

Enhancing & Documenting the Impact of Research Outcomes

Intellectual Property and Technology Transfer: Responsibilities & Rewards to Scientists (& your Cooperators)

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Office of Technology Transfer



MWA New Scientist Training
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St. Louis, MO



Overview for this Session

- Technology transfer: What, Why, When & How do we do it
- Policies, procedures, and precautions
 - Patenting to protect IP; *notebooks*
- Cooperative Research And Development Agreements (CRADA)
- Special issues in working with DOE Bioenergy Research Centers
- Examples of current successes



Technology Transfer: *the adoption of research outcomes for public benefit*



Tech Transfer in the 1940's . . .



A. J. Moyer, Peoria, IL, 1941 --- mass production of penicillin

Technology Transfer: *ARS Research Outcomes Launch an Entire Industry*



Potato flakes & dehydration; Philadelphia (ERRC);
1950's-70's --- 9 patents, 70 publications

ARS Mission

To conduct research to develop *and transfer* solutions to agricultural problems of high national priority and provide information access and dissemination to:

- ensure high-quality, safe food, and other agricultural products
- assess the nutritional needs of Americans
- *sustain a competitive agricultural economy*
- enhance the natural resource base and the environment, and
- *provide economic opportunities* for rural citizens, communities, and society as a whole.



U.S. Technology Transfer Legislation

Bayh-Dole Act, 1980

Extramural research , federally funded (our university cooperators)

Stevenson-Wydler Act, 1980

Federal Technology Transfer Act, 1986 (FTTA)

National Technology Transfer and Advancement Act, 1995

Technology Transfer Commercialization Act, 2000

Intramural research by federal employees, federally funded

- CRADA authority, T2 obligation of federal scientists, royalties increased to \$150K / inventor / year
- right to negotiate exclusive license without Federal Register notice; confidentiality of data up to 5 years (CRADA)
- extends licensing to “protectable” invention



U.S. Technology Transfer Legislation

Why has Congress spend so much time on this issue?

- To help translate research results into practical products
- To give taxpayers a return on their investment in research
- To promote economic competitiveness and job creation

Today, this is really important in the context of global competition and sustainable economic development

Federal Law

“Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional.”

15USC§3710(a)(2)

“Each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory.”

15USC§3710(a)(3)



ARS Goals of Technology Transfer

- Public mission – a problem solving agency
- *Transfer* of technology is the primary objective --- not income
- Protect intellectual property *principally* if it enhances technology transfer
- Facilitate development of cooperative research agreements

Technology Transfer Activities Add Value for ARS Scientists in . . .

- identifying researchable problems
- ensuring the relevance and adoption of the research outcomes
- obtaining extramural funding
- increasing “political” support for the research
- increasing and documenting the impact of the research
- increasing the potential for your promotion
- royalty sharing



Office of Technology Transfer

Coordinates Tech Transfer activities in ARS

- Has authority to develop and sign Cooperative Research And Development Agreements (CRADAs) for ARS and to review those of other USDA agencies
- Has sole authority for licensing any inventions developed from intramural research within any of the USDA agencies (including Forest Service, FSIS, APHIS)



Office of Technology Transfer

Centralized in policy and approvals, licensing, marketing;
decentralized in negotiation and implementation of CRADAs

Patenting

- 9 registered patent agents (1 Ph.D, 4 w/ law degrees)
- Located in Beltsville, MD; Peoria, IL; Albany, CA

Marketing

- Targeted marketing (staff of 3)
- Web subscribe *Tech Alerts*
- Partnering opportunities

Licensing

- 4 senior licensing specialists (2 w/ law degrees; 1 MBA)
- HQ based

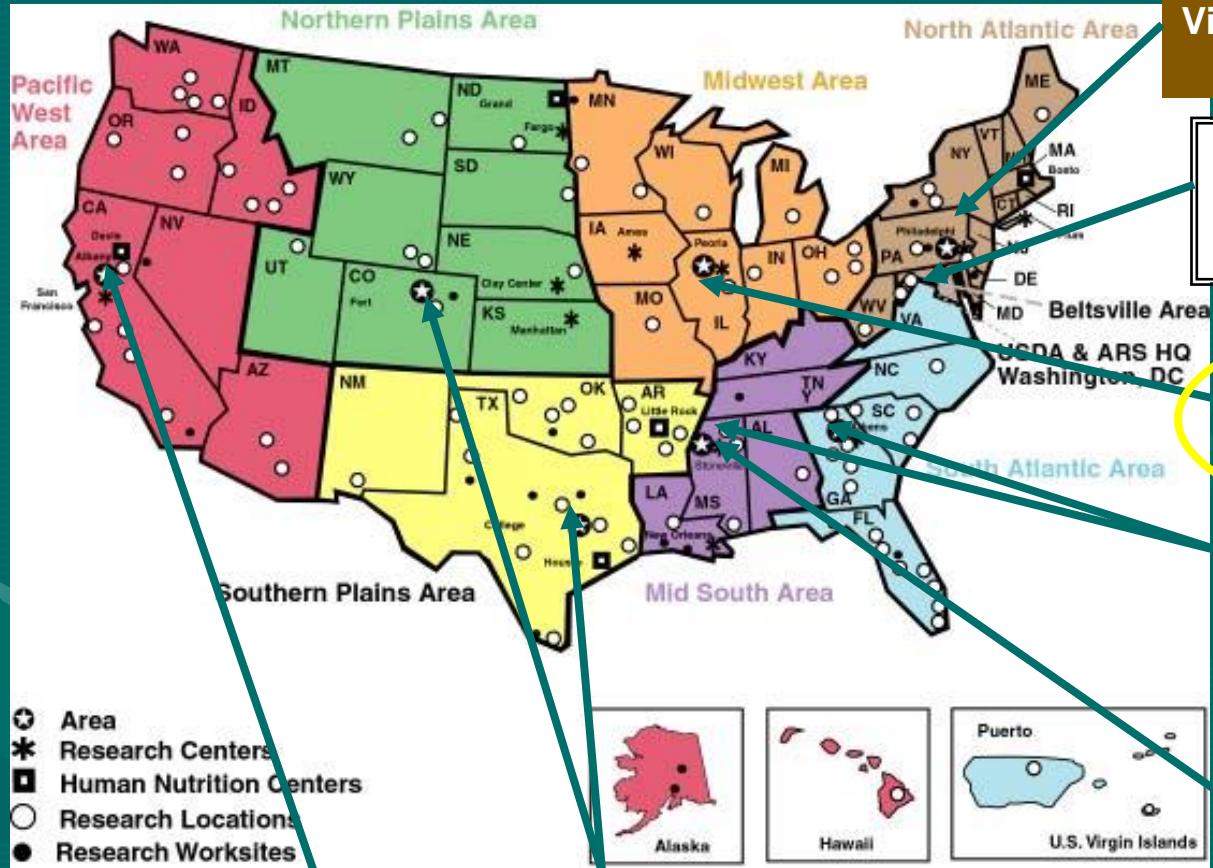


Tech Transfer Coordinators

- 7 specialists with life science / ag background (4 Ph.D, 1 law degree)
- Distributed across geographic Areas of ARS

Office of Technology Transfer

Technology Transfer Coordinators



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Office of Technology Transfer

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- Area
- * Research Centers
- Human Nutrition Centers
- Research Locations

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Basic Technology Transfer Process

Incorporate this process early in the 5 year research program cycle

- Identify transfer mechanisms for each expected outcome
 - publication
 - personal interface and exchange
 - patenting and licensing
- Evaluate its commercial potential
- Identify partner(s) and formalize relationship(s), as appropriate
- Develop and document technology

Transferring the technology enhances the impact of your research outcomes!

Types of Intellectual Properties

- Patents (“...otherwise protectable...”)
- Plant Variety Protection Certificates (PVPCs)
- Breeders rights
- Trade secrets (proprietary information)
- Trademarks
- Copyrights

New National Patent Committees (Oct. 2007)

Three “*Subject Matter*” Committees

- Life Sciences
- Chemical
- Mechanical and Measurement

Each cover all geographic Areas of ARS

Each Area will have at least 2 members on each Committee, rotate at 5 years.

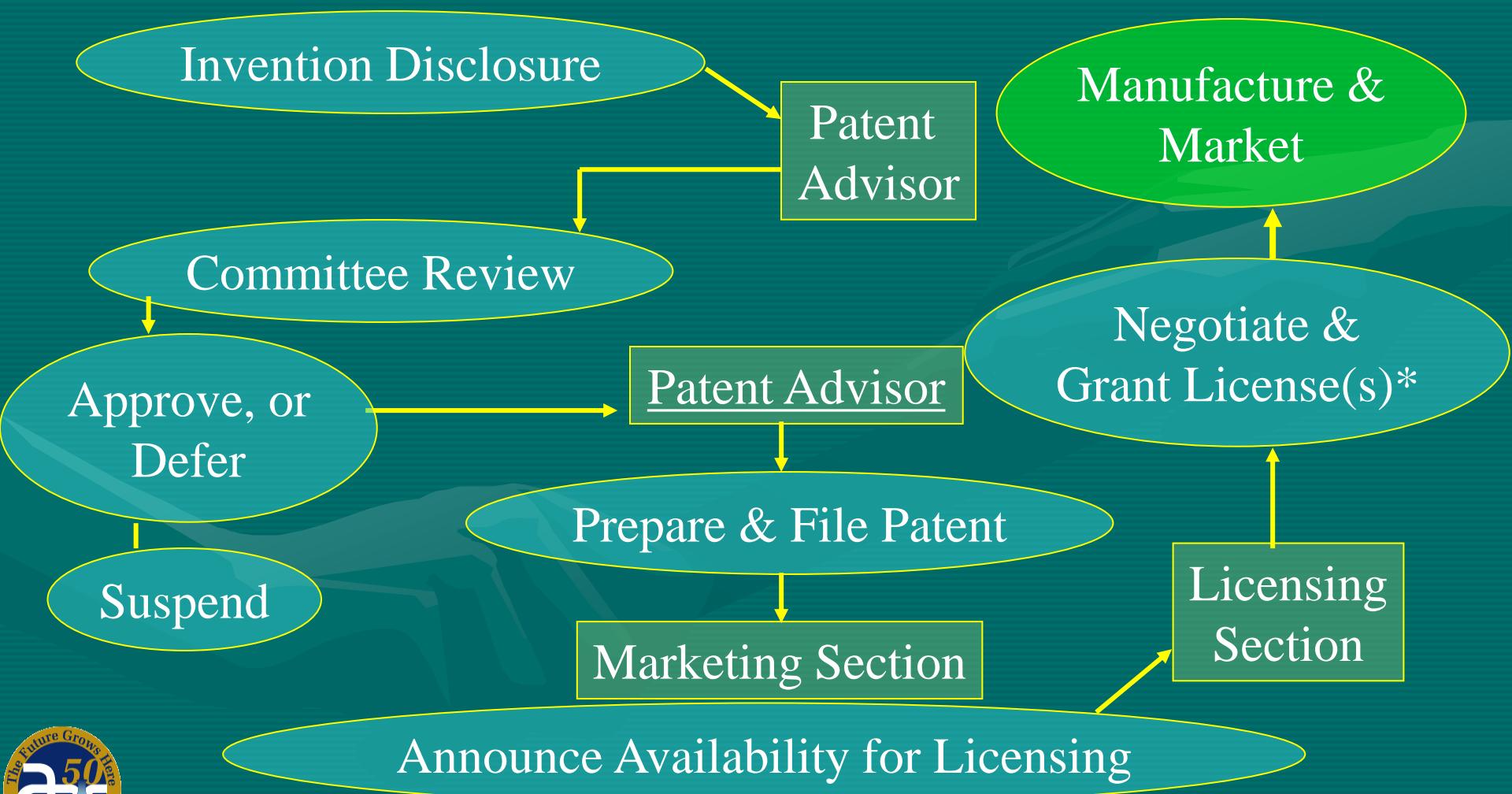


Advantages of National Committees to Agency

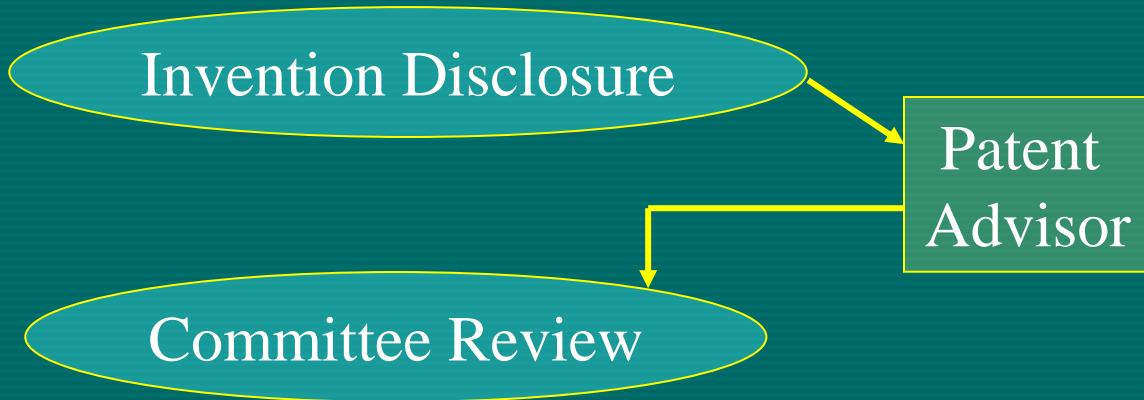
- Uniform committee recommendations across the Agency
- Committee recommendation within three months of filing an Invention Disclosure (meet quarterly)
- Scientists and management notified of annual schedule at the beginning of each fiscal year



Process for Protecting Intellectual Property for Commercialization

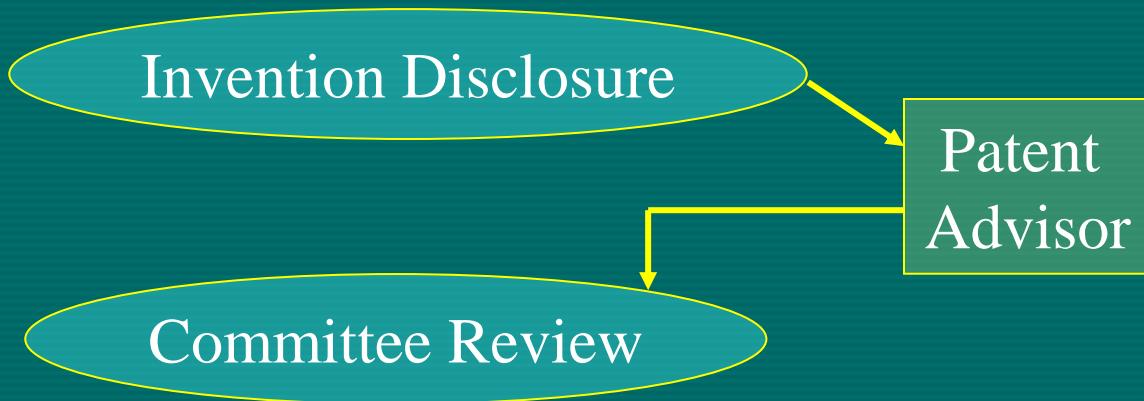


Patent Committee Criteria



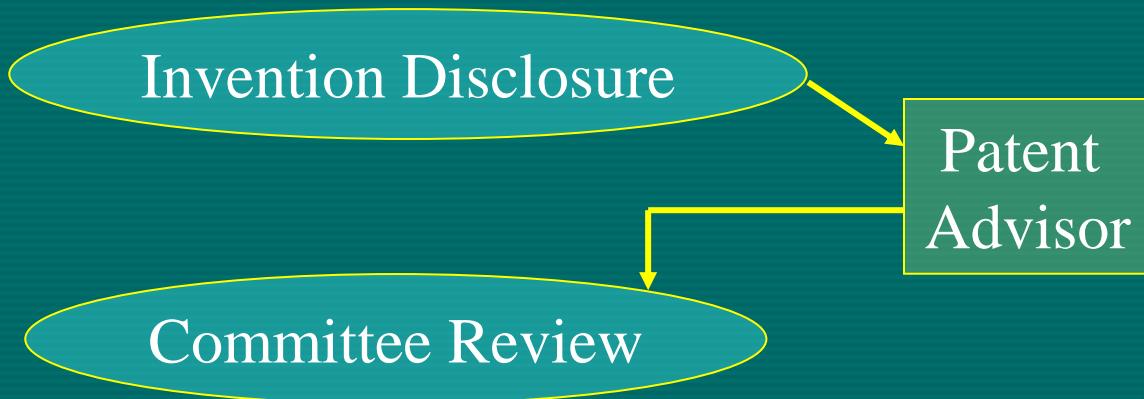
Q1: Is there current commercial interest in the invention or a high probability of commercialization in the future?

Patent Committee Criteria



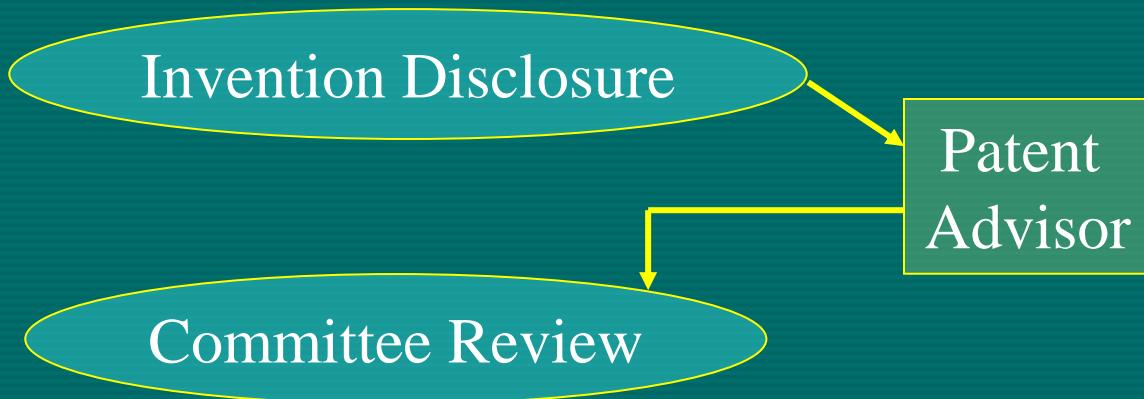
Q2: Is the magnitude of the market relative to the cost of commercialization sufficiently large to warrant a patent?

Patent Committee Criteria



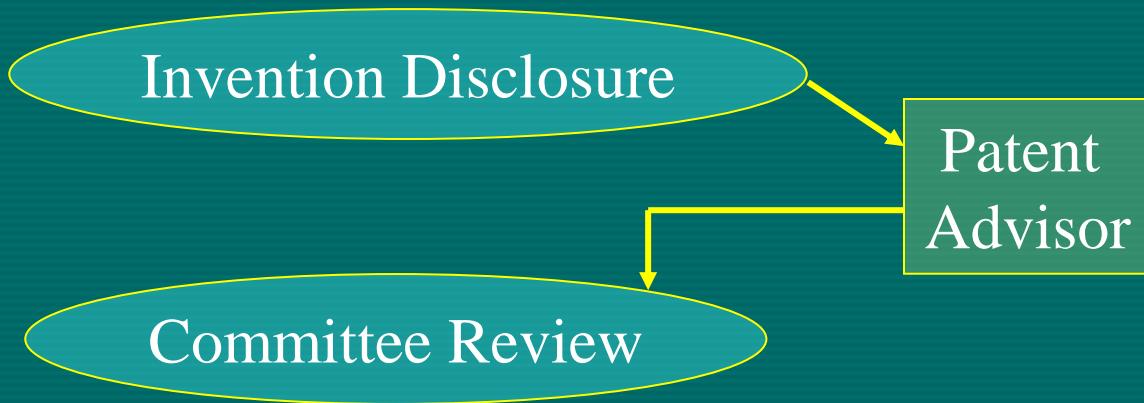
Q3: Would the patent likely play a significant role in transferring the technology to the user?

Patent Committee Criteria



Q4: *Would a patent be enforceable, i.e., is the invention drawn to, or does it employ a unique and readily identifiable material or device which could be bought or sold?*

Patent Committee Criteria

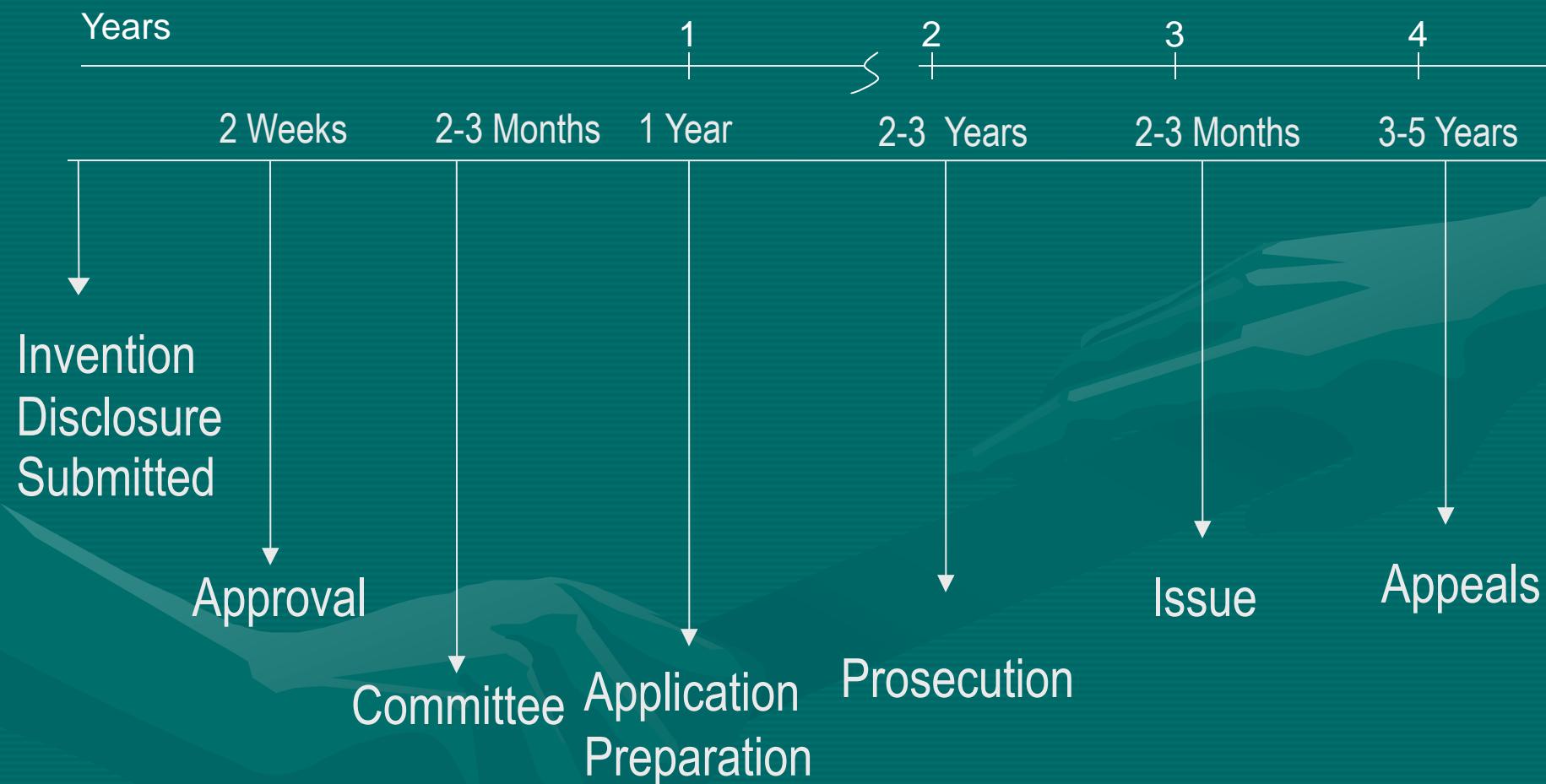


Q5: Is the invention of sufficient scope to justify patenting?

By the way . . .

- The research results are work products that belong to ARS, not the scientist
- ARS decides whether or not to apply for a patent, not the scientist
- ARS decides whether or not to protect foreign patent rights, not the scientist
- Such decisions require:
 - No premature public disclosure
 - Timely (early) filing of an invention disclosure
 - Timely and complete responses to requests from the Patent Advisor

The Patenting Process



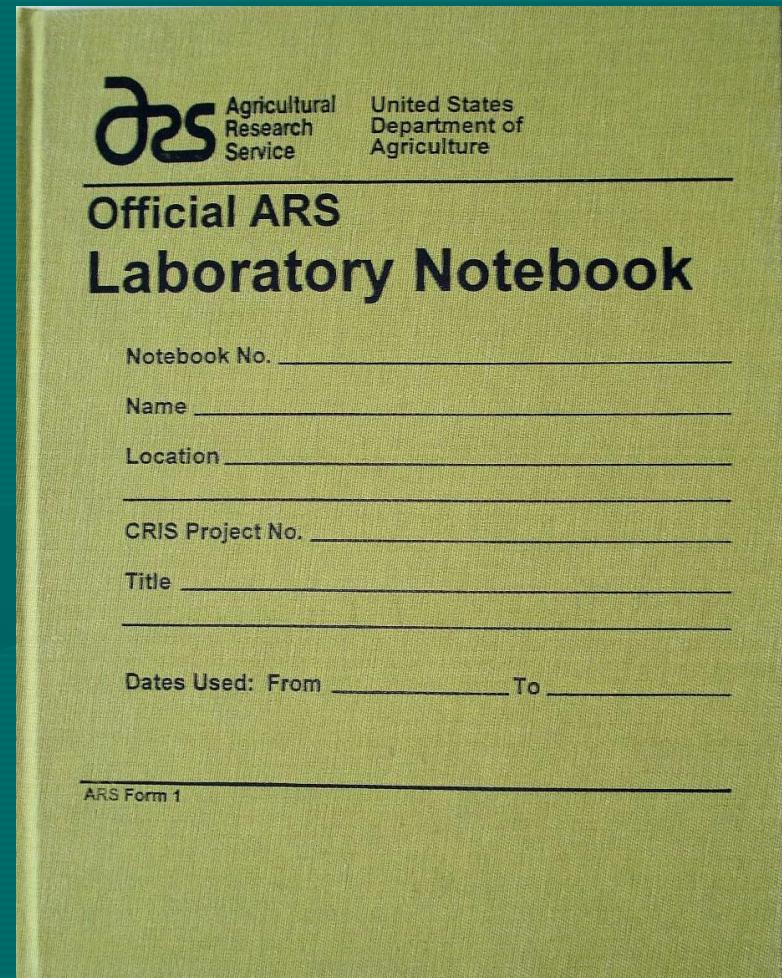
Due Diligence in Protecting Intellectual Property: *Inventorship & Laboratory Notebooks*

- Ownership of intellectual property is determined by inventorship
- An inventor must be able to **document** their contribution to “conception & reduction to practice” for at least one claim in an allowed patent
- **Documentation** has strict legal requirements
 - Signed & witnessed lab notebook pages
 - Consecutive numbered bound pages, single line through errors (deletions) in data

Good Laboratory Notebook Practices

 ARS Laboratory Notebooks are *bound notebooks*

*Always
Use Official ARS
Laboratory Notebook
(ARS FORM 1)*



Confidentiality Agreement

- Used only when contemplating entering into a partnership. Otherwise we do not disclose or receive confidential information.
- Can be one way or two way
- *Protects patent rights*
- ARS standard format may be downloaded from the OTT website
- Handled at scientist level (copy to TTC)
- Reported monthly by OTT to Area, NPS



Material Transfer Agreement

- Used when transferring out materials which may be or will be or are patented, or when required by provider
- ARS standard format may be downloaded from the OTT website
- Reviewed to prevent “reach through” and other clauses that are contrary to ARS policy
- Handled by TTC, signature required
- Reported monthly by OTT to Area, NPS



Models for Developing and Transferring Technologies to the Private Sector

Background Invention
(developed in USDA)

The screenshot shows the ARS website with a search bar, a sidebar for 'Browse By Subject' (with 'Partnering' highlighted), and a main content area for a patent titled 'New Method to Make an Industrial Lubrication Fluid'. The content includes sections for 'Projects' (listing 'Chemical Systems For Soybean Oil Conversion To Industrial Products'), 'Docket Number: 7106', 'Serial Number: 11717524', and a detailed 'Technology Description' about a vegetable oil-based lubricant. A small logo for the Midwest Area National Center for Agricultural Utilization Research is visible.

Seek Private
Sector Interest
For Commercialization

Marketing Section

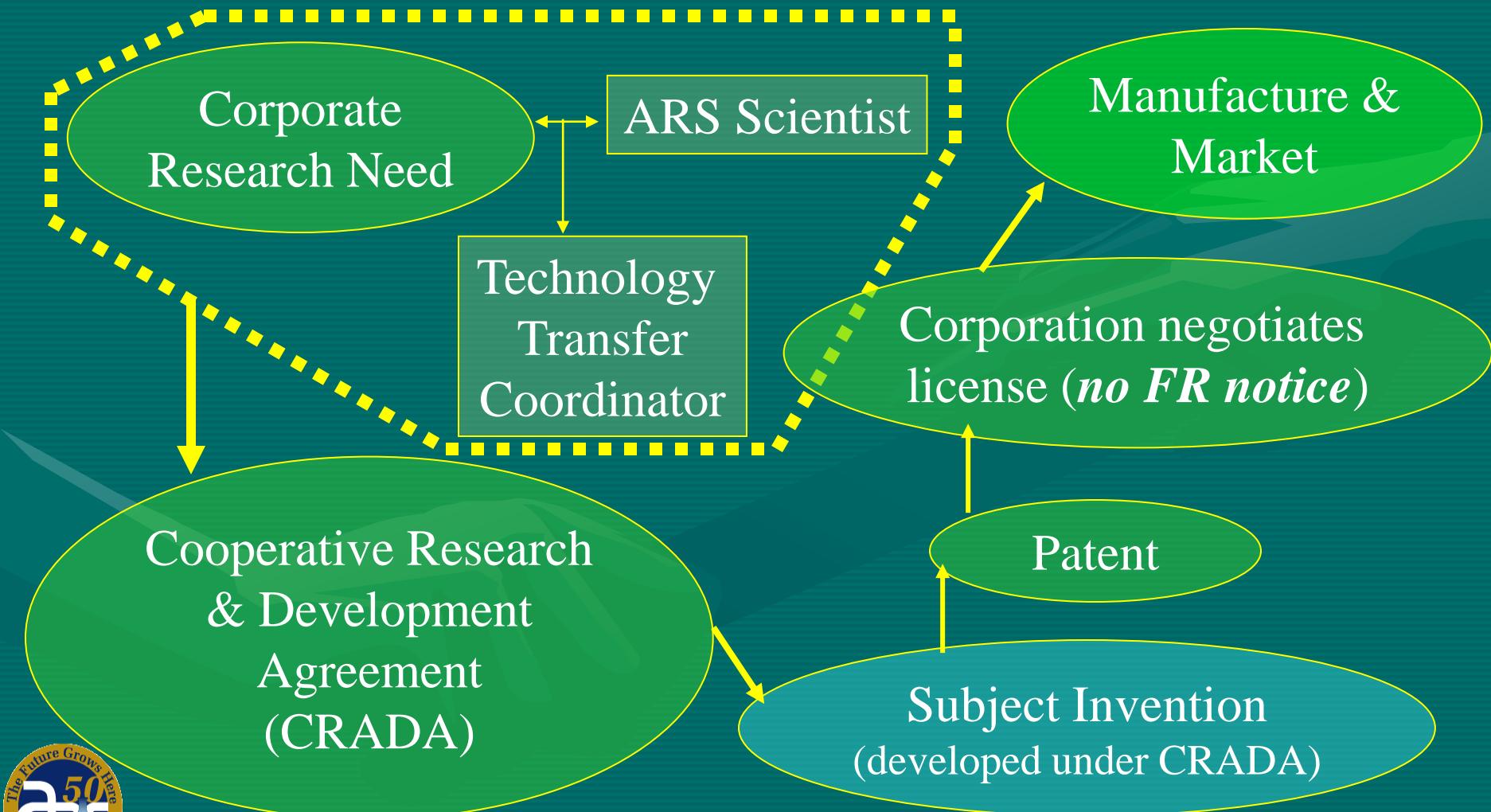
- Creates summary
- Places on OTT website

Federal
Register
Notice

Corporate
response

Licensing
Section

The CRADA Model for Developing and Transferring Technologies to the Private Sector



Cooperative Research and Development Agreement (CRADA)

- A joint research and development effort (with at least one non-Federal, U.S. partner) where an outcome has the possibility of developing to a commercial product
- A cooperative partnership ***that may lead*** to the development of intellectual property

Cooperative Research and Development Agreement (CRADA)

➤ Benefits to Firms:

- Access to ARS research capacity
- First right to negotiate Exclusive License for Subject Inventions without FR notice
- Confidentiality (competitive advantage)
- Opportunity to compete in global markets

➤ Benefits to ARS:

- Results-Oriented Research/Impact
- Market information
- Identification of Licensee
- Resources (For the Project)



□ CRADA Negotiations

Firms May Provide:

- Expertise
- Materials
- Equipment
- Employees
- Money
- Facilities

*ARS May Provide Any of the Above
Except Money*



CRADA Partners

- May be an individual company, group of firms, association, university or combination of above
- May include, but not be limited to, cooperation with another Federal agency
- ARS actively seeks CRADAs with small and/or minority-owned businesses
- No need to “compete” for CRADAs, we are free to choose the best partner
- Developed by TTCs
- Cleared through line management, NPS, Ethics
- Reported monthly by OTT to Area, NPS

Caution

To prevent a public disclosure and loss of patent rights a *Confidentiality Agreement* should *always* be used when a scientist is discussing, with non-federal* personnel, research results that may have patent potential.

* For federal personnel, a verbal reminder of the confidential nature is appropriate.



Policies

- We do not patent ‘tools’
- We always allow license-free research
- We favor public releases over protection of plant IP (this is changing to a “case-by-case” review)
- Licenses may be given preferentially to small businesses

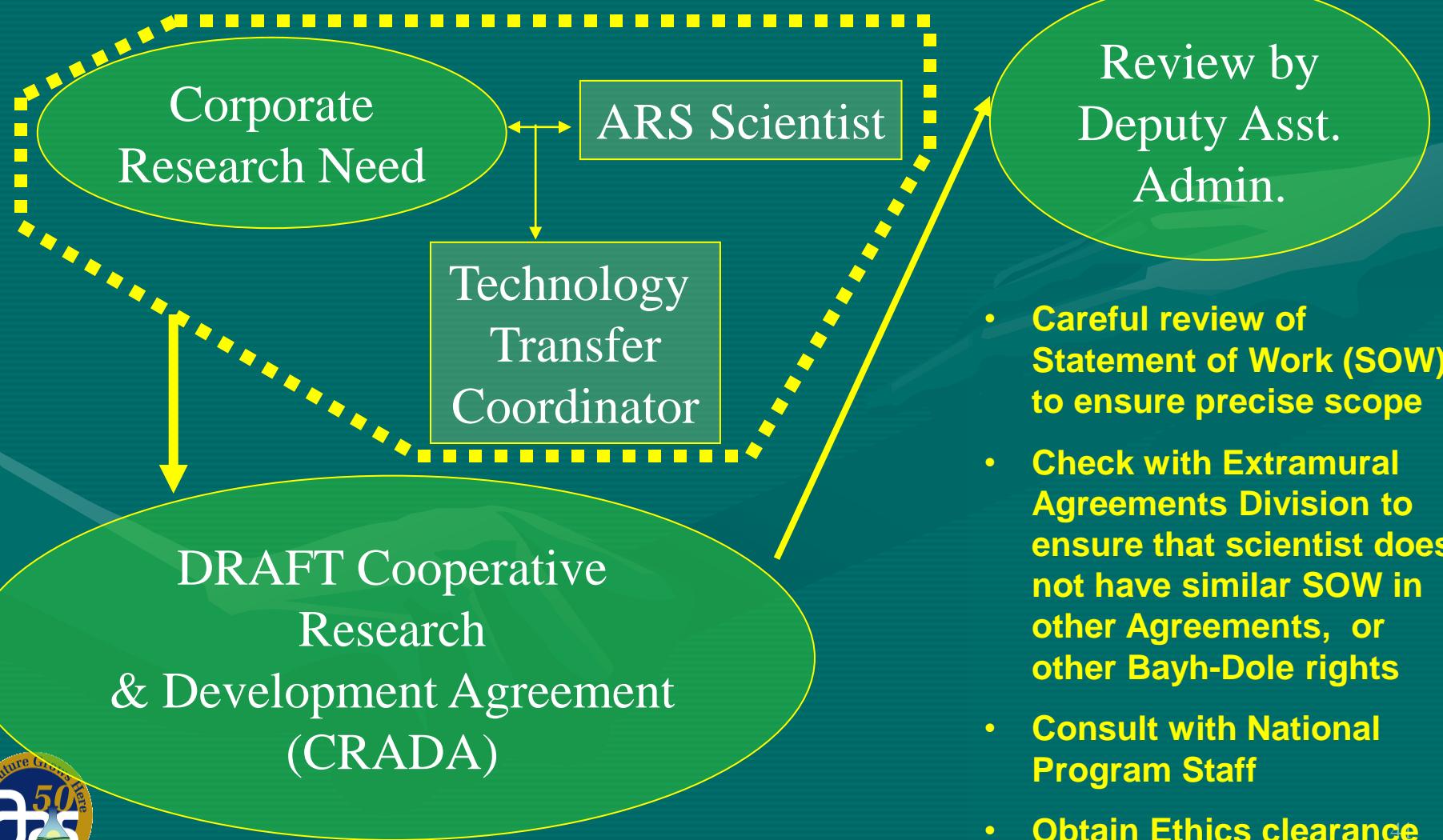
Precautions

We do not patent ‘tools’ --- others do!

Know the technology you are using:

- *If you use patented genes or patented tools to insert genes, royalties to patent holders may result.*
- *In other words, your new “cheap and better” technology just got expensive for a commercial producer!*

Avoiding “Nightmare” CRADAs



Dept. of Energy (funded) Bioenergy Research Centers

Participation of ARS Scientists with BRCs

- DOE established 3 Bioenergy Research Centers (ca. \$125M each over 5 years), located in Berkeley, CA; Madison, WI; and Oakridge, TN
- Only DOE “National” labs were permitted to receive funds with BRC member universities and private sector companies
- No funds available to other federal agencies (GOGO)
- An Intellectual Property Policy was mandated for each of the 3 centers using DOE principles
 - IP Plans cover the entire management of IP protection, licensing, and revenue distribution



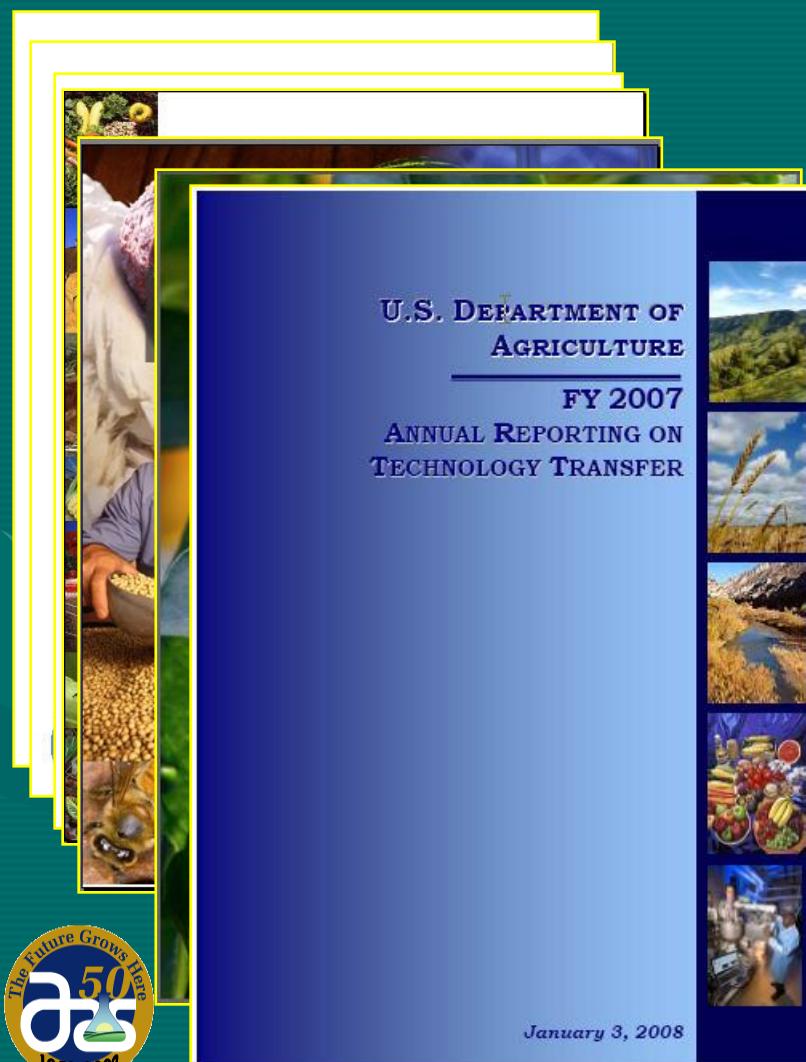
Dept. of Energy (funded) Bioenergy Research Centers

Participation of ARS Scientists with BRCs (cont'd)

- Participation by ARS scientists is permitted, but under several constraints as defined in a Memorandum of Understanding between ARS and DOE
 - BRC cooperators cannot provide funds to ARS, only in-kind contributions are authorized
 - Any joint invention by an ARS scientist and a BRC entity must be reported to the BRC, and will be managed entirely by the BRC institution designated to manage the IP
- See your TTC for guidance in establishing any bioenergy-related partnership. Specific guidance is also provided in the document “Plain Language Guide on ARS DOE BRC Cooperative Research”.



Annual Report to Congress on Technology Transfer --- “Downstream Outcomes”



Biobased Products

Crop Production and Protection

Novel sweetener reaches market

The Low Glycemic Index Sweetener Team

Domestic production of hypoallergenic rubber

ARS researchers

and characterize

surveyed more than 100

microbial isolates

from culture collections and natural isolations.

This research led to the discovery of a novel low-glycemic index sweetener, called Xtend™ sucromalt.

The new product provides food and beverage customers with a natural and slow release carbohydrate syrup.

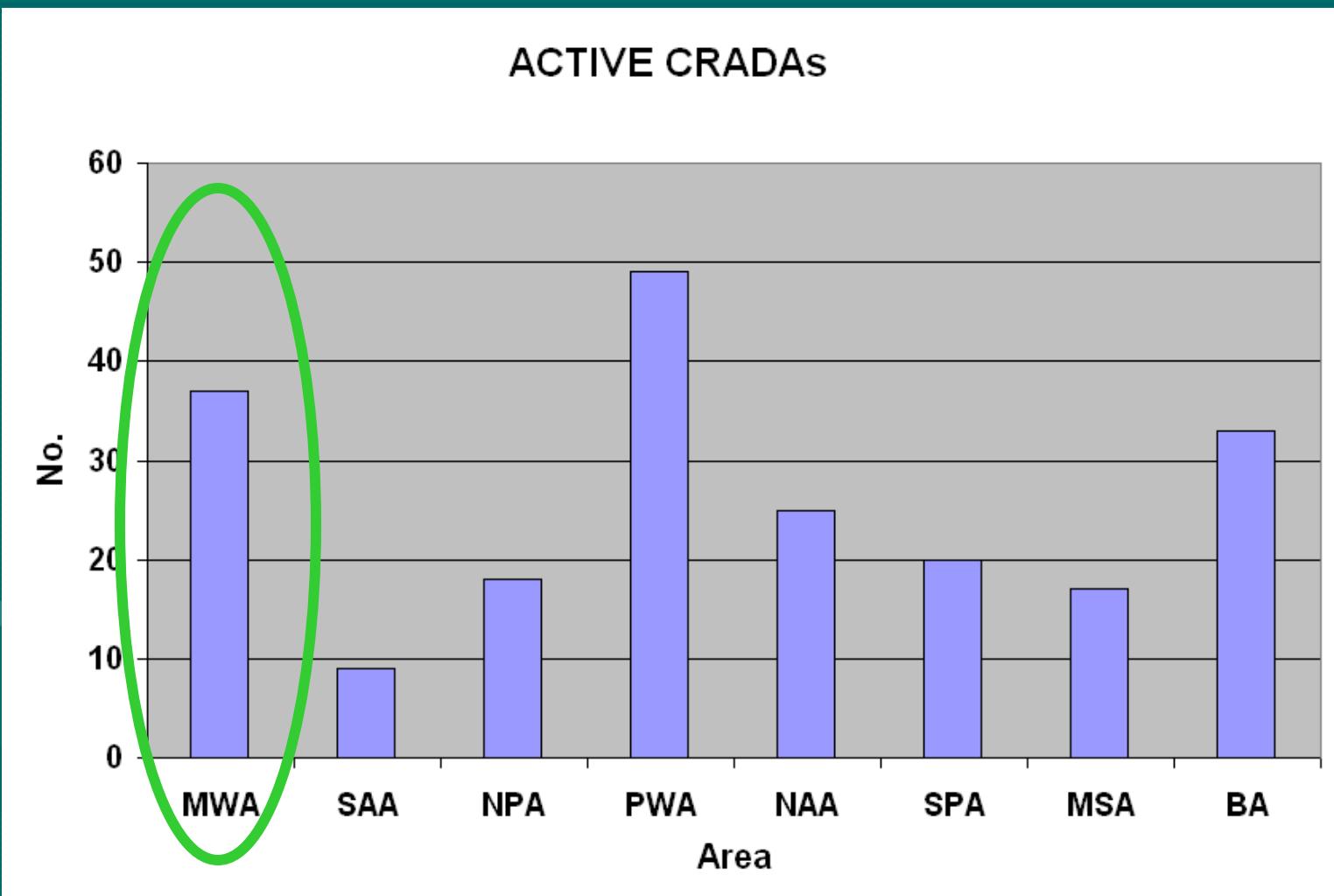
This fully digestible, low glycemic syrup provides natural sweetness for products such as nutritional beverages and bars, cereals, ice cream, jams and jellies, and yogurts.

The product is named sucromalt because it is derived from a combination of sucrose (cane or beet sugar) and maltose (corn sugar).

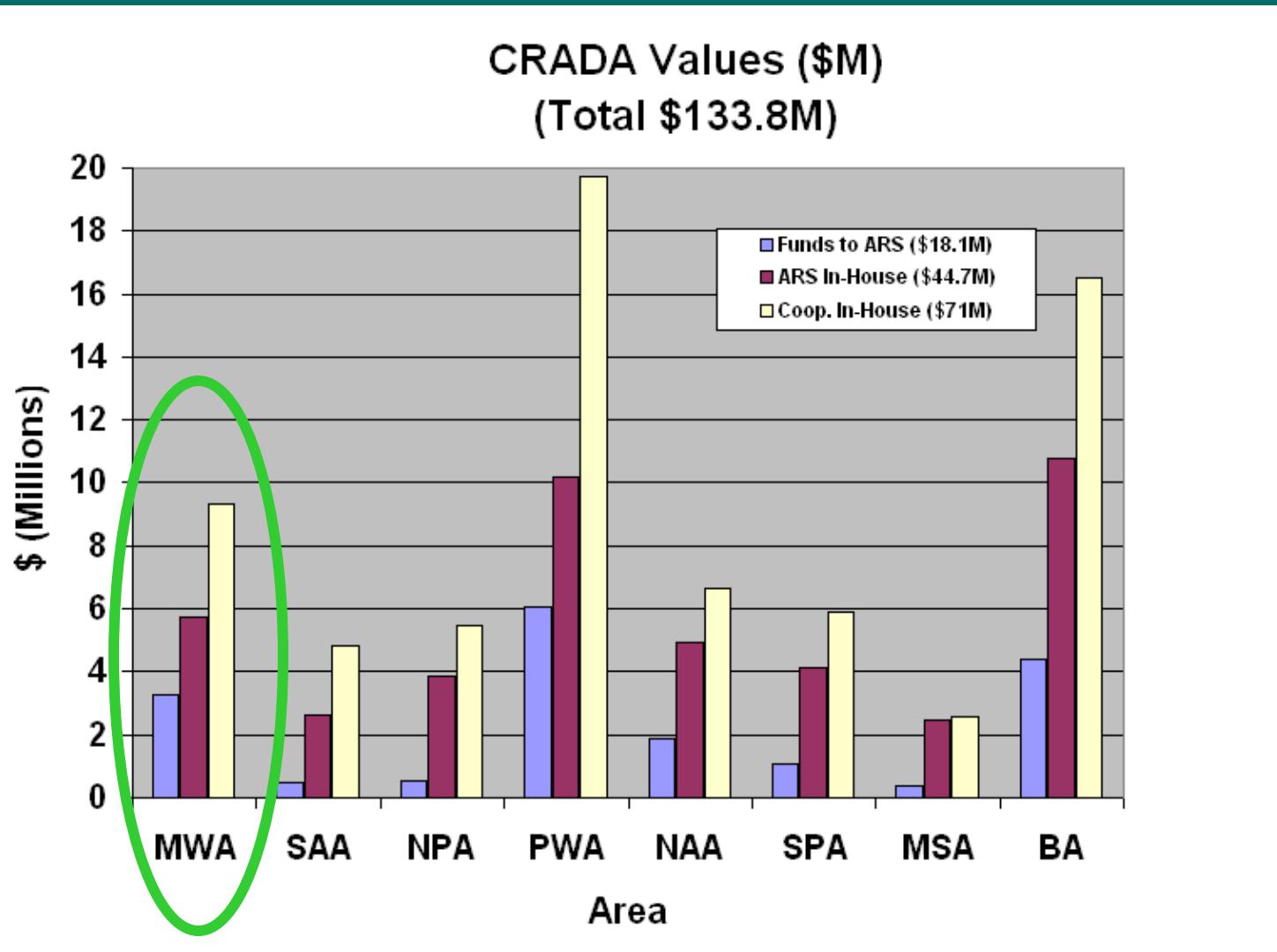
Annual Report to Congress on Technology Transfer --- FY 2007 Metrics

- CRADAs:
 - Active: 207
 - New: 55
 - Amended: 77
- Material Transfer Agreements: 788 (564 outgoing)
- Invention Disclosures: 116
- Patent Applications Filed: 105
- Patents Issued: 36

FY 2007 CRADA Metrics – How Does MWA Compare?



FY 2007 CRADA Metrics – How Does MWA Compare?



Annual Report to Congress on Technology Transfer --- FY 2007 Metrics

- Licenses:
 - Active: 339 (130 with universities)
 - New: 25
 - Biological Materials: 22 (5 new)
- Licenses with products on market: 100+
(28 from university co-owned)
 - 30 are plant materials (plant patent or Plant Variety Protection Certificate)
- Total Income: \$3,634,228
 - To Inventors: \$1,031,340



Current Technologies In Successful Commercialization ...



Preserving color, crispness, and flavor of fresh cut apples --- “Apple Dippers”® (Attila Pavlath / Dominic Wong, PWA; Mantrose-Hauser) (license, CRADA, infringement)

Current Technologies In Successful Commercialization . . .



100% natural fruit bars from fruit puree (Tara McHugh, PWA; HR Mountain Sun; “Gorge Delights”) (license, CRADA)

Current Technologies In Successful Commercialization . . .



Helping people with peanut allergies:
“Sunbutter”®
(Harmeet Guraya / Isabel Lima, MSA; Red River Commodities)
(CRADA)

Current Technologies In Successful Commercialization . . .



Sweet Scarlet



Autumn King

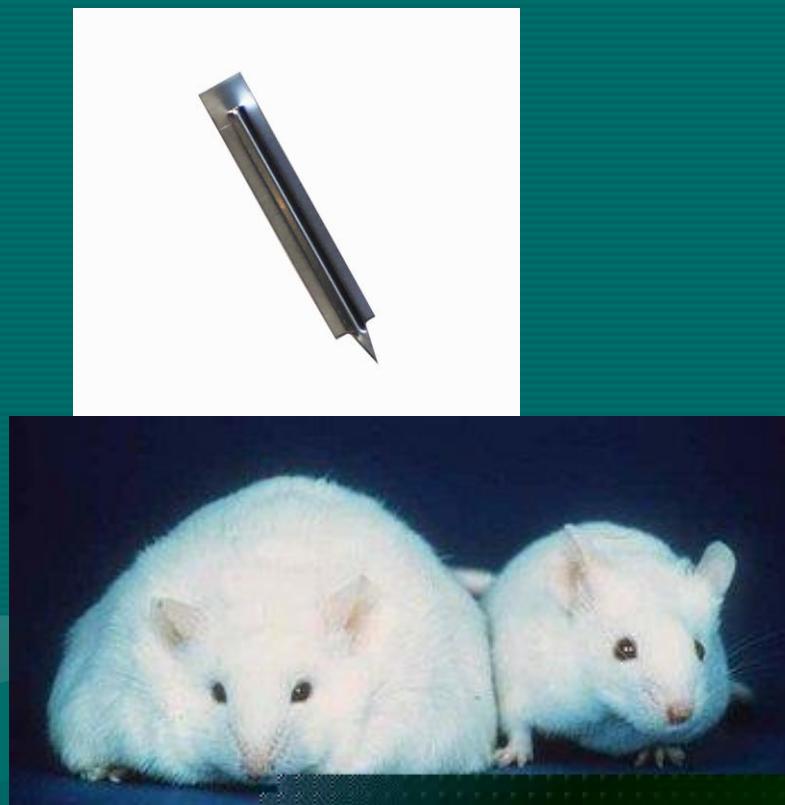


Scarlet Royal

Table grape varieties --
(David
Rampling,
PWA;
California
Table Grape
Commission)

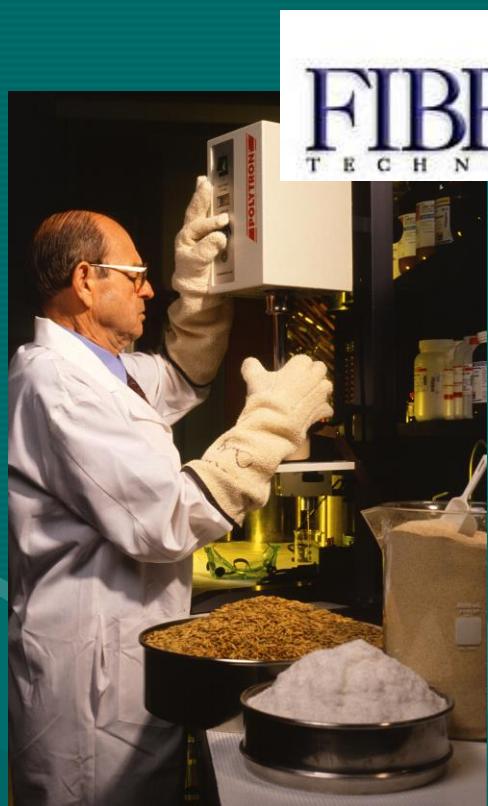
(license &
infringement)

Current Technologies In Successful Commercialization . . .



Humane mouse bleeding lancet:
“Goldenrod”® (W. Golde / P. Gollibin / L. Rodriguez, NAA; MEDipoint, Inc.)
(CRADA)

Current Technologies In Successful Commercialization . . .



George Inglett,
MWA
(Oatrim, Z-trim,
Nutrim, Calorie-trim)



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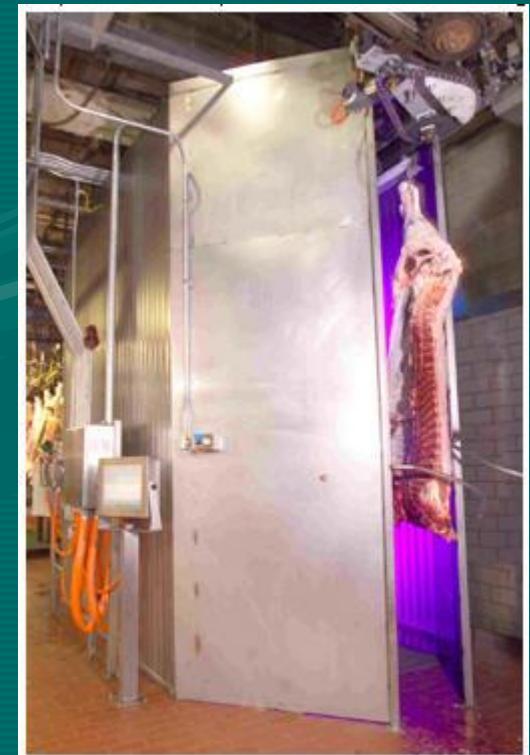
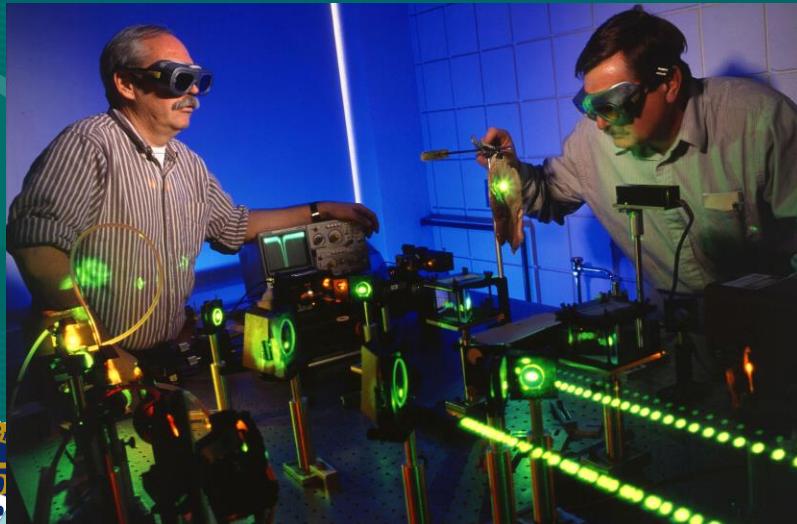
Current Technologies In Successful Commercialization . . .

eMERGE



Tom Casey, Mark Rasmussen
Jacob Petrich (Iowa State U.), MWA

(CRADA)



Current Technologies In Successful Commercialization . . .



Licensed exclusively to Agrilube / Bunge (Feb 2006)

First sale in March, 2006.

Biodegradable soy-based hydraulic fluid (Sevim Erhan, MWA; test with National Park Service)

Summary of Key Points

- Tech Transfer accountability is a legal requirement of every federal scientist and engineer. Commercialization of ARS research outcomes is among the most demonstrable positive outcomes of Congressional investment in ARS --- *and is reflected in the RPES evaluations.*
- Every ARS scientist should rely on their Technology Transfer Coordinator (TTC) and Patent Advisor (PA) for guidance throughout the research process -- especially in bioenergy-related research with a BRC.
 - Always use ARS Form 1 Laboratory Notebooks properly maintained to document research for each project
 - Use Material Transfer Agreements and Confidentiality Agreements with external potential partners
 - Report inventions to PA and TTC early in the discovery process
- *Enjoy your career in ARS!*



The Office of Technology Transfer is at

your service....



Photo: Quiet Waters Park, Annapolis, MD
(Joann Perkins)

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<http://www.ars.usda.gov/Business/Business.htm>