Research Tool Patents and Biomedical Research: Findings and Implications

John P. WALSH

University of Tokyo/University of Illinois at Chicago

The Changing Context of Biomedical Innovation

- 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
Concerns Raised

- **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**
Concerns Raised

- 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
Findings—in brief

- Anti-commons—no
- Access—some
- Norms—decline, but scientific competition at least as much as commerce
- Redirection—little impact of IP, licensing opportunities
Anti-commons

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

- 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).
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

- 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
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

- 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)
Conclusions

- 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
Questions, Comments, Suggestions?

Prof. John P. WALSH
Research Center for Advanced Science and Technology
The University of Tokyo
4–6–1 Komaba
Meguro-ku, Tokyo 153–8904
jwalsh@uic.edu

http://www.uic.edu/~jwalsh
Proposed solutions

- Patent pools
  - Assume base of common patents (essential, non-substitutable)
  - But, generally want unique subset (or large number of distinct, though perhaps overlapping, subsets) on case by case basis
- Clearing house (~ASCAP) better
  - Provides monitoring service (one problem with current system is high cost of monitoring infringement [although helps create the informal research exemption])
  - Reduces transaction costs for both sellers (negotiating with large number of heterogeneous users) and buyers (one-stop shopping)
Proposed Solutions

- Research Exemption?
  - Informally, already exists (due to economic and structural factors in addition to norms)
  - Formal exemption likely not apply to diagnostics, which is key problem area
    - Medical practice exemption did not cover diagnostics
  - Still have material transfer problem, which is more central (in part because blocks research)
  - And, research exemption does not solve anti-commons problem for product development
  - Contract-based exemption may help create free space
Retained Rights Clause (Stanford)

- **Retained Rights.** Stanford retains the right, on behalf of **itself and all other nonprofit academic research institutions**, to practice the Licensed Patent and use Technology for any purpose, including sponsored research and collaborations.

- Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution.

- Stanford and any such other institution has the right to publish any information included in the Technology or a Licensed Patent.
Proposed Solutions

- Materials repositories
  - Require depositing (journals, funders)
  - Uniform access rules (e.g. repositories not accept materials with overly restrictive (or any) MTAs)
  - Research exemption/Humanitarian Use clauses in MTA?

- More generally, encourage standard terms and discourage reach through