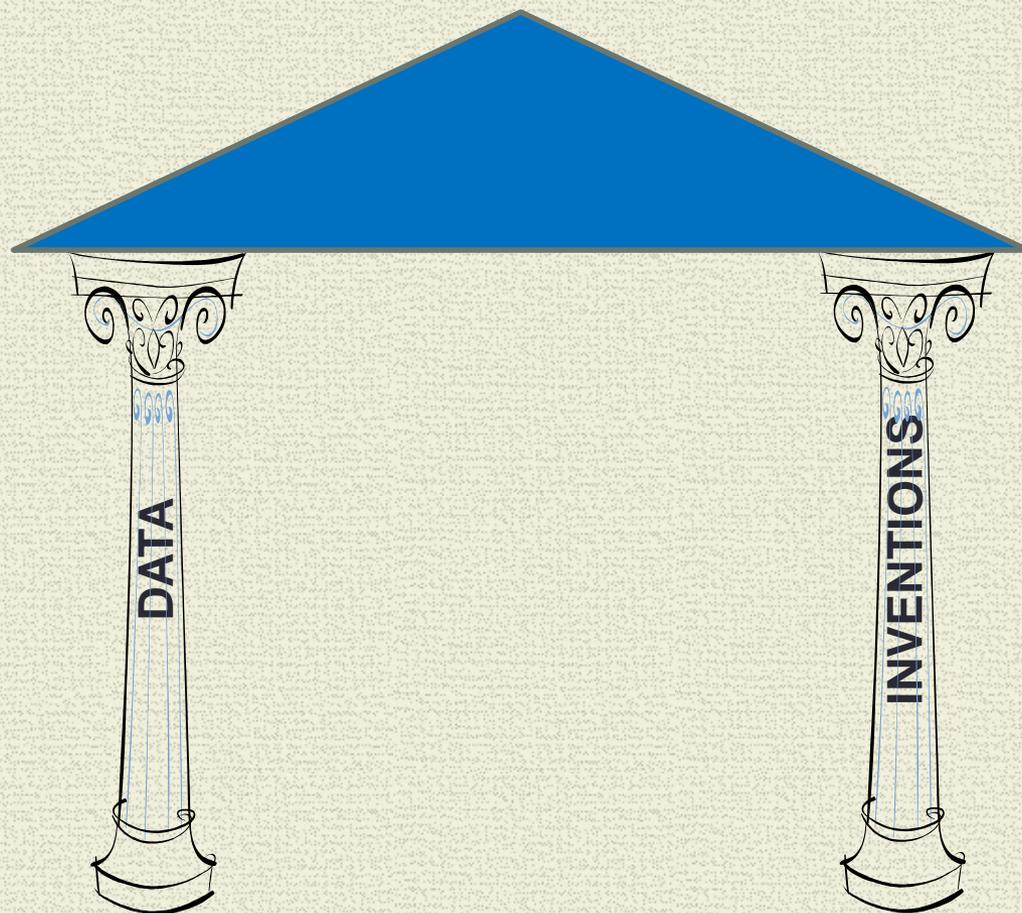


INTELLECTUAL PROPERTY IN GOVERNMENT-SUPPORTED R&D

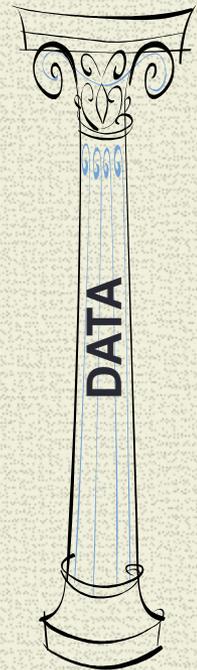
Dale D. Berkley, Ph.D., J.D.
HHS Office of General Counsel

Data and Invention Rights are the Dominant IP in R&D Contracts



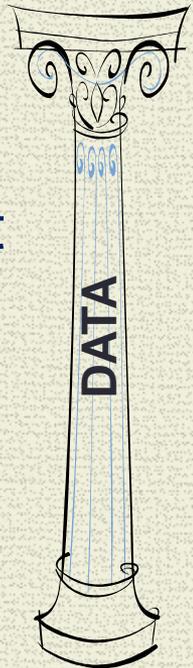
Data Rights are Governed by Two Mutually-Exclusive FAR Provisions

- ❖ Rights in Data-General (52.227-14)
- ❖ Special Works (52.227-17)



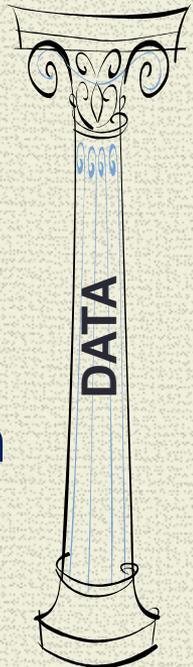
Rights in Data-General is the Default Data Rights Provision

- ❖ It gives the Contractor the right to use, release to others, reproduce, distribute, or publish **any data first produced** or specifically used by the Contractor in the performance of this contract.
- ❖ It gives the Government **Unlimited rights**---the right to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.



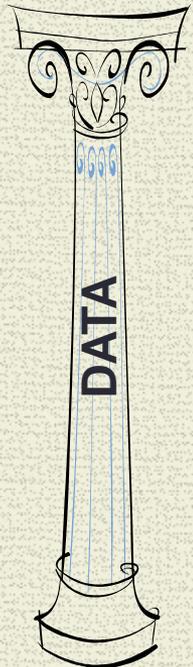
Rights in Data-General Acknowledges Limited Rights Data

- ❖ **Limited rights data** are Contractor data that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.
- ❖ The Contractor **must identify Limited rights data** and if delivered the Government may only use them for its own manufacturing purposes or as delimited in a separate “Alternate” provision.



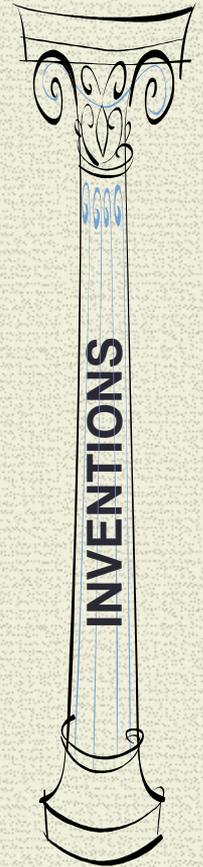
Rights in Data-General Acknowledges Restricted Computer Software

- ❖ **Restricted computer software** means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.
- ❖ The Contractor must identify **restricted computer software** and if delivered the Government may only use it consistent with a **Restricted Rights Notice**.



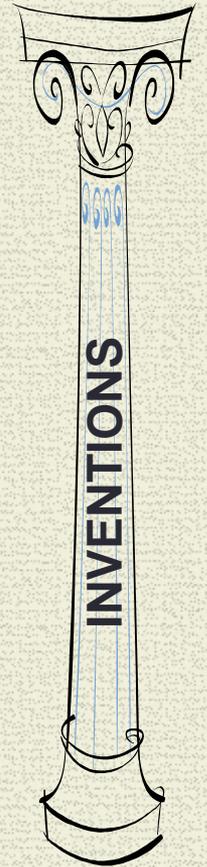
Invention Rights are Governed by a Single FAR Provision that Codifies the *Bayh-Dole Act*

- ❖ Patent Rights—Ownership by the Contractor (52.227-11)



Invention Rights

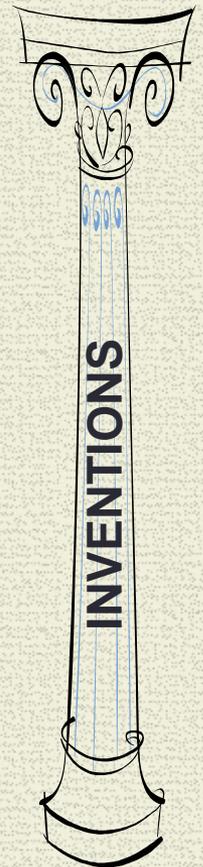
- ❖ The Contractor, in a letter to the Government, elects title to any invention that it develops under the contract.



Invention Rights

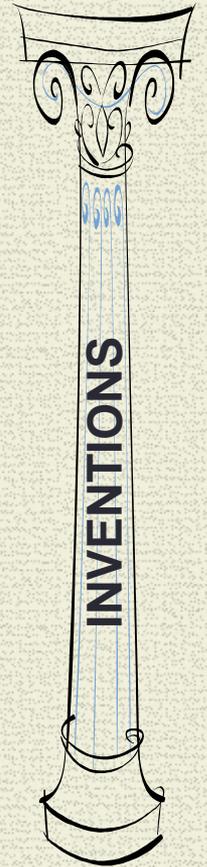
- ❖ The Government retains a “use” license to the invention.

It is a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on the Government’s behalf, the subject invention throughout the world.



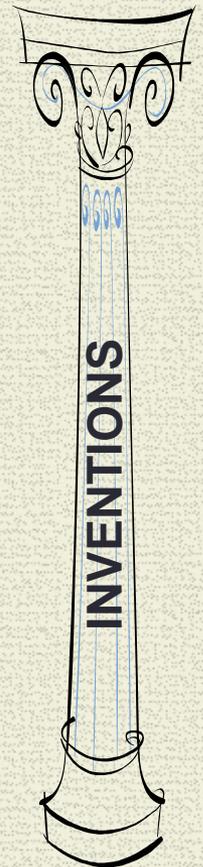
Invention Rights

- ❖ The Government does not gain any rights in the Contractor's **“Background Rights”** unless it purchases them.



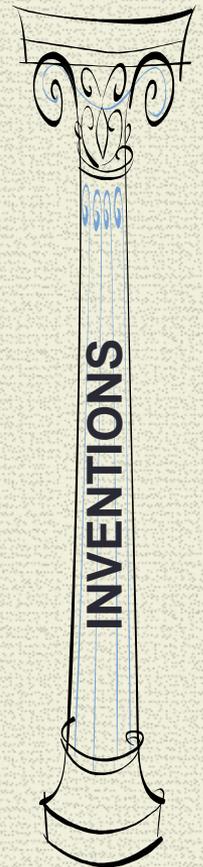
Invention Rights

- ❖ The Government retains the right to **“March-In”** and require the Contractor to grant a license to designated third parties under certain circumstances.
- ❖ This has never actually happened (see *CellPro*)



Invention Rights

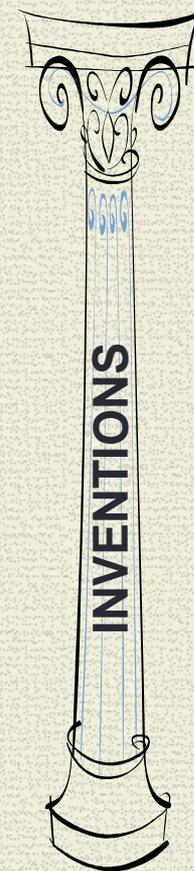
- ❖ The Government may determine, in advance of granting the contract, that **Exceptional Circumstances** warrant restriction or elimination of the Contractor's right to elect title to inventions made under the contract.



Invention Rights

Authorization and Consent (52.227-1)

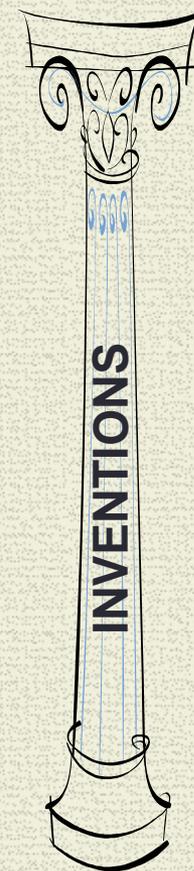
- ❖ The Government **authorizes and consents** to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent



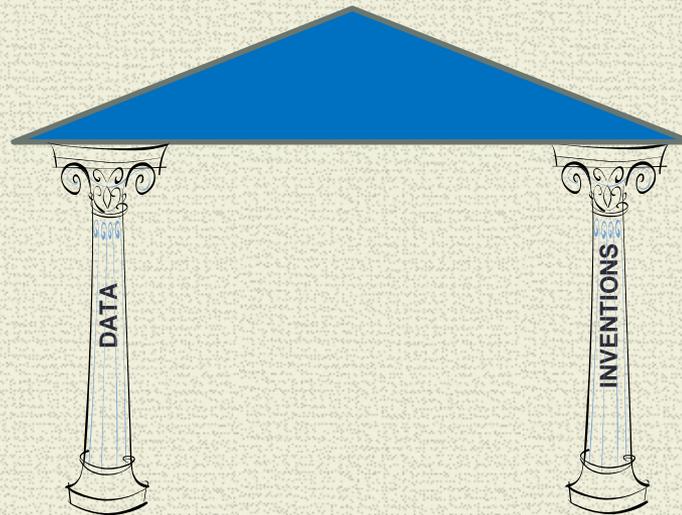
Invention Rights

Patent Indemnity (52.227-3)

- ❖ The Contractor shall **indemnify** the Government against liability, including costs, **for infringement** of any United States patent arising out of the manufacture or delivery of supplies, the performance of services, or the construction, alteration, modification, or repair of real property...



Thank you!



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Berkleyd@od.nih.gov