

Synthesizing Law for Synthetic Biology

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I. INTRODUCTION

In his influential 2005 article *Foundations for Engineering Biology*, Drew Endy, a professor in the Department of Bioengineering at Stanford University and “one of synthetic biology’s foremost visionaries,”¹ described the considerable promise and limitations of synthetic biology.² On the optimistic side of the ledger, it had already “been used to manipulate information, construct materials, process chemicals, produce energy, provide food, and help maintain or enhance human health and our environment.”³ However, he also lamented that “our ability to quickly and reliably engineer biological systems that behave as expected remains quite limited.”⁴ In the ensuing five years, synthetic biology has begun to realize its scientific potential and has reached the public consciousness.

In November 2010, the seventh annual International Genetically Engineered Machine (iGEM) competition will be

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1. Jon Mooallem, *Do-It-Yourself Genetic Engineering*, N.Y. TIMES MAG., Feb. 14, 2010, at 40, 42.

2. Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 449 (2005).

3. *Id.*

4. *Id.*

held at the Massachusetts Institute of Technology (MIT).⁵ It is expected that roughly two thousand synthetic biologists, organized into two hundred teams from dozens of countries, will participate. Starting with identical kits of BioBrick™ standard DNA parts (BioBricks), which can be combined in a manner analogous to Lego® bricks or even modified, teams will compete with each other to create synthetic genes, polypeptides, metabolic pathways, cells, and organisms that will be eligible for prestigious prizes at these synthetic biology Olympics. The Registry of Standard Biological Parts (the Registry), hosted by MIT, provides these kits of BioBricks to competitors and also requests that teams submit new or modified BioBricks back into the Registry.⁶ Since its inception in 2003,⁷ the Registry has received more than 12,000 DNA sequences.⁸ By comparison, there are only about 20,000 genes in the human genome.⁹

To illustrate the remarkable progress being made by synthetic biology, consider a few of the winning projects at the 2009 iGEM competition. On November 2, 2009, thousands of cheering synthetic biologists—mostly undergraduates with a relatively modest formal background in biology—gathered inside MIT's Kresge Hall to watch a combined team of Spanish students from the Universitat Politècnica de València and the Universitat de València (Team València) present the project that carried them to the finals. In a surprising turn of events, Team València began performing jumping-jacks on the stage. Yet, there was method in their strangeness. Soon, on a giant screen behind the team members, a pixilated but recognizable human figure appeared on a computer display and began mirroring Team València's calisthenics. However, this was no ordinary computer display. It was an LEC, or light emitting cell, display. The pixels on the computer screen were composed

5. See iGEM 2009 Main Page, http://2009.igem.org/Main_Page (last visited Jan. 23, 2010) [hereinafter iGEM Main].

6. Welcome to the Registry of Standard Biological Parts, http://partsregistry.org/Main_Page (last visited Feb. 4, 2010) [hereinafter Welcome].

7. *Id.*

8. Registry of Standard Biological Parts Statistics Snapshot, <http://partsregistry.org/cgi/partsdb/Statistics.cgi> (last visited Feb. 4, 2010) [hereinafter Registry].

9. JAMES D. WATSON ET AL., *MOLECULAR BIOLOGY OF THE GENE* 139 (6th ed. 2008).

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not of electronic or chemical components, but, rather, of living cells. As described by Team València, “[e]ngineered yeasts able to sense and respond to electrical signals are build [sic] (what we call LEC). Thanks to a homemade device these LECs work cooperatively in such a way that they are able to reproduce images in movement, building up a ‘bio-screen’ for the first time in history.”¹⁰ Team València had successfully created a living computer screen composed of genetically engineered yeast capable of responding precisely and efficiently in response to human commands effectuated through electrical signals. For their efforts, they won top awards in the categories of Best New Application Area and Best Experimental Measurement, and finished as Second Runner Up for the Grand Prize (that is, the Biobrick Trophy).¹¹

The team that did win the Grand Prize, from Cambridge University, United Kingdom,¹² also managed a remarkable feat of biological engineering by designing and constructing several artificial genes that will allow genetically engineered eubacteria to detect and report environmental toxins by changing color.¹³ These color sensors work with a “sensitivity tuner” to allow reporting-via-color of both the presence of a toxin as well as its concentration. They named the eubacterium that will carry out this elegant task “*E. chromi*” (that is, *chromi*—“of color”—rather than *coli*).¹⁴ Team Cambridge also won the award for Best Environment Project.¹⁵ Rounding out the top three teams, the First Runner Up was a team from the Universität Heidelberg, Germany,¹⁶ which “developed and successfully applied a synthesis method for synthetic promoters,¹⁷ and a strategy for their rational design.”¹⁸

10. iGEM 2009 Team Valencia Home Page,
<http://2009.igem.org/Team:Valencia/home> (last visited Jan. 24, 2010).

11. iGEM Main, *supra* note 5.

12. *Id.*

13. iGEM 2009 Team Cambridge Project Page,
<http://2009.igem.org/Team:Cambridge/Project> (last visited Mar. 7, 2010).

14. *Id.*

15. iGEM Main, *supra* note 5.

16. *Id.*

17. Promoters are fundamental regions of DNA that modulate the expression of genes (that is, gene function). BENJAMIN LEWIN, GENES IX 860 (2008) (“A promoter is a region of DNA where RNA polymerase binds to initiate transcription.”).

18. iGEM 2009 Team Heidelberg Project Page,

The fact that these synthetic biological creations were designed and built by undergraduate students illustrates the power and potential of synthetic biology. Unsurprisingly, professional biologists, including academics and other medical researchers, as well as commercial enterprises are also using synthetic biology to design and develop new genes, gene combinations, genomes, metabolic pathways, viruses, cells, and organisms. The Registry makes BioBricks available not just to participants in the iGEM competition, but to academic research laboratories as well.¹⁹ Perhaps the most famous of these products so far is artemisinin, a drug effective at treating malaria. Amyris Biotechnologies has continued the research of Jay Keasling, a University of California Berkeley biochemical engineering professor, to produce a synthetic platform for producing artemisinin.²⁰ To accomplish this, Keasling and his research team spliced together several genes from different source organisms into the eubacterium *E. coli* to enhance production of artemisinin.²¹ Using synthetic biology, Keasling and his colleagues have “increased the amount of artemisinic acid that each cell could produce by a factor of one million, bringing down the cost of the drug from as much as ten dollars for a course of treatment to less than a dollar.”²² Another prominent goal to which synthetic biology is being applied is the engineering of a synthetic cellulase enzyme capable of efficiently converting cellulose from plant waste into simpler sugars that could, in turn, be used in the inexpensive production of renewable bio fuels. Both Amyris and another biotechnology company, LS9, are currently using synthetic biological techniques to pursue this potentially lucrative, and socially useful, goal.²³

The growing excitement surrounding the potential of synthetic biology has now penetrated the public consciousness.

<http://2009.igem.org/Team:Heidelberg/Project> (last visited Jan. 18, 2010).

19. Welcome, *supra* note 6.

20. Michael Specter, *A Life of Its Own*, NEW YORKER, Sept. 28, 2009, at 56, 58.

21. Vincent JJ Martin et al., *Engineering a Mevalonate Pathway in Escherichia Coli for Production of Terpenoids*, 21 NATURE BIOTECH. 796, 797 (2003).

22. Specter, *supra* note 20, at 58.

23. See Mooallem, *supra* note 1, at 42; Amyris - Our Products, http://www.amyris.com/index.php?option=com_content&task=view&id=33&Itemid=300 (last visited Jan. 29, 2010).

Though the field had already achieved considerable scientific success and recognition, its public profile attained new heights over the past year, as two of the most influential U.S. magazines—The New Yorker and The New York Times Magazine—both published feature articles about synthetic biology within a five-month period.²⁴

It is easy to understand the field's appeal. Synthetic biology offers an approach to, and technologies for, radically altering the meaning of biology, as well as the meaning of "alive." By reimagining biology from the perspective of engineers, computer programmers, and hackers, synthetic biologists hope to move beyond the strictures imposed on genes, cells, and organisms by eons of evolution by natural selection. Furthermore, by emphasizing open standards for, and relatively free sharing of, biological "parts," making those parts widely available to those both within and outside the biological research establishment, and encouraging users of those parts to alter, combine, and employ them in novel, unsupervised, and unexpected ways, many synthetic biologists hope to create a community of open source biology engineers and biohackers capable of constructing anything from cellular computers to self-constructing wooden houses.

This article examines how the law may adapt to the challenges offered by synthetic biology. Part II provides an overview of the science that underpins the field. Part III analyzes how intellectual property law, particularly patent, copyright, and trademark law, will accommodate some of the unique features spawned by synthetic DNA. Part IV analyzes the open innovation²⁵ approach to innovation that has driven the development of synthetic biology so significantly, and examines a nascent attempt to enshrine open innovation values, as well as concerns over biosafety,²⁶ into law.

II. SYNTHETIC BIOLOGY

The current explosion of interest in synthetic biology is the culmination of a century of biological efforts to control, change,

24. Mooallem, *supra* note 1; Specter, *supra* note 20.

25. Throughout this article, "open innovation" is intended to function as an umbrella phrase that includes user, open, and collaborative innovation.

26. In this article, "biosafety" is intended to include both biosafety and biosecurity.

reengineer, and remake living systems at the molecular level. From experiments on fruit fly genetics conducted by Thomas Hunt Morgan in the “Fly Room” at Columbia University²⁷ in the 1910s and 1920s to the elucidation of DNA as a double-helix of nucleic acids by James D. Watson and Francis Crick in 1953,²⁸ knowledge of molecular biology and methods for genetic manipulation improved at an accelerating pace, finally allowing the “engineering” and “programming” of living cells and their genomes. This allowed a conceptual break with the previous, largely descriptive, molecular biology, and ushered in a new paradigm of genetic manipulation at the molecular level.

A. GENETIC ENGINEERING

In the early 1970s, Stanley N. Cohen, a professor at Stanford University School of Medicine, and Herbert Boyer, a professor at the University of California, San Francisco, developed a technique that revolutionized the field of biology. Using a restriction endonuclease, Cohen and Boyer, assisted by several colleagues, cut open a DNA plasmid from the eubacterium, *Escherichia coli*, inserted foreign DNA into the gap in the plasmid, and then sealed this foreign DNA into the *E. coli* plasmid using DNA ligase.²⁹ Their experiments demonstrated that DNA from different sources could be deliberately recombined into patterns distinct from those in nature.³⁰

The invention of “recombinant DNA” allowed cells and organisms to be genetically engineered.³¹ In turn, it fostered the creation of a new industry: biotechnology. Several years after the initial demonstration of genetic engineering by Cohen and Boyer, a human gene, somatostatin, was successfully spliced into *E. coli*.³² As Sally Hughes has summarized, genetic

27. See WATSON, *supra* note 9, at 12–13.

28. See EVELYN FOX KELLER, *THE CENTURY OF THE GENE* 3 (2000).

29. Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. U.S.A. 3240, 3240 (1973).

30. *Id.* at 3244.

31. Sally Smith Hughes, *Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology*, 92 ISIS 541, 542 (2001).

32. *E.g.*, Keiichi Itakura et al., *Expression in Escherichia Coli of a Chemically Synthesized Gene for the Hormone Somatostatin*, 198 SCI. 1056, 1056 (1977).

engineering offered “a simple method for isolating and amplifying any gene or DNA segment and moving it with controlled precision, allowing analysis of gene structure and function in simple and complex organisms.”³³ This simple method has advanced genetic research immensely by allowing direct manipulation of and experimentation on genomes.

Although genetic engineering began as a method for introducing a single foreign gene into the natural genome of another cell, the techniques it has engendered have grown significantly in complexity and in their power to modify existing cells and organisms. Within five years of the first deliberate recombination of DNA, ambition for the field had vaulted towards “the new era of ‘synthetic biology’ where not only existing genes are described and analyzed but also new gene arrangements can be constructed and evaluated.”³⁴ Synthetic biology has since moved well beyond this early conception of the field as one of rearranging genes. Now the field envisions not just the redesign of existing organisms, but even the *de novo* design and “programming” of genes and organisms.

B. GENETIC PROGRAMMING

Numerous metaphors have been used to describe gene function. The metaphor most congruent to the goals of synthetic biology is the gene as algorithm. In this conception of the gene, DNA encodes a set of instructions for carrying out functions via biochemistry just as a computer program encodes a set of instructions for carrying out functions via electricity. Sir Francis Crick, one of the Nobel Prize-winning co-discoverers of the specific chemical structure of DNA, observed that “DNA makes RNA, RNA makes protein, and proteins make us.”³⁵ French geneticists François Jacob and Jacques Monod established that some genes encode biochemical products that, in turn, regulate the expression of other genes.³⁶ They proposed that “the genome contains not only a series of blue-prints, but a co-ordinated program of protein synthesis and the means of

33. Smith Hughes, *supra* note 31, at 542.

34. Waclaw Szybalski & Ann Skalka, *Nobel Prizes and Restriction Enzymes*, 4 *GENE* 181, 181–82 (1978).

35. Francis Crick, *On Protein Synthesis*, 7 *SYMP. SOC'Y FOR EXPERIMENTAL BIOLOGY* 139 (1958).

36. *E.g.*, WATSON ET AL., *supra* note 9, at 561.

controlling its execution.”³⁷ James Bonner further elaborated this metaphor, suggesting that organisms are constructed and maintained by a “master programme constituted in turn of a set of subprogrammes or subroutines,”³⁸ each of which, in turn, comprises “a list of cellular instructions or commands.”³⁹

One of the guiding principles of synthetic biology is that genes and cells can be programmed like computers. As Arjun Bhutkar has described, “A primary objective of this nascent research area is to create a programmable microorganism from scratch.”⁴⁰ Pregnant in this description is the bold assumption that living organisms are capable of being programmed in a manner analogous to programming computers. To be programmable like a computer, an organism or cell would probably have to possess at least some computer-like characteristics, such as relative structural simplicity and functional predictability. By contrast, if an organism or cell were to exhibit structural complexity or functional unpredictability, programming it would be difficult and would not tend to yield consistent results. One approach synthetic biology takes to ensure programmability is the deliberate reengineering of biological parts and systems to make them structurally simplified and functionally predictable.

C. BIOLOGY AS ENGINEERING

In 1958, Edward L. Tatum and George W. Beadle won the Nobel Prize for Medicine.⁴¹ Their research on the fungus *Neurospora* produced strong evidence that each gene controls the synthesis of a specific enzyme.⁴² In his Nobel Prize acceptance speech, Tatum suggested a future in which biology would move beyond description and experimentation into design and manipulation:

37. François Jacob & Jacques Monod, *Genetic Regulatory Mechanisms in the Synthesis of Proteins*, 3 J. MOLECULAR BIOLOGY 318, 354 (1961).

38. JAMES BONNER, *THE MOLECULAR BIOLOGY OF DEVELOPMENT* 134 (1965).

39. KELLER, *supra* note 28, at 86.

40. Arjun Bhutkar, *Synthetic Biology: Navigating the Challenges Ahead*, J. BIOLAW & BUS., Vol. 8, No. 2, 2005, at 19, 20.

41. Edward Tatum - Biography, http://nobelprize.org/nobel_prizes/medicine/laureates/1958/tatum-bio.html (last visited Feb. 2, 2010).

42. WATSON ET AL., *supra* note 9, at 19.

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With a more complete understanding of the functioning and regulation of gene activity in development and differentiation, these processes may be more efficiently controlled and regulated, not only to avoid structural or metabolic errors in the developing organism, but also to produce better organisms.

. . . [Understanding the genetic code] may permit the improvement of all living organisms by processes which we might call biological engineering.⁴³

The 1970s saw the limited implementation of Tatum's "biological engineering" (or "genetic engineering"), which has since flowered into a sophisticated array of molecular biological techniques commonly known as "biotechnology." A group of biologists now hope to take biology beyond conventional genetic engineering into a future where biology and engineering science merge into a new field called "synthetic biology."

For biology to give rise to an engineering discipline of synthetic biology, ethos, insights, and approaches from engineering science may be necessary. First and foremost, there exists a fundamental threshold question about the nature of biological systems, such as genes, genomes, cells, and organisms. Is biology impenetrably complex, unmanageably complicated, and essentially unpredictable, or can biological systems and their components be understood, manipulated, and controlled to an extent sufficient to synthesize artificial versions? The latter is a necessary prerequisite for the successful adoption of engineering principles to biology and for the creation of synthetic biology as an engineering discipline.

Drew Endy, one of the leading voices advocating synthetic biology as a discipline, has portrayed this question as a welcome challenge and suggested it can be resolved empirically.⁴⁴ In his 2005 manifesto for synthetic biology, *Foundations for Engineering Biology*, Endy,⁴⁵ forcefully and optimistically outlines the major challenges and future of the field.⁴⁶ If biology is amenable to engineering, then engineering science may offer a potentially powerful conceptual approach

43. Edward Tatum - Nobel Lecture, http://nobelprize.org/nobel_prizes/medicine/laureates/1958/tatum-lecture.html (last visited Feb. 2, 2010).

44. Endy, *supra* note 2, at 449.

45. Stanford University School of Medicine and School of Engineering Department of Bioengineering Faculty Page, <http://bioengineering.stanford.edu/faculty/> (last visited Mar. 7, 2010).

46. Endy, *supra* note 2, at 449–53.

necessary to the success of synthetic biology. As summarized by Endy, this approach involves at least three general principles: (1) standardization, (2) decoupling, and (3) abstraction.⁴⁷ In the biological context, standardization would involve “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.”⁴⁸ Decoupling would decompose larger tasks into smaller tasks more amenable to specialization and discrete completion; for example, the design of a metabolic pathway composed of multiple genes might be separated from the construction of the individual genes and of the whole pathway.⁴⁹ Abstraction would comprise at least two steps: breaking a biological engineering problem into hierarchical levels of complexity (“abstraction hierarchies”) and redesigning the basic components of engineered biological systems to simplify the construction and deconstruction of such systems.⁵⁰ In theory, implementation of the engineering science approach could lead to the wide availability of standard biological parts that could be combined into biological devices, which, in turn, could be used to build biological systems.⁵¹ Nevertheless, as important as this engineering science approach may be, the ethos of open science, and a concomitant distaste for intellectual property, represents what may be an even more significant influence in the development of synthetic biology.

III. PROPRIETARY SYNTHETIC BIOLOGY

Synthetic biology promises to challenge fields beyond science and technology. It is sure to unsettle notions of how the intellectual property laws should apply to biotechnological inventions. Three ways in which synthetic biology may force change to legal doctrine are discussed below. First, human-designed DNA sequences, systems, cells, and organisms may avoid criticisms about patents claiming “products of nature.”⁵² Second, synthetic DNA sequences may qualify for copyright

47. *Id.* at 450–52.

48. *Id.* at 450.

49. *Id.* at 451.

50. *Id.* at 451–52.

51. *Id.*

52. *E.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

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protection as “original works of authorship fixed in [a] tangible medium of expression.”⁵³ Third, synthetic biology may create new routes to trademark protection of its resulting products and services by enabling the routine inclusion in DNA sequences (or other engineered biological structures) of distinctive motifs capable of serving as legally effective indications of source.

A. SYNTHETIC GENE PATENTS

Judge Learned Hand provided the legal basis for the patenting of DNA. At about the same time as the birth of modern genetics, Judge Hand decided *Parke-Davis & Co. v. H. K. Mulford & Co.*,⁵⁴ a case involving purified adrenaline. Considering the issue of whether adrenaline—a known chemical found in nature—could be patentable subject matter, he found that, when the inventor had removed adrenaline “from the other gland-tissue in which it was found . . . it became for every practical purpose a new thing commercially and therapeutically.”⁵⁵ Thus, Judge Hand concluded, “That was a good ground for a patent.”⁵⁶ By the 1970s, advances in biotechnology had allowed the nucleotide sequences of genes to be determined. In 1971, the claim element “gene” appeared for the first time, in U.S. Patent No. 3,710,511.⁵⁷ In 1973, the first patent issued with “DNA” as a claim element.⁵⁸ By 1982, specific nucleotide sequences coding for specific polypeptides (that is, human chorionic somatomammotropin (claim 1) and animal growth hormone (claim 4)) had been successfully claimed in U.S. Patent No. 4,363,877,⁵⁹ the first patent claiming the nucleotide sequences of genes *per se*.⁶⁰

53. 17 U.S.C. § 102 (2006).

54. *Parke-Davis & Co. v. H. K. Mulford & Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912).

55. *Id.* at 103.

56. *Id.*

57. *See* Procedures for Use of Genic Male Sterility in Production of Commercial Hybrid Maize, U.S. Patent No. 3,710,511 (filed Apr. 21, 1971) (issued Jan. 16, 1973).

58. *See* Diagnostic Method Utilizing Synthetic Deoxyrilonucleotide Oligomer Template, U.S. Patent No. 3,755,086 (filed Feb. 9, 1971) (issued Aug. 28, 1973).

59. *See* Recombinant DNA Transfer Vectors, U.S. Patent No. 4,363,877 (filed Apr. 19, 1978) (issued Dec. 14, 1982).

60. *See Gene Patents and Global Competition Issues*, GENETIC

After the *Diamond v. Chakrabarty* decision in 1980,⁶¹ patent applications and issued patents claiming DNA sequences increased rapidly.⁶² Today, patenting DNA sequences is routine. The USPTO *Utility Examination Guidelines* state that “[a] patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature.”⁶³ The phrase “[‘isolated DNA’] or a similar term (e.g., ‘modified DNA’ or ‘purified DNA’) is widely used to distinguish the claimed DNA from its naturally occurring counterpart, i.e., genomic DNA encoding [the same polypeptide].”⁶⁴ Such claims are “unquestionably patentable over the corresponding products of nature,”⁶⁵ although they must also satisfy criteria of patentability other than being statutory patentable subject matter.⁶⁶

Despite the longstanding *Parke-Davis* ruling, some have argued that DNA sequences should not constitute patentable subject matter because they are derived from natural (“genomic”) DNA sequences.⁶⁷ Synthetic biology allows these concerns to be avoided entirely. Genes constructed using synthetic biological techniques will have their origins in human imagination and will, thus, not be products of nature. Even if the courts were to accede to the wishes of those opposing the patent eligibility of genes isolated from natural genomic sources,⁶⁸ synthetic genes would remain patentable subject due to their non-natural origins. In fact, opposition to gene patents as products of nature would incentivize preferential investment in research, development, and patenting of synthetic genes.

ENGINEERING & BIOTECH. NEWS, Jan. 1, 2006, available at <http://www.genengnews.com/articles/chitem.aspx?aid=1163>.

61. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

62. Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J. L. SCI. & TECH. 157, 178 figs.1 & 2 (2010).

63. United States Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

64. Fish & Richardson P.C., Master Class™: Biotech Course Materials, Vol. 1, pg. I-5 (May 11-12, 2005).

65. Fish & Richardson P.C., Master Class™: Biotech Course Materials, Vol. 1, pg. I-5 (May 11-12, 2005).

66. See, e.g., *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

67. See, e.g., Andrew W. Torrance, *Patent Rights and Civil Wrongs: The ACLU Lawsuit*, BIO-IT WORLD, July 2009, available at <http://www.bioitworld.com/comment/2009/07/06/ACLU-lawsuit.html>.

68. See, e.g., *id.*

Recent tumult regarding the patentability of isolated human genes is likely to raise the prospective value of synthetic genes. On May 12, 2009, the American Civil Liberties Union (ACLU) filed a lawsuit to challenge the eligibility of human genes for patent protection.⁶⁹ As the complaint stated,

Every person's body contains human genes, passed down to each individual from his or her parents. These genes determine, in part, the structure and function of every human body. This case challenges the legality and constitutionality of granting patents over this most basic element of every person's individuality.⁷⁰

The patents in question claimed specific mutations in tumor suppressor genes BRCA1 ("BRCA1, early onset") and BRCA2 ("BRCA2, early onset").⁷¹ A positive test result for these tumor suppressor genes usually show a substantial increase in risk of developing breast and ovarian cancers in one's life.⁷² On March 29, 2010, the court granted the ACLU summary judgment that human genes constituted unpatentable subject matter.⁷³ The decision from the court was decisive:

The claims-in-suit directed to "isolated DNA" containing human BRCA1/2 gene sequences reflect the USPTO's practice of granting patents on DNA sequences so long as those sequences are claimed in the form of "isolated DNA." This practice is premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. Many, however, including scientists in the field of molecular biology and genomics, have considered this practice a "lawyer's trick" that circumvents the prohibitions on the direct patenting of DNA in our bodies but which, in practice, reaches the same result. . . . It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to "isolated DNA" containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35U.S.C. §101.⁷⁴

Myriad Genetics is highly likely to appeal this decision to the Federal Circuit, with strong support from the many

69. Complaint, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 2010 WL 1233416 (S.D.N.Y. 2010) (No. 09 Civ. 4515).

70. *Id.* at 1.

71. *Id.* at 2.

72. BRAC*Analysis*®, Frequently Asked Questions, <http://www.bracnow.com/faqs/#50> (last visited May 13, 2010).

73. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09 Civ. 4515, 2010 WL 1233416, at *51 (S.D.N.Y. Mar. 29, 2010).

74. *Id.* at *2.

companies, universities, and other institutions who own potentially valuable gene patents. A further appeal to the U.S. Supreme Court is also likely, given the economic and public health importance of this issue. What is certain is that this stunning court decision has focused intense interest on the potential synthetic biology holds for designing genes unlike those “found in nature.” The promise of synthetic biology represents an important new pathway to obtaining patent rights that successfully claim DNA.

B. SYNTHETIC GENE COPYRIGHTS

A number of previous authors have discussed the applicability of copyright law to DNA sequences.⁷⁵ However, none of these discussions were written with the benefit of considering the recent explosion in the field of synthetic biology. Even so, none of these authors conclusively reject the copyrighting of DNA sequences. In light of how plausible these authors appear to consider the copyrightability of non-synthetic DNA, the case favoring copyrightability of synthetic DNA is *a fortiori*.

Copyright protection applies to “original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.”⁷⁶ Fixation can occur in any “form, manner, or medium.”⁷⁷ However, the mode of fixation must be “sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than a transitory duration.”⁷⁸ Since DNA is composed

75. *E.g.*, Tani Chen, *Can a Biological Sequence Be Copyrighted?*, INTELL. PROP. & TECH. J., Mar. 2007, at 1; 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); James G. Silva, *Copyright Protection of Biotechnology Works: Into the Dustbin of History?*, B.C. INTELL. PROP. & TECH. F., Jan. 28, 2000, http://www.bc.edu/bc_org/avp/law/st_org/iptf/articles/content/2000012801.html

76. 17 U.S.C. § 102 (2006).

77. H.R. REP. NO. 94-1476, at 52 (1976).

78. 17 U.S.C. § 101 (2006).

of stable chemical nucleotides, DNA sequences should easily meet this requirement. Furthermore, DNA possesses definite sequences of nucleotides that can easily be determined,⁷⁹ copies of DNA may be synthesized routinely and in effectively unlimited quantities,⁸⁰ and molecular DNA has been known to last for at least many thousands of years with its nucleotide sequence intact.⁸¹ The authorship requirement might pose a barrier to the copyrightability of genes and other DNA sequences derived entirely from natural genomes. A challenge would be posed by 17 U.S.C. §102, which provides that “[c]opyright protection subsists . . . in original works of authorship.”⁸² By analogy, someone other than the author could not claim copyright protection for a preexisting manuscript simply by discovering its existence.⁸³ However, synthetic biology can involve the design and construction of new, human-designed DNA sequences. Here the synthetic biologist designs the particular DNA sequence, and “writes” it when she synthesizes the sequence.⁸⁴ Since there is an author in this case, such DNA sequences should qualify as “original works of authorship.” Furthermore, although DNA sequences lack the explicit statutory recognition as copyrightable subject matter that computer software possesses, synthetic DNA sequences may be eligible for copyright protection under the expansive interpretation of “works of authorship” manifested by Congress in the legislative history of the 1976 amendments to the Copyright Act.⁸⁵ Finally, DNA sequences can be “perceived,

79. See, e.g., F. Sanger et al., *DNA Sequencing with Chain-Terminating Inhibitors*, 74 PROC. NAT'L ACAD. SCI. U.S.A. 5463 (1977).

80. See, e.g., 2 JOSEPH SAMBROOK & DAVID W. RUSSELL, *MOLECULAR CLONING: A LABORATORY MANUAL* 8.4 (3d ed. 2001).

81. See, e.g., Eske Willerslev & Alan Cooper, *Ancient DNA*, 272 PROC. R. SOC'Y B 3, 3–5 (2005).

82. 17 U.S.C. § 102 (2006).

83. Of course, non-authors may obtain copyright protection through contractual means for works authored by others.

84. In fact, fixing a DNA sequence via more conventional tangible forms of expression, such as writing the nucleotide sequence down on paper, may also suffice.

85. See H.R. REP. NO. 94-1476, at 51 (1976) (“The history of copyright law has been one of gradual expansion in the types of works accorded protection, and the subject matter affected by this expansion has fallen into two general categories. In the first, scientific discoveries and technological developments have made possible new forms of creative expression that never existed before. In some of these cases the new expressive forms—electronic music, filmstrips,

reproduced, or otherwise communicated, either directly or with the aid of a machine or device.”⁸⁶ The genetic code of DNA is well understood by biologists. DNA sequences are easily reproduced.⁸⁷ And, machines and routine laboratory methods allow the specific nucleotides in DNA sequences to be determined.⁸⁸

There is no explicit mention of DNA sequences in 17 U.S.C. § 102, nor do any of the eight enumerated categories of copyrightable subject matter obviously include DNA sequences. There are, however, several significant respects in which DNA, genes, arrays of genes, and genomes (not to mention their RNA and polypeptide products) fit within the “literary works” category,⁸⁹ both generally and as computer programs. Like the English alphabet of twenty-six letters, DNA is composed of an alphabet of four nucleotide “letters”: A, T, G, and C.⁹⁰ Triplets of these nucleotide letters form “codons” that correspond to specific amino acids. When strung together in a linear chain, amino acids comprise polypeptides. A synthetic biologist can “write” strings of nucleotides (for example, genes) in any pattern she wishes. Some patterns of nucleotide letters could be written to produce specifically desired linear chains of amino acids. At a higher level of organization, a synthetic biologist could compose arrays of multiple synthetic genes in particular patterns to produce complex results inside and outside cells. Literary works are defined in § 101 as “works . . . expressed in words, numbers, or other verbal or numerical symbols or indicia, regardless of the nature of the material objects . . . in which they are embodied.”⁹¹ Nucleotides, DNA, RNA, genes, amino acids, polypeptides, and proteins are certainly “indicia,” and the letters used to denote nucleotides and amino acids, as well as the codes used to denote genes may also qualify as “verbal . . . symbols.” Furthermore, the statement “regardless

and computer programs, for example—could be regarded as an extension of copyrightable subject matter Congress had already intended to protect, and were thus considered copyrightable from the outset without the need of new legislation.”).

86. 17 U.S.C. § 102.

87. See, e.g., SAMBROOK & RUSSELL, *supra* note 80, at 8.4–8.17.

88. See, e.g., Sanger et al., *supra* note 79, at 5463.

89. 17 U.S.C. § 102.

90. A similar molecule, RNA, is composed of adenine, uracil (instead of thymine), guanine, and cytosine. The RNA alphabet is A, U, G, and C.

91. 17 U.S.C. § 101 (2006).

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of the nature of the material objects . . . in which they are embodied”⁹² could certainly include DNA or its related molecules.

Section 102 does not restrict eligibility for copyright protection only to the seven enumerated categories. Rather, the section introduces the enumerated categories with the phrase “include[s] the following categories.”⁹³ In the “Definitions” section of the Copyright Act, § 101 explains that “including . . . [is] illustrative and not limitative.”⁹⁴ The House Report accompanying the 1976 Copyright Act reinforce this broad interpretation:

The use of the word “include,” as defined in section 101, makes clear that the listing is “illustrative and not limitative,” and that the seven categories do not necessarily exhaust the scope of “original works of authorship” that the bill is intended to protect. Rather, the list sets out the general area of copyrightable subject matter, but with sufficient flexibility to free the courts from rigid or outmoded concepts of the scope of particular categories.⁹⁵

When considered in conjunction with the expansive phrase in § 102, “any tangible medium of expression, now known or later developed,”⁹⁶ synthetic DNA sequences fit comfortably within the category of “literary works.”⁹⁷

In 1974, the National Commission on New Technological Uses of Copyrighted Works (CONTU) issued a report concluding that “computer programs, to the extent that they embody an author’s original creation, are proper subject matter of copyright.”⁹⁸ The CONTU was careful to distinguish copyrightable subject matter, such as creative expression in computer software, from uncopyrightable subject matter, such as “ideas, procedures, processes, systems, methods of operation, concepts, principles, or discoveries.”⁹⁹ Moreover, it emphasized that “one is always free to make the machine do the same thing as it would if it had the copyrighted work placed in it, but only

92. 17 U.S.C. § 101 (2006).

93. 17 U.S.C. § 102.

94. 17 U.S.C. § 101.

95. See H.R. REP. NO. 94-1476, at 53 (1976).

96. 17 U.S.C. § 102.

97. *Id.*

98. NAT’L COMM’N ON NEW TECHNOLOGICAL USES OF COPYRIGHTED WORKS, FINAL REPORT OF THE NAT’L COMM’N ON NEW TECHNOLOGICAL USES OF COPYRIGHTED WORKS 1 (1978) [hereinafter NAT’L COMM’N].

99. *Id.* at 18 (citing 17 U.S.C. § 102 (b)).

by one's own creative effort rather than by piracy."¹⁰⁰ Formal recognition of computer software as copyrightable subject matter occurred in 1980, when Title 17 (the "Copyright Act") was amended to include explicit copyright protection for computer software.¹⁰¹ Section 101 of the Copyright Act defines "computer program" as "a set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result."¹⁰² Although there are some special limitations on the exclusive rights conferred to owners of copyrights on computer software,¹⁰³ this form of expression is now routinely protected by copyright.

Synthetic biology is largely based on a conception of genes, cells, and organisms as programmable. In a measured version of this conception, Endy has suggested that "synthetic biology provides an opportunity to test the hypothesis that the genomes encoding natural biological systems can be 're-written,' producing engineered surrogates that might usefully supplant some natural biological systems."¹⁰⁴ However, as a more ambitious articulation has portrayed it, "[a] primary objective of [synthetic biology] is to create a programmable microorganism from scratch,"¹⁰⁵ and it is increasingly possible to "program living organisms in the same way a computer scientist can program a computer."¹⁰⁶ Consequently, if computer software is copyrightable, perhaps "biological software" is, or ought to be, as well.

It is relatively easy for a human mind to understand the "meaning" of a DNA sequence. Once a proper reading frame has been determined for the sequence,¹⁰⁷ one only has to recognize triplets of nucleotides and assign corresponding

100. NAT'L COMM'N, *supra* note 98, at 21.

101. See H.R. REP. NO. 96-1307, pt. 1, at 23-24 (1980).

102. 17 U.S.C. § 101 (2006).

103. 17 U.S.C. § 117 (2006).

104. Endy, *supra* note 2, at 449.

105. Bhutkar, *supra* note 40, at 20.

106. The BioBricks Foundation, <http://bbf.openwetware.org/> (last visited Jan. 7, 2010).

107. LEWIN, *supra* note 17, at 860 ("A reading frame is one of three possible ways of reading a nucleotide sequence. Each reading frame divides the sequence into a series of successive triplets. There are three possible reading frames in any sequence, depending on the starting point. If the first frame starts at position 1, the second frame starts at position 2, and the third frame starts at position 3.")

amino acids to each triplet. Thus, someone of modest skill in genetics could examine a DNA sequence of 300 coding nucleotides, in proper reading frame, and then determine the specific 100 amino acid sequence of its corresponding polypeptide. By contrast, it is much more difficult for one of similar skill in computer software to understand the “meaning” of either object code or source code. With respect to computer software, both source code and object code are eligible for copyright protection.¹⁰⁸ Source code is a form of a computer program expressed in a programming language understandable to humans. Object code, by contrast, is a form of a computer program expressed in binary (that is, “1s” and “0s”); object code cannot generally be understood by the human mind. If object code is eligible for copyright protection, then, *a fortiori*, so should DNA sequences, which can be relatively easily understood.

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. A gene is a set of instructions for producing a polypeptide.¹⁰⁹ A cell (or even an organism), via the molecules, metabolic pathways, and signaling pathways it contains, acts in response to the set of instructions encoded in its genes to carry out a certain result. Thus, “a [gene encodes a] set of statements or instructions to be used directly or indirectly in a [cellular] computer in order to bring about a certain [metabolic or signaling] result.”¹¹⁰ Given that one of the primary goals of synthetic biology is to engineer cells and genes to become ever more like computers and computer software, as synthetic biology succeeds in making DNA appear more similar to computer software, DNA sequences will likely move towards copyrightability by analogy to computer software. Alternatively, if cells and organisms are already computers and genes are already software, then DNA sequences are already eligible for copyright protection.

Whether or not cells are computers and genes are computer software is largely an empirical question. Endy offers

108. *E.g.*, *Apple Computer, Inc. v. Franklin Computer Corp.*, 714 F.2d 1240, 1248 (3d Cir. 1983), *cert. dismissed*, 464 U.S. 1033 (1984).

109. LEWIN, *supra* note 17, at 852 (“A gene is the segment of DNA specifying a polypeptide chain . . .”).

110. *Cf.* 17 U.S.C. § 101 (2006). The bracketed material is added to show how DNA sequences can fit into the existing definition of computer software.

a number of examples, including:

- [a] DNA sequence that programmes a biofilm to take a photograph and perform distributed edge-detection on the light-encoded image . . .
- [a] DNA sequence that programmes any mammalian cell to count up to 256 in response to a generic input signal . . . [and a] DNA sequence that programmes any prokaryote to produce 25 gl^{-1} artemisinic acid.¹¹¹

However, rather than characterizing any of these examples as science fiction or hopeful thinking, Endy notes that “each application is physically plausible, or is the direct extension of an already demonstrated result.”¹¹² This suggests that synthetic biology is well on the way towards cells as computers and genes as computer software. The consequences for the copyrightability of synthetic DNA sequences are significant.

Copyright law limits protection to works of authorship that do not monopolize a particular function.¹¹³ If a DNA sequence of a synthetic gene were to represent the only way of producing an RNA or polypeptide with a particular function, then that sequence would not likely possess strong copyright protection. However, if multiple DNA sequences could produce the RNA or polypeptide with a particular function, then any one individual sequence would likely have much stronger copyright protection. In addition, as long as a work of authorship is original, it cannot infringe the copyright of another work of authorship, even if the two works of authorship are identical. Thus, even a copyright protecting a particular synthetic DNA sequence would not prevent others from independently designing an identical or similar DNA sequence. In other words, independent invention of identical or similar synthetic DNA sequences would act as a counterbalance to any monopoly rights conferred on the first author. Copying would still constitute copyright infringement, but independent invention would be permissible. This would stand in stark contrast to the rights conferred by patents claiming DNA sequences because the strict liability regime of patent law does not relieve independent inventors from liability.

111. Endy, *supra* note 2, at 449.

112. *Id.*

113. See 2 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 2.01[A] (Matthew Bender, rev. ed., 2009).

C. SYNTHETIC GENE TRADEMARKS

One of the technologies that enables synthetic biology is DNA synthesis.¹¹⁴ It is technically routine, rapid, and increasingly inexpensive to design a DNA sequence *de novo* and then construct it nucleotide by nucleotide.¹¹⁵ Numerous companies offer DNA synthesis as a service.¹¹⁶ Research into “DNA printers” has already achieved notable technical successes.¹¹⁷ Machines for synthesizing custom DNA with high-fidelity are likely to become standard equipment in biological laboratories (and perhaps even beyond) in the near future. In addition to its many more scientific applications, DNA synthesis allows one to design patterns or motifs within a strand of DNA capable of serving as an indicator of source.

One of the purposes of a trademark or servicemark is to alert consumers as to the source of the goods or services to which the mark is connected.¹¹⁸ Furthermore, “[b]y identifying the source of the goods, [trademarks] convey valuable information to consumers at lower costs.”¹¹⁹ The Lanham Act defines “trademark” expansively as “includ[ing] any word, name, symbol, or device, or any combination thereof.”¹²⁰ The Supreme Court has interpreted the Lanham Act as describing “the universe of things that can qualify as a trademark . . . in the broadest terms.”¹²¹ The Court has stated, however, that “[t]he functionality doctrine prevents trademark law, which seeks to promote competition by protecting a firm’s reputation, from instead inhibiting legitimate competition by allowing a producer to control a useful product feature.”¹²²

114. This process is sometimes referred to alternatively as “gene synthesis.”

115. Mark Welch et al., *Design Parameters To Control Synthetic Gene Expression in Escherichia Coli*, PLOS ONE, Sept. 2009, at 1, 1.

116. *E.g.*, GENEART, <http://geneart.com/english/index.html> (last visited January 26, 2010); GenScript USA Inc., <http://genscript.com> (last visited Jan. 26, 2010).

117. *E.g.*, Yoshihide Hayashizaki & Jun Kawai, *A New Approach to the Distribution and Storage of Genetic Resources*, 5 NATURE REVS. GENETICS 223, 223 (2004).

118. S. REP. NO. 79-1333, at 3 (1946).

119. *Scandia Down Corp. v. Euroquilt, Inc.*, 772 F.2d 1423, 1429 (7th Cir. 1985), *cert. denied*, 475 U.S. 1147 (1986).

120. Lanham Act § 45, 15 U.S.C. §1127 (2006).

121. *Qualitex Co. v. Jacobson Products Co., Inc.*, 514 U.S. 159, 163 (1995).

122. *Id.* at 164.

A specific pattern or motif spliced into a synthetic DNA sequence could serve a trademark function if it identified the source of that DNA. To avoid the restrictions of the functionality doctrine, such a DNA trademark would best be placed outside of the coding (or functional) portion of the DNA sequence. Only human creativity would limit the patterns of nucleotides that synthetic biologists might choose to incorporate into a synthetic DNA sequence. To serve as an indicator of source, relevant consumers would have to recognize the pattern or motif intended to indicate source. Consumers of synthetic DNA sequences, however, would certainly scrutinize such sequences very carefully as a matter of course, and it would be difficult for them not to notice a DNA trademark. As the field of synthetic biology becomes more commercially important, DNA trademarks are likely to play increasingly important roles as indicators of source.

IV. OPEN SYNTHETIC BIOLOGY

It has long been widely assumed that technological innovation was best spurred by either governmental funding or property-like incentives, such as patents and copyrights. The United States Constitution explicitly enables Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹²³ However, the rise in importance of open source and free software, as well as insight into the phenomena of user, open, and collaborative innovation, has revealed an increasingly significant alternative to proprietary models of innovation. Within the field of synthetic biology, there are influential scientists, notably Drew Endy, Tom Knight, and Randy Rettberg, who have vigorously tried to push the field in the direction of open innovation.

A. OPEN INNOVATION

Lawrence Lessig has noted that, although “[g]etting more progress is the constitutional aim of patents . . . the question that must always be asked of any patent regime is whether we have good reason to believe that patents have that effect.”¹²⁴ Lessig doubts the veracity of the traditional proprietary model

123. U.S. CONST., art. I, § 8, cl. 8.

124. LAWRENCE LESSIG, *THE FUTURE OF IDEAS* 205 (2002).

of innovation, concluding instead that “[t]he strongest conclusion one can draw is that whatever benefit patents provide (except in industries such as pharmaceuticals), it is small.”¹²⁵ Eric von Hippel, the leading scholar on open and user innovation, is similarly dubious, noting that “[s]tudies find that innovators in many fields view patents as having only limited value.”¹²⁶ Moreover, “most innovators do not judge patents to be very effective [in spurring innovation], and . . . the availability of patent grant protection does not appear to increase innovation investment in most fields.”¹²⁷ Von Hippel has warned that, “with a few exceptions, innovators do *not* think that patents are very useful either for excluding imitators or for capturing royalties in most industries,”¹²⁸ and that “the characteristics of present-day intellectual property regimes as actually experienced by innovators are far from the [beneficial] expectations of theorists and policy makers.”¹²⁹ He notes a growing realization “that intellectual property rights are bad for innovation too in many cases.”¹³⁰

An increasing body of empirical research supports the hypothesis that intellectual property protection may harm, rather than spur, technological innovation. More than two decades ago, von Hippel reported that “empirical data seem to suggest that the patent grant has little value to innovators in most fields.”¹³¹ In 2004, Bessen and Hunt presented empirical evidence that, “on average, as firms’ investments in patent protection go up, their investments in research and development actually go down.”¹³² And, in their descriptively named book, *Patent Failure*, Bessen and Meurer offered the following observation:

[I]t is not clear that the entry of imitators is necessarily detrimental to innovation as in the canonical reward theory model. If firms can obtain some rents even when competing against a limited number of

125. *Id.* at 206.

126. ERIC VON HIPPEL, *DEMOCRATIZING INNOVATION* 10 (2005).

127. *Id.* at 112.

128. *Id.* at 84.

129. *Id.* at 112.

130. *Id.*

131. ERIC VON HIPPEL, *THE SOURCES OF INNOVATION* 48–51 (1988).

132. James Bessen & Robert M. Hunt, *An Empirical Look at Software Patents* (Federal Reserve Bank Of Philadelphia, Working Paper No. 03-17/R, 2004).

other firms, then competition might actually increase innovation.¹³³

Their results “suggest that much innovation is not dependent on patenting.”¹³⁴ They lament that “innovators have grown frustrated with the failings of the American patent system.”¹³⁵ The authors also minimize the actual effect the patent system has on innovation, arguing “patents are neither the only nor even the most important means of encouraging innovation. On average, patents make a rather small contribution in this regard.”¹³⁶ In 2009, an experimental study that directly compared proxies of innovation, productivity, and social utility in a patent system, a combination patent/open source system, and a commons, found that the commons outperformed the proprietary systems in every category examined, and by statistically significant amounts.¹³⁷

Moser has presented historical evidence showing that, at least during the nineteenth century, countries with patent systems did not experience significantly greater rates of technological innovation than countries without patent systems.¹³⁸ The conclusion that Bessen and Meurer make is damning:

Our empirical analysis indicates that the patent system provides little innovation incentive to most public firms; these are the firms that perform the lion's share of R&D. So it seems unlikely that patents today are an effective policy instrument to encourage innovation overall.¹³⁹

Heller and Eisenberg have long suggested that too much patenting may result in an inefficient “tragedy of the anticommons.”¹⁴⁰ Bessen and Meurer concur, noting that “our evidence implies that patents place a drag on innovation. Without this drag, the rate of innovation and technological progress might have been even greater, perhaps much

133. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATORS AT RISK 89 (2008).

134. *Id.* at 90.

135. *Id.* at 2.

136. *Id.* at 118.

137. Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 131, 160–62 (2009).

138. Petra Moser, *How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs* 24–33 (NBER Working Paper Series, Working Paper No. 9909, 2002).

139. BESSEN & MEURER, *supra* note 133, at 216.

140. See, e.g., Heller & Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698–701 (1998).

greater.”¹⁴¹ Josh Lerner, conducting an empirical analysis of patent reforms in sixty countries over 150 years, even noted a modest negative correlation between the strengthening of a country’s patent system and patenting activity by domestic companies.¹⁴²

These results are inconsistent with the traditional assumption that the availability of intellectual property protection spurs technological innovation. Yochai Benkler have noted, however, that “[i]ncreasing patent protection . . . increases the costs that current innovators have to pay on existing knowledge more than it increases their ability to appropriate the value of their own contributions,”¹⁴³ and that patents may lower, rather than raise, rates of productivity.¹⁴⁴ Yochai and Benkler have instead proposed that “commons-based strategies” may spur rates of innovation in fields such as software, agriculture, and drug development more than proprietary systems.¹⁴⁵ Open biology and open synthetic biology represent non-proprietary modes of biotechnological innovation.

B. OPEN BIOLOGY

There is a strong ethos in the nascent synthetic biology community in favor of maintaining open standards for and free availability of standardized biological parts. Although patent protection has traditionally been one of the economic pillars of the pharmaceutical and biotechnology industries, “open source biology” appears to be maintaining a strong lead over more proprietary approaches to synthetic biology innovation. One reason for this relative openness may be the academic backgrounds of some influential synthetic biologists. For example, the troika most responsible for the BBF and the iGEM competition came to the field biology from a background in engineering and computer science: Drew Endy received his undergraduate degree in civil engineering;¹⁴⁶ Tom Knight is a

141. BESSEN & MEURER, *supra* note 133, at 146.

142. YOCHAI BENKLER, *THE WEALTH OF NETWORKS* 39 (2006) (citing Josh Lerner, *Patent Protection and Innovation Over 150 Years 2* (Nat’l Bureau Of Econ. Research, Working Paper No. 8977, 2002)).

143. YOCHAI BENKLER, *THE WEALTH OF NETWORKS* 39 (2006).

144. *Id.* at 49–50.

145. *Id.* at 317–55.

146. Mooallem, *supra* note 1, at 44.

Senior Scientist at the Massachusetts Institute of Technology (MIT) Computer Science and Artificial Intelligence Laboratory;¹⁴⁷ and Randy Rettberg is an electrical engineer and computer scientist.¹⁴⁸ The origins of the open source philosophy lie within the computer software community.

Open source software differs markedly from proprietary software. Open source software involves “computer source code publicly available for licensees to use, modify, and redistribute, provided that these licensees make their enhancements available to others on the same terms.”¹⁴⁹ The Open Source Initiative (OSI), a prominent institution in the open source community, has stated that software may qualify as open source if distributed under a license conforming to the Open Source Definition (OSD).¹⁵⁰ Among the requirements of the OSD are free redistribution, availability of source code, free redistribution of derivative works, non-discrimination against potential users or fields of use, and technology neutrality.¹⁵¹ In an alternative conception proposed by Steven Weber, open source software must comply with three conditions: (1) “[the s]ource code must be distributed with the software or otherwise made available for no more than the cost of distribution,” (2) “[a]nyone may redistribute the software for free, without royalties or licensing fees to the author;” and (3) “[a]nyone may modify the software or derive other software from it, and then redistribute the modified software under the same terms.”¹⁵² By any objective measure, open source software has been an influential and successful model for producing valuable software. The Linux operating system, the Apache web-server, and the mySQL database system all demonstrate the efficacy of the open source model of software design.¹⁵³

Biology has seen several previous attempts at using the open source approach. Led by biologist Richard Jefferson,

147. *Id.*

148. *Id.*

149. Donna M. Gitter, *Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases*, 43 HOUS. L. REV. 1475, 1476 (2007).

150. Open Source Initiative, <http://opensource.org/> (last visited Jan. 15, 2010).

151. *Id.*

152. STEVEN WEBER, *THE SUCCESS OF OPEN SOURCE* 5 (2004).

153. *Id.* at 6.

CAMBIA (derived from the Spanish verb *cambiar*, meaning “to change”), a non-profit biotechnology research organization, began as an attempt to develop open source, instead of proprietary, biotechnology platforms for the genetic modification of crops that would avoid patent infringement.¹⁵⁴ CAMBIA’s BiOS (Biological Innovation for Open Society) initiative explicitly aimed to duplicate the success of non-proprietary software development:

Similar to the ethos of the Free Software movement, the BiOS Initiative is not about cheap or free stuff, either pharmaceuticals or food. It’s about creating the freedom to innovate based on what has come before, and the freedom to deliver the fruits of such innovation with few constraints.¹⁵⁵

The International HapMap Project (IHMP) represents another biological science initiative modeled after the successes of open source software. IMHP is a “partnership of scientists and funding agencies from Canada, China, Japan, Nigeria, the United Kingdom, and the United States to develop a public resource that will help researchers find genes associated with human disease and response to pharmaceuticals.”¹⁵⁶ The HapMap (or map of haplotypes) “is a catalog of common genetic variants that occur in human beings.”¹⁵⁷ The IHMP is attempting to create a public domain database of haplotypes by encouraging researchers not to patent their research, but, instead, to contribute their haplotype data freely to the IHMP genetic database. By “making this information freely available, the [IHMP] will help biomedical researchers find genes involved in disease and responses to therapeutic drugs.”¹⁵⁸ Researchers do not require licenses to gain access to the IHMP database, where data “can be downloaded with minimal

154. Cambia – Enabling Innovation, <http://www.cambia.org/daisy/cambia/home.html> (last visited Feb. 26, 2010).

155. THE CAMBIA BIOS INITIATIVE, BIOLOGICAL INNOVATION FOR OPEN SOCIETY: IMPLEMENTATION PHASE 2006 – 2008 7 (2006), *available at* <http://www.bios.net/daisy/bios/2029/version/default/part/AttachmentData/data/BiOS%20Initiative%20Phase%202006-2008.pdf>.

156. International HapMap Project Home Page, <http://www.hapmap.org/> (last visited Feb. 26, 2010).

157. International HapMap Project, What is the HapMap?, <http://hapmap.ncbi.nlm.nih.gov/whatishapmap.html.en> (last visited Feb 26, 2010).

158. International HapMap Project, About the HapMap, <http://hapmap.ncbi.nlm.nih.gov/thehapmap.html.en> (last visited Jan. 15, 2010).

constraints.”¹⁵⁹ Although one of the goals of the IHMP is to minimize hindrances on genetic research caused by patents, it does not oppose patents claiming haplotypes “as long as this action does not prevent others from obtaining access to data from the [IHMP].”¹⁶⁰

Another organization, the Tropical Diseases Initiative (TDI), has been organized around the principles of open source biology. The TDI was founded to spur medical research into treatments for tropical diseases that devastate poor and vulnerable populations in developing countries, focusing especially on diseases that have attracted little research and, as a result, development of fewer drugs to treat them.¹⁶¹ As with the IHMP, the TDI has acknowledged an important role for the patent system in spurring medical research, conceding that “patent incentives and commercial pharmaceutical houses have made Western health care the envy of the world.”¹⁶² Furthermore, proponents of the TDI have lamented that “[t]o date, open-source methods have made little headway beyond software.”¹⁶³

C. OPEN SYNTHETIC BIOLOGY

In the realm of synthetic biology, two interrelated institutions have taken the lead in promoting the ethos of open biology: the BioBricks Foundation (BBF) and the iGEM competition. The BBF is a non-profit foundation founded by synthetic biologists at MIT, Harvard, and University of California, San Francisco.¹⁶⁴ Its stated mission is to promote “the development and responsible use of technologies based on BioBrick™ standard DNA parts that encode basic biological functions.”¹⁶⁵ Synthetic biologists and biological engineers can combine BioBricks inside living cells, in a manner analogous to combining pieces of Lego®, to “program living organisms in the

159. *Id.*

160. International HapMap Project, Data Release Policy, <http://hapmap.ncbi.nlm.nih.gov/datareleasepolicy.html>.en (last visited Jan. 15, 2010).

161. Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLOS MED. 183, 183 (2004).

162. *Id.*

163. *Id.* at 184.

164. The BioBricks Foundation, *supra* note 106.

165. *Id.*

same way a computer scientist can program a computer.”¹⁶⁶ The Registry is a repository for BioBricks and technical information about how to make and use BioBricks, currently housed at MIT.¹⁶⁷ Anyone can contribute BioBricks to the Registry, but biologists are especially encouraged to ensure that any BioBricks submitted conform to BBF technical standards and are accompanied by sufficient information to enable their efficient and predictable use. The BBF “supports an open technical standards setting process that is used to define BioBrick™ standard biological parts, and other technical matters relevant to synthetic biology research and applications.”¹⁶⁸

Open synthetic biology represents a confluence of ideas from the open source software and open source biology movements, as well as the fields of biology, synthetic chemistry, engineering, and computer science. What makes it practicable is the distinctive chemical basis of heredity: genes. Genes are composed of deoxyribonucleic acid (“DNA”), a linear chain of deoxyribonucleotides (“nucleotides”) consisting of adenine (“A”), thymine (“T”), guanine (“G”), and cytosine (“C”). Genes are somewhat analogous to software algorithms. Their linear patterns of As, Ts, Gs, and Cs encode corresponding linear arrays of ribonucleotides. Some ribonucleotides perform direct metabolic functions within a cell, while most further encode linear arrays of amino acids, called polypeptides. Depending upon their particular nucleotide sequences, polypeptides may perform structural, signaling, or enzymatic functions within and between cells. Combinations of genes may encode groups of polypeptides that perform complicated functions, such as controlling cell division, immune response, or metabolic pathways. Although the understanding of gene function is still in its infancy, most biologists assume that combinations of genes are also responsible, at least in part, for highly complex phenomena that take place at the level of the organism, such as locomotion, hibernation, reproduction, and behavior.

Genes may be identified, characterized, isolated, and replicated. Their nucleotide sequences and genomic locations can be deliberately altered, or even inserted into novel host

166. *Id.*

167. *Id.*

168. *Id.*

cells. Significantly, genes and chromosomes may also be designed from scratch, and then synthetically manufactured in large quantities. Just as a supplier of open source software might make its software easily available to anyone requesting it, the Registry makes BioBricks easily available to those conducting biological research or competing in the iGEM competition.¹⁶⁹ And, as with open source software, the expectation is that those receiving BioBricks may further modify them structurally, or use arrays of BioBricks to achieve novel biological structures or functions, and then resubmit such modifications back into the Registry.

D. A CONSTITUTIONAL LICENSE FOR SYNTHETIC BIOLOGY

Synthetic biology possesses a distinctively democratic character. From its foundation as a field, a core of influential synthetic biologists, notably Drew Endy, Tom Knight, and Randy Rettberg, as well as prominent institutions, such as the BBF, the Registry, and the iGEM competition, have been dedicated to ensuring that synthetic biology maintains its fundamentally open character. Each of the three stated goals of the BBF reflects this “open-source ethic:”¹⁷⁰ (1) “to develop and implement legal strategies to ensure that BioBrick™ standard biological parts remain freely available to the public;” (2) “to support the development of open technical standards that define BioBrick standard biological parts,” and (3) “to develop and provide educational and scientific materials to allow the public to use and improve existing BioBrick™ standard biological parts, and contribute new BioBrick™ standard biological parts.”¹⁷¹

By supporting open technical standards and open standard setting, the BBF has attempted to define standards for BioBricks that others would follow. In fact, the tremendous success the BBF has experienced in amassing BioBricks in the Registry—more than 5,000 currently available for order by iGEM competition teams and academic laboratories¹⁷²—has made the BBF influential on the rest of synthetic biology.

169. iGEM 2007 Wiki Main Page, http://parts.mit.edu/igem07/index.php/Main_Page (last visited Feb. 2, 2010).

170. Mooallem, *supra* note 1, at 45.

171. The BioBricks Foundation, *supra* note 106.

172. Registry, *supra* note 8.

There already exists a significant incentive for synthetic biologists to design their own DNA sequences to comply with BBF technical standards to ensure interoperability with the largest possible set of other DNA sequences. Network effects could drive the widespread, or even universal, adoption of BBF standards.

Discouraging intellectual property protection for new BioBricks is more difficult. Some fear that excessive patenting of DNA sequences could act to discourage, or even stifle, biological research through what Eisenberg and Heller have called a “tragedy of the anticommons.”¹⁷³ The experience of patents claiming human genes is often cited as a cautionary tale. Approximately twenty percent of all human genes were claimed in issued U.S. patents by 2005.¹⁷⁴ Widespread patenting of human genes was described by some as a “gold rush.”¹⁷⁵ Although empirical evidence has, thus far, cast doubt on the existence of a tragedy of the anticommons caused by human gene patents,¹⁷⁶ proponents of open synthetic biology worry that their burgeoning field might be especially vulnerable to excessive patenting. Furthermore, as suggested earlier, synthetic DNA sequences may be especially easy to patent or copyright.¹⁷⁷

In an effort to manage challenges to synthetic biology posed by intellectual property, as well as to address other issues, such as biosafety, attribution, standards, and liability, the BBF has proposed The BioBrick™ Public Agreement, Version 1a (the “BioBrick Agreement”).¹⁷⁸ The draft agreement, comprised of both The BioBrick™ Contributor Agreement (“Contributor Agreement”) and The BioBrick™ User Agreement (“User Agreement”), has been publicly posted on the BBF’s website in hopes of attracting support, comments, and suggestions.

173. Heller & Eisenberg, *supra* note 140, at 698–701.

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

175. Tom Hollon, *Gene Patent Revisions to Remove Some Controversies*, 6 *NATURE MED.* 362, 362 (2000).

176. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 *UMKC L. REV.* 295, 353–54 (2007).

177. See *supra* Part III.A, III.B.

178. See *infra* Part VI; for a copy of the Agreement, see <http://hdl.handle.net/1721.1/50999> (last visited May 12, 2010).

The first sentence in the Preface of both the Contributor and User Agreements begins with a broad statement of BBF's mission and values:

[The BBF] was established [1] to foster and advance innovation, research, standardization, and education in synthetic biology [2] through the open design, construction, distribution, understanding, and use of BioBrick™ compatible parts, namely standardized genetic materials and associated functional information, [3] in ways that benefit the world.¹⁷⁹

The Preface identifies three significant goals of the BBF. The first goal is to promote the development of the synthetic biology as a field. The word “standardization” signals the influence of an engineering approach, and a desire to avoid the messiness and unpredictability of traditional biological science.

The second goal signals that, not only does the BBF promote the development of synthetic biology as a field of scientific endeavor, such development should adhere to principles of openness at every stage of development. Moreover, the adjective “open,” by modifying all of “design, construction, distribution, understanding, and use,” implies opposition to “closed” intellectual property protection.¹⁸⁰ The Contributor and User Agreements both attempt to minimize the threats that patents and other forms of intellectual property might pose to achieving and maintaining an open model of synthetic biology. Section Three of the Contributor Agreement requires contributors not to assert any intellectual property rights they may have in BioBricks they contribute against the BBF or users. Thus, contributors provide assurance that users will have freedom to use contributed BioBricks. In Section Four, contributors must specifically identify any intellectual property rights that pertain to any BioBricks they contribute belonging to them or to third parties. The User Agreement contains a complementary Section Two, which requires users to acknowledge their awareness of contributors' obligations under

179. See *infra* Part VI, The BioBrick™ Public Agreement v1a, Preface.

180. However, note that the Preface later recognizes the possibility that some BioBricks may be encumbered by patent rights. The Contributor Agreement states: “Some such genetic materials may be subject to patents; some will not be. The patent-related provisions in this Contributor Agreement may or may not apply to the Materials” and the User Agreement states: “Some such genetic materials may be subject to patents; some will not be. The patent-related provisions in this User Agreement may or may not apply to the Materials (as defined by one or more Contributors in their respective Contributor Agreements).”

Sections Three and Four of the Contributor Agreement. Consistent with the BBF's ethos of openness, these provisions favor the use of full disclosure of information in light of the possible existence of patent rights relevant to the use of BioBricks. The full disclosure approach followed by the BioBrick Agreement raises two important issues. First, it is not obvious what incentives contributors would have to contribute their BioBricks, especially if they must effectively relinquish any intellectual property rights they may have in order to do so. Second, the BBF will have to decide how to proceed if third party intellectual property rights encumber a contributed BioBrick. Possible responses include not accepting the BioBrick, accepting the BioBrick but refusing to provide it to users, or simply assuming the risk that providing the BioBrick to users might trigger indirect infringement of any associated intellectual property rights. Although the BioBrick Agreement focuses on the use and contribution of BioBricks, the influence wielded by the BBF as the predominant—perhaps even dominant—source of synthetic biological building blocks has the potential to extend far beyond BioBricks *per se*. The use of “BioBrick™ compatible parts” in the BioBrick Agreement, rather than the logically more restrictive “BioBrick™ standard DNA parts” commonly used on the BBF website, further signals the ethos of openness that suffuses the BioBrick Agreement.

The third goal flows from the modifying statement “in ways that benefit the world.”¹⁸¹ Concerns about biosafety surround not only the technologies being developed by synthetic biology but also the ethos of openness that pervades the field. Nightmare scenarios include “the malicious use of DNA sequences posted on the Internet to engineer a new virus or more devastating biological weapons.”¹⁸² Endy has noted that gene synthesis technology has already enabled the resurrection of the devastating 1918 influenza virus and could be used to produce genes of other dangerous pathogens.¹⁸³ Whereas previous biotechnological advances have often been perceived as either subject to proprietary restrictions, or inaccessible to members of the public lacking requisite academic credentials or

181. See *infra* Part VI, The BioBrick™ Public Agreement v1a, Preface.

182. Mooallem, *supra* note 1, at 45.

183. Endy, *supra* note 2, at 452.

access to expensive and secure laboratories, the openness of synthetic biology signals a democratization of access to its powerful technologies. Critics may worry that open access will not distinguish between beneficial and malicious users, and will thereby create the potential for biotechnological mischief by criminals, terrorists, hostile countries, or even careless biohackers. The Preface signals that only beneficial uses should be made of synthetic biology, though the very need to state this positive value indicates an awareness of its opposite. Section Seven of the Contributor Agreement and Section Four of the User Agreement both indirectly address biosafety by requiring that parties to the agreements comply with the laws in their jurisdiction. Obviously, such compliance is required regardless of the BioBrick Agreement. Section Five of the User Agreement, however, expressly requires users to “refrain from using the [BioBricks] in connection with any intentionally harmful, negligent, or unsafe uses.”

The approach to biosafety taken by synthetic biology marks something of a departure from previous approaches the biological sciences have taken to manage risk and the perception of risk. Rather than restricting the technology to well-credentialed, institutionally-based scientists working in restricted-access laboratories, the ethos of synthetic biology demands a more open, democratic, and transparent approach. The BBF distributes kits of BioBricks to teams of undergraduates from all over the world. It encourages users to modify and combine BioBricks in novel ways, and then to share these modifications with the wider biological community. This spirit is more akin to computer hacker culture than to traditional biology. However, “[w]hat’s available to idealistic students, of course, would also be open to terrorists.”¹⁸⁴ The BioBricks Agreement represents an attempt to address concerns about biosafety through contract, while simultaneously encouraging a degree of open access. Such an approach is sure to engender criticism from those who fear the results of disseminating synthetic biological knowledge and materials; these concerns will likely grow in response to technical progress in this promising field of biology. However, a contrasting perspective doubts the feasibility of successfully restricting access to a technology as powerful, attractive, and

184. Specter, *supra* note 20, at 64.

easy to engage in—even at home using inexpensive equipment¹⁸⁵—as synthetic biology, and, instead, views openness as an advantage because it could provide a distributed network of many practitioners bound to notice and report malfeasance.

A few additional aspects of the BioBrick Agreement are worth noting. Section Two of the Contributor Agreement requires contributors to agree to let the BBF insert a “BioBrick™ Identification Tag” into the DNA sequence of any contributed BioBrick. Users must make related promises in Section Three of the User Agreement, agreeing not to remove any “BioBrick™ Identification Tag” from a BioBrick and to ensure that the BioBrick Agreement logo is displayed prominently whenever a BioBrick, or modification thereof, is made available, commercialized, or distributed; Section Five of the Contributor Agreement informs contributors of this user obligation. This trademark policing is intended to ensure that BioBricks remain both standardized, compatible, and accessible. Finally, the BioBrick Agreement provides for attribution. Section Five of the Contributor Agreement allows contributors to request that users attribute BioBricks to their contributors when those users describe those BioBricks. Section Three of the User Agreement requires that users promise to make such attributions to contributors.

The BioBrick Agreement may be viewed simply as a license agreement. By defining the obligations of contributors and users, it attempts to avoid *ex ante* disputes arising over ownership, intellectual property rights, attribution, and liability. Minimizing legal uncertainty may promote the growth of the Registry and the use of BioBricks. Like the open source and free software licenses that inspired it, however, the BioBrick Agreement may also be viewed in a more expansive light. Rather than a mere license, the BioBrick Agreement may be viewed as reflecting an initial effort to draft a legal constitution to guide the beneficial development of the field of synthetic biology. As with many other constitutions, the Preface articulates a number of value-laden, interpretive principles unnecessary to a mere license governing behavior

185. Jeanne Whelan, *In Attics and Closets, 'Biohackers' Discover Their Inner Frankenstein: Using Mail-Order DNA and Iguana Heaters, Hobbyists Brew New Life Forms; Is It Risky?*, WALL ST. J., May 12, 2009, at 1.

between two private actors. These principles—technological progress, openness, and beneficial uses—may represent the constitutional values of a field that aspires to more than efficient contracting and legal compliance. As Michael Specter recently suggested, “[t]he industrial age is drawing to a close, eventually to be replaced by an era of biological engineering.”¹⁸⁶ If synthetic biology realizes even a fraction of its potential, a clear articulation of constitutional values may prove much more valuable to development of the field than a license.

186. *Id.* at 65.

V. CONCLUSIONS

Synthetic biology aims to effect a paradigm shift in the biological sciences. If it is successful in importing engineering principles, such as standardization, decoupling, and abstraction, into the biological sciences, it may transform biology into a field in which it is routine to design and construct genes, proteins, metabolic pathways, cells, and whole organisms rapidly, inexpensively, and easily. Already, a number of institutions have helped synthetic biology achieve considerable success. The BBF and the Registry have successfully built a collection of thousands of BioBricks, and the iGEM competition has attracted participation from thousands of contestants, hundreds of teams, and dozens of countries. While the ethos of openness that pervades synthetic biology promises a democratization of biology, significant challenges to its openness still exist. The proprietary restrictions imposed by “closed” intellectual property create legal risk and uncertainty. Ironically, synthetic DNA sequences are likely more easily patentable and copyrightable than are DNA sequences derived from natural sources, thus creating the possibility that synthetic biology may increase, rather than decrease, intellectual property restrictions. Furthermore, concerns about biosafety may be exacerbated by open access to the products and methods of synthetic biology. To this end, the BBF has produced the BioBrick Agreement, a licensing framework intended to govern the legal relationships between the BBF, BioBricks contributors, and BioBricks users. The BioBrick Agreement has the potential to be more than a mere license. In fact, like a constitution, it could help define some of the foundational values and principles that synthetic biology might espouse to ensure that its social contributions prove beneficial to a degree commensurate with its scientific potential.