Patenting and Licensing of University Research in the United States:

Historical Trends and Recent Developments

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Markets for Patents Conference at the University of Michigan

Mary Sue Coleman on University Research Commercialization

“If the key component of our future economic development is innovation, then America’s research universities are among its most valuable assets... higher education and our technology transfer operations play a pivotal role, one that has become more central to America’s economic prosperity than ever before.”

Prominent University Technologies

Vitamin D

COUMADIN (Warfarin Sodium Tablets, USP) Crystalline
The Pre-World War II Era

- Frederick Cottrell, a University of California, Berkeley professor and inventor, founded the Research Corporation in 1912 to manage university patents and support scientific research.
- University patenting drew on research collaboration with industry in a number of sectors.
- Considerable ambivalence within U.S. universities over a direct university role in management of patenting and licensing.
Frederick Cottrell on University Licensing

“A certain minimum amount of protection is usually felt necessary by any manufacturing concern before it will invest in machinery or other equipment, to say nothing of the advertising necessary to put a new invention on the market.”

“That a number of meritorious patents given to the public absolutely freely by their inventors have never come upon the market chiefly because ‘what is everybody’s business is nobody’s business.’” (1912)

The Postwar Era

Growth in federal funding of university research during and after WWII led a number of federal agencies to require formal patent policies at universities conducting federally sponsored research.

By the late 1950s, most research universities had adopted formal policies:
- But at least some of these policies, especially in medical schools, discouraged or prohibited patenting.
- Many universities “outsourced” patent and licensing management to entities such as the Research Corporation.
- Public universities appear to be more active in direct management of patenting and licensing.

US Research University Patents % of all Domestic-Assigned US Patents, 1963-1999
The Bayh-Dole Act of 1980

Enacted by Congress to encourage commercial development of federally funded inventions in university and government labs

- The Act enabled institutions to obtain patents on inventions and to license these to private parties, including exclusive licenses
- Bayh-Dole replaced a complex web of Institutional Patent Agreements (IPAs) between individual federal funding agencies and individual universities

The Economist on Bayh-Dole:

“Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980.”

“Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own.”

“The Economist”

“Innovation’s Golden Goose”
What the Bayh-Dole Act Doesn’t Say

No distinction among types of inventions
• Computer circuit = cell regulatory pathway?

No distinction between use of inventions
• Developing and producing the invention for resale
• Using the invention for research

Other Developments During the 1970s and 1980s

• *Diamond v. Chakrabarty*: Life forms are deemed patentable by the US Supreme Court in 1980

• Creation of the Court of Appeals for the Federal Circuit, 1982

Other Developments During the 1970s and 1980s

• Biomedical academic research funding grows by roughly 8%/yr in real terms from 1960s onward
• “War on Cancer” spurs research in molecular biology

• Barry Manilow album hits #1
“Before & After” Bayh-Dole at the University of California and Stanford

- Growth in annual invention disclosures at both universities accelerated before 1980
- Biomedical portion of overall disclosures also increased before 1980
- At both institutions, biomedical inventions’ share of patenting and licensing income grows before and (especially) after 1980

Licensing Income at Columbia, Stanford, and UC

- Licensing income grew significantly from 1970 to 1995 (1985 to 1995 at Columbia)
  - (e.g., from 180k$ to $38M at Stanford)
- Biomedical licenses account for a large proportion of top 5 earners (over 90%)
- Top 5 licenses generate a large proportion of gross income (UC 66%, Stanford 85%, Columbia 94%)

The Skewed Distribution of Innovation Value

<table>
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<th>Date set</th>
<th>Number of observations</th>
<th>Percent of value in top 10%</th>
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<tbody>
<tr>
<td>German patents</td>
<td>772</td>
<td>84</td>
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<tr>
<td>US patents</td>
<td>222</td>
<td>81–95</td>
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<td>Harvard patents</td>
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<td>1980s drugs</td>
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Source: Scherer and Harhoff (2000)
Recent History

1991-99: Tripling of US patent applications and licenses:

- University of California $80 million royalties in 1999 (95% biomedical);
- Columbia $75 million (2000 est.)
- 15 schools earned over $9 million

Recent History (2)

But,

- Revenues depend on a few blockbusters (e.g. Taxol); big fluctuations as patents end
- 117 schools had revenues below $9 million
- Revenues are far less than industry pays for sponsored research
- Overhead: patent filing costs, counsel fees and tech transfer office expenses. Many technology transfer offices lose money.

Concerns about University Research Commercialization

“A danger was involved, especially should the experiment prove highly profitable to the university and lead to a general emulation of the plan. University trustees are continually seeking for funds and in direct proportion to the success of our experiment its repetition might be expected elsewhere . . . the danger this suggested was the possibility of growing commercialism and competition between institutions and an accompanying tendency for secrecy in scientific work.”

Frederick Cottrell (1932)
Concerns about University Patenting and Exclusive Licensing

- Patenting of “upstream” discoveries that are still some distance away from end-product development but are nonetheless of immediate interest to scientific researchers
- “Reach-through” provisions in licensing agreements
  - Patenting and exclusive licensing often not necessary for transfer of university technology to industry
  - Potential conflicts between scientific and financial interests jeopardizing universities’ “privileged position” in society

Recent Developments

- In early 1990s, Rochester scientist discovered genetic instructions for producing Cox 2, an enzyme that causes inflammation
- USPTO considered patent application for 8 years
- Rochester attempted to impose royalties on Pharmacia for Celebrex drug ($1.5B sales in 1999)
- Patent declared invalid in Federal court
- Supreme Court refused to hear appeal in November 2004

Recent Developments

- 1983 patents on inserting genes into cell DNA
- Columbia received $600 million in royalties until 2000
- Columbia sought special 15-month extension from Congress (worth $70-100M)
- In 1995 filed new patent application with minor differences
- In 2002, new patent awarded, Columbia demands additional royalties
- Several Pharma firms challenged patent in court, causing Columbia to withdraw royalty demands
- Columbia subsequently sought “reissue” of 2002 patent
Recent Developments

VS. DUKE

John Madey

- Physicist who developed high-powered laser
- Duke built special lab, received $MM in research grants
- Madey left Duke in late 1990s over dispute
- Madey filed patent infringement suit against Duke
- Duke claimed “research exemption”
- In 2002, CAFC rejected Duke’s claim
- Supreme Court refused to hear appeal

Summary

- Universities have been an important source of new technologies for decades
- Bayh-Dole Act important, but not the only factor explaining rise in university patenting and licensing
- With the rise of university patenting has come new frictions