Santa Clara University School of Law

Santa Clara High Technology Law Journal

Volume 30 | Issue 2 Article 3

January 2013

Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property

Andrew W. Torrance

Linda J. Kahl

BRINGING STANDARDS TO LIFE: SYNTHETIC BIOLOGY STANDARDS AND INTELLECTUAL PROPERTY

Andrew W. Torrance† & Linda J. Kahl††

Abstract

In aspiring to become a true engineering discipline for the biological sciences, the field of synthetic biology has a unique opportunity to create and encourage the widespread adoption of standards to enhance innovation and social impact in the field. This article presents a study of the standards setting efforts by the institutions, firms, governments, and individuals within the field of synthetic biology.

Numerous standards have been proposed in synthetic biology, including those relevant to structure, function, description, measurement, data, information exchange, software, biosafety and biosecurity, and even law. At the present time, the adoption of technical standards has been relatively modest and no one technical standard appears to have dominated the field. Standards covering policies in biosecurity, by comparison, are more firmly established and biosecurity practices governing commercial orders for synthetic DNA have been widely adopted.

Among standards-setting groups within the synthetic biology community, most have expressed a preference that standards remain open and accessible to the community as a whole. Recent developments, including the U.S. Supreme Court's decision in AMP v. Myriad *and the Leahy-Smith America's Invents Act, could help give greater clarity to the scope of patent rights covering innovations and*

---

† Professor, University of Kansas School of Law; A.M., Ph.D., J.D., Harvard University; B.Sc., Queen's University, Ontario, Canada. Dr. Torrance is currently a Visiting Scholar at the MIT Sloan School of Management.

†† Director, Legal Program, The BioBricks Foundation; Ph.D., Princeton University; J.D. Santa Clara University School of Law; B.S. University of California at Los Angeles. Dr. Kahl is currently a Visiting Scholar in the Department of Bioengineering at Stanford University, and leads the Ownership, Sharing, Access and Innovation Systems (OASIS) project for SynBERC, a multi-university Synthetic Biology Engineering Research Center funded by the U.S. National Science Foundation. The authors gratefully acknowledge Jorge Contreras, Drew Endy, and Emma Frow for helpful discussions, Richard Gilbert and Steve Merrill for comments on a previous draft, and Cliff Brazil for research assistance.

standards in synthetic biology. Copyright and trademark may provide alternatives mechanisms for conferring rights in synthetic biology inventions, setting and reinforcing standards, or promoting open innovation.

Whether formal policies requiring the disclosure and licensing of property rights covering technical standards could be made mandatory or would ultimately be beneficial to the field of synthetic biology remain open questions. What is certain is that the synthetic biology community is unusually attuned to debates surrounding intellectual property and standards setting, and views its engagement in these debates as vital to ensure the continued success of synthetic biology.

TABLE OF CONTENTS

INTRODUCTION

In his 1958 Nobel Prize acceptance speech, Edward Tatum described the application of biology as "the improvement of all living organisms by processes which we might call biological engineering."[1] "Synthetic biology" has emerged over the past decade as a presumptive heir to Tatum's vision. Synthetic biology has developed two broad emphases.[2] One involves the synthesis of large DNA molecules of specified nucleotide sequence. A competitive industry of gene synthesis companies has emerged to synthesize made-to-order DNA molecules on a commercial scale, and speed and cost improvements of DNA synthesis are making this technology increasingly accessible. The second emphasis involves the design and implementation of genetic circuits constructed from basic genetic components. A distinct feature of synthetic biology is its conscious reliance on engineering approaches.[3] In fact, influences from engineering, as well as computer science, have led to more consideration of standards setting, interoperability, and interchangeability in synthetic biology than is usual in other areas of biology. Many in the synthetic biology community also support an ethos of open innovation, and have concerns about the adverse effects intellectual property rights (primarily patents) could have on the development of their field.[4]

Numerous standards have been proposed in synthetic biology, including those relevant to structure, function, description, measurement, data, information exchange, software, biosafety and biosecurity,[5] and even law. Adoption of most of these proposed

---

1. Edward Tatum, *Nobel Lecture: A Case History in Biological Research*, NOBELPRIZE.ORG. http://www.nobelprize.org/nobel_prizes/medicine/laureates/1958/tatum-lecture.html (last visited Nov. 9, 2013).

2. Tal Danino, et al., *A Synchronized Quorum of Genetic Clocks*, 463 NATURE 326 (2010) (explaining how "'[s]ynthetic biology' can be broadly parsed into efforts aimed at the large-scale synthesis of DNA and the forward engineering of genetic circuits from known biological components").

3. *See, e.g.*, Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 449 (2005).

4. *See, e.g.*, Sibylle Gaisser & Thomas Reiss, *Shaping the Science-Industry-Policy Interface in Synthetic Biology*, 3 SYST. SYNTH. BIOL. 109, 112 (2009) (stating that "[t]he unclear patent situation creates a feeling of uneasiness among scientists").

5. The term "biosafety" refers to issues related to the safety of humans, nonhuman organisms, or ecosystems from the potential for accidental or uncontrolled release of experimental organisms, standards for which are presented in the *NIH Guidelines for Res. Involving Recombinant or Synthetic Nucleic Acid Molecules* (November 2013), http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf. There are also amendments that modify the scope of the NIH guidelines (announced September 5, 2012). *See* Dep't of Health &

standards has thus far been quite modest.[6] A notable exception involves biosecurity, where standards for screening DNA synthesis orders have been widely adopted.[7] The simultaneous wealth of proposed standards and dearth of adopted standards may be due, in part, to the relative youth of the synthetic biology field and its rapid technical evolution. For example, early enthusiasm for structural and assembly standards may become less urgent as the technology of large-molecule DNA synthesis improves. Nevertheless, interest in standards setting remains a prominent feature of the synthetic biology field.

A number of organizations have articulated standards setting in synthetic biology as an important goal. These include the BioBricks Foundation (BBF),[8] the International Genetically Engineered Machine (iGEM) Foundation,[9] the Synthetic Biology Engineering Research Center (SynBERC),[10] BIOFAB: International Open Facility Advancing Biotechnology (BIOFAB),[11] the Synthetic Biology Open Language (SBOL) Team,[12] the Synthetic Biology Standards Network (SynBioStandards Network),[13] the International Association of Synthetic Biology (IASB),[14] the International Consortium for Polynucleotide Synthesis (ICPS),[15] and the Flowers Consortium.[16]

Human Servs., *National Institutes of Health* (Sept. 5, 2012), http://oba.od.nih.gov/oba/rac/fractions/77_FR_54584.pdf. This report will focus on standards for "biosecurity" which encompasses safety issues that arise from the potential for intentional or malevolent release of harmful organisms, whether natural or experimental.

6. Linda J. Kahl & Drew Endy, *A Survey of Enabling Technologies in Synthetic Biology*, J. BIOL. ENG. (May 10, 2013), http://www.jbioleng.org/content/7/1/13.

7. *See, e.g.*, Markus Schmidt & Gregor Giersch, *DNA Synthesis and Security*, *in* DNA MICROARRAYS, SYNTHESIS AND SYNTHETIC DNA 285, 297 (Marissa J. Campbell ed., 2011), *available at* http://www.markusschmidt.eu/pdf/NOVA-Schmidt-print.pdf ("Despite the co-existence of several guidelines for DNA synthesis (companies), the overall field can be regarded as being under good control from a security point of view.").

8. *See* BIOBRICKS FOUNDATION, http://biobricks.org (last visited Jan. 27, 2014).

9. *See* IGEM, http://igem.org (last visited Jan. 27, 2014).

10. *See* THE SYNTHETIC BIOLOGY ENGINEERING RESOURCE CENTER, http://www.synberc.org (last visited Feb. 1, 2014).

11. *See* BIOFAB INTERNATIONAL OPEN FACILITY ADVANCING BIOTECHNOLOGY, http://biofab.org (last visited Feb. 1, 2014).

12. *See* SYNTHETIC BIOLOGY OPEN LANGUAGE, http://www.sbolstandard.org (last visited Feb. 1, 2014).

13. *See* SYNTHETIC BIOLOGY STANDARDS NETWORK, http://www.synbiostandards.co.uk (last visited Feb. 1, 2014).

14. *See* INTERNATIONAL ASSOCIATION OF SYNTHETIC BIOLOGY, http://www.ia-sb.eu/go/synthetic-biology/ (last visited Feb. 1, 2014).

15. Hans Bügl et al., *DNA synthesis and biological security*, 25 NAT. BIOTECHNOL. 627 (2007) (articulates the recommendations of the International Consortium for Polynucleotide

Another prominent player has been the U.S. Department of Health and Human Services, which, in 2010, issued guidance on how to screen DNA synthesis orders that has been widely adopted by the DNA synthesis industry.[17] At a more informal level, many scientists and a number of commercial firms have proposed standards relevant to various aspects of synthetic biology.[18] In addition, there has been considerable interest in standards within the Do-It-Yourself Biology (DIYbio) movement, whose success in attracting wide participation may be influenced by the existence of standard components and protocols capable of use by amateur biologists.[19]

Many in the synthetic biology community have voiced concerns that excessive intellectual property rights may have an adverse impact on the progress of the field.[20] In theory, negative effects caused by patent rights covering commonly used components or methods in synthetic biology could be exacerbated if those patented components or methods were to be adopted as standards. However, little evidence exists to suggest that this is currently the case. In practice, the past few years have seen tremendous flux in how courts interpret the patent-eligibility of both methods, such as diagnostic tests, and components, such as isolated DNA molecules, essential to synthetic biology. Notably, the Supreme Court invalidated claims to methods of combined diagnosis and therapy in *Mayo v. Prometheus*[21] and to isolated genomic DNA in *AMP v. Myriad*.[22] There is a substantial likelihood that the scope of subject matter in biotechnology currently considered patent-eligible will narrow, perhaps significantly. Copyright may be particularly suited to providing an alternative to patent protection for synthetic DNA, though its applicability to DNA is currently uncertain.

Synthesis (ICPS) for an oversight framework for research involving commercial DNA synthesis).

16. *See* FLOWERS CONSORTIUM, http://www.synbiuk.org (last visited Feb. 1, 2014).

17. Dep't of Health and Human Servs., Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA, 75 Fed. Reg. 62,820 (Oct. 13, 2010).

18. *See, e.g.*, Adam Arkin, *Setting the Standard in Synthetic Biology*, 26 NAT. BIOTECHNOL. 771 (2008).

19. *See, e.g.*, Todd Kuiken, *DIYbio: Low Risk, High Potential*, THE SCIENTIST (Mar. 1, 2013), http://www.the-scientist.com/?articles.view/articleNo/34443/title/DIYbio--Low-Risk--High-Potential.

20. *See, e.g.*, Arti Rai & James Boyle, *Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons*, 5 PLOS BIOL. (March 13, 2007), http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.0050058.

21. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

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

This report resulted from a study of standards setting efforts by the institutions, firms, governments, and individuals within the field of synthetic biology. It is based on a review of the relevant published literature and web-based information. Section I provides a brief introduction to the field of synthetic biology. Section II surveys standards, standards setting efforts, and related institutions. Section III discusses intellectual property issues and rights relevant to synthetic biology and standards setting. Section IV summarizes the findings of the report.

I. OVERVIEW OF SYNTHETIC BIOLOGY

In aspiring to become a true engineering discipline, the field of synthetic biology differs markedly from most other fields within biology. During the early days of synthetic biology's emergence, Drew Endy suggested standardization, decoupling, and abstraction as important principles for the engineering of biology.[23] He described standardization as "the definition, description and characterization of the basic biological parts, as well as standard conditions that support the use of parts in combination and overall system operation."[24] However, he has also acknowledged the possibility that biology may be too complex to yield easily to engineering approaches.

Biology differs substantially from the physical and computer sciences. Biological systems tend to be more complex and less predictable, making both understanding and (re)designing them challenging. There may be theoretical limits on the ability to describe and reconstruct any but the simplest biological systems, with little prospect of overcoming these limits in the near future.[25] In addition, practical limitations include the difficulty in defining and measuring the functions of standard biological parts—such as BioBricks, the unpredictability of genetic circuitry (necessitating exactly the kinds of trial and error experimentation synthetic biology is meant to avoid), the challenges posed by biological complexity, the mutual incompatibility of many standard parts, and the tendency for variability within biological units to render biological systems prone to failure.[26] For example, synthetic gene networks tend to be resistant to precisely programmed behavior due to cell-by-cell variability and

23. Endy, *supra* note 3, at 450.
24. *Id.*
25. Christof Koch, *Modular Biology Complexity*, 337 SCIENCE 531 (2012).
26. Roberta Kwok, *Five Hard Truths for Synthetic Biology*, 463 NATURE 288 (2010).

intrinsic stochasticity.[27] Jesse Stricker urged "caution must be exercised when making simplifying assumptions in the design of engineered gene circuits."[28]

The applied nature of synthetic biology has resulted in a small industry that is rapidly evolving.[29] Commercial synthetic biology represents a modest fraction of the biotechnology industry, and firms have experienced mixed success. Among the most prominent are DNA 2.0, Inc.,[30] and Blue Heron Biotech, LLC,[31] providers of synthetic genes; Amyris, Inc.,[32] which engineered a pathway for synthesizing a precursor to the anti-malarial artemisinin; LS9, Inc. (recently acquired by Renewable Energy Group, Inc.)[33] and Qteros, Inc.,[34] developers of biofuels; Ginkgo BioWorks,[35] a biological engineering company; and Synthetic Genomics, Inc., a developer of synthetic genomics technologies, such as Gibson Assembly,[36] and owner of a substantial patent portfolio.[37] Codon Devices, Inc., an early DNA synthesis firm, went bankrupt in 2009,[38] although a new venture, Gen9, Inc., has since emerged and is developing technology to support synthesis and assembly of larger DNA constructs.[39]

A prevalent theme within the synthetic biology community is the value of an open science ethos.[40] This ethos often promotes open

---

27. Danino et al., *supra* note 2.

28. Jesse Stricker et al., *A Fast, Robust and Tunable Synthetic Gene Oscillator*, 456 NATURE 516 (2008).

29. SYNBIOBETA, http://synbiobeta.com (last visited Jan. 30, 2014).

30. DNA 2.0, INC., https://www.dna20.com (last visited Jan. 30, 2014).

31. BLUE HERON BIOTECH, LLC, http://www.blueheronbio.com (last visited Jan. 30, 2014).

32. AMYRIS, INC., http://www.amyris.com (last visited Jan. 30, 2014).

33. Press Release, Renewable Energy Group, Inc., Renewable Energy Group Enters Indus. Biotech with Acquisition of LS9 (Jan 22, 2014), *available at* http://www.regi.com/news/2014/01/22/renewable-energy-group-enters-industrial-biotech-acquisition-ls9.

34. QTEROS, INC., http://www.qteros.com (last visited Jan. 30, 2014).

35. GINGKO BIOWORKS, http://ginkgobioworks.com (last visited Jan. 30, 2014).

36. SGI-DNA, http://www.sgidna.com/products.php. (last visited Jan. 27, 2014).

37. Among the patent applications owned by Synthetic Genomics, Inc. are U.S. Patent No. 20070122826 (filed Oct. 12, 2006) ("Minimal Bacterial Genome"); U.S. Patent No. 20070264688 (filed Dec. 6, 2006) ("Synthetic Genomes"); and U.S. Patent No. 20110053273 (filed May 19, 2010) ("Methods for Cloning and Manipulating Genomes").

38. Todd Wallack, *Codon Devices Closing as Financing Dwindles*, THE BOSTON GLOBE (April 3, 2009), http://www.boston.com/business/healthcare/articles/2009/04/03/codon_devices_closing_as_financing_dwindles/.

39. GEN 9, INC., http://www.gen9bio.com (last visited Jan. 30, 2014).

40. Stephen M. Maurer, *Before It's Too Late – Why Synthetic Biologists Need an Open-*

sharing of information among biologists as well as considerable attention to the effects that patent rights may have on the evolution of the field. For example, the BioBricks Foundation and the iGEM Foundation have tended to promote open sharing of both parts and information, while trying to develop methods for detecting and avoiding patents that might interfere with such openness.[41] However, it appears highly likely that universities and firms have already acquired considerable patent rights in various aspects of synthetic biology—patent rights that could interfere with open science practices.[42] Thus far, there is little evidence that patents covering aspects of synthetic biology have, in fact, been used in this manner.

One notable feature of standards setting and intellectual property in synthetic biology is the recurring participation of a relatively small group of academic scientists, a substantial minority of them with formal training as engineers, who have serially founded and led many of the institutions noted above.

II. STANDARDS AND STANDARDS-SETTING IN SYNTHETIC BIOLOGY

A. Technical Standards

Within the synthetic biology community, researchers are actively working to develop technical standards for genetically encoded functions that will enable the efficient production, distribution and re-use of biological parts. To date, technical standards relevant to synthetic biology applications are being developed in at least four broad categories: physical composition, functional composition, units of measurement, and data exchange.[43]

Physical composition standards support the physical assembly of

---

Parts Collaboration – and How to Build One, 10 EMBO REPORTS 806 (2009); Joachim Henckel & Stephen M. Maurer, *The Economics of Synthetic Biology*, MOL. SYST. BIOL., June 5, 2007, *available at* http://www.nature.com/msb/journal/v3/n1/full/msb4100161.html; David Cohn, *Open-Source Biology Evolves*, WIRED (Jan. 17, 2005), http://www.wired.com/medtech/health/news/2005/01/66289?currentPage=all.

41. An example of this is the development by the BioBricks Foundation of the BioBrick User and Contributor Agreements, together, the BioBrick Public Agreement (BPA), *The BioBrick Public Agreement (BPA)*, BIOBRICKS FOUNDATION, https://biobricks.org/bpa/ (last visited Feb. 18, 2014), and the requirement that all participants in the iGEM competition contribute the parts they make to the iGEM Registry of Standard Biological Parts. *See What about these standard parts?*, IGEM, http://igem.org/About (last visited March 4, 2014).

42. Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745 (2007); Davy van Doren, Stefan Koenigstein, & Thomas Reiss, *The Development of Synthetic Biology: A Patent Analysis*, 7 SYST. SYNTH. BIOL. 209-20 (2013).

43. *See Technical Standards Framework*, BIOBRICKS FOUNDATION, http://biobricks.org/programs/technical-standards-framework (last visited Jan. 27, 2014).

individual biological parts into multi-component systems. One of the earliest examples of a physical composition standard in synthetic biology is the original BioBrick assembly standard (BBF RFC 10), which uses iterative restriction enzyme digestion and ligation reactions to assemble small biological parts into larger composite parts.[44] This standard initially served as the primary means for physical assembly of biological parts by teams participating in the iGEM competition,[45] and thousands of parts in the iGEM Registry of Standard Biological Parts[46] have been constructed following this standard. As technology has advanced, the BioBrick assembly standard has undergone a number of refinements and other physical composition standards that provide additional flexibility for the physical assembly of biological parts have been introduced.[47]

Although the BioBrick assembly standard and other methods that build upon this standard have proven useful to many groups,[48] it is

---

44. Thomas Knight, *Idempotent Vector Design for Standard Assembly of BioBricks* (MIT Artificial Intelligence Lab. & MIT Synthetic Biology Working Grp., 2003), *available at* http://hdl.handle.net/1721.1/21168.

45. IGEM, *supra* note 9.

46. *See Registry of Standard Biological Parts*, IGEM, http://parts.igem.org/Main_Page (last visited March 4, 2014).

47. *See, e.g.*, Ira Phillips & Pamela Silver, *BBF RFC 23: A New BioBrick Assembly Strategy Designed for Facile Protein Engineering*, DSPACE@MIT (Apr. 18, 2006), http://hdl.handle.net/1721.1/32535; Thomas Knight, *BBF RFC 2: Draft Standard for BioBrick BB-2 Biological Parts*, DSPACE@MIT (Nov. 19, 2008), http://hdl.handle.net/1721.1/45139; Reshma P. Shetty, Drew Endy & Thomas F. Knight, *Engineering BioBrick Vectors from BioBrick Parts*, J. BIOL. ENG. (April 14, 2008), http://www.jbioleng.org/content/2/1/5; Michael Ellison et al., *BBF RFC 47: BioBytes Assembly Standard*, DSPACE@MIT (Oct. 29, 2009), http://hdl.handle.net/1721.1/49518; Katja Arndt et al., *BBF RFC 25: Fusion Protein (Freiburg) BioBrick Assembly Standard*, DSPACE@MIT (Apr. 18, 2009), http://hdl.handle.net/1721.1/45140; Sergio G. Peisajovich et al., *BBF RFC 28: A Method for Combinatorial Multi-Part Assembly Based on the Type IIs Restriction Enzyme AarI*, DSPACE@MIT (Sept. 16, 2009), http://hdl.handle.net/1721.1/46721; J. Christopher Anderson et al., *BglBricks: A Flexible Standard for Biological Part Assembly*, J. BIOL. ENG. (Jan. 20, 2010), http://www.jbioleng.org/content/4/1/1; Sean C. Sleight et al., *In-Fusion BioBrick Assembly and Re-engineering*, 38 NUCLEIC ACIDS RES. 2624 (2010); Reshma Shetty et al., *Assembly of BioBrick Standard Biological Parts Using Three Antibiotic Assembly*, 498 METHODS ENZYMOL. 311 (2011).

48. *See, e.g.*, Karmella A. Haynes et al., *Engineering Bacteria to Solve the Burnt Pancake Problem*, J. BIOL. ENG. (May 20, 2008), http://www.jbioleng.org/content/2/1/8; Bruno Afonso et al., *A Synthetic Circuit for Selectively Arresting Daughter Cells to Create Aging Populations*, 1 NUCLEIC ACIDS RES. 2727 (2010); Raik Grunberg et al., *Building Blocks for Protein Interaction Devices*, 38 NUCLEIC ACIDS RES. 2645 (2010); Hsin-Ho Huang et al., *Design and Characterization of Molecular Tools for a Synthetic Biology Approach towards Developing Cyanobacterial Biotechnology*, 38 NUCLEIC ACIDS RES. 2577 (2010); Marco Constante et al., *A Biobrick Library for Cloning Custom Eukaryotic Plasmids*, PLOS ONE (August 25, 2011), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0023685; Elisabeth

now possible to assemble biological parts without the use of restriction enzymes. Methods such as Gibson Assembly,[49] Seamless Ligation Cloning Extract (SLiCE),[50] and others,[51] enable the seamless construction of large DNA molecules and do not impose sequence constraints on the design of biological parts. Yet another approach, often used in conjunction with other physical assembly methods, is *de novo* DNA synthesis.[52] With continued improvements in the capacity to synthesize DNA constructs at ever more affordable prices, *de novo* synthesis of multicomponent devices and systems may become feasible.[53] So far, no single approach has become a *de facto* standard for the physical assembly of biological parts and physical composition standards will likely continue to evolve.[54]

Functional composition standards support the ability of assembled biological parts to function in a predictable manner. As an example, the Expression Operating Unit (EOU) is a genetic layout architecture that enables forward engineering at the genome scale by ensuring that independent expression elements perform reliably across different genetic contexts.[55] Other tools that help rationally

---

Linton et al., *Translocation of Green Fluorescent Protein by Comparative Analysis with Multiple Signal Peptides*, 7 BIOTECHNOL. J. 667 (2012); Raul Cuero, J. Lilly & David S. McKay, *Constructed Molecular Sensor to Enhance Metal Detection by Bacterial Ribosomal Switch-Ion Channel Protein Interaction*, J. BIOTECHNOL., March 2012, at 1; Liping Du et al., *Multigene Expression In Vivo: Supremacy of Large Versus Small Terminators for T7 RNA Polymerase*, 109 BIOTECHNOL. & BIOENG. 1043 (2012).

49. Daniel G. Gibson et al., *Enzymatic Assembly of DNA Molecules up to Several Hundred Kilobases*, 6 NAT. METHODS 343 (2009).

50. Yongwei Zhang et al., *SLiCE: A Novel Bacterial Cell Extract-Based DNA Cloning Method*, 40 NUCLEIC ACIDS RES. e55 (2012).

51. *See, e.g.*, Baogong Zhu et al., *In-Fusion Assembly: Seamless Engineering of Multidomain Fusion Proteins, Modular Vectors, and Mutations*, 43 BIOTECHNIQUES 354 (2007); Carola Engler et al., *A One Pot, One Step, Precision Cloning Method with High Throughput Capability*, PLOS ONE (Nov. 5, 2008), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0003647; Jiayuan Quan & Jingdong Tian, *Circular Polymerase Extension Cloning of Complex Gene Libraries and Pathways*, PLOS ONE (July 30, 2009), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0006441; Patrick M. Boyle et al., *A BioBrick Compatible Strategy for Genetic Modification of Plants*, 6 J. BIOL. ENG. 8 (2012); Arjen J. Jakobi & Eric G. Huizinga, *A Rapid Cloning Method Employing Orthogonal End Protection*, PLOS ONE (June 7, 2012), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0037617.

52. Peter A. Carr & George M. Church, *Genome Engineering*, 27 NAT. BIOTECHNOL. 1151 (2009).

53. Robert Carlson, *The Changing Economics of DNA Synthesis*, 27 NAT. BIOTECHNOL. 1091 (2009).

54. Kahl, *supra* note 6.

55. Vivek K. Mutalik et al., *Precise and Reliable Gene Expression via Standard*

predict the modulators of gene expression, such as the ribosome binding site (RBS) calculator[56] and calculators for promoter strength,[57] also are useful as an approach for the functional composition of assembled biological parts and devices.

Standards for units of measurement enable independent researchers to make measurements of genetically encoded functions that account for variation introduced by differences in experimental conditions and instruments. They are also sharable across multiple laboratories. As an example, the Relative Promoter Unit (RPU) is a standard unit for reporting promoter activity, where RPU is defined as a ratio of the absolute activity of a sample promoter relative to the absolute activity of a standard reference promoter.[58] Because the RPU is a relative measure, as opposed to an absolute measure, it is not tied to a single measurement procedure and so different laboratories are free to select whatever procedures they find most convenient and suitable. The concept of the RPU was initially demonstrated using promoters in *E. coli*, and has since been extended for promoter characterization in mammalian cells.[59] Another measurement standard that has been proposed is Polymerase Per Second, or PoPS.[60] Conceptually similar to the current in a wire that connects two electronic components, PoPS represents the flow of RNA polymerase molecules along the DNA.[61] By defining PoPS as the number of times that an RNA polymerase molecule passes a specific point on DNA per unit time, PoPs provides a measure of transcription rate and can be used to characterize molecular devices such as genetic circuits.[62]

Transcription and Translation Initiation Elements, 10 NAT. METHODS 354 (2013).

56. Howard M. Salis, Ethan A. Mirsky & Christopher A. Voigt, *Automated Design of Synthetic Ribosome Binding Sites to Control Protein Expression*, 27 NAT. BIOTECHNOL. 946 (2009).

57. Virgil A. Rhodius, Vivek K. Mutalik & Carol A. Gross, *Predicting the strength of UP-elements and full-length E. coli σ^E promoters*, 40 NUCLEIC ACIDS RES. 2907 (2012).

58. Jason R. Kelly et al., *Measuring the Activity of BioBrick Promoters Using an In Vivo Reference Standard*, J. BIOL. ENG. (March 20, 2009), http://www.jbioleng.org/content/3/1/4.

59. Lars Velten et al., *Units for Promoter Measurement in Mammalian Cells*, DSPACE@MIT (Oct. 21, 2009), http://hdl.handle.net/1721.1/49501.

60. For a colorful and amusing description of PoPS, the reader is referred to a comic book authored by Drew Endy and Isadora Deese and illustrated by Chuck Wadey. Drew Endy & Isadora Deese, *Adventures in Synthetic Biology*, MIT SYNTHETIC BIOLOGY WORKING GROUP, http://mit.edu/endy/www/scraps/comic/AiSB.vol1.pdf (last visited Feb. 19, 2014).

61. *Id.*

62. Prasanna Amur Varadarajan & Domitilla Del Vecchio, *Design and Characterization of a Three-Terminal Transcriptional Device through Polymerase Per Second*, IEEE TRANS. NANOBIOSCIENCE, Sept. 2009, at 281 (describing PoPS as analogous to an electrical current, and

Data exchange standards enable researchers to query and retrieve information needed to more efficiently design new biological parts, devices, and systems for synthetic biology applications. As an example, Synthetic Biology Open Language (SBOL) is a software standard for the electronic exchange of specifications and descriptions of genetic parts, devices, modules, systems, and engineered genomes.[63] The SBOL semantic was used to create the Standard Biological Parts Knowledgebase (SBPkb), which has been populated with the 13,000 parts from the iGEM Registry of Standard Biological Parts and is anticipated to serve as the first node in a framework for a semantic web of distributed knowledge in synthetic biology.[64] In addition, SBOL visual (SBOLv) has been proposed as a graphical notation standard for the visual display of information about the physical composition of basic and composite parts used in the development of biological devices.[65] Additional standardization efforts for data exchange have focused on the development of datasheets that describe the formal specifications for basic and composite parts, and example datasheets summarizing the relevant physical characteristics and performance features of biological parts have been proposed.[66]

B. Technical Standards-Setting Organizations

As in other engineering disciplines, standards are best developed by consensus and this is no less true in synthetic biology (Table 1).[67] An organizational framework to help define, evaluate, and propose technical standards in synthetic biology has been created by the BioBricks Foundation.[68] This framework, known as the BioBrick Request for Comments (RFC) process, has been instrumental in

characterizing a three-terminal transcriptional device using PoPS as input and output).

63. *SBOL Team*, SYNTHETIC BIOLOGY OPEN LANGUAGE, http://www.sbolstandard.org./community (last visited Jan 27, 2014).

64. Michal Galdzicki et al., *Standard Biological Parts Knowledgebase*, PLOS ONE (Feb. 24, 2011), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0017005.

65. Jacqueline Quinn et al., *BBF RFC 93: Synthetic Biology Open Language Visual (SBOLv) version 1.0.0*, DSPACE@MIT (March 31, 2013), http://hdl.handle.net/1721.1/78249.

66. *See, e.g.*, Barry Canton, Anna Labno & Drew Endy, *Refinement and Standardization of Synthetic Biological Parts and Devices*, 26 NAT. BIOTECHNOL. 787 (2008); Taek S. Lee et al., *BglBrick Vectors and Datasheets: A Synthetic Biology Platform for Gene Expression*, J. BIOL. ENG. (Sept. 20, 2011), http://www.jbioleng.org/content/5/1/12; Kenneth Evan Thompson et al., *SYNZIP Protein Interaction Toolbox: In Vitro and In Vivo Specifications of Heterospecific Coiled-Coil Interactions Domains*, 1 ACS SYNTH. BIO. 118 (2012).

67. *See infra* Table 1.

68. BIOBRICKS FOUNDATION, *supra* note 8.

facilitating discussion and coordinating the efforts of multiple researchers in technical standards development.[69] Initiated in 2008, the BioBrick RFC process was inspired by and modeled upon the RFC process of the Internet Engineering Task Force, and currently contains over 100 technical documents.[70] These documents may propose a technical standard, describe best practices or protocols, or simply provide information.[71] As new BioBrick RFCs are added, they may comment upon, extend, or replace earlier RFCs. In this way the BioBrick RFC process serves as a convenient, useful vehicle for documenting and distributing information so that a general consensus may eventually emerge and lead to the widespread adoption of technical standards.

Technical standards development efforts also have been initiated by the BIOFAB. The concept for creating a BIOFAB was initially proposed in 2006.[72] Drawing upon analogies to the semiconductor industry, the idea was put forth that a fabrication platform using standardized methods and libraries of compatible biological parts could empower engineers to design and build sophisticated biological devices and systems with greater efficiency and speed than is possible using conventional molecular biology approaches.[73] Towards that end, the world's first biological design-build facility was founded in 2009 and located in Emeryville, California.[74] Funded by a 2-year grant from the National Science Foundation, the Emeryville BIOFAB was operated in partnership with Lawrence Berkeley National Laboratory, the BioBricks Foundation, and SynBERC.[75] There, the BIOFAB team developed a mathematical framework for quantifying the intrinsic activities of genetic elements and designed a genetic

69. *See RFC Process*, BIOBRICKS FOUNDATION, http://biobricks.org/programs/technical-standards-framework/ (last visited Feb. 1, 2014).

70. A listing of assigned RFC numbers and documents may be found at *The BioBricks Foundation: RFC*, OPENWETWARE, http://openwetware.org/wiki/The_BioBricks_Foundation:RFC#BBF_RFC_0:_Instructions_to_BBF_RFC_Authors (last visited Jan. 30, 2014).

71. Daniel Tarjan et al., *BBF RFC 0: Instructions to BBF RFC Authors*, DSPACE@MIT (Nov. 10, 2008), http://hdl.handle.net/1721.1/44960.

72. David Baker et al., *Engineering Life: Building a FAB for Biology*, SCI. AM., June 2006, at 44.

73. BIOFAB, *supra* note 11.

74. *Id*.

75. The Emeryville BIOFAB facility maintains a neutral posture with respect to intellectual property rights so that the facility will be able to support partnerships with academic and commercial entities, some of whom might work with the BIOFAB in developing both improved open access and propriety parts. *See SynBERC Parts on Demand*, BIOFAB, http://biofab.org/projects (last visited Jan. 30, 2014).

layout architecture to help eliminate the functional uncertainty that arises from the reuse of transcription and translation control elements with sequence-distinct protein coding regions.[76] A second BIOFAB, founded at Stanford University in 2012 and supported by the BioBricks Foundation, aims to map the central dogma of yeast and contribute standardized biological parts to the public domain.[77] The BioBricks Foundation aspires to build a network of BIOFABs around the world to create synergy and foster the development of community-driven technical standards and production of standardized biological parts.[78]

Additional efforts in technical standards development have been initiated by the SBOL Team.[79] Development of the SBOL standard began in 2008 (then in a format known as Provisional BioBrick Language, or PoBoL),[80] and this community-based effort has consistently grown in size and sophistication as the SBOL standard continues to evolve to meet the needs of synthetic biology researchers and engineers.[81] The core data model for the SBOL standard supports organization of the essential information for synthetic DNA sequences,[82] and extensions to the core data model support visualization of biological designs and the communication of additional information.[83] The SBOL standard underlies the SBPkb, which is a semantic web resource that allows researchers to query and retrieve information about biological parts from the iGEM Registry of

76. Vivek K. Mutalik et al., *Quantitative Estimation of Activity and Quality for Collections of Functional Genetic Elements*, 10 NAT. METHODS 347 (2013); Mutalik, *supra* note 55.

77. *See Stanford BIOFAB*, BIOBRICKS FOUNDATION, http://biobricks.org/programs/technical-program (last visited Jan. 30, 2014).

78. *See Global BIOFAB Network*, BIOBRICKS FOUNDATION, http://biobricks.org/programs/technical-program (last visited Jan. 30, 2014).

79. SBOL is an open-specification, open-source project in which a diverse community of individuals from academia, industry and public benefit organizations work collaboratively to create data exchange standards for describing and communicating information about genetic parts, devices, modules, and systems. *See* SYNTHETIC BIOLOGY OPEN LANGUAGE, *supra* note 12.

80. Michal Galdzicki et al., *BBF RFC 31: Provisional BioBrick Language (PoBoL)*, DSPACE@MIT (May 15, 2009), http://hdl.handle.net/1721.1/45537.

81. Michael Galdzicki et al., *BBF RFC 87: Synthetic Biology Open Language (SBOL) Version 1.1.0*., DSPACE@MIT (Oct. 11, 2012), http://hdl.handle.net/1721.1/73909.

82. Jean Peccoud et al., *Essential Information for Synthetic DNA Sequences*, 29 NAT. BIOTECHNOL. 22 (2011).

83. Quinn, *supra* note 65; Jeffrey Johnson et al., *BBF RFC 68: Standard for the Electronic Distribution of SBOLv Diagrams*, DSPACE@MIT (Dec. 05, 2010), http://hdl.handle.net/1721.1/60086.

Standard Biological Parts.[84] Similarly, the Joint BioEnergy Institute Inventory of Composable Elements (JBEI-ICE), a public registry of biological parts developed by the Joint BioEnergy Institute, supports the SBOL data exchange standard.[85] In addition, several SBOL-compliant software tools have been developed for synthetic biology (Table 2).[86]

Synthetic biology standards also have been addressed by the Synthetic Biology Standards Network (SynBioStandards Network), an interdisciplinary network for UK academics working in synthetic biology.[87] Though it does not consider itself to be a standards setting organization, the SynBioStandards Network aims to develop a common language among researchers from the fields of engineering, biological sciences, computer science, and the social sciences and to develop approaches, tools, and protocols that may become gold standard and adopted by synthetic biology researchers worldwide.[88]

Standards setting efforts have been prominent throughout the development of synthetic biology, at least in part due to participation in the field by engineers, computer scientists, and others who are familiar and comfortable with technical standards.[89] One worry has been that the imposition of standards too early in the evolution of synthetic biology might canalize the trajectory of the field, discouraging alternative directions and impeding innovation. However, little evidence exists to support this worry. None of the technical standards proposed thus far have been made mandatory for the field as a whole, and no governance body with the authority to impose mandatory technical standards for synthetic biology has yet been established. In fact, even the most promising technical standards

84. Galdzicki, *supra* note 64.

85. Timothy S. Ham et al., *Design, Implementation and Practice of JBEI-ICE: An Open Source Biological Part Registry Platform and Tools*, 40 NUCLEIC ACIDS RES. e141, (2012), *available at* http://nar.oxfordjournals.org/content/40/18/e141.full.pdf+html.

86. A vast array of software tools have been developed for synthetic biology, some of which are SBOL-compliant. *See infra* Table 2. For recent review see Adrian L. Slusarczyk, Allen Lin & Ron Weiss, *Foundations for the Design and Implementation of Synthetic Genetic Circuits*, 13 NATURE 406 (2012).

87. The SynBioStandards Network was funded for three years beginning in June 2008 by the Arts & Humanities Research Council, the Biotechnology and Biological Sciences Research Council, Economic & Social Research Council, and the Engineering and Physical Sciences Research Council. *See About the SynBioStandards Network*, SYNTHETIC BIOLOGY STANDARDS NETWORK, http://www.synbiostandards.co.uk/about.php (last visited Feb. 19, 2014).

88. *Id.*

89. Adam Arkin, *Setting the Standard in Synthetic Biology*, 26 NAT. BIOTECHNOL. 771 (2008); Arti Rai, *Unstandard Standarization: The Case of Biology*, 53 COMMS. ACM 37 (2010).

seem to have served in a transitory capacity given the speed at which scientific and technical advances in synthetic biology occur. For example, a number of proposed technical standards pertaining to the physical assembly of DNA fragments into larger DNA molecules are being displaced by distinctly different methods, such as Gibson Assembly and *de novo* DNA synthesis.[90] The iterative and progressive nature of technical standards development has been embraced by the synthetic biology research community, as evidenced by the BioBricks Foundation's RFC process, which provides an avenue for the improvement, and even outright replacement, of earlier proposed technical standards.[91] Only in the realm of biosecurity has any standard risen to the level of wide acceptance within the synthetic biology community, and there, the primary proponent of the standard adopted was the U.S. federal government. At the present time, standards setting efforts do not appear to have affected the development of synthetic biology adversely.

Table 1. Standard Setting Organizations and Intellectual Property Policies in Synthetic Biology

Standards Setting Organization	Example Technical Standards	Intellectual Property Policy
BioBrick Request For Comments (RFC) process Started: 2006	**Physical Composition:** BioBrick standard (BBF RFC 10) BglBrick standard (BBF RFC 21) BioFusion standard (BBF RFC 23) Freiburg standard (BBF RFC 25) AarI cloning standard (BBF RFC 28) **Units of Measure:** Relative Promoter Unit (RPU) (BBF RFC 19) Relative Mammalian Promoter Unit (RMPU) (BBF RFC 41)	The BioBricks Foundation advocates open technology platforms and technical standards, and encourages the donation of basic bioengineering knowledge into the public domain. The BioBricks Foundation does not hold any patents relating to technical standards and retains copyright to documents filed in the BioBrick RFC process.

90. Kahl, *supra* note 6.

91. *RFC Process*, *supra* note 69.

Table 1. (continued)

Standards Setting Organization	Example Technical Standards	Intellectual Property Policy
Synthetic Biology Open Language (SBOL) Team Started: 2008	**Data Exchange:** Synthetic Biology Open Language (SBOL) SBOL visual (SBOLv)	SBOL is an open-specification, open-source, community-based project. SBOL has been submitted to the BioBrick RFC process (BBF RFC 87) as a software standard for the electronic exchange of specifications and descriptions of genetic parts, devices, modules, systems, and engineered genomes. SBOLv has been submitted to the BioBrick RFC process (BBF RFC 93) as a graphical notation to support the description and specification of genetic designs.
BIOFAB: International Open Facility Advancing Biotechnology (BIOFAB) Started: 2009	**Functional Composition:** Expression Operating Unit (EOU)	The Emeryville BIOFAB facility maintains a neutral posture with respect to intellectual property rights so that the facility will be able to support partnerships with academic and commercial entities. The Stanford BIOFAB aims to contribute parts to the public domain.

Table 2. SBOL-Compliant Software tools for Synthetic Biology

Software Tool	Description	URL
Bacillo Bricks[92]	A catalogue of *Bacillus subtilis* virtual parts, provided in the form of mathematical models that can be composed to create genetic circuits.	http://intbio.ncl.ac.uk/?projects=standard-virtual-parts
Benchling	Enables design, analysis and sharing of sequence data in the cloud.	https://benchling.com
Clotho[93]	A data model-based tool and plugin environment that provides a data model for representing biological objects, a common API for manipulating these objects, and a common platform for developing Apps for designing synthetic biological systems.	http://www.clothocad.org
DeviceEditor[94]	A web-based visual design environment that mimics the intuitive visual whiteboard design process practiced in biological laboratories.	http://j5.jbei.org
Eugene[95]	A human- and machine-readable language for the specification of biological constructs.	http://eugenecad.org
Gene Designer[96]	A software tool for designing DNA sequences *de novo*	https://www.dna20.com/genedesigner

92. Goksel Misirli et al., *BacillOndex: An Integrated Data Resource for Systems and Synthetic Biology*, 10 J. INTEGRATED BIOINFORMATICS 224 (2013).

93. Bing Xia et al., *Developer's and User's Guide to Clotho v2.0: A software platform for the creation of synthetic biological systems*, 498 METH. ENZYMOL. 97 (2011).

94. Joanna Chen et al., *DeviceEditor Visual Biological CAD Canvas*, J. BIOL. ENG. (Feb. 28, 2012), http://www.jbioleng.org/content/6/1/1.

95. Lesia Bilitchenko et al., *Eugene – A Domain Specific Language for Specifying and Constraining Synthetic Biological Parts, Devices, and Systems*, PLOS ONE (April 29, 2011), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0018882.

96. Alan Villalobos et al., *Gene Designer: A Synthetic Biology Tool for Constructing Artificial DNA Segments*, 7 BMC BIOINFORMATICS 285 (2006).

Table 2. (continued)

Software Tool	Description	URL
GenoCAD[97]	A web-based application to design protein expression vectors, artificial gene network, and other genetic constructs	http://genocad.org
iBioSim[98]	A project-based tool for the analysis of genetic circuits,metabolic networks, cell signaling pathways and other biological and chemical systems.	http://www.async.ece.uth.edu/iBioSim
j5[99]	A web-based software tool to automate the design of scar-less multipart DNA assembly protocols	http://j5.jbei.org
JBEI-ICE[100]	An open source registry platform for managing information about biological parts.	https://public-registry.jbei.org
MoSeC[101]	A Java application for synthetic biology design that takes a model annotated with the DNA sequence information of genetic elements and converts it into a DNA sequence	http://intbio.ncl.ac.uk/?projects=mosec
Proto BioCompiler[102]	A platform for biological system designers to express desired system functions using a user-friendly, high-level, biologically-focused programming language.	http://proto.bbn.com/commons/

97. Michael J. Czar, Yizhi Cai & Jean Peccoud, *Writing DNA with GenoCAD*, NUCLEIC ACIDS RES. (May 8, 2009), http://nar.oxfordjournals.org/content/37/suppl_2/W40.full?sid=d98aeb4e-4f35-4e8e-939d-967a5ea028cc.

98. Chris J. Myers et al., *iBioSim: A Tool for the Analysis and Design of Genetic Circuits*, 25 BIOINFORMATICS 2848 (2009).

99. Nathan J. Hillson, Rafael D. Rosengarten & Jay D. Keasling, *j5 DNA Assembly Design Automation Software*, 1 ACS SYNTHETIC BIOL. 14 (2012).

100. Ham, *supra* note 85.

101. Goksel Misirli et al., *Model Annotation for Synthetic Biology: Automating Model to Nucleotide Sequence Conversion*, 27 BIOINFORMATICS 973 (2011).

102. Jacob Beal, Ting Lu & Ron Weiss, *Automatic Compilation from High-Level Biologically-Oriented Programming Language to Genetic Regulatory Networks*, PLOS ONE (August 5, 2011), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0022490.

Table 2. (continued)

Software Tool	Description	URL
SBPkb[103]	A semantic web resource that allows researchers to query and retrieve standard biological parts for research and use in synthetic biology.	http://www.sbolstandard.org/sbol-in-use/sbpkb
TeselaGen	A DNA design and assembly platform for Bio CAD/CAM systems	https://www.teselagen.com
TinkerCell[104]	An application for bringing together models, information and algorithms.	http://www.tinkercell.com

C. Biosecurity Standards Setting

The development and implementation of standards for biosecurity has been of paramount importance in the field of synthetic biology. As in other fields, research in synthetic biology may generate "dual use" findings that could be socially beneficial, such as new therapies, diagnostic methods, crops, and industrial processes, as well as harmful, such as new pathogens, toxins, or biological weapons. Consequently, an early topic of discussion and planning among the synthetic biology community was how to minimize the risk of harmful applications of the technology. As early as 2005, researchers, policy analysts and security experts in universities, research institutions, commercial firms, and government organizations have worked to develop biosecurity standards for synthetic biology.

At the first Synthetic Biology conference (SB 1.0), in 2005, there was some discussion of biosecurity issues among the synthetic biology community. Leading up to, and during, SB 2.0, in 2006, a discussion about biosecurity led to a formal proposal that synthetic biologists adopt a set of community biosecurity standards.[105] With funding from the Carnegie Corporation Foundation and MacArthur Foundation, Stephen Maurer, Director of the Berkeley Information Technology and Homeland Security Project, led a project that

103. Galdzicki, *supra* note 64.

104. Deepak Chandran, Frank T. Bergmann & Herbert M. Sauro, *TinkerCell: Modular CAD Tool for Synthetic Biology*, J. BIOL. ENG. (Oct. 29, 2009), http://www.jbioleng.org/content/3/1/19.

105. *Synthetic Biology: SB2.0/Biosecurity Resolutions*, OPENWETWARE, http://openwetware.org/wiki/Synthetic_Biology:SB2.0/Biosecurity_resolutions (last visited Feb. 1, 2014).

proposed six resolutions related to promoting an ethic of biosecurity.[106] Another effort, funded by the Alfred P. Sloan Foundation, resulted in the development of a number of policy, technical, and other options to address the risks and benefits posed by dual-use nature of synthetic biology research.[107]

In the wake of SB 2.0, several consortia of DNA synthesis companies developed their own standards for detecting orders for DNA sequences of concern (Table 3). The International Consortium for Polynucleotide Synthesis (ICPS) developed a plan for creating an effective oversight framework for the DNA synthesis industry.[108] A rival German effort, led by the International Association of Synthetic Biology (IASB), developed a code of conduct for assessing the safety of DNA sequence orders that would rely on both (1) automated searches for matches with sequences of concern (e.g., the U.S. list of sequences of concern) and (2) human double-checking.[109] The International Gene Synthesis Consortium (IGSC), comprised of the world's leading gene synthesis companies, established a harmonized protocol for preventing the misuse of gene synthesis.[110] In addition, the U.S. Department of Health and Human Services (HHS) issued guidance aimed at reducing the risk that synthetic DNA will be misused deliberately to create dangerous organisms.[111] Efforts to articulate and refine biosecurity standards for dual-use research in synthetic biology and other life science fields are ongoing.[112]

---

106. Stephen M. Maurer, *End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It*, 45 VAL. U. L. REV. 1387 (2011).

107. Michele S. Garfinkel et al., *Synthetic Genomics: Options for Governance*, 5 BIOSECURITY & BIOTERRORISM, 359 (2007).

108. Bügl, *supra* note 15.

109. *The IASB Code of Conduct for Best Practices in Gene Synthesis*, INTERNATIONAL ASSOCIATION SYNTHETIC BIOLOGY (Nov. 3, 2009), http://www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_code_of_conduct_final.pdf.

110. *Harmonized Screening Protocol: Gene Sequence and Customer Screening to Promote Biosecurity*, INTERNATIONAL GENE SYNTHESIS CONSORTIUM (IGSC) (November 18, 2009), http://www.genesynthesisconsortium.org/resources.php.

111. Dep't of Health and Human Servs., *supra* note 17.

112. *See, e.g.*, *Enhancing Responsible Science: Considerations for the Development and Dissemination of Codes of Conduct for Dual Use Research*, NAT'L SCI. ADVISORY BD. ON BIOSECURITY (NSABB), http://oba.od.nih.gov/oba/biosecurity/documents/COMBINED_Codes_PDFs.pdf (last visited Feb. 19, 2014).

Table 3. Biosecurity Standards in Synthetic Biology

Standards Setting Organization	Year started	Biosecurity Standards
The International Consortium for Polynucleotide Synthesis (ICPS)	2007	The ICPS developed a plan for creating an effective oversight framework for the DNA synthesis industry.
International Association of Synthetic Biology (IASB)	2008	The IASB established a code of conduct for best practices in gene synthesis, which is primarily based on a self-policed system among gene synthesis and assembly firms.
International Gene Synthesis Consortium (IGSC)	2009	The IGSC developed a harmonized protocol for gene sequence and customer screening to prevent the misuse of gene synthesis.
U.S. Department of Health and Human Services (HHS)	2010	The HHS recommendations include screening customers as well as DNA sequences, follow-up screening as necessary, and consulting with U.S. government contacts as needed.

D. Legal Standards Setting

The development of legal standards to enable synthetic biology researchers to use and share biological parts was first proposed by Drew Endy in 2005.[113] Over several years beginning late in 2008, the BioBricks Foundation developed a two-part legal agreement designed to standardize the use and contribution of biological parts, collectively referred to as the BioBrick Public Agreement (BPA).[114] The BioBrick User Agreement is designed to oblige signors to abide by a set of rules for using biological parts responsibly. The BioBrick Contributor Agreement is designed to govern the responsible contribution of biological parts for others to use. The BPA purports to impose a legal standard on users and contributors of genetically encoded functions, and includes provisions on attribution, safety, and

113. Endy, *supra* note 3, at 450 ("[L]egal standards are needed to define means by which large collections of parts encoding basic biological functions, from a myriad of sources, can be easily shared and used in combination to realize many applications.").

114. *The BioBrick Public Agreement (BPA)*, BIOBRICKS FOUNDATION, https://biobricks.org/bpa/ (last visited Feb. 19, 2014). For purposes of full disclosure, the authors wish to note that Andrew W. Torrance contributed to early drafts of the BPA at the invitation of the BioBricks Foundation.

intellectual property rights.[115] Of special note, contributors who sign the BioBrick Contributor Agreement promise not to assert any existing or future intellectual property rights they possess to any parts they contribute under the contract.[116]

III. INTELLECTUAL PROPERTY AND SYNTHETIC BIOLOGY STANDARDS

Four principle types of intellectual property protection are relevant to the protection of synthetic biology inventions: (1) patent, (2) trade secrecy, (3) copyright, and (4) trademark. Thus far, only patent and trade secrecy have played substantial roles in protecting such inventions, though both copyright and trademark have been suggested.[117] The subject matter protectable by patent or trade secrecy is broad, spanning such innovations as new DNA, RNA, polypeptide molecules, genomes, cells, organisms, and a myriad of methods of using them either singly or in combination. Because trade secrets are, by their very nature, difficult to catalogue, the discussion here focuses on patents. Patent protection for DNA molecules, such as those deposited into the iGEM Registry of Standard Biological Parts and other publicly available registries of biological parts, will serve as an additional focus, though the patent law principles discussed are applicable to other products and methods of synthetic biology.

A. Patent

The United States Patent and Trademark Office has granted patents claiming isolated or purified DNA molecules since at least the 1970s.[118] The 1990s race to sequence the entire human genome precipitated a flood of patent applications (many later maturing into patents) claiming human DNA that peaked around 2000.[119] Patenting DNA has been criticized as being unethical[120] and for causing a

115. *Id.*

116. *See Contributors*, BIOBRICKS FOUNDATION, https://biobricks.org/bpa/contributors/ (last visited Feb. 19, 2014).

117. Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J. L. SCI. & TECH. 629 (2010).

118. Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J. L. SCI. & TECH. 157 (2010).

119. *Id.*

120. Tom Hollon, *NIH Researchers Receive Cut-Price BRCA Test*, 6 NAT. MED. 610 (2000).

genetic "tragedy of the anticommons."[121] By one account, roughly 20% of known human genes are claimed in a U.S. patent.[122] Although a recent empirical study has brought this estimate into question,[123] if such assessments are even somewhat accurate, synthetic biologists may be at substantial risk of infringing prodigious numbers of patent claims to DNA sequences. As such, existing patent rights may encumber the products and methods of synthetic biology.

Since at least 2005, uncertainty has been rising about whether or not isolated or purified natural-source DNA constitutes legitimate patentable subject matter. In 2005, a Court of Appeals for the Federal Circuit panel held that a set of patent claims expressing sequence tags (ESTs) lacked utility and enablement, casting doubt on the patentability of partial-gene DNA sequences.[124] In 2007, Xavier Becerra (Democrat Congressman from California) and Dave Weldon (Republican Congressman from Florida) unsuccessfully championed passage of the *Genomic Research and Accessibility Act*.[125] Section 106 of this Act would have barred genes from patent eligibility, stipulating that "[n]otwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[126] Although this proposal has never been passed by the U.S. Congress, Section 33 of the Leahy-Smith America Invents Act of 2011 did amend U.S. patent law to ban the patentability of any invention "directed to or encompassing a human organism."[127] Lacking legislative history, court interpretation, and formal incorporation into the U.S. Code, it is as yet unclear what legal influence Section 33 may have on the patentability of human DNA sequences.

Most relevant to synthetic biology is the litigation initiated in 2009 by the American Civil Liberties Union (ACLU) and its allies against the biotechnology firm Myriad Genetics, Inc. and the United States Patent and Trademark Office.[128] Myriad Genetics, Inc. owns

---

121. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

122. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239 (2005).

123. Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 NAT. BIOTECHNOL. 240 (2012).

124. *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

125. Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (1st Sess. 2007).

126. *Id.*

127. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 340 (2011).

128. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Off., 669 F. Supp. 2d 365

rights to several patents claiming, among other inventions, human BRCA1 and BRCA2 gene variants predictive of breast and ovarian cancer.[129] In its initial complaint in an action for declaratory judgment, the ACLU stated its opposition to the patent-eligibility of human genes, and challenged "the legality and constitutionality of granting patents over this most basic element of every person's individuality."[130] In March 2010, Judge Sweet, of the Southern District of New York, decided that genes "containing sequences found in nature . . . are deemed unpatentable subject matter."[131] Myriad appealed the decision to the Federal Circuit. On July 29, 2011, a panel of three judges largely reversed the lower court, and restored the patentability of DNA.[132]

In response, the ACLU filed a petition for a writ of *certiorari* to the U.S. Supreme Court, which vacated the Federal Circuit's decision on March 26, 2012,[133] and instructed that court to reconsider the patentability issues in light of *Mayo v. Prometheus*, a patentability decision the Court had made a week before.[134] The patent claims at issue in *Mayo v. Prometheus* were directed to methods of diagnosis using human metabolites, not to DNA molecules *per se*.[135] However, the Supreme Court clearly signaled its discontent with the Federal Circuit's panel decision.[136] On August 16, 2012, the same panel of Federal Circuit judges broadly reaffirmed their earlier panel decision, again upholding the patent-eligibility of isolated DNA.[137] The Court of Appeals for the Federal Circuit declined to reconsider the panel decision by rehearing the case *en banc*, and the case arrived again

(S.D.N.Y. 2009).

129. *See, e.g.*, U.S. Patent No. 5,709,999 (filed Mar. 1995), U.S. Patent No. 5,747,282 (filed June 7, 1995), U.S. Patent No. 5,753,441 (filed Jan. 5, 1996), U.S. Patent No. 5,837,492 (filed Apr. 29, 1996), U.S. Patent No. 6,033,857 (filed Mar. 20, 1998), U.S. Patent No. 5,654,155 (filed Feb. 12, 1996), U.S. Patent No. 5,750,400 (filed Feb. 12, 1997), U.S. Patent No. 6,051,379 (filed Dec. 2, 1997), U.S. Patent No. 6,951,721 (filed Aug. 8, 2001), U.S. Patent No. 7,250,497 (filed June 9, 2003), U.S. Patent No. 6,083,698 (filed Dec. 11, 1997).

130. Complaint at 1, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Off., 669 F. Supp. 2d 365 (S.D.N.Y. 2009) (No. 09CV04515).

131. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Off., 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

132. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Off., 653 F.3d 1329 (Fed. Cir. 2011).

133. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).

134. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

135. *Id.* at 1295.

136. *See id.* at 1302-03.

137. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Off., 669 F. Supp. 2d, 365 (S.D.N.Y. 2009).

before the Supreme Court.[138] Oral arguments were heard on April 15, 2013, and the Supreme Court issued a decision on June 13, 2013 holding natural, unmodified DNA—even when isolated or purified from a genome—to be subject matter ineligible for patent protection.[139] Together, the *Mayo v. Prometheus* and *AMP v. Myriad* decisions have rendered nonsynthetic DNA and many of its uses unpatentable.

Today, most existing patents directed to DNA molecules claim nucleotide sequences identical or similar to those derived from naturally occurring genomes. As the cost, speed, and accuracy of DNA synthesis technology continues to improve, the design and production of synthetic DNA molecules from nucleotide sequences created through computer-aided design processes may become more prominent. Even though the *AMP v. Myriad* decision has rendered natural-source DNA unpatentable, human-designed synthetic DNA is likely to remain patent-eligible. In an *amicus curiae* brief filed before the first Court of Appeals for the Federal Circuit panel decision, the U.S. Department of Justice argued that "isolated but otherwise unaltered genomic DNA is not patent-eligible subject matter under 35 U.S.C. Section 101,"[140] but that DNA molecules that are "the synthetic results of scientists' manipulation of the natural laws of genetics" could be patent-eligible.[141] The Supreme Court largely adopted this reasoning in its *AMP v. Myriad* decision.[142] It is important to note, however, that the decision addressed only whether isolated DNA or cDNA molecules constitute patentable subject matter under 35 U.S.C. Section 101. The Court specifically expressed no opinion whether cDNA molecules satisfy the other statutory requirements for patentability such as novelty, non-obviousness, or enablement/definiteness under 35 U.S.C. Sections 102, 103, and 112.[143]

Although thousands of patent claims to natural, unmodified DNA sequences are now firmly in the public domain, there is a strong prospect that human-designed synthetic DNA will remain patent-eligible for the foreseeable future. The full impact of the *AMP v.*

---

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

139. *Id.*

140. Brief for the United States as Amicus Curiae in Support of Neither Party, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Off., 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406).

141. *Id.* at 15.

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

143. *Id.*

Myriad decision, particularly concerning the validity of patent claims to synthetic DNA and its uses, will become more apparent as the lower courts interpret this decision in subsequent cases.

B. Trade Secrecy

Many owners choose to keep the details, or even the very existence, of their intellectual property secret. Some information is difficult to protect by trade secrecy, particularly products or services whose intellectual property is self-disclosing. For example, it would be difficult to maintain secrecy about the nucleotide sequence of a synthetic DNA construct due to the ease of reverse engineering that construct using routine DNA sequencing methods followed by DNA synthesis. By contrast, trade secrets inherent in a protein product whose desired functioning depended on a particular folding pattern would be easier to preserve due to the great difficulty in reverse engineering tertiary and quaternary structure.[144] By the very nature of this form of intellectual property protection, little is known about the extent of reliance on trade secrecy across industries or technological fields, in general, or in synthetic biology, in particular.

In a confluence of patent and trade secrecy law, Section 273 of the Leahy-Smith America Invents Act added a defense to patent infringement for prior commercial use of an invention claimed in a patent not owned by a university.[145] This defense is available only for commercial uses,[146] though the patent statute defines such uses to include premarketing regulatory review[147] and nonprofit laboratory uses.[148] Since this amendment to U.S. patent law has yet to be interpreted by the courts, it is unclear how it might affect patents and trade secrets in the field of synthetic biology. Nevertheless, it appears to place a modest limit on how patent rights may affect long-standing commercial and research uses of synthetic biological products and processes.

---

144. The Biologics Price Competition and Innovation Act of 2009, passed as part of the Patient Protection and Affordable Care Act of 2010, allows the developer of a biologic to maintain regulatory data exclusivity for at least 12 years after the biologic is licensed by the FDA. *See* 42 U.S.C.A. § 262 (West 2014). Specifically, Section 262 grants biologics developers a new form of data-based exclusive rights in exchange for potential loss of patent term caused by entry into the market of generic biologics competitors. *Id.*

145. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 297-98 (2011).

146. *Id.*

147. *Id.*

148. *Id.*

C. Copyright

Copyright protection is relevant to standards development in synthetic biology in several respects. The documents created to describe technical standards, such as those of the BioBricks Foundation's RFC process, are subject to copyright protection. Software tools developed for synthetic biology applications, including the SBOL standard, also are subject to copyright protection. A third way in which copyright protection may be relevant to standards development in synthetic biology is the potential for copyright protection of DNA sequences.

Copyright eligibility for DNA sequences has been discussed for many years.[149] Though not all scholars agree, the case has been made that synthetic DNA sequences may be especially strong candidates for copyright protection, in part because the deliberate design of nucleotide sequences allows considerable scope for creative expression.[150] For example, when Synthetic Genomics synthesized the first mycoplasma genome, it included several decipherable sentences among within the genome.[151] At least one firm has already asserted copyright protection for synthetic DNA sequences,[152] although to date there has been no litigation.

Copyright affords legal protection against unauthorized copying for "original works of authorship fixed in any tangible medium of expression, now known or later developed".[153] In addition to conventional targets for protection, such as books and paintings, copyright law has proved capable of adapting to cover additional forms of creative expression like architecture and computer

149. Duncan M. Davidson, *Common Law, Uncommon Software*, 47 U. PITT. L. REV. 1037, 1104-05 (1986); Irving Kayton, *Copyright in Living Genetically Engineered Works*, 50 GEO. WASH. L. REV. 191 (1982); Donna Smith, Comment, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083, 1096-1108 (1988); Dan L. Burk, *Copyrightability of Recombinant DNA Sequences*, 29 JURIMETRICS J. 469, 531-32 (1989); Andrew W. Torrance, *DNA Copyright*, 46 Val. U. L. REV. 1, (2011); Christopher M. Holman, *Copyright for Engineered DNA: An Idea Whose Time Has Come?*, 113 W. VA. L. REV. 699 (2011).

150. *See, e.g.*, Torrance, *supra* note 149, at 30.

151. Daniel G. Gibson et al., *One-Step Assembly in Yeast of 25 Overlapping DNA Fragments to Form a Complete Synthetic Mycoplasma genitalium Genome*, 105 PNAS 20404 (2008).

152. Illumina, Inc. asserts copyright protection for some of the oligonucleotide primers compatible with its DNA sequencing machines in a letter it has sent to customers. Letter from Illumina, Inc. to Illumina, Inc. customers (Sept. 7, 2012), *available at* http://supportres.illumina.com/documents/myillumina/6378de81-c0cc-47d0-9281-724878bb1c30/2012-09-18_illuminacustomersequenceletter.pdf (last visited March 4, 2014).

153. 17 U.S.C. § 102 (2012).

software.[154] Like patent protection, copyright protection for DNA sequences originating in naturally occurring genomes is least justifiable. The case for copyright protection would likely strengthen as a DNA sequence of interest acquired more characteristics of human design and synthetic production. Of course, the case for copyright protection would be far weaker for DNA sequences designed using directed evolution approaches since DNA sequences would evolve as a consequence of natural selective processes and not as a result of DNA sequence design by human authors.[155]

Copyright eligibility for DNA sequences, were it available, would create a much quicker and cheaper route to protection than does patent protection, and the resulting protection could last almost an order of magnitude longer. On the other hand, doctrines such as fair use could permit more uses by others—especially for purposes of scholarship or education—of copyrighted DNA sequences than does patent protection, and a DNA copyright framework might allow the application of open source principles to synthetic biology.[156] Now that natural-source DNA molecules have lost their eligibility for patent protection, copyright stands ready to provide an existing alternative form of protection. Nevertheless, copyright eligibility for DNA sequences remains uncertain and untested.

D. Trademark

Trademark protection may be available for a mark that indicates a single origin for goods or services bearing that mark.[157] Trademark law imposes few restrictions on eligible subject matter, as long as the mark achieves its purpose as an indicator of origin, and customer confusion is avoided.[158] Even synthetic DNA sequences might qualify as trademarks if they were used in commerce, and served as designations of origin for products or services.

---

154. 17 U.S.C. § 101 (2012); 17 U.S.C. § 117 (2012).

155. Directed evolution, like natural evolution, involves the mutation of nucleic acid sequences followed by the selection for variants that display desirable phenotypes. *See* Ryan E. Cobb, Tong Si & Huimin Zhao, *Directed Evolution: An Evolving and Enabling Synthetic Biology Tool*, 16 CURRENT OPINION CHEM. BIOL. 285 (2012) (describing advances in the use of directed evolution in synthetic biology).

156. Note that, as with open source software code, coexistent patent rights could still create risks of infringement for making, using, selling, offering to sell, or importing synthetic DNA sequences.

157. *See, e.g.*, ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 735-36 (5th ed. 2010).

158. *Id.*

The BioBricks Foundation has registered "BioBrick" as a U.S. trademark.[159] Currently, the BioBricks Foundation may use this trademark as a mild form of leverage to support its standards. In relevant part, Section 3(a) of the BioBrick User Agreement requires that "User agrees not to remove or alter any BioBrick identification tag included in the Materials . . . ."[160] The BioBrick Contributor Agreement defines this aspect of the "Materials" in its preamble as "the particular standardized genetic material(s) . . . and any associated sequence . . . information," and Section 2 of the BioBrick Contributor Agreement requires contributors to allow the addition of a "BioBrick™ identification tag" to any genetic material they contribute.[161] If desired, the BioBricks Foundation could assert its trademark rights more vigorously to promote its BioBrick-related standards by restricting the descriptor "BioBrick" to only those DNA molecules fully conforming to specified standards.

E. Synthetic Biology, Biotechnology, and Intellectual Property

Many of the intellectual property issues that arise in specific context of synthetic biology also pertain to the broader field of biotechnology. However, synthetic biology differs in its reliance on approaches from engineering and computer science, including an emphasis on standards. Due to their unique features, some synthetic biological inventions may be eligible not only for patent protection, but also for copyright, and even trademark, protection. Innovations in synthetic biology may become subject to complicated policy debates about which forms of intellectual property protection are most appropriate, just as innovations in software were a generation ago.[162] As such, it is important to address the potential confusion surrounding intellectual property issues in synthetic biology, particularly with

159. "BioBrick" is a registered trademark of the BioBricks Foundation *See* BIOBRICK, Registration No. 3836261. It is registered in international classes 41 and 42. *Id.* Its description in class 42 is "Research and development services in the fields of biology and biological engineering; providing information in the fields of biology and biological engineering." *Id.*

160. *The BioBrick User Agreement*, BIOBRICKS FOUNDATION, https://biobricks.org/bpa/users/agreement/ (last visited Jan. 31, 2014) ("User agrees not to remove or alter any BioBrick™ identification tag or data included in the Materials . . . .").

161. *The BioBrick Contributor Agreement*, BIOBRICKS FOUNDATION, http://biobricks.org/wp-content/themes/bbf/bpa-sample.php (last visited Jan. 31, 2014) ("Contributor agrees that Materials may be modified to include a BioBrick™ identification tag . . . .").

162. Arti Rai & James Boyle, *Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons*, PLOS BIOL. (March 13, 2007), http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.0050058.

regards to standards setting initiatives. This must be done in order to avoid the prolonged uncertainty that could undermine the necessary commercial investment for bringing useful synthetic biology applications to market.

CONCLUSIONS

There has been considerable discussion and activity surrounding standards setting in synthetic biology. This may be due, in part, to the interdisciplinary backgrounds of many of the field's leading participants. A number of institutions within synthetic biology have made standards setting a priority, and many standards have been proposed, including those pertaining to the structure, function, and description of genetic components, data sharing, biosecurity, and law. Despite this interest in standards, progress in standards setting has been quite modest so far. Standards for physical assembly of DNA fragments are continuing to evolve, and methods such as Gibson Assembly and *de novo* DNA synthesis are gaining acceptance as alternate approaches for the construction of large DNA molecules. Moreover, standards for other technical aspects of synthetic biology have begun to emerge, including functional composition standards that support the ability of assembled biological parts to function in a predictable manner, standards for units of measurement, and data exchange standards. At the present time, standardization efforts do not appear to have impeded innovation in synthetic biology and no single technical standard appears to have dominated the field of synthetic biology. By comparison, standards covering policies in biosecurity appear to be better established, and a U.S. government-proposed biosecurity guidance governing commercial orders for synthetic DNA has been widely adopted.

Patent rights that encumber components and methods have long been a concern among those in synthetic biology, especially as a perceived threat to the field's prominent ethos of open biological innovation. Currently, there is little evidence that patent rights adversely affect synthetic biological research. In fact, the patent-eligibility of natural-source DNA molecules has now been ended by the Supreme Court in its *AMP v. Myriad* decision, and the new AIA has created a broadened defense of prior commercial use that offers some protection from patent infringement for some uses of synthetic biological products and processes. Copyright and trademark may provide alternatives mechanisms for conferring rights in synthetic biological inventions, setting and reinforcing standards, or promoting open innovation. Among the standards-setting groups that have

formed within the synthetic biology community, most have expressed a preference that standards remain open and accessible to the community as a whole. This preference, however, has not yet been incorporated into formal policies requiring the disclosure and licensing of intellectual property rights covering technical standards. Whether such policies could be made mandatory or would ultimately be beneficial to the field of synthetic biology remain open questions. What is certain is that the synthetic biology community is unusually attuned to debates surrounding intellectual property and standards setting, and views its engagement in these debates as vital to ensure the continued success of synthetic biology.