UC San Diego

Technology Transfer Office

Technology Transfer @ UC San Diego

BILL ATHING

Finance & Operations Manager - Technology Transfer

Overview of UC San Diego TTO

UCSD TTO

- Brief History
- What we do
- How we do it
- What are the results

Brief History of Relevant Laws

- Bayh-Dole Act 1981
  - Universities can own and patent fed funded work
  - Free license to Feds, march in rights
- Tax-Act
  - Sets rules regarding private use of tax-free-bond funded facilities
    - Establishes requirement for fair-value of publicly supported invention and IP
- CA Political Reform Act 1974
  - Underlies many COI issues affecting PI's

Bayh-Dole Act, 1980

- The Bayh-Dole Act (Patent and Trademark Act Amendment, 1980) allowed Universities to retain title to (own) inventions made under federally-funded research
- Act was instrumental in encouraging Universities to participate in technology transfer activities.
- Universities are encouraged to collaborate with commercial entities to promote the utilization of inventions arising from federal funding by licensing to industry for commercial product development in the public interest.

WAS THE DESIRED GOAL OF FEDERAL RESEARCH SPENDING ACHIEVED

- A SIMPLE MEASURE = NEW CONSUMER PRODUCTS
- THE ANSWER: NEW PRODUCTS WERE NOT COMING OUT OF THE RESEARCH SPENDING AND WERE IN FACT HURTING NEW PRODUCT DEVELOPMENT
-

History of Tech Transfer

- UCOP TTO formed in 1979
  - Handled all campus level activity
  - 450 miles too far to be effective
- UCSD TTO formed 1994 - 2 FTE's
- 1998-2006 Alan Paau era – growth to 25 FTE's
- 2006-Present – Jane Moores, AVCIP

What TTO does

Management of UCSD Intellectual Property

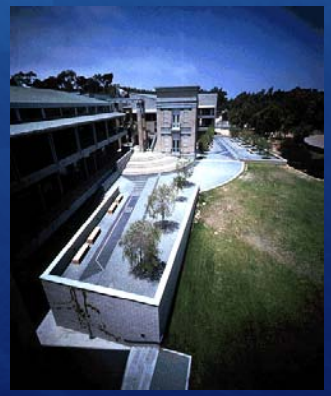
- Statutory Protection (patents-new & improved products and processes with useful application; Copyright-original works of authorship fixed in tangible medium software, images, films)
- Invention and Copyright Licensing
- Transfer of Tangible Materials (if UCSD property e.g. Cell lines, transgenic mice, plasmids)
- Trademarks (related to IP)

Resource & Service Center for Intellectual Property Matters

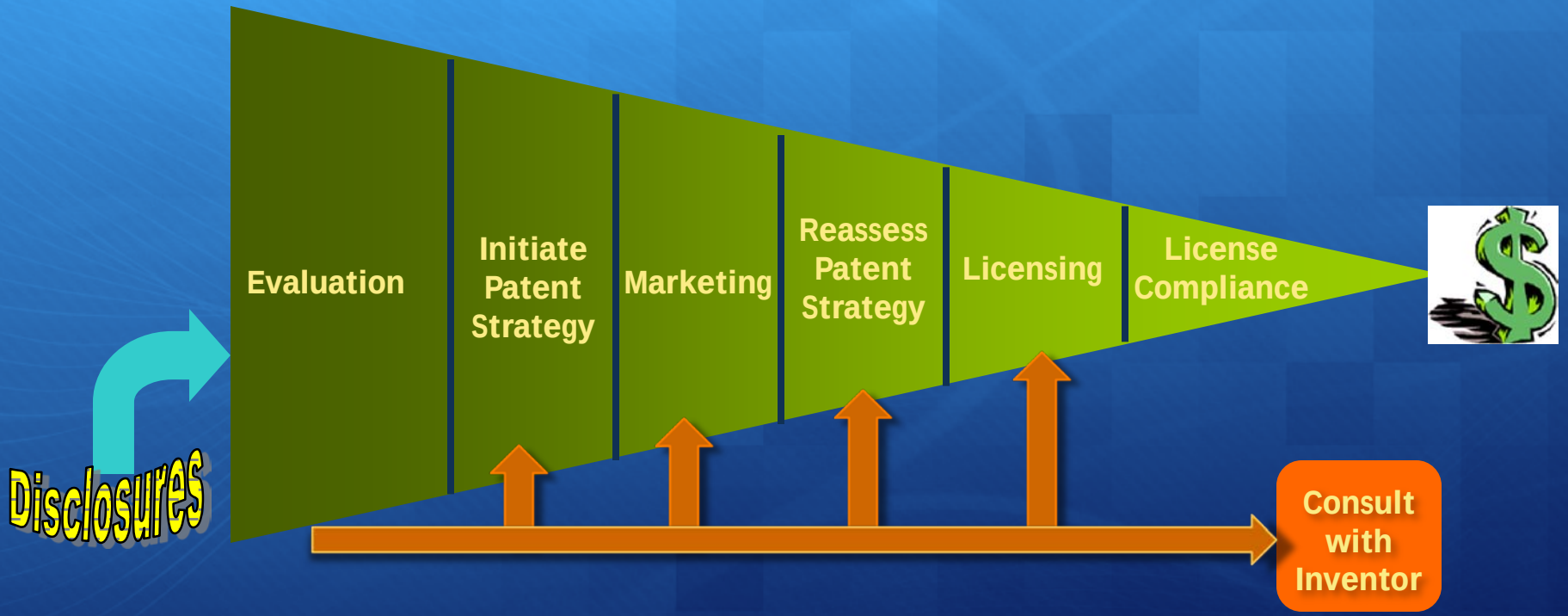
- Services (to researchers, other administrative departments)
- Education (to UCSD faculty, staff & students; other universities) Outreach (to companies/potential licensees)

Mission Statement

- Promote and facilitate the transfer of UCSD innovations for the benefit of the University community and the public
  - Enhance the research experience of UCSD researchers through technology transfer
  - Promote and target regional economic development by leveraging UCSD innovations
  - Provide financial incentives to researchers to stimulate technological innovations



Technology Transfer Process Flow Chart



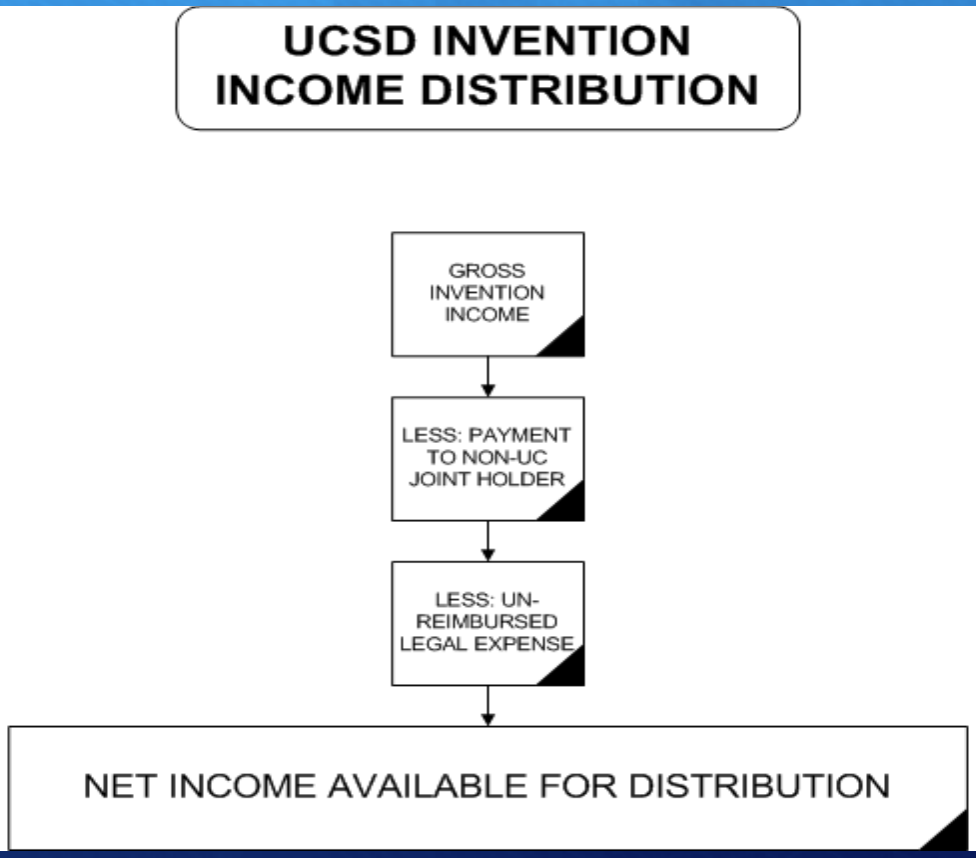
2,300+ Available Innovations

1,400+ Active Patent Applications

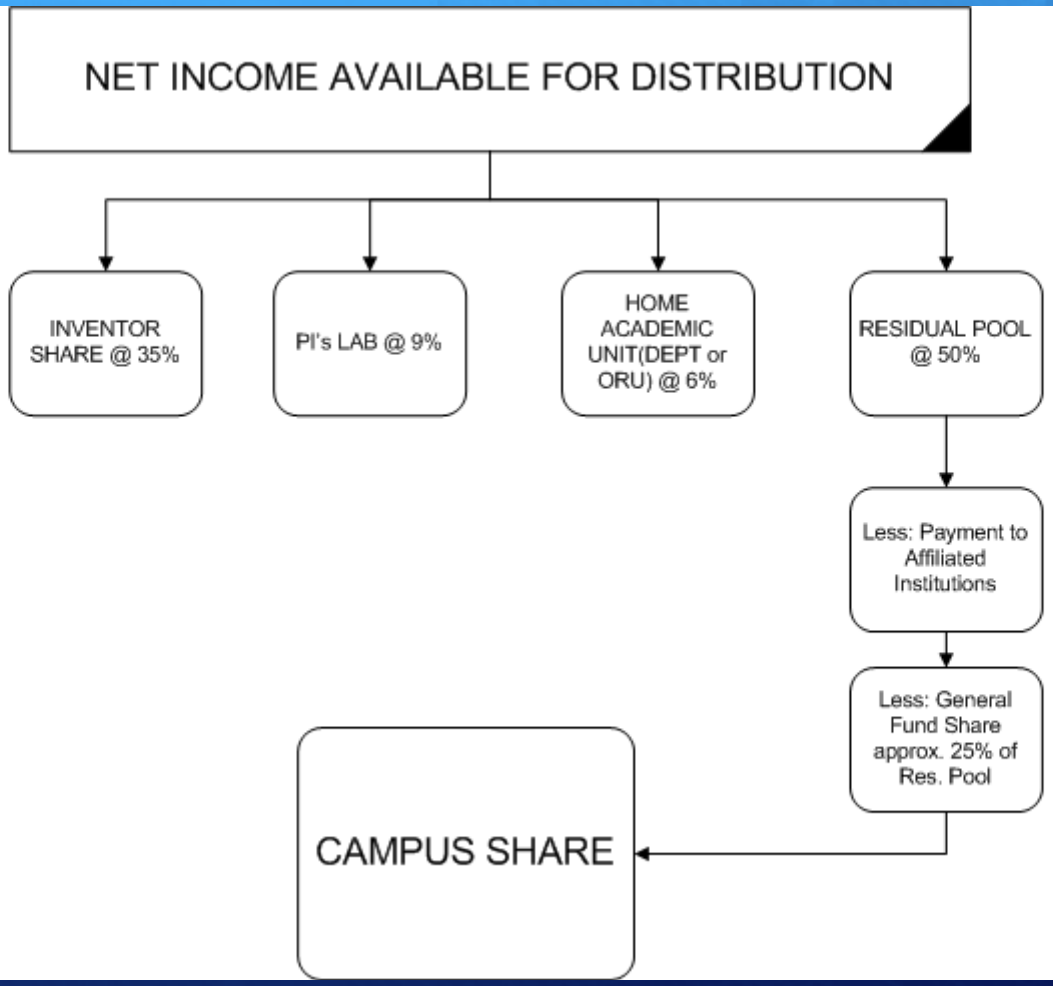
1,500+ Active Patents

400+ Active Licenses

Sample Flow of Invention Income



UCSD INVENTION INCOME DISTRIBUTION



Technology Transfer in US Universities - The Environment

Unique Legal, Academic, and Political Environment :

- Bayh-Dole Act of 1980 (US)
- Tax Reform Act of 1986 (US - Tax Free Bond Issues)
- Political Reform Act (CA)/Conflict of Interests (US)
- Academic Freedom and Integrity Issues
- NIH guidelines
- 9 Points to Consider/University Guidelines
- Missions of the University and its Current Emphasis
- Stakeholders' Expectations
- Export Regulations

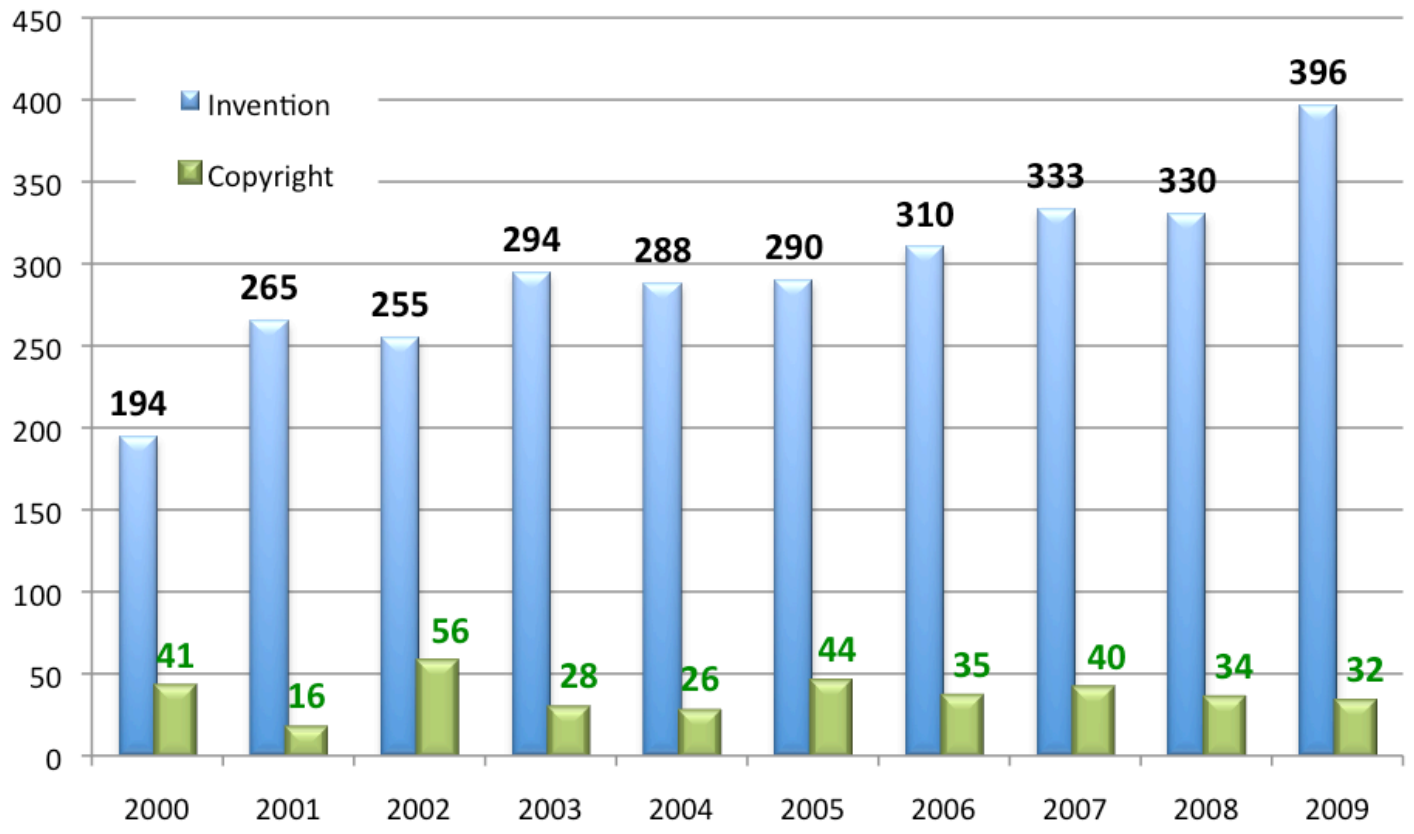
UC Guiding Principles in Licensing (2001)

1. Primary objective in developing a licensing strategy for an invention should be to benefit the public.
2. Licensee should be capable of bringing the invention to the market.
3. License agreement should include diligence terms that support the timely development, marketing, and deployment of the invention.
4. University should receive fair consideration for the grant of commercial licensing rights.
5. License agreement should support the academic principles of the University.
8. Licensing decisions based on legitimate institutional academic & business considerations--not personal financial gain.

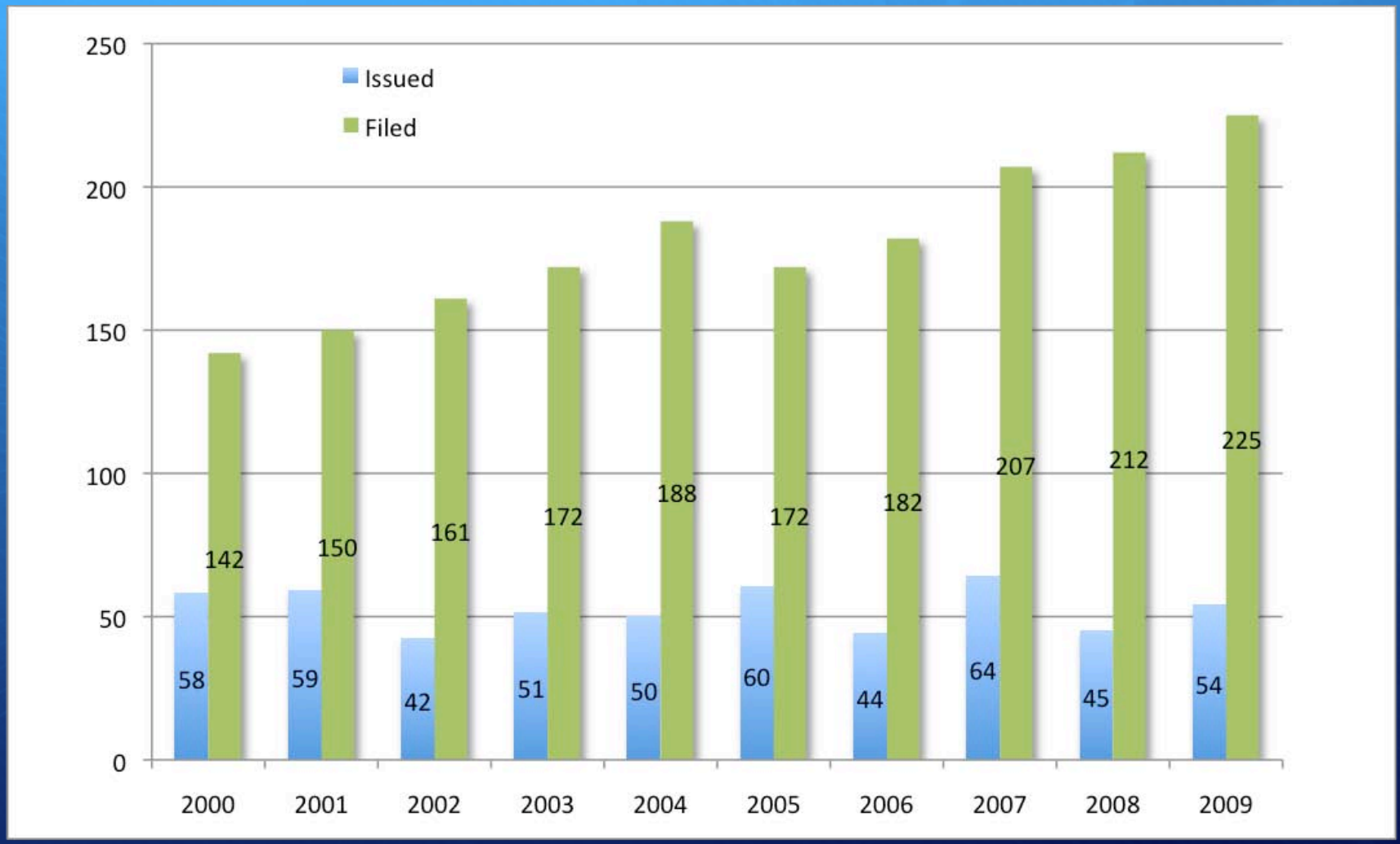
Nine Points to Consider in Licensing University Technology (March 2007)

- 1. Reserve the right to practice licensed inventions for University and other non-profit & government organizations
- 2. Exclusive licenses structured in a manner that encourages technology development and use
- 3. Strive to minimize the licensing of future improvements
- 4. Anticipate and help to manage TT-related conflicts of interest
- 5. Ensure broad access to research tools
- 6. Enforcement action should be carefully considered
- 7. Mindful of export regulations
- 8. Mindful of implications of working with patent aggregators
- 9. Consider including provisions that address unmet needs such as neglected populations or geographic areas, improved therapeutics, diagnostic and agricultural technologies for the developing world

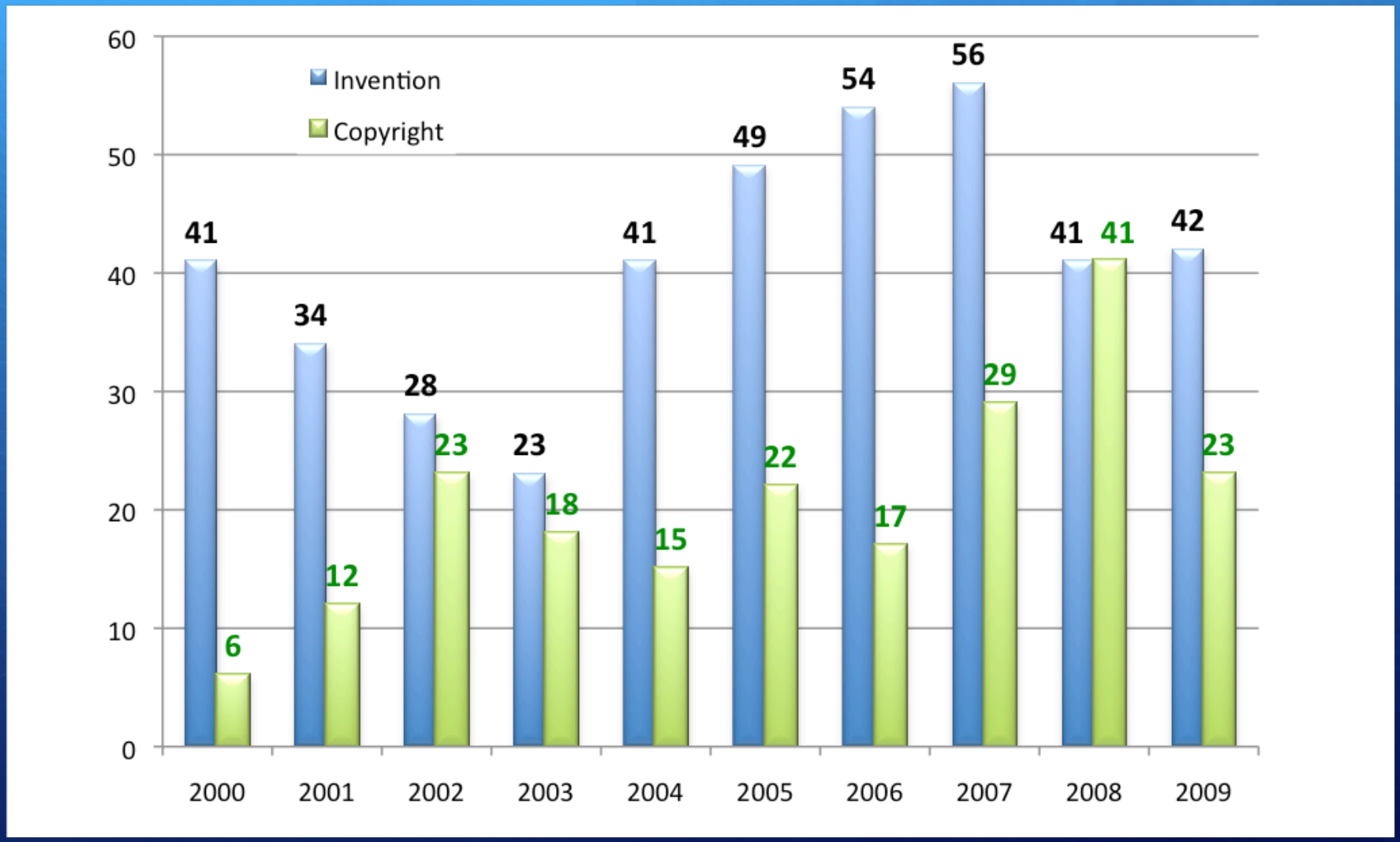
Intellectual Property Disclosures



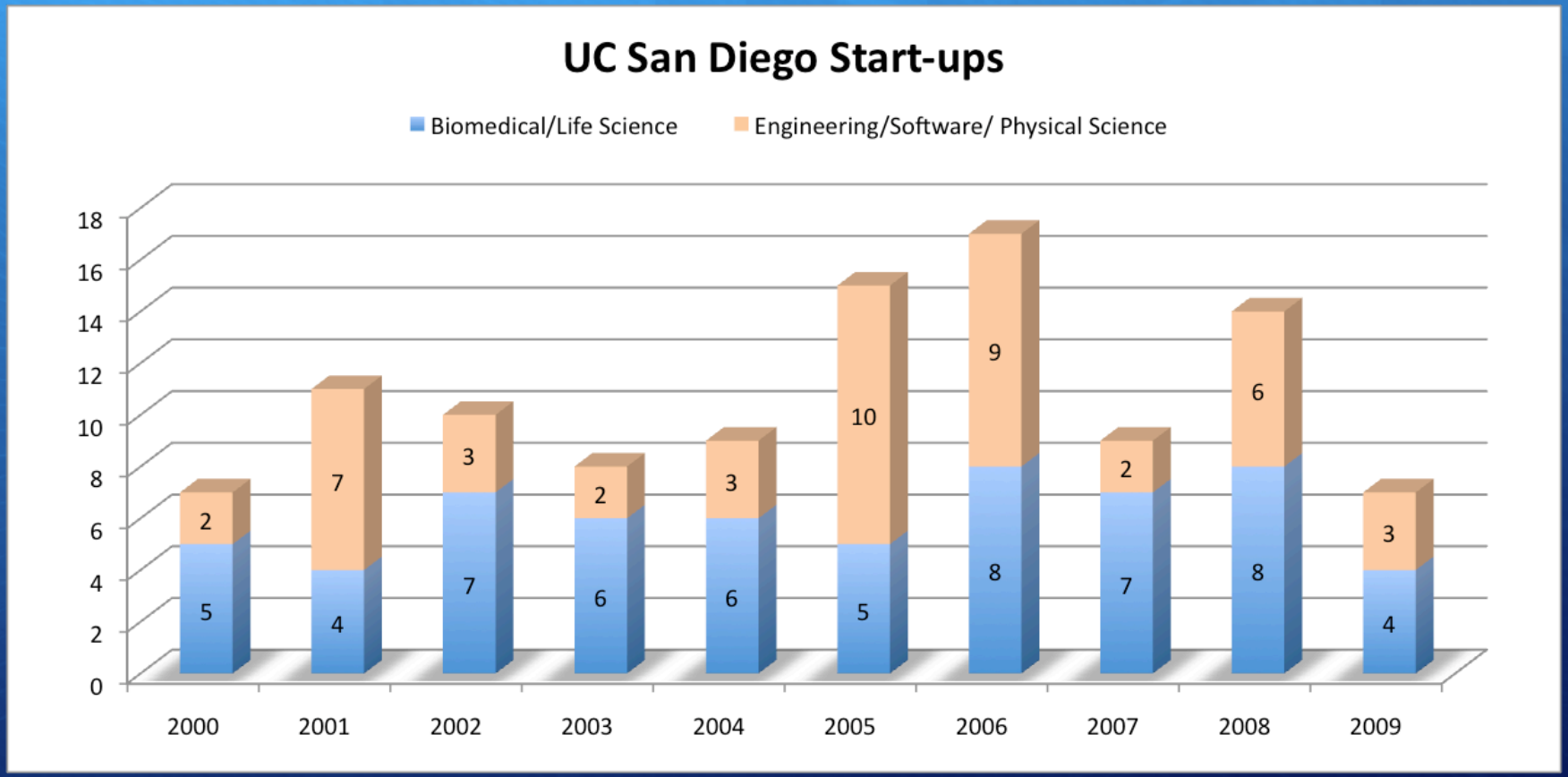
U.S. Patent Activity



Revenue-based Licenses



UC San Diego Start-ups
(>130 total)



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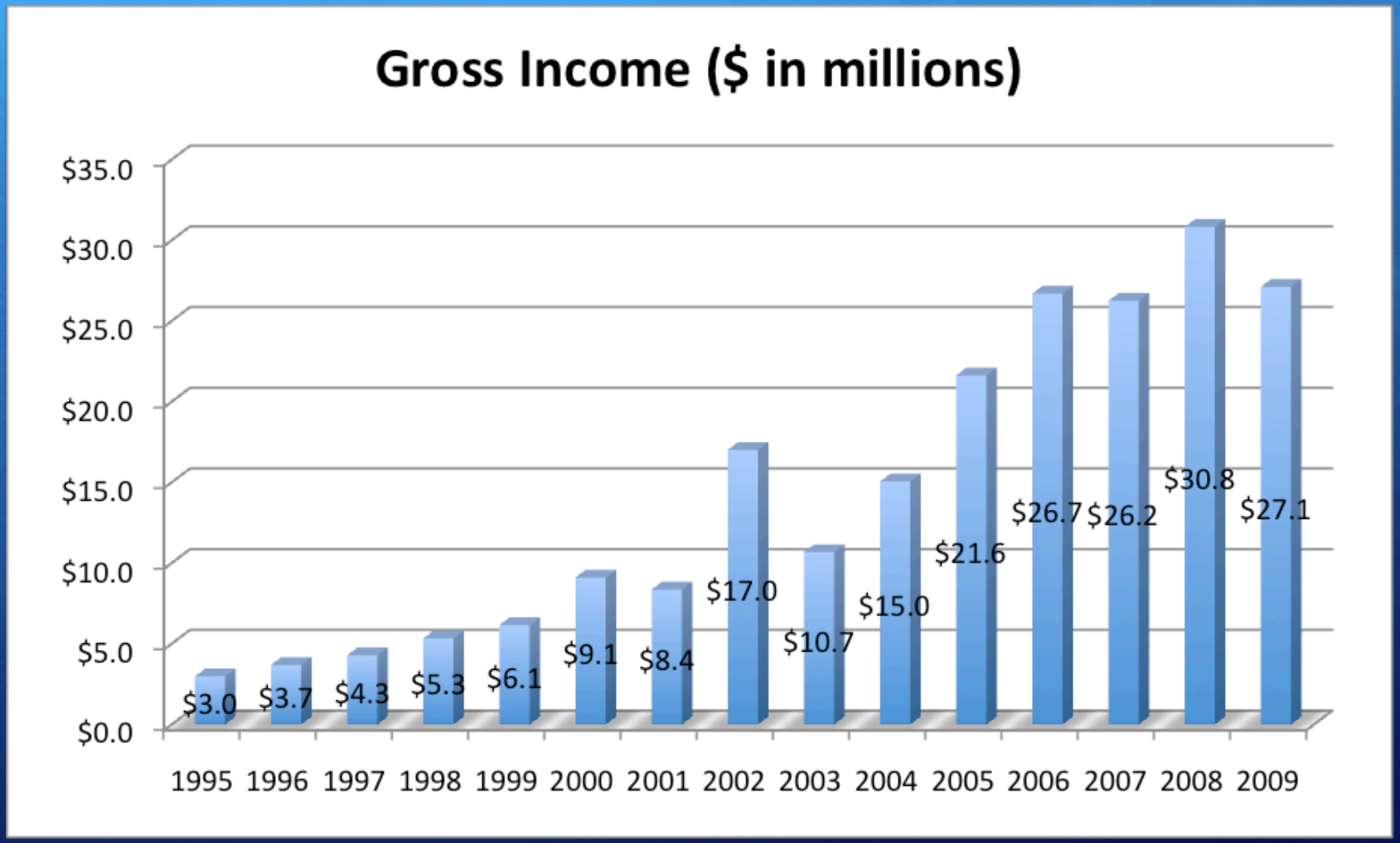
Gross Revenue



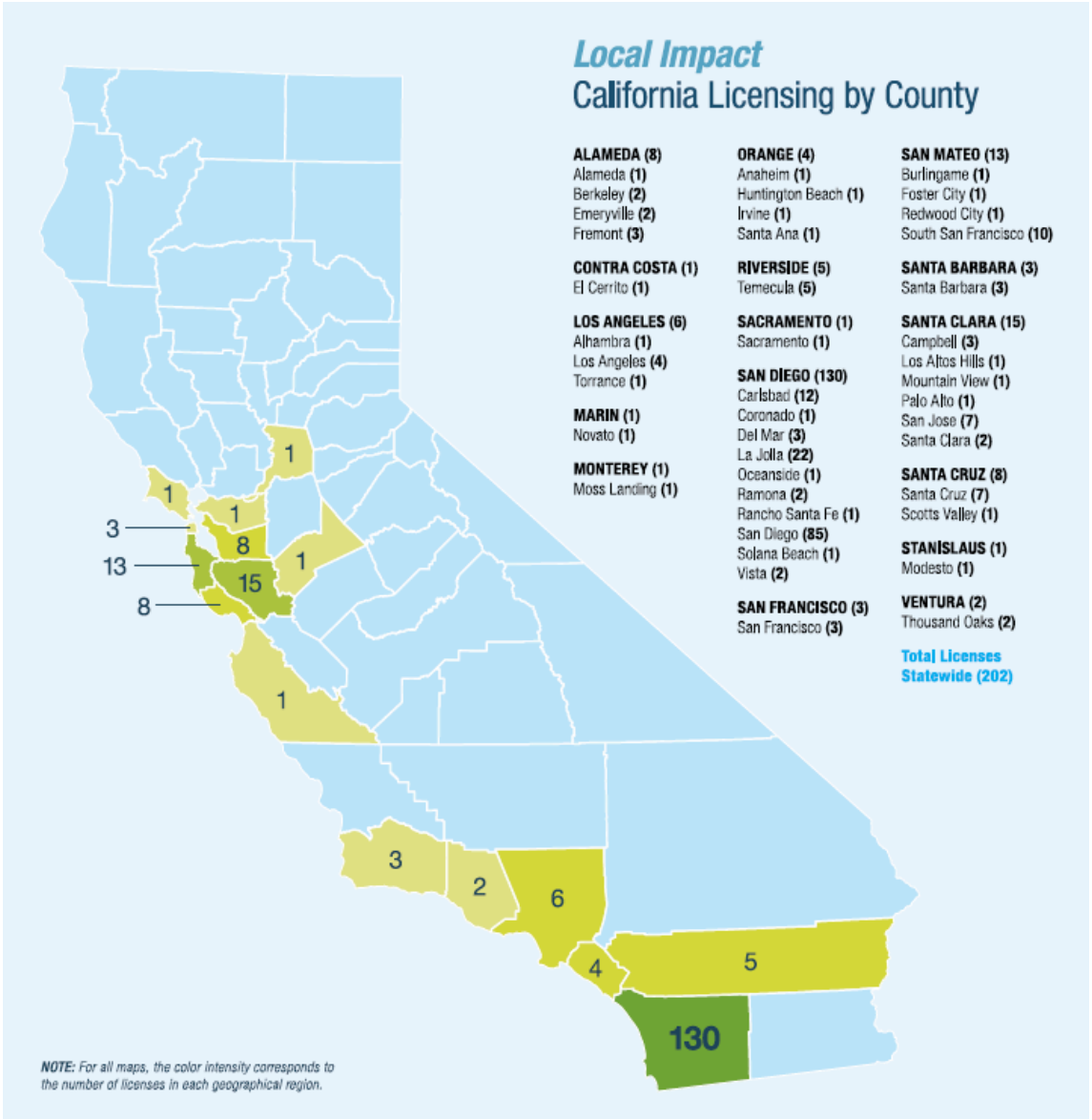
UCSD Top Inventions

Invention (Year disclosed)	
Human Cytomegalovirus Diagnostic (SD, 1982)	
Radiographic Media (SD, 1979)	
Interstitial Cystitis Therapy (SD, 1980)	
Egf Receptor Antibodies (SD, 1983)	
Firefly Luciferase (SD, 1984)	
UC-wide	
% of Total Income from Top 5 Inventions	**~50%**
% of Total Income from Top 25 Inventions	~ 75%

License Agreements in FY2009

- Local Impact – National Influence – Global Reach
- More than 400 active license agreements at year end.
- Highest concentration of licensees are in the state of California
- One-third of licensees are based in the San Diego region

License Agreements in California (FY2009)



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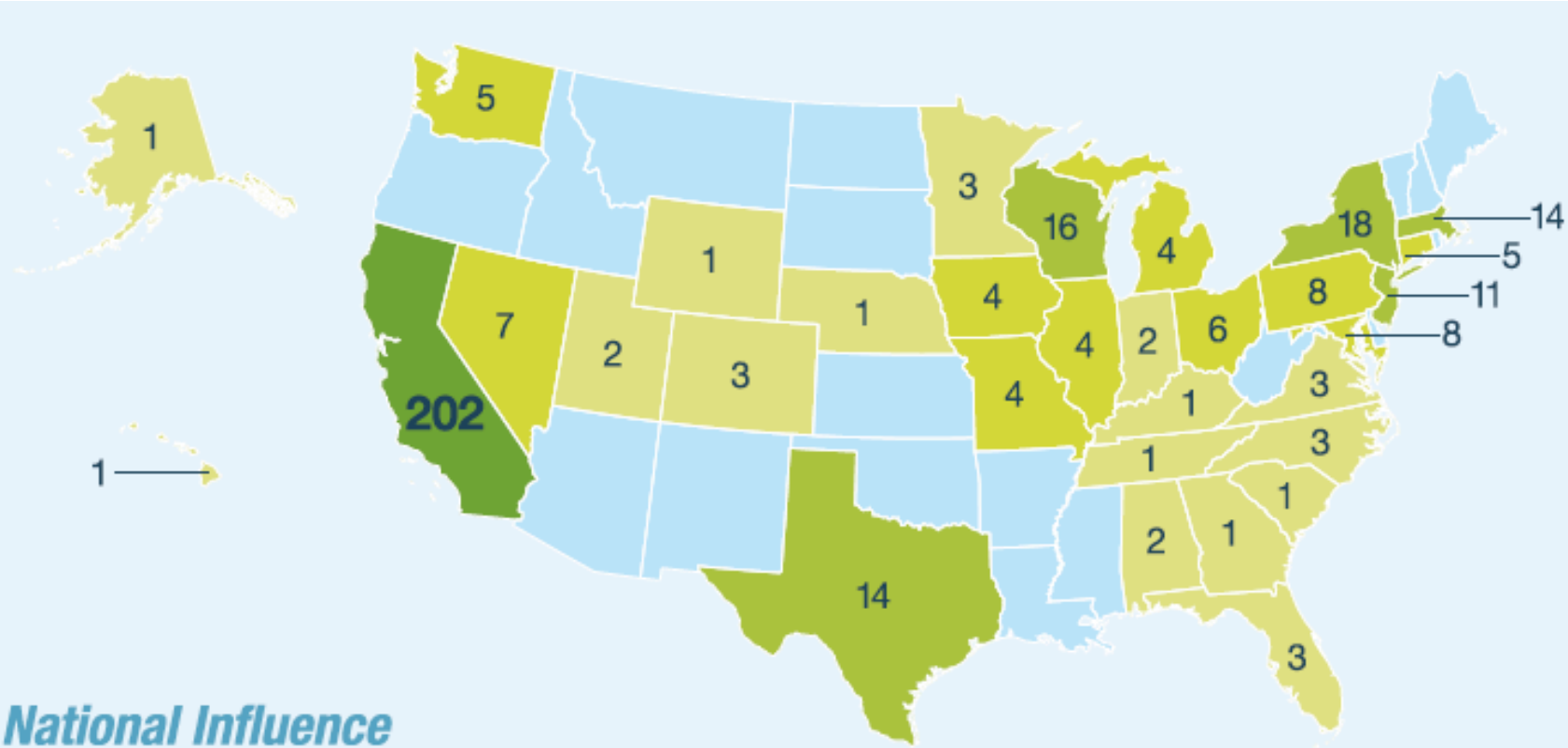
License Agreements in the U.S. (FY2009)



Alaska **(1)**, Alabama **(2)**, California **(202)**, Colorado **(3)**, Connecticut **(5)**, Florida **(3)**, Georgia **(1)**, Hawaii **(1)**, Iowa **(4)**, Illinois **(4)**, Indiana **(2)**, Kentucky **(1)**, Massachusetts **(14)**, Maryland **(8)**, Michigan **(4)**, Minnesota **(3)**, Missouri **(4)**, North Carolina **(3)**, Nebraska **(1)**, New Jersey **(11)**, Nevada **(7)**, New York **(18)**, Ohio **(6)**, Pennsylvania **(8)**, South Carolina **(1)**, Tennessee **(1)**, Texas **(14)**, Utah **(2)**, Virginia **(3)**, Washington **(5)**, Wisconsin **(16)**, Wyoming **(1)** **U.S. Total (359)**

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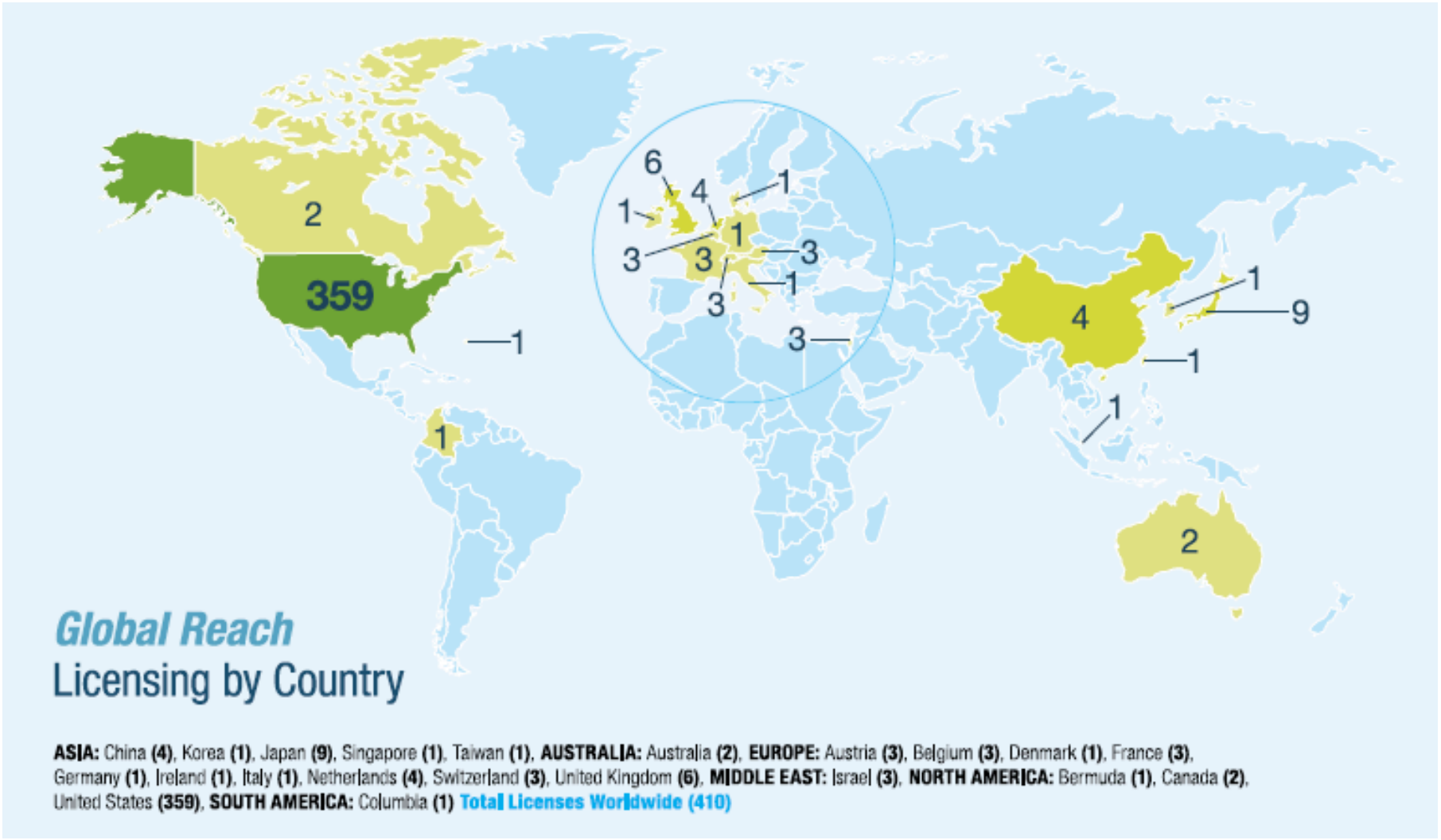
License Agreements Around the World (FY2009)



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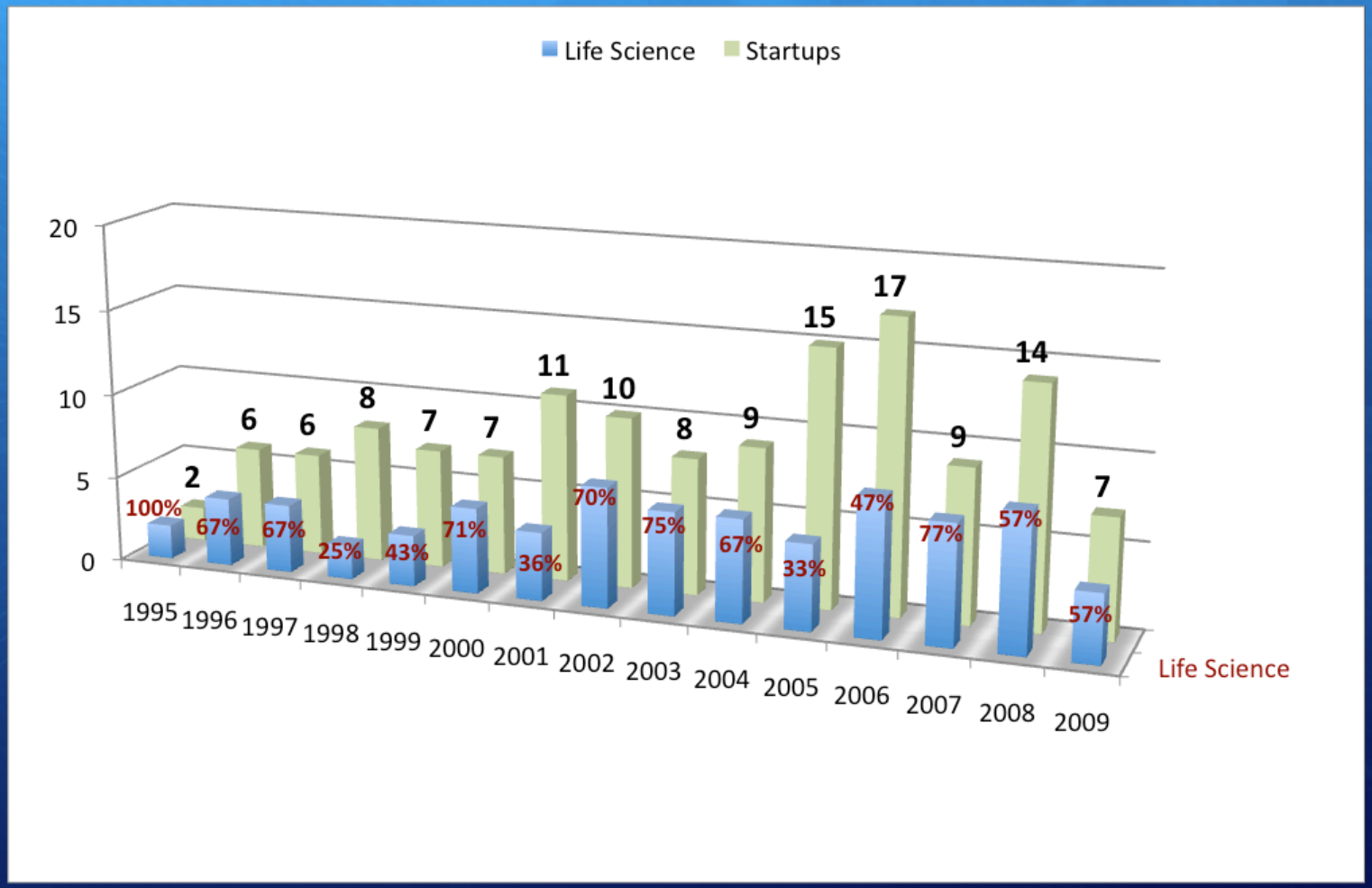
http://invent.ucsd.edu

Start-ups formed with UCSD foundational technology



University of California Top 25 FY2009

Invention (Campus, Year Disclosed)	Income (in thousands)
Hepatitis-B Vaccine (SF, 1979 and 1981)	$15,909
Treatment of Intracranial Aneurysms (LA, 1989)	$11,427
Interstitial Cystitis Therapy (SD, 1980)	$8,723
Egf Receptor Antibodies (SD, 1983)	$5,947
Bovine Growth Hormone (SF, 1980)	$5,488
Subtotal (Top Five Inventions)	$47,494
Total Income (Top 25 Inventions)	**$74,698**
Total Income (All Inventions)	**$98,705**
% of Total from Top 5 Inventions	**48.1%**
% of Total from Top 25 Inventions	**75.7%**

- QUESTIONS ????

Technology Transfer Office

UC San Diego

Technology Management Strategy

- Our baseball philosophy:
  - get “at bat” as often as possible
- Program Implementation:
  - Equal access by active marketing broadly
  - Partnership in spirit by risk and benefit sharing
  - Low entry hurdles to encourage all players
  - Reasonable royalty when product is sold
  - Diligent performance and patent cost requirements
  - Transparency - Sample agreements on web site

Ways to Partner with the University

- *Licensing*
  - *inventions*
  - *tangible materials*
  - *copyrights*
- *Research*
  - *sponsored research/collaborations*
  - *research centers*
- *Joint grant submissions*
  - *UC discovery grants*
  - *SBIR/STTR*

UC Guiding Principles in Licensing
(Dec 2000, Revised Oct 2001)

1. Primary objective in developing a licensing strategy for an invention should be to benefit the public.
2. Licensee should be capable of bringing the invention to the market.
3. License agreement should include diligence terms that support the timely development, marketing, and deployment of the invention.
4. University should receive fair consideration in exchange for the grant of commercial licensing rights.
5. License agreement should support the academic principles of the University.
6. Licensing activities should be carried out within delegated authority.
7. License agreement should be approved for legal integrity and consistency.
8. Licensing decisions should be based upon legitimate institutional academic & business considerations--not on personal financial gain.

UC Guiding Principles in Licensing

(Dec 2000, revised Oct 2001)

1. The primary objective in developing a licensing strategy for an invention should be to benefit the public.
2. The licensee selected should be capable of bringing the invention to the marketplace.
3. The license agreement should include diligence terms that support the timely development, marketing, and deployment of the invention.
4. The University should receive fair consideration in exchange for the grant of commercial licensing rights.

UC Guiding Principles in Licensing

5. The license agreement should support the academic principles of the University.

6. Licensing activities should be carried out within delegated authority.

7. The license agreement should be approved as to legal integrity and consistency.

8. All decisions made about licensing University inventions should be based upon legitimate institutional academic and business considerations and not upon matters related to personal financial gain.

IRS Requirements: tax act

- *Tax exempt bonds are committed to be used for "governmental purposes" i.e. related to university's mission of education, research and public service*
- *The IRS limits the amount of "private business use" of facilities financed with tax-exempt bonds, including research facilities*
- *For each bond issue, no more than 5%/10% of the bond proceeds (up to $150M bond issue) may be used for private business use*
- *Research agreements with private companies can create private use if they have certain characteristics but there is a safe harbor provision*

Bayh-Dole Act Provisions

- University can elect to own titles to inventions that arise from work with federal government funding
- Preference for small businesses
- Preference for US manufacture
- Royalty-sharing with inventors
- Residual revenues must be used to support research and educational activities
- Confirmatory paid-up NXL to Govt to practice invention
- Government has “march-in” rights
- No assignment of titles to third parties w/o approval
- Reporting requirements

UC Guiding Principles & Commitments in Interactions with Industry

1. Open dissemination of research results
2. Commitment to students
3. Accessibility for research purposes
4. Public benefit
5. Informed participation
6. Legal integrity and consistency
7. Fair consideration for university & public
8. Objective decision-making

Nine Points to Consider in Licensing University Technology (March 2007)

- *1. Reserve the right to practice licensed inventions for University and other non-profit & government organizations*
  - *Preserve ability of all universities to perform research (including research sponsored by commercial entities) and publish results of research*
    - *Recitals*
    - *Reservation of rights*
- *2. Exclusive licenses structured in a manner that encourages technology development and use*
  - *Necessity for significant investment of time & resources may require exclusive license. Don't grant overly broad rights (all fields of use). All uses may not be appreciated at time of initial licensing.*
    - *Exclusive in limited field*
    - *Diligent development (termination or NXL if not met)*
    - *Recovery of unused fields after certain period*
    - *Mandatory sublicenses*

Nine Points to Consider…..

3. *Strive to minimize the licensing of future improvements*
   - *Enslave a faculty member's research program to the licensee. Can reach through to other faculty. Limit to inventions dominated by original licensed patents.*
     - *…continuations-in-part (but only to the extent the claims thereof are enabled by disclosure of the parent application)….*
4. *Anticipate and help to manage technology transfer-related conflicts of interest*
   - *Especially a problem for faculty start-ups but also if have interest in any potential licensee*
     - *TT100. Statement of Economic Interest; position (management, employee, officer, advisor), investment/equity (or spouse or child) worth >$, income (loan gift, consulting) within last year >$*
     - *Licensing officer conflicts*

Nine Points to Consider…….

5. Ensure broad access to research tools

- *Consistent w/ NIH guidelines, charitable foundations, mission of university, publication requirements*
  - *Non Exclusive License*
  - *XL for sale, but not use, of patented technology*

- *6. Enforcement action should be carefully considered*
  - *Primary mission is to use patents to promote technology development for the benefit of society. Litigation seldom the preferred option.*
    - *Contractual or ethical obligations to protect rights of existing licensees*
    - *Blatant disregard of infringer for University's rights—won't take reasonable licensee*

Nine Points to Consider…..

7. *Mindful of export regulations*
   - *Federal laws governing how information, technologies and commodities can be transmitted overseas to anyone (including US citizens) or to a foreign national on US soil (deemed export).*
     - *Fundamental research exclusion can be affected if license conf info'*
     - *Check if license w foreign company*
     - *Licensee agrees to observe all Us and foreign laws wrt transfer of LP and technical information*

8. *Mindful of implications of working with patent aggregators*
   - *Good patent aggregators--add value by advancing technology or overcoming legal barriers (freedom to operate)*
   - *Bad patent aggregators (patent trolls)—extracts payments in absence of any enhancement to licensed technology*

Nine Points to Consider…..

9. Consider including provisions that address unmet needs such as neglected populations or geographic areas, improved therapeutics, diagnostic and agricultural technologies for the developing world

"Universities should strive to construct licensing arrangements in ways that ensure that [] underprivileged populations have low- or no-cost access to adequate quantities of [] medical innovations."

"Licensing activities alone,, without significant added funding, can, at most, enhance access to medicines for which there is a demand in wealthier countries. Diseases that afflict only the global poor have long suffered from a lack of investment in R &D: the prospects of profit do not exist to draw commercial development, and public funding for diseases suffered by those who live far away form nations that can afford it is difficult to obtain and sustain."

Technology Transfer Office

UC San Diego