



*The Only Government-  
wide Forum for  
Technology Transfer*

## **CRADA WORKSHOP**

**Robert L. Charles, Esq.**  
**Army Medical Research and  
Materiel Command**  
**(301) 619-7663**  
**robert.charles@us.army.mil**



## ***ROBERT L. CHARLES, ESQ.***

- Chair, FLC Legal Issues Committee (2002-present)
- Attorney Advisor, Army Medical Research and Materiel Command (2001-present)
- Responsible for technology transfer, assistance agreements, and patent licensing
- Twenty-year active-duty career as Judge Advocate with the U.S. Army



## ***DISCLAIMER***

The opinions expressed by Mr. Charles during this workshop are his own and do not represent the position of the U.S. Government, the U.S. Department of Defense, the U.S. Army, Mrs. Charles, or the Charles children.



# PART 1

# BACKGROUND



## ***BACKGROUND***

- Until 1950, federal employees owned their government-funded inventions (U.S. v. Dubilier Condenser Corp., 289 U.S. 178 (1933))
- After 1950, the federal government owned its employees' inventions (Executive Order 10096)
- The federal government owned inventions arising out of funding agreements, e.g., procurement contracts and grants



## ***BACKGROUND (Cont.)***

- Research-related assistance agreements and government contracting boomed from 1950s on, e.g.:
  - Nuclear weapons and energy
  - DOD (Cold War)
  - Agriculture
  - Space race
  - Medical



## ***BACKGROUND (Cont.)***

### **Problem**

- Federal ownership of federally funded inventions was a counterproductive policy
- U.S. taxpayers paid for 70% of U.S. R&D through federal government
- No effective means, mechanisms, or policies to get \$ billions in federal R&D investment in potentially useful technologies for commercial products into the U.S. economy



## ***BACKGROUND (Cont.)***

### **Additional Problem**

In the 1970s, the U.S. economy appeared to be losing ground quickly to the Japanese and Germans with regard to bringing new technologies to market



## ***BACKGROUND (Cont.)***

### **Solution**

- Federal technology transfer legislation from 1980-present
  - Stevenson-Wydler Act
  - Bayh-Dole Act
  - Federal Technology Transfer Act of 1986 and amendments



## ***BACKGROUND (Cont.)***

### **Results**

- Technology transfer a mission of the federal government
- Federal agencies receive greater, more flexible patent and licensing authority
- Mechanisms to implement technology transfers, including CRADAs
- ORTAs and FLC established and funded
- Incentives established for government inventors and their labs
- Businesses, universities, and not-for-profits keep title to inventions made with federal funds



## **PART 2**

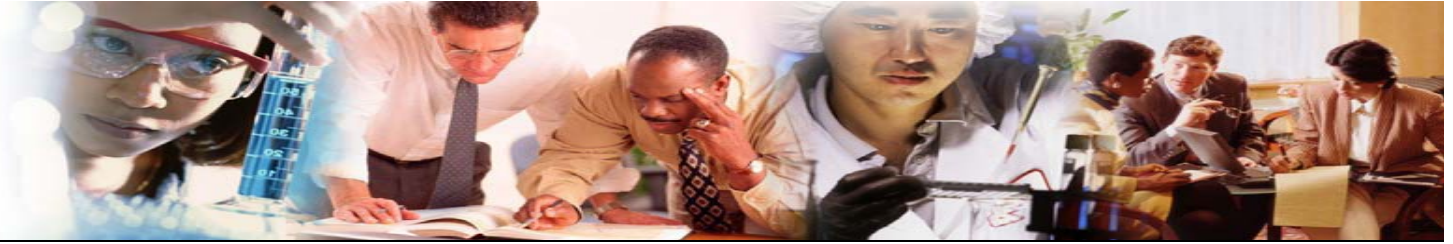
# **WHAT IS A CRADA?**



## ***WHAT IS A CRADA?***

### **The Big Picture**

- A means, mechanism, and authority given to federal agencies and labs to implement the Stevenson-Wydler Act technology transfer mandate
- A new kind of government contract for R&D collaborations between federal labs & nonfederal parties
  - Allows great flexibility and discretion
  - Allows for the transfer of government intellectual property (IP) to nonfederal partners
  - Allows for R&D collaborations between federal labs and nonfederal parties



## ***WHAT IS A CRADA? (Cont.)***

### **Legal Definition**

“ . . .any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources, with or without reimbursement (but not funds to the non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research and development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31 . . .”

—15 USC § 3710a(d)(1)



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more *Federal laboratories...*”

The term “*laboratory*” means:

“A facility or group of facilities owned, leased, or otherwise used by a Federal Agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”

—15 USC 3710a(d)(2)(A)



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more *Federal laboratories* ...”

Yellowstone National Park is a federal laboratory

Edmonds Institute, et al. v. Bruce Babbitt, et al., 93 F. Supp 63, (USDC DC, April 12, 2000)



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories *and one or more non-Federal parties...*”

“Non-Federal parties” means: “units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency).”

—15 USC § 3710a(a)(1)



## ***WHAT IS A CRADA? (Cont.)***

Acceptable nonfederal CRADA parties:

- British government-owned laboratory?
- German government-owned university?
- World Health Organization?
- Industrial development organization founded under the United Nations?



## ***WHAT IS A CRADA? (Cont.)***

- “...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel...”
- Example: CRADA Statement of Work (SOW) that provides for the federal lab to send a microbiologist and a technician to the CRADA partner’s facility for two weeks to carry out tests and evaluation of the partner’s technology using both parties’ unique testing equipment



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides... services...”

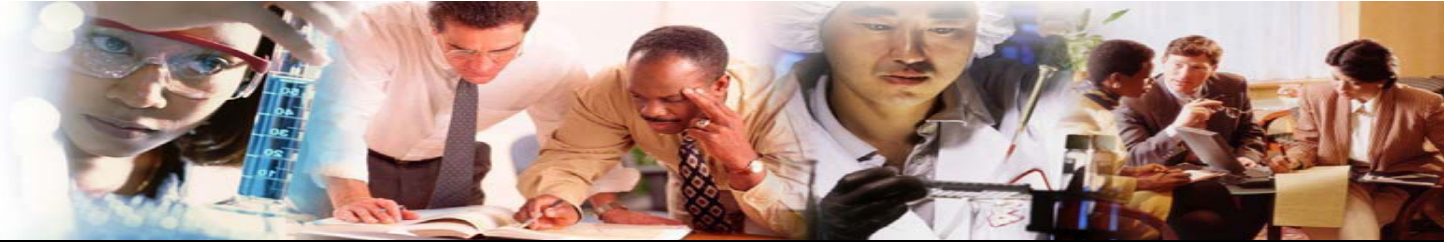
- Example: CRADA SOW that provides for the federal lab to use its proprietary assay technology to test CRADA partner’s drug for new use, with the lab providing the partner a report and the partner paying for the lab’s costs



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides...*facilities*...”

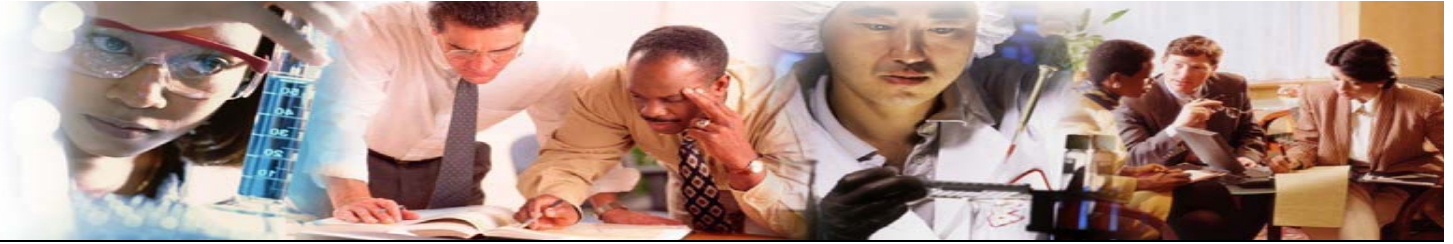
- Example: CRADA SOW that provides for the nonfederal CRADA partner to send two scientists to work at a federal lab for six weeks to use lab’s unique technology to test CRADA partner’s drug for anti-Alzheimer’s properties



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides ... *equipment*...”

- Example: CRADA SOW that provides for the federal lab to buy a microscope and send it to the CRADA partner’s overseas lab for the partner’s contracted technician to read slides, and the parties agree that the microscope becomes the property of the partner at the end of the agreement



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides . . . *intellectual property*...”

- Example: CRADA SOW provides for the federal lab to grant to the nonfederal CRADA partner a nonexclusive license to use a lab’s patented invention for five years to carry out CRADA research and to develop other specified commercial technology. The CRADA partner pays the lab \$10,000 for the license  
(We will discuss CRADA IP issues in more detail later!)



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides (these and other resources) *with or without reimbursement...*”

- This is stand-alone, discretionary to the lab, statutory authority to negotiate and receive reimbursement from \$0.00 up to fair market value for whatever the lab will provide or has provided



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement ***(but not funds to the non-Federal parties)***...”

- The lab cannot provide funds, but it can direct the partner to other potential funding sources, such as grants, SBIR, state economic development funds, etc.



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which . . . *the non-Federal parties provide funds*...”

- No augmentation of appropriations problem
- No miscellaneous receipts problem
- Can use funds to hire personnel to carry out the agreement who will not be subject to the full-time-equivalent restrictions of the agency (see 15 USC 3710a(b)(3)(B))



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which . . . *the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources...*”

- Provides authority for the lab to accept, retain, and use funds, personnel, services, and property from a collaborating party (see 15 USC 3710a(b)(3)(A))



## ***WHAT IS A CRADA? (Cont.)***

All resources to be provided by the parties,  
including how much reimbursement goes to  
the lab, are

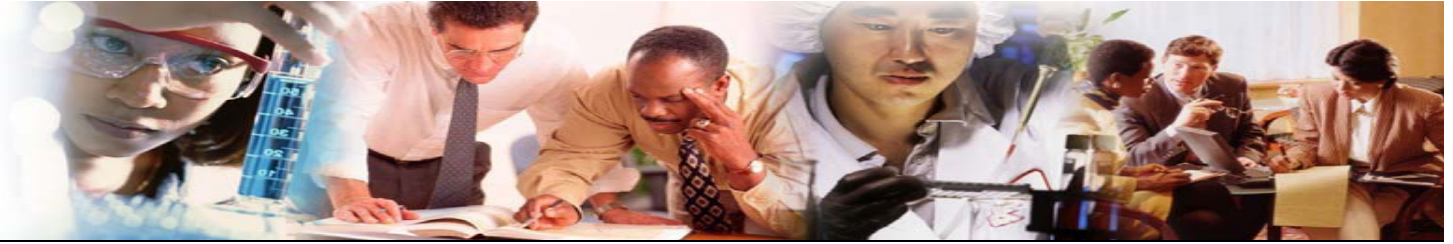
**NEGOTIABLE!**



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more federal laboratories and one or more non-federal parties... toward the conduct of *specified research and development efforts*...”

- No definition of R&D is provided in the statute



## ***WHAT IS A CRADA? (Cont.)***

### **What is R&D?**

- The SBIR statute (15 USC 638(e)(5)) indicates that R&D means: “any activity which is (A) a systematic, intensive study directed toward greater knowledge or understanding of the subject studied; (B) a systematic study directed specifically toward apply new knowledge to meet a recognized need; or (C) a systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.”



## ***WHAT IS A CRADA? (Cont.)***

### **Would this be considered R&D?**

A collaboration of prostate cancer funding organizations (federal and nonfederal) to create a publicly accessible database of their current areas of funded research that will give prostate cancer researchers, doctors, and patients, information on the state of funded research



## ***WHAT IS A CRADA? (Cont.)***

“...any agreement between one or more federal laboratories and one or more non-Federal parties...toward the conduct of specified research and development efforts *which are consistent with the missions of the laboratory...*”

- The agency determines the mission or missions of each of its laboratories (see 15 USC 3710a(e))



## ***WHAT IS A CRADA? (Cont.)***

***“...except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31...”***

- **LAWYER ALERT!**

There is no specific guidance for CRADAs in the Federal Acquisition Regulations (FARs), the OMB Circulars, or Principles of Federal Appropriations Law (a.k.a. “The Red Book”)



## ***WHAT IS A CRADA? (Cont.)***

CRADAs may not be used by an agency to circumvent the statutory and regulatory requirements of federal procurement laws.

(See Chem Services, Inc., v. US EPA, 12 F.3d 1256 (USCA 3<sup>rd</sup> Cir., 1993))



# **PART 3**

# **CRADA AUTHORITY &**

# **INTELLECTUAL**

# **PROPERTY**



## ***CRADA AUTHORITY***

### **Who Can Do What?**

- CRADA authority detailed in 15 USC 3710a:

“Each Federal agency *may* permit the *director* of any of its Government-operated Federal laboratories...”

“(1) to enter into cooperative research and development agreements on behalf of such agency . . .”

—15 USC 3710a(a)(1)

- Authority is not automatic—there should be delegation paperwork/policy letter
- No authority to delegate below the lab director level



## ***CRADA AUTHORITY (Cont.)***

“Each Federal agency *may* permit the *director* of any of its Government-operated Federal laboratories...

“(2) to *negotiate licensing agreements* under section 207 of title 35 . . . *for inventions made or other intellectual property developed at the laboratory* and other inventions or other property that may be voluntarily assigned to the Government.”

—15 USC 3710a(a)(2)

- Covers inventions made under CRADAS or otherwise



## ***ESSENTIAL DIGRESSION***

Basic Intellectual Property discussion relating to the exercise of CRADA authority



## ***INTELLECTUAL PROPERTY***

- Intellectual Property Rights (IPR)—The legal rights to things people create or invent
  - Trade secrets
  - Trademarks
  - Copyrights
  - Patents



## ***INTELLECTUAL PROPERTY (Cont.)***

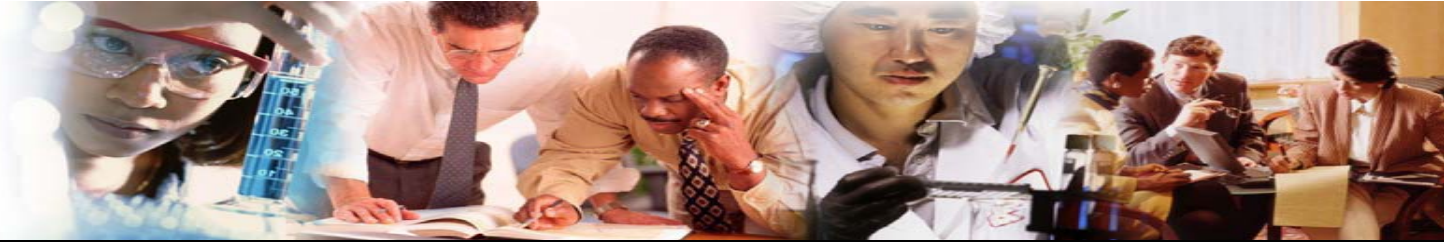
- Protecting IPR is absolutely necessary for economic prosperity in a free society
- IPR is one of the pre-conditions necessary to make worthwhile the investment of private resources required to bring products to market



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Trade Secrets**

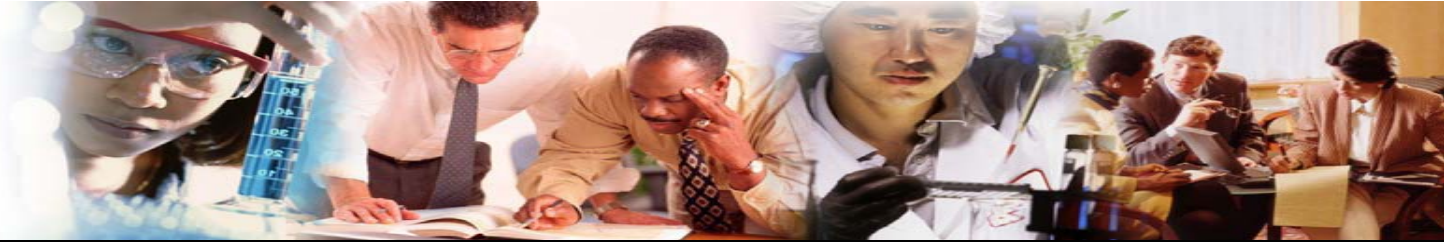
- Any information used in a company's business that is not generally known and confers an economic advantage over competitors, but only if "reasonable efforts" are made to maintain secrecy
- "Proprietary Information" and "Confidential Information" are commonly used to describe trade secrets
- Example of a trade secret—formula for Coca-Cola®



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Trade Secrets (Cont.)**

- Trade secrets are specifically provided for and protected under the CRADA statute
  - Trade secrets *obtained from a non-Federal participant* during CRADA research or as a result of CRADA activities shall not be disclosed (see 15 USC 3710a(c)(7)(A))
  - Trade secret type info *developed under a CRADA* may be protected from release up to 5 years after its development (see 15 USC 3710a(c)(7)(B))
  - Trade secrets *developed in anticipation of using it in a future CRADA* may be protected from release up to 5 years after its development. 15 USC 3710a(c)(7)(A); Delorme Publishing Company, Inc. v. NOAA, 917 F. Supp. 867 (USDC District of Maine, 1996)
  - An agency's royalty revenues and royalty rates from CRADA subject invention licenses are trade secrets and protected from release (see Public Citizen Health Research Group v. NIH, 209 F. Supp. 2d 37, (USDC DC 2002))



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Trade Secrets (Cont.)**

- Federal officers and employees can be fined and imprisoned for an unauthorized disclosure of trade secrets  
(18 USC § 1905)
- Theft of a trade secret may be considered espionage  
(18 USC § 1831-1839)
- State laws also prohibit unauthorized disclosure of trade secrets



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Trademarks**

- A name, symbol, logo, or combination that indicates the source and quality of goods and services, and distinguishes those goods and services from those of the competition (15 USC 1051-1072)
- Coke® or the Coca-Cola® bottle design, the Good Housekeeping Seal of Approval® (certification mark), or YMCA (service mark)



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Copyright**

- An exclusive right to reproduce, distribute, perform, display, or prepare derivative works of copyrightable material
- Must be original work
- Literary works, audiovisual works, music, dramas, software (can also be patented)
- Protection (long time) begins with creation of a work
  - Registration at Copyright Office is optional
  - Must register to prosecute infringers



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Copyright (Cont.)**

Copyright protection is not available for any work of the U.S. Government, but the U.S. Government may receive and hold copyrights transferred to it

—17 USC § 105



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Patents**

- A grant from the U.S. government for a limited time during which the owner can exclude others from making, using, offering to sell, selling, or importing, the invention that is claimed in the patent document
- Authorized in U.S. Constitution, Article 1, Section 8
- Grant is territorial—protection only in U.S.



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Patents (Cont.)**

- Patent gives IP owner a term-limited right to exclude others from using the idea (so the owner can exploit a monopoly over it if the owner wishes)
- In exchange, the patent owner gives the government (and world) enough information to enable the government to figure out how to make it



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Patents (Cont.)**

Unless they agree otherwise, *Joint Owners* may make, use, offer to sell, or sell the patented invention within the U.S., or import the invention into the U.S. *without the consent* of the other owners

—35 USC 262



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Patents (Cont.)**

- Conditions of patentability
  - Useful – Some utility, no matter how limited
  - Novel – Element(s) not described by prior art or previously known or used
  - Nonobvious – Unexpected or surprising development from viewpoint of person ordinarily skilled in the art



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Patents (Cont.)**

- Types of Patents
  - Utility – Functionality (do something)
  - Design – Ornamentality
  - Plant – Asexually reproducible plants



## ***INTELLECTUAL PROPERTY (Cont.)***

- Utility Patents
  - Process
  - Machine
  - Article of manufacture
  - Composition of matter
  - Improvements thereof
  - Term – 20 years from filing date



## ***INTELLECTUAL PROPERTY (Cont.)***

- Conditions Defeating Patentability
  - Invention *patented or described in a printed publication* anywhere in the world more than 1 year before application filing date
  - Invention in *public use* in U.S. more than 1 year before application filing date
  - Invention *on sale* in U.S. more than 1 year before application filing date
  - Invention *made by another* before you made it and the other inventor did not *abandon, suppress, or conceal it*



## ***INTELLECTUAL PROPERTY (Cont.)***

- Priority of Invention
  - U.S. uses a “*first to invent*” system
    - Date of conception
    - Date of reduction to practice
    - Reasonable diligence of one who was first to conceive and last to reduce to practice
  - Rest of world uses a “*first to file*” system



## ***INTELLECTUAL PROPERTY (Cont.)***

### **License**

- A contract between the owner or lawful user of IP (licensor) and another party (licensee) that permits the licensee to use the IP in accordance with the terms of the contract



## ***INTELLECTUAL PROPERTY (Cont.)***

### **License (Cont.)**

- **Exclusive license**

- Exclusive right granted by patent holder to licensee to use, manufacture, and sell patented article
- Permission to do something and contract not to give leave to anyone else to do same thing
- A license that binds licensor not to enlarge thereafter the scope of other licenses already granted, or increase the number of licenses

*—Black's Law Dictionary, abridged fifth edition*



## ***INTELLECTUAL PROPERTY (Cont.)***

### **License (Cont.)**

- **Exclusive license** can be limited or “partial” in scope by:
  - Territory
  - Time
  - Field of use
  - Right to sublicense



## ***INTELLECTUAL PROPERTY (Cont.)***

### **License (Cont.)**

- **Nonexclusive** license
- A license under which the licensor is not bound to enlarge thereafter the scope of other licenses already granted, or increase the number of licenses



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Invention Rights**

- The government owns the invention rights of government employees for inventions made:
  - During work hours, or
  - With government facilities, equipment, funds, information, or
  - Bearing a direct relation to or made in consequence of the official duties of the inventor

—Executive Order 10096



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Invention Rights (Cont.)**

- The government owns the inventions of government employees
- The government requests that the inventor *assign* his/her rights to the government



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Royalty Payments**

- If the government licenses or assigns the invention, it must pay the employees/inventors each year:
  - The first \$2,000 of royalties or other payments; and thereafter,
  - At least 15% of the royalties or other payments up to \$150,000 per year per person
  - President can approve additional royalty payments

—15 USC 3710C

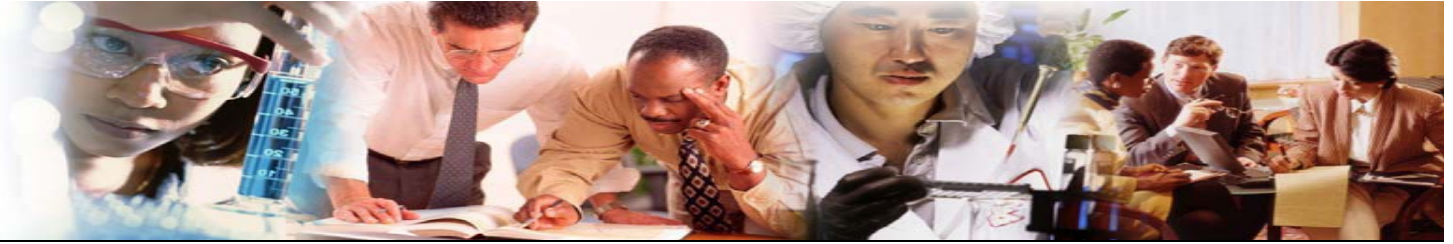


## ***INTELLECTUAL PROPERTY (Cont.)***

### **Royalty Payments (Cont.)**

The *lab* keeps at least the *majority share* of the balance of the licensing royalties and other payments

—15 USC 3710c



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Royalty Payments (Cont.)**

- The lab or agency may use the balance of the licensing royalties and other payments for:
  - Providing incentives to lab employee (not the inventor) who substantially increased the technical value of the invention
  - Rewarding its scientific, engineering, and technical employees
  - Scientific exchanges among the labs of the agency
  - Education and training of lab employees
  - Activities that increase the potential for technology transfer of the agency's labs
  - Payment of licensing-related costs
  - Mission R&D



## ***INTELLECTUAL PROPERTY (Cont.)***

### **A Short Digression**

Look at 15 USC 3710b



## ***INTELLECTUAL PROPERTY (Cont.)***

### **Royalty Payments (Cont.)**

- Royalties must be used or obligated by lab (or agency) during the fiscal year they were received or during the two succeeding fiscal years
- If not, the money goes to the Treasury

—15 USC 3710c(a)(B)



## ***INTELLECTUAL PROPERTY (Cont.)***

### **IPR and CRADAs**

If neither the government nor the partner intends to file for a patent or promote commercialization of a government sole CRADA subject invention, then the government inventor can obtain title to it

—15 USC 3710d



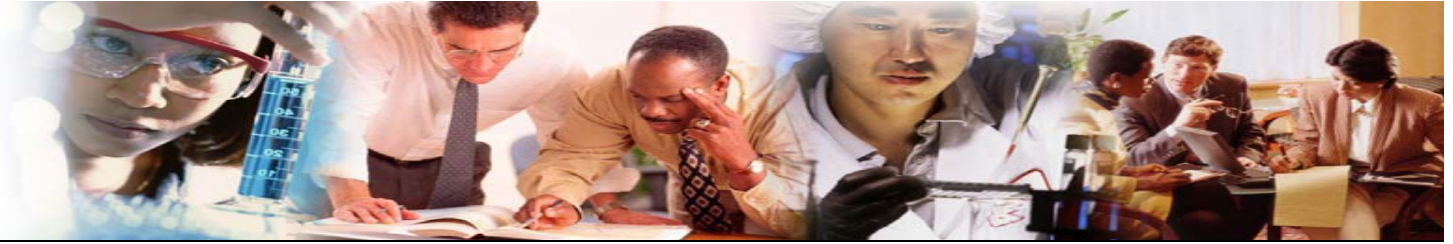
## ***BACK TO CRADA AUTHORITY (15 USC 3710a(b))***

- Laboratory may grant or agree to grant in advance to CRADA partner:
  - Patent licenses
  - Assignments
  - Or options to either in a lab employee's CRADA subject invention (either sole or joint invention)
- Negotiable



## ***CRADA AUTHORITY*** (15 USC 3710a(b)) (Cont.)

- Lab shall ensure that CRADA partner(s) has an option to choose an exclusive license *for a pre-negotiated field of use*
- Non-negotiable



## ***CRADA AUTHORITY (15 USC 3710a(b)) (Cont.)***

- Reality check on prenegotiated field of use:
  - Counter to nature of scientific endeavor
  - Opposed by many potential collaborators
  - Field of use can be negotiated as part of the licensing process after the invention is made
  - Standard operating procedure of labs is not to prenegotiate field of use of the option for an exclusive license



## ***CRADA AUTHORITY (15 USC 3710a(b)) (Cont.)***

- The option for the partner to choose an exclusive license on the government employee's invention is the most important incentive to induce a potential partner to agree to enter a CRADA
- It is the partner's chance to have a monopoly against its competition



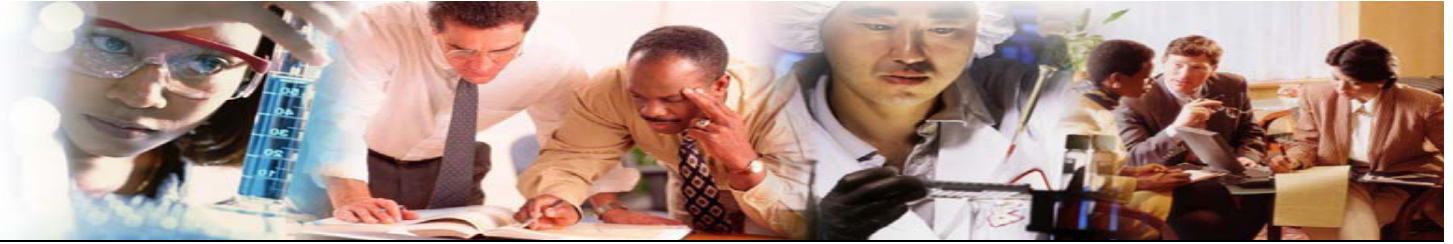
## ***CRADA AUTHORITY (15 USC 3710a(b)) (Cont.)***

- The lab may grant its partner an exclusive license (subject to certain rules/conditions) for a lab invention made before the CRADA
  - If the patent is directly within scope of the CRADA
  - For reasonable compensation when appropriate
- Negotiable



## ***CRADA AUTHORITY (15 USC 3710a(b)) (Cont.)***

- In consideration for the government's contribution under the CRADA, the license grants from the lab are subject to two “explicit (i.e., non-negotiable) conditions”



## ***CRADA AUTHORITY (15 USC 3710a(b)) (Cont.)***

### **Condition #1—Government-Use License**

- Lab maintains a nonexclusive, nontransferable, irrevocable paid-up license to
  - Practice the invention, or
  - Have it practiced throughout the world by or on behalf of the government
- Reality check on the government-use license
  - Many potential collaborators are afraid that federal government will use this license to compete against them in the market
  - You will need to convince them otherwise



## ***CRADA AUTHORITY (15 USC 3710a(b)) (Cont.)***

### **Condition #2: “March-in Rights”**

- When lab grants partner an exclusive license, the government maintains “march in” rights for “exceptional circumstances”
  - Public health or safety emergency
  - Public use requirement
  - Partner not substantially manufacturing in U.S. or is controlled by a rogue CRADA country
- Government can require the partner to license to someone else, or
- Government can grant someone else a license



## ***CRADA AUTHORITY*** ***(15 USC 3710a(b)(1)(B) & (C)) (Cont.)***

### **Condition #2: “March-in Rights” (Cont.)**

- Reality check on “March In” rights
  - While occasionally partners express concern about the prospect of the government activating “march in” rights, it has never, ever happened
  - Abbott’s Norvir anti-AIDS cocktail



## ***CRADA AUTHORITY (Cont.)***

- The lab should “normally” get the same nonexclusive license for any collaborator CRADA subject invention, but it is not required  
—15 USC 3710a(b)(2)
- Negotiable



## ***CRADA AUTHORITY (Cont.)***

- Labs may waive, in advance, any government ownership rights to joint CRADA subject inventions subject to the reservation of a nonexclusive license

—15 USC 3710a(b)(3)(D)

- Negotiable



## ***CRADA AUTHORITY (Cont.)***

- Labs may permit their employee or former employee/inventor to help commercialize the invention (subject to ethics rules)

—15 USC 3710a(b)(3)(C)

- Negotiable



## ***CRADA AUTHORITY (Cont.)***

### **Digression**

- Inventor involvement is often key and essential to getting early “angel” investors willing to put up the big \$\$\$ necessary to prepare a product for commercialization
- The inventor is the best “champion” for the invention



## ***CRADA AUTHORITY (Cont.)***

### **CRADA Implementation**

- A federal agency may issue regulations on procedures to implement 10 USC 3710a

—10 USC 3710a(c)



## ***CRADA AUTHORITY (Cont.)***

### **CRADA Implementation (Cont.)**

- The head of a federal agency may leave him/herself a 30-day window to review and disapprove or modify a proposed CRADA
- A written explanation of a disapproval or modification is required

—15 USC 3710a(c)(5)



## ***CRADA AUTHORITY (Cont.)***

### **CRADA Implementation (Cont.)**

- Agency head review
  - Pros
  - Cons
  - Waivers



# **PART 4**

# **CRADA**

# **RESPONSIBILITIES**



## ***CRADA RESPONSIBILITIES***

### **Conflicts of Interest**

- Agency shall
  - Review standards of conduct for resolving conflicts of interest
  - Establish guidelines
  - Propose statutory changes if necessary to resolve conflict-of-interest situations

—15 USC 3710a(c)(3)



## ***CRADA RESPONSIBILITIES (Cont.)***

### **Conflicts of Interest (Cont.)**

- Typical conflict-of-interest issues:
  - Government inventor as licensee
  - Government inventor as champion
  - Government inventor as stockholder of or moonlighter for developer or commercializer



## ***CRADA RESPONSIBILITIES (Cont.)***

### **Lab Director Responsibilities**

- Lab directors shall give:
  - “Special consideration” to small businesses and small business consortia
  - “Preference” to U.S. businesses that agree to “manufacture substantially” in the U.S.

—15 USC 3710a(c)(4)



## ***CRADA RESPONSIBILITIES (Cont.)***

### **Lab Director Responsibilities (Cont.)**

- Reality check for lab directors:
  - Whoever owns the underlying technology and has the requisite expertise and interest determines partner options
  - Manufacturer depends on market forces
  - No requirement to compete CRADAs



## ***CRADA RESPONSIBILITIES (Cont.)***

### **Lab Director Responsibilities (Cont.)**

- For “foreign CRADAs,” the lab director shall:
  - “Consult” with U.S. Trade Representative (Executive Order 12591)
  - Consider parity of treatment issues (15 USC 3710a(c)(4)(B))



## ***CRADA RESPONSIBILITIES (Cont.)***

### **Lab Director Responsibilities (Cont.)**

- Foreign CRADA reality check for lab directors:
  - Whoever owns the underlying technology and has the requisite expertise and interest determines partner options
  - Political balance vs. political suicide vs. importance of the R&D
  - Negotiate out manufacturing site in CRADA as appropriate



## ***CRADA RESPONSIBILITIES (Cont.)***

### **Agency Responsibilities**

- Agencies shall:
  - Maintain a record of all CRADAs (15 USC 3710a(c)(6))
  - Report T2 activities to OMB/Congress (15 USC 3710(f))
  - Make “separate determinations” of the mission(s) of each lab (15 USC 3710a(e))



# **PART 5**

# **MISCELLANEOUS**

# **ISSUES**



## ***MISCELLANEOUS ISSUES***

- Data rights are negotiable
- CRADA format
  - Negotiable
  - Substance is much more important



## ***MISCELLANEOUS ISSUES (Cont.)***

- Handling disputes – negotiable
  - Alternate dispute resolution (ADR) is an option
- CRADAs are federal contracts (see Chem Services, 816 F. Supp 328)
- Partner *may*(?) have access to U.S. Claims Court under Tucker Act (28 USC § 1491)



## ***MISCELLANEOUS ISSUES (Cont.)***

- Applicable law – Federal law of the U.S., as applied in a federal court of the United States
  - Non-negotiable
  - Location of federal court to litigate in is negotiable
  - Has there ever been any litigation between CRADA collaborators?



## ***MISCELLANEOUS ISSUES (Cont.)***

- Liability
  - Agencies bound by the Federal Tort Claims Act
  - State entities are bound by their state laws
  - Nothing has to be in CRADA; laws exist
  - For clinical trials with private company, get copy of insurance and negotiate indemnification policy of U.S.



## ***MISCELLANEOUS ISSUES (Cont.)***

- Indemnification
  - Labs bound by federal laws
  - State entities are bound by state laws
  - Nothing has to be in a CRADA but should protect government for clinical trials
  - Negotiate with private parties



## ***MISCELLANEOUS ISSUES (Cont.)***

- Statement of Work (SOW)
  - Can include milestones, go/no go
  - Payments before or after are OK, but remember, partners go bankrupt because labs can negotiate CRADA reimbursement, may be authority to renegotiate debt
  - Can be renegotiated as circumstances change



## ***MISCELLANEOUS ISSUES (Cont.)***

- Lab's use of in-house contractors to carry out CRADA work
  - Issue concerns Bayh-Dole rights
  - See *Federal Register*: April 2, 2004 (Vol. 69, Number 64, page 17299-17301)
  - Seek to get a waiver from contractor before work starts.



## ***MISCELLANEOUS ISSUES (Cont.)***

- Lab's use of outside contractors to carry out CRADA work
  - Issue is Bayh-Dole rights
  - Let the potential CRADA partner know
  - Seek to get a waiver from contractor before work starts
  - Have the CRADA partner hire the contractor



## ***MISCELLANEOUS ISSUES (Cont.)***

- Reimbursement for government employee travel under CRADA
  - Agencies handle differently depending on their application of 31 USC 1353 and 5 USC 4111
  - Recommendation—Use existing ethics/conflict of interest review and procedures for gifts of travel from nonfederal sources



## ***MISCELLANEOUS ISSUES (Cont.)***

- Federal R&D grant or contract money goes to a party intending to collaborate with a federal lab under a CRADA to do the R&D
  - Allowable
  - Granting activities have different rules on reimbursement for the federal lab “sub”



# QUESTIONS?