



# **Research Tool Patents and Biomedical Research: Findings and Implications**

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# The Changing Context of Biomedical Innovation

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- Patents provide important incentives for downstream biomedical innovation, but...
  - Technological change
    - Molecular biology revolution
    - Sequencing and bioinformatics
    - Combinatorial chemistry and HTP screening  
=> Increase in patentable inventions
  - Policy change (Bayh–Dole; Diamond v. Chakrabarty)
  - Growing commercial activity by universities
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# Concerns Raised

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- Anti-commons:
    - Demands of numerous claimants may lead to excessive licensing burden and the cessation of otherwise worthwhile projects
  - Access:
    - Limitations on subsequent discovery and improvement imposed by assertion of patents on upstream, foundational discoveries
    - Possible cost: diminished variety of attack
      - Firm specific libraries
      - Limited capabilities (small firms)
      - **Diverse strategies**
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# Concerns Raised

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- Erosion of the norms of open science, possibly undercutting research productivity
    - Restrictions on the sharing of research materials
    - Publication delay
  - Redirection of PRO effort away from science and toward commerce
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# Anti-commons

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- Walsh, et al. (USA): Preconditions exist, but little evidence of occurrence.
  - Straus (Ger) and Nicols and Neilson (Australia) have similar findings
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# Restricted Access

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- Walsh, et al. (USA), Straus (Ger), Nicols and Neilson (Australia): some evidence of limitations on access, although exclusivity is very rare
    - Academics generally have no problems with access to pure IP (although tangible property is different)
  - Thumm (Swiss): some concern over patents limiting access and shaping project choice
  - Murray and Stern; Sampat: Decline in citations after publication (sequences, but not techniques).
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# Working Solutions: Overcoming the Anti-Commons and Restrictions on Access

- Relevant number of patents is moderate: 0–12
- “Working Solutions” combine:
  - License negotiation
    - General purpose tools widely licensed
    - Even targets often licensed non-exclusively
    - “Unacceptable” terms may be negotiable
  - Inventing around
  - Off-shore (*Bayer AG v. Housey Pharmaceuticals*)
  - Challenge in court
  - “Informal Research Exemption”
    - Rational forbearance and community norms
    - Vulnerable since *Madey v. Duke*?

# Diagnostics: a special problem

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- Cho, Merz, et al.
    - Labs abandon tests due to patents (25–30%)
    - Research and (commercial) clinical practice intertwined
    - Requirements to do test in-house limit research gains from multiple investigators
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# Secrecy/Sharing

- Blumenthal (1997)
  - 20% delayed publication more than 6 months
  - 9% Refused request to share materials
  - Secrecy associated with commercial activity
- Campbell (2002)
  - 10% of requests for information/materials denied
  - Too much trouble and scientific competition key reasons, but also associated with commercial activity
- Walsh and Hong (2003)
  - Secrecy increasing, especially in experimental biology
  - Associated with academic competition for priority, effects of commercial activity mixed

# Conclusions

- Increasing complexity of patent landscape
- Little anti-commons breakdown
- Concern over commercial access to targets and other patented upstream discoveries (esp. diagnostics)
  - Academics rarely affected
  - Patents doing what they are supposed to do?
- Development of “working solutions”
  - Including “research exemption”
  - Supported by norms of exchange/access
  - Institutional pressures to increase access (journals, funders)

# Conclusions

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- Universities becoming increasingly tied to commercial activity
  - Some evidence of increasing secrecy among academics
    - Evidence for link to commercial activity mixed
    - Increasing scientific competition may be key driver
  - Access problems for academics may not be related to patents, but material transfers (which are influenced by scientific competition, cost/effort, as well as commercial interests)
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# Conclusions

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- Solutions need to be tied to problems
  - Institutional solutions to frictions in materials transfers may be key—publicly funded repositories with few use restrictions or reach through claim
    - Except maybe research exemption and humanitarian use?
  - Research exemption (created through licensing agreements) may provide pre-Madey level of comfort (though not 100% protection)
  - Patent clearinghouse may provide benefits to both suppliers and consumers
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# Questions, Comments, Suggestions?

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