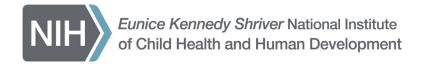
# Fostering Innovative Science via Technology Transfer

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Program Official, Contraception Research Branch, NICHD/NIH Wednesday, August 28, 2020



## Patents before 1980: Pre Bayh-Dole Act

- Federally funded research:
  - ~28,000 patents owned by Government
  - Provided non-exclusive licenses to any interested party
- Resulting Societal Impact:
  - 0 drugs developed by research institutes
  - Low pharmaceutical company priority
  - Technology Transfer: low impact



## Bayh-Dole Act - 1980

#### What did it do?

- Uniform patent policy federally funded recipients retain ownership of inventions
- University responsibility for commercialization how would they do it?







## Bayh-Dole Act - 1980

#### Impact:

- 2013: 153 new drugs/vaccines developed via federal funding
- Examples include:
  - Synthetic penicillin, Hepatitis B vaccine, Citracal calcium supplement, Cancer therapeutics, Human growth hormones, Treatments for Crohn's disease, Avian Flu vaccine, Clean water technologies







#### **Tech Transfer offices – Translational Resource**

#### **Goal: Get new Products on Market**

- Establish innovative climate
  - Champion current faculty
  - Attract/retain world-class faculty
- Public Benefits
  - Convert discoveries into products/services
- Strategic partnerships
  - Private sector engagement
- Economic development
  - Think globally act locally

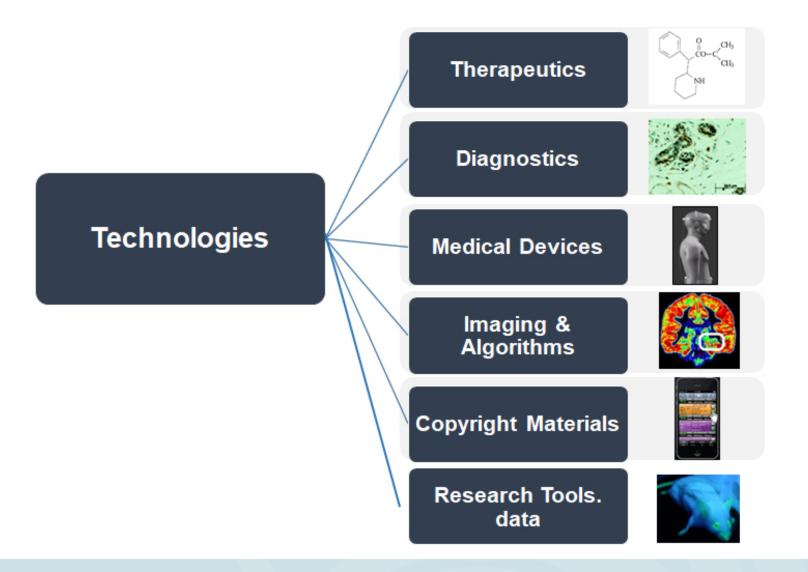


## A Common Arrangement: Know your Rights

- Ownership of ideas
  - Condition of employment, studentship, and/or resource usage
- Requirements:
  - Employees and Students must disclose Intellectual property
  - Ownership is then determined
  - Traditional academic copyrights owned by author(s)
- Revenue from licensing IP shared with Inventors

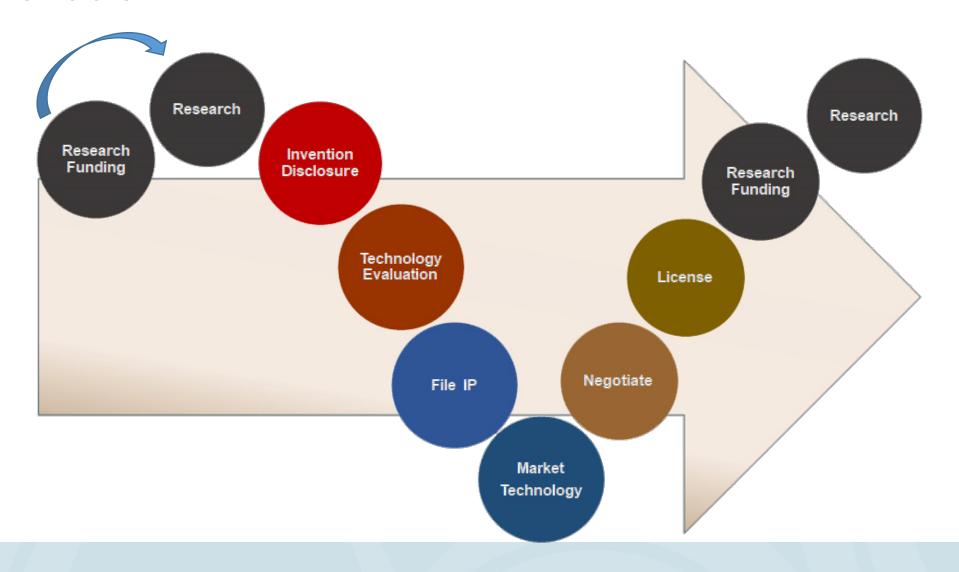


#### What interests Tech Transfer?





## When to engage Tech Transfer: shepherding innovation





## When would one want Copyright Protection

- Creator granted legal rights for:
  - Exclusive copying
  - Preparing derivative works
  - Distributing, performing
  - Displaying and transmitting copyrighted work
- Author granted legal right for exclusive use on expression of an idea
  - Specific expression of words, design or other form
  - Allows for multiple expressions to be available for same idea



## **Copyright Protection Length**

- Vests immediately © upon fixation
- Lasts the lifetime of author plus 70 years
  - 120 years for a work made for hire
- Copyright infringement: when exclusive right granted to creator is carried out by someone else without permission



## **Copyright Benefits/Detractors**

#### **Pros**

- Automatic rights
- Easy and relatively cheap registration and fees
- Provides right to control exclusive rights, such as reproduction, distribution, and derivation

#### Cons

- Copyright protects expressions of idea, not idea per se
- Expensive to enforce



## **Example: Duck, Duck, Punch**



- © protection
- Stroke rehabilitation game
- Dissertation project
- FDA approved



#### **Know How**

#### Distinct and unique body of knowledge

- Capitalizing on know-how "is still a bit of black magic," says Dipanjan "DJ" Nag, a director at intellectual capital equity firm Ocean Tomo. "It's very hard to define exactly what know-how is." Nag defines it as <u>trade secrets</u> and unfiled patents. Other technology transfer experts believe source code and research notes on software also would fall under the "know-how" umbrella.
- https://techtransfercentral.com/reprints/ttt/1207-licensing-your-know-how/
- Usually a high hurdle for replication



#### **Know-How: Benefits and Detractors**

#### Pros

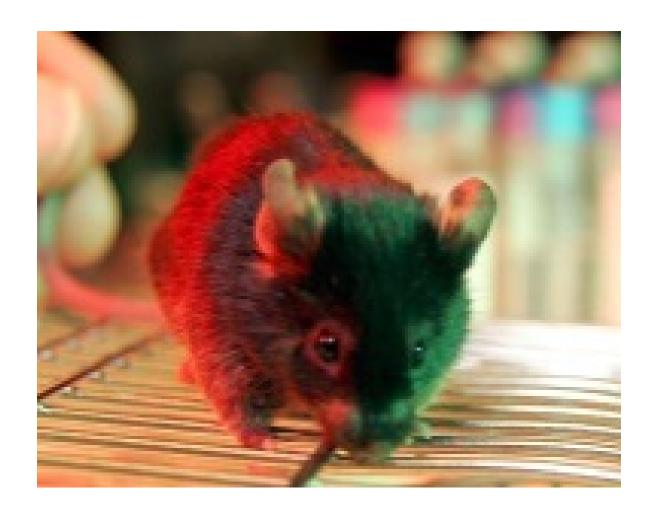
- Unlimited duration
- Worldwide protection
- No application required and no registration costs
- Effective immediately

#### Cons

- Not easily enforceable
- Not effective when reverse engineering possible



## Do Research Tools Qualify as Know-How?



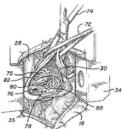
- Knock-out mice
- Cell lines
- Reagents



#### **Patents**

(12) United States Patent

(75) 1	SURGER Inventor: Assignee:	LLY INVASIVE CARDIAC VALVE Y PROCEDURE Delos M. Cosgrove, Hunting Valley, OH (US) Edwards Lifesciences Corporation, Irvine, CA (US) This patent issued on a continued prosecution application filed under 37 CFR LSQ(d), and is subject to the twenty year	WO 93/18712 WO 94/18881 WO 95/08364 WO 95/10218 WO 95/15715 WO 95/15719 WO 95/21573 WO 95/21573 WO 95/24040 WO 96/00033 WO 96/17644	9/1993 (WO) . 9/1994 (WO) . 3/1995 (WO) . 4/1995 (WO) . 6/1995 (WO) . 6/1995 (WO) . 7/1995 (WO) . 8/1995 (WO) . 1/1996 (WO) . 6/1996 (WO) .	
(75) 1	SURGER Inventor: Assignee:	Y PROCEDURE  Delus M. Cosgrove, Hunting Valley, OH (US)  Edwards Lifesciences Corporation, Irvine, CA (US)  This patient issued on a continued prosecution application filed under 37 CFR	WO 94/18881 WO 95/18304 WO 95/10218 WO 95/15192 WO 95/15715 WO 95/17919 WO 95/21573 WO 95/24940 WO 96/00033 WO 96/17644	9/1994 (WO) . 3/1995 (WO) . 4/1995 (WO) . 6/1995 (WO) . 7/1995 (WO) . 8/1995 (WO) . 9/1995 (WO) . 1/1996 (WO) .	
(75) I	Inventor:	Delos M. Cosgrove, Hunting Valley, OH (US)  Edwards Lifesciences Corporation, Irvine, CA (US)  This patent issued on a continued pros- ecution application filed under 37 CFR	WO 95/08364 WO 95/10218 WO 95/15192 WO 95/15715 WO 95/17919 WO 95/21573 WO 95/24940 WO 96/0033 WO 96/17644	3/1995 (WO) . 4/1995 (WO) . 6/1995 (WO) . 7/1995 (WO) . 8/1995 (WO) . 8/1995 (WO) . 1/1996 (WO) .	
(73)	Assignee:	OH (US)  Edwards Lifesciences Corporation, Irvinc, CA (US)  This patent issued on a continued prosecution application filed under 37 CFR	WO 95/10218 WO 95/15192 WO 95/15715 WO 95/17019 WO 95/21573 WO 95/24940 WO 96/00033 WO 96/17644	4/1995 (WO) . 6/1995 (WO) . 6/1995 (WO) . 7/1995 (WO) . 8/1995 (WO) . 1/1996 (WO) .	
(73)	Assignee:	OH (US)  Edwards Lifesciences Corporation, Irvinc, CA (US)  This patent issued on a continued prosecution application filed under 37 CFR	WO 95/15192 WO 95/15715 WO 95/17919 WO 95/21573 WO 95/24940 WO 96/00033 WO 96/17644	6/1995 (WO) . 6/1995 (WO) . 7/1995 (WO) . 8/1995 (WO) . 9/1995 (WO) . 1/1996 (WO) .	
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		Irvine, CA (US)  This patent issued on a continued pros- ecution application filed under 37 CFR	WO 95/17919 WO 95/21573 WO 95/24940 WO 96/00033 WO 96/17644	7/1995 (WO) . 8/1995 (WO) . 9/1995 (WO) . 1/1996 (WO) .	
		Irvine, CA (US)  This patent issued on a continued pros- ecution application filed under 37 CFR	WO 95/21573 WO 95/24940 WO 96/00033 WO 96/17644	8/1995 (WO) . 9/1995 (WO) . 1/1996 (WO) .	
(*) 1	Notice:	This patent issued on a continued pros- ecution application filed under 37 CFR	WO 96/00033 WO 96/17644	1/1996 (WO).	
(*)	Notice:	ecution application filed under 37 CFR	WO 96/17644		
(*)	Notice:	ecution application filed under 37 CFR		6/1996 (WO).	
		1.53(d) and is subject to the twenty year	WO 96/21489	7/1996 (WO).	
			WO 96/30073	7/1996 (WO).	
		patent term provisions of 35 U.S.C.	WO 96/32882	10/1996 (WO) .	
		154(a)(2).	WO 97/20506	6/1997 (WO).	
		Under 35 U.S.C. 154(b), the term of this		OTHER PUBLICAT	IONS
		patent shall be extended for 0 days.	I Card Sure	1995, 1995, 10:529-53	6 M Clive Robin
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				(List continued on nex	t page.)
	Re	ated U.S. Application Data			
				iner—V. Millio	
(63)	Continuatio	n-in-part of application No. 08/603,313, filed on		niner-Kelley O'Hara	
	Feb. 19, 19	96, now Pat. No. 5,752,526.		Agent, or Firm-Jame	s W. Inskeep; Gu
(51)	Int. CL7	A61B 19/00	Cumberbatch;	Debra D. Condino	
			(57)	ABSTRACT	
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(56)		References Cited		ss a predetermined num trasternal incision exte	
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4,3	81,345 *	9/1982 Carney 607/122		h, are then excised to	
	a.	ist continued on next page.)		heart or great vessels of appleted. The minimal	
		IGN PATENT DOCUMENTS		or replacement of the	
WO 93		2/1993 (WO) .	2	4 Claims, 17 Drawing	o Sheets



- Power to prevent others from:
  - Making
  - Using
  - Selling

the invention in country of patent

- Patents reward risk & fosters innovation
- Invention description crucial know how to make & use it
  - Community gains knowledge in trade for inventor to have a limited period of exclusivity
- Last 20 years
- Can be designed around
- Does NOT give you the right to make/use/sell yourself (Freedom-to-operate)

#### **Cost and Time Associated with Patents**

<b>Typical Patent Process Activity</b>	Money	Timeframe

Provisional Patent Filing \$1k to \$5k 12 months

U.S. Utility Filing ~\$20k 30 months

International Filings >\$100k N/A

Issuance of patent claims and \$\$ to \$\$\$\$ 2.5 to 4.5 + years

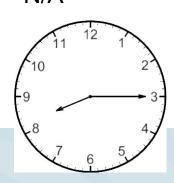
Maintaining applications

Defending patents and stopping infringers

\$\$\$ to \$\$\$\$\$



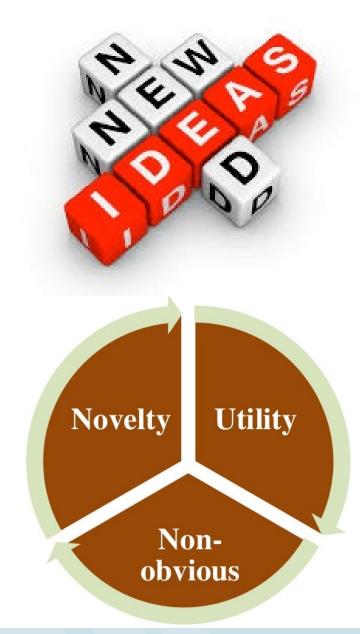
#### N/A





## **USPTO Patent Analysis**

- PRIOR ART.—A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, present in a patent application, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention;
- In other words, any public disclosure from the inventor or otherwise before the patent is filed!





### Prior Art: Public Disclosures-Publish or Perish Problem in Academia

- Manuscripts, public presentations(internal or external), dissertations, posters in public places
- Grant abstracts for awarded federal grants are public disclosures
- Public uses and sales





#### **Patent: Benefits and Detractors**

#### **Pros**

- Effective Tool against infringers
- Product credibility
- Helps gather investments
  - Critical for high risk ventures, e.g., medical device and drug development
- 20 years of protection
- Others must be granted permission to use through licensing

#### Cons

- High cost, lengthy patent process
- Invention must be fully disclosed
- Litigation cost high



## Tech. Transfer helps you, help people

- Bayh-Dole Act: Modernized Patent Policy
- Tech Transfer Enabling innovation
  - Culture
  - Climate
  - Think globally, act locally
- Provide mechanism to commercialize your ideas to help people



## Now, it's your turn

- Gratitude and Appreciations
  - Scott Davis, Ph.D., Patent Agent
  - Christine Dixon-Thiesing
  - Daniel, S. Johnston, Ph.D.

