Technology Transfer from Federal Laboratories

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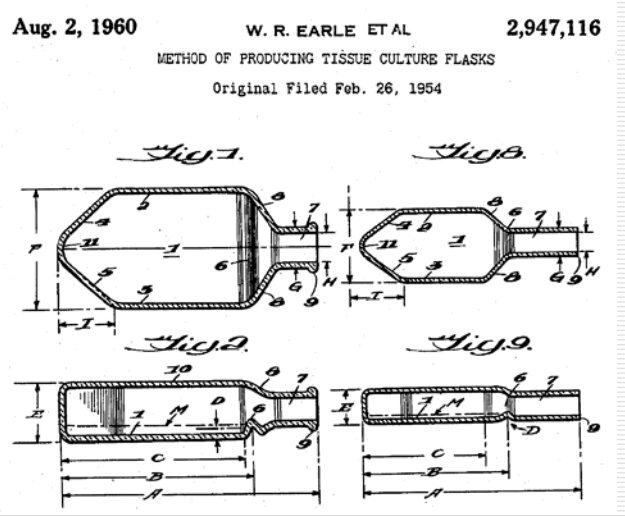
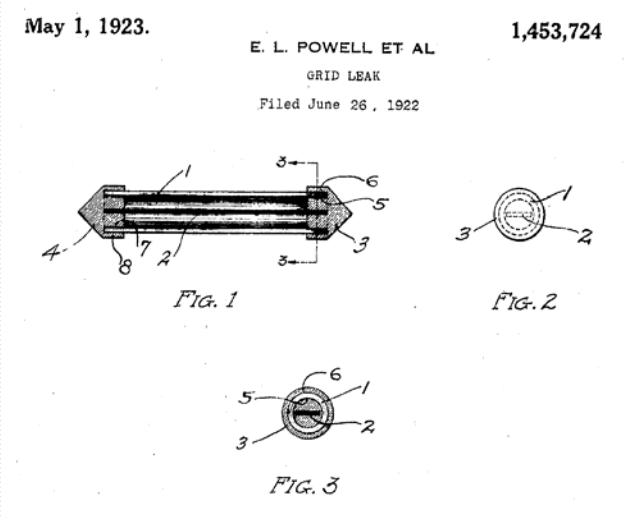
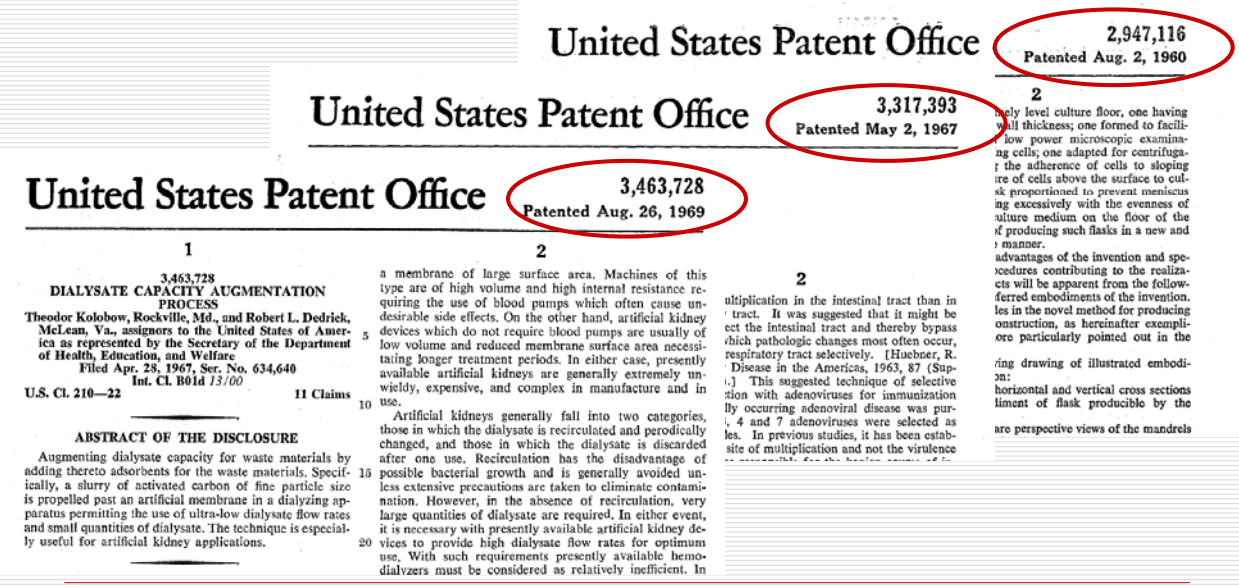
Early Technology Transfer Examples from Two of the Oldest Federal Laboratories (Patents)


Aug. 2, 1960 W. R. EARLE ET AL 2,947,116
METHOD OF PRODUCING TISSUE CULTURE FLASKS
Original Filed Feb. 26, 1954


May 1, 1923. 1,453,724
E. L. POWELL ET AL
GRID LEAK
Filed June 26, 1922
FIG. 1
FIG. 2
FIG. 3

Intramural Patents of National Institutes of Health (Est. 1930)

Successor to Marine Hospital Service (Est. 1887)



United States Patent Office

2,947,116
Patented Aug. 2, 1960

United States Patent Office

3,317,393
Patented May 2, 1967

United States Patent Office

3,463,728
Patented Aug. 26, 1969

1

3,463,728
DIALYSATE CAPACITY AUGMENTATION PROCESS
Theodor Kolobow, Rockville, Md., and Robert L. Dedrick, McLean, Va., assignors to the United States of America as represented by the Secretary of the Department of Health, Education, and Welfare
Filed Apr. 28, 1967, Ser. No. 634,640
Int. Cl. B01d 13/00
U.S. Cl. 210—22 11 Claims

ABSTRACT OF THE DISCLOSURE

Augmenting dialysate capacity for waste materials by adding thereto adsorbents for the waste materials. Specifically, a slurry of activated carbon of fine particle size is propelled past an artificial membrane in a dialyzing apparatus permitting the use of ultra-low dialysate flow rates and small quantities of dialysate. The technique is especially useful for artificial kidney applications.

2

a membrane of large surface area. Machines of this type are of high volume and high internal resistance requiring the use of blood pumps which often cause undesirable side effects. On the other hand, artificial kidney devices which do not require blood pumps are usually of low volume and reduced membrane surface area necessitating longer treatment periods. In either case, presently available artificial kidneys are generally extremely unwieldy, expensive, and complex in manufacture and in use.

Artificial kidneys generally fall into two categories, those in which the dialysate is recirculated and perodically changed, and those in which the dialysate is discarded after one use. Recirculation has the disadvantage of possible bacterial growth and is generally avoided unless extensive precautions are taken to eliminate contamination. However, in the absence of recirculation, very large quantities of dialysate are required. In either event, it is necessary with presently available artificial kidney devices to provide high dialysate flow rates for optimum use. With such requirements presently available hemodialyzers must be considered as relatively inefficient. In

2

ultiplication in the intestinal tract than in tract. It was suggested that it might be ect the intestinal tract and thereby bypass hich pathologic changes most often occur, respiratory tract selectively. [Huebner, R. Disease in the Americas, 1963, 87 (Sup-.] This suggested technique of selective tion with adenoviruses for immunization lly occurring adenoviral disease was pur-, 4 and 7 adenoviruses were selected as les. In previous studies, it has been estab-site of multiplication and not the virulence

2

ely level culture floor, one having all thickness; one formed to facili-low power microscopic examina-ng cells; one adapted for centrifuga-the adherence of cells to sloping ce of cells above the surface to cul-sk proportioned to prevent meniscus ing excessively with the evenness of ulture medium on the floor of the f producing such flasks in a new and manner.

advantages of the invention and spe-cedures contributing to the realiza-cts will be apparent from the follow-ferred embodiments of the invention. les in the novel method for producing onstruction, as hereinafter exempli-ore particularly pointed out in the

ring drawing of illustrated embodi-on:
horizontal and vertical cross sections liment of flask producible by the

are perspective views of the mandrels

Courtesy of Mark L. Rohrbaugh, Director of the Office of Technology Transfer at NIH

NIH OFFICE OF TECHNOLOGY TRANSFER NIH and FDA Invention and Patent Activity

(http://www.ott.nih.gov/about_nih/statistics.aspx)

ACTIVITY	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Invention Disclosures	400	403	388	367	419	402	353	340
New U.S. Patent Applications Filed[1]	196	199	186	173	178	176	156	147
Total U.S. Patent Applications Filed	382	396	347	309	354	343	300	304
Issued U.S. Patents	86	122	66	93	117	88	110	134
Executed Licenses	209	276	313	254	264[2]	259[3]	215[4]	226
Royalties ($ in millions)	$53.7	$56.3	$98.2	$82.7	$87.7	$97.2	$91.2	$91.6
Waivers							58[5]	73
Executed CRADAs (NIH Only)	84	87	80	51	44	72	77	66
Standard	36	43	39	22	23	33	33	39
Material	48	44	41	29	21	39	44	27

[1] Patent applications include only the first U.S. patent application for a new disclosure filed in the reporting period (data include CIP filings but not Divisional applications).
[2] This number includes 15 administrative amendments that modify executed license agreements to correct or clarify non-substantive terms or obligations.
[3] This number includes 26 administrative amendments that modify executed license agreements to correct or clarify non-substantive terms or obligations.
[4] This number includes 25 administrative amendments that modify executed license agreements to correct or clarify non-substantive terms or obligations.
[5] Waiver breakdown: 50 Inventor waivers and 8 US manufacturer waivers.

First Intramural Patent of Naval Research Laboratory (Est. 1923)

Patented May 1, 1923. 1,453,724

UNITED STATES PATENT OFFICE.

EDWIN L. POWELL AND CHARLES E. MOTTO, OF WASHINGTON, DISTRICT OF COLUMBIA.

GRID LEAK.

Application filed June 26, 1922. Serial No. 570,941.

To all whom it may concern:

Be it known that we, EDWIN L. POWELL and CHARLES E. MOTTO, citizens of the United States, residing at Washington, District of Columbia, have invented certain new and useful Improvements in Grid Leaks, of which the following is a specification.

Our invention relates to thermionic electron tube apparatus and more particularly tional view of the grid leak taken on line 3—3 of Fig. 1; and Fig. 4 is a diagrammatic layout of a radio receiving circuit illustrating the connection of the grid leak in the thermionic electron tube circuit.

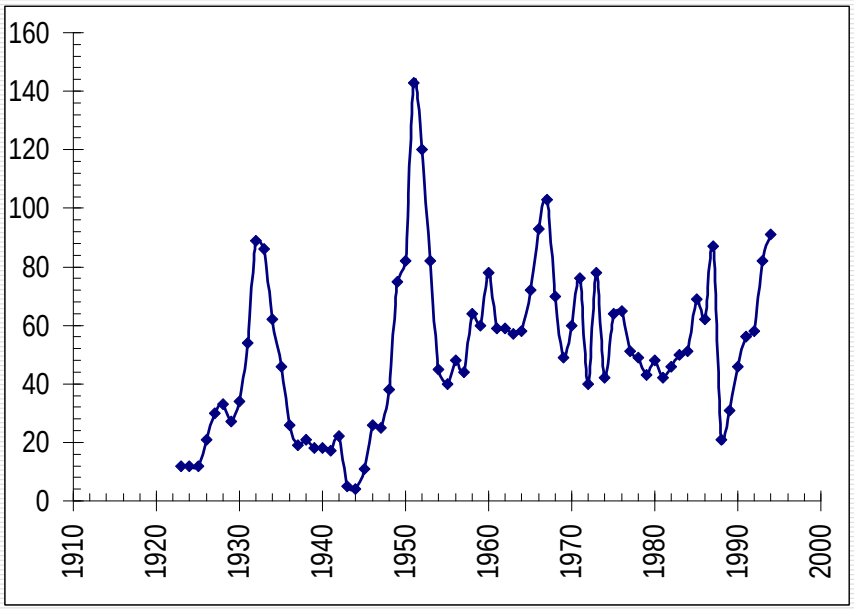
It will be understood that the principles of our invention may be embodied in various forms and that details are not material. The present embodiment of the invention, therefore, is to be considered as merely in-

Courtesy of Amy Ressing, Associate Counsel for Intellectual Property, Naval Research Laboratory

Intramural Patent Activity of Naval Research Laboratory (Est. 1923)

1923-1994

(3677 Total Patents)



Data Courtesy of Amy Ressing, Associate Counsel for Intellectual Property, Naval Research Laboratory

HEW (NIH) Patenting Policies

Harbridge House Government Patent Policy Study Final Report to Comm. on Gov't. Patent Policy, Fed. Council for S&T (1968)

- "The department's interest in inventions is almost the **reverse of that which generally prompts a private patent** application. **Its concern is not** to withhold the invention from the public or **to charge royalties** for its use but to assure the availability of the invention to all. This assurance may be lost if an individual claiming priority of invention files a patent application."
- patenting may be ... appropriately recommended when-
  - 1. . . . maximum assurance against potential **rival claims** by establishing priority of invention and diligence in reducing to practice [is advisable]; or
  - 2. it is deemed advisable, for **reasons of health or safety**, to retain control . . . of the invention itself, with **legal authority to impose restrictive conditions on its use**; or
  - 3. **other Federal agencies** have such an interest in the invention [and will] **prosecute the patent** application."
- Employee **inventions are not** the primary **focus of the annual performance reviews**.

Example of Technology Transfer from the Naval Research Laboratory (1920's)

(U.S. DOJ Investigation of Patent Practices & Policies – 1947)

the naval research laboratory in the late twenties. The staff of the naval research laboratory sold a number of patents in the field of radio to a patent holding company called Wired Radio, whose assets consisted almost entirely of such patents. That company entered into option contracts with a large number of the radio technicians employed at the laboratory under which the employees received amounts averaging between $50 and $100 per patent application, with an additional sum to be paid when the patent issued, the amount depend-

* * *

In the early thirties the Director of the Naval Research Laboratory ordered that option contracts between naval employees and private concerns were not to be renewed or extended, a step apparently impelled by the realization that too many inventions seemed to fit more closely into Wired Radio's pattern than into the Navy's. A further

Only "option contracts" eliminated; inventor licenses to firms permitted.

But . . .

Example of NRL Tech Transfer (1937)

(U.S. DOJ Investigation of Patent Practices & Policies – 1947)

The relationship between naval employees and private industry resulting from the interest in selling the former's inventions was, on at least one occasion, supplemented by an even closer business connection between them. That case involved an outstanding member of the Laboratory staff, Dr. Hayes of the Sound Division, who had been acting as a consultant for Texaco and was under contract for years to assign all of his patents to that company, allegedly at compensation of $25,000 per year.[119] In 1937 the Department made an effort to prohibit conflicting outside employment, whereupon Dr. Hayes offered to resign if he were obliged to relinquish his Texaco contract. Upon submission of the matter to the Judge Advocate General it was decided that he could retain his connection with Texaco while continuing in the Navy Department.

The justification advanced for permitting such arrangement was that the lure of commercial patent rights acted as an inducement to accept Government employment, and was particularly necessary in the late twenties when qualified men were hard to obtain. But the objections advanced to the arrangement were numerous:

Federal Laboratory Technology Transfer Legislative and Policy Milestones

Year	Initiative	
1979	President Carter "Industrial Innovation Initiatives"	Response to advisory committee recommendation to transfer government sponsored IP rights to private sector
1980	Stevenson-Wydler Technology Innovation Act (P.L. 96-480)	Enacted 10/21/80; many provisions not implemented. Established Research and Technology Applications Offices at each federal laboratory.
	Bayh Dole Act (P.L. 96-517)	*Intellectual property rights to R&D funding grantees*
1984	*National Cooperative Research Act (P.L. 98-462)*	*Limits antitrust liability in joint R&D among firms*
1986	Federal Technology Transfer Act (P.L. 99-502)	Provides explicit CRADA authority to GOGOs (where organic authority is lacking)
1987	President Reagan EO 12591 – "Facilitating access to science and technology"	Along with existing statutes, reiterates the basis for "Work for Others" and "Use of Facilities" programs
1989	National Competitivness Technology Transfer Act (P.L. 101-189)	Provides CRADA authority to GOCOs

Forms of Technology Transfer

TABLE 3.—TYPES OF INTERACTIONS BETWEEN R&D LABORATORIES AND FEDERAL LABORATORIES

Type of Interaction	Percent of Industrial R&D Laboratories Ranking Type of Interaction as Important[a]
Test facilities in government laboratories	32.7
Licensing of government patents[b]	15.7
Cooperative research and development agreement (CRADA)[b]	28.4
Inflows of scientists from government labs[b]	14.9
Outflows of scientists to government labs	7.2
Small business innovation research program (SBIR)	10.6
Government contractor	26.4
Inflows of ideas from government labs[b]	34.6
Outflows of ideas from government labs	21.2
Industry-government technology transfer centers[b]	25.0

Source: *Survey of Industrial Laboratory Technologies 1996.*

[a] An interaction is classified as important when it receives a score of 3–5 on a five-point Likert scale. Sample consists of all laboratories in the survey that report the data.

[b] Indicator of technology transfer.

Adams, Chang, and Jensen, The Influence of Federal Laboratory R&D on Industrial Research, Rev. of Economics and Statistics, pp 1003-1020 (2003)

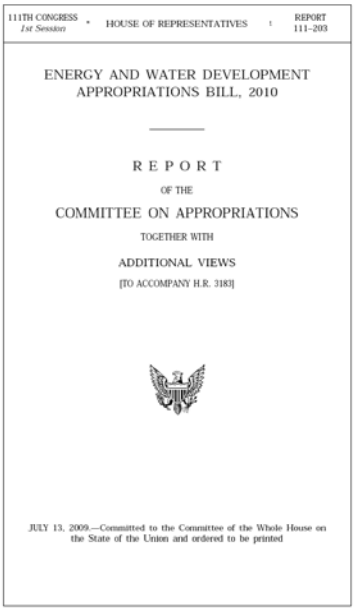
Quantitative Patent Data

Appropriate? Reliable? Meaningful?

- "[The agencies' passive approach to patent marketing] has proven to be an ineffective policy as evidenced by the fact that of the more than 28,000 patents in the Government patent portfolio, **less than 4 percent** are successfully licensed." (Senate Report 96-480, on the University and Small Business Patent Procedures Act, **December 12, 1979**).
- "[The contention that companies needed title or exclusive licenses to inventions] was supported by the fact that, although a portion of ideas patented by the Federal Government had potential for further development, application, and marketing, **by 1980 only five percent** of these were ever used in the private sector." (Congressional Research Service – Report for Congress 94-5001-SPR, June 14, 1994).
- "The Federal Government will spend approximately $18 billion in fiscal year 1986 on research and development at over 700 Federal laboratories. These laboratories employ one-sixth of the Nation's scientists and engineers. . . . Over the years, however, **only approximately 5 percent** of Federal patents have been licensed." (Senate Report 99-283 on the Federal Technology Transfer Act of 1986, **April 21, 1986**).
- "Currently, **only about 10 percent** of federal patents have been licensed to be commercialized." (DOE Press Release of **March 29, 2011**, http://www.energy.gov/10202.htm)

Increased Attention to Technology Transfer from Federal Laboratories

(House Report 111-203 – July 2009)



111TH CONGRESS 1st Session * HOUSE OF REPRESENTATIVES : REPORT 111-203

ENERGY AND WATER DEVELOPMENT APPROPRIATIONS BILL, 2010

REPORT

OF THE

COMMITTEE ON APPROPRIATIONS

TOGETHER WITH

ADDITIONAL VIEWS

[TO ACCOMPANY H.R. 3183]

JULY 13, 2009.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

In the past, the Committee has expressed concerns that the Department was not striking an appropriate balance between basic and applied research, development, demonstration, and deployment. The Committee continues to have these concerns, and encourages the Department to articulate a vision that strikes a deliberate balance between basic and applied research and implements it consistently across the Department's programs. The Committee has also expressed concerns that the Department does not have a comprehensive approach to transfer innovations from Department laboratories to industry. While individual program offices and national laboratories have spearheaded small initiatives, the Committee encourages the Administration to elevate this issue and implement a Department-wide technology transfer plan.

The Department currently supports a variety of research and development efforts that advance U.S. scientific innovation in mul-

DOE Contractor Attorneys' Association

Spring Meeting 2011

Panel on Technology Transfer

- **Katharine Ku**, Director of the Office of Technology Licensing, Stanford University and SLAC; Member, Committee on the Management of the University Intellectual Property, National Academy of Sciences
- **Ray O. Johnson**, Senior Vice President and Chief Technology Officer, Lockheed Martin Corporation; Board Member, Sandia Corporation
- **William H. Pratt**, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner

Observations

- Age of the office is important
  - 20-25 year proposition
- Metrics are not meaningful!
- Each deal is different
  - Flexible
  - Reasonable
  - Precedence

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Issues in Tech Transfer

- Conflict of interest
  - Individual
  - Institutional
- Research Commons/tools
- Retained rights
- Exclusivity vs. non-exclusivity
- Big companies vs. Small companies
- Physical Sciences vs. Life Sciences

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Best Practices

- Stay centered
  - Laboratory values come first
- Do what's best for the technology
  - Don't chase the $$$
    - The dollars will come if you do a good job
- Plant as many seeds as possible
  - Some will bear fruit

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Translation: Advice to Labs

- Stay Centered: tech transfer is a risk-taking decision; try to enable it
- Do what's best for the technology: get it out there, don't put stumbling blocks, minimize bureaucracy
- Plant as many seeds as possible: you will be lots of credit for doing this

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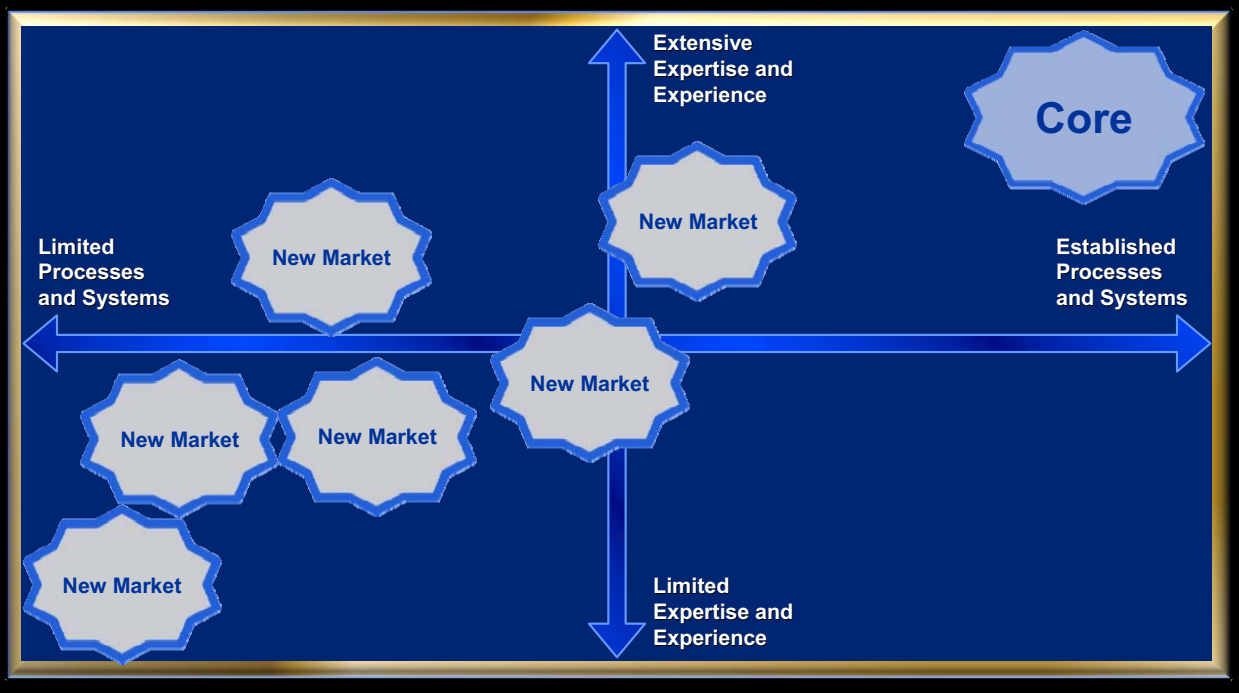
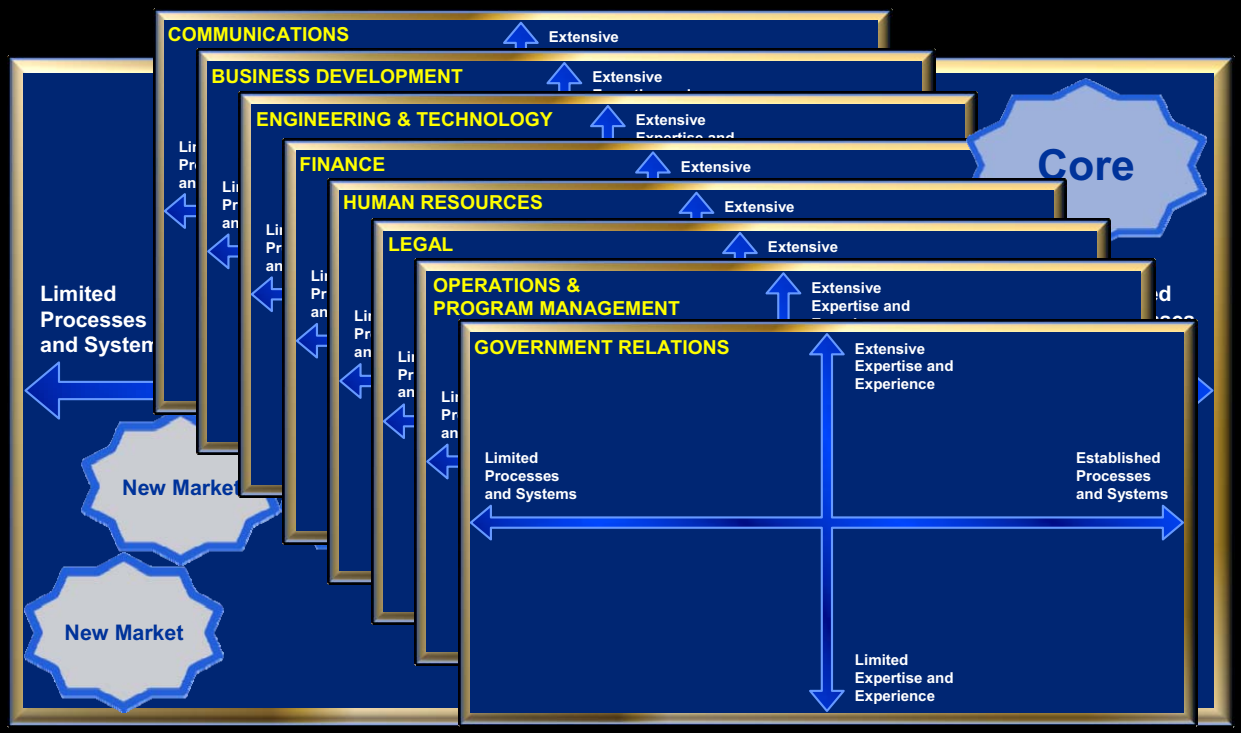
Specifics

- Have template agreements
- Be on flexible most aspects (particularly financial)
- Explain why can't be flexible on other provisions
- Be reasonable (have reasons)
- Try to be efficient/effective
- Try not to be bureaucratic

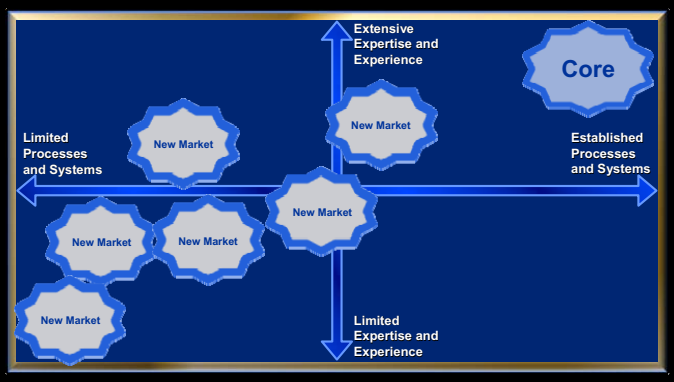
Innovation Space

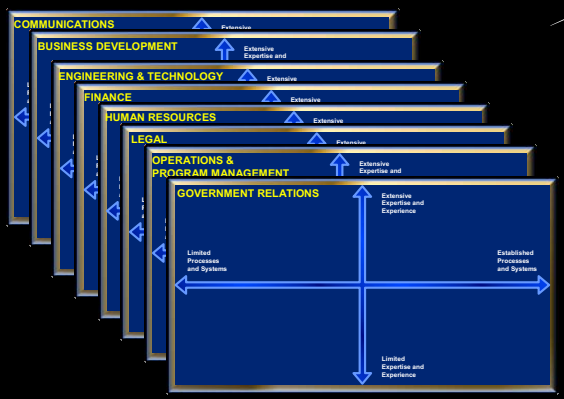


Innovation Space

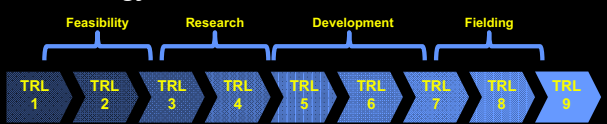


Innovation Readiness Levels

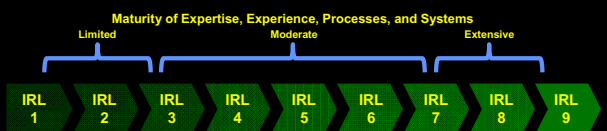




Technology Readiness Levels



Innovation Readiness Levels



Generated Data - Information Produced During the Course of the Project

- Ability to protect - key issue for many companies looking to fund work at a National Lab or participate in Cooperative Agreements
  - Without protection – USG gets Unlimited Rights and competitors gain early access
  - Major concern for many but not all companies

- **WFOs** – Typically, a company can designate all Generated Information as Proprietary Information
  - Not practiced by all Labs – which can result in loss of work for a Lab
    - Solution (in some cases) publishing carve-outs

Generated Data (con't)

- **CRADAs** - "Each Party may designate as Protected CRADA Information any Generated Information produced by its employees …***and, with the agreement of the other Party, so designate any Generated Information produced by the other Party's employees.***"
  - Very big concern– Will the Lab designate if requested?
  - Solution MOU with DOE

- **Financial Assistance Awards (Grants/Cooperative Agreements)**
  - Unlimited Rights in data first produced in performance of the project and all data delivered under the FAA
    - Exceptions: Funding under Energy Policy Act and American Recovery and Reinvestment Act (five-year confidentiality period)
  - Solution: Address concerns when listing deliverables and by exceptions to Additional Data Rights provisions

Obligations under the Patent Provisions

- **Generally speaking** – most obligations are acceptable to the majority of companies with some minor modifications or explanations
- **U.S. Competiveness Concerns** (CRADA)– Big issue

  U.S. Competiveness Provision: Products embodying Intellectual Property developed under a CRADA shall be **substantially manufactured** in the United States, and processes, services, and improvements covered by Intellectual Property developed under a CRADA shall be **incorporated into the Participant's manufacturing facilities in the United States** either prior to or simultaneously with implementation outside the United States. Such processes, services, and improvements, **when implemented outside the United States, shall not result in reduction of the use of the same processes, services, or improvements in the United States**.

  – What does "**substantially manufactured**" mean? Not expressly defined.
    - But see, NASA Regulations and Buy American Act
  – Major impediment in contracting with a National Lab – especially for U.S. subsidiaries of foreign corporations
  – Archaic in a global economy and can be counterproductive
  – Solution: MOU with DOE

Obligations under the Patent Provisions (con't)

- **Preference for U.S. Industry** – FAA
  – **Small business/non-profits:** "No small business … Nonprofit … [or] its assignee … shall grant to any person the exclusive right to use or sell any subject invention in the United States, unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be **manufactured substantially in the United States**." (**Bayh Dole Act)**
    - ARPA-E places similar requirement on federally-owned, contractor-operated laboratories receiving ARPA-E Funding
  – **Large Business Firms (with DOE waiver)**: any products embodying any waived invention or produced through the use of any waived invention will be **manufactured substantially in the United States (exceeds Bayh Dole Act)**.

Obligations under the Patent Provisions - Preference for U.S. Industry (con't)

- **Small business and non-profits (ARPA-E):** The Recipient agrees that "any products embodying any elected subject invention or produced through the use of any elected subject invention will be manufactured substantially in the United States for any use or sale in the United States… The Recipient further agrees to make the above condition binding on any assignee or licensee of, or any entity acquiring rights to, any elected subject invention, including subsequent owners of Recipient." (exceeds **Bayh Dole)**
- **Large Business Firms (ARPA – E):** Same as above, except requires substantial manufacturing in the U.S. for sale or use anywhere in the world

- Concerns
  - "Manufactured Substantially" – Not Defined
  - Affects ability to license
  - Hurdles for bringing in large companies into a project for cost sharing purposes

- Solutions (FAA):
  - Net Benefit Statement – possible if not receiving government funding
  - Waiver – need to show not commercially feasible in U.S. and alternative benefit to the U.S. May be more difficult to obtain if American Recovery and Reinvestment Act funding is involved

Thank-You!

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