 C Street, S.W.
WASHINGTON, DC 20515

CONCERNING

(b)(4)

Date: January 31, 2020

PR No. (b)(4)

Total Amount of the Agreement (b)(4)

Total Estimated Government Funding of the Agreement (b)(4)

Total Estimated Recipient Funding of the Agreement (b)(4)

Funds Obligated: (b)(4)

Period of Performance: September 30, 2017 through June 30, 2022 (Changed)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation

(b)(4)

Line of Accounting and Appropriation

(b)(4)

Line of Accounting and Appropriation

(b)(4)

Line of Accounting and Appropriation

(b)(4)

Line of Accounting and Appropriation

(b)(4)

(b)(4)

Modifications
are not always
available, or
transparent

DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADVANCED AGREEMENT BETWEEN THE ASSISTANT SECRETARY
FOR PREPAREDNESS AND RESPONSE (ASPR), BIOMEDICAL ADVANCED
RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)
AND
ASTRAZENECA
OTHER TRANSACTION AGREEMENT NUMBER: 75A501-20-C-00114 M
TITLE FOR: ChAdOx1nCoV-19 Vaccine Clinical Development and Manu

The purpose of this modification is to (b)(4) of the
Transaction Agreement (OTA)

Modification of subject Advanced Agreement to be as follows:

FROM:

(b)(4)

Allocation of patent rights are sui generis in OTA contracts

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in

<https://www.keionline.org/misc-docs/DOD-ATI-Regeneron-Contract-W15QKN1691002-6July2020.pdf>

Regeneron contract HHSO100201700020C

h. Compulsory Licensing Rights

The Recipient agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Recipient, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i.

(b)(4)



AstraZeneca OTA NUMBER: 75A501-20-C-00114 (\$413.2 million)

(Gag rules)

3. Special Contract Requirement

Advanced Agreement is in anticipation of Other Transaction Agreement No: 75A501-20-COO 114 between the Department of Health and Human Services and AstraZeneca.

AstraZeneca, or any entity or representative acting on behalf of AstraZeneca, may not refer to this Advanced Agreement or work/services furnished pursuant to the provisions of this Advanced Agreement or resulting OTA in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the OTA or the HHS Press Office.

...

Should any reference to this Advance Agreement or OTA be included in any news release or commercial advertising issued by or on behalf of AstraZeneca without the required written consent, the Government will consider the institution of all remedies available under applicable law.

Moderna Vaccine Contract 75A50120C00034

H.7 Acknowledgement of Federal Funding - Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded i.n whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority. under Contract No. 75A50120C00034."

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money; (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2} the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

Novavax contract MCDC2011-001, for COVID 19 vaccine

.....Rights of Reference to Regulatory Data

Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

...

b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.

Sharing rights internationally

FAR 27.303 Contract clauses.

(4) Use the clause at 52.227-13 with its Alternate I if-

(i) The Government must grant a foreign government a sublicense in subject inventions pursuant to a treaty or executive agreement; or

(ii) The agency head determines, at contract award, that it would be in the national interest to sublicense foreign governments or international organizations pursuant to any existing or future treaty or agreement. If other rights are necessary to effectuate any treaty or agreement, Alternate I may be appropriately modified.

(5) Use the clause at 52.227-13 with its Alternate II in the contract when necessary to effectuate an existing or future treaty or agreement.

<https://www.acquisition.gov/far/27.303>

52.227-13 Patent Rights-Ownership by the Government.

Alternate I (Jun 1989). As prescribed in 27.303(e) (4), add the following sentence at the end of paragraph (c)(1)(i) of the basic clause:

The license will include the right of the Government to sublicense foreign governments, their nationals, and international organizations pursuant to the following treaties or international agreements: _____ * [*Contracting Officer complete with the names of applicable existing treaties or international agreements. The above language is not intended to apply to treaties or agreements that are in effect on the date of the award but are not listed.]

Alternate II (Dec 2007). As prescribed in 27.303(e)(5), add the following sentence at the end of paragraph (c)(1)(i) of the basic clause:

The agency reserves the right to unilaterally amend this contract to identify specific treaties or international agreements entered into by the Government before or after the effective date of this contract, and effectuate those license or other rights that are necessary for the Government to meet its obligations to foreign governments, their nationals, and international organizations under treaties or international agreements with respect to subject inventions made after the date of the amendment.

<https://www.acquisition.gov/far/52.227-13>

37 CFR § 401.5 - Modification and tailoring of clauses.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

The agency reserves the right to unilaterally amend this funding agreement to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this funding agreement and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

WHO negotiations on transparency

WHA72.8 Improving the transparency of markets for medicines, vaccines, and other health products

URGES Member States in accordance with their national and regional legal frameworks and contexts:

(3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;

(4) to facilitate improved public reporting of patent status information and the marketing approval status of health products;

H.10 Validation of IP/Data

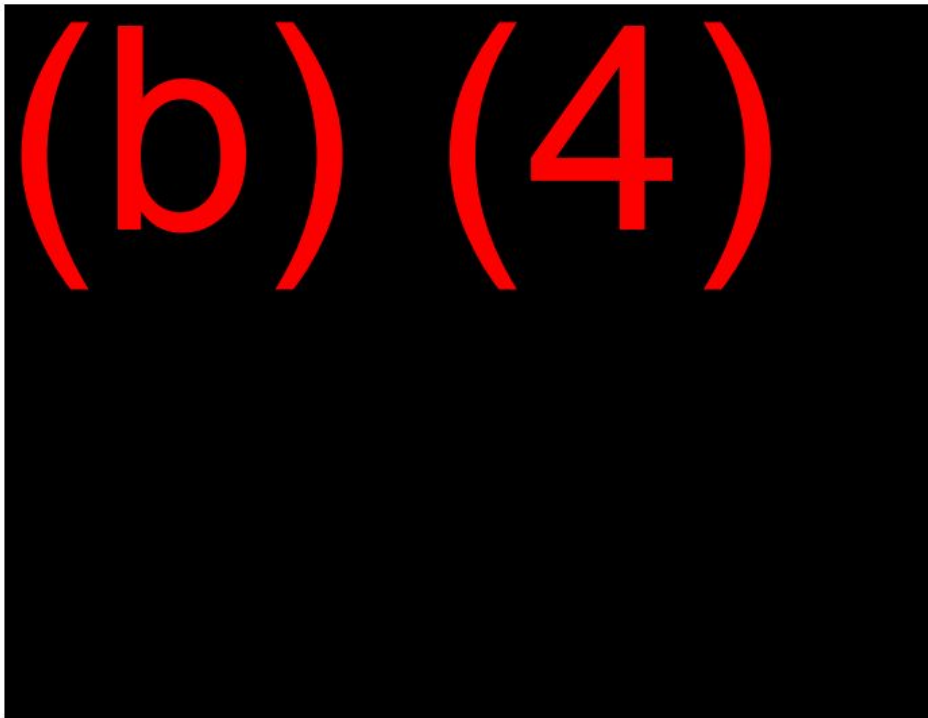
The Contractor represents that, to its knowledge, the intellectual property license(s) and other rights held by or granted to Contractor, including but not limited to the list of patents and patent applications listed below, are sufficient to enable Contractor to perform its obligations under this Agreement.

The Parties acknowledge that the following background intellectual property and technical data assertions have been made:

List of Lilly Patent Applications Related to LY-CoV555 (bamlinvimab) and LY-CoV016 (Etesevimab)

Lilly, contract
W911QY21C0016
for therapeutic

Redaction of patent applications
for bamlinvimab and Etesevimab



The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

Lilly, contract W911QY21C0016 for therapeutic

Redaction of patent
applications for
bamlinvimab and
Etesevimab

H.10 Validation of IP/Data

The Parties acknowledge that the following background intellectual property and technical data as made:

List of Lilly Patent Applications Related to LY-CoV555 (bamlinvimab)
Asserted October 19, 2020

1. Patent Family Titled: “Anti-Coronavirus Antibodies and Methods of Use”

- (b) (4)

2. Patent Family Titled: “Methods for Reducing Host Cell Protein Content in Protein Purification

- (b) (4)

The parties agree that, should additional information relevant to these assertions become available, the parties shall reevaluate said assertions as necessary in the future.

Recommendations for Pandemic treaty

1. Separate chapter on transparency, to address several different transparency concerns.
2. Obligation to share copies of research funding agreements, licenses and procurement contracts with the WHO for a contracts repository.
3. WHO publish best practices regarding transparency of contracts.