Inventions, Patents, and Working with Companies

March 3, 2011
Presented by Ken Holroyd
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.
The United States

The President of the United States shall have Power to make all Appointments whatsoever, in such Manner as he shall think proper; and to advise and consent to the Appointment of Ambassadors, other public Ministers and Consuls, to make Treaties, to nominate Judges of the Supreme Court, and to appoint Judges of the inferior Courts; to grant Reprieves and Pardons for Offenses against the United States, except in Cases of Impeachment; to conclude Peace, and to negotiate Lewis and Treaties, but with the Advice and Consent of the Senate; to appoint Ambassadors, other public Ministers and Consuls, to receive Ambassadors and other public Ministers; to decree War, and grant Letters of Marque and Reprisal; to appoint Ambassadors, other public Ministers and Consuls, to receive Ambassadors and other public Ministers; to appoint Ambassadors, other public Ministers and Consuls, to receive Ambassadors and other public Ministers; to appoint Ambassadors, other public Ministers and Consuls, to receive Ambassadors and other public Ministers; to appoint Ambassadors, other public Ministers and Consuls, to receive Ambassadors and other public Ministers.
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
1.4 Million Patent Examination Backlog at USPTO Projected for 2012
Patent Law Reform?

Different Issues in Pharmaceuticals vs. Electronics and Media
“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”
[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.

[German, singable]

Du hast eine Idee
Und läßt sie dir patentieren.
Und hoffst auf Gewinne
Durch Lizenzgebühren.
Du verwertet tut diese
Vermehrung der Software-Riese.
Du streckst, das dir gebührt!
Die Gedanken sind patentiert.

[French, singable]

Si toi tu as une idée
Et que la brevetttes,
N’espère pas gagner
En vendant des licences.
Un géant utilise
Ton idée et tu penses
Qu’ils va te dédommager ?
Nos pensées sont brevétées !

[English, singable]

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[German, singable]

Die Gedanken sind freil!
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 freil!

[English, not singable]

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[French, singable]

Nos pensées sont libres :
Qui peut les connaître ?
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 ?

[German, singable]

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Thoughts are patented.

[German, singable]

Die Gedanken sind patentiert.
Man darf sie besitzen.
Es sind angeschmiert,
die schmutzigen und schwitchen.
Man kann sie abmahnen
und kämpfen abhauen
mit Gebühren ungeniert.
Die Gedanken sind patentiert.

[English, not singable]

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“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)
Bayh-Dole Act

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
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 over 15 years ago

- Investment in 200-300 patents for HIV compound structures

- Expensive, risky litigation to enforce patent rights
# Sharing of Licensing Income
*(After Patenting/Licensing Expenses are Reimbursed)*

<table>
<thead>
<tr>
<th>PRESENT POLICY</th>
<th>Inventor/Creator</th>
<th>Inventor’s Lab</th>
<th>Inventor’s Dept</th>
<th>Inventor’s School</th>
<th>Tech Promotion Fund</th>
<th>Tech Research Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>University Central:</strong> First $100K per year</td>
<td>50%</td>
<td>10%</td>
<td>0%</td>
<td>30%</td>
<td>10%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>University Central:</strong> Above $100K per year</td>
<td>40%</td>
<td>10%</td>
<td>10%</td>
<td>25%</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Medical Center:</strong> First $100K per year</td>
<td>50%</td>
<td>0%</td>
<td>20%</td>
<td>20%</td>
<td>10%</td>
<td>0%</td>
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<td>10%</td>
</tr>
</tbody>
</table>

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.
$200B + Research

100,000 disclosures (discoveries)

Opportunity Assessment (Triage)

- Commercial potential
- Technical advantages
- Protectability
- Inventor profile

50% do not move forward

50,000 Patent Applications

25,000 Licenses

2,500 Start-ups

Positive exit (liquidation)

License Income (3.5% per year)

125 > $1M/year
50% <$10k cum.

50% do not move forward

$2M : 1 disclosure

(10% lics / 2.5% discl.)

$200B + Research

Autom Data FY1991-2000

Created by L Berneman, UPenn, modified by J Fraser, FSU
## Where Do the Licenses Go?

<table>
<thead>
<tr>
<th>FY</th>
<th>Total Licenses /Options</th>
<th>Start-Ups</th>
<th>Small Co’s</th>
<th>Large Co’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>’99</td>
<td>3,792</td>
<td>12%</td>
<td>50%</td>
<td>38%</td>
</tr>
<tr>
<td>’06</td>
<td>4,963</td>
<td>15%</td>
<td>49%</td>
<td>33%</td>
</tr>
</tbody>
</table>
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
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
Healthy Challenge...For All of Us!

The Valley of Death

Basic Research; Invention

Political picture of the “gap”

“Valley of Death”

Applied Research; Innovation

www.nist.gov
Technology Transfer and Enterprise Development

- **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

Research Funding

Impact and Income
484 Projects with 180 Companies
Pharma Dominates
$125 Million of Corporate Sponsored Research

Industry Mirror?

Project Length Averages 1.7 Years
About 15% of Total Research Revenues
Increase in Corporate Sponsored Research
Why?

Vanderbilt Medical Center

CTSA Award for Vanderbilt Sept '07

Total ($ Millions)

Mar '07 Aug '07 Jan '08 Jun '08 Nov '08
Unified Leadership for Clinical Research Processes & Improvement

VICTR

GRANTS AND CONTRACTS

CLINICAL TRIALS OFFICE

Gordon Bernard, MD CTSA PI and VICTR Leader

IRB

RESEARCH SUPPORT SERVICES

RESEARCH OPTIMIZATION COMMITTEE
Master Agreements Shorten Clinical Trial Contract Time

- Days
- 1st Negotiation
- Final Negotiation
- Contract Finalized

- Blue: Master
- Maroon: Stand Alone
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 is not too high.

- Challenges to validity of a patent often focus 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 to a person having ordinary skill in the art to which the claimed subject matter pertains.
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
Music City