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Intellectual Property and the "Mouse Commons"

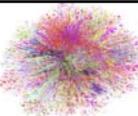
Mouse Models for Human Diseases

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Creating the "Mouse Commons"

- Commons is a shared and managed resource that is vulnerable to social dilemmas
- Problems include competition for use, free riding, and non-sustainability.
- Self-organized commons require strong collective-action and self-governing mechanisms, as well as a high degree of social capital on the part of stakeholders.



Knowledge / Resource Commons



- The commons of science, academia and scholarly communication are social and informational
- Involve nonrival goods (sharing without depletion)
- More value created as *more* people use the resource – "network effects"



Thinking about the Commons



ELINOR OSTROM
2009 Nobel Laureate
in Economic Sciences

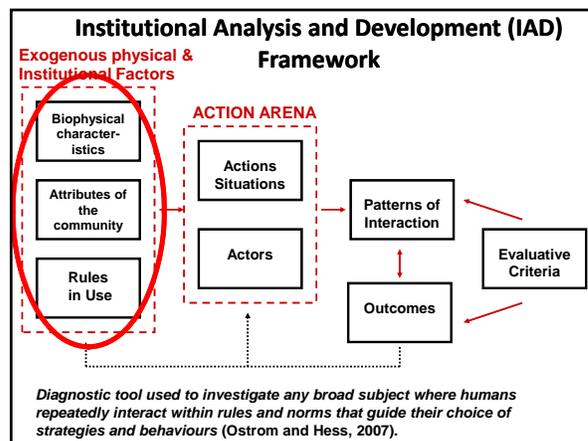
GOVERNING THE COMMONS



Requirements for a Robust Commons

- Clearly defined boundaries.
- Some degree of cultural homogeneity.
- Rules in use well matched to needs and conditions.
- Active participation by those affected by rules.
- Right of community members to devise their own rules is respected by external authorities.
- System for self-monitoring of behaviour.
- A graduated system of sanctions available.
- Community member have access to low-cost resolution mechanisms.

• From (Ostrom and Hess, 2007).



Biophysical Characteristics

- **Resource units/Artifacts**
 - Bio-materials (mice, ES cells, gametes, vectors, etc.)
- **Ideas**
 - Coherent thoughts, mental images, and innovative information – intangible content not captured by e.g., copyright.
- **Facilities/Repositories**
 - Store and resource units and make them available

Attributes of the Community

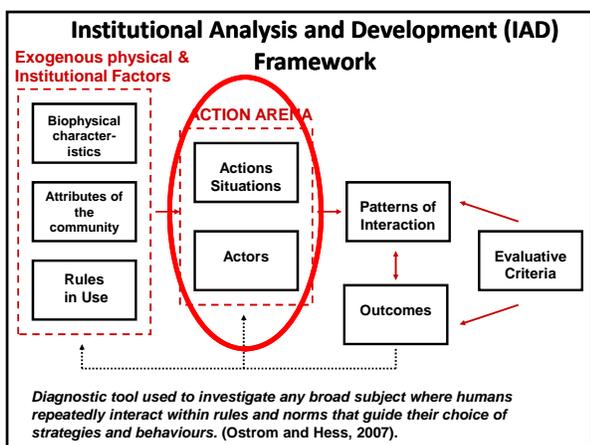
- **Users, providers, managers and policymakers**
- **Public and private**
- **Usually nested**
 - i.e., different groups functioning at various levels within the commons
- **May be fragmented and complex**
 - E.g., conflicting values within the academy where commercialization and industry linkages increasingly valued.

Rules in Use

- **Shared normative understandings of what a participant in a position must, must not, or may do in a particular action situation, backed by at least a minimal sanctioning ability for noncompliance (Ostrom and Hess, 2007).**

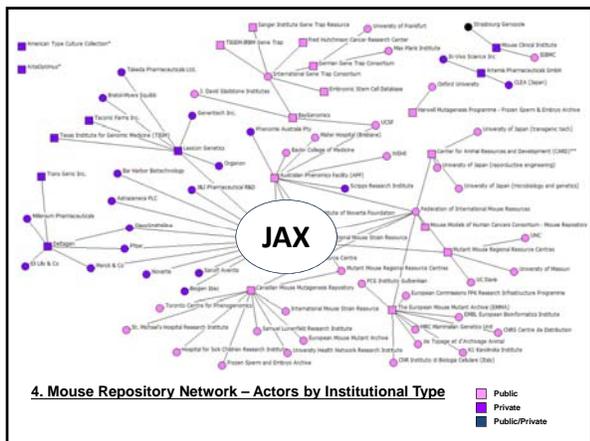
Rules in Use

- **FORMAL LAWS (IP, animal welfare, FDA)**
 - Often out of sync with new capabilities, community norms and technology
- **CONSTITUTIONAL**
 - Who may make the rules (e.g., IKMC, repositories, databases)
- **POLICIES AND GUIDELINES**
 - E.g., funding agencies, universities, journals, repositories
- **INFORMAL RULES/ COMMUNITY NORMS/ PRACTICES**
 - Citation, attribution, reciprocity and sharing, publication, creative/science commons



Action Arena

- **Participants making decisions within a situation affected by the physical, community, and institutional characteristics that will then result in varying patterns of interactions and outcomes (Ostrom, 2005)**
- **DIVERSITY OF ACTORS**



Action Situation and Actors: Building the Commons

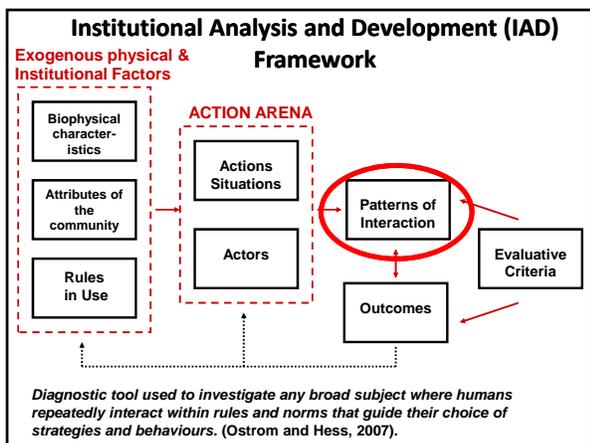
- Concerned with how actors cooperate or do not cooperate with each other: roles, actions and how actions affect outcomes (Ostrom and Hess, 2007).
- Particularly concerned with analyzing incentives.
 - Attribution incentives—employers and journals (see Rome Agenda)
 - Incentives to deposit
 - Build social capital and trust
 - Simplify process of participation
 - Guidelines and policies to require deposit or at least encourage and support deposit.
 - Institutional endorsement

Connecting rules in use with action arena: the MTA

- Material Transfer Agreements identified by the community as a substantial disincentive to accessing and providing materials
- Researchers should be free to breed mice for research purposes and cross-breed them to produce new strains (added value back to commons)
 - Rome Agenda (Schofield *et al.* 2009)

Connecting rules in use with action arena: the MTA Best Practices

- Jackson Laboratory
 - Mice to academic and not-for-profit researchers with the simple notification that mice are to be used solely for research purposes and not to be sold or transferred to 3rd parties without permission
- 1999 NIH Policy for biomedical research resources developed using NIH funds
 - No formal agreement
 - Simple letter of agreement of the UBMTA
 - Uniform Biological Materials Transfer Agreement (UBMTA)
- Licences to industry should be non-exclusive and contain a broad reservation of rights for academic and not-for-profit research institutions (Rome Agenda)
- No royalty or product reach-through (Rome Agenda)
- PLUS attribution/liability waiver



Patterns of Interactions

- Exogenous characteristics, incentives, actors and actions all contribute to the patterns of interactions
- How actors interact strongly affects the success or failure of the resource
- One can free-ride on the resource by not depositing materials (if expected to do so)
- Users do not free-ride, they add value through use – including industry
- Perverse side of the public good aspect of the repository is under-use
- May be strong conflicts when hyperchange in community of users and their values and goals

Dissecting the problems: Conflicting values and goals

- No doubt of increasing commercialization pressure on publicly funded research institutions and their researchers
- Mediated through technology transfer offices
- Patenting as a proxy for commercialization and a signal of changing values and norms of a community (of users)
- Impact on community norms and trust?
- Impact on sharing/willingness to contribute to and use a resource?

Mouse Patent Landscape: Method

- Delphion search US Granted Patents
 - Patents involving DNA (modified Cook-Deegan search algorithm)
 - AND Mouse search terms in claims
 - AND NOT Plant*
- Resulted in 6,979 patents
 - Examined claims of each patent
- Coded each 'accepted' patent (2,373 – 34%)
- 952 patented genes identified through Blast analysis
- (NB. Data slides deleted until peer review – publications forthcoming)

Conclusions on IP

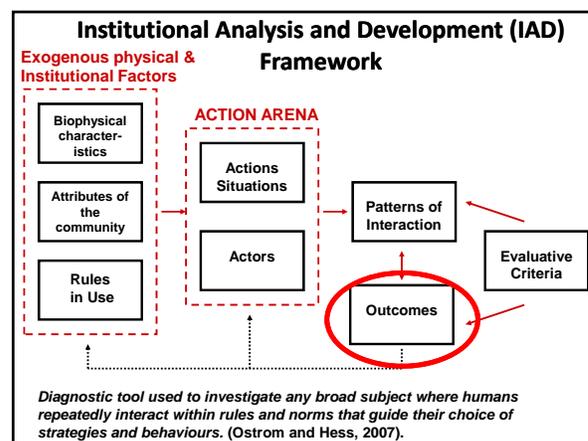
- Large number of overlapping patents both on products and methods.
- Most gene and DNA patents held by public sector, most cell lines and mice by private sector.
- Methods patents may be more of a blocking problem in the long-term than product patents
- Public resources are being established, however patents may impact on repositories and users, especially as research moves towards clinical application.
- Utility of maintaining and EXPENSE of public sector patents on research tools?
- Most important is change in CULTURE, collaboration, sharing ethos, competition and trust

Litigation: A sure way to destroy trust

- Current litigation:
 - 2010 Markman Hearing: THE CENTRAL INSTITUTE FOR EXPERIMENTAL ANIMALS, a Japanese corporation, (Plaintiff) v. THE JACKSON LABORATORY, a Maine corporation (Defendant)
 - "NOD/Shi Mouse" and "NOD/Shi-scid Mouse"
 - 2010 Demand for Jury Trial: Alzheimer's Institute of America, Inc (Plaintiff) v. Elan Corporation, PLC, Eli Lilly and Company, ANASPEC Inc, Immuno-Biological Laboratories, INC., Invitrogen Corp., The Jackson Laboratory, and Phoenix Pharmaceuticals (Defendants)
 - Swedish Mutation, etc.
- BUT SEE:
 - 2010: ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL., v. UNITED STATES PATENT AND TRADEMARK OFFICE

Other Challenges Identified by the Community

- Scientific challenges
- New, less established repositories
 - Quality control (quality of resource)
 - Long term sustainability of resource
- Acknowledgement (appropriate metrics) for participation in establishment of community resource
- Trust in partners and resource
- Concerns over broad methods patents



Outcomes



- Accessible repositories (access)
- Global use, provision and productions (equity)
- Appropriate standards (e.g., nomenclature, annotation)
- Cooperation and reciprocity (social capital)
- Quality Control (richness)
- Open science (enhanced access and >use)
- Compliance and participation (well-populated repositories)
- Sustainability and preservation of resource
- Additional returns (e.g., phenotyping – enhanced quality of resource)
 - (Ostrom and Hess, 2007).

Conclusions



- By understanding the nature of the community and its interactions and actions, it will be possible to calibrate rules, norms and community practices to enhance the value of the commons and lead to the desired outcomes
- Especially important in this heterogeneous community will be the building of trust and the enhancement of social capital
- Industry, through use of the resource, can only enhance the value of the resource and add to potential sustainability
- On evaluation—time will tell through use, utility and sustainability of the resource, as well as value-adding enhancements.

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