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Inventions, Patents, and Working with Companies

March 3, 2011

Presented by Ken Holroyd

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Patents directly provided for in the U.S. Constitution

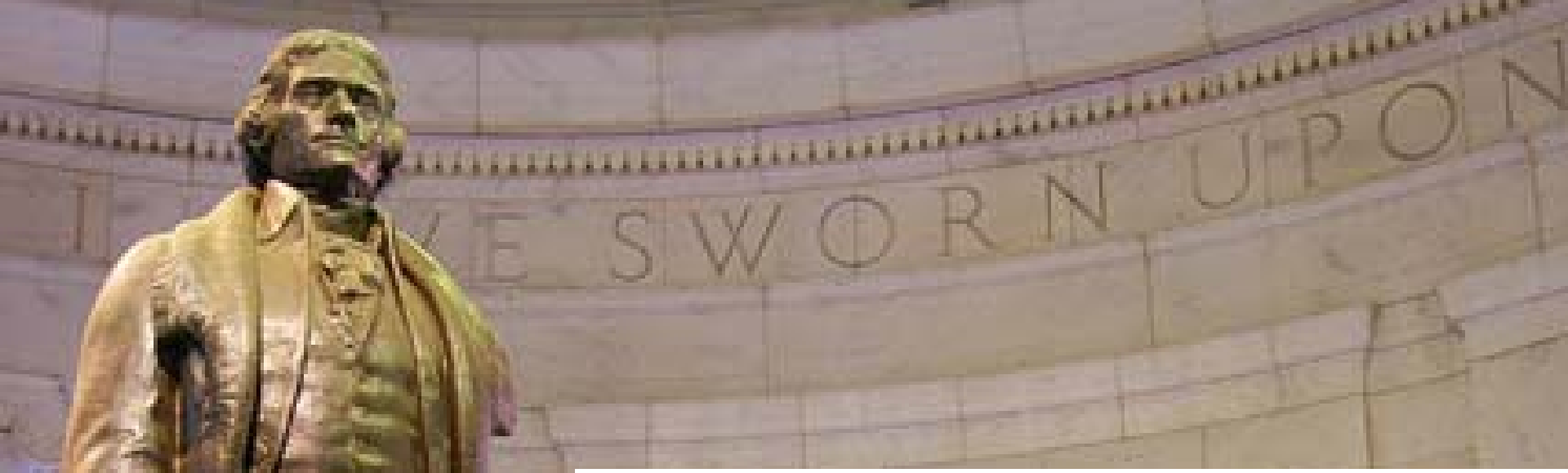
Why?

The Constitution of the United States of America

Article 1, Section 8, Clause 8

The Congress shall have the power...

to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.



X000001
July 31, 1790

The United States.

To all to whom these Presents shall come. Greeting.

Whereas Samuel Hopkins of the City of Philadelphia and State of Pensylvania hath discovered an Improvement, not known or used before, such Discovery, in the making of Pot ash and Pearl ash, by a new Apparatus and Process, that is to say, in the making of Pearl ash 1st by burning the raw Ashes in a Furnace, 2d by dissolving and boiling them when so burnt in Water, 3rd by drawing off and settling the Ley, and 4th by boiling the Ley into Salts which then are the true Pearl ash; and also in the making of Pot ash, by fluxing the Pearl ash so made as aforesaid; which Operation of burning the raw Ashes in a Furnace, preparatory to their Dissolution and boiling in Water, is new, leaves little Residuum; and produces a much greater Quantity of Salt: These are therefore in pursuance of the Act, entitled "An Act to promote the Progress of useful Arts", to grant to the said Samuel Hopkins, his Heirs, Administrators and Assigns, for the Term of fourteen Years, the sole and exclusive Right and Liberty of using, and vending to others the said Discovery, of burning the raw Ashes previous to their being dissolved and boiled in Water, according to the true Intent and Meaning of the Act aforesaid. In Testimony whereof I have caused these Letters to be made patent, and the Seal of the United States to be hereunto affixed. Given under my Hand at the City of New York this thirty first Day of July in the Year of our Lord one thousand seven hundred & Ninety.

G Washington

City of New York July 31st 1790.

I do hereby certify that the foregoing Letters patent were delivered to me in pursuance of the Act, entitled "An Act to promote the Progress of useful Arts", that I have examined the same, and find them conformable to the said Act.

Edm: Randolph Attorney General for the United States.

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The United States Patent System

- Government sponsored “monopoly” limited by time (20 years from filing) and geography

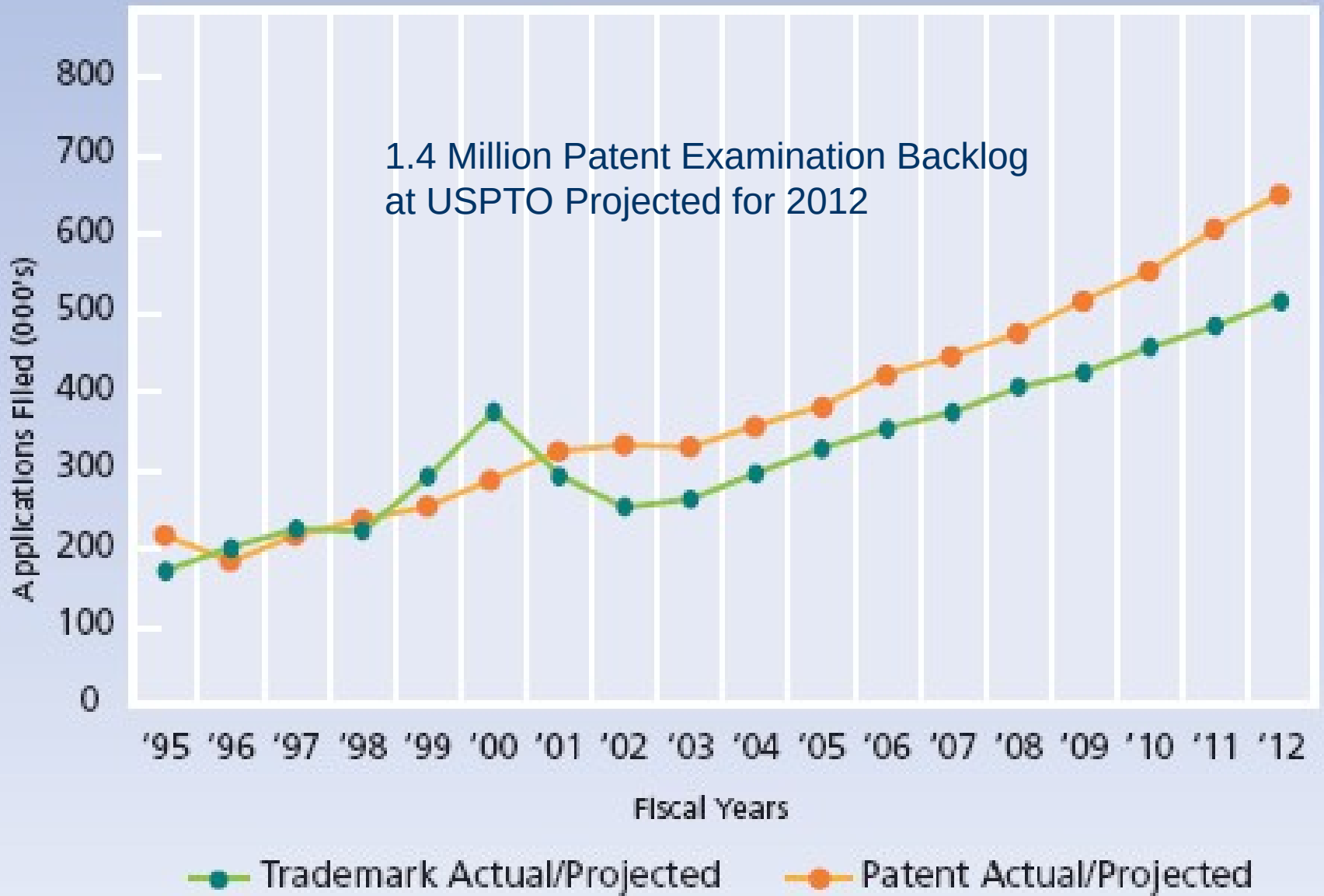
- ***Does not convey affirmative right – only the right to exclude others***

- Administered by the U.S. Patent and Trademark Office

Types of Intellectual Property

- Patents: design, plant and utility (latter relevant to medical research)
- Copyrights: protect works fixed in a medium
- Trade Secrets: best where the product can't easily be reverse engineered
- Trademarks: identify source of goods or services

Patent and Trademark Applications Filed



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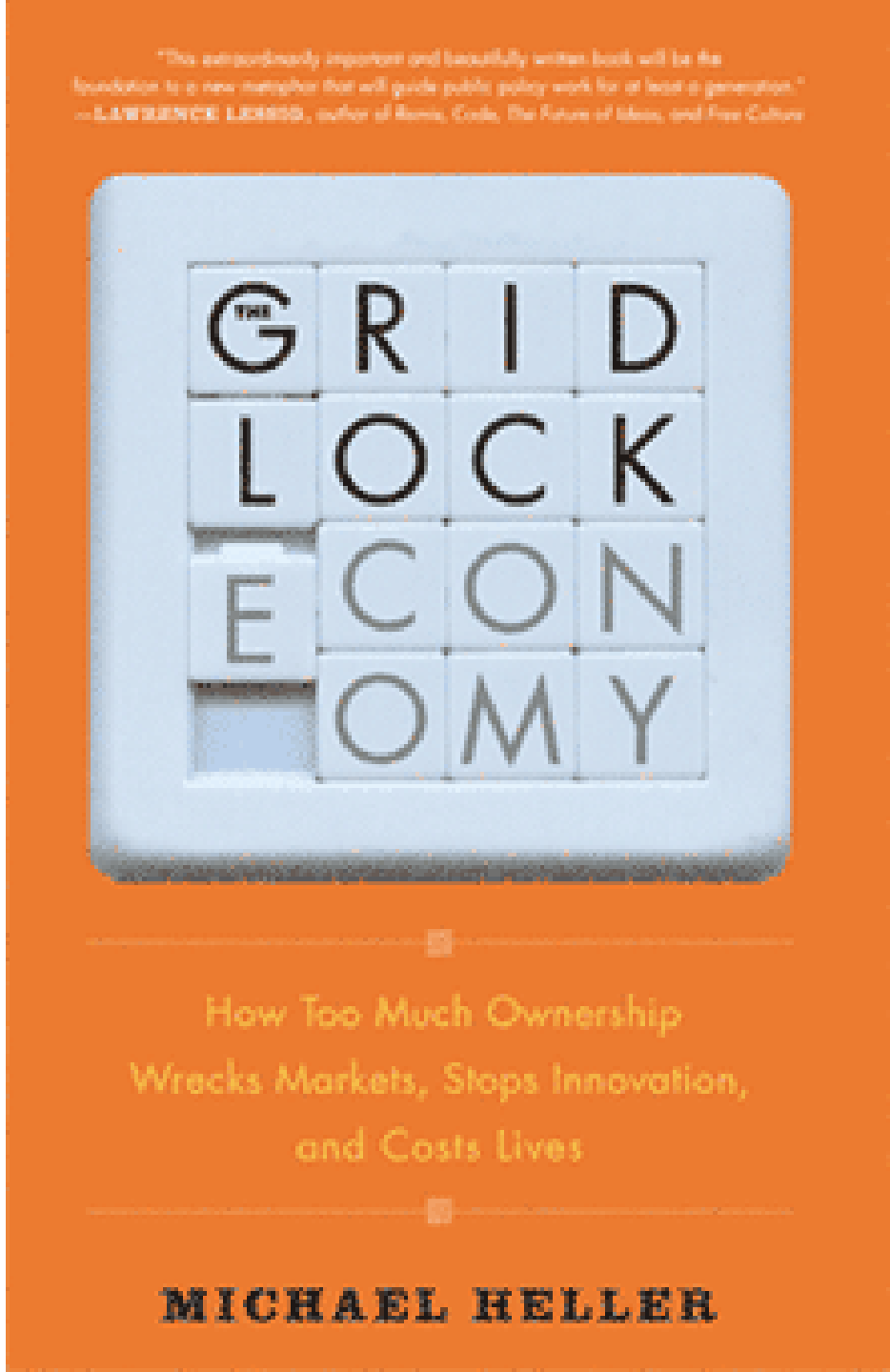
Patent Law Reform?

Different Issues in Pharmaceuticals vs. Electronics and Media



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“Scientists join patent protest
Wisconsin foundation backs its stem cell research

Posted: Jul. 3, 2007

The two foundations questioning the validity of the Wisconsin Alumni Research Foundation's key embryonic stem cell patents have bolstered their protest with comments from three more scientists”


LA ARTOIS
[German, singable]
Die Gedanken sind frei!
Wer kann sie erraten?
Sie fliehen vorbei
wie nächtliche Schatten.
Kein Mensch kann sie wissen,
kein Jäger erschießen
mit Pulver und Blei.
Die Gedanken sind frei!
Die Gedanken sind patentiert.
Man darf sie besitzen.
Es sind angeschmiert,
sie schuften und schwitzen.
Man kann sie abmahnen
und kräftig absahnen
mit Gebühren ungeniert.
Die Gedanken sind patentiert.
Du hast eine Idee
und läßt sie dir patentieren,
und hoffst auf Gewinne
durch Lizenzgebühren.
Um verwerten tut diese
Firma der Software-Riese.
Geld, das dir gebührt!
Gedanken sind patentiert.
[French, singable]
Nos pensées sont libres :
Qui peut les connaitre ?
Elles volent autour de nous
Comme des ombres vives
Impossibles à chasser,
on ne peut pas les tuer
Nos pensées sont libres) :
Qui peut les deviner ?
Nos pensées sont brevetées,
Qui peut les partager ?
Aucun espoir pour ceux
Qui inventent les idées !
D'autres viennent, menacent,
Attaquent, arnaquent,
Munis de leurs brevets.
Nos pensées sont brevetées !
Si toi tu as une idée
Et que la brevettes,
N'espère pas gagner
En vendant des licences.
Un géant utilise
Ton idée et tu penses
Qu'ils va te dédommager ?
Nos pensées sont brevetées !
[English, not singable]
Thoughts are free!
Who can guess them?
They rush past
like nocturnal shadows.
No person can know them,
no hunter can shoot them
with powder and lead.
Thoughts are free!
Thoughts are patented.
They can be owned.
Those who do hard work
are taken for a ride.
One can first warn, then sue them
and take their money
for licensing fees.
Thoughts are patented.
You have a good idea
and get it patented
hoping for some profit
through licensing fees,
because it is used by
a software giant nearby.
A lot of money is due to you.
Thoughts are patented.

Statement of Nobelist John Sulston (5/12/2009)

"I applaud the efforts of the ACLU and the Public Patent Foundation in challenging the patenting of human genes, and in particular the patents on BRCA1 and BRCA2. A patent on a gene specifically bestows the right to prevent others from using that gene. Rather than fostering innovation – one of the primary goals of the patent system – gene patents can have a chilling impact on research, obstruct the development of new genetic tests, and interfere with medical care.

Genes are naturally occurring things, not inventions, and the heritage of humanity. Like a mountain or a river, the human genome is a natural phenomenon that existed, if not before us, then at least before we became aware of it...."

History of Medical School Patenting

- Many universities involved with engineering and other practical matters from their founding
- Early examples: Vitamin D, and later Coumadin, at the University of Wisconsin
- AAMC report by McKusick (1948)
- The Research Corporation
- Bayh-Dole Act (1982)

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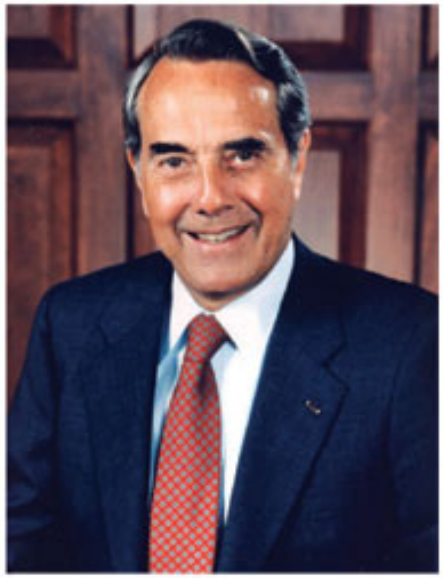
Bayh-Dole Act

Birch Bayh



Bob Dole

Allows universities (and other non-profit contractors) to:

Retain title to inventions produced under federal support

Patent technologies

License technologies

Requires universities (and other non-profit contractors) to:

Share royalties with inventors

Use royalties for laboratory purposes

Authorizes federal agencies to:

Protect government-owned intellectual property

Grant licenses for government-owned intellectual property

Set restrictions on licensing

Why Bother with Technology Transfer and Enterprise Development?

- Translate university research into public benefits
- Reward, recruit, and retain faculty
- Attracting further investment for development of new inventions
- Some control of development of new inventions
- Foster collaborations with industry
- Promote economic development
- Generate revenue to fuel the research enterprise

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Emory Receives $525 Million in 2005

Largest university intellectual property deal: for royalty buyout of AIDS drug emtricitabine

Emory Licensing Success Story

- 17 years of research in an area highly valued for intellectual property—composition of matter / chemical structure of potentially therapeutically important compounds
- Compound discovered over15 years ago
- Investment in 200-300 patents for HIV compound structures
- Expensive, risky litigation to enforce patent rights

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Sharing of Licensing Income (After Patenting/Licensing Expenses are Reimbursed)

PRESENT POLICY	Inventor/ Creator	Inventor's Lab	Inventor's Dept	Inventor's School	Tech Promotion Fund	Tech Research Fund
University Central: *First $100K per year*	50%	10%	0%	30%	10%	0%
University Central: *Above $100K per year*	40%	10%	10%	25%	5%	10%
Medical Center: *First $100K per year*	50%	0%	20%	20%	10%	0%
Medical Center: *Above $100K per year*	40%	0%	25%	20%	5%	10%

Source: *Vanderbilt Faculty Manual*

Growing Amounts of US University Technology Transfer

As of 2006:

- $13.8 trillion US GDP
- $45 billion - US R&D academic expenditures
- 4,963 new licenses
- 12,672 income yielding licenses
- 697 new products introduced in the market
- 4,350 new product introductions in last 8 years
- 553 new spinout companies
- 5,724 new spinouts since 1980.

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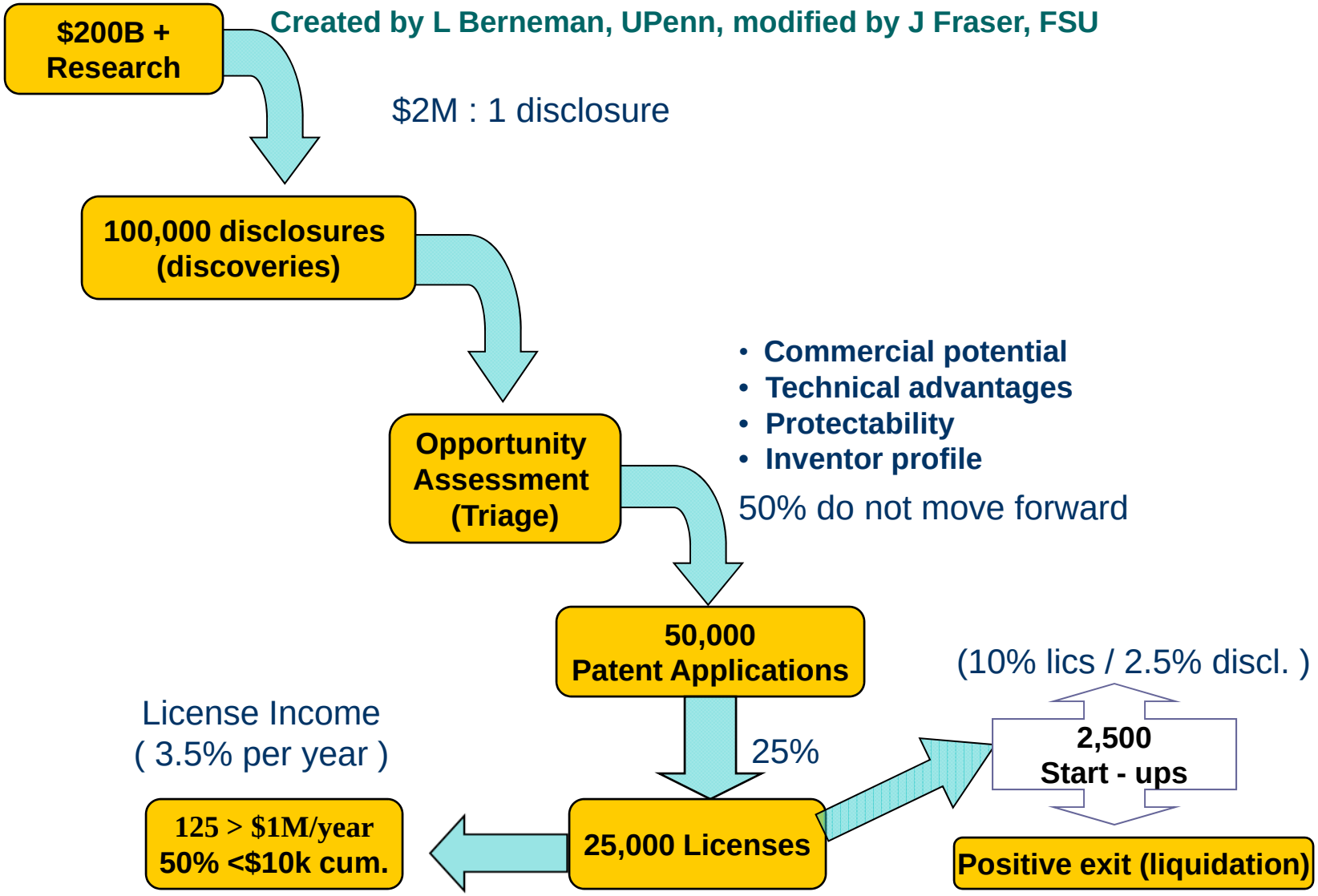
AUTM Data FY1991-2000

Created by L Berneman, UPenn, modified by J Fraser, FSU



Where Do the Licenses Go?

FY	Total Licenses /Options	Start-Ups	Small Co's	Large Co's
'99	3,792	12%	50%	38%
'06	4,963	15%	49%	33%

State by State Licensing Income

- All Fifty States: $1.32 billion (2004)
- Tennessee: $6.7 million (0.5%)
- New York: $306 million (23.2%)
- California: $196 million (14.9%)
- Massachusetts: $180 million (13.7%)
- Florida: $54 million (4%)
- Georgia: $34 million (2.6%)
- Virginia: $9.1 million (0.7%)

Parallels to State by State Venture Capital Investment

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Sample Success Stories Reflect Impact

- ✓ **Read 180** – *teaching kids to read*
- ✓ **Highway crash cushions** – *saving lives*
- ✓ **WizOrder** – *physician order entry*
- ✓ **Natural pesticides** – *serving our world*

McKESSON
Empowering Healthcare

TyraTech™

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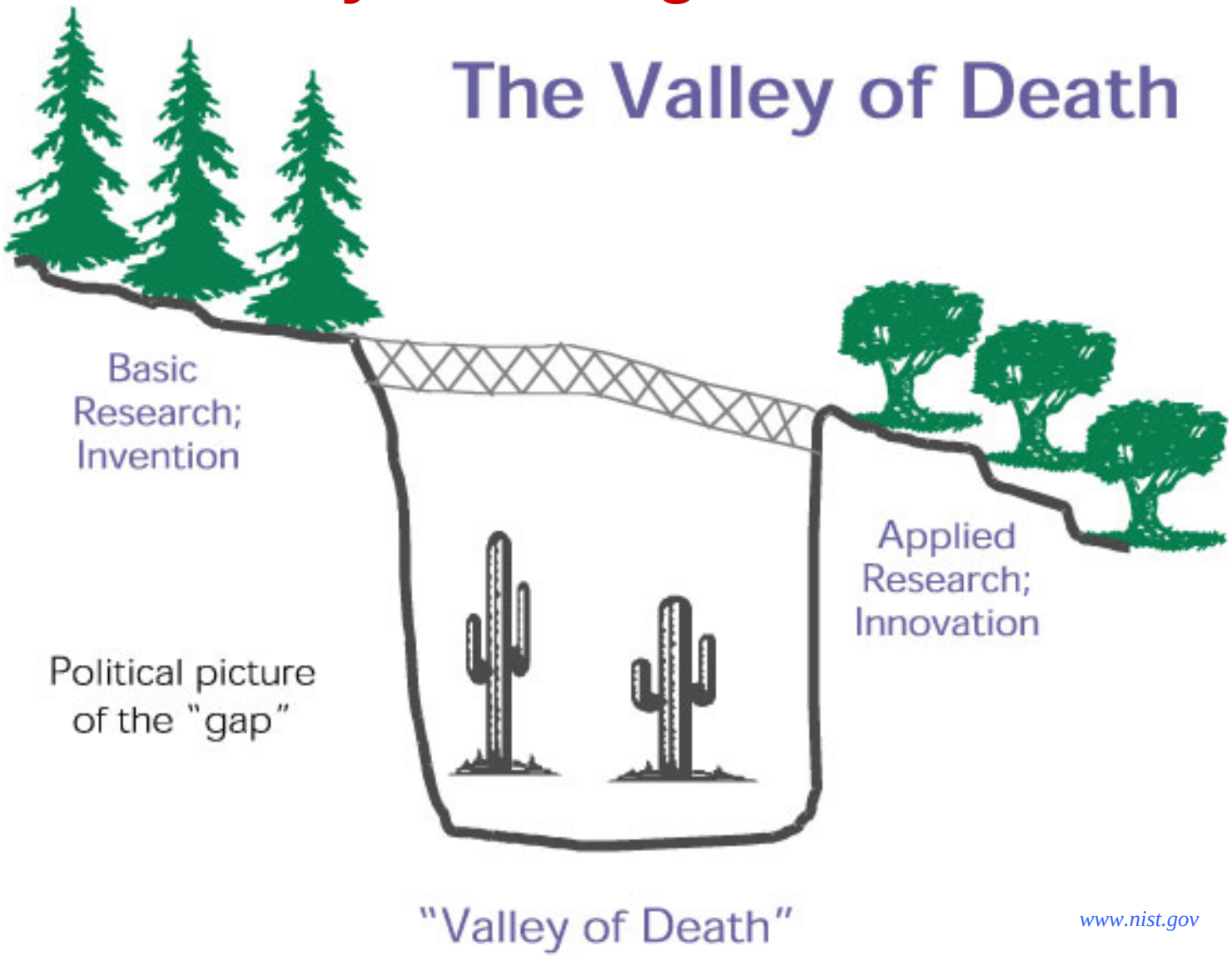
Healthy Challenge…For All of Us!



www.nist.gov

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Technology Transfer and Enterprise Development

Research Funding

- **New inventions** (identify and triage)
- **Commercially-viable IP** (protect)
- **Marketing** (technology push/market pull)
- **Transfer** (license)
  - existing small, medium, or large firm
  - start-up
- **Manage relationships**

Faculty service is essential in promoting technology transfer

Faculty service examples:

Material transfer agreements

Confidentiality agreements

Inter-institutional agreements

Sponsored research agreement support

Clinical trials agreement support

Intellectual property management

Revenue distribution

Start-up formation

Incubation partnerships

Investment contacts

Compliance services

General advising

Impact and Income

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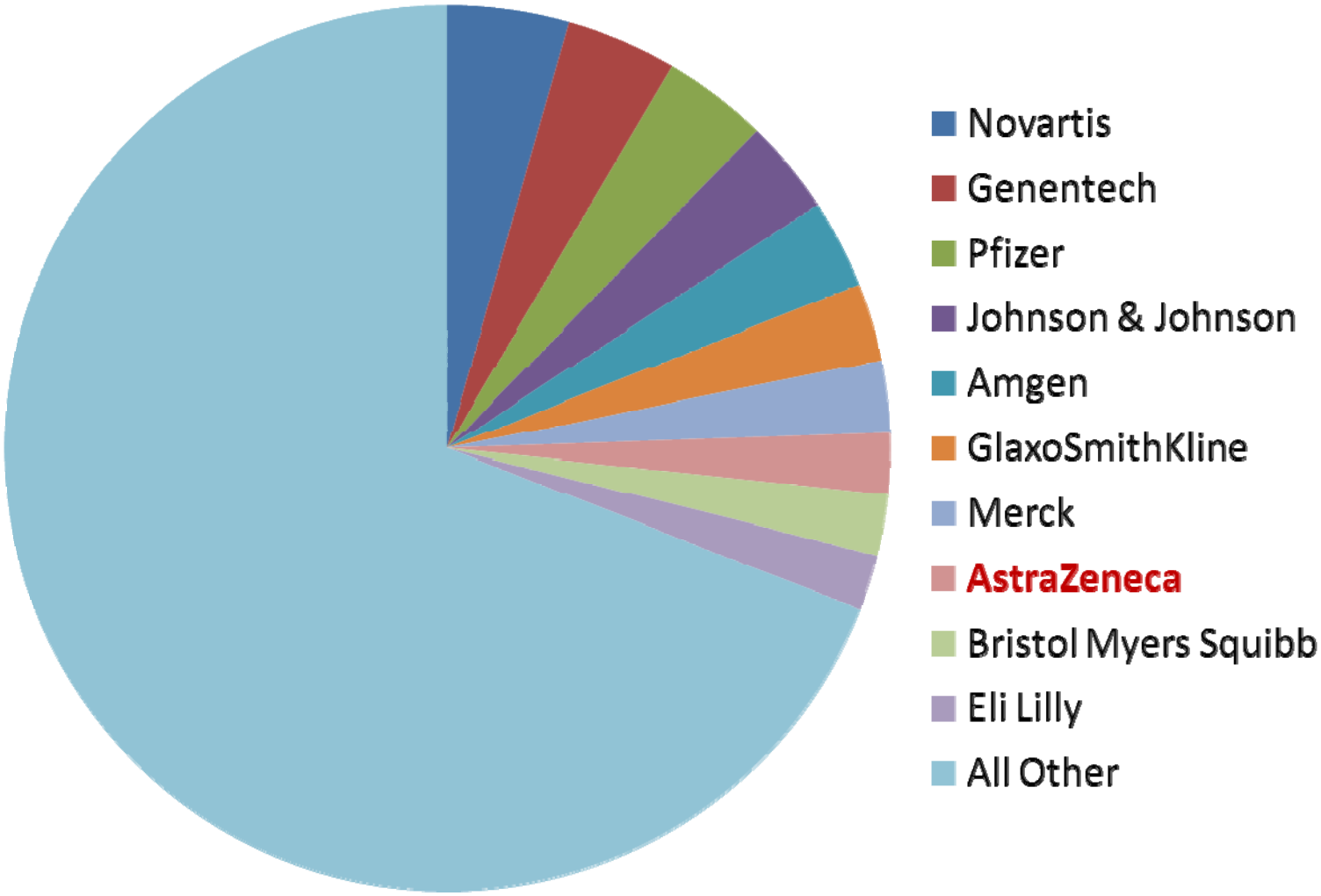
484 Projects with 180 Companies
Pharma Dominates



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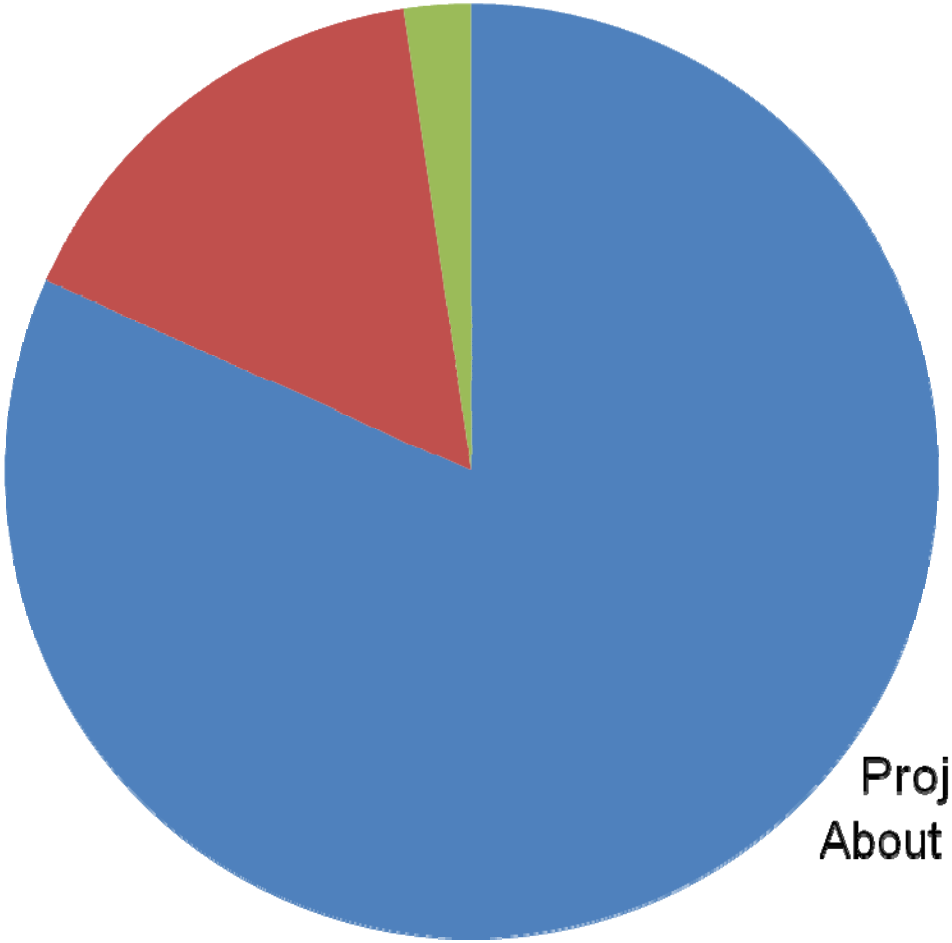
$125 Million of Corporate Sponsored Research Industry Mirror?



CLINICAL

PRE-CLINICAL AND BASIC

HEALTH SERVICES

Project Length Averages 1.7 Years

About 15% of Total Research Revenues

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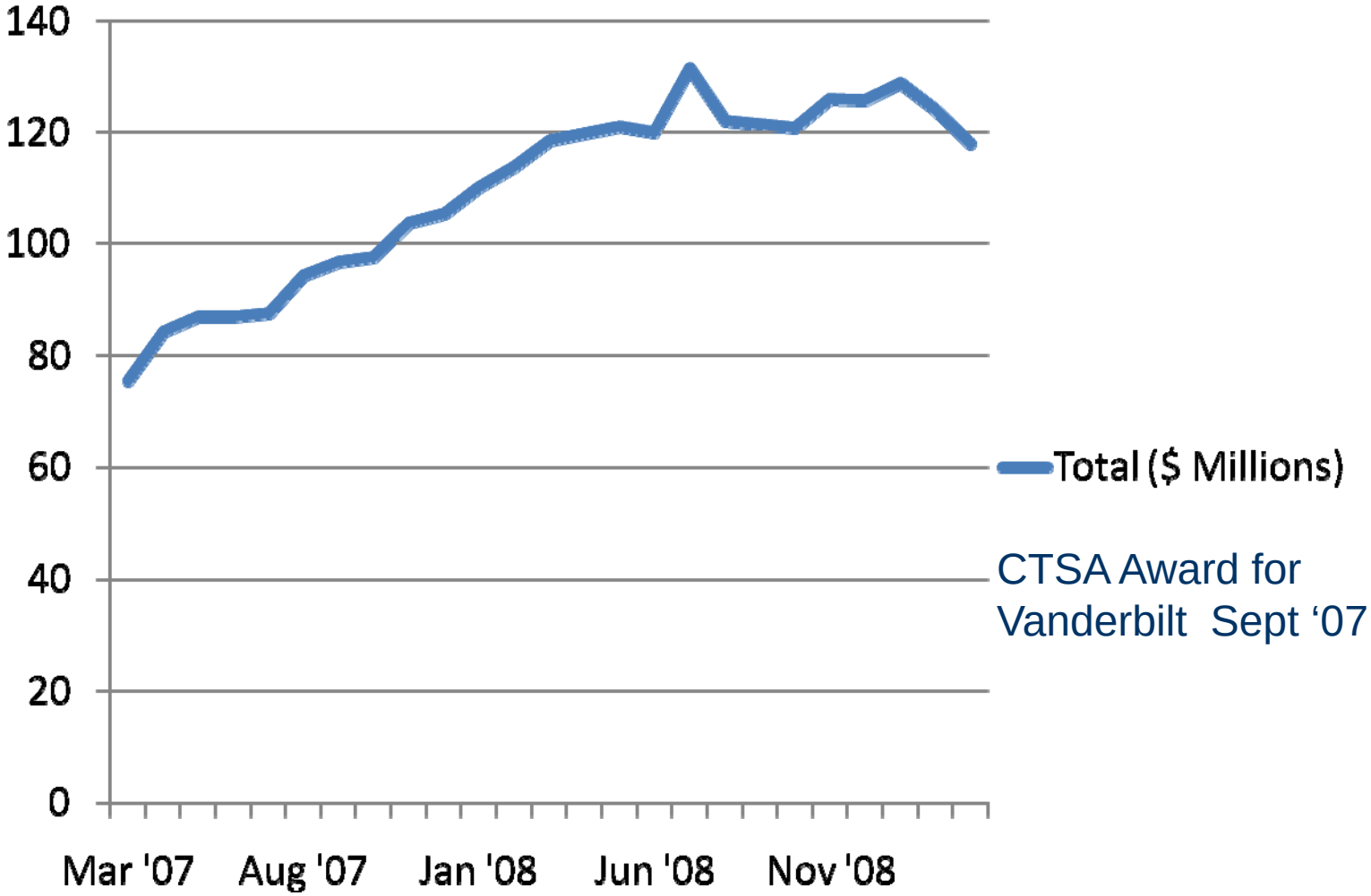
Increase in Corporate Sponsored Research Why?



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Unified Leadership for Clinical Research Processes & Improvement

VICTR

IRB

GRANTS AND CONTRACTS

RESEARCH SUPPORT SERVICES

CLINICAL TRIALS OFFICE

Gordon Bernard, MD
CTSA PI and VICTR Leader

RESEARCH OPTIMIZATION COMMITTEE

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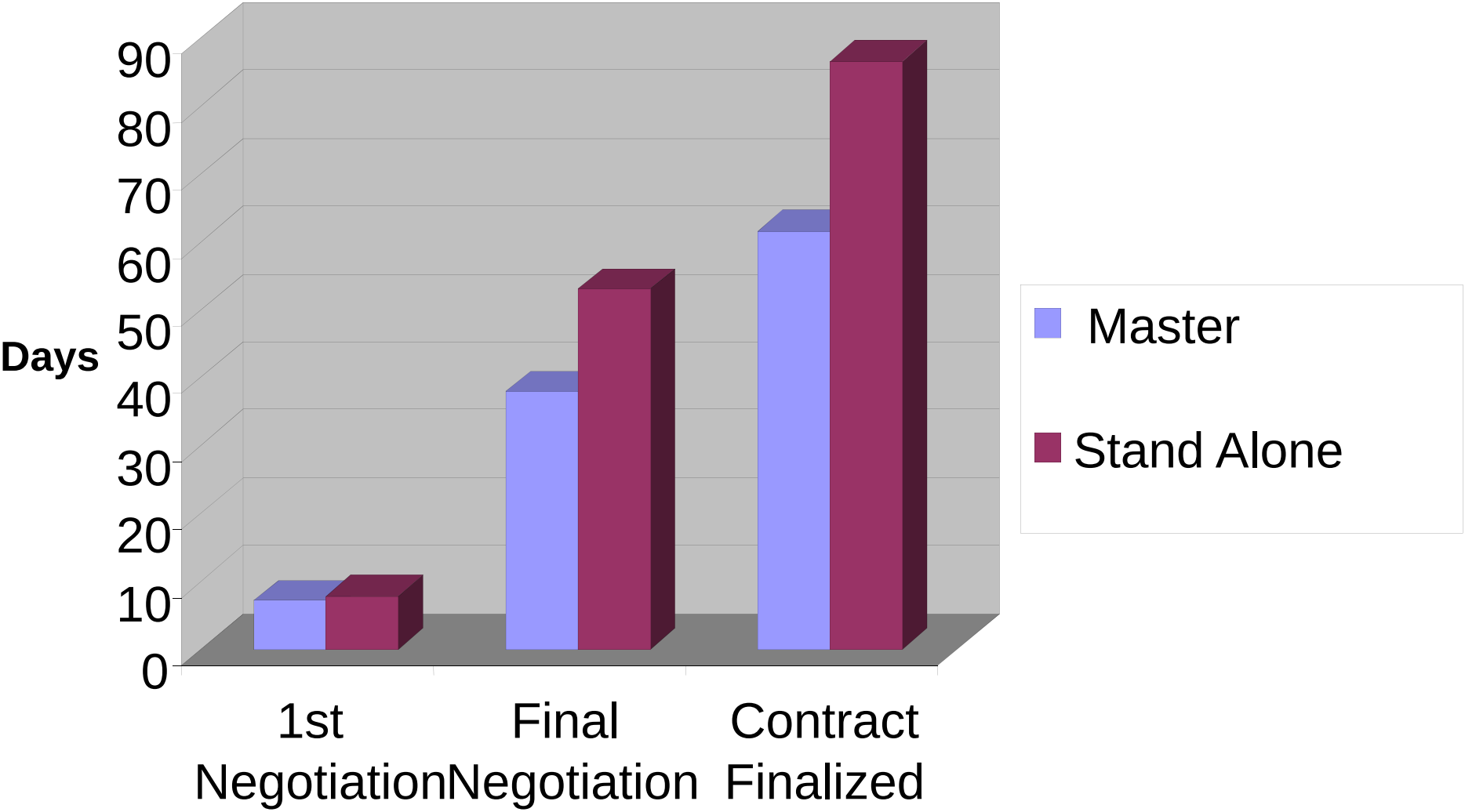
Master Agreements Shorten Clinical Trial Contract Time



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Linked Patent Licensing and Research

T1 PPP: Drug Discovery Partnership “Three-Peat”

The Wall Street Journal
JANUARY 8, 2009, 10:17 P.M. ET

J&J, Vanderbilt Team Up on Schizophrenia Drugs

By Shirley S. Wang

J&J, Michael J. Fox Foundation, Seaside Therapeutics

Public Disclosures and Patent Timelines

- Patent available up to one year after public disclosure in US
- No patent with any public disclosure in rest of world
- Abstracts, publications, public presentations (watch for web record of slides) all count as public disclosures
- Provisional patent often filed first, then up to one year later, non-provisional patent application
- Patent applications are published 18 months after filing—available for web search and analysis
- Patent office review in US typically starts 3-4 years after filing
- Fees for each stage of process, in US and internationally, increase along the way

Requirements for Securing a Patent in U.S.

- Statutory Subject Matter
- Novelty: new, first to invent (first to file outside US)
- Utility: specific, substantial, credible use
- Not Obvious: to person of ordinary skill in the art
- Written Description: clear and concise terms
- Enablement: enable others to make and use
- Best Mode: to carry out invention

Lawsuits: Patent Infringement and Patent Validity

- Patent litigation is expensive, and usually pursued only when substantial revenues or potential revenues are at stake
- Currently difficult to challenge issued patents successfully
- Other business arrangements to license patents are often made if the cost not too high
- Challenges to validity of a patent often on non-obviousness, or novelty, in various ways

What is Patentable Subject Matter ?

- Novel
  - Not made or done before
  - A process, machine, manufacture, composition or improvement
- Cannot claim products of nature, physical & chemical principles

Credible Utility

- Standard is whether a person of ordinary skill in the art would accept that the disclosed invention is currently available for such use
  - Perpetual motion machines not credible

Invention Can Not Be Anticipated

- Not anticipated by the prior art
  - Each and every element of the claimed invention must not be disclosed in a prior art reference
- Objective standard of someone skilled in the art of the invention

Invention Cannot Be Obvious

An invention is not patentable if:

the subject matter of the patent claims, as a whole, would have been obvious at the time the invention was made <u>to a person having ordinary skill in the art to which the claimed subject matter pertains</u>

Factors to Consider For Non-Obviousness

- Educational level of the inventor
- Type of problems encountered in the art
- Any prior art solutions to those problems
- Rapidity with which innovations are made
- Sophistication of the technology
- Educational level of the workers active in the field

Enablement Requirements

- **Written Description**: full, clear, concise and exact terms
- **Enablement:** must enable others to make and use the invention without undue experimentation
- **Best Mode**: must present best way to carry out the invention

Non-Infringement Patent Disputes

- Inventorship disputes: defining inventorship depends on statute, relates to conception of the idea or overcoming key research obstacles
  - Correct inventor list is important for future patent challenges
  - Inventorship distinct from authorship
- Interferences: who was the first to invent
- Ownership: research agreements, MTA's

Patent Strategy

- Develop a patent claim drafting strategy
- Select types of claims
- Prioritize goals for maximum protection
- Include licensing safeguards
- Analyze potential revenue flow: carefully define field of use
- Analyze target infringers
- Address all statutory hurdles

Potential Patent Law Reform

- Some differences in how life sciences vs. information and electronic technologies are developed, licensed, and used for products
- Potential changes in patent challenge processes
- Possible change of first to invent rather than first to file
- Balancing rights on inventors and follow on firms for maximizing societal innovation

Common Invention Areas

- New use for a compound
- New use and mechanism for a compound
- New drug target for a disease with prototype therapy
- New compound
- New diagnostic test
- New research reagents and methods
- New software
- New business methods

Interesting Recent Patent Cases

- Eli Lilly vs.Harvard/ MIT—mechanism of drug action with a common pathway
- Genentech vs. MedImmune—licensee challenge for patent validity
- Research university infringement of research reagent patent cases

Intellectual Property in Agreements

- Similar issues for all agreements
  - Sponsored Research Agreement
  - Material Transfer Agreement
  - Clinical Trial Agreement

Ideal IP Clause for All Agreements

- What you invent is yours
- What I invent is mine
- What we jointly invent is jointly owned
- Inventorship follows US patent law
- Ownership follows inventorship
- Sponsorship does not equal ownership

Common Problem IP Clauses

- Non-Exclusive Royalty-Free License (NERF)
  - For sponsor's internal research only– often OK
  - To make, use, and sell, and sublicensable – usually not OK—allows company to commercialize our inventions for free
- Background intellectual property
- Right of first refusal
- Potential rights to other current or future faculty inventions in similar areas based on confidential information

What if Sponsor Wants to Own Our IP?

- Not OK in Sponsored Research Agreement
  - Financial sponsorship does not equal ownership
  - We should own what we invent
  - Grant royalty-bearing license, make, use, or sell
  - Grant NERF license for internal purposes only
  - Often difficult to value what is not known
- Can be OK in Limited Instances
  - Sponsor Initiated Clinical Trial Agreement
  - Contract research (for example, serum assays)
  - Usually not OK in PI initiated Clinical Trial Agreement Residual federal rights still need to be protected

Background Intellectual Property

- What is it?
  - What should you do?
    - Don’t agree to give rights to background IP
    - Really is a license agreement
- Problems with Background IP
  - Scope
  - Identify it
  - Limit it to one PI
  - Control it
- Compare to Future IP

Right of First Refusal

- What is it?
  - Gives the holder the right to meet any other offer before the proposed contract is accepted.
  - When Sponsor has a NERF license and **does not** exercise its option to negotiate an exclusive, royalty-bearing license
  - AND, reserves a right of first refusal
- What Does it Mean?
  - If you negotiate an exclusive, royalty-bearing license with another company, before you sign contract, you have to offer that deal to Sponsor

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Music City