KEI Briefing Note 2022:1
Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents
July 19, 2022

Introduction[1]

A KEI review of contracts between the United States government and private companies to provide countermeasures for COVID 19 illustrates the simplicity of the legal mechanism used by the federal government to eliminate exclusive rights to use patented inventions for federal programs, and the surprising frequency that this was done for COVID 19 countermeasures.

Using the U.S. Freedom of Information Act, KEI obtained a number of research and development and procurement contracts related to COIVD 19, Many of the contracts contained significant redactions. For 62 contracts, KEI was able to identify language relating to the government authorization to use patented inventions without the permission of patent holders. Among the 62 contracts, 54 provide a broad authorization to use any U.S. patented invention. Five contracts authorize the use of any inventions that were not "commercially available to the public by the Recipient." Another 3 contracts contained a clause stating that there was no consent, express or implied, for such authorization.

28 USC § 1498, Statutory authority

Under U.S. Law, the federal government can authorize third parties to use patented inventions without the consent of the patent holder. The relevant statute is 28 USC § 1948, titled Patent and copyright cases. The statute addresses not only patents, in paragraph (a), and copyrights in paragraph (b), but also plant variety protection in paragraph (d) and the protection of semiconductor chip products and original designs in paragraph (e).

The statute states that "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture."

To clarify the scope of the exception, the statute further states that "the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."

The authorization to use patents for the government can be made by any agency in the federal government, and the authorization can be oral or in writing, express or implied, and broad or limited.

During the COVID 19 pandemic, the U.S. government has provided dozens of authorizations to use patents to companies large and small. The best known case involves the Moderna vaccine, and the federal government's authorization has been highlighted by Moderna in court filings relating to the infringement of patents by third parties in this case:

> Arbutus Biopharma Corporation and Genevant Sciences GMBH, Plaintiffs, v. Moderna Inc. and Modernatx, Inc., Defendants. C.A. No. 22-252 (MSG), In The United States District Court For The District Of Delaware.. (link)

Less well known are a large number of similar government use authorizations for COVID 19 countermeasures by the U.S. government.

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FAR 52.227-1 - Authorization and Consent

Most of the authorizations involve the use of the Authorization and Consent set out in different revisions of Federal Acquisition Regulation FAR 52.227-1, which is used either as a template for a contractual authorization or simply referenced in a contract.

Through the U.S. Freedom of Information Act, KEI has obtained a large number of COVID 19 contracts. In some cases KEI was able to identify a U.S. government use authorization. In other contracts, KEI was unable to determine if such authorizations exist, given the redactions the government has made.

The beneficiaries of the government use authorizations involving well known companies like Corning, Eli Lilly, Merck Moderna, Novavax, Philips, Qiagen, Sanofi or Siemens, as well as many small companies and a few universities. The contracts were for COVID 19 countermeasures, including vaccines, drugs, diagnostic tests and other technologies.

In each of these cases, the authorization is broad, done without naming specific patents for which the non-voluntary use is authorized, applies to patents that may be granted at a later date, and does not require prior negotiation with patent holders. The U.S. government assumes responsibility for compensating patent owners, if any, who can demonstrate their inventors were used by the contractor.

KEI may update this briefing note at a later time as additional contracts are made available and redactions on existing documents are removed through litigation.

Table 1 below lists the specific authorization language for the 62 contracts.

Table 1: Selected COVID contracts, and provisions with Authorization and Consent for government use under 28 U.S. Code § 1498

Contract	Authorization and Consent Clause
Novavax, Army, W911QY20C0077, June 4, 2020	The clauses “52.227-I and 52.227-I Alt I” are incorporated by reference, at Page 14.
Beckman Coulter Inc., HHS/ASPR/BARDA, 75A50120C00189, Sept. 28, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)
Beckman Coulter Inc., HHS/ASPR/BARDA, 75A50119C00078, Sep. 30, 2019	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 36)
Controlant HF, Army, W911QX21C0010, Nov. 25, 2020	52.227-1 Authorization and Consent JUN 2020
Cue Health, HHS/OS/ASPR, HHSO100201800016C, 6/4/2018	52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr 1984)
Current Health, HHS/ASPR/BARDA, 75A50120C00190, Sep. 25, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Eli Lilly, Army, W911QY21C0016, Oct. 26, 2020	52.227-1 Authorization and Consent JUN 2020
Emergent Biosolutions, HHS/ASPR/BARDA, Contract Number: HHSO100201200004I Task Order Number: 75A50120F33007	“In addition, this task order incorporates FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).” (Page 12)

Velocity DX, Army , W911QY20D0031, Aug. 12, 2020	FAR 52.227-1 Authorization and Consent JUN 2020 (Page 14)
ANP, Army, W911QY20D0019, May 24, 2020	FAR 52.227-1 Authorization and Consent DEC 2007 (Page 13)
Maxim Biomedical, Army, W911QY20F0244, May 11, 2020	FAR 52.227-1 Authorization and Consent DEC 2007 (Page 17)
Maxim Biomedical, Army, W911Qy20D0018, May 11, 2020	52.227-1 Authorization and Consent DEC 2007
Diasorin Inc. , HHS/ASPR/BARDA, 75A50120C00070, April 10, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984)
Diasorin Inc. HHS/ASPR/BARDA, 75A50120C00017, March 11, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984)(Page 30)
Empatica, HHS/ASPR/BARDA, 75A50120C00132, June 12, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Esperovax, HHS/ASPR/BARDA, 75A50120C00154, March 20, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Evidation Health Inc., HHS/ASPR/BARDA, 75A50120C00091, Apr. 17, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Genmark Diagnostics, Inc., HHS/ASPR/BARDA, 75A50120C00022, March 20, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Hememics, HHS/ASPR/BARDA, 75A50120C00074, April 9, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Hememics, HHS/ASPR/BARDA, 75A50120C00074_Mod_00001, June 3, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Hologic Inc., HHS/ASPR/BARDA, 75A50120C00015, March 6, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Immunexpress, HHS/ASPR/BARDA, 75A50120C00125, June 11, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
Inbios International, Inc., HHS/ASPR/BARDA, 75A50120C0009C, 4/26/2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Luminex Aries, HHS/ASPR/BARDA, 75A50120C00043, March 27, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr. 1984) (Page 28)
98Point6Inc., HHS/ASPR/BARDA, 75A50120C00151, Sep. 11, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 28)
Chembio Diagnostic Systems, Inc., HHS/ASPR/BARDA, 75A50120C00138, July 5, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Merck, HHS/ASPR/BARDA, HHSO100201600031C, Sep. 29, 2016	52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr 1984) (Page 87)
NOWDIAGNOSTICS INC. , HHS/ASPR/BARDA, 75A50120C00156	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 28)
Ophirex, Army/USAMRAA, W81WXH20C0066, June 19, 2020	52.227-1 Authorization and Consent DEC 2007

	52.227-1 Alt I Authorization And Consent (Dec 2007) - Alternate I APR 1984
Orasure Technologies Inc., HHS/ASPR/BARDA, 75A5012C00061, April 2, 2020	52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Orasure Technologies Inc., HHS/ASPR/BARDA, 75A50120C00122	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Orasure Technologies Inc., HHS/ASPR/BARDA, 75A50120C00061	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Ortho Clinical Diagnostics, HHS/ASPR/BARDA, 75A50120C00123, June 12, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 28)
Qiagen Inc., HHS/ASPR/BARDA, 75A50120C00014, March 12, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Quidel Corporation, HHS/ASPR/BARDA, 75A50120C00110, May 29, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Philips North America LLC, HHS/ASPR/BARDA, 75A50120C00097, May 7, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 59)
Mesa Tech International, HHS/ASPR/BARDA, 875A50120C00019, March 13, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Nanomix Inc., HHS/ASPR/BARDA, 75A50120C00060, 4/2/2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 30)
Tangen Biosciences, HHS/ASPR/BARDA, 75A50120C00085,April 15, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 28)
Sonica LLC, HHS/ASPR/BARDA, 75A50119C00043, Aug. 1, 2019	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 27)
Sonica LLC, HHS/ASPR/BARDA, 75A50119C00043_Mod_00003, June 30, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 27)
University of Connecticut, HHS/ASPR/BARDA, 75A50120C0016, August 18, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 28)
Vaxess Technologies Inc., HHS/ASPR/BARDA, 75A50120C00160, 8/6/2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 28)
Verndari, HHS/ASPR/BARDA, 75A50120C00153	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Sepsis Alliance, HHSO100201900021C_Mod_0002, HHS/ASPR, 5/7/2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 25)
MBIO Diagnostics Inc., HHS/ASPR/BARDA, 75A50120C00130, June 17, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984) (Page 28)
Siemens Healthcare Diagnostics Inc., HHS/ASPR/BARDA, 75A50120C00111, May 28, 2020	FAR 52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)
Vital Connect Inc., HHS/ASPR/BARDA, 75A50120C00108, 5/20/2020	52.227-1 Dec 2007 Authorization and Consent, Alternate 1 (APR 1984)(Page 30)

World Enterprises, Inc., Army, W 911SR21C0008, November 13, 2020	52.227-1 Alt I Authorization And Consent (JUN 2020) - Alternate I APR 1984
Prototype Other Transaction Agreement, The Medical Technology Enterprise Consortium, U.S. Army Medical Research and Material Command, W81XWH-15-9-0001, January 25, 2016	10.3. Authorization and Consent. The Government authorizes and consents under 28 U.S.C. 1498 to all use and manufacture of any invention described in and covered by a United States patent in the performance of this Agreement or any subaward at any tier. (Page 37)
Moderna, HHS/ASPR/BARDA;, DOD/Army/JPEO-CBRND/DCMA, W911QY20C0100 8/9/2020	52.227-1 Authorization and Consent JUN 2020 52.227-1 Alt I Authorization And Consent (JUN 2020) - Alternate I APR 1984
Moderna, HHS/ASPR/BARDA, 75A50120C00034, 4/16/2020	52.252-2 Clauses Incorporated by Reference (Feb 1998) This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available, Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/ The following FAR clauses, pertinent to Section I, are hereby incorporated by reference: … 52.227-1 Authorization and Consent Dec 2007
Moderna, HHS/ASPR/BARDA, HHSO10020160029C, 9/1/2016	52.227-1 Dec 2007 Authorization and Consent, Alternate I (Apr 1984)
Protein Sciences Corporation (Sanofi), HHS/ASPR/BARDA, HHSO100201600005I, 2/14/2020	52.227-1 - Authorization and Consent, Alternate I (Apr 1984) (Dec 2007) (Page 53)
NOT COMMERCIALLY AVAILABLE	
Cytiva, Army , W911NF2130001, Oct. 3, 2020	11.2 Authorization and Consent for Non-commercial Products. The Government authorizes and consents to all use and manufacture, in performance of this Agreement, of any invention described in and covered by a United States patent, except for deliverables under this Agreement that are commercially available to the public by the Recipient. (Page 10)
Sio2 Medical Products, Army, W911NF2030003, June 5, 2020	“11.2 Authorization and Consent for Non-commercial Products. The Government authorizes and consents to all use and manufacture, in performance of this Agreement, of any invention described in and covered by a United States patent, except for deliverables under this Agreement that are commercially available to the public by the Recipient.” (Page 14)

Retractable Technologies, Inc. (RTI) , HHS/ASPR/BARDA; DOD/Army/DCMA W911SR2030004, 7/1/2020	11.2 Authorization and Consent for Non-commercial Products. The Government authorizes and consents to all use and manufacture, in performance of this Agreement, of any invention described in and covered by a United States patent, except for deliverables under this Agreement that are commercially available to the public by the Recipient. (Page 13).
Corning, Army, W911NF2030004, June 5, 2020	“11.2 Authorization and Consent for Non-commercial Products. The Government authorizes and consents to all use and manufacture, in performance of this Agreement, of any invention described in and covered by a United States patent, except for deliverables under this Agreement that are commercially available to the public by the Recipient.” (Page 18)
Johns Hopkins, Army Contracting Command, W911QY2090012, June 8, 2020	“C. Authorization and Consent for Non-commerical Products. The Government authorizes and consents to all use and manufacture, in performance of this Agreement, of any invention described in and covered by a United States patent, except for deliverables under this Agreement that are commercially available to the public by the Awardee.”
NO CONSENT CONTRACTS	
Inovio Pharmaceuticals, Inc., Army, W911QY-20-9-0016, June 22, 2020	“A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement”
60 Degrees Pharmaceuticals, LLC The Army, W911QY-21-9-0011,Dec. 4, 2020	“A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.”
Ology Bioservices (previously Nanotherapeutics, Inc.), DOD/Army, W911QY2090003, 2/21/2020	ARTICLE 14. Miscellaneous Clauses. A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

ANNEX, FAR 52.227-1 Authorization and Consent,

FAR FAC Number: 2022-06
Effective Date: 05/26/2022
As prescribed in 27.201-2(a)(1), insert the following clause:

Authorization and Consent (Jun 2020)

(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.

(End of clause)

Alternate I (Apr1984). As prescribed in 27.201-2(a)(2), substitute the following paragraph (a) for paragraph (a) of the basic clause:

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

Alternate II (Apr1984). As prescribed in 27.201-2(a)(3), substitute the following paragraph (a) for paragraph (a) of the basic clause:

(a) The Government authorizes and consents to all use and manufacture in the performance of any order at any tier or subcontract at any tier placed under this contract for communication services and facilities for which rates, charges, and tariffs are not established by a government regulatory body, 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 specifications or written provisions forming a part of this contract or with specific written instructions given by the Contracting Officer directing the manner of performance.

ANNEX, Article 44.2 of the WTO TRIPS agreement

Part III of the WTO TRIPS agreement concerns the enforcement of intellectual property rights. Within Part III, is Section 2: Civil And Administrative Procedures And Remedies. Within Section 2, is Article 44, which deals with injunctions. For non-voluntary use of patented inventions, Article 44 looms large.

Under the paragraph 44.1, judicial authorities, particularly in the United States, can decline to grant injunctions to prevent an infringement, often in connection with a requirement that the infringing entity pay a royalty, including on future sales. In such cases, the result is a limitation on remedies that permits non-voluntary use of the invention. Some courts refer to such outcomes as court ordered compulsory licenses, although other terms are also used, such as an order to pay a running royalty.

Under the second paragraph, 44.2, WTO members can even eliminate the statutory right to obtain an injunction, if “reasonable remuneration” or “adequate compensation” are paid to the patent holders. The U.S. government use statute, 28 USC § 1498, is implemented under Article 44.2 of the TRIPS. This provides the absolute simplest flexibility in the TRIPS for non-voluntary use of inventions or other types of intellectual property. By merely limiting the availability of an injunction, a WTO member can ignore the somewhat complex and restrictive regulatory conditions in Articles 31 and 31bis of the TRIPS agreement (as well as restrictions relevant to other types of intellectual property rights in the TRIPS).

The text of Article 44 follows.

Article 44 - Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available