Synthetic Biology, Social Dimensions and Global Policy: A co-evolutionary perspective

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Themes
1) Innovation Systems Approach to Institutional co-evolution with technical advances
2) Early in the game: Proposals and “Influence Strategies”

Intellectual Property Rights
Meeting Patentability Barriers:
Engineer & target synthetic elements for well-defined functions
Clearly articulate at least one beneficial purpose, ideally at the level of synthetic elements/networks
Novelty, Non-obviousness, Enablement not an issue.

Licensing & Stimulation of further research:
Degradation of experimental use exemption doctrine
Free availability of synthetic elements to research community, or compulsory licensing

Higher Levels of integration:
2-part test proposed for plant & animal patents*:
Part 1: “Applicants must show that the organism under review would have little chance of developing naturally”* → Synthetic elements/networks designed to implement functions without a natural counterpart (exception: synthetic genome)
Part 2: “Applicants must also provide evidence that natural selection would actually work against the organism but for the intervention of human interest and technology”* → Synthetic networks/organisms designed to operate in controlled environments and not function in the wild

Bio-safety & Regulation
Individual Rights and Duties † †:
Researcher/Community code of conduct
Evolved to
Regulation By Administrative Agencies:
Application specificity at the synthetic organism level
Well-defined lifespan outside controlled environment
Well characterized “disable signal” (temporal, stimulus,..)
No means for genetic exchange with natural life-forms
Free avail. of publicly funded research on synth. elements
Evolved to
Legislative Pre-emption:
Potential to become key issue at higher levels of integration

Market Stimulation
Target Setting
Energy, Environmental, Therapeutic etc.
Financial incentives
Evolved to
Beyond Financial Instruments:
Global Infrastructure definition/support:
Synthetic organism distribution and containment
Niche Market Support: (Environmental cleanup, SB approaches for third-world disease)
Evolved to
Systematic Learning Platform
Provide means for incorporating real-world SB learning and social feedback into regulatory, and technical design:
Global Annual policy workshops

Governance / Policy
International Governments
EU
Standards Bodies
Consortiums
IP Rights (PTO)
Regulatory Entities

Technology Push
University Research
Private/Public Sector
Facilitators
Private Grants
Venture Cap.
Society

Technology Pull
Utility
Greater Public Good
Consumer

Global Coordination
Standards:
Aligned sequence screening approach.
Shared repository of offenders.
Evolved to
Infrastructure:
Common framework for distribution, tracking, and containment of SB products.

Public Perception
Address Public Uncertainty:
Global Annual Policy Workshop.
Proactive communication of SB vision & regulatory approach.
Evolved to
Normalization strategies & Network Management:
SB Normalization strategies via communication of success stories especially those involving greater public good.
Network Management through policy instruments

“Ethical Principles”
Sequence Level:
Mandatory screening
Customer tracking
Evolved to
Higher Levels:
Clear articulation of instrumental versus intrinsic value †
Robust characterization of lower levels of hierarchy prior to higher levels of integration


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