

Non-voluntary use of patents in the United States

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KEI Side Event
WHO INB8
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US authorization and consent to use patents during COVID-19

28 U.S.C. §1498(a). Patent and copyright cases

(a) 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. [. . .]

For the purposes of this section, 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.

[Link to text](#)

Note: (b) covers copyright, (d) plant varieties, and (e) semiconductor chip designs

The Federal Acquisition Regulation (FAR) contains standard solicitation provisions and contract clauses, that when referenced in a contract, have the same force and effect as if they were given in full text.

Several sections of the FAR are related to rights in data, inventions, and copyrights.



FAR

FAC Number: 2023-05
Effective Date: 09/22/2023

Part 52

[52.227-2 Notice and Assistance Regarding Patent and Copyright Infringement.](#)

[52.227-3 Patent Indemnity.](#)

[52.227-4 Patent Indemnity-Construction Contracts.](#)

[52.227-5 Waiver of Indemnity.](#)

[52.227-6 Royalty Information.](#)

[52.227-7 Patents-Notice of Government Licensee.](#)

[52.227-8 \[Reserved\]](#)

[52.227-9 Refund of Royalties.](#)

[52.227-10 Filing of Patent Applications-Classified Subject Matter.](#)

[52.227-11 Patent Rights-Ownership by the Contractor.](#)

[52.227-12 \[Reserved\]](#)

[52.227-13 Patent Rights-Ownership by the Government.](#)

[52.227-14 Rights In Data-General.](#)

[52.227-15 Representation of Limited Rights Data and Restricted Computer Software.](#)

[52.227-16 Additional Data Requirements.](#)

[52.227-17 Rights in Data-Special Works.](#)

[52.227-18 Rights in Data-Existing Works.](#)

[52.227-19 Commercial Computer Software License.](#)

[52.227-20 Rights In Data-SBIR Program.](#)

[52.227-21 Technical Data Declaration, Revision, and Withholding of Payment-Major Systems.](#)

[52.227-22 Major System-Minimum Rights.](#)

[52.227-23 Rights to Proposal Data \(Technical\).](#)

Parent topic: [Subpart 52.2 - Text of Provisions and Clauses](#)

Part 52 - Solicitation Provisions and Contract Clauses

Subpart 52.2 - Text of provisions and clauses

52.227 - Provisions and clauses relating to patents, data and software

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

52.227-1 Authorization and Consent (June 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

Link to FAR [52.227-1](#)

Including FAR 52.227-1 in a contract

The text of a standard FAR clause can be included in a contract, or, more commonly, simply included by reference.

PART II – CONTRACT CLAUSES

I. CONTRACT CLAUSES

I.1 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:

FAR Clause	Title	Date
52.202-1	Definitions	Nov 2013
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Sep 2006
52.203-7	Anti-Kickback Procedures	May 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	May 2014

FAR 52.227-1 reference in Moderna's mRNA COVID 19 vaccine contract

52.224-2	Privacy Act	April 1984
52.224-3	Privacy Training	Jan 2017
52.225-13	Restrictions on Certain Foreign Purchases	Jun 2008
52.225-25	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications	Aug 2018
52.227-1	Authorization and Consent	Dec 2007
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Dec 2007
52.227-11	Patent Rights-Ownership by the Contractor	May 2014
52.227-14	Rights in Data – General	May 2014
52.227-14	Rights in Data – General, Alternate II (Dec 2007)	May 2014
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.232-9	Limitation on Withholding of Payments	Apr 1984

Using FAR 52.227-1

There is no requirement to negotiate with the patent holder, contact the patent holder or identify the patents used.

There are no restrictions on exports or imports. (no TRIPS 31.f, 31bis or June 17, 2022 conditions attached)

There is no balancing test or grounds required, and no waiting period. The federal government has a clear right to use 52.227-1 whenever it chooses.

The patent holder is entitled the compensation, but only from the federal government.

FAR 52.227-3 Patent Indemnity (April 1984)

(a) The Contractor shall indemnify the Government and its officers, agents, and employees against liability, including costs, for infringement of any United States patent (except a patent issued upon an application that is now or may hereafter be withheld from issue pursuant to a Secrecy Order under 35 U.S.C.181) arising out of the manufacture or delivery of supplies, the performance of services, or the construction, alteration, modification, or repair of real property (hereinafter referred to as "construction work") under this contract, or out of the use or disposal by or for the account of the Government of such supplies or construction work.

(b) This indemnity shall not apply unless the Contractor shall have been informed as soon as practicable by the Government of the suit or action alleging such infringement and shall have been given such opportunity as is afforded by applicable laws, rules, or regulations to participate in its defense. Further, this indemnity shall not apply to—

(1) An infringement resulting from compliance with specific written instructions of the Contracting Officer directing a change in the supplies to be delivered or in the materials or equipment to be used, or directing a manner of performance of the contract not normally used by the Contractor;

(2) An infringement resulting from addition to or change in supplies or components furnished or construction work performed that was made subsequent to delivery or performance; or

(3) A claimed infringement that is unreasonably settled without the consent of the Contractor, unless required by final decree of a court of competent jurisdiction.

Examples

KEI collection of contracts with FAR 52.227-1, 2, 3 or 11 ([link](#))

Also: <https://drugdatabase.info/far-52-227-1-contracts/>

U.S. rights in inventions that it funds

In a standard funding agreement, the U.S. government obtains a worldwide royalty-free right to have patented inventions be used by or for the federal government, as well as a march-in right.

The rights in a standard contract are also set out in a section of the FAR.

Non-voluntary use of patents invented with federal funding

The Bayh-Dole Act

The US government retains rights in inventions that it funds, including a worldwide royalty-free right to use inventions by or for the federal government, and a march-in right for licenses to third parties.

FAR 52.227-11

FAR 52.227-11 sets out the standard agreement on the relative rights of the U.S. government and the contractor in any inventions that were funded in whole or in part from the funding agreement.

This regulation, which is worth reviewing, sets out a number of important terms and conditions, including obligations to disclose the inventions to funding agencies, a world-wide royalty-free right for the US government to use a patented invention, and the federal government right to march-in and grant licenses to third parties.

Link to FAR [52.227-11](#)

Bayh-Dole rights as a research exception

Federal agencies have often used the Bayh-Dole government-use license to permit non-voluntary use of patents for medical research.

Broad Bayh-Dole March-In Licensing Rights Affirmed in Alzheimer's Mouse Patent Dispute

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by Dennis Crouch

The Federal Circuit recently upheld the US government's royalty-free license rights over an Alzheimer's disease research patent under the Bayh-Dole Act. *University of South Florida Board of Trustees v. United States*, 22-2248 (Fed. Cir. February 9, 2024). The decision confirms the broad scope of the government's licensing rights under the Act — namely that it can include work that predates the funding agreement. It also comes at a salient time, as the Biden Administration weighs the idea of more aggressively exercising “march-in rights” under the Act to promote affordability of taxpayer-funded inventions. [Read the Decision.](#)

Exceptions to standard Bayh-Dole rights

The standard Bayh-Dole rights can be modified using exceptions in the Bayh-Dole Act.

Section 202(a):

- (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government,
- (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter,

Section 202(c)(4)

or the right to included expanded rights in determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement,

Or when an “Other Transactions Agreement” (OTA) is used.

Biden Instagram message on march-in rights

Hundreds of billions of taxpayer dollars are spent on research, discovery, and development of new prescription drugs. And while I firmly believe that the strength of a nation can be measured by the boldness of its science, the quality of its research, and the progress it helps bring forth, I also believe that the folks who paid for the research – you – ought to be able to access and afford the final product.

That's why my Administration is proposing that if a drug made using taxpayer funds is not reasonably available to Americans, the government reserves the right to "march in" and license that drug to another manufacturer who could sell it for less.

This is an important step toward ending Big Pharma price gouging. It's good for competition., It's good for our economy. And it's good for the millions of Americans who can't afford their medications – who know all too well that fine line between dignity and dependence that the price of a prescription drug can draw.

Compulsory licenses under the eBay decision

On May 15, 2006, the US Supreme Court decided a case regarding an injunction to prevent the online auction eBay from infringing a patent owned by MercExchange, L.L.C. The decision, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), set out a four-part test to consider before an injunction is granted. Courts now routinely can consider granting compulsory licenses, sometimes referred to as “running royalties,” which allow the non-voluntary use of patented inventions.

When using this flexibility in TRIPS (Article 44), there are no restrictions on exports.

In the eBay injunction case compulsory licenses have been used in many cases involving medical devices, software, automobiles, and other technologies.

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