Synthetic Biology: Challenges of Ownership, Access & Rights

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10 Key Challenges for Ownership, Access & Rights in Synthetic Biology

- **It's an IPR Law Professor's Dream Final Examination**
- **It's More than Patents, or Open Source**
- **It's More than Just Intellectual Property – Expanding the Toolkit for Openness, Research and Innovation**
  - **Public-private Infrastructure Platforms**
  - **Standards**
  - **Collaborative Mechanisms and Knowledge Markets**
  - **Antitrust/Competition Policy**
- **It's Global: Globalization of the Research Base; Global Innovation and Value Chains; and Global Applications to meet Grand Challenges (health, energy, environment, food)**

1. Complexity of the Patent Landscape

- **A cumulative and complex general purpose set of technologies with multiple applications? What level, and what effects of patenting? Different rules for multiple layers? Patent thickets? Freedom to Operate? Incentives and Risk-taking? Patents that Protect Openness?**
  - **Foundational patents – U. Tennessee; NIH; Stanford; Sangamo; JCVI/Synthetic Genomics; Scarab Genomics (Wisconsin)** (Kumar/Rai 2007)
  - **Research Infrastructure and Tools – protocols, designs, tests**
  - **Patents on biological molecules; biological functions; classes of molecules**
  - **Standard genetic parts as functional items**
  - **Interfaces and chassis**
  - **Devices (one person's part may be someone else's device)**
  - **SynBio technology evolution (devices made from other devices)**
  - **DNA construction and editing – proprietary rights on large-scale gene synthesis**
  - **Computer software and modeling; CAD tools**
  - **Downstream Applications of SynBio**

Unresolved Patent Issues Will Shape SynBio's Future

- **Scope of patentability** – SynBio ideas, biological functions, molecules with specific functions, a specific sequence and/or methods of operation
- **Patent quality, scope and strength** – uncertainty, ambiguity, time-scale
- **Application of patent standards (prior art, enablement, nonobviousness)**
- **In U.S., pending cases are likely to have a major impact on SynBio patents**
  - ***In re Bilski*** ("mental steps" inventions and new "machine or transformation into new state" test to be reviewed by Supreme Court)
  - ***KSR International v. Teleflex*** implementation re nonobviousness
  - **ACLU/Myriad litigation** – patentability of genes and diagnostic methods
- **Application of 10 Patent Policy Levers to SynBio (**Lemley/Burk 2003)
- **Research Tools and Research Exemption issues** (Oye/Wellhausen 2008)
- **Material Transfer Agreements, including ownership/access/rights**
- **University technology transfers and licensing v. Knowledge Commons**
- **Development of SynBio Community Norms of Openness? (Example: Non-assertion Agreements)**

Key IPR Issues "Under the Radar" in SynBio Beyond Patents

- Panoply of Different IPR Rights Converge in SynBio and in many cases, it's the Bundle of Rights that matter
- **Design Rights**
  - Design Rights and Design Patents re technically-driven interoperability issues (10 years protection)
  - "Must Fit" and "Must Match" IPR exemption for parts?
- **Databases** (15 years protection)
  - EU Database Directive – "intellectual creation" + "investment"
  - OECD Guidelines for Access to Human Genetic Research Databases and national guidelines
- **Copyright** – thin and questionable application to SB, but
  - Originality and expression in increasingly long synthesis
  - Decoupling of biological parts and systems design from manufacture and production
  - References and annotations?
- **Sui Generis Rights** – e.g., Mask Works and Plant Breeder's Rights
- **Trademarks**
  - e.g., the BioBrick™ logo and ID tag are important quality control tools
  - Formats make a difference (e.g., trademarked DVD formats)

3. Competing Visions of Openness

- **Open Science** (Public domain; BioBricks library/BBF) **v. Open Source** (IPR-driven; GPL, BSD, CC) **v. Open Standards v. Open Innovation**

- **Semi-commons as a new lens to view SynBio – interacting common and private uses that are dynamic/scalable over the same resources and that can adjust through contracting and other mechanisms**
  - Allen (2000); Fennell (2009); Michelman (1985)
  - Privately and commonly-owned elements are always interacting, and they must be dynamic and able to shift over time (Demsetz 1987)
  - Configure ownership in different ways under different circumstances – both are better off through the existence and interaction with the other
  - Mixed Ownership reflects different scales (simultaneous or over time) at which different activities best undertaken
  - Same Resources used in multiple ways with many spillovers
  - Creative Commons as an example: public use rights and public ownership rights -- Loren (2006)

4. Clashes of Cultures on Multiple Levels

- Multidisciplinary, convergence, complexity – each with its own IPR culture and IPR world views (Biotech-Pharma/ IT software/computing/Chemical industry synthesis/ Semiconductors/Systems engineering cultural divides)
- Limited alignment of interests on ownership/access – multiple players span multiple arenas: universities, industry (MNEs and SMEs), government, public research organizations, NGOs, the iGEM generation, libertarian hacker communities
- Convergence and Globalization - changing nature of global research base, global innovation and global ICT-enabled
- From Trust (Community) to Contract as SynBio grows and develops in multiple directions
  - Benefits from creating tradable, securitizable, assignable IPR, parts, etc.
  - Proliferation of new intermediate IPR knowledge markets and mechanisms
- IPR Regimes interact with SynBio at different points in innovation

5. User-Driven Innovation and Platform Infrastructure Openness And Access Are Key for SynBio - Requires Government Initiatives and Policies (and Support) for Leveraging Shared Resources

- User-driven Innovation or "Democratizing Innovation" (von Hippel) will dominate in SynBio; therefore, public policies for ownership/access should be more aligned with users than producers
- Example: Characterization of genetic parts – model of the NCI's Nanotechnology Characterization Lab + NIH rules of road
  - Open Source: publicly-funded development with openly distributable products and data
  - Open Development: community-driven development to align needs with priorities
  - Open Access: data and characterization have value beyond original purpose for collection/submission. Scientific verification. Reuse. Obligation to share publicly-funded data and parts
  - Federated: Scalable. Local control of uses. No central control

6. Standards – IPR Interface as Key Driver for SynBio

- Standards = the inevitable outgrowth of systems and user needs but must be adaptable as science and tools change

- SynBio interoperability, modularity, compatibility, connectivity ("functional composition") increasingly will require standards and common specifications for different purposes (physical, logical layers, interfaces/connectivity, applications)

- Characteristics of standards as key - Who Controls? What Rules? Implementation?
  - De Facto: market competition-driven? Does it drive faster innovation and adoption with greater flexibility?
  - Open Standards: Standard Setting Organizations – SSOs through open process (proprietary v. non-proprietary)
  - Open Source Standards (OSS): royalty-free

Standards – IPR Interface

- Rules for Standard-setting, including specifications
  - IPR policy?
  - Search IPR?
  - Should standard include IPR essential to implement the standard?
  - Licensing provisions?
- Key emerging standards-IPR issues for SynBio -
  - RAND specifications: *ex ante* disclosure v. *ex post*
  - Royalty-free licensing? (e.g., OSS or W3C model)
  - Open Source licensing v. open standards conflicts
  - Harmonization of SSO-IPR terms (ABA project)

7. IPR Beyond Biotech/IT – Lessons of Semiconductors (and Nanotechnology)

- **Increasing complexity of designs, equipment and fab facilities – 1,000+ inventions must be integrated; increasing shift from standard functions to more complex specifications**

- **Integrated semiconductor producers – an example of an innovative, stable but closed sharing community with strong IPR and patent thickets**
  - **Patent thickets facilitate pro-innovation, knowledge-sharing arrangements**
  - **Cross-licensing**
  - **Uses IPR only to exclude those who don't share or don't play by rules**
  - **Avoids the "free rider" problems in pure, open sharing regimes**

- **Design boutiques depend on strong IPR and enforce it**

- **Reuse is critical element -- it fuels innovative designs and integration**

- **Creation of IPR Blocs -- a UNIT OF REUSABLE DESIGN; assemble IPR packages; FTO; key to reuse and integration**

8. Increase Focus on Collaborative Mechanisms, Knowledge Markets and Networks (OECD)

- **<u>Collaborative Mechanisms</u> - SynBio as a Real-world Test-bed for Experimentation (OECD 2009)**
  - **<u>Patent Pools</u>: Create SynBio Patent Pools (IPR, Standards, and "One-Stop Shopping") where essential patent, blocking positions become acute and threaten research/innovation**
  - **Encourage Clearinghouses, exchanges, prizes**
  - **Pre-competitive consortia (NIH model has worked well)**
  - **Contractual "workarounds"**

- **<u>Knowledge Networks and Markets</u> – OECD Agenda**
  - **-- OECD/NAS Workshop (Oct. 2008)**

9. A Global SynBio Community Requires a Greater Focus on Global IPR-related Issues

- World Trade Organization (WTO)
  - TRIPS, including Art. 29 (no technology-exceptionalism)
  - Doha Development Round and Technology Transfer
- World International Property Organization (WIPO) – Access to Knowledge/Development Agenda issues
- Convention on Biological Diversity – "Access and Benefit Sharing" links to SynBio
- IPR, SynBio and Global Challenges – Energy, Environment, COP15
- SynBio compatibility with other global IPR issues – e.g., WHO rules for sharing influenza sequence data and biological materials
- Major global disconnects –e.g., US v. EU
  - Ordre public and morality tests in EU and elsewhere; databases; software/algorithm patents
  - Different tests for IPR-competition –standards interface
  - European Patent
- Different National approaches – e.g., new China Anti-Monopoly Law

10. Reinvigorated Antitrust to Counterbalance IPR and Promote Openness/Competition

- Antitrust rules to create and enforce openness/access
  - Market power
  - Strategic conduct and behavior with IPR
- Technology and Research Markets
- Essential Facilities Doctrine
- Antitrust as the “standards police”
- Protect competition, not competitors
- Market will facilitate open access to the extent that open access is efficient (Chicago)

And There are Still Other Ownership/Access Issues that Require Attention for SynBio

- IPR and Liability - e.g.,
  - Linkage of liability with Open Source Licensing regimes
  - Clauses -- “As Is” ; “Without warranty”; “User assumes all risk”
  - Direct and contributory liability and infringement issues
  - Limitations on liability

- IPR and National Security
  - Invention Secrecy Act
  - U.S. Export Controls, IPR and SynBio

- IPR and Entrepreneurship/SMEs in Synthetic Biology
  - SMEs: The FTO/Intellectual Assets Paradox
  - Capital Formation and Sustainable Growth

- Intellectual Assets for Value Creation - OECD (2005-2008)
  - Governance, Disclosure, Organizational Innovation

THANKS!

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