BEFORE PEER PRODUCTION: INFRASTRUCTURE GAPS AND THE ARCHITECTURE OF OPENNESS IN SYNTHETIC BIOLOGY

David Singh Grewal*

In memoriam Mark Fischer (1950 – 2015)∝

* Professor of Law, Yale Law School, and Director, BioBricks Foundation. The views expressed here are my own, and do not reflect the views of any of the organizations or entities with which I am or have been affiliated. Among those to whom I owe thanks, I am especially grateful to Drew Endy, President of the BioBricks Foundation (BBF) who worked to educate me about synthetic biology, and later invited me to join the board of directors of the BBF, and to the late Mark Fischer, who was the lead drafter (along with Drew Endy, Lee Crews, and myself) of the BioBrick™ Public Agreement, and to whose memory this Article is dedicated. I am also grateful to other past and present directors and staff of the BBF, including Richard Johnson, Linda Kahl, Tom Knight, Thane Krier, Nathalie Kuldell, Holly Million, Jack Newman, Randy Rettberg, and Pamela Silver. I have benefitted from conversations about synthetic biology and open source theory with a number of other scientists, including Rob Carlson, George Church, Jason Kelly, Manu Prakash, Zach Serber, Reshma Shetty, Christina Smolke, Ron Weiss and with a number of lawyers, scholars, and open source advocates including Yochai Benkler, James Boyle, Daniela Cammack, Paul Cammack, Paul Goldstein, Hank Greely, Janet Hope, Margot Kaminski, Mark Lemley, Stephen Maurer, Eben Moglen, Lisa Ouellette, Jedediah Purdy, Arti Rai, Pamela Samuelson, Jason Schultz, and Andrew Torrance, and especially Talli Somekh, who first introduced me to synthetic biology and noted the connections between my work in network theory and new developments in biotechnology. At Yale Law School, I have enjoyed the benefit of my colleagues' feedback on these ideas, and want to thank especially Amy Kapczynski, Bruce Ackerman, Ian Ayres, Jack Balkin, Oona Hathaway, Robert Post, Scott Shapiro, and Reva Siegel. I presented drafts of this Article at the Yale Law School Faculty Workshop, and the Law and Biosciences workshop at Stanford Law School, and am grateful for many useful comments. I presented earlier thoughts on openness in synthetic biology in several forums: the Fourth International Conference on Synthetic Biology; the Berkman Center, Harvard Law School; the Information Society Project, Yale Law School; and the BioLaw conference at the University of Kansas Law School. I also want to thank the students in my "Open Source Systems" and "Collective Action" seminars at Yale Law School, where some of these ideas were first discussed. I owe particular gratitude to my superb research assistants, Matthew Ampleman, Shaun Mahaffy, Alexandra Perloff-Giles, and to the dedicated editors of the *Stanford Technology Law Review*.

∝ A few days before I had planned to send him a first draft of this Article, I received the tragic and unexpected news that my friend and colleague Mark Fischer had died. His premature death means the loss of a brilliant and creative attorney and lifelong advocate for open innovation. Mark was the lead drafter of the BioBrick™ Public Agreement, discussed extensively in these pages, and (two decades earlier) the GNU Emacs License, the precursor to the famous GPL v.1. He also served as counsel to the BioBricks Foundation, and represented many other clients engaged in creative and scientific work. All of us who use free or open source software—which is

CITE AS: 20 STAN. TECH. L. REV. 143 (2017)

ABSTRACT

Legal scholarship on intellectual property needs to be reoriented to consider how state action helps to generate the infrastructure of emerging fields in ways that prove conducive to their development. In this Article, I contribute to that reorientation through an in-depth analysis of one important emerging technology, synthetic biology. The ambition of synthetic biology is to make biology easier to engineer through standardization and associated technical processes. Early successes indicate the scientific promise of the field and help to explain why its advocates are concerned to see the field develop in an open and publicly beneficial manner. What openness might mean in the patent-dominated context of biotechnology remains unclear, however, and requires a reassessment of software's "copyleft" concept that provided initial inspiration to the scientists and activists working on open synthetic biology.

In this Article, I focus on the efforts of the BioBricks Foundation (BBF), the leading non-profit in synthetic biology, to promote the open development of the field. I explore the rationale behind the BBF's decision to pursue a "public domain" strategy via a new legal agreement, the BioBrick™ Public Agreement. The success of open development in synthetic biology depends, however, not only on the particular form of legal license or agreement used to govern the distribution of innovation, but on overcoming what I call "infrastructure gaps" that inhibit cooperative action toward collective outcomes. Such cooperation is the hallmark of peer production projects in the information economy and the hope of many synthetic biologists is to replicate that success in biotechnology.

The viability of this public domain strategy for open synthetic biology depends on establishing peer production without the backing of legal coercion provided through a "share-alike" licensing provision as seen in free software. In scrutinizing the motivations behind peer production, I borrow from recent philosophical work to argue for the potential rationality of decentralized cooperation, even where individual contributions to a collective project are small. Such cooperation depends, however, on threshold effects that mark points where individual contributions become efficacious in producing desired collective outcomes. In many emerging fields, including synthetic biology, these thresholds may be characterized by the presence or absence of shared technical platforms that enable further innovation.

---

to say, anyone reading this text—are in his debt. And if the twenty-first century sees the open development of beneficial biotechnologies, that, too, will be owing partly to Mark's early efforts. This Article would have been much improved by his insights and advice, which he always gave so generously to the many projects and people he supported in his wondrously full life. He is missed.

Platforms are special kinds of infrastructure, as recent work from law and political economy has shown. The question of how such platforms are to be produced requires considering further the role of state action in infrastructure provision. I argue that the success of openness in synthetic biology depends on meeting infrastructural prerequisites that are mainly, if not exclusively, provided through state action. Such state action may proceed, however, through "hidden" modalities of the kind that theorists of industrial organization have identified, and which ought to be a central concern of legal scholars and advocates interested in the theory and practice of open source technology development.

TABLE OF CONTENTS

I. INTRODUCTION

Beginning in the 1990s, and drawing on the occasional hint from earlier decades, scientists working in areas such as molecular biology, biochemistry, and some areas of biological engineering began to explore the possibility of standardization in the life sciences. What standardization might mean in the life sciences was (and remains) contested, but the examples from which these scientists drew analogies were clear. Standardization of some kind is central, perhaps even constitutive, of almost any contemporary scientific or industrial process.[1] Proponents of standardization in the life sciences already employed standards familiar to all the experimental sciences—protocols of measurement, communication, and data management necessary for the transmission and confirmation of scientific results—and they wondered whether standards regulating physical manipulation and control comparable to those in engineering and other applied sciences might have analogues or extensions in the field of biology.[2]

1. On standardization, see STEPHEN MIHM, MASTERING MODERNITY: WEIGHTS, MEASURES, AND THE STANDARDIZATION OF AMERICAN LIFE (forthcoming 2017); STANDARDS AND THEIR STORIES: HOW QUANTIFYING, CLASSIFYING, AND FORMALIZING PRACTICES SHAPE EVERYDAY LIFE (Martha Lampland & Susan Leigh Star eds., 2009); Stefan Timmermans & Steven Epstein, *A World of Standards but Not a Standard World: Toward a Sociology of Standards and Standardization*, 36 ANN. REV. SOC. 69, 89 (2010). *See generally* DAVID SINGH GREWAL, NETWORK POWER (2008).

2. *See, e.g.*, Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449 (2005). For a discussion of Endy's ground-breaking article, see MANUEL PORCAR & JULI PERETÓ, SYNTHETIC BIOLOGY: FROM IGEM TO THE ARTIFICIAL CELL 45-46 (2014). *See also* discussion *infra* Part II.A.

Their endeavor was marked by the denomination of a new subfield: "synthetic biology," which might more simply have been called bioengineering or biological engineering if those terms were not already in use to describe the disciplines of applied agricultural or medical engineering.[3] The mission of synthetic biology, according to Drew Endy, one of its leading theorists and practitioners, is to "make biology easy to engineer."[4] The strategy is to produce and promote engineering standards at the bio-molecular level, with the aim of developing a suite of "standard biological parts"[5] to replace the current ad hoc, artisanal methods common in biotechnology.

Alongside this defining scientific and technical ambition, the early pioneers of synthetic biology shared a commitment to the development of the field in an open manner. As with standardization, the question of what "openness" might mean in this domain was (and remains) contested. Again, however, the examples from which these scientists drew analogies were clear. The early pioneers of synthetic biology were almost all academics working beneath the protective umbrella of a *de facto* "research exemption" from claims of intellectual property infringement,[6] and were therefore accustomed to the relatively free flow of ideas in a competitive status-system based on publicity not price.[7] Moreover, they had before them—and used daily—the fruits of the earlier open source revolution in computing.[8] In fact, a number of the seminal figures in the early development of synthetic biology were polymath scientists who migrated mid-career from electronics or computer science

3. It was familiar in academic nomenclature to call medical engineering "bioengineering" and agricultural engineering "biological engineering" before synthetic biology was inaugurated as a field. This is now changing, with both terms being used to describe more foundational approaches associated with synthetic biology and allied fields. For example, the new Stanford Department of Bioengineering was established in 2002 and is intended to "develop bioengineering as a fundamental engineering discipline." *See Department Overview*, STANFORD BIOENGINEERING (May 14, 2017), https://bioengineering.stanford.edu/about/department-overview [https://perma.cc/YDV7-LHYX]. The first use of the term "synthetic biology" is widely cited to Nobel Laureate Waclaw Szybalski, who called in 1978 for a "new era of 'synthetic biology' where not only existing genes are described and analyzed but also new gene arrangements can be constructed and evaluated." Waclaw Szybalski & Ann Skalka, *Nobel Prizes and Restriction Enzymes*, 4 GENE 181, 181-82 (1978). *But see* Luis Campos, *That Was the Synthetic Biology that Was*, *in* SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 5 (Markus Schmidt, et al. eds., 2009) (discussing the early history of standardization efforts in biology and early twentieth-century uses of the term "synthetic biology," apparently unknown to later scientists, including Szybalski's own failure to recollect his early use in 1978 once the field had emerged in earnest several decades later. *See id.* at 6 n.2).

4. *See generally* Endy, *supra* note 2.

5. For a discussion of the concept of standardized parts, see *infra* Part II.A.

6. *See* DAVID MOWERY, ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES 186-87 (2004) (discussing the *de facto* academic research exemption).

7. *See generally* Paul Blackmore & Camille Kandiko, *Motivation in Academic Life: A Prestige Economy*, 16 RES. POST-COMPULSORY EDUC. 399 (2011) (describing academic work as motivated by considerations of prestige, not profit).

8. *See generally* OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION (Chris DiBona & Sam Ockman eds., 1999) for a collection of manifestos, interviews, and comments from the pioneers of F/OSS in computing.

to biotechnology, bringing with them both an engineering mindset and a first-hand knowledge of technological innovation in an arena marked for a decade or more by the promulgation of "free" or "open source" software (F/OSS).[9] These dual commitments to standardization and openness were notable from the first development of synthetic biology and contrasted strikingly with established practice in much of the biotechnology industry, in which the technical possibility of standardization remains underexplored,[10] and in which aggressive patenting is a central aspect of business strategy.[11]

More than a decade has passed since the emergence of the field,[12] and it is now possible to assess the advances made in these two core commitments to standardization and openness. In terms of standardization, the past few years have seen some striking early confirmations of its promise, which are notable against the backdrop of continuing skepticism about its applicability to the life sciences.[13] Early successes have included the use of engineered strains of yeast to produce the anti-malarial drug artemisinin at a fraction of the price of the naturally derived compound,[14] and the popularity of the annual "International Genetically Engineered Machines" (iGEM) competition, a synthetic biology contest in which thousands of college and high school students from around the world use standard biological parts to produce novel biological constructs.[15] Less publicly visible but extremely important theoretical and experimental breakthroughs include the possibility of precisely controlling gene expression, a prerequisite for building sophisticated genetic systems.[16] Likewise, the arrival of a powerful new technique

9. For example, Tom Knight and Randy Rettberg both migrated mid-career from careers in computer and electrical engineering to biology; among other achievements, Knight had helped construct the first ARPANET (the precursor to the Internet) and Rettberg the Internet protocol suite (TCP/IP). Both were later founding members of the BBF. Anne Trafton, *Rewiring Cells: How a Handful of MIT Electrical Engineers Pioneered Synthetic Biology*, MIT TECH. REV. (Apr. 19, 2011), https://www.technologyreview.com/s/423703/rewiring-cells [https://perma.cc/XM8F-B683].

10. *See* Alistair Elfick, *Constrained Creativity: An Engineer's Perspective*, *in* SYNTHETIC AESTHETICS: INVESTIGATING SYNTHETIC BIOLOGY'S DESIGNS ON NATURE 181, 187 (Alexandra Daisy Ginsberg, et al. eds., 2014) ("Genetic modification (GM) of the late twentieth century was a practical art, highly skilled, artisan, and craft-like. DNA was tailored for bespoke production of high value products."); *see also* Timothy Gardner & Kristy Hawkins, *Synthetic Biology: Evolution or Revolution? A Co-Founder's Perspective*, 17 CURRENT OPINIONS CHEMICAL BIOLOGY. 871, 874 (2013) ("Also driving the convergence of thought [concerning standardization in cellular engineering] was a frustration with the artisanal methods of the past two decades of genetic engineering.").

11. *See generally* Sharon Oriel, *Making a Return on R&D: A Business Perspective*, *in* THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY INNOVATION 118 (David Castle ed., 2009) (discussing the role of patents in biotechnology sector).

12. Editorial, *Ten Years of Synergy*, 463 NATURE 269 (2010).

13. For cautions about the field's technical potential, see Roberta Kwok, *Five Hard Truths for Synthetic Biology*, 463 NATURE 288 (2010).

14. *See infra* Part II.B.1.

15. *See infra* Part II.B.2.

16. *See infra* notes 75-79 on the use of bicistronic architecture to achieve precise gene expression, thus demonstrating the potential to construct "standard biological parts."

for editing genes—the use of "clustered regularly-interspaced short palindromic repeats" or CRISPR—demonstrates not only the growing possibility of reliable and cheap gene editing, but the enormous demand for such methods in biotechnology.[17]

These and other breakthroughs suggest that the standardization agenda of synthetic biology, and the broader mission of turning biology into an engineering discipline, will come to fruition—though the progress may prove slower than early advocates had hoped. How has the commitment to the open development of synthetic biology fared? This Article focuses on the history of recent legal efforts to achieve "openness" in synthetic biology. I necessarily consider what openness might mean in synthetic biology and allied disciplines, as well as the future prospects for open development in biotechnology generally. While the example of "copyleft"[18] in F/OSS projects—the use of unconventional copyright licenses that require open source code and the sharing of derivative works—has proven enormously influential, no similar hack has yet proven conducive to the open development of biotechnology, despite several years of legal work aimed at advancing it. In analyzing these dynamics, I focus in some detail on the efforts of the main organization working to promote open synthetic biology, the BioBricks Foundation (BBF). Despite initial enthusiasm for a copyleft analogue for biotechnology, the BBF ultimately decided to pursue what might be called a "public domain" agenda via a new legal agreement, the BioBrick™ Public Agreement, which lacks the "share-alike" provisions of several F/OSS licenses, most importantly, the GNU Public License (GPL).

While I am mostly concerned with understanding the legal governance of innovation in synthetic biology, this case study may offer broader lessons for scholars interested in technology law, including the organization of open-source communities. One of the main conclusions of this Article is that the model of copyleft in F/OSS, which has established the paradigm of open technical development, has proved of limited applicability to "wetware"[19] rather than software. I suggest this is so for two reasons. The first is the difference in legal governance between the copyright-based industry of software and the patent-based

17. CRISPR promises to reduce dramatically the cost and difficulty of editing DNA. Unlike its expensive and complicated precursor technology, the use of zinc finger nucleotides in gene editing, the CRISPR method is reliable and cheap:

> it relies on an enzyme called Cas9 that uses a guide RNA molecule to home in on its target DNA, then edits the DNA to disrupt genes or insert desired sequences. Researchers often need to order only the RNA fragment; the other components can be bought off the shelf. Total cost: as little as $30.

Heidi Ledford, *CRISPR, the Disruptor*, 522 NATURE 20, 21 (2015).

18. The term "copyleft" was coined by free software pioneer Richard Stallman to describe the deployment of copyright law to anti-proprietary effect. *See* SAM WILLIAMS, FREE AS IN FREEDOM: RICHARD STALLMAN AND THE FREE SOFTWARE REVOLUTION 128-29 (2010) (on the use of "copyleft" in first the GNU Emacs license and then the famous GPL).

19. OPENWETWARE (June 20, 2014), http://openwetware.org/wiki/Main_Page [http://perma.cc/YT6N-PEXV] (adapting the use of "hardware" and "software" from computing to describe biological organisms and parts as "wetware").

domain of biotechnology.[20] The second is the magnitude of what has been termed the "capital cost"[21] of effective open development, where this cost is determined by the presence (or absence) of a viable technical platform for biotechnological innovation.[22] Synthetic biology lacks the advantages that F/OSS advocates and practitioners have long taken for granted: a legal regime that can be made conducive to sharing as well as established technical infrastructures that support it.

A detailed investigation of the obstacles to achieving openness in synthetic biology should prove of relevance beyond the confines of biotechnology. Many other emerging technical fields are also subject to patenting and lack a viable—and open—platform conducive to further innovation. The experience of synthetic biology suggests not only that the model of open licensing developed for F/OSS may not port easily to other technical domains, but that open-source advocates should consider more carefully how open collaboration depends upon infrastructural resources that cannot themselves be bootstrapped into existence through legal hacks or generated piecemeal in an uncoordinated fashion by communities of innovators.

Focusing on the role that technical platforms play in enabling innovation suggests a possible precondition to what legal scholars have termed "commons-based peer production" (or "peer production" for short).[23] In emerging fields, infrastructures of many kinds prove prerequisites for the production of innovation, whether that production is achieved in a conventional proprietary manner or through the activity of open communities working with shared resources. Drawing lessons from the example of synthetic biology, I conclude that for at least some scientific or technical communities, effective *state* action to close "infrastructure gaps" constitutes a prerequisite for the success of peer production. Such state action may proceed through mechanisms of public funding, governmental coordination, or other more subtle elements of industrial policy.

A focus on infrastructure gaps offers a way to reconsider the role of the state in innovation policy. In recent decades, legal scholarship has been transformed by the study of successful examples of peer production, which have complicated and challenged older narratives concerning the role of conventional incentives

---

20. *See infra* Part III.B.

21. *See, e.g.*, Yochai Benkler, *Sharing Nicely: On Shareable Goods and the Emergence of Sharing as a Modality of Economic Production*, 114 YALE L.J. 273, 278 (2004). For a critical note on the idea of "capital cost" as so used, see GREWAL, *supra* note 1, at 218.

22. *See* discussion *infra* Part V.B-C.

23. *See generally* YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM (2006) (arguing that the declining costs of communication and access to media in the so-called "networked information economy" lead to a new mode of production: decentralized, commons-based peer production); Yochai Benkler, *Coase's Penguin, or, Linux and the Nature of the Firm*, 112 YALE L.J. 369, 375 (2002) (discussing "peer production" in the context of F/OSS); Yochai Benkler, *Freedom in the Commons: Towards a Political Economy of Information*, 52 DUKE L.J. 1245, 1256 (2003) (discussing the ideal of the digital commons); Benkler, *supra* note 21 (extending the idea beyond the F/OSS context to diagnose a more general mode of production where technological circumstances permit); *see also infra* notes 236-238 and accompanying text.

provided by intellectual property in the production of innovation. The role of the "commons" or the sharing community is now increasingly recognized in studies of innovation, which complement and correct earlier presuppositions predicated on a market-based transactional framework.[24] One effect of the focus on the commons has been a skeptical stance toward coordinated public action achieved through the instrumentality of the state.[25] However salutary this has been in some respects, the next reorientation in intellectual property scholarship must be towards "bringing the state back in"[26] by studying the prerequisites for production in either market or non-market transactional frameworks, particularly the role of coordinated public action in overcoming infrastructure gaps.

This Article is intended as a contribution to that reorientation through a detailed analysis of the case of synthetic biology. I begin in Part II by introducing the ambition of synthetic biology to "make biology easier to engineer" through standardization and associated technical processes. Here, I also outline some of the early successes that indicate the promise of this field—and which help to explain why its pioneers have been keen to see it develop in an open and publicly beneficial manner.[27] In Part III, I turn to the question of how this commitment to openness has fared, examining the strained analogy to copyleft and the reasons for which the BioBricks Foundation has pursued a "public domain" strategy to promote openness.

The success of this strategy depends on the viability of peer production, since without a legal mechanism to ensure "commons-expansion,"[28] the growth of the synthetic biology commons will have to occur through voluntary contributions of the kind familiar in other open technical endeavors. I argue for the rationality of peer production in Part IV, at least under particular conditions. However, such cooperation in projects of peer production will often depend on the viability of the collective enterprise as a whole, as determined by thresholds above which individual contributions prove efficacious, but below which contributions prove wasted effort.

In the context of synthetic biology—and probably many other emerging fields—these thresholds are determined by the presence or absence of shared technical platforms that enable innovation. Platforms are special kinds of infrastructure, and may best be understood as partitioning a system into a small number of stable, core components (the "platform") and a larger number of variable ones ("applications"

---

24. *See* Benkler, *supra* note 21, at 305-07 (analyzing market, state and commons as "transactional frameworks").

25. *See* text accompanying *infra* notes 332-336.

26. On what "bringing the state back in" might mean for intellectual property law scholarship, see *infra* note 338 and accompanying text.

27. For example, the BioBricks Foundation describes its origins among scientists who wished "to ensure that this emerging field would serve the public interest," and elaborates its mission as ensuring that "the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet." BIOBRICKS FOUND. (Feb. 4, 2016), http://biobricks.org/about-foundation [http://perma.cc/UH7M-EDEA].

28. On "commons-expanding" legal arrangements, see *infra* note 160 and accompanying text.

or "products"), and structuring the interfaces between them. For example, in synthetic biology, a core set of standard biological parts (and associated standards) would provide a platform for downstream development of either a proprietary or an open variety. It is this platform that constitutes the essential prerequisite for the production of further innovation in the field. Drawing on the analysis of infrastructure and platforms, I diagnose an "infrastructure gap" where a key foundational resource is missing. Synthetic biology is marked by a number of infrastructure gaps that currently inhibit its development on either a proprietary or peer production model.

For reasons I discuss briefly in Part V, neither market-based nor commons-based peer production can be counted on to overcome the infrastructure gaps that will inhibit both forms of production. Instead, I argue, the success of synthetic biology, including its open development, requires the development of platform infrastructures that ultimately only the state can provide, recognizing that these may emerge through innovative forms of partnership with respect to funding and industry governance. Successful state action may proceed through "hidden" modalities of the kind that theorists of industrial organization have begun to diagnose,[29] and which I argue should be the focus of much greater attention in the legal scholarship on innovation and its governance.

II. ENGINEERING LIFE: THE PROMISE OF SYNTHETIC BIOLOGY

In 2003, MIT researcher Tom Knight, who was then working in an artificial intelligence laboratory, outlined a proposal for an "assembly standard" for genetic engineering.[30] In place of ad hoc tinkering and artisanal approaches, Knight argued that biotechnology should advance through the use of standard, interchangeable genetic constructs that could be used in building biological systems. In that task, an "idempotent vector"[31] of the kind he developed would prove foundational for further biotechnological innovation. Knight drew a direct analogy with the standardization of screws in the industrial economy and expressed the hope that similar progress could be made in standardizing biological "parts."[32]

---

29. *See infra* text accompanying notes 323-326

30. Tom Knight, MIT Intelligence Lab, Idempotent Vector Design for Standard Assembly of BioBricks (2003), http://dspace.mit.edu/handle/1721.1/21168 [http://perma.cc/UT8X-DL3X]. Knight's standard is now considered the original BioBrick™ assembly standard: "Assembly Standard 10" in the iGEM Registry of Standard Biological Parts. The Registry of Standard Biological Parts, formerly operated out of MIT by Randy Rettberg, is now run through iGEM. *See also* Tom Knight, Draft Standard for BioBrick Biological Parts (2007), http://dspace.mit.edu/handle/1721.1/45138 [http://perma.cc/B2JR-BSXQ].

31. Knight, *Idempotent Vector Design, supra* note 30, at 2 (describing an "idempotent vector" as one which participates in processes where "each reaction leaves the key structural elements of the component the same"). Such idempotent vectors are interchangeable parts in the sense that they can be transferred to perform the same function in an analogous environment.

32. As Knight explained:

> We anticipate advantages similar to those which accompany the standardization of screw threads in mechanical design—the widespread ability to interchange parts, to assemble sub-components, to outsource assembly to others, and to rely extensively on previously manufactured components.

In synthetic biology, the concept of a "standard biological part" encompasses genetic material such as DNA, plasmids, protein coding sequences, ribosomal binding sites, and so on, including combinations of parts that together attain special functionality, called "devices," such as inverters, receptors and protein generators.[33] To describe the varied and complex material of life in this manner is to employ a functionalist, engineering idiom unfamiliar to earlier generations of biological researchers, many of whom have been skeptical that biological components could ever be reliably engineered.[34] However, along with Knight, several other scientists—many of them with backgrounds in engineering disciplines rather than biology—had similar ambitions with respect to biotechnology.[35]

The late 1990s saw a convergent agenda on biological standardization, with academics at Boston University exploring "genetic applets,"[36] researchers at the Molecular Sciences Institute in Berkeley[37] performing early work on standardization (and coining the term "synthetic biology" to replace an earlier neologism, "intentional biology"),[38] and scientists at Harvard,[39] MIT,[40] and elsewhere pursuing similar lines of inquiry. The ambition of these scientists was to make biology into a genuine engineering discipline, which they understood would

---

> Here, we present a simple sequence and assembly standard as part of an experiment to see how far this idea of standardized interface technology can be applied. The key notion in the design of our strategy is that the transformations performed on component parts during the assembly reactions are idempotent in a structural sense. That is, each reaction leaves the key structural elements of the component the same. The output of any such transformation, therefore, is a component which can be used as the input to any subsequent manipulation. It need never be constructed again—it can be added to the permanent library of previously assembled components, and used as a compound structure in more complex assemblies.

Knight, *Idempotent Vector Design*, *supra* note 30, at 2.

33. For a description and discussion of genetic material as "parts" and "devices," see Barry Canton et al., *Refinement and Standardization of Synthetic Biological Parts and Devices*, 26 NATURE BIOTECH. 787, 788-89 (2008).

34. *See infra* text accompanying note 72.

35. For discussions of the early history of synthetic biology by practitioners, see ROB CARLSON, BIOLOGY IS TECHNOLOGY: THE PROMISE, PERIL, AND NEW BUSINESS OF ENGINEERING LIFE 84-86 (2010); GEORGE CHURCH & ED REGIS, REGENESIS: HOW SYNTHETIC BIOLOGY WILL REINVENT NATURE AND OURSELVES 184-89 (2012); Gardner & Hawkins, *supra* note 10, at 872-74. For a history of standardization efforts in biology, even in the pre-genomic era, see Campos, *supra* note 3.

36. Timothy S. Gardner, et al., *Construction of a Toggle Switch in Escherichia coli*, 403 NATURE 339, 342 (2000).

37. These researchers included Drew Endy, Rob Carlson, and Carlos Bustamante, among others. Drew Endy, frequently called an "evangelist" for the field of synthetic biology, is one of its most visible and effective proponents; for a history of Endy's influence, see Luis Campos, *Outsiders and In-Laws: Drew Endy and the Case of Synthetic Biology*, *in* OUTSIDER SCIENTISTS: ROUTES TO INNOVATION IN BIOLOGY 331 (Oren Harman & Michael R. Dietrich eds., 2013). Endy later moved to MIT and is now a professor in the bioengineering department at Stanford University. Rob Carlson, a physicist by training, later became a consultant and strategist in the field of synthetic biology, as well as the author of BIOLOGY IS TECHNOLOGY, cited *supra* note 35, an accessible introduction to the field and its social and technical promise.

38. *See* Campos, *supra* note 3, at 17.

39. For example, George Church. *See, e.g.*, CHURCH & REGIS, *supra* note 35.

40. For example, Tom Knight. *See, e.g.*, Knight, *Idempotent Vector Design*, *supra* note 30.

entail standardized constructs and shared technical protocols. As an Editorial in *Nature* put it about a decade after: "those in the field may not agree on what it is, but they seem to know when it started."[41]

Synthetic biology would, if successful, turn biology into a technology,[42] completing a gradual move in this direction that has been occurring over the last century or more. The ambition of manipulating biology featured in a number of earlier twentieth-century studies, for example the interest in induced mutation and the mechanisms of heredity.[43] More generally, these twentieth-century movements built on several millennia of agricultural innovation, much of it accidental, that has transformed most of the earth's ecosystems through the propagation of a very small number of staple organisms: rice, wheat, corn, cotton, cows, and a few other species now absorb an enormously greater share of annual solar radiation than they did ten thousand years ago. The spread of agriculture itself may be understood as a massive, deliberate, but largely uncontrolled standardization of ecosystems at the planetary level.[44]

What gives synthetic biology greater promise than these earlier efforts to control biology (whether at the level of organisms or ecosystems) is the mid-twentieth century genetic revolution, which suggests the possibility of standardization from nucleotides through cellular parts and metabolic systems to living organisms and ecosystems. Indeed, while the ambition of synthetic biology remains radical, its technical practices rely on background discoveries and techniques that are now basic to genomics, including the discovery of protein synthesis[45] and the invention of recombinant DNA.[46] In historical retrospect, it may come to be seen as unsurprising that, fifty years after the initial discovery of DNA, and a few decades after genetic sequencing and synthesizing technologies

41. Editorial, *supra* note 12, at 269. This convergence on an engineering paradigm for biotechnology is not surprising, but a comprehensive study of the inflection points in the emergence of an engineering discourse in biology, including its relation to technological changes in other areas of science, remains to be written.

42. As in the title of Rob Carlson's book, *Biology is Technology*. *See* CARLSON, *supra* note 35.

43. On the history of artificially induced mutations in twentieth-century biology (including before the era of genetic-scale engineering), *see* MAX PLANCK INST. FOR HIST. OF SCI., MAKING MUTATIONS: OBJECTS, PRACTICES, CONTEXTS (Luis Campos & Alexander von Schwerin eds., 2009); *see also* Campos, *supra* note 3.

44. On human-induced natural change and its consequences, see JEDEDIAH PURDY, AFTER NATURE: A POLITICS FOR THE ANTHROPOCENE (2015).

45. The central dogma of biology provides the conceptual framework for protein synthesis, whereby DNA is transcribed into complementary messenger RNA (mRNA) sequences, which in turn provide the templates for the creation of proteins. These mRNA sequences encode for amino acids, the building blocks of proteins, in a series of 3-nucleic segments called "codons." For foundational articles, see F.H.C. Crick, *On Protein Synthesis*, 12 SYMP. SOC'Y FOR EXPERIMENTAL BIOLOGY 138 (1958); François Jacob & Jacques Monod., *Genetic Regulatory Mechanisms in the Synthesis of Proteins*, 3 J. MOLECULAR BIOLOGY 318 (1961).

46. *See* Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids in Vitro.*, 70 PROC. NAT'L ACAD. SCI. U.S. 3240 (1973); Stanley N. Cohen et al., *Nonchromosomal Antibiotic Resistance in Bacteria: Genetic Transformation of Escherichia coli by R-Factor DNA*, 69 PROC. NAT'L ACAD. SCI. U.S. 2110 (1972).

became widely available,[47] scientists converged on the ambition to transform biology into an engineering discipline on par with practices familiar outside the life sciences. It nevertheless remains a highly controversial and surprising thought that living matter may prove as "engineerable" as the piles of sand and lumps of unrefined metal ore out of which humans have constructed tools to transform the landscape-level ecology of the earth.[48]

The enterprise of synthetic biology rather obviously raises numerous bioethical controversies.[49] Its success to any reasonable extent would furthermore have significant economic,[50] social and cultural,[51] environmental,[52] aesthetic,[53]

47. For an excellent history and overview of genetics, see Horace Freeland Judson, *A History of the Science and Technology Behind Gene Mapping and Sequencing*, *in* THE CODE OF CODES: SCIENTIFIC AND SOCIAL ISSUES IN THE HUMAN GENOME PROJECT 37 (Daniel Kevles & Leroy Hood eds., 1992).

48. Note that among professional engineers, the ambition to engineer biological systems is increasingly accepted and far less surprising than for non-engineers, and has become the substance of white papers that transcend engineering subspecialties. *See, e.g.*, Stanford Engineering, How Good Can We Get at Engineering Living Matter? (2015), https://dh1rvgpokacch.cloudfront.net/atavist/63313/document/raw/whitepaperh-1448049335-72.pdf [http://perma.cc/KK95-5FPX].

49. James Anderson et al., *Engineering and Ethical Perspectives in Synthetic* Biology, 13 EMBO REP. 584 (2012); Ainsley J. Newson, *Current Ethical Issues in Synthetic Biology: Where Should We Go From Here?*, 18 ACCOUNTABILITY IN RES. 181 (2011); Paul Rabinow & Gaymon Bennett, *Synthetic Biology: Ethical Ramifications 2009*, 3 SYST. SYNTHETIC BIOLOGY 99 (2009); Paul B. Thompson., *Synthetic Biology Needs a Synthetic Bioethics*, 15 ETHICS POL'Y ENV'T 1 (2012).

50. There has been relatively little work attempting to ascertain the likely economic impact of synthetic biology. On the size of the "bieconomy" overall, see Robert Carlson, *Estimating the Biotech Sector's Contribution to the US Economy*, 34 NATURE BIOTECHNOLOGY 247 (2016); and for an early effort, see Robert Carlson, *Laying the Foundations for a Bio-Economy*, 1 SYST. SYNTHETIC BIOLOGY 109 (2007). According to an estimate by Carlson, the bioeconomy is over 2% of US GDP; as he acknowledges, this figure probably undercounts many relevant commodity flows. This percentage is also bound to grow enormously if synthetic biology realizes its early promise. *See* Robert Carlson, The Need for Bioeconomy Data and Metrics 1 (2014), https://cns.asu.edu/sites/default/files/carlsonr_synbiopaper_2014.pdf [http://perma.cc/6BRV-XYVH]; *see also* Jim C. Philp et al., *Synthetic Biology, the Bioeconomy, and a Societal Quandary*, 31 TRENDS BIOTECHNOLOGY 269 (2013). For an ambitious attempt at a critical political economy of genomics as part of a "biocapitalist" regime, see KAUSIK SUNDER RAJAN, BIOCAPITAL: THE CONSTITUTION OF POSTGENOMIC LIFE (2006).

51. SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES (Markus Schmidt et al. eds., 2009); Markus Schmidt et al., *A Priority Paper for the Societal and Ethical Aspects of Synthetic Biology*, 3 SYST. SYNTHETIC BIOLOGY 3 (2009); Helge Torgersen, *Synthetic Biology in Society: Learning from Past Experience?*, 3 SYST. SYNTHETIC BIOLOGY 9 (2009).

52. Potential environmental risks, especially related to biodiversity, have been discussed by the international Convention on Biological Diversity (CBD). *See* U.N. Env't Programme, Convention on Biological Diversity, Subsidiary Body on Sci., Technical and Tech. Advice, *New and Emerging Issues Relating to the Conservation and Sustainable Use of Biodiversity—Potential Positive and Negative Impacts of Components, Organisms and Products Resulting from Synthetic Biology Techniques on the Conservation and Sustainable Use of Biodiversity*, U.N. Doc. UNEP/CBD/SBSTTA/18/INF/3 (May 20, 2014), http://www.cbd.int/doc/meetings/sbstta/sbstta-18/information/sbstta-18-inf-03-en.pdf [http://perma.cc/VY6W-8QB9].

53. *See* Elfick, *supra* note 10. Stanford University and the University of Edinburgh have an ongoing research program on the artistic and aesthetic dimensions of synthetic biology, one result

and perhaps even spiritual[54] consequences. However, except as these issues intersect with my particular concern to understand the *legal* regulation of innovation in this new field, I do not consider them here. Nor am I concerned with the regulation of biological risk, which currently occupies much of the attention paid to synthetic biology, particularly in interdisciplinary and policy venues.[55] Finally, I am not concerned to assess comprehensively the scientific success of the endeavor to date, except inasmuch as early signs of its seriousness and promise prove necessary to understand its legal and institutional importance. To understand these legal and institutional dimensions, however, it is necessary to understand at least the outlines of the synthetic biological project. Accordingly, I discuss in the first Subpart below the aim of turning biology into an engineering discipline before considering in the next Subpart some of the early visible successes of the field.

A. *Biology: An Engineering Discipline?*

The early advocates of synthetic biology were familiar with standardization given the engineering backgrounds that many of them shared, and they hoped to establish similar practices in biology. As early as Tom Knight's discussion of the standardization of screw threads in his presentation of the first BioBricks assembly standard, the historical success of standardization in the industrial economy has served as the point of departure for synthetic biology, and as an explicit benchmark

---

of which was the publication of SYNTHETIC AESTHETICS, *supra* note 10; *see also*: SYNTHETIC AESTHETICS (Feb. 4, 2016), http://www.syntheticaesthetics.org [http://perma.cc/8N9K-2KC8].

54. The consequences of success in synthetic biology may even raise religious and theological questions, given the salvational dimensions that some religious scholars have identified in the ambition and rhetoric of the field. *See* Gaymon Bennett, *Mediating Salvation: How SynBERC Proposed to Deliver the Promised Future of Synthetic Biology (Abstract)*, *in* SOCIAL SCIENTISTS' ADVENTURES IN SYNTHETIC BIOLOGY 7 (2012), https://www.kcl.ac.uk/sspp/departments/sshm/research/csynbi-PDFs/ProgrammeSocialScientistsAdventuresSB.pdf [http://perma.cc/RS8E-2DAB]; *see also* Peter Dabrock, *Playing God? Synthetic Biology as a Theological and Ethical Challenge*, 3 SYST. SYNTHETIC BIOLOGY 47 (2009). More generally, its success would bring the life sciences fully within the ambit of an instrumentalizing rationality, criticized by Heidegger and others in the twentieth-century as characteristic of the inhumanity of industrial modernity. *See* Martin Heidegger, Die Frage nach der Technik [The Question Concerning Technology], Vorträge und Aufsätze (1954), *translated in* THE QUESTION CONCERNING TECHNOLOGY AND OTHER ESSAYS 3 (William Lovitt trans., 1977). This is not the occasion to analyze the metaphysics upon which this deep criticism depends nor to defend an alternative conception of humanity and its teleology in which these new technologies would play an important role.

55. On biosecurity, see NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, ADDRESSING BIOSECURITY CONCERNS FOR SYNTHETIC BIOLOGY (2010). *See also* Hans Bügl et al., *DNA Synthesis and Biological Security*, 25 NATURE BIOTECHNOLOGY 627 (2007); Catherine Jefferson et al., *Synthetic Biology and Biosecurity: Challenging the "Myths"*, FRONTIERS PUB. HEALTH, Aug. 2014, at 115; Alexander Kelle, *Ensuring the Security of Synthetic Biology—Towards a 5P Governance Strategy*, 3 SYST. SYNTHETIC BIOLOGY 85 (2009). On the public apprehension of risk in this area, see Dan M. Kahan et al., *Risk and Culture: Is Synthetic Biology Different?* (GW L. Faculty Publ'n & Other Works, Working Paper No. 201) (2009), http://scholarship.law.gwu.edu/faculty_publications/201/ [https://perma.cc/HS3A-D4ND].

of success.[56] "Making biology easier to engineer," as Drew Endy succinctly articulated the ambition, would require standardization and related processes.[57] These include not only standardization, discussed at greater length below, but "decoupling," meaning the reduction of complicated problems into composite simpler problems,[58] and "abstraction," meaning the organization of complexity into a hierarchy delineating principles and tasks by ontic level, which is to say different levels of biological organization.[59] Figure 1 provides a visual illustration.[60] Progress in these foundational tasks aims at the development of "a design and construction framework that makes routine the incorporation of basic biological functions into many-component integrated genetic systems that behave as expected."[61]

56. *See* discussion *supra* note 1.

57. *See* Endy, *supra* note 2, at 449.

58. *Id.* at 451.

59. *Id.* ("To be useful, biological engineering abstraction hierarchies must (1) allow individuals to work at any one level of complexity without regard for the details that define other levels, yet (2) allow for the principled exchange of limited information across levels."). Note that this abstraction hierarchy is predicated on a conception of the part-whole relationship, which might be susceptible to mereological nihilism. (It does not, however, presuppose mereological essentialism, since the abstraction would itself be, at least in large part, *constructed* as an ontological hierarchy.)

60. Figure 1 is from Endy, *supra* note 2, at 451 fig.2.

61. Canton et al., *supra* note 33, at 787. The authors note that "[m]ature engineering disciplines have developed similar frameworks by using the concept of abstraction to define sets of standardized, functional objects that can be used in combination, together with composition rules that specify how such objects should be assembled." *Id.* Note that the theoretical foundations of synthetic biology—*standardization*, *decoupling*, and *abstraction*—may come to be of further use in yet grander syntheses of biology and information science, including in biosemiotics. *See, e.g.*, Stephen Philip Pain, *Inner Representations and Signs in Animals*, *in* INTRODUCTION TO BIOSEMIOTICS 409, 441-442 (Marcello Barbieri ed., 2007) (on the adaptation of Endy's work in synthetic biology to biosemiotics).

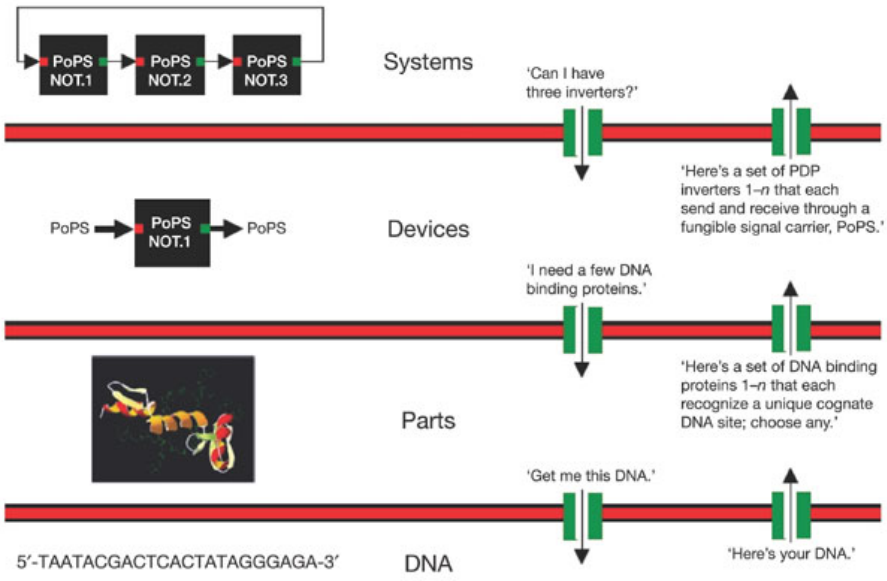

Figure 1: Abstraction Hierarchy for Synthetic Biology (taken from Endy, supra *note 2, at 451).*

Beyond the shared interest in reliable genetic constructs, however, there is considerable divergence in the field, as would be expected with any emerging technology. Some synthetic biologists argue for a concentration on fundamentals—a "parts" agenda focused on standardization and construction[62]—while others are moving in the direction of what is sometimes called "systems biology," with less emphasis on reducing biological engineering to its foundational elements.[63] As the historian of science Luis Campos, an observer of the field since its earliest days, explains, "[d]espite the deterministic implications of the metaphorical 'emerging technology' label, synthetic biology today remains a diverse collection of endeavors, technologies and actors. To reify and ossify such a complex social constellation would be to miss the phenomenon of interest entirely."[64]

Standardization nevertheless remains the most widely cited and familiar aim of the discipline. As one of the founders of the field, Timothy Gardner, explains, "the

62. *See* Canton et al., *supra* note 61; *see also infra* Part II.B.2 (discussing iGEM Registry of Standardized Parts).

63. The line between synthetic biology and systems biology is unclear; many academic departments group these novel approaches to biological engineering together. Arguably, systems biology focuses on the organization of biological systems and is thus less "reductionist" than synthetic biology, though the two approaches may also be seen as complementary. George M. Church, *From Systems Biology to Synthetic Biology*, 1 MOLECULAR SYS. BIOLOGY 132 (2005); Priscilla E.M. Purnick & Ron Weiss, *The Second Wave of Synthetic Biology: From Modules to Systems*, 10 NATURE REVS. MOLECULAR CELL BIOLOGY 410 (2009).

64. Luis Campos, *The BioBrick™ Road*, 7 BIOSOCIETIES 115, 116 (2012).

central premise of Synthetic Biology is that standardization of reusable biological components is the most efficient and effective way to engineer biology."[65] Standards are pervasive in the industrial economy and can be understood as complex coordinative regimes that become materially embodied. As historian Steven Mihm notes:

> Standardization can encompass a wide range of coordinating mechanisms. These include uniform accounting standards; metrological standards governing units of measurement; technical standards defining a uniform industrial component; and quality standards that define various commodities. Such standards, more often than not, gain currency via cooperation, not competition.[66]

Standards also exhibit economies of scale in their adoption by new users, a process I have elsewhere described as a form of power ("network power").[67] As Mihm argues on similar lines: "it is the cumulative acts of adoption within a community or network that invest standards with power as coordinating mechanisms."[68]

Standardization is thus an eminently human construction that necessarily occurs in a community; as two sociologists define it, it is "a process of constructing uniformities across time and space, through the generation of agreed-upon rules."[69] Whether the life sciences will ultimately be able to support such constructed uniformities is not obvious.[70] Complications include the fact that biological systems evolve both in space and time, are subject to unexpected interactions both within and without any ontic level, and may give rise to "emergent properties."[71] As the esteemed scientist Frances Arnold argued in 2006: "There is no such thing as a standard component, because even a standard component works differently depending on the environment . . . . The expectation that you can type in a sequence and can predict what a circuit will do is far from reality and always will be."[72]

Endy's response to these complexities is indicative of the ambitions of the field:

---

65. Gardner & Hawkins, *supra* note 10, at 872 ("[w]hile Synthetic Biology has rapidly catapulted itself to the status of a field, it remains fundamentally a proposition originally formulated by Adam Arkin and Drew Endy in a whitepaper submitted in 1999 to help DARPA define its Biocomputing research program."). *See also* Drew Endy & Adam Arkin, A Standard Parts List for Biological Circuitry (1999), http://dspace.mit.edu/bitstream/handle/1721.1/29794/Arkin.Endy.DARPA.pdf?sequence=1 [http://perma.cc/E8Z9-KPEP].

66. Mihm, *supra* note 1, at 8.

67. *See generally* GREWAL, *supra* note 1 (describing the economies of scale to the adoption of shared standards as constituting a form of power).

68. Mihm, *supra* note 1, at 9.

69. Timmermans & Epstein, *supra* note 1, at 71.

70. Arti Rai, *Unstandard Standardization: The Case of Biology*, 53 COMM. OF THE A.C.M., 37, 37 (2010).

71. Emergent properties "emerge" at one level of systemic complexity without being exhibited in the parts that make up the whole. Scott D. Findlay & Paul Thagard, *How Parts Make Up Wholes*, 3 FRONTIERS IN PHYSIOLOGY 455 (2012); Alex B. Novikoff, *The Concept of Integrative Levels and Biology*, 101 SCI. 209 (1945).

72. As cited in Andrew Pollack, *Custom-Made Microbes, at Your Service*, N.Y. TIMES (Jan. 17, 2006), http://www.nytimes.com/2006/01/17/health/science/custommade-microbes-at-your-service.html [https://perma.cc/P9Y2-YUTD].

"Thankfully, these concerns are best evaluated by attempting to surmount them."[73] This response is not mere bravado, but also reflects a fundamental, if usually unarticulated epistemological orientation that marks the applied and experimental sciences: the view that practical capacity itself defines the limits of the knowable. As anthropologists Paul Rabinow and Gaymon Bennett put it, "post-genomics has seen the intensification of an engineering disposition in biology: understanding through making and remaking."[74]

Accumulating experimental results from the last few years suggest an increasing capacity to make—and, therefore to understand—reliably engineerable genetic constructs or "standard biological parts." A major technical difficulty in synthetic biology has been achieving precision in gene expression, without which no sophisticated biological constructs can be expected to behave as desired. In 2013, a major breakthrough in controlling gene expression came with the use of bicistronic architecture (i.e., a two-gene design within a single vector), which enabled researchers to achieve 93% accuracy in predicting arbitrary gene expression levels.[75]

The importance of the bicistronic architecture may become clearer by contrasting two experiments developing computational functions in engineered biological systems. In a 2012 study, without the use of bicistronic architecture, Endy and colleagues constructed a system of "rewritable" genetic data storage.[76] However, this breakthrough came only after experimentally screening over 700 different genetic designs to find one that realized rewriteable genetic memory.[77] By contrast, in a slightly later experiment in 2013, focused on building genetic "logic gates" that enable basic computational functions, Endy and colleagues used bicistronic architecture and other newly available standard biological parts to control gene expression.[78] They succeeded in building genetic systems encoding six Boolean operations, and without the need for extensive screening, since every one of these genetic constructs following the newly realized genetic expression standards worked the first time as intended.[79] Thus, about a decade after the field first emerged, there was now reason to believe that reusable, reliable, context-independent standard biological parts can be developed—and become the basis for more sophisticated engineered biological systems.

---

73. Endy, *supra* note 3, at 449.

74. PAUL RABINOW & GAYMON BENNETT, DESIGNING HUMAN PRACTICES: AN EXPERIMENT WITH SYNTHETIC BIOLOGY 15 (2012). They go on to explain: "The challenge for synthetic biologists is to take biology beyond the guild-like restrictions of artisanal *savoir faire* and to make it into a full-fledged engineering discipline, with all this entails in terms of standardization, modularization, and regularization." *Id.*

75. Vivek K. Mutalik, et al., *Precise and Reliable Gene Expression via Standard Transcription and Translation Initiation Elements*, 10 NATURE METHODS 354, 359 (2013).

76. *See* Jerome Bonnet et al., *Rewritable Digital Data Storage in Live Cells via Engineered Control of Recombination Directionality*, 109 PROC. NAT'L ACAD. SCI. U.S. 8884 (2012).

77. *Id.* at 8886 tbl.1 (right-hand column).

78. Jerome Bonnet, et al., *Amplifying Genetic Logic Gates*, 340 SCI. 599 (2013).

79. Personal communication with Drew Endy.

B. *Early Successes*

In spite of recent breakthroughs, the ambition to achieve engineerable biological systems through standardization and associated practices remains, at the time of writing, mostly unrealized, with major technical challenges unresolved.[80] However, there have been some visible early successes in the endeavor, which suggest why the field has captured the attention of scientists and non-scientists alike. Two early successes in particular seem worth describing in modest detail, in order to reveal how private actors, networks of peers, and research scientists are making biology "easier to engineer." The first is the synthetic production of the anti-malarial drug artemisinin. The second is the growth of the International Genetically Engineered Machines (iGEM) competition, which brings high school and college students from around the world into synthetic biology. In both examples, researchers have faced the problem of what legal instruments should govern the production and distribution of biotechnological innovation and what technical platforms are available to enable its open development.

1. *Synthetic Artemisinin Production*

One of the most visible early successes in synthetic biology is the artificial production of artemisinin, a medicinal product extracted from *Artemisia annua* ("sweet wormwood"), first identified by traditional healers as a remarkably effective treatment for malaria.[81] However, the cultivation of *A. annua* is highly labor intensive, which makes the natural production of artemisinin costly.[82] Moreover, the complex nature of the artemisinin compound makes chemical synthesis a challenging and undesirable target for most drug companies. Given these challenges, artemisinin is currently in short supply: the compound's efficacy has led

80. Roberta Kwok, *Five Hard Truths for Synthetic Biology*, 463 NATURE 288 (2010). For a list of relevant remaining tasks of standardization, see Andrew W. Torrance & Linda J. Kahl, *Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property*, 30 SANTA CLARA HIGH TECH. L.J. 199, 206-220 (2014). Note that the technical difficulties to be surmounted may be minor compared to the broader cultural, legal, and institutional changes required for the technology to succeed.

81. The chemical derivatives of artemisinin constitute the leading antimalarial drug treatment recommended by the World Health Organization (WHO). WORLD HEALTH ORGANIZATION, GUIDELINES FOR THE TREATMENT OF MALARIA ix (2d ed.. 2010). http://apps.who.int/medicinedocs/documents/s19105en/s19105en.pdf [https://perma.cc/5VV5-4T4Y]. Artemisinin derivatives have replaced historic antimalarial therapies because the latter are compromised by increasing drug resistance. To prevent artemisinin-resistance from developing, the WHO has advanced the use of artemisinin-based combination therapies (ACTs), which use multiple antimalarial acting compounds, the primary constituents being artemisinin derivatives. *Id.*

82. Without subsidies, ACTs are twenty to forty times more expensive than traditional antimalarial treatments, some of which have been compromised by the emergence of resistant malarial strains. *See* Allen Lewis Malisa & Deodatus Kiriba, *Artemisinin Combination Therapies Price Disparity Between Government and Private Health Sectors and Its Implication on Antimalarial Drug Consumption Pattern in Morogoro Urban District, Tanzania*, 5 BMC RES. NOTES 165, 165-66 (2012).

to calls for a 15-fold increase in production from 2004 levels to meet a global demand of 400 million adult malarial treatments.[83]

To fill this gap, a synthetic and systems biology group at the University of California, Berkeley, led by Jay Keasling, engineered a semi-synthetic means of producing artemisinin through engineered biological processes, with the potential to provide up to a third of global need, and at much lower cost.[84] In partnership with Amyris Biotechnologies, Inc. (which Keasling co-founded), the Institute for One World Health, the Bill & Melinda Gates Foundation, and the University of California, Berkeley, Keasling's group helped engineer a production process that is now being used by Sanofi, a leading pharmaceutical company, to supplement the global supply of naturally produced artemisinin.[85] This cost reduction is realized by mass-producing artemisinin through an *S. cerevisiae* (yeast) chimera comprised of a synthetic gene and naturally occurring *S. cerevisiae*, *A. annua*, and bacterial genes.[86] The Keasling lab's contribution to the synthetic gene—its reconstruction and optimization—employed a method now common in synthetic biology and widely available.[87] The standardization of key methods and materials allowed for the conversion of a simple and relatively inexpensive input, Acetyl coenzyme A, into a valuable and complex chemical product.[88]

---

83. Victoria Hale et al., *Microbially Derived Artemisinin: A Biotechnology Solution to the Global Problem of Access to Affordable Antimalarial Drugs*, 77 AM. J. TROPICAL MED. & HYGIENE 198, 199 (2007).

84. Stephan Herrera, *Synthetic Biology Offers Alternative Pathways to Natural Products*, 23 NATURE BIOTECHNOLOGY 267, 270-71 (2005); *see also* Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629, 630-32 (2010).

85. *See* Press Release: PATH, First Antimalarial Treatments Produced with Semisynthetic Artemisinin Enter Market (Aug. 12, 2014), http://www.path.org/news/press-room/685 [https://perma.cc/EXY9-9EVB].

86. The biological parts that were standardized for this purpose include a genetic construct of eight genes, first inserted into a model organism, *E. coli*, and now used in *S. cerevisiae*. Most of the genes were isolated and cloned by the Keasling group. However, two of the genes and several pieces of facilitating genetic material—e.g., cloning vectors—were isolated by other laboratories and fully described in the published literature. *See* Vincent J.J. Martin et al., *Engineering a Mevalonate Pathway in* Escherichia coli *for Production of Terpenoids*, 21 NATURE BIOTECHNOLOGY 796, 797 (2003).

87. For a discussion of "codon optimization" in the Keasling lab's work, see Anthony JR, Anthony LC, Nowroozi F, Kwon G, Newman JD, Keasling JD. *Optimization of the Mevalonate-Based Isoprenoid Biosynthetic Pathway in* Escherichia coli *for Production of the anti-Malarial Drug Precursor Amorpha-4,11-diene.* 11 METABOLIC ENGINEERING 13 (2009). For the present commercial ubiquity of this technique, see, e.g., *GeneArt® Gene Synthesis Codon Optimization Challenge*, THERMO FISHER SCI., INC. (Feb. 15, 2016), http://www.lifetechnologies.com/us/en/home/products-and-services/promotions/geneart-gene-synthesis-codon-optimization-challenge.html [https://perma.cc/KJQ9-3TQ8].

88. This use of synthetic biology in metabolic engineering of this kind is one of the most promising areas of its application. *See* Jay D. Keasling, *Synthetic Biology and the Development of Tools for Metabolic Engineering*, 14 METABOLIC ENGINEERING 189 (2012); Josuha K. Michener et al., *Applications of Genetically-Encoded Biosensors for the Construction and Control of Biosynthetic Pathways*, 14 METABOLIC ENGINEERING 212 (2012); Christina D. Smolke, et al., *Controlling the Metabolic Flux Through the Carotenoid Pathway Using Directed mRNA Processing and Stabilization*, 3 METABOLIC ENGINEERING 313 (2001).

If this genetic construct proves commercially successful, it may increase access not just to artemisinin, but also a range of current and prospective drugs. The WHO has already approved the sale and use of synthetic artemisinin-based combination therapies as antimalarial treatments, and similar compounds are now being considered for synthetic production.[89] Potential cost reductions depend on the economies of scale inherent in large-scale fermentation reactions and the compatibility of *S. cerevisiae* with this industrial-scale production method.[90] Much remains to be seen, but the early success in metabolic engineering suggests the possibility of widespread and commercially viable synthetic production of a range of important and otherwise rare compounds.[91] The synthetic production of artemisinin, however, has depended upon conventional patenting and commercialization techniques, subsidized through private philanthropy, and thus cannot be scaled straightforwardly for the large and relatively comprehensive collection of foundational standard biological parts that would be required for the open development of the field as a whole.[92]

2. *The iGEM Competition*

While the synthetic production of artemisinin has proceeded through a major industrial partnership and advanced laboratory research, a different kind of success is realized in the annual International Genetically Engineered Machine (iGEM) competition.[93] iGEM is a keystone event in the synthetic biology

89. *See* Chris J. Paddon & Jay D. Keasling, *Semi-Synthetic Artemisinin: A Model for the Use of Synthetic Biology in Pharmaceutical Development*, 12 NATURE REV. MICROBIOLOGY 355, 363 (2014). Critics note that the artificial synthesis of artemisinin threatens the livelihood of agricultural producers of *Artemisia*, and possibly the supply chain for the naturally produced drug, if the introduction of synthetic products is not carefully sequenced. *See* ETC Group, Artemisinin and Synthetic Biology: A Case Study, (2014), http://www.etcgroup.org/sites/www.etcgroup.org/files/ETC-artemisinin-synbio-casestudy2014.pdf [https://perma.cc/V99Y-3NPQ].

90. Industrial fermentation reactions are typically performed in large anaerobic digesters that convert simple organic matter into biomass, methane, and other gas products. These digesters' use is thoroughly modeled and standardized for beer production and wastewater treatment. Thus, by providing a metabolic pathway that could essentially be "dropped in" to this organism and system, Keasling's group has transferred the artemisinin-producing capabilities of *A. annua* firmly into the standardized realm of engineering.

91. One of the most promising endeavors in this area is the biosynthetic production of opioids, demonstrated in Christina Smolke's Stanford bioengineering laboratory. *See* Stephanie Galanie, et al., *Complete Biosynthesis of Opioids in Yeast*, 349 SCI. 1066, 1095 (2015). The technique has been taken into commercial development through a new synthetic biology company, Antheia, which aims "to make and fairly provide medicines to all who need them." *See* ANTHEIA (Aug. 13, 2015), http://antheia.bio [https://perma.cc/R9VD-76XF].

92. On the likely prohibitive cost of patenting a feasible collection of standard biological parts, see *infra* note 171.

93. For an overview, see Christina D. Smolke, *Building Outside of the Box: iGEM and the BioBricks Foundation*, 27 NATURE BIOTECHNOLOGY 1059, 1099 (2009). *See also* James Brown, *The iGEM Competition: Building with Biology*, 1 IET SYNTHETIC BIOLOGY 3 (2007); Cristina Vilanova & Manuel Porcar., *iGEM 2.0—Refoundations for Engineering Biology*, 32 NATURE BIOTECHNOLOGY 397, 420-24 (2014).

community, bringing together college and high school students who use kits of standardized biological parts to create innovative biological systems. One of its primary goals is to develop a network of rising synthetic biologists and to instill in them a collaborative ethos reflective of the iGEM goals, as well as the experience of using shared standards and open access tools in biotechnology.[94]

Held in Cambridge, Massachusetts annually since 2004, and now involving multiple regional competitions worldwide, each iGEM competition hosts several thousand students as the formal culmination of summer-long design and research programs.[95] Past winners have subsequently produced peer-reviewed journal articles detailing their development of *E. coli* biofilms that can take pictures,[96] genetic sorting algorithms that can act like computers,[97] and feedback mechanisms that can reduce sepsis-causing inflammation in mammalian cells.[98] What is remarkable about these successes is their proof of concept over a very short period of time, usually just a few months, without professional assistance.[99] In a period during which synthetic biology is still gaining its footing as a field, iGEM has demonstrated that the standardization of parts can facilitate the creation of biological circuitry, alternative feedback systems, and computing devices—and all by teams of student-amateurs working over summers.

An important consequence of this annual event has been to draw new biological innovations into the Registry of Standard Biological Parts. Teams are provided with synthetic biological kits containing 384 wells of dried genes, vectors, and other genetic material—all taken from the Registry—and must in turn submit their entries for the competition to the Registry. The result is an expanding collection for future teams: the expansion of the synthetic biology commons achieved through an educational competition. The Registry has grown to

94. For a description of the outcomes related to this goal, see Thiprampai Thamamongood et al., *Cultivation of Synthetic Biology with the iGEM Competition*, 17 J. ADV. COMPUTATIONAL INTELLIGENCE 161, 163 (2013).

95. In the inaugural, inter-collegiate competition held the following year, five universities fielded teams. Over the following nine years, more than a hundred universities from twenty-six countries participated in the iGEM competition. In 2014, the grand prize-winners and runners up were from Heidelberg University (Germany), Imperial College (United Kingdom), and National Chiao Tung University (Taiwan), respectively, with University of California, Davis, winning the grand prize in the "overgraduate" (i.e., older student) category. *See* Torrance, *supra* note 84, at 630-32 (discussing the several IGEM competitions, including the prize-winning entries).

96. Anselm Levskaya et al., *Synthetic Biology: Engineering* Escherichia coli *to See Light*, 438 NATURE 441, 441 (2005) (altering *E. coli* function by insertion of cyanobacteria color-producing genes). The authors infer that the technology can be further advanced for use in biologic printing or investigating cell signaling. *Id.*

97. Jordan Baumgardner et al., *Solving a Hamiltonian Path Problem with a Bacterial Computer*, 3 J. BIOLOGICAL ENGINEERING 11 (2009); Karmella Haynes et al., *Engineering Bacteria to Solve the Burnt Pancake Problem*, 2 J. BIOLOGICAL ENGINEERING 8 (2008).

98. Monika Ciglič et al., *Engineered Human Cells: Say No to Sepsis*, 1 IET SYNTHETIC BIOLOGY 13, 13 (2007).

99. Indeed, the first peer-review iGEM publications (2005-2009) were generated shortly after the founding of the project (2003-2004).

encompass more than twenty thousand discrete genetic sequences and circuits, largely as a result of the iGEM competition.

As with any open-source system, the iGEM competition faces challenges of quality control and maintaining standardization across decentralized endeavors. Recognizing the necessity of standardized parts for such a community, iGEM pushed for early standardization, which met dissent from research groups that had developed their own standards.[100] More than divergent standards, however, the low quality of many parts has often frustrated projects: in 2008, 45% of survey respondents indicated that poor-quality parts were a major detriment to their work.[101] The variable quality of parts is well known in the iGEM community: the first competition demonstrated to organizers that more commercial-grade DNA vectors, greater standardization of parts, and a better developed sense of engineering abstraction and hierarchy were needed to create successful projects.[102] Along with the lack of a suite of reliable standard biological parts, another complexity for the iGEM competition has been the legal ambiguity around the standardized parts in the Registry, given the lack of any prevalent open-licensing scheme in biotechnology.[103]

These challenges notwithstanding, iGEM provides an example of the promise of synthetic biology. In terms of community building and education, the competition remains perhaps the major gateway for new generations of synthetic biologists. In technical terms, iGEM continues to improve, as the peer-reviewed publications that have come out of recent iGEM projects demonstrate. Recent winners show greater sophistication in deploying new standards of genetic assembly,[104] circuit possibilities,[105] and cell-interaction patterns[106] that advance beyond familiar biological constructs to novel computational and metabolic processes. But the future success of iGEM may be hampered by the lack of a legal framework enabling the sharing of standard biological parts once winning projects move out of academia and into the conventional biotechnology sector, where openness and standardization continue to be unfamiliar and often resisted.

---

100. *See* Smolke, *supra* note 93, at 1100.

101. Rudolph Mitchell et al., *Experiential Engineering Through iGEM—An Undergraduate Summer Competition in Synthetic Biology*, 20 J. SCI. EDUC. TECH. 156, 160 (2011).

102. *See* Smolke, *supra* note 93, at 1099.

103. While iGEM has very sensibly relied on the *de facto* "research exemption," given that its participants are all students, and most do not produce innovations that are plausibly commercializable, it has also been a strong supporter of the BioBricks Foundation's efforts to develop new legal instruments for open synthetic biology. The BPA, discussed *infra* Part III.C, is now used by many iGEM teams.

104. Shotaro Ayukawa et al., *Construction of a Genetic AND Gate Under a New Standard for Assembly of Genetic Parts*, 11 BMCGENOMICS S16, S16 (2010); Robert Conrado et al., *DNA-Guided Assembly of Biosynthetic Pathways Promotes Improved Catalytic Efficiency*, 40 NUCLEIC ACIDS RES. 1879, 1879 (2011).

105. Chunbo Lou, et al., *Synthesizing a Novel Genetic Sequential Logic Circuit: A Push-on Push-off Switch*, 6 SYS. BIOLOGY 350, 350 (2010).

106. Chenli Liu et al., *Sequential Establishment of Stripe Patterns in an Expanding Cell Population*, 334 SCI. 238, 238 (2011).

III. 'OPEN SOURCE' SYNTHETIC BIOLOGY

When Drew Endy called for "vibrant, open research communities"[107] to lead the development of synthetic biology, his appeal was made in recognition of the success of open technological development elsewhere in the information economy. His call was predicated on the hope that "open source"-style legal and institutional arrangements could govern the future growth of synthetic biology as well. In this appeal, the example of free or open source software (F/OSS) loomed especially large.[108]

The aim of Endy and his colleagues is the realization in synthetic biology of what has been called "commons-based peer production,"[109] forms of creative endeavor in which communities of innovators share foundational resources—ideas, practices, technologies—and collectively accomplish what none of them can individually. This kind of peer production is sought in synthetic biology both for intrinsic reasons, given the character of the creative freedom and scientific collegiality it is thought to promote, as well as for instrumental ones. In the latter vein, the anticipated synthetic biology revolution was understood by its early advocates to be beyond the capacity of even exceptionally talented individuals to produce single-handedly. It would thus require an entire scientific community dedicated to the task. Synthetic biologists accordingly sought to adopt the strategy employed by other open collaborative communities, most famously in F/OSS production, in which it has been shown that, "given enough eyeballs, all bugs are shallow,"[110] to cite what has been dubbed "Linus's Law." The early establishment of

---

107. *See* Endy, *supra* note 2, at 449.

108. *See* Arti Rai & James Boyle, *Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons*, 5 PLOS BIOLOGY 389, 391 (2007) ("The idea of a synthetic biology commons draws inspiration, in part, from the prominence of the open source software model as an alternative to proprietary software."); *see also* Torrance, *supra* note 84, at 653-54 ("[T]he troika most responsible for the BBF and the iGEM competition [Endy, Knight, and Rettberg] came to the field [of] biology from a background in engineering and computer science . . . . The origins of the open source philosophy [in synthetic biology] lie within the computer software community."). For a discussion of the analogies and disanalogies of "open source biotech" and F/OSS, see Alan G. Isaac & Walter G. Park, Open Development: Is the 'Open Source' Analogy Relevant to Biotechnology?, in THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY INNOVATION 225, 241-42 (David Castle ed., 2009).

109. Benkler, *Coase's Penguin*, *supra* note 23, at 375. *See infra* Part IV.C for a more extensive discussion of the concept.

110. The "law" is named after Linus Torvalds of Linux fame. It was articulated famously in Eric S. Raymond, *The Cathedral and the Bazaar*, *in* THE CATHEDRAL AND THE BAZAAR: MUSING ON LINUX AND OPEN SOURCE BY AN ACCIDENTAL REVOLUTIONARY 27, 30 (1999). For a concise description of how this works in F/OSS production, see Paul Vixie, *Software Engineering*, *in* OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION 91, 98-99 (1999), observing that "[a]n additional advantage enjoyed by open-source projects is the 'peer review' of dozens or hundreds of other programmers looking for bugs by reading the source code rather than just by executing packaged executables." Note that the ambition to develop a community of synthetic biologists similar to the community of digital hackers raises potential biosafety problems that I do not address in this article. *See supra* note 55 on biosecurity generally. These concerns have become most acute in relation to the nascent community of "DIY Bio"—"Do-it-yourself biologists" or bio-hackers—whose relation to the mainstream of primarily university-based

iGEM was not simply for its scientific or pedagogical value, but part of a campaign to induct a cadre of future scientists who would take such open collaboration for granted.[111]

It remains unclear, however, how best to instill the norms of open collaboration and reciprocity that characterize successful communities of peer production in other domains. It is also unclear what contribution legal strategies can make in this effort. From early in the emergence of the field, Endy and other founders of the BBF enlisted lawyers and legal scholars to help analyze the intellectual property laws governing synthetic biology, conscious of the role that the GNU General Public License (GPL) had played in the Free Software movement.[112] The First International Meeting on Synthetic Biology (SB 1.0), which took place in 2004 at MIT, had a panel discussion on "biological property rights" in an otherwise tightly-targeted scientific agenda.[113] An important early workshop in 2007, jointly organized by MIT and the Duke Center for Public Genomics, resulted in a careful mapping of the intellectual property landscape with respect to synthetic biology.[114] Over the following five years, the BBF worked with a range of attorneys and legal scholars, notably at Duke, Berkeley,[115] Yale,[116] and Stanford Law Schools.[117] The most crucial legal assistance came when Mark Fischer, a Boston-based attorney with several decades' experience working on intellectual property, including drafting open source licenses, began working intensively with the BBF on a pro bono basis.[118]

---

synthetic biology remains ambiguous. *See, e.g.*, Campos, *supra* note 37, at 344-45 (on Endy's changing relation to the DIY movement). For a journalistic account of DIY biology, see MARCUS WOHLSEN, BIOPUNK: DIY SCIENTISTS HACK THE SOFTWARE OF LIFE (2011).

111. Personal communications with Drew Endy and Randy Rettberg.

112. For the current version of the GPL, see *GNU General Public License*, GNU OPERATING SYS. (June 29, 2007), https://www.gnu.org/licenses/gpl-3.0.en.html [https://perma.cc/9FCA-86K7]. For a history of discussions of intellectual property law in early synthetic biology workshops and conferences emphasizing "granular description" and analyzing personal interactions as key to understanding the orientation to intellectual property, see Campos, *supra* note 64.

113. MIT, The First International Meeting on Synthetic Biology (2004), http://openwetware.org/images/7/79/SB1.0_overview.pdf [https://perma.cc/629J-LAGC]. Note that all subsequent SB meetings have included a component on "human practices," including the legal, institutional and social issues surrounding intellectual property.

114. *See* Rai & Boyle, *supra* note 108, and an elaboration in Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745 (2007).

115. At Berkeley Law School's Samuelson Clinic, in addition to Pam Samuelson, the BBF benefited from the help of Jason Schultz, Jennifer Lynch, and a team of clinical students.

116. I have served as a Director of the BioBricks Foundation since 2009. My involvement with the BioBricks Foundation first began through discussions with Drew Endy when he was at MIT and I was a graduate student (and later a Junior Fellow) at Harvard University, continuing into my current appointment at Yale Law School.

117. Endy is now based at Stanford Bioengineering and has organized conferences with Stanford Law School. *See Symposium Tackles Intellectual Property Challenges for Synthetic Biology*, NSF ENGINEERING RES. CTRS. (May 14, 2017,) http://erc-assoc.org/achievements/symposium-tackles-intellectual-property-challenges-synthetic-biology [https://perma.cc/LVR2-GPT3].

118. Mark Fischer had worked in the early 1980s with free software pioneer Richard

Ten years after the first discussion of these issues at SB 1.0, we are now in a better position to assess the progress made toward peer production in synthetic biology, along with the value of different legal strategies employed to that end. In this Part, I analyze recent legal efforts to achieve "open source" synthetic biology. I focus particularly on the work of the BBF, not only because I was personally involved with it,[119] but also because, as Luis Campos explains, "IP concerns in synthetic biology . . . initially emerged out of a complex ecology of practices surrounding BioBricks."[120]

To put this experiment in open synthetic biology in context, I begin in the first Subpart below by introducing the intellectual property law governing biotechnology. In the next, I consider the effort to produce a "copyleft" analogue for the domain of synthetic biology, arguing that the model of F/OSS has ultimately proved difficult to adapt to synthetic biology. I conclude in the final Subpart by examining the "public domain" approach realized in the BioBrick™ Public Agreement (BPA), the first open legal tool in synthetic biology.

A. *Intellectual Property in Synthetic Biology*

The early successes in the field have raised the question of how synthetic biology is to be governed with respect to intellectual property. While I discuss "open source" approaches to distributing synthetic biological innovations in the second and third sections below, it is important to situate these against the conventional treatment of biotechnology within intellectual property law.[121]

Since *Diamond v. Chakrabarty* affirmed the patentability of a microbe that metabolized crude oil, the U.S. patent system has invited patenting of living organisms, provided they are "not nature's handiwork," but reflect genetic modifications (proving the "result of human ingenuity").[122] Above the microbial level, showing such ingenuity would require relatively precise genetic modifications of multi-cellular organisms, as occurred less than a decade after *Chakrabarty* with the Harvard "Oncomouse," the world's first patented, transgenic, multi-cellular organism.[123] In the United States, at least, the general rule has been

---

Stallman on the drafting of GNU Emacs License, the immediate precursor to the GPL v.1. *See* Williams, *supra* note 18, at 124 (noting Fischer's involvement with the drafting of the GNU Emacs license). Fischer's involvement with the BBF began in 2008, when Drew Endy asked him to help develop new legal tools that would catalyze the synthetic biology community, and ended with Fischer's death in early 2015. For a discussion of his work with the BBF, see Campos, *supra* note 64.

119. *See supra* note 116 on my involvement.

120. Campos, *supra* note 64, at 116.

121. My focus in this Part concerns mainly *American* intellectual property law. For a partial corrective to this parochialism, see Ralf Perrey & Konstanze Lenhard, *Recent Developments in the Patentability of Inventions Relating to Medicine, Pharmaceuticals, and Biotechnology According to European Patent Practice*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 479 (2007) (discussing struggles over ordre publique gene patents abroad).

122. 447 U.S. 303, 309-10 (1980).

123. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988). Harvard researchers developed the

to conduct a case-by-case patent review to determine the patentability of transgenic organisms.[124] Below the microbial level, the patenting of cellular parts, including genetic material, is now very widespread, if controversial. For example, there are many patents on synthetic DNA strands that satisfy the basic requirements of U.S. patent law.[125]

There has been ongoing debate in many jurisdictions as to whether isolated genetic material should be patentable—that is, whether the mere refinement of naturally occurring material is a sufficient alteration for it to be considered the product of human ingenuity.[126] Absent bright-line indicators in the U.S. federal patent statute, Judge Learned Hand's rule in *Parke-Davis v. Mulford* has served as a widely influential, although contested, authority, holding that isolation and purification of naturally occurring material can constitute novelty.[127] *Parke-Davis* was cited with great frequency in the second half of the 20th century, but its historical circumstances and uncertain precedential value belie a simple application of this rule—perhaps particularly as biotechnology has progressed.[128]

The legal treatment of expressly *altered* genetic material became much clearer under the compromise rule recently established in *Association for Molecular Pathology v. Myriad Genetics*.[129] In that 2013 case, the Supreme Court held that

---

cancer-susceptible mouse through a modification to activate an oncogene increasing mammary tumors (for use in testing). DuPont later owned the patent, which expired in 2005. *See generally* Douglas Hanahan, Erwin Wagner and Richard Palmiter, *The Origins of Oncomice: A History of the First Transgenic Mice Genetically Engineered to Develop Cancer*, 21 GENES & DEV. 2258 (2007) for a history of oncomice in cancer research. For a background to the Harvard patent, see *id.* at 2267-68. The patentability of a genetically engineered multi-cellular organism was controversial, with significant delays or reversals of the patent in Canada and the European Community. *See* Adam Inch, *European Patent Convention: A Moral Roadblock to Biotechnological Innovation in Europe*, 30 HOUS. J. INT'L L. 203, 217-19 (2007); Teresa Scassa, *A Mouse Is a Mouse Is a Mouse: A Comment on the Supreme Court of Canada's Decision on the Harvard Mouse Patent*, 3 OX. UNIV. COMM. L.J. 105, 105 (2003).

124. *See* Jerzy Koopman, *The Patentability of Transgenic Animals in the United States of America and the European Union: A Proposal for Harmonization*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 103, 123-132 (2002) (providing an overview of the patenting of transgenic animals in US law).

125. Some transgenic life forms have been found to meet the non-obviousness, novelty, and not previously disclosed requirements under 35 U.S.C. §§ 101-103 (2012). One of the more famous of these engineered life forms is *Mycoplasma laboratorium*, produced by the Venter Institute and awarded U.S. Patent No. 20,070,122,826 A1; *see also Move over Dolly. Synthia Is on Her Way*, ECONOMIST (June 14, 2007), http://www.economist.com/node/9333408 [https://perma.cc/A573-FQNA].

126. According to some scholars, the confusion began with *Parke-Davis* which upheld a patent on a refined but naturally occurring substance, adrenaline. *See, e.g.*, Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV. 257 (2013) (on the history of that patent and Judge Learned Hand's role in articulating its rationale).

127. 189 F. 95, 102 (S.D.N.Y. 1911), *aff'd in part and rev'd in part*, 196 F. 496 (2d Cir. 1912). On the enduring and controversial legacy of *Parke-Davis*, see Beauchamp, *supra* note 126, at 296-310.

128. Beauchamp, *supra* note 126, at 305-310 (considering the complexities of the *Parke-Davis* rule as it applies to biotechnology, and in anticipation of the *Myriad* case).

129. Ass'n for Molecular Pathology v. Myriad Genetics Inc., 133 S. Ct. 2107 (2013).

genetically isolated DNA ("gDNA") is not patentable under 35 U.S.C. § 101, but that complementary DNA fragments ("cDNA") are, assuming they meet the other relevant criteria.[130] The distinction was based on a reading of the statute as implicitly excluding "natural phenomena"[131] along with a determination that gDNA is the unaltered product of nature while cDNA is a synthetic creation.[132] The *Myriad* opinion provides little guidance to district courts in applying these principles beyond the specific determinations regarding gDNA and cDNA, thus leaving them to grapple with complexities concerning the patentability of isolated but unaltered products and the extent of alteration required to constitute a non-natural product.[133] For example, the distinction may leave open patenting opportunities for DNA sequences that are altered only slightly from the natural sequence, provided they meet the ambiguous standard of "marked difference" established by the USPTO and satisfy other tests, such as utility and non-obviousness.[134]

For synthetic biologists, *Myriad* nevertheless makes clear that the enterprise of engineering living matter will be a patentable one from the foundational practice of assembling standardized genetic parts all the way up through the production of microbial, plant, and animal organisms from those parts. In all likelihood, as several scholars have noted, the *Myriad* decision will likely incentivize further research in synthetic biology owing to its emphasis on alteration.[135] Importantly, under current patent law, "making biology easier to engineer" will mean making life easier to own. The engineered modifications that interest synthetic biologists require just the sort of "human ingenuity" that will change something given by nature into something available for proprietary intellectual property. This fact poses numerous ethical complexities concerning the commodification of life,[136] which are not the

130. *See id.* at 2117 (finding that "separating that gene from its surrounding genetic material is not an act of invention").

131. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012) (noting that the Court has "long held that [§ 101] contains an important implicit exception. '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable.") (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981))).

132. While the cDNA sequence is given by nature, these patentable sequences are altered in the sense that they are redacted versions of naturally occurring DNA.

133. *See* Tup Ingram, Association for Molecular Pathology v. Myriad Genetics, Inc.*: The Product of Nature Doctrine Revisited*, 29 BERKELEY TECH. L.J. 385, 416 (2014).

134. *See* Alex Boguniewicz*, Discovering the Undiscoverable: Patient Eligibility of DNA and the Future of Biotechnical Patent Claims Post-Myriad*, 10 WASH. J.L. TECH. & ARTS 35, 49 (2014).

135. *See* Torrance, *supra* note 84, at 640 (writing before *Myriad* but anticipating a change in the reliance on *Parke-Davis*: "[O]pposition to gene patents as products of nature would incentivize preferential investment treatment in research, development, and patenting of synthetic genes").

136. *See* Jane Calvert, *The Commodification of Emergence*, 3 BIOSOCIETIES 383 (2008); *see also* sources cited *infra* notes 153-154 on the commodification of the research universities. From my discussions, it seems clear that some synthetic biologists seek an alternative to proprietary ownership through the "open" development of the field owing in part to ambivalence about the way that their endeavor might change basic values concerning social solidarity and the place of the natural world, particularly if directed by commercial pressures.

focus of this Article, but which might be at least partly abated through the open development of the field.

Perhaps the main concern motivating the commitment to openness among the early founders of synthetic biology was not commodification as much as a worry that the IP-centric practices of conventional biotechnology would inhibit its development. Some of these early innovators came to the ambition of "making biology easier to engineer" not only with the success of F/OSS in their personal and professional experience, but with the memory of seeing fights over intellectual property prove an inhibition to innovation in other technical domains.[137] Their anxiety about the role of intellectual property often seemed to reflect an engineer's frustration with lawyers and their inhibitory role in corporate decision-making around technology.[138] Under the regime established in *Myriad*, we should expect synthetic biology to come under further pressure from these IP-centric practices.

This concern to maintain openness reflects the increasingly well-documented claim that strong intellectual property protections can prove counterproductive to the production and diffusion of innovation, particularly in emerging technologies.[139] As Arti Rai and James Boyle explain, "[c]onsiderable historical evidence, including evidence from virtually every important industry of the 20th century, suggests that broad patents on foundational research can slow growth in the industry."[140] Rai and Boyle note that the problem is particularly acute in synthetic biology, which puts into stark relief "a difficulty that the law has

137. During our interactions while both serving as members of the BBF board, Randy Rettberg, the director of the iGEM competition and an early advocate of the open development of synthetic biology, vividly recounted to me how, in his former career as an engineer in a large Silicon Valley firm, he watched lawyers from competing technology companies measure the height of stacks of patents to be exchanged in complex cross-licensing arrangements. The effect of these arrangements was to maintain the market share of a small number of established, IP-intensive firms and lock out competition from dynamic, emerging enterprises.

138. Stories of the kind discussed *supra* note 137 were common in my interactions with synthetic biologists and may reflect a general division of professional training and fiduciary duty between lawyers and engineers. Since lawyers serve as fiduciaries for existing parties, they necessarily work with present interests in mind and accept the status quo as a normatively legitimate baseline. By contrast, the scientists and engineers with whom I have interacted have a future-oriented and technologically driven sense of the present as a baseline to be overcome, and of status quo interests as presumptively illegitimate, at least wherever they appear to inhibit the realization of technological innovation.

139. *See* Gavin Clarkson & David DeKorte, *The Problem of Patent Thickets in Convergent Technologies*, 1093 ANNALS N.Y. ACAD. SCI. 180, 181-85 (2006); Richard C. Levin, et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 786-88 (1987); Robert P. Merges & Richard R. Nelson, *On Limiting or Encouraging Rivalry in Technical Progress: The Effect of Patent Scope Decisions*, 25 J. ECON. BEHAV. & ORG. 1 (1994); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 916 (1990). As an empirical analysis shows, patents increase in value as they cover more foundational materials in industries that are more competitive—that is, consistent with theory, they are more valuable when they enable more deviation from market discipline. *See* Joshua Lerner, *The Importance of Patent Scope: An Empirical Analysis*, 25 RAND J. ECON. 319, 319 (1994); *see also* Isaac & Park, *supra* note 108, at 232-34 (discussing patent thickets, patents on research tools, and the 'anti-commons' effect as they affect biotechnology).

140. Rai & Boyle, *supra* note 108, at 390.

frequently faced over the last 30 years—the assimilation of a new technology into the conceptual limits posed by existing intellectual property rights," specifically, the anxiety that the limits of existing law "would impede the potential of the technology."[141] For example, patents on foundational technologies can act as what Carl Shapiro calls "blocking patents," which he analogizes to control over the building blocks of a pyramid (in which lower-down blocks must be set before succeeding ones).[142] Monopoly control of such technologies can inhibit downstream product innovation.

In synthetic biology, this concern about the patenting of foundational advances that become obstacles to later development is not merely hypothetical. Recall that the breakthrough of "bicistronic architecture" to advance reliably genetic constructs was put to early use in developing computational functions in engineered biological systems.[143] This promising line of research aims at the possibility of "programmable cells," akin to operating systems for personal computers.[144] However, several years before these foundational technical advances were made, a very broad patent covering "molecular computing elements" was granted to the U.S. Department of Health and Human Services for an unrelated innovation.[145] The patent reads so broadly that it "would seem effectively to patent the basic functions of computing when implemented [through] genetic means."[146]

In addition to blocking patents, another major concern, particularly for an emerging field, is the proliferation of patents with overlapping or confusing claims that inhibit innovation by generating legal ambiguity concerning the use or development of a technology. Shapiro famously called this circumstance a "patent thicket," defining it as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[147] Rai and Boyle note that, "in the area of information technology, there is evidence that patent thickets or 'anti-commons' create difficulties for subsequent researchers above and beyond those created by foundational patents,"[148] a circumstance created by the fact that "many products in information technology represent combinations of dozens, if not hundreds, of patented

141. *Id.* at 389.

142. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL'Y & ECON. 119, 120 (2001).

143. *See supra* notes 75-79 and accompanying text.

144. Marcia Stone, *"Transcriptors," Reliable Parts—Gateway to Programmable Cells?*, 8 MICROBE MAG. 272, 272-73 (2013).

145. U.S. Patent No. 6,774,222 (issued Aug. 10, 2004) (discussed in Rai & Boyle, *supra* note 108, at 390, and in Kumar & Rai, *supra* note 114, at 1752 n.41).

146. Rai & Boyle, *supra* note 108, at 390. As Rai and Boyle suggest further, the reluctance of the Federal Circuit to allow unwritten knowledge in the determination of the nonobviousness threshold presents a further problem given the informal collaborations and domain-specific background knowledge in emerging fields—and is perhaps particularly acute when the "reduction to practice" is ambiguous. *Id.*

147. *See* Shapiro, *supra* note 142, at 120.

148. Rai & Boyle, *supra* note 108, at 390.

parts."[149] The problem is already apparent in biotechnology around key biological parts. For example, the green fluorescent protein widely used to report gene expression[150] is now subject to overlapping and complex patent claims now managed through a corporate patent pool.[151] Such patent thickets are likely to become denser and more widespread as the field of synthetic biology matures.

Finally, it is worth noting that the gulf between a proprietary intellectual property regime and the "peer production" of the research universities is more acute for synthetic biologists today than for earlier waves of innovators. Consider, by contrast, the relative freedom of those involved in the development of Unix, TCP/IP and related interfaces and networking protocols in the early decades of computing.[152] Synthetic biology must develop against the backdrop of increasing commercialization in the research universities, which reflects several trends, including the prodigious growth of university endowments and a resulting reorientation to STEM disciplines that both use these funds and, via licensing of university intellectual property, contribute disproportionately to them;[153] the growth of technology licensing offices as part of university resource policy;[154] evolutions in law that facilitate patenting higher up in the research chain;[155] and the continued impact of the Bayh-Dole Act, with its mandate for the

149. *Id.*

150. Roger Y. Tsien, *The Green Fluorescent Protein*, 67 ANN. REV. BIOCHEMISTRY 509 (1998).

151. The complex and overlapping patent claims surrounding GFP were solved—albeit through corporate monopolization—through the creation of a patent pool controlled by GE Healthcare; however, there is no reason to think that all patent thickets will be solved as easily. On the GFP patent pool (called AvGFP), see Birgit Verbeure, *Patent Pooling for Gene-Based Diagnostic Testing*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS 3, 18-19 (Geertrui Van Overwalle ed., 2009). For the BBF's solution to this problem, see *infra* note 197 and accompanying text (discussing how "free fluorescent proteins" contributed to public domain via the BPA).

152. *See* STEVEN WEBER, THE SUCCESS OF OPEN SOURCE 20-53 (2004) (on the early history of open computing).

153. On the commercialization of academic research, see Hans Radder, *The Commodification of Academic Research*, *in* THE COMMODIFICATION OF ACADEMIC RESEARCH: SCIENCE AND THE MODERN UNIVERSITY 1 (Hans Radder ed., 2010).

154. On the licensing and patent strategies employed in the commercialization of academic science, see Sigrid Sterckx, *Knowledge Transfer from Academia to Industry through Patenting and Licensing: Rhetoric and Reality*, *in* THE COMMODIFICATION OF ACADEMIC RESEARCH: SCIENCE AND THE MODERN UNIVERSITY 44 (Hans Radder ed., 2010). Note that Stanford University presents an interesting and important exception—and valuable template—in explicitly allowing its faculty to decide whether to introduce an innovation into the public domain in lieu of patenting. *See* STANFORD UNIVERSITY, RESEARCH POLICY HANDBOOK 9.1.A.3 (2016), https://doresearch.stanford.edu/policies/research-policy-handbook/intellectual-property/inventions-patents-and-licensing [https://perma.cc/R3R9-APXK] ("The inventors, acting collectively where there is more than one, are free to place their inventions in the public domain if they believe that would be in the best interest of technology transfer and if doing so is not in violation of the terms of any agreements that supported or related to the work.")

155. Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

commercialization of publicly-funded academic research.[156] Moreover, conventional biotechnology is both more concentrated (i.e., oligopolistic) and more IP-centric than many other sectors, with patent fights an established part of firm strategy.[157] Perhaps no group of previous researchers in history would have had as much reason to question intellectual property and its role in their endeavor as the early founders of synthetic biology, working on new biotechnologies inside the highly commercialized research universities of the 1990s and 2000s, but with a shared background in F/OSS. It is laudable but unsurprising, then, that a concern to maintain "openness" has been at the forefront of the field from its first days.

B. *Copyleft: A Flawed Analogy?*

The question for the founders of synthetic biology was thus not whether but how to try to maintain "openness," particularly as the field matured and began to move from government and university research labs into corporate contexts. The first puzzle was what openness should mean in the context of biological innovation, which cycled around two main views. The first and most basic ideal was that a biological part should be "free to use"—that is, its use by a scientist or engineer would not constitute an infringement of intellectual property rights nor bring with it any other formal legal obstacles.[158] This ideal of a biological part being "free" focused on *legal* rights, not the sharing of non-legal costs. For example, the practice of charging reasonable fees for the shipping of biological materials (when a physical sample is required) is common, consistent with the Universal Biological Materials Transfer Agreement,[159] and would not violate the ideal of "free to use" in the way that charging fees for the use of the intellectual property would.[160]

The complexity here comes—just as it has in the debate over "free" and "open source" software (including "free" versus "open source" software)[161]—in how

156. The effect of the Bayh-Dole Act on commercialization and university research priorities remains unclear. For a critical assessment, see Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECHNOLOGY 320 (2006), and for an overview by the National Research Council of the National Academies of the Bayh-Dole Act's effect on university research and the public interest, see MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST (Stephen A. Merrill & Anne-Marie Mazza eds., 2011).

157. *See* Oriel, *supra* note 11, on patents and business strategy.

158. *Frequently Asked Questions*, BIOBRICKS FOUND., https://biobricks.org/bpa/faq/#8 [https://perma.cc/3THF-NZ3E].

159. *See* Nat'l Inst. of Health, Uniform Biological Material Transfer Agreement § 15 (1995), https://grants.nih.gov/grants/guide/notice-files/not95-116.html [https://perma.cc/ZQD4-HN6U] ("The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs.")

160. More generally, as a study of open biology suggests, "[a] standard is called 'free and open' when any party is licensed to read and implement it without payment. This is usually understood to imply an open standards process, structured to circumscribe the market power of specific vendors or groups." Alan G. Isaac & Walter G. Park, *Open Development: Is the "Open Source" Analogy Relevant to Biotechnology?*, *in* THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY INNOVATION 225, 236 (David Castle ed., 2009).

161. On the practical and symbolic importance of this terminological contrast, see Richard

to treat "derivative" products or downstream developments that build on foundational or upstream "free to use" technologies.[162] It is relatively straightforward to accept that a user should only be "free to use" an innovation consistent with its being maintained for free use on the same terms by others. But is this freedom realized—or abrogated—when a freely used part is used to construct a larger system that is not offered to others on the same terms? And what form of legal governance should—or could—deliver one or the other of these outcomes?

In an early paper on the legal governance of synthetic biology, Rai and Boyle examined the methods by which different forms of openness could be conceived and legally pursued in synthetic biology. They noted that synthetic biology raised "an issue that has seemed of only theoretical interest until now—the tension between different methods of creating 'openness.'"[163] They distinguished a "commons" and a "public domain" strategy for the open development of a field, and argued that the case of synthetic biology was difficult to fit into existing open-source practice.

The "commons" strategy is the most familiar: it relies on intellectual property law to safeguard and expand a collection of shared resources. This strategic use of intellectual property law meant for proprietary purposes is often called a "hack"—understood in this instance to mean a clever repurposing—as seen in the "copyleft" arrangements undergirding the success of GPL in F/OSS.[164] As Rai and Boyle explain, "[c]ertain types of open source licenses also have a 'commons-expanding' aspect: these 'copyleft' licenses not only make source code freely available, but they also require those who distribute improvements to the source code to make the improvements available on the same terms."[165] Adapting this model to synthetic biology would mean finding a way to deploy intellectual property law to protect biological innovations, which would then be distributed under terms that would advance non-proprietary ends via proprietary means. It would require that derivative products be licensed on the same terms that any "free-to-use" parts were obtained, the model here being the "share-alike" provision of the GPL.

The synthetic biologists involved with the BBF were initially drawn to this model of openness, with the GPL providing the exemplar of a legal innovation protecting a shared commons.[166] Their hope was to create a synthetic biology "commons," for which the Registry of Standard Parts used by the iGEM teams and others served as a model. However, the options available to synthetic biologists looking to repurpose existing intellectual property law to generate such a commons proved much less promising than in the case of F/OSS. When copyright was

---

Stallman, *Why Open Source Misses the Point of Free Software*, GNU OPERATING SYS., http://www.gnu.org/philosophy/open-source-misses-the-point.en.html [https://perma.cc/8V2Q-M8WQ].

162. *Id.*

163. Rai & Boyle, *supra* note 108, at 389.

164. *GNU General Public License*, *supra* note 112; *see also* WILLIAMS, *supra* note 18, at 128-29.

165. Rai & Boyle, *supra* note 108, at 391.

166. Personal communication with Drew Endy and others.

extended to software in the late 1970s and early 1980s, it created legal obstacles to sharing that prompted Richard Stallman to declare that "charging money for software was a crime against humanity"[167] and to release "free" software first under the GNU Emacs license and later the GPL.[168] But a copyleft analogue has proven much harder to develop in biotechnology, in spite of the inspiration it provided to the scientists pursuing the open development of synthetic biology.

The first and most important obstacle is that the "commons-expanding" strategy requires using existing intellectual property rights for leverage with respect to derivative works.[169] In a field currently governed by *patents* rather than copyright, the BBF board first considered whether patent licensing could be used to promote open-source synthetic biology. Unlike copyright, which affixes automatically and costlessly, patenting is expensive, laborious, and non-trivial (requiring the specification of claims covering the scope of protection). Any obvious analogy from "copyleft" to some version of "patent-left" breaks down at this point, though the ideal of a "commons-expanding" strategy remains possible, if costly.

To pursue such a strategy, advocates of openness in synthetic biology would need either to identify a few core innovations (parts or, more likely, assembly standards) that could prove foundational for the field—and which, if patented, would provide the basis for a "commons-expanding" patent license, or else to go to the expense and trouble of patenting many individual parts. The first approach of trying to patent a few core technologies was considered by the BBF board to violate the principle of openness, both by setting a bad example for corporate actors without the same values and also by risking an unintended inhibition of the field in terms of its commercial development, which would need to be able to scale across both for-profit and non-profit sectors.[170] The second approach of trying to patent a sufficient assemblage of parts which could then be licensed to others on

167. WILLIAMS, *supra* note 18, at 85.

168. On the origin of the GNU Emacs, see *id.* at 77-88, and on the drafting of the GNU Emacs license, see *id.* at 123-43. That license, the precursor to the later GPL, was drafted once Stallman decided to work through the changing intellectual property landscape, and in discussion with Mark Fischer. As Fischer recalls, "'Richard had very strong views about how it should work,' Fischer says, 'He had two principles. The first was to make the software absolutely as open as possible. The second was to encourage others to adopt the same licensing practices.'" *Id.* at 124.

169. As Rai and Boyle note, "[c]opylefted software relies heavily on the existence of property rights—specifically, copyright in the source code." Rai & Boyle, *supra* note 108, at 391.

170. For example, given a foundational patent on a few key parts or processes, the BBF could attempt "commons expansion" under a share-alike licensing provision of one kind or another. But how it would require licensees to treat their own innovations remained unclear, with no obviously attractive solution. If patenting of these new parts (and release on the same terms of the BBF's patent) were required, this demand would represent a large expenditure, given the costs of patenting, and thus slow the growth of a peer community, while also consolidating both larger firms and the IP-centric nature of biotechnology. If patenting was not required—or indeed precluded—on the terms of the original license, it would set up familiar incentive problems by making it difficult to commercialize synthetic biological applications, which would make initial venture funding difficult to obtain, which would similarly slow the development of the field given the large initial capital costs required in biotechnology.

"commons-expanding" terms was deemed prohibitively expensive, and a misuse of funds, even if adequate funds for this purpose could be made available.[171]

The non-viability of a "patent-left" strategy left two further options, both of which attempted to leverage intellectual property to create a "commons." The first was to consider the use of "patent pools" or other forms of creative cross-licensing of patents to achieve openness. This approach—broadly called "BiOS" or Biological Open Source—has been attempted in a few areas of biotechnology.[172] The main examples here are the CAMBIA initiative for pooling agricultural biotechnologies and a few other patent pools related specifically to biomedical technologies.[173] While these approaches may prove attractive for some synthetic biological applications, the BBF board considered them too exclusionary to provide a general solution, since they usually require either some initial patents bartered for entrance to the cross-licensing arrangement or else the payment of an entry fee for the use of the pooled patents.[174] Either approach conflicted with the desire to establish a collection of "free to use" biological parts. It is worth noting that a similar dilemma has been faced by other non-profit groups, similarly inspired by the example of F/OSS, which have also moved away from the creative use of patent licenses to more straightforward modes of disseminating materials.[175]

---

171. For example, on a core assemblage of 10,000 standard biological parts, the patenting costs to achieve minimal protection in the United States alone (supposing $25,000 per patent) would run to a quarter billion dollars. To achieve worldwide patenting, and on a larger assemblage, would cost much more. When confronted with this hypothetical, Drew Endy replied that if the BBF ever had such funds, it should spend them on creating new parts rather than obtaining patents on existing ones.

172. JANET HOPE, BIOBAZAAR: THE OPEN SOURCE REVOLUTION AND BIOTECHNOLOGY 316-18 (2008). An interesting early effort along these lines was a license produced by the Samuelson clinic for the BBF that included a scheme for profit-sharing from derivative works produced from the initially-licensed intellectual property. The BBF board ultimately decided that this license was inappropriate for the kind of user base which it anticipated attracting, as well as likely difficult to administer (in its profit-sharing regime). *See The BioBricks Foundation: Legal*, OPENWETWARE (May 14, 2017), http://www.openwetware.org/wiki/The_BioBricks_Foundation:Legal [https://perma.cc/47Y3-X5XU].

173. On CAMBIA, *see generally* Nele Berthels, *CAMBIA's Biological Open Source Initiative*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 194 (Geertrui Van Overwalle ed., 2009); HOPE, *supra* note 172, at 316-18; CARLSON, *supra* note 35, at 203-05.

174. It was argued that charging an entry fee could conflict with the BBF's need to accommodate an anticipated heterogeneous user base. It is true that these fees could be varied—as CAMBIA's BiOS is—to reflect both the nature of the licensee (i.e., for-profit or non-profit) and the size of the enterprise. The administrative and management burdens that this would impose have proven difficult for CAMBIA and were thought inappropriate to an entire field, for reasons of scaling, unlike CAMBIA's specific patents covering agricultural biotechnology.

175. In addition to CAMBIA, the *Open Source Seed Initiative* seems to have taken a similar path. *See* Jack Kloppenburg, *Re-Purposing the Master's Tools: The Open Source Seed Initiative and the Struggle for Seed Sovereignty*, 41 J. PEASANT STUD. 1225, 1226 (2014) ("[W]e have encountered a variety of technical, legal obstacles to drafting workable licenses that are making us rethink our relative emphasis on the normative goal of reintroducing an ethos of sharing for germplasm exchange versus the pragmatic goal of creating a legally enforceable mandate for sharing."); *see also id.* at 1237-41. For a further discussion of the challenges to translating F/OSS praxis to seed sharing, see Jack Kloppenburg, *The Unexpected Outcome of the Open Source Seed*

The second possibility mooted was to attempt to follow copyleft not just in the inspiration, but also in the details, through the application of copyright to synthetic biology. What Rebecca Eisenberg wrote in 1990 remains largely true today: "copyright protection for DNA sequences has failed to make its mark outside the scholarly literature."[176] That said, post-*Myriad*, the copyrightability of DNA has received renewed attention from legal scholars,[177] and at least one company, Illumina, Inc., claims copyright in some oligonucleotide primers (though that copyright has never been challenged).[178]

This thought that DNA (particularly cDNA) might be copyrightable follows rather naturally on the analogy between synthetic biology and computing, and the extension of copyright to software.[179] Legal scholar Andrew Torrance notes the "striking"[180] similarities between DNA sequences and computer algorithms. If, as

---

Initiative's Licensing Debate, OPENSOURCE.COM (June 3, 2014), https://opensource.com/law/14/5/legal-issues-open-source-seed-initiative [https://perma.cc/AQC5-9ZUY] [hereinafter Kloppenburg, *The Unexpected Outcome*].

176. Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 721 n.3 (1990).

177. *See, e.g.*, Ethan R. Fitzpatrick, *Open Source Synthetic Biology: Problems and Solutions*, 43 SETON HALL L. REV. 1363 (2013); Christopher M. Holman, *Copyright for Engineered DNA: An Idea Whose Time Has Come?*, 113 W. VA. L. REV. 699 (2011); Joseph N. Michelotti, *Genes As Intellectual Property*, 11 MICH. ST. U. J. MED. & L. 71 (2007); Andrew W. Torrance & Linda J. Kahl, *Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property*, 30 SANTA CLARA HIGH TECH L.J. 199 (2014); Andrew W. Torrance, *DNA Copyright*, 46 VAL. U. L. REV. 1 (2011).

178. See Torrance, *supra* note 177, at 2-3 (discussing Illumina's claim that its commercially available oligonucleotide sequences are protected by copyright).

179. The interest in copyrighting DNA followed the statutory extension of copyright to computer code and was discussed beginning in the 1980s. *See* ROBERT COOK-DEEGAN, THE GENE WARS: SCIENCE, POLITICS, AND THE HUMAN GENOME 309-10 (1994); *see also* Dan L. Burk, *Copyrightability of Recombinant DNA Sequences*, 29 JURIMETRICS J. 469, 531-32 (1989); Duncan M. Davidson, *Common Law, Uncommon Software*, 47 U. PITT. L. REV. 1037, 1104-05 (1986); Jorge A. Goldstein, *Copyrightability of Genetic Works*, 2 BIO/TECHNOLOGY 138 (1984); Donna Smith, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083, 1096–108 (1988); *see also* sources cited *supra* note 177.

180. Torrance cites early geneticists such as James Bonner for the analogy between DNA and a computer program. Torrance, *supra* note 177, at 13. *See also* JAMES BONNER, THE MOLECULAR BIOLOGY OF DEVELOPMENT 134 (1965) (characterizing the genome as a "master programme constituted in turn of a set of subprogrammes or subroutines"); François Jacob & Jacques Monod, *Genetic Regulatory Mechanisms in the Synthesis of Proteins*, 3 J. MOLECULAR BIOLOGY 318, 354 (1961) ("[T]he genome contains not only a series of blue-prints, but a co-ordinated program of protein synthesis and the means of controlling its execution."). Legal scholar Christopher Holman argues that engineered genetic sequences are analogous to computer code because both contain instructions that can be read and executed. Christopher M. Holman, *supra* note 177, at 703 ("In view of the close analogy between software and engineered DNA, the further extension to encompass engineered genetic sequences is a relatively modest incremental expansion."). Torrance goes further, suggesting that DNA sequences could be considered a form of computer software, rather than simply analogous to computer software. Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, *supra* note 84, at 647 ("Rather than portray DNA sequences as analogous to computer software, a synthetic biologist might consider DNA sequences actually to be a form of computer software.").

Arjun Bhutkar asserts, synthetic biologists aim "to create a programmable microorganism from scratch,"[181] then, Torrance reasons, genetically engineered biological parts should be entitled to the same copyright protection as software.

Not all legal scholars are convinced. Rai and Boyle also examined this strategy in their early article on synthetic biology, but gave reasons to doubt that copyright either could or should be extended to synthetic biological innovations. Noting that the argument for extending copyright to synthetic biology must depend on an analogy to software, they argue that, "software itself fits poorly into copyright's categories"[182] because of its algorithmic and partly device-based nature. The difficulty arises because copyright should not apply to unique functional expressions, only original ones.[183] Thus, the extension of copyright law would be restricted precisely to those cDNA sequences that have functional analogues in terms of protein expression.[184]

Such a restriction would (appropriately) defeat the effort to gain a monopoly over a genetic function through copyright law, but would thereby limit its utility for either commercial or "copyleft" purposes. Perhaps more worryingly, in the event that copyright was extended (inappropriately) to DNA sequences with unique protein expression, it would introduce monopoly rights of long duration into biotechnology, given the much greater length of copyright terms compared to patent terms. The ability to achieve a "copyleft" hack using newly extended copyright law could thus come at the cost of enabling a much broader "enclosure" movement,[185] which would run precisely counter to the hope for an open development of the field.[186] For these reasons, the BBF decided not to pursue an

---

181. Arjun Bhutkar, *Synthetic Biology: Navigating the Challenges Ahead*, 8 J. BIOLAW & BUS. 19, 20 (2005).

182. Rai & Boyle, *supra* note 108, at 391.

183. As Torrance notes, short sequences of DNA would likely be uncopyrightable; where such sequences encode corresponding amino acids, idea and expression would merge. Consequently, he argues, these "short building-block sequences of DNA" would remain in the public domain, while longer and more complex DNA sequences would enjoy copyright protection. Torrance, *supra* note 177, at 35-36.

184. For a discussion of merger doctrine in biotechnology, see Michael D. Murray, *Post-Myriad Genetics Copyright of Synthetic Biology and Living Media*, 10 OKLA. J.L. & TECH. 71, 111 (2014) ("[I]f the functioning appears to follow the form of the work, the merger doctrine will limit the scope of copyright protection for the original and any derivative works."). For a comparison with uncopyrightable computer programs, see *id.* at 117.

185. James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33, 37 (2003) (arguing that the new "enclosure" movement in intellectual property is similar to the earlier enclosure of common lands because "once again things that were formerly thought of as either common property or uncommodifiable are being covered with new, or newly extended, property rights.")

186. Note that the argument for the desirability or appropriateness of copyright extension to synthetic biological innovations may not be changed much by the much-anticipated dematerialization of the field. Dematerialization supposes that physical parts will one day cease to be relevant, replaced simply by genetic sequence information, which can be transmitted to sequencing machines electronically. Successful dematerialization will require that constructing DNA de novo become far cheaper, which seems to have been occurring roughly in line with Rob Carlson's prediction that the cost of DNA sequencing technology will fall in an exponentially

open agenda for synthetic biology through the expansion of copyright law.

C. *The BioBrick™ Public Agreement and the Public Domain*

After an in-depth examination of these issues over several years, the BBF was left more or less where Rai and Boyle had predicted the field of synthetic biology would have to end up: pursuing a "public domain" conception of openness.[187] This strategy eschews intellectual property claims and seeks instead to motivate contributions to a "public domain," outside property claims.[188] As a statutory matter, the public domain is a *defense* against a claim of infringement, the defense being that the innovation was already in the public domain.[189] Considered affirmatively, the public domain presents the ideal of a space free from intellectual property rights rather than an ideal of a commons protected through the innovative deployment of proprietary intellectual property law.[190] Adapting this ideal to synthetic biology, the BBF has attempted to find a way to distribute standardized synthetic biological parts clear of the encumbering claims of intellectual property, even though this means foregoing protections of the kind that a license would provide, and which copyleft has relied upon for commons-expansion.

As discussed in the previous section, the BBF did not intend to develop a public domain strategy for building the synthetic biology commons. The background thought motivating the initial drafting work[191] toward what would later become the BioBrick™ Public Agreement (BPA) was that the innovative copyright licenses

---

declining "cost curve." *See* Robert Carlson, *The Pace and Proliferation of Biological Technologies*, 1 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCI. 203, 207 (2003). Note that even a dematerialized field of synthetic biology will arguably remain algorithmic and functional, and thus inappropriate for copyright extension for reasons discussed in the paragraph accompanying this note.

187. Rai and Boyle suggested in the conclusion to their study that, short of the highly uncertain route of pursuing sui generis intellectual property protection, "[i]n the end, a public domain strategy . . . may not be ideal, but it is certainly a good start." Rai & Boyle, *supra* note 108, at 392.

188. The "public domain" has moved from an affirmative defense against claims of patent infringement to a core idea in legal scholarship on intellectual property. *See* JAMES BOYLE, THE PUBLIC DOMAIN (2008); Boyle, *supra* note 185 at 58-61; Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965 (1990); David Lange, *Recognizing the Public Domain*, 44 LAW & CONTEMP. PROBS. 147 (1981); David Lange, *Reimagining the Public Domain*, 66 LAW & CONTEMP. PROBS. 463 (2003). For the use of the public domain in a research setting, see Stanford University's patent and technology licensing policy, discussed *supra* note 154.

189. 17 U.S.C. § 301 (2012). For an overview of uses of the public domain, see *Welcome to the Public Domain*, STANFORD UNIV. LIBR., http://fairuse.stanford.edu/overview/public-domain/welcome [https://perma.cc/ET8D-T77K].

190. *See* discussion *supra* note 188.

191. Mark Fischer was asked by Drew Endy to lead the drafting of the BioBricks Public Agreement (BPA). He worked with a small team that included Endy and me, who were both on the Board of the BBF, and Lee Crews, a patent attorney at Fish & Richardson. The BBF also earlier benefitted from discussions with a group of students and professors working in Pam Samuelson's intellectual property clinic at Boalt Hall, under the direction of Jason Shultz, and from wide-ranging conversations with other legal academics and open-source advocates and activists.

governing F/OSS—preeminently the GPL—were sine qua non contributions to peer production. Our early ambition was to achieve a similar legal hack for synthetic biology. However, the model of F/OSS proved difficult to port to a biotechnological domain governed primarily by patent law, owing both to the cost of patents and the functional specifications required in patent claims. The BPA was thus drafted with an increasing consciousness that, as the principal drafters came to admit, there would be no "slam dunk" legal solution to the problems facing peer production in synthetic biology.[192]

Without such a solution, the drafters began to consider alternative arrangements aimed at rendering intellectual property claims as minimally intrusive as possible, a strategy that Mark Fischer described as "check your patents at the door."[193] However, in terms of legal requirements, it was not initially obvious what such a strategy would require, nor how precisely to effectuate it in the field of synthetic biology. Like other scientists, the synthetic biologists working with the BBF were familiar with the idea of defensive publication (or disclosure), the revelation of a scientific innovation in a public manner that preempts later patent claims by others.[194] The drafters of the BPA decided to work with this practice in mind, with the aim of producing a "public agreement" in lieu of an innovative licensing technique.

After several years of discussion and drafting based on these considerations the BioBricks Foundation released the BPA, the first open legal tool for synthetic biology.[195] Its intended purpose was to avoid intellectual property as much as possible, rather than trying to leverage it for commons-expansion. The hope was to keep at least a core collection of standard biological parts "free to use" by giving them away outside the constraints of intellectual property. Early contributions made under the BPA have included the parts built by the first Biofab project,[196]

---

192. The three lead drafters, Mark Fischer, Drew Endy and I, all came to this view after considering alternative approaches over several years. Our work was recognized by the White House "Champion of Change" award given to Drew Endy and the BBF. *See Drew Endy, Ph.D.*, WHITE HOUSE (Feb. 4, 2016), https://www.whitehouse.gov/champions/open-science/drew-endy,-ph.d.- [https://perma.cc/8ZSN-NGJQ]; *see also Open Science Initiative Developed by YLS Associate Professor David Grewal '02 and Stanford Bioengineer Receives White House Honor*, YALE LAW SCHOOL, (Jun. 21, 2013) https://www.law.yale.edu/yls-today/news/open-science-initiative-developed-yls-associate-professor-david-grewal-02-and-stanford-bioengineer [https://perma.cc/V6UT-3WEA].

193. Personal communication with Mark Fischer.

194. 35 U.S.C.A. § 102(a)(1) (West 2017) ("the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention").

195. For the text of the BPA, *see* BIOBRICKS FOUND. (Feb. 4, 2016), https://biobricks.org/bpa/ [https://perma.cc/XT3L-MAAG]. For discussions of the BPA in recent legal scholarship, *see* Torrance, *supra* note 84, at 659-63; Alison McLennan, *Building with BioBricks*, *in* INTELLECTUAL PROPERTY AND EMERGING TECHNOLOGIES: THE NEW BIOLOGY 185-86, 190-97 (Matthew Rimmer & Alison McLennan eds., 2012).

196. *See infra* note 310; *see also* GAYMON BENNETT, BIOFAB HUMAN PRACTICES REPORT 3.0: OPEN TECHNOLOGY PLATFORMS: (HOW) SHOULD THE BIOFAB GIVE THINGS AWAY? (2011), http://biofab.synberc.org/sites/default/files/HPIP_Report%203.0_v1_0.pdf [https://perma.cc/VJ2AMJM6].

associated with the bicistronic architecture used to control gene expression, as well as a set of "free fluorescent proteins" that may serve in place of the widely used "green fluorescent protein" which is the subject of so many complex patent claims.[197]

The BPA is structured as a *contract* between "contributors" and "users" of synthetic biological parts centered on a "non-assert covenant" rather than a license of intellectual property rights between a licensor and licensees.[198] Instead of offering commons-expanding terms to licensees using existing intellectual property, it is structured around a "covenant not to assert" any existing (or future) intellectual property rights that the contributing party may have, or may later seek, against any party who signs the BPA.[199] Further, the public revelation of the contributed "materials"—dated with a digital time-stamp controlled by a third-party certifier[200]— serves the purpose of defensive disclosure.

Two features of the BPA deserve particular discussion, both of which should be credited to Mark Fischer.[201] The first is its innovative structure, which is optimized for digital sharing. The second is its reliance on a non-assertion clause written into an ordinary agreement rather than a share-alike clause in an intellectual property license, which reflects a public domain strategy for building a synthetic biology commons.

The structure of the BPA is optimized for digital sharing and online scaling in anticipation of the future growth of the synthetic biology community. Under a

---

197. *See* Drew Endy, *IP-Free EiraCFP (Cyan Fluorescent Protein)*, IGEM (Feb. 4, 2014), http://parts.igem.org/Part:BBa_J97000 [http://perma.cc/JLB3-6VAL] (for the free fluorescent proteins); *see also supra* notes 150-51 (discussing the GFP).

198. Contributors do not leverage existing intellectual property rights, as licensors do with copyleft in software. In an otherwise illuminating discussion of the BPA (one of the few so far in the legal literature), Torrance unfortunately refers to the agreement as a "license" at several points; see Torrance *supra* note 84, at 663-64. Unlike conventional and unconventional IP licenses, the BPA does not rely on any existing intellectual property rights, but is, rather, a *contract* structured around a non-assertion covenant.

199. *The BioBrick™ User Agreement v1.0*, BIOBRICKS FOUND. (Feb. 3, 2016), https://biobricks.org/bpa/users/agreement/ [http://perma.cc/GMQ8-D6PT].

200. The BPA uses the Irish digital-content company Digiprove to certify contributions under the BPA with a digital time-stamp and unique fingerprint. *See* DIGIPROVE (Feb. 3, 2016), http://www.digiprove.com/index.aspx [http://perma.cc/QD9L-6LWG].

201. These two features are perhaps BPA's most innovative, and are both owed to Mark Fischer's insights. A third feature worth mentioning, though not in the specific context of open-source production, is the commitment that Users make to "refrain from using the Materials in connection with any intentionally harmful, negligent, or unsafe uses." *See Biobrick™ User Agreement*, *supra* note 199 § 5. The inclusion of this clause reflected Drew Endy's long-time concern, shared by the BBF board, that synthetic biology be developed in an ethically responsible manner. Whether it would ultimately prove enforceable or otherwise tractable (given the ambiguities in, for example, the injunction against "unsafe" usage) is not altogether clear. However, the BPA was understood to be an exercise in normative guidance for an emerging scientific community in addition to a legal instrument. The restriction may be of further benefit to Contributors by specifying the range of acceptable ways in which they consent to have their contributions used. Nevertheless, this clause is under consideration for possible elimination in a revision to the BPA, which will otherwise be identical in its essentials, however simplified in some respects.

licensing model, a concern with scaling would not prove acute, since contributors could grant a non-exclusive, worldwide license authorizing the use of materials by any user who agreed to abide by its terms (as with, for example, the GPL).[202] Given that the BPA is a contractual agreement, however, the potential transaction costs would become prohibitively high for a community that, if successful, would grow exponentially. The BPA addresses this problem by separating out the offer and acceptance halves of the agreement into two separate "agreements"—the BioBrick™ Contributor Agreement (BBCA) and BioBrick™ User Agreement (BBUA)—which each contain terms referencing the other.[203] Each Contributor who shares a contribution via the BPA (by clicking through and signing the Contributor Agreement) contracts with all present *and future* Users who have or will have signed the User Agreement. A Contributor must thus sign a specific Contributor Agreement for each contribution, but only once, and not with respect to each User, while any User, clicking through just once, gains access to all present and future contributions. The effect is to multilateralize the Agreement and reduce the transaction costs of what would, otherwise, require separate bilateral contracts for each Contribution. This structure was designed in anticipation of a pattern observed in other open-source communities, which tend to have more users than contributors,[204] and thus to avoid the need for Contributors to contract with many separate Users while allowing the more numerous Users easy access to a growing suite of Contributions.

The second feature of the BPA worth examining in detail is the non-assertion covenant at its core. A non-assertion covenant is a promise by an intellectual property rights holder not to assert these rights against others.[205] Under the Contributor Agreement (BBCA Sec. 3), the Contributor promises not to assert against any Users either existing intellectual property rights or any that may come to be issued on the contributed material in the future. It is this promise that the Contributors give to Users, in exchange for modest commitments by Users, such as providing attribution to the Contributor (where requested, as per BBCA Sec. 5) and agreeing to use the materials in an appropriate fashion (as per BBUA Sec. 5).[206]

In its essentials, then, the BBF's public domain strategy consists of the verified public disclosure of an innovation, which should serve to defeat later patent claimants, along with a commitment by the inventor not to pursue infringement claims against BPA signatories. The non-assertion clause was drafted to cover both

---

202. *GNU General Public License, supra* note 112.

203. *BioBrick™ Public Agreement*, BIOBRICKS FOUND. (Feb. 3, 2016), https://biobricks.org/bpa/contributors/ [http://perma.cc/5JMS-LY3Z].

204. On the differing composition of F/OSS communities, *see* Kevin Crowston & James Howis, *The Social Structure of Free and Open Source Software Development*, 10 FIRST MONDAY (Feb. 7, 2005), http://firstmonday.org/article/view/1207/1127 [https://perma.cc/R49T-H86V].

205. For an overview, see Anatole Krattiger, *The Use of Nonassertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (Anatole Krattiger et al. eds., 2007), http://www.iphandbook.org/handbook/ch07/p06/ [https://perma.cc/J8P5-638H].

206. As per BBUA § 5. *See supra* note 201 for further discussion.

unpatented material, which is thereby publicly disclosed, and already patented material. The BPA does not, however, address the treatment of derivative or downstream works that may utilize the innovations so disclosed, as I discuss further in the next Part.

While the contractual nature of the BPA is an important element of the Agreement, the BPA nevertheless provides several key benefits to Contributors and Users, consistent with a public domain strategy, even if it should fail to be read as an enforceable contract. First, as mentioned above, it protects the contributed materials from intellectual property claims that others might make through the functional equivalent of defensive publication. Second, even if not all the elements of the BPA prove contractually enforceable, it is likely that the non-assertion covenant at its heart would be upheld, for reasons discussed below, thus protecting Users' rights to contributed materials. Relatedly, the fact that the materials might be passed on from a User to a third-party non-signatory, with whom the original Contributor lacks privity, is much less worrisome when we consider that the main purpose of the BPA is to disseminate new innovations, not to control their distribution.[207] Finally, the BPA addresses several other elements that are important for community coherence, regardless of their legal status. It offers a needed clearinghouse function through its digital platform, embeds the norm of attribution that has proven important in other peer production contexts, and specifies best practices in terms of ethical use.[208]

Non-assertion covenants began to receive attention in 2006 when major software companies including Sun Microsystems, Microsoft, and IBM announced that they would opt not to enforce particular otherwise-enforceable patents they owned.[209] These promises have been upheld by courts in several different instances, which have effectively treated these promises as equivalent to licenses to intellectual property. In *EOS GmbH Electro Optical Systems v. DTM Corp.*, the Court held that, because of the parol evidence rule, EOS (the exclusive licensee of patents owned by another company) was bound by a non-assertion clause stating that the licensee agrees not to assert any claims of infringement.[210] In a notable case involving a non-assertion clause, *TransCore v. Electronic Transaction Consultants*, the Federal Circuit effectively eliminated the distinction between a patent license and a covenant not to sue, thereby expanding the exhaustion doctrine in patent law.[211] Most recently, in *Technology Licensing Corp. v. JVC Americas Corp.*, a

207. What would be lost in this instance is mainly attribution where it was requested by the initial contributor—an important feature of the BPA but ultimately secondary to the main aim of making materials freely available.

208. *See* BPA, *supra* note 203.

209. *See* Krattiger, *supra* note 205, at 739-40..

210. EOS GMBH Electro Optical Sys. v. DTM Corp., No. SA CV 00-123DOCMLGX, 2002 WL 34536679 (C.D. Cal. Feb. 6, 2002).

211. *TransCore* involved a settlement agreement between TransCore, a company that manufactures, sells, and installs automated toll collection devices, and Mark IV Industries, under which TransCore signed an unconditional covenant not to sue. At issue was whether the non-assertion covenant in the settlement agreement precluded TransCore from suing Electronic Transaction Consultants Corp., which had purchased toll-collection systems from TransCore.

district court again treated a non-assertion covenant as, in effect, a license.[212]

The rationales for using non-assertion covenants vary.[213] For some companies, it proves strategically advantageous to allow others to develop technology platforms without fear of infringement, given either parallel products or limitations of company capacity. Non-assertion covenants may also be used by consortia to create open standards and provide conditional, multilateral assurances that work to the advantage of the major companies in a sector—sometimes with arguably anti-competitive effects—through the requirement that all participants in a common technical endeavor forego competition with respect to intellectual property.[214] Finally, there may be a variety of humanitarian and other reasons for which some owners of intellectual property would choose to promise not to assert infringement claims against others who use their intellectual property.[215]

The BBF's decision to put a non-assertion clause at the heart of the BPA reflected a combination of many of these rationales. It wished to encourage the open development of an emerging field—specifically, as I discuss below, a viable, open *platform*—for both scientific reasons and humanitarian ones.[216] Additionally, the advantage to making the BPA a non-assertion covenant was that it sidestepped the question of intellectual property as completely as possible. Rather than leveraging existing intellectual property to build a commons, the BPA opted for a

---

The district court granted ETC's summary judgment motion and the Federal Circuit affirmed, holding that activity under an unconditional covenant not to sue is activity "authorized by the patent holder." TransCore, LP v. Elec. Transaction Consultants Corp., 563 F.3d 1271, 1272 (Fed. Cir. 2009).

212. JVC asserted that it was protected from patent infringement claims by a non-assertion covenant. Tech. Licensing Corp. v. JVC Americas Corp., No. 12-C-1444, 2013 WL 212928 (N.D. Ill. Jan. 18, 2013).

213. For an overview, see AMANDA BROCK & IAN WALDEN, OPEN SOURCE AND PATENT NON-ASSERTION PLEDGES: A COMPARATIVE ANALYSIS 3-7 (2014).

214. In a 2004 order, the FCC upheld a Digital Transmission Content Protection (DTCP) agreement that contained a non-assertion clause. One of the commissioners wrote a separate concurrence, expressing concern about this clause:

> I fear that the 'non-assert' clause in the DTCP adopter agreement could hinder competition and suppress innovation . . . . [T]he license requires that companies give up any intellectual property rights they have in the DTCP technology before signing. Therefore a party may have to choose between the lesser of two evils: either don't participate in the relevant product market, or compete, but give up your intellectual property rights. I am concerned this result may be anti-competitive, may discourage future investment in intellectual property, and may generally be counter to good public policy.

19 FCC Rcd. 15876, 15926 (2004) (concurring statement of Commissioner Kevin J. Martin).

215. For example, Google has used non-assertion pledges to protect open source software. For its "Open Patent Non-Assertion Pledge" aimed at protecting open source software and reducing patent litigation, see *Patents in the Service of Open Source*, GOOGLE (Feb. 3, 2016), https://www.google.com/patents/opnpledge/ [http://perma.cc/LJB2-3QZZ].

Of course, rather than a non-assertion clause, it is also possible to grant a worldwide royalty-free license to use patented property, as the Gates Foundation did in the case of synthetic artemisinin *See supra* note 85. For a general discussion of non-assertions and world licenses, see Brock and Walden, *supra* note 213.

216. *See supra* note 27 on the scientific and humanitarian mission of the BioBricks Foundation.

choice to put otherwise patentable (or, indeed, patented) innovations into the functional equivalent of the public domain. By this route, both established and emerging parties can use the same legal instrument, whether they are companies holding intellectual property rights or academics or other researchers giving away innovations without wanting to go through the difficulty or expense of filing a patent claim.

Finally, it is worth noting that in response to the rising threat of software patents, the latest version of the GPL (v.3) uses non-assertion clauses very broadly, along with mandatory non-exclusive worldwide licenses of existing patents.[217] The fact that the GPL v.3 employs non-assertion to address software patents confirms the difficulty of creating any straightforward analogue to copyleft in the patent space. Likewise, smaller non-profit groups dedicated to sharing patentable materials have turned to non-assertion and similar strategies.[218] The drafters of the BPA expect that non-assertion clauses will come to be used more frequently in the future by groups of collaborators interested in sharing materials publicly.

The obvious disadvantage with such a public domain strategy is that it lacks the "commons-expanding" character of a GPL-style "share-alike" clause. It was understood by the board of the BBF that this would mean needing to mobilize non-legal norms of sharing and reciprocity to grow the synthetic biology commons, since there would be no legal coercion to bring in new contributions.[219] However, since a major focus of the BBF's work is education and community-building—from its sponsorship of a regular synthetic biology conference series to its collaboration with the iGEM competition and its sponsorship of the educational program BioBuilder[220]—it was comfortable with a strategy that would draw on these strengths rather than require expensive licensing for those who want to share synthetic biological innovations as well as ongoing legal supervision of licensees by a small non-profit organization.

Nevertheless, this disadvantage is not to be underestimated. Under the BPA, derivative works that incorporate or otherwise build on contributed biological parts can, within conventional legal limits, be patented—and thus kept out of a growing synthetic biology commons for the length of a patent term. The *de facto* research exemption may protect most academic scientists from a loss of control over innovations that their own work helps to prompt,[221] but corporate and other

---

217. *Version 3 of the GNU General Public License (GPLv3) Published; Significant Changes for Open Source Software Licensing*, MORRISON & FOERSTER (Aug. 13, 2007), http://www.mofo.com/resources/publications/2007/08/version-3-of-the-gnu-general-public-license-gplv [http://perma.cc/7D8T-6TDM]; *see also* Free Software Found., GPLv3 Third Discussion Draft Rationale 15-24 (2007), http://gplv3.fsf.org/gpl3-dd3-rationale.pdf [http://perma.cc/ACX6-QNHR].

218. *See, e.g.*, Kloppenburg, *The Unexpected Outcome*, *supra* note 175.

219. Multiple personal communications with Mark Fischer and BBF board members (particularly Drew Endy, Randy Rettberg, Tom Knight), 2010-2011.

220. Biobuilder develops teaching modules to bring synthetic biology into high school and early college classrooms. *See* BIOBUILDER (Feb. 5, 2016), http://biobuilder.org [perma.cc/YF4R-R7KY].

221. *See* discussion *supra* note 6.

actors—including possibly some groups within the corporatized university[222]—enjoy no such protection. Furthermore, while the BPA may help to keep a few key parts "free to use," it does not redress IP-centric practices in industrial biotechnology, which can push companies to pursue parallel research agendas determined by the distribution of intellectual property rather than the estimated likelihood of scientific or technical success, thus slowing the development of the field.

This worry, however, is twinned to an obverse hope. Once it was determined that a copyleft analogue was not readily available in synthetic biology, the BBF board saw one possible advantage to avoiding a share-alike clause: the emerging field might grow more quickly if its for-profit and non-profit sectors could be more closely integrated than has been the case with F/OSS and commercial software.[223] By *not* demanding that derivative works be governed by the same terms as contributions under the BPA, for-profit companies should be able to develop commercial applications based on contributed parts without fearing that derivative innovations must be similarly "free to use." Given the significant capital requirements of biotechnology at present, most start-ups will require significant initial investment, which is usually allocated on the basis of an anticipated stream of monopoly rents from intellectual property. Under these conditions, a share-alike licensing provision could have the effect of depriving them of needed commercial loans or investment capital.

IV. THE INFRASTRUCTURE OF PEER PRODUCTION

The public domain strategy adopted by the BBF has brought to the fore something largely untested in the case of F/OSS,[224] which is how much the success

222. On the commercialization of the research university setting, see discussion *supra* notes 153-156.

223. Multiple personal communications with BBF board members, and Mark Fischer, 2011. This hope is not merely a rationalizing of the inevitable, though it may have a wine from sour grapes character. It would be more plausible if the for-profit sector in this field could be expected to avoid patent thickets and blocking patents on foundational technologies, but there is no reason to expect diverse corporate actors to coordinate in this manner absent some form of governmental oversight, as discussed briefly in Part VI below.

224. The GPL's share-alike provision has only recently, and rarely, come up for judicial scrutiny. Several recent cases, mostly coming out of a dispute between Versata and Ameriprise, hinged on the enforceability of share-alike provisions and remedies for breaching those GPL terms. However, after dismissal of several claims, those cases were settled. *See* Y. Peter Kang, *XimpleWare, Versata Settle Insurance Software IP Dispute*, LAW360 (Feb. 11, 2015), http://www.law360.com/articles/620898/ximpleware-versata-settle-insurance-software-ip -dispute [http:// perma.cc/8B2S-P67S]; *see also* Aaron Williamson, *Lawsuit Threatens to Break New Ground on the GPL and Software Licensing Issues*, OPENSOURCE.COM (Jul. 30, 2014), http://opensource.com/law/14/7/lawsuit-threatens-break-new-ground-gpl-and-software -licensing-issues [http:// perma.cc/68LZ-W5T2]. Had they been decided, these cases would have considered several important issues, among them: (1) whether a third party beneficiary can enforce a share-alike provision; (2) whether violations of share-alike provisions would be considered copyright infringement and therefore eligible for injunctions and statutory damages to be determined in federal court; (3) what damages are appropriate in cases where GPL version 2

of commons-based peer production depends on legal enforcement of the terms of an unconventional copyright license and how much it is sustained by essentially non-coercive norms of community reciprocity. As a practical matter, the BBF has pursued its public domain agenda with the expectation that, whatever the motivations underlying it, the success of F/OSS in the digital economy reveals the possibility of open production. And yet, because its public domain strategy depends on non-legal mechanisms to expand the synthetic biology commons, the question of the motivation and capacity of individuals to contribute to collective projects remains a significant one. Without a commons-expanding license provision, the BBF has had to consider the normative foundations of peer production. How will the synthetic biology commons grow without a legal requirement imposed on the users of contributed parts? And are there non-legal prerequisites to successful peer production of the kind that the BBF hopes to galvanize in synthetic biology?

In this Part, I scrutinize the role of what I call infrastructural prerequisites to peer production. These prerequisites can be taken largely for granted in established fields. By contrast, I argue that the success of an emerging field such as synthetic biology depends on a set of infrastructures that enable production under either a proprietary or peer-to-peer model—that is to say, irrespective of the particular legal regime governing the distribution of innovation. Too determined a focus on the legal regime governing innovation may, in fact, obscure recognition of the fundamental role that non-legal infrastructures—shared resources, including physical and social platforms, technological routines and processes, and institutional norms—play in any kind of production. To varying degrees and in different respects, infrastructures prove the bedrock of all successful cooperative activity, however pursued. And yet, as I argue below, these infrastructures are usually prerequisites to the forms of routine production that they enable, whether proprietary initiatives channeled through the market or community-driven peer projects. They cannot, therefore, be generated by the activity they enable but must usually be available prior to it.[225]

Understanding how infrastructure enables downstream innovation allows us to recast the debate over the rationality of peer production. A great deal of the scholarly literature on peer production has focused not on the design of the infrastructures that enable production of either a proprietary or commons-based kind, but on the much-debated reasons for which individuals are motivated to contribute their labor, time, and expertise to collective creative endeavors that do not rely on conventional market incentives.[226] The backdrop to this persistent focus is the undoubted success of many F/OSS projects and the impetus they have given to other efforts at peer production, including the experiment in open synthetic biology.

---

share-alike provisions are violated; and (4) what constitutes a derivative of share-alike code.

225. *See* discussion *infra* Part V.B-C.

226. This puzzle has been a persistent one and, unsurprisingly, the subject of ongoing research and reflection, including among scholars of intellectual property law. *See* sources cited *infra* note 231 for a further discussion of these issues.

From a conventional perspective, especially as informed by the logic of the so-called "free rider" problem, this decentralized collaboration presents a puzzle. However, as I argue in Subpart IV.A below, the rationality of what Yochai Benkler has termed "commons-based peer production"[227] may depend on whether infrastructures are available to support it. In particular, as I discuss in Subpart IV.B, networked peer production depends on a particular kind of shared resource—platform infrastructures that distinguish a relatively invariable core set of elements in a system from a larger, more variable set that uses elements from the core.

Synthetic biology provides a particularly clear example through which to consider these problems since the infrastructural prerequisites for successful peer production are not yet established. In their absence, synthetic biology suffers from what I call "infrastructure gaps" that currently inhibit the growth of the field, which I discuss in Subpart IV.C below. In particular, the networked peer production that the BBF now envisages[228] requires platform infrastructures similar in architecture to those that have enabled decentralized peer production in F/OSS and related fields.

A. *The Rationality of Peer Production*

The backdrop to the puzzle concerning the rationality of peer production is the undoubted success of many F/OSS projects. We are now about three decades out from the beginning of the GNU Project to create a non-proprietary, complete UNIX-compatible software system; about two decades out from the release of the Linux kernel under the second version of the GNU GPL; and a decade and a half since "free software" was redubbed "open source software," and immediately began to grace the pages of the business weeklies.[229] Over the last decade, the example of F/OSS has traveled to new contexts, including the ambition to turn biology into an engineering discipline. In an increasing number of domains, global networks of "knowledge workers" are engaged in sharing, remixing, hacking, and generally upending (or wanting to upend) the strictures of "intellectual property" and all the commonplaces of what they see as an outdated industrial model of information production.[230] Many of these projects will undoubtedly fail, according to one measure or another. What has motivated academic reflection in this area is the surprising fact that so many have already succeeded, some of them with clear legal regimes that enable sharing and some without.[231]

---

227. *See* Benkler, *Coase's Penguin, supra* note 23, at 375.

228. *See infra* note 344 on the "bionet" that the BBF is now trying to build.

229. Richard Stallman, *supra* note 161.

230. *See generally* LAWRENCE LESSIG, REMIX: MAKING ART AND COMMERCE THRIVE IN THE HYBRID ECONOMY (2008). Everything has become fair game: old movies and encyclopedias, mechanical devices and the algorithms they embody, pharmaceuticals, and genes. For an overview of remix culture, see THE ROUTLEDGE COMPANION TO REMIX STUDIES (Eduardo Navas et al. eds., 2015).

231. For two studies of incentives in peer production, see Josh Lerner & Jean Tirole, *Some Simple Economics of Open Source*, 50 J. INDUS. ECON. 197 (2002); Karim Lakhani & Robert Wolf,

The puzzle that peer production of this kind can prove successful must be understood in relation to our assumptions concerning the rationality of individual contributions to cooperative activity and the role of legal coercion in sustaining such cooperation. Specifically, two interrelated arguments orient this puzzlement, though often implicitly. The first is the assumption that incremental contributions to a collective endeavor are not rational, at least without protection from defections by others—an assumption formalized in the free rider problem.[232] The second is that significant (i.e., non-incremental) contributions to a collective endeavor must be understood as exceptional. The corollary to the latter claim is that, as with acts of charity in the design of a system for needs provision,[233] these exceptional contributions should not become the basis for the theoretical analysis of production, nor of its institutional design in practice. I largely accept the latter point and its corollary, but wish to focus on the first argument above: the claim that individual contributions to a collective endeavor are not rational. A claim of this kind has been directed against the viability of peer production, and has in turn generated a variety of analyses and defenses in response.[234]

Across several seminal articles and books, Yochai Benkler has sought to characterize the ways in which individuals are motivated to create valuable information goods not through employment or other market-based transactions but for reasons of recognition, reputation, or other social motivations.[235] An important early article focused on peer production in F/OSS communities,[236] and was followed a few years later by a broader analysis of the dynamics of "shareable goods,"[237] both rival and nonrival, and both inside and outside the digital economy. Arguing that cooperative sharing can exist even in the absence of strong social ties,

---

Why Hackers Do What They Do: Understanding Motivation and Effort in Free/Open Source Software Projects, *in* PERSPECTIVES ON FREE AND OPEN SOURCE SOFTWARE (Joseph Feller et al. eds., 2005). For a detailed discussion of how legal ambiguity enables cooperation (in the case of the transnational open collaboration that produces the annual flu vaccine), see Amy Kapczynski, *Order Without Intellectual Property Law: The Flu Network as a Case Study in Open Science*, CORNELL L. REV. (forthcoming 2016).

232. The free riding problem is discussed extensively later in this section; for an overview of the problem, see text accompanying *infra* notes 249-254.

233. Istvan Hont & Michael Ignatieff, *Needs and Justice in the Wealth of Nations*, *in* WEALTH AND VIRTUE, 1 (Istvan Hont & Michael Ignatieff, eds., 1983).

234. The literature on peer production is now vast. For a brief history of the genesis of F/OSS, see Marshall Kirk McKusick, *Twenty Years of Berkeley Unix: From AT&T-Owned to Freely Redistributable*, *in* OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION 31 (Chris DiBona et al. eds., 1999). For theoretical overviews, see WEBER, *supra* note 152 and Eric von Hippel & Georg von Krogh, *Open Source Software and the "Private-Collective" Innovation Model: Issues for Organization Science*, 14 ORG. SCI. 209 (2003).

235. *See generally* YOCHAI BENKLER, THE PENGUIN AND THE LEVIATHAN: HOW COOPERATION TRIUMPHS OVER SELF-INTEREST (2011); Benkler, *supra* note 21, at 197; BENKLER, THE WEALTH OF NETWORKS, *supra* note 23.

236. In his influential 2002 article *Coase's Penguin*, Benkler introduced the term "peer production," which involves large numbers of people collectively and collaboratively producing something that continues to evolve over time. Benkler, *supra* note 23.

237. *See generally* Benkler, *supra* note 21 (introducing the concept of "shareable goods" and analyzing several forms of social cooperation using this framework).

at least under certain technological conditions, Benkler analyzed sharing as an important modality of economic production alongside market production and state-based (or managerial-hierarchical) production.[238]

Benkler's analysis and defense of sharing has been influential for scholars interested in developing more egalitarian property regimes[239] and analyzing emerging technologies,[240] even while it has been questioned or contested by others.[241] In examining the motivations for such sharing, Benkler notes the social-

238. *See id.* at 333. These and other insights were further developed in his later book, *The Wealth of Networks*, in which he argued that the declining costs of communication and access to media in the so-called "networked information economy" lead to a new mode of production: decentralized, commons-based peer production. BENKLER, *supra* note 23. He argues that these new forms of productive social organization create opportunities for both greater individual autonomy and greater economic justice.

239. Jedediah Purdy evokes Benkler's discussion of lumpy, mid-grained goods, arguing that "the proliferation of productive capital on a scale suited to individual ownership, in packages that routinely include substantially more capacity than the owner typically uses," as described by Benkler, enables people to engage in productive activity for self-realization, "self-expression," and "even play." Jedediah Purdy, *People as Resources: Recruitment and Reciprocity in the Freedom-Promoting Approach to Property*, 56 DUKE L.J. 1047, 1107-1110 (2007). *See also* JEDEDIAH PURDY, THE MEANING OF PROPERTY: FREEDOM, COMMUNITY, AND THE LEGAL IMAGINATION 149 (2010). Also building on Benkler's insights, Eric Johnson argues that the degree to which intellectual property is "shareable" depends upon the nature of the work: digital content such as digital photography, for example, is shareable, because both the camera and individual photos are lumpy and granular. Eric E. Johnson, *The Economics and Sociality of Sharing Intellectual Property Rights*, 94 B.U. L. REV. 1935, 1951, 1956-58 (2014). For such lumpy, medium-granular goods, money-based market transactions prove less efficient at using excess capacity than sharing; markets for such medium-granularity lumpy intellectual works only function, Johnson argues, because "creative labors are driven more by intrinsic motivation than external rewards." *Id.* at 1958.

240. *See* Jorge L. Contreras, *Data Sharing, Latency Variables, and Science Commons*, 25 BERKELEY TECH. L.J. 1601, 1628 (2010) (examining the temporal features of information commons and observing that the "aggregation and availability of data in 'science commons'" enables effective sharing); Carmit Soliman, *Remixing Sharing: Sharing Platforms as a Tool for Advancement of UGC Sharing*, 22 ALB. L.J. SCI. & TECH. 279, 285 (2012) (discussing user-generated content (UGC) in the context of sharing platforms in which modularity enables collective production); Jason R. Wiener, *Sharing Potential and the Potential for Sharing: Open Source Licensing as a Legal and Economic Modality for the Dissemination of Renewable Energy Technology*, 18 GEO. INT'L ENVTL. L. REV. 277, 293 (2006) (arguing that Benkler's model of shareable goods is an attractive alternative to market-based models for understanding the renewable energy technology characterized by "parallel processing, ease and cost of utilizing excess capacity, rapidity of resource's [*sic*] decay, and existence of secondary markets for capacity").

241. The portability of Benkler's model has been questioned, for example, by Steven Hetcher, who asks how many examples would fit the model of peer production and notes that Benkler himself is cautious about the likelihood of applying peer production models to, say, fiction writing given that "modularity and granularity lead to disjunction relative to our expectations of novels." *See* Steven A. Hetcher, *Hume's Penguin, or, Yochai Benkler and the Nature of Peer Production*, 11 VAND. J. ENT. & TECH. L. 963, 970 (2009). Relatedly, Henry Smith asserts that the optimal lumpiness of a resource is empirically variable, and that many situations, in contrast to the open-source model, seem to require coordination or market contracting. Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L. J. 1742, 1763-64 (2007).

psychological discussion of "intrinsic" and "extrinsic" motivations for action,[242] arguing that the distinction does not precisely capture the dynamics of sharing that concern him. He avoids needing to settle any distinction between intrinsic and extrinsic action, focusing instead on the viability of peer production where goods are shareable.[243] For the purposes of his immediate argument—delineating and defending sharing as a "common and underappreciated modality of economic production"[244]—it is sufficient to note that, owing to a variety of motivations, sharing is widespread and effective.[245]

It may, however, be possible to go further than Benkler does in defending the rationality of at least some forms of sharing by facing squarely the anxiety about free riding that hovers behind most discussions of the phenomenon.[246] Doing so would require contending with the dominant argument for the *irrationality* of this kind of cooperation, which supposes that individual contributors can (and thus rationally should) withhold their contributions—devoting their time and energy to other purposes—and instead "free ride" on collective endeavors of the kind represented in peer production. In the context of intellectual property, this argument has been used to support strong proprietary protections on the view that free riding will undermine the incentive to produce, absent property rights backed

242. Benkler, *supra* note 21, at 279. The jumping off point for much of the discussion of intrinsic and extrinsic motivation in social psychology is what Edward Deci and Richard Ryan have termed "cognitive evaluation theory." *See* EDWARD L. DECI & RICHARD M. RYAN, INTRINSIC MOTIVATION AND SELF-DETERMINATION IN HUMAN BEHAVIOR 129-159 (1985). Siegwart Linderberg attempts to make sense of the intrinsic/extrinsic distinction in this literature through attention to goal-oriented behavior, suggesting a "hierarchy of substantive goals" and a "hierarchy of operational goals" in which this motivation distinction is recast. Reframed in this way, the idea of "intrinsic motivation" is decomposed into elements concerned with "enjoyment" of an activity (which turns on what Linderberg calls its "multifunctionality") and our sense of "obligation" to do it (as in norm- or principle-governed activity). In neither of these cases is the external reward the (decisive) reason for acting. Siegwart Linderberg, *Intrinsic Motivation in a New Light*, 54 KYKLOS 317, 331-338 (2001).

243. It is worth noting that many other studies have emphasized the importance of "intrinsic" reasons for contributing to F/OSS projects. For example, in a study of 684 software developers working on 287 free or open source software projects, Karim Lakhani and Robert Wolf determined that most contributors were motivated by what they characterize as intrinsic concerns, such as the need for intellectual stimulation, learning new programming skills, or getting around an obstacle by building out the available program. Lakhani & Wolf, *supra* note 231, at 3-4, 13-19. Their emphasis on the "intrinsic" reasons for contributing is compatible with Benkler's argument concerning the profile of shareable goods (and may even require shareability, though it is not a focus of their analysis).

244. Benkler, *supra* note 21, at 332.

245. More precisely, Benkler suggests that the example of carpooling is driven by self-interested (non-market) exchange while the donation of spare computer cycles reflects a more generalized altruism comparable to Richard Titmuss's famous study of British blood donation. *See id.* at 321-23; RICHARD M. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY (1971) (classic study of the motivation and success of unpaid blood donation in the United Kingdom contrasted with the paid system in the United States).

246. As Lakhani and Wolf note, many "software industry executives, managers, and academics" have been "puzzled by what appears to be irrational and altruistic behavior by movement participants: giving code away, revealing proprietary information, and helping strangers solve their technical problems." Lakhani & Wolf, *supra* note 231, at 3.

by legal coercion.[247] In an analogy to physical property, it is thought that intellectual property protections will bring individual costs and benefits into line, thus guaranteeing efficiency—though, as Mark Lemley has shown, this argument does not hold up in the case of non-rival information goods.[248]

Strikingly, the debates over the rationality of peer production—and thus, ultimately, over its viability as a form of production rather than as a hobby or expressive practice—mirror older debates over the rationality of cooperation in collective projects. The argument that it would *not* be rational to contribute to a collective project can be traced back to Mancur Olson's famous discussion of the "problem of collective action,"[249] which came to be called simply, soon after the publication of his 1965 book, "free riding."[250] The free rider problem quickly came to occupy a central place in studies of collective action in the social sciences, but, within a decade or two of its diffusion across the academic subcultures, it generated a variety of critical philosophical responses.[251] These criticisms have attempted to recover an argument for the *rationality* of individual contributions to joint efforts, even in collective circumstances in which each action is small—perhaps even, as Olson had put it, unapparent to the other contributors.

The most important recent contribution to this line of criticism is political theorist Richard Tuck's reevaluation of Olson's analysis.[252] As Tuck summarizes,

---

247. *See* Mark Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 1033-46 (2005) (summarizing and criticizing the "free riding" justification for intellectual property rights).

248. In the intellectual property context, there may in fact be *socially beneficial* consequences of a great deal of sharing of intellectual property (often described as "free riding" though, as I explain below, it is often not the free rider problem analyzed in mid-twentieth-century public finance and social theory). Lemley has argued that the standard argument *against* free riding in ordinary (i.e., rivalrous) property regimes has to do with the depletion of resources, whereas in *intellectual property* regimes, these standard arguments do not apply. Quite the reverse, for with respect to intellectual property, free riding may be both individually rational and socially beneficial, subject to the qualification that it not hinder the initial development of the intellectual property (the construction of the non-rivalrous good). With that limitation, the optimal distribution in intellectual property regimes is as widespread sharing as possible. *See id.*

249. *See generally* MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION (1965) (arguing that cooperation in groups where individual contributions are negligible with respect to the whole will either be unsuccessful or require coercion to sustain).

250. In his 1965 book, Olson did not himself use the term "free riding" very extensively to describe the problem of collective action, even while noting the concern about the "free rider" among union organizers; see OLSON, *supra* note 249, at 76. It came into general use soon after, as evidenced by sources cited *infra* note 251.

251. Among the most important of these are BRIAN BARRY, SOCIOLOGISTS, ECONOMISTS, AND DEMOCRACY 13-46 (1978); DEREK PARFIT, REASONS AND PERSONS 67-86 (1984); Philip Pettit, *Free Riding and Foul Dealing*, *in* 83 J. PHIL. 361 (1986); Richard Tuck, *Is There a Free Riding Problem, and if So, What Is It?*, *in* RATIONAL ACTION: STUDIES IN PHILOSOPHY AND SOCIAL SCIENCE 147 (Ross Harrison ed., 1979).

252. *See generally* RICHARD TUCK, FREE RIDING (2008). While this Article is the first use of Tuck's analysis of free riding in the context of intellectual property law, it has been used by legal scholars working on questions of federalism, criminal justice, voting rights, and environmental law and policy. *See* Joseph Fishkin, *Weightless Votes*, 121 Yale L. J. 1888, 1895 (2012); Aziz Huq, *Does the Logic of Collective Action Explain Federalist Doctrine?*, 66 STAN. L. REV. 217 274-275

Olson's claim is that "where my contribution to a co-operative activity is relatively insignificant—that is, it apparently makes no difference to the outcome whether I contribute or not—then I have no instrumental reason to play a part in the activity."[253] Tuck shows that, at its heart, this claim turns on the problem of the vagueness of the thresholds that mark the point where individual contributions can become collectively efficacious in securing a desired outcome.[254]

While his argument can only be sketched here, Tuck explains that in the case of a precisely specified threshold—as occurs in voting—strategic cooperation among agents making even small contributions (e.g., a single vote) may be both desirable and feasible.[255] By contrast, cooperative endeavors of the kind that Olson analyzed are marked by thresholds of an admittedly "vague" or indeterminate variety, above which "enough" contributions will have to be made for the collectively beneficial result to obtain. These thresholds must be understood as similar to a determinate threshold (e.g., fifty percent plus one that governs this condition in the voting context), but without a specific or, indeed, specificable amount: "situations involving negligible contributions or increments are in fact threshold situations,"[256] albeit vaguely defined ones. Despite this vagueness, whenever there is a boundary to achieving a collectively beneficial outcome, strategic action remains possible—just as in the case of voting in which a determinate threshold exists.[257] The possibility of collectively achieving a beneficial outcome means that

(2014); Dan Markel, *Retributive Justice and the Demands of Democratic Citizenship*, 1 VA. J. CRIM. L. 1, 61-62 (2012); Jedediah Purdy, *The Politics of Nature: Climate Change, Environmental Law, and Democracy*, 119 YALE L.J. 1122, 1197 (2010). For an interesting contribution to the analysis of coordination problems in cyberspace, which does not engage Tuck's arguments but does use the philosophical literature on conventions and coordination games to understand peer production, see Hetcher, *supra* note 240, at 963, 978 ("peer production is properly modeled as involving coordination norms or conventions."). A few years after the publication of Tuck's book, the philosopher Shelly Kagan made a strikingly similar argument against Olson (in apparent ignorance of Tuck's work), developing a parallel analysis of the problem of collective action above and below thresholds (including vaguely specified thresholds). Shelly Kagan, *Do I Make a Difference?*, 39 PHIL. & PUB. AFF. 105 (2011).

253. TUCK, *supra* note 252, at 99. It is important to distinguish Olson's claim, which is at the heart of the free rider problem, from several other problems of collective action, which are not identical to free riding though often confused with it, including the Prisoner's Dilemma and the problem of voting. For a formal model of the Prisoner's Dilemma, see ANATOL RAPOPORT & ALBERT M. CHAMMAH, PRISONER'S DILEMMA 33-36 (1965). For Tuck's analysis of the prisoner's dilemma as distinguished from the free rider problem, see TUCK, *supra* note 252, at 19-29. Since the negligibility of any individual contribution is at the heart of the free rider problem, "many distinctive features of the prisoner's dilemma disappear at the point at which the agents concerned begin to treat their effect on one another as negligible." *Id.* at 28. The obvious way in which voting differs from the classic problem of public goods provision is that voting takes place in the context of a clear *threshold*: a determinate quantity of votes decides an election. *See id.* at 36.

254. Tuck, *supra* note 252, at 64-66, 99-104.

255. *Id.* at 37-50.

256. *Id.* at 95.

257. As Tuck writes:

> [w]hile we have essentially inexact knowledge (in some fashion) of where the threshold is to be found in *sorites* cases, and we have exact knowledge in cases such as voting, the basic character of our reasoning in the two kinds of cases will be the same. My contribution, even if it is negligible,

contribution to many cooperative contexts may be perfectly rational, on even the thinnest instrumental notion of rationality, given a reasonable judgment that *enough* other participants are contributing to an endeavor that our own contribution will prove causally efficacious.[258]

Applying this argument to the case of peer production should reorient our inquiry away from a concern with the motivations that lead an individual to contribute to what is deemed an irrational endeavor (on the logic of free riding) toward a concern with the conditions under which enough individual contributions of even a modest kind can prove collectively efficacious in securing a desired result. Benkler's analysis suggests this orientation as well: what he identifies as the sharing mode of production reflects, as he recognizes,[259] one particular pattern of collaboration under favorable social and technological conditions. These conditions may be marked by "thresholds"[260] that determine the efficacy of sharing, based on "technologically contingent physical-capital requirements for effective action."[261] If that sharing is undertaken for self-interested or "instrumental"[262] reasons—that is, to enjoy the benefit that a collective outcome provides to an individual—these thresholds can be understood as marking the point where individual actions can conduce to a desired collective outcome, in line with Tuck's analysis of free riding. For example, considering Benkler's analysis of F/OSS and carpooling, the threshold above which sharing becomes viable would reflect a "sufficient" density of widely distributed personal computers or privately owned but underutilized (low-occupancy) automobile trips. While the characteristics of these "lumpy, mid-grained" goods make them shareable, only a sufficient density of them creates the general prerequisites for a sharing modality of production.[263]

As I argue in the next section more extensively, this "sufficient density" marking thresholds that define the conditions for successful cooperation may best be understood in terms of the absence or presence of critical infrastructure that enables social cooperation. This infrastructure may be further conceptualized as a

---

> has causal efficacy in bringing it about that the threshold is crossed, as long as enough other contributions have been made or will be made.

Id. at 95-96.

258. *Id.* at 103-04

259. *See* Benkler, *supra* note 21, at 339-41.

260. *See id.* at 339 (arguing that when a "larger-scale physical-capital requirement is a threshold of effective action" the sharing modality will not be widespread); *id.* at 340 (arguing that "technology imposes *threshold* constraints on effective sharing" without precisely determining the extent of that sharing).

261. *Id.* at 358.

262. Benkler uses the term "instrumental" to mean self-interested in addition to instrumentally efficacious. *See id.* at 279 (contrasting "instrumental" and "noninstrumental" reasons for exchange).

263. See *id.* (on lumpiness and granularity in shareable goods). Benkler argues that "[c]reative labor in the context of peer production can be harnessed when a project is broken up into discrete modules, whose granularity is varied and sufficiently fine grained to allow individuals with diverse motivations to engage in the effort at levels appropriate for their motivations . . . ." *Id.* at 332.

kind of *platform* that makes routine sharing efficacious.[264] What Benkler identifies in his examples as a sufficient density of widely distributed physical-capital goods with excess capacity constitutes an open platform on top of which sharing routines can come to be successfully established, with each act of sharing analogous to an "application" built on top of it.

By contrast, where this infrastructure is missing, we can identify what I call an "infrastructure gap," which will inhibit peer production. As I discuss below, the success of peer production in synthetic biology may depend on resolving critical infrastructure gaps as much as any other obstacle—and creative legal hacks (as opposed to public policy changes) can play only a limited role in that resolution. To understand why this is so, however, requires an excursus into the theory of infrastructure, and of platform architecture in particular.

B. *Platform Goods as Infrastructure*

Platforms are now widely familiar in the digital economy, though relatively under-theorized.[265] The revolution in digital computing and the growth of the Internet has led to an increased scholarly interest in platforms as a kind of "infrastructure," which has been discussed in a variety of academic disciplines. A recent National Science Foundation report on infrastructure, focused on the question of cyber-infrastructures, has usefully situated the theory of infrastructure with respect to its dynamics, tensions, and design.[266] The authors concluded that successful examples of historic infrastructures, including the highway/roadway system, the electrical grid, the railways, the telephone system, and the Internet, become "*ubiquitous*, *accessible*, *reliable*, and *transparent* as they mature."[267] The tensions involved in the maturation of any successful infrastructure include disputes over "ownership, management, control, and access,"[268] for while infrastructures generate "vast benefits," they also determine winners and losers, if

264. *Id.*

265. The collection of essays in PLATFORMS, MARKETS AND INNOVATION (Anabelle Gawer, ed., 2009) is the first major, cross-disciplinary exploration of the subject. The most important economic theory on platforms models them as "two-sided markets." *See* Jean-Charles Rochet & Jean Tirole, *Platform Competition in Two-Sided Markets*, 1 J. EURO. ECON. ASSOC. 990 (2003). The theory is motivated, partly, by an interest in open-source platform development. *See* Josh Lerner & Jean Tirole, *The Open Source Movement: Key Research Questions*. 45 EURO. ECON. REV. 819 (2001). For an important extension of platform arguments to consider the legal regulation of the new "sharing" or "on-demand" economy, see Sabeel Rahman, *The Shape of Things to Come: The On-Demand Economy and the Normative Stakes of Regulating Twenty-First Century Capitalism*, 4 EUR. J. RISK REG. 1 (2016).

266. For the report of a National Science Foundation (NSF) workshop on infrastructure, especially cyber-infrastructures, see PAUL N. EDWARDS ET AL., NAT'L SCI. FOUND., UNDERSTANDING INFRASTRUCTURE: DYNAMICS, TENSIONS, AND DESIGN (2007), http://cohesion.rice.edu/Conferences/Hewlett/emplibrary/UI_Final_Report.pdf [https://perma.cc/NZ4M-XVMF].

267. *Id.* at *i*.

268. *Id.* at *ii*.

only in a relative sense.[269]

A major task for infrastructure creation, then, is careful *design*, which mitigates or manages the tensions of its maturation, with an eye to the dynamics of successful infrastructures.[270] The focus on infrastructure design parallels in significant respects a similar analysis that has been undertaken with respect to the question of *platform architecture*.[271] Indeed, platforms may be considered a particular kind of infrastructure, which should be understood as a kind of "shared resource" as Brett Frischmann puts it.[272] Each of the major examples of infrastructure from the NSF report could be identified as playing the role of a platform for the production of transport, communication, and power.

The information economy has seen the proliferation of platforms in many areas of production. In one of the first attempts to develop a typology of different platform types, Annabel Gawer notes the characteristics of "internal platforms," "supply chain platforms," and "industry platforms."[273] Perhaps the most relevant for the hopes of open synthetic biology is what Gawer calls an "industry platform," which enables shared efforts in an entire field. Important *industry platforms* include "Google, the Internet search engine, social networking sites such as Facebook, operating systems in cellular telephony, videogame consoles, but also payment cards, fuel-cell automotive technologies and some genomic technologies."[274] The operating system of a computer provides an obvious example of how an industry platform works: "Microsoft Windows is an industry platform—a building block, providing an essential function to a technological system—which acts as a foundation upon which other firms can develop complementary products, technologies or services." [275] As Gawer notes, and as has been much discussed in the scholarly literature, this means it is "subject to so-called network effects, which tend to reinforce in a cumulative manner early gained advantages such as an installed base of users, or the existence of complementary products."[276] In the next Subpart, I discuss the efforts of synthetic biologists to build such a platform enabling the rapid and reliable engineering of biology.

As a general matter, we can consider a platform "a set of common components, modules, or parts from which a stream of derivative products can be efficiently created and launched."[277] In an elegant and important study, Carliss Baldwin and

---

269. Issues of distribution and fairness are key to positive-sum games, and, arguably, any infrastructure may be positive-sum over its absence.

270. Specifically, the authors of the NSF report argue for specific strategies for navigating these tensions. *See id.*

271. BRETT M. FRISCHMANN, INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES 34 n. 25 (2012) (on terminology of platform and infrastructure).

272. *See generally id* (analyzing the law, economics and policy of infrastructure).

273. Annabelle Gawer, *Platforms, Markets and Innovation: an Introduction*, *in* PLATFORMS, MARKETS AND INNOVATION 1 (Annabelle Gawer ed., 2009).

274. *Id.* at 1.

275. *Id.* at 2.

276. *Id.* The network effects of platforms have been the subject of an enormous literature in industrial organization and intellectual property. *See* GREWAL, *supra* note 1, at 324 n.38-n.39.

277. MARC H. MEYER & ALVIN P. LEHNERD, THE POWER OF PRODUCT PLATFORMS (1997).

Jason Woodard draw on a variety of scholarly literatures working toward what they call a "unified view" of the architecture of platforms, noting that the term *platform* has been used variously in economics, industrial organization, and management studies.[278] From these diverse usages, they nevertheless extract a convergent analysis concerning how platforms function, noting "most importantly, the conservation or reuse of a core component to achieve economies of scale while reducing the cost of creating a wide variety of complementary components."[279] This observation leads Baldwin and Woodard to argue that "the fundamental architecture behind all platforms is essentially the same: the system is partitioned into a set of 'core' components with low variety and a complementary set of 'peripheral' components with high variety."[280]

These "common components" are the shared resource that makes platforms an infrastructure. Baldwin and Woodward explain that: "[t]he low variety components constitute the platform. They are the long-lived elements of the system and thus implicitly or explicitly establish the system's interfaces, the rules governing interactions among the different parts."[281] At their most basic, "platform architectures are united in that they partition a system into low- and high-variety components."[282] A platform might thus be understood as a particular kind of infrastructure consisting of shared resources (core components) that allow for the development of new capacities (complementary, peripheral components) in a network.[283]

---

278. Carliss Y. Baldwin & C. Jason Woodard, *The Architecture of Platforms: A Unified View*, *in* PLATFORMS, MARKETS, AND INNOVATION 19 (Annabelle Gawer ed., 2009). Baldwin and Woodard analyze three recent waves of scholarship on the role of platforms in technology development and organization strategy. The first began with Wheelwright and Clark, who described a "platform product" as a product created to "meet the needs of a core group of customers but [designed] for easy modification into derivatives through the addition, substitution, or removal of features." *Id.* at 20. After several successive modifications or additions to this basic position, a second wave of scholars interested in the control of technology began to study the way in which control of a platform allowed control over pathways of technical development and the extraction of rents. *Id.*at 20-21. This strand of scholarship was influenced by the competition between digital platforms (including the "browser wars" of the late 1990s). *Id.* It also intersected with studies of "openness" in design architectures by considering the ways in which openness might give one company or group of companies a strategic advantage over rivals. *Id.* A final, influential wave of scholarship on platforms drew on the economic theory of industrial organization, particularly concerning technical standards and network externalities, and theorized platforms as "products, services, firms or institutions that mediate transactions between two or more groups of agents." *Id.* at 21 (discussing the work of Rochet and Tirole, *supra* note 265, at 58).

279. Baldwin & Woodard, *supra* note 278, at 19.

280. *Id.*

281. *Id.*

282. *Id.* at 26.

283. Pier Paolo Patrucco, *Innovative Platforms, Complexity, and the Knowledge Intensive Firm*, *in* HANDBOOK ON THE ECONOMICS AND THEORY OF THE FIRM 358, 366 (Michael Dietrich & Jackie Krafft eds., 2012) ("Efficient platforms appear when the various incentives and complementary capabilities of a multiplicity of actors involved in a heterogeneous network are organized and aligned to ensure cohesion and coordination."). *See also id.* at 366-70 (discussing innovation platforms using Baldwin & Woodard's insights).

Building on their insight, economist Pier Patrucco argues that the division between "core components, relatively stable, and peripheral components, variables," is the foundation of the flexibility and innovation that platforms enable. Under this architecture, "to generate a new product or to meet a changing external environment does not require a radical change in the whole system, but simply a change in the peripheral components."[284] The efficiency of platform architecture comes precisely from this combination of core elements supporting variation and change. The combination reflects, at a deep level, the *engineered* nature of these platforms—which is why otherwise diverse theories of platforms converged on it.[285]

Elaborating their fundamental insight into platform architecture, Baldwin and Woodard proceed to develop a series of "analytical tools" to study platform dynamics. They suggest that "two different types of components [i.e., core and peripheral elements] can be combined into a working system because pre-specified interfaces regulate both sides."[286] These interfaces "must be stable relative to the components that depend on them,"[287] and they thus constitute part of the platform (informing its overall architecture). However the interfaces cannot be *too* stable, for platforms must ultimately be evolvable: "they cannot overly constrain the complements or they will reduce the variety and flexibility of the system as a whole."[288]

The interfaces that make up a platform thus constitute key junctures in their design and control—and the question of how such interfaces were managed would probably account for the winners and losers that the NSF study identified in historical examples of infrastructure development.[289] In terms of business strategy, interfaces prove a "source of strategic tension between platform owners and actual or potential complementors."[290] Some level of tension in this respect is irreducible, because it is intrinsic: the very advantages that platforms provide to innovators depend on these junctures. Indeed, even where there is no "platform owner"—when the platform is freely available, as with F/OSS governed by the GPL—the management of the relationship between source code and derivative, proprietary

284. *Id.* at 370 n.345.

285. Underlying the seeming proliferation of different disciplinary uses, Baldwin and Woodard were able to distill the central features of platform architecture because the "things called platforms have common roots in engineering design," and hence allow for the identification of structural commonalities, and ultimately a "unified view" of platform architecture. They note that, "most platform definitions focus on the reuse or sharing of common elements across complex products or systems for production." *Id.* at 22.

286. *Id.* at 26.

287. *Id.*

288. *Id.*

289. *See supra* discussion accompanying note 265.

290. Baldwin & Woodard, *supra* note 278, at 26. Note that this means the decision as to what parts of the system are governed by which intellectual property rules is crucial for the question of how agents take value out of a network. For an analysis of this point, see generally Joachim Henkel & Carliss Young Baldwin, *Modularity for Value Appropriation: Drawing the Boundaries of Intellectual Property* (Harvard Business School Working Paper No. 09-097, 2009).

code often turns on this same strategic tension.[291]

C. *Infrastructure Gaps in Synthetic Biology*

The digital revolution has been the major prompt to the development of theories of platform architecture. The complex dynamics of platform design are particularly notable in computing, in which hardware provides the functionality for software platforms on which applications run, and also visible in the electronic networks that link computers to one another. Similar dynamics, however, are also visible in biotechnology platforms. Genetic expression resembles the layered architecture of computing: in both domains, combinatorial information stored at one ontic level directs the functions of a supervening one.[292] This architecture is the basis of the "abstraction hierarchy" at the basis of synthetic biology.[293] [See Fig. 1.]

Given this parallel, the language of platform architecture aptly describes processes in biotechnology. As James Boyle argues of both biotechnology and the networked computer: "[e]ach is both product and platform. Innovations themselves, they are also constitutive technologies that enable still more innovations."[294] And, as in computing, the dependence of synthetic biological innovation on underlying platforms has generated an interest in community-level control of shared resources that fit poorly with intellectual property rights of a conventional kind.

Drawing on the analysis of infrastructure and platforms above, we can diagnose what might be called an "infrastructure gap" where a key foundational resource is missing, and thereby inhibits productive downstream activity. Foundational infrastructures determine the viability of production, especially perhaps peer production, where individual contributions to peer projects are predicated on the availability of underlying platforms. Infrastructure gaps thus mark the limit of effective collective action.

In my assessment, infrastructure gaps more than any other factor have so far limited the much-anticipated success of synthetic biology. The most immediate infrastructural prerequisites for its successful development are scientific and technical, though background social and institutional norms are vitally important (though not my focus at present).[295] At a foundational level, it may be helpful to

---

291. Henkel & Baldwin, *supra* note 290.

292. Indeed, given the functional advantages of such platform architecture, it is perhaps no surprise that biology itself seems predicated on a "core-periphery" arrangement that provides for individual heterogeneity as the basis for system-wide flexibility.

293. *See supra* Fig. 1.

294. BOYLE, *supra* note 188, at 39.

295. The practical realization of the promise of synthetic biology depends, of course, on more than the science. It requires a supportive institutional ecology: on active, collaborative, and well-funded research scientists and the network of institutions in which they pursue their work; on social norms governing the production and distribution of scientific research with public purposes in mind; and, at perhaps the highest level of generality, on background features of law

conceive a keystone collection of standard biological parts and associated assembly protocols as constituting a *platform* for further innovation. Borrowing from the platform theory outlined above, the immediate focus in synthetic biology should be on developing "core components" and stable "interfaces" at the genetic level—as, for example, in the use of bicistronic architecture to control gene expression. In biotechnology, however, this core-periphery distinction may need to be indexed to the ontic level in the "abstraction hierarchy" at which a scientist is working. For example, the core components at the "parts" level would be standard biological parts that are subject to frequent reuse: widely used ribosomal binding site sequences, gene coding sequences, promoters, inverters, terminators, and so on will play this role.[296] The lack of such parts has been a key problem for the field, including for iGEM teams,[297] and the call to create biofabrication facilities, discussed further below, is mostly focused on the construction of high-quality standard parts and associated assembly protocols.[298]

At a higher level of abstraction, however, and anticipating future developments, some of these core parts will likely serve as the foundation for a core set of "devices" which would in turn enable "systems," some of which would be widely used (and subject to a low level of variation), thus constituting platforms at the device and systems levels.[299] The ultimate platform at the systems level would be the "programmable cell" capable of serving as a "cellular operating system" similar to the platforms used widely in computing.[300] Making all this biological engineering possible across ontic levels would require a set of stable "interfaces" or standards underlying the whole of synthetic biology, most obviously assembly protocols, but also shared techniques for measurement, data recording and transmission, and the like.[301]

Above the cellular level, the platform analogy can be extended to the organisms, particularly to microbial host organisms or "chassis" in which cellular operations are conducted.[302] Several chassis already serve as the "workhorses" of

---

and principles of social coordination governing the legitimate and available modes of interpersonal interaction.

296. *Id.*

297. *See* Smolke, *supra* note 91, at 1099.

298. *Id.*

299. On the move from "parts" to "devices," see Canton et al., *supra* note 61.

300. As in computing, the development of "languages" of operating instructions for programming genetic functions is currently being explored in synthetic biology. *See* Michal Galdzickiet et al., Synthetic Biology Open Language (SBOL) Version 1.1.0 (2012), http://dspace.mit.edu/bitstream/handle/1721.1/73909/BBFRFC87.pdf?sequence=1 [https://perma.cc/5WJH-3QXZ]; P. Umesh et al., *Programming Languages for Synthetic Biology*, 4 SYST. SYNTHETIC BIOLOGY 265, 265-269 (2010).

301. The development of metrological standards in synthetic biology is now proceeding through a collaboration between Stanford University and the National Institute of Standards and Technology. *See* NIST-ABMS, ROAD MAP FOR METROLOGY IN SYNTHETIC BIOLOGY 1-3 (2013), https://sites.stanford.edu/abms/sites/default/files/ABMS_Workshop_Report_Final.pdf [https://perma.cc/H46V-ZXSQ].

302. Danchin Antoine, *Scaling Up Synthetic Biology: Do Not Forget the Chassis*, 586 FEBS LETTERS 2129 (2012).

the field, strains of *E. coli* and *Saccharomyces cerevisiae* chief among them. Above the microbial level, genetically engineered plants and animals, such as variants of *D. melanogaster* ("fruit flies") or the Harvard Oncomouse,[303] provide organismic platforms for further innovation.

Finally, technologies for developing platforms—platforms *for* platforms—are themselves the ultimate infrastructure required for the field's development. To develop a suite of standardized parts and associated assembly protocols, several leaders of the field pushed for the creation of a "bio fab," adapting the idea of a "fab" or fabrication facility from semiconductor wafer manufacturing and applying it to synthetic biology.[304] Chip fabs enabled electrical engineers to separate the design and manufacture of semiconductor circuitry—wafers could be designed by one group and built by another—and allowed for more rapid prototyping and experimentation among designers and more expertise and scale on the manufacturing side.[305] As the members of this "bio fab group"[306] explain: "[t]his combination of technology and methodology for designing and fabricating chips—the 'chip fab'—constitutes one of the most successful engineering paradigms of all time, and it is a valuable model for another nascent technology sector: fabrication of biological systems."[307] Chief among the requirements for establishing successful biological fabrication facilities is "a way to manufacture long pieces of DNA quickly, reliably and at a reasonable price,"[308] which would allow for the decoupling of conceptual design work and precise, automated manufacturing. The hope is that achieving this foundational infrastructure in synthetic biology will "spur advances as revolutionary as those achieved in the semiconductor industry."[309]

The first such design-build facility launched in 2009 in Emeryville, California, under the recursive acronym BIOFAB International Open Facility Advancing Biotechnology (BIOFAB),[310] and has since moved to Stanford University. The use

303. *See* Scassa, *supra* note 123 at 106.

304. David Baker et al., *Engineering Life: Building a FAB for* Biology, 294 SCI. AM. 44 (2006).

305. *Id.* at 51.

306. Writing in 2006, these members—David Baker, George Church, Jim Collins, Drew Endy, Joseph Jacobson, Jay Keasling, Paul Modrich, Christina Smolke, and Ron Weiss—note that they have, individually and collectively, begun "to identify and develop the equipment and techniques that could become the basis of a 'bio fab.'" *Id.* at 46. Members of this group have been founders of many of the most important institutions and companies in this area, including the BioBricks Foundation (discussed *passim*), Amyris Technologies (discussed in text accompanying *supra* note 67), and Codon Devices (discussed in text accompanying *supra* note 69).

307. Baker et al., *supra* note 304, at 46.

308. *Id.* at 46.

309. *Id.* at 51.

310. In what might be considered a proof of concept, the first BIOFAB team developed "bicistronic architecture" for reliable genetic constructs, as discussed in *supra* notes 75-79. The BIOFAB was a joint project of Stanford and the University of California, Berkeley, funded by the National Science Foundation, with additional support from Lawrence-Berkeley Labs, the BioBricks Foundation, and SynBERC, the Synthetic Biology Engineering Research Center. *See About the BIOFAB*: http://biofab.synberc.org [https://perma.cc/6L79-GLHU]. The recursive acronym is likely a nod to the recursive GNU (GNU's Not Unix) software project. *See* Robert

of bicistronic architecture to control gene expression was first achieved by the BioFab team, a group of professionals devoted to developing high quality parts to be contributed, via the BPA, to the public domain.[311] The BBF envisages a global network of these biofabs, "high throughput design/build facilities," for biology linked through the Stanford facility. At the same time, several companies offering DNA construction services have also branded themselves "biofabs,"[312] and a recent DARPA program announced in 2011 to support "living foundries" has committed over $100 million to building biological platforms.[313]

Additionally, with government support of various kinds, several synthetic biology companies are now attempting to build platform infrastructures for the field. Amyris Technologies has developed a technology for the rapid prototyping of chassis, an automated process for constructing and sorting through possible host organisms called "automated strain engineering" (ASE).[314] The company uses this "high throughput robotic assembly of microbial strains," mainly for developing efficient yeast varieties for its work producing chemicals from synthetic pathways.[315] Gingko Bioworks likewise has developed a robotic process—colloquially called the "pipe"—for building new strains of host organisms.[316] The pipe decouples design and fabrication and, through computer assisted design software, allows for a much more rapid engineering of biology than conventional manual methods.[317] These automated platforms for developing host organisms are, in essence, highly managed and standardized *ecologies* serving as the low-variability core component on top of which organismic variation is stimulated, studied, and selected. Broadly speaking, this emerging network of biofabs will work to redress crucial infrastructure gaps in synthetic biology. Once DNA sequencing

---

Sanders, *NSF Grant to Launch World's First Open-Source Genetic Parts Production Facility*, GENETIC ENG'G BIOTECH. (Jan. 20, 2010), http://newscenter.berkeley.edu/2010/01/20/biofab_synthetic_biology [https://perma.cc/CLN2-FTNG].

311. For a discussion of the values and strategies concerning openness and intellectual property at BIOFAB, see generally GAYMON BENNETT & THE BIOFAB TEAM, OPEN TECHNOLOGY PLATFORMS: (HOW) SHOULD THE BIOFAB GIVE THINGS AWAY? (2011), http://biofab.synberc.org/sites/default/files/HPIP_Report%203.0_v1_0.pdf [https://perma.cc/234G-XPMU].

312. Andrew Pollack, *How Do You Like Your Genes? Biofabs Take Orders*, N.Y. TIMES (Sep. 12, 2007), http://www.nytimes.com/2007/09/12/technology/techspecial/12gene.html [https://perma.cc/8ZFB-S9N5].

313. *DARPA Announces $110M Funding Opportunity*, CAL. LIFE SCI. INST. (May 15, 2017) http://califesciencesinstitute.org/darpa-announces-110m-funding-opportunity [https://perma.cc/GUP5-3QQ9].

314. Cormac Sheridan, *Synthetic Biology Firms Pivot from Biofuels to Cheap Biologics*, 34 NATURE BIOTECH. 1008, 1008 (2016) (discussing Amyris's "automated strain engineering" and corporate strategy).

315. Ellen Prediger, *Building Biological Factories for Renewable and Sustainable Products*, INTEGRATED DNA TECH. (Jan. 27, 2016), http://www.idtdna.com/pages/decoded/decoded-articles/your-research/decoded/2013/01/18/building-biological-factories-for-renewable-and-sustainable-products [perma.cc/NRL2-GHXH].

316. Reshma, *Ginkgo Organism Engineers and the Pipe*, THE GINGKO BIOWORKS BLOG (July 11, 2011), http://blog.ginkgobioworks.com/2011/07/11/ginkgo-organism-engineers-and-the-pipe/ [perma.cc/3HLS-FDRA].

317. *Id.*

and synthesis can be done quickly, reliably, and cheaply, it will become possible to build a *platform* for synthetic biology, capable of serving as the basic resource for decentralized peer production. The network of biofabs might be considered the platform for building this platform.

V. MARKET, COMMONS, AND STATE IN INNOVATION POLICY

The discussion in Part IV concerning infrastructure gaps in the development of synthetic biology is implicated in a broader question about the relationship of technological innovation to the institutional contexts in which it occurs. Infrastructure gaps of the kind now afflicting the field are difficult, if not impossible, for individual scientists and companies to fill. Necessary infrastructures cannot usually be generated either through peer production or through more standard forms of market-based proprietary production, outside the exceptional case of monopoly production of a platform. In other words, both modalities of market and peer production depend on infrastructural prerequisites that neither can ordinarily generate.

As described above, platforms consist in a set of reusable core parts, which are the inputs to later instances of decentralized innovation (on either a market or peer production model) in which these core parts are recombined in innovative ways. The incentive for any market actor to produce such a platform will be limited by resource constraints and the fact that the benefits of platform construction will be widely dispersed across the field, and thus difficult for any single actor to appropriate,[318] leaving to one side the social costs of monopoly control of a platform. It is true that in exceptional cases of private provision, a powerful company—a monopolist or market-leader—may be able to provide public infrastructure, but this will usually occur where the profile of future uses is relatively settled (e.g., building a road or rail line between known terminals). Private platform construction for entirely new endeavors—for example, synthetic biology rather than a new social media app—will usually run up against the problem that private investment in the platform must be undertaken without an adequate sense of the later uses of a public good with uncertain market value.[319]

Similarly, decentralized peer production will also prove generally incapable of producing fundamental infrastructure because it presupposes the sharing of incremental innovations among *peers* working on a common platform. If one party has the capacity to produce a new platform for others, it may best be conceived as an extraordinary gift by an exceptional individual, not the collective product of a network of equal contributors. For example, the initial work of Richard Stallman on the GNU project and of Linus Torvalds on the Linux kernel[320] were significant enough contributions to launch or transform F/OSS communities. These

318. FRISCHMANN, *supra* note 271, at 33-34, 65-75.

319. *Id.* at 143-44.

320. *See* WEBER, *supra* note 152, at 46-49 (2004) (discussing Stallman's early leadership of the GNU project); *id.* at 89-91 (discussing Linus Torvalds and Linux).

communities were, in essence, constituted by exceptional founding gifts of code, and they could not have been independently generated in a coherent manner.

For these reasons, the work of building platforms will generally fall to a public agency, even if that agency is made effective in partnership with private actors. More particularly, the possibility of achieving openness in emerging technical domains may depend on favorable public support to enable the production and distribution of infrastructural prerequisites for peer production. However, the recognition of the state as the dispositive context for innovation—apart from its familiar role in granting and enforcing intellectual property rights—has been largely neglected in contemporary legal scholarship.[321]

By contrast, a variety of academic literatures and policy discussions have persuasively linked the problem of innovation, particularly with respect to fundamental technological infrastructures, to public policy and state action. For example, the social science literature on industrial policy has sought to situate innovation in the context of state action.[322] In many countries, this is an obvious theoretical move, given explicit national industrial policies.[323] In the United States, however, it is less familiar, perhaps because the U.S. government disavows any explicit industrial policy and instead pursues innovation through what sociologist Fred Block has termed a "hidden" developmental state.[324] Block notes that over the past three decades—during a time of generalized public funding cuts—the U.S. government has dramatically expanded its financing of technological development.[325] However, the ideological predominance of what Block calls "market fundamentalism"[326] has forced this public investment into relative obscurity. The result is a "hidden development state"—more specifically, a "developmental network state" in which interconnected agencies support the production of fundamental innovation.[327]

---

321. A notable exception has been two conferences on "Innovation Law Beyond IP" held at Yale Law School in recent years. *See Innovation Law Beyond IP*, YALE L. SCH. INFO. SOC'Y PROJECT (Jan. 27, 2016), http://isp.yale.edu/event/innovation-law-beyond-ip [perma.cc/6BFH-TGXF]; *ISP Conference on Intellectual Property Law to Be Held March 28 and 29*, YALE L. SCH. (Feb. 25, 2015), https://law.yale.edu/yls-today/news/isp-conference-intellectual-property-law-be-held-march-28-and-29 [https://perma.cc/ZM7S-N9VH].

322. *See* Wesley M. Cohen et al., *Links and Impacts: The Influence of Public Research on Industrial R&D*, 48 MGMT. SCI. (SPECIAL ISSUE) 1, 13-14 (2002) (summarizing the results of research into impact of public R&D funding); *see generally* Block, *infra* note 324 (on the "hidden" industrial policy of the US, which operates through a host of scientific funding bodies).

323. *See* James Foreman-Peck & Giovanni Federico, *European Industrial Policy: An Overview*, *in* EUROPEAN INDUSTRIAL POLICY 426 (James Foreman-Peck & Giovanni Federico eds., 1999) (discussing the varieties of European experience with industrial policy).

324. Fred L. Block, *Swimming Against the Current: The Rise of a Hidden Developmental State in the United States*, 36 POL. & SOC'Y 169, 170 (2008).

325. *Id.*

326. *Id.* at 170. For Block's analysis of market fundamentalism, see generally FRED BLOCK & MARGARET R. SUMMERS, THE POWER OF MARKET FUNDAMENTALISM (2014).

327. One negative consequence of this hiddenness is to remove from public discussion the success stories that would bolster government support of industries. Block, *supra* note 324, at 194.

There are numerous problems with having an industrial policy that cannot speak its name, particularly problems of industry capture and inadequate deliberation, which come from a lack of transparency about development priorities.[328] Despite these shortcomings, the hidden U.S. innovation policy has been successful in stimulating developments across a range of scientific and technical fields through a host of federal agencies, including the Defense Advanced Research Projects Agency (DARPA), the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Energy, and several others.[329] By subsidizing the creation of computer science programs at major universities and funding progress on human-computer interfaces, DARPA was instrumental in enabling the creation of the personal computer, the Internet, and other groundbreaking systems that function as digital platforms. With respect to advancing biotechnology and drug development, NIH has played an analogous role, albeit with a peer-driven and open-ended focus that has proceeded in a more transparent if also more protracted manner.[330] Similar advances in other areas are unlikely, Block argues, without increasing the role of the federal government in brokering, funding, and facilitating opportunities for innovation.[331] To these tasks, we might also add the state's capacity to guide otherwise competing companies to share fundamental research, thus scaling up the resources available to tackle sector-wide infrastructure gaps, as seen in the creation of SEMATECH in the semiconductor industry.[332]

Block's work focuses attention on the role of the state in the creation of technological innovation, which has been too often neglected in legal-academic discussions.[333] Indeed, apart from its direct role in granting and enforcing intellectual property, the "state" has been strangely missing in the legal literature on innovation.[334] Amy Kapczynski, one of the few legal scholars to note this problem, argues that intellectual property scholarship needs "a serious, curious engagement

328. With those shortcomings in mind, Block advocates for a new paradigm of state involvement that would require (1) reciprocal benefits from corporations to be transferred to the public in exchange for public support; (2) greater social inclusion regarding the benefits of technological development; (3) increased public deliberation over funding priorities; and (4) a redeployment of public monies beyond the narrow focus on military applications. *Id.* at 199.

329. *Id.* at 174-79.

330. *Id.* at 178-179.

331. *Id.* at 199-200.

332. *See generally* Larry D. Browning et al., *Building Cooperation in a Competitive Industry: SEMATECH and the Semiconductor Industry*, 38 ACAD. MGMT. J. 113 (1995) (on the role of SEMATECH in fostering a framework of cooperative competition among semiconductor manufacturers).

333. For a notable exception, see Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 VT. L. REV. 347 (1999). *See also supra* note 321 (on two Yale Law School conferences aimed at remedying this neglect).

334. For a wonderfully lucid discussion of this problem, see Amy Kapczynski, *Intellectual Property's Leviathan*, 77 LAW & CONTEMP. PROBS. 131, 132 (2014) (arguing that both supporters and critics of conventional intellectual property adopt an overly limited view of the state as a "neoliberal Leviathan," even while assuming basic state capacities).

with the state of the modern state."[335] Intellectual property scholarship has instead tended to maintain a narrow focus on the *legal regime* governing access to knowledge. It is true that the insurgency of F/OSS motivated an influential subset of intellectual property law scholars to probe the relations of community-based reciprocity and non-market peer production. However, the role of the state in enabling this production does not take priority in these investigations, perhaps partly because of a background commitment to viewing F/OSS as an instructively anarchistic endeavor.[336] The state's influence on openness has generally been relegated, positively, to enforcing the copyright law that can be hacked for copyleft and, negatively, to putting regulatory obstacles in the way of openness.[337]

I can do no more at present than to sketch some of the ways in which "bringing the state back in"[338] would matter, with a focus on the specific case of synthetic biology. As the analysis of the public domain strategy above should have made clear, the difficulty in adapting conventional intellectual property law to support sharing in the biotechnology space is one that only state action can effectively redress, especially since copyleft-style hacks seem inadequate to the task. Reforms of intellectual property law could take the form of creating sui generis rights specific to biotechnology,[339] better registries for conducting patent searches determining the state of prior art,[340] and perhaps extending the carrier liability exemption and the take-down notice regime familiar from copyright to patent.[341] These and other

335. *Id.* at 132, 145 ("A call to bring the state back in is not a call to dislodge the generative new work being done on the commons, but rather to suggest that there is today no viable form of a prepolitical commons, and that theorists of the commons need to make space in both their accounts of the commons, and in their articulations of the political domain that they wish to bring into being, for a postneoliberal image of the state.").

336. *See* Yochai Benkler, *Practical Anarchism: Peer Mutualism, Market Power, and the Fallible State*, 41 POL. & SOC'Y 213, 220-26 (2013) (analyzing peer production as an anarchistic mutualism); Eben Moglen, *Anarchism Triumphant: Free Software and the Death of Copyright*, FIRST MONDAY (Aug. 1999), http://firstmonday.org/ojs/index.php/fm/article/view/684/594 [perma.cc/6WQA-AG7W] (defending free software as an example of anarchistic production). For a criticism of the anarchist orientation in a great deal of "techno-utopian" work on F/OSS, see GREWAL, *supra* note 1, at 215-24.

337. For the positive but limited conception of state agency, see Benkler, *supra* note 336, at 221-22 (discussing how F/OSS depends on state power in the form of property law). For the negative assessment, see YOCHAI BENKLER, THE WEALTH OF NETWORKS, *supra* note 23, at 379-382, 470-71 (discussing how state policy is "tilted" in favor of proprietary IP).

338. For an analogous move in political sociology, see BRINGING THE STATE BACK IN (Peter Evans et al. eds., 1985). Amy Kapczynski argues persuasively about this move in intellectual property law scholarship. *See supra* note 334.

339. Rai & Boyle, *supra* note 108, at 392.

340. Beth Simone Noveck, *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J. L. & TECH. 123, 143-151 (proposing an open review process for patent applications) (2006); *see generally* Arti K. Rai, *Allocating Power Over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L. J. 907 (2004) (analyzing reports by the Federal Trade Commission and the National Academy of Sciences on the allocation of fact-finding powers within the U.S. patent system, including reform proposals for the functioning of the Patent Office).

341. To make peer production more viable outside software and visual content, the Safe Harbor and associated takedown procedures established under the Digital Millennium Copyright Act, 17 U.S.C. § 512(c) (2012) currently restricted to copyrighted works, could be usefully

reforms would have the purpose of making sharing easier, particularly of foundational advances in the service of platform construction.

Other than reforming the intellectual property landscape, public funding provides the most obvious role for state action. Private financing of foundational technological development, including infrastructure provision, is likely to be both inadequate (given the shorter planning-horizons of private firms) and inefficient (to the extent it is incentivized through the granting of monopoly rights over innovations). Neither are community-led efforts likely to be successful where there is not yet an existing platform on which decentralized peer production can proceed. Large private philanthropies can play a role in delivering needed resources, but they are themselves hybrid public-private organizations, given the prominence of tax policy in creating them. In terms of funding, only the state can reliably provide the resources necessary for the platform construction that must precede either successful peer production or proprietary development. Again, it can do so in various ways, including through delegated agencies, peer-reviewed competitive processes, and tax incentives for private philanthropy.

If the state is the essential or ultimate provider of infrastructure, the dynamics of this provision ought to be part of the analysis of F/OSS beyond the more particular concern with the details of licensing regimes. For, as I argued above, the availability of adequate infrastructure may determine the thresholds marking the rationality of peer production.[342] The dynamics governing the provision of such platforms should become a central part of our investigation into open innovation.

Recognition of the state as the ultimate provider of platforms is essential to synthetic biology in particular, owing to the infrastructure gaps inhibiting the field. Public power is needed to build platforms—which is to say, to regulate, finance, coordinate, and support the networked construction of them—for the sake of the downstream innovation they enable. Initial moves in this direction are already beginning: the DARPA grant to support "living foundries" envisages precisely this kind of platform construction,[343] although this funding remains small in proportion to the required resources. The BBF has recently begun a new initiative to prompt a major infrastructure development for biotechnology—producing a "Bionet" for the sharing of biological materials—with a generous grant from a private philanthropic foundation.[344] Ultimately, however, the success of this endeavor will depend on being able to use philanthropic money to leverage broader public-private partnerships and government financial and regulatory support of the

extended to online databases for genetic materials and other patentable areas. Such an extension would not only support sharing but likely reduce patent infringement.

342. *See* text accompanying *supra* notes 259-265.

343. *See* text accompanying *supra* note 313.

344. The project is the establishment of a "BioNet" for the rapid sharing of synthetic biological parts, which is in the early phase of its development. *See programs/BIONET*, BIOBRICKS FOUND. (Apr. 8, 2017), http://biobricks.org/bionet [https://perma.cc/UZZ7-V5FT]; *see also The BioBricks Foundation*, HELMSLEY CHARITABLE TRUST (Mar. 20, 2015), http://helmsley79.rssing.com/browser.php?indx=52025383&item=5 [https://perma.cc/5SXJ-N7FZ].

kind that Block describes in his analysis of the networked developmental state.

Why should the state prove central to platform construction? While it may be possible to provide at least some infrastructure on a private basis,[345] infrastructural resources—as with all public goods—will tend to be undersupplied if left to individual market participants.[346] Yet the state may have this special role for reasons that go far beyond the well-rehearsed arguments concerning public goods provision. Understanding this role may require asking what kind of goods platforms are—and what kind of thing a state is.

The theory of platforms discussed in Part IV.B above suggests that a platform is not essentially material, but rather a materially embedded social practice. It is dependent upon the coordinated demarcation of an established core from peripheral routines; in other words, it is a coordinating convention that enables derivative forms of cooperative action. Yet the established core and associated interfaces of a platform cannot be indelibly fixed, for platforms must be able to evolve over time, relying on higher-order forms of coordination that facilitate the construction of new platforms.

But what coordination regime can enable the production of new regimes of coordination? It is not turtles all the way down: the state, understood as *political* infrastructure, is the foundation of this process.[347] Describing the nature and essential functions of the modern state has been the project of political theory since the term—*lo stato*, *l'estat*, the state—was transformed from the description of a ruler's *status* to an abstraction concerning a form of political regime, initially in the consolidating monarchies of early modern Europe.[348] It should come as no surprise that the state should prove the predominant provider of infrastructure as well as the platform-enabler of last resort once we recognize that it is the main social instrumentality charged with generating coordination regimes, whether through direct government agencies or the generalized sociability that law enables. The state is itself the foundational coordination regime that allows further forms of coordination, a meta-platform or platform of platforms.

---

345. *See* FRISCHMANN *supra* note 271, at 95-99.

346. *See* FRISCHMANN, *supra* note 271, at 74-77 (examining the divergence between private and social valuations of infrastructure, which can lead to its undersupply when it is provisioned through the market mechanism).

347. More than half a century ago, in an important analysis of the "state-action" doctrine in constitutional theory that connected legal positivism with ordinary language philosophy (following H.L.A. Hart), legal philosopher Alf Ross argued that a focus on the "peculiar legal character of public authority" would clear up the apparent "mysticism" in discussions of "the State" as an abstraction. Ross writes, "To the systematic unity of the legal order . . . the conception of 'the State' is the corresponding unity." *See* Alf Ross, *On the Concepts of 'State' and 'State Organs' in Constitutional Law*, 5 SCANDINAVIAN STUD. L. 113, 118-19, 124-25 (1961).

348. On the political theory of the modern state, see generally Nicholai Rubinstein, *Notes on the Word* Stato *in Florence Before Machiavelli*, *in* FLORILEGIUM HISTORIALE 313 (J.G. Rowe & W.H. Stockdale eds., 1971); Nicholai Rubinstein, *The History of the Word* Politicus *in Early-Modern Europe*, *in* THE LANGUAGES OF POLITICAL THEORY IN EARLY-MODERN EUROPE 41 (Anthony Pagden ed., 1987); Alan Harding, *The Origins of the Concept of the State*, 15 HIST. POL. THOUGHT 57 (1994).

It seems fitting that the success of synthetic biology, which would enable the reengineering of the natural world, should ultimately depend upon the successful mobilization of state capacity—that is, upon our political self-construction.[349] After all, the foundational defense of the modern state was as a political technology that would enable the collective engineering of our social life. The extension of this possibility to the natural world is the ambition of synthetic biology today, and the hopes for the open development of the field reflect the profound stakes of such a radical ambition.

VI. CONCLUSION

Legal scholarship on intellectual property needs to be reoriented to consider how state action works to generate the infrastructure of emerging fields in ways that prove conducive—or inimical—to their open development. In this Article, I contributed to that reorientation through an in-depth analysis of one important emerging technology. I argued that the success of open development in the field of synthetic biology depends not only on the particular form of legal license or agreement used to govern the distribution of innovation, but on overcoming infrastructure gaps that inhibit cooperative action for collective outcomes. Such cooperation is the hallmark of peer production in the information economy, and the hope of many synthetic biologists is to replicate that success.

The ambition of synthetic biology is to "make biology easier to engineer" through standardization and associated technical processes. Early successes indicate the promise of this field and help to explain why advocates of openness are concerned to see it develop in a publicly beneficial manner. What openness might mean in the patent-dominated context of biotechnology remains unclear, however, and has required a reassessment of the analogy to "copyleft" that had provided initial inspiration to the scientists and activists interested in open synthetic biology. I focused especially on the role of the BioBricks Foundation in this effort and explored the rationale behind the decision to pursue a "public domain" agenda via a new legal agreement, the BioBrick™ Public Agreement.

The success of this public domain strategy depends on the viability of peer production without the advantages of legal coercion available through a "share-alike" licensing provision. In scrutinizing the motivations behind peer production, I borrowed from recent philosophical work critical of the conceptualization of the free rider problem to argue for the rationality of decentralized cooperation, even where individual contributions to a collective project are small. The rationality of such cooperation depends, however, on threshold effects that mark the efficaciousness of individual action in collective endeavors. In the context of intellectual property, I argued that these thresholds are determined by the presence

349. Both aims were prefigured in Hobbes's first and unsurpassed description of the modern state as, at once, an "Artificiall Man" and a "Mortall God." *See* THOMAS HOBBES, LEVIATHAN 10, 120 (Richard Tuck ed., 1991). For criticism of this modern social regime and the hypostatizing mindset that accompanies it and its technologies of power, *see supra* note 51.

or absence of shared technical platforms. Platforms are special kinds of infrastructure, as recent work from law and political economy on infrastructure has shown. The question as to how such platforms are to be produced led to a discussion of the role of state action in the creative economy. I argued that the success of openness in synthetic biology depends on infrastructural prerequisites that, ultimately, only the state can provide. Such state action may proceed, however, through "hidden" modalities of the kind that theorists of industrial organization have identified, and which ought to be a central concern of legal scholars and advocates interested in the theory and practice of open source.