IG/16 24 June 2008



UNITED NATIONS DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS STATISTICS DIVISION

Seminar

Addressing Information Gaps in Business and Macro-Economic Accounts to Better Explain Economic Performance

New York, 23 – 24 June 2008 United Nations, Conference room C

Public sector intellectual property Rick Brenner





Public Sector Intellectual Property ---- A Quandary?

A Perspective from the U.S. Department of Agriculture

Richard J. Brenner, Ph.D. Assistant Administrator of ARS Office of Technology Transfer (Ms. D. June Blalock, Patent Licensing Coordinator)



June 23-24, 2008 United Nations, NYC Addressing Information Gaps in Business and Macro-Economic Accounts

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Definition of Terms

Intellectual assets: documented information, innovations, and know-how
 Intellectual property (IP): subset of intellectual assets that can be legally protected
 Technology transfer (T2): conversion of intellectual assets into goods and services useful to end users (farmers, processors,

consumers)

Intellectual Property License (or "freedom-to-operate") ≠ Technology Transfer



Assets Required for Effective Technology Transfer

> Intellectual "capital"

- human capital: people, their knowledge, skills and experience
- intellectual assets: documented know-how and protected innovations
- Complementary assets: manufacturing capacity, market access and distribution capacity, product registration expertise

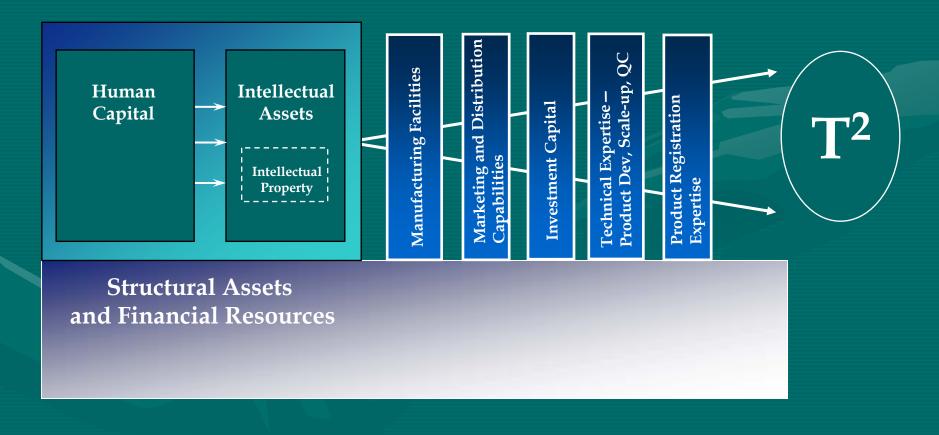


Structural assets: buildings and equipment, financial resources, infrastructure

A Model of a Public/Private Partnership

Intellectual Capital

Complementary Assets





Operating Assumptions

The development costs for innovative technologies are significant and the financial returns are unpredictable. > IP protection is a *necessary incentive* for private investment in financially risky innovations. Private sector delivery of products and services is often the most effective and efficient means of technology transfer. Intellectual property protection for innovations is available and enforceable.



U.S. Technology Transfer Legislation -- public sector, *non-federal* researchers --

Bayh-Dole Act, 1980

- Extramural research with federal funds (university, private research firms, etc.)
- Right to take title to invention and license according to institution policies & practices
- Rights "flow with the funds"
- If elect <u>not</u> to take title, or if patent prosecution / patent maintenance is abandoned, *rights must be returned to federal government*



U.S. Technology Transfer Legislation -- public sector, *federal* researchers --

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

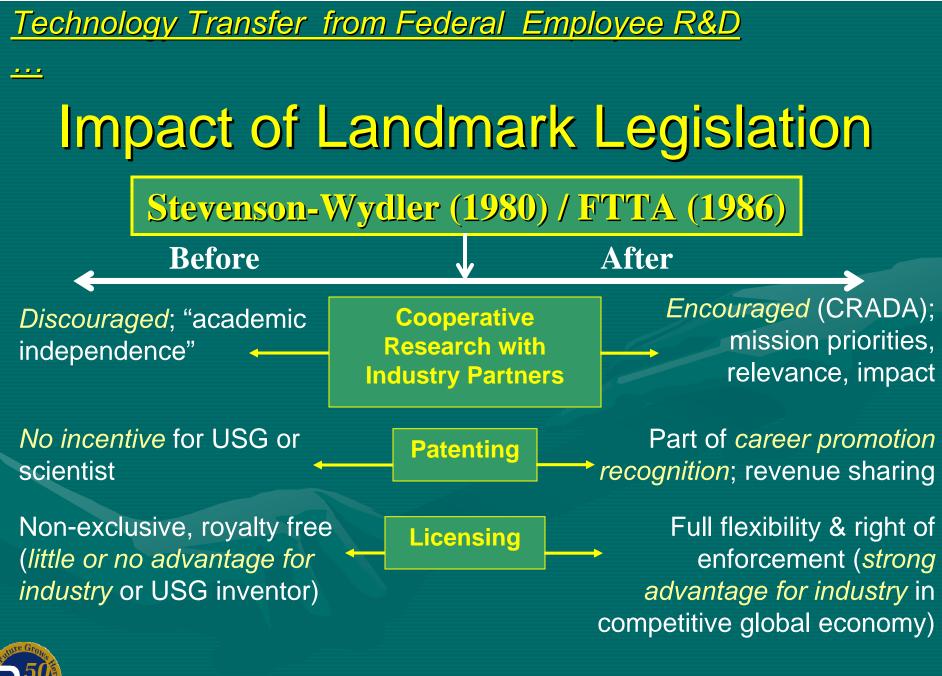
Special Cooperative Research And Development Agreement (CRADA) authority with private sector companies

right to negotiate exclusive license without Federal Register notice; confidentiality of data up to 5 years

Technology transfer becomes an obligation of federal scientists; royalties capped at \$150K / inventor / year

Extends licensing to "protectable" invention





USDA's Agricultural Research Service (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.



How Does the Private Sector Access Intellectual Assets of ARS Public R&D?

Through the Office of Technology Transfer...

Licensing current protected technologies (including plants) to private sector firms for commercial production.

Cooperative Research and Development Agreements (CRADAs) establish research partnerships to solve industry problems.



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

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, delegated by the Secretary of Agriculture for licensing any inventions developed from intramural research within any of the USDA agencies (including Forest Service (FS), Food Safety Inspection Service (FSIS), Animal & Plant Health Inspection Service (APHIS))



ARS Technology Transfer Policy Goals

- Use the patent system to facilitate technology transfer
- Provide an incentive for investments by the private sector
- Support small business enterprises and entrepreneurs
- Support investments by private sector partners in international markets



Federal Licensing Regulations 37 CFR 404.2

"It is the policy and objective of (this regulation) to use the patent system to promote the utilization of inventions arising from federally supported research or development."



37 CFR 404.2, paraphrased

A federally owned invention should be patented when a private sector partner is needed to achieve technology transfer *and*

that partner requires some scope of exclusivity to protect the capital investments needed to commercialize the invention.



Public / Private Partnerships: Licensing of USDA Inventions

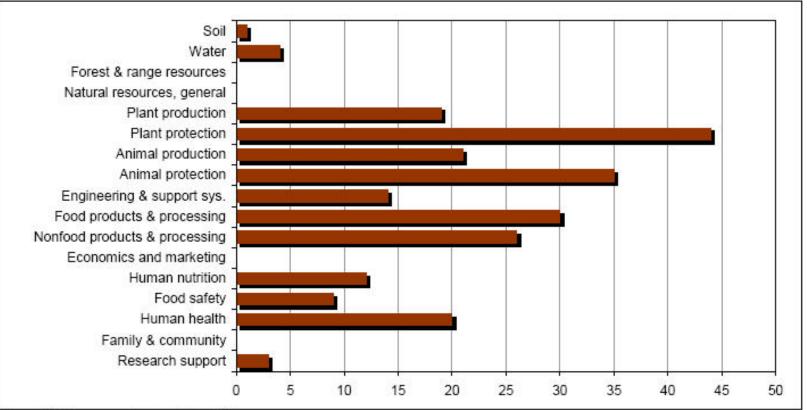
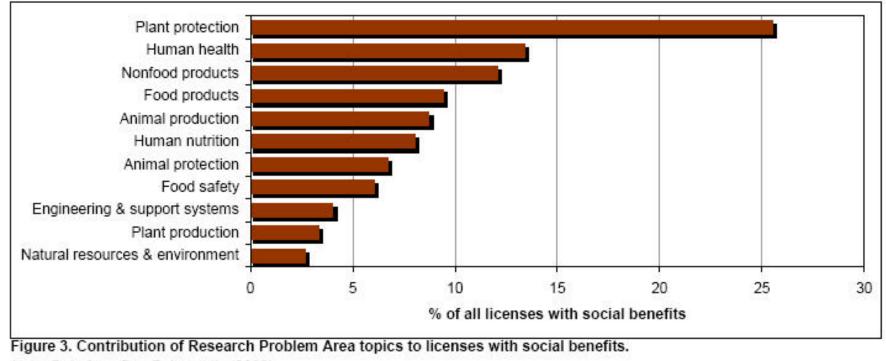


Figure 2. Licenses of patents by ARS.

Note. Patents may be licensed more than once. Patents may be captured in more than one category. Data from Day Rubenstein (2003).



Public / Private Partnerships: Relationship to Social Benefits



Note. Data from Day Rubenstein (2003).



Public / Private Partnerships: Relationship to Social Benefits

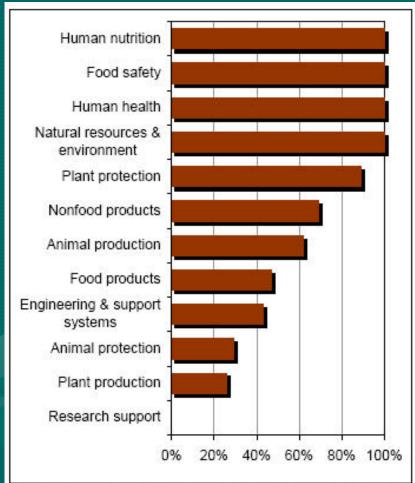


Figure 4. Percent of each category's licenses with social benefits.

Note. Data from Day Rubenstein (2003).

Public / Private Partnerships: Cost Sharing in CRADAs

Table 2. Public and private contributions to costs of joint research.

	Public contribution	Private contribution ^a
Technology area	Share of ro	w total (%)
Postharvest utilization of agricultural commodities	36.6	63.4
Plants	33.4	66.6
Animals	36.5	63.5
Natural resources	40.2	59.8
Human nutrition and well- being	52.0	48.0
All research	36.1	63.9

^a Private contribution includes grants given to ARS and inhouse research conducted by private-sector partner in support of the CRADA project. Contribution based on the value of resources contributed to 366 CRADA agreements between USDA and outside cooperators between 1987 and 1995 (out of a total of 528 CRADA projects during this period.) Note. Data calculated from ARS databases.



The Question Posed by USDA's Economic Research Service

Does ARS IP Management Promote or Inhibit Technology Transfer?



Government Patenting and Technology Transfer

Paul W. Heisev John L. King

Kelly Day Rubenstein Robbin Shoemaker



Conclusions ...

> Intellectual property rights, such as patents, protect new inventions from imitation and competition. A patent's major objective is to provide incentives for invention, sacrificing short-term market efficiency for long-term economic gains.



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More widespread use of patenting and licensing by **ARS** has not reduced the use of traditional instruments of technology transfer such as scientific publication

Conclusions ...

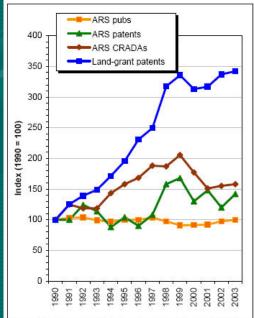


Figure 1. Indices of ARS technology transfer, 1990-2003. Note. Data from ERS analysis of data from ARS; CSREES; USPTO: Institute for Scientific Information Current Contents.



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Conclusions ...

As commercial partners gain experience with the technology and learn more about the market, mutually advantageous revisions to license terms can maintain the incentives through which private companies distribute the benefits of public research.



Models for Developing and Transferring Technologies to the Private Sector



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



→ ARS Scientist

Technology Transfer Coordinator Corporation negotiates license (*no FR notice; confidentiality*)

Manufacture &

Market

Cooperative Research & Development Agreement (CRADA)

Patent

Subject Invention (developed under CRADA)



Technology Transfer: the adoption of research outcomes for public benefit

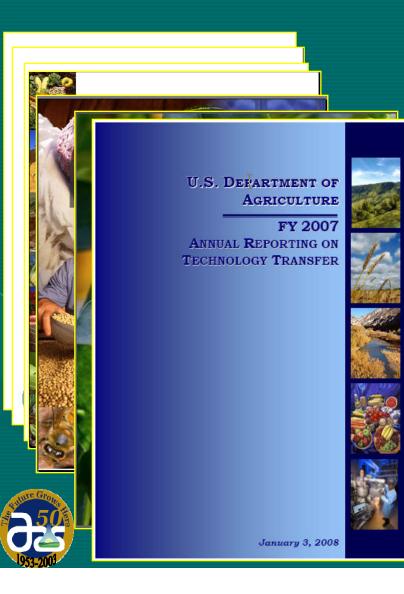




Annual Report to Congress on Technology Transfer --- "Downstream Outcomes"

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Biobased Products



Domestic production of hypoallergenic rubber --Natural rubber is a strategic raw material used in over 40,000 applications. The United States consumes over 20% of the world supply of natural

Crop Production and Protection





Novel sweetener reaches market -- ARS researchers at the USDA/ARS Bioproducts and Biocatalysis Research Unit at the National Center for Agricultural Utilization Research (NCAUR), in Peoria, IL, are working in partnership with Cargill on the use of enzymes to convert sugar and corn syrup to value-added complex carbohydrates. Using ARS-developed methods to produce

and characterize novel carbohydrate products from agricultural materials, ARS and Cargill 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 sweeteness 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).

The Low Glycemic Index Sweetener Team of Gregory Cote, Timothy Leathers, Melinda Nunnally, and Sheila Maroney (Midwest Area, Peoria, IL), Ting Carlson and Anton Woo (Cargill, Inc) won a 2007 Superior Effort ARS Technology Transfer Award for this work.

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

Licenses:

Active: 339 (130 with universities)
New in 2007: 25
Biological Materials: 22 (5 new in 2007)
Licenses with products on market: 108 (28 from university co-owned inventions)
30 are plant materials (plant patent or Plant Variety Protection Certificate)

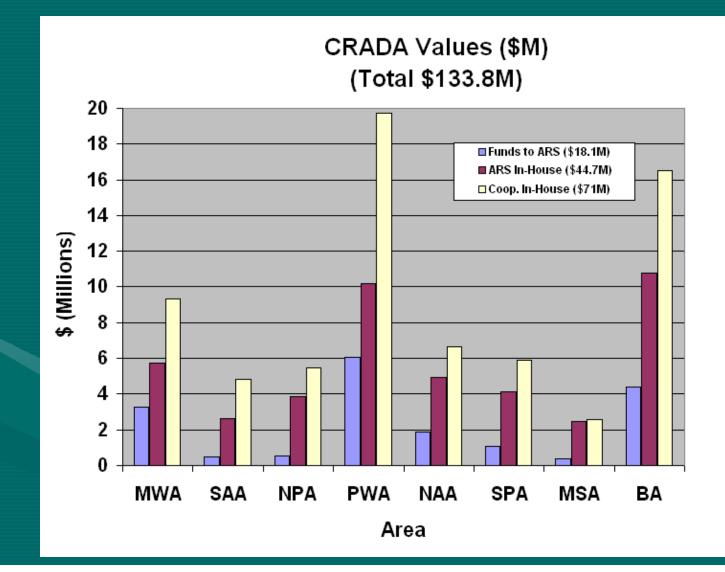


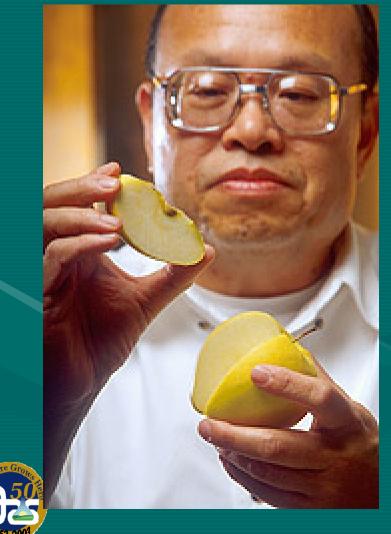
Annual Report to Congress on Technology Transfer ---- FY 2007 CRADA & Patent Metrics

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

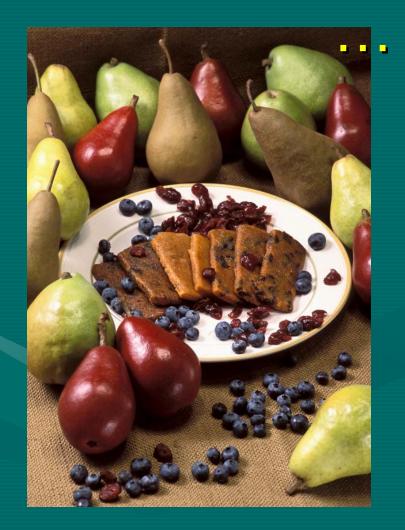


Annual Report to Congress on Technology Transfer --- FY 2007 CRADA Value





Preserving color, crispness, and flavor of fresh cut apples ----"Apple Dippers"® (Attila Pavlath / Dominic Wong) Mantrose-Hauser (license,



100% natural fruit bars from fruit puree (Tara McHugh)

HR Mountain Sun; "Gorge Delights" (license, CRADA)





Helping people with peanut allergies: "Sunbutter"® (Harmeet Guraya / Isabel Lima)

Red River Commodities (CRADA)

Current Technologies on the Road to Success ...



George Inglett (Oatrim, Ztrim, Nutrim, Calorie-trim)

Products



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Table grape varieties --(David Ramming) California Table Grape Commission

(license & infringement)



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

(CRADA)



MERGE





Licensed exclusively to Agrilube / Bunge (Feb 2006) First sale in March, 2006.

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







Codling Moth Kairomone and Pheromone (CRADA, patents,

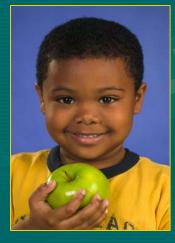
Technology Transfer: Successes from Crop Protection and Quarantine



Based on ARS research outcomes, FDA approves Tylan Soluble (Elanco Animal Health) for controlling American foulbrood disease in honey bees (know-how; public sector data from 'intellectual assets') Technology Transfer: Successes from Crop Protection and Quarantine Enhancing Trade



APHIS accepts ARS findings and establishes Final Rule for lower generic phytosanitary radiation treatment for fruit flies; lower cost, decreased treatment time, more competitive in global markets.



ARS demonstrates apples from U.S. won't vector fire blight to other nations; WTO rules in favor of U.S., Japan opens market to U.S. apples.



U.S. University Technology Transfer FY 2005 Metrics

- 628 new businesses were created and 527 new commercial products were launched based on innovations developed at U.S. universities, largely with Federal funds
- 4,932 new licenses; 28,349 active licenses among AUTM* reporting institutions
- >\$42 B in R&D at member U.S. academic centers

*Source: Association of University Technology Managers (AUTM) http://www.autm.net; metrics reflect 151 institutions responding to 2005 survey

AUTM now provides "Better World" reports to highlight selected outcomes



U.S. Biotechnology Transfer Policy Outcomes

(arising from federal & private sector R&D investments)

As of Dec. 31, 2005, there were 1,415 biotechnology companies in the U.S. (329 publicly held) with health-care revenues of \$50.7 B.

The market capitalization of the publicly traded companies was \$410 B

The U.S. biotechnology industry employed 198,300 people as of December 2003.

Source: Biotechnology Industry Organization (BIO) http://www.bio.org



How to Facilitate Knowledge of "...who owns what, who can exploit what..."

Build IP management *technical* capacity (i.e., professional services to meet both public and private needs)



Public Intellectual Property Resources in Agriculture (PIPRA)

Assists in accessing IP for developing nations and small businesses (freedom to operate)

US-India Agricultural Knowledge Initiative (USAID funded through Michigan State University)

IP training and capacity building



Key message: Model intellectual asset management policies (USDA) that promote economic activity

Public Sector Intellectual Assets: Benefits to Society and Economic Activity

Availability of new products and services (innovation from R&D investments)

Less expensive or improved products and services (innovation from R&D investments)

Creation or retention of local jobs

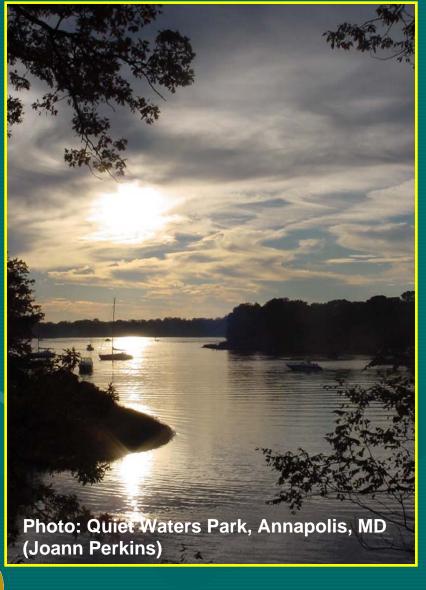
- Promotes / sustains entrepreneurial activities
- Downstream impacts on other businesses providing supporting products or services



Impacts on the quality of life for consumers



Onited States Department Of Agriculture Agricultural Research Service



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





United States Department Of Agriculture S Agricultural Research Service

Postings for UN Website



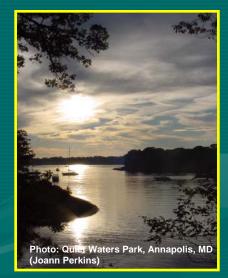
AUTM 2008 Better World Report Part1.pdf

- AUTM 2008 Better World Report Part 2.pdf
- BEA-07-48 R&D spending 07 and GDP.pdf
- Can Technology Transfer Help Public-Private Sector Do More with Less The Case of the USDAs Agricultural Research Service.pdf



Government Patenting and Technology Transfer.pdf

- USA Today 5June08 Bayh-Dole helps US compete.pdf
- - USDA FY2007 Tech Tran Annual Report FINAL



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