History and Approaches to Technology Transfer from US Federal Laboratories

Government-University-Industry Research Roundtable

The National Academies

May 29, 2014

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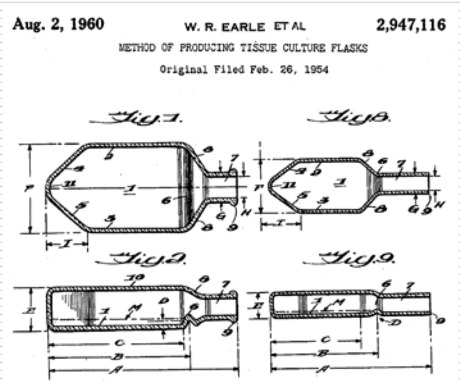
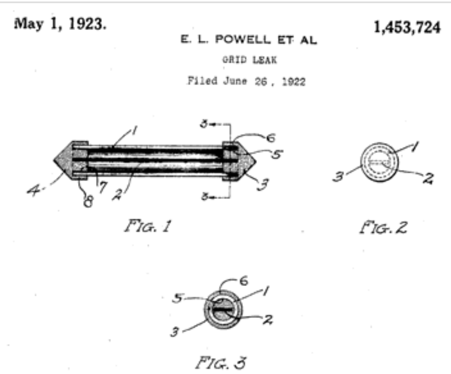
Southeastern Universities Research Association, Inc. and
Jefferson Science Associates, LLC – Management and Operating Contractor of the Jefferson Lab

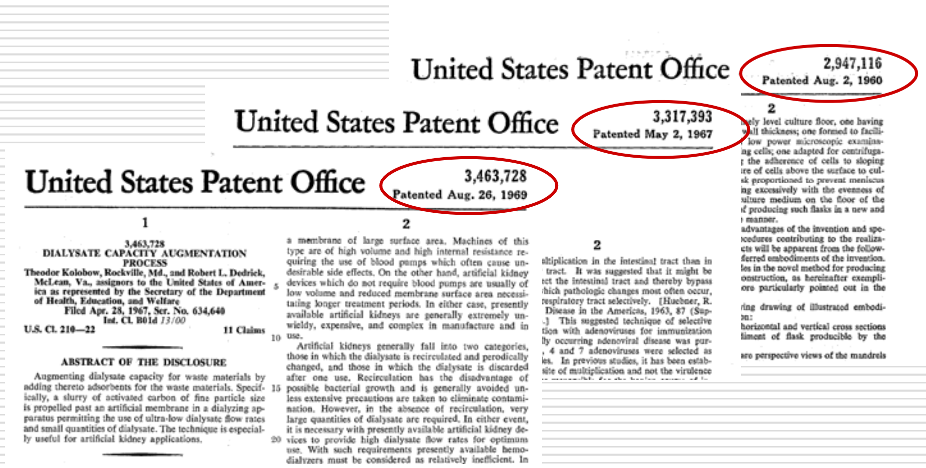
Early Technology Transfer Examples from Two of the Oldest Federal Laboratories (Patents)





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

Successor to Marine Hospital Service (Est. 1887)



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

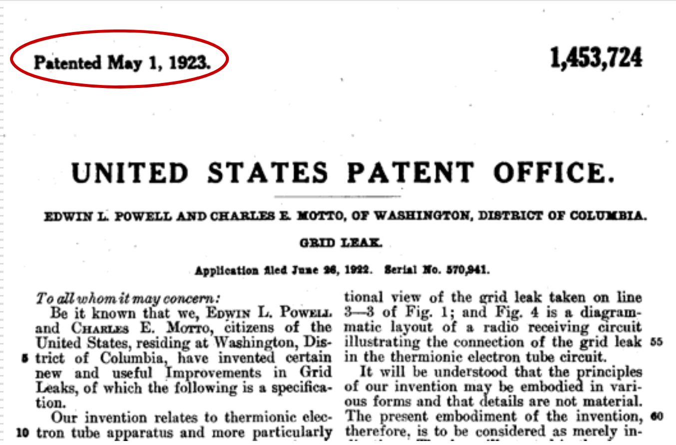
NIH OFFICE OF TECHNOLOGY TRANSFER
NIH and FDA Invention and Patent Activity

(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.

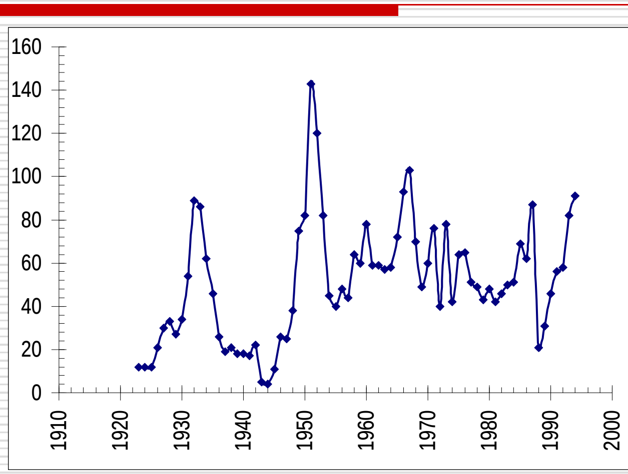
It will be understood that the principles of our invention may be embodied in various forms and that details are not material. The present embodiment of the invention, therefore, is to be considered as merely in-

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.
$100 in 1925 = $1,354.70 in 2014!

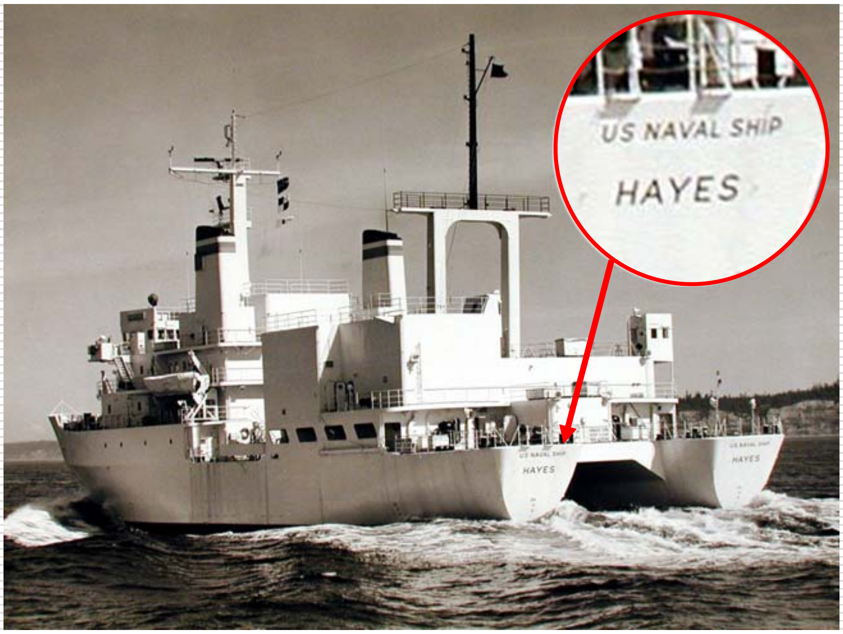
But . . .
Example of NRL Tech Transfer (1937)

(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:

$25,000 in 1937 = $411,583.33 in 2014!!!



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 (42 U.S.C. § 2053), 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

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)

What's a Federal Laboratory?

Gov't-Owned Gov't-Operated (GOGO)	Government-Owned Contractor-Operated (GOCO)	
	Federally Funded Research & Development Center (FFRDC)	Other
• Federal Employees conducting research & administration • May perform 'inherently governmental' functions • May have many site support contractors and contractor employees involved with research and with administration	• Special long-term R&D need that cannot be met as effectively either in-house or by existing contractors (special FAR provision – generally exempt from recompetition) • Access to gov't & supplier data (incl. sensitive & proprietary), employees, equipment, sites – beyond typical contractual relationship • Independent entities with clear, federally mandated limitations and restrictions on their activities	• Generally subject to periodic recompetition
• Naval Research Laboratory (DOD) • National Institutes of Health (HHS) • Nat. Instit. of Standards & Tech. (DOC) • Langley Research Center (NASA) • Nat. Energy Tech. Lab (DOE)	• Jefferson Lab (DOE) • Jet Propulsion Lab (NASA) • Nat. Ctr. for Atmospheric Research (NSF)	• Hubble Space Telescope (NASA) • Knolls Atomic Power Laboratory (DOE)

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)

Federal Laboratories Modes of Tech Transfer

User Facilities	Intellectual Property	Expertise/People
• Short/Long Term • Permanent (Dedicated)	• Patents • Copyrights	• CRADAs (Cooperative Research and Development Agreements) • WFOs (Work For Others agreements) • ACT (Agreements for Commercializing Technologies) • Students

Tom Russo Presentation to GWU Research Advisory Board, May 14, 2014

Federal Labs Distinguished from Commercial Consultants

- Advance Payments – Federal Labs (GOGO and GOCO) are prohibited from working on credit; advance payments (typically 60 days) are required
- Indemnification of the Federal Government
- Promised Results v Best Efforts
- Certain Reserved Government Rights in Intellectual Property
- U.S. Preference

John Lucas DOECAA Presentation April 26, 2012

Cooperative Research & Development Agreements (CRADAs)

- Authorized by Stevenson-Wydler Technology Innovation Act of 1980 (as amended); available at most Federal Laboratories (GOGO & GOCO)
- Sponsor (customer) can be public agency, private firms, or universities (laboratory contributions possible)
- IP Rights disposition
  - Nonexclusive, nontransferable, irrevocable, paid-up worldwide **license to the laboratory and Government**
  - **Foreground inventions involving laboratory employee available to customer under exclusive license for field of use**; inventions solely by customer's employees are owned by customer, but license for Gov't purposes.
  - Foreground trade secret-like information **protected up to 5 years from FOIA** and customer's trade secrets and privileged commercial/financial information not to be disclosed
- **Royalties paid to laboratory can be used for payments to inventors, research, employee incentive and training programs, IP administrative costs**

John Lucas DOECAA Presentation April 26, 2012

Work For Others Agreements (WFOs)

- Department of Energy Laboratories
- Sponsor (commercial customer) pays full cost recovery (no Fed. $)
- IP Rights disposition
  - Per class patent waiver, sponsor has <u>right to elect to own</u> new inventions ("subject inventions")
    - Government use license
    - U.S. Preference
  - Sponsor may itself commercialize inventions or may license; royalties belong to sponsor
  - <u>Sponsor may mark Lab-generated data as proprietary and remove it from the Lab</u>
  - Where sponsor does not elect to own inventions, they stay at the Lab, as do licensing royalties

John Lucas DOECAA Presentation April 26, 2012

ACT Features / WFO Differences

- ACT available at select DOE National Labs (WFO authority)
- **M&O Contractor pays all patent and commercialization costs** and assumes risks of the commercial customer or Government (e.g., **payment of advance funding, indemnification of Gov't**, etc.)
- Government rights are generally limited to research purposes
- DOE Contracting Officer approves work scope under reasonable best efforts, NOT terms and conditions; work may begin with Preliminary DOE approval.
- **M&O Contractor can negotiate an ownership interest in subject inventions in its private capacity** (not as M&O contractor); contractor has responsibility for recovering costs from commercial customer

Case Study: Dilon Technologies & Jefferson Lab (the Company)

- 1996: Dilon Technologies is established when two entrepreneurs (Slane & Ash) visit NASA Langley Research Center and Jefferson Lab in search of technology(ies) to commercialize.
  - They pursue medical imaging research that had been a Jefferson Lab – UVA collaboration –derived from specialized Jefferson Lab accelerator components.
- 2003: First US sale of Dilon's single-photon emission computed tomography (SPECT) "Gamma Camera" for breast cancer detection; additional markets follow:
  - France (2006)
  - Korea (2007)
  - China (2009)
  - Germany (2011)
  - Russia (2012)

Case Study: Dilon Technologies & Jefferson Lab (the Collaboration)

- 1997: Dilon licenses all patents, pending patents, and patent applications filed within 2 years in 5 technology areas.
  - Dilon will license additional Jefferson Lab patents and patent applications in 2009, 2011, 2013.
- 1998: Application is filed for Jefferson Lab's first granted patent for "Gamma Camera" for breast cancer imaging
- 1998: **Applied Research Center**, a tech incubator facility, built by City of Newport News on VA land adjacent to Jefferson Lab; Dilon is one of the first tenants and co-located with Jefferson Lab collaborators.
- 2000: Dilon enters into its first CRADA with Jefferson Lab. In the coming years Dilon will enter into 5 additional CRADAs:
  - 2001
  - 2002 (2 CRADAs)
  - 2013 (Collaboration also includes U. Virginia)
  - 2014 (Collaboration also incudes Hampton U.)

Case Study: Advanced Photon Source and Eli Lilly (the Facility)

- 1996: Argonne National Laboratory opens the Advanced Photon Source – the world's largest X-ray source.
  - Total construction time was 6 years and project cost at completion was $812 million.
- Today: Facility includes 35 separate sectors operated by Argonne, universities, industrial firms, government agencies, research institutes (or consortia of these)
  - Beamlines: 63
  - APS employees: approximately 450
  - Firms: more than 180
  - Universities: 560
  - Research Institutes: more than 240
  - Dedicated Sectors: Eli Lilly, Dupont/Northwestern/Dow, AbbVie/Bristol-Meyers Squibb/Merck/Novartis/Pfizer, Notre Dame/U. Florida/ IIT/ ANL/ EPA/ BP/ UOP, etc.

Case Study: Advanced Photon Source and Eli Lilly (the User)

- 1992: Lilly joins 12 other firms to form collaboration to build dedicated experimental beam line at APS. Typical beam line costs $5 to $15 million.
- 2000: Structural GenomiX (SGX) invests $15 million at APS for world's first commercially-owned/operated beamlines for high-throughput XRD.
- 2008: Lilly acquires SGX, including its APS facility.
- 2011: Lilly invests $2.3 million to upgrade APS beamline
  - Robotic control of 540 samples (doubling throughput)
  - Results to Lilly researchers in California, Indianapolis, UK, Spain, and China 14 minutes analysis; <40 hours sample prep to results
  - 150 Lilly researchers directly involved with preparation, analyzing, and exploiting results of APS samples
  - 10 Lilly experimental compounds in Phase I or Phase II clinical trials developed using APS
  - 25% of Lilly beam time to available to others for non-proprietary research.

Thank-You!

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