Accessing DOE Laboratory Technologies Legal Mechanisms & Issues



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http://www.sc.doe.gov/Technology_Transfer/index.htm http://www.gc.doe.gov/lab_partnering.htm

Topics for Discussion

- Legal Framework
- Identify and categorize Labs
- Pathways to Access Technology
- Legal Mechanisms
- Entrepreneur in Residence Pilot



Congress is very interested in licensing and commercialization



- Bayh-Dole Act
- Federal Non-nuclear Energy Act
- Atomic Energy Act
- Stevenson-Wydler Technology Innovation Act of 1980
- Trademark Clarification Act of 1984 (amended Bayh-Dole)
- Federal Technology Transfer Act of 1986 (amended Stevenson-Wydler)
- National Competitiveness Technology Transfer Act of 1989 (amended Stevenson-Wydler)
- National Defense Authorization Act for Fiscal Year 1994 (amended Stevenson-Wydler)
- Technology Transfer Commercialization Act of 2000
- National Defense Authorization Act of 2000 (amended Stevenson-Wydler)
- EPACT 2005
- Executive Order 12591

These laws govern technology transfer at DOE Labs & Facilities. Among other things, they provide that:



- Technology Transfer is a mission activity
- Labs have local control of technology transfer transactions
 - Agreements will be made with the local lab contractor
 - Those that require DOE approval are handled by local DOE officials.
- Lab directors are authorized to enter into Work for Others and Cooperative Research and Development Agreements (CRADAs)
- Royalties from licensing by lab or government stay at lab, and are shared with inventors
- Benefits to the US economy must be considered in each transaction

Secretarial Policy Statement on Lab Technology Transfer* sets forth Guiding Principles for the conduct of Lab tech transfer

- Direct involvement of Lab
- Fairness of opportunity
- Promotion of domestic economy
- Prevention of inappropriate competition
- Protection of national security
- Involve partners with substantial business plans
- Leverage of government resources
- Royalties should serve as an incentive for innovation
- Promotion of access by small business and entrepreneurs
- Absent DOE mission objectives, consistency and speedy closure on transactions
- Lessons learned forums are encouraged

Over 20 DOE National Laboratories/Facilities offer full range of tech transfer functions



- Ames National Laboratory
- Argonne National Laboratory
- Brookhaven National Laboratory
- Fermi National Accelerator Center
- Idaho National Laboratory
- Lawrence Berkeley National Laboratory
- Lawrence Livermore National Laboratory
- Los Alamos National Laboratory
- National Energy Technology Laboratory
- National Renewable Energy Laboratory
- Oak Ridge National Laboratory

- Princeton Plasma Physics Laboratory
- Pacific Northwest National Laboratory
- Sandia National Laboratories
- Savannah River National Laboratory
- Stanford Linear Accelerator Center
- Thomas Jefferson National Accelerator Facility
- Kansas City Plant
- Pantex Plant
- Y-12
- Nevada Test Site

DOE Laboratories are divided into two* groups with two different sets of rules



- 1. Government-Owned Contractor-Operated (GOCO)
 - All but NETL (National Energy Technology Lab)
- 2. Government-Owned Government- Operated (GOGO)
 - NETL

There are two paths to gain access to DOE technologies



- 1. License existing technologies created with prior government funding
 - License to IP owned by the Laboratory contractor (i.e. license issued by lab contractor)
 - License to IP owned by the U.S. Government (i.e. license issued by U.S. Government)
- 2. Partner with the Laboratory for further R&D on existing technologies either partly or wholly funded by the private partner
 - Partnering agreement will provide for disposition of rights in new discoveries made under the partnering agreement
 - Partnering agreement and a license to background IP of lab may be coupled together

Technology transfer contract provisions vary depending on how the marketing of the invention is funded



- All contracts allow lab contractor to elect to take title to new inventions made
 - If contractor uses public funds, then license will be subject to
 - Fairness of opportunity, U.S. competitiveness, and special conflicts of interest guidelines
 - 100% of royalties are returned to lab
 - IP transfers to successor contractor
 - If contractor uses private funds (e.g., Battelle at Pacific Northwest, Oak Ridge; or lowa State at Ames)
 - Contractor may keep 49% of net royalties
 - Transfer of patents to successor is not guaranteed

• Lab contractors are empowered to

- Assert ownership in copyrights and biological materials
- License technology (Patents, copyrights, biological materials)
- Enter into Partnership transactions like CRADAs, WFOs, User Agreements with private sector
- Ombuds to help resolve tech transfer complaints

Generally licensing technologies from the Laboratory contractor is more convenient than from the government

- government
- Not subject to Federal Licensing regulations; same freedom as university to license
- Usually no DOE approval
- No public notice required for exclusive or partially exclusive licenses
- Subject to statutorily-required reserved govt. rights: Govt. use license and marchin rights
- Indemnity and product liability must be addressed
- Conflicts of interest must be addressed
- Preference to those who agree to substantial manufacture in US for sales in US
- If publicly funded, Contract requires addressing:
 - Fairness of opportunity: make known opportunity to license
 - US competiveness: substantial manufacture in US or other net benefit to US economy for all sales
- Royalties and/or equity interests are OK
- Portfolio includes patents, copyrights in software, bailment of biological materials, trademarks, protected data
- Portfolio does not include Lab Trade Secrets, Lab "know how", license to future improvement technology funded by licensee
- Generally no grant backs

There are multiple issues to consider before signing a exclusive license* from a Lab



- Equity and/or royalty interests to licensor
- Field of use limitation
- Geographic limitations including foreign rights
- Reserved Govt. rights
- Infringement suits
- U.S. Manufacturing
- Assignability and sublicensing
- Business plan milestones
- Product liability indemnity
- Warranties re: IP rights or performance of technology
- Export control
- Costs of US and foreign patent prosecution
- Disputes
- Termination

There are multiple ways you can partner with our labs



- **CRADA** (Cooperative Research and Development Agreement)
 - Collaborative research of benefit to DOE mission
 - Lab time can be funded by DOE or sponsor
 - Statute determines title to IP
 - DOE approval is required
 - Partner guaranteed option to negotiate an exclusive license
 - Labs may not provide funds to the sponsor
 - "Protected data"

• Work for Others

- Nonfederal Sponsor
- Access to unique capability,
- Private sponsor pays full cost and owns new IP
- DOE approval required

• User Agreement

- Standard formats for different types:
 - Proprietary
 - precompetitive
 - regular user

M&O contract governs each transaction which has a range of IP negotiating options available to lab

Licensing patents from the Government or from GOGO (NETL) is different from GOCO



- Subject to regulations at 10 CFR 781
- Exclusive or partially exclusive licenses requires public notice with opportunity for public to object
- Except under a CRADA, technical data produced at GOGO can only be protected by patent
- The license must address US competitiveness
- Requires business plan
- DOE portfolio includes
 - Lab inventions with long term commercial potential: e.g. nuclear
 - Classified inventions
 - Russian and Ukrainian inventions arising from DOE, and State Department programs

Licensing patents from the Government or from GOGO (NETL) is different from GOCO



Gov't Operated (GOGO)

Contractor Operated (GOCO)

Exclusive Licensing	Only after publication	No publication required
Software Licensing	Not permitted (by law)	Permitted
Royalties	1 st \$2000, 15% of Rest, Capped @ \$150k/yr/ invention	No-cap – follow contractor's policy (universities as high as 50%)
CRADA Selection	Preference to small businesses; U.S. firms for U.S. mfg.	Same
Royalties	Lab R&D and Licensing expenses	Same

DOE labs are involved in thousands of transactions (



Туре	2004	2005	2006
Active WFO	1884	1922	2416
Active CRADAS	610	634	631
Active Tech licenses	4345	5677	5916
Patent licenses			1420
Lic. income	\$25 m.	\$27 m.	\$35 m.
Pat. Applic.	661	812	726

Entrepreneur in Residence pilot has been lunched



- Premise
 - Place EIRs from VC firms at Labs to mine Lab's IP for possible licensing and spin-offs
- Funding Opportunity Announcement issued by DOE
 - Satisfied fairness of opportunity
 - Included Nondisclosure Agreement (inclusion avoided having to negotiate terms of the NDA post-award)
 - Included model license agreement providing exclusivity in a field of use, based on the VC-friendly Stanford model, modified to include terms required by Lab's M&O Contract, business terms left open, tied to business plan
 - 50% cost share, each get \$100K for this one-year program to fund placement of an EIR at a Lab