

Effects of Research Tool Patents and Licensing on Biomedical Innovation

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Presentation to the OECD Conference on IPR, Innovation
and Economic Performance
August 28-29, 2003

Research funded by The National Academies'
Science, Technology and Economic Policy Board and the
National Science Foundation.

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Concerns Raised and Study Goal

- Anti-commons: Numerous claimants to IP on research tools lead to breakdown and loss of collective surplus, impeding development & commercialization of promising therapeutics
- Limitations on subsequent discovery and improvement due to restricted access to patented upstream, foundational discoveries
- Project goal: to explore the degree to which these concerns have materialized.

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Data and Method

- 70 interviews
- 10 pharmaceuticals firms
- 15 biotech firms
- University personnel
- Patent attorneys, government officials, etc.

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Do the preconditions for “Anti-commons” tragedies exist?

- Yes
 - Growing number of patents on research tools
 - Many biotech firms
 - Increase in university patenting
 - Defensive patenting

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Preconditions for Restricted Access?

- Foundational discoveries and research tools now commonly patented
 - Recombinant DNA [Cohen-Boyer]
 - PCR and taq polymerase
 - Cre-lox, OncoMouse, etc.
 - Targets for intervention (COX-2, telomerase, etc.)
- Concern over patent scope
 - Reach through-COX-2 (U. of Rochester) was a concern, but now diminished with the federal court decision

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Anti-Commons “tragedies”?

- Breakdowns: Vast majority of respondents (over 90%) say “Never happens”
- Licensing fees for tools
 - Have risen
 - Not a problem for larger firms, but can challenge smaller firms and universities
 - Also, patent holders often price discriminate
- Royalty stacking: Managed
- Projects not undertaken?
 - Unlikely, but difficult to know
 - Commercially marginal projects impacted
 - Mitigated by ample technological opportunities
- Overall: Manageable

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Restricted Access

- Possible cost: diminished variety of attack
- Forms:
 - Exclusive licensing
 - Exclusive use of IP by owner
 - High fees
- The concern over access is less one of how pervasive it is, but the possibility that restricted access to a small number of foundational discoveries can have important social consequences

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Evidence of limited access

- Lots of tools and targets have limited access
- Complaints about target access widespread (about one-third of sample)
- Prices can be high for small firms and universities (if they pay attention)
- Owners say it is appropriate to exclude
- But in most cases, while some users were excluded, multiple firms have access.

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Working Solutions: Overcoming the Anti-Commons and Restrictions on Access

- Relevant number of patents is moderate: 0-12
- “Working Solutions:”
 - License negotiation
 - Inventing around
 - Off-shore
 - Challenge in court
 - Infringement/“Informal Research Exemption”

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Universities: Infringement or the “Informal Research Exemption”

- Faculty feel free to use technologies for “research”
- Firms generally refrain from asserting (though clinical diagnostics are exception) against universities
 - Little to gain and reputation to lose
 - University research adds value
- Community:
 - Repeated game with information sharing
 - Norms of research: collegiality and open access
 - Outsiders defect (e.g., duPont)

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Firms: Infringement/“Informal Research Exemption”

- Hard to detect and 6 year statute of limitation
- About one third mention using this strategy, most say others do this
- Some claim research exemption, or that patent scope very narrow
- May take license later if target proves useful
- If need be, can challenge in court, invalidate

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Institutional Responses

- “Public” databases
 - GenBank
 - Merck Gene Index
 - The SNPs Consortium
- But CRO’s initiated by large drug firms may reflect attempt to grab rents from biotech segment
- NIH advocating for public researchers (e.g., Cre-lox and OncoMouse, Stem Cells)
- New PTO utility guidelines-ESTs
- Court’s narrowing of broad early claims, though still much uncertainty

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Conclusions

- Increasing complexity of patent landscape
- Little anticommons breakdown
- Access: Concern over targets and other patented upstream discoveries, especially those that are foundational and rival-in-use (e.g., Geron's embryonic stem cells)
- Development of "working solutions"
 - Including informal "research exemption"
 - Supported by norms of exchange/access
 - Institutional pressures to increase access

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Conclusions (cont.)

- Could still see problems in future
 - Recent CAFC decision in *Madey v. Duke*, by publicly removing already narrow research exemption, may undermine use of informal research exemption and chill academic research—though limited evidence as yet.
- But remember:
 - Patents key to incentives to discover new tools
 - Even at a price, tools increase R&D productivity

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