

The Patent System and Biomedical Research

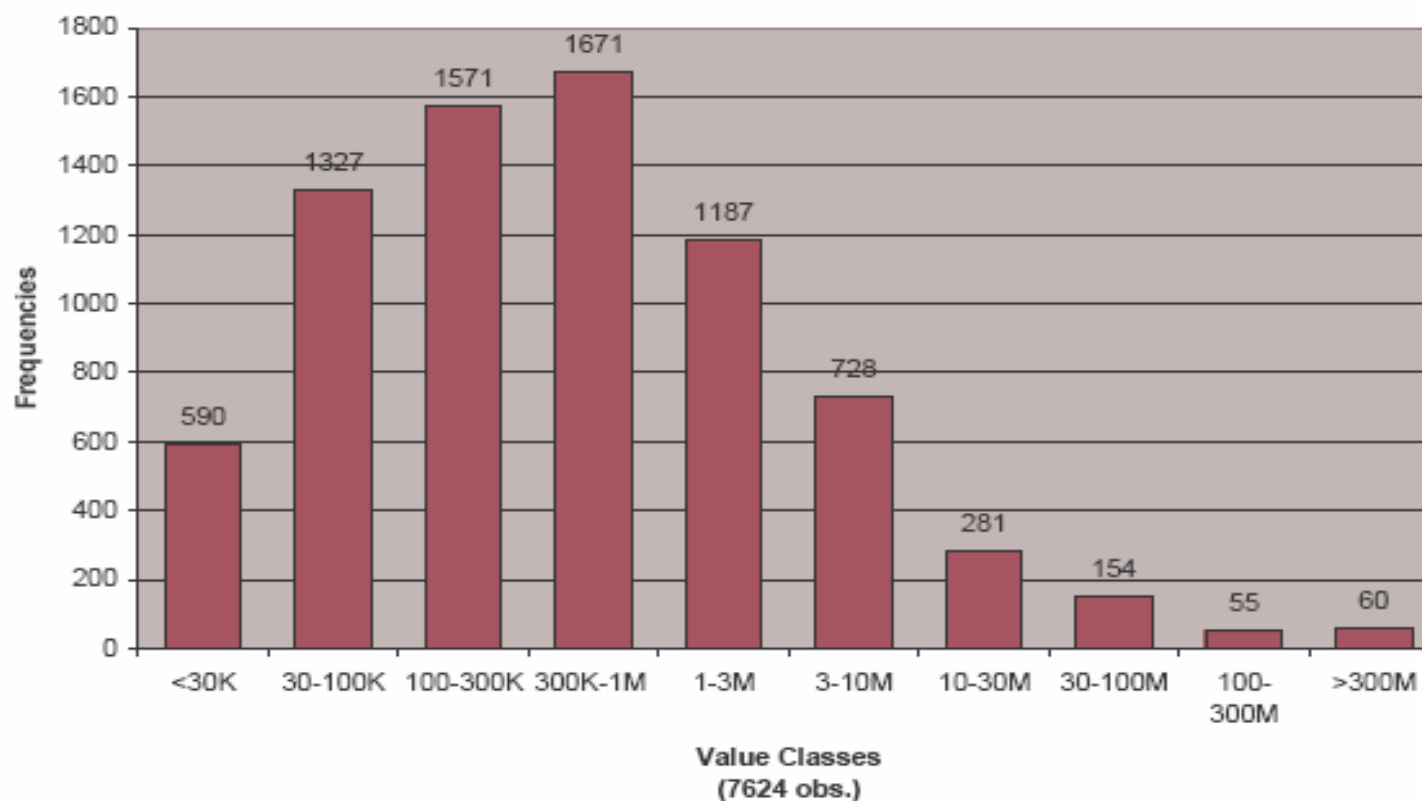
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Outline

- ⊕ Patents as incentive for innovation
- ⊕ Patents as facilitating a market for technology, and a division of innovative labor
- ⊕ Patents as roadblocks for commercialization
- ⊕ Patents as roadblocks for research

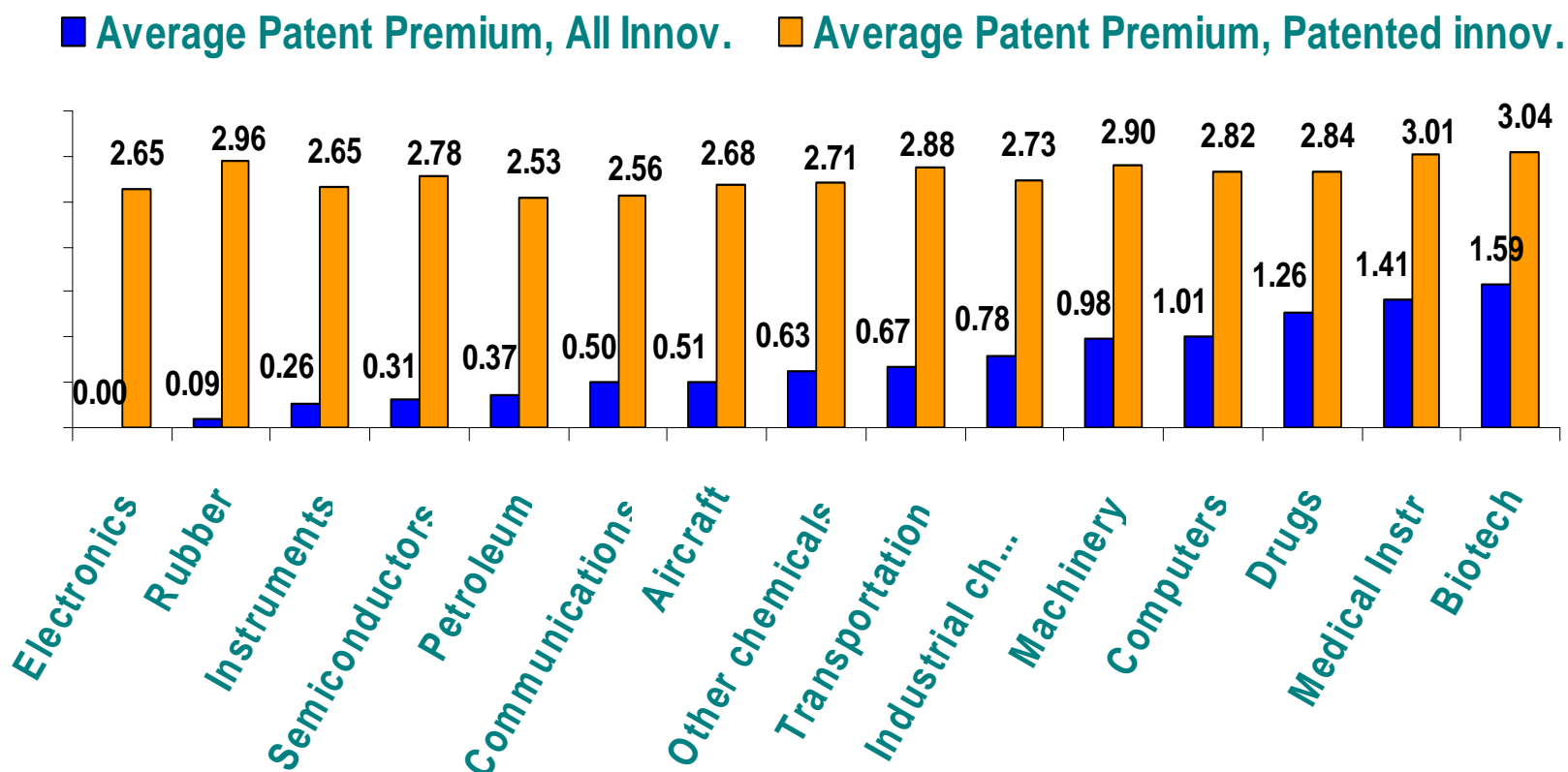
Distribution of Patent Values (Gambardella, Harhoff and Verspagen, “Value of patents”, 2005)



Patent value distribution is skewed but high average value between 300K and 1 million Euro

Patent protection is valuable, even in industries that do not patent a lot.

(source: Arora, Ceccagnoli and Cohen, 2003, NBER)



Patent protection stimulates R&D

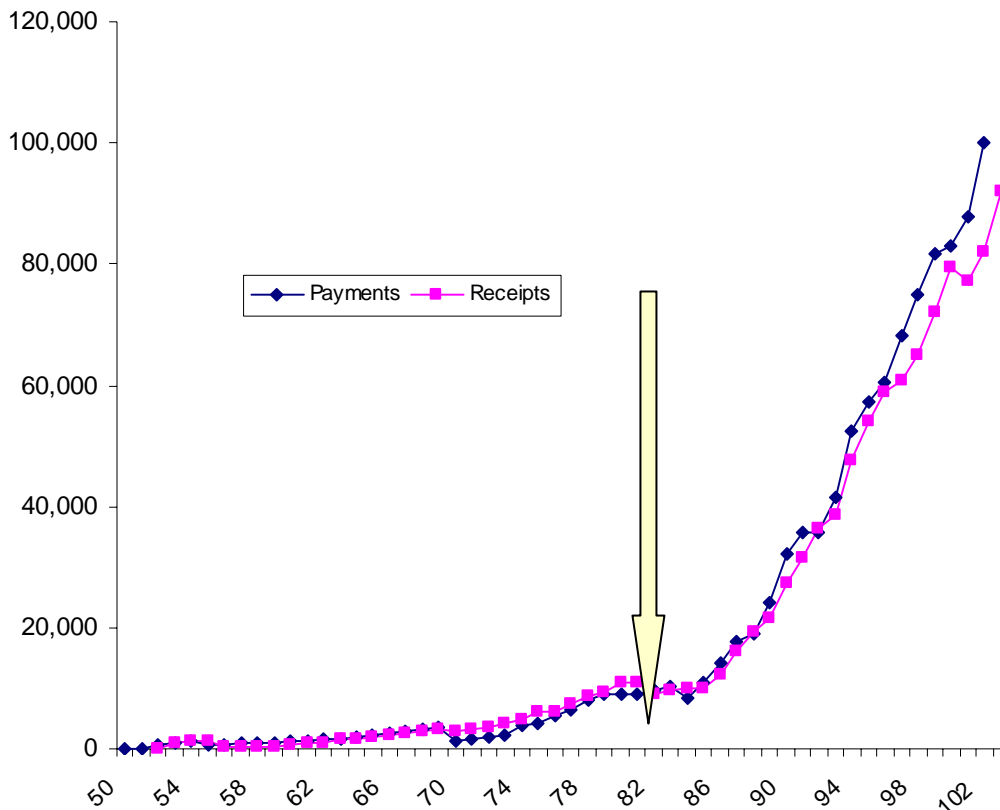
% increase in R&D and patenting with doubling of patent premium

	R&D	Patents/ R&D
All	33%	59%
Semiconductor	28	72
Biotech	48	28

source: Arora, Ceccagnoli and Cohen, 2003, NBER

Patents also facilitate technology licensing and specialized technology suppliers

Royalty and Licensing fees, World (1950-2003)
millions USD



Source: Athreye and Cantwell, 2005

U.S. International Transactions in Technology and Innovation, 2002

In millions of dollars

	Receipts	Payments
<u>Trade in Research and Development and Testing Services</u>		
Unaffiliated Transactions	1,142	1,028
Affiliated Transactions	6,500	1,600
<u>Industrial Process Licensing and Sale</u>		
Unaffiliated Transactions	4,039	2,049
Affiliated Transactions, estimated by author	11,269	7,341
Total	22,950	12,018

Source: Carol Robbins, 2006, BEA

Markets for technology are growing rapidly, globally and in the United States

There is a functioning market for technology

Distribution of IRS Receipts for Types of IP-Licensing Service Commodities across Industry Sectors, 2002, Billions of Dollars

Sector	Licensing of Rights to Use IP Protected as Industrial Property	Licensing of Rights to Use IP Protected by Trademarks	Licensing of Rights to Use IP Protected by Copyright	Licensing of Rights to Use a business format under a franchise	Payments for rights to use Natural Resources and Other intangibles	Total
Manufacturing	59.5	9.4	1.0	2.9	-	72.8
Distributive Services	1.0	6.9	0.1	5.1	-	13.1
Information	1.9	4.9	6.6	0.0	0.1	13.5
Finance and Insurance	0.2	0.7	0.0	1.4	0.0	2.4
Professional and Business Services	3.0	0.2	1.6	1.5	0.4	6.7
Other Industries	1.0	0.7	0.1	4.8	0.8	7.5
Total	66.6	22.8	9.4	15.7	1.3	116

The Market for Technology in the 1990s

Number and value of tech. licensing deals, 1985-97 (millions of 1992 dollars)

	SIC	Average value per trans	No. of trans.	Tot value of trans.	Average annual value.
Chemicals And Allied Products	28	12.88	3488	44931	3744
Industrial Machinery And Equipment	35	72.51	1330	96443	8037
Electronic & Other Electric Equipment	36	13.13	2450	32167	2681
Instruments And Related Products	38	13.10	862	11296	941
Communication	48	26.13	302	7891	658
Business Services	73	3.65	3640	13278	1106
Engineering & Management Services	87	11.02	625	6888	574
Others		35.03	1099	4221	352
Total		187.46	13796	217113	18093

Source: Arora, Fosfuri and Gambardella, 2001

- ⊕ **\$18-20 bn in licensing+royalty deals.**
- ⊕ **\$20-30 bn in R&D funding and equity investment for outsourced R&D**
 - Undercounting: LDC / E Europe under-reported.
 - Chemical process licensing under-reporting severe.
 - Exclude general purpose software licensing deals
- ⊕ **Market for Tech ≈ 10-20% of civilian R&D**
- ⊕ **Bio-Pharma is particularly licensing intensive**

Pharmaceuticals -Biotech

- The top 20 pharmaceutical companies are becoming increasingly dependent on licensing

- 19.5% of their total ethical sales were from licensed products in 2004 compared with 17.5% in 2002.
 - Projected to increase to 26.1% by 2010.

- Evolved eco-system of technology suppliers & tools suppliers (biotechs), technology market places, and specialized CROs and development organizations

- 18.00% of top-50 pharma products in 2002 (16.79% in terms of sales) have been jointly developed

2003 R&D in Pharma

PhRMA Companies	\$ 34.5 billion
Top 100 biotech firms	\$ 17.9 billion

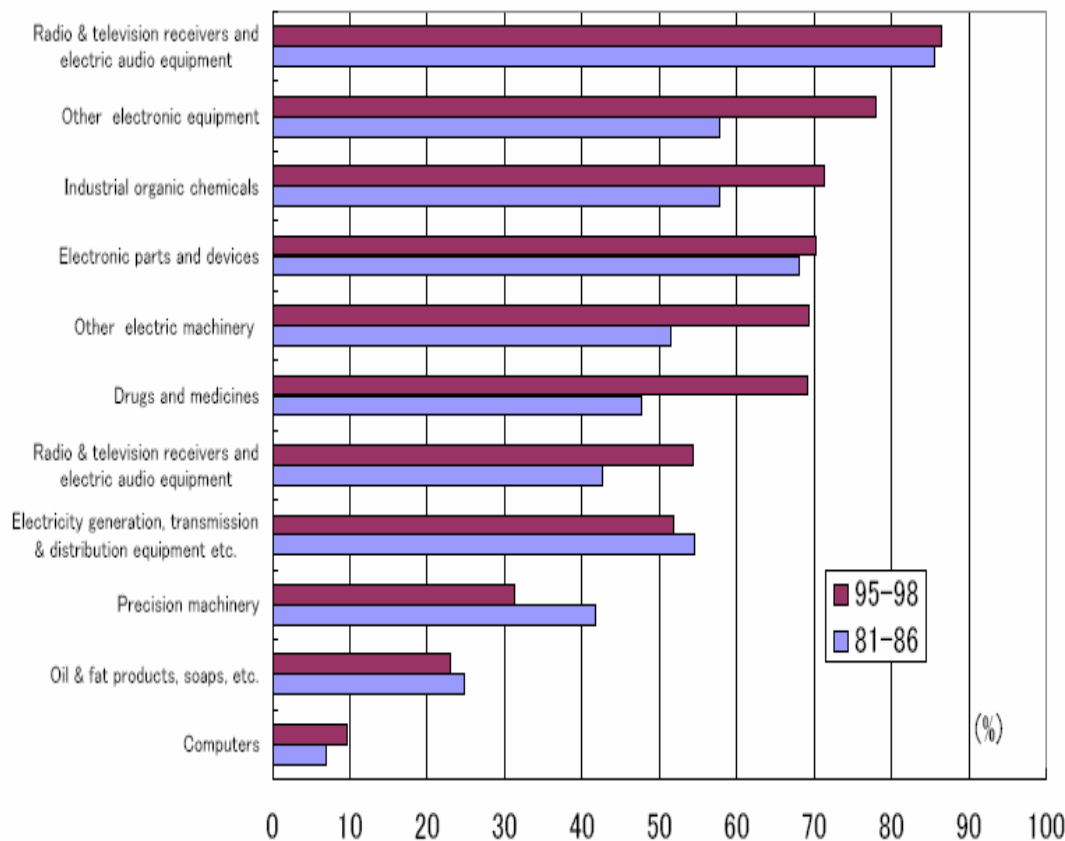


CanBiotech
Biotech Portal
& B2B Marketplace



Patents underpin Markets for Technology

Frequency of patents in licensing contracts in Japan, 1990s



Source: Nagaoka, 2003: *Patents and the other IPRs in use*

1. Rarely are patents the most important component – (Taylor and Silverston; Contractor, 1980)
2. Yet, patents are frequently present and important
3. Patent policy must not discriminate against business models based on technology licensing instead of manufacturing
4. Particularly salient for small firms

Patents and market for technology: Patents promote licensing by small firms

- Patents are used for licensing by smaller firms lacking complementary assets, and for commercialization by larger firms.
- Patents support entry by smaller, research oriented firms
- Technology licensors play a vital role in the innovation eco-system

10% increase in Patent Effectiveness Leads to:

	<u>Small Firm</u>	<u>Large Firm</u>
% increase in licensing propensity	6%	2%
% increase in the propensity to license patented innovations	1%	-3%

Source: Arora and Ceccagnoli, "Patenting and licensing", 2005

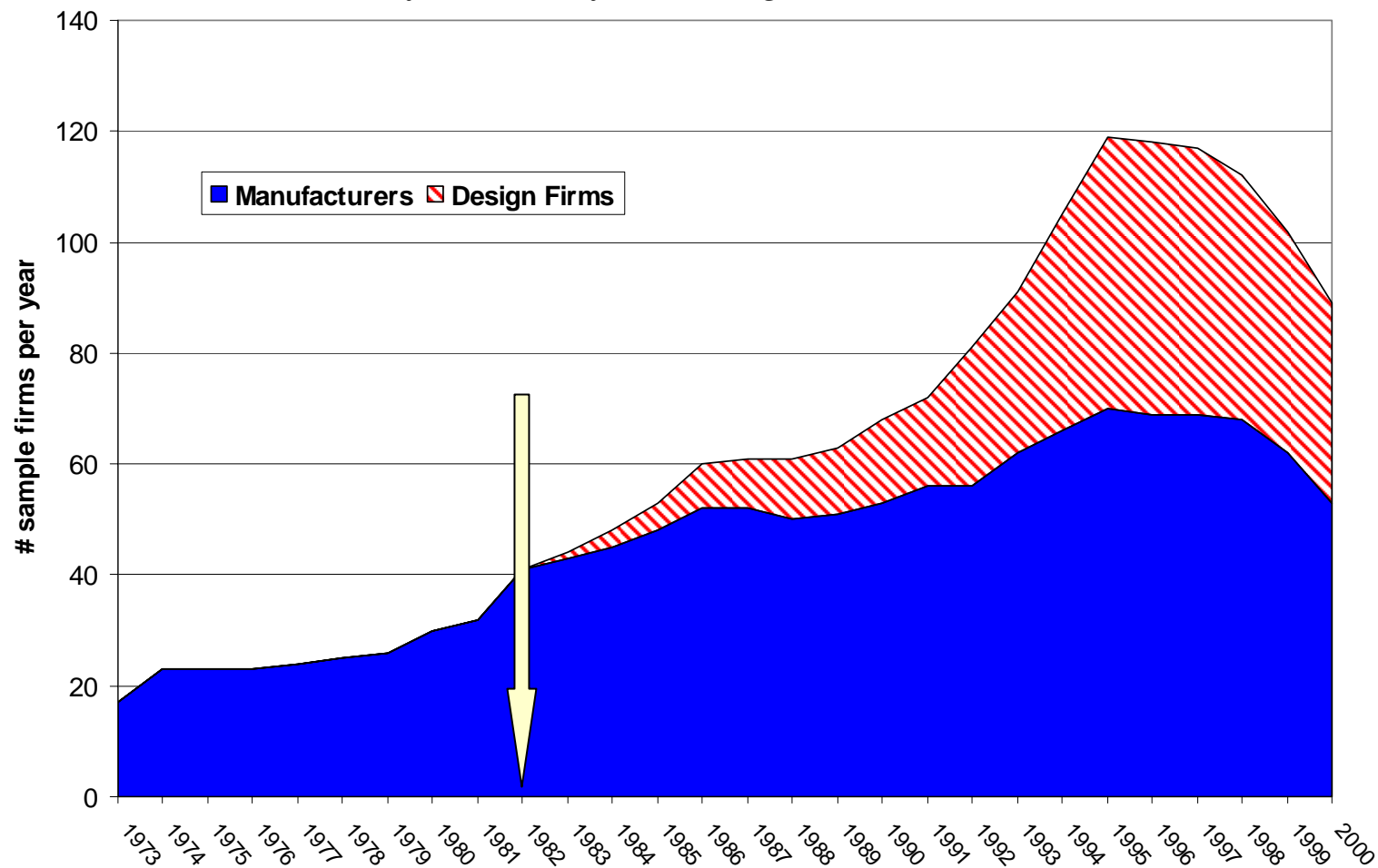
Gambardella, et al., 2007

1. *By using the PatVal-EU dataset we find that the most important determinant of patent licensing is firm size.*
2. *Patent breadth, value, protection, and other factors suggested by the literature also have an impact, but not as important.*

Patents promote entry of specialized design firms in semiconductors

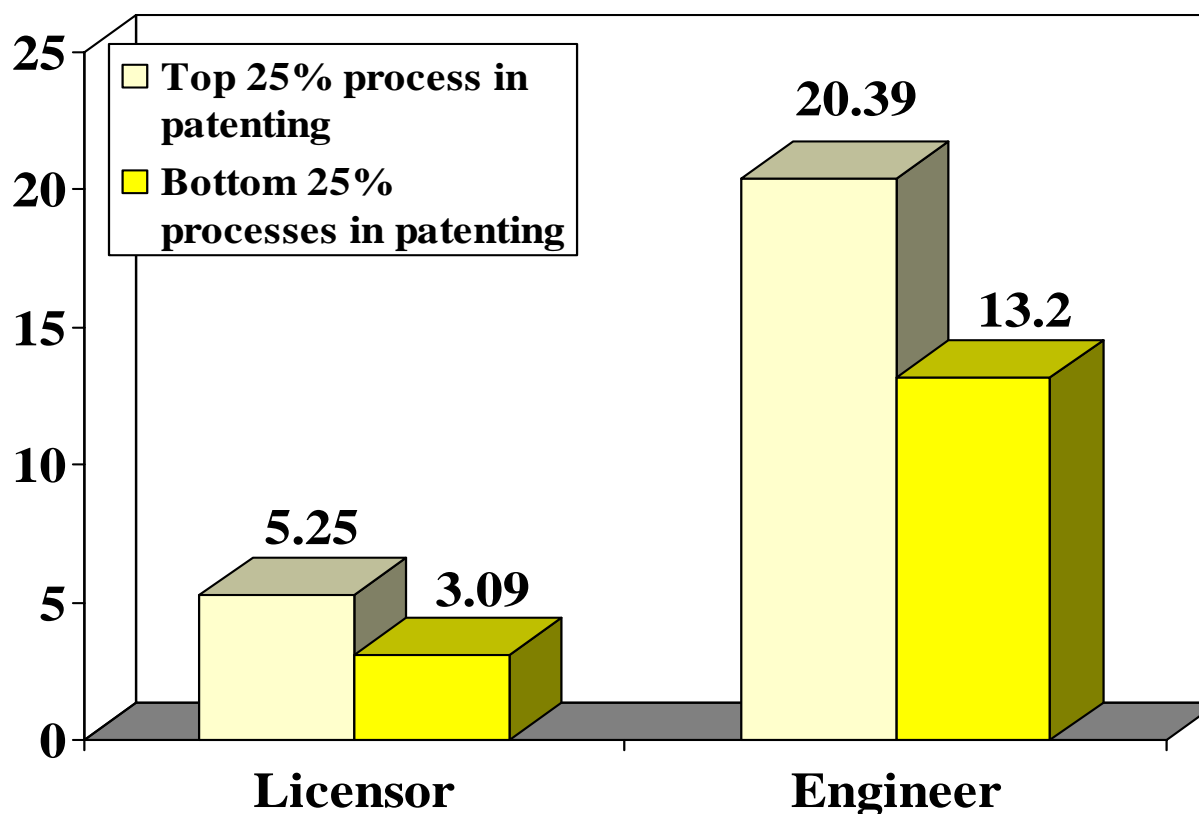
U.S. semiconductor mfg. and design firms, by year

(Ziedonis, 2003, "The Enforcement of Patent Rights in the United States")



Patents promote entry of specialized tech suppliers in chemicals

**Average # of Specialized Engineering Firms by process category,
139 process technologies (1980-90)**

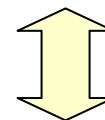


Source: Arora, Fosfuri & Gambardella, "The division of inventive labor", 2003

Patents promote tech licensing : Alkermes-Genentech Supply Agreement (Arora and Merges 2004)

- Alkermes's proprietary microencapsulation drug delivery technology
- Alkermes has to supply know-how
- Alkermes has to customise for Genentech's HGH and supply at pre-determined price
- Deal involves a "product" but value is from technology
- Both parties need safeguards

Alkermes could fail / under-invest

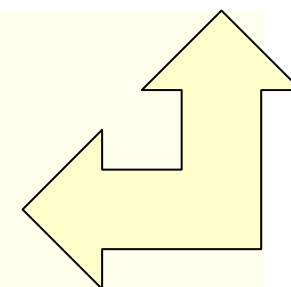


Genentech has broad contractual rights

Can terminate unilaterally
 Not responsible for expenses or capital costs
 May even take over Alkermes's manufacturing facility

If Genentech squeezes Alkermes?

- Alkermes can withdraw patents
 - In 2000, had 43 patents covering
 - Microencapsulation process itself
 - Polymers and materials for coating
 - Microencapsulated formulation of HGH (4 patents)
- Alkermes patents will prevent Genentech from using Alkermes technology if terminate, greatly reducing value of know-how



Patents as roadblocks

- ⊕ Anti-commons and patent thickets as blocking research and commercialization –
 - ⊞ pre-conditions for anti-commons in bio-pharma exist
 - diffuse ownership of patents
 - inexperienced owners
 - owners with limited stakes in production
 - ⊞ As yet not materialized (see evidence summarized in Barfield and Calfee, pp 37-43)
 - ⊞ Patents may divert or delay research, but principally by researchers that themselves seek commercial applications.
 - Even here, Walsh, Cho and Cohen (2005) – patents less important than scientific rivalry
- ⊕ Foundational or research tool patents may block follow on research
 - ⊞ greater danger, due to misguided business models or miscalculations
 - ⊞ variety of public and private responses to upstream patents mitigate problems
 - ⊞ **The principal danger is that creating more red tape and bureaucracy will reduce scientifically valuable but commercially low value research.**
- ⊕ Patents covering diagnostic tests create largest public policy dilemma.
 - ⊞ Problem arises mostly because clinical practice is an integral part of university hospital research.

Patents as potential roadblocks

- Bad patents create problems - Absolutely.
- Bad patents in the hands of players with short term strategies create bigger problems – Absolutely, BUT
- Patent policy must not discriminate against business models based on licensing. In a knowledge based economies, prejudices in favor of material production is simply that.
- Investing in improving the quality of patents is a good idea.
- An important aspect is to get the USPTO to recognize that its mission is not to serve inventors but to serve society.