Technology Transfer & Commercialization

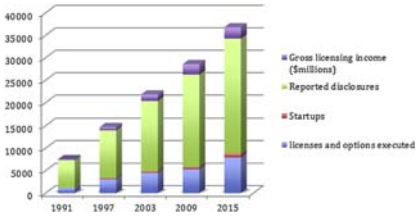
Prof. Steven S. Saliterman
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

Technology Transfer

- Process by which new innovations flow from the basic research bench to commercial entities and then to public use.
- Property of the academic institution rather than the individual inventor.
- Technology transfer offices are tasked with seeing to it that such intellectual property rights are properly managed and commercialized.
- Intellectual property (IP) rights are secured through patents, trademarks, copyrights, and trade secrets.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

Academic Center Innovation…



Growth in Disclosures, Startups, Executed Licenses and Options, and Reported Gross Licensing Incomes 1991–2015.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

United States R&D Funding

- Before World War II, almost all R&D in the United States was *conducted in federal facilities* by *federal employees*.
  - Government policy generally made all patents from such work available to the general public in order to encourage product development.
- Following the war, use of government facilities for R&D declined, but the government nevertheless remained a huge contributor to R&D through *federal research grants, salaries, and other contributions*.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

Bayh-Dole Act of 1980

- Until the latter half of the 20th century, the government had few policies to encourage the public use of its huge reservoir of R&D.
- The Bayh-Dole Act allowed the *funded entity* to retain title to any invention created as a result of government contracts and grants.
- U.S. government no longer takes title to inventions created by government contractors and grantees, although it continues to be the single largest sponsor of all R&D in the nation.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

- The Bayh-Dole Act gave *research institutes ownership* of patents resulting from federally funded research.
- They generally commercialize such IP assets by granting access rights to (mostly) for-profit commercial entities by way of a license—while in most cases retaining ownership of the underlying IP.
- They must attract private manufacturers or investment bodies such as venture capital enterprises.
- Strength of the IP and the quality of research are foremost attractors.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

Academic Institutions

- Technology Transfer Office's (TTO, OTC) role:
  - Determine whether an invention can likely be patented or copyrighted. In so doing, determine if the university will claim title to it.
  - To source innovations.
  - To manage IP protection,
  - Provide commercialization promoting resources (such as gap funding programs, access to business savvy mentors and entrepreneurs as well as regulatory consultants, connections to industry and investment bodies, etc.).
  - Negotiate and execute licensing deals.

Prof. Steven S. Saliterman

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

- Methods for Transfer of Technology:
  - Through publication of innovations to the general public without taking further measures of a commercial nature.
  - Through sponsored research agreements with private industry.
  - Through the formation of startup companies.

Prof. Steven S. Saliterman

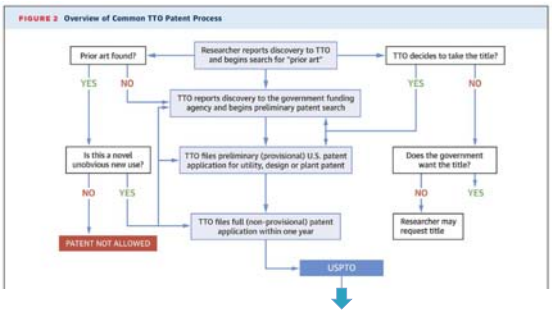
Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.

Exceptions to Automatic Patent Assignment…

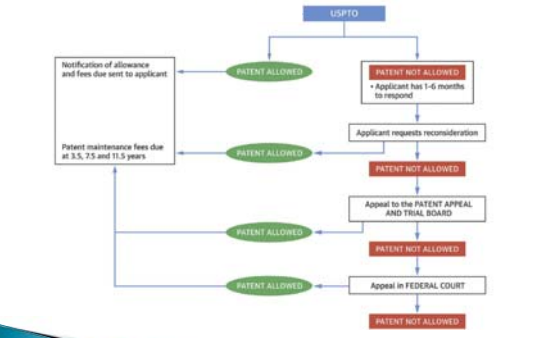
- If the inventor is a student at the university, but not employed by the university, and did not receive any direct support from the university regarding the invention.
- If the inventor is an employee, but the invention was developed entirely on the employee's own time, did not involve the use of any university resources, and the invention is not related to university business, or to any actual or demonstrably anticipated research or development.

Prof. Steven S. Saliterman

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.



Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85–97.



Technology Transfer

- Technology transfer begins when the inventor discloses an invention to the University.
- Is there commercial value or social impact?
- Sponsored Research Agreements (SRA) (grants associated with commercial companies) may require subsequent development by the sponsoring company.
- Find a licensee/partner (many may be considered).
  - Type, risk, current stage, cost, market size, profit margin, patent status, cost of research, scope of license and comparable royalties.
- Patent process can take 2 to 4 years.
- Research for new drugs may take up to 12 years.

Van Norman, Gail A., and Roi Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 2: The Commercialization Process. *JACC: Basic to Translational Science* 2, no. 2 (2017): 197–208.

Commercialization – Comparison

- In private industry, TT often occurs through the sale of IP, products, or services.
- In universities, the majority of TT typically occurs through the licensing of IP. This includes partnership relationships.
  - Opportunities for new research collaborations and funding; and for the exchange of materials, information, and personnel with private industry.
  - Brookings Institution indicates that 84% to 87% of universities will not realize enough income to cover the costs of a TTO.*

McDevitt FL, Mendez-Hinds J, Winwood D, et al. More than money: the exponential impact of academic technology transfer. Technol Innov 2014;16:75–84.
*Valdivia WD. University start-ups: critical for improving technology transfer. The Brookings Institution. November 20, 2013.

TABLE 3 Top 10 U.S. Universities by Cumulative Patents Issued From 1969 to 2012

University	Number of Patents in 2012	Cumulative Patents 1992-2012
University of California entities	361	7,586
Massachusetts Institute of Technology	216	4,017
Stanford University	182	2,405
California Institute of Technology	136	2,382
University of Texas	141	2,337
University of Wisconsin	167	2,194
Johns Hopkins University	79	1,557
Cornell University	55	1,366
University of Michigan	97	1,267
University of Florida	70	1,238

From U.S. Patent and Trademark Office. U.S. Colleges and Universities Utility Patent Grants, Calendar Years 1969-2012. Available at: https://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/org_gr/t250_univ_ag.htm. Accessed February 11, 2017.

Van Norman, Gail A., and Roi Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 2: The Commercialization Process. *JACC: Basic to Translational Science* 2, no. 2 (2017): 197–208.

Sponsored Research Agreements (SRA) – Issues

- Academic freedom.
- Shift away from research
- Personal and institutional conflicts of interest.
- Misappropriate use of public funds for commercial and for-profit pursuits.
- Delayed publication for purpose of "academic lead."
- Knoll case* – University of California San Francisco prevented from publishing results of equivalent levothyroxine by Flint Laboratories as it was detrimental to their commercial interest.
- SRAs bias research conclusions.

*Brody H. The "thyroid storm" story. In: Hooked. Ethics in the Medical Profession and the Pharmaceutical Industry. New York: Rowman and Littlefield Publishers, 2007:103–6.

Venture Capitalists

- Promoting and developing promising university inventions that are in an intermediate stage of development and not yet ready to attract a larger commercial sponsor.
- Interact with entrepreneurs and TTO contacts.
- Approach inventors to form companies around inventions.
- Relationship between the researcher and investing firm is critical.
- Inquire as to prior companies the VC has supported.
- "Faculty startups."
  - University supportive?
  - Requisite skills?
  - Conflicts of interest?

Van Norman, Gail A., and Roi Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 2: The Commercialization Process. *JACC: Basic to Translational Science* 2, no. 2 (2017): 197–208.

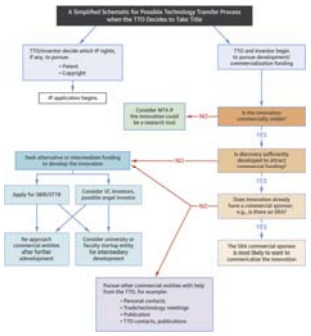
Sharing with the Inventor

- Sharing with the inventor is a requirement under federal law.
- Fewer than 1/3 of university patents are licensed. Few of these earn significant revenue.
- The share commonly paid to inventor is 30% of revenues earned by the institution after deducting patent and marketing costs.

Van Norman, Gail A., and Roi Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 2: The Commercialization Process. *JACC: Basic to Translational Science* 2, no. 2 (2017): 197–208.

Summary

- Technology Transfer.
  - Bayh–Dole Act of 1980.
  - Academic institutions.
  - Role of the Technology Transfer Office.
  - TTO patent process.
- Commercialization
  - SRA – Sponsored Research Agreements.
  - Venture capitalists.
  - Sharing with the inventor.
- Addendum –
  - Transfer process when the TTO takes to take title.
  - Material transfer agreements.
  - Obligations in accepting federal funding & US Government rights.
  - Common elements in a license contract.
  - Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs



Van Norman, Gail A., and Roi Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 2: The Commercialization Process. *JACC: Basic to Translational Science* 2, no. 2 (2017): 197–208.

Prof. Steven S. Saliterman

TABLE 4 Materials Transfer Agreements: National Institutes of Health Recommended Elements

Ownership remains with the Provider (of the material).
Provider is not liable for any damages arising from the Recipient's use of the material.
No reimbursement is required of the Recipient, except the Provider's preparation and distribution costs of the material.
No use in humans.
No commercial research use.
No distribution to third parties.
The Recipient must acknowledge the Provider as the source.

- Materials that do not have significant commercial value but may be useful in noncommercial research are sometimes nonexclusively transferred to other parties via materials transfer agreements (MTAs).

Department of Health and Human Services, National Institutes of Health. Principles and guidelines for recipients of NIH research grants and contracts on obtaining and disseminating biomedical research resources: final notice. Federal Register, Vol. 64 No. 246. Thursday, December 23, 1999.

Prof. Steven S. Saliterman

TABLE 1 Obligations of Institutions Accepting Federal Funding for Research

Obtain written agreements with employees to disclose discoveries and assign them to the institution.
Disclose invention to the federal agency providing support within 2 months of employee disclosure.
Elect title (if they are going to) within 2 years after federal disclosure.
File a patent application within 1 year after election of title.
Include a statement with patent application that the U.S. government has rights to the invention and identifying the federal agency providing support.
Submit a confirmatory license to the federal agency providing support.
Notify the federal agency within 10 months of filing of the application and countries in which the patent will be pursued.
Submit periodic reports annually to the funding agency regarding use of the invention.
Give preference to issuing licenses to small businesses if they have the resources and capability to commercialize the invention.
NOT assign the rights to inventions to third parties, including the inventor, without prior approval of the funding agency.
Require any exclusive licensee to substantially manufacture within the United States any product that will be sold in the United States, unless this requirement is waived by the funding agency.
Share with the inventor a portion of any income the institution receives from licensing of the invention.
Use the balance of income from licensing of the invention (after costs of patent and license processes are reimbursed) to support education and research.

COGR: Council on Government Relations, an association of research universities and independent research institutes. A tutorial on technology transfer in the U.S. colleges and universities. August 1, 2011.

Prof. Steven S. Saliterman

TABLE 2 U.S. Government Rights Regarding Inventions That Result From Federally Funded Work and Research

Rights to a nonexclusive, nontransferable, irrevocable, paid-up license to the invention, to practice it or have it practiced on its behalf throughout the world.
Can require the university to assign title to the government if the university fails to report the invention, does not elect title, or does not file for patent within the required period of time.
Can require the university to license the invention to third parties (including the right to require the university to cancel existing exclusive licenses), or the right of the government itself to grant those license (so-called "march-in rights"), *provided 1 of the following circumstances occurs:* 1) the invention has not been brought into public use within a reasonable time; 2) where health or safety needs are not being met; or 3) where the U.S. manufacturing requirement has not been met and was not waived by the funding agency.
Can make a Determination of Exceptional Circumstances that there are compelling reasons why the right of the university to retain title should be restricted or eliminated.

Department of Health and Human Services, National Institutes of Health. Principles and guidelines for recipients of NIH research grants and contracts on obtaining and disseminating biomedical research resources: final notice. Federal Register, Vol. 64 No. 246. Thursday, December 23, 1999.

Prof. Steven S. Saliterman

TABLE 6 A Partial List of Common Elements in a License Contract

Exclusive or nonexclusive license
Field of use
Geographic restrictions
Term of license
Diligence requirements - performance milestones
Annual reviews
Licensing renewal intervals and fees
Royalties and sublicensing provisions
Reimbursement of University costs (e.g. costs of obtaining a patent)
Indemnifications and insurance
Research and development funding
Equipment and facilities
Consulting agreements
Access to proprietary and technical information about the invention
Whether equity shares (in the case of startups) may serve as payment

Adapted from Razgaitis (20).

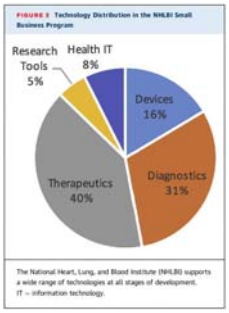
Residual ownership rights.

Van Norman, Gail A., and Roi Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 2: The Commercialization Process. *JACC: Basic to Translational Science* 2, no. 2 (2017): 197–208.

Prof. Steven S. Saliterman

SBIR and STTRs

- The federal government Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs represent the largest seed stage funding sources for companies in the world.



The National Heart, Lung, and Blood Institute (NHLBI) supports a wide range of technologies at all stages of development. IT = information technology.

Marek, K. W. "The National Heart, Lung, and Blood Institute Small Business Program: A Comprehensive Ecosystem for Biomedical Product Development." *JACC Basic Transl Sci* 1, no. 7 (Dec 2016): 660–65.

Prof. Steven S. Saliterman

TABLE 1 Comparison of SBIR and STTR Programs

SBIR	STTR
Principle investigator must be >50% employed by the small business.	Formal cooperative R&D effort is between the small business and a U.S. research institution.
Small businesses majority owned by multiple VCs, hedge funds, or private equity firms are eligible to apply.	The small business must do a minimum of 40% of the work; research institution must do a minimum or 30% of the work.
	Principle investigator may be primarily employed by either the small business or the research institution.

Both programs are designed for small business concerns, organized, for-profit U.S.-based businesses with fewer than 500 employees.

R&D = research and development; SBIR = Small Business Innovation Research; STTR = Small Business Technology Transfer; VC = venture capital.

Marek, K. W. "The National Heart, Lung, and Blood Institute Small Business Program: A Comprehensive Ecosystem for Biomedical Product Development." *JACC Basic Transl Sci* 1, no. 7 (Dec 2016): 660–65.

Prof. Steven S. Saliterman