LEAP
Synthetic Biology
Leadership Excellence Accelerator Program

Integrating Responsible Innovation Research into Commercialization Practices for Synthetic Biology R&D

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Abstract

Research universities are de facto science and technology policy laboratories[1] attempting to reconcile powerful incentives to accelerate R&D commercialization with ethical and democratic commitments to responsible innovation (RI). Social scientists have called for applying RI research tools to education programs that teach university scientists about entrepreneurship (e.g., Innovation Corps)[2]; but silos separating RI research from commercialization practices persist in national legislation and in practice.[3] It is time for university administrators, grant agencies, and principal investigators to integrate these activities. This action plan aims at an administrative vision to guide this integration, taking synthetic biology R&D as a focus. R&D commercialization entails a push and pull of competing commitments to investors, regulators, consumers, inventors, varied ethical perspectives, and public values.[4] Technology transfer experts emphasize that "whoever gets it to market in the fastest and most effective manner wins,"[5] but accelerated commercialization is only part of the story. The bigger situation is that research universities are in a position to redesign the DNA of corporate personhood and the ethos of responsible innovation, shaping the transformative potential of emerging technologies by paying equal attention to the material and social sides of innovation.[6]

[1] Crow, Michael M., and Christopher Tucker. "The American Research University System as America's De Facto Technology Policy." *Science and Public Policy* 28 (1), (2001): 2–10.
[2] Youtie, Jan. "Exploring Public Values Implications of the Innovation CorpsProgram." Paper prepared for the Public Values Consortium, Phoenix, Arizona, January 7–8, 2015.
[3] H.R. 591, 114th Congress, *Engineering Biology Research and Development Act of 2015*.
[4] Shimasaki, Craig, ed. *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies.* Oxford: Academic Press, 2014.
[5] Pappano, Laura. "Got the Next Great Idea?," *New York Times*, July 19, 2012. Accessed July 19, 2016. http://nyti.ms/18mHKIZ.
[6] Jasanoff, Sheila. "Interview at STEPS Centre Symposium," September 24, 2009. YouTube video. Accessed July 29, 2016. https://www.youtube.com/watch?v=Wchh88BFE70.

Introduction: Exploring the social and ethical dimensions of good science

A young scientist entering today's research university enrolls in a rapidly evolving culture of discovery that co-locates educational excellence with "basic and applied" research, prototyping, small-volume production, and business development.[7] Business incubators are sprouting up on campuses all over the map. It is not uncommon for law students to offer legal advice to student scientists and engineers who collaborate with business students to build an emerging technology company.[8]

The same student scientist struggling to bring a new invention to market might spend her free time contributing to open-source innovation at an off-campus community lab. She might also take an industrial R&D internship. These hybrid institutional affiliations and skillsets expose young scientists to a variety of ethical perspectives about how innovation ought to function in society, and what it means to be a good scientist. To understand what these young scientists are going through, social scientists interested in responsible innovation need to adapt their research techniques to these shifting knowledge production patterns.

For several years, I have been documenting laboratory scientists' attitudes toward existing commercialization pathways. Many of these workers are convinced that the particular combinations of legal, financial, technical, and cultural expertise offered in university and industry technology transfer offices unnecessarily constrain the style of commercialization that shapes the fate of their laboratory inventions. For these lab-level innovators, a true culture of discovery at research universities requires networks of legal, financial, technical, and cultural expertise to co-evolve with the ethical aspirations of those whose inventions enable social change. My contention is that social scientists can use responsible innovation research methods to facilitate this co-evolution.

The current science and technology policy landscape

At the level of national and international science-and-technology policymaking, the current trend of market legitimation is for legislators to combine a discourse of *responsible innovation* (RI) or *responsible research and innovation* alongside an imperative to accelerate commercialization of promising research. In practical terms, synthetic biology R&D, like nanotechnology and neuroscience, currently entails a division of labor in which responsible innovation research keeps a distance from commercialization practices, functioning as separate silos of activity.[9]

Deliberately merging these silos is a timely, legitimate opportunity. Since RI research has not yet ventured into this territory, a unique gathering of minds has to find ways of aligning the exploration of alternative commercialization pathways (e.g., ownership models, legal mechanisms, joint partnerships, new combinations of disciplinary expertise and stakeholder engagement) with existing commercialization decision processes without proliferating financial risks or closing off conventional spinoff and licensing pathways.

Fortunately, research universities have varied combinations of these resources on hand, often huddled in separate buildings focusing on discipline-specific research questions. With some concentrated effort on the part of university administrators (along with grant agencies and principal investigators), RI

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[7] For example, Arizona State University's Nano-scale Engineering Southwest Infrastructure project, MIT's Broad Institute, and Harvard's Wyss Institute.

[8] Importantly, these students might have each grown up in different countries. Prolonged exposure to diverse cultural and socioeconomic perspectives (or lack thereof) can be viewed as an independent variable that potentially affects scientist-entrepreneurs' preferred style of R&D commercialization.

[9] See, for example: S. 189, 108th Congress, 21st Century Nanotechnology Research and Development Act, which nevertheless mandates "…insofar as possible, integrating research on societal, ethical, and environmental concerns with nanotechnology research and development…"

researchers can create new communication networks around themes of RI cum knowledge commercialization. Engineering biology is a particularly appropriate area in which to concentrate "lines of force."[10]

The current synthetic biology landscape

These are the days of platform design and competition over R&D infrastructures, which will shape the coming decades of synthetic biology innovation. Scientists and software engineers are designing laboratory robotics software to automate labor-intensive genetics experiments, along with apps that anticipate and correct errors in planned experimental designs with the eye of an expert. Others are expanding the catalogue of species whose genetic machinery will become design space for engineering biology.

Powerful techniques for sculpting the DNA of wild populations are on hand, a prospect that calls for public deliberation about the risks and rewards of quarantined field tests and clinical trials. Huge sums are at stake in legal battles over key patents funded by taxpayer dollars, while others design legal mechanisms to guarantee a future of open innovation driven by a sharing ethos.[11] The same universities seeding biotech innovation ecosystems in the UK, US, China, Singapore, and elsewhere via capital-intensive spinoffs and joint partnerships with industry, government, and nonprofit sectors are also democratizing access to how-to manuals for engineering biology using high-quality, low-cost instrumentation and DNA synthesis suppliers.

Step one: challenging our assumptions about responsible R&D commercialization

Synthetic biologists are critically engaged with the constraints of competition on ethical commitments, but the conversation is often structured by tropes and assumptions about the potential for adapting alternative commercialization practices. In 2013, for example, the prominent Harvard synthetic biologist George Whitesides discussed just these questions with Alfred P. Sloan Foundation President Emeritus Ralph Gomery at an American Philosophical Society symposium[12] on the history and future of the US corporation:

> *Whitesides: "The question is: if one can structure a corporation in many different ways—and I can do it for profit, I can do it for social benefit, I can do it for value added, I can do it for anything else—presumably, in a competitive system, each of these experiments is being tried; and what one sees is the survival of corporations that behave in a certain way in a given set of regulations. Is the implication of that that only regulation and law can change the behavior of corporations as they presently stand?"*
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> *Gomery: "Nothing prevents anyone from starting a corporation on different lines. We could start a value added corporation tomorrow, or a bank on those lines. You don't have to convince the nation. You just have to convince enough people to do a small thing, and do it. Let's see how these things work, and see what groups wake up to how what we're doing now is not so successful. Then, let them try, without convincing anyone in Washington…on a small scale. And let's see what happens!"*

Clearly, some synthetic biologists presume the existence of "a competitive system" in which all potentially viable commercialization pathways are being explored to the full extent allowable by existing regulatory constraints. But if synthetic biology can teach the social sciences anything, it is that the evolution of

[10] Latour, Bruno. *The Pasteurization of France.* Translated by A. Sheridan (Part I) and J. Law (Part II), 171. Cambridge MA: Harvard University Press, 1988.
[11] Dusollier, Severine. "Sharing Intellectual Property Through Private Ordering," *Chicago-Kent Law Review* 82, 1391–1436.
[12] American Philosophical Society. "Panel Discussion," November 2013. American Philosophical Society Autumn Meeting. Accessed July 10, 2016. http://diglib.amphilsoc.org/islandora/object/video:1239.

competitive systems guarantees only idiosyncratic exploration of the available design space. Consider the transdisciplinary insight, for example, of "orthogonal translation" research in synbio. Cellular structures (ribosomes) that took a billion years to evolve are modified to churn out industrial polymers by reading 4-codon amino acid sequences that have never existed and would otherwise never exist, all without undermining the cell's basic life support systems.[13]

To stretch the analogy, research universities can modify existing de facto S&T policy by redesigning the division of labor currently separating RI research from commercialization practices, without undermining the existing metabolism of accelerated commercialization, so to speak. In practice, this requires university administrators (along with grant agencies and principal investigators) to design new opportunities for unorthodox combinations of scholar-practitioners from the traditional silos of the humanities, social sciences, natural sciences, etc. to explore the RI-commercialization design space. In this way, longstanding concerns about the direction of innovation pathways, social distribution of benefits and harms, and diversity of stakeholder participation in innovation inputs[14] can earn more spotlight in the synthetic biology landscape.

Step two: implementation pathways for RI-commercialization pilot programs

The administrative vision presented here views RI-commercialization research as a vital administrative function of the research university rather than a hybrid academic field of study. However, implementing this administrative vision can begin with academic research projects that probe the division of labor that separates RI research and commercialization practices in synthetic biology R&D. Two such implementation pathways come readily to mind: first, a series of case studies focused on current commercialization practices; and second, projects that use collaborative scenario planning to anticipate legal, ethical, social, and environmental aspects of tomorrow's synthetic biology research equipment, knowledge production, and commercialization practices. Both implementation pathways are properly viewed as early instances of a broader vision of university administration and de facto science and technology policy design.

Case studies that locate RI-commercialization activities within existing entrepreneurship boot camps for scientists and engineers (e.g., I-Corps) might proceed as follows.[15] First, trained RI researchers administer pre- and post-program interviews and questionnaires to I-Corps teams, prompting scientists and engineers to imagine legal, social, and ethical dimensions of business design in new ways. RI researchers could also collaborate directly with synthetic biologists during I-Corps introductory workshops, web lectures, and team research processes (e.g., identifying and engaging potential customers).

A second case study pathway might apply the same RI research techniques of the I-Corps approach at different locations in the innovation process on university campuses: technology transfer offices and business incubators, for example, where scientists and engineers access legal and economic expertise. Exploring legal, social, and ethical dimensions of R&D commercialization alongside lab-level innovators, tech transfer agents, and investors might clarify what is at stake in the push and pull of competing commitments mentioned previously. The goal of these efforts is to integrate RI research methods into the "the chaos and uncertainty of how a start-up actually works,"[16] including formative organizational choices about the composition of corporate charters, selecting boards of directors, science advisory boards, and so on. This research requires strong administrative leadership to attract competent participants with

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[13] Chin, Jason W. "Expanding and Reprogramming the Genetic Code of Cells and Animals," *Annual Review of Biochemistry* 83 (2014): 379–408.
[14] STEPS Centre. *Innovation, Sustainability, Development: A New Manifesto.* Brighton: STEPS Centre, 2010.
[15] A number of social science research tools might be readily adapted to I-Corps integration aside from those described here. See Fisher, Erik, Michael O'Rourke, Robert Evans, Eric B. Kennedy, Michael E. Gorman, and Thomas P. Seager. "Mapping the Integrative Field: Taking Stock of Socio-Technical Collaborations," *Journal of Responsible Innovation* 2(1), (2015): 39–61.
[16] Blank, Steve, Ann Muira-Ko, and Jon Feiber. Syllabus for Stanford University seminar *ENGR 245: The Lean Launch Pad.* Accessed August 25, 2016. http://web.stanford.edu/group/e245/cgi-bin/2011/wp-content/uploads/2010/12/e245-syllabus-rev12.pdf.

requisite expertise willing to explore alternative RI-based rationales for making these formative commercialization choices.

A series of RI-commercialization research projects rooted in anticipating future research and commercialization environments might proceed as follows. First, interdisciplinary teams identify trends in the costs, capabilities, and geographical diffusion of research equipment, industrial production, and technical know-how of synthetic biology. These teams then develop scenarios that incorporate those trends, focusing on plausible synthetic biology applications with powerful impacts on "the shape and make-up of the institutions at the interface between technology and the human experience."[17] For example, if costs of research equipment, small-volume production, and reliable quality controls fall significantly in coming decades (in various countries), networks of non-affiliated community labs and hackerspaces might become more prominent sources of synthetic biology innovation. If these lab venues continue to cultivate a unique, socially inclusive "sharing ethos," RI research might locate exploration of commercialization pathways here.

In 2016, small community labs attempting to produce low-cost human insulin with biotechnology techniques[18] currently lack the quality control infrastructure necessary to produce and distribute regulator-approved human insulin products. However, it is plausible to anticipate an eventual innovation ecosystem in which such labs are better equipped. RI-commercialization research might involve collaborating with today's community labs, S&T policy scholars, and social innovators to anticipate the implications of a scenario driven by a successful design and small-volume production process for insulin products. Potentially, there are profound lessons to be learned from a scenario in which synthetic biology designs are circulated via a sharing ethos to labs in low- and medium-income countries in which limited access to affordable insulin routinely results in death. A range of complicated economic, social, legal, ethical, and health and safety issues arise from this very plausible scenario. Thinking through these issues in a rigorous way would exemplify the effort to align RI research and commercialization practices at research universities.

[17] Crow, Michael, and Daniel Sarewitz. "Technology and Social Transformation." In *The Rightful Place of Science: Politics*, edited by G. Pascal Zachary, 85. Tempe, AZ: Consortium for Science, Policy and Outcomes, 2013.
[18] Stelzer, Andrew. "Oakland Hackers Take a Stab at Making Crowdfunded Insulin." *The California Report*, July 25, 2016. Accessed July 25, 2016. http://ww2.kqed.org/news/2016/07/25/oakland-hackers-try-to-make-insulin-and-disrupt-biotech/.