



OFFICE OF INTELLECTUAL PROPERTY & INDUSTRY SPONSORED RESEARCH

Benjamin Chu, Ph.D.
Technology Transfer Officer
bchu@research.ucla.edu



What is Intellectual Property?

- Intellectual property are creations of the mind that are protected by law from unauthorized use

Patent	Idea
Trade Secret	Idea
Copyright	Expression of an idea
Trademark	Expression of an idea

United States Patent [19]

Rose et al.

[11] Patent Number: **4,920,989**

[45] Date of Patent: **May 1, 1990**

[54] METHOD AND APPARATUS FOR AIDING IN THE REDUCTION OF INCIDENCE OF TOBACCO SMOKING

[75] Inventors: **Jed E. Rose**, Venice; **Murray E. Jarvik**, Santa Monica; **Karce D. Rose**, Healdsburg, all of Calif.

[73] Assignee: **Regents of the University of California**, Alameda, Calif.

[21] Appl. No.: **157,536**

[22] Filed: **Feb. 19, 1988**

Related U.S. Application Data

[62] Division of Ser. No. 727,525, Apr. 25, 1985.

[51] Int. Cl.³ **A24F 47/00; A61K 9/00**

[52] U.S. Cl. **131/270**

[58] Field of Search **514/314; 604/896, 897, 604/46; 131/270**

[56] References Cited

U.S. PATENT DOCUMENTS

4,473,083	9/1984	Maganas	604/46
4,579,858	4/1986	Ferno et al.	131/270
4,597,961	7/1986	Eiscorn	514/314
4,635,651	1/1987	Jacobs	131/220

FOREIGN PATENT DOCUMENTS

0930668	7/1973	Canada	604/897
---------	--------	--------	---------

OTHER PUBLICATIONS

Tobacco Alkaloids and Related Compounds edited by Von Euler, pp. 3-13, A Pergamon Press Book, 1965.

"Bronchial Effects of Aerosolized Δ^9 -Tetrahydrocannabinol in Healthy and Asthmatic Subjects" by Tasbin et al., *American Review of Respiratory Disease*, vol. 115, 1977.

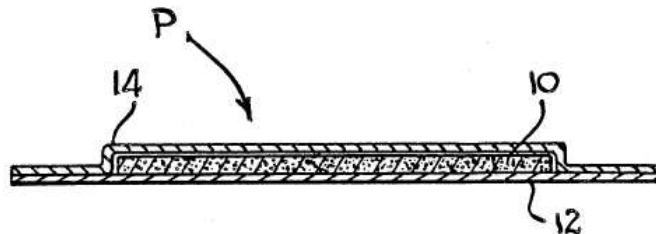
"Drug Permeation through Human Skin: Theory and In Vitro Experimental Measurement" by Chandrasekaran et al., *AICHE* (vol. 21, No. 5), Sep. 1975, pp. 985-993.

Primary Examiner—V. Millin
Assistant Examiner—J. L. Doyle
Attorney, Agent, or Firm—Robert J. Schaap

[57] ABSTRACT

A method of aiding in the reduction of incidence of tobacco smoking. The method comprises applying a patch containing nicotine to the skin of a person with whom smoking reduction is desired and allowing the nicotine to transdermally migrate into the person's bloodstream to achieve a desired systemic nicotine level. The method also comprises the simultaneous administration of a nicotine containing aerosol spray to the oral cavity of the user in order to provide the desired sensations in the respiratory tract to which the user is accustomed from normal tobacco smoke. A combination of the spray and transdermal patch is also provided such that an occlusive patch is applied to the skin of the person with whom smoking reduction is desired and the nicotine containing aerosol spray is delivered to the oral cavity simultaneously with the application of the nicotine from the patch.

29 Claims, 3 Drawing Sheets



What is a Patent?

- A right granted to an inventor by the Government to ***exclude others*** from: making, using, importing, selling, or offering to sell the invention for the life of the issued patent.
- “**Exclusion**” rather than “**right to use**” is key!
- The invention is defined by the allowed **claims** of the issued patent

The Patent Contract

- In exchange for the term of exclusivity provided by the issuance of a patent, the Inventor agrees to disclose **fully** the invention to the public.
- “**Fully**” is the operative word.

Patent specification **must**:

- **Enable** one skilled in the art to practice the invention; and
- **Describe** the **best mode** for carrying out the invention.

What is the life of a patent?

- 20 years from the filing date of a utility application
- 14 years from issuance for a design patent
- There are no enforceable rights during pendency of the patent application.

What is Patentable Subject Matter?

- 35 U.S.C. § 101 of the Patent Act:
“Whoever invents or discovers any new and useful *process, machine, manufacture, or composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor”
- U.S. patent law allows the patenting of “anything under the sun made by man.”
U.S. Supreme Court: Diamond v. Chakrabarty,
447 U.S. 303 (1980) (genetically engineered bacteria that broke down crude oil)

What are the “**patentability tests**”?

1. **Usefulness** – 35 U.S.C. § 101.
2. **Novelty** – 35 U.S.C. § 102.
3. **Non-Obviousness** – 35 U.S.C. § 103.

What is Patentable?

Composition of Matter (most valuable for medical/life science):

- Isolated cell or gene
- Chemical compound for a drug

Processes:

- Method of culturing cells

Machines:

- Medical devices

Manufacture

- Method of dry, isotropic selective etching for manufacture of silicon devices (xenon difluoride silicon etch for MEMS)

What is not patentable?

- Laws of nature
- Physical phenomena
- Abstract ideas
- Products of nature that are not altered by human intervention

They are in essence "the basic tools of scientific and technological work, . . . free to all men and reserved exclusively to none."

Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

What about plants, cells, and genes?

- “Isolated” or “Purified” cells (and proteins and genes derived from them) are not forms found in nature
 - Wisconsin Alumni Research Foundation owns three patents by James A Thompson on primate and human embryonic stem cells
 - Broad, foundational patents which claim both the cells (composition of matter claim) and the method of isolating them
- Genes exist in nature, but not in the “isolated” form
 - Myriad Genetics and University of Utah Research Foundation: BRCA1 and BRCA2
 - March 29, 2010 - genes for breast ovarian cancer invalidated in US District Court: Association for Molecular Pathology vs. United States Patent and Trademark Office (lawyer for the plaintiff: the ACLU)
 - Judge ruled that the idea of “isolating” a gene is a lawyer’s trick, and gene patents involve a “law of nature”: isolated DNA “is not markedly different from native DNA as it exists in nature.”
- Genetically engineered bacteria and plants are modified by man into a form not found in nature.
 - *U.S. Supreme Court: Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (genetically engineered bacteria that broke down crude oil). The creation of a bacterium that is not found anywhere in nature, constitutes a patentable "manufacture" or "composition of matter" under Section 101. Moreover, the bacterium's man-made ability to break down crude oil makes it very useful.

Patentability Requirements

- To be eligible for a U.S. patent, the application must be filed ***within 1 year*** of an enabling public disclosure
- To be eligible for a patent in most of the rest of the world, the patent application must be filed ***before*** an enabling public disclosure

Types of Public Disclosures

- Journal article online or in print
- Conference abstract online or in print
- Poster presentation
- Seminar, lecture or workshop open to the public
- Disclosure on a website
- Distribute samples
- Offer for sale or sell the product
- Demonstrate a prototype to a public group

Confidential Disclosures

- Meetings where all participants have agreed to non-use and non-disclosure
- Submitted manuscripts
- Grant applications until funded
- Under a written non-disclosure agreement

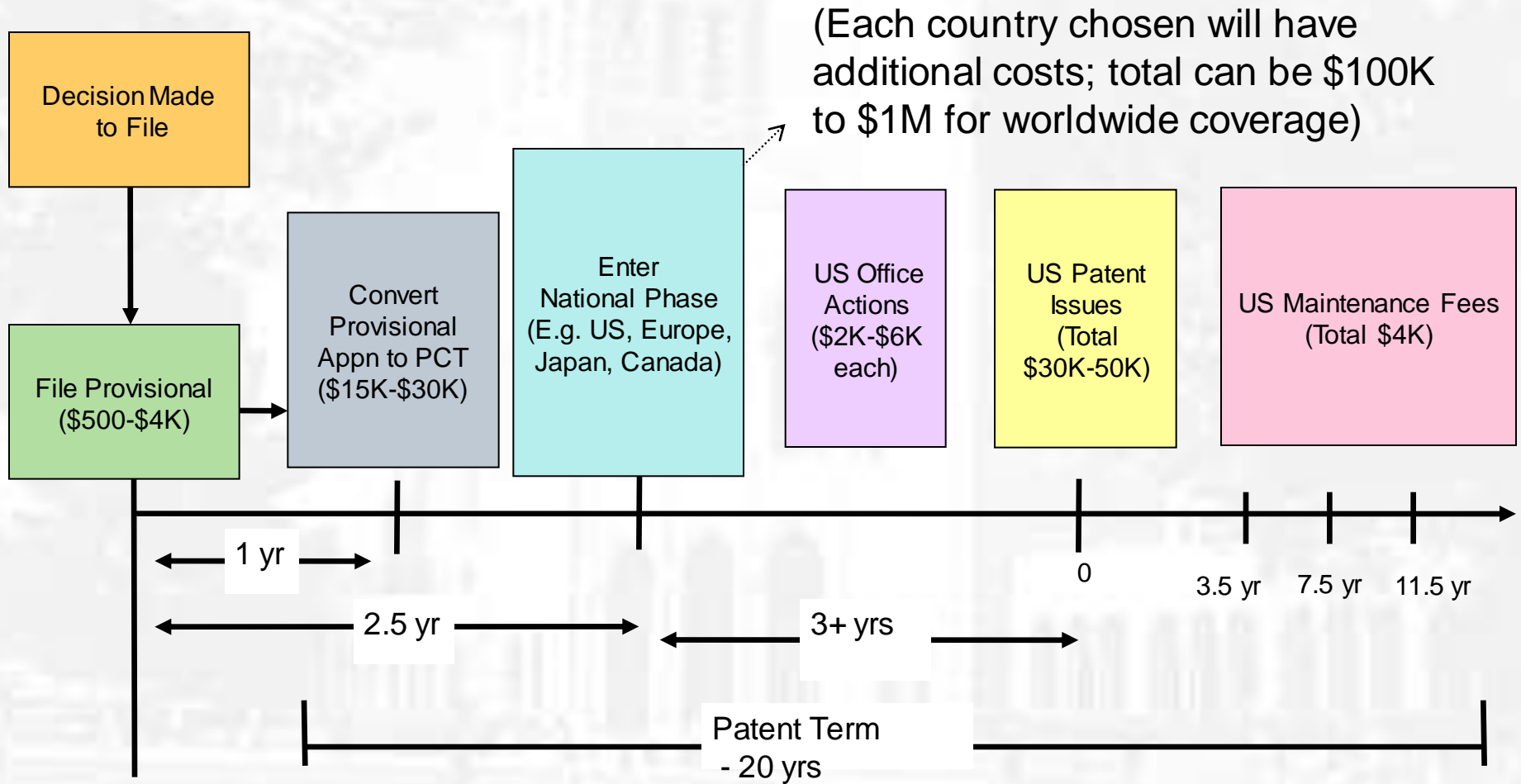
Who is an Inventor?

- Inventor is one who contributes to the conception of the invention, simply reducing the invention to practice is not inventive.
- Inventorship cannot be determined until the patent application claims are drafted, and can't be finalized until the claims are allowed.
- **Co-author does not necessarily mean co-inventor.**

Deciding between competing applicants: Lack of global harmony

- Outside the US: **First to file**
- US: **First to invent**. Therefore:
 - All experimental protocols and data should be entered in a notebook.
 - Notebook pages should be numbered and bound.
 - All entries should be dated and witnessed by someone who understands entry but is not a co-inventor.

Patent Timeline



- Trade secrets:
 - are not known to the public,
 - are protectable as long as the information remains secret, and
 - have been the subject of “reasonable efforts” to maintain confidentiality
 - Can include technical information, business plans, marketing plans, customer lists, etc

Copyrights

- Protection of an original work of authorship fixed in a tangible medium
- Protects the expression of the idea, not the idea itself
- Protects against copying of the idea of your work, but does not protect against the creation of similar works or of independently created works (even if it is exactly the same as yours!)
- Protects literary works, dramatic works, pictures, graphics, sculptures, movies, sound recordings, building designs, software, etc.

What can be copyrighted?

Copyrightable works include the following categories:

1. literary works;
2. musical works, including any accompanying words
3. dramatic works, including any accompanying music
4. pantomimes and choreographic works
5. pictorial, graphic, and sculptural works
6. motion pictures and other audiovisual works
7. sound recordings
8. architectural works
9. Software

Rights of copyright owner

- To **reproduce** the work,
- To **perform** the work publicly,
- To **distribute** copies of the work,
- To **display** the work publicly,
- To **make derivative works** based upon the work.

...and to exclude others from doing the same

Trademarks

- Word, symbol, name, device, color or combination thereof that identify the origin of goods or services
- Trademarks – identify goods
- Servicemarks – identify services
- Trade dress – identifies the look of the brand – a restaurant or the shape of the coke bottle



The Coca-Cola Company

Trademarks

- Goal is to prevent customer confusion
- Goal is NOT to help Coke build its brand
- Mark needs to be distinctive and needs to uniquely identify the product, service, or brand
- Test is for likelihood of confusion of the customer
- Competitors can sell similar products or services, but it can't be confusingly similar
 - Pepsi's mark is not at all confusing with Coke
- Balance of public rights and private rights
- Trademark lasts as long as it is being used in commerce.
- Trademark registration renewable every 10 years.

Genericide

Ever used these names as verbs?



Victims of genericide:

escalator, kleenex, aspirin, granola, zamboni, thermos...



OFFICE OF INTELLECTUAL PROPERTY &
INDUSTRY SPONSORED RESEARCH

The Mission of UCLA Tech Transfer

- **Educating the academic community about appropriate methods for protecting intellectual property**
- **Accelerating the development of UCLA discoveries for the public good**
- **Promoting economic growth in California**
- **Facilitating collaborations with industry for next-generation scientific breakthroughs.**

Bayh-Dole Act (35 U.S.C. §200-212)

- Federal law enacted in 1980
- A fundamental change to patent ownership.
- University owns patent rights to inventions sponsored by the U.S. government
- University reports inventions to government and tries to commercialize
- Government gets a non-exclusive license
- Preference for Small Business licensee
- Royalties must (1) be shared with inventor and; (2) be used for research and education. UCLA policy is 50% back to UCLA general fund, 15% to the department, and 35% to inventor(s).

By the Numbers: Licensing

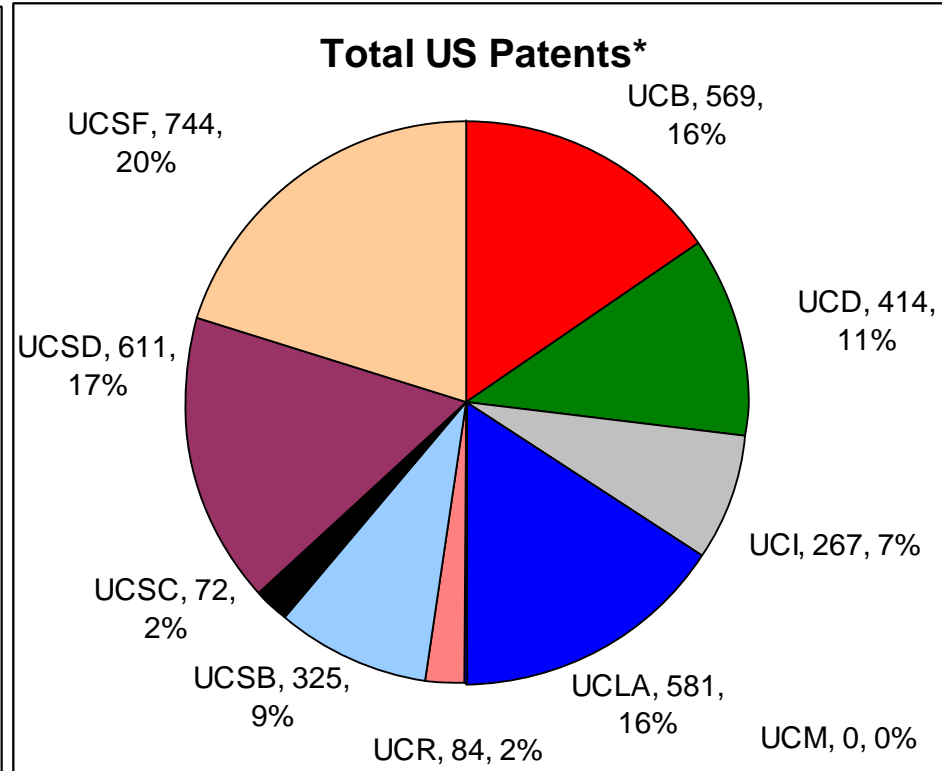
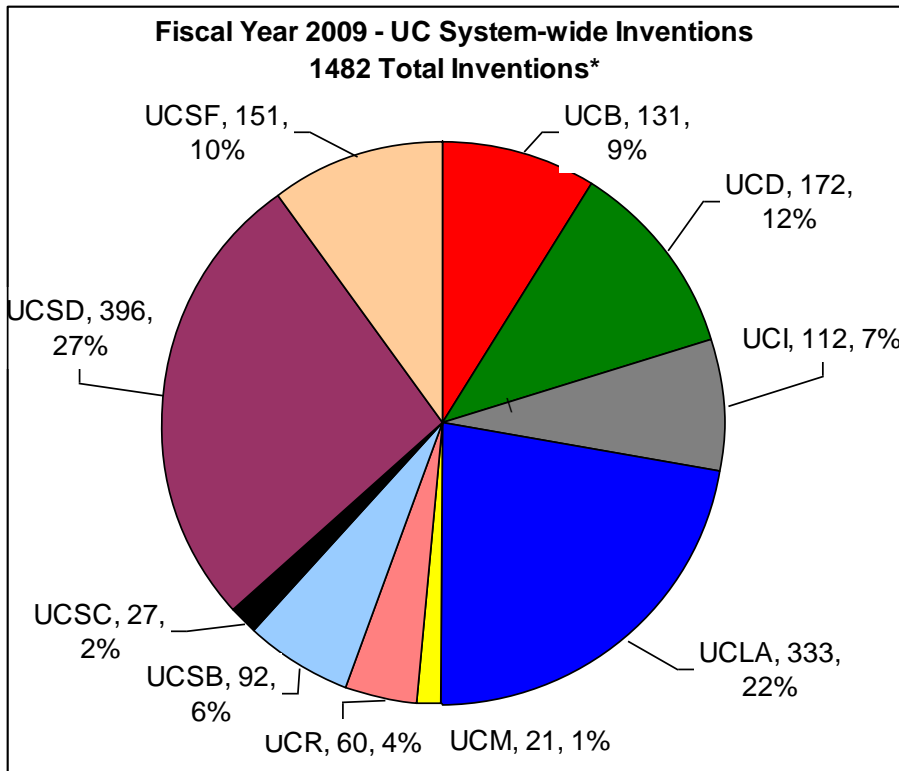
- **UCLA Licensing Income for FY2010 - \$27.5 M**
- **Inventor share (faculty and students) is 35%**
- **2018 total active inventions under management**
- **379 new inventions in FY2009-2010 (~50% from engineering/physical science)**
- **27 Start-ups formed (#1 in UC)**

By the Numbers: Material Transfer Agreements and Industry Sponsored Research

Fiscal Year 2010

- **Total Material Transfer Agreements: 1,037**
- **Total Number of Industry Contracts: 444**
- **Total Industry Sponsored Research Dollars:
\$28,347,563**

UC-Wide Inventions – By Campus



*Inventions having inventors from more than one campus are counted multiple times, once for each campus with an inventor.

*Patents associated with inventors from more than one campus are reported multiple times in this exhibit.



OFFICE OF INTELLECTUAL PROPERTY &
INDUSTRY SPONSORED RESEARCH

Licensing Income by Campus*

UCB	\$7,202,000
UCD	\$10,846,000
UCI	\$5,989,000
UCLA	\$29,215,000
UCM	\$63,000
UCR	\$2,502,000
UCSB	\$5,010,000
UCSC	\$320,000
UCSD	\$26,631,000
UCSF	\$32,867,000
Other**	\$5,403,000

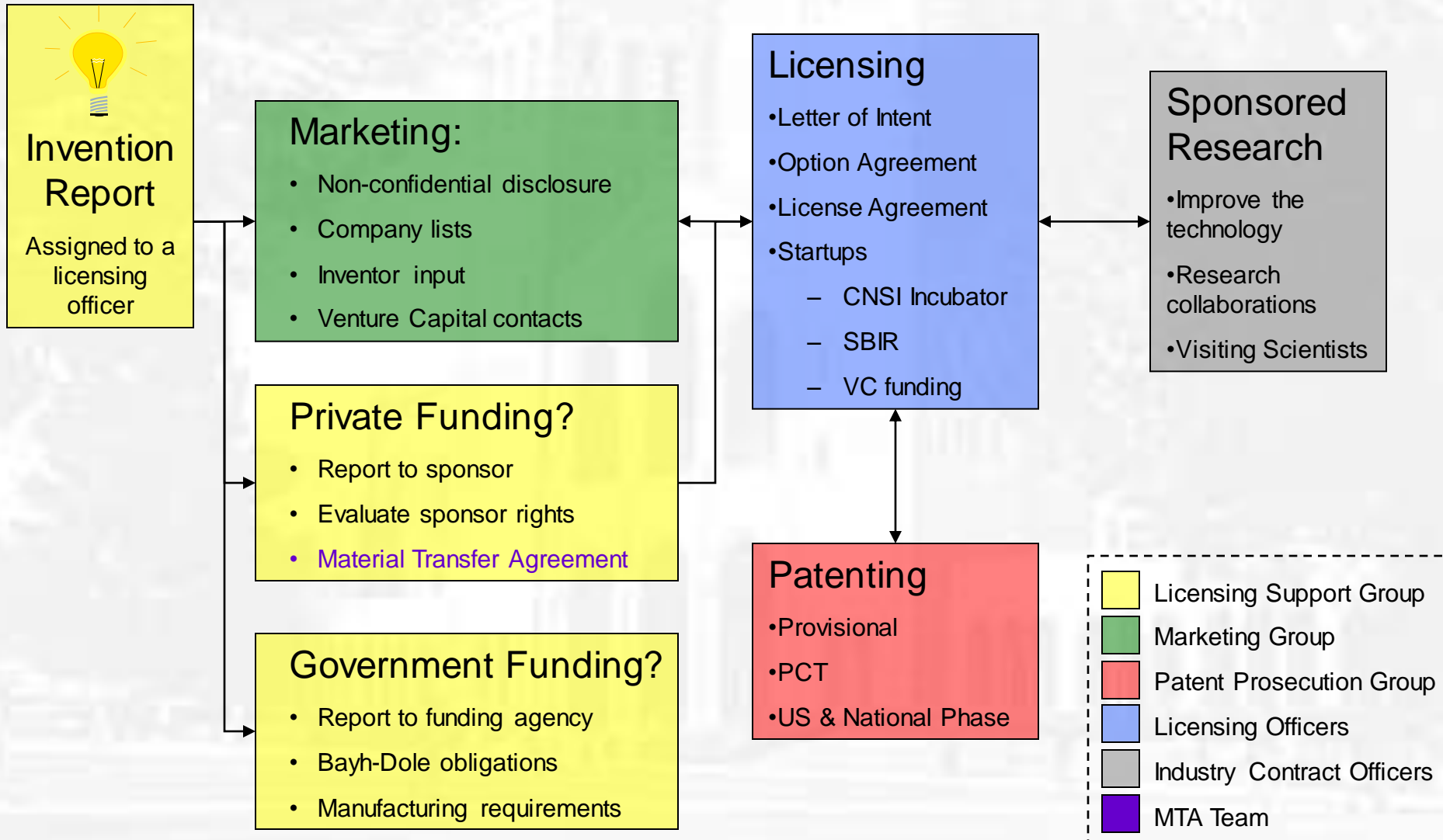
*Fiscal Year 2009, Total licensing income consists of two components: royalty and fee income, and patent/legal reimbursements.

**Total licensing income, primarily from a portfolio of IAS-managed DOE Laboratory inventions, most disclosed prior to the establishment of the Laboratory-based licensing offices.

What do we do?

- **Manage all inventions created by UCLA faculty, staff, postdocs, and students**
 - **Accept invention reports from the above people**
 - **Assign invention to a Licensing Officer who analyzes the report for several key aspects (obligations to third parties, patentability, commercial potential, potential licensees)**
 - **Make a decision on whether or not to file for patent protection**
- **Market the inventions to find a commercial partner**
- **Negotiate, sign, and manage all of the licensing agreements giving companies or start ups rights to practice university intellectual property.**
- **Negotiate, sign and manage all sponsored research agreements with industry sponsors.**

University Technology Process



Patent Commercialization Factors

- The inventor's lab has funding for ongoing development of the technology through initial proof of concept (e.g. *in vivo* testing, prototype development, etc.)
- potential to address a real unmet need in the market
- well-differentiated from competing solutions already on the market
- The patent claims would be enforceable (i.e. "method" patents are hard to enforce)
- published in high profile peer-reviewed journals
- Company feedback has been positive as to its potential value and feasibility
- Clear development milestones have been identified that would make this commercially relevant
- Inventor is interested in the possibility of collaborating with potential corporate partners and/or investors to get this technology to market

Types of Agreements

Non-Disclosure Agreement

- Allows for disclosure of confidential information
- Used to protect your intellectual property and unpublished work
- Frequently used by two parties to explore potential collaboration

Material Transfer Agreement

- Allows for transfer of materials to/from a Company/University
- i.e. cell lines, mice, tissue samples, silicon wafers...
- Protects ownership of material
- Protects against liability

Sponsored Research Agreement

- Sets out a scope of work and budget for work to be done at UCLA (paid for by a company)
- Sets out IP rights for inventions conceived and reduced to practice w/in the scope of work

Types of Agreements

Letter of Intent

- Short term (months)
- Grants a period of exclusive negotiation
- Financial commitment: relatively low, if no patent costs incurred

Option Agreement

- 1-2 year term
- Company can practice patent rights, but cannot sell a product
- Typically an exploratory and fundraising period for the company
- Financial commitment: Medium

License Agreement

- Term: Life of the patents
- Company can sell a product
- Financial commitment: a company will have funding in place before committing to a license

What's in it for you?

- **UCLA policy is 50% back to UCLA general fund, 15% to the department, and 35% to inventor(s).**
- **All UC employees are required to disclose to our office any potentially patentable inventions created while employed by UC (employment agreement).**
 - **UC owns all IP made by its employees or persons utilizing university resources**
- **If the Licensing Officer concludes that a patent should be filed, our office usually covers the costs of patenting until a commercial partner is found.**

LLC, S-Corp, or C-Corp?

Characteristic	LLC	S-Corp	C-Corp
Personal Liability	Members not typically liable	Shareholders not typically liable	Shareholders not typically liable
Management	Members choose their own structure (operating agmt)	Shareholders elect directors, officers manage day-to-day	Shareholders elect directors, officers manage day-to-day
Taxation	Pass through	Pass Through	Corporate then individual
Double Taxation	No	No	Yes. Corporate level, then distributed to shareholders as dividends
Capital Raising	May sell interests, but subject to operating agreement	Shares of stock sold, but limitations prevent corporations from owning shares of S-corp stock	Shares of stock are easily transferred
Operations	Some states have more requirements than others	Annual meetings, board of directors mtgs., stockholder mtgs.	Annual meetings, board of directors mtgs., corp. minutes, stockholder mtgs.
Ownership rules	Unlimited number of members	Up to 100 shareholders; only one class of stock	Unlimited number of shareholders and stock classes