

*Session 1: How Do Patenting and
Licensing Affect Research Access to
Tools and Upstream Discoveries?*

**Conference on Research Use of
Patented Inventions**

OECD

Spanish National Research Council
Spanish Patent & Trademark Office

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Panel Members:

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Concerns Raised

- Anti-commons:
 - Demands of numerous claimants may lead to excessive licensing burden, the cessation of otherwise worthwhile projects and the loss of collective surplus, impeding development and commercialization of drugs and therapies, and possibly even basic research
- Access:
 - Limitations on subsequent discovery and improvements imposed by assertion of patents on upstream, foundational discoveries
- Erosion of the norms of open science, possibly undercutting research productivity
 - Restrictions on the sharing of research materials and publication delay

Recent Research

I. Surveys Of Investigators' Experience with

- own IP
- others' IP and tangible research inputs

Walsh et al for NAS, 2005:

- US
- Biomedical (genomics and proteomics)
- "Academic"

AAAS (Asher et al), 2005:

- Multinational
- All fields
- All sectors

Recent Research, Cont.

II. Analysis of Scientific Literature Citations

Murray & Stern, 2005:

- US
- Biomedical
- Public and Private sector

Sampat, 2004:

- US
- Genomics
- Academic (NIH-funded)

Recent Research, Cont.

III. Patenting and Licensing

Nagaoka et al. on Research tool patents, 2006:

- Japan, US, EU
- Life Sciences
- Public and private sector

Nagaoka et al. on licensing, 2006:

- US, Japan
- Life Sciences
- Private sector primarily

Pressman, et al., 2005:

- US
- Genomic
- Academic

Some Other Recent Studies

Sampat, Bhaven N., *Patents on Academic Genomic Discoveries: Effects on Biomedical Research*.
Working Paper, University of Michigan Department of Health Management.

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Murray, Fiona and Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*. Unpublished manuscript 2004.

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Pressman, Lori et al. “The Licensing of DNA Patents by U.S. Academic Institutions: An Empirical Survey”, *Nature Biotechnology*, 34:1, January 2006, pp. 1-9.

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Do Academic Genomic Patents Curtail Subsequent Research?

- Key findings:
 - For genomic “techniques,” a patent grant has no statistically significant effect on citations to corresponding articles
 - For genomic “sequences,” a patent grant is associated with a 12 percent decline in citations to corresponding articles, all else equal ($p < .05$)
 - Murray and Stern (2005), using a different empirical approach and focusing on papers from *Nature Biotechnology* find that patents cause a 9 to 17 percent decline in citations to corresponding articles

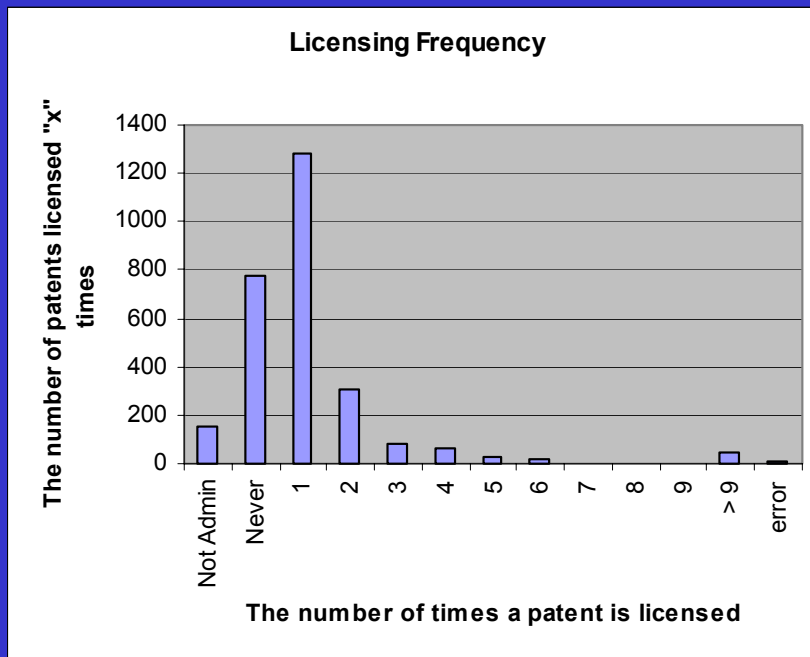
Source: B. Sampat

Do Academic Genomic Patents Curtail Subsequent Research?

- Reconciling results with Walsh et al.
 - Perhaps citations are affected more than subsequent research?
 - But this still requires “awareness” of patents
 - Perhaps results are driven by non-academic citers?
 - Currently testing for this

Source: B. Sampat

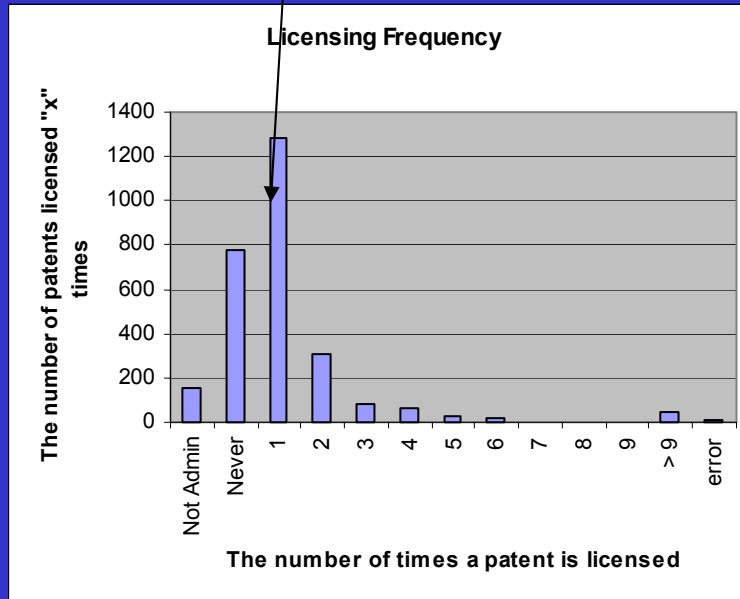
About 70% have, at one time, been licensed
 1- 2% were licensed >9 times



Licensing Status	# of patents
Not Admin	151
Never	773
1	1287
2	303
3	78
4	62
5	24
6	14
7	4
8	3
9	3
> 9	45
error	13

Source: L. Pressman

There is exclusivity data for 307 of the 1287 (24%) patents which were licensed once



172 were in Exclusive, All Field of Use licenses

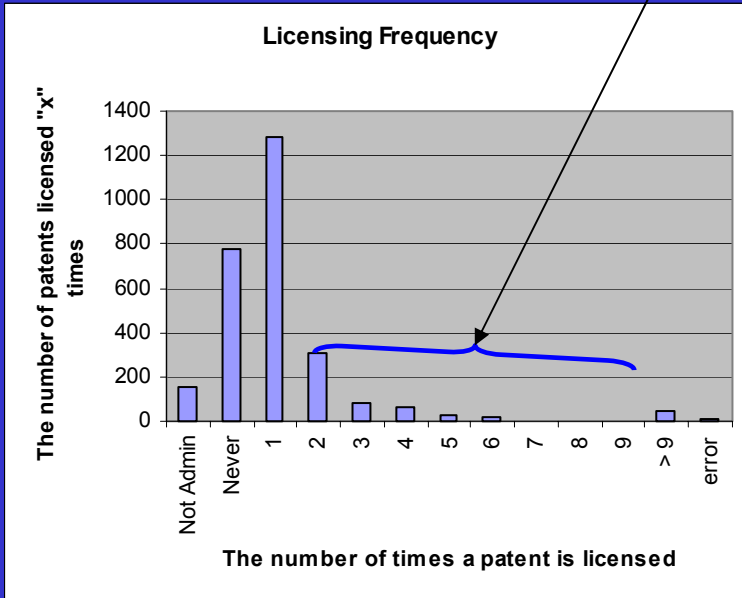
111 were in Exclusive, By Field of Use licenses

24 were in nonexclusive licenses

If you guessed that “once”, meant “Exclusive, All Fields of Use”, you’d be right only 56% of the time.

Source: L. Pressman

There is exclusivity data for 214 of the 491 patents which were licensed 2-9 times



7 were in Co-exclusive licenses

32 were in Exclusive, All field of Use licenses

98 were in Exclusive, By field of Use licenses

77 were in nonexclusive licenses

If you guessed that “2-9 times”, meant “nonexclusive”, you’d be right only 36% of the time.

Source: L. Pressman

**Exclusive licenses don't equate to “off the table”
for the next potentially interested party.**

Licenses terminate

Sublicenses are granted

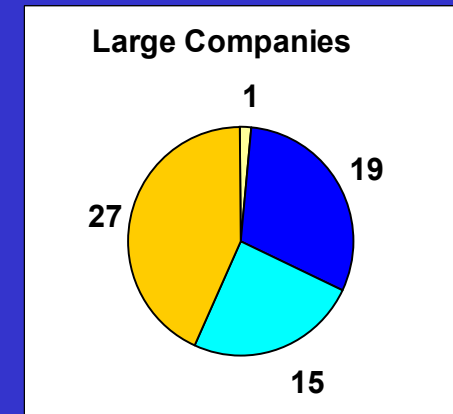
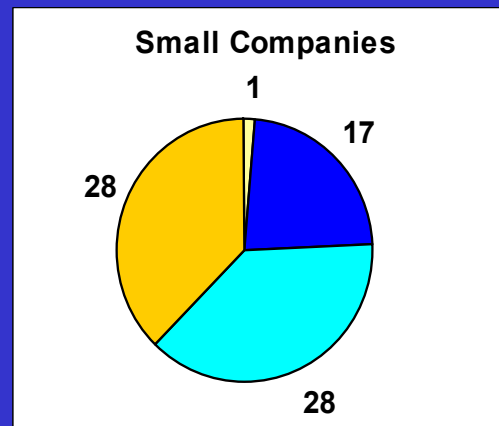
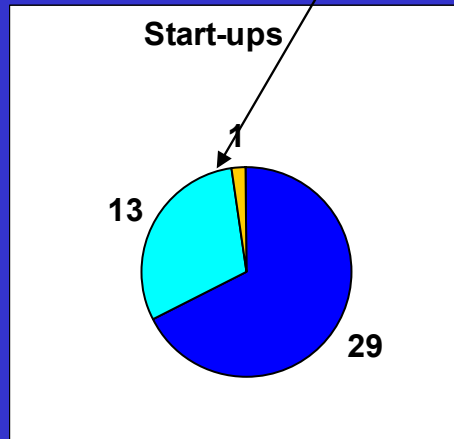
Exclusive, By field of use

**(Only about 170 of the approximately 500 patents for which we
have exclusivity information are Exclusive, All Fields of Use, and
we know that patents in Exclusive, All Fields of Use can be
licensed more than once.)**

Source: L. Pressman

Exclusivity by company size.

As expected, start-ups have, almost exclusively, exclusive licenses.



-  Exclusive, All Fields of Use
-  Exclusive, By Fields of Use
-  Nonexclusive
-  Coexclusive

Note; The "Blues" would be lumped as exclusive in the AUTM survey

Source: L. Pressman

50/179 licenses are no longer active

In only 2 cases because the patents expired

In 3 cases “terminated by institution”

In 35 cases “terminated by licensee”

Other: Both LICENSEE and LICENSOR changed their funding status so new terms were required to reflect the new arrangement

Other: converted to non-exclusive license

Other: Information not available; agreement archived

Other: Information unavailable

Other: Information unavailable; agreement archived

Other: Liquidity event

Other: Merger with another licensee.

Other: Short-term SRA : termination as per license term

Other: Terminated by mutual agreement of the parties

Other: Unknown. License agreement is missing.

Source: L. Pressman

The terminated licenses, in general, lasted fewer years (about 4.5*) than the ones which are still active (about 8), evidence that neither party has an interest in maintaining a useless contract.

There is no significant difference in % terminated by exclusivity

17/65 EAFOU terminated (26%)

16/56 EBFOU terminated (29%)

15/56 Nonexclusive terminated (27%)

2/2 coexclusive

* Broad Distributions

Source: L. Pressman

A few Observations Based on the Policy and Interview Portion of Survey

- The NIH guidelines about the sharing of research tools are widely known and are often adopted by technology transfer offices.
- There are even more usages of the term of “exclusive” than known initially, including, “Exclusive for use with company’s own patented technology”, is still called “exclusive”.
- Those schools interviewed reported always ensuring a research exemption for themselves, and starting about recently-about 5 years ago, putting in a general research exemption.

Sample: Nothing in this Agreement will limit the right of University to publish any and all technical data resulting from the research performed by the University relating to the Invention and to make use or practice the Invention, Licensed Product, Licensed Service, Licensed Method an associated technology **and allow other educational and non-profit institutions** to do so for educational and research purposes.

Source: L. Pressman