Repurposing and Repositioning: Policy and Legal Issues

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Outline of Talk

- Policy/Legal Challenges in Collaborative Research
 - Specific case of academic/private
- Parallels: NCATS and MRC approaches
- Distinctions
- What IP can be secured going forward?

General Legal/Policy Challenges

- Exchanging information across firm boundaries: Arrow's Information Paradox (AIP)
- IPRs (patents, trade secrecy) contracts → responses to AIP
- Contracts usually have provisions on
 - background/"existing technologies" (and associated IPRs)
 - foreground tech developments/Results (and associated IPRs)

Specific case of academic/commercial

- Different norms re: publication
- Different styles of negotiations (TTOs vs. private sector)
- Catalytic impact of "trusted intermediary"
 - Especially important when true collaboration between academic/private (as contrasted with contract research or sponsored academic research)
 - U.K. Model Industry Collaborative Research Agreement (mICRA) guidance draws distinction

Parallels: NCATS/MRC (1)

- Use of template agreements
- Funding from trusted intermediary
- Two stage process
 - 1st stage relatively open
 - MRC approach allows confidentiality for applicant information under MRC/AZ CDA)
 - Neither NCATS nor MRC give compound structure
 - 2nd stage operates under CDAs, CRAs/mICRA

Parallels: NCATS/MRC (2)

- Provisions for publication (with prior review by private sector partner)
 - 60 days total for NCATS, 6 months for MRC
- Distinctions between background/existing IP (e.g. IP held on molecule) and research results under collaboration

Divergences (1)

NCATS

- CRAs are (formally) bilateral
 - Modification of CRA requires approval of NIH
 - Nothing in CRA supersedes NIH grant
- IP in Results, licensing provisions specified in detail *ex ante*

MRC

- mICRA is (formally) tripartite
- IP in Results retained by academic org; AZ negotiates licenses once study completed

Divergences – IPR and licensing (2)

NCATS

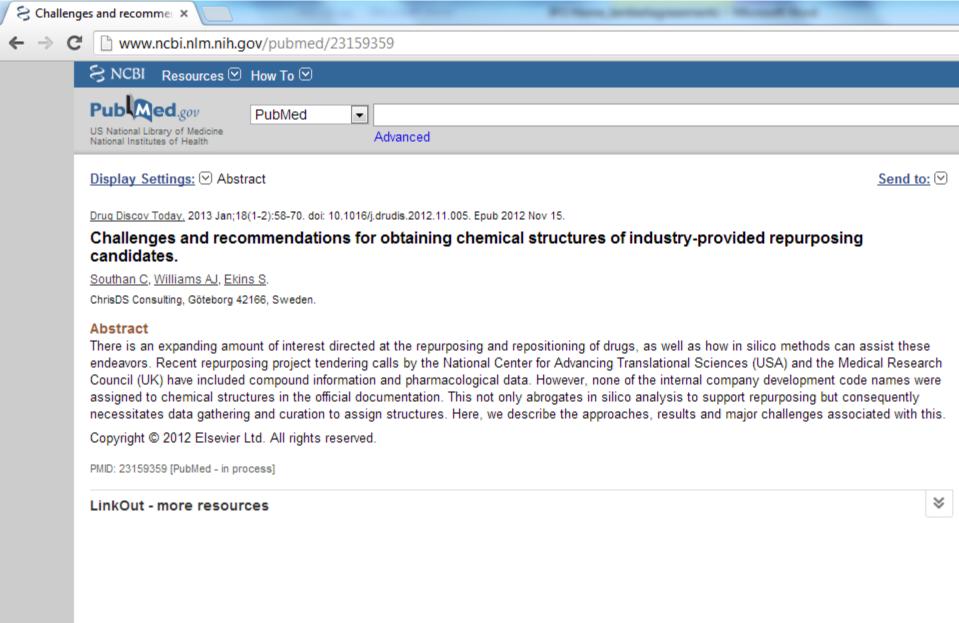
- Distinguishes AMC invention;
 Company Invention; Joint
 Invention
 - Company pays cost of AMC, Joint Invention filing if it agrees patent should be filed
- For all AMC, joint inventions Company has right to license exclusively, nonexclusively

MRC

- 5 IPR, licensing options in mICRA
- MRC/AZ approach →
 Versions 3 or 4 (academic partner holds rights in foreground Results and will license)

Company information at Stage One

- Neither NCATS or NRC discloses structure?
- How much should be disclosed?



Sufficient IPR? (U.S. perspective)

- Typically not much product patent life left
- Can get process/method-of-use patents
- Will method patents provide sufficient incentives to do full testing for FDA approval?
 - If molecule already being marketed for other use (unlikely), offlabel use of generic (*Caraco*)
 - Rai, Use Patents, Carve-Outs, and Incentives: A New Battle in the Drug Patent Wars, NEJM (2012)
 - If not being marketed, more exclusivity (no possibility of generic off-label use)

"Big Think" IP alternatives

- "Therapeutic only" exclusivities
 - E.g. MODDERN Cures Act of 2011
- General issue of patent system not (necessarily) working optimally for biopharma
 - FTC v. Actavis (2013) and reverse payments