Repurposing and Repositioning: Policy and Legal Issues

Arti K. Rai

Elvin R. Latty Professor

Duke Law School and Duke Institute for Genome Sciences & Policy

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?

Challenges and recomme ×
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Drug Discov Today. 2013 Jan;18(1-2):58-70. doi: 10.1016/j.drudis.2012.11.005. Epub 2012 Nov 15.

Challenges and recommendations for obtaining chemical structures of industry-provided repurposing candidates.

Southan C, Williams AJ, Ekins S.

ChrisDS Consulting, Göteborg 42166, Sweden.

Abstract

There is an expanding amount of interest directed at the repurposing and repositioning of drugs, as well as how in silico methods can assist these endeavors. Recent repurposing project tendering calls by the National Center for Advancing Translational Sciences (USA) and the Medical Research Council (UK) have included compound information and pharmacological data. However, none of the internal company development code names were assigned to chemical structures in the official documentation. This not only abrogates in silico analysis to support repurposing but consequently necessitates data gathering and curation to assign structures. Here, we describe the approaches, results and major challenges associated with this.

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LinkOut - more resources

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), off-label 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